MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP VIII ALL-RUSSIA GMP CONFERENCE

50 years GXP SID& GP

Typical Non-Conformities Identified during Pharmaceutical Inspections *by Pharmaceutical Inspectorate of the Ministry of Health of the Republic of Belarus.*

Head of Pharmaceutical Inspection Department
E.B. Lavnik

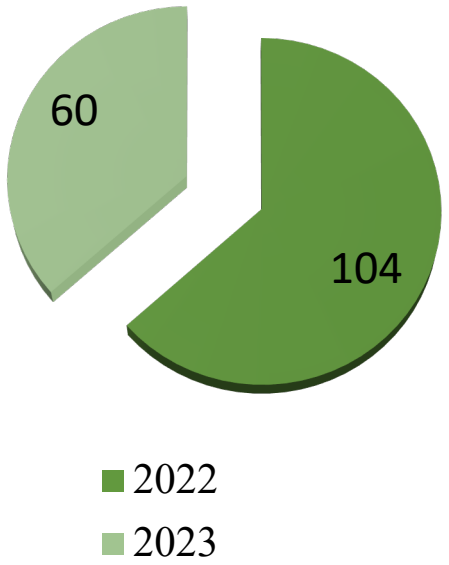
- **Legislation**
- 1. Treaty on the Eurasian Economic Union (as of March 24, 2022, as amended on May 25, 2023) (together with Appendices 1 - 33) (Signed in Astana on May 29, 2014) (as amended and additionally, entered into force on 04/03/2023);
- 2. Agreement on Common Principles and Rules for the Circulation of Medicines within the Framework of the Eurasian Economic Union (Concluded in Moscow on December 23, 2014);
- 3. Decision of the Council of the Eurasian Economic Commission No. 80 On Approval of the Rules of Good Distribution Practice within the Eurasian Economic Union (Adopted in Astana on November 03, 2016);
- 4. Decision of the Council of the Eurasian Economic Commission No. 83 dated November 03, 2016 (as amended on July 04, 2023) On Approval of the Rules for Conducting Pharmaceutical Inspections;
- 5. Decision of the Council of the Eurasian Economic Commission No. 77 (as amended on July 04, 2023) On Approval of the Rules of Good Manufacturing Practice of the Eurasian Economic Union (Adopted in Astana on November 03, 2016);
- 6. Law of the Republic of Belarus No. 161-3 dated July 20, 2006 (as amended on October 14, 2022) On the Circulation of Medicines;
- 7. Resolution of the Ministry of Health of the Republic of Belarus No. 102 dated November 18, 2020 (as amended on September 15, 2022) On Inspection (Pharmaceutical Inspections) for Compliance with Good Pharmaceutical Practices (together with the Regulation on the Procedure and Conditions for Inspection (Pharmaceutical Inspection) of Industrial Production Medicines for Compliance with the Requirements of Good Manufacturing Practice;
- 8. Technical Code of Good Practice TKP 030-2017 (33050) Good Manufacturing Practice;
- 9. RK-01 Quality System of the Pharmaceutical Inspectorate.

Pharmaceutical Inspectorate of the Ministry of Health of the Republic of Belarus

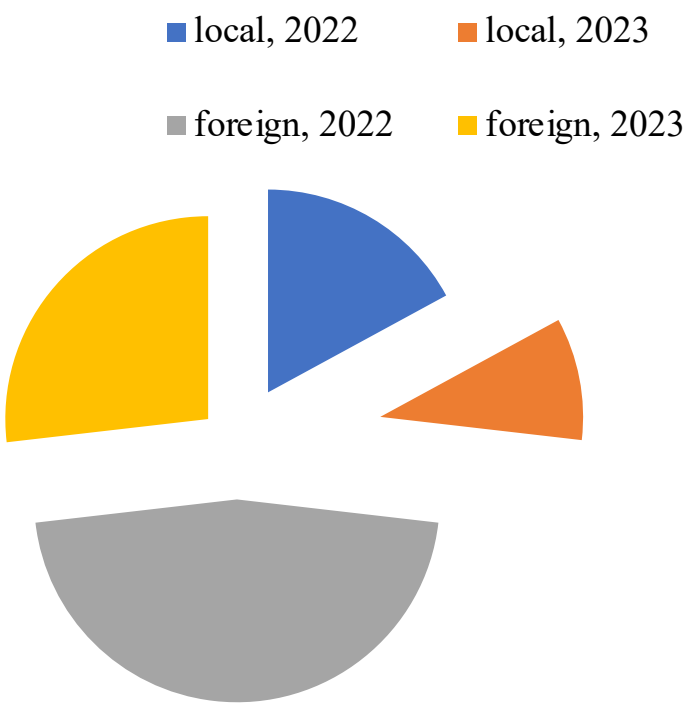
Good Manufacturing Practice (EAEU GMP).

