

## Multidisciplinary Study of the Quality of Medicines USA – Ukraine: The Role of the FDA and the National Regulator

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**Abstract.** A multidisciplinary comparison of drug quality assurance systems in Ukraine and the USA is carried out with an emphasis on the role of the national regulator of drugs of Ukraine and the FDA. Strengths and weaknesses and ways of harmonization to strengthen trust in Ukrainian generics are identified. Analysis of FDA reports and inspections is used. Convergence of standards has been established. Ukraine: GMP-EU/PIC/S, SPhU 2.8 (more than 2000 monographs), renewal of inspections. USA: cGMP, USP (more than 5000 monographs, legal status), more than 1000 inspections annually. Cooperation with the FDA (USP Memorandum 2011, USP Convention 2025) complements the SFU with USP articles, improves pharmaceutical legislation, laboratory infrastructure and professional responsibility of pharmacists and doctors in the legal relationship "doctor-patient-pharmacist". Strengths of Ukraine:

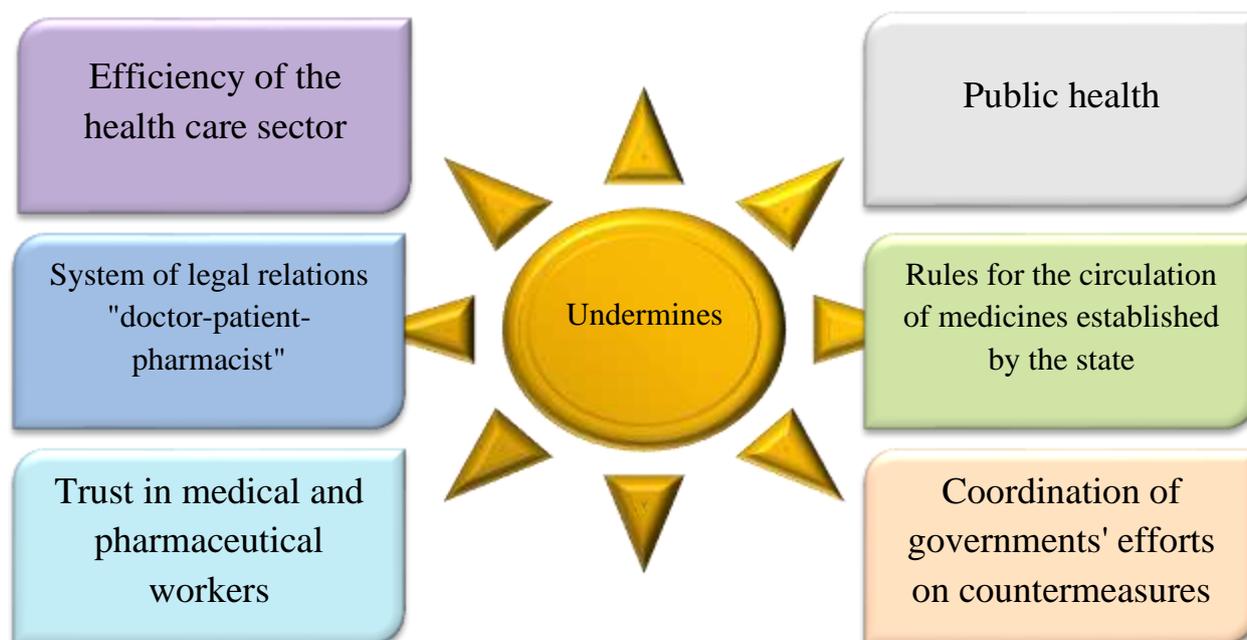
active removal of counterfeits, harmonization of Ph. Eur., protection of preferential programs. Weaknesses: Limited digital verification vs FDA Orange Book/DSCSA. Harmonization recommendations: mutual recognition of SPhU 2.8 and USP 48-NF 43; digital verification; expansion of laboratory capacity to FDA ORA level. State supervision in Ukraine and the United States forms a legal culture and protects patients' rights. Harmonization with the FDA ensures the competitiveness of Ukrainian generics, the safety of preferential programs and confidence in pharmaceutical services at the level of developed countries.

**Keywords:** quality of medicines, safety of medicines, circulation of medicines, pharmaceutical law, forensic pharmacy, FDA, national regulator of medicines.

**Introduction.** The state of health of citizens is determined by a complex of factors: the quality of the environment, drinking water, food, alcoholic beverages. High-quality and safe drugs sold through the pharmacy network and health care institutions ensure the protection of public health and the effectiveness of pharmacotherapy for an individual patient.

Experts from the World Health Organization (WHO), the European Commission, the FDA (USA) and the national regulator of medicines of Ukraine unanimously emphasize: low-quality, falsified, or substandard drugs pose a direct threat to life and health. According to the WHO, counterfeits annually cause up to 500 thousand deaths globally, impairing diagnosis, treatment, and prevention. In the United States, the FDA records systemic problems with generics (delayed dissolution, content mismatch), and in Ukraine – an increase in the circulation of illegal drugs through online platforms. Consequences: ineffective therapy, complications, disability, mortality [1-12].

The circulation of low-quality, falsified medicines undermines the efficiency of the health care sector [13, 14], which is shown in Fig. 1.



**Fig. 1.** What is the effect of the circulation of low-quality, falsified medicines.

According to the WHO, about every 10<sup>th</sup> drug in low- and middle-income countries is of poor quality or falsified. Countries spend \$30.5 billion on the purchase of low-quality and falsified medicines annually. Low-quality (fake, falsified) medicines imitate authenticity: logos, trademarks, labels, packaging, colors, shapes are identical or deceptively like the originals. Infringing intellectual property rights (trademarks, copyrights, patents). May infringe intellectual property rights (trademarks, copyrights, patents). Do not meet quality standards and specifications. In the context of the United States-Ukraine: the FDA records similar problems with imported generics (e.g. Biktarvy), Ukraine – with online trade. Harmonization of verification (SFU 2.8, 2025) is the key to protection [15].

Therefore, in modern conditions, the national regulator of medicines of Ukraine actively cooperates with the Food and Drug Administration (FDA) of the United States to improve partnership, strengthen international cooperation and ensure the quality of medicines during circulation. This interaction covers the exchange of experience in GMP inspections, verification of counterfeits and harmonization of pharmacopoeia standards (SPhU 2.8 ↔ USP 48-NF 43).

**The purpose of the study** was to conduct a multidisciplinary comparison of drug quality assurance systems in Ukraine and the United States, with an emphasis on the role of the FDA and the national drug regulator. Identify strengths and weaknesses. Propose ways of harmonization to strengthen trust in Ukrainian generics.

**Materials and methods.** Scientific literature, laws, and regulations have been worked out. The following publications were used as imperative material: publications of the EU, Food and Drug Administration, European Medicines Agency, PubMed, Verkhovna Rada of Ukraine, Cabinet of Ministers of Ukraine, Ministry of Health of Ukraine, State Service of Ukraine on Medicines and Drug Control. During the study, methods of analysis were used: documentary, retrospective, regulatory, systemic, forensic pharmaceutical, graphic.

The study of the article is a fragment of research works of Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" and State Enterprise "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines" on the topic "Interdisciplinary research into the quality system, standardization, validation, certification, safety and availability of medicines" (state registration number 0125U001529, implementation period 2025-2033).

