
RESEARCH OF PHARMACEUTICAL SECURITY AS A COMPONENT OF ECONOMIC SECURITY OF THE STATE

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Annotation. Today, socio-economic, political, environmental prerequisites have been formed for the formation of the pharmaceutical safety system of Ukraine, the institutionalization of which provides for the implementation of the relevant state policy, which will determine state priorities in certain areas of pharmaceutical safety in Ukraine.

The work is devoted to the study of approaches to the definition of "pharmaceutical safety" of the state, the description of the theoretical foundations, the gist and its components, as well as the assessment of the current state of the level of economic security of the pharmaceutical industry and the development of recommendations for ensuring the economic security of the pharmaceutical industry of Ukraine. Attention is paid to the role and place of pharmaceutical safety in the economic system of the state, the identification of threats and ways to achieve an appropriate level of pharmaceutical safety. It is concluded that the requirements for the economic security of the pharmaceutical industry do not correspond to the actions actually taken in this direction, the lack of a systematic approach to raising the level of domestic production for import substitution of medicines and solving many other problems in this area.

Keywords: pharmaceutical security, economic security, economic security problems, national security, medicines, economic security of pharmaceutical enterprises; E20, P23.

INTRODUCTION

The pharmaceutical industry is strategic for each country, taking into account not only the economic potential, priorities for the implementation of social policy, but also taking into account the country's vital functions in case of force majeure (natural disasters, man-made disasters, military operations).

The development of the health care system has a direct impact on the basic indicators of life in any country, and access to modern medicines leads to a reduction in health care costs by preventing disease and avoiding the need for hospitalization. Innovative medicines not only increase average life expectancy but also have a positive effect on increasing productivity and increasing labor force, business operations and jobs, training for doctors and patients, transfer of know-how, a general increase in the level of medical knowledge in the country, an influx of additional tax revenues, etc. Therefore, the pharmaceutical healthcare industry should be

considered as strategic for Ukraine, taking into account not only the economic potential, priorities for implementing social policies, but also taking into account the sustainable development and functioning of the state. Considering the social significance of safety problems in the pharmaceutical industry itself (safety of the use of medicines, economic safety of pharmaceutical industries), it seems appropriate to formulate the concept of pharmaceutical safety at the national level to ensure a comprehensive approach and a comprehensive solution to health issues. The multidimensional nature of security problems in the pharmaceutical industry should determine the formation of the state pharmaceutical safety policy today and systematically cover all these issues.

The analysis of publications devoted to the issue of pharmaceutical safety demonstrates the absence of a unified approach among scientists both to the definition of the term “pharmaceutical safety” and to comparison with other elements of economic security. Domestic researchers (A. Viktorova, L. Kovtun, K. Kosyachenko, O. Lebeda, V. Maltsev, A. Stefanova and others), addressing the issues of pharmaceutical safety, mainly focus on issues of quality, sufficient assortment and price drug policies [6, 9]. But systematic comprehensive research that would cover the development of mechanisms to counter threats associated with the improper and inefficient functioning of the pharmaceutical industry (taking into account foreign economic security, the safety of the domestic pharmaceutical market, pharmaceutical enterprises, intermediaries, consumers, environmental and military aspects) in domestic pharmaceutical and economic science up to still not. Emerging is the institutional provision of the pharmaceutical safety of Ukraine. General theoretical aspects of the economic security of the state are considered and highlighted in the works of E. Belousov, D. Zadykhailo, V. Pashkov, A. Sukhorukov, L. Shevchenko, and others. The works of A. Datsko, A. Datsko, V. Shapovalova, V. Chernykh is devoted to the definition of theoretical and methodological principles and criterias the formation of the state pharmaceutical safety, the analysis of indicators of pharmaceutical safety in the context of trends in the domestic pharmaceutical market, the development of conceptual approaches to the formation of the pharmaceutical safety system of Ukraine. Domestic researchers I. Gerasimenko, V. Golub, G. Olasyuk, and foreign scientists S. Golant, D. Kuznetsov, E. Korzhavomu, V. Moshkova are engaged in the economic security of the pharmaceutical industry and the improvement of terminology [4, 7].

The aim of the article is to study approaches to determining the pharmaceutical safety of the state, characterize the theoretical foundations, the gist and its components, as well as

assess the current state of the level of economic security of the pharmaceutical industry and develop recommendations to ensure the economic security of the pharmaceutical industry of Ukraine.

Methodology of the research – the theoretical and methodological foundation of the work based on the main theoretical references in the area of economic security in the pharmaceutical industry.

