MEDICAL DEVICES REGULATION IN THE KYRGYZ REPUBLIC

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

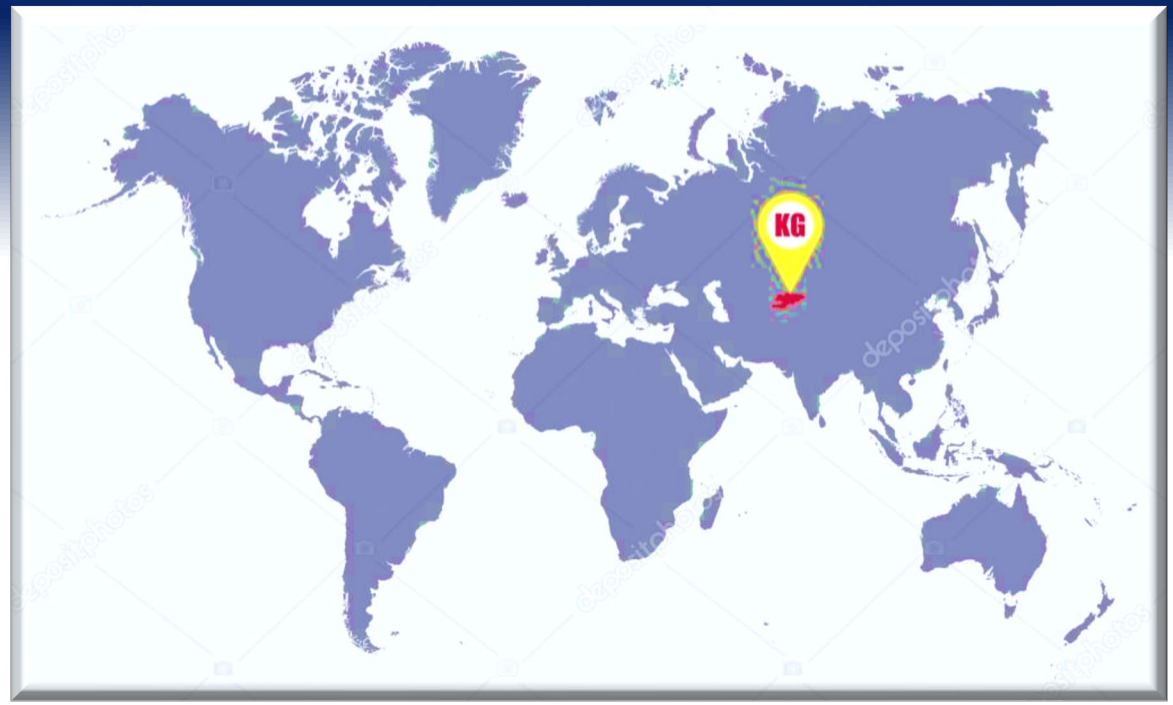
Kyrgyz Republic

National capital: Bishkek

Official language: Kyrgyz, Russian

Area: 199 951 sq km (85th place among the states of the world)

Population: 6.14 million people (2017)



Kyrgyz Republic
is a member
of the
Eurasian Economic Union

Contents

- Development of the strategic plan
- QMS: progress and development
- Database for medical devices
- Registration of medical devices
- Training
- International collaboration
- Next steps

TIMELINE

LAW ON MEDICINES INCLUDED MEDICAL DEVICES

JOINED IN EEU – (started to harmonize legislation with Union rules)

6 BYLAWS (On registration MD, on Monitoring of safety, quality and efficacy of MD, On inspection of production site of MD etc.) (WHO technical support)

2000

2012

2014

2017

2018

Approved 3 Technical regulations:
- on Medical Devices
- on IVD
- on implants

Law
on Medical Devices

GLOBAL BENCHMARKING TOOL

World Health Organization

NRA Functions are being assessed

- 01 - NATIONAL REGULATORY SYSTEM (RS)
- 02 - REGISTRATION AND MARKETING AUTHORIZATION (MA)
- 03 - VIGILANCE (VL)
- 04 - MARKET SURVEILLANCE AND CONTROL (MC)
- 05 - LICENSING ESTABLISHMENT (LI)
- 06 - REGULATORY INSPECTION (RI)
- 07 - LABORATORY TESTING (LT)
- 08 - CLINICAL TRIAL'S OVERSIGHT (CT)

