RSE “National center for drugs and medical devices expertise”

REGISTRATION AND EXPERTISE OF MEDICAL DEVICES IN THE REPUBLIC OF KAZAKHSTAN

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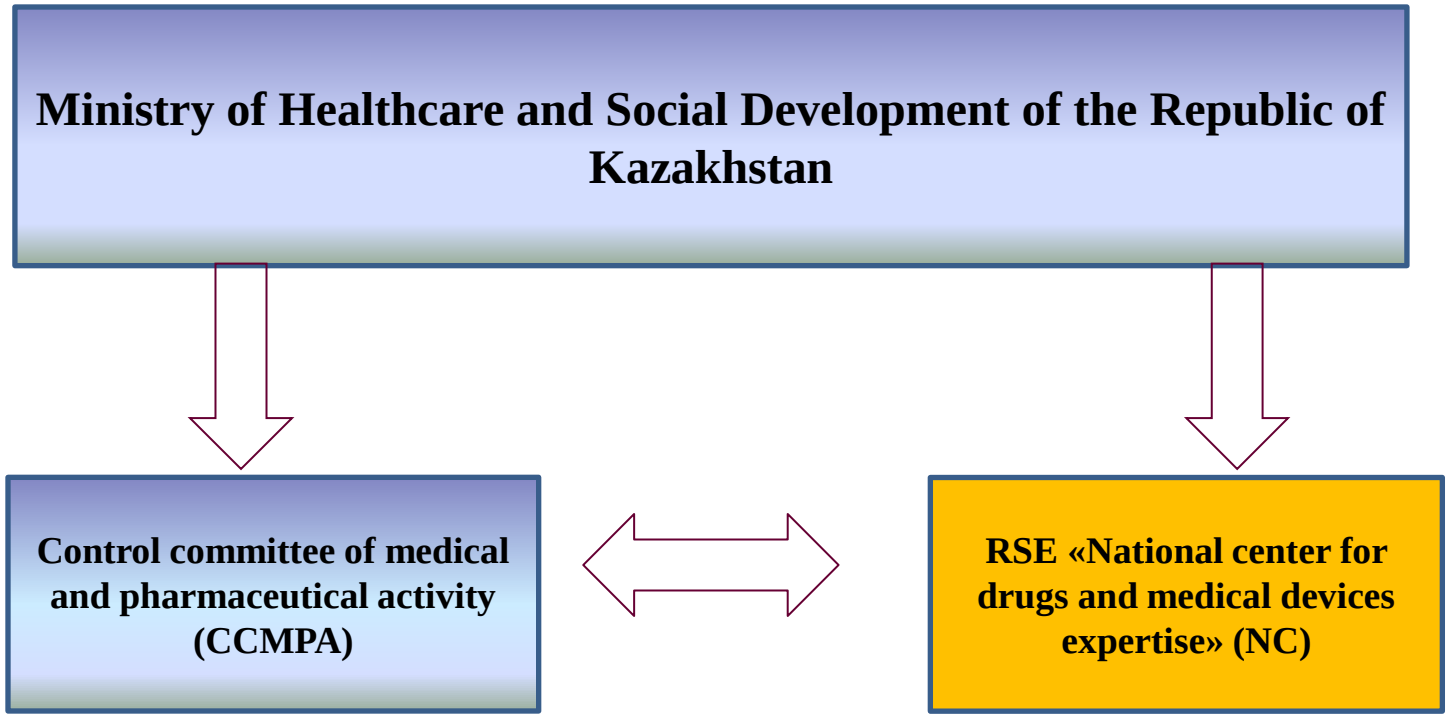
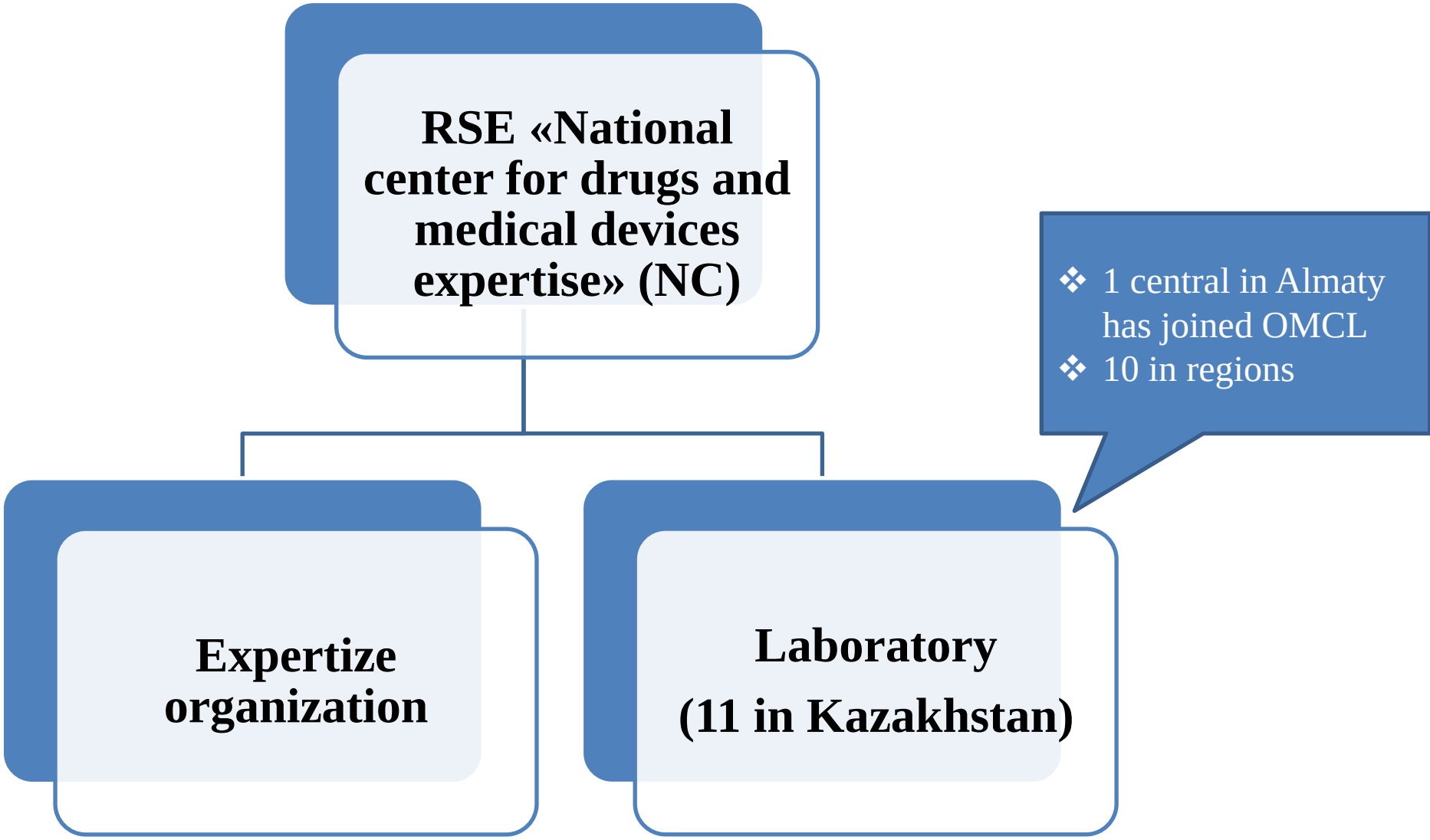
Bangkok, 2015

