The Federal Service on Surveillance in Healthcare Activity

Borzik I.K.
Deputy Head
of the Federal Service on Surveillance in Healthcare
Federal Service on Surveillance in Healthcare (Roszdravnadzor)

2004

Birjhevaya Sq, h. 1

By the decree of the President of the Russian Federation dated 9 March 2004 No.314 «About the system and structure of Federal bodies of Executive power» established a system of Federal bodies of Executive power, including Federal ministries, Federal services and Federal agencies

2014

Slavyanskaya Sq, h. 4, b. 1
Structure and Competence of Roszdravnadzor

Roszdravnadzor

Central Office, including 8 Divisions

Quality and safety control of healthcare practices
(10 competences)

11 Federal laboratory complexes

Control in the sphere of medicines circulation
(8 competences)

80 Regional Offices

Control of medical devices circulation
(5 competences)
Regional Offices of Roszdravnadzor

Each subject of the Russian Federation has a territorial body of Federal service on surveillance in healthcare (Roszdravnadzor)
Federal State Budgetary Institution “Information and Methodological Center for Assessment, Recording and Analyzing of Medical Equipment” of Roszdravnadzor

Organizational department

Analytical laboratory

Microbiological laboratory

Pharmacological laboratory

Immunological laboratory (Krasnoyarsk, Moscow)

Mobile laboratory
Federal State Budgetary Institution “All-Russian Scientific-research and Test Institute for Medical Engineering” of Roszdravnadzor

- Testing laboratory of medical supplies and tools
- Technical tests laboratory of medical devices
- Testing laboratory of mobile complexes for medical purposes
- Testing laboratory of instruments and equipment for functional diagnostics and physiotherapy
- Testing laboratory of medical devices software
- Testing laboratory of instruments and apparatus for radiation diagnosis and therapy
- Testing laboratory of electromagnetic compatibility of medical equipment
- Testing laboratory of instruments and apparatus for medical laboratory tests
- Department of toxicology testing and research materials and medical devices
- Laboratory of microbiological researching in medical devices
Federal laboratory facilities for quality control of medicines

- St. Petersburg
- Moscow
- Kazan
- Ekaterinburg
- Rostov-on-Don
- Krasnoyarsk
- Khabarovsk
- Gudermes

- Functioning laboratory complexes
- Federal laboratory facilities equipped with mobile Express laboratories for quality control
Control of Observance of Constitutional Guarantees and Rights in the Sphere of Health Protection of Citizens of the Russian Federation

Sphere of Roszdravnadzor state control

- State quality control of medical care
- Control of the circulation of medicines
- Control of medical devices circulation

- 231,587 Medical organizations (104,775 licenses)
- 4,262 Organizations producing and serving medical equipment (4,081 licenses)
- more than 1.2 million organizations under control
- 353,964 Organizations involved into circulation of medical devices
- 542,483 Organizations involved into circulation of medical devices
- 108,052 Pharmaceutical organizations (38,354 licenses)

8
Activity of Roszdravnadzor in the framework of the execution of the function on state control of quality of safety of medical practice

- Licensing of medical activity
- Observance of the rights of citizens
- Compliance with orders of medical care and standards of care
- Compliance procedures of conducting medical examination and surveys
- Compliance with medical and pharmaceutical workers of the limits on the exercise of their professional activities
- Test organization and implementation of departmental and internal control quality and safety of medical practice
<table>
<thead>
<tr>
<th>State Control in the Sphere of Medicines circulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical licensing, licensing of narcotic drugs, psychotropic substances and their precursors, the cultivation of narcotic plants</td>
</tr>
<tr>
<td>The Federal state supervision in the sphere of circulation of medicines (including medicines quality control, control over the conduct of preclinical studies of drugs, clinical trials of drugs, control over the disposal of medicines)</td>
</tr>
<tr>
<td>Monitoring the safety of medicines in circulation</td>
</tr>
<tr>
<td>Issuing permits for the importation into the territory of the Russian Federation and export from the territory of the Russian Federation potent substances, which are not precursors of narcotic drugs and psychotropic substances</td>
</tr>
<tr>
<td>Issuance of certificates for the right of importation (exportation) of narcotic drugs, psychotropic substances and their precursors</td>
</tr>
<tr>
<td>The issuance of approvals for the issuance of licenses for export and (or) import of organs and (or) human tissues, blood and its components</td>
</tr>
<tr>
<td>Issue opinions on the possibility of importing to the territory of the Russian Federation and export from the territory of the Russian Federation hematopoietic stem cells and bone marrow for the purpose of conducting unrelated transplantation</td>
</tr>
<tr>
<td>The monitoring of range and prices for vital and essential drugs</td>
</tr>
</tbody>
</table>
The functions of Roszdravnadzor under the state control and supervision in the sphere of medical device circulation

- Licensing of production and maintenance (except if the specified activity is carried out for own needs of a legal entity or individual entrepreneur) medical equipment

- State registration of medical devices

- Control over observance of the subjects of medical products circulation rules in the sphere of circulation of medical devices

- Issuing permits for the importation into the territory of the Russian Federation with the purpose of state registration of medical devices

- Safety monitoring of medical devices

- The register notices of commencement of business activity in the sphere of circulation of medical devices
Other functions of the Federal Service on Surveillance in Healthcare

