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Legal Foundations of the Professional Activities of Pharmacy Workers in Pharmacies and Their Branches in the Republic of Uzbekistan

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Abstract: Introduction. The analysis of legislative and departmental documents regulating the activities of pharmaceutical professionals in pharmacies aims to identify key challenges and define directions for further improvement. In the context of a constantly evolving pharmaceutical market and increasing demands for high-quality public service, a comprehensive review of existing norms and standards becomes increasingly relevant.

Objective. The aim of this study is to optimize the quality management system of pharmacy organizations based on Good Pharmacy Practice (GPP) principles and to conduct a comprehensive assessment of current legislative acts.

Materials and Methods. To achieve the research objectives, an analysis of regulatory and legal documents was conducted, along with a review and critical evaluation of the current requirements for pharmaceutical professionals. This approach allowed for the identification of key trends in the implementation of GPP and the assessment of the role of standardization in ensuring pharmacy service quality.

Results.

Legal framework conclusions: The implementation of modern quality management methods—such as GPP standards—has been found to significantly improve pharmacy efficiency.

Evaluation of licensing and standards: Compliance with legislative norms and quality standards plays a crucial role in ensuring effective pharmaceutical care.

Conclusion

The study and analysis of the legal foundations governing the professional activities of pharmacy workers and their branches in the Republic of Uzbekistan reveal that regulatory oversight in this field is based on clearly defined legislative provisions. Mandatory licensing, adherence to quality standards such as Good Pharmacy Practice (GPP), and compliance with qualification requirements for pharmaceutical personnel contribute to ensuring the population's access to high-quality, effective, and safe pharmaceutical products.

Keywords: Quality management systems, Good Pharmacy Practice (GPP), Pharmacist, Retail sale, Pharmaceutical activity, Rights and responsibilities of pharmaceutical professionals.

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Introduction

The analysis of legislative and departmental materials regulating the activities of pharmaceutical specialists in pharmacies aims to identify the main problems and determine directions for further improvement. In the context of a constantly changing pharmaceutical market and increasing demands for the quality of public services, the need for a comprehensive analysis of existing norms and standards becomes more relevant.

Objective of the Study

The objective of the study is to optimize the quality management system of pharmacy organizations based on the principles of Good Pharmacy Practice (GPP) and to conduct a comprehensive evaluation of current legislative acts.

Materials and Methods

To achieve the stated goal, an analysis of regulatory legal documents was conducted, along with a study and critical review of existing requirements for pharmaceutical specialists. This allowed for the identification of key trends in the implementation of Good Pharmacy Practice and an assessment of the role of standardization in ensuring the quality of pharmacy operations.

Results of the Study

As a result of the analysis of the legal foundations governing the activities of pharmaceutical workers in pharmacies and their branches in the Republic of Uzbekistan, it was found that the implementation of modern quality management methods, such as GPP standards, significantly enhances the efficiency of pharmacies. It was also established that compliance with legislative norms and standards contributes to the improvement of the quality of services and products provided.

Conclusion

The study and analysis of the legal foundations governing the activities of pharmaceutical workers in pharmacies and their branches in the Republic of Uzbekistan demonstrated that regulatory legal regulation in this sphere is based on clearly established legislative norms. The inclusion of mandatory licensing, adherence to quality standards such as Good Pharmacy Practice (GPP), and compliance with qualifications requirements for pharmaceutical workers ensure the population's access to quality, effective, and safe pharmacy products.

Keywords

Quality management systems, Good Pharmacy Practice, pharmacist, retail sales, pharmaceutical activity, rights and obligations of pharmaceutical workers.

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Introduction

The pharmaceutical industry of the Republic of Uzbekistan is one of the most dynamically developing sectors of the national economy. In recent years, significant progress has been made in improving licensing and regulatory procedures and ensuring public access to affordable and high-quality pharmaceutical products. This has contributed to the steady growth and expansion of the pharmacy network: in 2010, there were 8,794 pharmacies operating in the country, whereas today this number has increased to 14,230. On average, there is one pharmacy per 2,000–3,000 residents, confirming the expansion and accessibility of pharmaceutical services.

Nevertheless, despite the sector’s growth and improvements, a number of problems remain in ensuring the provision of medicines to both the population and healthcare institutions. Negative trends are also observed in the pharmaceutical market, causing public concern and growing mistrust toward industry representatives. One of the main issues is the violation of legal requirements for prescribing medications, including inappropriate dispensing of over-the-counter (OTC) drugs, which can have serious consequences for public health.

