Consolidated text of the Rulebook on detailed conditions for granting marketing authorisation for veterinary medicinal products includes the following documents:

1. Rulebook on detailed conditions for granting marketing authorisation for veterinary medicinal products ("Official Gazette of Montenegro", No. 022/26 of 20 February 2026),

2. Correction of the Rulebook on detailed conditions for granting marketing authorisation for veterinary medicinal products ("Official Gazette of Montenegro", No 024/26 of 25 February 2026), in which their dates of entry into force are indicated.

RULEBOOK
ON DETAILED CONDITIONS FOR GRANTING MARKETING AUTHORISATION FOR VETERINARY MEDICINAL PRODUCTS

("Official Gazette of Montenegro", No. 022/26 from 20 February 2026)

I GENERAL PROVISIONS

Article 1

This Rulebook shall prescribe detailed method of submitting application and required documentation for the issuance of a marketing authorisation for a veterinary medicinal product (hereinafter: marketing authorisation), content of the marketing authorisation, content of the summary of product characteristics, content and method of labelling, the list of abbreviations and pictograms and the rules on the unit size of small immediate packaging, as well as the content of the package leaflet, the list of variations that do not require assessment, detailed conditions, classification, procedures and required documentation for the variation of the marketing authorisation, as well as detailed procedure for suspension and withdrawal of marketing authorisation.

Article 2

Terms used in this Rulebook in the masculine grammatical form shall be considered as applying equally to the feminine form.

Article 3

The terms used in this Rulebook shall have the following meanings:

1) Reference Member State of the European Union means a Member State which, within a decentralised or mutual recognition procedure, prepares and issues the Assessment Report;
2) Assessment Report means a document prepared by the European Medicines Agency (EMA) or by the competent authority of a Member State of the European Union, containing the analysis and conclusions regarding the quality, safety and efficacy of the veterinary medicinal product, based on expert assessment of the submitted documentation, including regulatory recommendations and the basis for decisions on the granting, or variation of a marketing authorisation.

II CONDITIONS FOR GRANTING MARKETING AUTHORISATION

Article 4

Marketing authorisation may be issued to an applicant referred to in Article 220 paragraph 2 of the Law on Medicinal Products (hereinafter: Law), on the grounds of the assessment of the documentation prescribed by this Rulebook.

Article 5

The application for issuance of marketing authorisation shall be submitted to the Institute for medicines and medical devices (hereinafter: Institute) in accordance with the Law and this Rulebook.

The applicant referred to in paragraph 1 of this Article may be a natural of legal person with headquarters in Montenegro. The application referred to in paragraph 1 of this Article shall contain at least the following information:

1) name and address of the applicant;

2) information on the medicinal product (brand name, international non-proprietary name (INN), pharmaceutical form, strength and packaging);

3) name and address of the manufacturer of the veterinary medicinal product;

4) Anatomical Therapeutic Chemical classification code for veterinary medicinal products (ATCvet);

5) proposed dispensing classification of veterinary medicinal product;

6) target species of animals which the veterinary medicinal product is intended for;

7) type of the application, i.e. the legal basis for issuance of marketing authorisation (reference to the corresponding Article of the Law shall be made);

8) information on whether the veterinary medicinal product has been granted marketing authorisation in the European Union, and if so, the type and number of the procedure under which the authorisation was issued; and

9) date and signature of the responsible person for the procedure of issuance of marketing authorisation.

The application referred to in Article 3 of this Law shall be submitted for each pharmaceutical form, strength and packaging, using the form available on the portal of the Institute.

Article 6

The applicantion for issuance of marketing authorisation shall be accompanied by the following:

1) data from Annex I to this Rulebook which forms an integral part of it;

2) technical documentation required to demonstrate quality, safety and efficacy of the veterinary medicinal product from Annex II to this Rulebook which forms an integral part of it;

3) summary of the Pharmacovigilance System Master File (hereinafter: PSMF);

4) evidence that prescribed fees have been paid.

If the application refers to an antimicrobial veterinary medicinal product, together with the information and in addition to technical documentation and the summary referred to in paragraph 1 of this Article, the following shall also be submitted:

1) documentation on direct or indirect risks to public health or animal health or the environment arising from use of antimicrobial veterinary medicinal product on animals;

2) information on risk minimisation measures to constraint development of antimicrobial resistance associated with use of veterinary medicinal product.

