

Lecture 1.

**Pharmacy organization: legal and
economic foundations of its
functioning**

3rd year 5th semester

The activity of pharmacies in Russia are largely determined by the provisions of the Federal Law № 61-FZ "On Circulation of Medicines" from 12.04.2010. This law provides a definition of a pharmacy.

A pharmacy is an organization or a structural subdivision of a medical organization that carries out retail sales of medicines, storage, transportation, manufacture and delivery of medicines for medical use in accordance with the requirements.

Pharmacy is **engaged in business activity**. This means systematic receipt of profit from the sale of goods, performance of work or provision of services.

According to Russian law, individual citizens and legal entities can engage in entrepreneurial activities. **Legal entities** are organizations that necessarily keep their own balance sheet.

According to the legislation of Russia, all organizations can be commercial and non-commercial organizations. **Commercial organizations** are those that pursue profit as the main goal of their activities. **Non-profit organizations** do not have profit as the main goal of their activity. For example, non-profit organizations are public and religious foundations and unions. **A pharmacy is a commercial organization, as it is engaged in entrepreneurial activity in order to make a profit.**

According to the legislation in Russia there are the following **types of pharmacies**:

1. a pharmacy engaged in retail sales of medicinal products to the public:

- finished dosage forms;
- a manufacturing pharmacy with the right to manufacture medicinal preparations;
- a manufacturing pharmacy with the right to manufacture aseptic medicinal preparations.

2. a pharmacy that is a structural subdivision of a medical organization:

- finished dosage forms;
- a manufacturing pharmacy with the right to manufacture medicinal preparations;
- a manufacturing pharmacy with the right to manufacture aseptic medicinal preparations;
- a manufacturing pharmacy with the right to manufacture radiopharmaceutical drugs.

3. a pharmacy point

4. a pharmacy stall.

A pharmacy point differs from a pharmacy by its smaller size. In a pharmacy stall, unlike a pharmacy and a pharmacy point, it is not allowed to sell medicines under a doctor's prescription.

According to the structure of the assortment there are pharmacies with a wide range of products and pharmacies, the range of which is focused on a particular profile of activity (for example, gynecology, oncology). According to the work schedule there are pharmacies with a regular mode and round-the-clock pharmacies.

Requirements for the opening and operation of pharmacies:

A newly established pharmacy must be registered as a legal entity. In this case, the pharmacy receives a certificate of state registration. The head of the pharmacy draws up a charter of the organization. This document defines the tasks and functions of the pharmacy, the order of management of the pharmacy, the rights of the head and employees, the order of termination of activities. Then the head of the pharmacy opens a bank account. In order to obtain the right to provide pharmaceutical care, each pharmacy must obtain a license for pharmaceutical activities.

The basic principles of territorial location of a pharmacy:

- the pharmacy should be located in the most accessible location for the population (10-15 minute walk);
- the higher the population density in the area, the more profitable the pharmacy;
- the most favorable location of the pharmacy near transport stops, large stores, food markets, medical institutions.

The pharmacy performs the following functions:

1. logistics (receipt, storage and management of inventory).
2. Manufacturing (receipt of prescriptions, manufacturing, quality control and dispensing of medicines according to doctor's prescriptions).
3. Sales (sales of prescription and over-the-counter products).
4. Information (providing the public and doctors with information on drugs).
- 5.
5. Marketing (formation and implementation of assortment and pricing policy).
6. Medical (providing, if necessary, first aid).

Requirements to supply medicines and other goods of pharmacy assortment in pharmacy organizations are determined by the provisions:

- Federal Law № 61-FZ "On Circulation of Medicines" of 12.04.2010
- Order of the Ministry of Health of Russia from 31.08.2016 N 647n "On approval of the Rules of good pharmacy practice of medicinal products for medical use".

Federal Law No. 61-FZ "On Circulation of Medicines" defines the following procedure for retail sale of medicines:

1. Only finished pharmaceuticals registered in Russia or manufactured by pharmacies with a license for pharmaceutical activities are allowed to be sold.
2. Retail sale of medicines is allowed only in quantities necessary to comply with doctor's orders.
3. pharmacies are obliged to have in their assortment medicines from the list of minimum assortment of medicines necessary for providing medical care. This list is established by Decree of the Government of Russia from 12.10.2019 N 2406-r. Drugs that are not included in this list are introduced into the assortment of pharmacies as needed to meet customer demand.
4. Prescription drugs are dispensed only through pharmacies and pharmacy outlets. Over-the-counter drugs may also be sold through pharmacy kiosks.

The following types of pharmacy products are allowed to be sold:

1. pharmaceuticals,
2. medical products,
3. disinfectants,
4. items and means for personal hygiene,
5. utensils for medical purposes,
6. items and means for the care of the sick, newborns and children under the age of three,
7. eyeglasses and eyeglass care products,
8. mineral waters,
9. medicinal, children's and dietary food products,
10. biologically active additives,
11. Perfume and cosmetic products,
12. medical publications to promote healthy lifestyles.

The order of the Ministry of Health of Russia from 31.08.2016 N 647n "On approval of the Rules of good pharmacy practice of medicinal products for medical use" regulates all the main areas of pharmacy activities: the structure of the organization, requirements for the manager and staff, the quality management system in the pharmacy, the order of delivery of pharmacy assortment goods.

The head of the pharmacy develops a set of measures aimed at providing the population with quality, safe and effective products of pharmacy assortment. The head of the pharmacy determines the order of maintaining documents in the pharmacy, which are necessary for quality performance of pharmacy functions. The head of the pharmacy informs employees of their rights and duties, as well as the order of work of the pharmacy. In order to ensure uninterrupted provision of customers with goods of pharmacy assortment, the head of the pharmacy organizes a system of goods procurement, equipping the premises with necessary equipment. The head of the pharmacy monitors changes in Russian legislation and communicates information to the pharmacy staff.

The pharmacy must have personnel who have pharmaceutical education. **The main functions of pharmaceutical staff include:**

1. selling quality goods of pharmacy assortment;
2. providing reliable information on the goods of pharmacy assortment, on the rational use of medicines;
3. preparation of medicines according to prescriptions;
4. preparation of accounting documentation;
5. compliance with professional ethics.

A pharmacy must have premises and equipment to perform its functions. The premises comply with sanitary and hygienic norms and requirements. All premises of the pharmacy should be isolated from other entities. Access of unauthorized persons to the premises of the pharmacy should not be allowed. Premises of the pharmacy should be equipped with heating and air-conditioning systems, ventilation, natural and artificial lighting. The pharmacy must have a sign. The sign indicates the type of pharmacy, its name and operating hours. The premises must be equipped with equipment that allows to ensure the storage of medicines. Premises and equipment must meet the requirements of fire safety.