

**QUALITY CONTROL OF MEDICINAL PRODUCTS AS A LEGAL INSTITUTION:  
OBJECTIVES, METHODS, AND ISSUES OF NORMATIVE REGULATION**

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**Abstract.** This article is devoted to the analysis of quality control of medicinal products as a key institution of legal regulation in the pharmaceutical sector. The objectives, tasks, and methods of control are examined, as well as issues related to the normative consolidation of this mechanism in national and international contexts. Particular attention is paid to the legal nature of quality control, its significance for protecting public health, ensuring the safety of the pharmaceutical market, and maintaining trust in the healthcare system. Based on an analysis of the legislative acts of the Republic of Uzbekistan, the Russian Federation, international WHO documents, and scientific literature, gaps in the legislation are identified, and possible ways to address them are proposed.

**Keywords:** quality of medicinal products, state control, good practices (GxP), registration, pharmacovigilance, legal liability, pharmaceutical market.

**DORI VOSITALARINI SIFATINI NAZORAT QILISH HUQUQIY INSTITUT  
SIFATIDA: MAQSADLARI, USULLARI VA NORMATIV  
MUSTAHKAMLANISHDAGI MUAMMOLAR**

**Annotatsiya.** Ushbu maqola dorivor vositalar sifatini nazorat qilishni farmatsevtik faoliyatni huquqiy tartibga solishning asosiy instituti sifatida tahlil qilishga bag'ishlangan. Maqolada sifat nazorati maqsadlari, vazifalari va usullari, shuningdek, ushbu mexanizmning milliy va xalqaro kontekstdagi normativ mustahkamlanishidagi muammolar ko'rib chiqilgan. Maxsus e'tibor sifat nazoratining huquqiy tabiati, aholining sog'lig'ini muhofaza qilishdagi ahamiyati, farmatsevtik bozor xavfsizligini ta'minlash va sog'liqni saqlash tizimiga bo'lgan ishonchga qaratilgan. O'zbekiston Respublikasi va Rossiya Federatsiyasi qonunchiligi, shuningdek, JSST xalqaro hujjatlari hamda ilmiy adabiyotlarni tahlil qilish orqali qonunchilikdagi bo'shliqlar aniqlanib, ularni bartaraf etish yo'llari taklif etilgan.

**Kalit so'zlar:** dorivor vositalar sifati, davlat nazorati, to'g'ri amaliyotlar (GxP), ro'yxatga olish, farmakonazorat, huquqiy javobgarlik, farmatsevtik bozor.

**КОНТРОЛЬ КАЧЕСТВА ЛЕКАРСТВЕННЫХ СРЕДСТВ КАК ПРАВОВОЙ  
ИНСТИТУТ: ЦЕЛИ, МЕТОДЫ И ПРОБЛЕМЫ НОРМАТИВНОГО  
ЗАКРЕПЛЕНИЯ**

**Аннотация.** Статья посвящена анализу контроля качества лекарственных средств как ключевого института правового регулирования фармацевтической деятельности. Рассматриваются цели, задачи и методы контроля, а также проблемы нормативного закрепления данного механизма в национальном и международном контексте. Особое внимание уделяется юридической природе контроля качества, его значению для охраны здоровья населения, обеспечения безопасности фармацевтического рынка и доверия к системе здравоохранения. На основе анализа нормативных актов Республики Узбекистан, Российской Федерации, международных документов ВОЗ и научной литературы выявляются пробелы в законодательстве и предлагаются пути их преодоления.

**Ключевые слова:** качество лекарственных средств, государственный контроль, надлежащие практики (GxP), регистрация, фармаконадзор, правовая ответственность, фармацевтический рынок.

### Introduction

In the context of a market economy, product quality acquires particular significance and becomes one of the key factors influencing socio-economic development. The level of quality of goods and services directly affects the standard of living of the population, the competitiveness of the national economy, and the provision of social, economic, and environmental security. This issue is especially important in the field of circulation of medicinal products, since the quality of pharmaceutical products is directly related to the protection of human life and health.

