

Pursuant to the Article 97 paragraph 10 of the Law on Medicines ("Official gazette of Montenegro", No 56/11 and 6/13), Ministry of Agriculture and Rural Development has passed

**RULEBOOK
ON MORE DETAILED CONDITIONS AND MANNER OF DETERMINING FULFILLMENT
OF CONDITIONS FOR PERFORMING WHOLESALE OF VETERINARY MEDICINAL
PRODUCTS**

("Official Gazette of Montenegro", No 044/16 from od 25 July 2016)

Article 1

This Rulebook prescribes more detailed conditions for a legal person performing wholesale of veterinary medicinal products and the manner of determining the fulfillment of conditions.

Article 2

Legal person performing wholesale of veterinary medicinal products (hereinafter: veterinary wholesaler) shall act in accordance with Guidelines of Good Distribution Practice in terms of introducing and maintaining the quality management system, personnel, premises, equipment, documentation managing, work processes, complaints, veterinary medicinal products recalling, suspected falsified veterinary medicinal products, self-inspections and transportation.

Article 3

- (1) Veterinary wholesaler shall establish and maintain an effective quality management system with clearly defined and documented responsibilities, processes and risk management measures in relation to their activities.
- (2) Veterinary wholesaler may conclude a contract with legal or natural persons, based on the provisions of paragraph 1 of this Article.

Article 4

- (1) In addition to the person responsible for storage and distribution of veterinary medicinal products, a veterinary wholesaler shall, depending on size and type of an activity, have personnel with appropriate competence and experience, as well as knowledge of and training in Good Distribution Practice.
- (2) Person responsible for the storage and distribution (hereinafter: responsible person), is responsible for the receipt, storage, transportation and delivery/dispatch of medicines, as well as for a review of documentation that permits tracking of medicines
- (3) In performing activities referred to in paragraph 2 of this Article, a responsible person of the veterinary wholesaler, shall sign a statement on independence in decision-making.
- (4) For employees referred to in paragraph 1 of this Article, a veterinary wholesaler shall provide initial and continuing training in the implementation of Guidelines on Good Distribution Practice.

Article 5

- (1) In accordance with Guidelines on Good Distribution Practice, a veterinary wholesaler shall, depending on size and type of activity, have suitable premises and equipment for placing, storage, and distributing medicines in accordance with defined terms of storage.
- (2) Working and storage areas should be clean, dry and maintained within acceptable environmental conditions prescribed for storage of medicines, in accordance with the type of medicines and size of the expected marketing.
- (3) Storage areas must meet special conditions in terms of temperature, humidity and other conditions depending on characteristics and types of medicines.
- (4) Expired medicines, medicines that are subject to complaints, or were recalled from the market due to suspected quality, suspected falsified medicines, etc., must be physically segregated.
- (5) Access to medicines shall be restricted to authorised personnel only.

Article 6

- (1) Veterinary wholesaler shall provide suitable vehicles and equipment for transport and storage of medicines.

(2) Transportation vehicles and equipment referred to in paragraph 1 of this Article shall be maintained as to prevent exposure of medicines to conditions which could compromise their quality and integrity.

Article 7

(1) All standard operating procedures, instructions, contracts, records and data shall be documented in paper, or electronic form in a legible, clear and unambiguous manner.

(2) All data is recorded at the time of performing of each operation and in a manner to ensure tracking of all relevant operations, or events, with a clearly defined time, which permits tracking of a medicine and its recall from the market in the shortest possible timeframe.

Article 8

(1) Veterinary wholesaler shall, in accordance with the established program, conduct self-inspections in order to verify compliance with principles and guidelines of Good Distribution Practice, as well as to propose necessary corrective measures.

(2) All self-inspections and certain preventive and corrective measures shall be documented.

(3) All actions performed by the veterinary wholesaler shall be fully described in the documentation on quality management system and implemented in a manner to keep the identity and quality of the medicine.

Article 9

At the request of the veterinary wholesaler, the Agency shall issue a certificate on the implementation of Guidelines on Good Distribution Practice, based on the check of fulfillment of the conditions.

Article 10

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

No: 323-225/16-4

Podgorica, 18 July 2016

Minister,

Budimir Mugoša, m.p.