



27 May 2010
EMA/HMPC/291747/2010
Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 35th HMPC meeting, held 5-6 May 2010

The Committee welcomed observers¹ from Montenegro and Bosnia and Herzegovina.

Final Community herbal monographs and related documents

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

- 'Community herbal monograph on *Ilex paraguariensis* St. Hil., folium' (EMA/HMPC/580539/2008);
- 'Community herbal monograph on *Ribes nigrum* L., folium' (EMA/HMPC/142986/2009);
- 'Community herbal monograph on *Valeriana officinalis* L., radix and *Humulus lupulus* L., flos' (EMA/HMPC/142986/2009).

The final Community herbal monographs — as well as the respective HMPC opinions, assessment reports 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/htms/human/hmpc/hmpcmonographs.htm>

Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monographs, to be released for public consultation until 15 August 2010:

- Draft 'Community herbal monograph on *Tanacetum parthenium* (L.) Schulz Bip., herba' (EMA/HMPC/587578/2009);
- Draft 'Community herbal monograph on *Trigonella foenumgraecum* L., semen'
- Draft 'Community herbal monograph on *Leonurus cardiaca* L., herba' (EMA/HMPC/127428/2010).

¹ <http://www.ema.europa.eu/htms/euenlargement/euenlargement.htm>



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

<http://www.ema.europa.eu/htms/human/hmpc/hmpcmonographs.htm>

Other

The HMPC endorsed the MLWP recommendation to discontinue the assessment work of *Terebinthinae laricina* as only one combination product and no single-ingredient-product can be found on the European market and since no interested party reported a high priority level for this work.

Appointment of Rapporteurs and Peer-reviewers

The HMPC appointed a Rapporteur and a Peer-reviewer for the preparation of a Community herbal monograph/Community list entry on Hippocastani cortex.

Calls for submission of scientific data

A call for submission of scientific data is made for Hippocastani cortex, Arnicae flos and for *Visci albi herba*. Data are requested by 30 July 2010. Please refer to the 'Procedure for calls for scientific data for use in HMPC assessment work' published on the Agency website for guidance on the scope of data requested and recommendations about the submission of contributions:

<http://www.ema.europa.eu/pdfs/human/hmpc/100406en.pdf>

Initiatives to stimulate the conduct of clinical studies in children and paediatric data available in respect of authorised products

As anticipated in the MLWP 2010 work programme, a reflection paper is being developed on the necessity of initiatives to stimulate the conduct of clinical studies with herbal medicinal products in the paediatric population. The HMPC adopted the document for transmission to the PDCO for coordination, prior to release for public consultation. The HMPC was informed about the Agency coordinating role for the exchange of information on paediatric studies already completed, by the date of entry into force of Regulation (EC) No 1901/2006, in respect of products authorised in the Community as per the provisions of Article 45 of this regulation. The HMPC also noted the work-sharing² approach adopted by the CMDh for the assessment of these data. The HMPC expressed an interest in receiving the paediatric data collected in respect of herbal medicinal products, as such data could be evaluated by the HMPC for the purpose of establishing Community herbal monographs/Community list entries on the concerned herbal preparations.

New KPI on establishment of monographs and list entries

The HMPC agreed on a new Key Performance Indicator (KPI) for the establishment of Community herbal monographs. The committee endorsed the proposal from the ORGAM DG and MLWP for a new quantitative KPI related to the time required for the establishment of a monograph. A target will be established in 2012 on the basis of data to be collected in 2011 and historical data for the monographs finalised between 2006 and 2010 (time calculated from the first presentation of the monograph and supporting assessment report to the MLWP until adoption as final by the HMPC, including the standard 90-day public consultation period).

