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 V

LABELLING AND PACKAGE INSERT

Article 61

[[F1]1 The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the immediate packaging and the outer packaging. Member States shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included. The package leaflet shall be written in terms that are comprehensible to the general public and in the official language or languages of the Member State in which the medicinal product is marketed.

The first subparagraph shall not prevent the package leaflet from being written in several languages, provided that the information given is identical in all the languages.

Competent authorities may exempt labels and package leaflets for specific veterinary medicinal products from the obligation for certain particulars to appear and for the leaflet to be in the official language or languages of the Member State in which the product is placed on the market, when the product is intended to be administered only by a veterinarian.**]**

[[F1]2 The competent authorities shall approve package leaflets. Leaflets shall contain at least the following information, in the order indicated, which shall conform to the particulars and documents provided pursuant to Articles 12 to 13d and the approved summary of product characteristics:**]**

[[F1]a name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where appropriate, of the representative of the marketing authorisation holder;

b name of the veterinary medicinal product followed by its strength and pharmaceutical form. The common name shall appear if the product contains only one active substance and its name is an invented name. Where the medicinal product is authorised according to the procedure provided for in Articles 31 to 43 under different names in the Member States concerned, a list of the names authorised in each Member State;**]**

c the therapeutic indications;

d contra-indications and adverse reactions in so far as these particulars are necessary for the use of the veterinary medicinal product;

e the species of animal for which the veterinary medicinal product is intended, the dosage for each species, the method and route of administration and advice on correct administration, if necessary;

f the withdrawal period, even if this is nil, in the case of veterinary medicinal products administered to food-producing animals;

g special storage precautions, if any;

h particulars required to be indicated pursuant to Article 26(1), if any;

i special precautions for the disposal of unused medicinal products or waste materials from medicinal products, if any.

[F2]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 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.