

Research Article

Medicinal products as an object of commercial, civil and administrative legal relations: International standards and ways of improvement

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Received: 24 December 2025; **Manuscript No:** JDAR-26-186109; **Editor assigned:** 26 December 2025; **PreQC No:** JDAR-26-186109 (PQ); **Reviewed:** 09 January 2026; **QC No:** JDAR-26-186109; **Revised:** 16 January 2026; **Manuscript No:** JDAR-26-186109 (R); **Published:** 23 January 2026; **DOI:** 10.4303/JDAR/236492

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Abstract

Aim: The purpose of the article is medicinal products as an object of economic, civil and administrative legal relations: International standards and ways of improvement.

Methods: The methodological basis of the study is a set of general scientific, special legal and interdisciplinary approaches that provide a comprehensive understanding of the legal nature of medicines as an object of economic, civil and administrative legal relations, as well as an analysis of international standards and national practice of legal regulation in this area.

Results: The article provides a comprehensive analysis of the legal nature of medicines as an object of economic, civil and administrative legal relations. The features of the legal regime of medicines are revealed, taking into account their social significance, increased requirements for quality, safety and effectiveness. International standards of legal regulation of the circulation of medicines are analyzed, in particular, acts of the European Union (EU), recommendations of the World Health Organization (WHO) and the practice of the European Medicines Agency (EMA). The key problems of the national legislation of Ukraine in this area are identified and ways of its improvement are proposed, taking into account European integration processes.

Conclusion: Medicines are a complex and multifaceted object of legal regulation, combining elements of civil, economic and administrative legal relations. Their special legal regime is due to their social significance and the need to ensure a high level of protection of human rights in the field of healthcare. Harmonization of national legislation with international standards is a key factor in improving the legal regulation of the circulation of medicines and ensuring the effective functioning of the pharmaceutical market of Ukraine.

Keywords: EU contract law, EU internal market law, Medicinal products, Legal relations, Economic activity, Administrative and legal regulation, Civil and legal relations, International standards

Introduction

Legal regulation of the circulation of medicinal products is one of the most complex and at the same time socially significant areas of modern legal order, as it is directly related to the implementation of the fundamental human right to health protection and medical care. Medicinal products, acting as a specific object of civil, economic and administrative legal relations, require a comprehensive and coordinated regulatory approach that would ensure a balance between the private economic interests of pharmaceutical market entities and the public interests of the state and society.

The key problem of legal regulation in this area is the fragmentation and sectoral disunity of the norms regulating the circulation of medicinal products. Civil law, economic law and administrative law mechanisms often function autonomously, without proper coordination among themselves, which complicates law enforcement and creates legal uncertainty for participants in the relevant legal relations. This situation negatively affects the stability of the pharmaceutical market and the level of protection of the rights of medicinal product consumers.

A separate group of problems is the excessive regulatory complexity of administrative procedures in the field of state registration, licensing and quality control of medicines. Despite the declared orientation to European standards, the current mechanisms of public administration in Ukraine do not always comply with the principles of transparency, proportionality and legal certainty. This creates additional administrative barriers for business entities and limits patients' access to necessary medicines [1].

The problem of harmonizing national legislation with international and European standards in the field of circulation of medicines also remains a significant challenge. The implementation of the norms of European Union (EU) law and recommendations of the World Health Organization (WHO) is carried out fragmentarily, without a proper systematic approach, which leads to discrepancies in legal regulation and complicates the integration of Ukraine into a single European pharmaceutical space.

The relevance of the study is also due to modern socio-economic and security challenges, in particular the conditions of martial law and the need for post-war restoration of the healthcare system. In these conditions, the issue of ensuring the continuity of the supply of medicines, controlling their quality and preventing the circulation of counterfeit pharmaceutical products becomes of particular importance, which requires the improvement of both administrative-legal and economic-legal mechanisms of regulation.

The issue of legal regulation of medicines as an object of multi-level legal relations is complex and requires interdisciplinary scientific analysis. The relevance of this study is determined by the need to form a holistic and coordinated legal model of the circulation of medicines, which would meet international standards, ensure effective state control and at the same time guarantee the realization of the rights and legitimate interests of all participants in the relevant legal relations [2].