The concept of the quality of medicinal products has a complex and multidimensional nature, as it is formed at the intersection of medical, pharmaceutical, and legal approaches. Within the framework of modern legal science, the quality of a medicinal product is regarded as a legally defined characteristic reflecting the degree of compliance of a medicinal product with established regulatory requirements. From a legal perspective, this category is expressed through a system of standards and mandatory norms that ensure the stability of the properties of a medicinal product, the reproducibility of its characteristics, and its compliance with pharmacopoeial and other regulatory requirements.

The development of ideas concerning the necessity of controlling the quality of medicinal products has a long historical evolution. Certain elements of quality regulation can be traced back to ancient medical traditions. In particular, the works of **Hippocrates** and **Galen** contain references to the importance of proper preparation of medicinal substances and warnings about the potential dangers of improperly prepared or poor-quality remedies. However, a systematic framework for regulating the quality of medicines emerged much later, with the development of pharmacopoeias and the establishment of state institutions responsible for medical supervision and pharmaceutical control.

Significant scientific attention to the issue of medicinal product quality began to develop actively in the twentieth century. This growing interest was largely stimulated by several tragic events in the history of the pharmaceutical industry. One of the most notable examples is the **Thalidomide tragedy** of the early 1960s, when the use of an insufficiently tested drug resulted in numerous cases of severe congenital malformations in newborns<sup>1</sup>. This event demonstrated the necessity of establishing stricter mechanisms for scientific evaluation and regulatory oversight before medicinal products are allowed to be used in medical practice.

As a result of these developments, ensuring the quality of medicinal products has become a priority area of public health policy in many countries. An important role in shaping international approaches to the regulation of medicinal product quality has been played by the World Health Organization. Since the late 1960s, this organization has developed international guidelines aimed at ensuring the quality, safety, and efficacy of medicinal products<sup>2</sup>. According to WHO documents, the quality of a medicinal product is determined by a set of characteristics demonstrating its compliance with established regulatory requirements, including parameters related to composition, dosage form, purity, stability, and bioavailability<sup>3</sup>.

<sup>1</sup> The history of the Thalidomide tragedy. URL: <https://www.thalidomide-tragedy.com>.

<sup>2</sup> History of GMP. URL: [https://gmpplastic.com/blogs/useful-articles-on-lab-supplies-faq-section/history-of-cgmp?srltid=AfmBOoqT-7e5sucrfI52HK7C--U\\_BmA0trgyQvsfrma9XeUMnUW6OVI&utm](https://gmpplastic.com/blogs/useful-articles-on-lab-supplies-faq-section/history-of-cgmp?srltid=AfmBOoqT-7e5sucrfI52HK7C--U_BmA0trgyQvsfrma9XeUMnUW6OVI&utm).

<sup>3</sup> Model quality assurance system for procurement agencies // World Health Organization. [WHO] 2014. URL: [https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs986-annex3-who-model-quality-assurance-system-for-procurement-agencies.pdf?sfvrsn=4baca576\\_4&download=true](https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs986-annex3-who-model-quality-assurance-system-for-procurement-agencies.pdf?sfvrsn=4baca576_4&download=true).

### Main part

With the development of global pharmaceutical regulation, the concept of the quality of medicinal products has become increasingly formalized and legally structured. A significant role in this process has been played by the activities of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, within which the concept of Quality by Design (QbD) was introduced. This concept implies ensuring product quality through scientifically based design of both the medicinal product and its manufacturing process. According to the provisions of ICH Q8 (R2) Pharmaceutical Development, the quality of a medicinal product should be built into the product already at the stage of pharmaceutical development. The set of characteristics that determine the ability of a medicinal product to perform its intended therapeutic functions is achieved through controlled design of the manufacturing process and continuous monitoring of critical quality attributes<sup>4</sup>.

