Veterinary medicinal products: Community code. Codification

1999/0180(COD) - 13/12/2006 - Implementing legislative act

ACT: Commission Regulation 1950/2006/EC establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae.

CONTENT: no veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with Directive 2001/82/EC or in accordance with Regulation 726/2004/EC of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Veterinary medicinal products for food-producing animals including equidae may be authorised only on conditions that guarantee that the foodstuffs produced will be harmless to consumers as regards any residues of such medicinal products, in accordance with Council Regulation 2377/90/EEC laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

According to the Commission, the available range of authorised veterinary medicinal products, particularly for food-producing animals, is gradually decreasing.

By means of the derogation provided for in Directive 2001/82/EC, equidae intended for slaughter for human consumption may be administered substances essential for their treatment, hereinafter ‘essential substances’, subject to a withdrawal period of at least six months. For the purpose of that derogation, the list of essential substances is established in the Annex to this Regulation.

Essential substances may be used, for the specific disease conditions, treatment needs or zootechnical purposes specified in the Annex, where no medicinal product authorised for equidae would yield equally satisfactory results in terms of successfully treating the animal, avoiding unnecessary suffering for the animal, or ensuring the safety of those treating the animal.

The European Medicines Agency shall, at the request of the Commission, ensure that the Committee for Medicinal Products for Veterinary Use carries out a scientific evaluation of any draft amendment to the list set out in the Annex. Within 210 days of receiving such a request, the European Medicines Agency shall deliver an opinion to the Commission on the scientific suitability of the amendment. Where appropriate, the European Food Safety Authority shall also be consulted.

When Member States or veterinary professional associations ask the Commission to amend the list set out in the Annex they shall duly substantiate their request and include any relevant scientific data available.

ENTRY INTO FORCE: 18.12.2006.