The current stage of development of the legal system of Ukraine is characterized by an active transformation of the mechanisms for regulating public relations in the field of healthcare, which is due to both internal socio-economic challenges and European integration processes. A special place in this system is occupied by medicines, which simultaneously act as a commodity in civil and economic

circulation and an object of increased state control in the field of public administration. Such a dual legal nature determines the complexity of their regulatory regulation and requires a comprehensive scientific understanding [3].

Medicines are a specific object of legal relations, since their circulation is directly related to the implementation of the constitutional human right to healthcare and medical care. Unlike other goods, they affect human life and health, which necessitates the establishment of a special legal regime that combines the dispositive principles of private law with imperative mechanisms of public control. In this context, the issue of determining the place of medicines in the system of objects of civil, economic and administrative legal relations acquires special importance [4].

The relevance of the research topic is also due to the processes of harmonization of Ukrainian legislation with the law of the European Union (EU), which provides for the implementation of European standards in the field of registration, production, quality control and pharmacovigilance of medicines. The conditions of martial law and post-war reconstruction additionally actualize the problem of ensuring the availability and safety of medicines, as well as improving the mechanisms of state regulation of the pharmaceutical market [5].

The degree of scientific development of the issue indicates the presence of separate studies devoted to the civil-legal aspects of the circulation of medicines, economic-legal regulation of pharmaceutical activities and administrative procedures of state control [6]. At the same time, a comprehensive analysis of medicines as a multidimensional object of legal relations, taking into account international standards and European integration processes, remains insufficiently systematized, which necessitates the need for an interdisciplinary approach to research [7].

The purpose of the article is a comprehensive analysis of the legal nature of medicines as an object of economic, civil and administrative legal relations, as well as determining the main directions of improving national legislation taking into account international standards.

The scientific novelty of the study lies in the formation of a comprehensive approach to understanding medicines as an object of multi-level legal relations that function at the intersection of private and public law, as well as in

the development of proposals for harmonizing national legislation with international standards taking into account modern challenges.

The theoretical significance of the work lies in deepening doctrinal approaches to determining the legal nature of medicines and clarifying their place in the system of objects of legal regulation. The practical significance lies in the possibility of using the formulated conclusions and recommendations in regulatory activities, law enforcement practice and further scientific research.

Methods

The methodological basis of the study is a set of general scientific, special legal and interdisciplinary approaches that provide a comprehensive understanding of the legal nature of medicines as an object of economic, civil and administrative legal relations, as well as an analysis of international standards and national practice of legal regulation in this area [8].

The key to the study is a systemic approach, which allowed us to consider the circulation of medicines as a holistic multi-level system of legal regulation, covering the norms of private and public law, mechanisms of state control and self-regulation of the pharmaceutical market. The application of a systemic approach made it possible to identify the relationship between civil law, economic law and administrative law elements of the legal regime of medicines [9].

The use of the dialectical method of cognition provided the opportunity to study the development of legal regulation of the circulation of medicines in dynamics, taking into account socio-economic transformations, European integration processes and changes in international pharmaceutical law. This method revealed internal contradictions between private and public interests in the sphere of circulation of medicines and justified the need for their legal balance [10].

Among the general scientific methods, analysis and synthesis were used, which made it possible to isolate individual elements of the legal status of medicines as an object of legal relations and generalize them into a holistic concept of the legal regime. Induction and deduction were used to form theoretical generalizations and conclusions based on the analysis of regulatory material and the practice of its application [11].

The leading place in the study is occupied by special legal methods. In particular, the formal legal method was used to interpret the norms of national legislation of Ukraine and international legal acts regulating the circulation of medicines. The comparative legal method made it possible to compare the provisions of Ukrainian legislation with the law of the European Union (EU) and the recommendations of the World Health Organization (WHO), as well as to identify the main directions of harmonization and implementation of international standards [12].

The application of the structural-functional method allowed to determine the functional purpose of medicines in the system of legal relations and to characterize the role of public administration subjects in the field of pharmaceutical regulation. The logical-legal method was used to formulate scientifically based proposals for improving legislation and law enforcement practice.

