Veterinary medicinal products: Community code

2001/0254(COD) - 17/12/2003 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Franoise GROSSETETE EPP-ED, France) making some amendments to the Council's common position. The amendments adopted by Parliament were agreed in advance with the Council for both veterinary products : - biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action. When a biological medicinal product does not meet all the conditions to be considered as a generic medicinal product, the results of appropriate tests should be provided in order to fulfil the requirements related to safety (pre-clinical tests) or to efficacy (clinical tests) or to both; - environmental impact must be assessed and, on a case-by-case basis, specific arrangements to limit it must be envisaged. In any event this impact should not constitute a criterion for refusal of a marketing authorisation; - Member States should also take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days of the submission of a valid application; - 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.