Cases have also been reported where pharmaceutical goods are sold by employees without pharmaceutical education, which violates qualification requirements. Additionally, illegal dispensing of prescription medications without a valid prescription, violations in prescription writing by healthcare professionals, and the unsupervised use of medications by the population—especially antibiotics—pose major health risks.

Another critical issue is the illegal import and circulation of counterfeit, unregistered, and substandard medicines and medical devices. These pose a significant threat and are a primary cause of the unlawful presence of such products in pharmacies. In recent years, the illegal distribution of narcotic drugs, psychotropic substances, and potent pharmaceuticals has also continued. In the current year alone, 116 such cases have been identified.

In this context, one of the most important directions in the development of the pharmaceutical sector is the formation and enhancement of a quality management system in the pharmacy network. This requires continuous professional development of pharmacy personnel and supervisors, based on the application of current regulatory requirements. This approach will contribute to improved pharmaceutical services and minimize risks to public health.

Materials and Methods

The Law of the Republic of Uzbekistan "On the Protection of Citizens' Health" establishes the structure of the national healthcare system, which includes: the Ministry of Health of the Republic of Uzbekistan, the Ministry of Health of the Republic of Karakalpakstan, regional health departments, the Tashkent city health authority, and their subdivisions at the city and district levels. The national healthcare system also encompasses publicly owned institutions and those subordinated to government health authorities, including healthcare and research institutions; educational institutions for training and retraining medical and pharmaceutical personnel; pharmaceutical enterprises and organizations; sanitary and epidemiological institutions; forensic medical institutions; and enterprises engaged in the manufacture of medicines, medical products, and equipment, as well as other entities whose primary activity is related to the protection of public health.

According to the law, pharmaceutical activities may be carried out by legal entities and individuals only upon obtaining the appropriate license [3].

It is important to note that the procedure and conditions for issuing licenses for medical and pharmaceutical activities are regulated by the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 80, dated February 21, 2022. This document was adopted based on current legislation on licensing and permits and in accordance with Presidential Decree No. UP-6044, dated August 24, 2020, aimed at optimizing and digitizing interactions between the state and business entities. A unified electronic licensing platform was introduced to streamline this process.

Furthermore, the annexes to this resolution cover various areas of activity, including the pharmaceutical sector. Annex No. 29 outlines the licensing procedure for retail sales of pharmaceuticals and medical products. It mandates compliance with all legislative requirements concerning pharmaceuticals and pharmaceutical activities, particularly adherence to the state standard for Good Pharmacy Practice (GPP) and relevant technical regulations.

Additionally, each licensed legal entity must employ at least one pharmacist with a higher pharmaceutical or medical education who has undergone specialized training at a recognized higher pharmaceutical educational institution. Pharmacies must also employ pharmaceutical professionals whose licenses have not been revoked for legal violations, including severe breaches related to pricing regulations for medicinal products and medical devices. Moreover, the pharmacy manager must not be listed in the registry of disqualified individuals [8;11].

Legal and Regulatory Basis for Pharmaceutical Activity in Uzbekistan

The legal basis for the relevant regulations is established by the Presidential Decree of the Republic of Uzbekistan No. PP-2773 dated February 14, 2017, which outlines the following obligations for license holders engaged in pharmaceutical activities.

When conducting pharmaceutical activities, the licensee is required to:

Comply with the legislation governing pharmaceutical activity, including the state regulation of prices for medicinal products and medical devices;

Form personnel exclusively from individuals who are not listed in the official register of disqualified pharmaceutical workers;

Operate strictly within the scope of the licensed activities and at the address(es) specified in the licensing agreement, except for those addresses included in the official address register;

Adhere to the normative documents approved by the Ministry of Health of the Republic of Uzbekistan related to the production, manufacturing, and sale of medicinal products and medical devices, as well as comply with environmental and sanitary-hygienic standards and regulations.

Additionally, when manufacturing medicinal products, the licensee is obligated to conclude a contract for product testing with an authorized control and analytical laboratory [9].

The Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 80 further stipulates that, when opening a pharmacy branch as part of a legal entity, the licensee must employ at least one branch manager with either a higher pharmaceutical education or a specialized secondary professional qualification as a pharmacist assistant.

