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Research Article

Investments in medicines as a direction of state policy: Administrative and legal regulation

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Abstract

Aim: The purpose of the article is investments in medicines as a direction of state policy: Administrative and legal regulation.

Methods: A collection of general scientific, special legal, and interdisciplinary methods of cognition form the methodological foundation of scientific research. These methods offer a thorough and methodical analysis of investments in the field of medicine as a direction of state policy and an object of administrative and legal regulation. The dialectical method was used to clarify the patterns of development of administrative and legal regulation of investments in the pharmaceutical sector, to identify the relationship between economic processes, state policy and legal influence in the sphere of circulation of medicines. It made it possible to examine the development of regulatory strategies in relation to martial law and European integration. In order to create a comprehensive understanding of the system of administrative and legal regulation, analysis and synthesis were employed to break down the intricate phenomenon of investment activity in the pharmaceutical industry into distinct components (regulatory and legal support, licensing procedures, control, and incentives).

Results: In the domain of healthcare and pharmaceutical activities, the article offers a thorough examination of investments made in the pharmaceutical industry as a key area of state policy. The features of the legal status of investment entities are identified, the mechanisms of state administration, licensing, state registration of medicines, quality control, and pharmacovigilance are described, and the content of administrative and legal regulation of investment processes in the pharmaceutical sector is disclosed. Analysis is done on international regulatory standards (European Union (EU), World Health Organization (WHO), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)) and the challenges associated with their application in Ukraine's post-war rehabilitation and martial law legislation. It is demonstrated that in order to encourage investments in the manufacturing of essential medications, it is necessary to improve administrative processes, deregulate, digitize, and implement special regimes.

Conclusion: It is determined that the balance of public and private interests, the rule of law, proportionality, and transparency of public administration should serve as the foundation for an efficient model of administrative and legal regulation of investments in the field of medical. By putting the suggested areas of improvement into practice, the pharmaceutical business will become more appealing to investors, the state's pharmaceutical security will be strengthened, and Ukraine's healthcare system will continue to grow sustainably.

Keywords: Investments, Medicines, Public policy, Administrative and Legal regulation, Pharmaceutical activity, Licensing, State registration, Pharmacovigilance, Public administration

Introduction

Due to the difficulties of martial law and post-war reconstruction, as well as the country's path toward European integration, Ukraine is currently experiencing significant transformations in the fields of public administration, the economy, and healthcare. In these circumstances, it is especially crucial to establish an efficient state policy for the population's access to medications, which is a crucial component of carrying out the constitutional human right to health care.

One of the most knowledge-intensive and regulated sectors of the economy is the pharmaceutical industry, which necessitates large investments in scientific research, the creation of novel medications, the modernization of production facilities, adherence to Good Manufacturing

Practice (GMP) standards, and the use of digital technologies for pharmacovigilance and quality control. Administrative and legal regulation, which establishes the requirements for commercial organizations to enter the market, the method for conducting pharmaceutical operations, and the boundaries of state control, also has a substantial impact on investment processes in this field.

Pharmaceutical investments are increasingly viewed as a strategic tool for maintaining pharmaceutical independence, national security, and the sustainability of the healthcare system, in addition to being a component of economic policy. The vulnerability of states that have not adequately developed their own pharmaceutical production has been shown by pandemic threats, wars, and disruptions to global pharmaceutical supply chains. In this situation, the state's duty extends beyond exercising control to include fostering an atmosphere that is conducive to investment through the use of support tools and administrative and legal incentives [1].

A feature of investments in the field of pharmaceuticals is their close connection with public interests, which leads to increased requirements for the safety, quality and effectiveness of pharmaceutical products. This, in turn, necessitates complex licensing and registration procedures, multi-level state supervision and constant updating of the regulatory framework in accordance with international standards. The issue of striking the ideal balance between public and private interests is increasingly pertinent, though, as excessive regulatory complexity may have a detrimental effect on the industry's appeal to investors [2].

