Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

TITLE III

MARKETING

CHAPTER 3

Procedure for marketing authorization

[F1 Article 30

The marketing authorisation shall be refused if the file submitted to the competent authorities does not comply with Articles 12 to 13d and Article 15.

The authorisation shall also be refused if, after examination of the documents and particulars listed in Articles 12 and 13(1), it is clear that:

(a) the risk-benefit balance of the veterinary medicinal product is, under the authorised conditions of use, unfavourable; when the application concerns a veterinary medicinal product for zootechnical use, particular regard shall be had to the benefits for animal health and welfare and to consumer safety; or

(b) the product has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the species of animal which is to be treated; or

(c) its qualitative or quantitative composition is not as stated; or

(d) the withdrawal period recommended by the applicant is not long enough to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer, or is insufficiently substantiated; or

(e) the labelling or the package leaflet proposed by the applicant does not comply with this Directive; or

(f) the veterinary medicinal product is offered for sale for a use prohibited under other Community provisions.

However, when a Community legislative framework is in the course of being adopted, the competent authority may refuse authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer or animal health.

The applicant or marketing authorisation holder shall be responsible for the accuracy of documents and data submitted.**]**

Textual Amendments

F1 Substituted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.