REGULATIONS OF MEDICAL DEVICES IN THE REPUBLIC OF UZBEKISTAN

CENTER FOR PHARMACEUTICAL PRODUCTS SAFETY
MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN

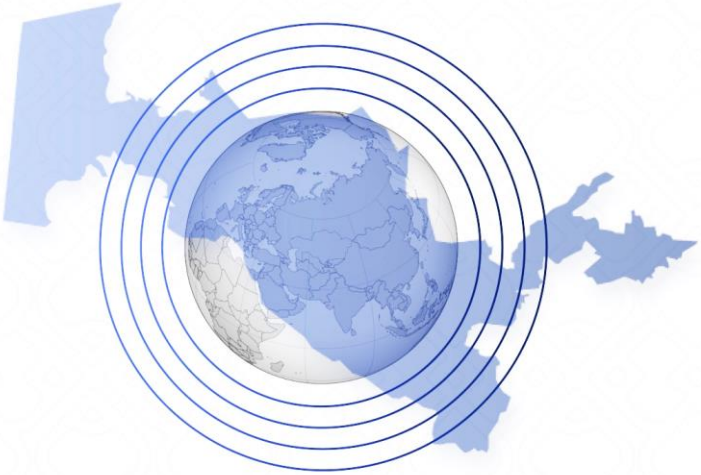
Uzbekistan

6%

GDP GROWTH OF 6% ANNUALLY, SIGNALLING A ROBUST ECONOMY

40 MILLION

LARGEST CONSUMER MARKET IN CENTRAL ASIA, POPULATION EXPECTED TO REACH 40 MILLION BY 2030



★ STRATEGIC GEOGRAPHICAL LOCATION AT THE CENTER OF MAJOR REGIONAL MARKETS

UNESCO Sites: Features stunning Islamic architecture, including Registan Square. Home to ancient Silk Road cities like Samarkand and Bukhara.

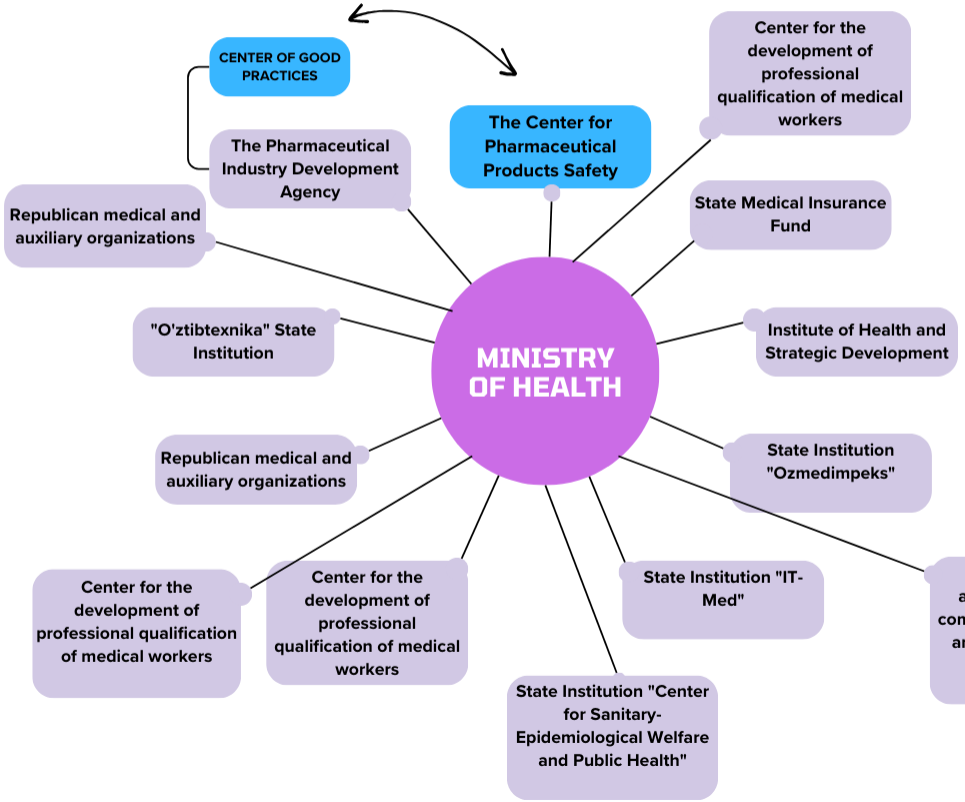
01

State Regulator

National Regulatory Authority

National Regulatory Authority of Uzbekistan was **established in 1995** and reorganized in 2023 as the **Center for Pharmaceutical Products Safety** according to the Decree of the President of the Republic of Uzbekistan, "On measures for effective organization of state management in the field of health care in the framework of administrative reforms“.

