NATIONAL
of medicines,
CENTER
medical devices
FOR EXPERTISE
and medical equipment

Ministry of Healthcare and Social Development of the Republic of Kazakhstan

Republican State Enterprise with the Right of Economic Use "The National Center for Expertise of Medicines and Medical Devices

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2016

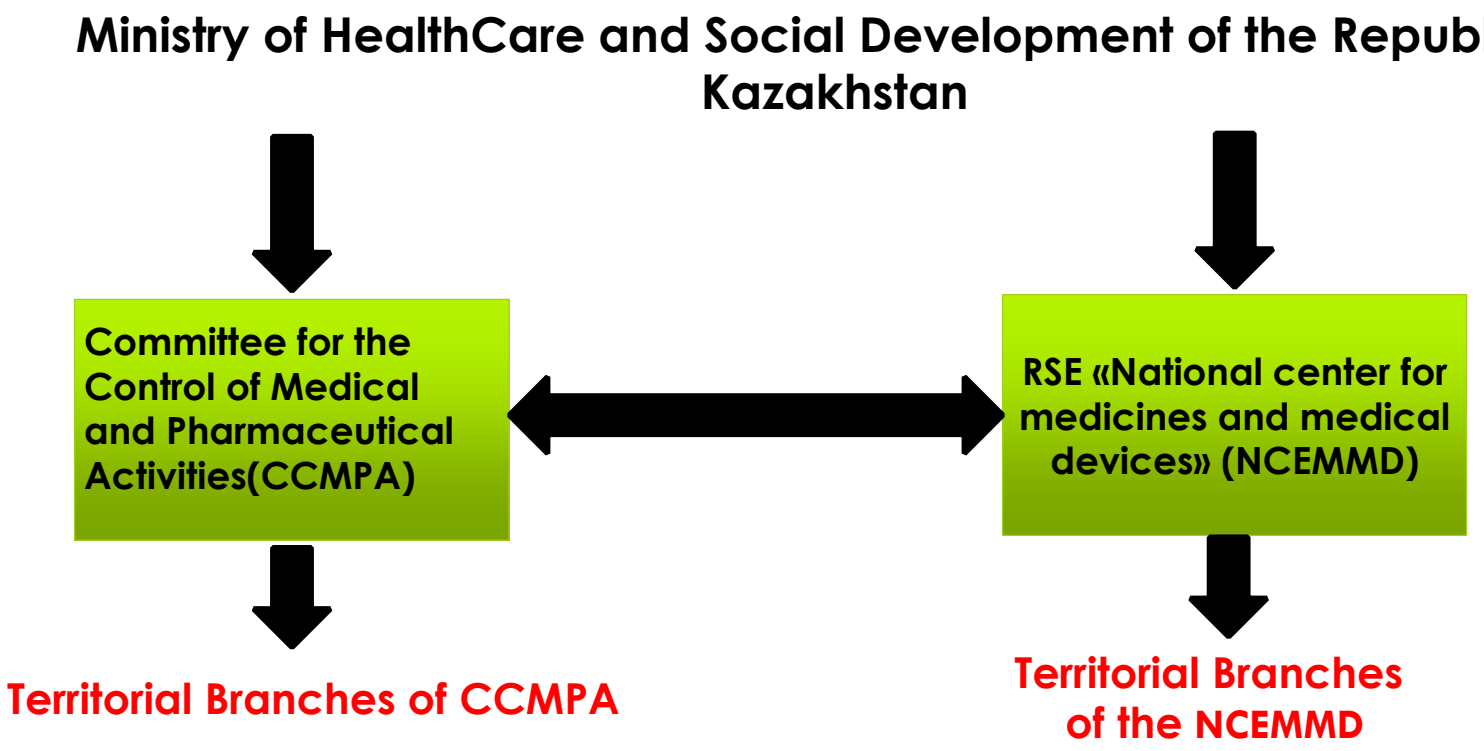
REPUBLIC OF KAZAKHSTAN

Kazakhstan is a unitary republic

Area 2,724,900 km2 (9th)
Population 17,693,500

Kazakhstan is a member of the United Nations, Organization for Security and Cooperation in Europe, Euro-Atlantic Partnership Council and the Organisation of Islamic Cooperation (OIC). It is an active participant in the North Atlantic Treaty Organisation Partnership for Peace program

THE SYSTEM OF REGULATION OF MEDICAL DEVICES



HISTORY

National Center was created on 17 November 1997. as a Center for drug “Dari-Darmek” which in Kazakh language means “

By Decree № 1081 of the Government of the Republic of Kazakhstan on October 2, 2002 organization was renamed to “National Center for Expertise of Medicines and Medical Devices” by Governmental Decree.

