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# Conditions and procedure for the provision of pharmacy services

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This regulation is enacted in accordance with section 31(6)(3) of the Medicinal Products Act of the Republic of Estonia.

## Chapter 1
## GENERAL PROVISIONS

### § 1. General provisions

This regulation establishes the requirements applicable to the enclosed premises, furnishings, technical equipment, personnel, work arrangements and records of general pharmacies, veterinary pharmacies and hospital pharmacies and their units (hereinafter, 'pharmacies'), to the pharmacies' reports regarding medicinal products and to the distance selling of medicinal products.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

## Chapter 2
## REQUIREMENTS FOR ENCLOSED PREMISES, FURNISHINGS AND TECHNICAL EQUIPMENT

### § 2. General requirements for enclosed premises

(1) A pharmacy must have at least the following rooms:
1) the sales area;
2) the preparation rooms (if the pharmacy prepares or divides up medicinal products into packages);
3) the storage room(s) (if necessary);
4) the personnel room(s);
5) the toilet.

(2) The preparation rooms comprise auxiliary rooms, washing rooms, sterilisation sections and dividing-up rooms.
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]

(3) The sterilisation section is composed of the airlock, the auxiliary room of the sterilisation section and the sterilisation room.

(4) Where a pharmacy is subject to the obligation to prepare medicinal products, the pharmacy must have an auxiliary room and a washing room.

(5) Where a general pharmacy or veterinary pharmacy that is not subject to the obligation to prepare medicinal products divides up medicinal products into packages, the pharmacy must have a dividing-up room and a washing room. The washing room may be part of the dividing-up room.

($5^1$) The personal dividing-up of medicinal products (hereinafter, 'personal dividing-up') using a machine must take place in a separate room or a separate section in a dividing-up room or in an auxiliary room.
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]

(6) A pharmacy may be located in a residential building, provided that the entrance to the pharmacy is separated from the residents' entrance. Pharmacies located in rural areas may share an entrance with the residents with the written consent of all apartment owners or of the general meeting of the apartment association.

(7) Where the pharmacy is located higher than on the first floor, visitors must have the option of using the elevator.

(8) The enclosed premises of a pharmacy must be separated from the surrounding enclosed premises by floor-to-ceiling partition walls. The sales area, preparation rooms and storage room(s) must form a single suite. This suite must contain at least one personnel room or a separate section containing the workplace of the manager of the pharmacy and a place for the storage of documents. Any additional rooms that the pharmacy has for personnel as well as for the storage of archives, tools, packaging and other items not required for its everyday work may be located separately.

(9) The floor of the sales area and preparation rooms may not be located lower below the ground surface than by half of the height of the area or rooms. The personnel, storage and additional rooms may be located in the basement.

(10) Pharmacy rooms must be used according to their intended purpose.

(11) Use of the rooms and hallways of the pharmacy as a thoroughfare may only be allowed to the personnel of the pharmacy. The presence of unauthorised parties in the preparation and storage rooms is not allowed.

(12) The layout plan of the enclosed premises of the pharmacy must be submitted to the State Agency of Medicines for review prior to the commencement of any construction work on or modification of the layout of the premises.

**§ 3. Sales area**

(1) The sales area is a separate room or a separate section of the room in which visitors are served. The sales area is to be fitted out with the furniture required for serving visitors and for storing medicinal products. The furnishings must be laid out such that pharmacy employees would not have to pass through the visitor section of the sales area in order to gain access to other enclosed premises of the pharmacy from the sales area.

(2) In a hospital pharmacy, the function of the sales area is fulfilled by the room or the separate section of a room for accepting orders, for storing medicinal products prepared for dispensation to the departments, and for dispensing the medicinal products. This room or section may not be used as a storage room.

**§ 4. Preparation rooms**

(1) Preparation rooms must be completely separated from other enclosed premises by walls and doors. The auxiliary room, the auxiliary room of the sterilisation section, the dividing-up room and the washing room must not allow for use as a thoroughfare.

(2) The auxiliary room may only be used for the preparation, dividing-up and inspection of medicinal products and of toiletry products and products that serve a medical purpose.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(3) The dividing-up room may only be used for the dividing up of medicinal products and of toiletry products and products that serve a medical purpose into packages, and, if necessary, for the washing of pharmacy utensils.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(4) The washing room may only be used for the washing and sterilisation of pharmacy utensils.

(5) The auxiliary room, washing room and dividing-up room may also be used for the purification (distillation) and testing of water.

(6) The windows and doors of preparation rooms must be kept closed at all times.

**§ 5. Storage room**

The storage room(s) is/are separate room(s) or separate section(s) of the room(s) in which it must be possible to ensure the conditions required for the appropriate storage of medicinal products.