**Results and discussion.** Low-quality and falsified medicines pose a significant threat to public health, especially in the context of this article comparing drug quality systems in Ukraine and

the United States. The British Pharmacopoeia, the United States Pharmacopoeia (USP), the European and Indian Pharmacopoeias, publish quality standards for medicinal products and determine the permissible limits for the content of the active pharmaceutical ingredient in a particular dosage form. Despite the existence of such standards, different countries have repeatedly described cases when drugs from different clinical and pharmacological groups (antibiotics, anti-tuberculosis, and antimalarial drugs) contained concentrations of the active pharmaceutical ingredient outside the officially established limits, and sometimes all samples taken from a certain group of drugs were substandard. Such medicines may be ineffective for the treatment of serious and common diseases (COVID-19, influenza, SARS, cancer, cardiovascular, neuropsychiatric diseases, HIV/AIDS), as they may contain the wrong ingredient, incorrect dosage or do not contain the declared active pharmaceutical ingredient at all. They can also be directly harmful to patients if they contain polluting impurities, potent, poisonous, or toxic substances. In the context of comparing Ukraine and the United States, this highlights the critical role of pharmacopoeia standards (SPhU 2.8, USP 48–NF 43) and the effectiveness of national regulators (Ukrainian market surveillance authority and FDA) in detecting, recalling, and preventing substandard and falsified drugs from reaching patients [16-18].

As noted by Ware K.B., Campbell R.D., Turner M., Walker J., Ramey S., Gilead Sciences brand drug manufacturers for the prevention and treatment of patients suffering from human immunodeficiency virus/acquired immunodeficiency syndrome in the United States have recently encountered counterfeit versions of their drugs. In some cases, antipsychotics and analgesics were used instead of the original substances [19-23]. Patients undergoing treatment human immunodeficiency virus/acquired immunodeficiency syndrome in health care facilities, or those who take pharmacotherapy prophylaxis human immunodeficiency virus, from taking falsified medicines risk jeopardizing their management strategies human immunodeficiency virus. Legal pharmaceutical manufacturers of original medicines advocate legal measures to counteract the illegal circulation of detected falsified medicines "under their brand". Within the scope of the investigation Food and Drug Administration in coordination with the marshals United States of America, local law enforcement agencies and during the trial, with the participation of Gilead experts, carried out operational and investigative measures in 17 locations in 8 states. Thousands of bottles of falsified medicines labeled by Gilead with documentation and labeling as medicines for human immunodeficiency virus / acquired immunodeficiency syndrome: Biktarvy® (biktegravir 50 mg tablets, emtricitabine 200 mg and tenofovir alafenamide 25 mg); Descovy® (emtricitabine 200 mg tablets and tenofovir alafenamide 25 mg).

During the investigation, it was established [24]:

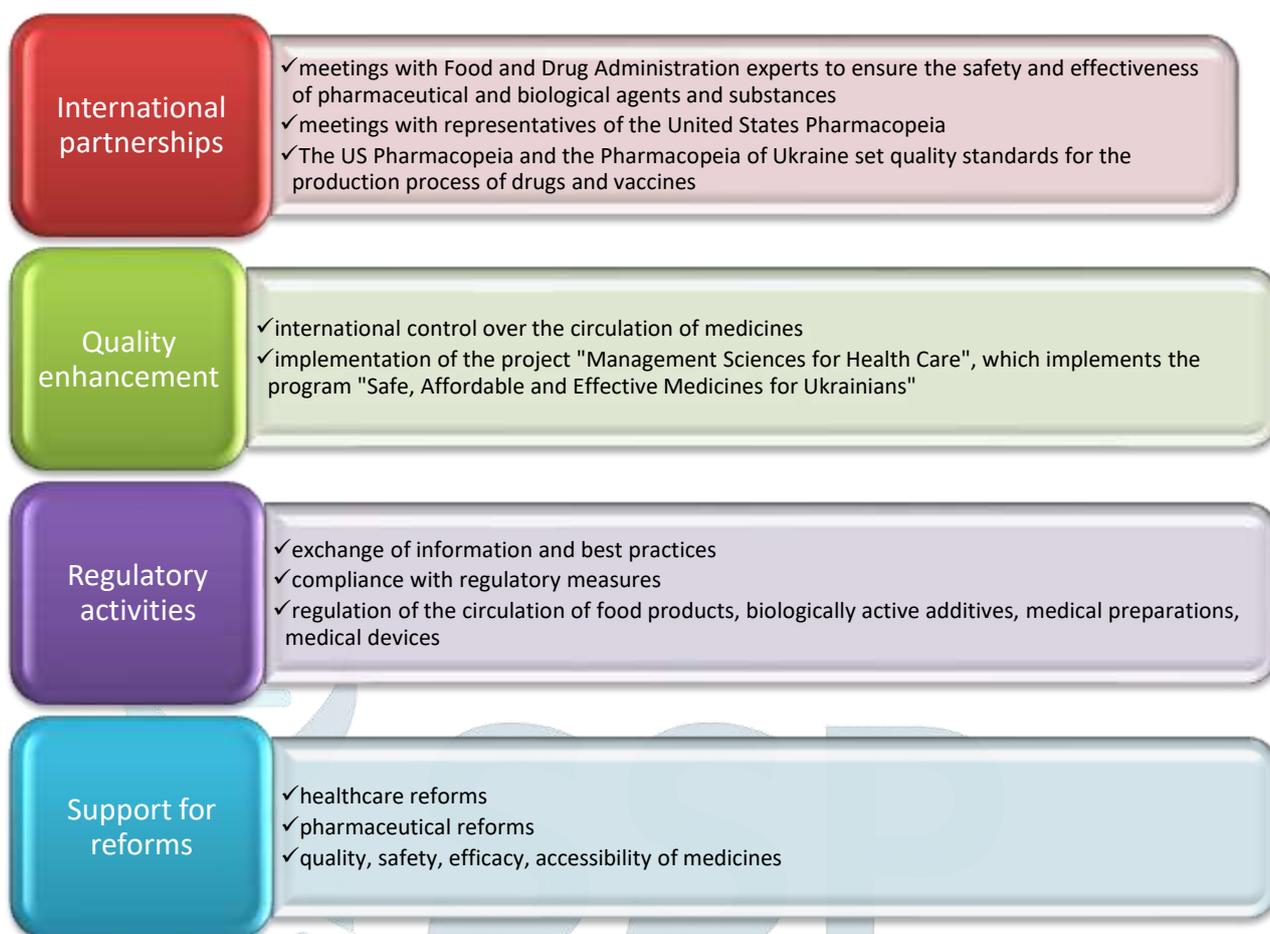
- ✓ Gilead Sciences sold falsified versions of drugs for the human immunodeficiency virus, Biktarvy and Descovy, worth about \$ 250 million by pharmacies over the course of 2 years;
- ✓ Johnson & Johnson reported that in December 2021, 3 cases were detected in which unauthorized distributors sold its brand in bottles of its own drug for the human immunodeficiency virus, Symtuza, that contained the wrong (counterfeit) pills.

During a recent meeting of the delegation of the Ministry of Health of Ukraine with officials of the Food and Drug Administration, areas of partnership were planned [25-27]. Key areas are shown in Fig. 2.

#### *Comparative context of Ukraine-USA*

USA (FDA): the strictest GMP system (since 1963). USP as a legally binding standard (USP 48-NF 43, 2025). Post-marketing surveillance through Orange Book and ANDA. However, the generic market (90% of prescriptions) is vulnerable: the example of Gilead Sciences is \$250 million of Biktarvy/Descovy fakes (2021-2022). The FDA conducts 1000+ inspections annually, withdraws problematic batches.

