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 VIII

SUPERVISION AND SANCTIONS

Article 83

1 **[**[F1]Member States' competent authorities shall suspend, revoke, withdraw or vary marketing authorisations when it is clear that:**]**

[[F1]a the risk-benefit assessment of the veterinary medicinal product is, under the authorised conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to consumer safety, when the authorisation concerns a veterinary medicinal product for zootechnical use;**]**

b the veterinary medicinal product does not have any therapeutic effect on the species of animal for which the treatment is intended;

c its qualitative and quantitative composition is not as stated;

d the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer;

e the veterinary medicinal product is offered for sale for a use which is prohibited by other community provisions**[**[F1];**]**

[[F2]However, pending Community rules, the competent authorities may refuse to grant authorization for a veterinary medicinal product where such action is necessary for the protection of public, consumer or animal health;**]**

[[F1]f information given in the application documents pursuant to Articles 12 to 13d and 27 is incorrect;**]**

g the control tests referred to in Article 81(1) have not been carried out**[**[F1].**]**

[[F2]h the obligation referred to in Article 26(2) has not been fulfilled.**]**

[[F3]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 and animal health.**]**

2 **[**[F1]Marketing authorisations may be suspended, revoked, withdrawn or varied when it is established that:**]**

[[F1]a the particulars supporting the application, as provided for in Articles 12 to 13d, have not been amended in accordance with Article 27(1) and (5);**]**

b any new information as referred to in Article 27(3) has not been communicated to the competent authorities.

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.

F2 Deleted 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.

F3 Inserted 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.