O‘ZBEKISTON RESPUBLIKASIDA DORI VOSITALARINI STANDARTLASHTIRISHNING ZAMONAVIY TIZIMI: NORMATIV-HUQUQIY VA INSTITUTSIONAL ASOSLAR

Yoqubova Umidaxon Ma‘sudjon qizi
Toshkent davlat yuridik universiteti
tayanch doktoranti

Annotatsiya. Maqolada O‘zbekiston Respublikasida dori vositalarini standartlashtirishning zamonaviy tizimining normativ-huquqiy va institutsional asoslari tadqiq etiladi. Standartlashtirishning huquqiy asoslari, vakolatli organlar tizimi hamda ularning dori vositalarining sifati, xavfsizligi va samaradorligiga qo‘yiladigan talablarni belgilash, joriy etish va ularga rioya etilishini ta’minlashdagi roli tahlil qilinadi. Standartlashtirish tizimining farmatsevtika sohasini davlat tomonidan tartibga solishning tarkibiy elementi sifatidagi kompleks xususiyati asoslab beriladi.

Kalit so‘zlar: *dori vositalari, standartlashtirish, sifat, xavfsizlik, davlat tomonidan tartibga solish, normativ-huquqiy tartibga solish, texnik jihatdan tartibga solish, farmatsevtika sohasi.*

СОВРЕМЕННАЯ СИСТЕМА СТАНДАРТИЗАЦИИ ЛЕКАРСТВЕННЫХ СРЕДСТВ В РЕСПУБЛИКЕ УЗБЕКИСТАН: НОРМАТИВНО-ПРАВОВЫЕ И ИНСТИТУЦИОНАЛЬНЫЕ ОСНОВЫ

Ёкубова Умидахон Маъсуджон қизи
Ташкентский государственный
юридический университет
базовый докторант

Аннотация. В статье исследуются нормативно-правовые и институциональные основы современной системы стандартизации лекарственных средств в Республике Узбекистан. Анализируются правовые основы стандартизации, система уполномоченных органов и их роль в установлении, внедрении и обеспечении соблюдения требований к качеству, безопасности и эффективности лекарственных средств. Обосновывается комплексный характер системы стандартизации как элемента государственного регулирования фармацевтической сферы.

Ключевые слова: *лекарственные средства, стандартизация, качество, безопасность, государственное регулирование, нормативно-правовое регулирование, техническое регулирование, фармацевтическая отрасль.*

THE MODERN SYSTEM OF STANDARDIZATION OF MEDICINAL PRODUCTS IN THE REPUBLIC OF UZBEKISTAN: REGULATORY AND INSTITUTIONAL FOUNDATIONS

Yoqubova Umidakhon Masudjon kizi
Tashkent state university of law
doctoral student

Abstract. The article examines the regulatory and institutional foundations of the modern system of standardization of medicinal products in the Republic of Uzbekistan. It analyzes the legal framework of standardization, the system of authorized bodies, and their role in establishing, implementing, and ensuring compliance with requirements for the quality, safety, and efficacy of medicinal products. The article substantiates the comprehensive nature of the standardization system as an element of state regulation of the pharmaceutical sector.

Keywords: *medicinal products, standardization, quality, safety, state regulation, regulatory framework, technical regulation, pharmaceutical sector.*

Medicinal products constitute a special type of product, the quality of which is directly related to the protection of public health and, in some cases, to the preservation of human life. Accordingly, state regulation of their production and circulation, as well as the assurance and control of the quality of medicinal products, are of particular public importance. One of the key instruments of such regulation is standardization, through which uniform requirements for the quality characteristics of medicinal products are established, appropriate methods for their assessment are determined, and conditions are created to ensure the uniformity of requirements at various stages of the product life cycle.

The significance of standardization in the pharmaceutical sector is determined not only by the need to ensure the quality and safety of medicinal products. It is directly related to the protection of public health, pharmaceutical security, consumer protection, the development of production, and the enhancement of the competitiveness of pharmaceutical products. The scientific and educational literature notes that standardization is aimed at ensuring pharmaceutical, environmental, and technological safety, as well as the rational use of resources[1].