ORGANIZATIONAL STRUCTURE OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN



National Regulatory Authorities

- The Center for Pharmaceutical Products Safety
- "CENTER OF GOOD PRACTICES"

Center for Pharmaceutical Products Safety and its Regional Offices

Functions and Tasks

- Issues and manages **state registration**, **certification**, and **technical regulation** of medicines, medical devices, and equipment
- Develops **regulatory legal documents** and the **State Pharmacopoeia**
- Oversees **certification bodies** and **testing laboratories** for medicines and medical products
- Develops policy for the sale, storage, and distribution **of narcotic drugs and psychotropic substances**
- Sets **reference prices** for the sale of pharmaceutical products
- Examines pharmaceutical products **at the request of law enforcement**
- Conducts **pharmacovigilance** and **post-marketing surveillance**

Recognition of Foreign MD Registrations

Presidential Decree No. PD-6221: Issued May 5, 2021, implemented from June 1, 2021.

Goal: Streamline the registration process for medical devices in Uzbekistan by recognizing international approvals, in **15 calendar days**.

Recognized Organizations:

- U.S. Food and Drug Administration (FDA), United States
- Notified Bodies authorized to issue the European Conformity (CE) certificate, European Union
- European Medicines Agency (EMA), European Union
- Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- Ministry of Food and Drug Safety (MFDS), Republic of Korea
- Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Accreditation of Laboratories

1. **Laboratory of Vaccines, Serum, and Microbiological Analysis**
2. **Laboratory for Quality Control and Standardization of Medicines**
3. **Laboratory for Pharmaco-toxicological Analysis**
4. **Laboratory for Quality Control of Medical Devices**

All laboratories have been accredited under **ISO/IEC 17025:2019** "General Requirements for the Competence of Testing and Calibration Laboratories" since December 7, 2021, and have been included in the **Global Fund** website as certified.

Development of the Pharmaceutical Industry in Uzbekistan

Overview of Growth:

- **1990s Landscape:**
  - **Producers: 4 manufacturers**
- **Current Landscape:**
  - **Producers:** Over **230 manufacturers**
  - More **than 3000 registered** products

