

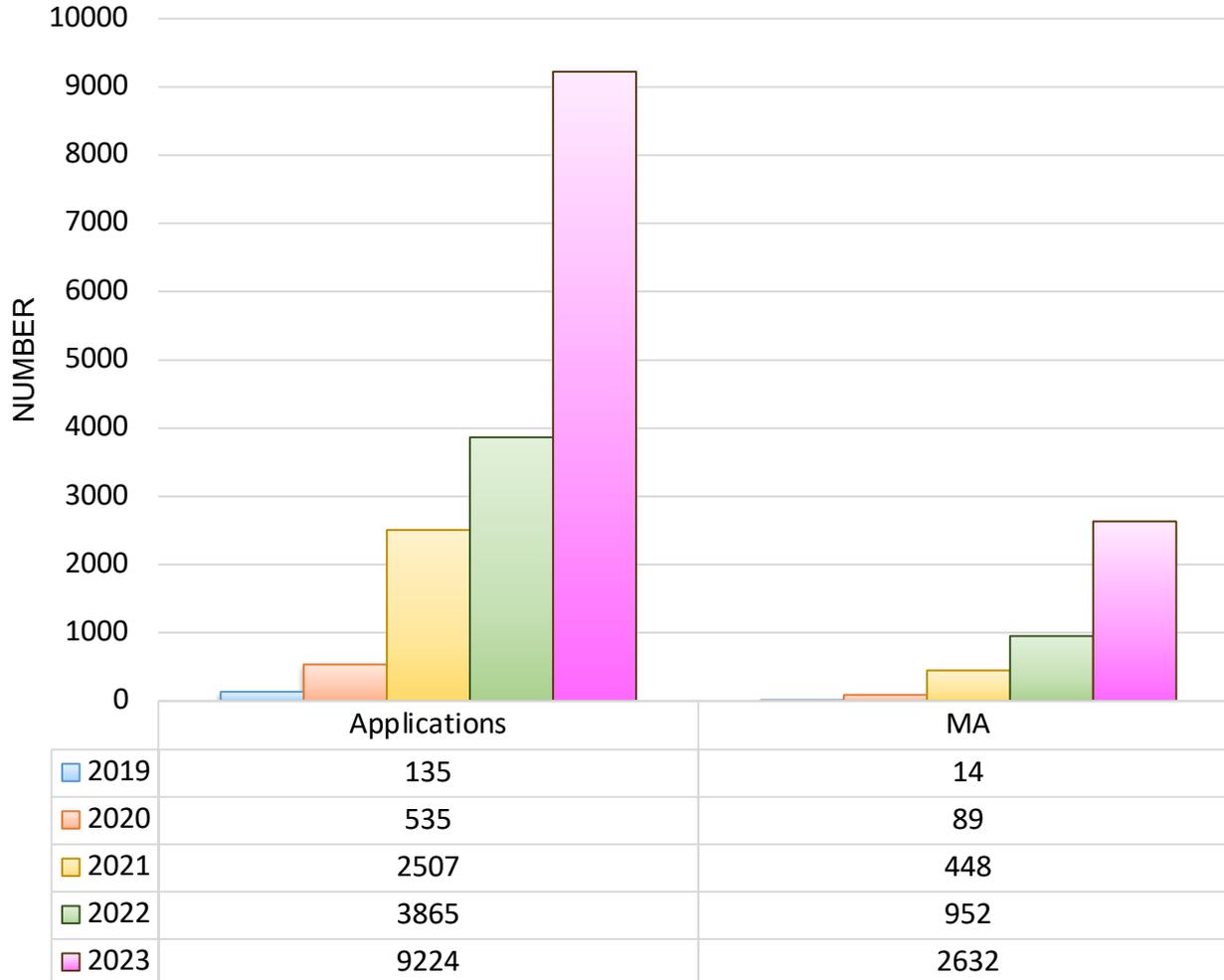
D.A. ROZHDESTVENSKY, PhD in Medical Science
EURASIAN ECONOMIC COMMISSION

**EAEU STRATEGY 2025:
RESULTS OF THE FIRST YEARS OF
FUNCTIONING OF THE COMMON MARKET OF
MEDICINES AND THEIR REGISTRATION
PROCEDURE ACCORDING TO THE EAEU
GUIDELINES**