In the Republic of Uzbekistan, the importance of standardization is increasing in the context of the development of the national pharmaceutical industry and the expansion of foreign economic activity. According to official data, in 2024 the volume of pharmaceutical products manufactured amounted to

[1] Министерство здравоохранения Республики Узбекистан. Центр развития медицинского образования. Ташкентский фармацевтический институт. Стандартизация и сертификация лекарственных средств. Методич. разработ. для студентов 5 курса по выполнению лаб. раб. – Ташкент, 2014. – С. 2.

UZS 5.1 trillion, while exports of pharmaceutical products and services amounted to USD 180.1 million[2]. The increase in the volume of pharmaceutical production and exports objectively enhances the importance of establishing uniform and reproducible requirements for the quality, safety, and efficacy of pharmaceutical products.

Under these conditions, standardization acquires not only technical but also legal and organizational-administrative significance. Through the normative establishment of quality requirements, the state formulates criteria for the conformity of medicinal products with established requirements, determines the rules for their assessment, and creates the regulatory and organizational conditions necessary for state control. Therefore, the modern system of standardization of medicinal products should be considered in conjunction with the legislation governing medicinal products and pharmaceutical activities, legislation on standardization, quality-related regulatory documents, and the activities of authorized state bodies.

Standardization of medicinal products constitutes a mechanism for establishing uniform requirements for the quality characteristics of pharmaceutical products. Its significance is determined by the need to ensure the stability and reproducibility of the characteristics of medicinal products throughout the entire period of their production and circulation. According to **G.U. Tillayeva** and **F.S. Djalilov**, standardization in the field of medicinal product circulation is aimed at ensuring guarantees of the quality of standardization objects, including products, services, and relevant processes[3]. This understanding makes it possible to regard standardization not merely as the establishment of individual technical indicators, but as a system for the consistent formulation of requirements for products and related processes.

Standardization is of particular importance for the protection of consumer rights. The establishment of uniform quality requirements for medicinal products creates objective criteria for assessing their conformity and contributes to the creation of conditions for protecting the population from products whose characteristics do not comply with established requirements.

In the pharmaceutical sector, standardization is also associated with ensuring the interchangeability and compatibility of medicinal products. The existence of uniform requirements for product characteristics creates conditions for the sustainability of the supply of medicinal products, the prevention of shortages, and the availability of quality pharmaceutical products.

At the same time, the significance of standardization of medicinal products should not be limited exclusively to the technical assurance of quality. The specific nature of medicinal products as goods directly associated with human life and health determines their particular public significance. In this context,

[2] Официальный сайт «Dori-Darmon»: Режим доступа: https://doridarmon.uz/ru/news/v-2024-godu-proizvedeno-farmatsevticheskoj-produktsii-na-51-trln-sumov.

[3] Тиллаева Г.У., Жалилов Ф.С. Стандартизация и сертификация медицинской и фармацевтической продукции. Учебное пособие. – Ташкент, 2021. – С. 10.

standardization acquires a public-law dimension, since, by establishing uniform requirements, the state determines the criteria that medicinal products must meet, forms the regulatory basis for their assessment, and creates conditions for the exercise of state control.

Thus, standardization performs interrelated regulatory, assurance, organizational, and control functions. The regulatory function is expressed in establishing requirements for the quality characteristics of products and related processes; the assurance function consists in creating conditions for the stability and reproducibility of quality; the organizational function lies in determining the procedure for the development, approval, registration, and application of the relevant documents; and the control function is manifested in the use of established requirements as criteria for conformity assessment. This understanding makes it possible to regard the standardization of medicinal products as an integral element of state regulation of the pharmaceutical sector.