Strategic plan Department of drug provision and medical equipment

Agency: establishment of a Mission Statement

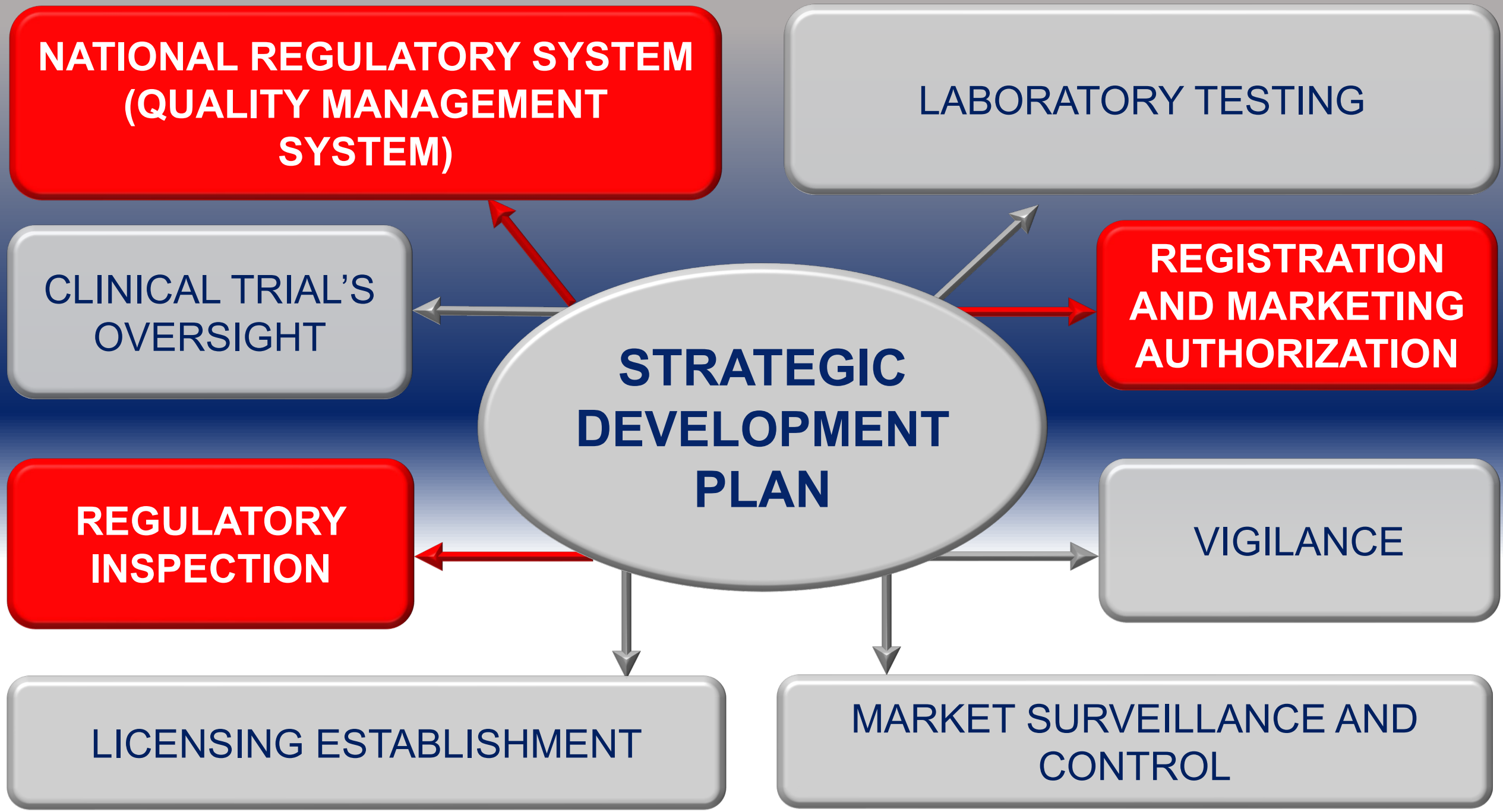
Mission: Ensuring guaranteed access of the population to high- quality, effective and safe medicines and medical devices

Key elements of the strategic plan: medical devices

- Regulatory strengthening
- Harmonization activities regarding EEU
- Oversight of Clinical trials
- Increasing staff with priority for inspections
- Introducing a Track and trace system

Implementation

- QMS
- Registration


NATIONAL REGULATORY SYSTEM (QUALITY MANAGEMENT SYSTEM)
LABORATORY TESTING
CLINICAL TRIAL'S OVERSIGHT
REGISTRATION AND MARKETING AUTHORIZATION
STRATEGIC DEVELOPMENT PLAN
REGULATORY INSPECTION
VIGILANCE
LICENSING ESTABLISHMENT
MARKET SURVEILLANCE AND CONTROL

Registration of medical devices: challenges

- Harmonization between Eurasian Economic Union-members
- Short transition period
- Limited experience by staff
- Introduction of IT-system

Training of staff

- To find proper training opportunities, remains a challenge
- AB certification (France) involved in training of inspectors
- In autumn training by BSI on the topics
  - Training on Risk Management (RM): describing the relevance and context; outlining the structure and purpose and elaborating on the key principles of ISO 31000.
  - Training on the standard ISO 19011:2018 for auditing quality management systems
- An exchange visit with a European country is being planned
- Training on Post Market surveillance of medical devices is being planned
- By the end of the year
  - Comprehensive training plan for staff
  - On the ground training of staff in implementing QMS
  - Inspectors trained on on-site inspection

International collaboration

- Member of the Eurasian Economic Union
- Study visits to Eurasian Economic Union member countries
- Kyrgyz Republic applies for membership of AHWP
- Reaching out to mature jurisdictions for specific questions
- IMDRF documents and information is very important
- WHO documents and information is very important
- WHO: ongoing support

Way forward and next steps

- QMS: step by step implementation
- Digitalization of processes
- Track and trace system of medical devices
- To find training opportunities for regulatory authorities
- Registration of medical devices by Eurasian Economic Union rules

Thank you for your attention!

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