European Medicines Agency
*Post-authorisation Evaluation of Medicines for Human Use*

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

# Meeting report, 21-22 July 2005

The Committee on Herbal Medicinal Products met for the sixth time at the EMEA offices on 21-22 July 2005.

The Committee welcomed Dr Wissinger-Gräfenhahn and Prof. Pelkonen who were elected as co-opted members at the last meeting to support the Committee with additional expertise in clinical pharmacology and toxicology respectively. The Committee is now awaiting experts nominations from HMPC members with a view to appointing three additional co-opted members in the areas of paediatric medicine, experimental/non-clinical pharmacology and in traditional medicinal products such as Traditional Chinese, Ayurvedic and Anthroposophic herbal medicinal products in November 2005.

**Reports from drafting groups meetings**

*Organisational matters*
The drafting group on organisational matters started a general discussion on organisational aspects related to the interpretation of requirements to show medicinal use throughout a period of 30 years for traditional herbal medicinal products. Further work took place on a draft assessment report template for use by rapporteurs when evaluating an application for registration of a traditional herbal medicinal product. It was agreed to develop separate templates for the assessment of traditional and well-established use herbal medicinal product application reflecting also the potential outcome, i.e. the inclusion in the List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products or the development of a Community monograph.

The Committee supported the preparation by the drafting group of guidance to applicants on the use of the CTD structure for traditional use registration applications.

*Quality*
The drafting group reviewed comments made by the CVMP on its proposal for revision of the 'Guideline on quality of herbal medicinal products' (EMEA/CPMP/2819/00, EMEA/CVMP/814/00). The Committee made slight amendments to the proposal, which will be released for consultation by both the CHMP and CVMP until 1 October 2005.
The revised guideline can be found at the following location:
http://www.emea.eu.int/whatsnewp.htm

The Committee adopted a concept paper for the preparation of a guideline on the declaration of herbal substances/herbal preparations in finished herbal medicinal products. The Committee endorsed the suggestion from the drafting group that comments from industry could be taken into account during the development of the guideline, should industry wish to submit comments.
The concept paper is released for consultation until end of September 2005, however comments from industry on the declaration of herbal substances and herbal preparations can be received until the end of 2005.
The concept paper (EMEA/HMPC/241953/2005) can be found at the following location:
http://www.emea.eu.int/pdfs/human/hmpc/24195305en.pdf
Comments should be sent to hmpc.secretariat@emea.eu.int

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.eu.int http://www.emea.eu.int

The Committee endorsed the revised proposal for amendment of the Annex 7 to the guide to good manufacturing practice (GMP) on the manufacture of herbal medicinal products/traditional herbal medicinal products. Coordination with the *ad hoc* GMP Inspection Services Group was successful and the Committee looks forward to the publication of the revised text in Volume 4 of the Rules governing Medicinal Products in the EU.

The Committee endorsed comments made by the drafting group on the CHMP/ICH 'Note for guidance on data elements and standards for drug dictionaries' (CPMP/ICH/168535/2005) (topic M5) following a presentation by the EMEA Secretariat to the drafting group on the objectives and principles developed in the guideline. Besides some general comments, the Committee will forward some specific comments on the principles for the mapping of herbal substances and herbal preparations.
The CHMP/ICH note for guidance, which is under consultation in Step2 of the ICH process until the end of September 2005 can be found at the following location.
http://www.emea.eu.int/pdfs/human/ich/16853505en.pdf

Finally, the Committee endorsed the drafting group's suggestion that the Committee adopt as its own guidance the 'Points to consider on Good Agricultural and Collection Practice (GACP) for starting materials of herbal origin' developed by the previous Herbal Medicinal Products Working Party.
The Committee has released its draft 'Public statement on good agricultural and collection practice for starting materials of herbal origin' (EMEA/HMPC/246816/2005) for 3-month consultation. It can be found at the following location, under "Quality":
http://www.emea.eu.int/pdfs/human/hmpc/24681605en.pdf
Comments should be addressed to hmpc.secretariat@emea.eu.int.

*Safety and Efficacy*
The Committee adopted for release for 3-month public consultation a draft guideline on the clinical assessment of fixed combinations of herbal substances/herbal preparations (EMEA/HMPC/166326/2005). The Committee informed the CHMP Efficacy Working Party about the release of this draft guideline, inviting comments during the consultation period. Comments should be addressed to hmpc.secretariat@emea.eu.int.
The guideline can be found at the following location, under "Efficacy":
http://www.emea.eu.int/pdfs/human/hmpc/16632605en.pdf

The Committee made some progress in the area of Community herbal monographs and List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. Draft monograph/List entry for Valerian root are expected to be released for consultation at the end of August/beginning of September 2005. Drafts for Linseed and Ispaghula husk should be released after the HMPC meeting on 19-20 September 2005.
Rapporteurs were appointed for a number of plants for which bibliographic references had been made available by ESCOP[1] to members of the past Herbal Medicinal Products Working Party for the preparation of core-data. Despite having taken due note of the priority list of plants submitted by AESGP[2], the Committee agreed to work first on those plants where supportive bibliography is readily available for assessment.