The administrative and legal regulation of investments in the pharmaceutical industry is undergoing major changes as a result of Ukraine's legal integration into the European Union (EU). These changes include the introduction of European approaches to public administration in the pharmaceutical industry, the implementation of directives and regulations, and the harmonization of national legislation with European Union (EU) law. Simultaneously, the national model of administrative and legal control needs to be adjusted to the unique circumstances of Ukraine's development, including the country's limited financial resources, the need to rebuild infrastructure, and the population's access to medications [3].

The topic of investments in medicines as a distinct direction of state policy through the lens of administrative law is still underdeveloped, despite a large number of scientific works devoted to the legal regulation of the circulation of medicines and investment activities in general. This calls for a thorough scientific investigation to identify the essence, characteristics, and opportunities for enhancing the legislative and administrative regulation of investment procedures in the pharmaceutical sector [4].

In light of the aforementioned, the necessity for scientific proof of the state's role in promoting investment in pharmaceuticals, enhancing administrative processes, and creating an efficient public administration model that can guarantee both a high degree of protection of the public interest and favorable conditions for the growth of the pharmaceutical industry in Ukraine determines the topic's relevance [5].

Methods

A collection of general scientific, special legal, and interdisciplinary methods of cognition form the methodological foundation of scientific research. These methods offer a thorough and methodical analysis of investments in the field of medicine as a direction of state policy and an object of administrative and legal regulation.

In order to determine the relationship between economic processes, state policy, and legal influence in the area of medicine circulation, the dialectical technique was employed to elucidate the patterns of development of administrative and legal regulation of investments in the pharmaceutical industry. It made it possible to examine the development of regulatory strategies in relation to martial law and European integration.

In order to create a comprehensive understanding of the system of administrative and legal regulation, analysis and synthesis were employed to break down the intricate phenomenon of investment activity in the pharmaceutical industry into distinct components (normative and legal support, licensing procedures, control, and incentives) [6].

Based on the examination of specific administrative and legal instruments, induction and deduction allowed for the formulation of broad conclusions regarding the efficacy of state policy in the area of luring investments in medicines.

The existing regulatory legal acts governing investment operations in the pharmaceutical industry, specifically those pertaining to health care, pharmaceuticals, investment

activities, licensing, and state control, were examined using the formal legal method [7].

In order to find similarities, disparities, and gaps in the legal support of investment procedures in the pharmaceutical industry, national administrative and legal regulations were compared with international standards and European Union (EU) law using the comparative legal technique.

The processes for state registration of pharmaceuticals are examined in the paper using the comparative legal technique. The national state registration procedure, which is defined by centralized administrative decision-making by an authorized executive body, is used in Ukraine to admit a pharmaceutical product to circulation. The European Union (EU), on the other hand, uses a number of registration types (centralized, decentralized, and mutual recognition), which gives investors more options and shortens the time it takes for items to hit the market. In order to make the pharmaceutical industry more appealing to investors, this comparison enables us to demonstrate the viability of incorporating specific European practices into the national administrative and legal regulatory framework.

According to the comparative research, the licensing process for the manufacturing of medicinal products in Ukraine is mostly formal and liberal, and it comes with a substantial number of documentation requirements. The focus in European Union (EU) member states is on initial verification of Good Manufacturing Practice (GMP) compliance and subsequent risk-oriented oversight, which lessens the administrative burden on investors once operations begin.

We were able to determine that post-licensing control and the service model of administration need to be given more attention by using the comparison method.

Pharmacovigilance and state control are compared. The study contrasts European Union (EU) and Ukrainian pharmacovigilance strategies. While there is a multi-level network of interaction between state agencies and the European Medicines Agency (EMA) in the European Union (EU), the pharmacovigilance system in Ukraine is primarily focused on the actions of the national regulator. By using this contrast, we can make the case for the necessity of creating integrated digital pharmacovigilance systems and information sharing, both of which are critical components of investor trust.