Article 7

The documentation required for issuing marketing authorisation (hereinafter: documentation) shall be submitted in the form of a European dossier (hereinafter: EU dossier), which refers to medicinal products for use in veterinary medicine, in line with the guidelines of the European Commission.

Main parts of the EU dossier are listed as follow:

1) Part 1: Summary of the dossier

2) Part 2: Quality documentation (physicochemical, biological or microbiological data)

3) Part 3: Safety documentation (safety and residue testing)

4) Part 4: Efficacy documentation (non-clinical and clinical studies)

The content and structure of the documentation referred to in paragraph 1 of this Article are provided in Annex II to this Rulebook.

Article 8

Along with the application for issuance of marketing authorisation and the information and documentation prescribed by the Law and this Rulebook, the applicant shall also submit a written authorisation issued by the marketing authorisation holder in the European Union or by the manufacturer of the medicinal product, confirming that the applicant is authorised to represent them in the procedure for granting a marketing authorisation in Montenegro.

The authorisation form referred to in paragraph 1 of this Article shall be published on the official website of the Institute.

Article 9

The Institute shall, in the procedure for granting marketing authorisation, assess the acceptability of the

proposed name of the veterinary medicinal product.

The Institute may consider proposed name of the veterinary medicinal product unacceptable, if it is not in accordance with Article 7 paragraph 1 items 45 and 100 of the Law and provisions of this Rulebook.

A proposed name of veterinary medicinal product may not:

1) be misleading due to its similarity with the scientific/international non-proprietary name or commonly used name;
2) be misleading due to its similarity with the approved name of another veterinary medicinal product;
3) be misleading by implying therapeutic efficacy;
4) be misleading with regard to the composition of the veterinary medicinal product;
5) be misleading with regard to the safety of the veterinary medicinal product;
6) contain promotional wording;
7) be misleading with regard to the dispensing classification of the veterinary medicinal product.

Article 10

Along with the application for the issuance of marketing under the accelerated procedure in accordance with Article 232 of the Law, in addition to the documentation prescribed by this Rulebook, the following shall also be submitted;

1) identical documentation (consolidated file covering modules 1 - 4) approved in the centralised procedure (hereinafter: CP), decentralised procedure (hereinafter: DC) or mutual recognition procedure (hereinafter: MRP)
2) a statement confirming that the documentation on the basis of which marketing authorisation is requested in Montenegro is identical to the documentation on the basis of which the Assessment Report was prepared and issued, including all variations that were approved up to the date of submission of the application, i.e. that the submitted documentation is valid in the EU Member sStates. In case there are differences compared to the documentation approved within CP, DC or MRP, they shall be clearly stated and explained
3) a list of variations that have been submitted and approved in the CP, DC or MRP by the date of submission of the application to CInMED, along with the information on the status of each variation in the procedure, as well as whether they have been implemented into the dossier submitted to CInMED. As for variations that have been approved and implemented, it is necessary to submit relevant approvals from the CP, MRP or DC procedure;
4) Assessment Report issued by the EMA or the Reference Member State for medicinal products authorised through DCP or Mutual Recognition Procedure MRP, including questions and answers by procedure day, i.e. the Quality, Non-clinical and Clinical Assessment of the response to the (outstanding) questions raised by the RMS and CMSs, and preliminary reports from all stages of the MRP or DC procedure;
5) a declaration by the applicant stating that, in the event of suspension or withdrawal of the marketing authorisation in the European Union, or in the event of any urgent safety restrictions, the Institute will be notified without delay.

III CONTENT OF THE MARKETING AUTHORISATION

Article 11

The marketing authorisation shall contain at least the following information;

1) marketing authorisation number;
2) name and address of the marketing authorisation holder;
3) name of veterinary medicinal product;
4) pharmaceutical form;
5) strength;
6) qualitative and quantitative composition of the active substance(s);
7) type and packaging size;
8) name and address of the manufacturer(s) responsible for batch release;
9) Anatomical Therapeutic Chemical classification code of the veterinary medicinal product (ATCvet);
10) dispensing classification of the medicinal product;
11) conditions and obligations in accordance with Article 233 of the Law;
12) validity period of the marketing authorisation.

