



The European Agency for the Evaluation of Medicinal Products
Post-authorisation Evaluation of Medicines for Human Use

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PRESS RELEASE

Meeting of the Working Party on Herbal Medicinal Products

4-5 November 2002, EMEA London

The Working Party on Herbal Medicinal Products (HMPWP) met for the seventeenth time at the EMEA offices in London on 4-5 November 2002 under the chairmanship of Dr K. Keller.

During the meeting the Working Party addressed a range of organisational and technical issues, the main elements of which are summarised below:

- The Working Party heard a brief report on the Quality Working Party (QWP) review of comments received on the draft CPMP Note for guidance on stability testing: stability testing of active substances and related finished products (CPMP/QWP/122/02). The comments raised by the HMPWP aimed at extending the applicability of this guideline to herbal drug substances and preparations.
- The European Pharmacopoeia (Eur. Ph.) representative reported on the collaboration between some HMPWP members and the Eur. Ph. Certification Unit, which resulted in the adoption (by the working party) of a draft for the content of a future addendum to the Procedure for the "Certification of suitability to the monographs of the European Pharmacopoeia" for herbal drugs and herbal preparations, as foreseen in the Guideline "Note for Guidance on the quality of herbal medicinal products". This draft will be forwarded to the Steering Committee of the Certification procedure for endorsement.
- The Working Party finalised comments on the document from the Biotech Working Party (BWP) 'Points to consider on quality aspects of medicinal products containing active substances produced by stable transgene expression in higher plants' (CPMP/BWP/764/02), which is under consultation until November 2002.
- The HMPWP discussed a number of Pharmacovigilance and safety issues associated with herbal products and will continue to liaise with the Pharmacovigilance Working Party (PhVWP) for an exchange of information and consideration of possible actions.
- The Working Party finalised three new core-data after review of the corresponding monographs from ESCOP (European Scientific Cooperative on Phytotherapy) and related bibliographic literature. These documents are **released for consultation until end of February 2003**:
 - *Menthae x piperitae aetheroleum*
 - *Menthae x piperitae folium*
 - *Urticae folium*
- The HMPWP noted the comments already received from certain Interested Parties on the eight core-data, which are under consultation until the end of November 2002. All comments received will be reviewed by the respective Rapporteurs and discussed during the February 2003 HMPWP meeting.

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 14
E-mail: mail@emea.eu.int <http://www.emea.eu.int>

The Working Party held a hearing on 4 November 2002 with European Interested Parties. The Working Party heard representatives from European Industry Associations (AESGP, EHPM), Scientific Societies (ESCOP, Europam, GA) and Health Professional and Consumer Organisations (BEUC, CPEM, EHPA)*. They had been invited to present their views on the regulators' efforts to release to patients and healthcare professionals more and better information on herbal medicinal products, on their possible contribution to these activities and on possible new measures for further transparency in the area of herbal medicinal products.

The Working Party confirmed the dates for 2003:

- 24-25 February 2003
- 30 June-1 July 2003
- 3-4 November 2003

Noël Wathion

Head of Unit

Post-Authorisation Evaluation of Medicines for Human Use, Tel. (+44-20) 74 18 85 92

* AESGP (European Proprietary Medicines Manufacturers' Association), EHPM (European Federation of Associations of Health Product Manufacturers), Europam (European Herb Growers Association), ESCOP (European Scientific Cooperative on Phytotherapy), GA (Society for Medicinal Plant Research), BEUC (Bureau Européen des Unions de Consommateurs), CPEM (Standing Committee of European Doctors), EHPA (European Herbal Practitioners Association).