**§ 6. Personnel room**

The personnel rooms are intended for the storage of documents, of the outerwear and uniforms of the personnel, as well as for having meals and resting, if necessary.

**§ 7. Total floor area of the pharmacy**

(1) In a town whose population is 4,000 or more or in a city that is not part of a rural municipality, the floor area of a general pharmacy must be at least 80 $m^2$in other settlements at least 50 $m^2$.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(2) The floor area of the branch pharmacy of a general pharmacy must be at least 25 $m^2$.
[RT I, 12.07.2014, 167 – entry into force 09.06.2019]

(3) As an exception, the floor area of a general pharmacy may be less than 50 $m^2$if the general pharmacy is located in the security control area of an airport or if the general pharmacy is located in a settlement other than a town whose population is 4,000 or at a distance that is greater than 5 km from the nearest pharmacy in a town that is part of a rural municipality or if the transport connection to the nearest pharmacy is poor, and on condition that the quality of the service provided by the pharmacy is not compromised due to the reduction of the floor area.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(4) As an exception, the floor area of a branch pharmacy may be less than 25 $m^2$if the branch pharmacy is located in the security control area of an airport or if the branch pharmacy is located at a distance that is greater than 5 km from the nearest pharmacy or if the transport connection to the nearest pharmacy is poor, and on condition that the quality of the service provided by the pharmacy is not compromised due to the reduction of the floor area. If the branch pharmacy prepares or divides up medicinal products into packages, it is subject to the requirements applicable to the floor area of the general pharmacy.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(5) If a veterinary pharmacy or its branch pharmacy divides up medicinal products into packages, the floor area of the pharmacy must be at least 50 $m^2$. The floor area of a veterinary pharmacy or of the branch pharmacy of a veterinary pharmacy that does not divide up medicinal products into packages must be at least 30 $m^2$.

(6) The floor area is composed of the area of the enclosed premises located within the pharmacy suite.

**§ 8. Floor area of rooms**

(1) The floor area of the sales area must be at least:
1) 30 $m^2$in a general pharmacy located in a city whose population is 4,000 or more or in a city that is part of a rural municipality;
2) 20 $m^2$in a general pharmacy located in other settlements, except in the cases referred to in section 7(3);
3) 15 $m^2$in a veterinary pharmacy and its branch pharmacy;
4) 15 $m^2$in the branch pharmacy of a general pharmacy, except in the cases referred to in section 7(4);
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(2) The floor area of the preparation rooms must be at least:
1) 5 $m^2$for the auxiliary room and 9 $m^2$if the personal dividing-up room referred to in section forms a part of the auxiliary room;
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]
2) 4 $m^2$for the washing room;
3) 5 $m^2$for the dividing-up room, augmented by the least required floor area of the washing room or personal dividing-up room if one of these forms a part of the dividing-up room;
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]
$3^1$) 4 $m^2$for the personal dividing-up room;
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]

4) in the sterilisation section — 3 $m^2$ for the airlock, 5 $m^2$ for the auxiliary room and 8 $m^2$ for the sterilisation room.

(3) Hospital pharmacies are subject to the requirements established in regard to preparation rooms.

**§ 8[1]. Pharmacy bus**

(1) In a pharmacy bus, it must be possible to serve the clients inside the bus and access must be provided to persons with a mobility disability.

(2) The schedule of the pharmacy bus and the times and locations when and where the pharmacy bus provides its service must be clearly displayed on the bus such that this information would also be visible from the outside.

(3) Preventive measures must be in place to exclude the access, including outside the working hours, of unauthorised persons to the pharmacy bus and the medicinal products inside.

(4) The State Agency of Medicines publishes on its website the information regarding the pharmacy buses, their travelling schedule and the times and locations at which they provide their services.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

**§ 9. Requirements for furnishings and technical equipment**

In order to comply with the requirements arising from the legislation governing the handling of medicinal products, the pharmacy must have:
1) the furnishings, working equipment and other technical equipment as needed;
2) security measures (including a security alarm system);
3) the telephone.

# Chapter 3
# REQUIREMENTS FOR THE PHARMACY PERSONNEL AND WORK ARRANGMENTS

**§ 10. Requirements for personnel**

(1)The work of a general pharmacy, hospital pharmacy or veterinary pharmacy (hereinafter, ‘main pharmacy’), including that of any unit of the pharmacy, is managed and supervised by the manager of that pharmacy.
(2) The work of a general pharmacy, hospital pharmacy or veterinary pharmacy (hereinafter, ‘main pharmacy’), including that of any unit of the pharmacy, is managed and supervised by the manager of that pharmacy.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(3) The manager of the main pharmacy must appoint, in writing, the person(s) to act as substitute(s) for him or her, except where the pharmacy has no other employee who possesses the relevant specialised education.

