IMDRF International Medical Device Regulators Forum

NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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State Control and Registration of Medical Devices of Roszdravnadzor

Order of Roszdravnadzor No. 6478 dated 19.07.2017

"About approval of order of the implementation of counseling procedures related to the state registration of medical devices by Federal State Budgetary Institution "Russian Scientific and Research Institute for Medical Engineering" of Roszdravnadzor and Federal State Budgetary Institution "Center of monitoring and clinic-economic expertise" of Roszdravnadzor "

Entered into force on 10.09.2017

The main provisions

- Opportunity of implementation of counseling procedures related to the state registration of medical devices by two subordinated Institutions of Roszdravnadzor;
- Forms of counseling: oral, written;
- Term of counseling: 20 working days from the date of enter into an agreement

State Control of the Circulation of Medical Devices Using the Risk-oriented Approach

There are 9 criterions of risk category classification of organization accordance with kinds of their activity

Manufacturers of medical devices and authorized representatives of the manufacturer of medical devices

Organizations of carrying out

- Installation, adjustment, maintenance, repairs of medical devices
- Application of medical devices and clinical trials (for medical organizations)
- Import, export of medical devices
- Sales of medical devices
- Transportation of medical devices
- Utilization and disposal of medical devices
- Technical trials and toxicity studies
- Storage of medical devices

Referring Organizations of Carrying Out Their Activity in the Sphere of Medical Devices to Categories of Risk for 2018

Category of risk	Frequency of inspections	Quantity of organizations
Significant risk	1 time in 3 years	312 (0,26%)
Average risk	not more than 1 time in 5 years	925 (0,79%)
Moderate risk	not more than 1 time in 6 years	3709 (3,15%)
Low risk	-	112 846 (95,80%)

Quantity of organizations of carrying out their activity in the sphere of medical devices – 117 792

The List of Mandatory Requirements in the Sphere of Circulation of Medical Devices

The list of legal acts and their separate parts (provisions) containing mandatory requirements compliance with which is assessed during inspections (**Order of Roszdravnadzor No. 4043 dated 27.04.2017**)

Federal laws	**2**
Decrees of the President of the Russian Federation, Regulations and Orders of the Government of Russian Federation	**7**
Legal acts of federal execute bodies	**11**

Regulation No.1517 dated 30.12.2015

«On state regulation of prices for MD included into the list of MD implanted in the human body while providing medical assistance under the program of state guarantees of free rendering to citizens of medical care»

Approved:

The Order of the Government of Russian Federation № 2229-r dated 22.10.2016 (in redaction of the Order of the Government of Russian Federation № 1587-r dated 25.07.2017)

«On approval of the list of MD implanted in the human body while providing medical assistance under the program of state guarantees of free rendering to citizens of medical care»

As of September 15, 2017:

- agreed on weighted average prices for 32 types of medical devices;
- 177 prices of different medical devices are registered

Procurement of medical devices within a program of state guarantees of free rendering to citizens of medical care based on registered prices of medical devices will begin **on January 1, 2018**

Documents developed in the Framework of Eurasian Economic Union entered into force on the 6th of May 2017

Documents Developed in the Framework of Eurasian Economic Union

The procedure for the formation of the list of standards as a result of which, on a voluntary basis, ensures compliance of the medical devices with general safety and efficiency requirements (Recommendation of Collegium of Eurasian Economic Commission No. 16 dated 04.09.2017)

The list of standards as a result of which, on a voluntary basis, ensures compliance of the medical devices with general safety and efficiency requirements (Recommendation of Collegium of Eurasian Economic Commission No. 17 dated 04.09.2017)

Thank you for your attention!

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