The economic security of the state is one of the most important components of a holistic system of national security as a complex of protection of national interests, as well as the basic, decisive condition for observing and realizing national interests. Although in many policy documents on the development of Ukraine the tasks of leveling the risks associated with threats to pharmaceutical safety are recognized as one of the priorities, it is stated that the dangers associated with inadequate regulation and development of the pharmaceutical market are significantly exacerbated. The components of economic security are:

- industrial safety;
- demographic security;
- energy security;
- external economic security;
- investment and innovation security;
- macroeconomic security;
- food security;
- social security;
- financial security [2, 8].

For the formulation of the conceptual apparatus of the pharmaceutical safety of the state and the identification of the relationships between the concepts, we consider it appropriate to consider the pharmaceutical safety of the state in a broad and (narrow) applied sense. In a narrow sense, the pharmaceutical safety of the state covers the safety of pharmaceutical development, preclinical and clinical trials of a drug, production safety (including the safety of substances used for the manufacture of medicines), drug safety during handling (transportation, storage, disposal, medical use, pharmacovigilance), etc.

Pharmaceutical safety in the broad sense provides for the creation of an appropriate regulatory framework necessary for the effective functioning of the pharmaceutical safety system:

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- improvement of its organizational structure;
 - prediction of changes occurring in them, and potential threats to pharmaceutical safety;
 - development of scientifically based proposals and recommendations for creating a strategy of pharmaceutical safety of the state;
 - assessment of the effectiveness of actions to ensure pharmaceutical safety and determine the costs for these purposes;
 - participation in bilateral and multilateral cooperation in the field of pharmaceutical safety.

In most cases, the term «pharmaceutical safety» by domestic scientists is used in an applied sense, as a synonym for the term «drug safety». Researchers who limit the interpretation of «pharmaceutical safety» to the safety of their pharmacological action, determine that it is formed at the stage of pharmaceutical development, during industrial production, preclinical and clinical studies, at the stage of registration and monitoring of drug safety, is carried out throughout their life cycle and should be ensured by observing the appropriate standards of pharmaceutical practice [7].

In a several works the term «vital security» is introduced and it is considered as a component of national security, that is, the safety of life and health of citizens. It is emphasized that the problem of determining, qualifying and economic and legal regulation of ensuring vital security as an object of legal economic order can be the key to the effective functioning of the health system. Moreover, it is important to proceed from the fact that at a certain stage the issue of vital security as a component of national security goes beyond the boundaries of the economic and legal context and acquires constitutional and legal political significance [10].

Z. Golant defines the concept of economic security of the pharmaceutical industry as the state of the financial, scientific, research, technological, industrial and human potential of the industry, institutional, legal, organizational and economic relations of government bodies and manufacturers, ensures its ability to operate on an innovative basis and guarantees accessibility for the population and high medical effectiveness of vital and important medicines. The researcher identifies two main systemic threats to the economic security of the country's pharmaceutical industry:

- 1) immediate threat (inability to provide the population with the basic range of medicines, the entire production cycle of which is located in the country);

2) strategic threat (low level of innovation and technology used in the development and production of medicines).

The author focuses on four principles of ensuring the economic security of the pharmaceutical industry:

- 1) the principle of dominance of the innovation model of industry development;
- 2) the principle of the rule of quality, efficacy and safety of medicines;
- 3) the principle of priority of the national pharmaceutical industry in implementing state programs in the field of providing the population with medicines;
- 4) the principle of import substitution of domestic drugs, the full production cycle of which is located in the country [4].

In connection with the objective need to expand the facilities and entities that are involved in pharmaceutical safety in certain countries, international organizations in the field of healthcare and pharmacy have developed several regulatory documents and introduced organizational and economic mechanisms to ensure it, not only for the quality of medicines.

This problem is being actualized due to the lack of a clear legislative definition of the term «pharmaceutical security of the state» in Ukraine, which creates uncertainty in the actions of the state administrative apparatus and leads to errors in the formation of regional and state economic development and health programs. Accordingly, the formation of the development policy of the pharmaceutical industry should take into account the dualistic interests of the subjects of this market:

- firstly, the pharmaceutical market should most effectively meet the needs of the population in medicinal products, determining the priority of consumer protection about the range, prices of pharmaceutical products;

- secondly, manufacturers and distributors of pharmaceutical products seek to maximize profits and therefore form pricing, assortment policy according to the business attractiveness of the market segment, often ensuring the implementation of social policy priorities [3].

