



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Meeting report

Committee on Herbal Medicinal Products (HMPC)

Report of the 37th HMPC meeting, held 15-16 September 2010

The HMPC welcomed a new committee member from Spain, Adela Núñez Velázquez. Dr Núñez Velázquez was formerly the Spanish alternate on the HMPC.

Final Community herbal monographs/Community list entries

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

Final Community herbal monographs

- 'Community herbal monograph on *Arctium lappa* L., radix' (EMA/HMPC/246763/2009)
- 'Community herbal monograph on *Leonurus cardiaca* L., herba' (EMA/HMPC/127428/2010)
- 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus Zygis* Loefl. ex L., aetheroleum' (EMA/HMPC/131901/2009)¹

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 in due course 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

Final Community list entries

- 'Community list entry on *Thymus vulgaris* L. and *Thymus zygis* Loefl. ex L., aetheroleum' (EMA/HMPC/225527/2009)

Once available in all EU languages, the Community list entry, together with the respective HMPC opinion and assessment report, will be transmitted to the European Commission for adoption.

¹ The monograph had been adopted in January 2010. Following the introduction of changes to bring consistency between the assessment report, the monograph and the list entry, the HMPC readopted the monograph and supporting documents.

Draft Community herbal monographs

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

- Draft 'Community herbal monograph on *Achillea millefolium* L., flos' (EMA/HMPC/143949/2010)
- Draft 'Community herbal monograph on *Achillea millefolium* L., herba' (EMA/HMPC/290284/2009)
- Draft 'Community herbal monograph on *Commiphora molmol* Engler, gummi-resina' (EMA/HMPC/96911/2010).

Draft monographs together with the 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 the following document:

- 'Public statement on *Euphrasia officinalis* L. and *Euphrasia rostkoviana* Hayne, herba' (EMA/HMPC/727465/2009)

The Committee confirmed that no monograph/list entry will be established as no adequate data are available on liquid water extracts which are *ex tempore* made as infusions for application as an ocular impregnated dressing and on nasal ointments for the relief of local nasal irritation in common cold. Since the efficacy of the claimed uses is undocumented, and external eye application of *ex tempore* preparations is not hygienic and not safe, therapeutic use cannot be recommended. The final public statement will be published in due course on the Agency's website.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000070.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Following discussion by the HMPC on the draft monograph on *Oleae folium*, the MLWP was invited to further work on the assessment report with a view to explaining the orientation decided by the committee as regards the therapeutic indication. The release of the draft monograph and draft assessment report is expected at the November meeting.

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

The MLWP held its 28th meeting at the European Medicines Agency on 13-15 September 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 relating to the assessment of Agni casti fructus, Centellae asiaticae herba, Quercus cortex, Juniperi aetheroleum, Tanacetii parthenii herba, Tormentillae rhizoma and Viola tricoloris herba cum flore. The working party progressed the draft monograph on Hederae helix folium. The MLWP further discussed draft monographs on Bursae pastoris herba and Plantaginis lanceolatae folium and reviewed in parallel meetings of 4 small groups draft monographs on Agropyri repentis rhizoma, Caryophylli aetheroleum, Chamomillae romanae flos, Fumariae herba, Cucurbitae semen, Liquiritiae radix and Pelargonii radix.

An updated 'Overview of status of HMPC assessment work – September 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 next meeting of the MLWP is scheduled for 22-24 November 2010.

Quality Drafting Group (Q DG)

The HMPC heard a report on the work carried out during the Q DG meeting on 29 July 2010.

The HMPC adopted the final 'Reflection paper on level of purification of extracts to be considered as herbal preparations (EMA/HMPC/186645/2008) together with the 'overview of comments received during the public consultation' (EMA/HMPC/435996/2010).

The Q DG had revised, summarised and extended previous Question & Answer documents related to the quality of HMP such as the 'List of questions & answers (Q&A) received during the HMPC assessors training on quality issues emerging for herbal medicinal products (held on 7 December 2007, EMA)' (EMA/531300/2008). The new harmonised document 'Questions & answers on quality of herbal medicinal products' (EMA/HMPC/41500/2010)' was adopted by the HMPC and includes 12 new Q&A on stability that complement the reflection paper on stability testing (EMA/HMPC/3626/2009).

All documents will be available at the Agency website:

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

The next meeting of the Q DG is scheduled for 14 October 2010.

Organisational matters Drafting Group (ORGAM DG)

The next meeting of the ORGAM DG is scheduled for 13 October 2010 when discussion will start on remaining topics of the 2010 work programme not addressed so far.

http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/12/WC500020090.pdf

Other matters

The HMPC extended farewell to Dr Keller who chaired the last HMPC meeting of his second mandate as HMPC Chair - see the report in Annex. Elections of new HMPC Chair and Vice-Chair will take place on 24 November 2010.

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

The Agency celebrates Dr Keller's long-lasting contribution to herbal medicines



On 15 September, the HMPC members joined the Agency Executive Director, Mr Thomas Lönngrén, during a farewell celebration in honour of Dr Konstantin Keller. This year celebrates the 14th year of activities of the Agency in the field of herbal medicines. Back in June 1997 under the initiative of Mr Fernand Sauer, an ad hoc working group on herbal medicinal products was created and Dr Keller was elected as Chair. Since that time, the group of experts evolved under his chairmanship with different status, until the creation in September 2004 of the HMPC. The committee was established upon the adoption of new European legislation following the dynamic input of Ms Dagmar Roth-Behrendt and Professor Giuseppe Nisticò. For the last 6 years, Dr Keller has continued to lead Europe's best assessors and experts in that field to the success known to date with over 65 final Community herbal monographs published on the Agency website and a greater harmonisation in the assessment of these products in Europe. The work of Dr Keller in this field had started long before 1997 and his long-lasting chairmanship reflects the depth of his expertise and contribution. Dr Keller has indeed played a key role in shaping European integration of herbal medicines on the pharmaceuticals scene, at all political, scientific, legal and regulatory levels. Professor Fritz Kemper, former ESCOP President and Dr Hubertus Cranz, AESGP Director general gave speeches pointing to milestones in the career of Dr Keller and celebrating his vision and legacy to Europe and beyond. Mr Noël Wathion and Mr Tony Humphreys shared memories from the close collaboration between Dr Keller and the Agency Secretariat over the years and thanked him for so valuably offering to the Agency a combined scientific and regulatory excellence.