ЕЭК ЕВРАЗИЙСКАЯ экономическая комиссия

SINGLE MARKET OF MEDICAL DEVICES IN THE EURASIAN ECONOMIC UNION

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LEGISLATION REGULATING THE MARKET OF MEDICAL DEVICES: ACTS

Treaty on the Eurasian Economic Union of May 29, 2014 (Articles 31 and 100) Came into force on January 1, 2015

Agreement on Common Principles and Rules of Circulation of Medical Devices in the EAEU of December 23, 2014

Came into force on February 12, 2016

Protocol of accession of the Republic of Armenia to the Agreement of December 2, 2015

Came into force on April 26, 2016

The single market of medical devices was launched on May 6, 2017 (main sublaw documents came into force)

POWERS IN THE SPHERE OF CIRCULATION OF MEDICAL DEVICES IN THE EAEU

Establishment of uniform rules and requirements ← Eurasian Economic Commission

Implementation of the uniform requirements and rules. ← Authorized bodies of the Member States

Implementation of state control (surveillance)

Monitoring of safety, quality and efficacy of medical devices

LEGISLATION REGULATING THE MARKET OF MEDICAL DEVICES: EEC ACTS

26 ACTS OF THE EURASIAN ECONOMIC COMMISSION:
10 EEC Council Decisions,
13 EEC Board Decisions and 3 EEC Recommendations

COMMON ACTS

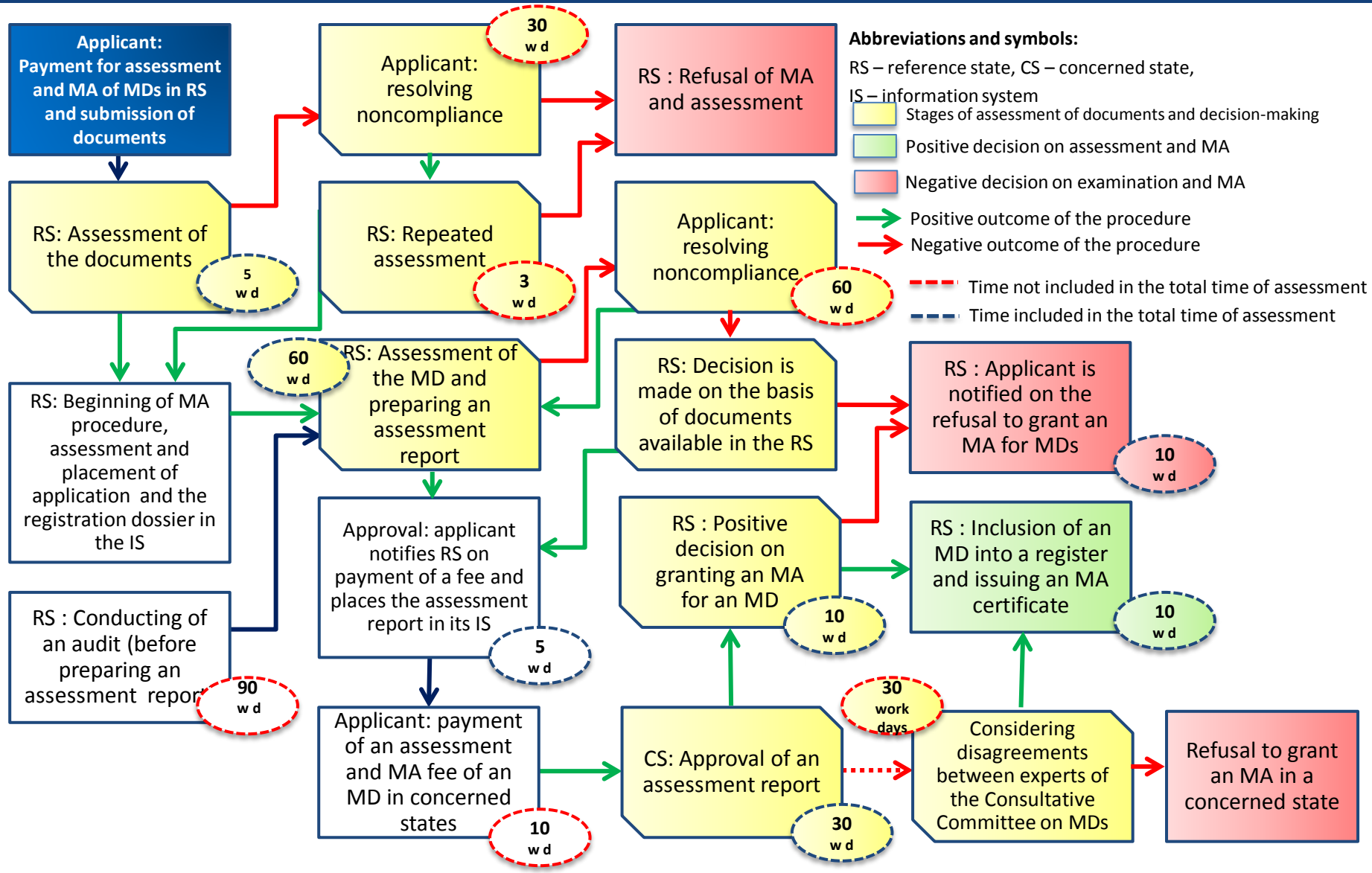
Marketing authorization and assessment rules ♦ Special mark of MA ♦ MD nomenclature ♦ Registers and information bases♦ Measures for dangerous MDs ♦ Electronic form of the registration dossier ♦ Regulation on Consultative Committee on MDs

