Medicinal Product Review and Registration within EAEU

Ways to Harmonize Procedures: Experience of the Republic of Armenia

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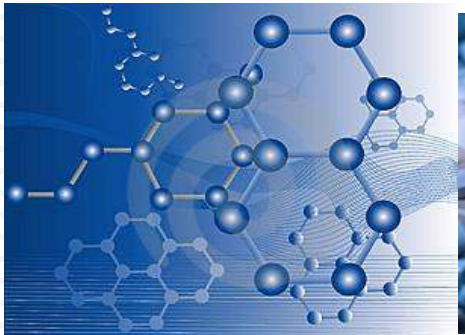


The Republic of Armenia

Territory	29,800 km^2
Population	2,969,000 (2012)
	130 mln US $

Share of medicine imports in the sales volume of the market, %	**90**
Share of medicines from EAEU countries in the sales volume of the market, %	25

E. Gabrielyan Scientific Center of Drug and Medical Technology Expertise

KEY AREAS OF THE CENTER ACTIVITIES

1. Medicinal product and medical device review and assessment for state registration.
2. Import and export review.
3. Specialized organizational studies.
4. Control over narcotic drugs and psychotropic substances.
5. Medicinal product side effect monitoring.
6. Medicinal product rational use concept introduction.
7. Expert review of medicinal product clinical trials.
8. Information and publishing.
9. Legislation.
10. Research.
11. Education.
12. Staff training and continuing education.

National Regulation System

GOVERNMENT

Ministry of Healthcare

Medicinal product regulation

Licensing agency

Established in1997

SCDMTE

Established in 1992

Healthcare and Labour Inspectorate at the Government

Established in 2015

SUPERVISION (GPP)



Quality Assurance Laboratory

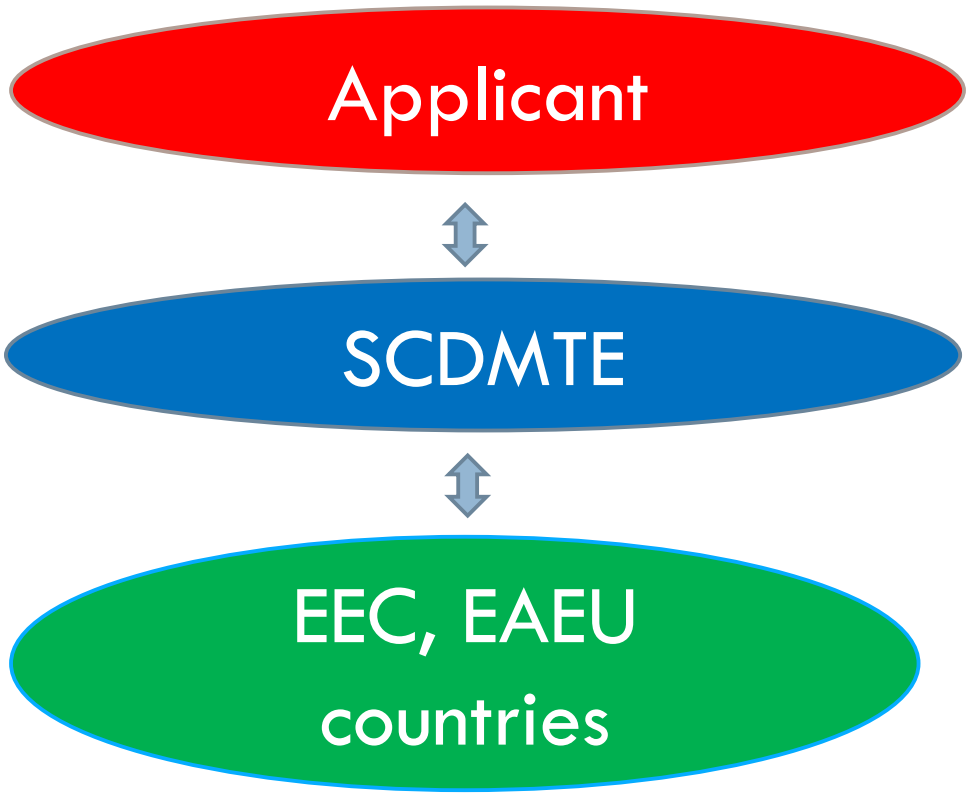
SCDMTE

Medicinal Product Review and Registration: Regulatory Framework

- National legislation
- Treaty on the Eurasian Economic Union of 29.05.2014 (effective from 1.01.2015)
- Protocols on accession to PA treaties of 2.12.2015 (effective from 26.04.2016)
- Medicinal product circulation acts

Experience of Compliance with EAEU Requirements

MP Registration



Dossier preparation according to EAEU requirements, e-CTD generation

e-CTD acceptance and validation
Interaction in the integrated information system

Interaction in the integrated information system

Current Situation

3 medicinal product registration filings

- 2 of them – under the decentralized procedure
- 1 mutual recognition

1 application for a GMP inspection

National Legal Features

- Streamlined procedure for registration of products prequalified by WHO

- Streamlined procedure for registration of products registered in ICH countries

Mutual Recognition

- Rational use of regulator resources

EU and US reach a milestone in mutual recognition of inspections of medicines manufacturers 07/2019

- Timely provision of quality, safe, and efficient medicines to the population
- Minimization of artificial barriers to medicinal product registration.

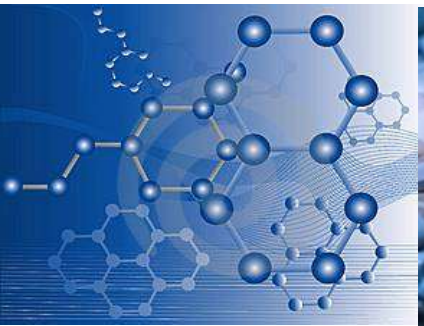
Our Proposals

- Leveraging ICH regional (IR, AR) country experience
- Use of WHO recommendations

Since 2014, Armenia has become part of the WHO Collaborative Procedure for Accelerated Registration

- Opportunity to retain national legislation advantages.

Thank you!



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