Summing up, we note that the pharmaceutical security of the state comprehensively takes into account the need to mitigate the risks associated with the development, production, promotion, consumption and disposal of pharmaceutical products in the context of the safety of the population, state pharmaceutical enterprises, the environment, as well as the country's defense and economic independence. Therefore, the pharmaceutical security of the state is defined as the socio-economic and environmental status of the state in which:

-all its citizens are stably and guaranteed provided with medicines and medical supplies in the required quantity, assortment, and appropriate quality, at affordable prices;

- at which the guaranteed necessary stock of medicines and medical devices in case of emergency is formed;

- the pharmaceutical market has a low level of import dependence (the total share of domestic pharmaceutical supply with domestic production needs meets the pharmaceutical safety criterion set by the World Health Organization at least 70%);

- domestic pharmaceutical industry enterprises systematically and economically soundly introduce the production of innovative products;

- guaranteed political, economic and physical security, as well as transparent competition and access to markets for all operators of the pharmaceutical market;

- the development, production, use and disposal of pharmaceutical products meet international environmental safety standards;

- domestic pharmaceutical enterprises and intermediaries are competitive in the global pharmaceutical market, and the state occupies a leading position among the leading exporters of pharmaceutical products.

The pharmaceutical market in Ukraine is one of the fastest-growing (about 20% per year) and dynamically developing. The production of pharmaceuticals, compared to the same period in 2017, increased in 2018 by 22.5% in monetary terms and by 4% in commodity terms. Ukraine is one of the largest drug manufacturers in Eastern Europe. To date, the pharmaceutical industry of Ukraine, according to the State Service of Ukraine on Medicines and Drugs Control, is represented by 120 enterprises that have licenses for the production of medicines [5].

According to PharmaBoardroom, the TOP-10 manufacturing companies leading in terms of sales in the commercial pharmaceuticals market of Ukraine included four Ukrainian enterprises – JSC Farmak with a market share of 5.6%, Arterium Corporation with a market share of 3, 7%, CJSC Pharmaceutical Firm Darnitsa with a market share of 3.4%, LLC Pharmaceutical Company Zdorovie with a market share of 3.2% in value.

The export of Ukrainian pharmaceuticals is quite developed, Ukraine exports medicines to 50 countries. The main importers are the CIS countries. The three leaders include Uzbekistan, Kazakhstan, and Russia – in 2018 they purchased products for a total of 94.6 million \$ – these are mainly dosed drugs. The only major buyer in Southeast Asia is Vietnam – 4.9 million \$ (antibiotics and cardiac drugs). The largest importer in South America is Brazil (insulin) [5].

Now in Ukraine, a significant reserve of import substitution of drugs of cardiology, anesthesiology, rheumatology, antimicrobial agents is being formed, which allows abandoning 63% of imported analogues. The domestic pharmaceutical industry provides jobs for more than 25 thousand citizens of Ukraine, excluding pharmacists.

The current situation at the level of the ukrainian pharmaceutical industry indicates the presence of threats to the development of the economic security of the pharmaceutical industry.

The author has investigated the external (Fig. 1) and internal (Fig. 2) threats to the economic security of the pharmaceutical industry.

Common problems include the conditions of the activity of enterprises in Ukraine, namely, financial-economic changes, instability of price and economic policies of the state, the low purchasing power of the population, insufficient working capital of the main customers.

Domestic pharmaceutical production is in most cases an integrated interaction of foreign manufacturers and domestic enterprises. A characteristic feature of the pharmaceutical market of Ukraine is its high dependence on imports of basic raw materials and supplies, which links both the cost structure and the level of selling prices to fluctuations in the national currency against the euro and the dollar. The raw materials and materials of Ukrainian production are mostly represented by auxiliary materials, while at the same time, low price segment products occupy part of the Ukrainian pharmaceutical market. Therefore, the pharmaceutical industry of Ukraine is not yet able to provide the domestic market with the main range of modern medicines, the entire production cycle of which would be located in Ukraine.

