



ANALYSIS OF THE ACTIVITIES OF PHARMACEUTICAL WORKERS BASED ON E LEGISLATION

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<https://doi.org/10.5281/zenodo.18309154>

ARTICLE INFO

Received: 25th December 2025

Accepted: 30th December 2025

Online: 31st December 2025

KEYWORDS

Quality systems, Good pharmacy practice, Pharmacist, Retail sales, Pharmaceutical activities, Rights and responsibilities of pharmaceutical workers.

ABSTRACT

The rights and responsibilities of pharmaceutical workers are stipulated by a number of legislative regulations that define and regulate individual labor relations and directly related social relations based on balancing and coordinating the interests of workers, employers, and the state.

The quality of drug supply, particularly in retail establishments, is a pressing issue in the republic. Separate regulations define the rights and responsibilities of pharmacists working in pharmacies and branches.

Introduction. The pharmaceutical industry of the Republic of Uzbekistan is one of the most dynamically developing sectors of the country's economy. In recent years, opportunities have been created for radically improving licensing and permitting procedures and providing the population with affordable, high-quality pharmaceutical products. This has contributed to the stable growth and expansion of the pharmacy network: while in 2010 there were 8,794 pharmacies in the country, today their number has increased to 14,230. On average, there is one pharmacy per 2,000–3,000 residents, confirming the development and expansion of access to pharmaceutical services [10].

However, despite growth and improvements in the industry, a number of problems persist in providing medications to both the public and healthcare facilities. Furthermore, the pharmaceutical market is experiencing negative situations that are causing legitimate public objections and mistrust of industry representatives. One of the main problems is the violation of legal requirements for prescribing medications and the non-compliance with prescribing criteria for over-the-counter medications, which has serious consequences for public health.

An equally serious problem is the illegal entry of counterfeit, unregistered, and substandard medications and medical products into the republic, which is the main reason for the illegal circulation of these drugs in pharmacies. In recent years, the illegal trafficking of narcotic drugs, psychotropic substances, and potent substances has also continued, with 116 cases identified this year.



Purpose of the Study. The purpose of the study is to optimize the pharmacy organization's quality management system based on the principles of Good Pharmacy Practice (GPP) and a comprehensive assessment of current legislation.

Material and methods. The Law of the Republic of Uzbekistan "On the Protection of Citizens' Health" regulates the following provisions regarding membership in the state healthcare system, which includes: the Ministry of Health of the Republic of Uzbekistan, the Ministry of Health of the Republic of Karakalpakstan, healthcare authorities of the regions, the city of Tashkent, their divisions in cities and districts. The state healthcare system also includes state-owned and subordinated to the governing bodies of the state healthcare system medical and preventive and research institutions ; educational institutions for the training and retraining of medical and pharmaceutical workers ; pharmaceutical enterprises and organizations, sanitary and preventive institutions, forensic medical examination institutions; enterprises for the production of medicines, medical devices and medical equipment; as well as other enterprises, institutions and organizations whose main activities are related to the protection of citizens' health.

According to the Law, pharmaceutical activities can be carried out by legal entities and individuals with the appropriate license [3].

It should be noted that the procedure and conditions for issuing licenses for medical and pharmaceutical activities are regulated by Resolution No. 80 of the Cabinet of Ministers of the Republic of Uzbekistan dated February 21, 2022.

This document was adopted based on a mechanism aimed at optimizing and digitalizing interactions between the state and business entities. A uniform licensing format has been established using a specialized electronic platform.

In addition , the legal entity must have at least one employee on staff - a pharmacist with a higher education or a specialist with a higher medical education who has completed special training at a higher pharmaceutical educational institution, as well as pharmaceutical workers of pharmacies whose licenses have not been revoked due to violations of legal documents, including gross violations of the procedure for determining prices for drugs and medical devices, in addition to the presence of a pharmacy manager who is not included in the register .

Resolution No. 80 of the Cabinet of Ministers of the Republic of Uzbekistan established that, when opening a pharmacy branch by a licensee as part of a legal entity, there must be at least one employee - the head of the pharmacy branch with a higher pharmaceutical education or secondary specialized vocational education in the specialty of assistant (assistant) pharmacist/chemist.

Information entered into the register of addresses and the register of employees is excluded from them after three years from the date of its entry [6].

