MINISTRY OF HEALTH

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Pursuant to Article 49, paragraph 5 of the Medicinal Products Act (Official Gazette 76/13), the minister of health hereby issues the

ORDINANCE

ON CONDITIONS FOR PERFORMING RETAIL SALE AND GRANTING PERMITS TO SPECIALISED SHOPS FOR THE RETAIL SALE OF MEDICAL DEVICES

Article 1

This Ordinance lays down the conditions to be met by natural and legal persons for the performance of retail sale of medical devices in specialised shops for the retail sale of medical devices, and the necessary documents and information for the granting of permits for performance of this activity.

Article 2

1) The retail sale of medical devices is performed by natural and legal persons who, pursuant to a special act, have received authorisation for performance of pharmacy activities, and specialised shops for the retail sale of medical devices that have received a permit from the Agency for Medicinal Products and Medical Devices (hereinafter: Agency) for the retail sale of medical devices.

2) Specialised shops may only sell those medical devices that meet all the requirements stipulated by the Medical Devices Act (hereinafter: Act) and are suitable for such sale with regard to their intended purpose, and the environment in which the medical devices are envisaged for use.

3) Specialised shops may only sell medical devices in the original manufacturer's packaging.

Article 3

A specialised shop must:

- bear the name and surname of the natural person, or name of the legal person performing the activity of the retail sale of medical devices,
- state the hours of operation.

Article 4

In addition to the general conditions prescribed for retail trade, a specialised shop must also meet the following specific requirements:

1. employ a responsible person of the appropriate professional qualifications depending on the risk class of the medical device offered for retail sale, as follows:
   - for risk class I and IIa medical devices – a person with a minimum of completed secondary school education, depending on the intended use of the medical device,
   - for risk class IIb and III medical devices – a person with a minimum of completed professional study, depending on the intended use of the medical device,
2. have the appropriate premises as stipulated in Article 6 of this Ordinance,
3. keep the corresponding documentation by type and quantity of medical devices, and according to risk classes, in a manner than enables the recall of medical devices from the market and the action of the relevant inspection service.

Article 5

The responsible person from Article 4 of this Ordinance performs the following tasks:

- procurement, receipt, warehousing and keeping of medical devices,
- sale of medical devices,
- informing, advising and familiarising customers with the proper use of medical devices,
- keeping records on the quantities and types of medical devices.

Article 6

1) Specialised shops are required to secure the following areas:

- space for the sale of medical devices,
- storage for medical devices,
- washroom,
- dressing room.

2) In addition to the general regulations governing physical planning and construction, the premises of specialised shops must meet the requirements of functional connectivity, such that it enables unhindered course of work and the secure keeping of medical devices, and are equipped such that it is possible to establishment, maintenance and control of the storage conditions for medical devices.

3) If the specialised shop also sells other products, they must be separate from the medical devices such that the sale of other products does not affect the medical devices.

4) The floors of the premises must be smooth and executed in a manner that enables cleaning, washing and, if required, disinfection.

5) All premises must be well ventilated, and if the natural ventilation is insufficient, it is necessary to ensure efficient artificial ventilation.

6) The size and equipping of the premises must be appropriate for the medical devices that are the subject of the activity, and for the scope of the envisaged sale.

Article 7

The application for the permit for the retail sale of medical devices in specialised shops is submitted by the natural or legal person from Article 49 of the Act to the Agency.

Article 8

With the application for the permit for the retail sale of medical devices in specialised shops, the applicant is required to append documentation containing the following information and documents:

- full name of the legal person, or name and surname of the natural person who will perform the retail sale of medical devices and the address and contact data,
- list of the group of medical devices by risk classes intended for sale,
- evidence of the right to use the commercial premises,
- description of the premises in line with Article 6 of this Ordinance and the floor plan of the premises, with scale marked, drafted by a certified architect,
- evidence of professional qualifications of the responsible person,
- evidence of the employment of the responsible person,
- evidence of paid procedural costs,
- evidence of paid administrative fees.

Article 9

1) In the procedure for granting the permit for the retail sale of medical devices in specialised shops, the fulfilment of the prescribed requirements is determined by a two-member committee appointed by the Agency.

2) A record is compiled on the established state of facts, which is signed by the committee members and the applicant.

3) During the procedure from paragraph 1 of this Article, the Agency may request the applicant to submit additional documentation or substantiation, and to determine a deadline of not more than 30 days for the removal of any deficiencies established during the process.

4) The permit for the retail sale of medical devices in specialised shops is granted with regard to the manner of performing the activity and the risk class of the medical device.

Article 10

Upon entry of this Ordinance into force, the following shall cease to have effect:

- Ordinance on the conditions for granting permits to specialised shops for the retail sale of medicinal products and medical devices (Official Gazette 29/05, 81/06 and 5/07).
- Ordinance on good practice and conditions for the granting of a permit for the sale of medical devices (Official Gazette 54/05 and 81/06).

Article 11

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

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Zagreb, 21 October 2013

Minister

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