In the scientific literature, it is emphasized that the concept of the quality of medicinal products goes beyond purely technological or pharmaceutical considerations and becomes an object of comprehensive legal regulation. As noted by **C. Valentina**, quality requirements for medicinal products apply not only at the stage of state registration but also throughout the entire life cycle of the product—from preclinical research to post-marketing monitoring. Particular attention is given to the fact that no medicinal product can be considered absolutely safe; therefore, the control of its quality and safety must be continuous and accompany the product throughout all stages of its development and use. In this regard, the participation of the medical community in pharmacovigilance processes becomes especially important<sup>5</sup>. The effectiveness of these mechanisms is further enhanced by the introduction of digital technologies, including systems for monitoring and traceability of medicinal products, which make it possible to track each package of a medicinal product throughout the supply chain up to the final consumer.

From the perspective of pharmaceutical science, the quality of a medicinal product is defined as a set of characteristics that determine its ability to meet the therapeutic needs of patients. This approach is reflected in the works of **I. Mazur**, **L. Kucherenko**, **L. Cherkovskaya**, and **O. Kryvosh**, who describe the quality of medicinal products as an integrated characteristic that includes indicators of efficacy, safety, and compliance with established regulatory requirements<sup>6</sup>. One of the key mechanisms ensuring these characteristics is compliance with the standards of Good Manufacturing Practice, which establish strict requirements for the organization of the manufacturing process, quality control systems, and documentation procedures. Modern approaches to ensuring the quality of medicinal products also take into account a broader range of factors, including the environmental impact of production processes, occupational health and safety, and the economic efficiency of pharmaceutical manufacturing.

In legal doctrine, the quality of medicinal products is regarded as one of the fundamental conditions for their lawful circulation in the pharmaceutical market. This position is reflected in the legislation of Russia, particularly in Federal Law No. 61 On Circulation of Medicines. According to Article 4, paragraph 22 of this law, the quality of a medicinal product is defined as

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<sup>4</sup> ICH harmonised tripartite guideline. Pharmaceutical development Q8 (R2) // International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use. – 4 Version, 2009. – P. 13.

<sup>5</sup> Валентина К. От разработки до оборота: регуляторные особенности жизненного цикла ЛП. Режим доступа: <https://gxnews.net/2024/05/ot-razrabotki-do-oborota-regulyatornye-osobennosti-zhiznennogo-czikla-lp/?utm>.

<sup>6</sup> Мазур И.А. Стандартизация лекарственных средств: учебно-методическое пособие // И.А. Мазур, Л.И. Кучеренко, Л.Г. Черковская, О.В. Кривош. – Москва.: под редак. профессора И.А.Мазура, 2013. – С. 10.



its compliance with the requirements of a pharmacopoeial monograph or, in the absence of such a monograph, with the regulatory documentation submitted during the state registration procedure<sup>7</sup>. Thus, quality is formally established as a legally binding criterion for the authorization of a medicinal product for circulation.

The provisions of the law establish a direct legal relationship between the quality of a medicinal product and the permissibility of its presence in the legal pharmaceutical market. Violations of quality requirements may result in the application of legal sanctions, including administrative and criminal liability. Therefore, within the framework of Russian legal doctrine, the quality of a medicinal product is considered an essential prerequisite for its lawful circulation, and the absence of such quality makes the presence of the medicinal product on the pharmaceutical market legally impermissible.

At the same time, an analysis of the current legislation of Uzbekistan demonstrates that the national legal system does not contain a specific provision establishing a formal legal definition of the term “quality” in relation to medicinal products. Although the term referring to substandard medicines appears in several provisions of the Law of the Republic of Uzbekistan On Medicines and Pharmaceutical Activity, particularly in Articles 3, 19, and 23, the legislation does not provide a comprehensive or explicit definition of the concept of the quality of medicinal products. Such a situation indicates an insufficient level of normative specification of this key regulatory criterion within the national legal framework. The absence of a clearly articulated definition may create certain difficulties in law enforcement practice, which in turn highlights the need for further legislative clarification and development in this area.