In 2022, in accordance with the plan, the following was conducted:
104 inspections:
28 inspections of local manufacturers of medicines;
76 inspections of foreign manufacturers of medicines;
20 unscheduled inspections;
34 inspections as part of medicines registration.
59.57% of the 2022 inspection plan.
In 2023, in accordance with the plan, the following was conducted:
60 inspections:
16 inspections of local manufacturers of medicines (26.7%);
44 inspections of foreign manufacturers of medicines (73.3%).
52 inspections in accordance with the plan for 2023 (86.7%)
8 unscheduled inspections (13.3%)
9 inspections as part of medicines registration (15 %).

Inspections



Manufacturers

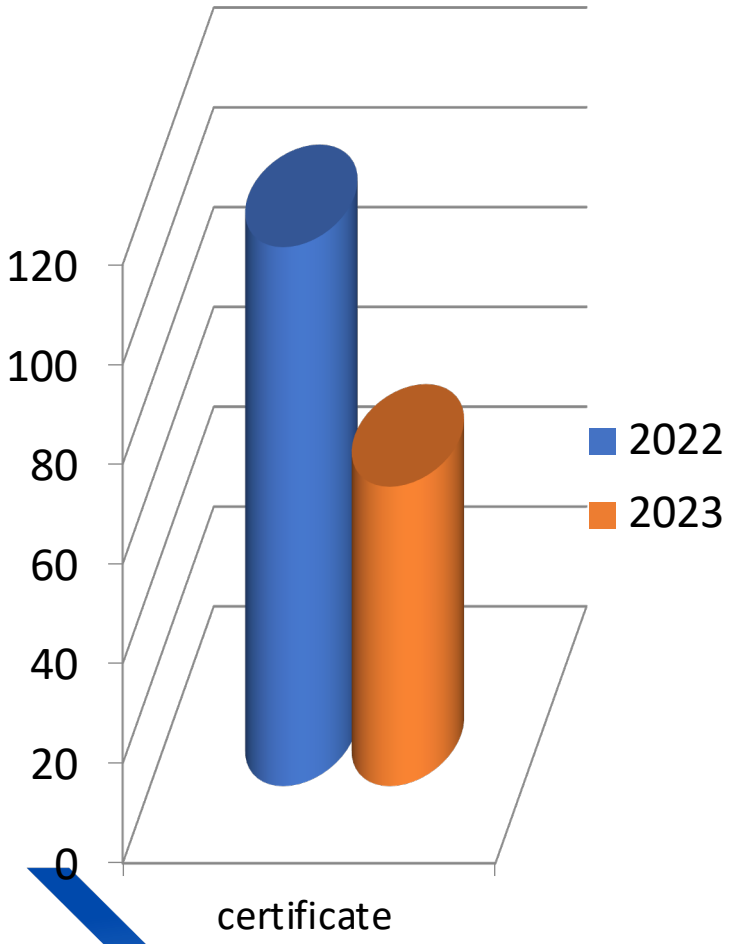


Following the results of inspections in 2023, **60** EAEU GMP certificates were issued:
18 to local manufacturers of medicines,
52 to foreign manufacturers of medicines.

Do not comply with EAEU GMP requirements
7 manufacturers of medicines:
5 local manufacturers
2 foreign manufacturers**.**

Following the results of inspections in 2022, **108** EAEU GMP certificates were issued:
32 to local manufacturers of medicines;
76 to foreign manufacturers of medicines;

Do not comply with EAEU GMP requirements
6 local manufacturers of medicines.