IV SUMMARY OF THE PRODUCT CHARACTERISTIC, LABELLING AND PACKAGE LEAFLET OF VETERINARY MEDICINAL PRODUCT

Summary of the product characteristics

Article 12

The summary of the product characteristics shall contain, in the order indicated below, the following information:

1. name of the medicinal product followed by the strength and the pharmaceutical form
2. qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the veterinary medicinal product.
3. Clinical particulars
    - 3.1. Target species;
    - 3.2. indications for use, specifying the target species;
    - 3.3. Contraindications;
    - 3.4. Special warnings;
    - 3.5. special warnings and precautions for the use of the veterinary medicinal product, including special precautions for safe use of the veterinary medicinal product in target species of animals, special warnings for persons administering the veterinary medicinal product to animals and special warnings for environmental protection;
    - 3.6. frequency and seriousness of adverse reactions;
    - 3.7. Use during pregnancy, lactation or lay;
    - 3.8. interaction with other medicinal products and other forms of interaction;
    - 3.9. Amounts to be administered and administration route;
    - 3.10. Overdose (symptoms, emergency procedures, antidotes), if necessary;
    - 3.11. special restrictions on use;
    - 3.12. special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to limit the risk of resistance development;
    - 3.13. when applicable, withdrawal period, even when it is zero;
4. pharmacological properties
    - 4.1. Anatomical Therapeutic Chemical classification code of the veterinary medicinal product (ATCvet);
    - 4.2. pharmacodynamics;
    - 4.3. pharmacokinetics;

For an immunological veterinary medicinal product, immunological data shall be provided instead of items 4.1., 4.2. and 4.3;

5. pharmaceutical particulars
    - 5.1. major incompatibilities;
    - 5.2. shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time;
    - 5.3. special precautions for storage;
    - 5.4. nature and composition of immediate packaging;
    - 5.5. requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;
6. name of the marketing authorisation holder;
7. marketing authorisation number;
8. date of the first marketing authorisation;
9. date of the last revision of the summary of the product characteristics;
10. if applicable, for veterinary medicinal products referred to in Article 227 or 228, the statement:
    - " marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation“; or

- " marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation'";

11. information on the collection systems referred to in Article 310 applicable to the veterinary medicinal product concerned;

12. classification of the veterinary medicinal product as referred to in Article 237 paragraphs 1-3 of the Law.

In the case of generic veterinary medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in Montenegro, or EU Member State at the time of placing of the generic veterinary medicinal product on the market may be omitted.

Labelling of immediate packaging of veterinary medicinal products

Article 13

The immediate packaging of a veterinary medicinal product shall contain the following information and shall, subject to Article 14 paragraph 4, contain no information other than:

1) name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

2) statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;

3) batch number; name and address of the manufacturing holder or the manufacturer (or its logo);

4) target species;

5) expiry date (month and year);

6) special storage precautions, if any;

7) route of administration and

8) 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 referred to in articles 18 and 19 of this Rulebook.

Identification code may be added to the information required under paragraph 1.

Labelling of the outer packaging of veterinary medicinal products

Article 14

The outer packaging of a veterinary medicinal product shall contain the following information and shall contain no information other than:

1) information referred to in Article 13 paragraph 1 of this Rulebook;

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

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

4) warning that the veterinary medicinal product is for animal treatment only;

5) recommendation to read the package leaflet;

6) in the case of homeopathic veterinary medicinal products, the statement 'homeopathic veterinary medicinal product';

7) n the case of veterinary medicinal products not subject to a veterinary prescription, the indication or indications;

8) marketing authorisation number.

The identification code for the veterinary medicinal product may be provided on the outer packaging instead of the marketing authorization number.

The information referred to in paragraph 1 of this Article shall appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms referred to in 18 and 19 of this Rulebook.

Where there is no outer packaging, all the information referred to in paragraphs 1 and 2 of this Article shall appear on the immediate packaging.

Labelling of small immediate packaging units of veterinary medicinal products

Article 15

By way of derogation from Article 13, immediate packaging units which are too small to contain in a readable

form the information referred to in that Article shall contain the following information and shall contain no information other than:

1) name of veterinary medicinal product;

2) quantitative particulars of the active substances;

3) batch number;

4) expiry date (month and year).

