IMDRF International Medical Device Regulators Forum

# NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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**Russian Government Regulation No. 160 dated 10.02.2017 «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»**

- **The subordinated Institution carries out expert advising on procedures related to State registration of MD, in order, established by Regulator.**

**Order of the Ministry of Health No. 11n dated 19.01.2017**
«About approval of requirements to the content of technical and operational documentation of medical device's manufacturer»

## The Main Novels

1. **Obligatory requirements to technical and operational documentation of MD.**
2. **Define requirements to technical and operational documentation of IVD MD.**

## 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»

**Included:**

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.

**Approved:**

**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»

# On January 1, 2015
# The Treaty on Eurasian Economic Union entered into force

## 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.

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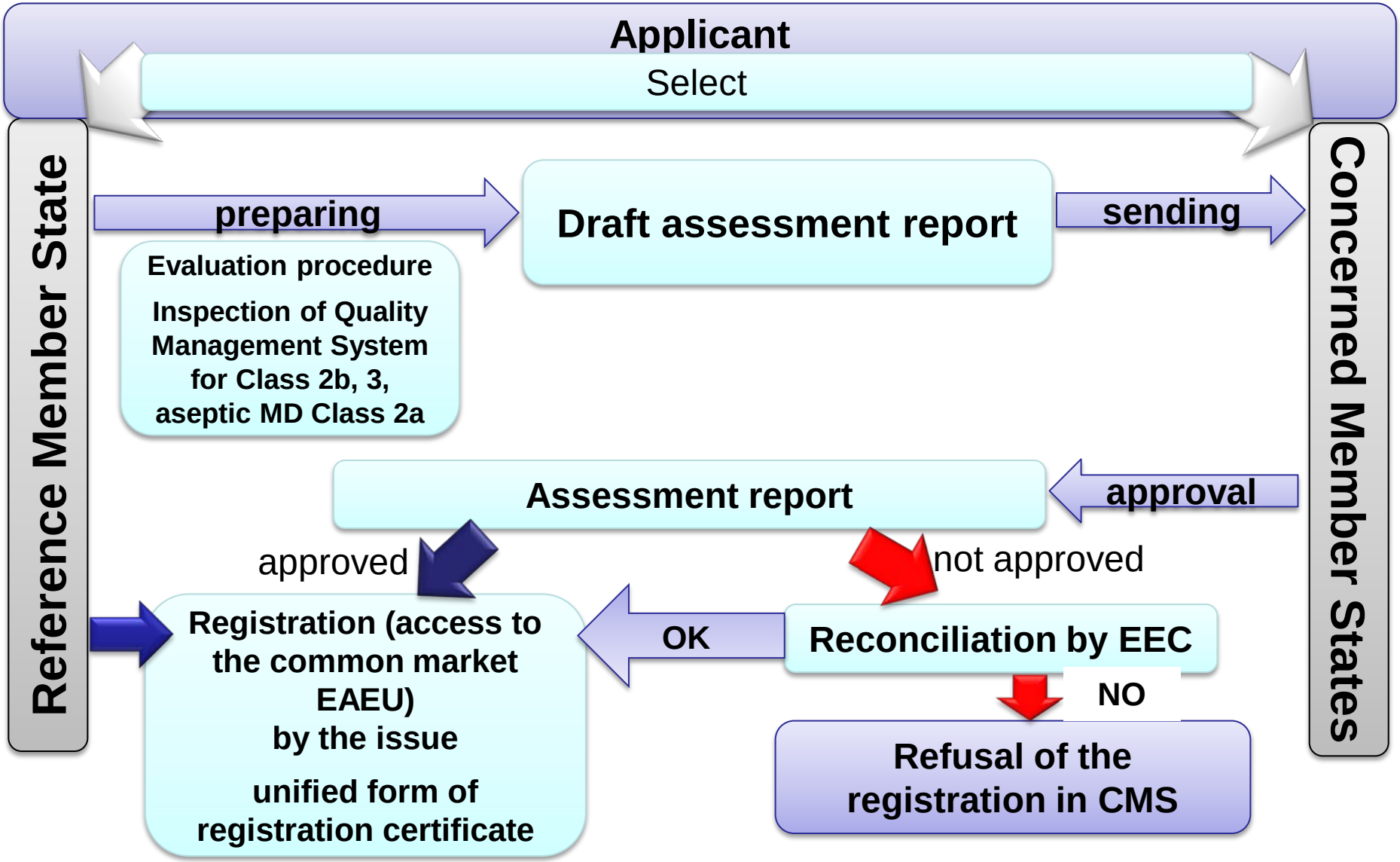
# Authorization procedure



# 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

**"Counterfeit MD" – medical device, which is issued or being in circulation with violations of the requirements of the legislation of the State – member of the Eurasian Economic Union in the field of intellectual property;**

**"Substandard MD" – medical device, which doesn't comply with common requirements of safety and performance, requirements of labelling, technical documentation and users manual, and which can't be used safely for the purposes, established by manufacturer;**

**"Falsified MD" – medical device, deliberated with false information on its composition, characteristics or (and) manufacturer.**

**Suspension of circulation of MD for 180 days, with the possibility of subsequent cancellation of registration certificate for MD**

# Thank you for your attention!

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