Eurasian Economic Union Common Pharmaceutical Market Development Strategy

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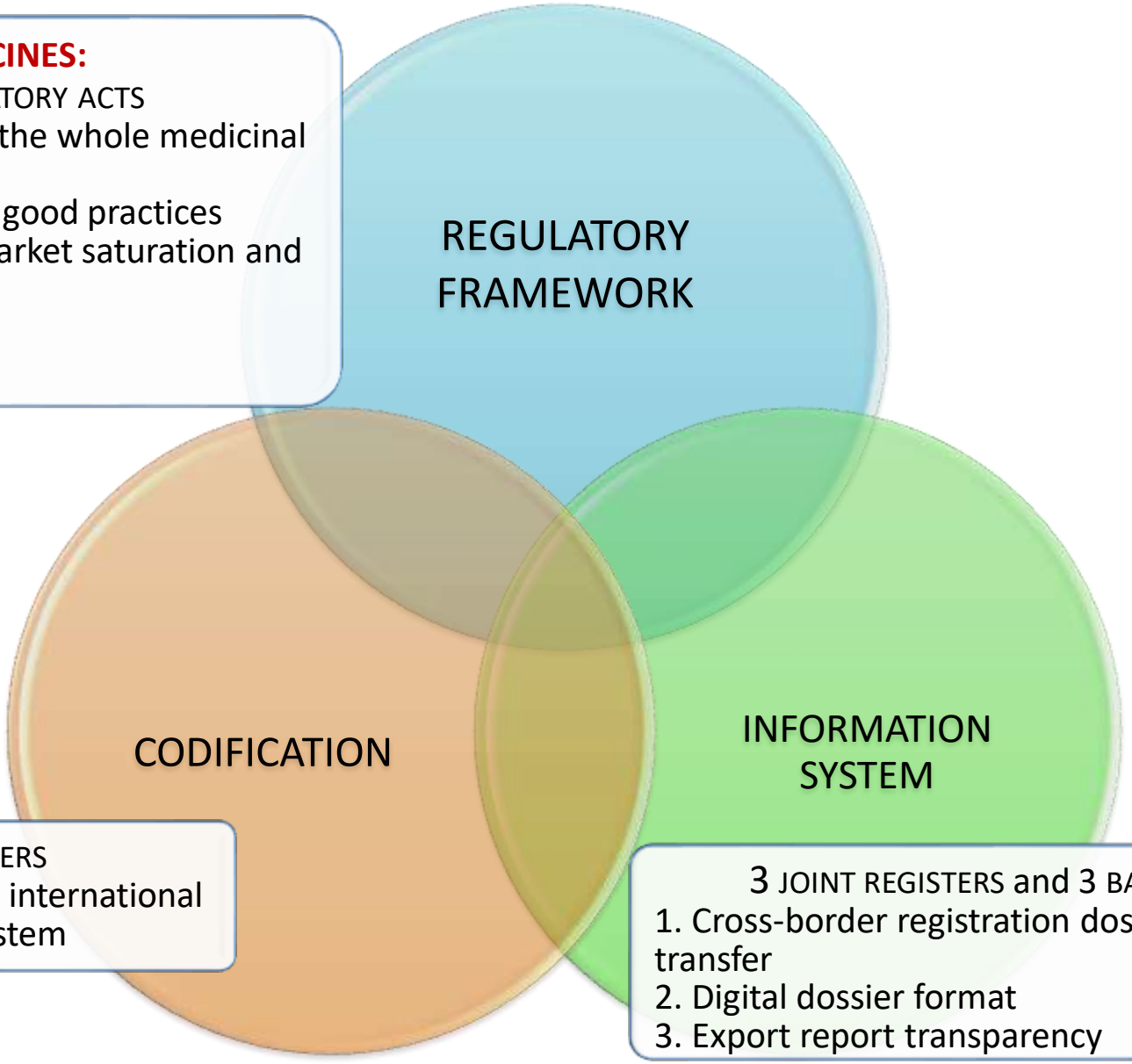
Common Pharmaceutical Market: Current State

MEDICINES:

47 REGULATORY ACTS

1. The system covers the whole medicinal product lifecycle
2. Implements global good practices
3. Ensures internal market saturation and export potential