Industry Economic Figures

IMPORT
$ 2.4 BILLION

4800+ TYPES OF IMPORTING PRODUCTS

EXPORT
$ 130 MILLION

1200+ TYPES OF EXPORTING PRODUCTS

Tashkent Pharma Park

03

Facts and Stats

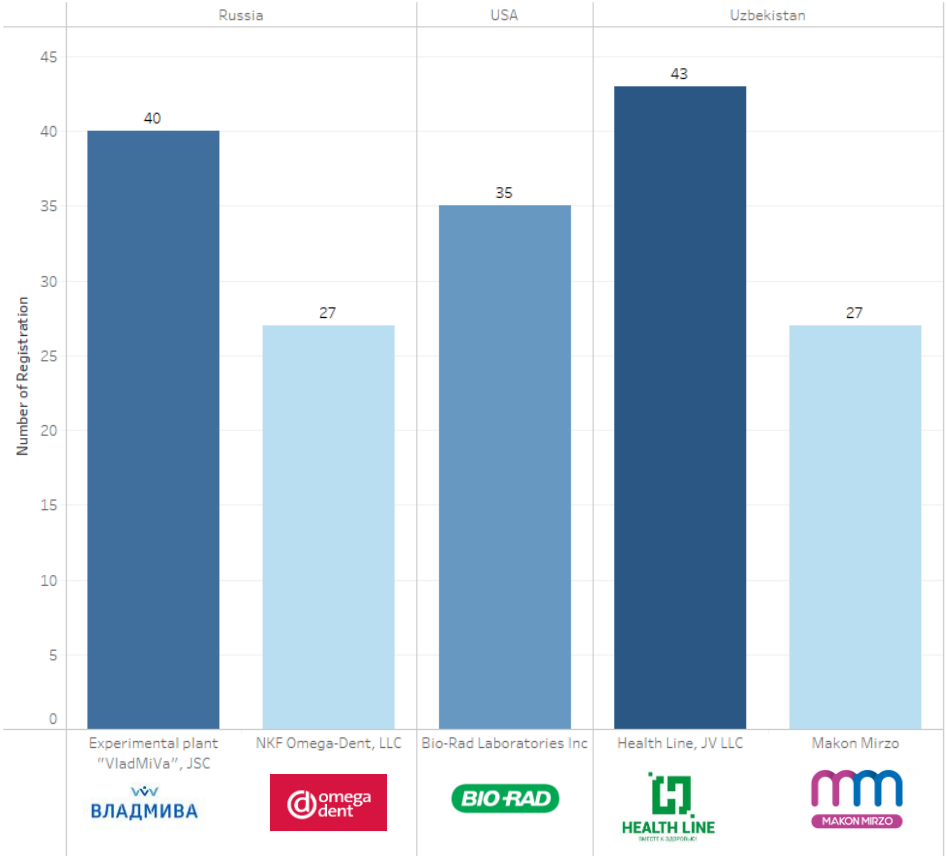
Registration Data

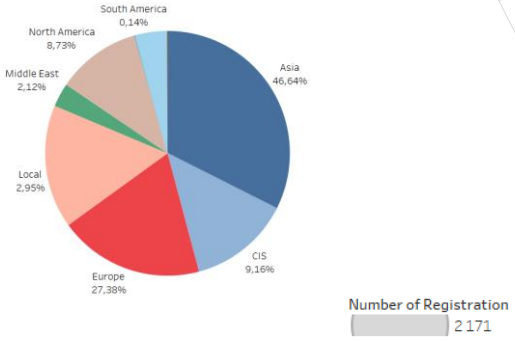
Definitions of Medical Products in Uzbekistan

1.Medical Devices:
Any instrument, apparatus, or implant intended for medical use in diagnosing, treating, or preventing diseases, often in direct patient care.
(Example: pacemakers, infusion pumps)
1.1 In-Vitro Diagnostics (IVD):
Devices or tools used to perform tests on samples (like blood, tissue, or other bodily fluids) to detect diseases, monitor health, or determine treatment effectiveness.
(Example: laboratory diagnostic kits and reagents)
2.Medical Equipment:
Tools and machines designed for diagnosis, treatment, or prevention of diseases and other medical conditions. These are generally used in clinical or hospital settings.
(Example: MRI scanners, surgical instruments)

