Consolidated text of the Rulebook on more detailed conditions and manner of determining the fulfillment of conditions for the wholesale of medical devices includes the following:

1. Rulebook on more detailed conditions and manner of determining the fulfillment of conditions for the wholesale of medical devices ("Official Gazette of Montenegro" No 132/21 from 21 December 2021) and

2. Rulebook on amendments to the Rulebook on more detailed conditions and manner of determining the fulfillment of conditions for the wholesale of medical devices ("Official Gazette of Montenegro", No 072/22 from 11 July 2022) in which their date of entry into force is provided.

RULEBOOK

ON MORE DETAILED CONDITIONS AND MANNER OF DETERMINING THE FULFILLMENT OF CONDITIONS FOR THE WHOLESALE OF MEDICAL DEVICES*

("Official Gazette of Montenegro", No. 132/21 from 21 December 2021, 072/22 from 11 July 2022)

I. BASIC PROVISIONS

Subject

Article 1

This Rulebook prescribes more detailed conditions to be met by legal persons performing wholesale of medical devices (hereinafter: wholesaler), manner of determining the fulfillment of these conditions, as well as the content of the wholesale authorisations.

Use of gender sensitive language

Article 2

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

Expressions

Article 3

Terms used in this Rulebook shall have the following meaning:

1) **quality assurance** is a traceable process by which quality is introduced in all phases of the wholesale and which ensures constant supervision of distribution of medical devices, as well as storage under appropriate safe conditions so that contamination with other products is avoided, resupplying in accordance with the shelf life of the medical device, delivery of appropriate medical devices without delay and quick and efficient withdrawal of defective products from the market;

2) **quarantine** is the status of medical devices that are physically, or in some other effective manner, isolated until a decision on their approval, or rejection is made;

3) **medical device defect** is a flaw of a medical device in relation to identity, quality, durability, reliability, safety, or performance. Flaws of the medical device include malfunctions, use errors and inadequate labeling;

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

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

6) **Good Distribution Practice** is a system of quality assurance guidelines relating to the organization, implementation and monitoring of the distribution of a medical device from a manufacturer to an end user;

7) **falsified medical device** is any device with a false presentation of its identity, or of its source, or its CE marking certificates, or documents relating to CE marking procedures. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights;

8) **category of medical devices** is a set of medical devices that have a common area of intended use, or common technology;

9) **purpose** is the use for which a medical device is used in accordance with the data provided by the manufacturer in the labeling, in the instructions for use, or in promotional material;

10) **vigilance of a medical device (hereinafter: vigilance)** is a system and set of activities that ensures the collection, assessment, understanding and response to findings about risks arising from the use, or administration of a medical device, especially in terms of reporting incidents in order to improve and protect health and safety of patients, users and others. If necessary, mentioned activities ensure provision of information that reduce the likelihood of an incident recurring, or mitigate the consequences of that incident.

II. CONDITIONS REGARDING PERSONNEL, PREMISES AND EQUIPMENT

1. Conditions regarding personnel

Responsible person

Article 4

Wholesaler, in accordance with the law, shall have an employee (hereinafter: responsible person) at every site where wholesale is carried out, who is constantly available and responsible for the following:

1) receipt, storage, holding and delivery of medical devices;

2) maintenance of the quality assurance system;

3) vigilance and monitoring of medical devices on the market;

4) reporting of suspected falsified medical device;

5) keeping records of equipment maintenance and calibration procedures;

6) other activities in accordance with the guidelines of Good Distribution Practice.

Responsible person, depending on the risk class of the medical device wholesale of which is carried out shall hold a diploma from: medical, dental, pharmaceutical, veterinary, mechanical engineering, technology, electrical engineering, chemical, biological, or other appropriate faculty. Also, he/she shall

have an additional training for the jobs referred to in paragraph 1 of this Article and at least three years of work experience.

Responsible person may authorize other employees to perform activities referred to in paragraph 1 of this Article, in accordance with the guidelines of Good Distribution Practice.