Since 2017, the licensing authority has maintained official registers of pharmacy addresses and pharmacy workers whose licenses have been revoked due to violations of pharmaceutical regulations, including gross violations in pricing rules for pharmaceuticals and medical devices. The data entered into these registers are automatically removed after three years from the date of entry [11].

Professional Responsibility and Legal Compliance

According to Article 30 of the Law of the Republic of Uzbekistan “On the Protection of Citizens’ Health”, which regulates the provision of emergency and urgent medical care, medical and pharmaceutical professionals are obligated to provide emergency care to citizens. Failure to fulfill this obligation, as well as any harm caused to public health due to negligence, is subject to legal liability as defined by law. Thus, the social orientation of pharmaceutical practice includes participation in emergency healthcare systems. This was particularly evident during the COVID-19 pandemic, when pharmacists, alongside medical professionals, played a crucial role in supplying medicines and providing essential pharmaceutical care.

Article 41 of the same law (“The Right to Engage in Medical and Pharmaceutical Activities”) defines the status and educational requirements for such activities. Only individuals who have obtained a diploma from a higher or specialized secondary medical or pharmaceutical educational institution in Uzbekistan have the right to engage in pharmaceutical practice.

Individuals with medical or pharmaceutical degrees obtained abroad may be permitted to practice in Uzbekistan in accordance with procedures established by the Cabinet of Ministers.

Medical and pharmaceutical professionals who have not worked in their field for more than three years are permitted to resume their activities only after completing retraining programs at designated institutions or after passing certification conducted by the Ministry of Health of the Republic of Uzbekistan.

Additionally, individuals without a higher education in medicine or pharmacy may be allowed to work in positions requiring specialized secondary medical education, as regulated by the Ministry of Health.

Students of higher and secondary medical educational institutions may also participate in providing medical assistance under the supervision of licensed professionals, in accordance with their training programs and regulations established by the Ministry of Health.

The law further stipulates that individuals illegally engaged in medical or pharmaceutical practice are subject to legal liability.

It also outlines responsibilities concerning the confidentiality of medical information. For instance, individuals who have legally obtained access to confidential medical information are held equally accountable for its disclosure as medical and pharmaceutical professionals.

According to Article 46, if unqualified performance of duties by a medical or pharmaceutical professional causes harm to life or health, compensation must be provided in accordance with the law. However, compensation does not exempt such individuals from disciplinary, administrative, or criminal liability as prescribed by legislation [3].

Classification of Pharmaceutical Positions

One of the key aspects of pharmaceutical regulation is the recognition of pharmaceutical job titles within the national system for classifying occupations. In order to modernize the regulatory framework for job titles and occupational structures under market conditions and current management principles—and to align these with the training of pharmaceutical specialists at higher and secondary educational institutions—the Director General of the Agency for Technical Regulation under the Ministry of Investments, Industry and Trade of the Republic of Uzbekistan issued Order No. 05-1507 on February 13, 2023.

This document introduced amendments to state standard O‘Z DST 3513:2021, which governs the Classifier of Official Positions and Job Titles (KODSPR-2020) [13].

In total, the classifier includes 12,151 official job titles and corresponding qualification requirements. A detailed analysis was conducted to assess the eligibility of various pharmaceutical specialists for work across different branches of pharmaceutical activity. Out of 49 job titles authorized to operate in the pharmaceutical sector, the following are approved for employment in pharmacies and their branches:

Approved Pharmaceutical Job Titles and Legal Requirements for Retail Pharmaceutical Activity

The following job titles are officially recognized for work in pharmacies and their branches under the national classification system:

Head of a healthcare organization engaged in pharmaceutical activity
Pharmacist (Provisor)
Analytical Pharmacist
Intern Pharmacist
Information Pharmacist
Prescription Pharmacist
Pharmaceutical Technologist
Pharmacy Technician
Analytical Pharmacy Technician
Marketing Pharmacy Technician
Technological Pharmacy Technician
Cosmeceutical Pharmacy Technologist
Pharmacy Assistant for Storage, Supply, and Distribution of Medicines
Pharmaceutical Care Organizer (Consultant-Pharmacy Assistant)
Assistant Pharmacist
Prescription Pharmacy Technician
Phytobar Operator
Laboratory Pharmacy Technician

The Law of the Republic of Uzbekistan "On Medicinal Products and Pharmaceutical Activity", in its revised version dated January 4, 2016, regulates the retail sale of medicinal products and medical devices (excluding ophthalmological devices) in Article 20. According to the law, such retail sales may only be carried out by pharmacies and their branches.