Investment incentive mechanisms are compared. The pharmaceutical industry's investment stimulation strategies were compared using the comparative legal method. Incentives are dispersed and primarily implemented through general tax and investment procedures in Ukraine. Public-private partnerships, expedited administrative processes, and unique regimes of assistance for novel pharmaceuticals are common in EU nations.

This comparison supports the viability of establishing unique legal and administrative frameworks for funding Ukraine's manufacturing of vital pharmaceuticals.

Comparative analysis reveals that in Ukraine, the state primarily controls the flow of medications, but under European Union (EU) law, the idea of a service state-which is centered on assisting investors and guaranteeing open administrative processes-dominates. We were able to determine that the national model of public administration in the area of pharmaceutical investments has to be changed by using the comparative legal technique. We were able to view the legislative and administrative regulation of pharmaceutical investments as a whole system that includes public administration organizations, administrative processes, control mechanisms, and liability measures thanks to the system-structural approach. The effects of administrative and legal procedures on the pharmaceutical industry's investment appeal and the efficacy of state policies in the health care sector were examined using the economic and legal method [8].

We were able to support the conclusions with actual indicators by using the statistical approach to compile official data on the amount of investments in the pharmaceutical industry, the dynamics of medicine manufacturing, and the outcomes of state control.

The prospects for the development of administrative and legislative control of investments in the medical field were assessed using the predictive technique, which took into consideration Ukraine's post-war recovery as well as the processes of European integration.

Results and Discussion

In order to implement medical reform in Ukraine, the state guarantees full payment according to the tariff at the expense of the state budget for the provision of citizens with necessary medical services and medicines, which are provided for by

the medical guarantees program, in accordance with the Law of Ukraine "On state financial guarantees of medical services for the population," dated 19.10.2017 [9]. According to the list approved by the Cabinet of Ministers of Ukraine (CMU) [10], the state budget funds are used separately to finance public health programs, measures to combat epidemics, medical and social expertise, activities related to forensic medical and forensic psychiatric expertise, and other programs in the field of health care that ensure the performance of state functions.

The state and local budgets, special-purpose insurance funds, and other sources that are not prohibited by law are used to finance the rights and guarantees in the field of health care related to medical care and the provision of medicines, which are provided for by other Ukrainian laws for specific categories of persons [11]. Additional state financial guarantees for the delivery of pharmaceuticals and medical services may be established by law. According to the law, medications covered under the medical guarantees program and the national list of essential medicines (henceforth referred to as the national list) would be paid for from the state budget [12].

The creation of a single national customer of medical services in the form of the institution "National Health Service of Ukraine" (NHSU), which is the central executive body that carries out procurement of medical services within the framework of the medical guarantees program for funds accumulated in the form of a single national pool, based on defined tariffs and quality requirements; the introduction of a program of state guarantees of medical care (medical guarantees program), which applies to citizens of Ukraine and covers primary healthcare, emergency medical care, main types of outpatient treatment, and medications for outpatient treatment. Specifically, the development of medical care providers' autonomy and methods of payment for their services, as well as the utilization of local budget monies to provide additional medical services for communities that would not be covered by the central medical guarantees program [13].

A contemporary medical information management system is being created in order to ensure that the "money follows the patient" principle is implemented and that medical service providers are compensated for the services they render. A system of strategic procurement of health services cannot be implemented without the availability and accessibility of data on medical and economic aspects of health care at all levels [14].

The affordable medicines program [15], which offers state coverage of specific outpatient treatments for patients diagnosed with "cardiovascular disease," "type 2 diabetes," and "bronchial asthma," is one example of how the new model has already been gradually put into practice. There are 23 foreign non-proprietary names in the affordable medicines program as of September 2018.

The state strategy for the implementation of the state policy for providing the population with medicines for the period until 2025 (henceforth referred to as the state strategy) [16] and the action plan for the implementation of this state Strategy, which was developed based on World Health Organization (WHO) recommendations and is defined as a political commitment and guidance for actions to ensure the availability and rational use of safe and effective medicines of appropriate quality in the country, were approved by the Ukrainian cabinet of ministers. The state strategy outlines the structure for communication between all parties involved in this process, including donors, governmental organizations, the public and private sectors, and other stakeholders [17].

