**UDK [339.5:615.2/4]:346.548**
**JEL Classification: F13, F52, I18, O32**
**Doi: 10.31767/su.4(107)2024.04.04**

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# International Trade of Pharmaceutical Products and Issues of National Security

With the COVID-19 pandemic, the world entered a reality that can be called "medicines power". The closure of factories in China due to strict quarantine, the ban on exporting certain goods from India in early 2020, the unavailability of air transportation, and blocked sea routes caused disruptions in supply and blocked value-added chains. It became evident: there is a threat of depend on the import of active pharmaceutical ingredients and medicaments, medicinal, and pharmaceutical products, production of which is concentrated in Asia. It is clear that countries with scientific, technological, innovational and production capabilities to ensure the needs of healthcare sector (including pharmaceutical goods), are less vulnerable and dependent on imported supplies (mostly from unfriendly nations). On the contrary, countries lacking adequate resources face national security threats. These threats are especially exacerbated during epidemics, crises, environmental disasters, and military conflicts. The aim of this article is to analyze of EU policy and the key trends in the export of pharmaceutical industry products from the EU, especially after the large-scale russian military invasion of Ukraine in February 2022 (and the European Council's strong condemnation of russia's aggressive war against Ukraine, and the imposition of a series of sanctions); in particular the identification of the volume of exports to russia and Ukraine; the development of recommendations for Ukraine regarding the development of the pharmaceutical industry and reducing external dependence on supplies and threats to national security.

The analysis showed that in 2023, russia ranked 6th among the largest EU partners for the import of medicinal products, medical and pharmaceutical goods. The EU exported medicaments, medicinal, and pharmaceutical products to russia worth €8.8 billion (medicaments, medicinal, and pharmaceutical products became the leaders in exports from the EU to russia in 2022–2023). Ukraine paid $1.96 billion for the import of this goods; in 2023, the expenses increased to $2.21 billion (close to the amount paid in 2019, which was $2.24 billion), despite a significant decrease in Ukraine's population due to migration, casualties, and the temporary occupation of Ukrainian territories. Since the responsibility of governments lies in efforts to care for the nation's health, ensure the efficiency of the economic system and social stability, the article justifies the need to initiate negotiations with European partners regarding the construction of pharmaceutical enterprises (relocating from Asia), specifically for the production of pharmaceutical and biological ingredients, as well as finished medicines, within Ukraine. Such measures are a rational and politically justified decision. This will help reduce the EU and Ukraine's external strategic dependence on supplies (including from unfriendly countries) and ensure the regulation and management of the industry's development in national interests. In case of threats, this will allow measures to influence the structure and volume of production, which, as the 2020 lockdown showed, turned out to be impossible with the placement of production capacities in countries where the free flow of goods becomes difficult in crisis situations.

***Key words:*** *pharmaceutical industry, medicaments, medicinal, pharmaceutical products, international trade, high-tech pharmacy, exports, national security.*

**Introduction.** Military technologies have reached such a level of complexity and destructive power that world leaders in political conflict resolution and achieving ambitious goals since the end of the 20th century and to the present day have begun to apply alternative levers – goods that have political value. In the 1970s, in contrast to the oil power, when international supplies of black gold became a political weapon, the doctrine of "food power" was formulated. With the COVID-19 pandemic, the world entered a reality that can be called "medicine power". The closure of factories in China due to strict quarantine, the ban on exporting certain goods from India in early 2020, the unavailability of air transportation, and blocked sea routes caused disruptions in supply and blocked value-added chains. It became evident: the "powers that be" (both politically and economically self-confident countries) face a problem: they

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depend on the import of active pharmaceutical ingredients (APIs) and medicaments, medicinal, and pharmaceutical products, production of which is concentrated in Asia.

The European Parliament's resolution on the shortage of medicines confirmed the loss of European independence in the healthcare sector: 40% of finished medicines in the EU come from third countries; up to 80% of chemical APIs for the European industry are produced outside the Union (in the 1990s, their share was no more than 20%) [1].

