

Veterinary medicinal products: Community code

2001/0254(COD) - 27/11/2003

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) amending the Council's common position under the 2nd reading of the codecision procedure. It retabled a number of key amendments adopted by Parliament at 1st reading which had not been accepted by Council: - the procedure for granting a marketing authorisation for medicinal products should be completed within 150 days (rather than 210 days as proposed by the Council) after a valid application has been submitted, including 80 days for scientific data analysis and preparation of the assessment report; - a definition of "food-producing animals" should be inserted in the directive as follows: "(a) animals bred, raised, kept or slaughtered specifically for the purposes of producing food for human consumption, or (b) those animals bred, raised and kept for sport and leisure purposes, from the time when they become destined for the food chain"; - the 10-year data protection period for veterinary medicinal products should be extended by one year for each extension of the marketing authorisation not only to another food-producing species, as specified in the proposal, but also to one or more "significant new therapeutic indications", meaning those which, during the scientific evaluation prior to their authorisation, are held to bring a "significant clinical benefit" in comparison with existing therapies; - Member States should ensure that unused medicinal products or waste and packaging from used products are delivered to the collection systems which exist. In Member States which do not have appropriate collection systems, unused veterinary medicinal products should be returned to the point of purchase; - in order to guarantee the total independence of the competent authorities, activities connected with pharmacovigilance, the operation of communication networks and market surveillance should receive public funding.