



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 September 2011
EMA/HMPC/767990/2011
Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 43rd HMPC meeting, held 12-13 September 2011

The HMPC Chair welcomed Dr B. Jansone, new alternate member from Latvia. During the plenary meeting, the HMPC renewed the three-year term of Prof. G. Laekeman, co-opted member with expertise in experimental/non-clinical pharmacology and Dr H. Pinto Ferreira, co-opted member with expertise in general and family medicine.

Final Community herbal monographs

Upon recommendation from the MLWP as a result of its 12-14 July 2011 meeting, the HMPC adopted the following final Community herbal monographs and related documents:

- 'Community herbal monograph on *Cynara scolymus* L., folium' (EMA/HMPC/150218/2009)
- 'Community herbal monograph on *Fumaria officinalis* L., herba' (EMA/HMPC/574766/2010)
- 'Community herbal monograph on *Syzygium aromaticum* (L.) Merrill et L. M. Perry, floris aetheroleum' (EMA/HMPC/534924/2010)

These monographs were adopted by consensus. 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 February 2012:

- Draft 'Community herbal monograph on *Cucurbita pepo* L., radix' (EMA/HMPC/136024/2010)
- Draft 'Community herbal monograph on *Aesculus hippocastanum* L., cortex' (EMA/HMPC/354156/2011)



- Draft 'Community herbal monograph on *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia x vulgaris* Heyne L., or their mixtures, flos' (EMA/HMPC/337066/2011)
- Draft 'Community herbal monograph on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix' (EMA/HMPC/461160/2008)

NB: The release of this monograph follows progress achieved since July 2009 when the HMPC had published a public statement explaining the reasons why no monograph could be established at that time. Following interpretation received from the European Commission in July 2010 on indications appropriate for traditional herbal medicinal products, the HMPC/MLWP were able to prepare a monograph on the traditional medicinal uses of nettle root.

The deadline for public consultation announced in July for the two following monographs is prolonged from 15 November until 15 December 2011, given the delay in the publication of the documents:

- Draft 'Community herbal monograph on *Zingiber officinale* Roscoe, rhizoma' (EMA/HMPC/749154/2010)
- Draft 'Community herbal monograph on *Rhodiola rosea* L., rhizoma et radix' (EMA/HMPC/232091/2011)

Final public statements

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

- Final 'Public statement on *Chelidonium majus* L., herba' (EMA/HMPC/743927/2010)

The overview of comments received during the public consultation will be published together with the final documents.

Draft public statements

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

- Draft 'Public statement on *Citrus bergamia* Risso et Poiteau, aetheroleum' (EMA/HMPC/56155/2011)
- Draft 'Public statement on *Tilia tomentosa* Moensch., flos (EMA/HMPC/510064/2011)
- Draft 'Public statement on *Viscum album* L., herba (EMA/HMPC/57109/2011)

The data currently available do not allow the HMPC to develop a Community herbal monograph for these herbal substances/preparations. The draft public statements will be published on the Agency's website for comments by 15 February 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=WC0b01ac0580033a9d

Draft monographs/list entries/public statements subject to a public consultation can be found [here](#) by using the tab '*Browse by status*', selecting '*Draft published*' and clicking on '*Submit*'. The list of herbal substances currently under active public consultation will appear in alphabetic order.

Other

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

Rapporteurs were appointed for the establishment of monographs/list entries on *Fucus vesiculosus*, *Phaseoli fructus*, *Rubi folium* and *Sambuci fructus*.

Following these appointments, calls for data will be published. The deadline for the submission of scientific data in response to each respective call is 15 February 2012.

These appointments have been reflected in the Rapporteurships' distribution given in the HMPC priority list (EMA/HMPC/278067/2006) 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

Quality Drafting Group (Q DG)

The HMPC adopted the work programme and meeting dates for the Q DG in 2012. The work programme will be available on the following page:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000049.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e9b

The HMPC also confirmed the nomination of two observers in the European Pharmacopoeia Expert Groups on Phytotherapy 13A and 13B, respectively I. Chinou and H. Neef.

The next meeting of the Q DG is scheduled for 13 October 2011.

Organisational matters Drafting Group (ORGAM DG)

Upon recommendation from the ORGAM DG, the HMPC adopted the following document:

- 'Public statement on the interpretation of therapeutic indications appropriate to traditional herbal medicinal products' (EMA/HMPC/473587/2011)

The document will be available on the following page:

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

The HMPC adopted the work programme and meeting dates for the ORGAM DG in 2012. The work programme will be available on the following page:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000048.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e9a&jsenabled=true

The next meeting of the ORGAM DG is scheduled for 14 December 2011, when comments received on the procedural and guidance documents released in July will be reviewed.

Other relevant information

HMPC 2012-2015 work programme

Upon appointment of sponsors and lead sponsors, the HMPC adopted its work programme for the period 2012-2015. For the various projects/topics, specific deliverables and associated timelines will be

developed. Some projects will be dependant on capacities from the Committee members as the projects are to be realised on top of the activities in support of the HMPC core-tasks. The work programme will be available 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

Report from the September 2011 Working Party on Community Monographs and Community List (MLWP)

The MLWP held its 34th meeting at the European Medicines Agency on 13-15 September 2011.

The MLWP finalised the assessment of *Agropyri repentis rhizoma*, *Caryophylli flos*, *Chamomillae romanae flos*, *Colae semen*, *Oenotherae biennis oleum*, *Oleae folium* and *Plantaginis lanceolatae folium* for a peer-review prior to transmission to the HMPC for adoption at its November meeting.

The Working Party made significant progress on the scientific work towards the finalisation of assessment of *Echinaceae angustifoliae radix*, *Lavandulae aetheroleum*, *Lavandulae flos* and *Pelargonii radix*. The MLWP progressed the scientific work on *Levistici radix*, *Matricariae aetheroleum* and *Matricariae flos*; when adopted by the MLWP, draft monographs/public statements will be adopted by the HMPC for release for a 3-month public consultation. The MLWP discussed the draft assessment report and monograph on *Grindeliae herba* and on *Solani dulcamarae stipites*.

The MLWP concluded its assessment of the comments received in July 2011 regarding the changes in the monograph on *Uvae ursi folium* concerning the gender-specific indication. The set of documents will be discussed by the HMPC in November.

The next meeting of the MLWP is scheduled for 22-24 November 2011.

CHANGE TO PUBLIC CONSULTATION ON HERBAL MONOGRAPHS AND LIST ENTRIES

With a view to improving the process supporting the establishment of Community herbal monographs and Community list entries, the HMPC/MLWP will apply a new approach to the public consultation on draft monographs, list entries, public statements and supporting documents. This approach shall facilitate the assessment of comments, suggestions and corresponding justifications.

Interested parties are invited to send
comments together with a copy of the cited references.

When the reference consists of a book chapter, the copy must include
the page of the book showing the year of publication.

As of 2012, comments without copies of the supporting literature will not be considered.

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