



20 December 2010
EMA/HMPC/775051/2010
Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 38th HMPC meeting, held 24-25 November 2010

The Committee elected Dr W. Knöss as the new Chair and re-elected Dr I. Chinou as vice-Chair, both with a 3-year mandate that started on 24 November 2010.

The HMPC welcomed Dr Niamh Curran as new alternate member from Ireland and Ms Marija Jovanović, as new observer from Serbia.

Emiel van Galen was re-elected as Chair of the Organisational matters Drafting Group (ORGAM DG).

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:

Final Community herbal monographs

- 'Community herbal monograph on *Cimicifuga racemosa* (L.) Nutt., rhizoma' (EMA/HMPC/600717/2007)
- 'Community herbal monograph on *Juniperus communis* L., aetheroleum' (EMA/HMPC/12402/2010)
- 'Community herbal monograph on *Potentilla erecta* (L.) Raeusch., rhizoma' (EMA/HMPC/5513/2010)
- 'Community herbal monograph on *Quercus robur* L., *Quercus petraea* (Matt.) Liebl. and *Quercus pubescens* Willd., cortex' (EMA/HMPC/3203/2009)
- 'Community herbal monograph on *Tanacetum parthenium* (L.) Schulz Bip., herba' (EMA/HMPC/587578/2009)
- 'Community herbal monograph on *Viola tricolor* L. and/or subspecies *Viola arvensis* Murray (Gaud) and *Viola vulgaris* Koch (Oborny), herba cum flore' (EMA/HMPC/131734/2009)
- 'Community herbal monograph on *Vitex agnus-castus* L., fructus' (EMA/HMPC/144006/2009)



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

Priority will be given to the publication of monographs in order to facilitate the use in marketing authorisation and simplified registration applications.

Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monographs, for public consultation until 15 April 2011:

- Draft 'Community herbal monograph on *Capsella bursa-pastoris* (L.) Medikus., herba' (EMA/HMPC/262766/2010)
- Draft 'Community herbal monograph on *Cynara scolymus* L., folium' (EMA/HMPC/150218/2009)
- Draft 'Community herbal monograph on *Filipendula ulmaria* (L.) MAXIM., flos' (EMA/HMPC/434894/2010).
- Draft 'Community herbal monograph on *Filipendula ulmaria* (L.) MAXIM., herba' (EMA/HMPC/434881/2010).
- Draft 'Community herbal monograph on *Plantago lanceolata* L., folium' (EMA/HMPC/437858/2010).

Draft monographs 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 the following documents:

- 'Public statement on *Centella asiatica* (L.) Urban, herba' (EMA/HMPC/727465/2009)

The Committee confirmed that no monograph/list entry will be established despite existing data on the safety, efficacy and the historical use within the Community of products containing an extract that is not considered as a herbal preparation. Although some data are available on other herbal preparations, these data were not found sufficient and consistent according to requirements of Article 16a(1) of Directive 2001/83/EC. The final public statement will be published on the Agency's website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000046.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

- 'Draft Public statement on *Chelidonium majus* L., herba' (EMA/HMPC/743927/2010)

The currently available clinical and toxicological data cannot be considered adequate to fulfil the criteria required for developing a Community herbal monograph. The Committee concluded that the

extent and the quality of scientific data have not been sufficient to come to a positive benefit-risk assessment for oral treatment, while the cutaneous use is insufficiently supported by data on monotherapy. If new information on clinical safety and efficacy of *Chelidonium majus* L., herba as a single ingredient 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 April 2011.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000051.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Following coordination with the Paediatric Committee (PDCO) the HMPC adopted a

- 'Reflection paper on the necessity of initiatives to stimulate the conduct of clinical studies with herbal medicinal products in the paediatric population' (EMA/HMPC/833398/2009).

The draft reflection paper will be published at the Agency website for comments by 15 April 2011:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000427.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580034cf7

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

The MLWP held its 29th meeting at the European Medicines Agency on 22-24 November 2010.

In addition to the work that supported the adoption by the HMPC of the above-mentioned draft and final monographs/list entries/public statements and related documents, the MLWP made significant progress on the scientific work towards the finalisation of assessment of *Hederae heliis folium* and *Trigonellae foenugraeci semen* and the publication of the draft monographs on *Agropyri repentis rhizoma*, *Cucurbitae semen*, *Fumariae herba*, *Lavandulae aetheroleum*, *Oenotherae biennis oleum*, and *Thymi herba / Primulae radix*. The MLWP further discussed draft monographs on *Caryophylli aetheroleum*, *Pelargonii radix* and *Symphyti radix*, and reviewed in parallel meetings of 2 groups draft monographs on *Zingiberis rhizoma*, *Lavandulae flos* and *Visci albi herba*.

An updated 'Overview of status of HMPC assessment work – November 2010' (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

The HMPC adopted the MLWP work programme that will be published at the Agency website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000046.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e98

Upon agreement by the HMPC, the MLWP met representatives from the Kooperation Phytopharmaka on 24 November, in order to discuss the issue of lacking genotoxicity data to establish Community list entries by the HMPC. The ongoing collaborative testing initiative by the German phytopharmaceutical industry and experiences with the guidelines EMEA/HMPC/107079/07 and EMEA/HMPC/67644/09 were presented. Industry welcomed in particular the bracketing and matrixing principle for herbal extracts to facilitate the testing expenditure. Possibilities to make the obtained genotoxicity data available for the assessment work of the HMPC were discussed including timelines considering standard confidentiality provisions. Once adopted, the report from the hearing will be published at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac058003529f&jsenabled=true#section_1

The next meeting of the MLWP is scheduled for 24-26 January 2011.

Quality Drafting Group (Q DG)

The HMPC heard a report on the work carried out during the Q DG meeting on 14 October 2010.

Beside topics in support of the work of the MLWP, the CHMP-QWP, and EDQM, the Q DG continued discussing the improvement of guidance on the use of the CTD format for herbal medicinal products in particular with regard to Module 3.

The HMPC adopted the Q DG work programme 2011 (EMA/HMPC/641599/2010) that will be published at the Agency website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000049.jsp&url=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e9b&jsenabled=true

The next meeting of the Q DG scheduled for 16 December 2010 will be held together with the Chairs of the Ph. Eur. expert groups 13A, 13B and TCM in order to strengthen the coordination in monograph and guidance development.

Organisational matters Drafting Group (ORGAM DG)

The HMPC heard a report on the work carried out during the ORGAM DG meeting on 13 October 2010.

New procedural guidance was discussed that will be further developed in 2011 as outlined in the ORGAM DG work programme 2011 (EMA/HMPC/728009/2010). The work programme was adopted by the HMPC and will be published at the Agency website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/HMPC/people_listing_000048.jsp&url=menus/about_us/about_us.jsp&mid=WC0b01ac0580028e9a

The next meeting of the ORGAM DG is scheduled for 13 December 2010.

Other relevant information

The HMPC had the pleasure to welcome a representative from the Natural Health Products Directorate, Health Canada, as a possible starting point for future cooperation. The Director of the Bureau of Clinical Trials and Health Sciences participated at MLWP and HMPC discussions and provided information on the regulatory framework and scientific assessment approach for Natural Health Products in Canada.

Contact for further information

Anthony Humphreys

Head of Regulatory, Procedural and Committee Support

Tel.: +44 (0)20 7418 8583

Fax: +44 (0)20 7523 7051

E-mail: hmpc.secretariat@ema.europa.eu