The immediate packaging units referred to in paragraph 1 of this Article shall have an outer packaging containing information required in Article 14 paragraphs 1 to 3 of this Rulebook.

Article 16

The following types of immediate packaging shall be considered to be small immediate packaging units within the meaning of Article 15 of this Rulebook:

1) blisters or strips;

2) ampoules and small single-dose containers other than ampoules;

3) container or any other form of packaging that is in direct contact with the veterinary medicinal product and has a nominal volume of up to and including 50 ml.

By way of derogation from paragraph 1, item c), multilingual immediate packaging units not exceeding a nominal volume of 100 ml shall be considered small immediate packaging units if the following conditions are fulfilled:

1) immediate packaging unit is too small or has a shape or configuration that makes it impossible to accommodate the information referred to in Article 13 paragraph 1 of this Rulebook;

2) veterinary medicinal product is classified as subject to veterinary prescription in accordance with Article 237 of the Law.

Additional information on the immediate packaging or outer packaging of veterinary medicinal products

Article 17

By way of derogation from Article 13 paragraph 1, Article 14 paragraph 1 and Article 15 paragraph 1 of this Rulebook, the Institute may, on request of the applicant, allow an applicant to include on the immediate packaging or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics and which is not an advertisement for a veterinary medicinal product.

Abbreviations and pictograms to be used on the packaging of veterinary medicinal product

Article 18

Abbreviations and pictograms are given in Annexes III and IV to this Rulebook and form an integral part thereof.

The abbreviations and pictograms may be used to replace the written information required on the labelling of immediate packaging and on the outer packaging of veterinary medicinal products referred to in Article 13 paragraph 1 and Article 14 paragraph 1 of this Rulebook.

Abbreviations and pictograms that are not listed in Annex III and Annex IV to this Rulebook may not be used to replace written information referred to in paragraph 2 of this Article.

Article 19

The abbreviations and pictograms shall only be used to replace the corresponding text as set out in the Annexes and may not be used to replace any other information concerning the veterinary medicinal product.

Abbreviations and pictograms used on the labelling of a veterinary medicinal product shall be explained in full text in the package leaflet of the veterinary medicinal product concerned.

Abbreviations shall be displayed in the same format as laid down in Annex III to this Rulebook.

Pictograms shall:

1) be proportionate to the overall size of the labelling of immediate packaging or outer packaging of veterinary medicinal products;

2) be presented in a sufficiently readable format;

3) have a black symbol and no additional visual aspects such as shading;
4) stand out clearly on the colour and presentation of the labelling of immediate packaging or outer packaging;;
5) not negatively affect the readability of the rest of the information on the labelling of immediate or outer packaging due to their location.

Package leaflet

Article 20

The marketing authorisation holder shall make readily available a package leaflet for each veterinary medicinal product containing at least the following information:

1) name address of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing authorisation holder;
2) name of the veterinary medicinal product, followed by its strength and pharmaceutical form;
3) qualitative and quantitative composition of the active substance or substances;;
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 collection systems referred to in Article 310 of the Law;
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 medicinal product as referred to in Article 237 paragraphs 1-3 of the Law.

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.

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

By derogation from paragraph 1, the information required in accordance with this Article may be provided on the packaging of the veterinary medicinal product.

General requirement regarding product information

Article 21

The information listed in Articles 13, 14, 15 and 17 of this Rulebook shall comply with the summary of product characteristics as set out in Article 12 of this Rulebook.

Package leaflet of registered homeopathic veterinary medicinal products

Article 22

By way of derogation from Article 20 paragraph 1 of this Rulebook, the package leaflet of homeopathic veterinary medicinal products registered in accordance with Article 229 of the Law shall contain at least the following information:

1) scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or of the pharmacopoeias used officially in Member States;
2) name and address or registered place of the registration holder and, where appropriate, of the manufacturer;
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 warning, if necessary;

8) registration number, i.e. the number of the entry into the Register of homeopathic veterinary medicinal products;

9) withdrawal period, if applicable;

10) statement ‘homeopathic veterinary medicinal product’.

