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Patient Health Protection

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

The 52nd HMPC meeting, held 13-14 May 2013

The Chair of the Committee on Herbal Medicinal Products (HMPC) welcomed all delegates and experts to the 52nd meeting of the Committee and announced the nomination of A. Obmann as new alternate member from Austria.

The Committee appointed S. Bager as HMPC representative for the newly constituted Healthcare Professionals Working Party (HCPWP, formerly Health Care Professionals Working Group) and re-nominated him as appointed HMPC representative in the Patients & Consumers' Working Party (PCWP), each for a 3-year term.

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 monographs and related documents by consensus:

- 'Community herbal monograph on *Melissa officinalis* L., folium' (EMA/HMPC/196745/2012)
- 'Community herbal monograph on *Plantago afra* L. et *Plantago indica* L., semen' (EMA/HMPC/599747/2012)
- 'Community herbal monograph on *Plantago ovata* Forssk., semen' (EMA/HMPC/304390/2012)

The HMPC further adopted the following revised final Community herbal monograph by majority vote:

- 'Community herbal monograph on *Plantago ovata* Forssk., seminis tegumentum' (EMA/HMPC/199774/2012)

In view of only minor changes to the monographs, a public consultation was not considered necessary after careful assessment of new scientific data, reflected in the revised assessment reports.

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Draft Community herbal monographs

Upon recommendation from the MLWP, the HMPC adopted the following draft Community herbal monographs, for public consultation until 15 September 2013:

- Draft 'Community herbal monograph on *Curcuma xanthorrhiza* Roxb., rhizoma' (EMA/HMPC/604600/2012)
- Draft 'Community herbal monograph on *Eucalyptus globulus* Labill., *Eucalyptus polybractea* R.T. Baker and/or *Eucalyptus smithii* R.T. Baker, aetheroleum' (EMA/HMPC/307781/2012)
- Draft 'Community herbal monograph on *Fucus vesiculosus* L., thallus' (EMA/HMPC/313674/2012)

The draft monographs and supporting draft assessment reports and lists 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

Other

Revision of Regulatory Q&A (EMA/HMPC/10484/2013)

Back in 2011, the HMPC had been called by a National Competent Authority as well as the European Commission (EC) to discuss the eligibility of natural camphor for traditional use registration (TUR) in combination products, in the context of the national implementation of the provisions of Directive 2004/24/EC for traditional herbal medicinal products already on the market in the Member States at the time the Directive came into force.
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/06/WC500128647.pdf

The HMPC liaised with the EC on the practical difficulties encountered by the Member States, in the absence of an extension of the scope of the TUR to traditional products not composed exclusively of herbal substance(s), herbal preparation(s), combination(s) thereof and/or vitamins and minerals with an ancillary action. Extensive discussions took place on the regulatory framework offered by the European Pharmaceutical legislation and the HMPC could reach a recommendation at European level for D-camphor, levomenthol, 1,8-cineol, thymol and rutoside that are of herbal origin. Taking into account the long-standing use of these ingredients also in combination with herbal substances and/or herbal preparations, the HMPC is of the opinion that these five substances are eligible for TUR provided that the medicinal product itself fulfils all requirements for a THMP. Such HMPC recommendation was reached after a majority vote and can be found in question 2 of the revised 'Regulatory Questions & Answers on herbal medicinal products', which will be available at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000355.jsp&mid=WC0b01ac0580118a1d

Re-evaluation of the Validity of the Bronchitis Severity Scale (BSS)

Following the assessment of newly submitted data on the validity of the Bronchitis Severity Scale (BSS) in clinical evaluation of medicines used in patients in the therapeutic area 'cough and cold', the HMPC considered the BSS to be an acceptable, valid measurement instrument, following the proposal by the Rapporteurs who assessed the validity report. Starting from July, the HMPC will check consequences for existing monographs in this therapeutic area, according to each respective data situation, in line with the 'Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries' (EMA/HMPC/326440/2007 Rev.2).

Overview on paediatric uses for herbal medicines according to HMPC monographs

The HMPC adopted the document 'HMPC Monographs: Overview of recommendations for the uses of herbal medicinal products in the paediatric population' (EMA/HMPC/228356/2012), which summarises the indications and limitations for the use in children as assessed by the HMPC. The document intends to facilitate access to information on the paediatric uses of herbal substances across HMPC monographs in particular for health care professionals. Following consultation of the PDCO, the document will be published at the Agency website and regularly updated:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cf

Union reference dates and frequency of PSUR submission for herbal substances

The Committee endorsed a reduced list of herbal substances for exceptional inclusion in to the 'EURD list' (European Union reference dates and frequency of submission of periodic safety update reports (PSUR)). Following a risk-based review of previously listed herbal substances in line with provisions of Directive 2010/84/EU amending Directive 2001/83/EC, a task group of the PSUR project team comprising national pharmacovigilance and herbal medicines experts proposed the adaptation of the EURD list, which was presented to the PRAC and CMDh in May 2013. As the EURD list can be amended whenever considered necessary in response to the emergence of relevant new safety information, new herbal substances may be added in the future upon requests by National Competent Authorities.