It should be noted that, in accordance with Article 30 of the Law of the Republic of Uzbekistan "On the Protection of Citizens' Health," which regulates emergency and urgent medical care, medical and pharmaceutical workers are obligated to provide emergency medical care to citizens. Failure to fulfill this obligation, as well as causing harm to public health, is subject to legal liability in accordance with the established procedure.



the right to engage in medical and pharmaceutical activities belongs to persons who have received a diploma of graduation from a higher or secondary specialized medical educational institution in the Republic of Uzbekistan.

At the same time, persons who have received a diploma of medical or pharmaceutical education in foreign countries are admitted to medical or pharmaceutical activities in the manner established by the Cabinet of Ministers of the Republic of Uzbekistan.

In accordance with this norm, persons illegally engaged in medical and pharmaceutical activities are liable in accordance with the Law.

This Law regulates the provisions governing the liability of medical and pharmaceutical workers. For example, individuals who have been duly provided with information constituting a medical secret are equally liable for the disclosure of medical secrets as medical and pharmaceutical workers.

Also, according to Article 46 of the Law, in the event of unqualified performance of their professional duties by medical and pharmaceutical workers, resulting in harm to the life and health of citizens, damages are compensated in the manner established by law.

Compensation for damages does not exempt medical and pharmaceutical workers from disciplinary, administrative or criminal liability in accordance with the law [1].

One of the key aspects is the presence of pharmaceutical job titles in the national classification system of professions and positions. In order to modernize the regulatory framework governing the names and structure of professions in the context of a market economy and modern management principles, as well as to ensure consistency with the system of training pharmaceutical specialists in higher and secondary specialized education institutions, the order of the General Director of the Agency for Technical Regulation under the Ministry of Investment, Industry and Trade of the Republic of Uzbekistan dated February 13, 2023, No. 05-1507 was issued. This document amended and supplemented the state standard O'Z DST 3513:2021 concerning the classifier of positions of employees and professions of workers (KODSPR-2020) [8].

A total of 12,151 job titles and requirements for them have been approved according to the classifier. This list was analyzed for the feasibility of pharmaceutical specialists in various fields.

The Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activity" in its new edition was approved on January 4, 2016. Article 20 of this Law of the Republic of Uzbekistan regulates the basic provisions for the retail sale of medicines and medical devices (except ophthalmic medical devices), which may only be carried out by pharmacies and their branches .

According to Appendix No. 2 to the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan dated April 6, 2017, No. 185, adopted in pursuance of the Law dated January 4, 2016, No. ZRU-399, a regulation governing the retail sale of medicines and medical devices was approved. The document establishes that when carrying out these activities, pharmacies and their branches must strictly adhere to the requirements stipulated by state standards, sanitary and hygienic regulations, labor protection rules,



safety regulations, fire safety, as well as other regulatory acts in the field of technical regulation [7].

The Resolution of the President of the Republic of Uzbekistan dated May 6, 2019 “On measures for the further development of the system of medical and pharmaceutical education and science” No. PP-4310 provides requirements for educational areas.

The country is implementing a set of measures aimed at modernizing the system of medical and pharmaceutical education, integrating international educational standards, developing scientific research focused on priority tasks in the field of public health, and forming an effective model of professional training of personnel [5].

The volumes of credits accumulated in continuous professional medical education have been approved and are reflected in Table 1.

Table 1

No.	Training contingent	Loan volumes *	
		Total	Of these, no less than per year
1.	Medical and pharmaceutical personnel with higher education	288 **	36
2.	Medical and pharmaceutical personnel with secondary specialized education	180 ***	36

Volume of credits earned in continuing professional medical education

It should be noted separately that loans are collected over a period of five years.

** Of the 288 credits, 144 are earned in the relevant medical educational institutions and organizations through training at the expense of the State Budget of the Republic of Uzbekistan, and the rest are on a fee-paying basis.

*** Of the 180 credits, 144 are earned in the relevant medical educational institutions and organizations through training at the expense of the State Budget of the Republic of Uzbekistan, and the rest through participation in seminars, conferences, webinars, master classes, simulation trainings and other training courses [10].

The rights and responsibilities of pharmaceutical workers are provided for by a number of legislative regulations.

The Labor Code of the Republic of Uzbekistan, the new version of which was introduced on April 30, 2023, defines and regulates individual labor relations and directly related social relations based on ensuring a balance and coordination of the interests of employees, employers, and the state.