(4) The manager of the main pharmacy must assign responsibility for the activities of a pharmacy unit to a person who must possess an education in the field of pharmacy; the person assigned responsibility for a unit of a veterinary pharmacy may also possess the education of a veterinarian.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(5) A job description must be prepared for each employee of the pharmacy. The job description is a written document in which the manager of the pharmacy establishes the employee’s duties and sphere of responsibility.

**§ 11. General requirements for work arrangements**

(1) Information regarding the name and business hours of the pharmacy must be displayed in front of the entrance to the pharmacy. In a branch pharmacy, the information must include the business hours and a reference to the fact that the pharmacy is a branch pharmacy, also stating the name of the general pharmacy or veterinary pharmacy that established the branch pharmacy.

(2) Where a pharmacy is open 24 hours a day in a city or county, a notice must be displayed outside stating the name and location of the pharmacy.

(3) The State Agency of Medicines must be immediately notified of any changes in the business hours or contact information of the pharmacy (telephone, fax, e-mail address).

(4) In the case of closure, including temporary closure, of a general pharmacy or veterinary pharmacy or their branch pharmacy, the written notice to consumers shall contain information on the duration of the closure of the pharmacy as well as the location and business hours of the nearest pharmacy or pharmacies.

(5) The State Agency of Medicines and consumers shall be notified at least five days in advance of any scheduled closure of the pharmacy for more than one week.

(6) The State Agency of Medicines must be notified without delay of any forced entry into the pharmacy, any theft or loss of medicinal products or prescriptions or any counterfeit or presumably counterfeit medicinal products or prescriptions.

(7) The work arrangements of hospital pharmacies are subject to subsections 3, 5 and 6 of this section.

**§ 12. Requirements for the provision of pharmacy services**

(1) All employees of the pharmacy must bear a name badge, showing the name and (in case of a specialised education) position (assistant pharmacist, pharmacist, veterinarian) of the employee. The status of a trainee must be specified separately.

(2) Medicinal products not subject to medical prescription may be displayed in the sales area, grouped according to their pharmacological function or therapeutic indication. Medicinal products subject to medical prescription may not be visible to visitors.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(3) Where veterinary medicinal products are dispensed at the pharmacy by a veterinarian, the veterinarian must have a separate point of sale which is marked accordingly.

(4) Medicinal products for human use that are dispensed for veterinary use are received by the veterinarian from an assistant pharmacist or pharmacist.

(5) Medicinal products dispensed for veterinary use must be marked with words Ainult veterinaarseks kasutamiseks [for veterinary use only]. For the aforementioned marking, a printed sticker or a stamp may be used, which may not cover important information on the original labelling that is required for identification of the medicinal product, including the batch number and shelf life.

(6) Where a medicinal product subject to medical prescription is dispensed by a trainee, the prescription or shipment document must bear, in addition to the signature of the trainee, the signature of his or her supervisor.

(7) Where additional steps (e.g., dissolving) are required for the administration of a medicinal product, the person dispensing the medicinal product must explain this to the buyer of the medicinal product, offer the corresponding service and, if the customer so desires, prepare the medicinal product for administration.

(8) The pharmacy must document any complaints filed with respect to medicinal products or the provision of pharmacy service, recording the particulars of the person filing the complaint, the medicinal product, the nature of the complaint and the circumstances related to the complaint. The steps taken to resolve the complaint at the pharmacy must be documented.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(9) [Repealed – RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(10) [Repealed – RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(11) The pharmacy that prepared the medicinal products dispenses those products together with a cover document which must contain at least the following information:
1) the name and address of the pharmacy that ordered the medicinal product;
2) the name and address of the pharmacy that prepared the medicinal product;
3) the number of the prescription, and number or date of issue of the order form;
4) the date of dispensation of the medicinal product;
5) the price of the medicinal product;
6) the signatures of the persons dispensing and receiving the medicinal product.

(12) The activities of a hospital pharmacy are subject to subsections 1, 5, 6, 8, 11 of this section.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

**§ 12[1]. Requirements for distance sale of medicinal products**

(1) The website used for the distance sale of medicinal products must clearly and visibly display the following information:
1) the name of the general pharmacy and the address of its place of business, the business name of the holder of the activity licence for the provision of pharmacy services and the number and term of validity of the activity licence;

2) the contact information of the State Agency of Medicines and a hyperlink to the webpage of the State Agency of Medicines that displays the list of pharmacies engaged in distance sale of medicinal products and other information concerning the distance sale of medicinal products;
3) the terms and conditions for the ordering and delivery of medicinal products, including the time required for the confirmation of orders, the methods of delivery of medicinal products and the amount of the shipping fee;
4) the options for receiving advice on medicinal products;
5) references to package leaflets that have been published on the website of the State Agency of Medicines;
6) information stating that no refund is possible for dispensed medicinal products and that dispensed medicinal products will only be accepted by the pharmacy for the purpose of destruction.

