Orphan medicinal products

1998/0240(COD) - 15/06/1999 - Modified legislative proposal

In its amended proposal, the Commission accepted the majority of amendments put forward by the Parliament in its first reading. These amendments relate to: - the integration in the proposal of medicines intended for serious and chronic conditions; - provisions that the sponsor of an orphan medicinal product shall provide the European Agency for the Evaluation of Medicinal Products with a report on the state of development of the designated medicinal product, and that in order to secure the transfer to another sponsor of the designation of an orphan medicinal product, the holder of that designation shall submit a specific application to the Agency; - provision for the possibility to obtain the designation of a medicinal product as an orphan medicinal product, at any stage of the development of the medicinal product before an application for marketing authorisation is made; - the terms 'similar medicinal product' and 'clinical superiority' have been removed from the text; - modification of the definition of 'sponsor' to cover not only those who are seeking to obtain designation of a medicinal product as orphan medicinal product, but also those who have already obtained designations; - clear statement that the Committee for Orphan Medicinal Products (COMP) is part of the European Agency for the Evaluation of Medicinal Products; - provision for the possibility for the COMP to seek the assistance of external experts; - requirements regarding the disclosure of information by members of the COMP, even after their duties have ceased; - addition of a clarification that the new form of intellectual property created by the designation of an orphan medicinal product is without prejudice to other intellectual property rights; - medicinal products dedicated as orphan medicinal products shall be eligible for research aid for SMEs provided under the Fifth Framework Programme for RTD. The Commission, however, did not accept the EP amendments that sought to give the EP the right to select the members of the COMP, as well as that which sought to strengthen the financial contribution of the European Agency for the Evaluation of Medicinal Products in view of its new tasks. The Commission rejected the idea of the creation of a fund to promote innovation in orphan medicines which would be managed by the Agency and established using the income from the sale of orphan medicines. In parallel, the Commission also introduced an amendment following discussions which took place among the delegations within the Council mainly on the subject of comitology. It is envisaged that in the event of disagreement within the COMP regarding the designation of a medicine, the opinion shall be adopted by a majority of two-thirds of the Committee and the opinion should be given within 90 rather than 60 days of the receipt of a valid application.