RUSSIA
Yaroslavl
Kirov
Nizhniy Novgorod
Perm
Nizhniy Tagil
Izhevsk
Yekaterinburg
Tyumen
Kazan
Kurgan
Penza
Ufa
Chelyabinsk
Omsk
Samara
Saratov
Magnitogorsk
Orenburg
Volgograd
Astrakhan
Krasnoyarsk
Tomsk
Kemerovo
Novosibirsk
Novokuznetsk
Barnaul
Biysk
MONG.
KAZAKHSTAN
Astana
Karaganda
Atyrau
Lake Balkhash
Aral Sea
Caspian Sea
Makhachkala
AZER
Baku
UZBEKISTAN
Tashkent
KYRGYZSTAN
Bishkek
Osh
TAJIKISTAN
Dushanbe
TURKMENISTAN
Ashgabat
Mary
CHINA
IRAN
Tehran
AFGHANISTAN
Kabul
Herat
Kandahar
Mazar-e Sharif
PAKISTAN
Islamabad
Lahore
INDIA

Organizational structure of healthcare system in the expertise and registration of drugs and medical devices



Organizational structure of National center for drugs and medical devices expertise



Relationships between National Center and international organizations

Legal and regulatory framework governing the state registration of medical devices

- **Code of the Republic of Kazakhstan “Public health and the Health Care system“**
- **№735 18.11.2009 MoH decree «Rules for state registration, renewal and amendment to the registration dossier of drugs and medical devices“**
- **№736 18.11.2009 MoH decree “Rules for drugs and medical devices expertise“**
- **Decree of the Government of the Republic of Kazakhstan dated from February 24, 2014 № 142 “About approval of public services standards in the sphere of pharmaceutical and medical devices activity"**

EXPERTISE AND REGISTRATION OF MD IN THE REPUBLIC OF KAZAKHSTAN

I STAGE

- **EXPERTISE PROCEDURE**

II STAGE

- **REGISTRATION PROCEDURE**

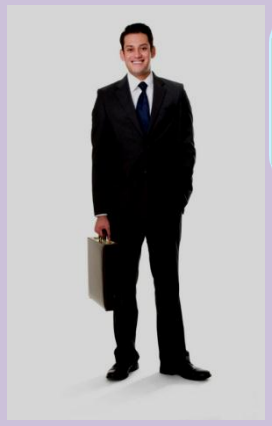
Result

- **Regulatory Approval** (5 years)

*** AFTER ONE REGISTRATION DURING RENEWAL A PERMANENT REGULATORY APPROVAL IS GRANTED**

MD EXPERTISE PROCEDURE

APPLICANT



APPLICATION
ERD
SAMPLES

NC

Control committee of medical and pharmaceutical activity (CCMPA) of MoH&SD

PERFORMS EXPERTISE ON SAFETY, EFFICIACY AND QUALTIY

Notifies through internet-source www.dari.kz on sending the document to state authority