In addition, the study used the method of legal modeling, which formulated possible directions for improving the national model of regulating the circulation of medicines, taking into account international standards and the needs of the national healthcare system.

The combination of these methods ensured the comprehensiveness, objectivity and scientific validity of the research results, and also allowed to form practically oriented conclusions and recommendations for improving the legal regulation of the circulation of medicines in Ukraine [13].

Results and Discussion

The legal nature of medicines as an object of multi-level legal relations

Medicines occupy a special place among the objects of legal regulation, as they combine the properties of a civil goods and a socially significant object of public interest [14]. Their legal nature is characterized by complexity, which determines the simultaneous functioning within the framework of civil, economic and administrative legal relations. Unlike ordinary objects of civil circulation, medicines have a special legal regime that limits the principle of freedom of contract and autonomy of will of the parties in order to protect human life and health [15].

In the civil legal aspect, medicines act as movable things that can be the subject of transactions, but only if the

imperative requirements of the law regarding their quality, safety and effectiveness are met [16]. The economic and legal dimension defines medicines as a key resource of the pharmaceutical market, where the state acts not only as an arbitrator, but also as an active regulator of economic processes. The administrative-legal component forms the mechanism of public administration of the circulation of medicines through the system of permits, control and supervision [17].

The issue of legal protection, creation, production and use of medicinal products in Ukraine is regulated by the constitution of Ukraine dated 06/28/1996, the civil code of Ukraine dated 01/16/2003, the economic code of Ukraine dated 01/16/2003, the law of Ukraine “on medicinal products” No. 123/96-VR dated 04/04/1996, the law of Ukraine “fundamentals of the legislation of Ukraine on health care” dated 11/19/1992, by-laws, as well as international legal agreements [18]. It is worth noting that the harmonization of national legislation with the provisions of international legal acts contributed to reformist transformations in the field of medicine and brought the national regulatory framework closer to the regulatory standards of the law of the countries of the European community [19].

Art. 2 of the law of Ukraine “On medicinal products” establishes: “Medicinal product-any substance or combination of substances (one or more APIs and excipients) that has properties and is intended for the treatment or prevention of diseases in humans, or any substance or combination of substances (one or more APIs and excipients) that may be intended for the prevention of pregnancy, restoration, correction or change of physiological functions in humans by exerting pharmacological, immunological or metabolic action or for establishing a medical diagnosis” [20].

The civil legal regime of medicinal products is determined by the fact that they belong to things. However, their value primarily lies in their purpose, that is, special therapeutic properties. According to the law of Ukraine “On medicinal products”, medicinal products are the result of the creative work of the author, who may apply for a patent for this medicinal product. So, the law defines drugs as an object of IP law, namely-as an object of industrial property law. But not all drugs are considered innovative, have an inventive level and are suitable for use. “Not every result of creative

activity is recognized as an object of intellectual property law, but only that which meets the requirements of the civil code of Ukraine, and the results of creative activity, which for one reason or another have not become an object of intellectual property rights protection, can be defined as objects of civil law, but not intellectual property rights” [21].

Features of civil-legal and economic-legal regulation of the circulation of medicines

Civil-legal relations in the sphere of circulation of medicines are characterized by limited discretion and enhanced protection of consumer rights. The establishment of special conditions for the admission of medicines to the market, the prohibition of the circulation of unregistered drugs, as well as increased requirements for informing consumers indicate the dominance of public interest over private.

At the same time, as Moskalyuk notes, the national pharmaceutical market consists of 85-90% generic drugs and only 10-15% original ones. This situation is difficult not only from the standpoint of protecting citizens’ rights to quality medical care and access to the latest developments in the medical field, but also from the standpoint of protecting IP rights [22].

However, the UN millennium declaration recognizes the need for “a generic pharmaceutical industry to ensure the availability of life-saving medicines in developing countries” [23]. In particular, the WHO is entrusted with a fundamental function in balancing the tasks of public health, intellectual property and innovation [24].

