Pursuant to Article 139 paragraph 9 of the Law on Medicinal Products ("Official Gazette of Montenegro", No. 80/20), the Ministry of Health

RULEBOOK ON DETAILED CONDITIONS AND MANNER OF DETERMINING THE FULFILLMENT OF CONDITIONS FOR PERFORMING WHOLESALE OF MEDICINES FOR HUMAN USE

(Rulebook has been published in the "Official Gazette of Montenegro", No. 45/21 of April 29, 2021)

I. GENERAL PROVISIONS

Article 1

This Rulebook prescribes more detailed conditions to be fulfilled by a legal entity that performs wholesale of medicines for human use (hereinafter: medicines), the content of the wholesale marketing authorization, as well as the manner of determining the fulfillment of conditions for medicines wholesale.

Article 2

Terms used in this rulebook for natural persons in the masculine gender mean the same terms in the feminine gender.

Article 3

Terms used in this rulebook have the following meaning:

1) supply means activities that include the provision, sale and giving medicines free of charge to a wholesaler, pharmacy or other health care institution;

2) deviation from the quality standard of the medicine is any difference in appearance, physico-chemical, microbiological and pharmaceutical-technological properties between the medicine and the data from the marketing authorization, as well as any discrepancy between the outer and inner packaging of the medicine and instruction for use of that medicine compering with the data from the marketing authorisation (hereinafter: defect);

3) quarantine is the status of materials that are physically or in some other efficient way isolated until a decision is made on their approval or rejection;

4) validation is an activity which proves that a certain procedure, process, equipment, material, activity or system gives the expected results;

5) qualification is an activity that proves that certain equipment works properly and gives the expected results.

II. CONDITIONS FOR A LEGAL ENTITY PERFORMING WHOLESALE OF MEDICINES

1. Conditions regarding staff

Article 4

The wholesaler, in accordance with the law, should have an employee responsible for the storage and distribution of medicines (hereinafter: the responsible person), who is responsible for:

1) receipt, storage, keeping, transport and delivery of medicines;

2) review of documentation that enables traceability of medicines;

3) record keeping and maintenance of the quality system;

4) reporting a suspicion of a substandard or falsified medicine, and

5) has other responsibilities in accordance with the Guidelines on good distribution practice.

Depending on the scope and type of activity, the wholesaler should have the appropriate staff with experience, knowledge and education in the application of the Guidelines on Good Distribution Practice.

For employees referred to in paragraph 1 and 2 of this Article, the wholesaler provides conduction of appropriate training for the application of the Guidelines on Good Distribution Practice.

Article 5

The responsible person and employees of the wholesaler that conducts wholesale of radiopharmaceuticals should be trained for work in the field of radiopharmacy, as well as to work with ionizing radiation sources and implementation of measures of protection against ionizing radiation.

Employees who handle medicines that require special conditions, such as highly active, toxic, radiopharmaceuticals and medicines for infectious diseases are specially trained and educated to handle these types of medicines.

Article 6

The wholesaler should have an organizational chart of employees who perform wholesale of medicines in accordance with the Guidelines on Good Distribution Practice.

The organizational chart referred to in paragraph 1 of this Article shall determine the mutual relationship of employees of the wholesaler of medicines, their responsibilities, authorizations and a description of duties performed by those employees.

2. Conditions in terms of space

Article 7

The wholesaler should have adequate space, as follows:

1) for receiving, keeping and storing medicines, as well as starting substances for manufacture, under determined storage conditions, and a wholesaler that has an authorization for import of medicines should have space with provided quarantine conditions for products that are still in the quality control procedure;

2) for shipping medicines;

3) for the accommodation of returned, rejected, withdrawn, falsified or medicines with defect;

4) for the wardrobe;

5) sanitary facilities, and

6) office premises.

Space referred to in paragraph 1 points 4, 5 and 6 of this Article should be separated from the space where medicines are stored.

Article 8

In addition to the space referred to in Article 7 of this rulebook, depending on the type and group of medicines for which it has wholesale authorization, the wholesaler should also have a specially secured space for accommodation and storage of:

1) active substances for the manufacture of penicillin antibiotics;

2) active substances for the manufacture of cytostatics;

3) flammable and explosive substances;

4) active substances belonging to narcotic drugs or psychotropic substances, as well as finished medicines containing these substances;

5) starting materials and finished products belonging to the group of poisons;

6) immunological and biological medicines that have the property of infectious material;

7) radiopharmaceuticals, and

8) other medicines for which special conditions of accommodation and storage have been determined.

