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

Order of the Ministry of Health from 11.03.2016 № 155n

«On Approval of Administrative Regulations of Federal Service on Surveillance in Healthcare of Public Services for the Reception and Registration of Notifications about the Beginning of the Implementation of Activities in the Sphere of Circulation of Medical Devices (with the Exception of Clinical Trials of Medical Devices, Their Manufacture, Installation, Commissioning, Application, Operation, including Maintenance and Repair)»

Entered into force **23.04.2016**

The Main Provisions

1. **Determined the procedure and time of acceptance and accounting of notifications of the beginning of the following activities in the sphere of circulation of medical devices: technical tests, toxicological researches, manufacture, import on territory of the Russian Federation, export from the territory of the Russian Federation, storage, transportation, implementation, utilization and disposal of medical devices.**
2. **Notifications of the beginning of the activities in the sphere of circulation of medical devices are received by Roszdravnadzor in 1 day and published in official web site in 10 days.**

Order of the Ministry of Health from 25.03.2016 № 184n

«On Approval of Administrative Regulations of Federal Service on Surveillance in Healthcare of Public Services for Issuing Permits for Import of Medical Devices for the Purposes of Their Registration»

Entered into force **10.06.2016**

The Main Provisions

1. **A form of application for permission to import medical devices for the purposes of state registration to the Russian Federation territory and requirements to submitted documents are approved.**
2. **Determined the order and the period of consideration of the application, which amounted to 5 working days.**

Order of the Ministry of Health from 18.07.2016 № 521n

«On the Amendment of Certain Administrative Regulations of the Federal Service on Surveillance in Healthcare on Execution of the State Functions and Rendering State Services in the Sphere of Circulation of Medical Devices and Implementation of Pharmaceutical Activities»

Entered into force **20.08.2016**

Order of the Ministry of Health from 14.10.2013 № 737n

«On Approval of Administrative Regulations of Federal Service on Surveillance in Healthcare of Public Services on State Registration of Medical Devices»

Main Amendments

1. **Procedure of making amendments into the registration documents of MD is updated.**
2. **Procedure of making amendments into the registration certificate for MD is prolonged to 15 working days.**
3. **Procedure for getting a duplicate of registration certificate for MD is prolonged to 7 working days.**
4. **The form of notice of initiation of clinical trials is approved.**

Documents, developed in the Framework of Eurasian Economic Union

1. The rules of pre-market approval procedure of MD;
2. The procedure for application by RA of member States of the Eurasian economic Union measures on suspension or prohibition of use of MD that are hazardous to life and (or) human health, substandard, counterfeit or falsified MD and withdrawal them from circulation on the territory of the Union;
3. On a special mark of MD circulation on the market of the Eurasian economic Union;
4. General requirements for safety and performance of MD, requirements for labeling and user manuals;
5. General requirements for safety and performance of MD, requirements for labeling and user manuals;
6. The rules of conducting of researches (trials) on evaluation biological compatibility of MD;
7. The rules of conducting of clinical and clinical-laboratory trials (researches) of MD;
8. The requirements for implementation, maintaining and evaluation of MD QMS depending on potential risk of application;
9. The list of MD being a subject to assignment to measuring devices while providing State registration;
10. The order of formation and conducting of information system in the sphere of MD circulation;
11. The rules of classification of MD depending on potential risk of application;
12. The rules on MD nomenclature;
13. The rules of monitoring of safety and performance of MD.

Thank you for your attention!

AstapenkoEM@roszdravnadzor.ru

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