Ukraine: harmonization with GMP-EU/PIC/S (SPhU II, Supplement 8 from 01.08.2025), 20+ manufacturers certified. The national regulator has resumed inspections (14 thousand inspections, Q1 2025), and an organization for drug verification has been created. Challenges: transparency of bioequivalence, online trade.

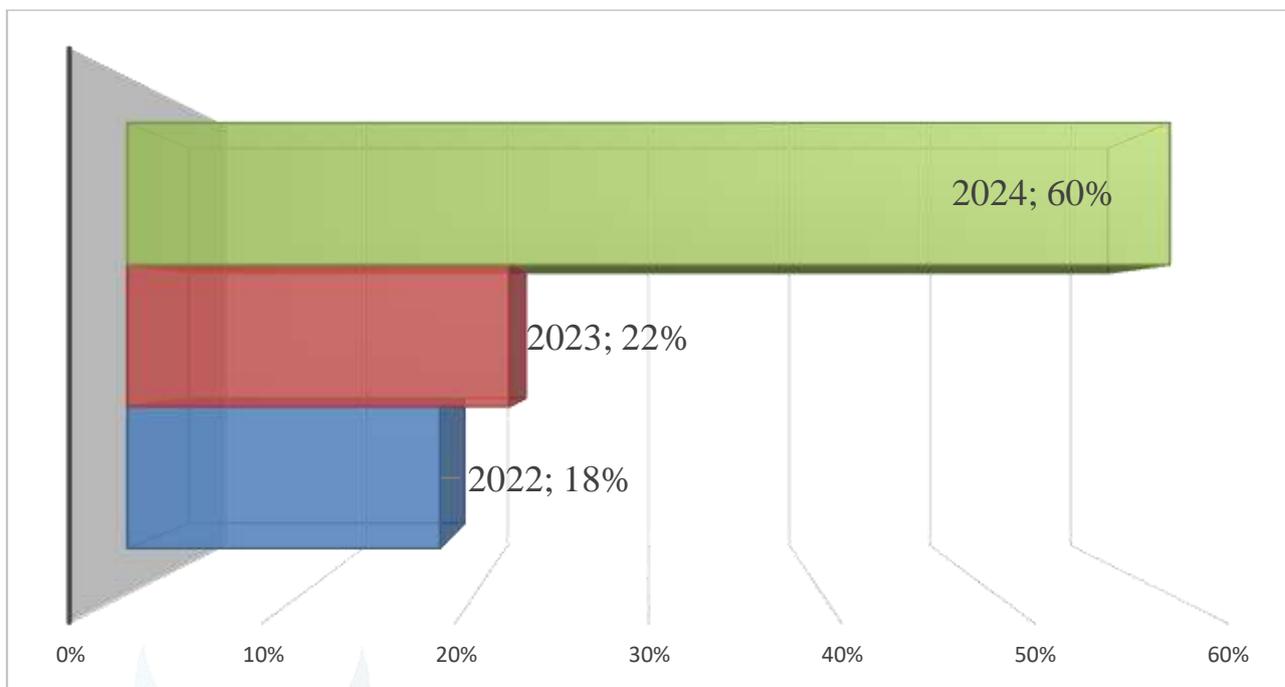


**Fig. 2.** Key areas of partnership between Ukraine and the United States of America.

The quality and safety of medicines of all clinical-pharmacological, classification-legal, nomenclature-legal groups in circulation in the pharmaceutical market of Ukraine directly affects the life and health of patients, including privileged categories of citizens (combatants, liquidators of the Chernobyl nuclear power plant, disabled people of I-II groups, etc.). This is ensured by the national regulator of medicines in accordance with the Resolution of the Cabinet of Ministers of Ukraine No. 1303 of 13.08.1998 "On Streamlining the Free and Preferential Dispensing of Medicines by prescription in the case of outpatient treatment of certain groups of the population and for certain categories of diseases" and the International Classification of Diseases of the 11th revision (ICD-11). Comparison with FDA (USA): USP 48-NF 43 guarantees the quality of medicines for Medicaid/Medicare, like Ukrainian preferential programs. Harmonization of SPhU 2.8 with USP strengthens the protection of vulnerable groups in Ukraine [28-46].

The country has a state multi-level system of quality control of medicines, which is provided by the national regulator of medicines and its territorial divisions in each administrative-territorial unit of Ukraine. The quality control system of medicines includes three main areas: 1) state control of medicines when imported into the territory of Ukraine; 2) control by authorized persons; 3) inspections of the national drug regulator during scheduled and unscheduled inspections of drug circulation. These measures guarantee the withdrawal of low-quality, substandard, falsified, and unregistered drugs from circulation.

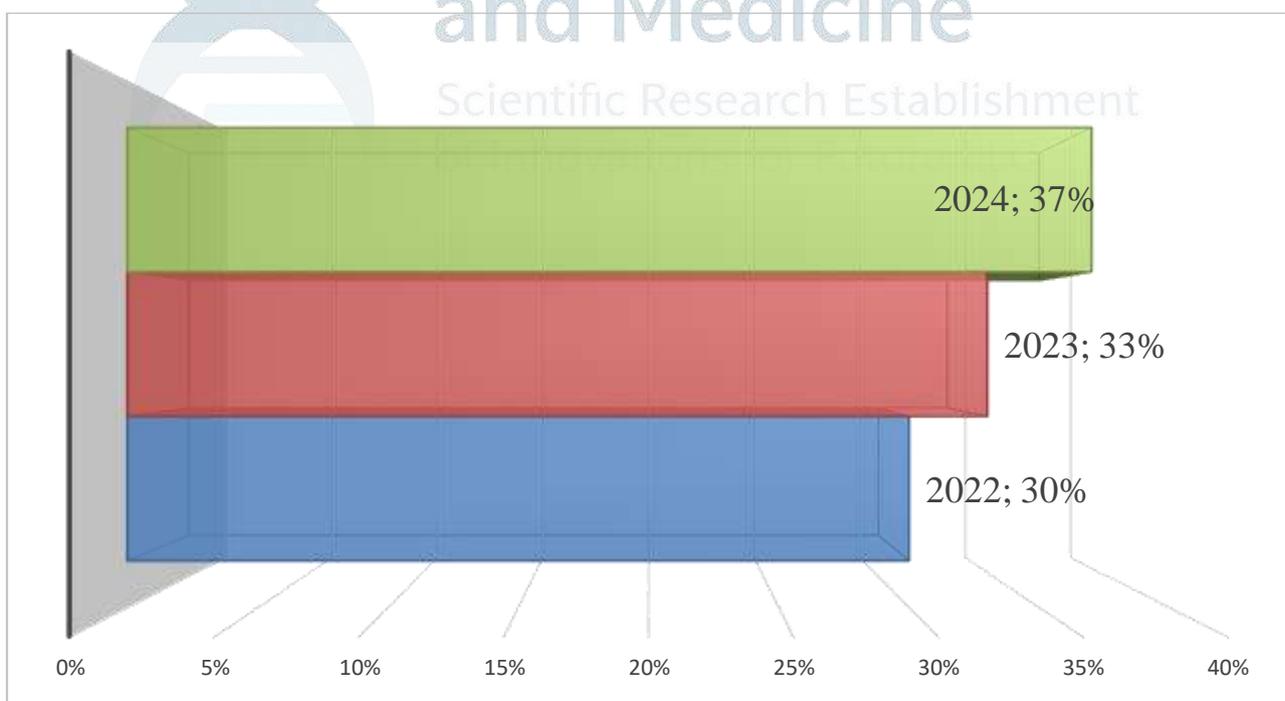
*Comparison with the FDA (USA):* a similar multi-level system (Import Alert, ANDA inspections, postmarket surveillance). But the FDA has a more developed digital infrastructure (Orange Book, BE database) and conducts 1000+ inspections annually. imported in violation of the law) during 2022–2024 [47].



