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**W01 The European Pharmacopoeia and quality standards for herbal drug preparations: An update**

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The fourth edition of the European Pharmacopoeia contains more than 120 monographs on herbal drugs whereas only a small number of monographs deal with herbal drug preparations such as extracts, tinctures, fatty oils and essential oils.

Since general monographs on extracts, fatty oils and essential oils have been finalized it might be expected that the more than forty monographs on these herbal drug preparations, which are currently under study, will be finished in the near future.

In this way it will become possible to improve the quality standards of many commercial herbal medicinal products in Western Europe, especially since a harmonisation of the quality criteria of these products has been realised with the ones set up by the regulatory authorities. The different specifications for herbal drug preparations such as extracts, tinctures, fatty oils and essential oils will be reviewed.

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**W02 Harmonised assessment criteria for efficacy and safety of herbal medicinal products**

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ESCOP, the European Scientific Cooperative on Phytotherapy, was founded in 1989 as an umbrella organisation of national scientific associations on phytotherapy. Within its objective to establish harmonized criteria for the assessment of herbal medicinal products, ESCOP has prepared monographs on important plants and their medicinal use taking into consideration relevant scientific literature and different viewpoints from all countries involved. The format is in line with the European guideline on Summaries of Products Characteristics (SPCs). In terms of definition of the plant material and quality requirements, reference is made to the European Pharmacopoeia or to national pharmacopoeias. In the pharmacological part, all relevant *in vitro* and *in vivo* data as well as clinical studies have been evaluated, each statement being supported by references. Six fascicules including a total of 60 monographs on efficacy and safety of medicinal plants and their preparations have been published, and further ones as well as revisions of the existing ones will soon be available.

Based on the "Guidelines for the Assessment of Herbal Medicines" which define basic criteria for the evaluation of quality, safety and efficacy, WHO's Traditional Medicine Programme (TRM) has prepared a document entitled "Model Monographs of Widely used Medicinal Plants". These monographs include summaries of the botanical characteristics and chemical constituents as well as clinical applications, pharmacology, etc... Two volumes, each consisting of approx. 30 model monographs have already been finalised, and a third and fourth volume are in preparation.

The EMEA Working Group on Herbal Medicinal Products expressed its opinion that the monographs drafted by ESCOP and WHO "offer a valuable and updated overview on published scientific literature, which together may be used in support of the demonstration of the safety and efficacy of a medicinal product". The group is currently evaluating these monographs in order to develop official assessment criteria for herbal medicinal products.