



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

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EMEA/HMPWP/83/01

## **PRESS RELEASE**

### **Meeting of the EMEA Working Party on Herbal Medicinal Products**

**29-30 October 2001, EMEA London**

The EMEA Working Party on Herbal Medicinal Products (HMPWP) met for the fourteenth time at the EMEA offices in London on 29-30 October 2001 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 HMPWP finalised a guidance document on how to prepare an Herbal medicinal product application using the CTD format. The proposal will be forwarded to the European Commission and the NTA Group for further consideration.
- The Working Party noted the proposal for Revision of Annex 7 to GMP Provisions on Herbal Medicinal Products adopted by the ad hoc EMEA GMP Inspection Services at their meeting in October 2001. This proposal will be forwarded to the European Commission.
- The HMPWP reviewed the comments received during the consultation period with Interested Parties on the "Points to Consider on good agricultural and collection practice for starting materials of herbal origin" (EMEA/HMPWP/31/99). An updated version will be circulated to the ad hoc EMEA GMP Inspection Services.
- The Working Party discussed the applicability of the following guideline to herbal drug substances and preparations: CPMP Note for guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98).
- The HMPWP discussed a number of Pharmacovigilance and safety issues associated with herbal products and will liaise with the CPMP PhVWP for an exchange of information and consideration of possible actions.

The Working Party held a public hearing on 29 October 2001 with representatives from European Industry Associations (AESGP, EFPIA, EHPM), Scientific Societies (ESCOP, Europam, GA) and Health Professional and Consumer Organisations (CP, EHPA, PGEU, EFNMU)\*. At the meeting they had the opportunity to present their views on the future activities of the HMPWP and their possible contribution to these activities.

The Working Party agreed on the following meeting dates for 2002: 11-12 March, 1-2 July and 4-5 November 2002.

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\* AESGP (European Proprietary Medicines Manufacturers' Association), EFPIA (European Federation of Pharmaceutical Industries and Associations), 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), CP (Standing Committee of European Doctors), EHPA (European Herbal Practitioners Association), PGEU (Pharmaceutical Group of the European Union), EFNMU (European Federation of Natural Medicine Users).