Political figures in the United States became alarmed the alarm: the country imports nearly 80% of APIs for generics (non-patented medicines), on which millions of Americans rely. This poses a threat to national security, as foreign companies could limit or completely stop supplies during periods of heightened geopolitical tension or natural disasters. It is assumed that unscrupulous manufacturers could interfere with the composition of medicines, making them ineffective or turning them into weapons [2]. American politicians have pointed out the national security, economic, and public health issues arising from the United States' dependence on Chinese pharmaceutical products. In particular, during hearings on the growing U.S. dependence on biotechnology and pharmaceutical products from China, national security risks were discussed, including the ability to protect and meet the healthcare needs of military personnel, first responders, and the general population, given the current and potentially growing level of dependence. It was emphasized that the national security risks from importing medicines and their ingredients cannot be overstated, as pharmaceutical drugs are crucial, for example, to the Department of Defense's ability to enhance the health of its soldiers and protect them from nuclear, biological, and chemical threats. If the producing and supplying countries of these medicines and their components decide to limit or withhold supplies, it would have a devastating impact on the domestic pharmaceutical production of importing countries and could lead to a severe shortage of pharmaceutical products for both civilian and military use.

The Pharmaceutical Manufacturers of Ukraine Association, at the start of quarantine restrictions 2020, addressed an open letter to the country's leadership, noting that the shortage of ingredients for generics is a key issue for the domestic pharmaceutical industry [3].

These and similar statements indicate that countries with scientific, technological, innovational and production capabilities to ensure the needs of healthcare sector (including pharmaceutical goods), are less vulnerable and dependent on imported supplies (mostly from unfriendly nations). On the contrary, countries lacking adequate resources face national security threats. These threats are especially exacerbated during epidemics, crises, environmental disasters, and military conflicts.

**Literature review.** The interest of scientists in the topic of analysis of the pharmaceutical industry and trends in international trade is growing every year, especially after the global COVID-19 pandemic. Based on the results [4–7] the authors emphasize the need for government support in coordination and collaboration, rather than competitive struggle, when addressing global challenges and common security threats. A number of studies examine pharmaceutical trade in the context of national security [8]. Some studies focus on the collection and analysis of data on government interventions within the framework of medicines supply policies and the reduction of threats, with the aim of assessing the effects and impact of these measures on new challenges [9].

Ukrainian researchers have addressed the issues of strategic directions for the development of Ukraine's pharmaceutical industry, the challenges and prospects of EU membership, and the potential consequences for this industry [10; 11]. The paper provides an assessment of the competitive environment of the European Union's pharmaceutical market and a statistical evaluation of Ukraine's foreign trade in pharmaceutical products [12]. In Article [13], the state of the Ukrainian pharmaceutical industry under martial law is analyzed, and it is concluded that the existing production and scientific capacities, along with qualified personnel, allow for the rapid expansion of the range of medicines within the framework of public-private partnerships and state orders, which will enhance the resilience of the healthcare system in times of extreme conditions. The author of the work [14] emphasizes the need for state policy and the introduction of economic incentives, such as tax benefits, investment incentives, and the possible establishment of special economic zones for the pharmaceutical sector. Drawing on the best international practices, it is proposed to develop a comprehensive strategic document for the sustainable development of the pharmaceutical industry in Ukraine and addressing today's challenges. It should be noted that the conceptual foundations of the strategy for the development of the Ukrainian pharmaceutical industry were proposed in a 2020 study [15].

The aim of this article is to analyze of EU policy and the key trends in the export of pharmaceutical industry products from the EU, especially after the large-scale Russian military invasion of Ukraine in February 2022 (and the European Council's strong condemnation of Russia's aggressive war against Ukraine, and the imposition of a series of sanctions); in particular the identification of the volume of exports to russia and Ukraine; the development of recommendations for Ukraine regarding the

development of the pharmaceutical industry and reducing external dependence on supplies and threats to national security.

**Results and discussion.** For the EU leadership, the pharmaceutical industry has been a long-standing strategic priority, as evidenced by the European Commission's 1994 Communication on the principles of industrial policy in the pharmaceutical sector of the EU, which stated that this industry is one of the most effective high-tech sectors in Europe [16]. It creates a large number of jobs in the economy, plays a key role in the healthcare system, as well as in the social security system (the ability to finance the consumption of pharmaceutical products has a direct impact on national social security budgets).