Sends electronic conclusion on safety, efficacy and quality of MD

ERD-electronic registration dossier

EXPERTISE OF MD FOR SAFETY, EFFICIACY AND QUALITY

PRIMARY EXPERTISE

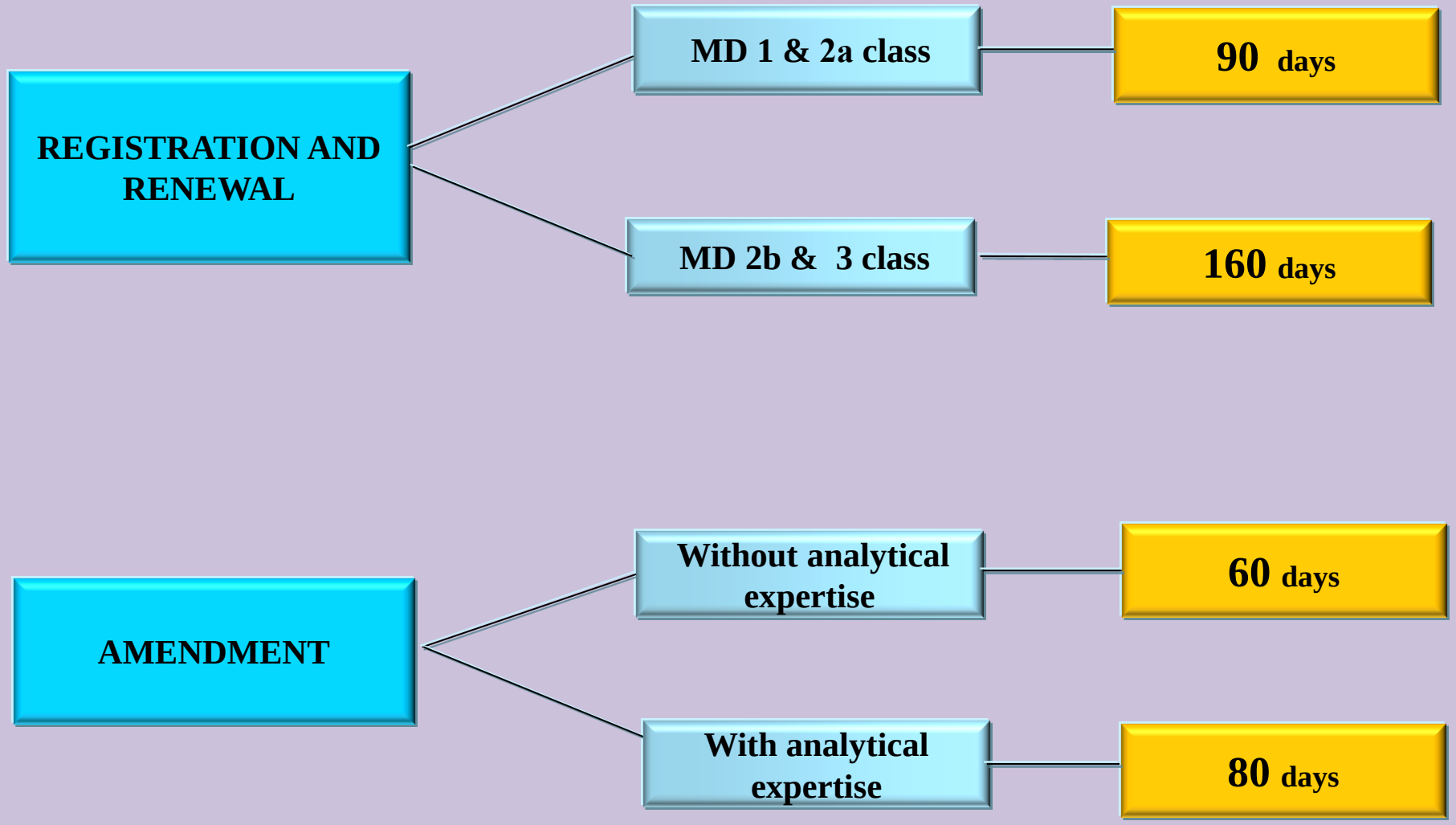
ANALYTICAL AND TECHNICAL EXPERTISE OF MD

SPECIALIZED EXPERTISE

CONCLUSION ON SAFETY, EFFICACY AND QUALITY

- **Each subsequent stage is carried out on the basis of the positive conclusion of the previous**
- **Expert organization requests if necessary clarifications and corrections of the registration dossier**
- **Remedial actions terms= 30+60 (on justification) = not over 90 calendar days on each stage**

MD EXPERTISE TERMS



REGISTRATION PROCEDURE OF MD

APPLICANT

1. Application
2. ID of the authorized representative
3. Copy of **favorable** conclusion from expert authority
4. Confirmation of payment fee to the budget
5. Electronic data on information of body to receive service

Control committee of medical and pharmaceutical activity (CCMPA) of MoH&SD

Registration Approval (for 5 years)

All processes are managed electronically and are transparent for an Applicant (manufacturer/authorized representative) and Regulators

