EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/639244/2012
Patient Health Protection

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

The 48th HMPC meeting, held on 24 September 2012

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts and announced the nomination of Niamh Curran and Anna Cunney as new member and alternate member from Ireland.

Final Community herbal monographs

Upon recommendation from the MLWP as a result of its 22-24 May 2012 meeting, the HMPC adopted the following final Community herbal monograph and related documents by consensus:

- 'Community herbal monograph on *Thymus vulgaris* L. and *Thymus zygis* L., herba and *Primula veris* L. and *Primula elatior* (L.) Hill, radix' (EMA/HMPC/130042/2010)
- 'Community herbal monograph on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix' (EMA/HMPC/461160/2008)

Revised Community herbal monographs

As a result of the 5-year systematic review according to the reflection paper EMA/HMPC/326440/2007 and procedure EMA/HMPC/124695/2011 the HMPC adopted the following revised final Community herbal monograph and related documents by consensus:

- 'Community herbal monograph on *Primula veris* L. and *Primula elatior* (L.) Hill, radix' (EMA/HMPC/143370/2006 Rev.1)
- 'Community herbal monograph on *Primula veris* L. and *Primula elatior* (L.) Hill, flos' (EMA/HMPC/64684/2007 Rev.1)

Given the minor changes to the monographs a public consultation was not considered necessary after careful assessment of new scientific data.

The new and revised 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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Other

Public statement on pyrrolizidine alkaloids

Upon recommendation from the MLWP the HMPC adopted the draft 'Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)' (EMA/HMPC/893108/2011) for 3 months public consultation. The document will be published in due course on the EMA website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000497.jsp&mid=WC0b01ac05804545f1

Assessor's training on non-European traditional medicines

The annual assessor's training organised by the HMPC secretariat was held on 25 September 2012 at the EMA and attended by HMPC/MLWP members and other national assessors of herbal medicinal products (directly or online). Challenges in the assessment of products used in Europe on the basis of Chinese/Ayurvedic medical traditions in comparison to those of European phytotherapy were discussed. The topic at the HMPC work programme 2012-2015 is triggered by increasing applications for products e.g. from Traditional Chinese or Indian medicine to be marketed in Europe using provisions of Directive 2004/24/EC.

In four sessions (quality related safety issues, safety and long-standing use, plausibility and efficacy, national experiences with applications), experts from academia, industry/trade, practitioners and authorities gave presentations and answered questions by the participants. Quality topics included authentication, labelling, specific processing methods, and exchangeability of substances in combinations and subsequent toxicological risks and challenges for Ph. Eur. monograph development. Three practitioners of TCM and Ayurveda gave an insight on the scientific background and current practice explaining fundamental differences in medical diagnosis, description of symptoms, treatment and use of medication (usually traditional combinations). It was completed by a presentation on the clinical evidence and suitable endpoints for herbal substances with traditional Asian indications. Finally, representatives of three agencies summarised national experiences from scientific advice and applications.

The committee intends to further reflect central questions, specific obstacles and harmonised assessment approaches towards possibilities for monograph development for substances used in non-European traditional products and develop regulatory guidance in this area. In this context the committee will consider a continued dialogue with interested parties and welcome if organisations in the field express their interest to establish regular contacts in line with the HMPC rules of procedure regarding interested parties.

Management board meeting and Report on Action plan herbal medicines 2010-2011

The Committee heard a feedback by the HMPC Chair from the discussion at the EMA management board meeting 7 June 2012 following his presentation on HMPC achievements and future challenges. The board had adopted the public report on 'Action plan for herbal medicines 2010-2011' (EMA/HMPC/45679/2012) which has been published at the EMA website:

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 European Medicines Agency has published the list of European Union reference dates and frequency of submission of periodic safety update reports (PSUR) known as the 'EURD list'. In line with the cover note of the EURD list 'further work is foreseen by the EU regulatory Network on herbal and homeopathic substances in terms of their inclusion in the EU reference dates list'. Taking into account comments from all member states, the HMPC intends to adopt a proposal for herbal medicinal products and traditional herbal medicinal products for submission to the PRAC in November 2012.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q meetings (virtual) held on 14 June, 26 July, and 6 September 2012.

Several topics are currently discussed in coordination with EDQM (revision of the Ph. Eur. monograph on extracts, CEP procedure for herbal substances) as well as the Scientific Advice Working Party (support on quality questions for herbal medicinal products). The DG Q further started discussions towards appropriate guidance on the use of recovered solvents for extraction and quality requirements for essential oils.

The HMPC adopted the DG Q work programme for 2013 continuing largely the projects started in 2012. The work programme will be published at:

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

The next meeting of the DG Q (virtual) was held on 18 October 2012.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM meeting (virtual) held on 4 July 2012, in particular the progress concerning the template for Patient Leaflets with suggested wordings concerning advice on the preparation by end-users of medicinal herbal teas; comments received from the QRD group were assessed. Comments from PCWP members will be discussed during the next meeting (these consultations were announced in the March 2012 HMPC meeting report).

The HMPC adopted the DG ORGAM work programme for 2013 with 5 virtual meetings scheduled.

The work programme will be published at:

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

The next meeting of the DG ORGAM (virtual) was held on 17 October 2012.

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

The MLWP held its 39th meeting at the European Medicines Agency on 26-28 September 2012.

Systematic review

As part of the pilot phase on the systematic review of adopted monographs and supporting documents, the MLWP endorsed the revised monographs, and supporting documents on Plantaginis ovatae seminis

tegumentum, Plantaginis ovatae semen, and Psyllii semen for peer-review, prior to transmission to the HMPC for possible final adoption in November 2012. The working party discussed the revision of the monographs on Anisi aetheroleum, and Anisi fructus.

Post-finalisation

The MLWP is currently assessing the need for revision of monograph and assessment report on Liquiritiae radix based on a revised Overview of comments.

Finalisation

The Working Party finalised the assessment of Cucurbitae semen and Visci albi herba for transmission to the HMPC for adoption. The MLWP also endorsed the monographs and supporting documents on Levistici radix and Grindeliae herba for peer-review, prior to transmission to the HMPC for possible final adoption in November 2012.

Drafts

The MLWP endorsed the draft monographs, and supporting documents on Sambuci fructus and Origani dictamni herba for peer-review, prior to transmission to the HMPC for possible release in November 2012 for public consultation. After a detailed assessment of available data the publication of draft public statements for Angelicae sinensis radix and Withaniae somniferae radix as well as the cancellation of the assessment on Hyoscyami herba will be proposed to the HMPC in November.

The working party continued its assessment of Juglandis folium, Rubi idaei folium and Camelliae sinensis non fermentata folium. The MLWP discussed the draft assessment reports and monographs on Eucalypti aetheroleum, Fucus vesiculosus, Ginkgo folium, Melaleucae alternifoliae aetheroleum, Phaseoli fructus sine semine, Curcumae xanthorrhizae rhizoma and Marrubii herba. The working party discussed a report from the Rapporteur on the assessment of Arnicae flos.

The next meeting of the MLWP is scheduled for 20-22 November 2012.

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