

Republic of Latvia

Cabinet

Regulation No. 337

Adopted 31 May 2016

## **Labelling Regulations of Veterinary Medicinal Products**

*Issued pursuant to  
Section 5, Clauses 3 and 12 of the Pharmaceutical Law*

### **I. General Provisions**

1. This Regulation prescribes the procedures for labelling veterinary medicinal products and the requirements to be met for package leaflets.
2. The labelling of veterinary medicinal products and the package leaflet shall be prepared in accordance with the requirements of this Regulation, and the information on veterinary medicinal products shall be indicated in accordance with the recommendations of the European Commission (sample available on the website of the Food and Veterinary Service (hereinafter – the Service)) referred to in Section 25.<sup>2</sup> of the Pharmaceutical Law.
3. Information on the labelling of the primary and secondary packaging of veterinary medicinal products and the package leaflet shall be indicated in accordance with the requirements of the Official Language Law. If the information on the labelling of veterinary medicinal products imported in Latvia (except for veterinary medicinal products which are imported and stored for the purpose of exporting them to other Member States or countries which are not Member States of the European Union or the European Free Trade Association that have signed the Agreement on the European Economic Area) is not provided in the official language, a sticker shall be attached to the packaging of medicinal products with the labelling text in the official language.
4. The marketing authorisation owner (holder) of veterinary medicinal products, the manufacturer and importer of the veterinary medicinal products, or the holder of the authorisation for the distribution of parallel imported veterinary medicinal products shall attach the sticker with the labelling information in the official language to the packaging of medicinal products and insert the package leaflet in the secondary packaging or attach the package leaflet thereto prior to the commencement of distribution of veterinary medicinal products in Latvia. The sticker shall cover therapeutic indications, target species and other information which is not approved for medicinal products registered in Latvia but may be approved in another country. The sticker may not cover the name, strength, expiry date and manufacturing batch number of the veterinary medicinal product indicated on the packaging. Addition of information (including the insertion of the package leaflet in the secondary packaging or attachment thereto) may not affect the quality of the relevant medicinal product.

### **II. Labelling of Veterinary Medicinal Products**

5. The Service shall approve the labelling of the primary and secondary packaging of veterinary medicinal products, including the sticker referred to in Paragraph 3 of this

Regulation if it complies with the requirements of this Section. The information indicated on the labelling of the primary and secondary packaging of veterinary medicinal products shall not differ from the information in the summary of product characteristics and other accompanying documents, which have been appended to the marketing authorisation of veterinary medicinal products (hereinafter – the marketing authorisation) and prepared in accordance with the laws and regulations regarding the procedures for the registration of veterinary medicinal products. If the labelling text is prepared in several languages, it shall provide the same information in all the languages.

6. The following shall be indicated in clearly legible letters and numbers on the labelling of the primary and secondary packaging:

6.1. the name of the veterinary medicinal product, followed by its strength and pharmaceutical form. Common name (International Nonproprietary Name recommended by the World Health Organization or, if such a name does not exist, its recommended usual common name) shall be used if the veterinary medicinal product contains one active substance and concurrently it is the name invented by the manufacturer;

6.2. the name of the active substances and other substances of the veterinary medicinal product, qualitative and quantitative composition of active substances in one dose of the veterinary medicinal product or according to the type of use, volume or weight of the veterinary medicinal product. The names of active substances shall be indicated using the common names;

6.3. packaging size;

6.4. target species;

6.5. indications;

6.6. method and route of administration (if necessary) of the veterinary medicinal product, leaving a free space for reference to the therapeutic dose;

6.7. the withdrawal period from the body of the animal of the veterinary medicinal product intended for food-producing animals for all animal species included in the marketing authorisation and the relevant food products (meat, edible offal, eggs, milk and honey). The withdrawal period shall also be indicated for food products of animal origin for which the specified withdrawal period of medicinal products is zero;

6.8. if necessary, special warnings regarding precautionary measures that shall be taken when giving the medicinal product to animals, or other information important for the protection and safety of human and animal health;

6.9. expiry date of the veterinary medicinal product;

6.10. special conditions for storage (if any);

6.11. specific precautions relating to the disposal of waste derived from veterinary medicinal products or unused veterinary medicinal products;

6.12. the words “For animal treatment only”;

6.13. the words “Prescription veterinary medicinal product” if the medicinal product is registered as a prescription medicinal product, or the words “Supply to veterinary practitioners only” if activities with the veterinary medicinal product may be performed only by a veterinary practitioner, or other conditions of supply and use or limitations (if applicable);

6.14. the words “Keep out of the sight and reach of children”;

6.15. the given name, surname or corporate name, legal address or registered place of commercial activity of the marketing authorisation owner (holder) and representative of the marketing authorisation owner (holder) (if applicable);

6.16. the number of the marketing authorisation;

6.17. the batch number assigned by the manufacturer of veterinary medicinal products.

