



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

Press Release

AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS MEETING

6-7 JULY 1998

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

The fifth meeting of the Ad Hoc Working Group on Herbal Medicinal Products was held at the EMEA offices in London on 6-7 July 1998.

The working group reviewed comments from Interested Parties on its proposals for revised/new guidance in the field of quality, safety and efficacy of herbal medicinal products. These proposals had been released in January 1998 by the EMEA for a 3-month consultation period. Comments were received from National/European trade associations, from pharmaceutical companies, research societies and professional bodies. The working group finalised the guidance documents, which will be included in the final report of the group to the EMEA and the European Commission and will be published.

The working group continued to work on further proposals in the field of quality with the finalisation of tabulated formats specific to herbal medicinal products to facilitate the preparation of Expert Reports on Chemical, Pharmaceutical and Biological Documentation (Notice to Applicants Volume 2B Part IC1).

The working group also finalised a proposal for new guidance "Fixed combination of herbal medicinal products with long-term marketing experience - Guidance to facilitate mutual recognition and use of bibliographical data".

These proposals will be forwarded to the EMEA Executive Director for release in September 1998 for a 3-month consultation with Interested Parties.

The working group continued its discussion on the global assessment of monographs published by the European Scientific Cooperative on Phytotherapy (ESCOP) and reviewed existing Summary of Product Characteristics (SPCs) for Ispaghula and Ispaghula husk. The group agreed on a timetable for the preparation by different delegations of core-SPCs for a number of herbal medicinal products, based on the evaluation of respective ESCOP monographs and bibliographic data.

The members of the Ad Hoc Working Group on Herbal Medicinal Products were informed by the EMEA that the meeting initially scheduled for November 1998 would have to be postponed until January 1999 for budgetary reasons.