As the European Medicines Agency (EMA, the organization responsible for the registration procedure of medicines in the EU) emphasizes, the use of unregistered medicines for humanitarian reasons in the treatment of COVID-19 is not part of a clinical trial, and therefore such information should not be classified as a trade secret. Therefore, all information obtained in the process of these studies should not be monopolized either as objects of patenting or as exclusive information about medicines [25]. The following organizations call for the introduction of access to information on the treatment of COVID-19: IFLA (International Federation of Library Associations and Institutions), which in a letter to WIPO speaks of the need to use all possible mechanisms of IP law to ensure maximum access to the results of research on the treatment of COVID-19 in the world [26], as well as the International Organization “Médecins Sans Frontières”,

which called on governments not to patent medicines for COVID-19 and to give up property interests to the main goal—the survival of humanity [27].

As is known, in world practice there are several legal mechanisms for ensuring access to generic and innovative medicines, which are able to mitigate the patent monopoly on them. It is worth noting that in Ukraine the following mechanisms are legally regulated:

- Compulsory licensing of inventions related to medicines in order to ensure and protect the health of the population (Article 30 of the law of Ukraine “on protection of rights to inventions and utility models”) [28]
- Managed access agreements, which ensure access to innovative medicines and are regulated by Article 79-1 of the fundamentals of Ukrainian legislation on healthcare [29].
- Use of a patented medicine in the form of a generic copy in extraordinary circumstances in the interests of the state (Article 31 of the law of Ukraine “on protection of rights to inventions and utility models”) [30].

On March 30, 2020, the law of Ukraine “On amendments to certain laws of Ukraine regarding the provision of treatment for Coronavirus Disease (COVID-19)” (the law on combating COVID-19) was adopted [31]. This law amends the fundamentals of legislation on healthcare and the law of Ukraine “on medicinal products”. These amendments are important because they have expanded the choice of treatment methods and techniques in the context of a pandemic, taking into account global experience [32].

Economic-legal regulation is aimed at streamlining entrepreneurial activity in the pharmaceutical sector, taking into account the principles of fair competition and social responsibility of business. Of particular importance are the mechanisms of licensing, state control over pricing and the implementation of international standards of good practice (GMP, GDP, GPP). The results of the study show that the effectiveness of economic and legal regulation largely depends on the consistency of economic incentives and administrative restrictions [33].

Administrative and legal mechanism of regulation and supervision

Administrative and legal relations in the sphere of circulation of medicinal products are formed in the process

of implementing the state’s public policy in the field of healthcare. The central place in this mechanism is occupied by the procedures of state registration of medicinal products, licensing of pharmaceutical activities, pharmacovigilance and state quality control [34].

The results of the study show that the current system of administrative regulation in Ukraine is characterized by fragmentation and excessive complexity of procedures, which negatively affects the availability of medicinal products and creates additional administrative barriers for business entities. At the same time, strengthening the risk-based approach and digitalization of administrative procedures correspond to modern European trends and contribute to increasing the efficiency of state control [35].

The influence of international standards on the formation of a national regulatory model

International standards in the field of circulation of medicinal products play a decisive role in the formation of a modern legal model of pharmaceutical regulation. A study of the practice of the European Union (EU) shows that the unification of procedures for registration, pharmacovigilance and quality control of medicinal products ensures a high level of protection of patients’ rights and stability of the pharmaceutical market [36].

The results of the comparative legal analysis indicate the presence of significant differences between the legislation of Ukraine and EU law, in particular in the field of post-registration supervision, manufacturer liability and transparency of regulatory decisions. At the same time, the implementation of European standards creates the prerequisites for increasing the competitiveness of the national pharmaceutical sector and the integration of Ukraine into the single European market for medicinal products [37].

Main results of the study and directions for improving legal regulation

The study found that: Medicinal products are a complex object of legal relations, the legal regime of which is formed at the intersection of private and public law; civil and economic regulation of the circulation of medicines in Ukraine requires further coordination with administrative and legal control mechanisms; international standards of the EU and WHO serve as a key reference point for the modernization of national legislation [38].

The feasibility of: Simplifying and unifying administrative

procedures in the sphere of circulation of medicines; strengthening legal liability for violation of requirements for the quality and safety of medicines; introducing digital tools for pharmacovigilance and state control; systematic harmonization of Ukrainian legislation with European Union (EU) law is substantiated [39] (Table 1).

