

Orphan medicinal products

1998/0240(COD) - 27/07/1998 - Legislative proposal

PURPOSE: to lay down a Community procedure to designate orphan or uneconomic medicinal products and provide incentives for their research, development, and marketing. **CONTENT:** an orphan medicinal product is defined as one intended to diagnose, prevent or treat a condition affecting less than 5 per 10,000 persons in the Community. Designation also covers the treatment of serious communicable diseases that need incentives to develop and will be carried out by a Committee for Orphan Medicinal Products, which will receive a special contribution from the Community to cover all or part of the Agency's fees with regard to designating orphan medicinal products. The granting of a market authorisation for a product by the Agency entitles the sponsor to ten years' market exclusivity, subject to certain health protection criteria. Market exclusivity may be withdrawn after six years if it can be proven that the product no longer complies with the orphan medicinal criteria or the price charged allows the earning of an unreasonable profit. Also, a second applicant may be granted market authorisation for a similar product if the first applicant gives its consent or cannot supply sufficient quantities of the product, or if the second product is found to be clinically superior. Provision is also made for further incentives to be made available for the development of orphan medicinal products by the Community and by Member States, and for progress in this field to be monitored.