MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP VIII ALL-RUSSIA GMP CONFERENCE

50 years GXP SID& GP

Temporary Procedure Established for 2020-2023 by the National Legislation of the EAEU Member States for the Pharmaceutical Market with Respect to Medicines Registration

OBJECTIVE: protection of life and health of the population, ensuring uninterrupted supplies of medicines within the Union.

On Temporary Measures to Establish the Features of the Circulation of Medicines for Human Use.

Resolution of the Commission Council No. 96 dated June 10, 2022

On the Rules of Registration and Expert Evaluation of Medicinal Products for Human Use.

Resolution of the Council of the Eurasian Economic Commission No. 78 dated November 03, 2016.

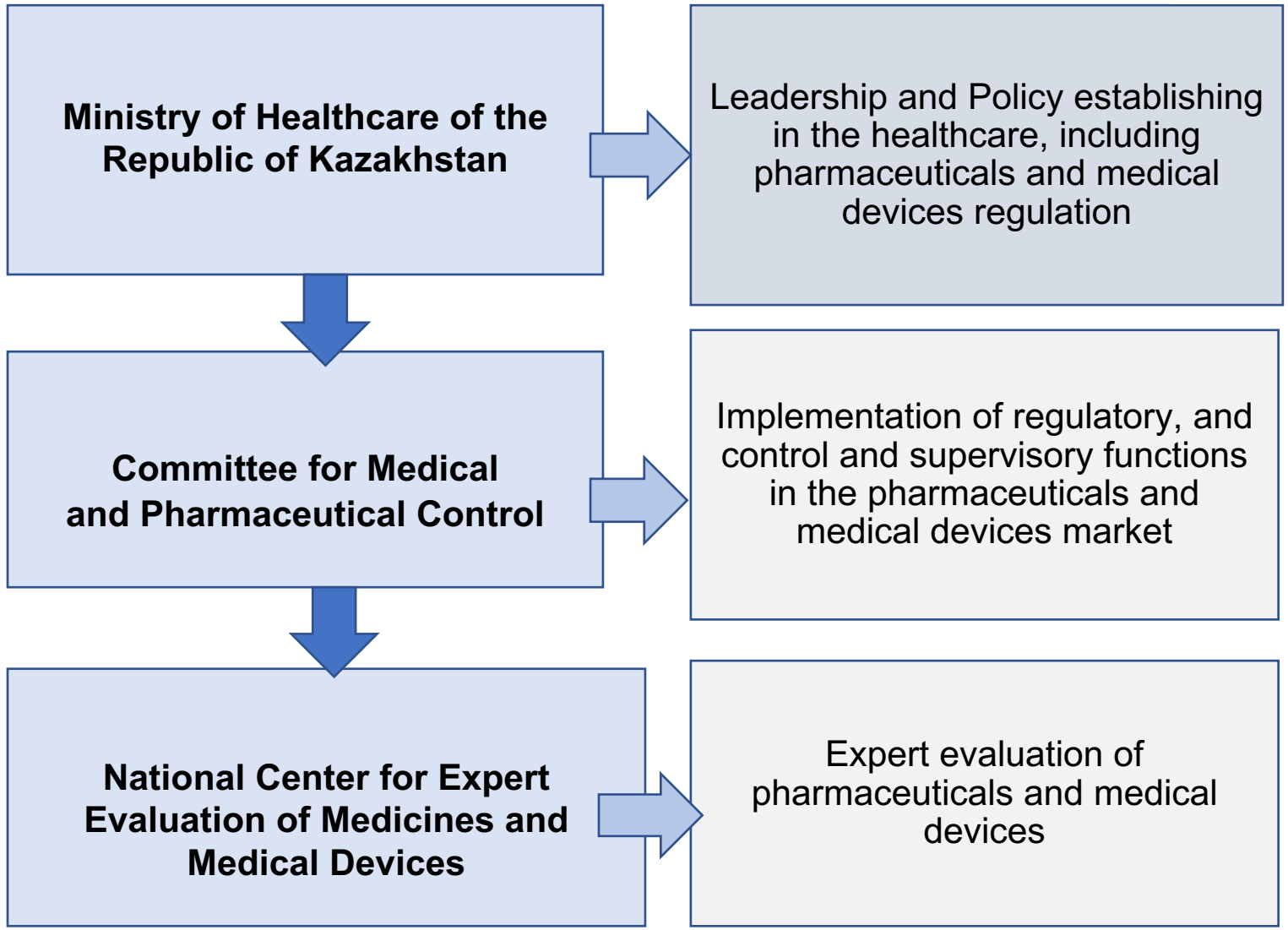
Amendments have been made to national legislation regarding the registration of strategically important medicinal products and medical devices:

