Based on Article 273 of the Law on medicines (“Official gazette of Montenegro”, No 14/26),

The Management Board of the Institute with the consent of the Ministry of Health adopted

RULEBOOK ON CONDITIONS FOR MANUFACTURING OF VETERINARY MEDICINAL PRODUCTS

I GENERAL PROVISIONS

Article 1

This rulebook prescribes the detailed conditions, content of the application and supporting documentation for the issuance of the manufacturing authorisation for veterinary medicinal products.

This rulebook also applies for manufacturing of veterinary medicinal products intended only for export.

Article 2

Terms used in this Rulebook for natural persons in masculine gender include the same terms in feminine gender.

Article 3

Terms used in this rulebook shall have the following meaning:

1) **manufacturer** means any legal or natural person engaged in all or some activities of medicine manufacturing in accordance with Article 266 of the Law on medicines (hereinafter: the Law);
2) **qualified person** means a person who meets the requirements laid down in Article 270 of the Law and shall ensure that each batch of the veterinary medicinal product has been manufactured and subjected to quality control in accordance with the Law on Medicines.
3) **pharmaceutical quality system** means the total sum of the organised arrangements made with the objective of ensuring that veterinary medicinal products are of the quality required for their intended use;
4) **good manufacturing practice** means the part of the quality assurance which ensures that medicinal products are consistently produced, imported and controlled in accordance with the quality standards appropriate to their intended use.

Article 4

Manufacturing of veterinary medicinal products shall be conducted in accordance withthe Law, provisions of this rulebook and GMP guidelines.

Inspection of compliance of medicines manufacturing with the provisions referred to in paragraph 1 of this article shall be conducted by a pharmaceutical inspector of the Institute for Medicines and Medical Devices of Montenegro (hereinafter: the Institute) in accordance with

the Compilation of Union Procedures on Inspections and Exchange of Information of European Union.

All provisions of this Rulebook also apply to all the persons who conduct the activity of importation of veterinary medicinal products from countries that are not part of the European Union (hereinafter: third countries).

Article 5

The manufacturer is obliged to ensure that the manufacturing operations are carried out in accordance with Good manufacturing practice and with the manufacturing authorisation.

Persons who perform importation of veterinary medicinal products from third countries shall ensure that the products have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down in the European Union and that such products have been manufactured by manufacturers duly authorised to do so.

Article 6

The manufacturer shall ensure that all manufacturing or import operations are carried out in accordance with the documentation approved in the application for that marketing authorisation for a veterinary medicinal product.

The manufacturer shall regularly review his manufacturing methods in light of scientific and technical progress.

If a variation to the marketing authorisation for a veterinary medicinal product dossier is necessary, marketing authorisation holder shall apply for an adequate variation in accordance with law.

II CONDITIONS FOR THE GRANTING OF A MANUFACTURING AUTHORISATION

Quality management

Article 7

Manufacturers shall establish, implement and maintain an effective pharmaceutical quality system, involving the active participation of the senior management and the personnel of the different departments.

Personnel

Article 8

The manufacturer is obliged to have at each manufacturing or import site a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the objective of the pharmaceutical quality system.

The duties of the managerial and supervisory staff, including the qualified persons referred to in Article 269, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organisation chart. Organisation charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures.

The staff referred to in paragraph 2 of this article shall be given sufficient authority to discharge their responsibility correctly.

All the personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice.

Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.

Premises and equipment

Article 9

The premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations.

The premises and manufacturing equipment referred to in paragraph 1 of this article are laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.

Premises and manufacturing equipment referred to in paragraph 1 of this article which are used for manufacturing or import operations, which are critical to the quality of the products, shall be subjected to appropriate qualification.

Documentation

Article 10

The manufacturer shall be establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. The documentation system shall ensure data quality and integrity. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the manufacture of each batch to be traced.

The manufacturer shall retain the batch documentation for at least 1 year after the expiry date of the batches to which it relates or at least 5 years after the certification in a register or equivalent document dedicated for that purpose, that every batch has been manufactured and controlled in accordance with the Law, whichever is the longer period.

