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EAEU Unified Pharma Market: Admission procedures, advantages, tendencies

Diana Movsesyan
Head of Yerevan office, SCHNEIDER GROUP
Daniil Korobko
Senior Legal Expert, Moscow Office, SCHNEIDER GROUP
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Agenda: Part I

- EAEU: unified pharma market
- EAEU: legal and regulatory
- National registration procedure
- EAEU procedures, advantages
- EEU / CIS market size
- EAEU: tendencies

EAEU: unified pharma market

In November 2016, the Eurasian Economic Union's members agreed on all key regulations in order to establish **the EAEU Unified Market**.

The Union brings together Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia

EAEU: legal and regulatory

- Creation of a single market of pharmaceuticals within the EAEU
- Unified registry of pharmaceuticals
- Unified policy and approach to quality control systems, circulation, efficacy, and safety of pharmaceuticals
- Harmonization of state pharmacopeias, facilitation of mutual recognition of medicinal products registered in any of the Member State
- Mutual recognition of results of pre-clinical and clinical trials conducted in any of the Member State.

National registration procedure: transition period

National procedure

2016-2020

Termination of circulation in case of non compliance with the EAEU requirements

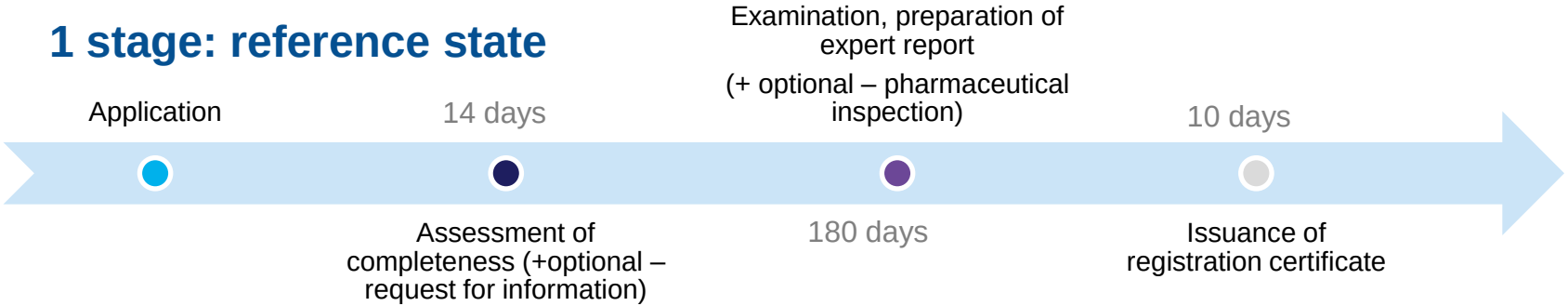
After January 2025

EAEU procedures, advantages

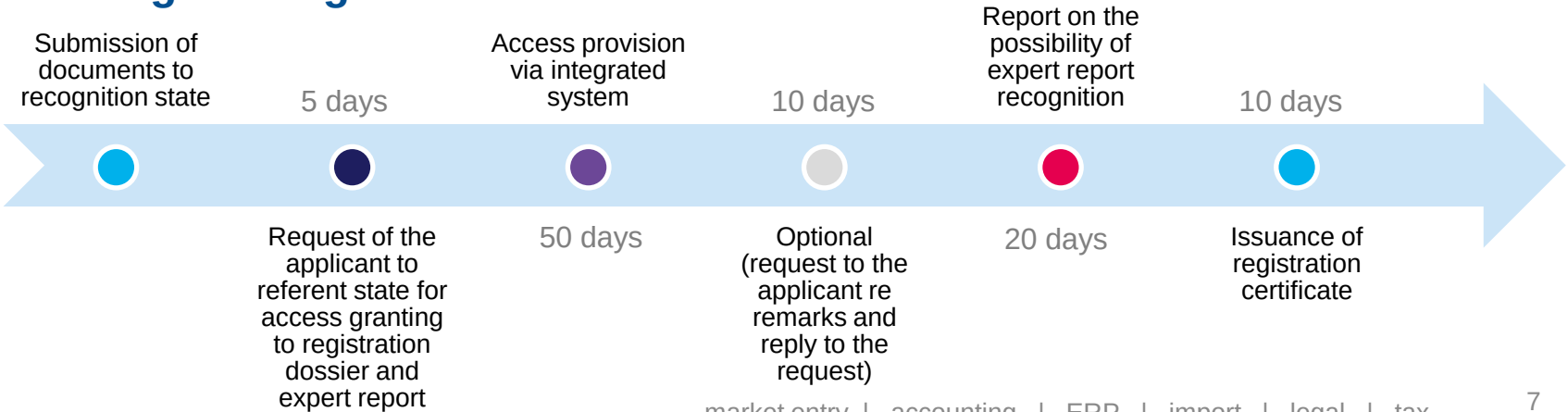
- Decentralized procedure
  - Approx. 210 days from the date of submission of the latest application
  - Parallel consideration in the reference and recognition states
  - Registration refusal in one country leads to refusals in other countries
- Mutual recognition procedure
  - 1st stage – Examination and registration in the reference state (approx. 210 days)
  - 2nd stage – Recognition in recognition state (approx. 100 days)