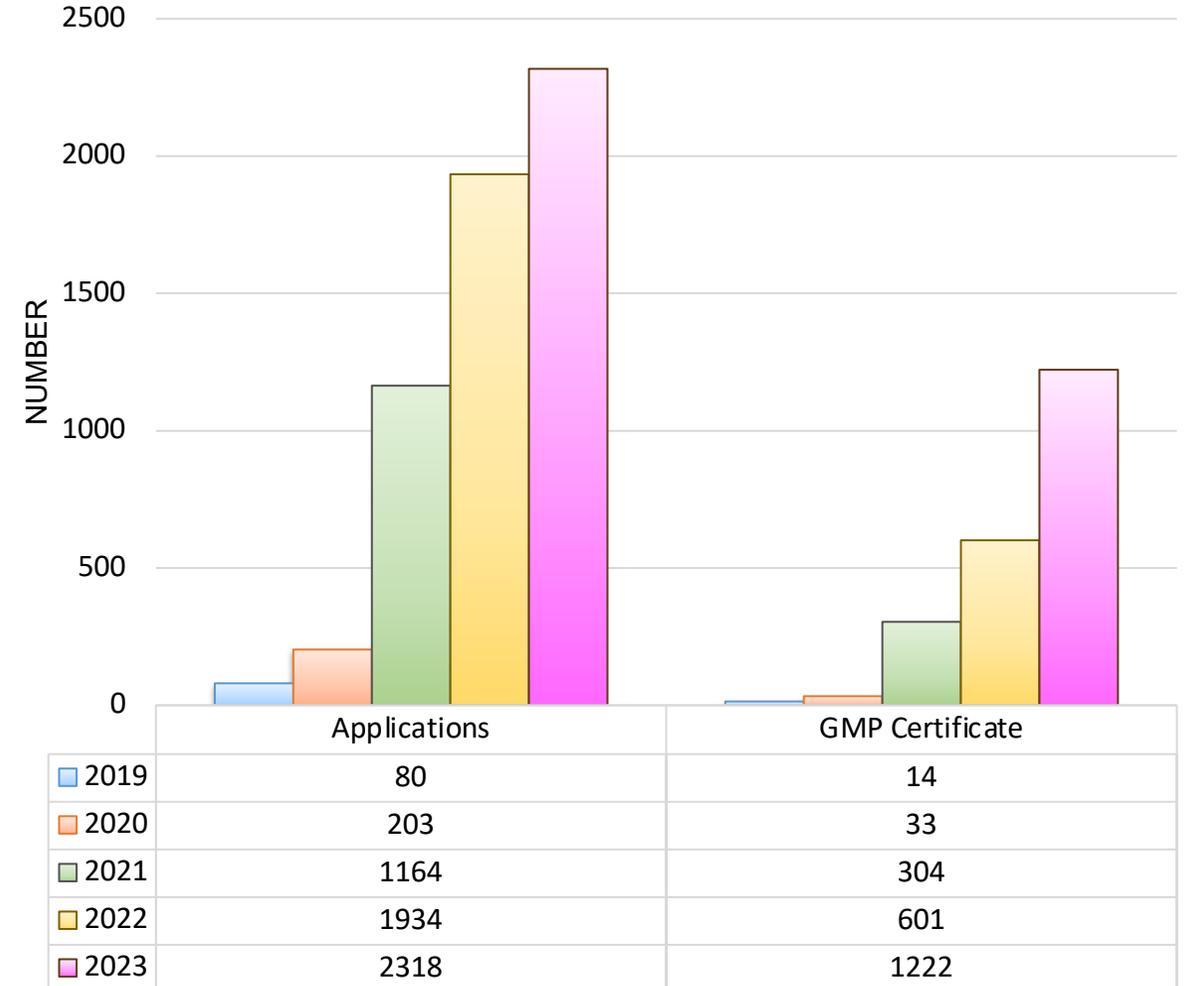
STATISTICS ON MEDICINAL PRODUCTS REGISTRATION AND SITE INSPECTIONS



MEDICINAL PRODUCTS REGISTRATION



MANUFACTURING SITE INSPECTIONS



2022-2023 KEY REGULATIONS



REGULATION

DETAILS (PREPARATION STAGE)

Amendments to the Rules of Carrying-out Pharmaceutical Inspections

- Changes to the GMP Certificate form for its compliance with EU requirements
- Procedure for remote inspections
- Procedure for pharmacovigilance inspections
- Procedure for inspections of research centers (GCP)

Decision of the Commission Council No. 127 dated 19/08/2022
Decision of the Commission Council No. 66 dated 23/06/2023
Decision of the Commission Council No. 74 dated 04/07/2023
Legal editing
Public discussion
from 05.09.2023 to 20.10.2023

Amendments to the Rules for Registration and Expert Evaluation of Medicinal Products for Human Use

- Changes to the harmonization procedure
- Changes to the variation procedure

Decision of the Commission Council No. 60 dated 22/05/2023

Commission Board on 25/09/2023
Public discussion 10/2023

2022-2023 KEY REGULATIONS



REGULATION

DETAILS (PREPARATION STAGE)

Changes to the Guidelines for Preparation of a Quality Normative Document for a Medicinal Product

Decision of the Commission Council
No. 137 dated 04/10/2022

Addendum to the EAEU Pharmacopoeia (2nd issue of Volume 1):

Decision of the Commission Council
No. 150 dated 25/10/2022
Printed version as of 31.03.2023

- Monographs on dosage forms;
- Monographs on general analytical methods (ending);
- Monographs on analytical methods for biological medicinal products

Changes to the Nomenclature of pharmaceutical forms:

- General updating of the nomenclature
- Inclusion of perfusion solutions to the list

Legal editing
Decision of the Commission Council
No. 51 dated 29/03/2022



VIII ALL-RUSSIA
GMP CONFERENCE

ORGANIZERS



GENERAL PARTNER



STRATEGIC PARTNER



GENERAL
INFO PARTNER



GENERAL INFO AND
ANALYTICAL PARTNER



STRATEGIC
INFO PARTNER

