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

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 22-23 March 2005

The Committee on Herbal Medicinal Products met for the fourth time at the EMEA offices on 22-23 March 2005.

Following the agreed participation of the European Pharmacopoeia as permanent observer in the work of the Committee, Dr K. Keller, Chairman, welcomed to the Committee Dr E. Pel as representative of the European Directorate for the Quality of Medicines.

The Committee made progress on the co-option of experts in clinical pharmacology and toxicology with the establishment of a short-list of experts, who will be invited to present their professional career, involvement in the field of herbal medicines and expertise in the above-mentioned areas with a particular focus on clinical trials and on toxicology of natural compounds. Following the presentations on 31 May, the Committee will elect one co-opted member in clinical pharmacology and one co-opted member in toxicology.

The Committee discussed a number of legal and regulatory topics, in particular the guideline proposed by the European Commission on the definition of serious risk to public health. The Committee sent its comments to the Commission.
The guideline can be found at the following location:
http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/02_05/guideline_risk_human_02-05.pdf

The Committee had a preliminary discussion on the safety of herbal preparations for external use containing camphor, Eucalyptus oil, Mint oil and/or Peppermint oil. This follows the publication by the French Medicines Agency (AFSSAPS) of press releases on 3 and 28 December 2004 concerning the withdrawal from the French market of a cosmetic product containing terpenic derivatives (essential oils containing camphor and eucalyptol) following cases of undesirable neurological effects, leading in particular to convulsions, in infants.

The Committee made final arrangements for the organisation of a training session for EU assessors on 2 June 2005 on the CTD Quality Part for herbal medicinal products applications and of a presentation on the pharmacovigilance of herbal medicinal products during the plenary meeting on 31 May-1 June.

The Committee discussed the possiblity to hold a meeting with Interested Parties, which could be scheduled at the end of the HMPC meeting on 22-23 November 2005. Pending the establishment of a list of Interested Parties for the HMPC, those Interested Parties included in the list will be invited to propose relevant questions to be addressed during such a meeting.

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Reports from drafting groups meetings

Organisational matters
The drafting group on organisational matters finalised a number of documents, which the Committee adopted for release for public consultation until 15 July 2005:

- a proposal for the 'Structure of the List of herbal substances, preparations and combinations thereof' (EMEA/HMPC/100824/2005)
- a draft 'Guideline on the documentation to be submitted for inclusion in the List of herbal substances, preparations and combinations thereof' (EMEA/HMPC/107399/2005)
- a draft 'Procedure for the appointment by the HMPC of a Rapporteur responsible in the simplified procedure for the evaluation of a proposal for inclusion in the List of herbal substances, preparations and combinations thereof for the development of a Community herbal monograph' (EMEA/HMPC/108877/2005)
- a draft 'Template for a Community herbal monograph' (EMEA/HMPC/107436/2005)
- a draft 'Timetable for the finalisation of a Community herbal monograph [not resulting from any referral procedure]' (EMEA/HMPC/126542/2005)
- a draft 'Template for submission of a request for expert advice on herbal medicinal products' (EMEA/HMPC/119889/2005).

All documents will be available at the following location:
http://www.emea.eu.int/htms/general/direct/legislation/legislationhuman.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 specifications: test procedures and acceptance criteria for herbal drugs, herbal drug preparations and herbal medicinal products' (EMEA/CPMP/2820/00, EMEA/CVMP/815/00). The Committee endorsed the proposal, which was transmitted to the Committee for Medicinal Products for Human Use and to the Committee for Medicinal Products for Veterinary Use for review by the joint CHMP/CVMP Quality Working Party (QWP).
The drafting group also finalised a proposal for the revision of Annex 7 (Manufacture of herbal medicinal products) of the guide to good manufacturing practice (volume 4 of the Rules Governing Medicinal Products in the European Union). The Committee adopted the proposal for transmission to the *ad hoc* GMP Inspection Services.
The HMPC agreed that guidance to applicants on the applicability of the Active Substance Master File Procedure (ASMF) for traditional herbal medicinal products should be prepared in the form of an annex to the CHMP guideline. A concept paper will be proposed to the QWP.
Following a request from a Committee member and discussion in the drafting group, the Committee adopted a position on the status of natural camphor, menthol and propolis, i.e. their eligibility to be regarded as traditional herbal substances. The Committee stated that none of them meet the legal definition of a herbal substance.
The Committee position can be found at the following location:
http://www.emea.eu.int/pdfs/human/hmpc/10885005en.pdf
Finally, some members of the drafting group agreed to review draft QWP guidelines recently released for consultation by the CHMP, so as to identify whether aspects specific to the quality of herbal medicinal products should be taken into consideration.

Safety and Efficacy
The Committee adopted a draft 'Guideline on non-clinical documentation for well-established and traditional herbal medicinal products – guidance to mutual recognition and use of bibliographic data' finalised by the drafting group. The draft guideline was transmitted to the CHMP Safety Working Party for comments with a view to releasing the draft guideline at the next HMPC meeting.
Further discussion took place in the drafting group and during the plenary session on a draft 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. Members expressed their views on the possible approaches towards the borderline between well-established use and traditional use.

Revised monographs and information to be included in the List of herbal substances, preparations and combinations thereof will be prepared for Valerian and Linseed covering their well-established and traditional uses, pending conclusions reached on the borderline between the two areas. First draft monographs were circulated for Ispaghula husk, Ispaghula seed and Psyllium seed.

The Committee adopted public statements on soya / peanut protein, chamomilla, estragole, methyleugenol, asarone, capsicum/capsaicin, Aristolochia species, pulegone & menthofuran. These were originally developed as position papers and adopted by the Herbal Medicinal Products Working Party (HMPWP) following public consultation. The Committee adopted the HMPWP position papers without changes; these are released for public consultation until the end of June 2005.
These documents will be available at the following location:
http://www.emea.eu.int/pdfs/human/hmpc/hmpcguide.htm
Comments should be sent to: hmpc.secretariat@emea.eu.int

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