Draft decree
on the package leaflet and labelling of certain veterinary medicinal products

NOR:

The Prime Minister,

On the report of the Minister of Labour, Health, Solidarity and Families,

Having regard to 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;

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, and in particular notification No. 2024/130/FR;

Having regard to the Public Health Code, in particular Article L. 5141-16 thereof;

In view of the French rural and sea fishing code;

Having regard to the opinion of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) on 22 November 2023 and 14 March 2025;

Having heard the Council of State (social division),

Hereby decrees:

Article 1

1 Subsection 1 of Section 4 of Chapter I of Title IV of Book I of Part Five of the Public Health Code is renamed ‘Registration, labelling and package leaflets of veterinary medicinal products intended exclusively for pet animals referred to in Article L. 5141-5-1’;

2 It is supplemented by three articles R. 5141-61-6 to R. 5141-61-8, which are worded as follows:

‘Art. *R. 5141-61-6*. The primary packaging for the veterinary medicinal products referred to in Article L. 5141-5-1 shall bear only the following details:

'1 The name of the registered veterinary medicinal product;

'2 The qualitative and quantitative composition as an active substance per unit of intake or, depending on the form of administration, for a given volume or mass, using the common names;

‘3° The lot number, preceded by the words ‘Lot’;

‘4° the name, company name or logo of the proprietor of the registration;

'5 The target species;

‘6° The expiry date in the format ‘mm/yyyy’, preceded by the abbreviation ‘Exp. ’;

'7 Special storage precautions, where appropriate;

'8 The method of administration and, if necessary, the route of administration.

‘By way of derogation, immediate packagings which are too small for all the information referred to in the preceding subparagraphs to appear legibly on them must bear only the particulars of 1°, 2°, 3° and 6° above. These immediate packaging units shall be placed in an outer packaging bearing the particulars provided for in Article R. 5141-61-7.

‘Art. *R. 5141-61-7*. – The labelling of the outer packaging of the veterinary medicinal products referred to in Article L. 5141-5-1 must contain the following particulars only:

‘1° The indication in very conspicuous characters ‘registered veterinary medicinal product’;

'2 The name of the registered veterinary medicinal product;

'3 The qualitative and quantitative composition as an active substance per unit of intake or, depending on the form of administration, for a given volume or mass, using the common names;

'4° The name and address of the registration holder;

'5 The method of administration and, if necessary, the route of administration;

'6 The therapeutic indication(s);

'7 The target species;

‘8° The expiry date in the format ‘mm/yyyy’, preceded by the abbreviation ‘Exp.' ;

'9 The pharmaceutical form;

'10 The capacity of the sales model;

'11 Where appropriate, special conservation precautions;

'12 A special warning, if required, for the medicinal product;

'13 A warning stating that the veterinary medicinal product must be kept out of the sight and reach of children;

'14 A recommendation to read the package leaflet;

'15 The manufacturing batch number;

'16 The registration number.

‘*Art. R. 5141-61-8.* – The package leaflet for the veterinary medicinal products referred to in Article L. 5141-5-1 shall bear only the following details:

'1 The name or company name and address of the registration holder;

'2 The name of the registered medicinal product;

'3 The qualitative and quantitative composition of the active substance(s);

'4 The target species, the dosage for each species, the mode and route of administration and, where appropriate, the indications necessary for proper administration;

'5 The indications for use;

'6 Special storage precautions, where appropriate;

'7 Information essential for the protection of the safety and health of humans and animals;

‘8° Contraindications;

‘9 Adverse reactions;

'10 Information on the system for collecting medicinal product waste;

'11 The registration number;

'12 The name or company name and address of the local pharmacovigilance representative referred to in Article 77(3) of 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, if different from those of the holder of the registration referred to in point 1. '

Article 2

Article R. 5141-71 is reintroduced in the same code, worded as follows:

‘*Art. R. 5141-71.* - The immediate packaging of a homeopathic veterinary medicinal product referred to in Article L. 5141-9 shall bear the following mandatory and exclusive particulars:

'1° The scientific name of the strain(s) followed by the degree of dilution, using the symbols of the European or French Pharmacopoeia. If the homeopathic veterinary medicinal product is composed of several strains, the labelling may mention an invented name in addition to the scientific name of the strains;

‘2° The lot number, preceded by the words ‘Lot’;

‘3° the name, company name or logo of the proprietor of the registration;

'4 The target species;

‘5° The expiry date in the format ‘mm/yyyy’, preceded by the abbreviation ‘Exp. ’;

'6 Special storage precautions, where appropriate;

'7 The method of administration and, if necessary, the route of administration.