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8 - territorial branches

3 – offices

MAIN OBJECTIVES OF THE NATIONAL CENTER

2 basic functions:
1. Expertise of medicines and medical devices during the state registration, reregistration and dossier amendments

2. Safety and quality evaluation of registered medicines and medical devices

Preclinical studies and bioequivalence studies	Legislation drafting	Development of the State Pharmacopoeia	Price monitoring	Taking part in pharmacovigilance and ADR monitoring
Archiving registration dossier	Database maintenance of the State Registry of medicines and devices	Informational, analytical (“Kazakhstan Pharmacy” periodical)	Advertisement evaluation	Evaluation of clinical trials results

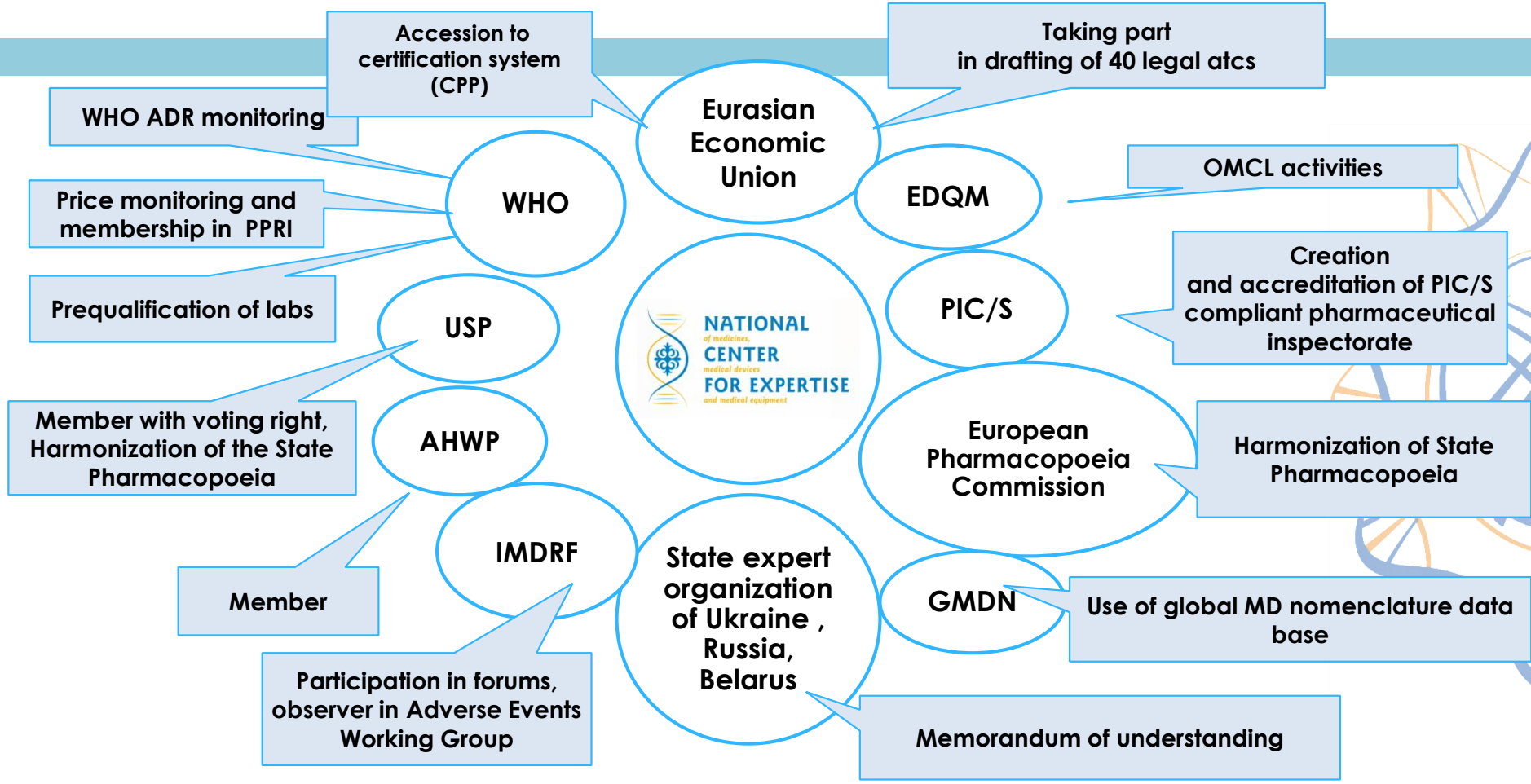
INTERNATIONAL COOPERATION

- RSE "NCEMMD" is **AHWP member**,
- has an Observer status in **IMDRF Adverse Event Terminology Working Group** since 2015
- RSE "NCEMMD" has an **Official Observer status** in ICH since 2016 **Observer status** in European Pharmacopoeia Commission since 2006.
- In 2010 with the active participation of the National Center, Republic of Kazakhstan became a member of the United States Pharmacopoeia Convention with the right of voting;
- National Center has initiated admission of the Republic of Kazakhstan into the WHO International Programme on Monitoring of side effects of medicines. Access was given to database of the WHO, and possibility of experience exchange with other countries on the side effects by participation in annual conference in Uppsala, Sweden;

INTERNATIONAL COOPERATION

- Representatives of the NCEMMD are members of working groups on developing normative documents during formation of a common market of medicines and medical devices of the Eurasian Economic Community (EAEC).
- NCEMMD has initiated Memorandum of Cooperation between the Republic of Kazakhstan and TUV SUD Product Service GmbH to implement international standards during registration of medical devices, improve medical device system regulation and training of the NCDE specialists in this field;
- In 2014 National Center signed memorandums of mutual cooperation to provide safety, efficacy and quality of drugs with the Federal Service for Supervision of Healthcare of the Russian Federation, "Scientific Centre of Medical devices" of Ministry of Healthcare and Social Development of the Russian Federation, “Centre of Expertise and tests in Healthcare” of the Republic of Belarus, “Ukrainian scientific pharmacopoeia center of medicines quality”.

INTERNATIONAL RELATIONS OF THE NATIONAL CENTER



MD APPROVAL SCHEME IN THE REPUBLIC OF KAZAKHSTAN

FOR THE RENEWED LICENCE MD IN RoK, A PRE-SCHEDULED RENEWAL IS PERFORMED WITH GRANTING A PERMANENT MARKETING AUTHORISATION