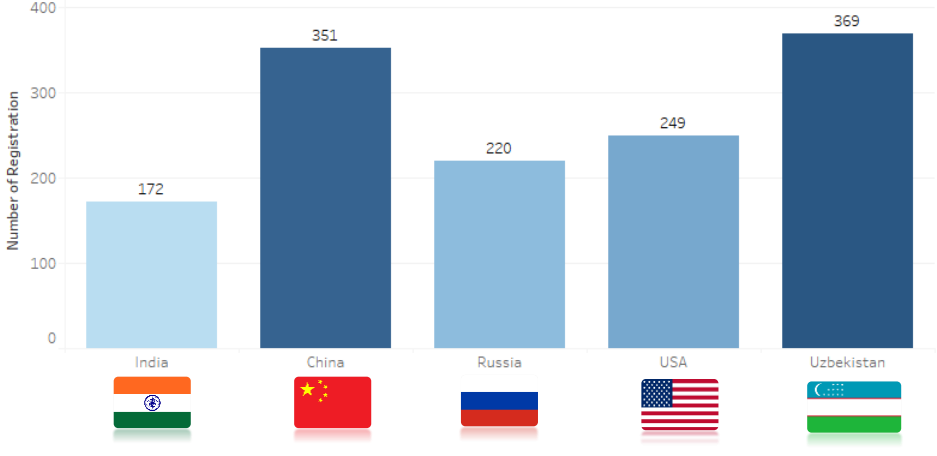
Medical Device

Top 5 Manufacturers by Medical Device Registrations



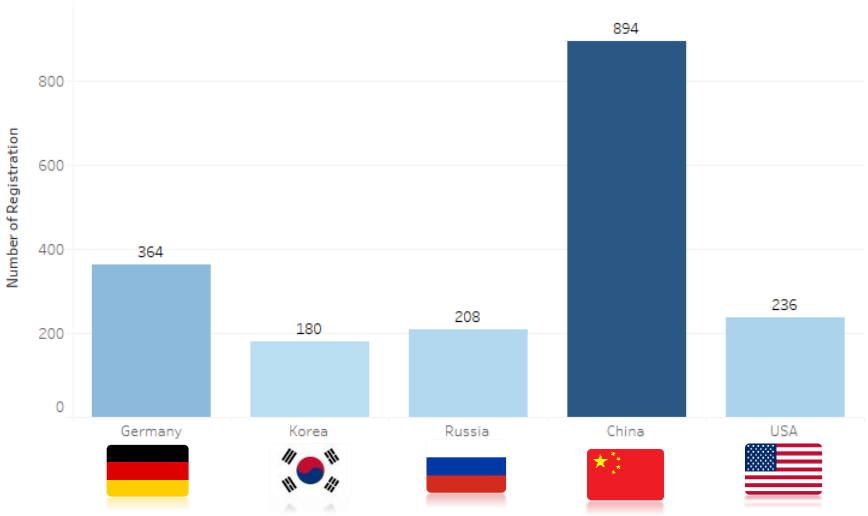


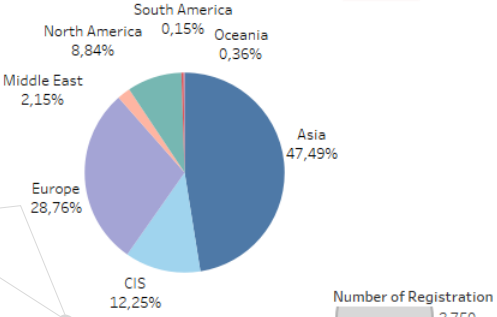
Top 5 Countries by Medical Device Registrations

