Conditions and procedure for storage and transportation of medicinal products

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This Regulation is established on the basis of subsection 34 (5) of the Medicinal Products Act (RT I 2005, 2, 4).

§ 1. General provisions

(1) This Regulation establishes the requirements for the storage and transportation of medicinal products by enterprises and authorities engaged in the handling of medicinal products (hereinafter enterprise engaged in the handling of medicinal products). The requirements of this Regulation shall not be applied to medicinal products for personal use.

(2) For the purposes of this Regulation, the following definitions shall be used:
1) room temperature – +15...+25 C°;
2) cool – +8...+15 C°;
3) cold – +2...+8 C°;
4) storage facility for medicinal products (hereinafter storage facility) – any room or place where medicinal products are stored.

§ 2. General requirements for storage of medicinal products

(1) In all enterprises engaged in the handling of medicinal products, a person responsible for the storage of medicinal products or, in his or her absence, his or her substitute shall be designated in writing by the head of the enterprise or a person appointed by the same.

(2) Holders of an activity licence issued under the Medicinal Products Act for handling of medicinal products shall be allowed to store medicinal products only in the places of business specified in the activity licence for handling of medicinal products.

(3) Work procedure rules shall be established by the head of the enterprise engaged in the handling of medicinal products or a person appointed by the same for the storage and transportation of medicinal products, specifying:
1) the place of storage of medicinal products, separately specifying the different storage conditions required for different medicinal products;
2) temperature range in the storage facility;
3) temperature measuring equipment;
4) locations of thermometers, recording of temperatures;
5) frequency of and methods for verification and calibration of the equipment;
6) rules of procedure for cases where the storage conditions fail to comply with the established requirements;
7) frequency of and methods for checking the alarm system, if an alarm system is available;
8) maintenance of temperature regulation equipment;
9) restriction of third-party access;
10) storage of medicinal products during transportation.

(4) Third-party access to medicinal products shall be prevented.

(5) Storage conditions shall ensure the preservation of medicinal products, without affecting the quality of medicinal products or causing contamination of medicinal products.

(6) When storing medicinal products, the following shall be physically separated and appropriately labelled:
1) narcotic drugs and psychotropic substances or medicinal products containing the same;
2) veterinary medicinal products;
3) aromatic substances;
4) colouring matter;
5) flammable and explosive substances;
6) unusable medicinal products (defective medicinal products, expired medicinal products, medicinal products the dispensing of which has been terminated);
7) samples of medicinal products;
8) investigational medicinal products;
9) medicinal products received as foreign aid;
10) medicinal product, which raises concerns with regard to the requisite quality of the medicinal product due to its accompanying documents or other reasons (including falsified medicinal products);
11) medicinal product without accompanying documents.

7) In addition, enterprises holding an activity licence for handling of medicinal products shall physically separate and appropriately label the following:
1) incoming medicinal products until completion of a delivery inspection;
2) medicinal products without accompanying information in Estonian.

8) Instead of labelling the medicinal product itself, the place of storage of the medicinal product may be labelled (room, shelf, etc.).

9) Stable humidity and temperature levels shall be maintained in the storage facility. At room temperature, relative humidity shall not exceed 60 %. A room in which medicinal products are stored shall be fitted with a thermometer or another temperature recording device and, in enterprises engaged in the handling of medicinal products, a hygrometer. A refrigerator in which medicinal products are stored shall be fitted with a thermometer.

10) Thermometers and hygrometers shall be installed away from any heating element, at a height of at least 1.5 metres from the floor, at a distance of 2 to 3 metres from any doors that lead outside, and in one or several locations, depending on the size of the room. Thermometers and hygrometers shall have an optimal scale and be installed in a suitable position.

11) Enterprises engaged in the manufacture of medicinal products and enterprises engaged in the wholesale distribution of medicinal products shall fit their place of storage of medicinal products with a temperature recording device or another device which would allow to check whether the temperature has been maintained at the required level over a certain period of time, or provide another solution which would allow to achieve similar results (e.g. enhanced frequency of monitoring).

12) Storage conditions shall be checked on a daily basis in all storage facilities and refrigerators. Temperature levels shall be monitored in different sections of the storage facility and the refrigerator. All checks shall be documented and the documents preserved for a period of at least one year.

13) During the period of storage, the condition of the packaging of medicinal products and changes in the appearance of medicinal products shall be monitored. Should any changes occur in the appearance of the medicinal product, the compliance of the medicinal product with the quality requirements shall be checked.

14) Work arrangement within the enterprise engaged in the handling of medicinal products shall ensure that the medicinal products with the earliest expiry date are dispensed in the first order.

15) Medicinal products shall be stored on the conditions established by the manufacturer or marketing authorisation holder.

