

Lecture No. 11.

Legal basis for the transition to the pharmaceutical market.

Privatization of pharmaceutical organizations.

Consumer rights protection system. Legislation of the Russian Federation on the protection of consumer rights.

An important document that regulates the relationship between the seller and the buyer is the Law of the Russian Federation N 2300-1 “On the Protection of Consumer Rights” dated 02/07/1992. Its effect also applies to the sale of pharmaceutical products.

Basic terms.

Consumer is a person who wants to purchase or purchases goods for personal needs and other needs that are not related to business activities.

Seller - an organization with any legal form or an individual entrepreneur who sells goods under a sales contract.

A defect in a product is the failure of a product to meet the requirements stipulated by law or the terms of the contract, the description at the time of sale, or the purposes for which the product is usually used.

Protection of consumer rights - measures that the state implements to regulate relations that arise between the seller and the consumer.

Deficiency of a product (work, service) is a non-compliance of the product (work, service) with the mandatory requirements provided for by law or in the manner established by it, or with the terms of the contract.

A significant defect of a product (work, service) is an irremovable defect or deficiency that cannot be eliminated without disproportionate costs or time, or is detected repeatedly, or appears again after its elimination.

Safety of a product (work, service) - the safety of a product (work, service) for life, health, consumer property and the environment under normal conditions of its use, storage, transportation and disposal, as well as the safety of the process of performing work (providing a service).

In accordance with the Law “On Protection of Consumer Rights” **Buyers** of pharmacy organizations **have the right:**

- purchase pharmacy products of appropriate quality, safe for life and health (Articles 4, 5, 6, 7);
- obtain information about pharmaceutical products, their suppliers and manufacturers (Articles 8, 9, 10);
- receive public and state protection of their interests.

For pharmacists, the most important article is Article 18, which defines the rights of a pharmacy client to return a product with hidden or visible defects. It allows buyers, when purchasing goods of inadequate quality, to demand:

- replace the product with a similar one, but without identified defects;
- replace the product with one similar in effect, but from a different manufacturer or brand;
- receive compensation for the difference between a defective product and its replacement;
- return the money that was paid for the defective product.

It should be remembered that medicines of proper quality, in accordance with Decree of the Government of the Russian Federation No. 2463 “On approval of the Rules for the sale of goods under a retail purchase and sale agreement...” dated December 31, 2020, are included in the list of goods that cannot be returned. This rule does not apply to low-quality medicines.

In accordance with the Decree of the Government of the Russian Federation No. 2463 “On approval of the Rules for the sale of goods under a retail purchase and sale agreement...”, general rules for the sale of goods under a retail purchase and sale agreement have been approved, which were developed in accordance with the Law of the Russian Federation “On the Protection of Consumer Rights” and regulate the relations between sellers and consumers when selling goods under a retail purchase and sale agreement, including relations between sellers and consumers when selling goods remotely.

At retail facilities (except for places that are determined by the seller and are not intended for free access by consumers), it is not permitted to restrict the rights of consumers to search and receive any information in any form from any source, including by photographing the product, unless such actions violate the requirements legislation of the Russian Federation and international treaties of the Russian Federation.

When selling goods, the consumer is given the opportunity to familiarize himself with the necessary goods independently or with the help of the seller.

The seller is obliged to ensure **the availability of price tags** for the goods sold, indicating the name of the goods, the price per unit of goods or per unit of measurement of the goods (weight (net weight), length, etc.).

When the seller sells goods that can be measured, the seller is obliged to use measuring instruments that are in good condition and comply with the requirements of the legislation of the Russian Federation on ensuring the uniformity of measurements.

In cases where these Rules provide for the seller's obligation to provide **the consumer with a cash or sales receipt**, such obligation is recognized as fulfilled also when sending a cash or sales receipt to the consumer using electronic and other technical means, unless otherwise provided by federal law.

When carrying out retail trade at the location of the consumer outside of retail facilities by directly familiarizing the consumer with the product (at home, at the place of work and school, in transport, on the street and in other places), the sale of food products **without consumer packaging** , as well as **medicines, is not allowed , medical products.**

The sale of goods is carried out using cash register equipment in accordance with the Federal Law "On the use of cash register equipment when making payments in the Russian Federation".

Rules for the sale of goods during the remote method of selling goods under a retail purchase and sale agreement

When selling goods remotely, the seller is obliged to enter into a retail purchase and sale agreement with any person who has expressed an intention to purchase the goods under the terms of the offer.

The seller's obligations to transfer the goods and other obligations related to the transfer of the goods arise **from the moment the seller receives the consumer's message** about the intention to enter into a retail purchase and sale agreement, unless the seller's offer contains another condition regarding the moment the seller becomes **obligated to transfer the goods to the consumer** .

