MINISTRY OF HEALTH

2693

Pursuant to Article 46, paragraph 3 and Article 47, paragraph 4 of the Medicinal Products Act (Official Gazette 76/13), the Minister of Health hereby issues the

ORDINANCE

ON GOOD PRACTICE IN THE WHOLESALE OF MEDICAL DEVICES AND CONDITIONS FOR ENTRY IN THE REGISTER OF WHOLESALE DISTRIBUTORS OF MEDICAL DEVICES

I. GENERAL PROVISIONS

Article 1

This Ordinance lays down the requirements to be met by persons performing the wholesale of medical devices, the procedure for entry in the Register of wholesale distributers of medical devices, and good practices in the wholesale of medical devices.

Article 2

1) The wholesale of medical devices includes the procurement, receipt, warehousing, sale, delivery, except for the issuance to the end customer, individual for personal use, and the import and export of medical devices.

2) The wholesale of medical devices may be performed by persons from Article 47 of the Medical Products Act (hereinafter: Act).

Article 3

1) The wholesale distributor may only perform the wholesale of medical devices in the manufacturer's original packaging.

2) At the time of entry and import of medical devices, the wholesale distributor is obliged to possess the manufacturer's statement of compliance with the important requirements.

II. ENTRY IN THE REGISTER OF WHOLESALE DISTRIBUTORS OF MEDICAL DEVICES

Article 4

1) The wholesale distribution of medical devices, in addition to the general conditions prescribed for wholesale, are obliged to:

1. designate a responsible person dependent on the risk class of the medical devices being sold, as follows:

- for medical devices with a Class I risk – have a responsible person with a minimum of completed secondary school education depending on the intended purpose of the medical device, or a person with a minimum of secondary school education with a minimum of five years work experience in the appropriate tasks,
- for medical devices with a Class IIa risk– a person with a minimum of completed professional study depending on the intended purpose of the medical device, or a person with a minimum of professional study with a minimum of five years work experience in the appropriate tasks,
- for medical devices with Class IIb and III risk and in vitro diagnostic medical devices and active medical devices for installation – a person with at least completed undergraduate university study, or professional study of the same qualification level in one of the following areas: natural sciences, biomedicine and health care, or another corresponding area of study depending on the intended use of the medical device, or a person with a minimum of completed appropriate undergraduate university study, or professional study from another area of study with a minimum of five years of work experience in the appropriate tasks,

2. ensure appropriate premises and equipment that ensure proper storage and handling of medical devices in accordance with the manufacturer's requirements;

3. perform the activity of wholesale of medical devices in accordance with the good practice of medical device wholesale, pursuant to Appendix I of this Ordinance.

2) The provisions of paragraph 1, subparagraph 2 of this Article do not apply to the wholesale distributor who performs the procurement and delivery of medical devices without the retention of the medical devices in the warehouse facility.

Article 5

1) The responsible person from Article 4, item 1 of this Ordinance:

- oversees the receipt, storage, safe keeping and delivery of medical devices;
- carries out and coordinates the recall of a medical device from distribution;
- keeps records and documentation,
- performs other tasks pursuant to the good practice of wholesale of medical devices.

2) The responsible person from Article 4, item 1 of this Ordinance is obliged to be educated on or have the corresponding education on good practices for the wholesale of medical devices, and vigilance for medical devices.

Article 6

1) Wholesaler distributors are obliged to ensure the appropriate premises, depending on the scope of the activity, including:

1. area for the receipt and dispatch of medical devices;
2. area for the storage and keeping of medical devices;
3. area for the storage of packaging;
4. area for medical devices recalled from distribution.

2) In addition to the premises from paragraph 1 of this Article, the wholesale distributor shall also have the following space:

1. a washroom with entry area,
2. a changing room.

3) The space from paragraph 1, item 4 of this Article must be physically separated from the area for the storage and keeping of medical devices.

Article 7

The application for entry into the Register of wholesale distributors of medical devices is submitted by the natural or legal person from Article 2 of this Ordinance to the Agency for Medicinal Products and Medical Devices (hereinafter: Agency).

Article 8

1) With the application from Article 7 of this Ordinance, the applicant is obliged to append documentation containing the following information and documents:

1. filled out form OČ-VELE from the Appendix to this Ordinance and which forms its integral part,
2. proof of completed education of the responsible person, in original or certified photocopy,
3. labour contract for the responsible persons, original or certified photocopy,
4. proof of ownership or lease of the commercial premises, original or certified photocopy,
5. description of the space and floor plan of the space, with scale, drafted by an certified architect, original or certified photocopy,
6. list of equipment and technical information on the equipment,
7. list of procedures pursuant to the good practice of the wholesale of medical devices in the applicable scope,
8. proof of paid procedural costs of the entry in the register,
9. proof of payment of the administrative fee.

2) The applicant that does not have its own premises and equipment, instead of the documents and information from paragraph 1, items 4, 5 and 6 of this Article, is obliged to append the service contract for the receipt, delivery, storage and transport of medical devices with a wholesale distributor that is entered in the register of medical device wholesale distributors and that possesses the premises and equipment pursuant to Article 6 of this Ordinance.

