IMDRF International Medical Device Regulators Forum

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

Federal Projects

Expected results of the federal project “Development of first aid system”

- More than 350 new first aid and ambulance stations will be created
- More than 1200 first aid and ambulance stations will be upgraded in 62 regions of Russian Federation
- More than 1300 mobile medical centers will start working to the 2022 year
- The strategies of air ambulance will be developed in all regions of Russian Federation

Russian Government Regulation No. 584 dated 16.07.2009 «About notification procedure of beginning the individual types of business realization» (last update No.1352 dated 12.11.2018)

Entered into force on 01.01.2019

- **Legal entities have to provide notification about starting their business according to the list of work items and services in the MD circulation. Such as: distribution, technical and toxicological tests, import and export on the territory of Russia, storage, transportation, realization, utilization, destruction of MD;**
- **Simplification of medical device circulation and no need to get additional certification/legislation for mentioned work items in the MD circulation.**

Guidelines about order of carrying out of expertise of safety, quality and efficiency of Medical Devices for the purpose of state registration

Approved by December 26, 2018

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 № 3053-r dated 31.12.2018 (in redaction of the Order of the Government of Russian Federation № 2229-r dated 22.10.2016)

«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 March 14, 2019:

- list of MD implanted in the human body contains 368 types of MD of them 213 types of MD are subject to the state regulation of prices;
- agreed on weighted average prices for 134 types of medical devices;
- 2952 prices of different medical devices are registered

Documents Developed in the Framework of Eurasian Economic Union

The requirements for implementation, maintaining and evaluation of MD QMS depending on potential risk of application (Decision of the Council of the Eurasian Economic Commission No. 106 dated 10.11.2017)

Entered into force on 15.03.2019

Documents of 3rd level, developed with purpose for realization of the Decision No. 106

- Requirements for organizations, which are legalized to carry out inspection of medical device manufacturing, according to standards of introduction, supporting and evaluation of quality management system of MD depending on classification of potential risk of their using
- Requirements for inspectors and order of complacence to those requirements
- Inspecting authority's quality control and authorization rules

Documents Developed in the Framework of Eurasian Economic Union

Criteria for borderline products to the be categorized as a medical device in the framework of Eurasian Economic Union (Recommendation of the Council of the Eurasian Economic Commission No. 25 dated 12.11.2018)

Entered into force on 16.05.2019

The main provisions

- The main articles are about MD's prescription, that is one of the main requirements for categorization of the product. Using of MD provides its medical purpose. Which must be single or main.
- The categories of borderline products: perfume and beauty products, personal hygiene products, disinfectants, equipment, products for rehabilitation, and disabled persons, sports equipment, personal protection equipment, software, packaging, equipment for physiotherapy , furniture, MD with added pharmaceuticals, IVD products.

Thank you for your attention!

AstapenkoEM@roszdravnadzor.ru

Ph.D., Elena Astapenko

**The Head of the Division of Organization of
State Control and Registration of Medical Devices of Roszdravnadzor**