(2) Logs recording the operations carried out in relation to the distance sale of medicinal products must be preserved, including logs recording the operations carried out by technical support. The logs must be preserved for one year.

(3) The website used for the distance sale of medicinal products must list medicinal products subject to medicinal prescription, medicinal products not subject to medicinal prescription, veterinary medicinal products and other products such that they can be clearly distinguished and such that selections of medicinal products are compiled according to the name of the active substance.

(4) The website used for the distance sale of medicinal products may not display references or links designed for the preferring of particular proprietary medicinal products or for their ordering on terms and conditions other than the usual terms and conditions.

(5) The provider of pharmacy services ensures that distance sale orders of medicinal products not subject to medical prescription contain the age of the patient and an explanation regarding the patient's need for the medicinal product.

(6) The provider of pharmacy services ensures that distance sale orders of medicinal products subject to medical prescription contain only the number of the prescription.

(7) Free-of-charge individual advice by a pharmacist or assistant pharmacist as to the correct and safe use of the medical product and the preservation of the medicinal product must be ensured in connection to the distance sale of medicinal products. Such advising must take place before the confirmation of the order.

(8) When providing the advice, and on the website used for the distance sale of medicinal products, attention is to be drawn among other things to the need to carefully read the package leaflet before using the medicinal product, and it is to be recommended that the patient consult with a physician or pharmacist if the symptoms persist or if the medical product causes an adverse reaction.

(9) If the provider of pharmacy services who offers distance selling of medicinal products allows the option of refusing the advice by a pharmacist or assistant pharmacist, the person ordering the medicinal product must confirm, in order to refuse the advice, that he or she is aware of the option of receiving advice and of the correct and safe use and preservation of the medicinal product.

(10) The provider of pharmacy services who offers distance selling of medicinal products ensures the recording of the content of the order and of the advice in a format that can be reproduced and the preservation of that content for the duration of one year.

(11) Each distance selling order of medicinal products must be assigned an individual number that permits the particular order to be linked to the advice on medicinal products and the dispensation and delivery of the medicinal products.

(12) The distance selling of medicinal products must be conducive to the rational consumption of medicinal products. The provider of pharmacy services who offers distance selling of medicinal products must analyse the orders and, when suspecting misuse or abuse of medicinal products, establish restrictions on the dispensation of medicinal products. The provider of pharmacy services must without delay notify the State Agency of Medicines of the imposition of such restrictions.

(13) The provider of pharmacy services who offers distance selling of medicinal products must, for the purpose of arranging the delivery of medicinal products, enter into a written agreement with an undertaking who provides delivery services, which stipulates the obligations of the parties with a view to ensuring the preservation of the quality of medicinal products and their delivery to the correct recipient. If the provider of pharmacy services delivers the medicinal products to recipients itself, the arrangements for the shipping of medicinal products are described in the work procedure rules.

(14) The provider of pharmacy services who is engaged in distance selling of medicinal products must prepare a risk analysis regarding the arrangements concerning the delivery of medicinal products and the factors affecting it. On the basis of the results of the risk analysis, the provider of pharmacy services performs regular checks on the deliverer of the medicinal products and documents the results of such checks.

(15) The documents concerning the distance selling of medicinal products must be preserved following the procedure provided in section 20 of this regulation separately from other documents.

[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(16) The requirements set out in subsections 13–15 of this section are also applied to the provision of the service of delivery of medicinal products referred to in section 31($5^7$) of the Medicinal Products Act.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

**§ 13. Work procedure rules and persons responsible for operations that affect the quality of and that are related to the handling of medicinal products**

