



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 47th HMPC meeting, held 21-22 May 2012

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates, reminding them about the cancellation of the July 2012 meeting as a consequence of the organisation of the Olympic Games in London. The next meeting of the HMPC will start on 24 September 2012 and will be followed by an assessors' training on non-European traditional medicines.

Final Community herbal monographs

Upon recommendation from the MLWP as a result of its 27-29 March 2012 meeting, the HMPC adopted the following final Community herbal monograph and related documents by consensus:

- 'Community herbal monograph on *Glycyrrhiza glabra* L. and/or *Glycyrrhiza inflata* Bat. and/or *Glycyrrhiza uralensis* Fisch., radix' (EMA/HMPC/571119/2010)

The HMPC adopted the following final Community herbal monographs and related documents by a majority vote:

- 'Community herbal monograph on *Aesculus hippocastanum* L., cortex' (EMA/HMPC/354156/2011)
- 'Community herbal monograph on *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia x vulgaris* Heyne or their mixtures, flos' (EMA/HMPC/337066/2011)

The final Community herbal monographs as well as the HMPC opinion, assessment report and overview of comments received during the consultation period (if any), 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=menu/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Final public statements

Upon recommendation from the MLWP, the HMPC adopted the following final public statements by consensus:

- 'Public statement on *Citrus bergamia* Risso & Poiteau, aetheroleum' (EMA/HMPC/528177/2011)



- 'Public statement on *Tilia tomentosa* Moench, flos' (EMA/HMPC/510064/2011)

The final public statements, assessment reports and overview of comments received during the consultation period (if any), 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

Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monographs, for public consultation until 15 October 2012:

- Draft 'Community herbal monograph on *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, semen' (EMA/HMPC/897344/2011)
- Draft 'Community herbal monograph on *Cichorium intybus* L., radix' (EMA/HMPC/121816/2010)

All draft documents 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

Other

Referral procedure "Adequacy of evidence of the long-standing use"

Name: Venoforton, oral liquid

Type of procedure: Article 16c(1)c of Directive 2001/83/EC, as amended

The HMPC adopted an opinion within the referral procedure on Venoforton, oral liquid (Leky Natury, Tadeusz, Polański, PL) containing a combination of 5 herbal preparations. The procedure had started in March at the request of Poland, seeking an opinion by the Committee on the adequacy of evidence of long-standing use of the product. The opinion is provided to the triggering Member State for consideration within their assessment of the traditional use registration application for Venoforton, oral liquid as well as to the other Member States of the European Union.

Cancellation of assessment works

The HMPC agreed upon recommendation of the MLWP to cancel the assessment work for *Cichorii intybi folium*. After thorough assessment by the Rapporteur, market information and scientific data are insufficient to establish a monograph. The herbal substance will be deleted from the HMPC priority list.

Public statement on thujone

The HMPC adopted a revision of the 'Public statement on the use of herbal medicinal products containing thujone' (EMA/HMPC/732886/2010 Rev.1) with a revised 'Overview of comments received during the public consultation' (EMA/HMPC/85696/2012 Rev.1). The MLWP was asked to review accordingly the monographs on *Absinthii herba* and *Salviae officinalis folium*.

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

The HMPC heard a report on the uptake of traditional use registrations (TUR) and marketing authorisations (MA) granted since the implementation of Directive 2004/24/EC in all Member States.

The report published first in May 2011 has again been updated according to a new survey carried out reflecting the status by December 2011. The revised report can be found at:

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

The next update is scheduled for beginning 2013 reflecting the status by end of 2012.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 25 April 2012.

The HMPC adopted the revision 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.1) as well as an appendix 1 for this guideline, consisting of a Best Practice Guide. The appendix 1 provides further clarification on the exact location of relevant parts of the documentation, and the corresponding scientific guidelines, in the CTD Module 3 'Quality' (EMA/HMPC/351875/2011). The revised guideline will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000264.jsp&mid=WC0b01ac0580118a1d

The HMPC adopted the draft 'Concept paper on non-pharmacopoeial reference standards for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/312890/2012) for 3-month public consultation in preparation of a guideline's development. The concept paper will be published here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000365.jsp&mid=WC0b01ac0580029569

The next DG Q meeting (virtual) is scheduled for 14 June 2012.

Drafting Group on Organisational matters (DG ORGAM)

The next meeting of the DG ORGAM (virtual) is scheduled for 4 July 2012.

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

The MLWP held its 38th meeting at the European Medicines Agency on 22-24 May 2012.

The Working Party finalised the assessment of *Pelargonii radix* and *Thymi herba*/Primulae radix for transmission to the HMPC for adoption. The MLWP also endorsed the monographs and supporting documents on *Cucurbitae semen* and *Symphyti radix*, for peer-review, prior to transmission to the HMPC for possible final adoption in November 2012. The MLWP made further progress on the scientific work towards the finalisation of the assessment of *Visci albi herba*. The finalisation of the assessment by MLWP of *Urticae radix* had been postponed to September.

The working party continued its assessment of *Juglandis folium*, *Rubi idaei folium*, *Sambuci fructus* and *Organi dictamnii herba*. The MLWP discussed in small groups the draft assessment reports and monographs on *Eucalypti aetheroleum*, *Fucus vesiculosus*, *Ginkgo folium*, *Ginseng radix*, *Melaleuca alternifoliae aetheroleum* and *Phaseoli fructus sine semine*. The working party discussed reports from Rapporteurs on the assessment of *Adhatodae vasicae folium*, *Andrographidis paniculatae folium*, *Angelicae sinensis radix* and *Camelliae sinensis non fermentata folia*.

As part of the pilot phase on the systematic review of adopted monographs and supporting documents, the sets of documents for *Melissae folium* and *Primulae flos*, will be further amended according to the conclusions of the MLWP, which reviewed the documents at the request of the HMPC on 22 May. Further work will take place on the revision of the monographs on *Anisi aetheroleum*, *Anisi fructus* and *Plantaginis ovatae seminis tegumentum* and their supporting documents.

A hearing of AESGP during the MLWP meeting took place on 23 May. The report from this hearing will be published on the Agency website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac058003529f

The next meeting of the MLWP is scheduled for 26-28 September 2012.

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