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Patient Health Protection

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

The 46th HMPC meeting, held 26-27 March 2012

The Chair of the Committee on Herbal Medicinal Products (HMPC) announced the nomination of Dr Barbro Gerdén, new alternate member from Sweden, and welcomed Ms Tatjana Ponorac, new observer from Bosnia and Herzegovina.

The Committee also welcomed the attendance of representatives from the Natural Health Products Directorate at Health Canada, Mr Scott Sawler, Director General and Mr Nana Bafi-Yeboa, Head of Bureau of Product Review and Assessment.

Final Community herbal monographs

Upon recommendation from the MLWP as a result of its 24-26 January 2011 meeting, the HMPC adopted the following final Community herbal monographs and related documents by consensus:

- 'Community herbal monograph on *Echinacea angustifolia* DC., radix' (EMA/HMPC/688216/2008)
- 'Community herbal monograph on *Fraxinus excelsior* L. or *Fraxinus angustifolia* Vahl, folium' (EMA/HMPC/239271/2011)
- 'Community herbal monograph on *Lavandula angustifolia* Mill., aetheroleum' (EMA/HMPC/143181/2010)
- 'Community herbal monograph on *Lavandula angustifolia* Mill., flos' (EMA/HMPC/734125/2010)

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

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

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

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Including the above-mentioned six monographs, the HMPC has approved its **100th Community herbal monograph**. Taking into account a total number of around 200 herbal substances estimated to have a relevant tradition of medicinal use in the European Union, this represents a substantial achievement. The HMPC marked this adoption on 27 March 2012, almost 6 years after the publication of the first four final monographs in July 2006. The adoption of over 40 monographs in 2011 (half final and half draft) indicates that the HMPC has successfully taken up its role despite the many hurdles. The voluntary dimension of the work carried out by Rapporteurs was acknowledged by Mr Guido Rasi when addressing the HMPC in November 2011, during his greeting speech at the plenary meeting of the committee. Since the end of 2010 under the leadership of Dr Werner Knöss (BfArM) and relying on the preparatory work by one working party and two drafting groups, the HMPC has established itself in a few years as an essential platform for discussion, developing tools that foster an increasing European harmonisation, as shown in the regular reports on the uptake of the traditional use registration scheme and on MA for well-established herbal medicines.
The approval of the 100th monograph on Rhodiolae roseae rhizoma et radix marks a milestone as the HMPC also entered into the process of defining its new priorities for the years to come. Maintenance of these monographs at a scientific state-of-the art, assessment of the remaining 'major' plants used in Europe and adjustment to the regulatory activities at the level of the Member States are on the top of the HMPC's agenda. The HMPC Chair will certainly illustrate the challenges of herbal medicines' regulations in Europe when reporting to the EMA management board in June, one year after the end of the transition period for the national implementation of Directive 2004/24/EC. Whilst some provisions remain to be fully operated like those governing mutual recognition, the important role played by Community herbal monographs has now been demonstrated.

Final public statements

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

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

No comments have been received during public consultation.

Draft Community herbal monographs

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

- Draft 'Community herbal monograph on *Eucalyptus globulus* LABILL., folium' (EMA/HMPC/892618/2011)
- Draft 'Community herbal monograph on *Grindelia robusta* Nutt., *Grindelia squarrosa* (Pursh) Dunal, *Grindelia humilis* Hook. et Arn., *Grindelia camporum* Greene, herba' (EMA/HMPC/748220/2011)
- Draft 'Community herbal monograph on *Levisticum officinale* Koch, radix' (EMA/HMPC/524621/2011)
- Draft 'Community herbal monograph on *Solanum dulcamara* L., stipites' (EMA/HMPC/734361/2011)

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

Start 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 started a referral procedure for Venoforton, oral liquid (Leky Natury, Tadeusz, Polański, PL) containing a combination of 5 herbal preparations. The procedure was initiated by Poland 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 for this referral procedure 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.

Cancellation of assessment works

The HMPC agreed upon recommendation of the MLWP to cancel the assessment work for Pruni spinosae flos and for Pruni spinosae summitates. After thorough assessment by the Rapporteur, market information and scientific data are insufficient to establish a monograph. Both substances will be deleted from the HMPC priority list.

