



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 42nd HMPC meeting, held 11-12 July 2011

The HMPC Chair welcomed Dr Pavla Muzikářová, new alternate member from the Czech Republic. During the plenary meeting, the HMPC renewed the three-year term of Prof. G. Calapai, co-opted member with expertise in clinical pharmacology.

Final Community herbal monographs

Upon recommendation adopted by the MLWP in May 2011, the HMPC adopted the following final Community herbal monographs and related documents:

- `Community herbal monograph on *Achillea millefolium* L., flos' (EMA/HMPC/143949/2010)
- `Community herbal monograph on *Achillea millefolium* L., herba' (EMA/HMPC/290284/2009)
- `Community herbal monograph on *Commiphora molmol* Engler, gummi-resina' (EMA/HMPC/96911/2010)
- `Community herbal monograph on *Capsella bursa-pastoris* (L.) Medikus, herba' (EMA/HMPC/262766/2010)
- `Community herbal monograph on *Filipendula ulmaria* (L.) Maxim., flos' (EMA/HMPC/434894/2010)
- `Community herbal monograph on *Filipendula ulmaria* (L.) Maxim., herba' (EMA/HMPC/434881/2010)

With the exception of the monograph on Millefolii flos, they 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=menu/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 November 2011:

- Draft 'Community herbal monograph on *Zingiber officinale* Roscoe, rhizoma' (EMA/HMPC/749154/2010)
- Draft 'Community herbal monograph on *Symphytum officinale* L., radix' (EMA/HMPC/572846/2009)
- Draft 'Community herbal monograph on *Glycyrrhiza glabra* L. and/or *Glycyrrhiza inflata* Bat and/or *Glycyrrhiza uralensis* Fish, radix' (EMA/HMPC/571119/2010)
- Draft 'Community herbal monograph on *Fraxinus excelsior* L. and *Fraxinus oxyphylla* M. Bieb, folium' (EMA/HMPC/239271/2011)
- Draft 'Community herbal monograph on *Rhodiola rosea* L., rhizoma et radix' (EMA/HMPC/232091/2011)

Draft monographs and supporting 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 subject to a public consultation can be found [here](#) using by 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

Public statements

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

- Draft 'Public statement on *Allium cepa* L., bulbus' (EMA/HMPC/347189/2011)

The data currently available do not allow the HMPC to develop a Community herbal monograph. If new information on the period of traditional medicinal use or evidence to support a well-established medicinal use is made available, such documentation will be re-assessed by the HMPC. The draft public statement will be published on the Agency's website for comments by 15 November 2011.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000156.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

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 *Origanum dictamnii* herba, *Prunella africanae* cortex, *Rosae flos*, *Rosae aetheroleum* as well as on *Adhatoda vasicae* folium, *Picrorhiza kurroa* rhizoma and *Withania somniferae* radix.

The last three appointments have been made within the context of the submission by Indian Authorities of eight proposals for monographs on medicinal plants used in Ayurvedic medicine, for consideration by the HMPC. The Committee had investigated the period and extent of use of the plants and had noted signals which might support a traditional use in the EU in the last 15 years for three amongst the eight plants, whilst two were already covered by a monograph. The HMPC looks forward

to receiving from the Indian Authorities and from any interested party further evidence of the medicinal uses for the above-mentioned three herbal substances and preparations thereof. For reference, please consult the 'Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs' (EMA/HMPC//2010) which can be found here.

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

This assessment work will run in parallel to the work ongoing at the European Pharmacopoeia towards the development of pharmacopoeial standards for several Ayurvedic herbal substances. The European Directorate for the Quality of Medicines (EDQM) should be contacted for further information (<http://www.edqm.eu/en/Homepage-628.html>).

Following these seven appointments, calls for data will be published. The deadline for the submission of scientific data in response to each respective call is 15 November 2011.

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.js&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf

Calls for submission of scientific data to support the systematic review of adopted monographs

To support the systematic review of 10 monographs, according to a new procedure adopted by the HMPC (see Organisational Matters Drafting Group), calls for data will be released, which invite the submission of **scientific literature published since the end date of the public consultation on the monograph and supporting documents**, for:

Anisi fructus, Anisi aetheroleum, Lini semen, Melissaefolium, Passiflorae herba, Primulaeflos, Primulaeradix, Plantaginis ovatae semen, Plantaginis ovatae seminis tegumentum and Valerianae radix.

Submissions are sought by 15 November 2011. Information about calls for data can be found here:

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

Quality Drafting Group (Q DG)

The HMPC heard a report on the work carried out during the Q DG meeting held on 16 June, which led to the adoption by the Committee of an updated version of the 'Regulatory Q&A on herbal medicinal products (EMA/HMPC/345132/2010 Rev.1) with two additional questions on comparability of herbal preparations, which can be found under 'General' 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 also adopted a Best practice guide, developed as a first annex to 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)'. Work is ongoing in the Q DG for the development of a second annex, a mock CTD submission. The revised guideline will only be published when both annexes have been prepared.