Separate regulations define the rights and responsibilities of pharmaceutical workers operating in pharmacies and branches.

Pharmacists working in pharmacies are obligated to provide consumers with accurate information about the medications and medical devices they sell. Upon request, pharmacists must provide relevant documents confirming the stated price and proper quality of the medications and devices.

Based on the Labor Code of the Republic of Uzbekistan, disciplinary liability of the employee is provided.



Disciplinary liability is legal liability that occurs for an employee committing a disciplinary offence and is expressed in the application of disciplinary measures to that employee.

The types of disciplinary liability are general and special disciplinary liability.

Considering the importance of the social sphere and the potential risk of harm to the life and health of the population, the measure of responsibility for pharmaceutical workers is also regulated by separate rules.

The issue of quality of drug supply, especially in retail organizations, is relevant in the republic [3].

Results and discussion. It should be noted that in recent years, the republic has implemented comprehensive measures to improve the circulation of medicines, medical devices, and medical equipment. At the same time, the country's leadership has defined a policy and continues the process of reforming the pharmaceutical industry, ensuring safety, improving the state registration of pharmaceutical products, and streamlining the activities of pharmacies [5].

In order to further improve the provision of the population with medicines, medical products and medical equipment with guaranteed quality, safety and efficiency, as well as to improve the processes of streamlining the circulation of pharmaceutical products, Decree of the President of the Republic of Uzbekistan No. UP-20 "On additional measures to regulate the pharmaceutical industry" dated January 23, 2024 was signed . [4].

This Decree of the President of the Republic of Uzbekistan amends the Decree of the President of the Republic of Uzbekistan dated April 10, 2019 No. UP-5707 "On further measures to accelerate the development of the pharmaceutical industry of the Republic in 2019-2021", which provides for the following:

The following are subject to mandatory certification in accordance with national requirements of Good Pharmacy Practice (GPP):

until January 1, 2025 — chain pharmacies engaged in the retail sale of pharmaceutical products;

Until January 1, 2026 - other pharmacies.

Good Pharmacy Practice (GPP) includes rules for organizing pharmaceutical activities in the field of retail sales and manufacturing of medicines and medical devices by specialists with pharmaceutical education, aimed at ensuring the quality of pharmaceutical services.

Currently, the updated national standard O ' z has been approved by order No. 10/MSt dated April 26, 2024 of the State Institution "Research Institute of Standardization, Certification and Technical Regulation" (Institute of Standards of Uzbekistan) under the Agency for Technical Regulation of Uzbekistan , the Ministry of Investment and Foreign Trade of the Republic of Uzbekistan MSt 140:2024 "Good Pharmacy Practice (GPP)".

Separate clauses define the lists of information that must be provided to pharmaceutical personnel:



IF = 9.2

l) on newly adopted legislative acts on pharmaceutical activities and documents in the field of technical regulation, as well as amendments made to them;

m) on the results of the conducted internal audit and inspection by regulatory authorities;

n) on the necessary preventive and corrective measures to eliminate (prevent) violations of licensing requirements;

o) dissemination of information on the results of consideration of consumer complaints and suggestions.

Implementing a national standard requires teamwork from competent staff. Therefore, the project outlines the key responsibilities of a pharmacist, which include:

a) assessment of suppliers of high-quality medicinal products, medical devices and other goods included in the pharmacy assortment, as well as their acceptance, storage, sale and transfer to the pharmacy;

b) provision of reliable information about medicines, medical devices and other goods included in the pharmacy assortment, and their prices;

c) provision of information on the rational use of drugs;

d) prescription preparation and dispensing of medicinal products;

