Orphan medicinal products

1998/0240(COD) - 09/03/1999 - Text adopted by Parliament, 1st reading/single reading

At first reading under codecision procedure, the proposal for a European Parliament and Council regulation on orphan medicinal products was approved by the European Parliament, subject to amendments, notably in the following areas: - providing for additional incentive measures to combat the main infectious diseases prevailing in developing countries; - underlining the need for the protection of intellectual property rights to be ensured; - specifying that the Committee for Orphan Medicinal Products will be set up within the European Agency for the Evaluation of Medicinal Products; - requiring 3 members of this committee to be selected by the European Parliament rather than the European Commission; - allowing the committee, whenever necessary, to be assisted by an expert; - requiring committee members, even after their duties have ceased, to observe professional secrecy obligations; - allowing application for the status of orphan medicinal product to be made at any stage of the product's development before submission of a registration application; - requiring the sponsor to report to the Agency every year on the state of development of the designated medicinal product; - making extra provision with regard to transferring designation of an orphan medicinal product from one sponsor to another; - providing for assistance in the development of a protocol for pre-clinical and clinical trials during the development phase; - allowing the Agency, in exceptional cases and under specific conditions, to authorise the medicinal product being made available before marketing authorisation had been granted; - specifying that the scale of the Community's special annual contribution to the Agency be of a sufficient scale to cover all the applications submitted in order to produce the maximum incentive; - calling for the Commission to propose establishment of an Orphan Medicinal Product Innovation Promotion Fund; - requiring the Commission to adopt definitions of "similar medicinal product" and "clinical superiority" in the form of an implementing regulation in accordance with the procedure laid down in article 72 of regulation 2309/93/EEC and to draw up detailed guidance for the application of this article 72 and the implementing regulation; - making provision for designated orphan medicinal products to be eligible for particular aid for research and SMUs under the Fifth Framework Programme for R&TD; - requiring the Commission to publish a series of operational proposals to ensure uniform application without unjustified delay of Community and Member State incentives to support research, development and availability of orphan medicinal products; - making any application for designation as an orphan medicinal product after 01/04/99 subject to the requirements of the proposed regulation. The Parliament's rapporteur was Christian E.A. Cabrol (UPE,FR).