A retail purchase and sale agreement is considered concluded from the moment the seller issues to the consumer **a cash or sales receipt or other document** confirming payment for the goods, or from the moment the seller receives a message from the consumer about the intention to conclude a retail purchase and sale agreement.

When selling goods remotely using the information and telecommunications network "Internet" (hereinafter referred to as the "Internet") and (or) programs for electronic computers, the seller provides the consumer with confirmation of the conclusion of a retail purchase and sale agreement on the terms of the offer, which contains the essential terms of this agreement, after the seller receives a message from the consumer about the intention to enter into a retail purchase and sale agreement.

This **confirmation must contain the order number** or another method of identifying the order, which allows the consumer to obtain information about the concluded retail purchase and sale agreement and its terms.

The seller or a person authorized by him has the right to familiarize the consumer who has entered into a retail purchase and sale agreement by remote means of selling goods with the purchased goods **before they are transferred to the consumer**.

When selling a product remotely, **the seller provides the consumer with complete and reliable information characterizing** the product offered by posting it on the website and (or) website page on the Internet, and (or) in a program for

electronic computers, and (or) in means of communication (television, postal, radio communications, etc.), and (or) in catalogues, booklets, prospectuses, photographs or other information materials.

Legal entities registered on the territory of the Russian Federation and engaged in the sale of goods by remote means of selling goods on the territory of the Russian Federation are required to indicate the full company name, main state registration number, address and location, email address and (or) telephone number.

Individual entrepreneurs registered on the territory of the Russian Federation and selling goods by remote means of selling goods on the territory of the Russian Federation are required to indicate their last name, first name, patronymic (if any), main state registration number, email address and (or) telephone number.

The specified information is communicated to the consumer by posting it on the website (if available) and (or) the website page on the Internet (if available), as well as in a program for electronic computers (if available).

The delivered goods are transferred to the consumer at the address specified by him, and in the absence of the consumer - to any person who provided information about the order number, or other (including electronic) confirmation of the conclusion of a retail purchase and sale agreement or placing an order, unless otherwise provided by the legislation of the Russian Federation or retail sales agreement.

If the delivery of the goods was made within the terms established by the retail purchase and sale agreement, but the goods were not transferred **to the consumer through his fault, subsequent delivery is made within a new time frame agreed with the seller, under the conditions stipulated by the retail purchase and sale agreement.**

The costs of returning the amount paid by the consumer in accordance with the retail purchase and sale agreement **for goods of inadequate quality are borne**

by the seller. In other cases, the distribution of these costs is determined by the offer.

The sale of medicinal products for medical use through the remote method of selling goods is carried out in accordance with the Rules for issuing permission to carry out retail trade in medicinal products for medical use remotely, carrying out such trade and delivering these medicinal products to citizens, approved by the Decree of the Government of the Russian Federation of May 16, 2020 N 697 "On approval of the Rules for issuing permission to carry out retail trade in medicinal products for medical use by remote means, carrying out such trade and delivery of these medicinal products to citizens and amending certain acts of the Government of the Russian Federation on the issue of retail trade of medicinal products for medical use by remote means. ".

List of

durable goods that are not subject to the consumer's requirement to provide him with a product with the same basic consumer properties free of charge for the period of repair or replacement of such a product

Electrical household appliances used as toiletries and for medical purposes (electric shavers, electric hair dryers, electric hair curlers, medical electric reflectors, electric heating pads, electric bandages, electric blankets, electric blankets, electric hair dryer brushes, electric hair curlers, electric toothbrushes, electric hair clippers and other devices having contact with the mucous membrane and (or) skin)

List of

non-food products of good quality that are not subject to exchange

1. Products for the prevention and treatment of diseases at home (sanitary and hygiene items made of metal, rubber, textiles and other materials, medical products, oral hygiene products, spectacle lenses, child care items), medicines.

2. Personal hygiene items (toothbrushes, combs, hairpins, hair curlers, wigs, hairpieces and other similar products)
3. Perfume and cosmetic products
4. Textile goods
5. Sewing and knitwear
6. Products and materials made entirely or partially from polymeric materials and in contact with food products (dishes and containers and packaging materials for storing and transporting food products, including for one-time use)

Violations faced by pharmacy employees are shown in the table:

Violation	Example	Article of the Law “On Protection of Consumer Rights”
sale of goods of inadequate quality	dispensing expired medications or missing packaging	article 18
lack of information about the product and its consumer properties	dispensing an over-the-counter drug without instructions for use	article 12
an error in the dosage or name of the drug	dispensing the wrong medicine as a result of an error in the name dispensing the drug in the wrong form	paragraph 3, article 4

In this case, the pharmacist needs to be especially careful when dispensing the following goods and drugs:

- ✓ with similar names or similar spelling: for example, ranitidine and rimantadine, test strips for various glucometers;
- ✓ with a large selection of dosages: for example, a drug with dosages of 5, 10, 20 mg;
- ✓ with a large selection of dosage forms: for example creams, ointments and gels;

- ✓ combination and single drugs with similar trade names: for example, cefekon and cefekon N;
- ✓ prescription drugs - dispensing such a drug without a doctor's prescription. In this case, the pharmacist needs to be especially careful when dispensing the drug.

