

# **REGISTRATION OF MEDICINAL PRODUCTS IN ARMENIA**

Naira Romanonva

Head of Medicine Registration Department  
Center of Drug and Medical Technology Expertise

# MEDICINE REGISTRATION IN ARMENIA

Aim of regulation of medicinal products is the implementation of the national drug policy that provides availability of safe, effective and quality medicinal products in Armenia

**Effectiveness**

**Safety**

**Quality**

**Availability**

## REGULATION OF THE MEDICINAL PRODUCTS

---

**Clinical  
studies control**

**Registration**

**Pharmacovigilance**

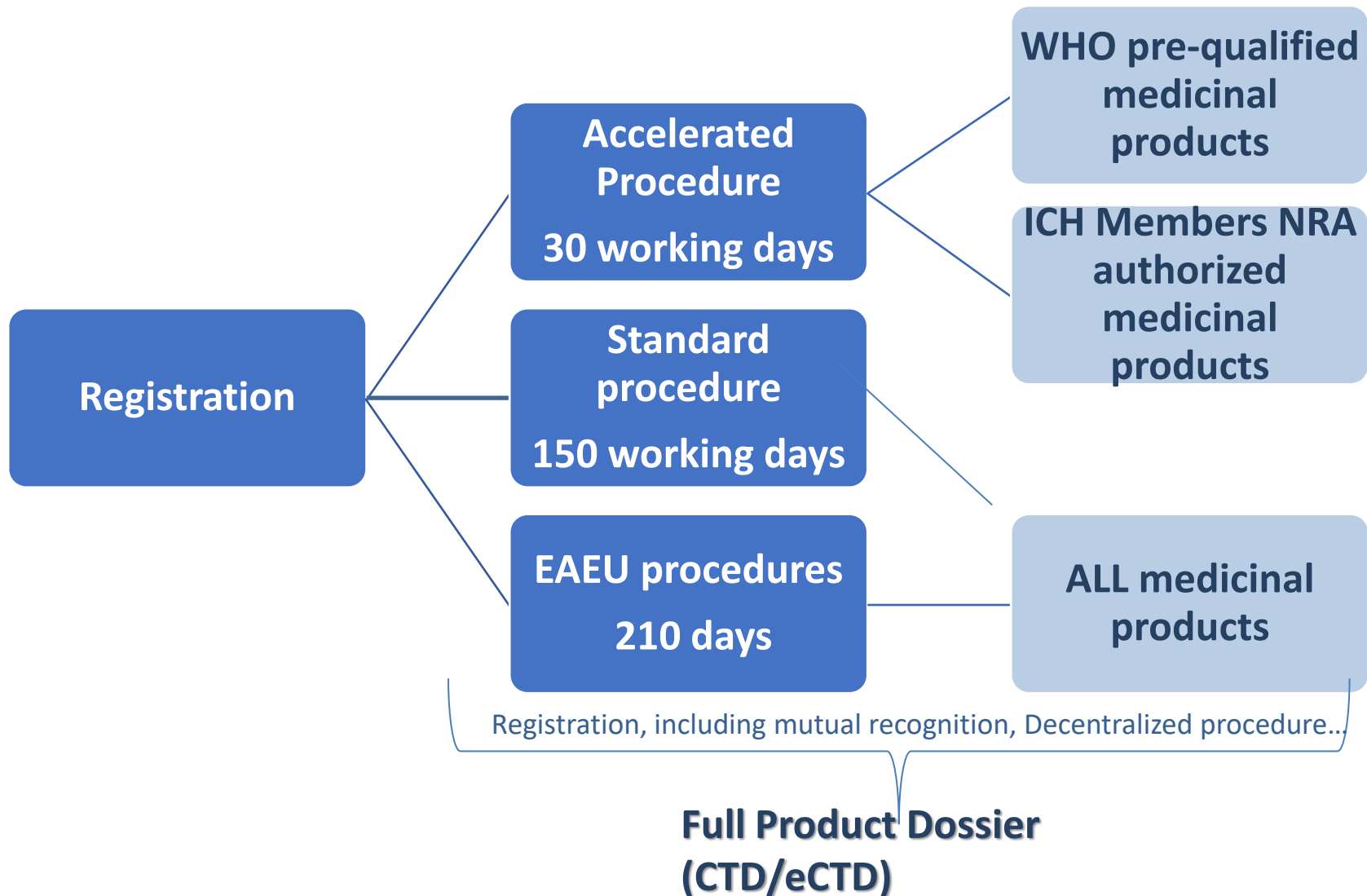
**Licensing**

**Import  
control**

**Market  
Control**

**Advertisement  
control**

# REGISTRATION PROCEDURES



# REQUIREMENTS ON MEDICINAL PRODUCTS REGISTRATION IN ARMENIA

Հայերեն Русский English

...

Search



«CENTER OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE» SNPO

Armenia, Yerevan 0051, 49/5 Komitas av., Tel.: (+374 60) 83-00-73, (+374 10) 23-16-82, 23-08-96

[Home](#) [About us](#) [Main Functions](#) [News and Announcements](#) [Publications](#) [Veterinary medicines](#) [Contacts](#)

Legislation

Assessments fees

Medicines Registration

Medicines Registration By EAEU Rules

Import and export of medicines

Clinical trials

GMP compliance

GDP compliance

Market surveillance

Essential Medicines

Drug safety monitoring

The Procurements Process

International cooperation

OTHER

## Medicines registration by EAEU rules

10 ▾

Decision EAEU N88 of November 03, 2016 on the Adoption of the Requirements for the Medication Guide and Summary of Product Characteristics of medicinal products for human use

Decision EAEU N76 of November 03, 2016 on the Adoption of the Requirements for the Labelling of Medicinal Products for Human Use and Veterinary Medicinal Products

Decision EAEU N151 of September 07, 2018 on approval of the Guidelines for preparation of the normative document on the medicinal product quality

Decision of EAEU N113 of July 17, 2018 on approval of the Guidelines for validation of the analytical procedures for medicinal products testing

Decision of EAEU N9 of January 30, 2020 on the making changes of the rules of medicines registration and assessments

Common Technical Document (CTD) by EAEU rules

Medicines registration application form by EAEU rules (updated 07.10.2022)

Decision of EAEU N78 of November 03, 2016 on the rules of medicines registration and assessments and Decision of EAEU N55 of June 14, 2016 on the making changes of the Decision of EAEU N78 of November 03, 2016 (updated 08.04.2024)

REGISTER OF  
MEDICINAL  
PRODUCTS

GUIDE TO USING  
«REGISTER OF  
MEDICINAL PRODUCTS»

REPORT ABOUT  
ADVERSE EFFECT  
OF MEDICINE  
Hot Line: (+374 10) 20-05-05,  
(+374 96) 22-05-05

ONLINE  
REPORT ABOUT  
ADVERSE EFFECT OF  
MEDICINE

UNIFIED  
ELECTRONIC  
PLATFORM FOR  
WHISTLE-BLOWING