The HMPC endorsed the Q DG comments on a draft Q&A, prepared by the Quality Working Party of the Committee for Medicinal Products for Human Use, on the quality requirements for starting materials of herbal origin used for semi-synthesis of active substances. Coordination will take place between the two groups.

Finally, the HMPC supported the participation of 2 members from the Q DG as representatives of the HMPC in future work on the ongoing revision by EDQM of the Ph. Eur. monograph on extracts.

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

Organisational matters Drafting Group (ORGAM DG)

The HMPC heard a report on the work carried out during the ORGAM DG meeting on 17 June 2011 (VITERO). This work led to the adoption by the HMPC of the following procedural and guidance documents:

Final

- '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) and the accompanying 'Template for a public statement when no Community herbal monograph is established' (EMA/HMPC/75972/2010) finalised. An overview of comments received during the public consultation has been prepared (EMA/HMPC/495353/2011).

Draft

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

These three documents are released for public consultation until 15 November 2011.

Revised

- 'Template for a Community herbal monograph' (EMA/HMPC/107436/2005 Rev.6), reflecting latest practice in the MLWP when establishing monographs.
- 'Procedure for calls for scientific data for use in HMPC assessment works' (EMA/HMPC/1004/2006 Rev. 4). This document was revised as a consequence of the preparation of the above-mentioned procedure on the review of adopted monographs, which anticipates the publication of calls for the submission of new literature and scientific data that became available since the finalisation of the monograph. Data collected will be assessed, as part of the steps for the systematic review of the need to revise (or not) the scientific content of a monograph.

New on the Agency website – for use by HMPC/MLWP members

- 'Template for submission by HMPC members or national competent authorities of questions for discussion by the HMPC' (EMA/HMPC/463090/2011).
- 'Template for information exchange for the preparation of AR supporting the establishment of Community herbal monographs and Community list entries' (EMA/HMPC/137093/2006).

The documents will be published on the European Medicines 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

The next meeting of the ORGAM DG is scheduled for 12 October 2011.

Other relevant information

Innovation Task Force and borderline products

The HMPC heard a presentation by the secretariat of the EMA Innovation Task Force (ITF) and its mandate. The Committee welcomed the invitation for a future involvement of experts from the HMPC in briefing meetings covering regulatory, technical and scientific issues raised by companies developing innovative herbal medicines, using new technologies or for borderline products containing herbal ingredients. Further information about the ITF can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000334.js&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800ba1d9

Progress report on Action plan for herbal medicines 2010-2011

The HMPC considered the second progress report on the different objectives and actions foreseen in the '[Action plan for herbal medicines 2010-2011](#)' and will discuss the preparation of a public report in September. The Committee noted the start of the second collection of information on the traditional use registrations and of MA under the WEU provisions granted in the EU Member States since the implementation of Directive 2004/24/EC. The data will be gathered and presented in the autumn, in a report expected to be published in the 4Q2011.

Work programmes, 2012 and beyond

The HMPC endorsed the draft 2012 work programmes for the MLWP, ORGAM DG and Q DG and their schedule of meetings was reviewed accordingly, anticipating a greater use of VITERO-based meetings. The Committee also considered the first proposal for a work programme of the HMPC for the period 2012-2015. All programmes will be further discussed for adoption by the September 2011 HMPC meeting.

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

The MLWP held its 33rd meeting at the European Medicines Agency on 12-14 July 2011.

The MLWP finalised the assessment of *Agropyri repentis rhizoma*, *Caryophylli aetheroleum*, *Chamomillae romanae flos*, *Chelidonii herba*, *Cynarae folium* and *Fumariae herba* for transmission to the HMPC for adoption at its September meeting. The Working Party made significant progress on the scientific work towards the finalisation of assessment of *Plantaginis lanceolatae folium*.

The MLWP concluded the scientific work on *Citri bergami aetheroleum*, *Cucurbitae semen*, *Hippocastani cortex*, *Tiliae flos*, *Tiliae tomentosae flos*, *Urticae radix* and *Visci albi herba*; draft monographs/public statements are expected to be adopted by the HMPC in September for release for a 3-month public consultation. The MLWP discussed the draft assessment report on *Levistici radix*.

After finalisation of the monograph and supporting documents on *Uvae ursi folium*, comments were received on the changes concerning the gender-specific indication. These comments will be assessed

and discussed at the September MLWP meeting. If endorsed, the adopted set of documents will be revised. As announced in the May 2011 HMPC meeting report, the MLWP established a monograph, the AR and the list of references on *Urticae radix*. The next procedural steps towards finalisation of the monograph and supporting documents will be discussed in September by the HMPC.

The next meeting of the MLWP is scheduled for 13-15 September 2011.

Contact for further information

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