14 June 2016
EMA/HMPC/398247/2016
Committee on Herbal Medicinal Products (HMPC)

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

The 70th HMPC meeting, held on 30-31 May 2016

The Vice Chair (30 May) and Chair (31 May) of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 70th meeting of the Committee including Miroslava Petríková, new Member for Slovakia.

The 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

Finalised herbal substance assessments leading to Public Statements

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

- Public statement on Balsamum peruvianum, by majority vote
- Public statement on Salviae fruticosae folium, by consensus

No comments had been received during public consultation that would lead to a different opinion of the HMPC as regards safety or adequacy of data to allow the establishment of EU herbal monographs on these substances.

The public statement 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

Call for scientific data (systematic monograph review)

In April the HMPC had agreed to initiate the systematic review of 13 herbal substances previously not prioritised in work plans for systematic review. This is the second wave of Calls for new scientific data supporting the review of:

- Avenae fructus
- Avenae herba

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- Calendulae flos
- Tanaceti partenii herba
- Verbasci flos

The call with a deadline for submission by **15 September 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

Scientific guidance

- Public statement on contamination of herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

Following information from some Member States and discussion with AESGP in April, upon recommendation of a specific task force, the HMPC adopted the public statement to support harmonised measures in EU member states with recommendations on transitional measures regarding risk management and quality control.

The statement can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac05804545f1

- Reflection paper on polycyclic aromatic hydrocarbons in herbal medicinal products (EMA/HMPC/300551/2015)

Since herbal substances and preparations can contain polycyclic aromatic hydrocarbons as contaminants, the HMPC invites interested parties to submit scientific data or documented information (new, published or unpublished) and comments relating to the levels of polycyclic aromatic hydrocarbons and the possible exposure of patients to these compounds as a result of using HMPs/THMPs in order to explore the need for appropriate controls to be introduced.

The RP will be published for 6 months consultation until **15 December 2016**:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac05804545f1

Procedural guidance

After coordination with QRD, upon proposal from the ORGAM DG, the HMPC agreed to an addendum for the generally applicable QRD template clarifying specifics for (traditional) herbal medicinal products:

- Addendum to the Quality Review of Documents templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures specific for (Traditional) Herbal Medicinal Products ((T)HMPs)

The document has been forwarded to CMDh.

The HMPC agreed to a revised

- Procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC

which aligns practice at all three committees and will be published after adoption at CHMP and CVMP.

The HMPC further adopted modifications in the

- Procedure for calls for scientific data for use in HMPC assessment works

Revision 5 of procedure EMA/HMPC/1004/2006 including templates to be used by interested parties will be published here:

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

Quality Drafting Group (QDG)

The HMPC heard a report on the QDG meeting held on 04 May 2016.

The DG had discussed the follow-up on the quality assessors training 2015 towards development of new Q&A and consideration in guidance documents. Furthermore a request by EDQM on early manufacturing steps in the context of certificates on suitability was discussed considering a need for additional guidance to be developed on GACP/GMP.

Upon proposal from QDG, HMPC agreed on a stepwise guidance update regarding controls of pyrrolizidine alkaloid contamination with some changes to be included in guidelines EMA/HMPC/201116/2005 Rev. 2 (quality; revision ongoing), EMA/HMPC/162241/2005 Rev. 2 (specifications; revision planned) and EMEA/HMPC/246816/05 (GACP; revision not yet scheduled).

The next meeting of the QDG will be held on 28 June 2016.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC heard a report on the DG ORGAM meetings held on 03 May 2016.

The DG had completed discussions regarding the use of the QRD template for herbal products for HMPC adoption and proposal to CMDh (see above).

The next meeting of the DG ORGAM is scheduled for 30 June 2016.

Report from the May/June 2016 meeting of the Working Party on European Union Monographs and List (MLWP)

The MLWP held its 61th meeting at the European Medicines Agency on 31 May–2 June 2016.

Monograph finalisation

Following public consultation, the MLWP endorsed the documents on Pruni africanae cortex and Origani majoranae herba for peer review and possible final adoption at the HMPC July meeting.

Since no majority vote had been found at the HMPC in April for the final monograph on Silybi marianae fructus, the MLWP further discussed possibilities for a monograph finalisation.

Monograph drafts

The MLWP discussed and endorsed the draft documents on Saccharomyces cerevisiae, Lecithinum ex soya and Soiae oleum raffinatum for early peer review and transfer to the HMPC for possible release in July 2016 for public consultation.

The working party continued its assessment of a combination herbal tea monograph (Species diureticae) and Fragariae folium.

Monograph revisions

Following public consultation, the working party finalised the revision of Harpagophyti radix and Althaeae radix for peer-review and possible final adoption at the HMPC July meeting. The MLWP continued the revision of Pelargonii radix and Salviae officinalis folium.

The MLWP further discussed the systematic review of Menthae piperitae aetheroleum, Menthae piperitae folium, Aloe, Sennae fructus, Sennae folium, Meliloti herba, Salicis cortex, Foeniculi amari fructus, Foeniculi amari aetheroleum, Foeniculi dulcis fructus and Oleae folium.

The next meeting of the MLWP is scheduled for 12-14 July 2016.

Guidance documents

The MLWP endorsed the draft revised 'Guideline on assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations' (EMA/HMPC/104613/2005) for transfer to the Committee for adoption in July 2016 for public consultation.

The MLWP endorsed the Concept paper on the revision of the 'Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration' (EMEA/HMPC/32116/2005) for transfer to the Committee for adoption in July 2016 for public consultation.

Contact for further information

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