It is strictly established that the retail sale of medicinal products must be based on prescriptions issued using forms approved by the Ministry of Health of the Republic of Uzbekistan, or sold over-the-counter only in accordance with approved medical usage instructions.

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This law, along with other relevant legislation, prohibits the procurement, retail sale, and use of substandard, falsified, and unregistered medicines and medical devices, as well as counterfeit versions of registered products.

Additionally, the law outlines the legal status and organizational forms of pharmacies, which may be created as legal entities or as structural subdivisions of legal entities holding a valid license for retail pharmaceutical activity and/or drug compounding. Pharmacy branches and pharmacies affiliated with healthcare institutions also fall under this definition [12].

The head of a pharmacy must hold a higher medical or pharmaceutical education, as required by the Law of the Republic of Uzbekistan No. ZRU-721 dated October 12, 2021. Meanwhile, the head of a pharmacy branch must have a pharmaceutical education.

To simplify retail pharmaceutical operations, Law No. ZRU-721 also introduced amendments concerning ophthalmological medical devices (optical products). Retail sales of such items may now be carried out through dedicated optical outlets, either as legal entities or as structural units of legal entities, with a notification to the relevant authority upon the start of such activity.

Branches of optical outlets and optical facilities within healthcare institutions are also included in this category. However, entities that already possess a license for the retail sale of medicinal products and medical devices do not need to submit separate notifications to engage in the retail sale of ophthalmological products.

Heads of optical outlets and their branches must hold higher or specialized secondary pharmaceutical education.

Retail activities involving ophthalmological medical devices must comply with established rules for manufacturing, dispensing, selling, and storing such products to ensure their quality and must follow all applicable sanitary, safety, and hygiene standards.

According to Appendix No. 2 of the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 185, dated April 6, 2017, adopted to enforce Law No. ZRU-399 of January 4, 2016, pharmacies and their branches must strictly follow the state standards, sanitary and hygienic regulations, labor protection rules, safety and fire protection regulations, and other technical norms applicable to pharmaceutical activity.

Continuous Professional Development and Educational Reforms

Given the increasing demand in Uzbekistan's healthcare system for highly qualified pharmaceutical professionals, and their growing social and professional responsibilities, the continuous improvement of pharmaceutical knowledge and skills has become critically important.

Continuous professional development is especially vital in the context of current reforms in state regulation of the pharmaceutical sector, rising quality standards for medicines and medical devices, and higher expectations for pharmaceutical service delivery and professional accountability.

The Presidential Decree of the Republic of Uzbekistan No. PP-4310 dated May 6, 2019, titled "On Measures for the Further Development of Medical and Pharmaceutical Education and Science", outlines key objectives for reforming educational tracks in this field.

A comprehensive national program is underway to modernize medical and pharmaceutical education, integrate international educational standards, and advance scientific research focused on public health priorities, while building an effective professional training system.

According to the Action Strategy for Five Priority Areas of Development of the Republic of Uzbekistan (2017–2021) and the Concept for the Development of the Healthcare System (2019–2025), the following priorities have been identified:

Introduction of a credit-modular system for medical and pharmaceutical education and continuing professional development;

Decentralization of retraining and advanced training systems for healthcare professionals, ensuring universal access to continuous education;

Establishment of monitoring and personalized tracking of educational progress during retraining and continuing education;

Advancement of medical and pharmaceutical science and innovation, aligning with global standards and promoting international scientific integration;

Development of teaching clinics, educational infrastructure, and production facilities at medical and pharmaceutical institutions to support a seamless integration of education, research, and practical healthcare.