The above table demonstrates the complex nature of the legal regime of medicines and confirms their special place in the system of legal relations. The analysis shows that medicines cannot be attributed exclusively to the objects of private law regulation, since their circulation is significantly limited by imperative norms of public law.

Table 1: Legal regulation of medicinal products within the framework of civil, economic and administrative legal relations.

Criterion	Civil law relations	Economic and legal relations	Administrative and legal relations
Legal nature of medicinal products	Object of civil rights (movable property, goods)	Object of entrepreneurial activity	Object of public administration
Main purpose of regulation	Protection of consumer rights and interests	Ensuring stability of the pharmaceutical market	Protection of public interests, life and health of the population
Subjects of legal relations	Manufacturers, distributors, consumers	Entities in the pharmaceutical sector	State authorities, regulatory bodies
Nature of legal impact	Mainly dispositive with imperative restrictions	Combination of market and regulatory mechanisms	Imperative, administrative
Key instruments	Contracts, liability for damage	Licensing, GMP/GDP standards, pricing	State registration, control, pharmacovigilance
International standards	Protection of consumer rights	European pharmaceutical regulations	EU norms, WHO recommendations
Main problems	Limited freedom of contract	Administrative barriers	Fragmentation and complexity of procedures

Within the framework of civil law relations, medicines formally correspond to the features of the object of civil rights, however, freedom of contract is significantly narrowed due to requirements for registration, certification and consumer information [40]. This indicates the priority of protecting human life and health over the principle of autonomy of the will of the parties [41].

Economic and legal regulation is focused on the organization of the pharmaceutical market as a strategically important sector of the economy. The analysis shows that the state actively intervenes in economic activity through licensing, standardization and pricing mechanisms, which is justified given the social significance of medicines, but at the same time creates risks of excessive regulatory burden [41].

In the administrative-legal sphere, medicinal products are an object of public administration, where the imperative method of legal regulation dominates. It is this level that provides preventive control of quality and safety, however, the results of the study indicate the need to simplify and unify administrative procedures in accordance with the standards of the European Union (EU) [41].

In general, the analysis of the table allows us to conclude

that effective legal regulation of the circulation of medicinal products is possible only if civil, economic and administrative legal mechanisms are coordinated. International standards play a key role in the formation of such a coordinated model and should become a methodological basis for further improvement of Ukrainian legislation.

Conclusion

Medicines are a multidimensional object of legal relations, operating at the intersection of civil, economic and administrative law. Civil law, economic law and administrative law mechanisms complement each other, ensuring a balance between private economic interests and public needs of society in the field of healthcare.

Within the framework of civil law, medicines are considered as an object of transactions and property, but their circulation is significantly limited by safety and quality standards. The establishment of special conditions for market admission and liability for damage indicate the priority of consumer rights and patient safety protection over the principle of freedom of contract.

Medicines are a strategic resource of the pharmaceutical market, where the state regulates the activities of business

entities through licensing, GMP/GDP standards and price control for socially significant drugs. At the same time, excessive administrative regulation can create barriers to business development and limit patients' access to medicines.

Administrative mechanisms provide preventive control of the quality and safety of medicines through state registration, pharmacovigilance and supervision of the activities of pharmaceutical entities. The results of the study indicate the need to unify procedures and their digitalization to increase the effectiveness of control.

Analysis of EU norms and WHO recommendations showed that international standards are an effective guideline for the modernization of national legislation of Ukraine. Their implementation contributes to improving the quality of regulation, integration of the pharmaceutical market of Ukraine into the European space and protection of consumer rights.

Based on the study, the following are proposed: Harmonization of Ukrainian legislation with EU norms in the field of registration and pharmacovigilance; simplification and unification of administrative procedures; increased liability for violations of requirements for the quality and safety of medicines; introduction of digital control and supervision tools; ensuring a comprehensive approach to legal regulation that combines civil, economic and administrative legal mechanisms.

The results of the study can be used in legislative, regulatory and law enforcement practice, as well as for further scientific research aimed at developing legal regulation of the circulation of medicinal products in Ukraine.

Acknowledgement

None.

Conflict of Interest

Authors have no conflict of interest to declare.

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