Accreditation of foreign professionals

Performs:
Control over the medicines circulation, intended for treatment of cancer

State control over:
Documented reliability data, provided by medical organizations
**New functions of Roszdravnadzor from January 1, 2014**

Roszdravnadzor is considering cases about administrative offences

<table>
<thead>
<tr>
<th>Article</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Art. 6.28</td>
<td>Violation of rules in the field of treatment of medical devices</td>
</tr>
<tr>
<td>Art. 6.29</td>
<td>The lack of information on conflict of interest</td>
</tr>
<tr>
<td>Art. 6.30</td>
<td>The neglect of duty of informing citizens about how to obtain free medical care under the program of state guarantees</td>
</tr>
<tr>
<td>Art. 14.4.2 part 1</td>
<td>Violation of the rules of the wholesale trade in medicines and order of retail trade in medicines</td>
</tr>
<tr>
<td>Art. 19.4 part 5</td>
<td>Failure to comply with the legal requirements of Roszdravnadzor and obstruction of official duties by the officials of Roszdravnadzor</td>
</tr>
<tr>
<td>Art. 19.5 part 21</td>
<td>Failure to comply within the prescribed period the provisions of the decision of Roszdravnadzor</td>
</tr>
<tr>
<td>Art. 19.7.8</td>
<td>Failure to submit or late submission in Roszdravnadzor the required information or submission of false information</td>
</tr>
</tbody>
</table>
Control activities of the Central office and territorial bodies of Roszdravnadzor in 2013

performed - **7808** control activities, of which:

*planned* – **6408** control activities

*unscheduled* – **11400** control activities

Results of Roszdravnadzor control activities in 2013

- the detection rate in 2013 was **40%**;
- the share of organizations - offenders increased by **12%** *(from 35 to 40%)*;
- identified violations **16120**;
- however, **1861 test** - is violation of the mandatory requirements;
- **in 349 (1,95%)** - the breach caused harm to the life and health of citizens.

- the protocols of administrative violations – **1753**, i.e. **9,8%**;
- the assigned administrative fines in the amount of 45 376 thousand rubles, which is **1.7 times** more compared to 2012;
- judicial authorities suspended **48** licenses;
- the decision of the court cancelled **5** licenses;
- the proportion of fines paid to the budget in comparison with 2012, decreased **from 80 to 68%**;
- the average fine was **3.6** thousand rubles (in 2012 to 3.4 thousand rubles)
# The Scheme of State Registration of Medical Devices in the Russian Federation

## Preparation of Documents

**Testing of medical devices**:  
- technical  
- toxicological  
- for the purposes of type approval of measuring instruments (if necessary)

### Preparation of Documents for State Registration of Medical Devices

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The review of documents</td>
</tr>
<tr>
<td>2</td>
<td>Elimination of violations (if necessary)</td>
</tr>
<tr>
<td>3</td>
<td>Stage I examination of the quality, effectiveness and safety of medical devices</td>
</tr>
<tr>
<td>4</td>
<td>Permission to conduct clinical trials</td>
</tr>
<tr>
<td>5</td>
<td>Refusal in state registration</td>
</tr>
</tbody>
</table>

## Registration of Medical Devices (Stage I)

### Clinical Trials of Medical Devices  
*(suspension of state registration of medical devices)*

### Registration of Medical Devices (Stage II)

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Renewal of state registration</td>
</tr>
<tr>
<td>2</td>
<td>The review of documents</td>
</tr>
<tr>
<td>3</td>
<td>Stage II examination of the quality, effectiveness and safety of medical devices</td>
</tr>
<tr>
<td>4</td>
<td>The decision on the state registration</td>
</tr>
<tr>
<td>5</td>
<td>Refusal in state registration</td>
</tr>
</tbody>
</table>
International Organizations Cooperating with Roszdravnadzor

- **Pharmaceutical Inspection Cooperation Scheme (PIC/S)** (as observers)
- **Organization of the Black Sea Economic Cooperation (BSEC)** (as a member of World Health Organization (WHO) (cooperation))
- **Working Group of Enforcement Officers of the Head of Medicines Agencies (HMA WGEO)** (as observers)
- **The international Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)** (as observers)
- **International Medical Device Regulation Forum (IMDRF)** (as a member of the Global Medical Device Nomenclature Agency (GMDN) (cooperation))

Federal Service on Surveillance in Healthcare
International Activities of Roszdravnadzor with Regulatory Agencies in Other Countries

- The Ministry of health of the Republic of Belarus
- National center for expertise of drugs, medical devices and medical equipment of the Ministry of health and social development of the Republic of Kazakhstan
- China Food and Drug Administration (CFDA)
- The National Institutes for Food and Drug Control, China (NIFDC)
- Central Drugs Standard Control Organization, Republic of India (CDSCO)
- Medicines and Medical Devices Agency of Serbia
- European Directorate for Quality of Medicines & HealthCare of the Council of Europe (EDQM)
- European Medicines Agency (EMA)
- State Service for the Drug Quality Control, Ukraine
- The state expert center of the Ministry of health of Ukraine
- Food and Drug Administration (US FDA)
- U.S. Pharmacopoeia Convention (USP)
- Pharmaceuticals and Medical Devices Agency, Japan (PMDA)
Thank you!

www.roszdravnadzor.ru

Borzik I.K.
Deputy Head
of the Federal Service on Surveillance in Healthcare