A number of official EU documents adopted in the 1990s laid the foundation for the expansion of production and export of the European pharmaceutical industry [17-18]. For EU member states, the EU leadership has defined the basic principles of industrial policy regarding pharmaceuticals, namely: encouraging innovation and corresponding changes in the legal framework; protecting new medicinal products with intellectual property rights both within the EU and in third countries; ensuring the accessibility of medicines for optimal protection of the health of European citizens; promoting research on innovative treatment methods, which is especially important from a public health perspective, and encouraging research into rare diseases and the development of related medicines; expanding the volume and geography of pharmaceutical exports produced within the EU.

In 2014, the document "Pharmaceutical Industry: A Strategic Sector of the European Economy" was adopted [19]. The priorities outlined in the document were implemented during 2014–2020 within the framework of specific financial initiatives in the field of healthcare, including the Health Program, the European Research Program Horizon 2020, and the EU Structural Funds for 2014–2020. The Innovative Medicines Initiative (IMI) became one of the flagship research programs in the healthcare sector, implemented based on public-private partnerships in the life sciences field between the EU and the European pharmaceutical industry. IMI is focused on accelerating the development of higher-quality and safer medicines, increasing the success rate of clinical trials for new drugs and vaccines, speeding up the early stages of drug development, and creating new biological markers for disease diagnosis and treatment evaluation [20]. The implementation of the program contributes to the creation, production, and export of high-tech medicines and their ingredients.

In November 2020, the Pharmaceutical Strategy for Europe was adopted [21]. The main objectives of this strategy are to support the competitiveness, innovation potential, and resilience of the EU pharmaceutical industry. In May 2021, the EU leadership presented a revised version of the New Industrial Strategy for Europe [22], taking into account the circumstances of the COVID-19 pandemic. Among its tasks is ensuring the resilience of industry and reducing the dependence of industrial ecosystems, including the Healthcare Industrial Ecosystem, which encompasses pharmaceutical and medical products, personal protective equipment, and medical services. The goal is to promote interaction among stakeholders and assist policymakers and investors in identifying key players in each ecosystem during the preparation of national and regional recovery plans and investment projects in the pharmaceutical and medical sectors. Priorities include: diversified international partnerships, the creation of industrial alliances, reducing dependence on imports, and increasing exports.

The guidelines of both the pharmaceutical and industrial strategies guide the governments of EU member states towards the implementation of policies to address the consequences of delocalization strategies and reduce dependence on offshore production of both APIs and finished pharmaceutical products and medical devices. To accelerate the achievement of these goals, the European Commission has approved several measures compatible with the internal market, including: aid to compensate for losses caused by extraordinary events (Articles 107 (2) b TFEU); aid to rectify serious disturbances in the economy of a member state (Articles 107 (3) b TFEU); aid to support the development of specific sectors or industries (Articles 107 (3) c TFEU), through which member states provide assistance to pharmaceutical companies and related industries. At the same time, EU leadership introduced an investment aid mechanism for the production of products related to COVID-19. These products include: medicines (including vaccines) and their intermediate products, APIs and raw materials; medical devices, medical equipment (including ventilators, protective clothing and equipment, as well as diagnostic tools) and necessary raw materials; disinfectants and their intermediate products, chemical raw materials required for their production; and data collection/processing tools. The intensity of the aid was up to 80% of the project costs. Several countries received approval from the European Commission for such aid, including Ireland, Germany, Poland, Hungary, the Czech Republic, and others. Central and Eastern European countries, in implementing mechanisms to support investment-innovative projects in pharmaceutical companies, relied not only on its own budget allocations but also received significant funds from European funds as part of the national

implementation of EU cohesion policy in research and development and innovation [22].

The results of the EU leadership's policy regarding the development of pharmaceutical production can be assessed through a statistical analysis of the export dynamics of products in this sector, using databases from Eurostat [23] and UN Comtrade [24].

According to the Standard International Trade Classification, Revision 4 (SITC Rev. 4), the foreign trade of medicaments, medicinal, and pharmaceutical products is analyzed by groups 541 and 542. Group 541 SITC Rev. 4 includes goods such as provitamins, vitamins, antibiotics (which are not packed as pharmaceuticals), plant alkaloids (not intended for use as medicines); hormones, prostaglandins, thromboxanes, leukotrienes; glycosides; glands or other organs; immunosera, vaccines; as well as other pharmaceutical products, excluding medicinal products. Group 542 SITC Rev. 4 includes medicinal products containing: antibiotics, hormones, and others (but not antibiotics), alkaloids (but not containing hormones or antibiotics), and other medicinal products not specified elsewhere. In foreign trade statistics, the term "Extra-EU" is used to evaluate transactions with all countries outside the EU (the rest of the world, excluding EU member states). In general, it represents the total sum of external transactions of EU member states.