Scientific and technological progress has also significantly influenced the evolution of the concept of the quality of medicinal products. At the turn of the 1990s and 2000s, international pharmaceutical practice underwent a conceptual shift from a traditional approach focused primarily on the control of finished products toward a broader model emphasizing process-based quality assurance. This transformation is reflected in the growing importance of regulatory standards known as Good Practices, including Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice, Good Distribution Practice, Good Storage Practice, and Good Pharmacovigilance Practice. Together, these standards form the comprehensive framework commonly referred to as the GxP system, which covers the principal stages of the life cycle of a medicinal product. From a legal perspective, compliance with these quality requirements represents a mandatory regulatory obligation, the violation of which may entail administrative, civil, or criminal liability.

Contemporary doctrinal approaches to the quality of pharmaceutical products are characterized by a high degree of internationalization. Researchers emphasize that the quality of medicinal products cannot be examined solely within the boundaries of a single national jurisdiction, since the cross-border nature of pharmaceutical circulation requires the application of harmonized regulatory standards. This issue is particularly relevant in the context of the increasing international trade in pharmaceutical products, the expansion of foreign economic activities of pharmaceutical companies, and the growing practice of mutual recognition of marketing authorizations between states. Such cooperation mechanisms can be observed, for example, within the framework of the Eurasian Economic Union, as well as through international initiatives of the World Health Organization aimed at harmonizing requirements related to the quality, safety, and efficacy of medicinal products.

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<sup>7</sup> Федеральный закон Российской Федерации № ФЗ-61 «Об обращении лекарственных средств» от 12.04.2010 г.

From the perspective of the theory of state and law, the quality of medicinal products should be considered not only as a regulatory parameter but also as an important legal guarantee for the protection of human health. This guarantee is enshrined in constitutional provisions, health legislation, sanitary regulations, and international agreements. In the context of the ongoing digitalization of healthcare systems, the concept of quality is further expanding through the implementation of electronic platforms designed to track the origin, authenticity, and movement of medicinal products throughout the supply chain. Such digital monitoring mechanisms enhance transparency within the pharmaceutical market and strengthen the effectiveness of regulatory oversight.

Thus, the concept of the quality of medicinal products has undergone a substantial transformation. Initially perceived primarily as an indicator of the suitability of a medicinal product for use, it has gradually evolved into a complex and multi-layered system of legal, scientific, and technological criteria. The development of this concept has been shaped both by the internal needs of national legal systems and by the challenges arising from the globalization of the pharmaceutical market.

The right to health protection is recognized as a fundamental social right of every individual and is enshrined in various national and international legal instruments. In particular, the Constitution of the Republic of Uzbekistan affirms that every person has the right to health protection. Within this framework, the state bears the obligation to ensure not only the accessibility of medical care but also its adequate quality, including the provision of safe, effective, and reliable medicinal products. One of the primary mechanisms for fulfilling this duty is the legal institution of quality control for medicines.

In the scholarly literature, quality control within pharmaceutical management systems is characterized not merely as an inspection activity but as an integrated mechanism based on a set of criteria and indicators aimed at ensuring the safety and efficacy of medicinal products. According to **A. Lindenbraten** and colleagues, control enables not only the evaluation of the compliance of managerial and clinical procedures with established normative requirements, but also the identification of systemic deviations and the formulation of corrective measures based on objective monitoring and analytical data<sup>8</sup>. Such an approach integrates control into both internal and external quality management systems and provides an organizational and legal foundation for enhancing the effectiveness of pharmaceutical services within modern healthcare models.

From a legal standpoint, control is understood not only as a component of the management cycle but also as an independent legal category with multiple functional dimensions. Legal doctrine emphasizes that control, as a managerial and legal function, is primarily characterized by the capacity to objectively evaluate the performance of the supervised entity, both in terms of compliance with statutory requirements and the appropriateness and efficiency of its actions.