(1) All pharmacies and their units must have written internal work procedure rules concerning operations that affect the quality of and related to the handling of medicinal products.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(2) The work procedure rules must describe in detail the following operations, the documenting of those operations and the preservation of the documentation:
1) the ordering of medicinal products, including the ordering of medicinal products that, under the Health Insurance Act, are subject to a price limit and with regard to which a price agreement has been concluded, the ordering of unauthorised medicinal products, and the shipping arrangements connected to the ordering of medicinal products;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
2) the receipt of medicinal products, including decisions concerning their pricing;
3) the storage of medicinal products and verification of the storage conditions;
4) the restriction of access to medicinal products by unauthorised persons;
5) the handling of narcotic drugs and psychotropic substances as well as of medicinal products containing such substances;
6) the preparation and dividing-up of medicinal products into packages;
7) the quality verification of prepared and divided up medicinal products;
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]
8) the preparation and testing of purified water;
9) the washing and sterilization of pharmacy utensils;
10) [Repealed – RT I, 10.05.2013, 1 – entry into force 13.05.2013]
11) the dispensation of medicinal products, including dispensation of unauthorised medicinal products and dispensation on the basis of order forms;
$11^1$) the arrangements for the distance selling of medicinal products, including the shipping arrangements;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
$11^2$) the arrangements for the delivery of medicinal products, in relation to the provision of the service of delivery of medicinal products referred to in section 31($5^7$) of the Medicinal Products Act.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]
12) the dispensation of medicinal products to the units of the pharmacy, including the shipping arrangements;
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]
13) the withdrawal of medicinal products from the market and their further handling, including the handling of medicinal products received from consumers for destruction;
14) the suspension of dispensation of medicinal products, the termination of dispensation and the recalling of medicinal products;
15) the handling of returned medicinal products;
16) the keeping of records of medicinal products and the preparation of reports regarding medicinal products;
17) the adherence by the pharmacy to health protection requirements, including the cleaning and maintenance of pharmacy rooms and equipment;
18) pest control on the enclosed premises of the pharmacy;
19) the processing of complaints;
20) the dissemination of advertisements of medicinal products on the enclosed premises of the pharmacy;
21) the performance of the internal audit.

(3) The work procedure rules may also describe other activities that involve the handling of medicinal products and that have not been listed in subsection 2 of this section.

(4) The work procedure rules must be up to date, signed and dated by the manager of the pharmacy. Previous versions of the work procedure rules must be preserved for a period of at least two years.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(5) The manager of the main pharmacy must appoint, in writing, the employee in charge of each operation and the substitute of that employee, except where the pharmacy only has a single employee who possesses the education required for the provision of pharmacy services.

(6) Employees must be familiar with the work procedure rules and legislation that their job duties are based on. The legislation regulating medicinal products and the work procedure rules must be available to employees at the pharmacy on a permanent basis.

(7) The manager of the pharmacy must provide information to the employees concerning the work procedure rules and the legislation referred to in subsection 6 of this section, and must, amongst other things, without delay provide information concerning any amendments to such rules or legislation. Employees must declare that they have obtained information concerning the work procedure rules and the relevant legislation by stating the relevant date and affixing their signature.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

**§ 14. The documenting of operations related to the handling of medicinal products**

(1) The documenting required under the legislation regulating medicinal products must take place during the execution or immediately upon the completion of the operation, unless otherwise provided in the relevant legislation. The operation must be documented by the person who executed the operation.
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]

(2) Any rectifications in the documentation must be dated and signed by the person who made those corrections such that the original entry remains visible and, where applicable, stating the reason for the rectification.

(3) The requirements set out in subsections 1 and 2 must also be observed when documenting an operation by electronic means.

**§ 15. Reception of medicinal products at the pharmacy**

(1) A separate location suitable for the purpose must be established for the reception of medicinal products.

(2) The persons authorised to conduct delivery inspections and to make pricing decisions must be appointed by the pharmacy in writing.

(3) Upon receiving a delivery of medicinal products, an inspection of the received products must be performed to ascertain the following:
1) the existence, formalization and correspondence to the product batch of the shipment documents and, where necessary, of the quality verification documents (certificates of quality);
2) the correspondence of the number and labelling of the packages to the shipment documents;
3) the shelf life expiration dates;
4) the storage conditions;
5) the existence of information in Estonian (outer package information in Estonian and information in Estonian on the package leaflet).

(4) The person who performs the inspection of the received consignment of medicinal products confirms the performance of that inspection by stating the date and affixing his or her signature on the cover document or on the memorandum of receipt of the goods.

(5) The starting materials used in the preparation or dividing-up of medicinal products into packages must be accompanied by a quality certificate. If there is cause to doubt the quality or identity of the starting material, this must be immediately notified to the State Agency of Medicines. In such cases, the starting material may only be used after the State Agency of Medicines has given the corresponding permission.

(6) The pharmacy may not accept medicinal products for the purpose of re-dispensation from persons who do not hold an activity licence for the manufacture of medicinal products, for wholesale trade in medicinal products, or for the provision of pharmacy services.

(7) Unpackaged herbal substances may also be purchased from persons who do not hold any of the activity licences referred to in subsection 6. In such cases, responsibility for the quality of the herbal substances lies on the pharmacy.

(8) The purchase and selling price of medicinal products must be documented and approved by the pharmacy employee who set or verified that price by stating the relevant date and affixing his or her signature. This requirement does not apply to hospital pharmacies.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

**§ 16. Storage of medicinal products at the pharmacy**

(1) As of the moment that medicinal products arrive at the pharmacy, the pharmacy is responsible for preserving the quality of those products.

