Orphan medicinal products

1998/0240(COD) - 27/09/1999 - Council position

The Council's common position corresponds almost completely with the amended Commission proposal. Apart from one exception, it thus incorporates all of the Parliament's amendments that were accepted by the Commission. In some cases, the Council has made textual clarifications or minor changes, which are, however, consistent with the general line taken in the European Parliament's amendments and the amended proposal. The Commission has approved all the Council's amendments. The amendments accepted unchanged or with minor editorial changes include those relating to : - the possibility of applying economic criteria when designating a product as an orphan medicinal product, initially restricted to communicable diseases, extending to all serious and chronic diseases; - the new form of intellectual property created by the designation of an orphan medicinal product which will not affect other intellectual property rights; - the Committee for Orphan Medicinal Products which will be a part of the European Agency for the Evaluation of Medicinal Products; - members of the Committee for Orphan Medicinal Products calling upon the services of additional experts if necessary; - members of the Committee respecting the requirements of professional secrecy even after their duties have ceased; - extending the possibility for a sponsor to apply for designation at any stage of the development of a medicinal product before an application for market authorisation is submitted; - the requirement of the sponsor to supply annual reports on the state of development of a designated medicinal product; - the intention to facilitate the transfer of designation rights from one party to another; this was considered necessary in view of the numerous mergers and restructuring operations that are a feature of the pharmaceutical industry; - medicinal products designated as orphan medicinal products will be eligible for aid for research for small and medium-sized undertakings provided under the Fifth Framework Programme for Rearch and Technological Development. The Council accepted the part of the amendment 19 (Article 8(5)) that deletes the definition of "similar medicinal product" and replaces it by a provision requiring the Commission, in consultation with the Agency and other interested parties, to adopt a definition as well as a definition of "clinical superiority" in the form of an implementating Regulation, and draw up detailed guidance for the application of Article 8. The Council did not accept the part that refers to the drawing up of detailed guidance for application of the implementating Regulation, as it considers it to be already covered by the reference to the provisions of Article 8 as a whole. The Council incorporated, in a slightly modified form, the amendment relating to research into rare diseases which is regarded as a priority by the Commission and the European Parliament. In addition, the Council did not accept the amendment referring to Agency assistance for undertakings in conductingtrials concerning assistance in the development of a protocol for pre-clinical trials.