



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

London, 18 November 1999
EMEA/HMPWP/32/99 rev.1

Meeting of the EMEA Working Party on Herbal Medicinal Products

28-29 October 1999, EMEA London

The EMEA Working Party on Herbal Medicinal Products met for the eighth time at the EMEA offices in London on 28 -29 October 1999 under the chairmanship of Dr K. Keller.

The working party noted the new Commission Directive amending the Annex of Council Directive 75/318/EEC regarding the well-established medicinal use, which lays down a legal basis for the assessment of well-established herbal medicinal products and the use of technical guidance documents prepared by the working party. As a consequence the points to consider paper on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications (EMEA/HMPWG/23/99) was updated, taking into account the new Directive. This document will be transmitted to CPMP for its December 1999 meeting before it will be released for further consultation with Interested Parties.

The European Commission representative updated members on initiatives taken at the Pharmaceutical Committee level to investigate the need for new legislative measures to address specific aspects of "traditional medicinal products".

The working party agreed to a proposal for guidance on good agricultural and collection practice in relation to GMP guide for Active Pharmaceutical Ingredients (APIs) (EMEA/HMPWP/31/99), based on its previous comments on draft texts for GMP and GAP.

The note for guidance on specifications: test procedures and acceptance criteria for herbal drugs, herbal drug preparations and herbal medicinal products (EMEA/HMPWP/19/99) was finalised.

The working party held a hearing on 28 October 1999 with representatives from European Industry Associations (AESGP, EFPIA, EHPM, Europam), Scientific Societies (ESCOP) and Health Professional and Consumer Organisations (CP, EHPA, PGEU, EFNMU)*. All representatives expressed their appreciation of the work achieved by the working party so far and reiterated their support for a continuation of the work, particularly in the field of development of core-Summary of Product Characteristics (SPCs). The working party was encouraged to also work on proposals for standards/assessment criteria for traditional herbal medicinal products should this approach be endorsed at European level.

The working party continued to work on ESCOP monographs and on draft core-SPCs prepared by appointed Rapporteurs based on an evaluation of the published literature.

The working party identified meeting dates for 2000 as follows: 2-3 March, 11-12 July and 30-31 October.

Please contact for further information:

Prof. Rolf Bass
Tel. (44-20-7) 418 8411
Fax (44-20-7) 418 8420

* 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), 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).