In the case referred to in paragraph 3 of this Article, responsible person shall not be relieved of the responsibility for those activities.

Wholesaler shall conclude a full-time employment contract with a responsible person, in accordance with the law.

Depending on the volume of wholesale and the number of represented classes and categories of medical devices, a wholesaler which, in addition to wholesale of medical devices, also performs wholesale of medicines, may have one responsible person, which should be specified in the marketing authorization.

Employees

Article 5

Depending on the degree of risk to the user according to which medical devices are divided and volume of wholesale, a wholesaler shall have an appropriate number of employees, as follows:

1) medical devices of class I and IIa - at least secondary level of education in relevant field completed, depending on the purpose of the medical device and at least one year of work experience;

2) medical devices of class IIb and III, in vitro diagnostic medical devices and active implantable medical devices - secondary level of education in the relevant field, or high level of education in medical, dental, pharmaceutical, mechanical engineering, technology, electrical engineering or other relevant faculty, depending of the class and category of medical device, and at least one year of work experience.

Employees referred to in paragraph 1 of this Article shall perform activities of receiving, storing, holding and delivering medical devices, as well as other tasks related to the wholesale of medical devices.

Wholesaler shall provide initial and continuing training on the wholesale of medical devices, as well as on the application of guidelines of Good Distribution Practice for employees referred to in paragraph 1 of this Article.

Employees who deal with high-risk medical devices

Article 6

Responsible person and employees referred to in Article 5 of this Rulebook, who come into contact with high-risk medical devices that are a source of ionizing radiation, shall be trained to work with sources of ionizing radiation and to implement measures for the protection from ionizing radiation.

Wholesaler shall provide continuous training for persons referred to in paragraph 1 of this Article.

Organisational chart

Article 7

Wholesale shall have an organizational chart, in accordance with the guidelines of Good Distribution Practice.

The organizational chart referred to in paragraph 1 of this Article shall determine mutual relationship of employees within the wholesaler, their responsibilities, authorizations and a description of the work they perform.

2. Conditions regarding premises

Type and size of premises

Article 8

Wholesaler shall have adequate premises for:

1) receipt, storage, holding and delivery of medical devices;

2) storage of packaging;

3) quarantine for storage of defective medical devices, or medical devices withdrawn from the market;

4) wardrobe;

5) sanitary premises;

6) office space.

Area of premises referred to in the paragraph 1 points 1, 2 and 3 of this Article shall be adjusted to the type, i.e. class and category of medical devices placed on the market, as well as to the volume of the wholesale, and must not be less than 40 m2.

Premises for receiving and delivering medical devices and quarantine shall be separated from premises for storing and holding medical devices.

If the wholesaler sells medical devices that are a source of ionizing radiation, it shall have a separate premise for the storage of these medical devices that meets conditions required by regulations governing protection against ionizing radiation.

Premises characteristics

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Premises referred to in the Article 8 of this Rulebook shall fulfill the following criteria:

1) that is built of solid material, that corresponds to the intended purpose in terms of building and size, that walls, floors and ceilings are flat and smooth and made of material that is not subject to cracking and crumbling, that may be quickly and easily cleaned or washed, and also disinfected;

2) that has adequate lighting, temperature, humidity and ventilation without detrimental direct, or indirect impact on prescribed and safe receipt, storage and holding of medical devices;

3) by equipment and devices lay-out it satisfies needs of uninterrupted performance of operational activities, without the risk and possibility of replacing, or mixing different products.

Premises shall be functionally connected so that the uninterrupted work flow and safe storage, holding and dispatch of medical devices are ensured.

Premises for receiving and dispatching medical devices shall be protected from atmospheric conditions.

Safety measures

Article 10

Wholesaler shall provide necessary safety measures to prevent unauthorized persons from entering premises for storage and holding of medical devices and an alarm system for continuous detection of unauthorized entry.

In premises referred to in paragraph 1 of this Article the wholesaler shall implement a pest control program and measures against spoilage and damage, as well as mutual contamination of products.

