Traditional herbal medicinal products

2002/0008(COD) - 17/01/2002 - Legislative proposal

PURPOSE : to establish a harmonised legislative framework for traditional herbal medicinal products and to provide a special registration procedure allowing the registration and the marketing of certain traditional herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy (amending Directive 2001/83/EC). CONTENT : the purpose of the proposed Directive is to lay down specific provisions traditional herbal medicinal products in the Community. It brings together the European experience and understanding in the field of traditional herbal medicines with the essential aim of safeguarding public health and satisfying the consumer choice. Trade in traditional herbal medicinal products within the Community is, at present, hindered by disparities between the national requirements and differences in basic traditional use concepts in EU. More specifically, the draft Directive aims to establish a harmonised legislative framework for traditional herbal medicinal products and hence is based on Article 95 of the EC Treaty. Since the differences currently existing between the situation in the Member States constitute an obstacle to the free movement of these goods within the Community, a certain harmonisation on the European level appears necessary and is consistent with the principle of subsidiarity. The draft Directive is limited to those provisions considered indispensable to attain a sufficient degree of harmonisation while ensuring the full protection of public health and therefore respects also the principle of proportionality. The proposed Directive provides for a special registration procedure allowing the registration and, hence, the marketing of certain traditional herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy. However, the same requirements apply to the manufacturing of these products and their quality. In order to further improve the protection of public health, the Directive provides a special legal framework for traditional herbal medicinal products, thus removing the differences and uncertainties about the status of these products currently existing in the Member States. For reasons of coherence and legibility of the regulatory framework, the specific provisions on traditional herbal medicinal products shall be introduced in the new Community code relating to medicinal products for human use, as contained in Directive 2001/83/EC. In addition, to ensure a full participation and involvement of experts in the field of herbal medicinal products, a new Committee for Herbal Medicinal Products shall be set up within the European Agency for the Evaluation of Medicinal Products. One of the Committee's major tasks will be to establish monographs that further harmonise and facilitate registration applications concerning herbal medicine.