List of Medical and Pharmaceutical Higher Education Programs, Duration of Study, and Qualifications Awarded

№	Field of Study	Duration of Study	Qualification Awarded
1	General Medicine	6 years	Family Physician
2	Professional Education (General Medicine)	6 years	Family Physician-Educator
3	Pediatrics	6 years	General Pediatrician
4	Military Medicine (General Medicine)	6 years	Military Doctor
5	Medical and Biological Sciences	4 years	Specialist in Fundamental Medicine
6	Preventive Medicine	5 years	Hygienist-Epidemiologist
7	Dentistry	5 years	General Dentist
8	Advanced Nursing (based on secondary specialized medical education)	3 years	Specialist in Advanced Nursing
9	Clinical Psychology	5.5 years	Clinical Psychologist – Social Worker
10	Pharmacy	5 years	Pharmacist
11	Professional Education (Pharmacy)	5 years	Pharmacist-Educator
12	Industrial Pharmacy (by specialization)	4 years	Pharmaceutical Technologist
13	Pharmaceutical Biotechnology	4 years	Pharmaceutical Biotechnologist
14	Biomedical Engineering	4 years	Biomedical Engineer
15	Standardization, Certification, and Quality Management of Medicinal Products	4 years	Analytical Pharmacist

This regulatory document introduces a system of continuous professional education for medical and pharmaceutical personnel, based on a credit-modular learning system, which includes annual professional development through problem-oriented modular educational programs conducted via seminars, conferences, webinars, master classes, simulation trainings, and other training courses aligned with international standards.

The approved credit hours required for continuous professional pharmaceutical education are as follows:

Pharmaceutical professionals with higher education: 288 hours

Pharmaceutical professionals with secondary specialized education: 180 hours

Credit Requirements for Continuous Professional Education

№	Category of Personnel	Credits*	
		Total	Minimum Annual Credits
1.	Medical and pharmaceutical personnel with higher education	288**	36
2.	Medical and pharmaceutical personnel with secondary specialized education	180***	36

It should be noted separately that credits are accumulated over a period of five years.

** Of the 288 credits, 144 are obtained at relevant medical educational institutions and organizations through training funded by the State Budget of the Republic of Uzbekistan, while the remaining credits are obtained on a paid basis.

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

The rights and obligations of pharmaceutical workers are provided for by a number of legislative regulatory acts.

The Labor Code of the Republic of Uzbekistan, the new edition of which came into force on April 30, 2023, defines and regulates individual labor relations and the related public relations based on ensuring a balance and reconciliation of the interests of employees, employers, and the state. These provisions also apply to pharmaceutical workers.

The rights provided by the Labor Code of the Republic of Uzbekistan include, among others:

the freedom of employees and employers to conclude an employment contract;

the right to determine the contractual (basic and additional) terms of the employment contract by mutual agreement of the parties;

the possibility to amend the employment contract by mutual agreement between the employee and employer;

the possibility to terminate any employment contract at any time by mutual agreement of the parties;

the right of the employee to terminate the employment contract on their own initiative in the manner established by this Code;

a workplace that complies with state regulatory occupational safety requirements;

timely and full payment of wages in accordance with qualifications, job complexity, and the quantity and quality of work performed.

Separate regulatory acts define the rights and duties of pharmaceutical workers engaged in activities in pharmacies and their branches. For example, the regulations on the retail sale of medicinal products and medical devices establish the following requirements for them.

In particular, when dispensing medicinal products and medical devices, a pharmacy employee with pharmaceutical education must inform the customer about the analogues of medicinal products and medical devices, the method of use in accordance with the instructions for use of the medicinal product and medical device, specifically the regimen of administration, single and daily doses, method of administration, storage conditions, and expiration date.

The pharmacy employee must also draw the customer's attention to the necessity of carefully reading the instructions for use of the medicinal product and medical device.

When communicating with clients, the pharmacy employee must observe ethical rules, demonstrate professionalism, and be knowledgeable.

Pharmaceutical specialists working in pharmacies are obliged to provide consumers with reliable information about the medicinal products and medical devices sold. Upon the customer's request, the pharmacy employee must provide the relevant documents confirming the established price and proper quality of the specified drugs and devices.

When retailing medicinal products and medical devices through e-commerce, pharmacies may, when necessary, deliver the purchased medicinal products and medical devices to the population. At the same time, the delivery of medicinal products and medical devices must be accompanied by a pharmacy employee who is a specialist with pharmaceutical education.

To ensure the supply of safe, high-quality, and effective drugs, the legislative acts of the Republic of Uzbekistan regulate the legal norms of responsibility for violations of approved rules and requirements in pharmacy.

According to the Labor Code of the Republic of Uzbekistan, disciplinary responsibility of the employee is provided.

Disciplinary responsibility is a legal responsibility that arises from the employee’s commission of a disciplinary offense and is expressed in the application of disciplinary penalties to this employee.