**Fig. 3.** Indicators of orders prohibiting the sale (trade), storage, and use of medicines (low-quality, suspicious, falsified or imported in violation of the law) during 2022-2024 [47].

*Comparison with the FDA (USA):* FDA issues 500-1000 Recall Notices (Class I-III) annually, recalling millions of units (e.g. 17 million doses of Gilead counterfeits, 2022). The Ukrainian system is effective for the local market, but needs to be scaled up and digitalized like the FDA.

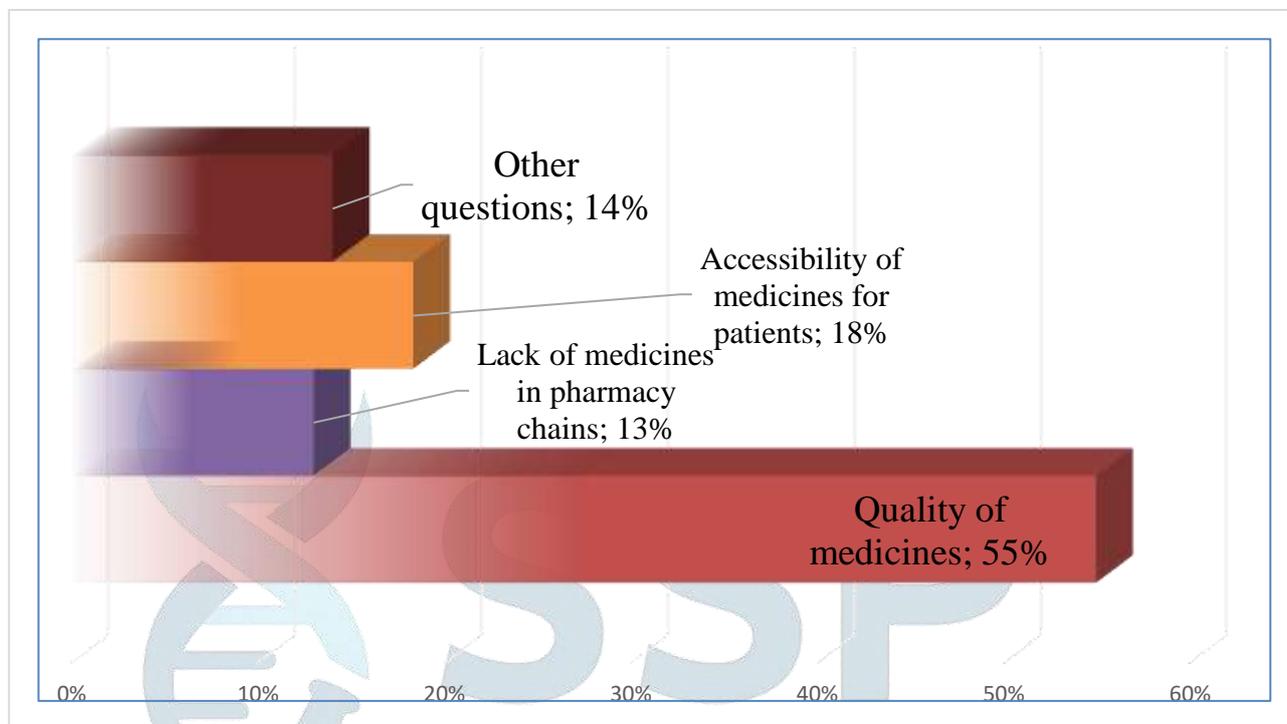
In recent years, the number of citizens' appeals regarding the sale of unregistered drugs or those imported in violation of the law has increased. The national regulator of medicines received appeals and complaints from citizens through the state institution "Government Contact Center", e-mail, postal address of the regulator, as well as from ministries and state institutions during 2022-2024 [47], which is shown in Fig. 4.



**Fig. 4.** Indicators of appeals and complaints from citizens regarding the quality of drugs during 2022-2024 [47].

*Comparison with the FDA (USA):* FDA receives more than 10 thousand complaints annually through MedWatch, Consumer Complaint System and Hotline (1-888-INFO-FDA). The FDA's digital infrastructure (online forms, AI analysis) provides a quick response and publication of reports. Ukraine needs a similar digital platform to monitor public opinion on the quality of medicines.

The reasons for appeals and complaints from citizens regarding the quality of drugs during 2022-2024 are shown in Fig. 5.



**Fig. 5.** Reasons for appeals and complaints from citizens regarding the quality of drugs during 2022-2024 [47].

It is important to note that one of the main achievements of 2024 for the national drug regulator is the adoption of the Resolution of the Cabinet of Ministers of Ukraine dated November 05, 2024 No. 1264 "On Amendments to the Resolution of the Cabinet of Ministers of Ukraine dated March 13, 2022 No. 303". According to it, from January 01, 2025 in Ukraine, scheduled inspections by specialists of the national drug regulator of the requirements of the legislation on the quality of drug circulation and compliance by business entities (pharmacies, enterprises, health care facilities) with licensing conditions in the pharmaceutical market, as well as in the field of circulation of narcotic drugs, psychotropic substances, and precursors, have been resumed.

*Comparison with the FDA (USA):* FDA conducts routine cGMP inspections annually (Risk-Based Inspection Program), covering 1000+ facilities. The resumption of inspections in Ukraine brings the system closer to FDA standards for post-marketing surveillance, which is critical for the credibility of generics and preferential programs.

Thus, in 2024, within the framework of the program "Laboratory Complex for Quality Control of Medicines and Medical Products", the national drug regulator issued 320 orders prohibiting the sale (trade), storage, and use of drugs. Detailing the 2024 orders:

- 74 orders – prohibition of circulation of 102 series of 60 items;
- 17 orders – prohibition of all series of 18 names of low-quality drugs;
- 201 orders – prohibition of circulation of 285 series of 175 items;
- 11 orders – prohibition of all series of 18 items imported in violation of the law;
- 10 orders – prohibition of circulation of 78 series of 10 names of suspected falsification;
- 7 orders – prohibition of circulation of 7 series of 7 items after the end of the temporary ban;
- 46 orders – temporary prohibition of sale, storage, and application;

- 9 orders – prohibition of circulation of 9 series of 9 names of low-quality drugs;
- 4 orders – prohibition of circulation of 4 series of 4 items imported illegally;
- 1 order – prohibition of circulation of 1 series 1 name of a person suspected of falsification;
- 22 orders – prohibition of circulation of 22 series of 21 items due to adverse reactions.