Premises referred to in paragraph 1 of this Article shall be regularly cleaned, disinfected and controlled depending on its purpose, and “no smoking/eating/drinking” notices , as well as other prohibitions that may affect hygienic conditions shall be displayed at a visible place.

3. Conditions regarding equipment

Equipment

Article 11

Wholesaler shall:

1) have appropriate equipment for receiving, storing, holding and delivering medical devices;

2) have appropriate equipment for monitoring temperature and humidity;

3) have an appropriate computerized system;

4) establish a plan for preventive maintenance of premises and equipment.

Equipment referred to in the paragraph item 1 points 1, 2 and 3 of this Article shall be designed, installed and maintained in accordance with conditions specified by the manufacturer.

Procedures for maintenance and calibration of equipment shall be performed in a way that does not jeopardize the quality and integrity of medical devices records of which shall be kept.

Equipment and computerized systems shall be appropriately qualified and/or validated, in accordance with guidelines of Good Distribution Practice.

Subject and scope of the qualification and/or validation shall be determined by a documented risk assessment, in accordance with the guidelines of Good Distribution Practice.

Transport of medical devices

Article 12

For transport of medical devices, the wholesaler shall have at its disposal the appropriate type and sufficient number of its own means of transport, or means of transport of persons with whom it has concluded a contract on entrusting transport activities.

Type and number of means of transport referred to in paragraph 1 of this Article shall be adjusted to the type, class and category of medical devices, as well as the volume of planned wholesale and shall meet conditions prescribed for storage of these medical devices.

Notwithstanding paragraphs 1 and 2 of this Article, wholesaler that carries out wholesale of certain classes and categories of medical devices which due to their specific conditions of storage and transport the manufacturer delivers directly to the end user is not obliged to have means of transport for this type of medical devices.

Wholesale means of transport shall be used only for the transport of medical devices.

Notwithstanding paragraph 4 of this Article, means of transport may be used to transport medicines, dietary supplements, children's food and other means of health care in a way that prevents replacement, contamination, or cross-contamination with medical devices.

For the transport of certain types of medical devices, means of transport shall be equipped for special transport conditions in accordance with prescribed storage conditions, i.e. transport (e.g. providing a "cold chain" with available records of temperature control and monitoring).

Equipment for transport of medical devices

Article 13

Equipment used for the transport of medical devices shall ensure that:

1) their identification is not lost;

2) contamination is avoided;

3) spoilage, breakage or theft is prevented;

4) they are protected against adverse effects of heat, cold, light, moisture, etc. during transport.;

5) are protected against pests, and

6) control and record of required conditions during transport is provided for medical devices for which a certain storage temperature is prescribed.

Protective clothes

Article 14

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

III. MANNER OF DETERMINING THE FULFILLMENT OF CONDITIONS FOR WHOLESALE OF MEDICAL DEVICES AND CONTENT OF WHOLESALE AUTHORISATION

Determining the fulfillment of conditions

Article 15

Prior to the issuance of a wholesale authorisation, the Institute of Medicines and Medical Devices shall check the following:

1) whether the applicant meets the requirements in terms of personnel, premises and equipment in accordance with this Rulebook and the Guidelines of Good Distribution Practice;

2) contracts on entrusted activities to other legal persons, in accordance with the law and Guidelines of Good Distribution Practice; and

3) other data of importance for issuing the wholesale authorisation, in accordance with the law.

Content of the wholesale authorisation

Article 16

Wholesale authorisation shall contain the following data:

1) logo, name and address of the Institute;

2) legal basis for issuing the authorisation;

3) number and date of issuing the authorisation;

4) name of a wholesaler which the authorisation is issued to;

5) seat of a wholesaler which the authorisation is issued to;

6) address(es) of site(s) of wholesale of medical devices;

7) authorization scope;

8) list of medical devices wholesale of which is performed;

9) class of medical device depending on the degree of risk to the user; and

10) other data of importance for the wholesale of medical devices.

Final provision

Article 17

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

Following regulations are transposed into this Rulebook:

- Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Council Directive 98/79/EC and Commission Decision 2010/227/EU.