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

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AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS

FINAL COMMENTS FOR REVISION OF GOOD MANUFACTURING PRACTICE (GMP) PROVISIONS

RELEASE FOR CONSULTATION BY THE EMEA	January 1998
DEADLINE FOR COMMENTS	April 1998
RELEASE OF FINAL PROPOSALS	September 1998

Note:

Modifications from the original texts proposed by the group are in *bold italic*.

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Final Comments for Revision of Good Manufacturing Practice (GMP) Provisions

The working group reviewed existing provisions in the Good Manufacturing Practice guide, in particular Annex 7 on the Manufacture of Herbal Medicinal Products. It confirmed the appropriateness of this guidance, though a few minor changes are suggested as follows:

Principle

- The working group indicated that a consistent quality of herbal drugs may need more detailed definitions of aspects of agricultural production. The selection of seeds, conditions of cultivation and harvesting represent an important aspect in producing a reproducible quality of herbal drugs. Ongoing discussions on Good Agricultural Practice (G.A.P) for medicinal plants should be monitored and cross-references should be included as soon as a consensus on G.A.P is obtained (see comments from the working group on the G.A.P document from Europam).

Documentation

- The working group indicated that "starting material" could be a medicinal plant, a herbal drug or a herbal drug preparation. A clear distinction should be made between these starting materials. In the case where, for example, a herbal drug preparation is the starting material, there is a need to go back to the source material and to obtain the data on the source of the plant. In those cases where such data are lacking the applicant has to justify why these data cannot be obtained. It was indicated that in those cases additional specifications on possible contamination are required. Some Member States' representatives reported on the difficulties they encounter in obtaining information on the origin of plants and production conditions.

- The working group agreed that ***water content*** should be included in the list of specifications to be provided for products such as medicinal plants and herbal drugs. Such a specification is not necessary for essential oils, fatty oils and resins.

- It was suggested to amend the seventh indent of the specifications for medicinal crude plants as follows: "assay of constituents of known therapeutic activity ***if identified***, or ***where appropriate*** of markers" (instead of "assay, where appropriate, of constituents of known therapeutic activity or of markers").

- The working group examined the issue of pesticide contamination and the European Pharmacopoeia representative reminded participants of the general method to test pesticide residues which provides a list of pesticides and their maximum limits and information on the methods of testing. Therefore it was suggested to add in the text "***in accordance with European Pharmacopoeia methods***" after "methods suitable to determine possible pesticide contamination and limits accepted" (eighth indent). The group underlined the need for a general monograph on herbal drugs in the European Pharmacopoeia because harmonised criteria for limits for toxic metals and mycotoxins are still lacking.

Sampling

- It was indicated that a reference sample of the plant material will be necessary in those cases where the plant is not well known in Europe, for example, herbal drugs coming from Asia. Samples of plant material are particular necessary if powders are used.