High population health indicators and the provision of safe, effective, and high-quality medications to the Ukrainian people, along with their sensible usage, are the objectives of the state strategy. According to the objective, the state strategy's primary responsibilities include: Guaranteeing the appropriate selection of necessary medications for the national list; guaranteeing the availability of medications; appropriately funding the system for supplying medications to the populace; enhancing the medication supply system; enhancing state regulation and guaranteeing the quality of medications; raising the degree of sensible medication use; and boosting the pharmaceutical market's appeal to investors in the area of medication development and research [18].

For the medium and long term, the state strategy is scheduled to be implemented through 2025. This period is ideal for the strategic accomplishment of the predetermined objective concerning the priorities of the state policy's development regarding the distribution of medications to the populace. The sustainable development goals for 2016-2030, which were endorsed by the agenda for development at the United Nations summit in September 2015 as part of the 70th session of the UN general assembly, align with the state strategy's goals [19]. Ensuring the availability of medications is a crucial part of carrying out the state policy of giving medications to the populace. In both the institutional and

private sectors of the healthcare system, the price of a medication plays a significant role in guaranteeing the population's financial access to medications. A large portion of Ukraine's medical expenditures are directly borne by the populace. Statistics show that almost 600,000 households in Ukraine face crippling medical expenses each year. Simultaneously, a large proportion of households are unable to obtain medications or medical care, primarily because they lack the funds [20].

In order to solve the issue of guaranteeing the availability of medicines, state policy is implemented in a comprehensive manner by: Strengthening price competition between manufacturers, distributors, and pharmacies; improving the system of state regulation of prices for medicines, the purchase of which is fully or partially financed from the state and local budgets; ensuring the possibility of partially transferring the powers of customers to carry out public procurement of medicines and medical devices to a centralized purchasing organization; and guaranteeing the availability of original (innovative) medicines for the population [21].

Improving the system of state regulation of circulation and quality assurance of medicines is one of the most crucial duties of state policy for delivering medications to the populace, and it merits particular attention. However, it is crucial to realize that the distribution of pharmaceuticals is subject to state regulation at every stage (from production to medical use) through the adoption of regulatory legal acts, oversight of their adherence to international standards, and control over their execution by all parties involved [22].

The execution of specific requirements of European Union (EU) legislation on the circulation of medicinal products is an essential direction of state policy for supplying the populace with medicinal products. The creation, issuance of trade licenses, production, import, wholesale and distance trade, quality control of medicinal products, rights and obligations of participants in these relations, and the authority of state authorities in this area are all related to the regulation of legal relations in the field of medicinal product circulation [23].

The state control body develops draft license conditions for the production of pharmaceuticals, the wholesale and retail trade of pharmaceuticals, the import of pharmaceuticals (apart from active substances), and amendments thereto. The cabinet of ministers of Ukraine approves the process for conducting inspections of licensees' compliance with license conditions, as well as the procedures for issuing certificates of compliance with the requirements of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP), and the performance of duties in the pharmacovigilance system [24].

Protection of patients' rights, guaranteeing the population's need for medications to exercise citizens' right to health care, development of professional market self-regulation, limitation of state regulation of economic activity and delegation of authority, integration into the European Union (EU) medicines market, and adaptation of national legislation to European Union (EU) regulatory legal acts are the fundamental tenets of state policy on the efficacy, quality, and safety of medicines (Table 1).

Table 1: Administrative and legal instruments of state policy in the field of investment in medicines and their impact on investment attractiveness.