Moreover, control entails the legal authority of the supervising entity to intervene in the activities of the regulated subject, including measures aimed at preventing violations and mitigating potential risks. A fundamental aspect of the control function is that it is based on legally established powers, which enable the responsible authorities to hold violators accountable,

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<sup>8</sup> Линдербрэтен А.Л. Основные принципы построения системы критериев и показателей для оценки качества и эффективности медицинской деятельности // А.Л. Линдербрэтен, Н.К. Гришина, С.М. Сердюковский, М.Е. Коломийченко, Е.Ю. Лудупова. – Москва.: Бюллетень национального научно-исследовательского института общественного здоровья имени Н.А. Семашко, 2020. № 2 – С. 31.

highlighting the close interrelation between control mechanisms, state enforcement, and the protection of public order<sup>9</sup>.

**S. Emelyanov** conceptualizes control as a systematic comparison of the actual state of an object with established normative requirements, followed by analysis and corrective action. Applied to medicinal products, this implies verifying compliance with quality standards to safeguard public health<sup>10</sup>. Within the pharmaceutical sector, the primary objective of control is to prevent the circulation of substandard, counterfeit, or potentially harmful products.

In this context, the quality control of medicinal products constitutes a specific form of state intervention, exercised through administrative-legal instruments such as inspections, expert evaluations, laboratory testing, and other procedures designed to determine the conformity of medicines with established safety and efficacy standards. Contemporary control encompasses all stages of the product lifecycle, including registration, manufacturing, storage, distribution, and post-marketing surveillance, with quality serving as the legally significant benchmark for regulatory action.

According to **F. Bidarova** and **B. Bidarov**, control in the pharmaceutical sector functions as a mechanism for ensuring that medicinal products meet national and international standards of quality, safety, and efficacy<sup>11</sup>.

International legal instruments similarly underscore the link between the right to health and state obligations to ensure the availability and quality of medicines. The United Nations Committee on Economic, Social and Cultural Rights, in General Comment No. 14 to Article 12 of the International Covenant on Economic, Social and Cultural Rights, emphasizes that the realization of the right to health requires medicines to be not only available but also acceptable and of adequate quality<sup>12</sup>.

The World Health Organization also highlights that the national quality control system is a central element of the state's pharmaceutical policy. Effective quality control mechanisms are essential to ensuring the population's right to health<sup>13</sup>.

Additionally, control serves as a legal deterrent within the pharmaceutical sector. It establishes a framework of responsibility for actors in the industry, compelling compliance with regulatory standards under the threat of sanctions. Collectively, these mechanisms render control an integral and legally formalized instrument for safeguarding public health through the lens of medicinal product quality.

Considering the complex, multi-stage nature of the pharmaceutical supply chain—including manufacturing, registration, storage, transport, distribution, and use—state control enables the establishment of a unified legal guarantee of quality across all stages of the medicinal product lifecycle. The effectiveness of such control is determined not only by the existence of regulatory

<sup>9</sup> Дубинец Е. Определение сущности функций управления контроль и надзор в сфере здравоохранения // Е. Дубинец, Н.А. Заруба. IX Всероссийская научно-практическая конференция молодых ученых «Россия молодая». – 2017. – С. 3.

<sup>10</sup> Емельянов С.А. Государственная система контроля качества, эффективности, безопасности лекарственных средств. Территориальная контрольно-аналитическая лаборатория: учеб. пособие. – Томск.: Сибирский государственный медицинский университет, 2009. – С. 9.

<sup>11</sup> Бидарова Ф.Н., Бидаров Б.С. Организация контроля соответствия лекарственных препаратов, находящихся в обращении, установленным обязательным требованиям к их качеству // Здравоохранение Российской Федерации, 2015. – С. 33.

<sup>12</sup> CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12). URL: <https://www.refworld.org/document-sources/un-committee-economic-social-and-cultural-rights-cescr>.

<sup>13</sup> WHO good practices for pharmaceutical quality control laboratories. World Health Organization: WHO Technical Report Series, № 957. – 2010. – P. 83.

requirements but also by the state's capacity to enforce them through institutions of supervision, licensing, and pharmacovigilance.

Legal doctrine stresses that state governance in healthcare loses its effectiveness without a system of control. Therefore, quality control of medicinal products constitutes an indispensable element of state healthcare management, reflecting the state's responsibility to society for ensuring the accessibility, safety, and effectiveness of pharmaceutical therapy.

