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

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OBJECTIVE: presentation of the Commission report to the European Parliament and Council on the application of Directives 92/73/EEC (homeopathic medicinal products for human use) and 92/74/EEC (homeopathic veterinary medicinal products). SUBSTANCE: the report is based on an in-depth study of the application of Directives 92/73/EEC and 92/74/EEC carried out by independent consultants on behalf of the European Commission. It notes a certain degree of disparity in the application of the Directives in the Member States and contradictions in their interpretation. Infringement procedures concerning full or partial non-transposition have been started (and are still in progress) against Belgium and France regarding Directive 92/73/EEC and against Belgium, France, Portugal and the United Kingdom regarding Directive 92/74/EEC. Before presenting a concrete proposal for the amendment of the Directives concerned, and in order to identify feasible solutions to the problems raised in the reports, the Commission is inviting the European Parliament and the Council to express their views and positions on the following suggestions: - the wording according to which each Member State must take due account of registrations and authorizations previously granted by another Member State could be reconsidered in order to define exactly the specific conditions under which existing national registrations should be mutually recognized or endorsed by other Member States; - Directive 92/73/EEC could be amended in order to increase the range of products subject to a simplified procedure; - Directive 92/74/EEC could be amended in order to make the simplified registration procedure also applicable to homeopathics intended to be administered to food-producing animals; - the possibility of using fantasy names for combination preparations could be introduced. The normal daily dosage could also be included in the labelling, and a warning to consult a doctor could also be considered, in order to make the labelling more consumer-friendly; - consideration could be given to making the provisions on clinical trials binding and to demanding explicitly that the specific rules for clinical trials in Member States should provide for the involvement of suitable experts in homeopathic medicine.