Revised list of interested parties to the HMPC

The HMPC adopted a revised list of interested parties, which can be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac058003529f

As per its rules of procedure, hearings with interested parties can be convened upon agreement by the HMPC when the need has arisen to discuss certain matters or for information purposes. Since 2009, the committee favours the organisation of focused hearings with individual associations upon receipt of specific issues/questions with a view to leading to a constructive dialogue with interested parties that contribute actively to the work of the HMPC. The revised list now includes, amongst the healthcare professionals associations, the 'European Ayurveda Medical Association', which responded to the call by the HMPC in 2012 to identify parties with an interest in non-European traditional medicines.

Drafting Group on Quality (DG Q)

The HMPC heard a report on the DG Q (virtual) meeting held on 18 April 2013.

The HMPC adopted new Q & A on stability related issues 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

Amendments are based on suggestions made by an interested party, which had been reviewed and modified by the DG Q taking into account relevant existing and upcoming guidance. The HMPC welcomed the submission of such proposals by interested parties as well as the immediate consideration by the DG Q to achieve clarity for applicants and up-to-date relevance at different levels in guidance documents.

The next meeting (virtual) of the DG Q will be held on 13 June 2013.

Drafting Group on Organisational matters (DG ORGAM)

The HMPC heard a report on the progress achieved during the 17 April DG ORGAM (virtual) meeting on the revision of the template for ARs supporting Community herbal monographs. The need for guidance and instructions to assessors had been identified and the new structure for the AR is expected to increase the quality in the presentation of the data assessed and the conclusions reached as well as consistency across different assessments.

Work will continue at the next virtual ORGAM DG meeting, which Rapporteurs in the MLWP will be invited to join on a voluntary basis, so as to illustrate the adjustments required in the template with real examples of assessment.

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

The MLWP held its 43rd meeting at the European Medicines Agency, 14-16 May 2013.

Finalisation

The MLWP noted that no comments had been received during public consultation on the following monographs and public statements: Adhatodae vasicae folium (PS), Andrographidis paniculatae folium (PS), Angelicae sinensis radix (PS), Juglandis folium (M), Marrubii herba (M), Origani dictamnus herba (M), and Withaniae somniferae radix (PS). After peer-review, all documents will be transmitted to the HMPC for possible final adoption at the July meeting.

Drafts

The MLWP endorsed the monographs on Arnicae flos, Melaleucae alternifoliae aetheroleum and Ononidis radix for early peer-review and transmission to the HMPC for possible release in July 2013 for public consultation.

The working party continued its assessment of Allii sativi bulbus and Ginkgo folium and discussed the first draft assessment reports and monographs on Rosae flos, Sisymbrii officinalis herba and Silybi mariani fructus. Furthermore the MLWP heard a second report on findings relevant for the assessment of Sabalis serrulatae fructus.

The HMPC requested the MLWP to integrate, in its on-going assessment to establish a monograph on Ginkgo folium, a US NTP[1] report published at the end of March 2013. A coordinated assessment will be conducted by toxicologists from Germany and Sweden, and O. Pelkonen, co-opted member in the HMPC with expertise in toxicology. The HMPC will discuss the toxicologists' assessment at its 8-9 July 2013 meeting and - if relevant - coordination of conclusions with relevant scientific committees/working parties in the Agency will be sought.

[1] http://ntp.niehs.nih.gov/

Guidelines

The Working Party discussed and endorsed a revised version of the 'Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)' (EMA/HMPC/893108/2011) for transfer to the HMPC, together with an overview of comments received during the public consultation, for possible adoption at its July meeting. Coordination with the Safety Working Party was recommended.

Consequences for the monograph on Symphyti radix were discussed and the finalisation of the monograph and supporting documents by the MLWP is foreseen for July 2013.

The next meeting of the MLWP is scheduled for 9-11 July 2013.

Hearing with association representing the self-medication industry

On 14 May, the MLWP held a hearing with representatives from AESGP, which HMPC members could also attend. A number of general issues related to the establishment of Community herbal monographs, list entries and public statements were discussed. Several procedural aspects were clarified, which will be taken up in the revision of the relevant procedural guidance. The HMPC/MLWP confirmed their willingness to receive new data on closed assessment works, yet case-by-case decisions will be made concerning the timeframe under which the data would be evaluated and the times by which the monographs, affected by the conclusions on the new data, would be revised. A full report on the matters raised at the hearing will be available at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000223.jsp&mid=WC0b01ac058003529f

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