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 VII

PHARMACOVIGILANCE

Article 78

1 Where, as a result of the evaluation of veterinary pharmacovigilance data, a Member State considers that a marketing authorization should be suspended, withdrawn or varied to restrict the indications or availability, amend the posology, add a contraindication or add a new precautionary measure, it shall forthwith inform the Agency, the other Member States and the marketing authorization holder.

[[F1]2 If urgent action is necessary for protecting human or animal health, the Member State concerned may suspend the marketing authorisation of a veterinary medicinal product, provided that the Agency, the Commission and the other Member States are informed on the following working day at the latest.**]**

[[F2]3 When the Agency is informed in accordance with paragraphs 1 or 2, it shall give its opinion as soon as possible, according to the urgency of the matter.

On the basis of this opinion, the Commission may request all Member States in which the veterinary medicinal is marketed to take temporary measures immediately.

Final measures shall be adopted in accordance with the procedure referred to in Article 89(3).**]**

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 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.