16) Medicinal products shall be stored in the manufacturer's or preparer's packaging. If the packaging of the medicinal product or the package leaflet does not contain notations regarding special conditions, the medicinal product shall be stored at room temperature.

17) Thermolabile medicinal products shall be stored in a cold room or refrigerator which maintains the required temperature level.

18) A refrigerator intended for storage of medicinal products may not be used for storing foodstuffs intended for personal consumption.

19) Photosensitive medicinal products shall be stored in a light-tight packaging, closed locker or dark room. An extra layer of light-tight packaging shall be used, if necessary.

20) Volatile and moisture-sensitive medicinal products shall be stored in a cool area, tightly closed. Highly hygroscopic substances shall be stored in a dry room, in hermetically sealed glass or plastic packaging, with the stopper coated in paraffin wax, if necessary.

21) Aromatic substances and colouring matter shall be stored in separate lockers, in tightly closed packaging.

22) Herbal substances shall be stored in a dry, well-ventilated room. Glass jars, paper bags, wooden, plastic or other packaging is suitable for storing herbal substances. Herbal substances containing essential oils shall be stored in tightly closed packaging.
(23) Disinfectants shall be stored separately from medicinal products and other pharmaceutical products. Disinfectants shall be sealed hermetically and stored in a cool and light-tight environment, unless otherwise specified by the manufacturer.

(24) Flammable and explosive substances shall be stored in a separate room. In pharmacies, health care institutions and social welfare institutions, ethyl alcohol and ethyl ether may be stored in a metal locker. Up to 3 kg of ethyl alcohol and 0.5 kg of ethyl ether may be stored in a locker the inside of which is coated with tin. Ethyl alcohol in bottles of 0.5 kg may be stored in a rotating or standard locker.

(25) Acid and alkali shall not be stored together with flammable and explosive substances.

(26) A separate place shall be designated for unusable medicinal products.

§ 3. Requirements for place of storage

(1) A holder of an activity licence for manufacture or wholesale distribution of medicinal products shall designate a separate room for storage of medicinal products; a holder of an activity licence for provision of pharmacy service shall designate a separate room or a room section for the storage of medicinal products. In other enterprises engaged in the handling of medicinal products, a separate lockable room or locker shall be designated for the storage of medicinal products.

(2) The storage facility shall allow rational positioning of medicinal products and unhindered access to goods. The walls, floor and ceiling of the storage facility shall be smooth, with the interior finishing allowing damp-cleaning. The fittings shall be of easily cleanable material.

(3) The storage facility shall be well-ventilated, clean and free of pests. Pest control shall be carried out, if necessary. Pest control shall be documented (date, method, person carrying out the pest control).

(4) Central heating or stationary electric heating is recommended for the storage facility. Where stove heating is used, the mouth of the stove shall open outside the storage facility.

(5) Enterprises engaged in the manufacture of medicinal products and enterprises engaged in the wholesale distribution of medicinal products shall use central heating or stationary electric heating in their storage facility.

(6) The storage facility shall be equipped with an alarm system.

(7) The storage facility shall accommodate any number of shelves, lockers or pallets required for the storage of medicinal products. Medicinal products are not allowed to be stored directly on the floor. Shelves and pallets shall be positioned at least 10 cm above the floor.

(8) Medicinal products shall be positioned away from heating elements in order to secure the required storage temperature.

(9) The storage facility shall be well-lit. The luminous intensity shall be a minimum of 200 lx, if daylight fluorescent lamps are used, and a minimum of 80 lx, if electric filament lamps are used.

(10) The storage facility for flammable and explosive substances shall comply with the design requirements, be dry and fitted with mechanic ventilation. The storage facility shall be isolated from the neighbouring premises via walls and doors made of non-combustible material. The storage facility shall be equipped with special-purpose lighting and fittings made of non-combustible material. Electric switches shall be positioned outside the storage facility.

§ 4. Transportation of medicinal products

(1) The transportation of medicinal products shall be handled in such a way as to maintain the quality of medicinal products, prevent contamination of medicinal products and avoid failure of the packaging and loss of possession of medicinal products. Unsuitable temperature, humidity, lighting and other conditions shall be avoided.

(2) The transport packaging of medicinal products requiring special conditions shall bear the corresponding label regarding the conditions of transportation.

(3) To maintain the quality of thermolabile medicinal products, the required temperature levels shall be maintained during the entire period of transportation. The temperature conditions during the period of transportation shall be checked upon delivery.

(4) The transportation of medicinal products shall be organised in such a way as to avoid the freezing of medicinal products, unless otherwise specified by the manufacturer or marketing authorisation holder.
transportation of flammable and explosive substances shall be governed by the transportation requirements established for such substances.

(5) Accompanying documents shall be provided for the transportation of medicinal products.

§ 5. Entry into force of the Regulation

This Regulation shall enter into force on 1 March 2005.

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