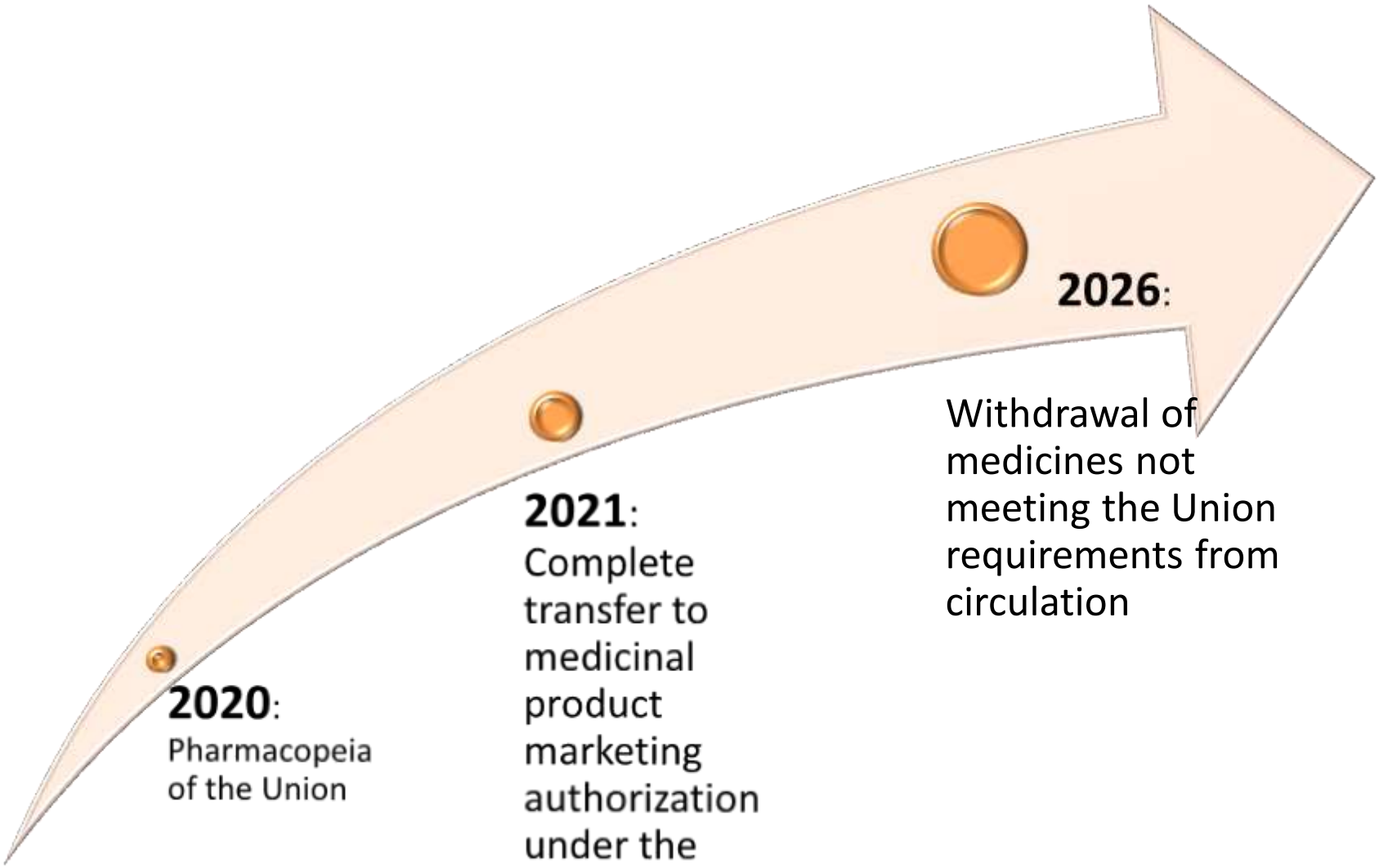


26 CLASSIFIERS

1. Integration into the international pharmacovigilance system

3 JOINT REGISTERS and 3 BASES

1. Cross-border registration dossier transfer
2. Digital dossier format
3. Export report transparency


2020:
Pharmacopeia of the Union
2021:
Complete transfer to medicinal product marketing authorization under the Union rules
2026:
Withdrawal of medicines not meeting the Union requirements from circulation

Medicinal Product Market Regulatory Framework: 'Third Level' Documents (2017 through 2019)

