



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2011
EMA/HMPC/93315/2011
Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 39th HMPC meeting, held 26-27 January 2011

The HMPC welcomed Ms Lucia Sevcekova from Slovakia and Dr Jacqueline Wiesner from Germany as new members. Dr Wiesner was formerly the German alternate member on the HMPC. The HMPC also noted the nomination of Dr Birgit Merz from Germany and Dr Carmen Purdel from Romania as new alternate members and Ms Marija Jovanović as new observer from Serbia.

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 monograph and related documents:

Final Community herbal monograph

- 'Community herbal monograph on *Trigonella foenum-graecum* L., semen' (EMA/HMPC/146221/2010)

The final Community herbal monograph 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 June 2011:

- Draft 'Community herbal monograph on *Agropyron repens* (L.) P. Beauv., rhizoma' (EMA/HMPC/563408/2010)
- Draft 'Community herbal monograph on *Syzygium aromaticum* (L.) Merrill et L.M. Perry, aetheroleum' (EMA/HMPC/534924/2010)



- Draft 'Community herbal monograph on *Chamaemelum nobile* (L.) All., flos' (EMA/HMPC/560734/2010)
- Draft 'Community herbal monograph on *Fumaria officinalis* L., herba' (EMA/HMPC/574766/2010)
- Draft 'Community herbal monograph on *Lavandula angustifolia* Mill., aetheroleum' (EMA/HMPC/143181/2010)
- Draft 'Community herbal monograph on *Lavandula angustifolia* Mill., flos' (EMA/HMPC/734125/2010)
- Draft 'Community herbal monograph on *Olea europaea* L., folium' (EMA/HMPC/430507/2009)
- Draft 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* L., herba; *Primula veris* L. and *Primula elatior* (L.) Hill, radix' (EMA/HMPC/130042/2010)

Draft monographs and their respective draft assessment report 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].

Other

Upon recommendation from the MLWP, the HMPC adopted a draft 'Public statement on the use of herbal medicinal products containing thujone' (EMA/HMPC/732886/2010) for public consultation until 15 May 2011. The document will be available at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000217.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580033a9e

After this public consultation and final adoption of this public statement, the HMPC intends to adopt/revise relevant monographs accordingly.

Following review of responses received to the invitation for interested parties to comment on the level of priority for anticipated assessment works and to propose additional herbal substances (see HMPC meeting report of May & July 2010), the HMPC endorsed the MLWP recommendation to add *Erysimi officinalis* flos, *Andrographidis paniculatae* folium and *Capsici fructus* to the inventory of herbal substances for assessment.

Appointment of Rapporteurs

The HMPC appointed a Rapporteur for the preparation of a Community herbal monograph/Community list entry on *Erysimi officinalis* flos and *Andrographidis paniculatae* folium. The herbal substances have been added to the HMPC priority list and a call for scientific data will be published on the Agency website.

Updated 'Inventory of herbal substances for assessment' (EMA/HMPC/494079/2007) and 'Overview of assessment work – Priority list (status January 2011)' (EMA/HMPC/278067/2006) will be 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

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

The MLWP held its 30th meeting at the European Medicines Agency on 24-26 January 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 made significant progress on the scientific work towards the finalisation of assessment of *Hederae heliis folium*, *Cinnamomi cortex*, *Cinnamomi aetheroleum* and *Uvae ursi folium*. The MLWP also progressed the scientific work towards the publication of draft monographs on *Echinaceae angustifoliae radix*, *Cucurbitae semen*, *Pelargonii radix* and *Zingiberis rhizoma*.

The MLWP further discussed draft monographs on *Oenotherae biennis oleum*, *Symphyti radix* and *Liquiritiae radix*, and reviewed in parallel meetings of 3 groups draft monographs on *Citri bergami aetheroleum*, *Colae semen*, *Matricariae flos* and *Matricariae aetheroleum*.

The next meeting of the MLWP is scheduled for 28-30 March 2011.

Quality Drafting Group (Q DG)

The HMPC heard a report on the work carried out during the Q DG meeting held on 16 December 2010. This meeting was held in the presence of the Chairs of the Ph. Eur. Expert groups 13A, 13B and TCM. One of the aims of the meeting was to strengthen the EMA/EDQM coordination in monographs' and guidance's development. The Q DG received an update on the status of Ph. Eur. monographs and the HMPC inventory of herbal substances for assessment will be updated accordingly. Comments on draft/revised texts will continue to be exchanged, e.g. the Q DG will prepare comments on the revised Ph. Eur. monograph on extracts.

The next meeting of the Q DG is scheduled for 17 February 2011.

Organisational matters Drafting Group (ORGAM DG)

The HMPC heard a report on the work carried out during the ORGAM DG meeting on 13 December 2010, a first meeting conducted via a virtual platform to gain experience with the use of such technical facilities.

The next meeting of the ORGAM DG is scheduled for 16 February 2011.

Other relevant information

Members were informed of the resignation of the current MLWP Vice-chair. The election of a new MLWP Vice-Chair will take place at the HMPC March meeting.

The HMPC was informed by the European Commission representative about the publication by DG SANCO of a Questions & Answers document on the registration of traditional herbal medicinal products, concerning the implications of the end of the transitional period (30 April 2011) set out in the Directive 2004/24/EC for national competent authorities in the Member States to apply the provisions of the Directive to THMP already on the market.

http://ec.europa.eu/dgs/health_consumer/index_en.htm under *What's new? Health*

http://ec.europa.eu/dgs/health_consumer/docs/traditional_herbal_medicinal_products_en.pdf

<http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/71&format=HTML&aged=0&language=EN&guiLanguage=fr>

Members of the HMPC shared information about the approach taken in some Member States for similar communication via press releases to inform the public of the national situation on their territory.

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