The Committee is looking forward to receiving clarification from the European Commission services on the provisions for the marketing authorisation of herbal medicinal products based on the provisions on "well-established use" so as to progress in the preparation of a guideline on the assessment of clinical safety and efficacy in applications for marketing authorisations for well-established herbal medicinal products or for registration of traditional herbal medicinal products.

[1] European Scientific Cooperative on Phytotherapy
[2] Association of the European Self-Medication Industry

**Regulatory scheme for traditional herbal medicinal products in Australia and in Canada**

The Committee heard presentations on the regulatory schemes that are applicable in Australia and Canada to medicinal products of herbal origin, especially the provisions established for herbal products defined as traditional.

Dr D. Briggs, Director of the Office for Complementary Medicines at the Therapeutic Goods Administration of Australia, presented the two-tiered regulatory system under which medicinal products considered of low-risk can benefit from an electronic submission environment with a view to being rapidly 'listed' and marketed, provided that well-defined requirements are met and indications are limited. Medicinal products considered of high risk must undergo a registration procedure with an assessment being conducted prior to the marketing of the product. For listed medicines including herbal listed medicines, the evidentiary requirements to support efficacy are linked to the level of indication/claim.

Dr P. Chan, Director of the Bureau of Product Review & Assessment in the Natural Health Products Directorate of Health Canada, explained the legal provisions applicable to the category of products called 'natural health products' that are distinct from conventional medicinal products. Herbal medicines are classified in the category of natural health products and their indications are dependent on the whole body of data available on the products. All types of supportive evidence available on herbal natural health products are evaluated against clearly defined criteria.

HMPC Members welcomed that the two authorities shared information on the regulatory environment in the area of (traditional) herbal medicines with the Committee and they made a plea for further collaboration with a view to sharing assessment expertise of complex multiconstituents herbal preparations, despite the differences in the legislative frameworks.

**Pharmacovigilance of Herbal Medicinal Products**

The Committee adopted a public statement on the document entitled 'CPMP List of herbal drugs with serious risks' dated 1992. The Committee was of the view that the publication of the document on the EMEA website was important from a public health point of view and will endeavour to work on an update of the document when time constraints imposed by the duties of the Committee in the field of traditional herbal medicinal products will allow addressing the required workload.
The HMPC public statement (EMEA/HMPC/246736/2005) can be found at the following location, under "Pharmacovigilance":
http://www.emea.eu.int/pdfs/human/hmpc/24673605en.pdf

The Committee forwarded to the Pharmacovigilance Working Party some comments on the report that resulted from the review by the PhVWP of the HMPC assessment report on hepatotoxicity cases associated with Cimicifuga racemosa (black cohosh). Recommendations are now being considered by national competent authorities.

**Discussion on Regulatory & Legal Topics**

The Committee discussed a number of legal and regulatory topics, in particular the European Parliament report on the proposal to amend the regulation on fees payable to the EMEA. The proposal provides for new fees in relation to activities in the field of traditional herbal medicinal products, such as expert advice on these products that applicants could seek from the Committee. As soon as adopted, the Council regulation amending Regulation (EC) No 297/95 on the fees payable to the European Medicines Agency will be published on the EMEA website.

The Committee noted the European Court of Justice decision of 12 July 2005 on the Directive on Food Supplements. The Committee together with the EMEA legal services will reflect on the possible consequences of this decision vis-à-vis the establishment by the HMPC of the List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products referred to in Article 16f.1 of Directive 2001/83/EC as amended.

**Coordination matters**

The Committee was informed about the progress made concerning the implementation of the provisions in Article 59 and in Article 64.2(d) of Regulation (EC) No 726/2004. The Committee agreed to the proposals concerning the cooperation between Community bodies. The Committee had no comments on the proposed 'EMEA Policy on the appropriate coordination between the scientific committees of the Agency'.

The Committee will prepare comments at the request of the BWP on the Good Agricultural and Collection Practice-related quality aspects of a scientific advice application for a product produced by a transgenic plant.

For further information, please contact:

Tony Humphreys
Head of Regulatory Affairs and Organisational Support Sector
Tel: (44-20) 7418 8583
Fax: (44-20) 7523 7051
hmpc.secretariat@emea.eu.int

  