



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

HMPC meeting report on Community herbal monographs, guidelines and other activities

The 45th HMPC meeting, held 23-24 January 2012

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed Dr Eeva Sofia Leinonen, new member from Finland and Pharm. Wim Vervaet, expert from Belgium who is in the process of being appointed as the new Belgian HMPC alternate member. The HMPC noted the nomination of Ing. Ján Slúka, new member from Slovakia.

The HMPC re-elected Prof. Ioanna Chinou as Chair of the Working Party on Community Monographs and Community List (MLWP) upon expiry of her first mandate as Chair. The Committee renewed the three-year term of Prof. S. Girotto, co-opted member with expertise in paediatric medicines.

Update of Community herbal monographs

Upon recommendation from the MLWP as a result of its September 2011 meeting, the HMPC adopted a new version of the 'Community herbal monograph on *Arctostaphylos uva-ursi* (L.) Spreng., folium' (EMA/HMPC/573460/2009) and related documents. The MLWP had been asked to assess the comments received in July 2011 regarding the changes in the monograph after the public consultation concerning the gender-specific indication, as reported in the September HMPC public meeting report.

The Community herbal monograph as well as a new HMPC opinion, revised assessment report and a cumulative overview of comments, 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&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Final and draft Community herbal monographs and public statements

The HMPC noted the number of final and draft Community herbal monographs and public statements expected to be presented to the HMPC for adoption in March 2012.



Other

Public statement on thujone

The HMPC adopted the final public statement on the use of herbal medicinal products containing thujone (EMA/HMPC/732886/2010). The public statement and the overview of comments will be published in due course here:

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

Appointment of Rapporteurs and calls for submission of scientific data for new assessment works

A Rapporteur was appointed for the establishment of a monograph/list entry on *Ononis spinosa* L., radix.

Following this appointment, a call for data will be published. The deadline for the submission of scientific data in response to the call is 15 May 2012.

This appointment, as well as the appointment of peer-reviewers for all herbal substances and preparations thereof which have been assessed so far, will be reflected in the Rapporteurs' and Peer-reviewers' distribution found in the HMPC priority list (EMA/HMPC/278067/2006 current update) published on the Agency's website at:

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

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 15 December 2011 together with the Chairs of the Ph. Eur. expert groups 13A, 13B and TCM. Based on the thorough discussion of the 2012 work programmes and current challenges faced by all groups, those topics were identified, where closed cooperation is required such as the essential coordination for the revision of the Ph. Eur. monograph on extracts or regarding topics at the DG Q work programme. The HMPC also addressed the modalities of the coordination with the European Pharmacopoeia at different levels including the participation of HMPC observers in meetings of Experts Groups organised by EDQM but also an increased use of remote meetings via Vitero.

The next DG Q meeting is scheduled for the 16 February 2012.

Drafting Group on Organisational matters (DG ORGAM)

Upon recommendation from the DG ORGAM, after the public consultation held in 2011, the HMPC adopted the following documents:

- 'Guidance for companies seeking scientific support and advice on traditional herbal medicinal products' (EMA/HMPC/127670/2011)
- 'Template for request for scientific support and advice on traditional herbal medicinal products' (EMA/HMPC/119889/2005 Rev.1)
- 'Procedure for the systematic review of adopted Community herbal monographs and supporting documents' (EMA/HMPC/124695/2011)

Also resulting from the work carried out during the December 2011 DG ORGAM, the HMPC adopted revisions of:

- the 'Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries' (EMA/HMPC/326440/2007 Rev.2)
- the 'Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, herbal preparations and/or combinations are not established' (EMA/HMPC/84530/2010/ Rev.1). The release of the corresponding template (EMA/HMPC/75972/2010 Rev.1) will follow.

Reference documents and relevant steps will be amended in the 'SOP/H/3163 Establishment of Community herbal monographs, Community list entries and related documents' to reflect latest practice and available guidance for this process. Current version of the SOP can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500002999.pdf

The next meeting of the DG ORGAM is scheduled for 15 February 2012 and will be held in the morning remotely using a Vitero interface, with a view to progress the development of a number of procedural documents to support the HMPC work.