(2) Medicinal products must be stored following the procedure established in accordance with section 34(5) of the Medicinal Products Act

(3) Medicinal products whose dispensation is only allowed at the request of a physician or veterinarian as well as other unauthorised medicinal products must be stored separately, must bear the relevant markings or be subject to other efficient measures ensuring their distinguishability.

**§ 17. The handling of defective medicinal products**

(1) When defective medicinal products are discovered, the defects must be documented, recording the information regarding the medicinal product, marketing authorisation holder, intermediary, the nature of the defect, circumstances related to the defect or the cause of the defect and further handling (storage, destruction, return to the supplier, etc.) of the defective medicinal product.

(2) The State Agency of Medicines must be immediately notified of any defective or presumably defective medicinal products discovered at the pharmacy. Notification is not required if it is clear that the defect was caused by incorrect handling at the pharmacy or during the shipping.

**§ 18. Suspension or termination of the dispensation of medicinal products and the recalling of medicinal products**

(1) The pharmacy must establish a system for the suspension or termination of the dispensation of medicinal products or for the recalling of dispensed medicinal products (hereinafter, 'restrictions on dispensation') in cases where:
1) the medicinal product is defective or is presumed to be defective or is counterfeit;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]
2) it turns out that an incorrect or expired medicinal product has been dispensed;
3) the corresponding order is given by the State Agency of Medicines, the manufacturer of the medicinal product, the wholesaler or the marketing authorisation holder.

(2) The State Agency of Medicines must be immediately notified of any restrictions on dispensation that have been introduced on the initiative of the pharmacy.

(3) Recalled medicinal products and medicinal products whose dispensation has been terminated must be identified and stored separately such that their dispensation is excluded until the decision is taken regarding their further handling.

(4) The restrictions on dispensation must be documented, including a description of the reasons for those restrictions and of subsequent actions, and a list must be prepared of persons who were notified of the restrictions. The inventory quantity of the medicinal product at the pharmacy and at any unit of the pharmacy must be recorded as of the moment of the establishment of the restriction on dispensation and the recalling of the medicinal product up to the determined level must be arranged. The data contained in the documentation must make it possible to identify the medicinal product.

**§ 19. Internal audit**

(1) At least once a year, the pharmacy must conduct an internal audit to monitor, with respect to the pharmacy and its units, the implementation of and compliance with the requirements established in legislation and the adherence to work procedure rules and job descriptions, and to make proposals concerning any measures to be taken.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(2) The internal audit must be formalised as a report. The report must state the audit findings and the proposals concerning any measures to be taken. The auditors must date and sign the report.

(3) Once a year, the pharmacy must perform an inventory of the medicinal products, specifying in the inventory report the name of the medicinal product, the strength of the active substance, the quantity in a package, and the number of packages. The results of the inventory must be submitted to the State Agency of Medicines upon the Agency's demand.

(4) The data of the last inventory must be available on site at the pharmacy and the unit of the pharmacy.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

**§ 20. Preservation of documents**

(1) Documents reflecting the receipt, dispensation and the keeping of records on medicinal products as well as their source documents (shipment documents, quality certificates, etc.) and prescriptions must be available on site at the pharmacy or the unit of the pharmacy at least until the completion of the marketing of the batch.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(2) The documents and prescriptions referred to in subsection 1 must be preserved by the pharmacy for at least three years after the date of dispensation of the medicinal product. Documents concerning any restriction on the dispensation of a medicinal product must be preserved for at least two years after the establishment of the restriction. Documentation concerning the preparation and dividing-up of medicinal products must be preserved for at least two years as of the date of the preparation or dividing-up of those products. Documentation

concerning the materials and equipment used in the preparation and dividing-up of medicinal products must be preserved for at least two years after the discontinuation of the use of the particular material or piece of equipment. Documentation concerning any irregularities, mistakes or complaints and any activities related to these must be preserved for at least 5 years after the drawing up of the document.
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]

(3) The shipment documents received in an electronic format from the wholesaler may be preserved in the electronic format, provided that a hard copy of the instrument of delivery and receipt of the goods is available that contains all of the particulars that must be shown in a wholesale cover document. Cover documents transmitted in the electronic format must be available on site at the pharmacy and must be reproducible.

