NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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The Scheme of State Registration of Medical Devices (because of COVID-19) in the Russian Federation

Russian Government order No. 1416 dated 27.12.2012 “Adoption of rules for state registration of medical devices” (as revised in the Russian Government order No. 299 Dated 18.03.2020)

Russian Government order No. 430 dated 03.04.2020 “About features of the circulation of medical devices, including state registration of a series (batch) of a medical device”

Single-use medical devices registered in the country of origin are not subject to registration in Russian Federation
Russian Government order **No. 1416 dated 27.12.2012** “Adoption of rules for state registration of medical devices” (as revised in the Russian Government order **No. 299 Dated 18.03.2020**)

**Came into force on 19 March 2020**

- In-country Testing of medical devices at Federal State Budgetary Institution “All-Russian Scientific-research and Test Institute for Medical Engineering” of Roszdravnadzor:
  - ✓ Technical tests
  - ✓ Toxicological test

- In-country Clinical trials of medical devices at Russian Authorized Hospitals
- The review of documents
- Expertise of the quality, effectiveness and safety of medical devices
- Elimination of violations (if necessary)
- Request additional materials and information
- The decision on the state registration
- Refusal in state registration

All documents must be certified in the country of origin in the prescribed manner.
Russian Government order No. 430 dated 03.04.2020 “About features of the circulation of medical devices, including state registration of a series (batch) of a medical device”

- Operational documentation of medical device
- Photos of medical device
- Documents confirming that the series (batch) of the medical device belongs to the applicant on legal grounds
- Technical tests according to the standard program
- Toxicological tests according to the standard program
- Clinical trials according to the standard program
  
  **All documents must be certified by the applicant**

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**Expertise of the quality, effectiveness and safety of medical devices**

- Request additional materials and information

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The decision on the state registration of a series (batch) of medical devices

Refusal in state registration

**Validity of the registration certificate** – 01.01.2021

**Came into force on 06 April 2020**
The order of the Ministry of Health of the Russian Federation No. 206n dated 20.03.2020 “About approval of the procedure of organization and carrying out of examination of quality, efficacy and safety of medical devices"

- Procedure of organization and carrying out of expertise of quality, efficiency and safety of medical devices at the state registration of medical devices and in case of making changes in dossier;

- Procedure of organization and carrying out of expertise of dossier of medical devices in case if this product is not medical device accordance with legal laws

Entered into force on 02.08.2020
Update of the order of the Ministry of Health of the Russian Federation No. 4n dated 06.06.2012 “About approval of nomenclature classification of medical devices"

- Classification of software as medical device depending on the potential risk of its use;
- Criteria of classification: type of information and condition of application;
- The document based on IMDRF principles of SaMD

Entered into force on 21.08.2020
The pilot project “Medical device Labeling”

Based on Unique Device Identification System (UDI) and IMDRF principles

Types of medical devices selected for pilot project:
- Coronary stents;
- Computer tomograph;
- Diapers;
- Hearing-aid
The pilot project “Patient registry”

Based on IMDRF principles

Types of medical direction selected for pilot project:
- Cardiosurgery;
- Orthopedics;
- Plastic surgery
Circulation of Medical Devices in Eurasian Economic Union

3 medical devices are registered in accordance with the rules for registration of medical devices of the EEU

The first Inspection of Quality Management System of medical devices was carried out in accordance with the rules for registration of medical devices of the EEU (which is harmonized with IMDRF principles)
The 22nd annual conference “State regulation of medicines and medical devices – PharmMedObrashenie-2020”

The Conference traditionally brings together more than 1000 interested experts from medical and pharmaceutical industries, representatives of federal and regional legislative and executive authorities of the Russian Federation, foreign regulatory authorities, scientific-research and public organizations, professional associations, wholesale and retail organizations and manufacturers of medical products

the 29th – 30th of October 2020
Moscow
Thank you for your attention!

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