Press Release

AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS MEETING

24-25 NOVEMBER 1997

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

The third meeting of the Ad Hoc Working Group on Herbal Medicinal Products, which was held at the EMEA offices in London on 24-25 November 1997, concluded the first series of meetings related to the facilitation of marketing authorisation of herbal medicinal products via the Mutual Recognition Procedure.

Over its three meetings this year and in accordance with its mandate defined last June by the EMEA Management Board, the group reviewed the criteria set out in Council Directive 75/318/EEC for the demonstration of chemical and pharmaceutical quality, pre-clinical safety, safety and clinical efficacy in the case of marketing authorisation applications for herbal medicinal products. Such criteria must be fulfilled to allow successful mutual recognition.

In the field of quality, the group reviewed existing guidance for Good Manufacturing Practice (GMP) which was considered acceptable. Minor modifications would suffice for updating Annex 7 'Manufacture of Herbal Medicinal Products' of GMP for medicinal products. Concerning documentation on pharmaceutical quality existing guidance is appropriate at present, although modifications would be necessary, in particular to the Note for Guidance "Quality of Herbal Remedies". Taking into account potential difficulties for the testing of complex mixtures, development of further guidance should be considered.

Guidance regarding requirements for non-clinical testing of herbal drug preparations was derived from available draft guidance on requirements for old substances with long term marketing experience. The proposed guidance takes into account experience available in humans for well-established herbal drug preparations.

Although efficacy was recognised as being the most difficult issue, the group agreed on some general principles and reached agreement on a core SPC for *Valerianae radix*. The group considered that the drafting of such core SPCs would be the most appropriate way to develop general guidance on criteria to assess efficacy data based on bibliographical documentation. ESCOP made a presentation to the working group on their study on the pharmacovigilance of herbal medicinal products.

The outcome of the work achieved by the working group was presented to Interested Parties who unanimously supported the continuation of this work beyond 1997. Industry upon request confirmed their willingness to co-operate in encouraging new research in the field of clinical pharmacology and clinical efficacy in order to obtain modern clinical data on herbal medicinal products. They also expressed a great interest in commenting on all proposals for revision of documents prepared by the working group. These proposals will be released by the EMEA Secretariat for consideration by Interested Parties including learned societies.

Full report will be given to the Management Board of the EMEA for consideration and circulated to CPMP, Mutual Recognition Facilitation Group and European Commission. Proposals for future work include establishment of listings of herbal medicinal products available in the Member States, preparation of core SPCs and drafting a Points to consider document on criteria to assess efficacy of herbal medicinal products and review fixed combinations.

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