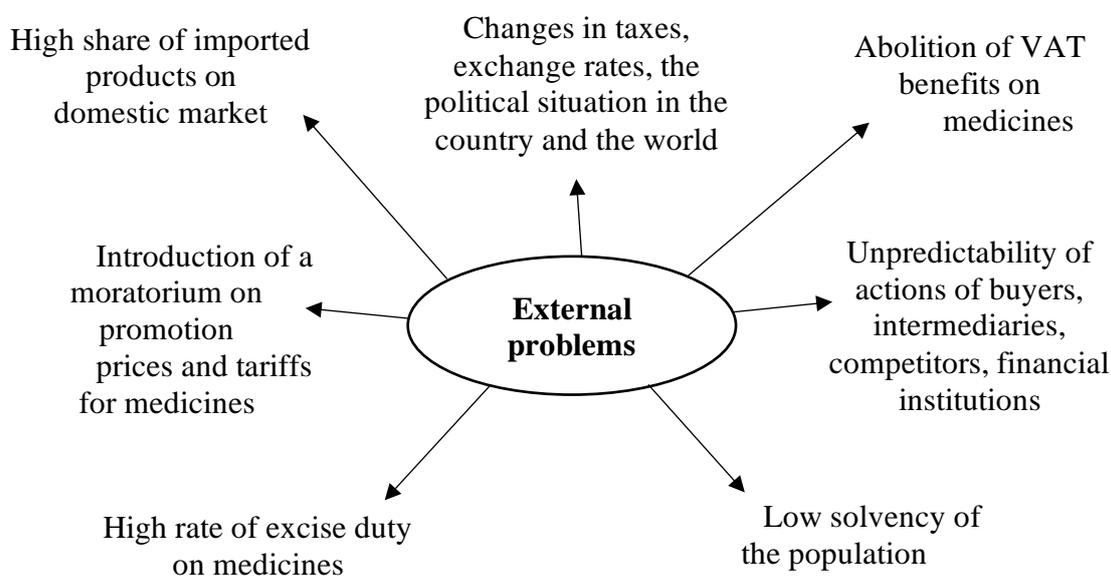


Figure 1. External problems of the economic security of the pharmaceutical industry

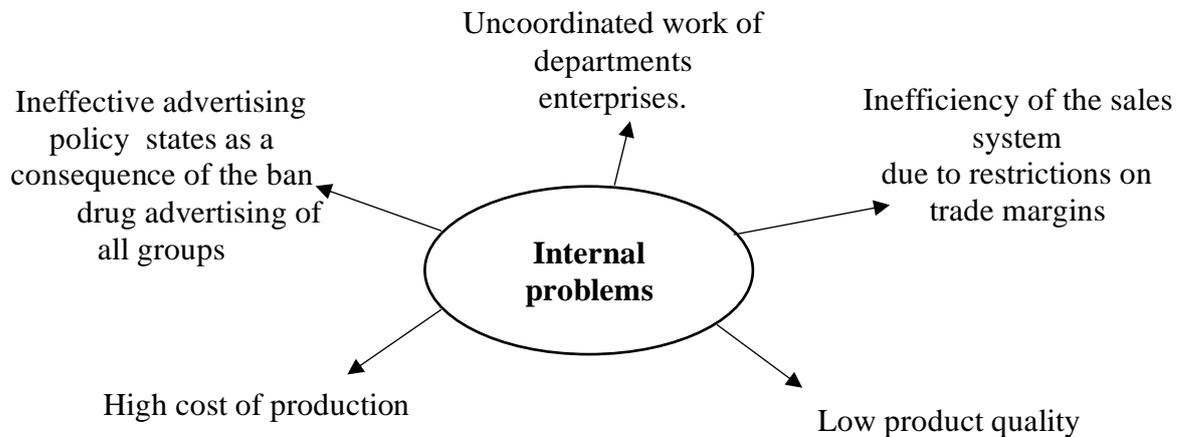


Figure 2. Internal problems of the economic security of the pharmaceutical industry

A threat to the market component of the economic security of the pharmaceutical industry is a very low solvency of the population. That is, in practice, the main goal of any industry is not fulfilled – to bring products to the consumer. To eliminate this threat, it is necessary to solve the problem of pricing and the accrual of interest on medicines of both domestic production and imported funds.

It should also be noted the inconsistency of many Ukrainian pharmaceutical manufacturings with the international GMP standard and other international standards. That is why the industry needs investment income for the introduction of modern technologies for the production of medicines at all pharmaceutical enterprises of Ukraine in to bring it closer to international standards and increase the volume of domestic products in the domestic and foreign markets. In particular, to ensure the level of economic security of the pharmaceutical industry, it remains possible to conclude direct agreements between pharmaceutical companies and the state [1].

There are specific problems in pharmaceutical production, such as the introduction of a moratorium on increasing prices and tariffs for medicines and medical products, the establishment of restrictions on the trade margin for distributors of domestic drugs, the high excise tax rate on drugs, the low technical level of production in the country, and the high cost of production, a drop in demand for OTC drugs, a shortage of raw materials from domestic producers and fluctuations in prices for imported raw materials. Under these conditions, achieving an adequate level of providing the population with medicines depends largely on the realization of the economic security of the pharmaceutical industry.

Another problem in ensuring the economic security of the pharmaceutical industry in Ukraine is the falsification of pharmaceutical products. The counterfeit market volume is just over 150 items that belong to the middle price category and are most popular with buyers. About a third of the total volume of counterfeit medicines enters the domestic market from India, China and Poland. The main reasons are the imperfection of the legal framework and the lack of a mechanism to hold accountable for the sale of counterfeit goods [9].