Safety	Efficacy	Quality
♦ Common rules for safety, efficacy and labelling ♦ Rules for technical tests of MDs ♦ Classification of MD according to the degree of risk ♦ Rules for conducting biological investigation ♦ List of standards for safety assessment and rules for its formation	Rules for clinical and clinical- laboratory studies Rules for safety, efficacy and quality monitoring	List of MDs classified as measuring instruments Requirements to assessment of QMS of medical devices

TRANSITION PERIODS IN THE SPHERE OF MD CIRCULATION

End of period	Characteristics	Document
	TRANSITION PERIOD IN THE SPHERE OF MD CIRCULATION	
31.12.2021	The possibility of the national MA, national MA certificate of medical device is valid	Rules of MA (EEC Council Decision of 12.02.2016 № 46)

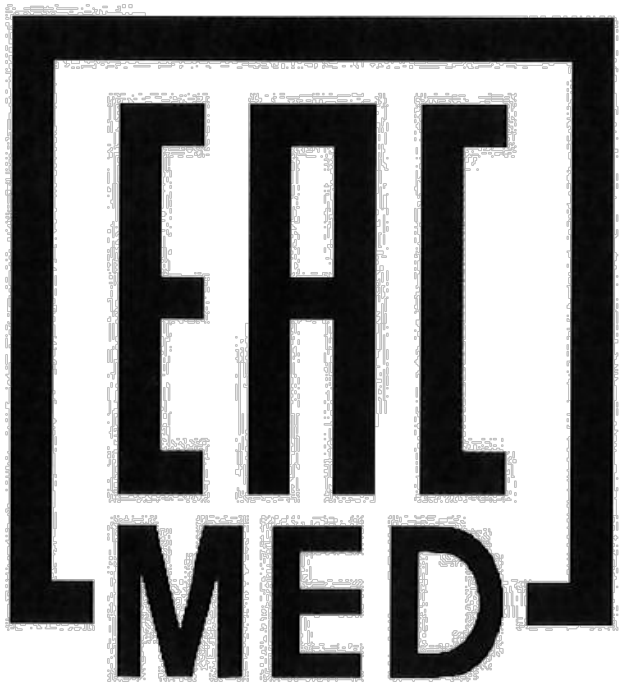
MARKETING AUTHORIZATION AND ASSESSEMENT OF MEDICAL DEVICES

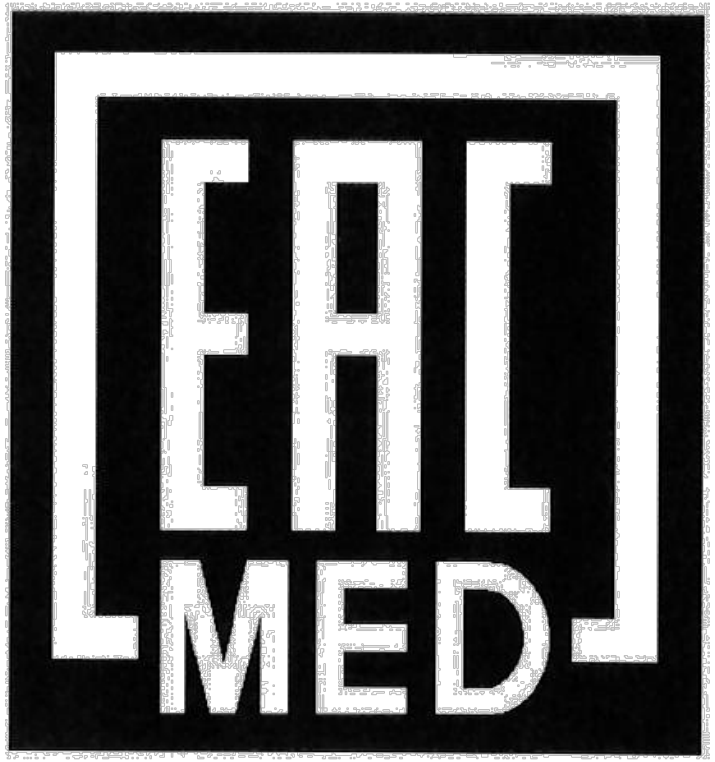


Overall time for evaluation and granting an MA:
Including «stop-times» ≈ 337 working days, without «stop-times» ≈ 114 working days

SPECIAL CERTIFICATION MARK

Decision of the EEC Council of 12.02.2016 № 26
approved the image of a special certification mark of medical devices' circulation on the market of the Eurasian Economic Union, as well as the regulation on it





LEGISLATION IN REGULATION OF MEDICAL DEVICES' CIRCULATION: THIRD LEVEL DOCUMENTS (2018-2019)

CRITERIA AND CLASIFICATIONS (3 DOCUMENTS)

- Criteria for inclusion of several modifications of MDs into one MA (EEC Board Decision of 24.07.2018 № 123)
- Criteria for classifying products as medical devices (EEC Board Recommendation of 12.11.2018 № 25)
- Criteria of differentiation of elements of medical devices (EEC Board Decision of 24.07.2018 № 116)

AUDITING OF QSM (4 DOCUMENTS)

- Requirements for auditing organizations (public discussion of the draft is finished)
- The rules of evaluation and authorization of auditing organizations
- Requirements to the auditors (the draft is under public discussion)
- Guidelines for the requirements of the QMS assessment

ASSESSMENT OF SAFETY , EFFICACY, QUALITY (1 DOCUMENT)

