IMDRF International Medical Device Regulators Forum

NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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Federal Projects

NATIONAL PROJECT "HEALTHCARE"

The order of the Ministry of Health of Russian Federation
Dated 22.02.2019 No.90n
"About approval of medical device list for regional cardiovascular center facilities, primary cardiovascular department facilities, which are based in medical organizations, subordinated by government agencies of Russian Federation subjects"

The order of the Ministry of Health of Russian Federation
Dated 12.02.2019 No.56n
"About approval of medical device list for medical organizations, subordinated by government agencies of Russian Federation subjects, which are delivering medical support for patients with cancer"

The order of the Ministry of Health of Russian Federation
Dated 22.05.2018 No260n
"About approval of departmental purpose-orientated program "Material and technical base development of ambulatory pediatric clinics facilities and ambulatory pediatric departments facilities in medical organizations"

Federal Projects

Expected results of the federal project "Development of first aid system"

374 new first aid and ambulance stations are planned to be built, 304 have started their work nowadays

More than 1300 mobile medical centers will start working to the 2022 year, 224 mobile medical centers have started their work in the 2019 year, and 60 mobile medical centers are registered as MD

Update of the order of the Ministry of Health of the Russian Federation No. 2n dated 09.01.2014 “About approval of the conformity assessment procedure for medical devices in the form of technical testing, toxicological studies, clinical investigations for the purpose of state registration of MD" and the order of the Ministry of Health of the Russian Federation No. 11n dated 19.01.2017 “About approval of content of technical and operational MD manufactures documentations requirements"

Entered into force on 07.07.2019

- **Legal developments in the part of requirements determination for documents, which confirms quality of pharmaceutical product and active pharmaceutical ingredient, contained within medical device**
- **Order itemization for outreach clinical investigations of MD in the purpose of state registration**

Russian Government Regulation No. 145 dated 08.02.2017 «About approval of organization and directing rules in unified information system in the sphere of buying catalogue of products, works and services for keeping central and local government needs and rules of using this catalogue» (last update No.444 dated 12.04.2018)

Entered into force on 12.04.2018

- **Catalogue forms are made with using Nomenclature classification of medical devices (The order of the Ministry of Health of the Russian Federation Dated 06.06.2012 No.4n) which is harmonized on GMDN classification of MD**
- **In MD catalogue technical, quantitative and qualitative characteristics are defined and formulated to separate catalogue positions**
- **For now MD catalogue holds 7830 types of MD, among them 2703 types have already formulated with technical, quantitative and qualitative characteristics**

The pilot project "Medical device Labeling" has already started

The following information must be according to the standards of MD Unique Device Identification System (UDI) in the contemplate code form of identification tag:
Lot and serial number, period of validity and cure date.

Under Reform of Government regulation actualization, the project of Federal law "About obligatory requirements for MD circulation" is in progress

- Basic principles and institutes
- Groups of Legal terminology
- Duration of legal arrangements of reviewing application
- Statutes effect of breaching obligatory requirements
- Blanket standards which organize limiting list of statutes included in subordinate legislation

