Republican State Enterprise on the Right of Economic Management **'National Center for Expertise of Medicines and Medical Devices'** of the Ministry of Health of the RK

# Medicinal product registration under EAEU rules. The first experience with EAEU CTD dossier assessment and expert opinion publishing. Key Review Issues.

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# Information on Filed Applications

**TOTAL APPLICATIONS ACCEPTED - 38:**

Under the mutual recognition procedure – 36 applications, including:

for registration – 15

for bringing into compliance – 21

Under the decentralized procedure – 2 (as the recognition state)

10 registration certificates issued within EAEU

# Experience with First Dossiers

Medicinal product registration dossiers have been filed in accordance with requirements of the Eurasian Economic Commission Council Resolution No 78 of November 3, 2016, in the common technical document (CTD) format.

# Quality of Application Filings

The expert review has identified the following issues:-

specifications on additives
medicine analysis certificates
active pharmaceutical substance and medicinal product stability study data.
safety and efficacy (in pre-clinical and clinical trials)
execution of an act, labelling, GMPD (general medicinal product description), in line with the Resolution requirements

# Expert Work Issues

1. Form of:
- The expert report on critical assessment of medicinal product quality aspects
- The expert report on assessment of pre-clinical (non-clinical) trial findings
- The expert report on assessment of clinical trials
- The expert report on assessment of pre-clinical and clinical aspects of generics
- The expert report on assessment of safety, efficacy and quality

2. Refusal to register and bring a medicinal product registration dossier in compliance with the Union requirements

3. Application withdrawal from review on the initiative of the applicant

# Current Review Issues
# (as concerns work in the Union's Basic Component)

- the procedure for entry of data, expert reports and all final documents into the basic component
- the procedure for entry of data on a medicine and final documents in the *Unified Register of EAEU Registered Medicinal Products*
- the procedure for transfer of an expert report and final documents to the Union member states

# Expectations/ Recommendations for the Industry and the Market

It is recommended to consult before filing the registration dossier for review. This is especially true for manufacturers from the Union member states as various issues may arise in transition to the CTD format (in bringing the registration dossier in compliance with EAEU requirements).

# Thank you for your attention!