4 May 2011
EMA/HMPC/288516/2011
Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 40th HMPC meeting, held 30-31 March 2011

The Committee welcomed observers from Kosovo, Bosnia and Herzegovina and Serbia.

M. Delbò was elected as MLWP Vice-Chair with a 3-year mandate that started on 31 March 2011.

Final Community herbal monographs

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 *Hedera helix* L., folium' (EMA/HMPC/289430/2009)
- 'Community herbal monograph on *Arctostaphylos uva-ursi* (L.) Spreng., folium' (EMA/HMPC/573460/2009)

The final Community herbal monographs as well as the respective HMPC opinion, assessment report and overview of comments received during the consultation period, 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 August 2011:

- Draft 'Community herbal monograph on *Oenothera biennis* L., oleum' (EMA/HMPC/277792/2009)
- Draft 'Community herbal monograph on *Echinacea angustifolia* DC., radix' (EMA/HMPC/688216/2008)
- Draft 'Community herbal monograph on *Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt, radix' (EMA/HMPC/560961/2010)

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- Draft 'Community herbal monograph on *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., semen' (EMA/HMPC/722367/2010)

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 for public consultation can be found by searching herbal substances by name or with the **status P** here (click on the 'View all' button). In addition, you can access under What's New? on the Agency homepage [draft monographs and list entries released for public consultation in the current month].

Adoption of the draft 'Community herbal monograph on *Echinacea angustifolia* DC., radix' (EMA/HMPC/688216/2008) was possible due to newly acquired documentation on the traditional use after an original decision was taken to draft a public statement due to insufficient evidence during the HMPC meeting held on 11-12 November 2009.

Other

Upon recommendation from the MLWP, the HMPC adopted the following documents:

- Draft 'Public statement on *Syzygium aromaticum* (L.) Merill et L.M. Perry, flos' (EMA/HMPC/112102/2011)

After reviewing information on the products containing *Syzygium aromaticum* (L.) Merill et L.M. Perry, flos and preparations thereof marketed in the European Union, it appears that no single-ingredient products for medicinal use are available. Furthermore, after consultation with interested parties on priority levels for anticipated assessment works in 2010, a low level of priority was identified for the establishment of a monograph on Caryophylli flos. The HMPC decided therefore that no Community herbal monograph will be established.

The draft public statement will be available on the Agency's website for public consultation until 15 August 2011:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000044.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Appointment of Rapporteurs

The HMPC appointed Rapporteurs for the preparation of Community herbal monographs/Community list entries on Capsici fructus, Guaranae semen and Camelliae sinensis non fermentatum folium. The herbal substances have been added to the HMPC priority list and a call for scientific data will be published on the Agency's website at:

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

New schedule for HMPC meetings

Practical arrangements were agreed by the Committee for a new schedule of HMPC and MLWP meetings starting from May 2011. So far, MLWP meetings of 2.5 days' duration were immediately followed by HMPC meetings of 1.5 days' duration. The Committee meetings will now be held before the working party meetings and Committee meetings will now be for one day only.

Since the mandate of the Committee was first approved, volumes of documents have substantially increased. This makes reporting to the HMPC immediately after a MLWP meeting difficult.

This new arrangement should lead to improved editorial/linguistic quality and greater consistency in documents as there will be 2-months of additional time given to Rapporteurs and respective Peer-reviewers to finalise sets of documents before their adoption by the HMPC.

The new meetings timetable aims to make efficiency gains at HMPC, MLWP and secretariat levels. It complements changes made in 2010 to the working methodology for the establishment of monographs and list entries e.g. the setting up of small groups running in parallel to review first draft monographs. The changes respond to a key objective identified in 2010 by the Head of Medicines Agencies (HMA) and the EMA Management Board to "improve the output of the Committee on Herbal Medicinal Products, in particular by increasing the quality and number of Monographs and List entries", included in the 'Action plan for herbal medicines 2010-2011'.

The next meeting of the HMPC will take place on 10 May 2011. The new meetings dates for the HMPC and MLWP in 2011 can be found on the Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fabout_us%2Flanding%2Fhmpc_meetings_landing_page.jsp&murl=menus%2Fabout_us%2Fabout_us.jsp&mid=WC0b01ac0580028e7f&year=2011&month=5&x=25&y=10

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

The MLWP held its 31st meeting at the European Medicines Agency on 28-30 March 2011.

In addition to the work that supported the adoption by the HMPC of the above-mentioned draft and final monographs/public statements and related documents, the MLWP finalised the assessment of Cinnamomi cortex and Cinnamomi aetheroleum, for adoption at the HMPC May meeting and made significant progress on the scientific work towards the finalisation of assessment of Urticae radix, Millefolii flos and Millefolii herba.

The MLWP also progressed on the scientific work towards the publication of draft monographs on Cucurbitae semen, Zingiberis rhizoma, Symphyti radix, Liquiritae radix and Fraxini folium. Orientations for the finalisation of the assessment of Visci albi herba were discussed. The MLWP further discussed draft monographs on Citri bergami aetheroleum and Rhodiolae roseae rhizoma.

As clarification on the interpretation of Directive 2001/83/EC as amended had been received from the European Commission as regards indications appropriate for traditional herbal medicinal products (see HMPC July 2010 meeting report EMA/HMPC/468796/2010), the MLWP received a positive feedback from the HMPC on the proposed orientations to implement the Commission's interpretation for the assessment of Urticae radix and Cucurbitae semen in the treatment of symptoms associated with benign prostate hyperplasia (BPH). The release of the final monograph on Urticae radix and the draft monograph on Cucurbitae semen is currently expected in July 2011 and September 2011, respectively.

The next meeting of the MLWP is scheduled for 11-13 May 2011.

Quality Drafting Group (Q DG)

The HMPC heard a report on the work carried out during the Q DG meeting held on 17 February 2011. The Committee adopted the concept paper on revision of 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)' (EMA/HMPC/111298/2011) for public consultation until 30 September 2011.

The Committee also endorsed corrections in the 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2819/00 Rev 1) and 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2820/00 Rev 1) in order to bring them up-to-date with modified guidance mainly from the European Pharmacopoeia.

The documents will be published on the Agency's website at:

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

The next meeting of the Q DG is scheduled for 16 June 2011.

Organisational matters Drafting Group (ORGAM DG)

The HMPC heard a report on the work carried out during the ORGAM DG meeting on 16 February 2011, in particular progress with the development of new procedural guidance for the systematic review of final monographs and for scientific support and advice to companies on traditional herbal medicinal products. Regarding the former, the HMPC recommended a pilot phase with some of the early adopted monographs to gain experience with assessing the need and recognising the benefits of the intended revision, considering the resources implications of such maintenance activity.

The next meeting of the ORGAM DG is scheduled for 15 June 2011.

Other relevant information

In accordance with the above-mentioned 'Action plan for herbal medicines 2010-2011', a survey has been conducted to reflect the uptake of the traditional use registration scheme across Europe by 31 December 2010. A preliminary analysis of the results was presented to the HMPC demonstrating a substantial increase of registrations granted by Member States in the second half of 2010. Further work is ongoing towards a compilation of the data to be published both on the EMA and HMA websites after liaison with the CMDh. Six-monthly updates are currently scheduled, the second survey targeting both traditional use registrations as well as marketing authorisations.

Following the contact established with Health Canada in November 2010, the HMPC welcomed Dr Scott Sawler (Director General of Natural Health Products Directorate, Health Canada) and Dr Don Boyer (Director of Bureau of Product Review and Assessment, Natural Health Products Directorate, Health Canada) as visitors to MLWP and HMPC meetings.

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