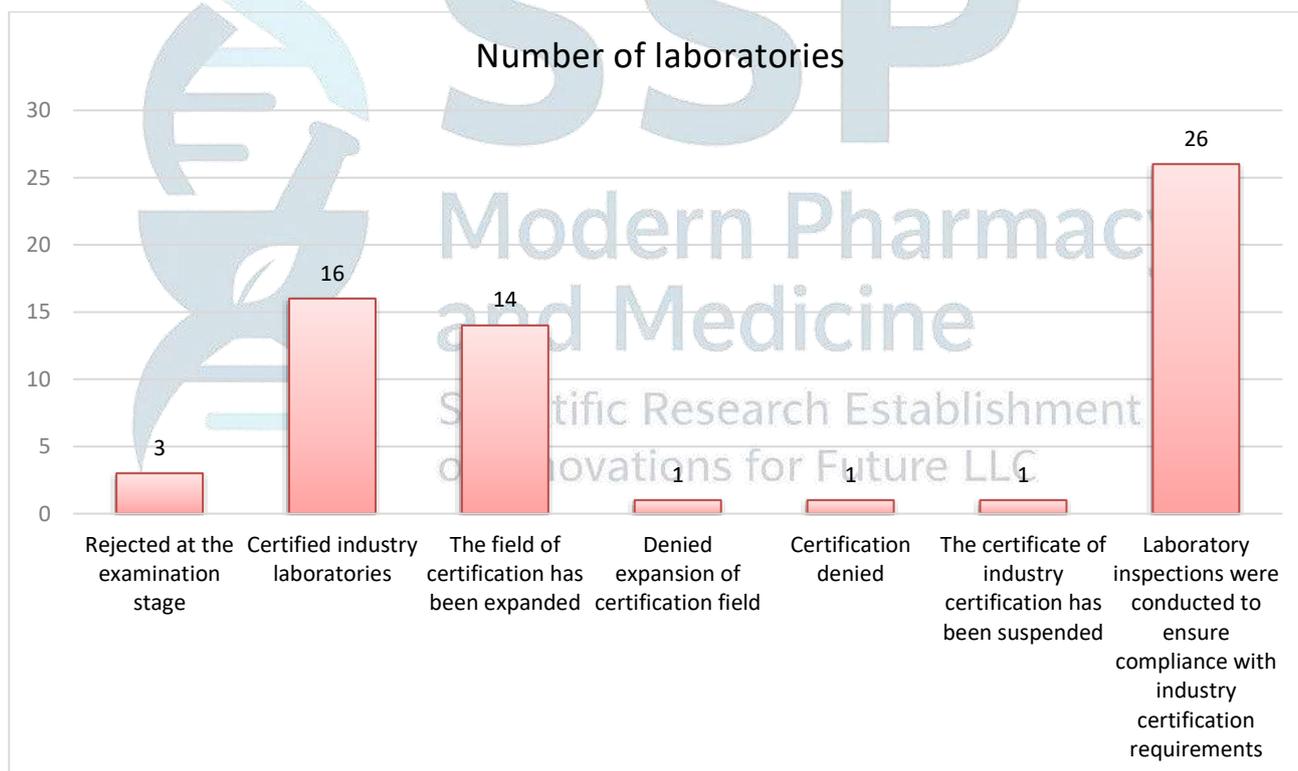
Decisions on implementation: 665 decisions were processed (18 negative, 648 positive); 59 letters on domestic and 607 letters on imported drugs were issued. 48 letters were sent to law enforcement and customs authorities regarding falsification and illegal trade of medicines via the Internet and health care facilities (Article 15 of the Law of Ukraine "On Medicines") [47].

*Comparison with FDA (USA):* similar activity – FDA Class I-III Recalls (2024: more than 1200 inspections), inspections import alerts. The scale of the Ukrainian system is impressive for the local market (320 orders), but requires digital reporting like the FDA Orange Book for transparency

An important role in the control over the circulation of medicines is played by laboratories that analyze medicines in accordance with the State Pharmacopoeia of Ukraine (SPhU II, Supplement 8 from August 01, 2025) [48].

*Comparison with FDA (USA):* Laboratories of the national drug regulator use SPhU 2.8 methods (HPLC, GC, in vitro dissolution), which are harmonized with USP 48-NF 43. The FDA applies identical standards in 13 of its own laboratories and a network of contracted laboratories (ORA, CDER). This provides an analysis of more than 100 thousand. samples annually. The development of laboratory infrastructure in Ukraine (PIC / S) brings the quality of control closer to the FDA level.

Indicators of sectoral certification of laboratories for drug quality control are shown in Fig. 6.



**Fig. 6.** Indicators of sectoral certification of laboratories for drug quality control during 2022-2024 [47].

The list of recommended laboratories authorized by the national drug regulator to carry out work on quality control of medicines includes:

- SE "Central Laboratory for Quality Analysis of Drugs and Medical Products" (Kyiv + Dnipro branches, Lviv);
- Laboratory of Pharmacopoeia Analysis of the State Enterprise "Ukrainian Scientific Pharmacopoeia Center for Drug Quality";

- State Laboratory for Quality Control of Drugs of the State Institution "Institute of Pharmacology and Toxicology of the National Academy of Medical Sciences of Ukraine";
- Laboratory of Pharmaceutical Analysis of the State Expert Center of the Ministry of Health of Ukraine;
- Laboratory for Quality Control of Drugs LLC "DOBROBUT-LIKILAB".

State supervision in the field of medicines (Article 108) is carried out to check compliance with the requirements of the legislation on the effectiveness, quality and safety of medicines and the rules for their circulation [49].

*Comparison with FDA (USA):* FDA uses 13 in-house ORA/CDER laboratories and a network of more than 50 contract laboratories, applying USP 48-NF 43. The Ukrainian network of 5 accredited laboratories (SPhU 2.8) is effective for the national market, but requires capacity expansion and digital integration as the FDA Laboratory Information Management System (LIMS) for the prompt exchange of test results.

From January 1, 2025, scheduled inspections by the national drug regulator of the requirements of the legislation on the quality of medicines and compliance by business entities with licensing conditions in the pharmaceutical market and in the field of drug circulation in accordance with the Resolution of the Cabinet of Ministers of Ukraine dated November 05, 2024 No. 1264 [50] have been resumed.

*Comparison with FDA (USA):* FDA applies the Risk-Based Inspection Program (annually more than 1000 routine cGMP/ANDA inspections). The renewal of inspections in Ukraine synchronizes the system with FDA standards for post-marketing surveillance.

Also, the Resolution of the Cabinet of Ministers of Ukraine dated September 06, 2024 No. 1052 renewed the planned measures of state market surveillance regarding the circulation of medical devices and their auxiliaries, active medical devices for implantation and medical devices for in vitro diagnostics [51].

*Comparison with FDA (USA):* FDA Center for Devices and Radiological Health (CDRH) provide similar oversight (510(k), PMA, QSR inspections), covering 21 CFR Part 820. The resumption of inspections in Ukraine harmonizes the regulation of medical devices with the FDA, protecting patients from substandard implants and diagnostics, especially in preferential programs.

At the weekly staff meeting of the Ministry of Health of Ukraine, the results of state supervision for the first quarter of 2025 were presented [52-56]. From January 01, 2025, the national drug regulator returned to full functioning:

- quality and safety control of drugs;
- compliance with licensing conditions in the pharmaceutical sector;
- supervision of the circulation of narcotic drugs and psychotropic substances.

Inspections have been resumed as an element of the projected safety policy in the pharmaceutical market.

➤ I quarter 2025: more than 200 inspections of pharmacies, health care facilities, manufacturers:

- 129 – quality control of drugs;
- 105 – production, wholesale, retail, import;
- Focus: licensing conditions, patient safety.

Systemic disorders identified:

- incompleteness of pharmacies with qualified pharmacists;
- lack of quality management systems;
- violation of the registration of narcotic drugs in hospitals;
- sale of prescription drugs without a prescription;
- circulation of expired drugs.