These specific problems, as well as increased competition in the Ukrainian pharmaceutical market and competition with cheaper products of manufacturers certified according to GMP (India, Russia, Belarus), indicate that the success of the pharmaceutical industry depends on the correctness of the chosen model of market behavior, sales policy, pricing and the like.

The considered problems in the field of economic security of the pharmaceutical industry in Ukraine allow us to highlight a some areas for ensuring economic security:

- formation and state support for the production of high-tech innovative drugs, chemical and biotechnological substances;
- providing the pharmaceutical industry with highly qualified personnel;
- stimulation of domestic production of cheap analogues of imported generic and innovative medicines and their inclusion in the list of vital and most important medicines;
- improvement of state regulation of prices for medicines;
- improvement of regulation in the field of state registration of medicines and certification of manufacturing companies for GMP compliance;
- development of a cluster approach in the localization of pharmaceutical production.

CONCLUSIONS

Analysis of approaches to determining the pharmaceutical security of the state, as well as an assessment of the current state of the level of economic security of the pharmaceutical industry in Ukraine, allows us to conclude that further theoretical and practical developments in this area are necessary.

This problem is actualized due to the lack of a clear legislative definition of the concept of «pharmaceutical security of the state», which creates uncertainty in the actions of the state administrative apparatus and leads to errors in the formation of regional and national economic development programs and health programs.

The theoretical and methodological foundation of the work based on the main theoretical references in the area of economic security in the pharmaceutical industry.

For the formulation of the conceptual apparatus of the pharmaceutical safety of the state and the identification of the relationships between the concepts, we consider it appropriate to consider the pharmaceutical safety of the state in a broad and narrow (applied) sense. We define the pharmaceutical safety of the state as the socio-economic and environmental status of the state in which: all its citizens are stably and guaranteed provided with medicines and medical supplies in the required quantity, assortment and appropriate quality, at affordable prices; at which the guaranteed necessary reserve for emergency situations is formed; the pharmaceutical market has a low level of import dependence; domestic pharmaceutical companies are systematically and economically soundly introducing the production of innovative products; guaranteed political, economic and physical security, as well as transparent competition and access to markets for all pharmaceutical market operators; development, production, use and disposal of pharmaceutical products meets international environmental safety standards. Domestic pharmaceutical enterprises and intermediaries are competitive in the global pharmaceutical market, and the state holds leading positions among the leading exporters of pharmaceutical products.

The author has investigated the external (high share of imported products on domestic market; changes in taxes, exchange rates, the political situation in the country and the world; abolition of VAT benefits on medicines; introduction of a moratorium on promotion prices and tariffs for medicines; unpredictability of actions of buyers, intermediaries, competitors, financial institutions; low solvency of the population; high rate of excise duty on medicines) and internal (uncoordinated work of departments enterprises; inefficiency of the sales system due to restrictions on trade margins; low product quality; high cost of production; ineffective advertising policy states as a consequence of the ban drug advertising of all groups) threats to the economic security of the pharmaceutical industry.

At the present stage, the pharmaceutical market cannot guarantee the appropriate level of pharmaceutical safety only through self-regulatory mechanisms, therefore, it is necessary to protect the strategic interests of the state according to certain criteria of pharmaceutical safety of Ukraine and introduce appropriate legal, organizational, economic, informational mechanisms to ensure it.

Based on the study, it can be concluded that the requirements for the economic security of the pharmaceutical industry do not correspond to the actions actually taken in this direction, and there is no systematic approach to increasing the level of domestic production for the purpose of import substitution of medicines. The prospects for the sustainability of the economic security of the pharmaceutical industry are directly related to the effectiveness of government regulation, which must be implemented in two interrelated areas – organizational, administrative and economic.

The considered problems in the field of economic security of the pharmaceutical industry in Ukraine allow us to highlight a some areas for ensuring economic security: formation and state support for the production of high-tech innovative drugs, chemical and biotechnological substances; providing the pharmaceutical industry with highly qualified personnel; stimulation of domestic production of cheap analogues of imported generic and innovative medicines and their inclusion in the list of vital and most important medicines; improvement of state regulation of prices for medicines; improvement of regulation in the field of state registration of medicines and certification of manufacturing companies for GMP compliance;

Further development of research in the field of pharmaceutical safety (both theoretical and applied aspects) will contribute to the effective functioning of the pharmaceutical industry not only as one of the components of the country's economy, but will also help to build an effective system to neutralize threats of the health of the population of Ukraine.

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