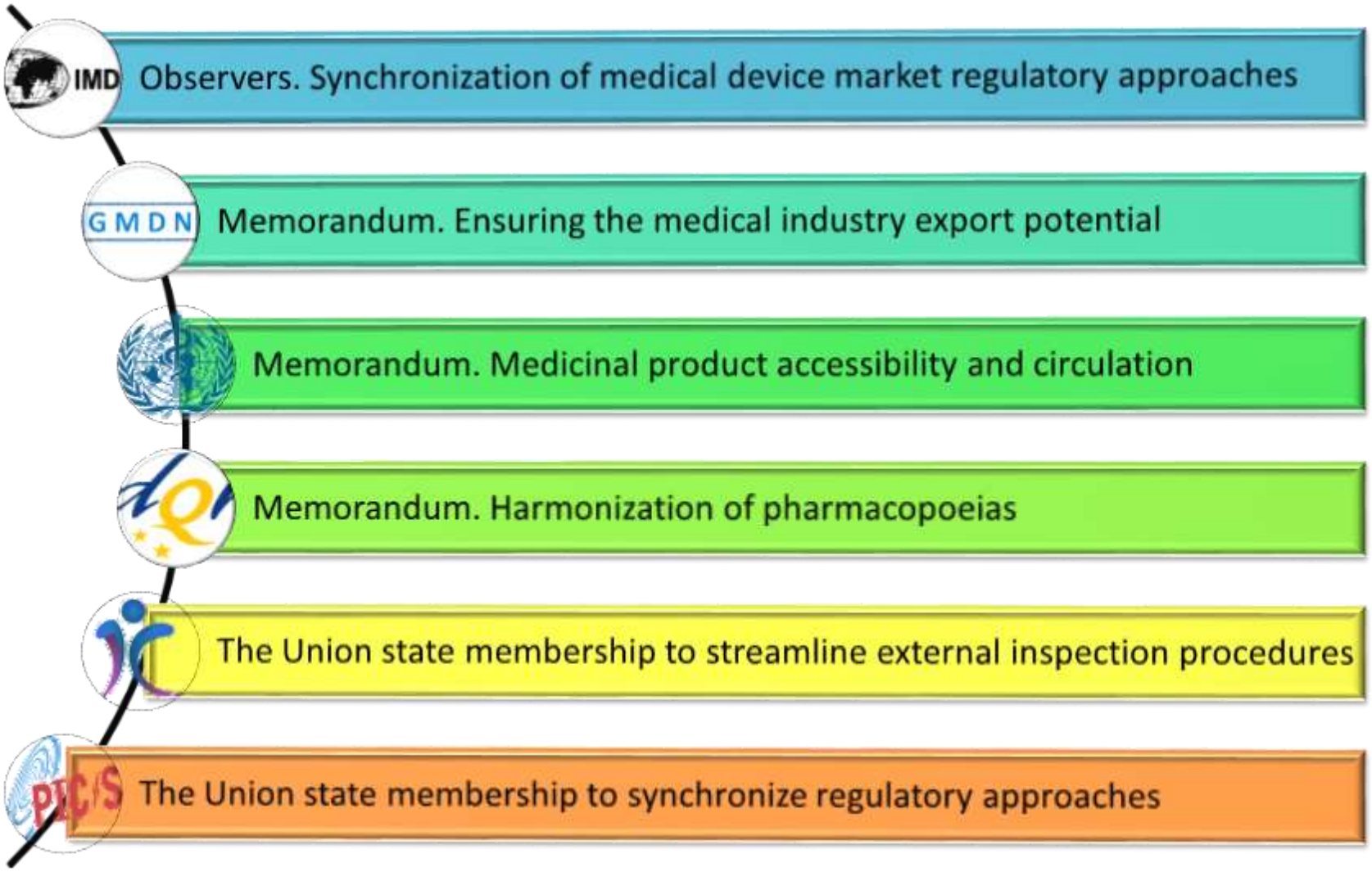
DESCRIPTION	DEVELOPMENT STAGE
MANUFACTURE OF MEDICINAL PRODUCTS (> 20 DOCUMENTS)	
Production process validation	Recommendation No 119 of 26.09.17
Pharmaceutical production water requirements	Recommendation No 31 of 13.12.17
Stability study requirements	Decision No 69 of 10.05.18
Modified pharmaceutical dosage form quality manual	Recommendation No 2 of 16.01.18
Analytical method validation	Decision No 113 of 17.07.18
Inhaler product quality manual	Recommendation No 6 of 10.05.18
Quality requirements to ND	Decision No 151 of 7.09.18
Finished pharmaceutical dosage form manufacturing manual	Recommendation No 3 of 29.01.19
REQUIREMENTS TO HERBAL AND HOMEOPATHIC MEDICINES (8 DOCUMENTS)	
Good Agricultural and Collection Practice (GACP)	Council Decision No 15 of 26.01.18
Herbal medicine quality	Recommendation No 6 of 10.05.18
Selection of acceptability tests and criteria for herbal substance, herbal medicine specifications	Recommendation No 6 of 12.02.19
PRE-CLINICAL AND CLINICAL TRIALS (> 20 DOCUMENTS)	
General clinical trial issues	Recommendation No 11 of 17.07.18
Combination medicinal product pre-clinical and clinical development manual	Recommendation No 25 of 2.09.19
Medicinal product dose selection manual	Recommendation No 8 of 12.03.19
GENERAL MEDICINAL PRODUCT CIRCULATION ISSUES (>20 DOCUMENTS)	
Trade name selection manual	Recommendation No 2 of 29.01.19
Grouping name rules	Recommendation No 13 of 23.04.19
Definition guide update	Recommendation No 10 of 19.03.19
Medicinal review laboratory testing scope defining manual	Recommendation No 28 of 10.09.19