3) The applicant that performs the activity of wholesale pursuant to Article 4, paragraph 2 of this Ordinance is not obliged to submit the documents and information from paragraph 1, items 4, 5 and 6 of this Article.

Article 9

1) In the procedure of entry in the Register of medical device wholesale distributors, the assessment of fulfilment of the stipulated conditions is established by a two-member committee appointed by the Agency.

2) A record is drawn up on the established state of facts and is signed by the members of the committee and the applicant.

3) During the procedure of entry into the Register from paragraph 1 of this Article, the Agency may request the applicant to submit additional documentation or substantiation, and may set a deadline to remove any shortcomings revealed in the review, which may not be less than 30 days.

4) Entry into the Register of wholesale distributors of medical devices is given with respect to the scope and manner of performing activities, risk class of medical devices, category of medical devices and the storage conditions of medical devices.

5) The provisions from paragraphs 1, 2 and 3 of this Article shall not apply to the applicant from Article 8, paragraphs 2 and 3 of this Ordinance.

III. TRANSITIONAL AND FINAL PROVISIONS

Article 10

With the entry of this Ordinance into effect, the Ordinance on good practice, conditions for issuing authorisation for wholesale distribution and imports and exports of medical products (Official Gazette 38/10) shall cease to have effect.

Article 11

This Ordinance shall enter into force on the eighth day from the date of its publication in the *Official Gazette*.

Class: 011-02/13-02/128

Reg no: 534-10-1-2-2/4-13-1

Zagreb, 18 September 2013

Minister

Prof. Rajko Ostojić, MD, PhD, m. p.

APPENDIX I

GOOD PRACTICE IN THE WHOLESALE TRADE OF MEDICAL DEVICES

PREMISES AND EQUIPMENT

1. The premises from Article 6 of this Ordinance shall be functionally connected to enable the undisturbed flow of operation and safe placement and keeping of medical devices, and be equipped in such a way as to enable the establishment, maintenance and monitoring of the keeping conditions stipulated by the manufacturer.

2. The area for the receipt of medical devices must be separate from the area for the dispatch and the area for the storage of medical devices.

3. The premises from paragraph 1 of this Article shall be constructed of solid materials and connected to the municipal infrastructure, with appropriate access for incoming and outgoing deliveries of medical devices that is protected from weather conditions.

4. The walls and ceilings of the premises must be such that enables cleaning and washing.

5. The floors of wholesale premises shall be smooth and made in a way that enables cleaning, washing and, if necessary, disinfection.

6. All premises must be ventilated, clean and dry. If natural air flow is insufficient, it is necessary to install effective artificial ventilation.

7. The premises and positioning of equipment must enable the implementation of pest control measures, the appropriate cleaning and washing measures, measures against spillage and breakage, and against the effects of microorganisms and cross-contamination of products.

8. All wholesale premises shall have natural lighting or the appropriate artificial lighting in accordance with the prescribed conditions of keeping medical devices.

9. The size and equipping of premises from item 1 of this Appendix must be suitable for the nature of the medical devices and the scope of envisaged distribution.

RECEIPT, STORAGE AND KEEPING

10. All consignments must be examined upon receipt to determine whether the packaging is damaged and whether it corresponds to the consignment order.

10.1. Medical devices requiring keeping under specific conditions must be immediately identified and placed in the space that corresponds to the keeping conditions as stipulated by the manufacturer.

11. Medical devices shall be kept separate from other products, protected from light, moisture and inadequate temperature, in accordance with the prescribed storage conditions.

11.1. The space in which the medical devices are kept requires regular cleaning, and a record shall be kept with the date and time and manner of cleaning performed.

11.2. When specific temperature storage conditions are required for a particular medical device, it is necessary to monitor the temperature and keep records thereof, and storage areas shall be equipped with devices that indicate changes in temperature outside the stipulated range.

12. In handling stock, there should be a system to ensure stock rotation depending on the date of receipt or the date of expiry. It is compulsory to conduct regular controls of the functioning of the system.

13. Medical devices whose shelf-life has expired, that have damaged packaging, or for which there is a suspicion of contamination, shall be kept separately.

DELIVERY AND TRANSPORT

14. All deliveries of medical devices must be accompanied by a document containing at least the following information:

- date,
- name of medical device,
- received or issued quantity and price of medical device,
- lot number or serial number of the medical device,
- name and address of the supplier or recipient.

15. Prior to delivery, the wholesale distributor is obliged to verify whether the medical device has been properly labelled and is accompanied by instructions for use, if applicable.

16. Medical devices must be transported in such a way that:

- their identification is not lost;
- adequate precautions are taken against spillage, breakage or theft;
- they are protected from unacceptable heat, cold, light, moisture, microorganisms or pests, or other adverse effects;
- the appropriate storage conditions are met as prescribed by the manufacturer.

16.1. The vehicle in which the medical devices are transported must be clean and adequately equipped so as to enable the maintenance of special storage and keeping conditions.

