# 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 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.