MINISTRY OF HEALTH

2348

Pursuant to Article 135, paragraph 4 of the Medicinal Products Act (Official Gazette 76/13 and 90/14), the Minister of Health hereby issues the

ORDINANCE

ON THE CONDITIONS FOR GRANTING PERMITS TO SPECIALISED RETAIL SALES OUTLETS OF MEDICINAL PRODUCTS

Article 1

This Ordinance lays down the conditions, manner, documents and data for the granting of a permit for performing the retail sale of medicinal products in specialised retail sales outlets for medicinal products (hereinafter: specialised retail sales outlets).

Article 2

1) In specialised retail sales outlets, the retail sale of medicinal products that are issued without a prescription (over-the-counter) may be performed, pursuant to the decision of the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency) on the marketing authorisation.

2) The Agency may set limitations for medicinal products permitted for issuance in specialised retail sales outlets for medicinal products, in terms of the dose and size of packaging of the medicinal product.

Article 3

Specialised retail sales outlets must have:

– name and seat of the legal or natural person,

– name and address of the specialised retail sales outlet,

– listing of the hours of operation.

Article 4

Specialised retail sales outlets may purchase and deliver medicinal products only in their original packaging.

Article 5

Specialised retail sales outlets may only purchase medicinal products from wholesalers holding a permit for performing the wholesale trade of medicinal products, and directly from

the manufacturer of the medicinal product seated in the Republic of Croatia or European Union Member State holding a valid production permit for the medicinal products they produce, and for which they have marketing authorisation in the Republic of Croatia.

Article 6

1) Specialised retail sales outlets, in addition to the general conditions stipulated for retail trade, must also meet the following special requirements:

1. employ a responsible person,

2. possess the appropriate premises,

3. keep records on the type and quantity of medicinal products, which enables the activities of the pharmaceutical inspection.

2) If the specialised retail sales outlet has a responsible person employed on a part time basis, it must have a professional person employed on a full time basis.

3) The specialised retail sales outlet must have the appropriate number of persons from paragraphs 1 and 2 of this Article employed, with regard to the hours of operation of the specialised retail sales outlet.

4) The professional person from paragraph 2 of this Article is a pharmaceutical technician who has passed the professional examination.

Article 7

1) The responsible person from Article 6, paragraph 1, item 1 of this Ordinance is a pharmacist holding a master's degree.

2) The responsible person is responsible for:

– procurement, takeover, warehousing and storage of medicinal products,

– issuance of medicinal products to the end user,

– notification of users on the manner of use of the medicinal product, precautionary measures and possible adverse reactions,

– keeping records on the type and quantity of medicinal products,

– keeping records on the storage of medicinal products that require special storage conditions,

– reporting of adverse reactions of medicinal products,

– drafting the annual report on consumption of medicinal products.

3) The tasks from paragraph 2, subparagraphs 1–5 of this Article may also be performed by the employed professional person.

Article 8

For performing retail trade of medicinal products in specialised retail sales outlets, the specialised retail sales outlets are obliged to ensure the functional connection of rooms that are equipped and designed in such a way to enable unhindered operation, and to ensure the safe housing, storage and issuance of medicinal products in accordance with the stipulated requirements.

Article 9

1) Specialised retail sales outlets must possess the following spaces:

– room for the issuance and promotion of medicinal products, which must be physically separated from rooms where other types of products are sold, which could affect the quality of the medicinal product,

– storage space,

– office space,

– employee washroom,

– cloakroom.

2) The specialised retail sales outlet must have the appropriate equipment that enables the establishment of microclimatic conditions, and the possibility for maintaining, controlling and monitoring the storage conditions for medicinal products in the storage space, pursuant to the stipulated requirements.

3) Walls, floors and ceilings must be made in a way that enables easy cleaning and washing, and, if necessary, disinfecting.

4) Medicinal products that are placed on shelves in the space for issuance and promotion, must be kept in a manner that prohibits the self-service sale of medicinal products.

Article 10

1) Specialised retail sales outlets must have a described documentation system, which consists of:

a) records of each order, which must contain the following data:

– name of the medicinal product, pharmaceutical form, strength and packaging of medicinal products,

– name of the marketing authorisation holder for the medicinal product / of the holder of the authorisation for the parallel import of the medicinal product,

– name of the manufacturer, lot number of the medicinal product, and expiry period,

– date of the order,

– quantity received,

– name and address of the supplier of the medicinal product;

b) records on the storage conditions for medicinal products in the storage space;

c) records of cleaning and maintenance of the premises;

d) records of equipment maintenance, including documentation on the calibration of instruments for monitoring the storage conditions of medicinal products;

e) records of education and professional development of the responsible and professional persons;

f) records on consumption of medicinal products.

2) The documentation from paragraph 1 of this Article must be kept for a minimum of 5 years in electronic or hardcopy form.

Article 11

The application for the granting of a permit for performing retail sale of medicinal products in specialised retail sales outlets is submitted to the Agency by the natural or legal person.

Article 12

In addition to the requirement from Article 11 of this Ordinance, the applicant is obliged to submit documentation containing the following data and documents:

1. excerpt from the court register, or crafts register, in the original or certified copy,

2. proof of ownership or lease of business premises, in the original or certified copy,

3. description of the space and layout of the space, drafted by a certified architect, in the original or certified copy,

4. diploma of the responsible person and certificate of completed education of the professional person, in the original or certified copy,

5. labour contract with the responsible or professional person, in the original or certified copy,

6. proof of payment of the costs of the permit granting procedure,

7. proof of payment of the administrative fee.

Article 13

1) In the procedure for granting a permit for the performance of retail sale of medicinal products in specialised retail sales outlets, pursuant to the provisions of the Medicinal Products Act (hereinafter: the Act), 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, and is signed by the committee members and authorised representative of the applicant who is present.

3) In the course of the procedure of granting the permit for the retail sale of medicinal products in specialised retail sales outlets, prior to granting the permit and following the establishment of the prescribed conditions, the Agency may require the applicant to submit additional documentation or provide additional verbal or written substantiation, if there are shortcomings in the application that may be removed.

4) The additional deadline for the removal of shortcomings may not be longer than 30 days.

5) The deadline for the granting of the permit for performing the retail sale of medicinal products in specialised retail sales outlets from Article 138, paragraph 1 of the Act shall not run during the period approved for the applicant to deliver additional documentation or to provide additional verbal or written substantiation.

Article 14

The specialised retail sales outlet for medicinal products is obliged to align its work and operations with the provisions of this Ordinance within 12 months from the date of entry of this Ordinance into effect.

Article 15

As of the date of entry of this Ordinance into effect, the Ordinance on the conditions for granting permits for specialised retail sales outlets for the retail sale of medicinal products (Official Gazette 134/08 and 119/10) shall cease to have effect.

Article 16

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

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Zagreb, 1 October 2014

Minister

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