The diversity of risks associated with the circulation of medicinal products necessitates a differentiated approach to the organization of quality control. In contemporary practice, pharmaceutical quality control is not a single, uniform procedure but rather a complex system of interconnected activities that vary in their legal basis, actors involved, and regulatory content. A scientific classification of the types of quality control allows for a more precise delineation of their functional roles, the identification of specific legal regulatory features, and the harmonization of control mechanisms throughout the life cycle of a medicinal product. Consequently, analyzing the various forms of quality control is essential for understanding the comprehensive legal framework that ensures pharmaceutical quality.

Scholars **V. Vnukova** and **I. Spichak** have proposed a classification of control types, which reflects the multidimensional nature of this regulatory activity<sup>14</sup>.



Each type of control performs a distinct function in safeguarding the safety, efficacy, and legal compliance of medicinal products, and their coordinated interaction ensures the integrity of the overall control system. Such a systematization clarifies the competencies of regulatory authorities, structures organizational and legal mechanisms, and enhances the effectiveness of law enforcement in the pharmaceutical sector. Overall, the analysis of control types demonstrates that ensuring compliance with standards is the result of coordinated efforts among various elements of the legal and organizational framework, all aimed at protecting public health and maintaining a stable pharmaceutical market.

In modern legal doctrine, quality control of medicinal products is recognized as a fundamental component of public regulatory governance in healthcare. Its primary objective is the protection of life and health. As a form of state intervention, control serves not only preventive and punitive purposes but also functions as a legal guarantee of the stability of

<sup>14</sup> Внукова В.А., Спичак И.В. Правовые основы фармацевтической деятельности: учеб. – Москва. ГЭОТАР-Медиа, 2018. – С. 187.

pharmaceutical circulation. Its legal significance lies in the fact that control is not merely technical or administrative; it is implemented as a set of authorized actions established by legislation to ensure that medicinal products conform to established quality standards.

The foremost and foundational purpose of quality control is the protection of public health. Article 40 of the Constitution of the Republic of Uzbekistan guarantees the right to health protection and obliges the state to develop healthcare systems and ensure the safety of medical care. This constitutional provision is operationalized through targeted pharmaceutical quality control policies, which are integral to the medical process. Unlike other consumer goods, medicinal products have direct physiological effects, meaning that noncompliance with quality standards may result in severe consequences, including fatal outcomes. In this context, quality control acquires a legal dimension as the execution of the state's obligations to safeguard the fundamental right to health. International legal scholarship supports this approach. As **F. Petrelli** notes, the quality of medicinal products is a prerequisite for their safety and efficacy, and therefore their quality must be monitored by the state as a public health protection function<sup>15</sup>.

The second critical goal of quality control is the prevention of harm. Here, control operates both preventively and repressively. Preventive measures include licensing, registration, evaluation, and standard approval, which are mandatory steps before a medicine is introduced into circulation. Repressive measures are implemented through inspections, laboratory testing, pharmacovigilance, and, in cases of noncompliance, product recalls, withdrawal of registration, and legal accountability.

**J. Woodcock**, former Director of the Center for Drug Evaluation and Research at the FDA, emphasized that pharmaceutical quality control is a mechanism of public consumer protection, especially given the limited technical knowledge of average users. In congressional testimonies and agency documents, she highlighted that the FDA ensures quality control procedures and oversight mechanisms specifically designed to protect the public from unsafe or substandard medicines.

In Uzbekistan, a similar approach is implemented through the activities of the Central Pharmacy and Pharmaceutical Oversight Body, as well as the electronic product tracking system “**Asl Belgisi**”, which allows tracing the movement of medicinal products from manufacturer to end user. The introduction of this system has become a key method of fulfilling the preventive objective of control: preventing the circulation of counterfeit and falsified products in the pharmaceutical market.

