

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

2001/0252(COD) - 17/02/2004 - Commission opinion on Parliament's position at 2nd reading

The Commission can accept in full the 32 amendments to the Council's common position adopted by Parliament on the proposal for a regulation, the 30 amendments to the Council's common position adopted by Parliament on the proposal for a directive on medicinal products for human use and the 22 amendments to the Council's common position adopted by Parliament on the proposal for a directive on veterinary medicinal products. The Commission notes the convergence of views between the three institutions on the general approach and on the most important issues regarding the compulsory field of application of the centralised procedure, the administrative structure of the agency, the period of data protection, definitions, information for patients and the assessment of the environmental impact. The amendments adopted by Parliament mainly concern the issues of the compulsory field of application of the centralised procedure, the period of data protection and the administrative structure of the agency as far as the regulation is concerned, and the definitions, period of data protection, information for patients and assessment of the environmental impact as regards the two directives on medicinal products for human use and veterinary use.