

Veterinary medicinal products: Community code

2001/0254(COD) - 02/10/2002

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) amending the proposal under the codecision procedure (1st reading). The main amendments were as follows: - a clearer differentiation between provisions relating to non food-producing animals and those relating to food-producing animals; - extension of the scope for using medicinal products which have been authorised in another Member State for non-food-producing animals; - stepping up of pharmacovigilance requirements; - to ensure that the competent authorities are fully independent, public funding of activities relating to pharmacovigilance, the operation of communications networks and market surveillance; - speeding up the time within which generic medicines can be brought onto the market: the committee stipulated that applicants should not be required to provide the results of pre-clinical tests or pre-clinical trials if they can demonstrate that the medicinal product is a generic of a reference medicinal product authorised for 8 years in a Member State or in the Community, rather than 10 years as proposed by the Commission. The committee added, however, that such a generic medicinal product cannot be manufactured or placed on the market until ten years have elapsed since the first authorisation of the reference product; - the introduction of definitions of 'homeopathic medicinal product', 'risk related to use of the product' and 'risk/benefit balance'; - for homeopathic products, compliance with the provisions of the "Homeopathic Preparations" monograph of the European Pharmacopoeia; - extending the period following which an authorisation ceases to be valid (because the product was not actually marketed) from two years, as specified in the proposal, to three years; - speeding up assessment procedures, through shorter decision-making deadlines; - unused medicinal products to be returned to the point of purchase and not to be disposed of with other waste; - a ban on advertising to the general public of prescription-only veterinary medicines.