Mutual recognition procedure

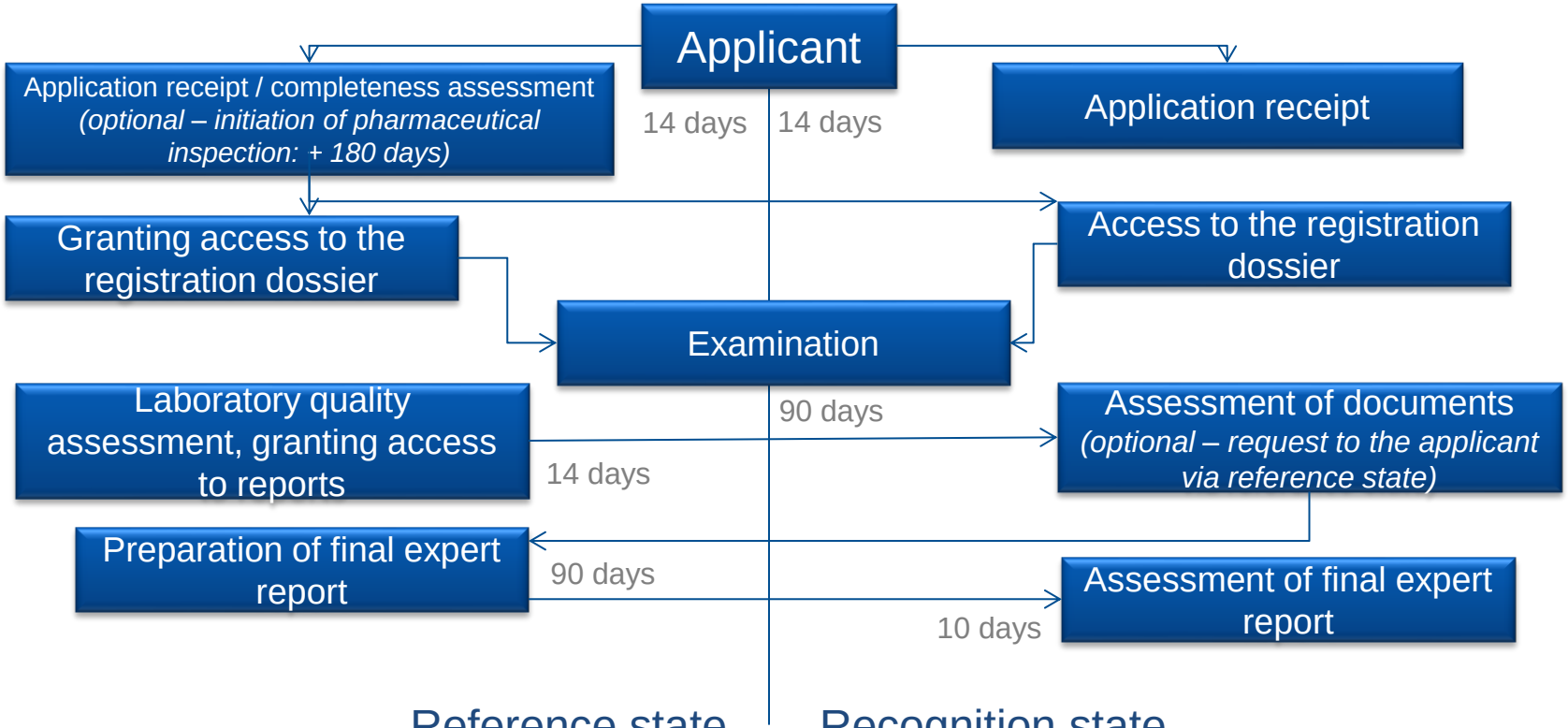
1 stage: reference state



2 stage: recognition state



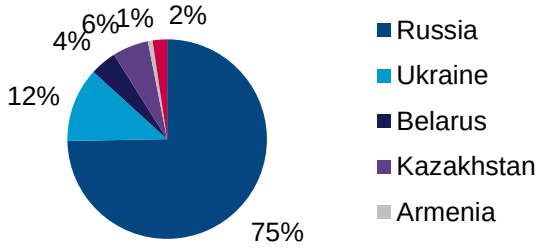
Decentralized procedure (1/2)