Article 9

Square footage and number of premises referred to in Article 7 and 8 of this rulebook should be adjusted to the type, i.e. group of medicines whose wholesale the wholesaler performs, as well as to the volume of wholesale.

The space of the wholesaler referred to in Article 7, paragraph 1, item 1 to 3 and Article 8 of this rulebook, as a rule, should have an square footage of at least $70m^2$.

Article 10

The space referred to in Article 7 and 8 of this rulebook should:

1) be built of solid material, that the construction-technical and in terms of size corresponds to the intended purpose, that the walls, floors and ceilings are of flat and smooth surfaces and made of material that is not subject to cracking and scattering, that they can be quickly and easily cleaned or washed, as well as disinfected;

2) have adequate lighting, temperature, humidity and ventilation without harmful direct or indirect impact on the prescribed and safe reception, storage and keeping of starting substances and/or medicines, and

3) meet, in terms of space and layout of equipment and devices, the needs of uninterrupted performance of operational activities, without the risk and possibility of replacement or mixing of different products.

The premises should be functionally connected so that the uninterrupted flow of work and safe storage, keeping and shipment of medicines is ensured.

Article 11

A wholesaler that performs wholesale of radiopharmaceuticals should have a storage space which, in addition to the conditions referred to in Article 10 of this rulebook, should also meet the following conditions:

1) the required level of hermetic closing of windows, doors and other openings is provided;

2) regular control of the level of radioactivity is provided, in accordance with the regulations governing protection against ionizing radiation and radiation safety;

3) regular cleaning and disinfection of the premises is provided in the manner determined by the regulations governing ionizing radiation protection and radiation safety, and

4) can be easily decontaminated, if necessary.

The wholesaler referred to in paragraph 1 of this Article need not have space for storage of radiopharmaceuticals that are labeled with radioisotopes that have a short half-life time.

Article 12

The wholesaler should implement a pest control program and measures against spoilage and damage in the storage space, as well as against mutual contamination of products.

The space referred to in paragraph 1 of this Article should be regularly cleaned, disinfected and controlled depending on its purpose and should have in a visible place signs prohibiting smoking, eating and drinking, as well as other prohibitions that may affect hygienic conditions.

Article 13

The wholesaler should provide:

1) appropriate approach for receiving and dispatching medicines;

2) that the receiving and dispatching areas are adequately separated from the storage area and protected from the weather;

3) necessary security measures in order to prevent unauthorized persons from entering the storage space, and

4) alarm system for continuous detection of unauthorized entry.

Article 14

The wholesaler in the medicines storage area provides conditions for keeping medicines separately from other products that may affect their quality, in accordance with the conditions specified by the manufacturer.

The wholesaler should have special premises intended for the storage of falsified medicines, expired medicines, withdrawn medicines and rejected medicines, which were in the supply chain, separately from all other medicines.

The medicines storage area should have an appropriate temperature and humidity, which the wholesaler regularly controls and keeps records of.

3. Equipment requirements

Article 15

The wholesaler should:

1) have appropriate equipment for receiving, storing and keeping medicines in accordance with the conditions determined by the manufacturer;

2) have appropriate temperature and humidity monitoring equipment, and

3) establish a plan for preventive maintenance of space and equipment.

Equipment for storage and distribution shall be designed, installed and maintained in accordance with a standard appropriate to its intended purpose.

Equipment maintenance and calibration procedures are performed in a manner that does not jeopardize the quality and integrity of the medicines, of which records are kept.

Equipment and IT support are appropriately qualified and/or validated.

The subject matter and scope of the qualification and/or validation is determined by a documented risk assessment.

Article 16

For the transport of medicines, the wholesaler should have at its disposal the appropriate type and sufficient number of its own means of transport or the means of transport of the person with whom it has concluded a contract on outsourced transport activities.

The type and number of means of transport should be adjusted to the type and group of medicines, the volume of planned wholesale and to meet the medicines storage conditions.