7. The pharmaceutical form and content of medicinal products in weight, volume or dose units shall be indicated on the secondary packaging.
8. Information referred to in Sub-paragraphs 6.4, 6.6, 6.7, 6.8, 6.10, 6.11, 6.12, 6.13 and 6.14 of this Regulation shall be provided in the official language.
9. If veterinary medicinal products do not have secondary packaging, the information referred to in Paragraphs 6 and 8 of this Regulation shall be indicated only on the labelling of the primary packaging.
10. For veterinary medicinal products which have ampoules as the primary packaging or whose primary packaging contains only one dosage of veterinary medicinal product, the information referred to in Paragraph 6 of this Regulation shall be indicated only on the secondary packaging.
11. For medicinal products referred to in Paragraph 10 of this Regulation, the labelling of the primary packaging shall contain the following information:
- 11.1. the name of the veterinary medicinal product, followed by its strength and pharmaceutical form, if necessary;
  - 11.2. the name and quantity of the active substances;
  - 11.3. the weight, volume or number of dosage of the content;
  - 11.4. the method of administration;
  - 11.5. the batch number assigned by the manufacturer of veterinary medicinal products;
  - 11.6. the expiry date of the veterinary medicinal product;
  - 11.7. the words “For animal treatment only”.
12. The information referred to in Sub-paragraphs 11.4 and 11.7 of this Regulation shall be provided in the official language.
13. If a small primary packaging of the veterinary medicinal product (except ampoules) contains one dosage of the veterinary medicinal product and it is impossible to include the information referred to in Paragraph 11 of this Regulation on its labelling, the information shall be indicated only on the labelling of the secondary packaging taking into account Paragraphs 6 and 8 of this Regulation.
14. The primary packaging of blisters shall include at least the following information:
- 14.1. the name of the veterinary medicinal product, followed by its strength and pharmaceutical form, if necessary;
  - 14.2. the corporate name of the marketing authorisation owner (holder);
  - 14.3. the date of expiry of the veterinary medicinal product;
  - 14.4. the batch number assigned by the manufacturer of veterinary medicinal products;
  - 14.5. the words “For animal treatment only”.
15. If the marketing authorisation owner (holder) makes any changes to the registration documentation of the veterinary medicinal product in accordance with the Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and the labelling of the veterinary medicinal product must be changed due to said changes, the marketing authorisation owner (holder) shall submit to the Service a mock-up of the labelling of the veterinary medicinal product with the respective changes within three months from the day when the Service has taken the decision on the approval of said changes.

16. If the marketing authorisation owner (holder) submits the mock-up of the labelling to the Service after the term referred to in Paragraph 15 of this Regulation, the marketing authorisation owner (holder) shall cover the expenses of the Service regarding the evaluation and approval of the mock-up of the labelling in accordance with the laws and regulations stipulating the procedures for making payments to the Food and Veterinary Service for the official supervision and control operations, and paid services thereof.

### **III. Requirements for the Package Leaflet of Veterinary Medicinal Products**

17. Package leaflet shall be inserted in every packaging of veterinary medicinal products or attached thereto.

18. If the information to be indicated in the package leaflet has already been provided entirely on the primary or secondary packaging of the veterinary medicinal product, the package leaflet in printed form may be omitted.

19. The package leaflet shall be prepared in the official language and in the language(-s) of the Member State in which the veterinary medicinal products are to be placed on the market. In the package leaflet, terms understandable to general public shall be used and the same content thereof may be in several languages.

20. The Service shall check the compliance of the package leaflet with the information provided in the summary of product characteristics and the requirements of this Regulation, and approve the mock-up of the leaflet.

21. If the veterinary medicinal products may be used (administered) only by a veterinary practitioner, the Service, regarding the respective labelling of the packaging of the veterinary medicinal product, is entitled to apply the derogating measure regarding the need to indicate the respective data in the official language. In this case, the marketing authorisation owner (holder) of veterinary medicinal products or the owner of the authorisation for the distribution of parallel imported veterinary medicinal products shall ensure that the package leaflet attached to the veterinary medicinal product is in the official language.