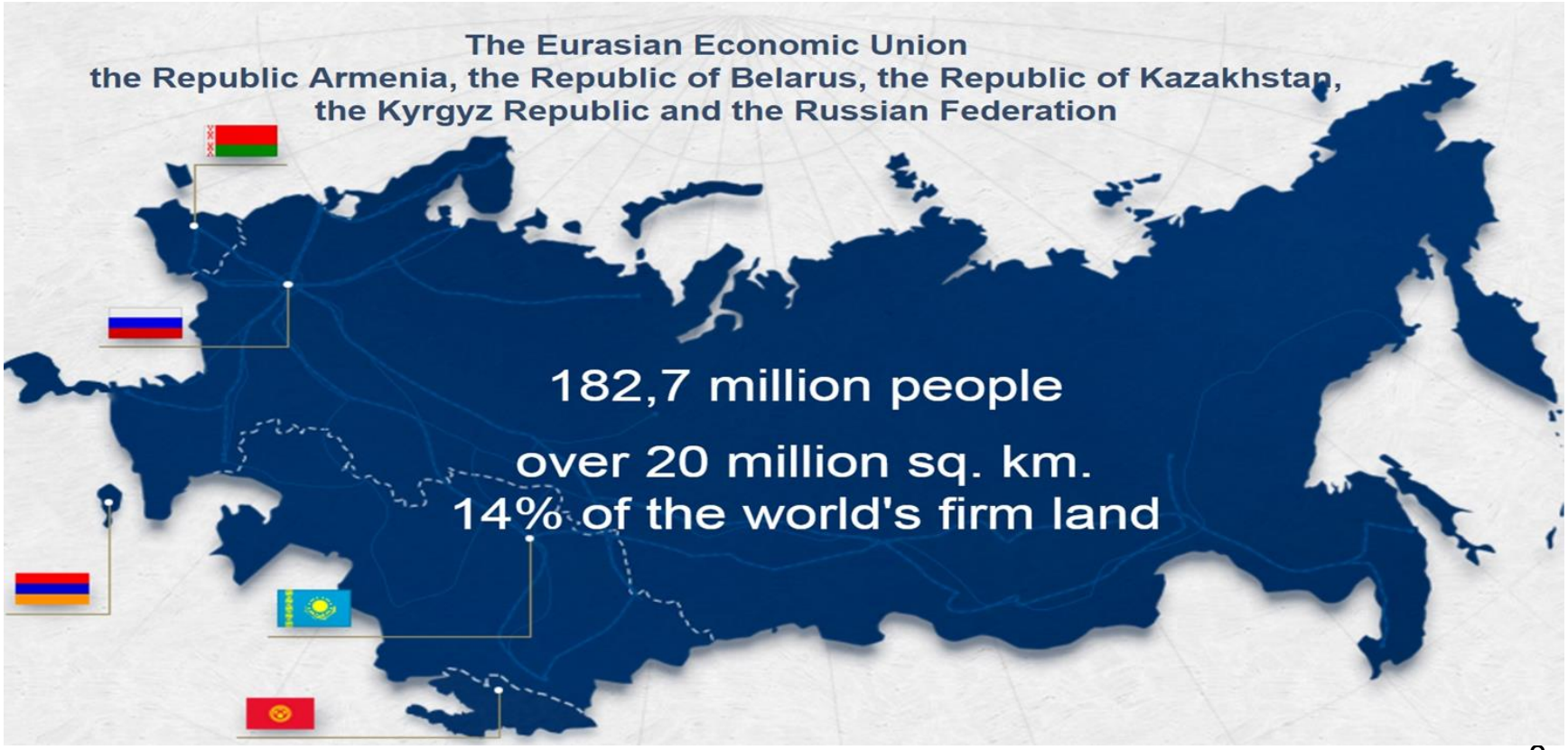
Subordinate legislation include obligatory requirements concretization, procedure descriptions, list of proposed reports and documents

MD circulation subjects:

- MD manufactures
- Organizations, which perform MD tests (except clinical investigations)
- Distributors / MD manufactures representatives
- Medical organizations, other organizations, applying MD

Circulation of Medical Devices in Eurasian Economic Union

Circulation of Medical Devices on January 1, 2015
The Treaty on Eurasian Economic Union
entered into force in Eurasian Economic Union



Documents Developed in the Framework of Eurasian Economic Union

The requirements for rating production to the MD's category 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 renting production to this category. Using of MD provides its medical purpose. Which must be single or main.
- The categories of dividing are perfume and beauty products, personal hygiene products, desinfactans, equipment, production for rehabilitation, and disabled persons, sports equipment, personal protection equipment, software, packaging systems, physiotherapeutical equipment, furniture, MD with adding pharmaceuticals, in vitro diognostical products

Authorization procedure due to EEU rules

Applicant

Select

Reference Member State

preparing

Evaluation procedure

Inspection of Quality Management System for Class 2b, 3, aseptic MD Class 2a

Draft assessment report

sending

Concerned Member States

Assessment report

approval

approved

not approved

Registration (access to the common market EAEU) by the issue

unified form of registration certificate

OK

Reconciliation by EEC

NO

Refusal of the registration in CMS

Thank you for your attention!

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