Pursuant to the Article 166 paragraph 6 of the Law on medicines ("Official Gazette of Montenegro", No 80/20), the Ministry of Agriculture, Forestry and Water Management hereby issues

RULEBOOK

ON THE CONTENTS AND METHOD OF LABELLING THE PACKAGING OF A VETERINARY MEDICINE AND CONTENTS OF THE PACKAGE LEAFLET FOR A VETERINARY MEDICINE*

("Official Gazette of Montenegro", No 082/23 from 30 August 2023)

Article 1

This Rulebook shall determine the contents and method of labelling immediate and outer packaging of a veterinary medicine and contents of the package leaflet of a veterinary medicine.

Article 2

The outer packaging of a veterinary medicine shall contain the following information:

1) information referred to in the Article 3 paragraph 1 of this Rulebook;

2) contents by weight, volume or number of immediate packaging units of the veterinary medicine;

3) warning that the veterinary medicine must be kept out of the sight and reach of children;

4) warning that the veterinary medicine is intended only for animal treatment;

5) recommendation to read the package leaflet;

6) in the case of homeopathic veterinary medicine, the statement ‘homeopathic veterinary medicine’;

7) in the case of veterinary medicines not subject to a veterinary prescription, indications;

8) number of the authorization for placing a veterinary medicine onto the market (hereinafter: marketing authorisation).

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 European Union.

Identification code for a veterinary medicine may appear on the outer packaging instead of marketing authorisation number of the veterinary medicine.

Where there is no outer packaging, all the information referred to in paragraphs 1 and 3 shall appear on the immediate packaging.

Article 3

The immediate packaging of a veterinary medicine shall contain the following information:

1) name of the veterinary medicine, its strength and pharmaceutical form;

2) name of active substances expressed qualitatively and quantitatively per unit of individual dosage or per unit of volume or weight, if that is in line with their pharmaceutical form, using their common names;

3) batch number;

4) name, or logo of the marketing authorization holder;

5) target species;

6) expiry date (month and year);

7) special storage precautions, if any;

8) routes of administration;

9) if applicable, the withdrawal period, even if such period is zero.

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 European Union .

An identification code shall be added to the information required under paragraph 1.

Immediate packaging units which are too small to contain in a readable form the information referred to in paragraph 1 of this Article shall contain the following information:

1) name of the veterinary medicine;

2) quantitative particulars of the active substance(s);

3) batch number;

4) expiry date (month and year).

Article 4

Institute for Medicines and Medical Devices may allow the inclusion on immediate, or outer packaging of a veterinary medicine of additional useful information which is compatible with the summary of the product characteristics and which is not an advertisement for a veterinary medicine.

Article 5

Package leaflet within the packaging is mandatory in case that the information about the medicine in question is not provided on the immediate, or outer packaging.

Package leaflet for the veterinary medicine refers exclusively to the veterinary medicine which it is attached to.

Package leaflet shall contain at least the following information:

1) name and address of the marketing authorization holder and the manufacturer, i.e., where applicable, representative of the marketing authorization holder;

2) name of the veterinary medicine, its strength and pharmaceutical form;

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

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

5) indications for use;

6) contra-indications and adverse events;

7) if applicable, the withdrawal period, even if such period is zero;;

8) special storage precautions, if any;

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

10) information on the system for collecting and disposing of waste from that veterinary medicine;

11) marketing authorisation number;

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

13) classification of the veterinary medicine in relation to the dispensing mode.

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 of this Article.

Package leaflet shall be written and designed to be readable, clear and understandable, in terms that are comprehensible to the general public.

Article 6

Information provided on the outer and immediate packaging of the medicine, on small units of immediate packaging and on the package leaflet of the veterinary medicine shall be in conformity with approved summary of product characteristics.

Article 7

The following information shall be provided in the package leaflet for homeopathic veterinary medicine that is entered into the Register of homeopathic veterinary medicines:

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

2) name and address of the holder of entry into the Register of homeopathic veterinary medicines;

3) method of administration and, if necessary, route of administration;

4) pharmaceutical form;

5) special storage precautions, if any;

6) target species and, where appropriate, dosage for each such species;

7) special warnings, if necessary;

8) marketing authorization number, i.e. number of the entry into the Register of homeopathic veterinary medicines;

9) withdrawal period, if applicable;

10) statement ‘homeopathic veterinary medicine’.

Article 8

In case of medicines for which the information on the original outer packaging is printed in a foreign language, the Institute for Medicines and Medical Devices may approve the use of an additional sticker for outer packaging in Montenegrin language at the request of the applicant for obtaining marketing authorisation, or marketing authorisation holder.

The request referred to in paragraph 1 of this Article shall be accompanied by the information on the annual consumption of the medicine in question on the territory of Montenegro, or an estimation of it, if that medicine has been marketed in Montenegro for less than one year, or has not yet been placed onto the market in Montenegro.

Additional sticker referred to in paragraph 1 of this Article shall contain the information referred to in the Article 2 of this Rulebook, except for the information that is comprehensible on the original packaging (expiry date, batch number).

All information about the medicine on the additional sticker must be legible, comprehensible and indelible.

Article 9

For medicines the packaging of which is labelled in one of the languages officially used in Montenegro, the Institute for Medicines and Medical Devices shall approve the use of an additional sticker with the following information in Montenegrin language:

1) name of the marketing authorization holder in Montenegro;

2) number of marketing authorization issued by the Institute for Medicines and Medical Devices.

If technically possible, the name of the medicine, along with the pharmaceutical form, its strength and packaging size may be provided on the additional sticker referred to in paragraph 1 of this Article.

Article 10

The additional sticker referred to in articles 8 and 9 of this Rulebook shall be provided by the manufacturer, or the wholesale authorization holder for the veterinary medicine.

Article 11

Packaging of the veterinary medicine that does not have marketing authorization, but has been approved for the purchase, i.e. import by the Institute for Medicines and Medical Devices shall contain the information on the importer for Montenegro and number of the Decision approving the import of the veterinary medicine in question.

Information referred to in the paragraph 1 of this Article shall be printed on the packaging, or on the additional sticker.

Article 12

The Rulebook on the contents and manner of labelling packaging of a veterinary medicine shall be repealed with the effect from the date of entry into force of this Rulebook.

Article 13

This Rulebook shall enter into force on the eighth day from its publishing in the “Official Gazette of Montenegro” and shall be applied from 1 December 2023 on.

∗ Provisions from articles 10, 11, 12, 13, 14, 15, 16 and 17of the 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 EE A relevance) have been transposed into this Rulebook.

No: 05-312/22-16187/3

Podgorica, 17 August 2023 godine

Minister,

Vladimir Joković, m.p.