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

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Press Release

AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS MEETING

18-19 JANUARY 1999

EMEA, 7 Westferry Circus, Canary Wharf, London E14 4HB

The sixth meeting of the Ad Hoc Working Group on Herbal Medicinal Products was held at the EMEA offices in London on 18-19 January 1999. A new draft mandate and work programme for the group was discussed and will be submitted by the EMEA Executive Director to the Management Board for approval, together with a comprehensive report on its activities in 1997-1998, which will be made public soon after.

The European Commission representative presented to the group the "Study on herbal medicinal products in the European Union" carried out by AESGP on behalf of the European Commission. The study report will be published shortly as an official European Commission publication and available through the European Commission distribution and sales offices.

The working group reviewed comments from Interested Parties on its proposals for new guidance "Fixed combination of herbal medicinal products with long-term marketing experience - Guidance to facilitate mutual recognition and use of bibliographical data" and for revision of the Notice to Applicants (EMEA/HMPWG/33279/98). These proposals had been released in September 1998 by the EMEA for a 3-month consultation period. The finalised proposals will be included in the report to the EMEA Management Board.

The following documents will be presented to the CPMP at its January 1999 meeting and subsequently made available for 3-month consultation with Interested Parties:

- Comments on the Commission Regulation (EC) No. 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a Member State;
- Comments on the European Commission guideline on dossier requirements for type I variations (III/5783/93);
- Comments on the CPMP Note for guidance on stability testing for a type II variation to a marketing authorisation (CPMP/QWP/576/96);
- Comments on the draft Directive on GMP guide for starting materials of medicinal products and inspections of manufacturers;
- Comments on the Good Agricultural Practice (G.A.P) document from the European Herbs Growers and Producers Association (Europam);
- Draft "Note for guidance on specifications: test procedures and acceptance criteria for herbal drug preparations (herbal drugs) and herbal medicinal products" (EMEA/HMPWG/1/99);
- Draft "Points to consider on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications" (EMEA/HMPWG/2/99).
- Draft core-SPC for *Ispaghula husk*.

The working group agreed to continue its assessment of ESCOP monographs and preparation of core-SPCs.

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