Results of inspections:

- licenses for 24 pharmacies have been suspended;
- 8 items of drugs are prohibited for circulation.

Control of narcotic drugs and psychotropic substances:

- 234 inspections of product characteristics;
- fines were imposed 765 thousand. UAH (510 thousand paid);
- 18 decisions on the suspension of customs clearance;
- 8 letters to law enforcement officers with signs of criminal offenses.

*Comparison with FDA (USA):* FDA Warning Letters and Form 483 (Q1: more than 250 inspections). Ukraine has achieved a similar level of activity (more than 200 inspections), but needs digital reporting (FDA Establishment Inspection Report database) and training for sustainable FDA-level surveillance.

#### *Forensic and Pharmaceutical Practice*

Below are typical examples from forensic pharmaceutical practice regarding the circulation of falsified drugs (Nos. 1-3).

*Example from forensic and pharmaceutical practice No. 1.* Investigators of the Investigative Department of the Main Directorate of the National Police in Lviv region under the procedural supervision of the Lviv Regional Prosecutor's Office initiated criminal proceedings under Part 2 of Art. 321-1 "Falsification of medicines or circulation of falsified medicines" of the Criminal Code of Ukraine [57, 58].

During the pre-trial investigation, it was established that on May 26, 2025 in the territory of Lviv region, operatives, and investigators of the Main Directorate of the National Police in Lviv region carried out investigative (search) actions together with the involvement of specialists of the State Service for Medicines and Drug Control in Lviv region, to identify medicines, as well as other relevant information according to their competence.

During the event, products were found that were outwardly like medicines labeled in a foreign language. According to the results of the event, violations of compliance with the requirements of the legislation on the quality of medicines were revealed. The State Service for Medicines and Drug Control in Lviv region submitted 447 urgent notifications to the State Service of Ukraine on Medicines and Drug Control on the detection of low-quality, falsified, or unregistered medicines.

Forensic examinations have been appointed; the investigation is ongoing.

*Example from forensic and pharmaceutical practice No. 2.* Investigators of the Main Investigation Department (as part of the pre-trial investigation body) of the National Police of Ukraine under the procedural guidance of the prosecutor of the Prosecutor General's Office initiated criminal proceedings under Part 2 of Art. 321-1 (Falsification of medicines or circulation of falsified medicines) of the Criminal Code of Ukraine [59, 60].

During the pre-trial investigation, it was established that on 01.08.2025 in the city of Kyiv, operatives of the Department of Strategic Investigations of the National Police of Ukraine with the participation of the State Service of Ukraine on Medicines and Drugs Control detected, documented, and stopped the illegal activities of an organized group of persons who carried out illegal trafficking (purchase, transportation, accounting, storage, etc.) – the sale of medicines of smuggled origin. That is, the sale of Russian-made medicines with signs of falsification, which entered the territory of Ukraine illegally, through pharmacy chains in Kyiv to the population and patients suffering from oncological and other health disorders.

With the sanction of the court, investigators and police officers conducted authorized searches at the places of sale and storage of medicines, as well as at the places of residence of the defendants, because of which the following were seized:

- more than two thousand packages of medicines;
- money, "draft" records;
- computer equipment with accounting documentation in electronic form, etc.

As part of the pre-trial investigation, several forensic examinations were appointed, the issue of seizing the seized is being decided.

In addition, a set of operational and investigative measures is being carried out to establish the full range of citizens involved in criminal activities. The pre-trial investigation is currently ongoing.

Example from forensic and pharmaceutical practice No. 3. A detective of the Bureau of Economic Security of Ukraine, under the procedural supervision of the prosecutor of the Office of the Prosecutor General of Ukraine, initiated criminal proceedings and notified the citizens of Ukraine of suspicion of committing a criminal offense under Part 3 of Art. 229 of the Criminal Code of Ukraine (illegal use of marks for goods and services, committed by prior conspiracy by a group of persons, which caused material damage on an especially large scale) [61].

During the pre-trial investigation, it was established that on July 22, 2025 in the city of Poltava, detectives of the Bureau of Economic Security of Ukraine, with operational support by officers of the Cyber Police Department of the National Police of Ukraine, established that a group of criminals illegally manufactured, forged, and distributed perfumery and cosmetic products of world-famous brands in one of the warehouses. Advertised and sold counterfeit perfume products via the Internet Delivered fakes using the postal transportation service.

The Bureau's detectives conducted searches in places of illegal production and seized the following from illegal trafficking:

- ❖ about 3 thousand. counterfeit perfume bottles;
- ❖ printing products and packaging with logos and signs of world-famous trademarks applied on them;
- ❖ another inventory;
- ❖ information carriers with files on accounting and sale of counterfeit products.

As a result of the violation of intellectual property rights, material damage was caused to international companies in the amount of more than UAH 8.5 million. The pre-trial investigation is ongoing.

These examples from forensic pharmaceutical practice (No. 1-3) indicate that:

- in the cities of Kyiv, Poltava and Lviv region, facts of illegal trafficking of falsified medicines and perfumery products, the circulation of which into legal circulation was stopped;
- Even though the State Service of Ukraine on Medicines and Drugs Control and its territorial bodies carry out painstaking preventive work, there is still a need to strengthen the level of state control over the quality of medicines, as well as the introduction of legislative proposals to prevent counterfeit products from being received by consumers through the legal sector of the Ukrainian economy.

It is important to emphasize that in accordance with Article 13 of the Law of Ukraine dated April 04, 1996 No. 123/96-VR "On Medicines", state control of the quality of medicines is understood as a set of organizational and legal measures aimed at compliance by business entities (regardless of the form of ownership) with the requirements of the legislation on ensuring the quality of medicines. Control over the quality of drugs and the conditions of their production is carried out by the national drug regulator in accordance with Art. 14 of the Law [62].

*Comparison with FDA (USA):* Like the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §351-352), where the FDA implements cGMP controls (21 CFR Part 210/211). Both systems (Articles 13-14 of the Law of Ukraine and the FD&C Act) provide preventive oversight. However, the FDA has a legally binding USP as a supplement to the legislation, which is a promising area of harmonization for SPhU 2.8.

Such a body is the national regulator of medicines and its territorial subdivisions, which act based on the Regulation approved by the Resolution of the Cabinet of Ministers of Ukraine dated August 12, 2015 No. 647 [63].

*Comparison with the FDA (USA):* FDA operates according to a similar decentralized model (CDER District Offices in more than 20 regions and ORA labs). Resolution No. 647 structures the Ukrainian system similarly to the FDA Organization Act (1938), providing local oversight. Harmonization of inspection procedures (SPhU 2.8 and USP/cGMP) will strengthen the efficiency of territorial units to the level of FDA District Offices.

According to paragraph 1 of the Regulation (Resolution of the Cabinet of Ministers of Ukraine No. 647 of August 12, 2015), the national regulator of medicines is the central executive body that implements state policy in the following areas:

- quality and safety control of medicines, medical immunobiological preparations;
- medical equipment and medical devices;
- trafficking of narcotic drugs, psychotropic substances, precursors; counteraction to their illegal trafficking;
- blood donation and the functioning of the blood system.

The activities of the regulator are directed and coordinated by the Cabinet of Ministers through the Minister of Health.

*Comparison with the FDA (USA):* The FDA as an independent agency within the HHS structure has a broader mandate (CDER, CBER, CDRH, CFSAN) and larger resources (\$6.7 billion budget 2025). The national regulator of medicines of Ukraine is functionally similar, but needs to expand its powers (postmarket surveillance, Orange Book-equivalent) for full harmonization with the FDA.

