NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

Ph.D., Elena Astapenko
The Head of the Division of Organization of 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

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

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

Decrees of the President of the Russian Federation, Regulations and Orders of the Government of Russian Federation

Legal acts of federal execute bodies

Total:

2

7

11
Approved:
«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»

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»

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

The Eurasian Economic Union
the Republic Armenia, the Republic of Belarus, the Republic of Kazakhstan,
the Kyrgyz Republic and the Russian Federation

182,7 million people
over 20 million sq. km.
14% of the world's firm land
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!

Aстапенко EM@roszdravnadzor.ru

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