² Mandate of the EMA/CMDh Subgroup on Paediatric Regulation
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/CMD_subgroups_working_groups/Paediatric_Regulation/CMDh-EMA-145-2009-Rev0_2009_06.pdf

Call for involvement of patients and consumers organisations operating in the field of herbal medicines in the activities of the European Medicines Agency

The HMPC further discussed the involvement of patients' and consumers' organisations in its activities, in particular the contribution to the provision of information on herbal medicines to the general public. In 2009, the need for reliable and understandable information about herbal medicines on the Agency website was acknowledged. The report from the first joint meeting between representatives from HMPC and patients' and consumers' organisations can be found here:

<http://www.ema.europa.eu/htms/human/hmpc/hmpcinterestedpart.htm>

Whilst the Agency further investigates the needs of patients and consumers, the HMPC is calling upon associations and organisations representing patients and consumers with an interest in herbal medicines to express their willingness in getting involved in this field of cooperation with the Agency. Further information about participation in the Agency activities can be found here:

<http://www.ema.europa.eu/Patients/getinvolved.htm>

Associations and organisations are invited to write the HMPC secretariat (hmpc.secretariat@ema.europa.eu) in response to this call for expression of interests. Any interested organisation will be evaluated by the Agency against a defined set of criteria in order to ensure that the Agency establishes contacts only with appropriate organisations that are genuinely acting in the interests of European patients and consumers.

Prioritisation of future assessment works

Views from interested parties on priorities for the establishment of monographs and list entries are being sought. A first prioritisation of the assessment of herbal substances and preparations thereof took place in 2005 with the contribution from various organisations. This is reflected in the column B of the 'inventory of herbal substances for assessment'.

<http://www.ema.europa.eu/pdfs/human/hmpc/49407907en.pdf>

Towards the end of its second mandate, with over 60 final monographs published, the HMPC now would like to prompt again interested parties to comment on the priority level of pending assessment works. In annex, 38 herbal substances for which a Rapporteur has been appointed in the past are listed, for which the assignment of a priority level is requested. This should assist the HMPC to meet the needs of the market, having regard to April 2011 (and beyond), deadline by which Member States shall apply the provisions of Directive 2004/24/EC to traditional herbal medicinal products on the market. Interested parties are invited to return the annex with a priority level assigned (High, Medium, Low) for the different herbal substances. Responses should be sent to the HMPC secretariat (hmpc.secretariat@ema.europa.eu) by the **end of July 2010**.

If they wish, interested parties are invited to also recommend additional herbal substances/preparations for assessment as well as combinations. Lists of herbal substances (scientific name of the plant according to the binomial system and plant part), preparations and combinations thereof will be welcome. The HMPC however would appreciate receiving a justification as to why a monograph/list entry should be established for the substances, preparations and combinations with a view on the priority level in each case.

Interested parties are encouraged to go beyond and submit proposals for Community herbal monographs/Community list entries with a justification for their priority level according to the procedure on the management of such proposals – link hereafter: <http://www.ema.europa.eu/pdfs/human/hmpc/32857507enfin.pdf>

This procedure points to the submission of overviews of non-clinical and clinical data supplemented by an Expert Report in support of the monograph/list entry. It also acknowledges that some interested

parties may not be in the position to provide such documentation, in which case they can be omitted. Information about the preparation of such proposals with an estimated timeline for their submission will be welcome by the set deadline (30 June).

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

The MLWP held its 26th meeting at the European Medicines Agency on 3-5 May 2010. In addition to the work that supported the adoption by the HMPC, of the above-mentioned draft and final monographs and related documents, the MLWP made significant progress on the scientific work relating to the draft monographs on *Agni casti fructus*, *Rosmarini aetheroleum*, *Rosmarini folium* and *Vitis viniferae folium*. The MLWP discussed draft monographs on *Cinnamomi aetheroleum*, *Cinnamomi cortex* and *Uvae ursi folium*.

The MLWP was successful with the organisation of parallel meetings of 4 small groups which reviewed draft monographs on *Millefoli herba*, *Cynarae folium*, *Bursae pastoris herba* and *Lavandulae aetheroleum*. These monographs will be further discussed in July. This new working methodology will be pursued in July when new assessment works will be also discussed in small groups.