The modern system of standardization of medicinal products in the Republic of Uzbekistan is based on a multi-level regulatory framework. It includes legislation governing medicinal products and pharmaceutical activities, legislation on standardization, regulatory quality documents, the State Pharmacopoeia, and subordinate regulatory legal acts. The combination of sector-specific and cross-sectoral sources is обусловлено by the comprehensive nature of the standardization of medicinal products: on the one hand, the requirements applicable to such products are determined by their pharmaceutical characteristics; on the other hand, standardization is carried out within the framework of the unified national system of technical regulation and standardization.

The Law of the Republic of Uzbekistan **“About Medicines and Pharmaceutical Activity”** is of key importance within the system of legal regulation. This legislative act establishes the legal and organizational foundations for regulating the circulation of medicinal products and sets requirements for their quality, safety, and efficacy. Of particular importance is the legislative linkage between the authorization of medicinal products for medical use and compliance with quality requirements[4].

This provision is of fundamental importance for determining the place of standardization within the system of state regulation. In this context, a standard is not merely a technical document but one of the instruments for establishing criteria for the conformity of a medicinal product with the applicable requirements. By establishing quality requirements and the relevant assessment procedures, legislation creates the legal basis for state control over the quality of medicinal products. Thus, standardization and quality control have a direct functional relationship: standardization establishes the substance and criteria of the requirements, while control ensures verification of compliance with them.

The application of Good Practices (GxP), including Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), and other relevant approaches,

[4] Закон Республики Узбекистан ЗРУ №-399 «О лекарственных средствах и фармацевтической деятельности» от 04.01.2016 г. – Ст. 8.

is also of substantial importance within the regulatory system. The integration of these requirements into the national system demonstrates its orientation toward internationally recognized approaches to ensuring the quality of medicinal products. As a result, the regulatory framework combines national legal mechanisms with internationally oriented requirements, making it possible to regard standardization simultaneously as an instrument of domestic state regulation and as one of the mechanisms for integrating the national pharmaceutical system into the international regulatory framework.

The State Pharmacopoeia of the Republic of Uzbekistan occupies a special place in the regulatory framework for ensuring the quality of medicinal products. The Pharmacopoeia contains requirements for the quality indicators of medicinal products, testing methods, storage conditions, packaging, and quality control. Accordingly, it constitutes a regulatory source ensuring uniform approaches to the assessment of the quality of pharmaceutical products.

The legal significance of the State Pharmacopoeia is primarily associated with the establishment of uniform criteria for quality assessment. The specification of quality indicators and testing methods makes it possible to use them in determining whether medicinal products comply with established requirements. At the same time, pharmacopoeial requirements are relevant not only at the production stage but also in the exercise of state control and supervision, since they provide an objective regulatory basis for determining the conformity of the quality of medicinal products.

Another essential element of the regulatory framework is the Law of the Republic of Uzbekistan **“About Standardization”**. Unlike the legislation governing medicinal products and pharmaceutical activities, this law is cross-sectoral in nature and establishes the general legal and organizational foundations of activities in the field of standardization. Its scope extends to various sectors of the economy, including the pharmaceutical industry.

The significance of the Law **“About Standardization”** lies in establishing a unified legal approach to the development, approval, application, and improvement of standards. Of particular importance is the distinction between mandatory requirements established by technical regulations and regulatory legal acts, and standards as instruments for ensuring compliance with established requirements. This distinction makes it possible to determine the legal nature of a standard. Formally, a standard and a mandatory requirement may differ in their legal nature; however, in the field of medicinal products, standards acquire particular significance due to their direct connection with sector-specific regulatory requirements and quality control procedures.

The specific nature of the pharmaceutical industry lies in the heightened public significance of requirements for the quality of medicinal products. Therefore, the provisions of standards and pharmacopoeial requirements are integrated into the system of state regulation through sector-specific legislation and subordinate regulatory legal acts. As a result, standardization serves as a

connecting element between technical requirements for products and administrative-legal mechanisms of state regulation.

Thus, the Law **“About Standardization”** establishes the general legal foundation of the national standardization system, while the legislation governing medicinal products and pharmaceutical activities provides its sector-specific elaboration, taking into account the particular characteristics of medicinal products.

