Homeopathic medicinal products: application of directives 92/73/EEC and 92/74/EEC. Commission report

1997/2170(COS) - 05/11/1998 - Text adopted by Parliament, single reading

In adopting the report by Mr Raphaël CHANTERIE (PPE, B), the European Parliament called for amendments to Directives 92/73/EEC and 92/74/EEC and for homeopathic anthroposophic medicinal products described in an official pharmacopoeia to be given the same status as homeopathic medicinal products. It called for a range of measures with regard to recognition, registration procedure and labelling. 1) Recognition: Parliament called on the Commission to investigate whether a system of mutual recognition of homeopathic medicinal products could be set up, which should be run by a Community body of duly authorised persons with expertise in this field. It called for the drawing up of rules on the compilation of files and applications for registration to be applied by Member States. Meanwhile, Member States should actually recognise registrations carried out, or authorizations granted, by other Member States. The conditions under which national registration should be mutually recognised or endorsed by other Member States should be defined. Parliament called for common safety criteria to be applied throughout the EU. 2) Registration: Parliament called on the Commission to investigate whether homeopathic medicinal products administered by means of injection, plaster, spray, drops, suppository or by any other route other than orally or for external use with no risk to the health or safety of the user could be considered for the special, simplified registration procedure. It called on the Commission to investigate ways and means of producing a valid Community list of degrees of dilution determined for the mother tincture and, in the absence of such a list, to revise and, if possible, to increase the existing degrees of dilution. 3) Labelling: Parliament called for the lifting of the ban on fantasy names, in particular for preparations. It advocated an obligatory indication of the dose or instructions for use on the label and, where appropriate, in the package insert. It called for an end to the obligation to use the statement 'homeopathic medicinal product without approved therapeutic indications', and for modification of the warning, on specific homeopathic medicinal products intended for humans, advising the user to consult a doctor if the symptoms persist 'during the use of the medicinal product'. It called on the Commission to submit a proposal, with the participation of experts, obliging Member States to draw up special rules for the pharmacological, toxicological and clinical tests for the testing of homeopathic medicinal products which were not eligible for the special, simplified registration procedure.