Traditional herbal medicinal products

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The committee adopted the report by Giuseppe NISTICO' (EPP-ED, I) amending the proposal under the 1st reading of the codecision procedure. It modified a number of the definitions contained in the proposal: - a "traditional herbal medicinal product" should also be allowed to contain non-herbal ingredients; - a "herbal medicinal product" should be any medicinal product "in different preparations, containing one or more active ingredients at pharmacologically active levels originating from herbal, plant or other vegetable substances, for which there is well documented experimental and clinical evidence for its efficacy and safety"; - as regards "traditional use", the committee proposed that, in order to obtain traditional use registration, the applicant may supply evidence showing that the herbal substances, herbal preparations or their active ingredients in the product have been in medicinal use outside the EU for a continuous period of time which, together with a minimum of 10 years within the EU, completes the required period of 30 years; with this amendment, the committee sought to shorten the required period of use within the EU from 15 years, as proposed by the Commission, to 10 years and also to make it possible to show that not just a particular product but also the herbal substances or preparations present as active ingredients in any product have been in medicinal use for at least 30 years. It pointed out that a medicinal product may have been on the market for a shorter time but consist of substances which have been used throughout the period in question. Other key amendments were as follows: - any possible side-effects and dangerous interactions with food and other drugs should be clearly indicated on labels and in user package leaflets; however, the committee deleted the requirement that consumers be informed if the efficacy of a product has not been clinically proven, on the grounds that negative information is not needed; - the committee called for the new Committee for Herbal Medicinal Products to take over the tasks of the Committee for Human Medicinal Products with regard to the evaluation of herbal medicines and to draw up a detailed classification of herbal medicinal products. This should include such indications as specified daily doses (rather than the specified strength of the product), possible adverse affects, possible interactions with drugs, alcohol and foods and any other information required for safe use, especially by children, pregnant women and elderly people; - in the absence of any extension of traditional use registration to other categories of medicinal products, after the Commission has reviewed the specific provisions for traditional herbal medicines (the committee suggested that the review take place three years after the directive comes into force), Member States should be allowed to apply their own rules for "traditionally used non-conventional medicinal products"; - lastly, the committee added a clause specifying that traditional herbal products containing a dose of herbal substances or herbal preparations below pharmacological level should continue to fall under food legislation even after the entry into force of the directive.