Medicinal Product Market Regulatory Framework: 'Third Level' Acts Planned for 2020

DESCRIPTION	Adoption, as planned
MANUFACTURE AND QUALITY (> 20 DOCUMENTS)	
Aseptic production process requirements	QI 2020
Hazardous substance medicine production manual	QII 2020
Pharmaceutical substance development and production manual	QII 2020
Technology and analytical methods transfer manual	QIII 2020
Foreign substance study and specification requirement establishment rules	QIII 2020
Pediatric pharmaceutical development manual	QIII 2020
Sterile medicine production process selection manual	QIII 2020
Radiopharmaceutical product development and quality manual	QIV 2020
REQUIREMENTS TO HERBAL AND HOMEOPATHIC MEDICINES (8 DOCUMENTS)	
Homeopathic product dossier guidelines	QIII 2020
Herbal substance product stability study requirements	
Manual on active substance or herbal substance extract content labelled on medicines and specified in directions for medical use	
PRE-CLINICAL AND CLINICAL TRIALS (> 20 DOCUMENTS)	
Manual on pre-clinical toxicity study in case of repeated (multiple) administration of active substances for human medicinal use	QII 2020
Manuals on quality and study of medicinal products based on liposomes, micells and medicines with nanoparticle coatings	QII 2020
GENERAL MEDICINAL PRODUCT CIRCULATION ISSUES (>20 DOCUMENTS)	
Pharmaceutical dosage form shelf life commencement manual	QI 2020

ECONOMIC ADVANTAGES	SOCIAL ADVANTAGES
1. Improving investment appeal of MP and MD facility localization	1. Expanding the range and public access to medicines and medical devices
2. Costs saving due to cooperation among sequence-linked manufacturers	2. Renovating diagnostic, imaging systems and medical treatment technology
3. Cost cutting at medical and pharmaceutical product marketing outside the Union	3. Improving patient's life quality
4. 'Related area' development: logistics, engineering, AI-IT	4. Easing the primary medical care burden in the Union

Common Medicinal Product and Medical Device Markets: Integration and Globalization

