Seminar No. 13.

Preparation of constituent documents of a pharmacy and documents for licensing pharmaceutical activities

Questions:

1. Pharmaceutical activities: definition, subjects of pharmaceutical activities.
2. Licensing of pharmaceutical activities: concept, goals, essence.
3. License, licensee: definition, requirements. presented to the licensee.
4. Preparatory work carried out to obtain a license.
5. The procedure for licensing pharmaceutical activities.
6. License for the activities of a pharmacy organization related to the trafficking of narcotic drugs
7. Supervision of licensing of pharmacy organizations.

1. Pharmaceutical activities are activities that include:

- wholesale trade in medicines;
- their storage;
- transportation;
- retail trade in medicines, including remotely;
- their release, storage, transportation;
- production of medicines.

Entities **engaged** in pharmaceutical activities include:

- organization of wholesale trade in medicines;
- pharmacy organizations;
- veterinary pharmacy organizations;
- individual entrepreneurs with a license for pharmaceutical activities;
- medical organizations licensed for pharmaceutical activities and their separate divisions.

Pharmaceutical activities must be carried out in accordance with the requirements established by law and are subject to mandatory licensing.

2. Licensing of pharmaceutical activities is a form of admission of legal entities and individual entrepreneurs to medical activities. Licensing of pharmaceutical activities is regulated by Federal Law No. 99 "Federal Law on Licensing of Certain Types of Activities" dated May 4, 2011 (reaction dated August 4, 2023) and Government Resolution No. 547 dated March 31, 2022 (valid for 7 years). **The licensing procedure** is determined by **the Government** , and Roszdravnadzor **issues permits** and inspects medical organizations **.**

The purpose of licensing is to control the work of organizations in the most significant public spheres.

The essence of licensing pharmaceutical activities is to comply with a strict procedure for admitting pharmacies and pharmaceutical companies to the production, dispensing and other work with medications. To do this, they approve a list of requirements that are checked both at the stage of obtaining a license and throughout the entire period of the pharmacy's activities. If a pharmacy already has a license for pharmaceutical activities, but the pharmacy intends to perform new work, provide new services that constitute pharmaceutical activities, not previously specified in the license, the license will have to be reissued.

The following types of activities are subject to licensing:

- ✓ production of medicines;
- ✓ technical maintenance of medical devices (except for the case if maintenance is carried out to meet the own needs of a legal entity or individual entrepreneur, as well as the case of maintenance of medical devices with a low degree of potential risk of their use);
- ✓ trafficking in narcotic drugs, psychotropic substances and their precursors, cultivation of narcotic plants;
- ✓ medical activities
- ✓ pharmaceutical activities;

3. License - a special permit for the right of a legal entity or individual entrepreneur to carry out a specific type of activity (perform work, provide services that constitute the licensed type of activity), which is confirmed by an entry in the license register.

Licensee - a legal entity (including a foreign legal entity, if the possibility of a licensed type of activity being carried out by a foreign legal entity is established in accordance with Part 4 of Article 12 of the Federal Law-99) or an individual entrepreneur who has a license.

Requirements for the licensee.

- To conduct pharmaceutical activities, the licensee must have premises that meet the established requirements;
- The licensee must have the necessary equipment available;
- To carry out pharmaceutical activities, a medical organization must have a license to carry out medical activities;
- The manager must have a higher pharmaceutical education and relevant work experience;
- A civil law or employment contract must be concluded with employees with pharmaceutical education;
- Veterinary education is acceptable for the manager and employees of an organization selling veterinary drugs;
- Compliance with legislation on the circulation of medicines;
- The licensee must obtain a sanitary and epidemiological certificate;
- When requested by the licensing authority, the licensee must provide properly completed documentation.

4 . To obtain a license to dispense medicines, a retail pharmacy or pharmacy of a medical organization carries out preparatory work:

1. Determines which products will be included in the pharmacy's assortment. The total volume of medications during the year and the profile of the department (for hospital pharmacies) are taken into account.