The functioning of the standardization system requires not only the establishment of requirements but also the normative determination of procedures for the development, approval, registration, amendment, and repeal of standards. In this regard, the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan **“On Additional Measures to Improve Standardization Activities”** is of substantial importance. This regulatory act specifies the provisions of the legislation on standardization and establishes the organizational and procedural mechanisms for the functioning of the national standardization system[5].

Of particular importance is the established procedure for the development, approval, registration, repeal, and amendment and supplementation of national standards. Procedural regulation makes it possible to regard a standard not as a static regulatory document but as an element of a continuously functioning system. Its life cycle includes initiation of development, preparation of a draft, review and coordination, registration, application, and, where necessary, amendment or repeal.

For the pharmaceutical industry, this approach is particularly important due to the development of medicinal product manufacturing technologies, changes in analytical methods, and the emergence of new requirements for product quality. Consequently, importance lies not only in the content of a particular standard but also in the existence of an established procedure for its development, application, and subsequent amendment. It is precisely the procedural component that ensures the functioning of standardization as a continuous process.

The normative establishment of requirements in itself does not ensure their practical implementation. The functioning of the standardization system requires a set of state bodies and specialized structures responsible for the development, coordination, application, and control of the relevant requirements. Pursuant to the Law of the Republic of Uzbekistan **“About Standardization”,** the principal participants in the national system include the Uzbek Agency for Technical Regulation, the national standardization body, state and economic administration bodies, and technical committees for standardization[6]. Their interaction forms the institutional foundation of the modern standardization system.

A distinctive feature of this system is the distribution of functions among bodies at different levels. Central structures ensure coordination and organizational support; the national standardization body carries out specialized activities related to the development and application of standards; sectoral bodies ensure the

[5] Постановление Кабинета Министров Республики Узбекистан № ПКМ-177 «О дополнительных мерах по совершенствованию деятельности по стандартизации» от 30.03.2024 г.
[6] Закон Республики Узбекистан № ЗРУ-800 «О стандартизации» от 03.11.2022 г. Ст. 5.

implementation of the relevant requirements in specific fields; and technical committees provide expert and scientific-technical support.

A central position in the institutional system is occupied by the Uzbek Agency for Technical Regulation under the Cabinet of Ministers of the Republic of Uzbekistan. Its current organizational status is associated with the implementation of measures provided for by the Decree President of the Republic of Uzbekistan **"On Measures to Further Improve State Administration in the Field of Technical Regulation"**. Within the established framework, the Agency coordinates activities in the fields of technical regulation, standardization, and metrology[7].

The activities of the Agency cover the formulation and implementation of state policy in the field of technical regulation and standardization, organization of the development and implementation of national standards and technical regulations, interaction with state bodies and business entities, as well as ensuring the conformity of the national system with international requirements. An important area of activity is also participation in conformity assessment and certification procedures related to ensuring compliance with established requirements.

Of particular importance is the Agency's role in ensuring interaction among the various participants in the national standardization system. This is of fundamental importance for the pharmaceutical sector, since requirements for medicinal products are formulated and implemented at the intersection of the general standardization system and sector-specific regulation. Therefore, the coordinating function of the Agency makes it possible to ensure a link between the general mechanisms of technical regulation and the special requirements applicable to medicinal products.

Another important area of activity is the orientation of the national system toward international harmonization. The Agency participates in ensuring the conformity of national regulation with international requirements, including relevant international standards and approaches of the World Trade Organization. The material under study also notes the importance of digitalization of technical regulation processes and the expansion of public services in this field, as well as professional training and advanced qualification of specialists.

The second important element of the institutional system is the Uzbek Institute of Standards under the Uzbek Agency for Technical Regulation. The legal status and organization of the Institute's activities are determined by the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan **"On the Organization of the Activities of the Uzbek Institute of Standards of the Agency for Technical Regulation of Uzbekistan"**.