The tasks of the State Service of Ukraine on Medicines and Drug Control are defined in paragraph 4 of the Regulation [63] and are shown in Fig. 7.

issues licenses to business entities for the production, import (except for active pharmaceutical ingredients), wholesale, and retail trade in medicines
forms and maintains a license register of types of economic activity for the production, import (except for active pharmaceutical ingredients), wholesale and retail trade of medicines and ensures the transfer of information to the Unified License Register
takes samples of medicines and medical devices in accordance with the established procedure to check their quality
carries out state control over compliance with the requirements of the legislation on ensuring the quality and safety of medicines and medical devices at all stages of circulation, including the rules for the implementation of good practices (production, distribution, storage, pharmacy)
monitors compliance by business entities with the licensing conditions for conducting economic activities for the production, import (except for active pharmaceutical ingredients), wholesale and retail trade of medicines
draws up protocols on administrative offenses and considers cases of administrative offenses in cases provided for by law
provides binding instructions on the elimination of violations of standards and technical conditions, pharmacopoeia articles and technological regulations, as well as on the elimination of violations during the production, storage, transportation, and sale of medicines, and exercises other powers determined by law

**Fig. 7.** Tasks of the State Service of Ukraine on Medicines and Drug Control [63].

The implementation of control functions by the national regulator of medicines and its territorial bodies is carried out based on the Law of Ukraine "On the Basic Principles of State Supervision (Control) in the Field of Economic Activity" [49] and "On Licensing of Types of Economic Activity" [64].

*Comparison with FDA (USA):* FDA operates on a similar principle through the Administrative Procedure Act (5 U.S.C. §551-559) and Good Guidance Practices, providing the legal basis for cGMP inspections.

cGMP (Current Good Manufacturing Practice) is the "Current Good Manufacturing Practices" – a US pharmaceutical standard approved by the FDA, which is an evolution of the basic GMP.

Key differences between GMP and cGMP: GMP (global standard, including Ukraine and EU):

- Basic principles of good production (personnel, premises, equipment, documentation, quality control);

- Static set of rules (WHO/EMA/PIC/S);
- cGMP (USA, FDA).

Dynamic standard – constantly updated considering new scientific data, risks, inspections. The emphasis is on the Quality Management System, not just production. Regulated by 21 CFR Parts 210/211 + USP 1078, legally binding. Risk-based approach – risk inspections (ANDA, high-risk generics). FDA cGMP inspections record systemic problems (validation failures, OOS investigations), which explains the recall of Biktarvy. It is advisable for Ukraine to adopt cGMP Quality Unit independence and annual product review to strengthen SPhU 2.8. Both systems use a comprehensive approach to government surveillance (routine, unscheduled inspections), which creates the basis for harmonization of SPhU 2.8 inspection procedures with FDA/USP standards.

Under martial law, the Government adopted Resolution No. 303 of March 13, 2022 "On the Termination of State Supervision (Control) Measures under Martial Law", which suspended scheduled and unscheduled measures of state supervision (control) for the period of martial law. However, in the presence of a threat to human rights, interests, life, and health, it was allowed to carry out unscheduled supervision measures based on decisions of central executive authorities [65].

*Comparison with FDA (USA):* FDA Emergency Use Authorization (EUA) during COVID-19 demonstrates a similar approach - temporary simplification of ANDA/cGMP under crisis conditions with enhanced post-crisis surveillance. The resumption of inspections from January 01, 2025 (Resolution No. 1264) synchronizes Ukraine with FDA post-emergency standards, restoring full-fledged drug quality control.

At the same time, on January 1, 2025, the Resolution of the Cabinet of Ministers of Ukraine dated November 05, 2024 No. 1264 "On Amendments to the Resolution of the Cabinet of Ministers of Ukraine dated March 13, 2022 No. 303" came into force. In accordance with it, the planned measures of state supervision (control) of the national drug regulator over compliance by business entities, in particular with the requirements of the legislation on the quality of medicines, were resumed; Licensing conditions for conducting economic activities for the production, wholesale and retail trade of medicines, (Resolution of the Cabinet of Ministers of Ukraine No. 929 dated November 30, 2016) (hereinafter referred to as the License Conditions) [66].

*Comparison with FDA (USA):* The renewal of routine inspections is like the FDA cGMP Compliance Program (21 CFR 210/211), where inspections under licensing conditions are mandatory for ANDA generics. This creates the basis for full FDA-level post-marketing surveillance, ensuring that preferential programs are protected from substandard drugs.

In this regard, the Order of the National Drug Regulator dated November 29, 2024 No. 1780 approved the Plan for the Implementation of State Supervision (Control) Measures for 2025 [53].

*Comparison with FDA (USA):* The FDA similarly develops an annual Compliance Program Annual Report Plan (Risk-Based Inspection Schedule), covering more than 1000 cGMP inspections. The approval of the Plan for 2025 synchronizes the Ukrainian planning system with the FDA, ensuring predictability of surveillance and protection of drug quality at the level of USP 48-NF 43.

The implementation of the State Supervision Plan for 2025 stimulates legislative activity to counteract the circulation of falsified drugs and increase the responsibility of pharmaceutical businesses and heads of health care facilities. On October 6, 2025, the Verkhovna Rada registered the draft Law "On Amendments to Certain Laws of Ukraine on Data Verification in the Field of Healthcare" (reg. No. 14100) link [67-69].

*Comparison with FDA (USA):* FDA Drug Supply Chain Security Act (DSCSA, 2023) implements full verification of drug serial numbers. Ukrainian project No. 14100 creates a similar tracking mechanism (serialization, verification) that harmonizes the system with FDA/DSCSA and USP 1033 to protect against counterfeits of the Biktarvy scandal level [69]: increasing the level of control over licensees' compliance with the Licensing Conditions for Conducting Economic Activities to Produce Medicines, Wholesale and Retail Trade in Medicines, Import of Medicines (except for Active Pharmaceutical Ingredients);

- normalization of the procedure for the transfer of information about pharmaceutical workers contained in the electronic health care system to the central executive body that implements

the state policy in the field of quality control and safety of medicines (State Service for Medicines and Drug Control), namely:

- surname, first name, patronymic (if any);
- registration number of the taxpayer's registration card (if any) or series (if any) and passport number of a citizen of Ukraine (for individuals who, due to religious beliefs, refuse to accept the registration number of the taxpayer's registration card and have reported it to the relevant supervisory authority and have a mark in the passport of a citizen of Ukraine);
- information about the educational and qualification level, specialty, advanced training and retraining, job title, specialization (if any).

Requests for information about pharmaceutical workers should include:

- name of the legal entity, surname, first name, patronymic (if any) of the individual entrepreneur who is a licensee and about whom information is requested;
- reference to the legal grounds and justification of the need to obtain information;
- list (composition) of information about pharmaceutical workers requested.

Quality standards of medicines in force in Ukraine, according to Tokmenko I. meet European standards and are constantly being improved [70]:

- ❖ the pharmaceutical industry is making efforts to harmonize the rules for the circulation of medicines and standards with EU rules and standards as part of its integration goals;
- ❖ pharmaceutical legislation is continuously improved to optimize the regulatory framework for pharmaceutical products, including standards for quality, safety and detection of side effects and countermeasures;
- ❖ changes in pharmaceutical legislation include updating existing rules and adopting new ones to align them with EU standards;
- ❖ using the experience of the Food and Drug Administration and the European Medicines Agency [71] in the pharmaceutical industry will be able to contribute to countering the circulation of falsified medicines and maintain a high level of quality of medicines in circulation in pharmacies and health care institutions, while ensuring the safety and effectiveness of pharmaceutical products to support public health.