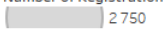


Medical Equipment

Top 5 Countries by Medical Equipment Registrations



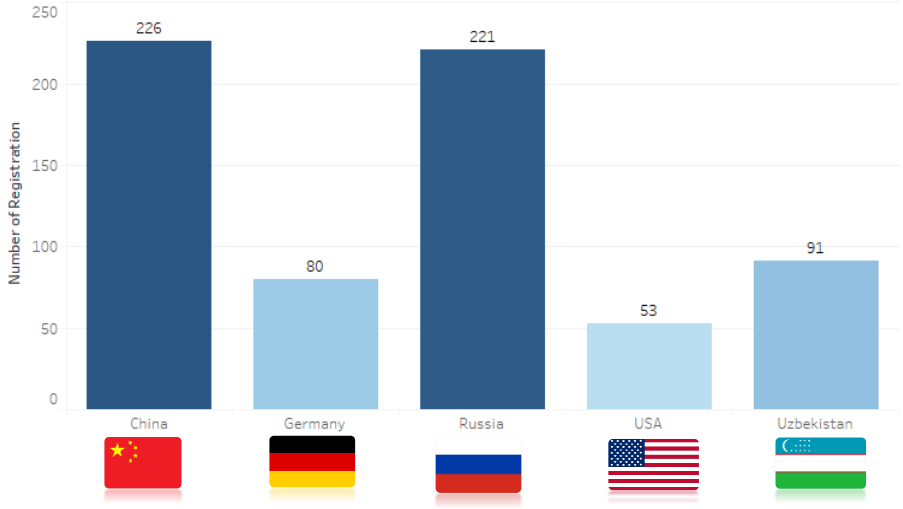


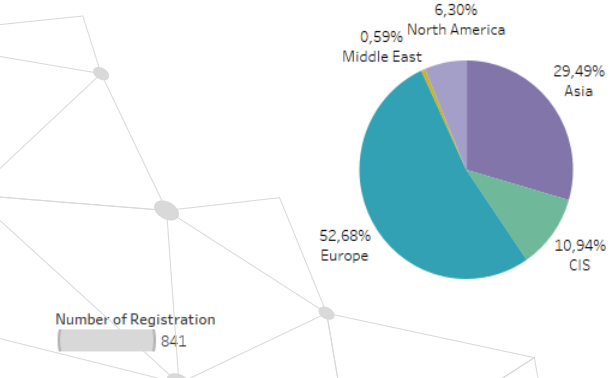


Top 5 Manufacturers by Medical Equipment Registrations

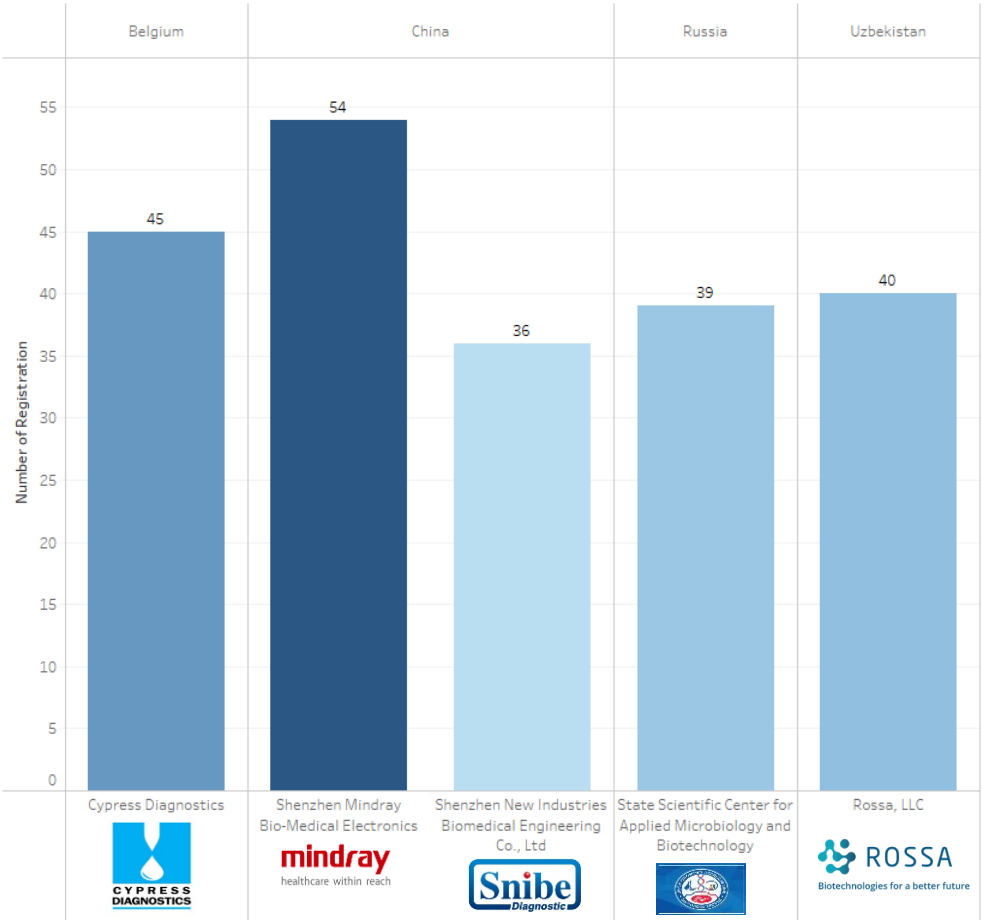
In-vitro Diagnostics

Top 5 Countries by In-Vitro Diagnostics Registrations

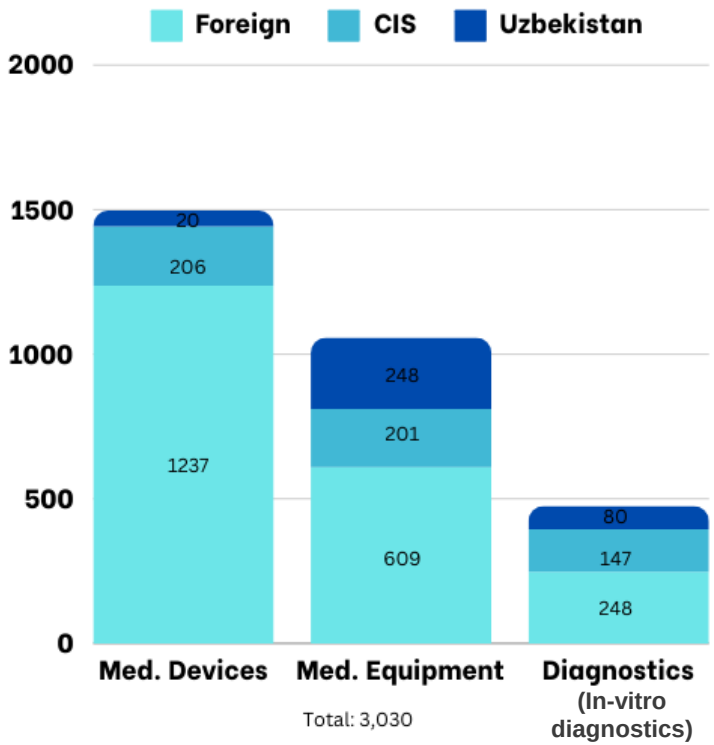




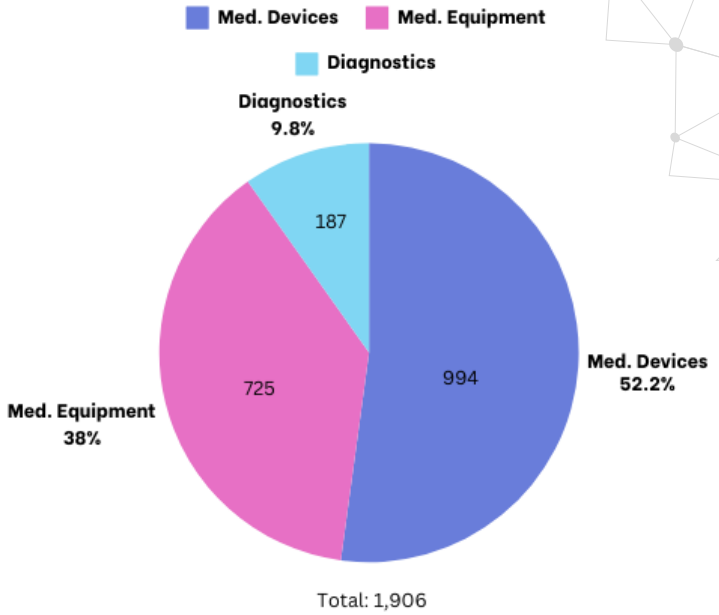
Top 5 Manufacturers by In-Vitro Diagnostics Registrations



REGISTERED PRODUCTS



REGISTRATION BY RECOGNITION



TOTAL NUMBER OF REGISTERED PRODUCTS: **4936**

03

Regulatory Convergence

GHWP, IMDRF, GRelP

Expectations and Future Collaboration

Adoption of IMDRF Guidelines: Implementing IMDRF documentation to align Uzbekistan's regulatory framework with global standards.

International Collaboration: Strengthening partnerships with GHWP member economies to enhance patient safety and market efficiency.

IMDRF International Medical Device Regulators Forum

GHWP

Capacity Building: Participating in GHWP Academy programs to boost the expertise and capabilities of the National Regulatory Authority (NRA).

GHWP Working Groups Participation: Active engagement in working groups, including:

- WG1 (Pre-Market Submission and CSDT)
- WG4 (Post-Market Surveillance)
- WG7 (Quality Management System)
- WG9 (Unique Device Identification)

Strengthening Good Reliance Practices through Collaboration

Recognition of Approvals: Leveraging decisions from trusted international regulators.
Expedited Access: Reducing timelines for safe and effective devices.
Transparency: Ensuring clear and consistent processes.

- To fully implement recognition, we must align with international best practices.
- Harmonization improves safety, quality, and trust in our regulatory system.

- Collaborate with **GHWP** to adopt global standards and streamline approvals.

Thank You!

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