



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 36th HMPC meeting, held 14-15 July 2010

The Committee welcomed a new observer from Montenegro.

Final Community herbal monographs/Community list entries

Upon recommendation from the Working Party on Community Monographs and Community List (MLWP), the HMPC adopted the following final Community herbal monographs/Community list entries and related documents:

Final Community herbal monographs

- 'Community herbal monograph on *Rosmarinus officinalis* L., aetheroleum' (EMA/HMPC/235453/2009)
- 'Community herbal monograph on *Rosmarinus officinalis* L., folium' (EMA/HMPC/13633/2009)
- 'Community herbal monograph on *Vitis vinifera* L., folium' (EMA/HMPC/16635/2009)

The final Community herbal monographs as well as the respective HMPC opinion, assessment report and overview of comments received during the consultation period, will be published in due course 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 Community list entries

- 'Community list entry on *Vitis vinifera* L., folium' (EMA/HMPC/5816/2010)
- 'Community list entry on *Hamamelis virginiana* L., folium et cortex aut ramunculus destillatum,' (EMA/HMPC/704562/2009)

Once available in all EU languages, the Community list entries, together with the respective HMPC opinion and assessment report, will be transmitted to the European Commission for adoption.



Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following [draft Community herbal monographs](#), for public consultation until 15 December 2010:

- Draft 'Community herbal monograph on *Cinnamomum verum* J.S. PRESL., cortex' (EMA/HMPC/246774/2009)
- Draft 'Community herbal monograph on *Cinnamomum verum* J.S. PRESL., corticis aetheroleum' (EMA/HMPC/706229/2009)
- Draft 'Community herbal monograph on *Arctostaphylos uva-ursi* (L.) Spreng., folium' (EMA/HMPC/573460/2009).

Draft monographs will be available on the Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000216.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580033a9d

Draft monographs/list entries for public consultation can be found by searching herbal substances by name or with the **status P** [here](#) (click on the 'View all' button). In addition, you can access under [What's New?](#) on the Agency homepage [draft monographs and list entries released for public consultation in the current month].

Other

During the public consultation, no comments or new data were received on the following draft document:

- 'Public statement on *Salvia officinalis* L., aetheroleum' (EMA/HMPC/41843/2009)

Consequently, the Committee confirmed that no monograph/list entry will be established due to safety concerns (high levels of thujone). The final public statement will be published in due course on the Agency's website.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000070.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Appointment of Rapporteurs

The HMPC added Uncariae cortex to the HMPC inventory and HMPC priority list and appointed a Rapporteur for the preparation of a monograph/list entry.

Calls for submission of scientific data

A call for submission of scientific data is made for Uncariae cortex. Data are requested by 30 October 2010. Please refer to the 'Procedure for calls for scientific data for use in HMPC assessment work' published on the Agency's website for guidance on the scope of data requested and recommendations about the submission of contributions:

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

Legal interpretation of the provisions regarding indications appropriate to traditional herbal medicinal products

The HMPC welcomed the legal interpretation received from the European Commission concerning the provisions of Article 16a(1)(a) of Directive 2004/24/EC, regarding the possibility for the indications of traditional herbal medicinal products to refer to a prior medical diagnosis with a view to excluding serious conditions, thus ensuring that patients safely self-medicate. Such medical diagnosis can be remote in time from the decision to take a traditional herbal medicine. Community herbal monographs with indications relating to traditional use may refer to a prior medical diagnosis intended to prevent treatment of more serious pathologies with traditional herbal medicinal products. In any case, the traditional herbal medicinal product still needs to be intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment. The traditional herbal medicinal product has to be a non-prescription medicine.

Cooperation with EFSA

The HMPC heard a report about a meeting held in June 2010 between representatives from the European Food Safety Authority, the European Medicines Agency and the European Commission organised in view of the process of adoption by the Commission of opinions on health claims for food presented by EFSA. The meeting was convened further to the duty for both agencies to identify any potential source of conflicts between their scientific opinions. Areas of overlap were discussed, taking into account the respective legal requirements (Regulation (EC) No 1924/2006 and Directive 2001/83/EC), assessment methodology (e.g. evaluation of clinical efficacy data for substantiation of health claims for botanicals versus benefit-risk assessment for the safe use in specified conditions for traditional herbal medicinal products) and the different purpose of food/food supplements with health claims and herbal medicinal products (e.g. regarding target population and duration of use). It was concluded that no divergence in opinions are present to date. A joint explanatory paper has been transmitted to the European Commission.

