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 58

1 **[**[F1]Except in the case of the medicinal products referred to in Article 17(1), the competent authority shall approve the immediate packaging and outer packaging of veterinary medicinal products. Packaging shall bear the following information, which shall conform with the particulars and documents provided pursuant to Articles 12 to 13d and the summary of product characteristics, and shall appear in legible characters:**]**

[[F1]a The name of the medicinal product, followed by its strength and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and its name is an invented name;

b A statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using the common names;**]**

c Manufacturer's batch number;

d Marketing authorization number;

[[F1]e Name or corporate name and permanent address or registered place of business of the marketing authorisation holder and, where appropriate, of the representative designated by the marketing authorisation holder;**]**

[[F1]f The species of animal for which the veterinary medicinal product is intended; the method and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;**]**

[[F1]g The withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk, honey), including those for which the withdrawal period is zero;**]**

h Expiry date, in plain language;

i Special storage precautions, if any;

[[F1]j Specific precautions relating to the disposal of unused medicinal products or waste derived from veterinary medicinal products, where appropriate, as well as a reference to any appropriate collection system in place;**]**

k Particulars required to be indicated pursuant to Article 26(1), if any;

[[F1]l The words ‘For animal treatment only’ or, in the case of the medicinal products referred to in Article 67, the words ‘For animal treatment only — to be supplied only on veterinary prescription’.**]**

2 The pharmaceutical form and the contents by weight, volume or number of dose-units need only be shown on the outer package.

3 The provisions of Part 1, A of Annex I, in so far as they concern the qualitative and quantitative composition of veterinary medicinal products in respect of active substances, shall apply to the particulars provided for in paragraph 1(b).

4 The particulars mentioned in paragraph 1(f) to (l) shall appear on the outer package and on the container of the medicinal products in the language or languages of the country in which they are placed on the market.

[F2 5 In the case of medicinal products that have been granted a marketing authorisation under Regulation (EC) No 726/2004, Member States may permit or require that the outer packaging bear additional information concerning distribution, possession, sale or any necessary precautions, provided that such information is not in infringement of Community law or the terms of the marketing authorisation, and is not promotional.

This additional information shall appear in a box with a blue border to separate it clearly from the information referred to in paragraph 1.**]**

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.

Article 59

[F1 1 As regards ampoules, the particulars listed in the first paragraph of Article 58(1) shall be given on the outer package. On the immediate packaging, however, only the following particulars shall be necessary:**]**

— name of veterinary medicinal product,
— quantity of the active substances,
— route of administration,
— manufacturer's batch number,
— date of expiry,
— the words ‘For animal treatment only’.

[F1 2 As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the particulars mentioned in paragraph 1, the requirements of Article 58(1), (2) and (3) shall apply only to the outer package.

3 The particulars mentioned in the third and sixth indents of paragraph 1 shall appear on the outer package and on the immediate packaging of the medicinal products in the language or languages of the country in which they are placed on the market.**]**

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.

*[*F1 *Article 60*

Where there is no outer package, all the particulars which should feature on such a package pursuant to Articles 58 and 59 shall be shown on the immediate packaging.**]**

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.

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.

F3 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.

F3 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.

[F1 Article 62

Where the provisions of this Title are not observed and a formal notice addressed to the person concerned has been ineffectual, Member States' competent authorities may suspend or revoke the marketing authorisation.**]**

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.

Article 63

The requirements of Member States concerning conditions of supply to the public, the marking of prices on medicinal products for veterinary use and industrial property rights shall not be affected by the provisions of this Title.

Article 64

1 Without prejudice to paragraph 2, homeopathic veterinary medicinal products shall be labelled in accordance with the provisions of this title and identified by the inclusion on their labels, in clearly legible form, of the words ‘homeopathic medicinal product for veterinary use’.

[F1 2 In addition to the clear mention of the words ‘homeopathic veterinary medicinal product without approved therapeutic indications’, the labelling and, where appropriate, package leaflet for the homeopathic veterinary medicinal products referred to in Article 17(1) shall bear the following information and no other information:**]**

— **[**F1 the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used in accordance with point (8) of Article 1. If the homeopathic veterinary medicinal product is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks,**]**

— name and address of the marketing authorization holder and, where appropriate, of the manufacturer,

— method of administration and, if necessary, route,

— expiry date, in clear terms (month, year),

— pharmaceutical form,

— contents of the sales presentation,

— special storage precautions, if any,

— target species,

— a special warning if necessary for the medicinal product,

— manufacturer's batch number,

— registration number.

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.