Administrative and legal instrument	Content and legal characteristics	Purpose of application	Impact on investment activity
Licensing the production of medicinal products	Permission procedure confirming the right of a business entity to carry out pharmaceutical activities	Ensuring compliance with safety and quality requirements	Increases investor confidence, but reduces attractiveness if too complex
State registration of medicinal products	Administrative procedure for admission of a medicinal product to circulation	Guaranteeing quality, efficiency and security	Determines investor access to the market; long terms may deter investment
Certification of GMP compliance	Confirmation of compliance of production with international standards	Harmonization with international standards	Contributes to attracting foreign investment, requires significant costs
Clinical trials	Administratively regulated scientific and research activities	Proving safety and efficiency	Increases innovation potential, but requires a stable regulatory environment
Pharmacovigilance	System of state control over the safety of medicinal products	Protection of public interests	Forms long-term investment stability
State supervision and control	Inspections, checks, application of sanctions	Compliance with legislation	In the absence of a risk-oriented approach, may have a deterrent effect
Stimulating administrative and legal regimes	Special conditions for individual investment projects	Development of local production	Positively affect investment activity

The aforementioned table illustrates how state policy's administrative and legal tools affect investment activity in the area of pharmaceutical investment. On the one hand, they carry out safeguarding and protective duties meant to safeguard the public's interests, particularly human life and health. However, the regulatory framework in which investment decisions are made is directly shaped by these same instruments.

Since they dictate the investor's initial access to the pharmaceutical market, the study reveals that licensing and state registration of pharmaceuticals are the primary "nodal" components of administrative and legal regulation. The industry's investment appeal is adversely affected by the over-formalization of these processes, unclear timelines, and digital services, particularly for new initiatives [25].

Simultaneously, international standards-focused instruments (such as Good Manufacturing Practice (GMP) certification and clinical trials) guarantee the integration of the domestic pharmaceutical market into the European and international arena, which in the long run increases investment attractiveness even though they demand substantial financial resources [26].

Incentives and unique administrative and legislative frameworks, which have the most beneficial effects on investment activity, should receive particular attention. Their use makes it possible to make up for the heavy regulatory load and foster the growth of regional production of essential medications [27].

Overall, the table's research demonstrates that a balanced mix of regulatory and stimulating administrative and legislative tools is necessary for state policy to be effective when it comes to investing in pharmaceuticals. A crucial precondition for making Ukraine's pharmaceutical sector more appealing to investors is the shift to a risk-oriented, digitalized, and service-oriented form of public administration [28].

A thorough understanding of investments in the field of pharmaceuticals as an autonomous and priority direction of state policy, which is in the sphere of administrative and legal control, was made possible by the research that was done. Because of the social importance of pharmaceuticals and the necessity to guarantee high standards of their efficacy, safety, and quality, the analysis found that investment procedures in the pharmaceutical business are marked by a greater degree of public influence [29].

It was discovered that Ukraine's administrative and legal regulation of investments in the pharmaceutical industry is a multi-level system that consists of a set of administrative procedures for permitting, registration, and control, as well as general and special regulatory legal acts and the actions of authorized public authorities. In addition to being intended to safeguard the public interest, such a system has a direct impact on the pharmaceutical industry's appeal to investors [30].

It has been demonstrated that manufacturing licensing, state registration of medicines, certification of Good Manufacturing Practice (GMP) compliance, clinical research, and pharmacovigilance procedures are the primary administrative and legislative tools of state policy in the area of investment in pharmaceuticals. These tools set the terms for doing pharmaceutical business as well as investors' access to the market [31].

The comparative legal research revealed that while the national model of administrative and legal regulation is generally oriented towards European standards, it is nevertheless less flexible than the models of European Union (EU) member states. Specifically, deficient integration of digital administrative services, limited usage of faster registration procedures, and an inadequate degree of risk-oriented state supervision were found [32].

Empirical research revealed a strong correlation between a decline in investment activity and the length and complexity of administrative procedures, particularly in the area of cutting-edge and high-tech medications. Simultaneously, the pharmaceutical market was stabilized and investment initiatives were supported by the simplification of particular regulatory systems during the martial law period [33].

