Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

2001/0252(COD) - 17/12/2003 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Rosemarie MÜLLER (PES, Germany) making some amendments to the Council's common position. The main amendments are as follows: - a new recital states that pharmaceutical law should continue to ensure that only efficacious, safe and top-quality medicinal products are exported, and the Commission should consider creating further incentives to carry out research into medicinal products against widespread tropical diseases; - the Agency's budget should be composed of fees paid by the private sector and contributions paid out of the Community budget to implement Community policies; - the Committee must formulate an opinion whenever there is disagreement in the assessment of medicinal product through the mutual recognition procedure. The opinion of the Committee must be made publicly accessible; - two indents are added to point 3 of the Annex, adding auto-immune diseases and other immune dysfunctions, and viral diseases. Thereafter, the Commission, having consulted the Agency, may present any appropriate proposal modifying point 3 of the Annex and the Council shall take a decision on that proposal by qualified majority. - clinical trials carried out outside the EU meet the ethical requirements of Directive 2001/20/EC; - the duration of the analysis of the scientific data in the file concerning the application for marketing authorization must be at least 80 days, except in cases where the rapporteur and co-rapporteur declare that they have completed their assessment before that time. On the basis of a duly reasoned request, the Committee for Human Medicinal Products may call for the duration to be extended; - whereas the Council's common position sought to provide data protection for a longer period for medicines approved under the centralised procedure, the committee said that medicinal products for human use authorised under this procedure should benefit from only an eight-year period of data protection and a ten-year period of marketing protection. Under certain circumstances, this latter period could be extended to a maximum of 11 years (known as the 8 + 2 + 1 compromise); - the database must include a section on medicinal products authorized for the treatment of children; - the Management Board will consist of one representative of each Member State, two representatives of the Commission and two representatives of the European Parliament. In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the EU.