Types of disciplinary responsibility include general and special disciplinary responsibility.

General disciplinary responsibility is the responsibility regulated by this Code and the internal labor regulations, consisting of the application of one of the disciplinary penalties provided by the Code to the employee, and applies to all employees except those for whom special disciplinary responsibility is established.

Special disciplinary responsibility is a form of responsibility established exclusively for certain categories of employees in accordance with current legislation, as well as charters and disciplinary regulations. It involves the application of specific disciplinary penalties to these employees, as provided by the relevant regulatory acts governing labor and professional activities in the specific field [2].

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 norms.

In particular, the production, manufacture, acquisition, storage, transportation for sale, or sale of substandard or counterfeit medicinal products or medical devices, as well as the retail sale of medicinal products or medical devices outside pharmacies and their branches, entails a fine ranging from fifty to one hundred basic calculation units, along with confiscation of instruments and items used to commit these offenses.

Violation of the procedure for retail sale by prescription of medicinal products that do not contain potent substances, narcotic drugs, their analogues, or psychotropic substances, entails a fine ranging from five to ten basic calculation units.

Violation of the procedure for retail sale by prescription of medicinal products containing potent substances entails a fine ranging from fifty to one hundred basic calculation units.

Article 1863 of the Criminal Code of the Republic of Uzbekistan regulates the measures of responsibility for the following activities: production, manufacture, acquisition, storage, transportation for sale, or sale of substandard or counterfeit medicinal products or medical devices; retail sale of medicinal products or medical devices outside pharmacies and their branches; and violation of the retail sale procedure by prescription of medicinal products containing potent substances.

In particular, the production, manufacture, acquisition, storage, transportation for sale, or sale of substandard or counterfeit medicinal products or medical devices, as well as the retail sale of

medicinal products or medical devices outside pharmacies and their branches, committed after administrative penalties for similar actions, is punishable by fines established by the legislation of the Republic of Uzbekistan.

The introduction of strict measures of responsibility in the country will contribute to reducing the types of violations related to the circulation of medicinal products and medical devices [2].

Issues of quality in drug supply, especially in retail organizations, are relevant in the republic.

By the Decree of the President of the Republic of Uzbekistan dated January 21, 2022, No. UP-55 "On Additional Measures for the Accelerated Development of the Pharmaceutical Industry of the Republic in 2022-2026," requirements were established for the systematic implementation of Good Practices (GxP) for pharmaceutical organizations, for the first time including pharmacies, namely:

From April 1, 2022, new manufacturing enterprises, wholesale and retail organizations in the pharmaceutical industry must be established in accordance with the requirements of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), and Good Pharmacy Practice (GPP);

The deadlines for mandatory certification of pharmaceutical organizations and the healthcare system of the republic to comply with Good Practices (GxP) requirements have been extended until January 1, 2024.

Results and Discussion:

It should be noted that in recent years, comprehensive measures have been implemented in the republic 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 state registration of pharmaceutical products, and streamlining pharmacy operations [5].

In order to further improve the provision of the population with medicines, medical devices, and medical equipment guaranteed for quality, safety, and efficacy, as well as to improve the processes of regulating pharmaceutical product circulation, the 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.

In this regard, the Ministry of Health of the Republic of Uzbekistan has been designated as the state authority responsible for ensuring the population’s access to quality and safe pharmaceutical products and for regulating the circulation of medicines and medical devices.

It was also established that from July 1, 2024, organizations engaged in the manufacture, wholesale, and retail sale of medicines and medical devices are recognized as organizations responsible for ensuring the population’s access to medicines and medical devices guaranteed for quality, safety, and efficacy, and special rules for state control are established regarding them.

At the same time, from July 1, a procedure for supervision of compliance with the requirements of issued licenses was introduced in organizations engaged in the manufacture, wholesale, and retail sale of medicines and medical devices by notifying the authorized body (except for control activities conducted based on complaints from individuals and legal entities) no more than once a year [6].

Furthermore, this Decree of the President of the Republic of Uzbekistan amended the Decree of the President dated April 10, 2019, No. UP-5707 "On Further Measures for the Accelerated Development of the Pharmaceutical Industry of the Republic in 2019-2021," providing the following:

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

By January 1, 2025 — pharmacy chains engaged in retail sales of pharmaceutical products;

By January 1, 2026 — other pharmacies.