EXPERTISE STAGES

- PRELIMINARY CONSULTATION
- PRIMARY EXPERTISE
- ANALYTICAL EXPERTISE
- SPECIALIZED EXPERTISE
- EXPERT REPORT

TIMELINE: Class I and IIa – 90 days, Class IIb and III MD 160 days

MEDICAL DEVICE VIGILANCE SYSTEM

Center of pharmacovigilance and monitoring of adverse reactions of the medicines and medical devices as part of NCEMMD

The **purpose** is to protect the health and safety of the patients, healthcare professionals and other users of a medical device
Development of legislation in accordance with internationally acclaimed guidelines and directives

Adverse event reporting:
Via paper report form
Via web-based portal
Adverse event database – analyze and evaluate adverse events

TESTING CENTER

- The Testing Center is a part of NCEMMD.
- The Testing Center is accredited in the state system of technical regulation of the Republic of Kazakhstan as complying with the requirements of ISO 17025 "General requirements for the competence of testing and calibration laboratories" by National Accreditation Center (NAC), which is a full member of the International Laboratory Accreditation Cooperation (ILAC) since October 2010.

Accreditation certificate details: №KZ.И.02.0010 valid until 08.12.2019.

LEGISLATION OF COMMON MARKET IN EAEU

SUPRANATIONAL LEVEL

Eurasian Economic Union EAEU Agreement 29 May 2014

Agreement of single principles and marketing rules for medicines and MD within EAEU 23 December 2014

NATIONAL LEVEL

Harmonized Russia, Armenia, Kazakhstan, Belarus and Kyrgyzstan

EURASIAN ECONOMIC UNION

Agreement on common principles and MD rules under the EAEU.
- Adopted uniform rules of registration and examination of MD.
- Registration of MD carried by the reference state on the basis of the results of examination of the MD and harmonization of the recognition by the expert opinion

Registration certificate of unlimited duration, and operates within the framework of the Union

Transitional period until 31/12/2021 year: at the choice of the manufacture (his authorized representative) examination and MD registration carried out in accordance with the legislation of the state - member of the Union or with the Rules of the EAEU

Documents confirming the registration of MD and issued by the competent authorities before the Agreement took effect, operate in the territory of a Member State until the expiry of their validity but not later than December 31, 2021

CURRENT PROJECTS

As a result of cooperation with the GMDN we have developed nomenclature of medical devices of the Republic of Kazakhstan.

Also we have prepared amendments to the Code of Health and examination regulations, where we have added requirements for the dossier in accordance with IMDRF Toc

THANK YOU FOR YOUR ATTENTION!