Orphan medicinal products

1998/0240(COD) - 16/12/1999 - Final act

PURPOSE : To lay down a Community procedure to designate orphan or uneconomic medicinal products and provide incentives for their research, development and marketing. COMMUNITY MEASURE : Regulation 141/2000/EC on orphan medicinal products. CONTENT : Broadly speaking, the Regulation defines an orphan medicinal product as one that is intended for the treatment of life threatening conditions affecting not more than 5 in 10,000 persons, and one that would not justify investment without incentives. The Commission needs to adopt provisions for implementation of this aspect of the regulation. A Committee is set up to advise the Commission. Medicinal products designated as orphan will be eligible for aid for research provided under the Fifth Framework Programme for Research. Market exclusivity will be granted for 10 years but this period will be reduced to 6 if, at the end of the fifth year, it is established that the product is sufficiently available not to justify the maintenance of market exclusivity. The Community and the Member States may provide further incentives. ENTRY INTO FORCE: The Regulation shall enter into force on 22/01/2000. It shall apply as from the date of adoption of the implementing Regulations provided for in Article 3(2) and Article 8(4).