- Code of the Republic of Kazakhstan On Public Health and Healthcare System (Code of the Republic of Kazakhstan No. 360-VI ZRK dated July 07, 2020);
- On Approval of the Rules for Conducting Expert Evaluation of Medicinal Products and Medical Devices (Order of the Ministry of Healthcare of the Republic of Kazakhstan No. 10 dated January 27, 2021);
- On Approval of the Rules for State Registration, Re-registration of a Medicinal Product or Medical Device, Making Amendments to the Registration Dossier of a Medicinal Product or Medical Device (Order of the Ministry of Healthcare of the Republic of Kazakhstan No. 16 dated February 09, 2021).

Resolution No.96 dated June 10, 2022

The Resolution authorizes the pharmaceutical market competent agencies to do the following:

- Establish a national-level temporary procedure for the circulation of medicines, including registration of medicinal products and making amendments to the registration dossier of medicinal products that is valid until December 31, 2023;



Resolution No.96 dated June 10, 2022

- Extend by 12 months the validity of documents in the field of circulation and registration of medicinal products for human use expiring in 2022 – Marketing Authorizations of medicinal products for human use issued in the manner prescribed by the law of the Union and GMP certificates of the Union (hereinafter referred to as Certificates);

- Amend certificates without conducting an inspection (during the validity period of the certificates) in the event of a change in the name and (or) address of the location of the manufacturer, or a foreign manufacturer, as well as the list of medicinal products manufactured at the same manufacturing site and under the same conditions;

