



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 February 2013
EMA/HMPC/44844/2013
Patient Health Protection

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

The 50th HMPC meeting, held 14-15 January 2013

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 50th meeting of the Committee.

Final Community herbal monographs

Upon recommendation from the MLWP as a result of its 20-22 November 2012 meeting, the HMPC adopted the following final Community herbal monograph and related documents by consensus:

- 'Community herbal monograph on *Cichorium intybus* L., radix' (EMA/HMPC/121816/2010)
- 'Community herbal monograph on *Eucalyptus globulus* Labill., folium' (EMA/HMPC/892618/2011)
- 'Community herbal monograph on *Solanum dulcamara* L., stipites' (EMA/HMPC/734361/2011)

The HMPC also adopted the following final Community herbal monograph and related documents by majority vote:

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

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=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 April 2013:

- Draft 'Community herbal monograph on *Juglans regia* L., folium' (EMA/HMPC/346737/2011)
- Draft 'Community herbal monograph on *Marrubium vulgare* L., herba' (EMA/HMPC/604271/2012)



Draft public statements

Upon recommendation from the MLWP, the HMPC adopted the following draft public statements, for public consultation until 15 April 2013:

- Draft 'Public statement on *Adhatoda vasica* Nees, folium' (EMA/HMPC/681468/2012)
- Draft 'Public statement on *Andrographis paniculata* Nees, folium' (EMA/HMPC/709282/2012)

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=WCOb01ac0580033a9d

Other

Start of referral procedure "Adequacy of evidence of the long-standing use"

Name: 'Frischpflanzenpresssaft aus Passionsblumenkraut'

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

The HMPC started a referral procedure for 'Frischpflanzenpresssaft aus Passionsblumenkraut' (pressed juice from *Passiflorae herba*; Walther Schoenenberger Pflanzensaftwerk GmbH & Co KG). The procedure was initiated by Germany to request an opinion by the Committee on the adequacy of evidence of long-standing use of the product. The HMPC appointed a Rapporteur and a Co-Rapporteur who will prepare assessment reports for the Committee. Although the legislation does not provide for a specific timeframe, the HMPC agreed to endeavour to issue a reasoned opinion within 60 days.

Call for submission of scientific data

The HMPC endorsed the release of calls for submission of scientific data to support the review/revision of the monographs for *Betulae folium*, *Calendulae flos*, *Echinaceae purpureae herba*, *Eleutherococci radix*, *Foeniculi amari fructus*, *Foeniculi amari fructus aetheroleum*, *Foeniculi dulcis fructus*, *Lupuli flos* with a deadline for submission on 15 May 2013. The calls 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=WCOb01ac0580033a9c

Scientific contributions in response to a call for the submission of scientific data can be provided to the Agency in electronic format (e-mail or CD-ROM) or paper format (two copies by post or fax).

Call for expression of interest by organisations in the field of non-European traditional medicines

As indicated in the September 2012 meeting report concerning the assessors training organised at the Agency, the HMPC intends to consider a continued dialogue with interested parties (IP) on non-European traditional medicines. As such the Committee would like to invite organisations in the field and not yet considered as IP to the HMPC to express their interest to become such IP to the HMPC, in order to establish regular contacts, in line with the HMPC rules of procedure. Requests for consideration as IP should be sent to the hmpc.secretariat@ema.europa.eu; they will be assessed against criteria established at the EMA for such contacts with [interested parties](#).

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 13-14 December 2012 including a session with the Chairs of the European Pharmacopoeia's Expert Groups 13A, 13B, TCM on matters relevant to the coordination between the EMA/HMPC and EDQM. Beside mutual information of ongoing and planned work, DG Q and EDQM had discussed in particular the revision of the Ph. Eur. monograph on extracts.

The HMPC adopted the following documents for public consultation until 15 May 2013:

- Draft 'Reflection paper on quality of essential oils as active substances in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/9947/2013)
- 'Concept paper on use of recovered/recycled solvents in the manufacture of herbal preparations for use in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/13658/2013)

The documents will be published on the EMA website at:

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

The DG Q had also finalised the quality part of the revised 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMA/HMPC/768094/2012 Rev. 1, including a new Appendix 1 'Best practice guide') taking into account comments received during public consultation. The revised guideline is anticipated to be finalised and adopted at the HMPC March meeting.

The HMPC agreed to postpone publication of the DG Q work programme for 2013 in order to review the capacity of the DG to carry out all tasks listed in the work programme as adopted by the HMPC in September 2012. This is to take into account the fact that all DG meetings in 2013 are now foreseen by EMA to be held virtually (rather than face to face), due to general budget restrictions which will also affect other activities, e. g. coordination with EDQM.

The next meeting of the DG Q will be held on 13-14 February 2013.

Drafting Group on Organisational matters (DG ORGAM)

The next meeting of the DG ORGAM (virtual) is scheduled for 11 February 2013.

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

The MLWP held its 41th meeting at the European Medicines Agency, 15-17 November 2013.

Systematic review

The working party discussed the revision of the monograph and related documents on *Melissae folium*.

Finalisation

The Working Party considered that, for finalisation of the assessment of *Symphyti radix*, it was preferable to consider the comments arising from the public consultation on the draft 'Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)' (EMA/HMPC/893108/2011). The public consultation will end on 15 February 2013, providing an opportunity for the working party at its March meeting to hear from the Rapporteur for the public statement whether new data have been provided, which are relevant to the assessment of *Symphyti radix*.

Drafts

Upon request by the HMPC, the MLWP agreed on a public statement on Sambuci fructus for transmission to the HMPC in March 2013 for release for public consultation. The working party finalised the assessment of Rubi idaei folium and Phaseoli fructus (sine semine) for transmission to the HMPC in March also for release for public consultation.

The MLWP endorsed the monographs on Camelliae sinensis non fermentata folia, Fucus vesiculosus and Ginseng radix for peer-review and transmission to the HMPC for possible release in March 2013 for public consultation.

The working party continued its assessment of Ginkgo folium and Melaleucae alternifoliae aetheroleum and discussed the first draft assessment report and monograph on Allii sativi bulbus.

The next meeting of the MLWP is scheduled for 12-14 March 2013.

Contact for further information

Anthony Humphreys
Head of Regulatory, Procedural and Committee Support
Tel.: +44 (0)20 7418 8583
Fax: +44 (0)20 7523 7051
E-mail: hmpc.secretariat@ema.europa.eu