For the first time in the Republic of Uzbekistan, the national standard "Good Pharmacy Practice. Basic Provisions" was approved in 2016. However, for a long time, it had a recommendatory nature and was not implemented by pharmacies. The Good Pharmacy Practice (GPP) standard was developed to ensure proper quality of pharmaceutical services provided by pharmaceutical workers to the population of the Republic of Uzbekistan, setting requirements for good pharmacy practice and the organization of quality management systems.

International experience was studied for the development of the national standard, including regulatory documents from the Russian Federation, the Republic of Belarus, the Republic of Kazakhstan, and the World Health Organization.

The standard applies to organizations engaged in retail sales of medicines, state bodies overseeing pharmaceutical activities of legal and physical entities in the field of circulation of medicines and medical devices [7].

The standard aims to ensure the population is provided with quality and safe medicines and medical devices, provide reliable information about medicines, promote a healthy lifestyle and disease prevention, ensure rational use of prescription medicines, influence prescribing and use of medicines, provide information about adverse drug reactions, and assist with self-medication; to ensure communication between doctors, patients, and pharmaceutical workers, which allows optimizing the use of medicines and medical devices and assessing treatment outcomes.

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

Currently, the updated national standard UzMSt 140:2024 "Good Pharmacy Practice (GPP)" was approved by Order No. 10/MSt dated April 26, 2024, of the State Institution "Scientific Research Institute of Standardization, Certification, and Technical Regulation" (Uzbekistan Standards Institute) under the Agency for Technical Regulation of Uzbekistan, Ministry of Investments and Foreign Trade of the Republic of Uzbekistan.

The main goals and objectives of the standard are:

To establish a unified order of requirements for the manufacture of medicines in pharmacies, quality control, storage, expiration date control, as well as for retail sale (distribution) of medicines and medical devices in pharmacies;

To ensure the quality and availability of medicines provided by the legislation of the Republic of Uzbekistan, as well as provide information about adverse effects identified in relation to medicines.

The national standard separately presents the requirements for the head pharmacist (pharmacy manager), which include the following:

a) To communicate the requirements of the standard, as well as the rights and responsibilities established by job descriptions, to subordinate pharmaceutical staff;

b) To satisfy consumer demand for pharmacy assortment products, excluding from the procurement system substandard, falsified, and unregistered in the Republic of Uzbekistan, as well as illegal specimens of medicines, medical devices, and dietary supplements that have not passed state registration in the Republic of Uzbekistan, thereby preventing the risk of their circulation;

c) To define and organize strict compliance with the policies and objectives aimed at effective interaction between medical workers, pharmaceutical workers, and consumers;

d) To take measures to optimize activities, increase turnover, and improve the knowledge and qualifications of pharmaceutical workers;

e) To continuously analyze the documentation of the quality management system and the results of internal audits and external inspections in order to continuously ensure the quality of pharmaceutical services;

f) To develop measures aimed at supporting and stimulating employee activities;

g) To approve standard operating procedures;

h) To organize in customer service areas of the pharmacy announcement corners in written form, conduct regular informational meetings, and establish information exchange related to the functioning of the quality system;

i) To establish and implement information systems in practice that allow operations related to product movement and the identification of falsified, unregistered in the Republic of Uzbekistan, and substandard medicines;

j) To equip the pharmacy with the necessary equipment that fully ensures the proper handling of pharmaceutical assortment products, including storage, accounting, sale, and dispensing.

Separate points define the lists of information that must be communicated to pharmaceutical personnel:

k) About newly adopted acts of legislation on pharmaceutical activities and documents in the field of technical regulation, as well as changes made to them;

l) About the results of internal audits and inspections by control authorities;

m) About necessary preventive and corrective actions to eliminate (prevent) violations of licensing requirements;

n) To communicate information about the results of consideration of consumer complaints and suggestions.

It is very important for the implementation of the national standard and the quality system in pharmacies of the republic that a provision regulating the appointment of a person responsible for the quality system by the head pharmacist was introduced. This person must have pharmaceutical education, appropriate qualifications, experience, and knowledge, must personally perform their duties, and maintain constant communication with the head pharmacist. The person responsible for the quality system may delegate part of their duties to other employees, but the responsibility remains with them.

The national standard also defines the presence of a job description for the person responsible for the quality system, clearly specifying the duties (powers, resources, and appropriate responsibility necessary for decision-making and task performance).

