

# Ministry of Health of the Republic of Armenia



## Drug Registration System in Armenia



**Varduhi Grigoryan**  
Head of Pharmaceutical Policy and  
Medical Technology Department  
The Ministry of Health of the  
Republic of Armenia



# Regulation in the Field of Drugs

## Purpose of Regulation

Implementation of the National Drug Policy to ensure

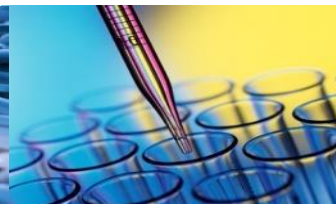
Efficiency

Safety

Quality

Accessibility

of drugs



# Regulation System Components

**Licensing**

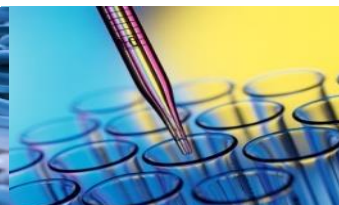
**Registration**

**Control of Import**

**Inspection**

**Promotion Control**

**Monitoring of Safety**



# Regulation in the Field of Drugs

## Registration

### Legislation

 **Law on Drugs**

 **Governmental Decree**

 **Oder of the Minister**

### Requirements

 **Form and Content of the File**

 **Packaging and Labeling**

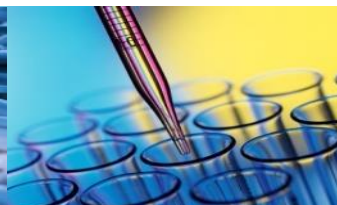
 **Criteria for refusal of registration**

 **Submission of post-registration changes**

### Authorized Bodies

■ **Drug Examination Center**

■ **Ministry of Health**



# Drug Registration in the Republic of Armenia

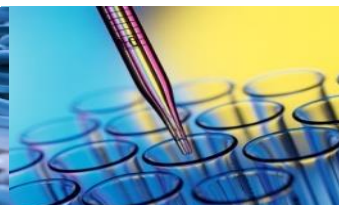
- Division of registration in the framework of the Eurasian Economic Union and national procedures

**National  
Registration**

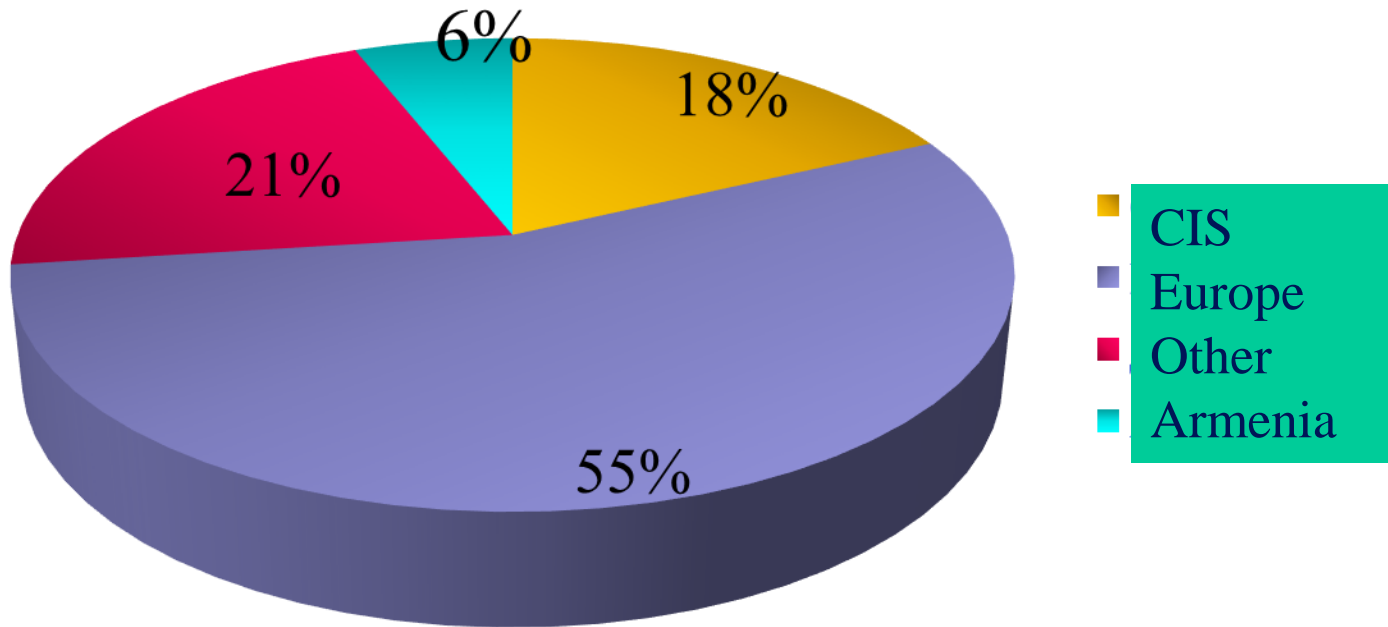
**EAEU Registration  
(210 days)**

**Standard  
Procedure  
(140 days)**

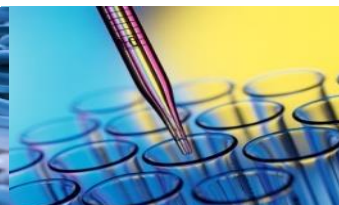
**Simplified procedure for the drugs  
registered in ICH countries or  
prequalified by WHO (30 days)**



# Drug Registration By Country

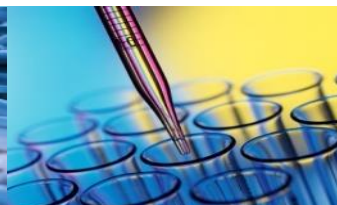


- **Small market volume**
- **Import-dependent market**
- **Absence of specific national requirements**



## Registration

- In the process of registration that category of administering a medicine is defined: *Prescription and OTC*
- The certificate is valid for 5 years
- The list of registered drugs, packages and product labels are publicly available on the website



# Problem

## Not Registered Drugs

### Solution

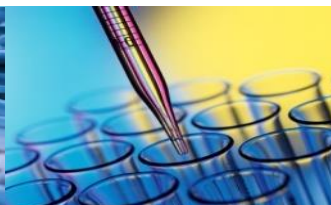
#### ✓ **Governmental Decree**

Permit for the participation in the state procurement of the unregistered drugs that have CMP certificate, registered in ICH countries or pre-qualified by WHO

#### ✓ **Law on Drugs**

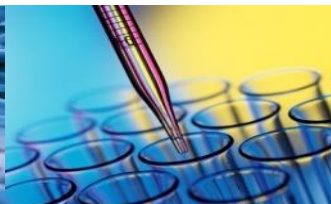
#### ✓ **Governmental Decree**

Permit for a single import by the order of the Ministry of Health of the Republic of Armenia





**Thank you for your attention!**



M3 PA