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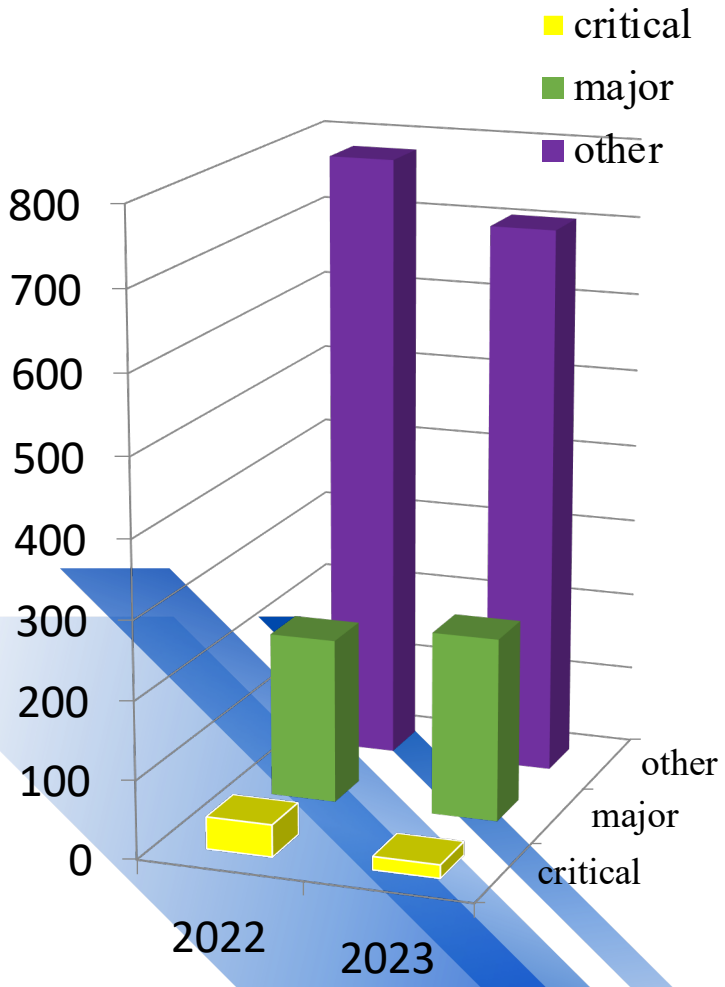

In 2022, inspectors identified the following non-conformities with the EAEU GMP requirements:

41 *critical* non-conformities (local manufacturers of medicines);

211 *major* non-conformities (***163*** non-conformities with local manufacturers of medicines, **48** non-conformities with foreign manufacturers of medicines)

781 *other* non-conformities (***405*** non-conformities with local manufacturers of medicines, ***376*** non-conformities with foreign manufacturers of medicines).

In 2023, inspectors identified the following non-conformities with the EAEU GMP requirements:

17 *critical* non-conformities (local manufacturers of medicines);

235 *major* non-conformities (***173*** non-conformities with local manufacturers of medicines, **62** non-conformities with foreign manufacturers of medicines)

705 *other* non-conformities (***295*** non-conformities with local manufacturers of medicines, ***410*** non-conformities with foreign manufacturers of medicines).

2022

1. Critical non-conformities:

Premises and equipment– 15;
Process validation, qualification of equipment and auxiliary systems – 14;
Risk of contamination – 6;
Storage conditions and environmental monitoring – 3;
Quality management system – 1;
Quality control – 1;
Data integrity assurance – 1.

2. Major non-conformities:

Premises and equipment – 86;
Process validation, qualification of equipment and auxiliary systems – 50;
Risk of contamination – 31;
Storage conditions and environmental monitoring – 14;
Quality control – 11;
Document management – 9;
Quality management system – 8;
Personnel – 2.

3. Other non-conformities: 781 (in relation to documentation and records management, personnel and other).

2023

1. Critical non-conformities:

Premises and equipment– 3;
Process validation, qualification of equipment and auxiliary systems – 3;
Risk of contamination – 2;
Storage conditions and environmental monitoring – 1;
Quality management system – 5;
Quality control – 7.

2. Major non-conformities:

Premises and equipment (including utilities) – 67;
Process validation, qualification of equipment and auxiliary systems – 44;
Risk of contamination – 28;
Storage conditions and environmental monitoring – 14;
Quality control – 38;
Water treatment system – 15;
Quality management system – 21;
Personnel – 8.

3. Other non-conformities: 705 (in relation to documentation and records management, personnel and other).

THANK YOU !