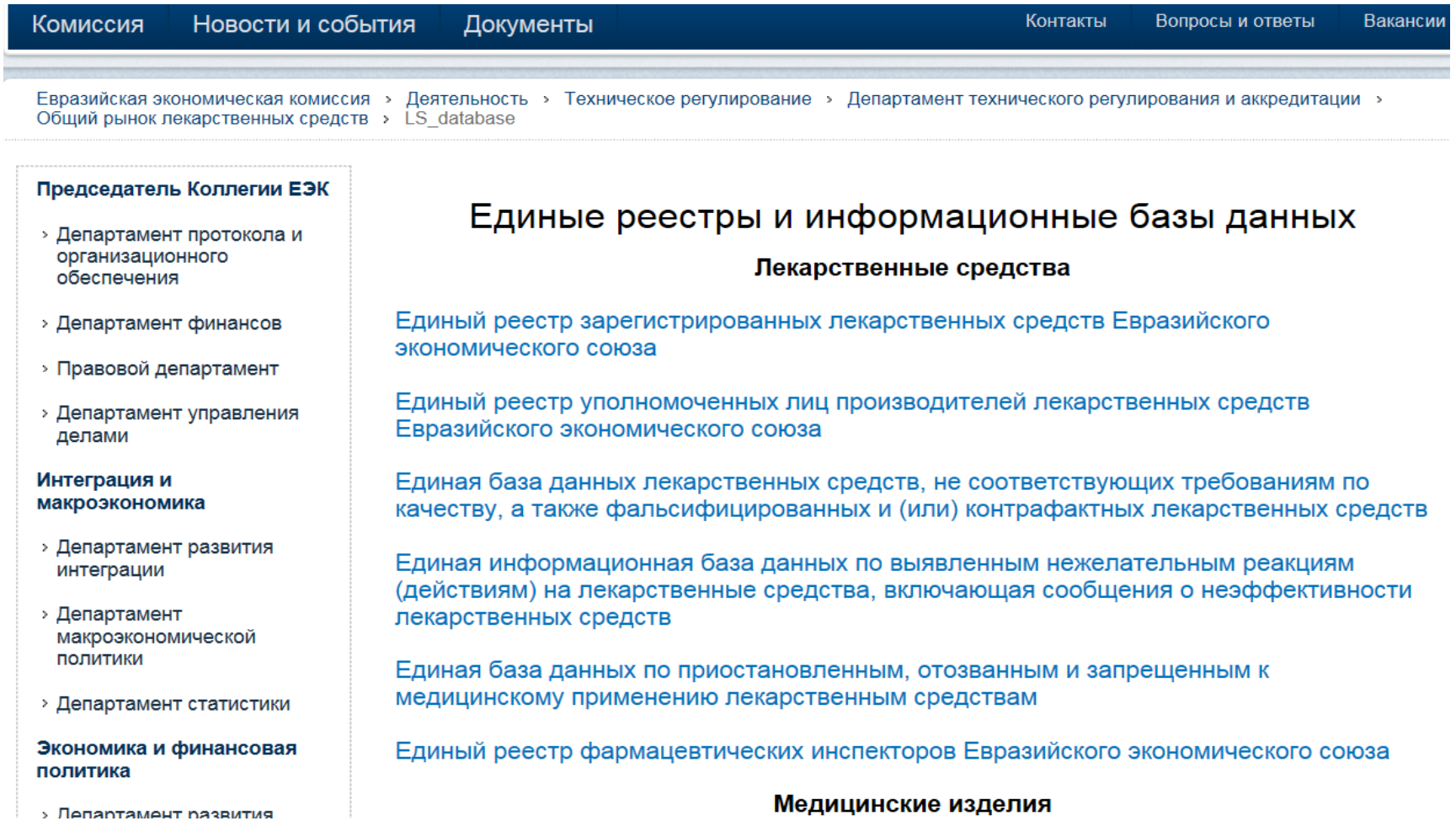


Common Registers and Informational Databases on Circulation of Medicinal Products within EAEU