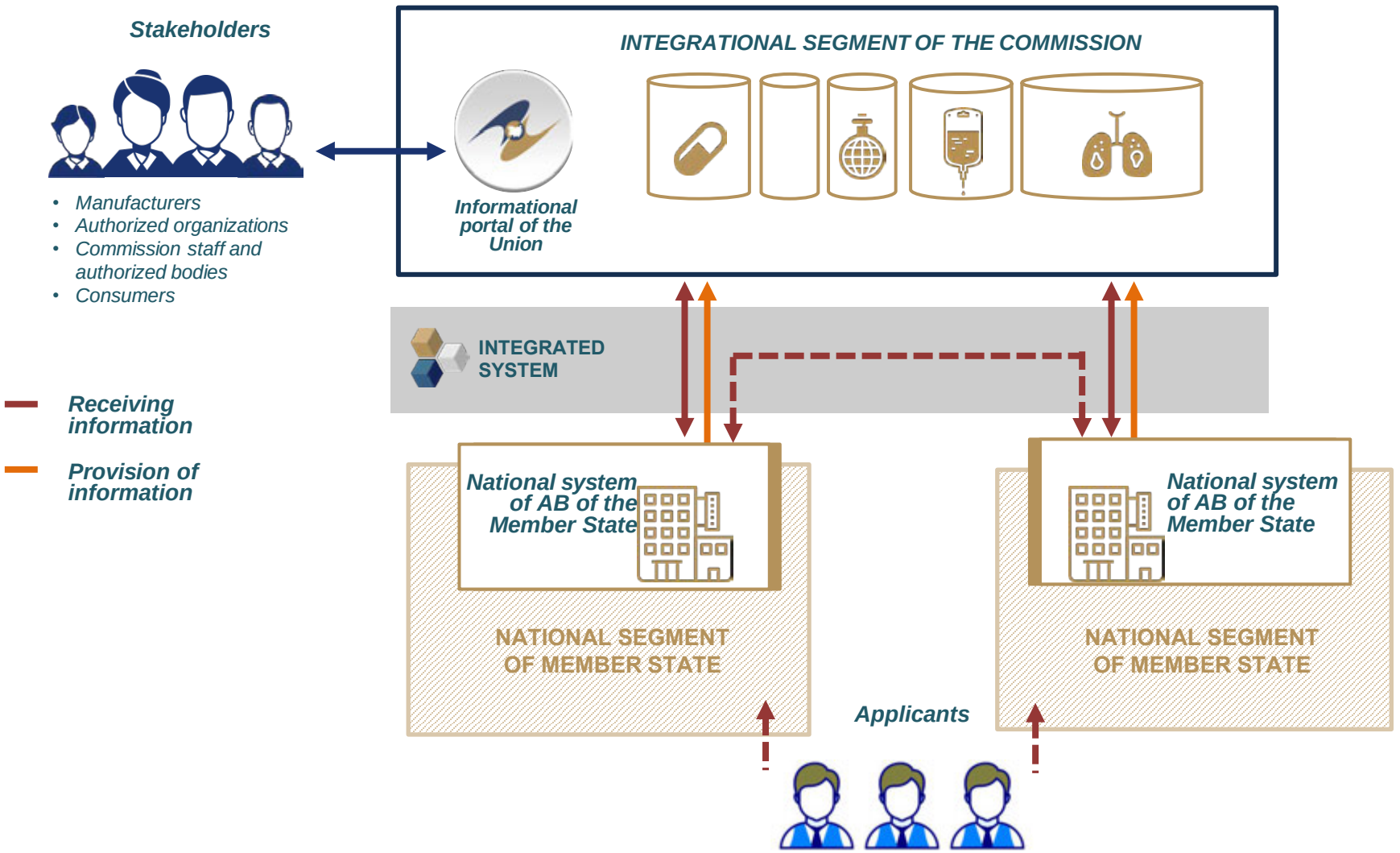
- Guidelines on safety, quality and efficacy auditing (public discussion of the draft is finished)

PREPARATION OF REGISTRATION DOSSIER (1 DOCUMENT)

- Guidelines on the content and structure of the registration dossier (the draft is under public discussion)

NAME OF THE COMMON PROCESS Included in the List of common processes in the Eurasian Economic Union (EEC Board Decision of April 14, 2015 № 29)	Legislative act
Forming, maintaining and using the Unified register of medical devices with MA in the Eurasian Economic Union	EEC Board Decision of 30.08.2016 № 92
Forming, maintaining and using the Unified register of authorized bodies of the Eurasian Economic Union, carrying out investigation (tests) of medical devices for their MA	EEC Board Decision of 30.08.2016 № 93
Forming, maintaining and using the Single information database of monitoring safety, quality and efficacy of medical devices (“MDs-vigilance)	EEC Board Decision of 30.08.2016 № 94

INFORMATION SYSTEM OF THE UNION: PARTICIPANTS OF THE PROCESS



REQUIREMENTS TO THE ELECTRONIC APPLICATION FORM AND DOCUMENTS OF THE REGISTRATION DOSSIER
(Decision of the EEC Board of 30.06.2017 № 78)

DOCUMENTS ON THE EAEU WEBSITE

http://www.eurasiancommission.org

Access:
Technical regulation →
Technical Regulation and Accreditation Department →
Creation of common markets of medicines and medical products
Hyperlink:
Acts in the sphere of circulation of medical products

Thank you for attention!

Eurasian Economic Commission
Technical Regulation and Accreditation Department

http://www.eurasiancommission.org
http://www.eaeunion.org/

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