Public statement on thujone

The HMPC is revising the 'Public statement on the use of herbal medicinal products containing thujone' (EMA/HMPC/732886/2010) and will decide on consequences for monographs on substances containing thujone during its May meeting.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meeting held on 16 February 2012.

The drafting group progressed with the revision of the 'Guideline on the use of the CTD format', and discussed guidance on acceptance criteria for non pharmacopoeial reference standards for herbal substances and herbal preparations, guidance on microbiological aspects of HMP, and guidance on the biopharmaceutical characterisation of HMP. The group decided on the necessary coordination with EDQM with regard to the CEP procedure related to HMP and the planned revision of the Ph. Eur. monograph on extracts.

The next DG Q meeting (virtual) is scheduled for 25 April 2012.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the progress during the DG ORGAM meeting on 15 February 2012 on documents (procedure and template) to support the preparation of summaries, written in lay language and available in the different EU languages, of the assessments carried out by the HMPC/MLWP of herbal substances and preparations thereof. Coordination took place on 26 March 2012 with members of the EMA Medical Information Sector and a pilot phase was agreed for the establishment of a few of such Assessment Report Summaries for the Public (ARSP). The process is expected to involve representatives from Patients & Consumers' Organisations as anticipated in a joint PCO-HMPC meeting held in the past.

The HMPC endorsed the circulation to the QRD of a template for Patient Leaflets with suggested wordings concerning advice on the preparation by end-users of medicinal herbal teas. After coordination with the QRD, the template will be transmitted to the PCWP for comments.

The next meeting of the DG ORGAM is scheduled for June 2012.

Other relevant information

Report on Action plan herbal medicines 2010-2011

The HMPC adopted a Public Report on the 'Action Plan for Herbal Medicines 2010-2011' (EMA/HMPC/45679/2012), which will be presented to the EMA management board at its June 2012 meeting. The report will be published here:

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

Union reference dates and frequency of PSUR submission for herbal substances

The HMPC provided the Agency with a recommendation on a limited list of herbal substances for which a safety concern may justify the need for PSUR submission. Herbal medicinal products are generally exempted (*public list of Union reference dates and frequency of submission of periodic safety update reports)* according to the provisions of Article 107b (3) and Article 107c (paragraphs 4 and 7) of Directive 2010/84/EU, and Article 26(g) of Regulation (EU) 1235/2010. The URD list is currently under public consultation:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/03/news_detail_001479.jsp&mid=WC0b01ac058004d5c1

Exchange with Health Canada

The HMPC heard a presentation by Mr Sawler on current key initiatives affecting the regulations of natural health products in Canada with a focus on changes in policy interpretation concerning levels of evidence in the fields of health claims for low risk natural health products and ingredients combinations.

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

The MLWP held its 37th meeting at the European Medicines Agency on 27-29 March 2012.

The Working Party finalised the assessment of Liquiritae radix for transmission to the HMPC for adoption. The MLWP also endorsed the monographs and supporting documents on Hippocastani cortex and Tiliae flos, as well as the public statement on Citri bergami aetheroleum and Tiliae tomentosae flos, for peer-review, prior to transmission to the HMPC for possible final adoption in May 2012. The MLWP made further progress on the scientific work towards the finalisation of assessments on Thymi herba/Primulae radix, Cucurbitae semen, Urticae radix as well as Visci albi herba.

The MLWP endorsed the draft monographs and supporting documents on Guaranae semen and Cichorii intybi radix for peer-review, prior to transmission to the HMPC for possible release in May 2012 for a 3-month public consultation, while proposing the cancellation of the assessment on Cichorii intybi folium.

The working party continued its assessment of Juglandis folium, Rubi idaei folium and Sambuci fructus and discussed the draft assessment reports and monographs on Arnicae flos and Origani dictamni herba.

As part of the pilot phase on the systematic review of adopted monographs and supporting documents, the MLWP adopted revised sets of documents for Melissae folium and Primulae flos, which will be transmitted after peer-review to the HMPC for adoption. The working party further discussed the revision of the monograph on Plantaginis ovatae seminis tegumentum and supporting documents.

The next meeting of the MLWP is scheduled for 22-24 May 2012.

Contact for further information

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