16.2. If the wholesale distributor does not have its own transport vehicles, it is obliged to contract transport services in such a way that the service provider is obliged to abide by the requirements from points 16 and 16.1 of this Appendix.

17. In the case of urgency, the wholesale distributor may enable urgent delivery of medical devices.

RETURNS AND RECALLS

18. All returns, rejections or recalls of medical devices, as well as discovery of counterfeit medical devices shall be recorded and the time of establishment of the said facts indicated.

18.1. If any returns, rejections or recalls are the result of suspicion in the quality of a medical device or of counterfeiting, the wholesale distributor is obliged to notify the Agency thereof without delay.

18.2. In the case of a return of functional medical devices, the same must be kept separate from other products until the corresponding decision is made.

18.3. Medical devices may be returned to distribution if:

- they are in the original, unopened packaging and are well protected,
- it is known that the products were kept and handled in accordance with the prescribed conditions,
- the remaining shelf life period is acceptable,
- they were verified by the responsible person.

18.4. The responsible person must issue a written decision on the return of medical devices to distribution, taking into account the nature of the product, special storage conditions if so prescribed, and the time passed since dispatch.

19. For the purpose of recalling a medical device from the market, a system must be in place to allow for the rapid identification and contact of all destinations and end users of the medical device, i.e. to keep corresponding records by identification codes, quantities and serial numbers of medical devices in a manner that allows for the recall of medical devices.

19.1. The wholesale distributor is obliged to inform customers of a recall of a medical device without delay.

19.2. At the request of the Agency or Ministry responsible for health, wholesale distributors are obliged to deliver information on the course and results of implementation of the procedure to recall a medical device.

19.3. Recalled medical devices must be kept separately from other medical devices and be specially labelled.

20. Should counterfeit medical devices be discovered in the distribution network, they shall be kept apart from other medical devices and marked as such.

20.1. The wholesale distributor is obliged to issue a written decision on the manner of handling medical devices from point 20 of this Appendix.

DOCUMENTATION AND RECORDS

21. The wholesale distributor shall keep written and dated records on all procedures on the implementation of good practice in the wholesale trade of medical devices that contain at least descriptions of the following procedures:

- receiving and checking of consignments;

- keeping, conditions of keeping and safety of the stock in the warehouse;
- cleaning and maintaining the premises and equipment;
- consignments in transport;
- orders and dispatches;
- management of returned products;
- recalled products,
- handling counterfeit medical devices and medical devices suspected of not meeting the requirements laid down in the Act.

21.1. The procedures from point 21 of this Appendix must be approved and signed by the responsible person with the date of the start of application.

22. Wholesale distributors are obliged to keep records on the implementation of procedures from point 21 of this Appendix.

22.1. Records must be clear, available to the Agency and ministry responsible for health upon their request, and enable the traceability of the medical device, i.e. simple verification of the origin of the medical device and the destination of dispatch via a tracking system for lot numbers or serial numbers.

22.2. The wholesale distributor is obliged to keep the records from point 22 of this Appendix for a minimum of ten years.

22.3. When the records from point 22 of this Appendix are kept in electronic form, they must be protected from unauthorised access in the database and with the registration of every entry or viewing of the database with information on the person performing that ask, and the secure archiving of data in the appropriate time intervals.

APPENDIX – OČ-VELE

FORM FOR ENTRY INTO THE REGISTER OF WHOLESALE DISTRIBUTORS

A. Administrative information	
Type of registration:	
☐ Entry into the register	
☐ Editing a registry entry	
Class:	Date:
B. Information on the applicant	
Company name/Name of craft:	OIB ID number:
Authorised representative / Craft owner:	
Address:	
Postal code:	City:
Telephone:	Fax:
E-mail:	Country:
C. Information on the scope and manner of performing the activity	
☐ Wholesale	☐ Import
☐ Wholesale in transit	
D. Information on the warehouse (if applicable)	
Address:	
Postal code:	City:
Telephone:	Fax:
E. Information on the responsible person for the trade of medical devices	
Name and surname:	OIB ID no:
Address:	
Postal code:	City:
Telephone:	Fax:

E-mail:

F. Information on medical devices

Risk class:

☐ Active medical devices for implantation

Medical devices:	In vitro diagnostic medical device:
☐ Class III	☐ Appendix II List A
☐ Class IIb	☐ Appendix II List B
☐ Class IIa	☐ Self-testing products
☐ Class I	☐ Other

Storage conditions:

☐ keep at room temperature

☐ keep in a cool place

☐ keep in a very cold place

Category:

☐ active medical device for implantation

☐ anaesthesiology and respiratory medical device

☐ dental medical device

☐ electro-mechanical medical device

☐ hospital equipment

☐ in-vitro diagnostic medical device

☐ medical device for implantation

☐ ophthalmological and optical medical device

☐ medical device for multiple use

☐ medical device for single use

☐ aid for the disabled ☐ radiological diagnostic and therapeutic products ☐ auxiliary therapy products ☐ products of biological origin ☐ equipment for health care institutions ☐ laboratory equipment ☐ medical software

G. Remarks	

I confirm that the data listed on this form are accurate.

……

Signature and stamp

In _____, _____ year.