As the analysis showed, the share of medicaments, medicinal, and pharmaceutical products (groups 541 and 542) in the total Extra-EU export increased from 5% in 2002 to 11% in 2020. Over the past few years, this figure has remained at the level of 10–11%. Until 2008, the share of exports of this category of goods remained fairly stable at around 5%. However, after the global financial crisis of 2008-2009, the share of export began to increase (Fig. 1, constructed by data from [23])). It should be noted that the 2023 figure Extra-EU trade of medicaments, medicinal, and pharmaceutical products was 2.2 times higher than in 2014. In 2022, the figure reached a historic high of €287 billion, but in 2023, there was a decrease of 3.5%, dropping to €277 billion. (Fig. 2, constructed by data from [23]).

The dynamics of medicament exports were significantly influenced by the growth rates of high-tech pharmaceutical exports, the volume of which outside the EU increased 2.8 times (from €50 billion in 2014 to €139 billion in 2023). The share of high-tech pharmaceuticals in medicaments, medicinal, and pharmaceutical products' exports grew from 40% in 2014 to 50% in 2023 (see Fig. 2). The high-tech category includes specific products from subgroups 541.3, 541.5, 541.6, as well as 542.1 and 542.2, including: antibiotics, hormones and their derivatives, glycosides, glands, antiserums, vaccines, as well as medicines containing antibiotics or their derivatives, hormones, or other products included in subgroup 541.5. The term "high-tech pharmacy" is commonly used in statistics with regard to these products. The increase in high-tech pharmacy supplies explains their position in the structure of high-tech goods exports. In 2023, out of the nine categories of high-tech goods (the Extra-EU export of high-tech goods reached €460.4 billion) pharmaceutical products accounted for 30% or €139.5 billion (Fig. 3, constructed by data from [23]).

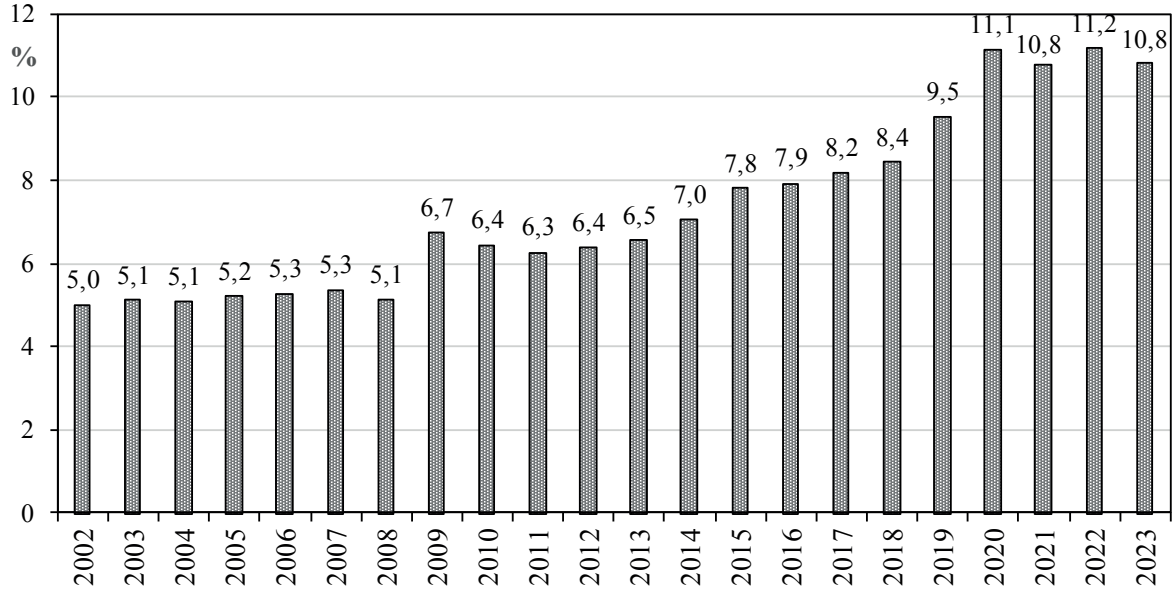



**Figure 1. The share of medicaments, medicinal, and pharmaceutical products (groups 541 and 542) in the total Extra-EU trade**