When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be made readily available in legible form and shall be provided to the competent authorities upon request. The electronically stored data shall be protected, by techniques such as duplication or back-up and transfer to another storage system, against unlawful access, loss or damage of data, and audit trails shall be maintained.

Production

Article 11

The manufacturer shall carry out the different production operations in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available by the manufacturer for the in-process controls. All process deviations and product defects shall be documented and thoroughly investigated.

The manufacturers shall take appropriate technical and organisational measures to avoid cross contamination and mix-ups.

Any new manufacturing or important modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly revalidated.

Quality control

Article 12

The manufacturer shall establish and maintain a quality control system placed under the authority of a person who has the requisite qualifications and is independent of production.

The person referred to in paragraph 1 of this article shall have at his disposal one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of starting materials and packaging materials and the testing of intermediate and finished medicinal products.

For medicinal products, including those imported from third countries, contract laboratories may be used if authorised in accordance with the Law.

During the final control of the finished medicinal product before its release for sale or distribution, the quality control system shall take into account, in addition to analytical results, essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of the product to its specifications, including the final finished pack.

Samples of each batch of finished medicinal product shall be retained for at least 1 year after the expiry date.

Samples of starting materials, other than solvents, gases or water, used in the manufacturing process shall be retained for at least 2 years after the release of the product.

Period referred to in paragraph 6 of this article may be shortened if the period of stability of the material, as indicated in the relevant specification, is shorter.

All samples shall be maintained at the disposal of the Institute.

For certain veterinary medicinal products manufactured individually or in small quantities, or when their storage could raise special problems, other sampling and retaining conditions may be defined in agreement with the Institute.

Work contracted out

Article 13

The manufacturer is obliged to make a written contract for manufacturing or import operation or operation linked thereto which is outsourced to another person.

The contract referred to in paragraph 1 of this article shall clearly define the responsibilities of each party and shall define, in particular, the observance of good manufacturing practice to be followed by the contract-acceptor and the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities.

The contract-acceptor referred to in paragraph 2 of this article shall not subcontract any of the work entrusted to him under the contract without written authorisation from the contract-giver.

The contract-acceptor referred to in paragraph 2 of this article shall comply with the principles and guidelines of good manufacturing practice and shall submit to inspections carried out by the Institute.

Complaints and product recall

Article 14

The manufacturers shall implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and at any time, veterinary medicinal products in the distribution network. Any complaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall be required to inform the Institute and, if applicable, the marketing authorisation holder of any defect that could result in a recall or an abnormal restriction on supply and, in so far as possible, indicate the countries of destination.

Any recall shall be made in accordance with the Law.

Self-inspections

Article 15

The manufacturer shall conduct repeated self-inspections as part of the pharmaceutical quality system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures. Records shall be maintained of such self-inspections and any corrective actions subsequently taken.

III CONTENT OF THE APPLICATION AND DOCUMENTATION FOR THE GRANTING OF A MANUFACTURING AUTHORISATION

Issuance of a Manufacturing Authorisation

Article 16

The application for the issuance of a manufacturing authorisation for veterinary medicinal products shall be submitted to the Institute in accordance with the Law.

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

Along with the application referred to in paragraph 1 of this article, the applicant shall submit documentation proving compliance with the requirements regarding premises, personnel and equipment, specifically:

1) proof of possession of appropriate premises (property deed or lease agreement);
2) a floor plan with a legend of the rooms, certified by a licensed architect;
3) a report on compliance with minimum technical and construction standards for conducting the activity;
4) a sanitary approval for conducting the activity;
5) a list of equipment and technical specifications of the equipment;

6) documentation on personnel;
7) a plan for the procedure for the destruction of medicinal products and a written statement by the applicant undertaking further handling of pharmaceutical waste in accordance with the law;
8) other documentation necessary for issuing the manufacturing authorisation, upon request of the Institute.