(4) Where a unit of the pharmacy orders goods directly from the wholesaler, a copy of the cover documents must also be available at the main pharmacy, kept separately from the cover documents of the main pharmacy. The cover documents that concern goods received by the unit of the pharmacy from the wholesaler and that are in an electronic format may also be available at the main pharmacy in an electronic format.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

# Chapter 4
# RECORDS AND REPORTS

### § 21. The keeping of records on medicinal products

(1) The dispensation of medicinal products subject to medical prescription by the general pharmacy and veterinary pharmacy must be reflected in the records that are kept concerning prescriptions and that contain the following information:
1) the number of the prescription or the prescription's registration number assigned by the pharmacy, or both;
2) the name of the patient, in the case of a veterinary medicinal product the name of the owner of the animal;
3) the name of the medicinal product dispensed;
4) the content of the active substance;
5) the quantity in a package and the number of packages;
$5^1$) the serial number of the medicinal products prepared or divided up as officinal formulae at the pharmacy;
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]
6) the retail price of the medicinal product;
7) the date of dispensation.

(2) Information regarding the dispensation of a medicinal product is recorded immediately upon dispensation by the person who dispensed the medicinal product.

(3) Records must be kept concerning unauthorised medicinal products. The receipt of unauthorised medicinal products must be registered (the name of the medicinal product, its quantity, supplier, date of receipt). These records may be kept either in an electronic format or on paper. Prescriptions and order forms for unauthorised medicinal products must be stored separately from the prescriptions and order forms for other medicinal products in the general pharmacy and veterinary pharmacy as well as in their units.
[RT I, 12.07.2014, 167 – entry into force 15.07.2014]

(4) The hospital pharmacy must keep records on all medicinal products. If records are not kept electronically, the keeping of records is based on the receipt and dispensation documents of the medicinal products.

### § 22. The keeping of records on narcotic drugs and psychotropic substances

[Repealed – RT I, 11.12.2014, 10 – entry into force 14.12.2014]

### § 23. The keeping of records on medicinal products prepared as officinal formulae, on the dividing-up of medicinal products into packages, on medicinal products prepared as magistral formulae and on the quality control

[Repealed – RT I, 11.12.2014, 10 – entry into force 14.12.2014]

### § 24. The keeping of records on medicinal products withdrawn from the market

(1) The pharmacy must keep records on medicinal products withdrawn from the market.

(2) The records must contain the following information:
1) the name of the medicinal product;
2) the strength of the active substance;
3) the package size;
4) the number of packages;
5) the holder of the marketing authorisation or, in the absence of the latter, the manufacturer;
6) the batch number;
7) the reason for withdrawal from the market.

**§ 25. The keeping of records on medicinal products received as foreign aid**

(1) The pharmacy must keep records on medicinal products received as foreign aid.

(2) The records must contain the following information:
1) the name of the medicinal product;
2) the strength of the active substance;
3) the package size;
4) the number of packages;
5) the manufacturer;
6) the batch number;
7) the supplier;
8) the date of receipt.

**§ 26. Submission of reports**

(1) The main pharmacy must submit a report to the State Agency of Medicines four times in a year.

(2) The reports must be submitted to the State Agency of Medicines as follows:
1) the report on the first quarter by May 1 (reporting period: January 1 – March 31);
2) the report on the second quarter by August 1 (reporting period: April 1 – June 30);
3) the report on the third quarter by November 1 (reporting period: July 1 – September 30);
4) the report on the fourth quarter by February 1 (reporting period: October 1 – December 31).

**§ 27. Information to be presented in reports**

(1) The report of the general pharmacy must contain the following information in the following order:
1) the total turnover of the pharmacy;
2) the total turnover of medicinal products, listing separately the turnover of medicinal products for human use not subject to medical prescription, the turnover of medicinal products for human use subject to medical prescription, the turnover of medicinal products dispensed on the basis of prescriptions issued in a Member State of the European Union, a Member State of the European Economic Area or the Swiss Confederation (hereinafter 'EU prescription'), listing electronic and paper prescriptions separately, and the turnover of medicinal products dispensed for veterinary use;
[RT I, 20.11.2018, 4 – entry into force 23.11.2018]
3) the turnover of medicinal products dispensed at the discount rate, listing separately the part paid by the patient and the part paid by the Estonian Health Insurance Fund;
4) the turnover of medicinal products sold to institutions, listing separately the turnover of medicinal products sold to health care providers and social welfare institutions, and other institutions;
5) the number of prescriptions, listing separately the number of prescriptions issued for dispensation at the discounted price, the number of prescriptions issued without the discount, the number of EU prescriptions, listing electronic and paper prescriptions separately, the number of prescriptions of and order forms for medicinal products prepared as magistral formulae and the number of veterinary prescriptions;
[RT I, 20.11.2018, 4 – entry into force 23.11.2018]
6) the preparation and dividing-up of medicinal products into packages, listing separately the number of packages of medicinal products prepared as officinal formulae, the number of packages of medical products prepared as magistral formulae, the number of packages resulting from the dividing-up, the number of times personally divided-up medicinal products have been dispensed to patients and the number of patients using personally divided-up medicinal products, the fee for the preparation of medicinal products and the fee for the dividing-up of medicinal products into packages;
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]
7) the purchase price of the medicinal products sold;
8) the personnel data as of the end of the reporting period, listing separately the number of assistant pharmacists, pharmacists, veterinarians and other employees.