2. Determines which bed capacity and which medical profile will be served by the pharmacy.

3. The number of pharmacists and other employees needed to be hired to ensure the functioning of the pharmacy is calculated. The workload per specialist is determined depending on the bed capacity.

4. The staffing schedule is drawn up and approved, job descriptions are developed.

5. Designate a room for a pharmacy and pharmaceutical warehouse.

6. The area of the pharmacy must be sufficient to accommodate the following premises: reception of medicines (1st floor, preferably with free access); storage area (small warehouse); premises for pharmacy staff; manager's office; rest and meal room; bathroom for employees; wardrobe or closet.

7. Convenient parking is provided for loading and unloading operations.

8. Furniture and equipment for the pharmacy are purchased (furniture for employees, racks for storing medicines, metal cabinets and safes for narcotics, etc.), instruments for temperature and humidity control are purchased. The requirements for equipping pharmacies are described in detail in Order of the Ministry of Health No. 646n dated August 31, 2016.

9. Work premises are equipped with personal computers, printing equipment, Internet access, necessary furniture and other devices.

10. Employees are hired and employment contracts are concluded with them. It is monitored whether pharmacists have appropriate education and specialist accreditation, and, if necessary, work experience.

5. The procedure for licensing pharmaceutical activities involves collecting a package of documents confirming all of the above conditions.

Submit the following documents to the licensing authority:

1. Application for a license.

2. Copies of contracts and other documents confirming that the pharmacy has premises for retail trade in medicines. This can be your own or rented

premises. Also confirm the availability of the necessary equipment for licensing pharmaceutical activities.

3. Copies of documents on receipt of specialized education by pharmacy employees.

4. Originals or certified copies of documents confirming the work experience of the pharmacy manager. A package of documents is generated in duplicate and a detailed inventory is drawn up. Keep one copy for yourself, the second is transferred to the licensing authority. The state fee is paid and the payment receipt is attached to the package of documents. The amount of the fee is paid in the Decree of the Government of the Russian Federation No. 328 of 03/09/2022.

Changes in the pharmaceutical licensing procedure are regulated by Government Decree No. 2164 dated November 29, 2022, which tightened licensing requirements for the manufacture of radiopharmaceuticals . According to the document, a new requirement for employees will apply to applicants for a license to manufacture radiopharmaceuticals. Such pharmacies will be required to employ specialists with higher or secondary pharmaceutical or medical education and additional professional education in the field of radiochemistry and radiation safety. This requirement is effective from March 1, 2023.

From September 1, 2023, applications for issuing a license or making changes to the register can only be submitted through State Services (Government Decree No. 2402 dated December 23, 2022).

Decree No. 2164 reduced the time frame for granting and changing a license. There are now 10 working days for issuing (previously 15), for making changes - 5 (previously it was 10).

If activities are carried out in closed administrative-territorial entities, in both cases the decision must be made within 20 working days.

The licensing authority makes a decision - enters the pharmacy into **the register of licensed organizations** or gives a refusal. **An electronic license is issued** , which is confirmed by an extract from the license.

6. To obtain a license, the license applicant electronically sends to the licensing authority an application for a license and the documents specified in Part 1 and Clause 4 of Part 3 of Article 13 of the Federal Law on Licensing of Certain Types of Activities, as well as:

copies of documents confirming the availability of premises and land plots;

information about the availability of a license to carry out medical activities;

a copy of the document confirming the specialist's accreditation;

copies of certificates confirming that employees are free from drug addiction, substance abuse, and chronic alcoholism; information on the availability of conclusions of the internal affairs bodies of the Russian Federation, provided for in paragraphs three and five of paragraph 3 of Article 10 and paragraph three of paragraph 7 of Article 30 **of the Federal Law "On Narcotic Drugs and Psychotropic Substances"** and Decree of the Government of the Russian Federation of May 20, 2022 **No. 911 "On the admission of persons to work with narcotic drugs and psychotropic substances, as well as to activities related to the circulation of precursors of narcotic drugs and psychotropic substances."**