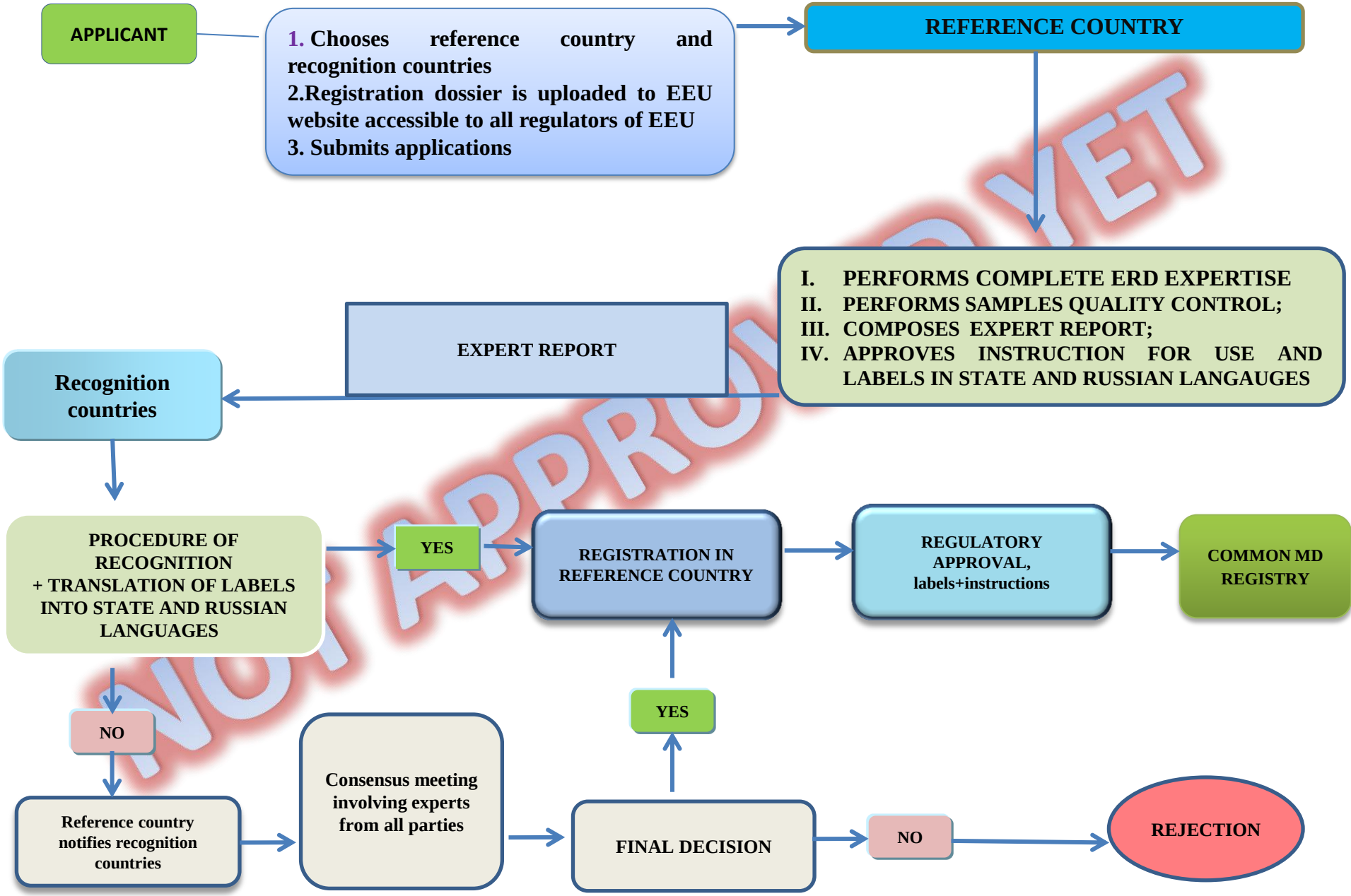




The last update about the Eurasian Economic Union

- On May 29, 2014 the Eurasian Economic Union was created
- On December 23, 2014 the Agreement on common principles and rules for the turnover of drugs and medical devices within the Eurasian Economic Union is signed
- The agreement is planned to develop 40 (15 of them are for regulation of MD) legal documents, 32 of them have been already developed
- The Republic of Kazakhstan is the developer of the founding document: "Rules for expertise and registration of drugs and medical devices“
- **ON THE 1ST OF JANUARY 2016 COMMON RULES FOR EXPERTISE AND REGISTRATION WILL COME INTO FORCE FOR EEU MEMBERS (KAZAKHSTAN, RUSSIA, BELORUSSIA, ARMENIA, KYRGYZSTAN)**

REGISTRATION AND EXPERTISE SCHEME OF MD in EEU



TRANSITIONAL PERIOD

01.01.2016 – 31.12.2021

During the transitional period there will be dual registration rules – EEU common rules and National rules. Regulatory Approvals for MD registered by National rules are valid in particular Member State before the expiry date, but no later than December 31, 2021.

Starting from 1, January 2022 ONLY EEU common rules will be applicable for MD registration

THANK YOU FOR YOUR ATTENTION!