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

London, 18 March 2005
Doc. Ref. EMEA/HMPC/83845/2005

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 27-28 January 2005

The Committee on Herbal Medicinal Products met for the third time at the EMEA offices on 27-28 January 2005. The three drafting groups established by the Committee met in parallel on 27 January in the morning.

The Committee reviewed members' nominations for the co-option of experts in clinical pharmacology and toxicology. No nomination was yet received in the field of paediatric medicines. Further time was granted to members to send new nominations. Presentations by the experts in clinical pharmacology and toxicology to the Committee were postponed to the meeting on 31 May-1June.

The Committee discussed a number of legal and regulatory topics, in particular documents published by the European Commission services such as the summary of a workshop organised by the Commission with representatives of Member States and of different industrial sectors on borderline products with pharmaceuticals.
The document can be found at the following location:
http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/01_05/FinalCommunication_on_borderline_25-01-05.pdf

The Committee heard a presentation on the Agency's new initiative concerning the involvement of patients and consumers' organisations in the EMEA activities as publicly announced in April 2004. The Committee will endeavour to actively contribute to the improvement of information made available to patients and consumers on herbal medicinal products.
The "EMEA/CPMP Working Group with Patients Organisations – Outcome of Discussions: Recommendations and Proposals for Action, Executive Summary" can be found at the following location:
http://www.emea.eu.int/pdfs/human/patientgroup/581904.pdf

Concerning the establishment of a list of interested parties, the Committee reviewed the responses received to the call for interest published in the meeting report from the November 2004 meeting. The Committee confirmed that classical homeopathy is outside the scope of its current mandate. The Committee invites any organisation that has not yet expressed an interest in being regarded as an interested party to contact the secretariat to the Committee.

Reports from drafting groups meeting

Organisational matters
Progress was made on a number of priority topics in relation to the establishment of the List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (List) and the preparation of Community herbal monographs. The drafting group presented to the Committee eight draft templates, forms and procedures. In particular, the structure of the List was well advanced whilst reflection had started on the scientific content of the expected supporting

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

documentation. A template for Community herbal monographs was also completed and a procedure for the appointment of rapporteurs was designed. Finally, a template was designed in relation to the Committee's task to provide scientific support and advice, to be used by applicants to put forward their request.

Quality
The drafting group made significant progress in the review of existing guidelines on the quality of herbal medicinal products to address specific aspects for traditional herbal medicinal products; coordination will be ensured between the CHMP, its Quality Working Party and the Committee for subsequent release for public consultation and adoption of the revised guidelines. The Committee was made aware of some concerns discussed in the drafting group on the potential risk of confusion resulting from the introduction in the guidelines of references to CTD sections, given that some sections on 'substances' refer to 'preparations' as well.

Safety and Efficacy
The Committee was presented with a number of documents that resulted from discussion in the drafting group. These include a draft guideline on "non-clinical documentation for well-established and traditional herbal medicinal products – guidance to mutual recognition and use of bibliographic data". The first draft monographs were circulated for Valerian and Linseed addressing both well-established and traditional uses. In addition to the monographs, the information to be included in the List for the same plants was submitted, supported by an assessment report. Once finalised, the documents will be released for consultation.
A preliminary discussion took place in the drafting group and during the plenary session on a key document that will explain the Committee's views on the borderline between herbal medicinal products and traditional herbal medicinal products. The draft guideline on the assessment of clinical safety and efficacy in applications for marketing authorisation for well-established or for registration of traditional herbal medicinal products yet requires further discussion. The Committee agreed that work on fundamental principles and practical examples should continue in parallel so as to integrate in the Committee's policy considerations resulting from real case assessment.
The Committee adopted an assessment report of cases of hepatotoxicity associated with the use of *Cimicifuga racemosa*, which a Committee member had brought to the attention of the Committee. Safety concerns about Cimicifuga have already been made public by some regulatory medicines agencies. The recommendations from the Committee were forwarded to the CHMP Pharmacovigilance Working Party for consideration.

Presentation & training
The Committee requested support from the EMEA Secretariat for the organisation of presentations and training sessions in various fields such as pharmacovigilance, CTD Quality part, traditional regulatory scheme for Committee members and/or assessors of herbal medicinal products applications.

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