Decentralized procedure (2/2)

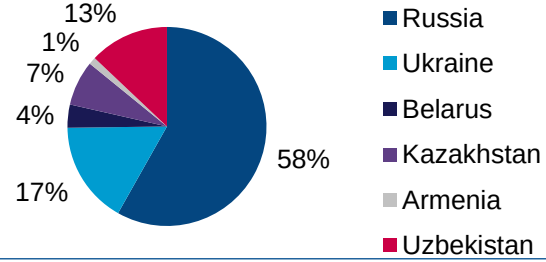
EAEU / CIS market size

Relative pharma market size by country from a total of USD 25.7bn based on sales in 2018, %



Sources: Fitch Solutions, DSM, IQVIA, SMD

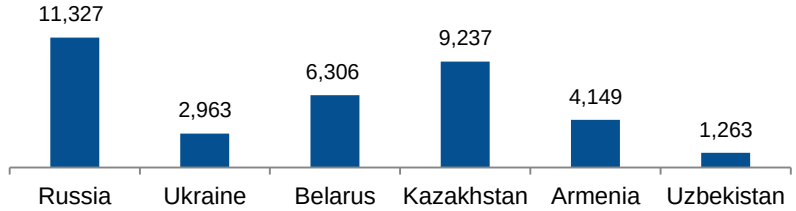
Population size by country, in combined population number, 2018, %



Source: World Bank

Combined size of pharma markets in Russia, Ukraine, Belarus, Kazakhstan, Armenia and Uzbekistan totaled **USD 25.7bn** in 2018.