The functions of the person responsible for the quality system are defined as ensuring:

a) Management of certain activities;

b) Implementation and maintenance of the quality management system;

c) Implementation of training programs for pharmaceutical staff involved in all pharmacy processes;

d) Timely organization and coordination of the withdrawal of medicines and medical devices from circulation;

e) Effective handling of complaints;

f) Selection and evaluation of suppliers;

g) Outsourcing (delegation to external sources) of necessary activities;

h) Self-monitoring according to an approved program within established deadlines and taking necessary measures to eliminate identified shortcomings;

i) Maintenance of necessary records on the performance of pharmaceutical workers' duties;

j) Decision-making regarding returned, recalled, refused to be received, recognized as having adverse effects, substandard, or falsified medicines and medical devices.

To implement the national standard, teamwork of competent employees is necessary. Therefore, the main tasks of the pharmaceutical worker are shown in the draft, which include:

a) Evaluation of suppliers of quality medicines, medical devices, and other goods included in the pharmacy assortment, as well as their receipt, storage, sale, and transfer within the pharmacy;

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

c) Providing information about the rational use of medicines;

d) Prescription preparation and dispensing of medicines;

e) Processing payment documents;

f) Adherence to pharmaceutical ethics and deontology.

To perform the above functions, the national standard provides norms. In particular, to issue qualified recommendations on the use of medicines, the pharmaceutical worker must possess relevant knowledge, skills, and sufficient experience, as well as systematically improve their knowledge of new medicines in the fields of pharmacotherapy and communication psychology.

Special requirements in the national standard are set for the pharmaceutical worker responsible for quality control of medicines and medical devices manufactured in pharmacies, who must have professional knowledge and skills in the field of quality control [14].

Today, based on the above-mentioned regulatory documents, Good Pharmacy Practice (GxP) requirements have been introduced in pharmacies operating in our country, and 3,300 certificates of compliance with GPP requirements have been issued to pharmaceutical enterprises.

Assessment of the Quality System Status of Pharmacies in the Republic of Uzbekistan

No.	Region	Number of Pharmacies with License	Number of Pharmacies Certified According to GPP Standard	Number of Pharmacies Requiring Optimization of GPP Process	Number of Pharmacies Not Compliant with GPP Standard
1	Republic of Karakalpakstan	681	184	325	141
2	Tashkent City	1,839	895	1,169	274
3	Tashkent Region	798	223	419	196
4	Andijan Region	1,079	234	562	328
5	Namangan Region	906	189	434	245
6	Fergana Region	1,230	477	938	461
7	Syrdarya Region	388	57	182	125
8	Jizzakh Region	480	76	156	80
9	Samarkand Region	1,435	232	629	397
10	Kashkadarya Region	768	318	468	150
11	Surkhandarya Region	1,045	151	494	343
12	Navoi Region	554	100	230	130
13	Bukhara Region	950	187	381	194
14	Khorezm Region	936	306	459	153
	Total	**13,089**	**3,629**	**6,846**	**3,217**

Regular training cycles are provided for by the national standard, and the effectiveness of periodic continuing education sessions for all pharmaceutical workers must be periodically assessed and documented in accordance with established procedures.

Conclusion

As a result of the conducted analysis of the legal foundations governing the activities of pharmaceutical workers in pharmacies and their branches in the Republic of Uzbekistan, it was found that the regulation of pharmaceutical activity in Uzbekistan is based on clear legislative norms, including mandatory licensing and quality standards.

Quality and safety assurance lies in compliance with legislative acts that guarantee the population access to quality, effective, and safe medicines. Special attention is given to the educational policy, which provides for systematic professional development of specialists based on a credit-modular training system. This supports workforce development and ensures the preparation of competent pharmaceutical workers ready to operate in modern conditions.

Furthermore, the tightening of accountability measures for violations in the pharmaceutical sector, including the circulation of substandard and counterfeit medicines, helps to minimize health risks to the population. Monitoring compliance with quality standards in pharmacies also contributes to increasing trust in the pharmaceutical industry.

The prospects for the development of pharmaceutical activity in Uzbekistan are linked to the mandatory certification of pharmacy organizations according to national standards by 2026, which will strengthen the industry’s position and create conditions for further improvement of service quality. The implementation of information technologies for monitoring medicines and managing quality will additionally enhance the efficiency of pharmacies and ensure public safety.

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