

Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor)

Federal Service on Surveillance in Healthcare and Social Development is a federal body of executive authority under the Ministry of Healthcare and Social Development of the Russian Federation.

It performs 46 State Functions, and more than 100 Administrative Procedures

Roszdravnadzor basic functions:

1. Surveillance:

- pharmaceutical activities ;
- compliance with state standards, technical requirements for medical products;
- compliance with the state standards of social services.

2. State Control:

- of quality of medical and social assistance;
- of production, quality, efficacy, safety, circulation and usage of medicines and medical devices;
- of preclinical and clinical trials of medicines and fulfilment of rules in laboratory and clinical practice.

3. Licensing:

- manufacture of drugs, medical and pharmaceutical activities;
- activities related to circulation of narcotic drugs and psychotropic substances;
- activities related to production and technical support of medical products, prosthetic and orthopedic appliances.

4. Registration:

- of medicines;
- of pharmaceutical substances;
- of medical devices;
- of medical technologies;
- of limit prices on the substantial and vital medicines.

5. Pharmacovigilance,

revealing and monitoring of adverse reactions at usage:

- of medical devices;

- of medicines for the use in clinical trials;
- of medicines.

6. Permissions

- for the use of new medical technologies;
- for import of medical products (for medical purposes) to Russian Federation;
- for clinical trials of medicines.

Performing of accreditation and certification of specialists in the sphere of drug circulation.

Roszdravnadzor Structure:

- Division of the Organization of State Control of the Quality of Medico-Social Help;
- Division of State Control of Circulation of Medical Products;
- Division of State Programmes Implementation Monitoring;
- Division of Licensing and Legislative Support;
- Division of Registration Medicaments;
- Division of Registration Medical Equipment and medical Technologies;
- Division of Finances, Accounting and Control;
- Support Office.

Federal State Institutions within Jurisdiction of Roszdravnadzor:

- FSI «Scientific Center for Expertise of Medical Products»
13 branches in subjects of the Russian Federation
- FSI «Consulting and Methodological Center for Licensing»
4 branches in subjects of the Russian Federation
- FSI «Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products»
- FSI «All-Russian Scientific Research and Testing Institute of Medical Technique»
- FSI «Privolgskiy Circuit Medical Center for Expertise of Quality of Blood Products and Fractionation of Donor Plasma»
- FSI «Center for Expertise and Quality Control of Medical Products»

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