Other relevant information

HMPC 2012-2015 work programme

The HMPC heard reports on the work which started amongst appointed sponsors and lead sponsors for several topics on the HMPC work programme for the period 2012-2015, which is published on the EMA website at:

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

As regards objectives and deliverables identified for the assessment of herbal substances with a non-European tradition background, the Committee welcomed a presentation on practical challenges faced at the level of the Belgium competent authority. Subsequently, the HMPC discussed different aspects related to herbal substances with a non-European tradition background. A structured approach shall be developed and the HMPC will carefully consider how to be a source of guidance within the remit of its competence as laid down in the European pharmaceutical legislation but considering that it represents a well-established forum with a high level expertise in that field and aiming at enhancing European harmonisation.

HMPC is considering reinforcing a better awareness of its scientific work and a better communication with the scientific community. Beside publication on the EMA website a larger dissemination of suitable topics is expected from publications in scientific and/or regulatory affairs journals. To support an efficient process in respect of the EMA policies in that domain, the Committee received a presentation on the scope and practical implementation of the EMA 'Policy on scientific publication and representation' (EMA/231477/2005 rev. 1), available on the Agency website at:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004627.pdf

Under the framework of its membership in the IRCH network as an organisation, the HMPC heard a report from the HMPC delegate, M. Delbò, who attended the fifth annual meeting of IRCH held 30 November-2 December 2011 in Guangzhou, China.

Successful use of the traditional use registration scheme in the Member States

The HMPC was reminded about the continued work to gather 6-monthly updated figures on MA/TU registrations applications received, under assessment, granted and withdrawn. The updated document EMA/322570/2011 (status June 2011) can be found here:

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106706.pdf

The next update shall cover data until 31 December 2011. As indicated in the November 2011 HMPC public meeting report, work is ongoing towards a deeper analysis of the data made available by all national official contact points on herbal medicines.

Union reference dates and frequency of PSUR submission for herbal substances

The HMPC was updated about ongoing collaborative work within the European regulatory network of national competent authorities and the Agency to generate a *public list of Union reference dates and frequency of submission of periodic safety update reports* according to the provisions of Article 107b (3) and Article 107c (paragraphs 4 and 7) of Directive 2010/84/EU, and Article 26(g) of Regulation (EU) 1235/2010. Although Herbal Medicinal Products are principally exempted from the new provisions, Member States have been asked to comment on a draft list of herbal substances and to identify herbal substances for which a safety concern may justify the need for PSUR submission and thus, inclusion in the Union references date list. The HMPC accepted to provide the Agency by the middle of March 2012 with a consolidated list.

Report from the January 2012 Working Party on Community Monographs and Community List (MLWP)

The MLWP held its 36th meeting at the European Medicines Agency on 24-26 January 2012.

The Working Party further discussed the assessment of *Pelargonii radix* and *Thymi herba/Primulae radix*; efforts are being made to reach conclusions at the March 2012 meeting. The MLWP made significant progress on the scientific work towards the finalisation of monographs on *Fraxini folium*, *Rhodiolae rosae rhizoma*, *Symphyti radix* and *Zingiberis rhizoma*.

The MLWP endorsed the monograph and supporting documents on *Eucalypti folium*, *Grindeliae herba*, *Levistici radix* for peer-review, prior to transmission to the HMPC for possible release in March 2012 for a 3-month public consultation. The working party continued its assessment of *Guaranae semen*. The MLWP discussed the draft assessment report and monograph on *Rubi idaei folium* and *Sambuci fructus*. Guidance was provided to Rapporteurs for *Juglandis folium*, *Andrographidis paniculatae folium* as well as for *Pruni spinosae flos* and *Pruni spinosae summitates* after a change in Rapporteurship.

As part of the pilot phase on the review of adopted monographs and supporting documents, the MLWP adopted a revised set of documents for *Primulae radix*, which will be transmitted after peer-review to the HMPC for adoption. This package is the first of ten packages intended for review/revision this year to gain experience with this process. The maintenance of scientific assessments at the state-of-the-art is vital for the long-term access to and reliance on the Committee conclusions in support of a safe and rational use of herbal medicines by European patients.

The next meeting of the MLWP is scheduled for March 2012.

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