Article 23

The Institute may, in the marketing authorisation procedure and upon a duly justified request by the applicant, approve the use of outer packaging labelled in a foreign language, provided that such packaging has been approved in the country of origin, that the Institute has been provided with documentation identical to the one approved in the country of origin, and that the annual consumption of the medicinal product in Montenegro does not exceed 1,000 packs. In such cases, the Institute shall also approve the use of an additional label in Montenegrin language, which is placed on the outer packaging of the medicinal product.

The additional label referred to in paragraph 1 of this Article shall contain information from Article 14 of this Rulebook, except for information that is understandable and clearly visible on the original packaging (expiry date, batch number).

All information about the medicinal product provided on the additional label shall be legible, understandable and indelible.

Article 24

The Institute may, during the marketing authorisation procedure and upon a duly justified request by the applicant, approve the use of outer packaging labelled in a language that is in official use in Montenegro, provided that such packaging has been approved in the country of origin and that the Institute has been provided with documentation identical to the one approved in the country of origin of the packaging. In such cases, the Institute shall also approve the use of an additional label in Montenegrin language, which is placed on the outer packaging of the medicinal product.

Additional label referred to in paragraph 1 of this Article shall contain the following information:

1) name and address of the marketing authorisation holder in Montenegro;

2) marketing authorisation number granted in Montenegro.

The additional label referred to in paragraph 1 of this Article may also include the name of the medicinal product, pharmaceutical form, strength, and pack size, if technically feasible.

Alternatively, the information required on the additional label referred to in paragraph 1 of this Article may be printed directly on the outer carton, provided that prior approval for such printing has been obtained from the competent authority in the country of origin of the packaging.

Article 25

The additional label referred to in Articles 23 and 24 of this Rulebook shall be provided by the manufacturer or the holder of the wholesale distribution authorization for veterinary medicinal products.

Article 26

The inclusion of the package leaflet, in the cases referred to in Articles 23 and 24 of this Rulebook, shall be ensured by the manufacturer or the holder of the wholesale distribution authorisation.

Article 27

A medicinal product for which the Institute has issued the import authorisation in accordance with Article 219 of the Law shall bear an additional label containing information about the importer and the number of the import authorisation issued by the Institute.

V CONDITIONS, MANNER AND REQUIRED DOCUMENTATION FOR VARIATIONS OF MARKETING AUTHORISATION FOR VETERINARY MEDICINAL PRODUCT

Article 28

The marketing authorisation holder shall follow scientific and technical developments in the field,

pharmacovigilance data and other relevant information concerning the medicinal product, and shall notify the Institute of any new findings related to the assessment of the quality, safety and efficacy of the medicinal product; the marketing authorisation holder shall submit an application for the variation of the marketing authorisation in line with new findings concerning the medicinal product.

Article 29

Variations referred to in Article 28 of this Rulebook are classified into variations that do not require assessment and variations requiring assessment, in accordance with the criteria referred to in Article 246 of the Law.

Variations that do not require assessment

Article 30

As for variations listed in Annex V to this Rulebook, which meet the requirements of that Annex, no assessment is required.

As for variations referred to in paragraph 1 of this Article, the marketing authorisation holder shall submit an application for variation to the Institute in accordance with Article 247 of the Law.

Along with the application for variation referred to in paragraph 2 of this Article, the applicant shall attach the following documentation:

1) a completed application form published on the Institute's website, signed by the applicant's responsible person;
2) documentation referred to in Annex V to this Rulebook relating to the variation and providing sufficient information for its assessment and
3) proof that the prescribed fees have been paid.

Application for variations requiring assessment

Article 31

Where a variation is not listed in Annex V to this Rulebook, the marketing authorisation holder shall submit to the Institute an application for a variation requiring assessment in accordance with Article 248 of the Law.

The application referred to in paragraph 1 of this Article shall contain at least the following information:

1) description of the variation;
2) data referred to in Article 6 of this Rulebook relevant to the variation;
3) details of the marketing authorisations affected by the application;
4) where the variation leads to consequential variations to the terms of the same marketing authorisation, a description of those consequential variations.