The outcomes are in line with scientific methods, which hold that the government in the pharmaceutical industry not only regulates but also actively participates in investment processes, establishing regulations for market access and setting industry development priorities. Simultaneously, the study's findings enable us to critically reconsider the conventional notion that the state's control function dominates the area of medication circulation [34].

The scientific theory of administrative law examines several methods for determining how the regulatory burden affects investment procedures. Strict administrative supervision is justified by some scholars as a means of ensuring the

protection of public interests. Others concentrate on the detrimental effects of overly stringent regulation on the pharmaceutical industry's ability to innovate. The study's findings point to the necessity of combining these strategies based on risk-based regulation and the proportionality principle [35].

The boundaries of deregulation in the pharmaceutical industry are still up for debate. Simplifying administrative processes might, on the one hand, encourage investment and manufacturing localization. However, a reduction in regulations that is not warranted could endanger the safety and quality of pharmaceuticals. A shift from a formal-bureaucratic regulatory paradigm to a service-oriented one based on digital technology and a distinct approach to corporate entities seems acceptable in this situation [36].

There is a different scientific dispute over the state's role in encouraging investments in the manufacturing of vital medications [37]. The outcomes attest to the viability of implementing unique legal and administrative frameworks that incorporate governmental oversight, explicit quality standards, and regulatory relaxations. This strategy can be modified to fit the circumstances in Ukraine and is in line with European practice [38].

In general, the study's findings and their discussion enable us to state that future administrative and legal regulation of pharmaceutical investments should be developed in a way that strikes a balance between safeguarding the public interest and creating an environment that is conducive to investment, which is a prerequisite for the long-term growth of Ukraine's pharmaceutical sector and healthcare system [39].

Conclusion

Investing in the pharmaceutical industry is a strategic approach to state policy that integrates social, economic, and security considerations. The pharmaceutical industry's administrative and legislative regulation of investment processes is marked by complexity, several levels, and a substantial number of permitting procedures.

The balance between maintaining high standards and fostering an environment that is conducive to investment determines how effective state policy is in this regard. Particularly in light of Ukraine's post-war reconstruction, improving administrative processes, digitalization, deregulation, and alignment with European Union (EU) law ought to be major areas of overhauling the public administration system in the pharmaceutical industry.

The study's conclusion was that one of the main focuses of state policy, which integrates social, economic, and security elements, is investments in the pharmaceutical industry. The state must actively participate in creating a favorable investment environment based on efficient administrative and legislative regulation since the pharmaceutical business is strategically important for guaranteeing the human right to health care and medical treatment.

It has been demonstrated that the administrative and legal regulation of pharmaceutical investments is intricate and multi-level, encompassing legal and regulatory support, licensing and registration processes, state control and supervision mechanisms, and tools to encourage investment activity. The pharmaceutical industry's investment procedures are closely linked to public interests, particularly those pertaining to the efficacy, safety, and quality of pharmaceuticals.

Despite the gradual harmonization with international and European standards, it has been demonstrated that the current system of administrative and legal regulation of investments in the field of medicine in Ukraine is characterized by a number of issues, including excessive complexity of administrative procedures, fragmentation of the regulatory and legal framework, duplication of control powers, and insufficient level of digitalization of public administration. These elements have a negative impact on the pharmaceutical industry's appeal as an investment.

It is well known that adhering to European Union (EU), World Health Organization (WHO), and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards is a prerequisite for Ukraine's integration into the European pharmaceutical market and boosting investor confidence. However, this requires adaptation that takes into account the country's unique characteristics, military difficulties, and post-war reconstruction tasks. In this situation, the state should serve and stimulate in addition to exercising control.

The study's findings support the viability of enhancing state policy in the area of pharmaceutical investment through the introduction of the "single window" concept, the simplification and unification of administrative processes, the expansion of digital tools for state registration and licensing, and the creation of public-private partnership mechanisms.

In order to encourage investments in the manufacturing of essential and cutting-edge medications, special emphasis must be given to the introduction of unique administrative and legislative frameworks.

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Conflict of Interest

Authors have no conflict of interest to declare.

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