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Future perspectives for the regulation of traditional herbal medicinal products in Europe

According to the European legislative framework, in particular the European Directive 2001/83/EC, herbal medicinal products require a pre-marketing authorisation including documentation of quality, safety and efficacy before gaining access to the market. Safety and efficacy of the product must in principle be proven by pharmacological-toxicological data and clinical studies. However, this legal provision includes the option of making reference to published bibliographic data in case of preparations having a well-established medicinal use which means – according to the Directive – recognised efficacy and an acceptable level of safety. In most of the European Member States, application for marketing authorisation of herbal medicinal products is performed in practice according to the general rules of the European Directives including the option of a bibliographic application.

In several countries, there is a group of products in the market which are harmless and of proven quality but whose efficacy is based on tradition instead of clinical trials or reference to bibliographies. In order to harmonise the legislative framework for all medicinal products, the European Community intends to introduce a simplified registration procedure for traditional herbal medicinal products without requiring the particulars and documents on tests and trials on safety and efficacy. However, the applicant has to present evidence on the traditional medicinal use of the product as well as a bibliographic review of safety data together with an expert report. In terms of quality requirements, the products will be subject to the same rules concerning their manufacture and quality control as all other medicinal products.

According to the new legal provisions which were adopted by the European Commission on 17 January 2002, traditional herbal medicinal products suitable for the new registration procedure will have limited indications as well as a specified strength and mode of administration. Within the European Community, 30 years of use must be documented or, in case the product has been available within the Community for at least 15 years, it appears acceptable that the evidence of 30 years may fully or partly relate to a use outside the Member States of the European Union. In addition to the general provisions on labelling and content of package leaflets, a specific statement will be included that the product is a traditional herbal medicinal product and that its efficacy has not been clinically proven but relies on tradition.

Furthermore, within the new European framework, a new Committee for Herbal Medicinal Products will be set up which will replace the existing Herbal Medicinal Products Working Party (HMPWP) whose status will be upgraded and whose tasks will be to establish Community herbal monographs. These monographs will be relevant for the assessment of documents in the area of the well-established medicinal use (such as ESCOP monographs) as well as on traditional herbal medicinal products. For the latter ones, the Committee will set up a list of herbal substances which are eligible for the traditional registration procedure including the therapeutic indication and further relevant information. Therefore, an applicant for a traditional use registration may refer to a herbal preparation included in this list instead of submitting the respective documents on safety and traditional use.

The new Directive, which will be an amendment to the existing Directive 2001/83/EC, is expected to be finally adopted approx. mid of 2003, followed by official publication and entry into force after that date. The Directive will be addressed to the Member States of the European Union which shall take the measures necessary to comply with the provisions by 31 December 2004. For traditional herbal medicinal products which are already in the market when the provision become effective, a transition period of five years will apply.

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