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

30 June-1 July 2003, EMEA London

The CPMP Working Party on Herbal Medicinal Products (HMPWP) met for the fifth time at the EMEA offices in London on 30 June-1 July 2003 under the chairmanship of Dr K. Keller.

The Chairman welcomed new observers from the Accession Countries (Slovak Republic, Poland).

The following topics were addressed:

- The Working Party prepared recommendations concerning the use of herbal medicinal products containing various substances, herbal substances or herbal preparations[1]:
  - Draft Position paper on the use of herbal medicinal products containing **asarone** (HMPWP/41/03)
  - Draft Position paper on the use of herbal medicinal products containing **methyleugenol** (HMPWP/337/03)
  - Draft Position paper on the use of herbal medicinal products containing **estragole** (HMPWP/338/03)
  - Draft Position paper on **Capsicum/capsaicin** containing herbal medicinal products (HMPWP/340/03)
  - Draft Position statement on **Chamomilla** containing herbal medicinal products (HMPWP/345/03)

- The Working Party prepared a draft Position paper on the **biopharmaceutical characterisation** of herbal medicinal products (HMPWP/344/03).

- The Working Party prepared three new draft core-data after review of the corresponding monographs from ESCOP (European Scientific Cooperative on Phytotherapy) and related bibliographic literature:
  - ***Salicis cortex*** (HMPWP/341/03)
  - ***Nettle root*** (HMPWP/342/03)
  - ***Thymi herba*** (HMPWP/343/03)

All above-referenced draft HMPWP documents are **released for consultation until end of October 2003**.

- The HMPWP finalised the core-data for ***Nettle leaf*** (HMPWP/1416/02 rev.1), based on comments received from Interested Parties during the consultation period (December 2002 to February 2003).

- The Working Party further revised the **SOP on recording of core-data** for herbal substances and herbal preparations (EMEA/HMPWP/41/01 Rev 2).

[1] The term "herbal substance" should be considered equivalent to the term "herbal drug" as defined in the European Pharmacopoeia and the term "herbal preparation" should be considered equivalent to the term "herbal drug preparation" as defined in the European Pharmacopoeia

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- The Working Party noted the release of the following documents on the European Commission website (http://pharmacos.eudra.org/)
  - revised version of the CTD (Introduction, Modules 1, 2, 3, 4 et 5),
  - new Annex I to Directive 2001/83/EC,
  - and two new regulations on variations (Regulations (EC) No 1084/2003 and No 1085/2003),
  which all include particular requirements for herbal medicinal products based on contributions from the HMPWP.

- The HMPWP agreed to meeting dates for 2004 as follows:
  16-17 February, 14-15 June and 8-9 November 2004.

The next HMPWP meeting will be held on 3-4 November 2003, during which a hearing with European Interested Parties will take place (Monday, 3 November from 4 pm onwards).

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