Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

CHAPTER II

MARKETING AUTHORISATIONS – GENERAL PROVISIONS AND RULES ON APPLICATIONS

Section 4

Labelling and package leaflet

Article 10

Labelling of the immediate packaging of veterinary medicinal products

1 The immediate packaging of a veterinary medicinal product shall contain the following information and shall, subject to Article 11(4), contain no information other than:

a the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

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 their common names;

c the batch number, preceded by the word ‘Lot’;

d the name or company name or logo name of the marketing authorisation holder;

e the target species;

f the expiry date, in the format: ‘mm/yyyy’, preceded by the abbreviation ‘Exp.’;

g special storage precautions, if any;

h route of administration; and

i if applicable, the withdrawal period, even if such period is zero.

2 The information referred to in paragraph 1 of this Article shall appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms common throughout the Union as listed in accordance with Article 17(2).

3 Notwithstanding paragraph 1, a Member State may decide that, on the immediate packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1.

Article 11

Labelling of the outer packaging of veterinary medicinal products

1 The outer packaging of a veterinary medicinal product shall contain the following information and shall contain no information other than:

a the information referred to in Article 10(1);

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b the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;

c a warning that the veterinary medicinal product must be kept out of the sight and reach of children;

d a warning that the veterinary medicinal product is 'for animal treatment only';

e without prejudice to Article 14(4), a recommendation to read the package leaflet;

f in the case of homeopathic veterinary medicinal products, the statement 'homeopathic veterinary medicinal product';

g in the case of veterinary medicinal products not subject to a veterinary prescription, the indication or indications;

h the marketing authorisation number.

2 A Member State may decide that, on the outer packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1. Such a code may be used to replace the marketing authorisation number referred to in point (h) of paragraph 1.

3 The information referred to in paragraph 1 of this Article shall appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms common throughout the Union, as listed in accordance with Article 17(2).

4 Where there is no outer packaging, all the information referred to in paragraphs 1 and 2 shall appear on the immediate packaging.

Article 12

Labelling of small immediate packaging units of veterinary medicinal products

1 By way of derogation from Article 10, immediate packaging units which are too small to contain in a readable form the information referred to in that Article shall contain the following information and shall contain no information other than:

a the name of veterinary medicinal product;

b the quantitative particulars of the active substances;

c the batch number, preceded by the word 'Lot';

d the expiry date, in the format: 'mm/yyyy', preceded by the abbreviation 'Exp.'.

2 The immediate packaging units referred to in paragraph 1 of this Article shall have an outer packaging containing information required in Article 11(1), (2) and (3).

Article 13

Additional information on the immediate packaging or outer packaging of veterinary medicinal products

By way of derogation from Articles 10(1), 11(1) and 12(1), Member States may, within their territory, and on request of the applicant, allow an applicant to include on the immediate packaging or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics and which is not an advertisement for a veterinary medicinal product.

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Article 14

Package leaflet of veterinary medicinal products

1 The marketing authorisation holder shall make readily available a package leaflet for each veterinary medicinal product. That package leaflet shall contain at least the following information:

a the name or company name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing authorisation holder;

b the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

c qualitative and quantitative composition of the active substance or substances;

d the target species, the dosage for each species, the method and route of administration and, if necessary, advice on correct administration;

e the indications for use;

f the contra-indications and adverse events;

g if applicable, the withdrawal period, even if such period is zero;

h special storage precautions, if any;

i information essential for safety or health protection, including any special precautions relating to use and any other warnings;

j information on the collection systems referred to in Article 117 applicable to the veterinary medicinal product concerned;

k the marketing authorisation number;

l contact details of the marketing authorisation holder or its representative, as appropriate, for the reporting of suspected adverse events;

m classification of the veterinary medicinal product as referred to in Article 34.

2 The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. That additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.

3 The package leaflet shall be written and designed to be readable, clear and understandable, in terms that are comprehensible to the general public. Member States may decide that it shall be made available on paper or electronically, or both.

4 By derogation from paragraph 1, the information required in accordance with this Article may, alternatively, be provided on the packaging of the veterinary medicinal product.

Article 15

General requirement regarding product information

The information listed in Articles 10 to 14 shall comply with the summary of the product characteristics as set out in Article 35.

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Article 16

Package leaflet of registered homeopathic veterinary medicinal products

By way of derogation from Article 14(1), the package leaflet of homeopathic veterinary medicinal products registered in accordance with Article 86 shall contain at least the following information:

(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the *European Pharmacopoeia* or, in the absence thereof, of the pharmacopoeias used officially in Member States;

(b) name or company name and permanent address or registered place of business of the registration holder and, where appropriate, of the manufacturer;

(c) method of administration and, if necessary, route of administration;

(d) pharmaceutical form;

(e) special storage precautions, if any;

(f) the target species and, where appropriate, dosage for each such species;

(g) a special warning, if necessary, for the homeopathic veterinary medicinal product;

(h) registration number;

(i) withdrawal period, if applicable;

(j) the statement ‘homeopathic veterinary medicinal product’.

Article 17

Implementing powers with respect to this Section

1 The Commission shall, when appropriate, by means of implementing acts, establish uniform rules on the identification code referred to in Articles 10(3) and 11(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2 The Commission shall, by means of implementing acts, adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Articles 10(2) and 11(3). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3 The Commission shall, by means of implementing acts, provide uniform rules on the size of small immediate packaging units referred to in Article 12. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

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