‘By way of derogation, immediate packagings which are too small for all the information indicated to appear legibly shall bear only the particulars listed in points 1, 2 and 5 above. These units of primary packaging shall be placed in an outer packaging bearing the particulars referred to in Article R. 5141-72. '

Article 3

Article R. 5141-72 of the same Code is amended as follows:

1. In the first paragraph, the words: ‘The labelling and, where appropriate, the package leaflet’ are replaced by the words: ‘I. – Labelling of the outer packaging’ and the word: ‘portent’ in the French version is replaced by the appropriate grammatical form: ‘porte’.

2° in the third paragraph, the words ‘française, si’ become ‘française’. If;

3° In the fourth subparagraph, the words: 'and, where applicable, the manufacturer' are deleted;

4 A V and a VI are inserted, worded as follows:

'13 A warning stating that the veterinary medicinal product must be kept out of the sight and reach of children;

'14 A recommendation to read the package leaflet. '

5 The Article shall be supplemented by a IV, worded as follows:

‘II. - The package leaflet for registered homeopathic veterinary medicinal products shall include, in addition to the information provided for in Article 16 of Regulation (EU) No. 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products:

'1 the name or company name and address of the local pharmacovigilance representative referred to in Article 77(3) of the same Regulation, if different from those of the registration holder;

'2 Information on the system for collecting medicinal product waste. '

Article 4

Article R. 5141-123-8 of the same code is replaced by the following provisions:

'*Art. R. 5141-123-8.* - I. - The labelling of the veterinary medicinal product covered by a parallel marketing authorisation may differ from that of the veterinary medicinal product which has obtained marketing authorisation in France, insofar as it includes:

'1 The name and address of the establishment responsible for modifying the packaging and the name and address of the holder of the parallel marketing authorisation;

'2 The parallel marketing authorisation number and the marketing authorisation number of the veterinary medicinal product in the State of origin instead of the marketing authorisation number in France.

‘II. – The package leaflet for the veterinary medicinal product covered by a parallel marketing authorisation may differ from that of the veterinary medicinal product which has obtained marketing authorisation in France, insofar as it contains the name and address of the establishment responsible for modifying the packaging, as well as those of the holder of the parallel marketing authorisation. '

Article 5

After Article R. 5142-66 of the same Code, a subsection 13 is added, worded as follows:

'Subsection 13

‘Provisions specific to the veterinary medicinal products referred to in Article L. 5142-1-2

‘ *Article R5142-89.* - The labelling of the veterinary medicinal products referred to in Article L. 5142-1-2 shall include:

'a) The name of the medicinal animal product followed by its strength and pharmaceutical form;

'b) The qualitative and quantitative composition as an active substance per unit of intake or, depending on the form of administration, for a given volume or mass, using the common names;

‘c) The lot number, preceded by the words ‘Lot’;

‘d) The name, company name or logo of the holder of the authorisation referred to in Article L. 5141-2-1;

'e) The target species;

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

‘g) Special storage precautions, where appropriate;

'h) The route of administration;

‘i) And, where applicable, the waiting time, even if that waiting time is zero. '

‘ *Article R5142-90.* - The outer packaging of veterinary medicinal products referred to in Article L. 5142-1-2 shall contain:

'a) The information mentioned in article R. 5142-89;

'b) The content by mass, volume or number of units of primary packaging of the veterinary medicinal product;

'c) A warning stating that the veterinary medicinal product must be kept out of the sight and reach of children;

'd) A warning stating that the veterinary medicinal product is ‘for veterinary use only;

‘e) Where appropriate, a recommendation to read the package leaflet. '

Article 6

The Minister of Labour, Health, Solidarity and Families, the Minister of Agriculture and Food Sovereignty, and the Minister attached to the Minister of Labour, Health, Solidarity and Families, with responsibility for Health and Access to Healthcare, are responsible, each in their respective areas, for the implementation of this decree, which will be published in the *Official Journal* of the French Republic.