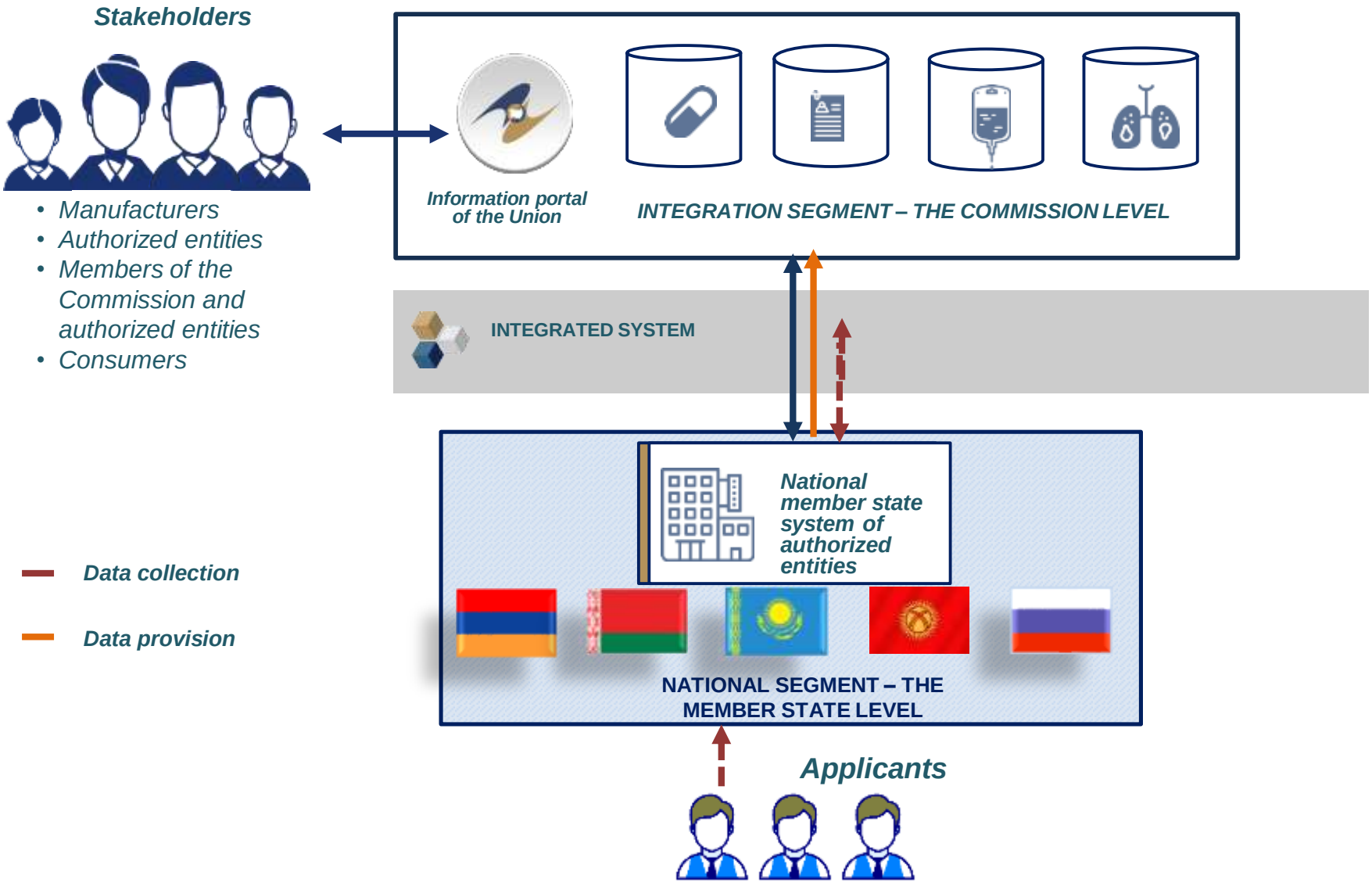
Title	Process documents	Establishment and maintenance rules	EEC Order о введении в действие
	EEC Resolution / Order date and number		
1. EAEU register of registered medicines	October 25, 2016 No 122	November 3, 2016 No 84	April 2, 2019 No 55
2. EAEU register of pharmaceutical manufacturer authorized representatives	October 25, 2016 No 123	November 3, 2016 No 74	November 12, 2018 No 171
3. Informational database of medicines non-compliant by quality, as well as adulterated and (or) counterfeit medicines identified in the member state territories	October 25, 2016 No 124	November 3, 2016 No 84	November 12, 2018 No 172
4. Informational database of identified adverse impact (effects) of medicines, including medicinal product inefficiency reports	October 25, 2016 No 125	November 3, 2016 No 84	November 12, 2018 No 173
5. Informational database of suspended, withdrawn and prohibited for use medicines	October 25, 2016 No 126	November 3, 2016 No 84	November 12, 2018 No 174
6. EAEU register of pharmaceutical inspectors	October 25, 2016 No 127	November 3, 2016 No 90	November 12, 2018 No 175

Areas for development in 2020: filling in ‘national section’ data

COMMON REGISTERS AND INFORMATIONAL DATABASES ON CIRCULATION OF MEDICINAL PRODUCTS WITHIN EAEU



http://www.eurasiancommission.org Access procedure:
'Technical regulation' → 'Department for technical regulation and accreditation' →
→ 'Formation of the common market for medicinal products'.


Stakeholders
• Manufacturers
• Authorized entities
• Members of the Commission and authorized entities
• Consumers
Information portal of the Union
INTEGRATION SEGMENT – THE COMMISSION LEVEL
INTEGRATED SYSTEM
National member state system of authorized entities
NATIONAL SEGMENT – THE MEMBER STATE LEVEL
Applicants
Data collection
Data provision

ЕЭК ЕВРАЗИЙСКАЯ экономическая комиссия

Thank you for your attention!
Have success in fruitful work!

Eurasian Economic Commission

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