Traditional herbal medicinal products

2002/0008(COD) - 09/04/2003 - Modified legislative proposal

The European Parliament adopted twenty-four amendments in total, of which the Commission accepted in full two; thirteen in principle; and rejected ten. The two accepted by the Commission are: - The recognition of herbal medicinal product in cases where a monograph has been established. - Presenting a Commission report to the European Parliament and the Council on the application of the Directive. The Commission can accept in part or in principle amendments relating, inter alia, to: - An extension of responsibilities for the new "Committee for Herbal Medicinal Product". Those responsibilities should include issues relating to national authorisations and registrations of herbal medicinal products, in particular the referral/arbitration procedure for such products. For medicinal products, which contain herbal ingredients without fulfilling the definition of herbal medicinal product, the new Committee for Herbal Medicinal Product should be entitled to give an opinion on the herbal ingredients when deciding on the product in its entirety. - A provision obliging Member States to recognise decisions by other Member States instead of a mere obligation to take due account of such decision. - An extension of the simplified registration procedure to include medicinal products containing non-herbal ingredients (such as vitamins and minerals or other non-biological substances for which there is well documented evidence regarding their safety.) - Amendments 8 and 15 relating to the specified daily dosage. The proposed Directive has been modified by the Commission to refer specifically to "the specified strength and posology" of a product. - On the question of labelling the Commission accepts in principle the amendments proposed by the Parliament though it does seek to clarify the wording to ensure that it is clear from the labelling and the leaflet that safety and efficacy are based on information on the traditional use without the regular scientific data. In addition, a clarification is needed that the product could be registered for more than one specified use. - A rewording of the provisions requiring users of herbal medicines to consult a doctor should adverse reactions occur - even if they are not mentioned in the leaflet accompanying the product. - The provision of information pointing to possible dangerous interactions with food and/or medicinal products. - On the question of advertising the Commission accepts that herbal medicinal products should include the statement that "the safety and efficacy of the product rely exclusively on information obtained from its long-term use and experience." - The use of monographs, publications or data in a simplified procedure - even if the Committee for Herbal Products has not yet established them. Such information however shall only be used in cases where the Committee for Herbal Medicinal Products has not yet established specific monographs. The amendments rejected by the Commission refer, inter alia, to those: - Allowing Member States to register certain herbal products even though they stem from outside of the Community. - Defining a herbal medicinal product. The definition outlined in the Commission proposal is identical to that of a scientific definition agreed within the Council of Europe. - On therapeutic indications and its classification as a "non-prescriptive" medicine. - Referring to the pharmacological activity of the herbal ingredients. - Regarding the data to be submitted by the applicant. - Requiring the Committee to draw up a classification of herbal medicinal products. - Excluding certain categories of products from the scope of the new Directive. - Allowing Member States to introduce or retain specific national law for traditional medicines other than those of herbal origin.