Medicinal products for human use: Community code. Codification

1999/0134(COD) - 06/11/2001 - Final act

PURPOSE : to codify and expand Community provisions on medicinal products for human use.

COMMUNITY MEASURE : Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

CONTENT : This directive codifies and assembles in a single text the following directives, which have been frequently and substantially amended: Council Directive 65/65/EEC, Council Directive 75/318/EEC, Council Directive 75/319/EEC, Council Directive 89/342/EEC, Council Directive 89/343/EEC, Council Directive 89/381/EEC, Council Directive 92/25/EEC, Council Directive 92/26/EEC, Council Directive 92 /27/EEC, Council Directive 92/28/EEC and Council Directive 92/73/EEC.

There are also the following main provisions:

- A Committee for Proprietary Medicinal Products is set up, attached to the European Agency for the Evaluation of Medicinal products, established in Regulation 2309/93/EEC. This body will deal with cases where there is disagreement between Member states about the quality, the safety or the efficacy of a medicinal product. A scientific evaluation of the matter is undertaken according to a Community standard, leading to a single decision on the area of disagreement which is binding on the Member States concerned.
- To avoid any unnecessary duplication of effort regarding the obtaining of marketing authorization, Member States must systematically prepare assessment reports in respect of each medicinal product which is authorized by them, and exchange the reports upon request. A Member State must suspend consideration of an application for marketing authorization if it is currently under active consideration in another Member State, with a view to recognising the decision made by the latter Member State.
- Minimum requirements are laid down for manufacture and imports coming from third countries and for the grant of authorization relating to them. - There are specific provisions for immunological medicinal products, homeopathic medicinal products, radiopharmaceuticals, and medicinal products based on human blood or plasma.

ENTRY INTO FORCE : 18 December 2001.