GDP per capita in 2018 at current prices in USD



Source: IMF

EAEU: tendencies

http://www.eurasiancommission.org/en/Pages/ses.aspx

Diana Movsesyan
Head of Yerevan Office
SCHNEIDER GROUP LLC

MovsesyanD@schneider-group.com
yerevan@schneider-group.com

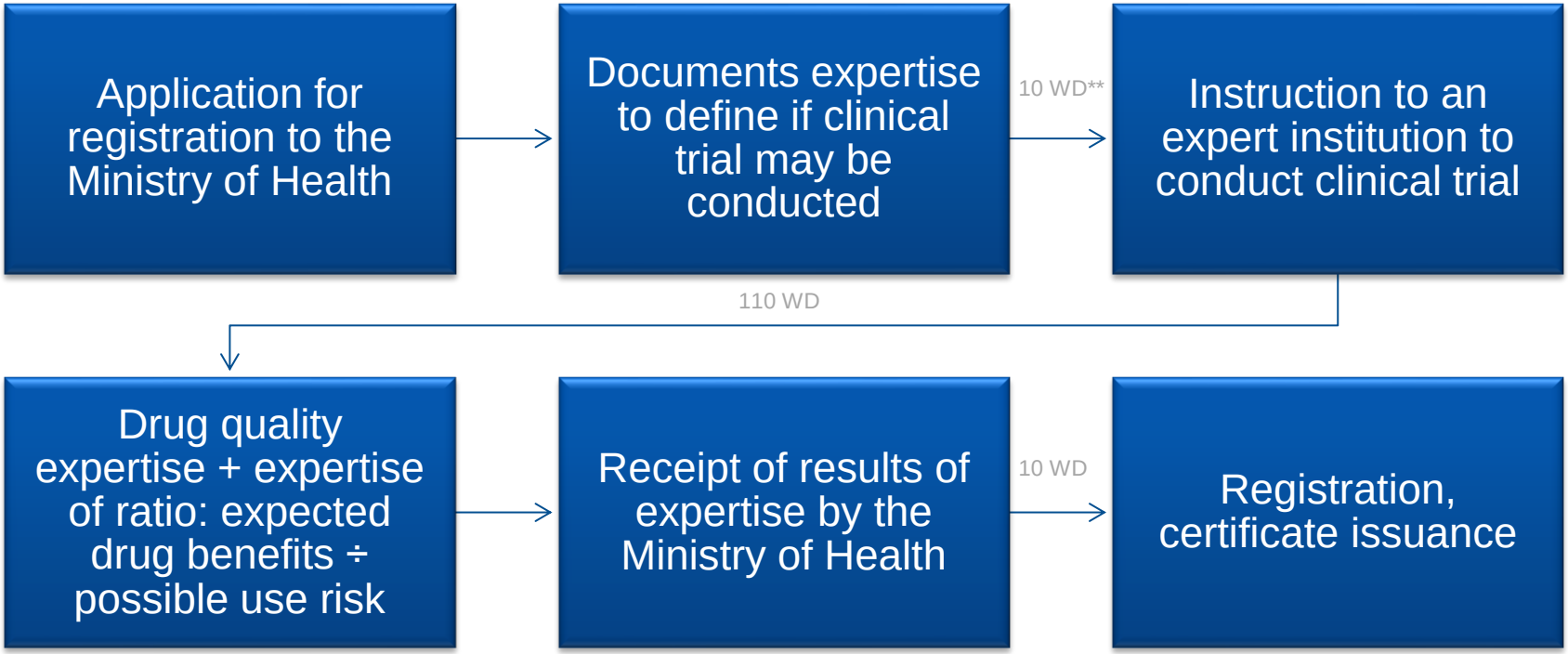
Agenda: Part II

- Russian pharma market advantages
- National drug registration procedure in Russia
- New procedure for introducing drugs into circulation in Russia
- Drug serialization in Russia
- Remote drug retail sale
- Tendencies in the Russian pharma market

Russian Pharma Market Advantages

- Largest share in the EAEU / CIS market
- One of the highest growth rates
  - 10,5%↗in 2019
  - Average 11-12%↗annually
- Attractive localization perspectives
- Growth of technological competencies

National Drug Registration Procedure in Russia*



*Approximate scheme for major group of drugs. Valid until 31.12.2020
**WD – working days

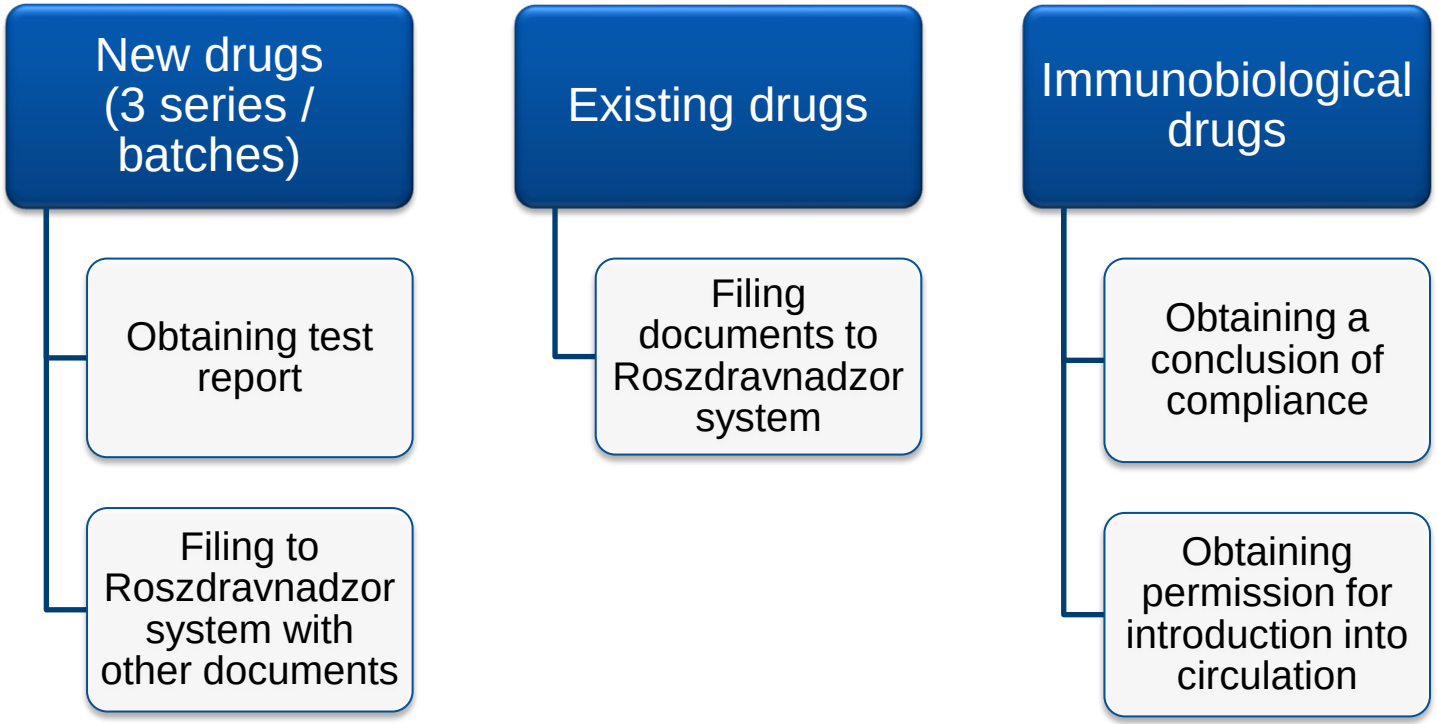
Introducing Drugs into Circulation: New Procedure

