IMDRF International Medical Device Regulators Forum

NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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NATIONAL PROJECT «HEALTHCARE»

The goal: increase in life expectancy at birth to 78 years to 2024 (to 80 years - to 2030)

Federal Projects

The development of a system of the provision of the primary health care: reduction of population mortality from 473,4 in 2017 to 350 cases per 100 of thousands of the population in 2024 (26%)	Provision of healthcare organizations qualified personnel
The fight against cardiovascular diseases: reduction of mortality from cardiovascular diseases from 587,6 cases in 2017 to 450 cases per 100 of thousands of the population in 2024 (23,4%)	Guidance National medical research centers
The fight against cancer: reduction of mortality of cancer from 587,6 cases in 2017 to 450 cases per 100 of thousands of the population in 2024 (7,8%)	The creation of a single digital Circuit in health on the basis of a Single state health information system
The development of the children's health: reduction of infant mortality from 5,6 in 2017 to 4,5 cases per 1000 born children in 2024 (19,6%)	The development of export of medical services

Russian Government Regulation No. 633 dated 31.05.2018 «On making amendments into the Russian Government Regulation No. 1416 dated 27.12.2012 «On approval of rules of State registration of medical devices in the Russian Federation»

Entered into force on 13.06.2018

- **Simplification of state registration procedure for IVD**
- **Exclusion type of MD from registration certificate. The type of MD indicated in the Registry of MD**
- **The possibility of use medicines registered only in the country their production in the production of MD**
- **The establishment of cases expertise of quality, efficiency and safety of MD in the changes in the MD registration dossier**

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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

Registration of medical devices (Stage I)

The review of documents

Elimination of violations (if necessary)

Stage I
examination of the quality, effectiveness and safety of medical devices
Request additional materials and information

Permission to conduct clinical trials

Refusal in state registration

Preparation of documents

Clinical trials of medical devices
(suspension of state registration of medical devices)

Registration of medical devices (Stage II)

Renewal of state registration

The review of documents

Stage II
examination of the quality, effectiveness and safety of medical devices
Request additional materials and information

The decision on the state registration

Refusal in state registration

The Scheme of State Registration of Medical Devices (for the MD class I and IVD) in Russian Federation

Entered into force on 13.06.2018

Pre-registration procedure

In-country Testing of medical devices at Russian Authorized Labs :

- ✓Technical tests
- ✓Toxicological test
- ✓Metrological tests (if necessary)

In country Clinical trials of medical devices at Russian Authorized Hospitals

The Registration dossier forming in Russian (application, check-list, test reports, report of clinical trials)

Registration of medical devices

Renewal of state registration

The review of documents

Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration

Refusal in state registration

Guidelines for carrying out of expertise of safety, quality and efficiency of the purpose of state registration of Software as a Medical Device

Approved by August 24, 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 № 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 12, 2018:

- list of MD implanted in the human body contains 382 types of MD of them 250 types of MD are subject to the state regulation of prices;
- agreed on weighted average prices for 80 types of medical devices;
- 2945 prices of different medical devices are registered

Documents, developed in the Framework of Eurasian Economic Union

1. About the criteria distinction elements of MD that are components of MD in order to its registration (Decision of the Council of the Eurasian Economic Commission No. 116 dated 24.07.2018)
2. About the criteria for inclusion several modification of MD related to one type of MD in accordance with the MD nomenclature of EEU in one registration certificate (Decision of the Council of the Eurasian Economic Commission No. 123 dated 24.07.2018)
3. About the criteria for classifying products to MD
4. Guidelines for carrying out of expertise of safety, quality and efficiency of MD registration dossier
5. Guidelines for content and structure of MD registration dossier documents
6. Requirements for organizations having the right to carry out inspection of the production of MD on compliance the requirements for implementation, maintaining and evaluation of MD QMS depending on potential risk of application

Thank you for your attention!

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