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 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);

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.