

Orphan medicinal products

1998/0240(COD) - 01/10/1999 - Commission communication on Council's position

While the Commission is broadly satisfied with the changes in the criteria for designation, the Council's common position is more restrictive than the Commission's modified proposal, and the Commission regrets the possibility that some rare conditions which have difficulty falling into the "life threatening" or "seriously debilitating" category may be excluded from the benefits of this regulation. Although the Commission agrees with the need to for consistency between the different Community policies, it considers that that the reference to prevalence and disease severity in the recently adopted Decision no 1295/1999/EC of the European Parliament and of the Council adopting a programme of Community action on rare diseases within the framework for action in the field of public health (1999 to 2003) was intended to provide a non definitive guide as to what might constitute a rare disease, whereas the current regulation relies upon these criteria for designation of orphan medicinal product with the result that the proposed definitions become more restrictive in their application. Nonetheless, the Commission welcomes the common position of the Council and particularly the fact that that it is supported unanimously by Member States. The Commission invites the Council and the Parliament to agree as quickly as possible on a final regulation in order to ensure that patients in the European Community suffering from rare diseases can benefit from the development of more safe and effective medicines.