($1^1$) The report of a general pharmacy must contain the following separately presented information in relation to the distance sale of medicinal products in the following order:
1) the total turnover of distance sales;
2) the total turnover of medicinal products, listing separately the turnover of medicinal products for human use not subject to medical prescription, the turnover of medicinal products for human use subject to medical prescription, the turnover of medicinal products dispensed to another Member State of the European Economic Area and the turnover of medicinal products dispensed for veterinary use;
3) the turnover of medicinal products dispensed at the discount rate, listing separately the part paid by the patient and the part paid by the Estonian Health Insurance Fund;
4) the number of prescriptions, listing separately the number of prescriptions issued at a discount rate, number of prescriptions issued without a discount rate and the number of prescriptions of medicinal products prepared as magistral formulae;

5) the distribution of the turnover of medicinal products dispensed for human use by county and its administrative units (county towns and towns that are part of a rural municipality in the county combined, rural municipalities in the county combined), listing separately the turnover of medicinal products subject to medical prescription and the turnover of medicinal products not subject to medical prescription;
6) the total number of distance sale consignments dispatched;
7) the total of fees charged for the delivery of distance sale consignments.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(2) The report of a hospital pharmacy must contain the following information in the following order:
1) the total turnover of the pharmacy;
2) the total turnover of medicinal products;
3) the turnover of medicinal products sold outside the hospital that operates the hospital pharmacy;
4) the personnel data as of the end of the reporting period, listing separately the number of assistant pharmacists, pharmacists and other employees.

(3) The report of a veterinary pharmacy must contain the following information in the following order:
1) the total turnover of the pharmacy;
2) the total turnover of medicinal products, listing separately the turnover of medicinal products not subject to medical prescription and medicinal products subject to medical prescription;
3) the turnover of medicinal products sold to institutions, listing separately the turnover of medicinal products sold to veterinarians;
4) the number of prescriptions;
5) the dividing-up of medicinal products into packages, including the number of divided-up packages and the fee for the dividing-up;
6) the purchase price of the medicinal products sold;
7) the personnel data as of the end of the reporting period, listing separately the number of veterinarians, assistant pharmacists, pharmacists and other employees.

**§ 28. Report form**

(1) The report, signed by the manager of the pharmacy, is submitted to the State Agency of Medicines electronically via the web environment (client portal) of the State Agency of Medicines.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(2) The State Agency of Medicines publishes on its website the report form and the guidelines for filling out the form.

**§ 29. Termination of the provision of pharmacy services**

(1) When the holder of an activity licence for the provision of pharmacy services is dissolved or terminates the activities listed in the activity licence, the medicinal products held by the pharmacy must be delivered to the holder of an activity licence for the handling of medicinal products or to the person referred to in section 33(2) of the Medicinal Products Act, or withdrawn from the market within two months after the date of dissolution, unless otherwise established by the State Agency of Medicines, and the State Agency of Medicines must be informed in writing of the delivery or withdrawal.
[RTL 2010, 20, 365 – entry into force 24.04.2010]

(2) When the provision of pharmacy services is terminated, the manager of the pharmacy is responsible for maintaining the quality of the medicinal products until the completion of the delivery (including delivery for destruction), on-site destruction or returning of the medicinal products, and the holder of the activity licence for the provision of pharmacy services or the person appointed by the holder is responsible for the preservation of the corresponding cover documents.

(3) When the delivery of medicinal products is completed, a report must be submitted to the State Agency of Medicines in accordance with the procedure provided in section 27 with regard to the period following the last quarterly report.

# Chapter 5
# IMPLEMENTING PROVISIONS

**§ 30. Implementing provisions**

(1) Veterinary pharmacies that were in operation before the entry into force of this regulation are subject to the requirements provided in sections 2(1–9), 4(1), 7(5), 8(1)(3) and 8(2) of this regulation starting 1 March 2006.

(2) Hospital pharmacies that were in operation before the entry into force of this regulation are subject to the requirements provided in section 3(2) of this regulation starting 1 March 2006.

(3) This regulation enters into force on 1 March 2005.

(4) The information specified in section 27(1)(6) of this regulation concerning the number of dispensation times of personally divided-up medicinal products, the number of patients using personally divided-up medicinal products and the fee for the dividing-up of medicinal products into packages, required for the inclusion in the reports of general pharmacies, is to be collected for the first time with respect to services provided in the first quarter of 2015 and the first reports including this information must be submitted by 1 May 2015.
[RT I, 11.12.2014, 10 – entry into force 14.12.2014]