14 April 2016
EMA/HMPC/271408/2016
Committee on Herbal Medicinal Products (HMPC)

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

The 69th HMPC meeting, held on 4-5 April 2016

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 69th meeting of the Committee.

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 Crataegi folium cum flore, by majority vote
- EU herbal monograph on Helichrysi flos, by consensus
- EU herbal monograph on Polygoni avicularis herba, by majority vote

The monographs together with the supporting documents including the overview of comments when available, 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 monograph

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

- EU herbal monograph on Thymi herba and Primulae radix, by majority vote

The trigger and scope of the revision were new scientific data with regard to the validity and use of the Bronchitis Severity Score (BSS; see also HMPC meeting report May 2013 and January 2015).

The final revised 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

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Other

Call for scientific data (systematic monograph review)

According to an MLWP proposal, the HMPC agreed to initiate the systematic review of 13 herbal substances previously not prioritised for review. Calls for new scientific data supporting the review and revision as necessary will be published in 3 waves. 1st wave:

- Ribis nigri folium
- Rusci aculeati rhizoma
- Sambuci flos
- Thymi aetheroleum

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

Guidance documents

The HMPC adopted the finalised revision 2 of the

- 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMA/HMPC/71049/2007, Rev.2)

including a 'mock- up module 3' as appendix 2. The Final guideline and the Overview of comments received during public consultation will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000355.jsp&mid=WC0b01ac0580118a1d

Pyrrolizidine alkaloid (PA) contaminations reported from NCAs

HMPC discussed measures taken in some MSs as well as the incoherent data situation regarding PA findings in herbal products. Since such quality issues linked with safety concerns (see also HMPC public statement EMA/HMPC/893108/2011) are not limited to single markets only, the need for coordinated European measures was emphasised. The HMPC agreed to communicate to EDQM an accelerated need for development of a validated Ph. Eur. method for PA analysis, to improve the data situation across MSs, to set up a task force in order to publish HMPC recommendations regarding transitory measures in relation to PA testing in herbal substances, and to reconsider long term measures including testing requirements such as revision of relevant guidelines under lead of the QDG.

Quality Drafting Group (QDG)

The HMPC heard a report on the QDG meeting held on 11 February 2016.

The DG had finalised the quality part for the revised herbal CTD guideline, mainly as regards comments received on the new Appendix 2 'mock-up module 3' (see above). The group had further discussed the revision of the 'Guideline on quality of herbal medicinal products/ traditional herbal medicinal products' and some topics in coordination with EDQM such as herbal specific issues in relation to Certificates of suitability (CEPs).

The next meeting of the QDG will be held on 04 May 2016.

Organisational Matters Drafting Group (ORGAM DG)

The HMPC heard a report on the DG ORGAM meetings held on 09 February and 16 March 2016.

The DG had continued discussions regarding the use of the QRD template for herbal products and finalised the non-quality part of the revised guideline EMA/HMPC/71049/2007, Rev.2 (see above).

The next meeting of the DG ORGAM is scheduled for 03 May 2016.

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

The MLWP held its 60th meeting at the European Medicines Agency on 5–7 April 2016.

Monograph finalisation

Following public consultation, the MLWP endorsed the documents on Balsamum peruvianum and Salviae fruticosae folium for peer review and possible transfer to the HMPC for final adoption in May 2016. The working party further discussed comments received on the draft monograph for Pruni africanae cortex.

Monograph drafts

The MLWP discussed and endorsed the draft documents on Allii sativi bulbus and Saccharomyces cerevisiae for transfer to the HMPC for possible release in May 2016 for public consultation.

The working party continued its assessment of Glycine max and discussed the approach towards a combination herbal tea monograph (Species diureticae).

Monograph revisions

The working party continued its assessment of Pelargonii radix following comments from public consultation.

The MLWP further discussed the systematic review and revision of Menthae piperitae aetheroleum, Menthae piperitae folium, Sennae fructus, Sennae folium, Meliloti herba, Salicis cortex, Foeniculi amaris fructus, Foeniculi amaris aetheroleum, Foeniculi amaris dulcis and Hyperici herba.

Hearing with AESGP

The MLWP discussed with AESGP representatives current issues in the herbal area linked to the documents finalised or partially under development by MLWP/HMPC. Topics of specific interest were: pyrrolizidine alkaloids, the public statement on the use of herbal medicinal products containing pulegone/menthofuran, revision of the 'Guideline on the assessment of clinical safety and efficacy for HMP/THMP', an announced draft reflection paper on polycyclic aromatic hydrocarbons (PAH), the methodology regarding prioritisation for assessment and review/revision of monographs, and HMPC involvement in revision of the 'Guideline on Excipients in the label and package leaflet of medicinal products for human use' as regards ethanol.

A more detailed hearing report will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac05807fa576

The next meeting of the MLWP is scheduled for 31 May – 2 June 2016.

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