Veterinary medicinal products: Community code

2001/0254(COD) - 03/04/2003 - Modified legislative proposal

The Commission accepted 16 of the Parliament's amendments. These include the following: - the requirement that the applicant submit documents as proof that he will be able to meet certain pharmacovigilance obligations; - defining the strength related to the effect of homeopathic medicinal products; - making public the rules of procedure for the co-ordination group in charge of decentralised procedures for marketing authorisation; - providing a timetable for the work to harmonise the summary of product characteristics for veterinary medicinal products authorised for not less than ten years; - it is obligatory for the committee to appoint a rapporteur for the assessment of a referral; - the Commission must prepare a draft decision in 15 not 30 days; -inspections can be carried out without prior notification; - the rules of procedure of the Standing committee must be published; 20 amendments were accepted in part or principle, including the following: - a more precise definition of homeopathic veterinary medicinal product and its identification; - a precision of the definition of risks with the use of veterinary medicinal products and the benefit/risk ration; - strengthening the exceptional nature of the use of veterinary medicinal products outside the authorised use for non-food producing species in a Member State, while allowing for the possibility of access to such products authorised in other Member States; - the requirement to supply information on the pharmacovigilance system intended for a product and specific tests relating to the potential environmental risks posed by the product, where appropriate; - an extension from three to five years for the development of products for use in additional non-food producing species; - information on marketing authorisations to be made available to the public; - obligatory referral of cases of risk to human or animal health or the environment where a Community interest is involved to allow for a scientific assessment of the question at Community level; this is extended to other referral procedures; - the transfer of the future report on the functioning of the decentralised system for authorisation of veterinary medicinal products to the European Parliament and the Council; - the prohibition of direct advertising of veterinary medicinal products containing psychotropic or narcotic substances; - the use of homeopathic veterinary medicinal products in exceptional circumstances where there is no authorised veterinary medicinal product for the treatment of a particular condition, under certain circumstances for food-producing animals; - requirement to renew the authorisation five years after the first marketing authorisation. After the first renewal, the authorisation will be considered as valid for an unlimited period; - the definition of veterinary medicinal product includes a reference to pharmacological, immunological and metabolic action; - derogation from establishing maximum residue limits for active substances for the Equidae species; - an abridged application for a generic product in a Member State even if the reference product has not been authorised in that State but only in another Member State. The Commission proposes certain modifications to bring this Directive into line with Directive 2001/83/EC. The Commission rejected 26 amendments.