An updated 'Overview of status of HMPC assessment work – May 2010' (EMA/HMPC/278067/2006) will be published on the Agency's website at:

<http://www.ema.europa.eu/pdfs/human/hmpc/27806706en.pdf>

Upon agreement by the HMPC, the MLWP met representatives from the Association of the European Self-Medication Industry (AESGP) on 4 May, in order to discuss a number of general issues related to Community herbal monographs/Community list entries and related documents adopted by the HMPC. Important issues such as genotoxicity study results, data protection and the type of indications granted in the traditional use part of the monographs were raised. AESGP was informed about a change in the policy of the working party as regards the release of draft assessment reports supporting draft monographs for public consultation, with a disclaimer pointing to their nature as 'working document, not yet fully edited'. The MLWP will retain the discretion not to publish a draft assessment report, if concurring with the views of the Rapporteur and Peer-reviewer that it has not reached a sufficiently advanced stage of preparation to be released.

Once adopted, the report from the hearing will be published at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpcinterestedpart.htm>

The next meeting of the MLWP is scheduled for 12-14 July 2010.

Organisation matters Drafting Group (ORGAM DG)

The HMPC heard a report on the work carried out during the ORGAM DG meetings on 11 February and on 14 April 2010, in particular progress in the preparation of a 'reflection paper on the publication of HMPC public statements when no Community herbal monographs/Community list entries can be established'. The ORGAM DG also started discussing the circumstances under which regulatory practice in the Member States triggers the need for a revision of an adopted monograph. Appropriate procedural guidance is being developed for the management of these cases, to ascertain the respective role of the Rapporteur for the monograph and the concerned Member State(s).

The next meeting of the ORGAM DG is scheduled for 16 June 2010.

Quality Drafting Group (Q DG)

The HMPC heard a report on the work carried out during the Q DG meeting on 15 April 2010, in particular progress with revising and streamlining Questions & Answers on quality matters and 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 15 June 2010.

Other matters

The HMPC noted the revised 'Action plan for herbal medicines 2010-2011' reflecting comments raised by the Heads of Medicines Agencies at their April meeting. The document, endorsed by the Agency Management Board in March³, will be published at:

http://www.ema.europa.eu/htms/general/manage/MB/MB_documents_2010.html

Contact for further information

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³ <http://www.ema.europa.eu/pdfs/general/manage/mbpr/16937110en.pdf>

Annex - Prioritisation of future HMPC assessment works

Herbal substances – Priority level: (intended year of preparation of monograph/list entry)	High	Medium	Low
Agrimoniae herba – 2011			
Agropyri repentis rhizoma – 2011			
Allii cepae bulbus - 2011			
Allii sativi bulbus – 2011			
Arnicae flos – 2010			
Carvi aetheroleum – 2011			
Carvi fructus – 2011			
Caryophylli flos – 2011			
Chamomillae romanae flos – 2011			
Citri bergami aetheroleum – 2010			
Colae semen – 2011			
Crataegi folium cum flore – 2011			
Crataegi fructus – 2011			
Curcumae xanthorrhizae rhizoma – 2011			
Eucalypti aetheroleum – 2011			
Eucalypti folium – 2011			
Fragariae folium – 2011			
Fraxini folium – 2011			
Fumariae herba – 2011			
Ginkgo folium – 2011			
Ginseng radix – 2011			
Grindeliae herba – 2011			
Juglandis folium – 2011			
Levistici radix – 2011			
Lichen islandicus – 2011			
Marrubii herba – 2010			
Melaleucaae alternifoliae aetheroleum – 2011			
Myrtilli folium – 2011			
Myrtilli fructus siccus – 2011			

Herbal substances – Priority level: (intended year of preparation of monograph/list entry)	High	Medium	Low
Pelargonii radix – 2011			
Pruni spinosae flos – 2011			
Pruni spinosae summitates – 2011			
Rhodiolae roseae rhizoma – 2011			
Salbalis serrulatae fructus – 2011			
Silybi mariani fructus – 2011			
Solani dulcamarae stipites – 2011			
Tiliae flos – 2011			
Tiliae tomentosae flos – 2011			

Organisation or individual	Contact details (e-mail address, telephone number, name of contact person)

Please return by 30 July 2010 this annex with assigned priority level to
hmpc.secretariat@ema.europa.eu