The wholesalers' vehicles are used only for the transport of medicines.

Notwithstanding paragraph 3 of this Article, means of transport may be used to transport dietary products, children's food, medical devices and other means of health care in a way that prevents substitution, contamination or cross-contamination with medicines.

For transport of certain types of medicines, means of transport should be equipped for special transport conditions in accordance with the determined storage conditions, ie transport (for example providing a "cold chain" with available records of temperature control and monitoring).

Transport of radiopharmaceuticals is performed by appropriate means of transport that meet the conditions prescribed by the law governing the transport of dangerous goods.

Article 17

Medicines transport equipment should ensure that:

1) their identification is not lost;

2) contamination is avoided;

3) spoilage, breakage or theft is prevented;

4) during transport protection against adverse effects of heat, cold, light, moisture, etc is provided;

5) protection against pests is provided, and

6) for medicinal products for which a certain storage temperature is prescribed, control and record the prescribed conditions during transport is provided.

Article 18

The consignment of medicines should be accompanied by appropriate documentation containing the relevant data depending on to whom the consignment was addressed and data on the vehicle that is used for transport, as well as a copy of the quality control certificate for each batch of medicine distributed.

Article 19

During the performance of operational activities at work, employees should wear protective clothing, i.e. work clothing that is appropriate for the work they perform at the wholesaler.

III. MEDICINES WHOLESALE AUTHORIZATION AND DETERMINATION OF FULFILLMENT OF CONDITIONS FOR MEDICINES WHOLESALE

Article 20

The medicines wholesale authorization shall contain the following data:

1) logo, name and address of the Institute for Medicines and Medical Devices (hereinafter: the Institute);

2) legal basis for issuing the authorization;

3) number and date of issuance of the authorization;

4) name of the authorization holder;

5) residence of the authorization holder;

6) address(es) of the wholesale site(s);

7) scope of the authorization;

8) attachments to the authorization, and

9) other data prescribed by the standardized form determined by the acts of the European Union and the EMA.

Article 21

The pharmaceutical inspector checks the compliance of wholesale distribution with the Guidelines on Good Distribution Practice in accordance with the Compilation of Community Procedures on Inspections and Exchange of Information of the European Union and prepares the Report on compliance of medicine distribution with the Guidelines on Good Distribution Practice, to which the wholesaler can submit comments and suggestions for eliminating non-compliance within a determined period.

After assessing the comments and suggestions referred to in paragraph 1 of this Article, the pharmaceutical inspector shall prepare a Report on the application of Guidelines on Good Distribution Practice (hereinafter: GDP Inspection Report) on the basis of which the Institute shall issue a Certificate of Guidelines on Good Distribution Practice compliance of a wholesale distributor (hereinafter: GDP certificate).

The period for which the GDP certificate is issued, in accordance with the law, is determined on the basis of a risk assessment performed by the Institute.

If the wholesale of medicines does not comply with the Guidelines on Good Distribution Practice, the Institute issues an appropriate Statement of Non-Compliance.

Article 22

The Institute regularly performs verification of compliance with the Guidelines on Good Distribution Practice on the basis of an annual verification program, which it prepares on the basis of risk analysis.

The Institute performs an extraordinary verification of compliance in case of reporting a suspicion of a defect, safety or falsified medicine or active substance, reporting an accident or error in the wholesale of medicines or active substances, as well as in other situations that may call into question or affect quality and safety of a medicine.

If during the verification from paragraph 1 and 2 of this Article non-compliances of the wholesale of medicines with the Guidelines on Good Distribution Practice are determined, the Institute shall order the wholesalers measures and a deadline for elimination of non-compliance in accordance with the law.

In order to determine whether the measures referred to in paragraph 3 of this Article have been implemented, the Institute shall re-check compliance and prepare a GDP Inspection Report. Based on the GDP Inspection Report, the Institute may issue a Statement of Non-Compliance.

IV. FINAL PROVISIONS

Article 23

On the day this rulebook enters into force, the Rulebook on detailed conditions and the manner of determining the fulfillment of conditions for medicines wholesale (Official Gazette of Montenegro, No. 72/15) shall cease to be valid.

Article 24

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

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Minister

MD Jelena Borovinić Bojović