IMDRF International Medical Device Regulators Forum

NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

Ph.D., Elena Astapenko
The Head of the Department of organization of
state control and registration of medical devices of Roszdravnadzor

The Law 323-FZ dated 21.11.2011 "The basis of health protection in Russian Federation"
Article 80. The program of state guarantees of free rendering to citizens of medical care.

The Order of the Government of Russian Federation № 2762-r dated 29.12.2014
«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»

Russian Government order 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:

1. Rules of state registration of maximum ex-works implantable MD prices;
2. Rules of maintaining the state register of maximum ex-works implantable MD prices;
3. The method of determining the maximum ex-works implantable MD prices, the maximum distributors margin.

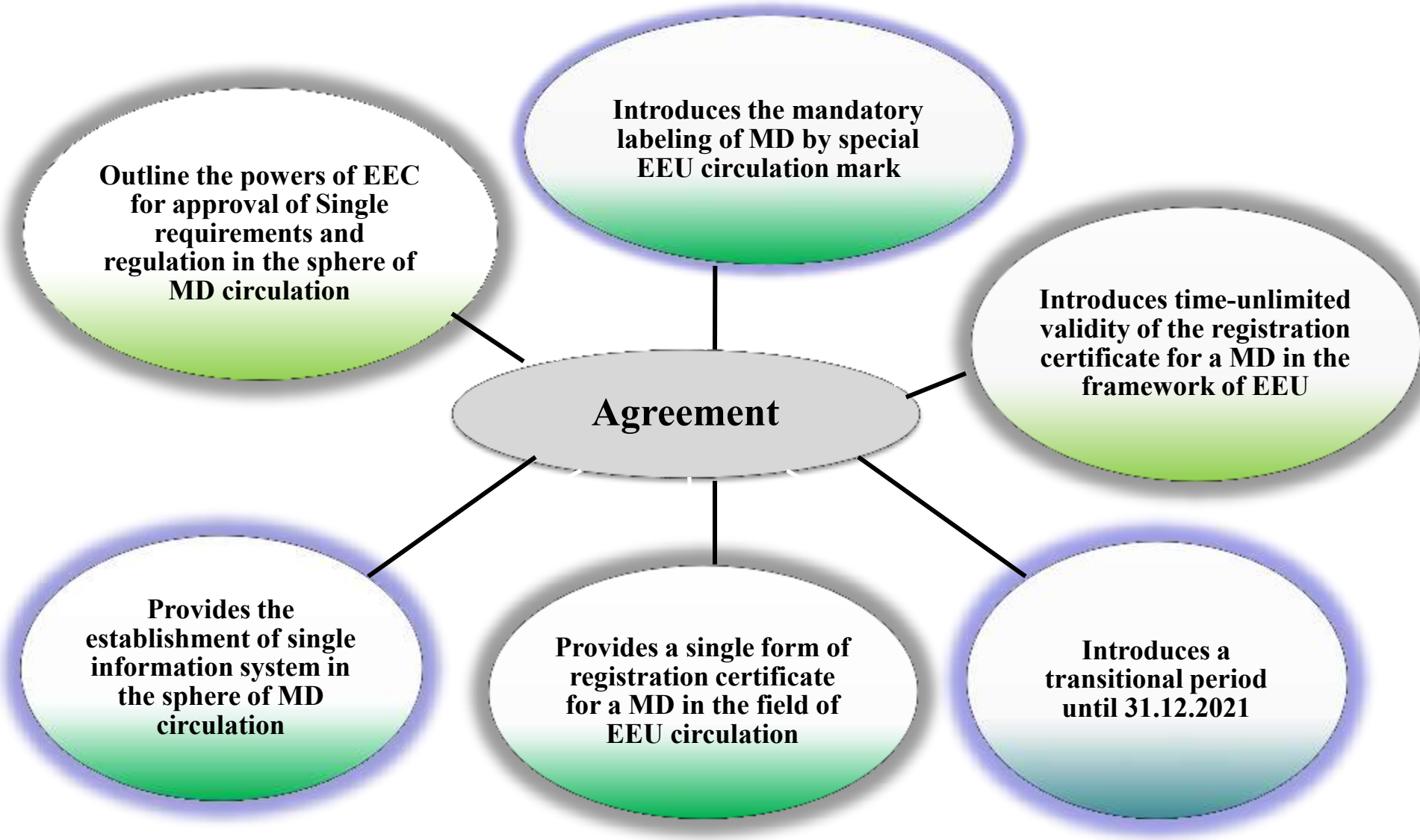
The Eurasian Economic Union

- Russian Federation
- Kazakhstan
- Belarus
- Armenia
- Kyrgyzstan

Entered into force on 01.01.2016

An agreement "On Single principles and rules of MD circulation" in the framework of EEU from 23.12.2014

Single rules of pre-market approval procedure, classification, conducting trials for registration purposes, single requirements of safety and efficiency except requirements for implementation, maintaining and evaluation of MD QMS


Introduces the mandatory labeling of MD by special EEU circulation mark
Outline the powers of EEC for approval of Single requirements and regulation in the sphere of MD circulation
Introduces time-unlimited validity of the registration certificate for a MD in the framework of EEU
Agreement
Provides the establishment of single information system in the sphere of MD circulation
Provides a single form of registration certificate for a MD in the field of EEU circulation
Introduces a transitional period until 31.12.2021

Documents, approved in the Framework of EEU

-The rules of pre-market approval procedure of MD;
- 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;
- On a special mark of MD circulation on the market of the Eurasian economic Union;
- General requirements for safety and performance of MD, requirements for labeling and user manuals;
- General requirements for safety and performance of MD, requirements for labeling and user manuals;
- The rules of conducting of researches (trials) on evaluation biological compatibility of MD;
- The rules of conducting of clinical and clinical-laboratory trials (researches) of MD;
- The requirements for implementation, maintaining and evaluation of MD QMS depending on potential risk of application ;
- The list of MD being a subject to assignment to measuring devices while providing State registration;
- The order of formation and conducting of information system in the sphere of MD circulation;
- The rules of classification of MD depending on potential risk of application;
- The rules on MD nomenclature;
- The rules of monitoring of safety and performance of MD.

Transitional period until 31.12.2021

- **registration of MD by the manufacturer (authorized representative) may be carried out in accordance with the Rules either in accordance with the legislation of a member state of the Eurasian economic union;**

- **medical devices, registered in accordance with the legislation of a member state of the Eurasian economic Union, are circulated only on the territory of that state;**

- **the documents confirming the fact of registration of MD and issued by the regulation authority of a member state of the Eurasian economic Union in the field of healthcare in accordance with the laws of this state, are valid until the end of their validity period, but not later than 31 December 2021;**

- **inspection of manufacturing in accordance with the Requirements for implementation, maintaining and evaluation of MD QMS according to potential risks is not carried out until 1 January 2018.**

Thank you for your attention!

AstapenkoEM@roszdravnadzor.ru

PhD., Astapenko E.M.

**Head of the Department of
organization of state control and
registration of medical devices of Roszdravnadzor**