The Institute acts as the national standardization body and carries out specialized activities related to the development, application, and improvement of national standards. One of its principal functions is the development of draft

[7] Указ Президента Республики Узбекистан № УП-41 «О мерах по дальнейшему совершенствованию государственного управления в области технического регулирования» от 27.02.2024 г.

national standards in accordance with the applicable legislation and approved standardization work plans.

Scientific and methodological research in the fields of standardization, metrology, and conformity assessment is of substantial importance. Scientific support makes it possible to take into account developments in the relevant fields and ensure the necessary substantiation of the regulatory documents being developed. An equally important function is the establishment and maintenance of a unified information database of national standards, since the accessibility of regulatory information constitutes a condition for transparency of the standardization system and uniform application of established requirements.

The Institute also participates in preparing proposals for the inclusion of international, interstate, and regional standards in the national standardization system. This is of particular importance for the pharmaceutical industry, since the development of medicinal product manufacturing is directly associated with international approaches to the quality and safety of pharmaceutical products.

Other areas of the Institute's activities include the preparation of methodological recommendations, retraining and advanced training of specialists, as well as international cooperation and exchange of experience with national standardization bodies of other states. Thus, the Institute of Standards performs primarily specialized regulatory-methodological and scientific-technical functions, complementing the coordinating activities of the Agency for Technical Regulation.

State and economic administration bodies responsible for the practical implementation of standard requirements in the relevant fields occupy a special place in the national system. In the pharmaceutical sector, the principal participants include the Ministry of Health of the Republic of Uzbekistan, the Agency for the Development of the Pharmaceutical Industry, the Center for Good Practices, and the Center for Pharmaceutical Product Safety.

These structures perform specialized functions related to ensuring the quality, safety, and efficacy of medicinal products. The Ministry of Health, as the relevant state authority, participates in the implementation of state policy in the field of medicinal product circulation, the formulation of quality requirements, and interaction with other participants in the system. Its participation in organizing processes related to quality control and inspection control is of substantial importance, as it ensures the connection between the national standardization system and sector-specific regulation of medicinal products.

The Agency for the Development of the Pharmaceutical Industry, in turn, performs a coordinating role in interaction with manufacturers and distributors. The material under study notes its participation in the implementation of standards and ensuring compliance with GMP and GLP requirements, modernization of production, and implementation of relevant quality approaches.

The specialized structures—the Center for Good Practices and the Center for Pharmaceutical Product Safety—perform functions directly related to control and conformity assessment. In particular, they participate in inspections, examination of manufacturing processes and documentation, as well as assessment of the

conformity of pharmaceutical operations with established requirements. Thus, sectoral bodies ensure the practical link between the general standardization system and specific processes of manufacturing and circulation of medicinal products.

Technical committees for standardization constitute an important element of the institutional system, and their activities are provided for by the Law of the Republic of Uzbekistan **“About Standardization”**. Their significance is determined by the need for scientific and expert support in the development of standards. Specialists and representatives of the scientific community possessing the necessary knowledge in specific fields participate in the relevant activities.

For the pharmaceutical sector, expert support is particularly important due to the complexity of medicinal products as objects of standardization. The development of quality requirements for pharmaceutical products requires consideration of technological, chemical, biological, and other characteristics. Therefore, regulatory documents should be based not only on legal requirements but also on an appropriate level of scientific and technical development.

According to official data, 33 technical committees for standardization operate in the Republic of Uzbekistan[8]. Their activities constitute an important element of the expert support of the national system. The results of the work of technical committees undergo the relevant stages of review and approval with the participation of the national standardization body and the Uzbek Agency for Technical Regulation. Thus, technical committees provide the expert component of standardization, while state bodies ensure its legal and organizational formalization.

Overall, the modern system of standardization of medicinal products represents an interconnected set of regulatory and institutional elements. The regulatory component includes the legislation **“About Medicines and Pharmaceutical Activity”, the Law “About Standardization”,** the State Pharmacopoeia, and subordinate regulatory legal acts. The institutional component is represented by the Uzbek Agency for Technical Regulation, the Uzbek Institute of Standards, sectoral bodies, and technical committees. Their interaction ensures the practical implementation of the established requirements.

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