The application for the notification of the variation referred to in paragraph 1 of this Article the following shall be shall be accompanied by the following:

1) documentation relating to the variation and providing sufficient data for its assessment, in accordance with the Guideline referred to in Article 32 of this Rulebook;
2) proof that the prescribed fees have been paid.

The application referred to in paragraph 1 of this Article shall be submitted on the form published on the Institute's website..

Article 32

Variations requiring assessment are classified in accordance with the Guideline EMA/CMDv/7381/2021 on the classification of variations requiring assessment and the required documentation accompanying the application for variation approval.

Article 33

The application for submission/approval of a variation for a medicinal product that has been authorised in Montenegro under the accelerated procedure in accordance with Article 232 of the Law, in addition to the documentation prescribed by this Rulebook, shall be accompanied by the following:

1) identical documentation for the variation (variation package) as approved within CP, MRP or DCP;
2) approval of the variation within CP, MRP or DCP;

3) assessment report issued by the EMA or the reference Member State within DCP or MRP, for variations type IB and II.

Consequential changes in the package leaflet

Article 34

When the variation entails consequential changes to the summary of product characteristics, labeling or package leaflet, these changes are considered part of the same variation for the purpose of assessment of the application.

Group of variations

Article 35

The marketing authorisation holder may submit the application containing several variations that are not listed in the Annex referred to in Article 30, paragraph 1 of this Rulebook in the following cases:

1) when multiple variations are submitted to the same marketing authorisation;

2) when one variation refers to different marketing authorisations.

VI WITHDRAWAL OF MARKETING AUTHORISATION FOR A VETERINARY MEDICINAL PRODUCT

Article 36

In accordance with Article 250 of the Law the marketing authorisation holder shall submit to the Institute the application for withdrawal of marketing authorisation using the form published on the website of the Institute.

The application referred to in paragraph 1 of this Article shall be submitted separately for each pharmaceutical form, strength and packaging of the medicinal product.

At the request of the Institute, along with the application referred to in paragraph 1 of this Article a proof that the prescribed fees have been paid and other necessary documentation shall be submitted.

VII TRANSITIONAL AND FINAL PROVISIONS

Article 37

Veterinary medicinal products for which a medicinal product authorisation has been issued or for which an application for a medicinal product authorisation has been submitted before the entry into force of this Rulebook may be used until 11 April 2029 even if the abbreviations and pictograms referred to in Articles 18 and 19 of this Rulebook do not comply with the provisions of this Rulebook.

Veterinary medicinal products for which a medicinal product authorisation has been issued or for which an application for a medicinal product authorisation has been submitted before the entry into force of this Rulebook may be used until 11 April 2031 even if the labelling of small immediate packaging units of veterinary medicinal products referred to in Articles 15 and 16 of this Rulebook does not comply with this Rulebook.

Article 38

The provisions of Article 12 paragraph 1 item 5.5. in the part relating to the requirement to use a take-back scheme for the disposal of unused veterinary medicinal products or waste resulting from their use shall apply in accordance with the Law.

Article 39

On the date of entry into force of this Rulebook, the provisions of the Rulebook on conditions for granting marketing authorisation for medicinal products ("Official Gazette of Montenegro", No. 21/16 and 55/19) in the part relating to veterinary medicinal products shall cease to apply.

Article 40

This Rulebook shall enter into force on the eighth day from the day of its publication in the "Official Gazette of Montenegro".

No: 3020/26/86/8-1364

Podgorica, 19 february 2026

Chair of the Steering Committee,

dr Jovan Milić, specialist in ophtalmology, m.p.

* This Rulebook transposes the provisions of 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, Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council, Commission Delegated Regulation (EU) 2023/183 of 23 November 2022 amending Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the requirements on compliance with good laboratory practice for veterinary medicinal products set out in Annex II to that Regulation and Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council, as amended by the Commission Implementin Regulation (EU) 2023/997 of 23 May 2023, Commission Implementing Regulation (EU) 2024/916 of 26 March 2024 and Commission Implementing Regulation (EU) 2025/163 of 30 January 2025 amending the Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council,Commission Implementing Regulation (EU) 2024/adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2024/878 dopting uniform rules on the size of small immediate packaging units of veterinary medicinal products as referred to in Article 12 of Regulation (EU) 2019/6 of the European Parliament and of the Council