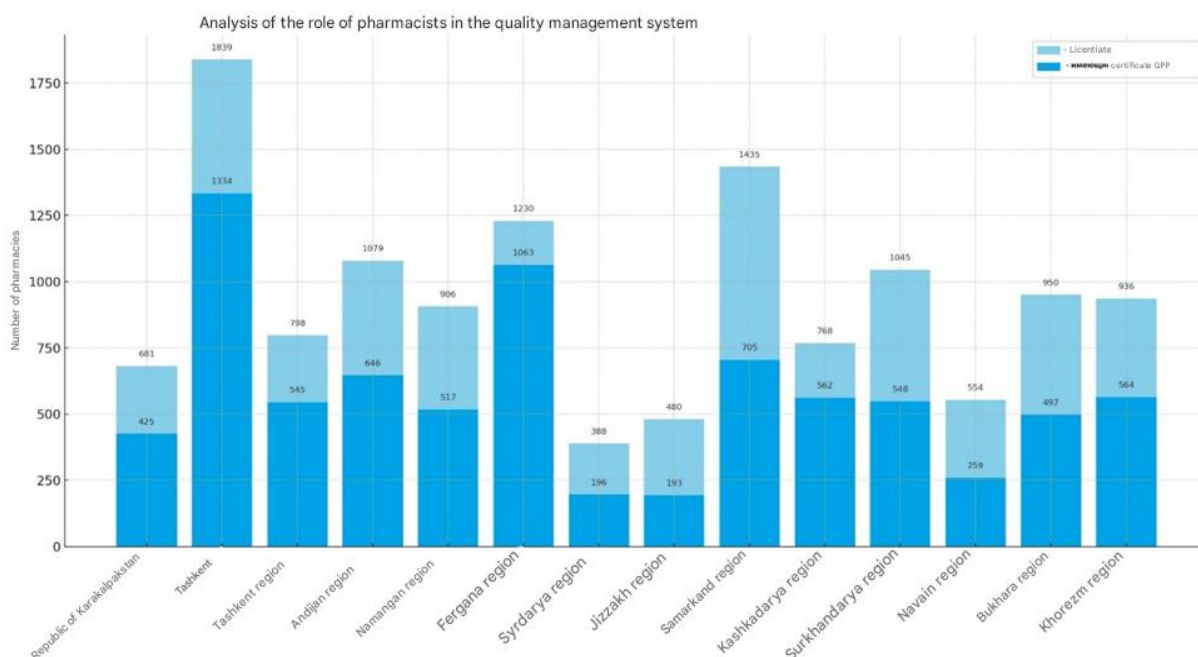
d) preparation of payment documents;

e) compliance with the standards of pharmaceutical ethics and deontology.

Special requirements in the national standard are imposed on the pharmacist who carries out quality control of medicines and medical devices manufactured in pharmacies, who must have professional knowledge and skills in the field of quality control [9].

Today, based on the above in accordance with regulatory documents, good pharmacy practice (GxP) requirements have been introduced in pharmacies operating in our country, and 8,054 certificates of compliance with GxP requirements have been issued to pharmaceutical companies.

Schedule 1



Analysis of the importance of pharmacists in the pharmacy system quality management-1 schedule

The national standard requires that relevant training cycles be conducted regularly; the effectiveness of training sessions for periodic professional development of all pharmaceutical workers will need to be periodically assessed and documented in accordance with the established procedure.

Conclusion

As a result of the analysis of the legal basis for the activities of pharmaceutical workers in pharmacies and their branches in the Republic of Uzbekistan, it was revealed that Quality and safety are guaranteed through compliance with legislation that ensures the public receives high-quality, effective, and safe medications. Particular attention is paid to educational policies that provide systematic professional development for specialists based on a credit-based, modular system of training. This promotes the professional development of staff and ensures the training of competent pharmaceutical workers prepared for work in today's environment.

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3. Decree of the President of the Republic of Uzbekistan dated January 23, 2024 No. UP-20 "On additional measures to regulate the pharmaceutical industry" (National Legislation Database, January 24, 2024, No. 06/24/20/0063)

4. Resolution of the President of the Republic of Uzbekistan dated May 6, 2019 No. PP-4310 "On measures for the further development of the system of medical and pharmaceutical education and science" (National Legislation Database, 07.05.2019, No. 07/19/4310/3100 24.02.2022, No. 06/22/78/0163);

5. Resolution of the Cabinet of Ministers of the Republic of Uzbekistan dated February 21, 2022 No. 80 "On approval of a unified regulation on the procedure for licensing certain types of activities through a special electronic system."

6. Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On measures to implement the Law of the Republic of Uzbekistan dated January 4, 2016 No. ZRU-399 "On Amendments and Additions to the Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activities" dated April 6, 2017 No. 185" (Collection of Legislation of the Republic of Uzbekistan, 2017, No. 14, Art. 228, No. 37, Art. 997; National Legislation Database, November 15, 2017, No. 09/17/915/0259, October 27, 2022, No. 07/22/411/0961);

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