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

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 31 May-1 June 2005

The Committee on Herbal Medicinal Products met for the fifth time at the EMEA offices on 31 May-1 June 2005.

The Committee elected 2 co-opted members following presentations by several experts. Dr U. Wissinger-Gräfenhahn was elected to support the Committee with additional expertise in clinical pharmacology and Prof. O. Pelkonen was elected to support the Committee with additional expertise in toxicology. The Committee will re-consider the need to co-opt additional members to complement the Committee's expertise in the area of paediatric medicines and of traditional medicines including Traditional Chinese Medicine by the end of the year.
The list of HMPC members and alternates can be found at the following location:
http://www.emea.eu.int/htms/general/contacts/HMPC.html

Reports from drafting groups meetings

Organisational matters
The drafting group on organisational matters finalised 2 Procedures, which the Committee adopted for release for public consultation until 15 October 2005:

- 'Procedure for the preparation of Community monographs for traditional herbal medicinal products' (EMEA/HMPC/182320/2005)
- 'Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use' (EMEA/HMPC/182353/2005)

Both documents are available at the following location:
http://www.emea.eu.int/htms/general/direct/legislation/legislationherbal.htm
Comments should be sent to: hmpc.secretariat@emea.eu.int

Quality
The drafting group finalised its proposal for the revision of the 'Guideline on quality of herbal medicinal products' (EMEA/CPMP/2819/00, EMEA/CVMP/814/00). The Committee endorsed the proposal, which was transmitted for review by the joint CHMP/CVMP Quality Working Party (QWP) and for adoption for release for consultation by both Committees.
The Committee agreed that the drafting group develop a document to provide guidance on the declaration of herbal substances/herbal preparations in finished herbal medicinal products.

Safety and Efficacy
The Committee reviewed the comments received from the CHMP Safety Working Party on the draft 'Guideline on non-clinical documentation for well-established and traditional herbal medicinal products – guidance to mutual recognition and use of bibliographic data'. Further coordination will take place for finalisation of the document before its release for public consultation.

Progress was made in the preparation of a harmonised view on the criteria for 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. The Committee sought 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".

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The Committee adopted a draft guideline on the clinical assessment of fixed combinations of herbal substances/herbal preparations, which will be subject to coordination with the CHMP before release for public consultation.

Pharmacovigilance of Herbal Medicinal Products
The Committee heard a presentation on the pharmacovigilance of herbal medicinal products by Dr J. Barnes from the Centre for Pharmacognosy & Phytotherapy of the London School of Pharmacy. The presentation stressed that herbal medicinal products are medicines and should be treated as such when measures and initiatives are taken to raise awareness in the public and amongst health-care professionals about the safety of medicines in the perspective of protecting and promoting public health.

The Committee envisaged possible actions vis-à-vis a list from 1992 of herbal drugs with serious risks that was adopted by the Committee for Proprietary Medicinal Products at that time. The list contains useful information on some plants with intrinsic risks and the Committee is looking at the relevance of the information and its need for update in the context of its priority tasks, notably in the field of traditional herbal medicinal products.

Discussion on Regulatory & Legal Topics
The Committee discussed a number of legal and regulatory topics, in particular the proposal from the European Commission for the revision of the guideline on the Summary of Product Characteristics. The Committee sent its comments to the Commission.

The Committee heard a short presentation on the final guideline 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' (EMEA/P/24143/2004), highlighting the main amendments brought to the document following its release for consultation. Clarification is given on the applicability of the guideline to the Community herbal monographs and to the List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, which the HMPC will adopt.
The final procedure and the overview of the comments received on the draft guideline can be found at the following locations:
http://www.emea.eu.int/pdfs/human/regaffair/2414304en.pdf
http://www.emea.eu.int/pdfs/human/regaffair/12581704en.pdf

The Committee was presented with draft documents prepared by the EMEA Secretariat for the implementation of the provisions in Article 59 and in Article 64.2(d) of Regulation (EC) No 726/2004, relating to the cooperation between Community bodies and the coordination between the EMEA scientific committees respectively. Comments from the HMPC were requested and will be reviewed in the further development of the documents.

The Committee discussed comments prepared at the request of the Committee on Orphan Medicinal Products on orphan medicinal product designation applications for medicinal products of herbal origin. The good co-operation of the two committees will be further developed via future designation applications.

Coordination also took place with the Mutual Recognition Facilitation Group concerning the expertise and involvement of the HMPC when (traditional) herbal medicinal products will be referred to the future coordination group on Mutual recognition and Decentralised procedure (CMD).

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