The process of supplementation and codification of the State Pharmacopoeia of Ukraine (SPhU) is carried out annually. From August 1, 2025, Appendix 8 to the SFU II edition (SFU 2.8) will come into force in accordance with the Order of the Ministry of Health of Ukraine dated June 20, 2025 No. 1005 [72]. Legal basis for the introduction of SFU 2.8: Art. 2 of the Law of Ukraine "On Medicines"; Law on Accession to the European Pharmacopoeia Convention; The Concept of Adaptation of Ukrainian Legislation to the EU; para. 8 of the Regulation on the Ministry of Health (Resolution of the Cabinet of Ministers of Ukraine No. 267 of March 25, 2015, as amended No. 90 of January 24, 2020) [72, 73].

*Comparison with USP (USA):* SPhU 2.8 (annual update) is like USP 48-NF 43 and USP 2025-2030 (biannual revision). Both pharmacopoeias have a legally binding status and ensure harmonization with Ph. Eur. (USP 1033). This creates the basis for mutual recognition of drug quality standards between the national regulator of Ukraine and the FDA.

During the development of the State Pharmacopoeia of Ukraine (SFU), the experience of the United States Pharmacopoeia (USP) was used, considering national specifics. USP 34-NF 29 entered into force on May 01, 2011 (published November 2010). USP-NF is issued annually with quarterly updates – the most dynamic pharmacopoeia standard in the world [48]. USP-NF structure: US Pharmacopoeia – drug quality standards; National formulary – requirements for excipients (not a restrictive list of drugs). The USP is issued by the non-governmental United States Pharmacopoeia Convention, but has a legally binding status (21 U.S.C. §351), defining minimum quality and safety standards for all drug traffickers.

*Comparison of SPhU and USP:* SPhU 2.8 (Ukraine): Annual Supplements, Ph. Eur. Harmonization. USP 48-NF 43 (USA): Annual Edition and Quarterly Supplements. Common: both pharmacopoeias are legally binding documents with regular updates, which creates the basis for mutual recognition of drug quality standards between the national regulator of Ukraine and the FDA.

The cooperation of the national drug regulator with USP is formally enshrined in the Memorandum of Understanding (2011), which provides: application of USP standards and methods of laboratory practice in Ukrainian laboratories; independent assessment of the quality of imported and domestic drugs; pharmacopoeias establish quality standards to produce drugs and vaccines; Regulators control quality from registration to the end of the expiration date.

*Comparison with FDA (USA):* The 2011 memorandum creates the basis for mutual recognition of SPhU 2.8 and USP 48-NF 43, like the FDA-EMA MoU. In 2025, a five-year meeting of the US Pharmacopoeia Convention (USP Convention) was held in the United States, bringing together more than 500 organizations: regulators, the pharmaceutical industry, the scientific community, and doctors. The program covered biologics, drug shortages, impurities, AI innovations, strengthening regulation and countering counterfeiting. Ukraine at the USP Convention highlighted: the evolution of supervision from martial law to full-fledged inspections (SFU 2.8, Resolution No. 1264); harmonization of SPhU and USP for the global healthcare ecosystem. USP Convention forms USP 2025-2030 is a strategic plan for FDA cGMP. Ukraine's participation at the USP Convention level creates a platform for mutual recognition of SPhU 2.8 and USP 48-NF 43, like FDA-EMA, ensuring trust in Ukrainian generics at the international level.

During the meeting of the USP Regional Office for Europe, the Roadmap for harmonization of USP resolutions for 2025-2030 with the priorities of European Pharmacy was presented. The USP Convention is a unique platform for interstate dialogue on the safety of drug trafficking, production stability, innovation, and the fight against shortages. Resolution 2025–2030 includes 7 priorities: 1) strengthening the global pharmaceutical supply chain; 2) increasing the availability of key drugs; 3) expanding access to biological products of guaranteed quality; 4) digital technologies for quality control; 5) strengthening global regulatory systems; 6) solving problems of quality of drugs, functional food products, dietary supplements; 7) environmental sustainability of drug life cycles. For Ukraine: SPhU 2.8 is harmonized with USP/Ph. Eur., which allows integration into the global initiatives of the USP Convention. Participation in the platform provides Ukrainian generics with access to FDA-level quality standards, shortage resolution, and countering counterfeiting at the level of Gilead Biktarvy recalls.

At the same time, the development of the legislative and regulatory framework remains a key condition for the implementation of pharmacopoeia standards SPhU 2.8 to counteract drug falsification. The registration in the Verkhovna Rada of draft law No. 14100 on data verification in the field of health care is a step towards strengthening control over healthcare workers and licensees. Such initiatives create a single information system to prevent violations of pharmaceutical circulation.

*Comparison with FDA (USA):* Draft Law No. 14100 is like the FDA Drug Supply Chain Security Act (DSCSA 2023) with serial number tracking. The integration of SPhU 2.8 with the DSCSA/USP 1033 verification system will provide Ukraine with drug quality control equivalent to the FDA Orange Book, protecting preferential programs from subprime generics.

The Ukrainian pharmaceutical control system is gradually approaching the standards of the FDA (USA) and the European Medicines Agency (EMA). This provides: a higher level of patient safety (SPhU 2.8 and USP 48-NF 43); protection of public health from substandard and falsified drugs; strengthening public confidence in national generics and the pharmaceutical system. Harmonization with the FDA (Memorandum 2011, verification No. 14100) creates prerequisites for mutual recognition of Ukrainian quality standards at the USP/cGMP level, ensuring the competitiveness of domestic drugs for preferential programs and the international market.

Thus, the state supervision of the national drug regulator over compliance with pharmaceutical legislation and SPhU 2.8 performs a strategic function: quality control of drugs of all clinical and pharmacological groups; formation of legal culture and professional responsibility of pharmacists and doctors; protection of patients' rights during the circulation of drugs (dispensing, use, administration) [74-76]. Cooperation with FDA and USP aims to improve legislation and regulations; development of laboratory infrastructure; improving the quality of pharmaceutical services; strengthening trust in the control system in the legal relations "doctor-patient-pharmacist-lawyer-expert".

**Conclusions.** A multidisciplinary comparison of drug quality assurance systems in Ukraine and the USA is carried out, with an emphasis on the role of the FDA and the national drug regulator. Strengths and weaknesses are identified. Ways of harmonization to strengthen trust in Ukrainian generics are proposed. It is substantiated that the quality of drugs determines the effectiveness of pharmacotherapy and public health. Falsified and substandard drugs (1/10 in middle-income countries) lead to losses of \$30.5 billion and mortality, undermining trust in the health care system. It has been proved that the national regulator of medicines of Ukraine implements multi-level supervision: import, licensing, inspections, laboratory control. SPhU II (Supplement 8, August 01, 2025) is harmonized with USP 48-NF 43 (Memorandum USP 2011), providing standards for generics. International cooperation is analyzed: participation in the USP Convention 2025, support for seven priorities of USP 2025-2030 (supply chains, biological products, digital verification No. 14100). Prospects for further research are outlined: mutual recognition of the SFU and USP/cGMP will protect preferential programs, strengthen exports and trust in the legal relations "doctor-patient-pharmacist". Ukraine is approaching FDA quality standards, ensuring the safety of drugs at the level of developed countries.

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