Decree of the Government of the Russian Federation of June 2, 2022 No. 1007 "On licensing activities for the circulation of narcotic drugs, psychotropic substances and their precursors, cultivation of narcotic plants" established a list of works and services that constitute the activity for the circulation of narcotic, psychotropic substances and their precursors, which are subject to licensing:

a) on the turnover of narcotic drugs, psychotropic substances and their precursors included in lists I - III and table I of list IV of the list of narcotic drugs, psychotropic substances and their precursors subject to control in the Russian Federation, approved by decree of the Government of the Russian Federation of June 30, 1998. No. 681 "On approval of the list of narcotic drugs, psychotropic

substances and their precursors subject to control in the Russian Federation" (hereinafter referred to as the list)

b) for the cultivation of narcotic plants included in the list of plants containing narcotic drugs or psychotropic substances or their precursors and subject to control in the Russian Federation, approved by Decree of the Government of the Russian Federation of November 27, 2010 No. 934 "On approval of the list of plants containing narcotic drugs ....." for use for scientific, educational purposes and in expert activities, for the production of narcotic drugs and psychotropic substances used for medical purposes and (or) veterinary medicine, as well as the narcotic plant opium poppy included in the specified list of plants, for industrial purposes, not related to the production or manufacture of narcotic drugs and psychotropic substances .

7. Supervision of licensing of pharmacies.

Interdepartmental inquiries will be used to verify compliance with licensing requirements. In this regard, the list of information in the application for amendments to the register of licenses has been reduced. It will only indicate the new address of activity or new types of work. Roszdravnadzor has revised checklists for pharmacy inspections. Whether or not a pharmacy meets licensing requirements will also be determined based on whether the enterprise complies with the requirements for the circulation of drugs and psychotropic substances. Changes in the checklists of Roszdravnadzor have been in effect since December 2022 on the basis of two orders of the department - dated 08/26/2022 No. 7974 and dated 08/26/2022 No. 7973. Order of Roszdravnadzor 7974 approved new forms of assessment sheets for control, both applicants for a pharmaceutical license and pharmacies with a valid license comply with licensing requirements.

Order of the Federal Service for Surveillance in Healthcare dated August 26, 2022 No. 7973 "On approval of the form of the assessment sheet, according to which the Federal Service for Surveillance in Healthcare and its territorial bodies assesses the compliance of the license applicant or licensee with licensing

requirements when carrying out activities related to the circulation of narcotic drugs, psychotropic substances and their precursors, and the cultivation of narcotic plants" (Registered 11/22/2022 No. 71056). Based on the results of the inspection, the compliance/non-compliance of the license applicant/licensee with the licensing requirements provided for by Decree of the Government of the Russian Federation dated June 2, 2022 N 1007 “On licensing activities for the circulation of narcotic drugs, psychotropic substances and their precursors, cultivation of narcotic plants” (highlight as appropriate) is established. .

The licensee's compliance with the established licensing requirements is assessed as part of an on-site inspection. That is, representatives of Roszdravnadzor or a regional authority go to the site and check whether the conditions stated in the application correspond to reality. After a positive decision, information about the license is entered into a unified register. The procedure for licensing pharmaceutical activities ends here, but inspections of pharmacies are carried out regularly. If one of the inspections reveals violations, the pharmacy may be fined and its license revoked. Supervision activities are carried out by Roszdravnadzor and its divisions.

Validity period of the license for pharmaceutical activities.

The document for admission to pharmaceutical activities is valid from the date specified in the license. **The license** for pharmaceutical activities itself is valid **indefinitely.** Instead of a classic license, the pharmacy receives an extract from the register. At the same time, if a pharmacy grossly violates licensing requirements, as proven by the results of inspections by supervisory authorities, the license can be revoked at any time or suspended for a certain period until the violations are eliminated.