- Changes to Federal Law of 12.04.2010 No. 61-FZ On the Circulation of Drugs and other new regulations
- Mandatory certification / declaration of drugs was cancelled:
  - New procedure from 29.11.2019
  - Responsible participants of circulation
    - Russian producers
    - Importers

New Procedure Exceptions

- Operations with drugs put into circulation before 29.11.2019 are permitted within the shelf life
- New requirements do not relate to the imported drugs:
  - for clinical research
  - for the examination of drugs for registration purposes
  - unregistered drugs to provide medical care according to vital indications of a particular patient

New Procedure Scheme



Filing Information to Roszdravnadzor

- Before introducing into circulation for each series / batch
- Key documents (Russian manufacturers / importers):
  - Quality confirmation / manufacturer's certificate of compliance with pharmacopoeial article (normative documentation)
  - Confirmation of a drug compliance with state registration requirements
    - by manufacturer’s authorized person / by authorized importer’s representative
  - Test report regarding the first 3 series / batches of a new drug

Drug Serialization in Russia

Registration of drugs and participants in the monitoring system

Labelling the packaging

Tracking the path of goods to the consumer

Convenient Aspects for Foreign Companies

- Drug certificate holder and drug manufacturers can be different persons
- Remote access to emission registration device
- Notice on labelling and payment for codes within 180 days, but no later than:
  - delivery to Russia (production outside Russia, except for import from the EAEU)
  - import to Russian warehouse (production outside Russia, import from the EAEU)

Current Serialization Deadlines

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Serialization of high cost nosology from 01.01.2020

21 day for testing after registration

Registration by 29.02.2020 (7 days from the beginning of activity)

☑

Serialization from 01.07.2020

Russian vs EAEU serialization

- Agreement on the labeling of goods by means of identification in the EAEU of 02.02.2018 (in force since 29.03.2019)
  - General standards for single labelling in EAEU
  - Currently applicable only to furs
- EAEU states already have own labelling projects
  - Potential obstacle for a single EAEU pharma market
  - May be difficult to bring national labelling practices to a single standard

Remote Drug Retail Sale: Key Documents

- Decree of the Russian President of 17.03.2020 No. 187 “On the Retail Sale of Drugs for Medical Use”
- Federal Law of 03.04.2020 No. 105-FZ – amendments to the Federal Law “On Circulation of Drugs”
- Order of the Russian Government of 16.05.2020 No. 697

Remote Drug Retail Sale: Channels

Remote Drug Retail Sale: Main

- Remote sale is permitted, except for:
  - prescription drugs
  - narcotic and psychotropic drugs
  - drugs with 25% alcohol or more
- Roszdravnadzor’s permit is required
- Special powers of the Government in case of emergency situation regime / disease spread threat
  - Until 31.12.2020
  - Right to regulate temporary drug sale
  - Possible remote sale of prescription drugs

Remote Drug Retail Sale: Admission Procedures

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Requirements for pharmacies

- Pharma license for retail (available for ≥ 1 year)
- ≥ 10 places of pharma activity in Russia
- Own / outsourced courier service ensuring appropriate temperature conditions
- Other

Remote sale permit

- Issued by Roszdravnadzor
- 5 working days after filing an application
- Online register of issued permits

Russian Pharma Market Tendencies

- Further harmonization of Russian pharma legislation with EAEU standards
- Establishment of price preferences for state and municipal procurement of goods
- Serialization perspectives:
  - Serialization compliance as a pharmaceutical license requirement
  - Further improvement of legislation
- Regulation of marketing services rendered by pharmacies

Russian Pharma Strategy 2030 (draft)

- Creation of export-oriented potential of the pharma industry
- Increase in localized production / deepening localization
- Growth of tech competencies
- Creating an educational system to meet the needs of the industry

Daniil Korobko
Senior Legal Expert, Moscow Office
KorobkoDV@schneider-group.com

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