A manufacturer of veterinary medicinal products, along with an application to amend or supplement a manufacturing authorisation, shall submit a description of the amendment or supplement with justification and the required documentation. In the case of an application for cessation of the license, the manufacturer shall provide justified reasons for ceasing the activity.

Proof of payment of the prescribed fees shall be submitted with the applications referred to in paragraphs 1 and 4 of this article.

Article 17

The importer of a veterinary medicinal product from a third country is obliged to specify the manufacturing site for all medicinal products for which an application for the issuance of a manufacturing authorisation is submitted.

For all manufacturing sites of medicinal products and pharmaceutical forms referred to in paragraph 1 of this article, the importer is required to hold a GMP certificate issued by the competent authority of a Member State of the European Union, or of a country with which the European Union has concluded a mutual recognition agreement regarding the results of compliance assessment with good manufacturing practice standards.

The importer is obliged to regularly maintain and renew the certificate referred to in paragraph 2 of this article, and to make it available upon request of the Institute.

Issuance of the GMP Certificate

Article 18

Following the issuance of a manufacturing authorisation or prior to the expiration of the period for which the GMP certificate was issued, the manufacturer shall submit an application for the issuance of a GMP certificate in accordance with the Law.

The GMP certificate is issued for the manufacturing site, for specific parts of the manufacturing process, production activities conducted at that site, and the pharmaceutical forms produced at that site, including the date of inspection.

The application referred to in paragraph 1 of this article shall be submitted using the application form published on the official website of the Institute.

Along with the application referred to in paragraph 1 of thisaArticle, the manufacturer shall submit documentation demonstrating compliance with GMP guidelines, in accordance with the request of the Institute.

Proof of payment of the prescribed fees shall be submitted along with the application referred to in paragraph 1 of this article.

Article 19

Within 7 days from the last day of the GMP inspection, inspector of the Institute shall issue Minutes of the GMP Inspection and deliver it to the applicant.

In the event that deficiencies are identified during the inspection referred to in paragraph 1 of this article, the applicant shall submit a written response to the inspector of the Institute

regarding the identified deficiencies no later than 30 days from the receipt of the Minutes of the GMP Inspection and shall propose corrective and preventive measures along with deadlines for resolving the identified deficiencies.

In cases of incomplete or unacceptable responses, the inspector shall request additional documentation from the inspected party, requiring correction or supplementation of the written response, and shall set a deadline for submission.

During this period, the deadline refered to in paragraph 3 of this article, for issuing the GMP certificate is suspended.

Inspector of the Institute shall issue a Report on the Application of Good Manufacturing Practice Guidelines (GMP Inspection Report) based on the Minutes of the GMP Inspection, and in cases of identified deficiencies, also based on the written response of the applicant.

Article 20

GMP certificate serves as proof of compliance with GMP guidelines for the manufacturing site of the veterinary medicinal product at the time of inspection, for a period of up to three years from the date the inspection was conducted.

Exceptionally from paragraph 1 of this article, Institute may decide to extend or shorten the validity period of the GMP certificate based on a risk assessment.

Article 21

If it is determined during the inspection that the manufacturer no longer performs activities in accordance with the requirements of good manufacturing practice, the Institute may suspend or revoke the GMP certificate or issue a Statement of Non-Compliance with GMP Guidelines.

IV TRANSITIONAL AND FINAL PROVISIONS

Article 22

Upon entry into force of this Rulebook, the Rulebook on More Detailed Conditions and Manner of Determining Fulfillment of Conditions for Manufacture of Medicines ("Official Gazette of Montenegro", No. 72/15) shall cease to be valid.

Article 23

The provisions of article 4 paragraph 3, article 8 paragraph 1 insofar as it relates to import, article 9 paragraph 3 insofar as it relates to import, article 13 paragraph 1 insofar as it relates to import, and article 17 shall apply from the date of Montenegro’s accession to the European Union.

Article 24

This Rulebook shall enter into force on the eighth day following its publication in the ,,Official Gazette of Montenegro”.

No. PRESIDENT OF THE BOARD OF DIRECTORS

In Podgorica, 2026 dr Jovan Milić, spec. oftalmology