Revision of 'Rules for classification of and access to HMPC documents'

The HMPC was informed of new recommendations from the Agency's Legal Service as regards the access to the name of HMPC members who have expressed a divergent position to a HMPC opinion. In view of recent case-law related to the interpretation of the provisions of Regulation 1049/2001, the Legal Service has advised that 'the release of the identity of HMPC members expressing divergent opinions is therefore in principle acceptable; it should not be considered covered by the exception of article 4(3) paragraph 2 of Regulation 1049/2001 unless in exceptional and duly motivated circumstances it can be demonstrated that the identity of the HMPC members should be protected for concrete and specific reasons, further to a case-by-case assessment either to protect the security of individuals (e.g. if scientific experts are exposed to a concrete and significant external threat) or to meet a functional need of the Agency (e.g. involvement of experts in the framework of international collaboration with regulatory authorities)'.

Prioritisation of future assessment works

The deadline for interested parties to comment on the priority level of pending assessment works is extended to **30 September 2010**. Please see the May HMPC meeting report for details.

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

The MLWP held its 27th meeting at the European Medicines Agency on 12-14 July 2010.

In addition to the work that supported the adoption by the HMPC of the above-mentioned draft and final monographs/list entries and related documents, the MLWP made significant progress on the scientific work relating to the assessment of Agni casti fructus (monograph), Cimicifugae rhizoma (monograph), Euphrasiae herba (public statement) and Thymi aetheroleum (list entry). The working party progressed draft monographs on Cynarae folium, Millefolii herba and Oenotherae biennis oleum. The MLWP further discussed a draft monograph on Symphyti radix and reviewed in parallel meetings of 4 small groups draft monographs on Lavandulae aetheroleum, Chelidonii herba, Cichorii intybi radix, Filipendulae ulmariae herba, Millefolii flos, Myrrha, Plantaginis lanceolatae folium and Thymi herba/Primulae radix.

An updated 'Overview of status of HMPC assessment work – July 2010' (EMA/HMPC/278067/2006) will be 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

The next meeting of the MLWP is scheduled for 13-15 September 2010.

Organisation matters Drafting Group (ORGAM DG)

The HMPC heard a report on the work carried out during the ORGAM DG meeting on 16 June 2010.

Upon a proposal from the ORGAM DG, in consultation of the MLWP, the HMPC adopted the following new and revised reference documents relevant for the preparation of monographs and list entries.

New:

- 'Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, preparations and/or combinations thereof are not established' (EMA/HMPC/84530/2010)
- 'Template for public statement when no monograph is established' (EMA/HMPC/75972/2010)

Revised:

- 'Template for a Community herbal monograph' (EMA/HMPC/107436/2005 Rev. 5)
- 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev. 1)
- 'Timelines for the establishment of Community list entries and Community herbal monographs' (EMA/HMPC/126542/2005 Rev. 2)
- 'Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries' (EMA/HMPC/326440/2007 Rev.1)
- 'Template for a Community list entry' (EMA/HMPC/439705/2006 Rev. 4)

All documents will be published on the Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000264.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580118a1d&jsenabled=true#section2

The next meeting of the ORGAM DG is scheduled for 13 October 2010.

Quality Drafting Group (Q DG)

The HMPC heard a report on the work carried out during the Q DG meeting on 15 June 2010.

The Q DG progressed with the revision of the Question & Answers on quality matters for herbal medicinal products for publication on EMA website (EMA/HMPC/41500/2010). Previously published Questions & Answers will be merged into one document and further extended. Publication is expected after the September HMPC meeting.

Beside tasks in coordination with the Scientific Advice Working Party, progress was made in particular with finalising the 'Reflection paper on level of purification of extracts to be considered as herbal preparations'.

The next meeting of the Q DG is scheduled for 29 July 2010.

Other matters

The European Medicines Agency has launched a newly structured website on 16 July 2010:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&murl=&mid=&jsenabled=true

Information on herbal medicinal products has improved and can be found at different pages within the overall structure, including a new search function by therapeutic areas for herbal medicines. Some key links are listed below:

- **Find medicine** (with herbal specific search according to (I) alphabetical order, (II) key words, or (III) therapeutic area):
http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d
- **Regulatory>Human medicines>Herbal products** (overview and all links to information relevant for herbal medicinal products):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf
- **About Us>Committees>HMPC** (overview and all links to relevant information on the HMPC):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000264.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e7c

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