Article 21. Replacement of goods of inadequate quality

If a consumer discovers defects in a product and submits a demand for its replacement, the seller (manufacturer, authorized organization or authorized individual entrepreneur, importer) is obliged to replace such product within seven days from the date of presentation of the specified demand by the consumer, and if necessary, additional verification of the quality of such product by the seller (manufacturer, authorized organization or authorized individual entrepreneur, importer) - within 20 days from the date of presentation of the specified requirement.

If the seller (manufacturer, authorized organization or authorized individual entrepreneur, importer) at the time of presentation of the demand does not have the goods necessary for replacement, the replacement must be carried out within 1 month from the date of presentation of such demand.

If it takes more than seven days to replace a product, at the consumer's request, the seller (manufacturer or an authorized organization or an authorized individual entrepreneur), within 3 days from the date of presentation of the request to replace the product, is obliged to provide the consumer, free of charge, for temporary use for the replacement period, a durable product that has these same basic consumer properties, ensuring its delivery at your own expense. A product of inadequate quality must be replaced with a new product, that is, a product that has not been used. When replacing a product, the warranty period is recalculated from the day the product is delivered to the consumer.

Article 22. Time limits for satisfying individual consumer requirements

The consumer's demands for a proportionate reduction in the purchase price of the product, reimbursement of expenses for correcting defects in the product by the consumer or a third party, return of the amount of money paid for the product, as well as a claim for compensation for losses caused to the consumer as a result of the sale of a product of inadequate quality or the provision of inadequate information about the product are subject to satisfaction by the seller (manufacturer, authorized organization or authorized individual entrepreneur, importer) **within 10 days from the date of presentation of the relevant request**

Types of liability for pharmacy employees in case of violation of consumer rights:

Legal norms allow three types of liability for violation of consumer rights by pharmacy employees: **civil, administrative or criminal.**

Main forms of civil liability:

- compensation for losses;
- compensation for moral damage;
- liability for failure to fulfill a monetary obligation.

Main forms of administrative responsibility:

1. dispensing of substandard medicines or medical devices in accordance with paragraph 2 of Article 6.33 of the Code of the Russian Federation on Administrative Offences:
 - a. fine for an official - 100,000 - 600,000 rubles;
 - b. fine for individual entrepreneurs - 100,000 - 600,000 rubles or administrative suspension of activities for up to 90 days;
 - c. fine for a legal entity - 1,000,000 - 5,000,000 rubles or administrative suspension of activities for up to 90 days;
2. misleading the buyer regarding the quality of the goods in accordance with Article 14.7 of the Code of the Russian Federation on Administrative Offences:
 - a. fine for an official - 10,000 - 30,000 rubles,

- b. fine for legal entities - 20,000 - 50,000 rubles;
- 3. failure to provide reliable and necessary information about a product or seller in accordance with Article 14.8 of the Code of the Russian Federation on Administrative Offenses:
 - a. warning or fine for an official - 500 - 1,000 rubles;
 - b. fine for legal entities - 5,000 - 10,000 rubles.

Criminal liability in this case is much less common and is associated with the risk or actual harm to the health or life of consumers. An example is Article 238.1 of the Criminal Code of the Russian Federation “Circulation of counterfeit, substandard and unregistered medicines, medical devices and circulation of counterfeit dietary supplements.”

Recommendations for pharmacy workers to minimize errors while respecting the legal rights of consumers:

First of all, it is necessary to understand and comply with the requirements of consumer protection legislation. This will help pharmacists quickly navigate the situation and make the right decision.

It is necessary to maintain order in the pharmacy; when selling goods, it is important to follow the rules for dispensing pharmaceutical products.

After a conflict situation involving a violation of consumer rights arises, it is important to analyze the error with all personnel and determine the correct actions. This will reduce the risk of a similar situation happening again. At the same time, it is necessary to minimize the impact of factors that may influence the pharmacist to make an error. These factors include fatigue and inattention, stress in the workplace.

To improve the quality of pharmacy service, employees should be regularly trained, helping them improve their knowledge.