Veterinary medicinal products: Community code. Codification

1999/0180(COD) - 06/11/2001 - Final act

PURPOSE : to codify and rationalise the rules on the marketing of veterinary medicinal products. COMMUNITY MEASURE : Directive 2001/82/EC of the European Parliament and the Council on the Community code relating to veterinary medicinal products. CONTENT : this Directive codifies and assembles in one text the following directives, which have been frequently and substantially amended: Directives 81/851/EEC, 81/852/EEC, 90/677/EEC, and 92/74/EEC. It also rationalises the marketing of veterinary medicinal products. No such product may be placed on the market of a Member State unless a marketing authorization has been issued in accordance with this directive or been granted in accordance with Regulation 2309/93/EEC. The particulars and documents required to obtain such authorization are set out. There are special provisions relating to homeopathic veterinary medicinal products. Provisions are also made for mutual recognition. A Committee for Veterinary Medicinal Products is set up, which is part of the European Agency for the Evaluation of Medicinal Products. The Committee will make a scientific evaluation where there is disagreement between Member States about the quality or the safety or the efficacy of a medicinal product. The Directive lays down the circumstances under which marketing authorization must be refused. One such circumstance is where the withdrawal period indicated is not long enough to eliminate health hazards arising from residues. The competent authorities are empowered to prohibit the use of an immunological veterinary medicinal product when the immunological responses of the treated animal will interfere with a national or Community programme for the diagnosis, eradication or control of animal diseases. This Directive does not apply to medicated feedingstuffs. ENTRY INTO FORCE : 18 December 2001.