Veterinary medicinal products: Community code

2001/0254(COD) - 26/11/2001 - Legislative proposal

PURPOSE : to amend Directive 2001/82/EC on the Community code relating to veterinary medicinal products. CONTENT : The Commission maintains a parallel approach as far as possible with the Community code relating to medicinal products for human use (see COD010253), taking into account the specific features of veterinary products. The costs of research and development to meet increased requirements as regards the quality, safety and efficacy of veterinary medicinal products are leading to a gradual reduction in the range of products authorised for food producing animals. The main amendments concern the following: -there are derogations from the authorization requirement either for certain new categories of pets, such as dwarf rabbits or ferrets, or for the use of a medicinal product on animals subject to compulsory specific health provisions with a view to export to non-member countries or import into the Community. -If no authorised medicinal product is available for a given species or disorder, it is proposed that the use of other products be made more straightforward. -economic incentives are introduced to encourage the pharmaceutical industry to place veterinary medicinal products on the market without delay. The main amendment is a proposal to increase the period of administrative data protection in some cases and hence provide for a more attractive return on investment for an economic operator. -the provisions on the analytical methods to be used to determine the amounts of residues have been amended. -the proposal amends the general provision on total exclusion from human consumption of foodstuffs from animals used for testing medicinal products if maximum residues have not been established. This provision is a major obstacle to the development of new medicinal products for food producing animals. The obligation for the prior establishment of maximum residue limits is abolished, and this measure is accompanied by a withdrawal period. -the provisions on homeopathic veterinary medicinal products are revised, especially with regard to the use of the simplified registration system. -the revision of the mutual recognition procedure in order to increase the scope for cooperation between Member States. A coordination group is established and its role in settling disagreements is defined. -the arrangements on immunological veterinary products are reviewed, partly by restricting the scope for official release of batches to certain types of products, i.e. live vaccines or immunological medicinal products for diseases covered by Community measures, which would mean particular responsibility for the competent authorities. It is also proposed to define the obligations on pharmaceutical companies and the competent authorities under these circumstances, particularly as regards the tests that need to be done by official control laboratories. -the pharmocovigilance procedures have been amended.