22. The information indicated in the package leaflet shall comply with the information in the summary of product characteristics and other accompanying documents which have been appended to the marketing authorisation and have been prepared in accordance with the laws and regulations regarding the procedures for the registration of veterinary medicinal products. The package leaflet shall include the following information:

22.1. the given name, surname or corporate name and legal address or registered place of commercial activity of the marketing authorisation owner (holder) and the manufacturer of veterinary medicinal products responsible for batch release (if different);

22.2. the name of the veterinary medicinal product, followed by its strength and pharmaceutical form. The common name shall be used if the veterinary medicinal product contains only one active substance and concurrently it is the name invented by the manufacturer;

22.3. the name and quantity of the active substances and other substances included in the veterinary medicinal product;

22.4. the therapeutic indications of the veterinary medicinal product;

22.5. the contraindications of the veterinary medicinal product;

22.6. the suspected adverse reactions to the veterinary medicinal products;

22.7. target species;

- 22.8. the dosage for each species, method or route of administration;
- 22.9. the instructions on the correct administration of the veterinary medicinal product;
- 22.10. the withdrawal period from the body of the animal of the veterinary medicinal products for all species of food-producing animals included in the marketing authorisation and the relevant food products (meat, edible offal, eggs, milk and honey). The withdrawal period shall also be indicated for food products of animal origin for which the specified withdrawal period of medicinal products is zero;
- 22.11. instructions for the storage of the veterinary medicinal products (if any);
- 22.12. information (if any) on precautions that shall be taken when giving the medicinal product to animals, or other information important for the protection and safety of human and animal health;
- 22.13. precautions relating to the disposal of waste derived from veterinary medicinal products and unused veterinary medicinal products (if any);
- 22.14. the words “Prescription veterinary medicinal product” if the veterinary medicinal product is subject to medical prescription of a veterinary practitioner or the words “Supply to veterinary practitioners only” if activities with the veterinary medicinal products may be performed only by a veterinary practitioner;
- 22.15. the date when the package leaflet was last approved;
- 22.16. other information, including the given name, surname or corporate name and legal address or registered place of commercial activity of the representative of the marketing authorisation owner (holder) (if applicable).

#### **IV. Requirements for the Labelling and Package Leaflet of Homeopathic Veterinary Medicinal Products**

23. A clearly legible sentences “Homeopathic veterinary medicinal product” and “Consult a veterinary practitioner if adverse reactions caused by a homeopathic veterinary medicinal product have been established” shall be indicated on the labelling of homeopathic veterinary medicinal products.

24. If the homeopathic veterinary medicinal products have been registered in accordance with the simplified registration procedure, the labelling and package leaflet of homeopathic veterinary medicinal products shall clearly indicate the sentence “Homeopathic veterinary medicinal product without approved therapeutic indications”.

25. The labelling and package leaflet of the homeopathic veterinary medicinal products referred to in Paragraph 24 of this Regulation shall include the following information:

25.1. the scientific name of the stock or stocks and the degree of dilution in accordance with the symbols of the pharmacopoeia. If the homeopathic veterinary medicinal product contains more than one stock, the invented name may be indicated on the labelling in addition to the scientific name of the stock;

25.2. the given name and surname or corporate name and legal address of the marketing authorisation owner (holder) of veterinary medicinal products and the manufacturer of veterinary medicinal products (if different);

25.3. the method and route of administration (if necessary);

25.4. the expiry date in clear terms (month and year);

25.5. the pharmaceutical form;

25.6. the composition of the veterinary medicinal product in one sales packaging;

25.7. instructions for storage or administration (if any);

25.8. the target species;

25.9. the information and warnings included in the summary of homeopathic veterinary product characteristics regarding the administration of the homeopathic veterinary medicinal products (if such are necessary);

25.10. the batch number of the homeopathic veterinary medicinal product assigned by the manufacturer of veterinary medicinal products;

25.11. the number of the marketing authorisation of the homeopathic veterinary medicinal product.

## **V. Closing Provisions**

26. The labelling and package leaflet of the veterinary medicinal products approved by the Service until 14 June 2016 shall be valid until any changes are made thereto.

27. The Regulation shall come into force on 15 June 2016.

## **Informative Reference to European Union Directives**

This Regulation contains legal norms arising from:

1) 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;

2) 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.

Prime Minister

Māris Kučinskis

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