National procedure for medicines registration

Registration until July 01, 2021

Re-registration until January 01, 2026

MA cancellation from January 01, 2026

Resolution No.96 dated June 10, 2022

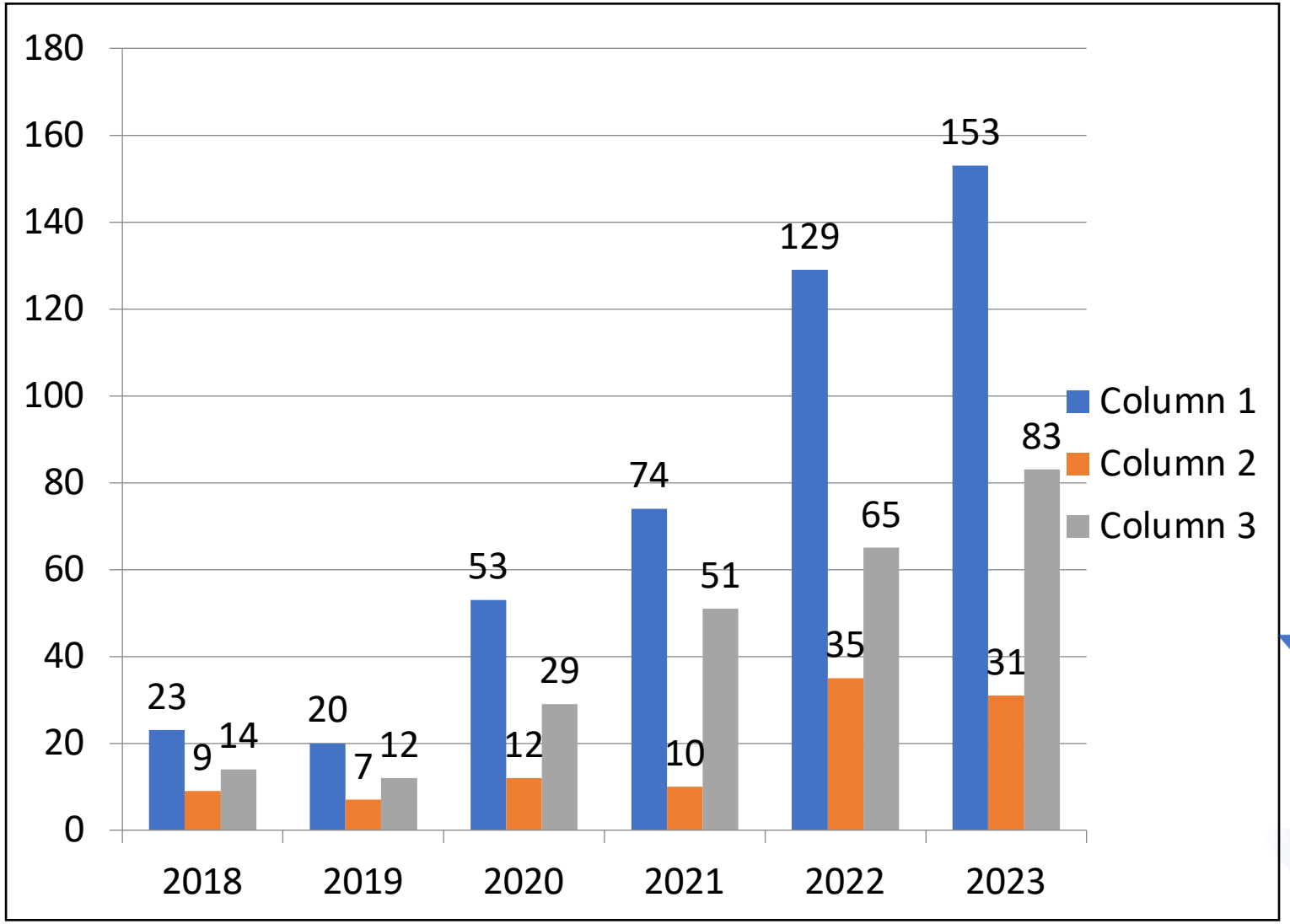
Medicinal products for human use are considered strategically important under the following conditions:

- Military actions and their elimination;
- Occurrence, prevention and mitigation of emergency situations;
- Threat of emergence and spread of new especially dangerous infectious diseases and mitigation of their consequences;
- Prevention, diagnosis, treatment of diseases and injuries resulting from exposure to adverse chemical, biological, radiation factors, as well as mitigation of their consequences;
- Absence or threat of absence of medicinal products or medical devices on the markets of the EAEU member states in the context of the introduction of restrictive economic measures in relation to at least one of the member states.

- In the event of a risk of shortage of medicinal products on the markets of member states (including that due to the introduction of economic measures in relation to one or more member states), renew the validity of the certificates, but for not longer than until December 31, 2024

- Apply temporary simplifications in terms of providing documents confirming the compliance of the manufacturing site (sites) with the requirements of Good Manufacturing Practice of the Union when filing an application for registration of a medicinal product (amending the registration dossier, confirmation of registration (re-registration) or aligning the registration dossier of the medicinal product with the requirements of the Union).

Comparative data (EAEU) of the Republic of Kazakhstan



1- Total number of applications
2 - Registration
3 - Bringing to compliance/aligning
2018 – September, 2023

TOTAL:
from 2018 to 2023 = 452 applications
Registration = 104
Aligning = 254
Changes = 94,
Completed changes = 55
MA issued = 66

237 applications in progress:
2020/1; 2021/21; 2022/63/; 2023/153

GMP VIII ALL-RUSSIA GMP CONFERENCE

ORGANIZERS

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

50 years GXP SID & GP

S·GROUP

GENERAL PARTNER

Binnopharm group

STRATEGIC PARTNER

GEDEON RICHTER
Health is our mission

GENERAL INFO PARTNER

GxP news

GENERAL INFO AND ANALYTICAL PARTNER

Фармацевтический ВЕСТНИК

STRATEGIC INFO PARTNER

ФАРМ МЕД ПРОМ