



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

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

The 51st HMPC meeting, held 11-12 March 2013

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 51st meeting of the Committee.

The HMPC re-elected Prof. O. Pelkonen as co-opted member with expertise in toxicology, for a 3-year term. Dr B. Kroes was re-elected by the committee as Chair of the HMPC Quality Drafting Group upon expiry of his second Chair's mandate.

The full composition of the HMPC can be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people_listing_000006.jsp&mid=WC0b01ac0580028e7e

Final Community herbal monographs

Upon recommendation from the MLWP, the HMPC amended the following documents, for which consensus had been recorded:

- in May 2012 for the 'Community herbal monograph on *Glycyrrhiza glabra* L. and/or *Glycyrrhiza inflata* Bat. and/or *Glycyrrhiza uralensis* Fisch., radix' (EMA/HMPC/571119/2010): a revised assessment report, revised list of references and revised overview of comments received during the consultation period;
- in September 2012 for the '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): a revised monograph, revised assessment report, revised list of references and revised overview of comments received during the consultation period.

The revised packages were presented to the Committee for adoption, following opinions on the two Community herbal monographs finalised in 2012, after it had appeared that changes were required prior to publication on the EMA website. The documents 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 July 2013:

- Draft 'Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium' (EMA/HMPC/283630/2012)
- Draft 'Community herbal monograph on *Panax ginseng* C. A. Meyer, radix' (EMA/HMPC/321233/2012)
- Draft 'Community herbal monograph on *Phaseolus vulgaris* L., fructus sine semine' (EMA/HMPC/317319/2012)
- Draft 'Community herbal monograph on *Rubus idaeus* L., folium' (EMA/HMPC/44211/2012)

The draft monograph with its assessment report and list of references will be available on the Agency's website at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp&mid=WC0b01ac058001fa1d

Draft public statements

Upon recommendation from the MLWP, the HMPC adopted the following draft public statement, for public consultation until 15 July 2013:

- Draft 'Public statement on *Sambucus nigra* L., fructus' (EMA/HMPC/32465/2013)

The public statement with its assessment work and list of references 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

Other

Referral procedure "Adequacy of evidence of the long-standing use"

Name: 'Frischpflanzenpresssaft aus Passionsblumenkraut'

Type of procedure: Article 16c(1)(c) of Directive 2001/83/EC

The HMPC adopted an opinion within the referral procedure on 'Frischpflanzenpresssaft aus Passionsblumenkraut' (pressed juice from Passiflorae herba; Walther Schoenenberger Pflanzensaftwerk GmbH & Co KG). The procedure had started in March at the request of Germany seeking an opinion by the Committee on the adequacy of evidence of long-standing use of the product. The opinion is provided to the triggering Member State for consideration within their assessment of the traditional use registration application for 'Frischpflanzenpresssaft aus Passionsblumenkraut' as well as to the other Member States of the European Union.

Cancellation of assessment work

The HMPC endorsed the MLWP recommendation to cancel the assessment work for Rosae aetheroleum upon identification by the Rapporteur that there are insufficient data on the use of the essential oil to establish a monograph.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q (virtual) meeting held on 13-14 February 2013.

The Committee adopted a revised work programme for DG Q for 2013 (EMA/HMPC/560318/2012), taking into account the constraints brought by the move to only virtual meetings and the impact of budget restrictions on the range of activities of the Q DG. Besides its primary role in establishing, on behalf of the HMPC, guidance on quality of herbal medicines, the group plays a major role in discussing issues arising from assessment of applications in the national competent authorities for harmonisation of assessment practice. The drafting group is also heavily involved in expressing scientific opinions requested via the HMPC by the European Directorate for the Quality of Medicines (EDQM) and by scientific groups at the EMA such as the Scientific Advice Working Party.

Examples of successful coordination with EDQM which were reported to the HMPC included:

- comments on the certification of suitability to monographs of the European Pharmacopoeia as regards the content of the dossier for herbal drugs' and herbal drug preparations' quality evaluation
- comments in relation to a planned revision of the assays in the Ph. Eur. monographs on Senna.

The HMPC adopted new Q & A on non-pharmacopoeial reference standards which will be integrated into the published 'Questions & Answers on the quality of herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/41500/2010) available at:

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

The HMPC adopted the following final documents:

- Revised 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMA/HMPC/71049/2007 Rev. 1) together with the 'Overview of comments received on the guideline' (EMA/HMPC/768094/2012). The guideline now includes a 'Best practice guide' as an appendix.

The timing for the preparation of a second appendix (Mock-up) will be dependent on the progress on other topics and available resources.

The documents will be published on the EMA website at:

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

The next meeting (virtual) of the DG Q will be held on 18 April 2013.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the DG ORGAM (virtual) meeting held on 11 February 2013. The Committee noted the contribution of the DG ORGAM in the finalisation of the revised guideline on the CTD (see Draft Group on Quality). Work continues to make available to Rapporteurs in charge of drafting monographs a template for supporting ARs that includes guidance and instructions to the assessors, aiming at improving the consistency in the presentation of the outcome of the assessment works that represent the conclusions reached at European level on herbal medicines, with a core-labelling laid down in the monographs themselves.

Report from the January 2013 Working Party on Community Monographs and Community List (MLWP)

The MLWP held its 42nd meeting at the European Medicines Agency, 15-17 January 2013.

Systematic review

The working party finalised the revision of the monograph and related documents on *Melissae folium* and progressed the revision of the monograph and related documents on *Plantaginis ovatae semen*, *Plantaginis ovatae seminis tegumentum* and *Psyllii semen*.

Finalisation

The Working Party heard a preliminary report on the comments received during the public consultation which ended on 15 February 2013 on the draft 'Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)' (EMA/HMPC/893108/2011). The MLWP will further discuss the assessment of *Symphyti radix* at its May meeting in conjunction with a more in depth discussion of the comments received and consequences for the monograph on *Symphyti radix*.

Drafts

The MLWP endorsed the monographs on *Curcumae xanthorrhizae rhizoma* and *Eucalypti aetheroleum* for peer-review and transmission to the HMPC for possible release in May 2013 for public consultation.

The working party continued its assessment of *Allii sativi bulbus*, *Fucus vesiculosus*, *Ginkgo folium* and *Melaleucaea alternifoliae aetheroleum* and discussed the first draft assessment report and monograph on *Ononidis radix*. The MLWP heard preliminary findings from the assessment of *Rosae flos* and *Sabalidis serrulatae fructus*.

The next meeting of the MLWP is scheduled for 14-16 May 2013.

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