



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

London, 28 March 2003

Doc. Ref: EMEA/CPMP/HMPWP/1090/03 Rev.1

PRESS RELEASE (revised)

Meeting of the Working Party on Herbal Medicinal Products

24-25 February 2003, EMEA London

The CPMP Working Party on Herbal Medicinal Products (HMPWP) met for the fourth time at the EMEA offices in London on 24-25 February 2003 under the chairmanship of Dr K. Keller.

The following topics were addressed:

- The Working Party heard reports on ongoing developments in the Community legislative and regulatory domains and will continue to contribute on draft texts relevant to the field of herbal medicinal products.
- The Working Party noted that the European Pharmacopoeia will publish the addendum to the Procedure for the "Certification of suitability to the monographs of the European Pharmacopoeia" for herbal drugs and herbal preparations in Pharmeuropa in April 2003.
- The Working Party organised a subgroup meeting on 26 February 2003 for the preparation of a concept paper on the biopharmaceutical characterisation of herbal medicinal products. This concept paper would be based on the CPMP Note for guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98), a FIP discussion paper "Biopharmaceutical characterisation of herbal medicinal products" and other published literature.
- The HMPWP discussed pharmacovigilance and safety related issues related to a number of herbal products. Position papers on the need for possible regulatory actions will be transmitted to the Pharmacovigilance Working Party (PhVWP).
- The Working Party finalised two new core-data after review of the corresponding monographs from ESCOP (European Scientific Cooperative on Phytotherapy) and related bibliographic literature.

These documents will be **released for consultation until end of July 2003**:

- *Lini semen*
- *Primula radix*

- The HMPWP reviewed the comments received from certain Interested Parties on the core-data for *Plantaginis ovatae testa*, *Plantaginis ovatae semen* and *Psyllii semen*. Comments received on the core-data for *Calendulae flos*, *Passiflorae herba*, *Melissae folium*, *Lupuli flos* and *Harpagophyti radix* as well as *Menthae piperitae aetheroleum*, *Menthae piperitae folium* and *Urticae folium* will be reviewed during the next HMPWP meeting.

The next HMPWP meeting will be held on 30 June-1 July 2003.

Contact for further information:

Noël Wathion
Head of Unit

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

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.eu.int <http://www.emea.eu.int>