A third goal of quality control is strengthening public trust in the healthcare and pharmaceutical regulatory system. Transparent, effective, and procedural state oversight fosters confidence in the safety of consumed medicinal products. This is particularly important in the context of a globalized pharmaceutical market, where many products are imported and undergo multi-stage registration processes. Only rigorous and consistent state-led quality control ensures that only safe and reliable medicines reach consumers. According to **A. Samoylova**, pharmaceutical quality control systems serve to protect citizens' rights to timely, effective, and safe medical care<sup>16</sup>.

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<sup>15</sup> Petrelli F. The requirements for manufacturing highly active or sensitising drugs comparing Good Manufacturing Practices // F. Petrelli, C. Alessandro, S. Stefania, G. Iolanda, M. Elena, C. Aldo. – Italy.: School of Medicinal and Health Products Sciences. – 2019.

<sup>16</sup> Федеральный специализированный журнал «Кто есть Кто в медицине». Режим доступа: <https://ktovmedicine.ru/2024/1/alla-samoylova-nasha-glavnaya-missiya-zaschita-prav-grazhdan-na-poluchenie-kachestvennoy-medicinskoy-pomoschi.html?utm>.

Public trust also has an economic dimension. Law-abiding pharmaceutical companies benefit from fair competition, while state authorities reduce costs associated with recalls, litigation, and compensation. From an international perspective, trust is essential for cross-border pharmaceutical activity. For example, within the framework of the Eurasian Economic Union, mutual recognition of inspection and control results is possible only if quality criteria are harmonized and procedures are transparent. Hence, robust state quality control contributes to enhancing the competitiveness of the national pharmaceutical sector.

Finally, quality control serves a stabilizing systemic function, maintaining the integrity of the legal regime governing pharmaceutical circulation. Legal scholarship emphasizes that control protects the rights not only of consumers but also of other market participants, including manufacturers, distributors, and pharmaceutical professionals. It ensures the balance of interests, prevents abuses, and creates predictable conditions for market functioning. This function is especially relevant during emergencies, pandemics, crises, and sudden demand surges, where healthcare system stability depends in part on reliable quality control procedures.

In conclusion, quality control of medicinal products in legal doctrine serves multiple objectives beyond simple compliance verification. It functions as a legal instrument through which the state exercises its public duties to protect life and health, maintain trust in healthcare institutions, uphold lawfulness in the pharmaceutical sector, and strengthen international credibility. Legal theory affirms that without effective control, the strategic goals of state pharmaceutical policy cannot be achieved. Accordingly, quality control must be regarded as a central institution in the legal regulation of medicinal products and a crucial form of state-legal response to risks threatening human life and health.

### **Conclusion**

The analysis of legal frameworks and scientific literature demonstrates that the concept of “medicinal product quality” is multidimensional, encompassing pharmaceutical, technological, and legal aspects. Quality is understood not only as the conformity of a medicinal product to established standards but also as a legally significant category that determines the lawfulness of its circulation and contributes to the protection of public health. State supervision, pharmacovigilance, inspections, and digital tracking systems constitute a key mechanism to ensure the safety, efficacy, and regulatory compliance of medicinal products. Contemporary practice indicates that the effectiveness of these measures directly depends on clear regulatory frameworks, alignment with international standards, and continuous monitoring throughout the product life cycle.

At the same time, the legislation of the Republic of Uzbekistan lacks a direct legal definition of “medicinal product quality.” Although substandard or poor-quality products are mentioned in certain provisions of the Law “On Medicinal Products and Pharmaceutical Activity,” the formal legal definition of quality is absent. This gap complicates uniform law enforcement, reduces the efficiency of control measures, and limits the state’s ability to ensure comprehensive protection of public health.

Based on these observations, it is advisable to introduce into the legislation of Uzbekistan a formal legal definition of “medicinal product quality,” specifying its essential characteristics and mandatory requirements. Such an amendment would formalize regulatory benchmarks, enhance accountability of manufacturers and distributors, provide legal clarity, and increase the efficiency of state management of pharmaceutical circulation.

In conclusion, medicinal product quality and its regulatory oversight should be considered fundamental elements of the legal framework governing pharmaceutical activity, aimed at protecting public health, ensuring lawful circulation of medicines, and fostering public trust in the healthcare system.

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