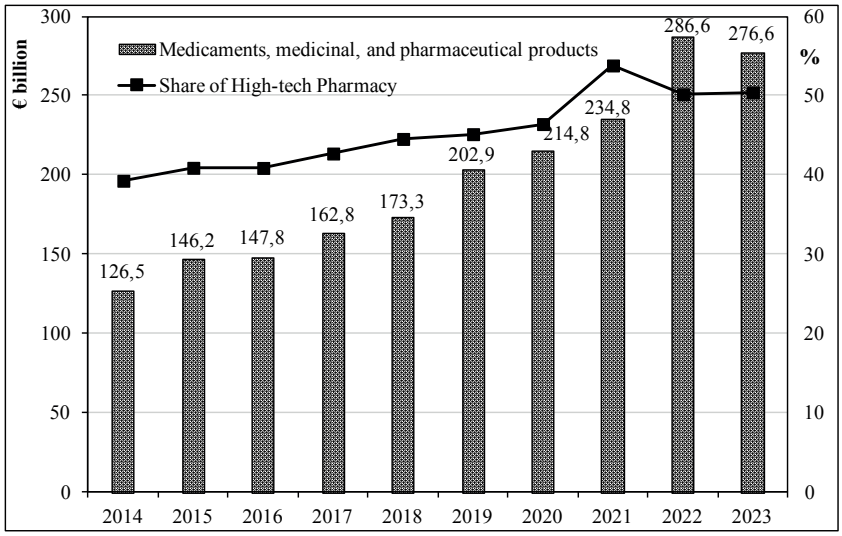



**Figure 2. The export of medicaments, medicinal, and pharmaceutical products (groups 541 and 542) and share of high-tech pharmacy**

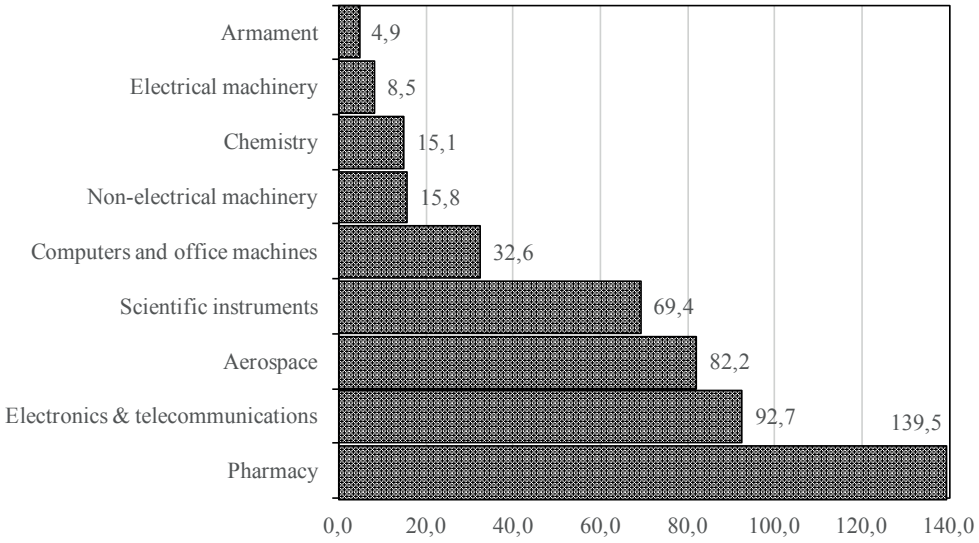



**Figure 3. Extra EU exports of high-tech pharmacy, 2023**

The TOP-5 countries that account for about 70% of the EU's medicaments, medicinal, and pharmaceutical products (including high-tech) exports are: United States, Switzerland, China, United Kingdom, and Japan (Fig. 4, constructed by data from [23]).

Fourteen countries imported high-tech pharmaceutical goods from the EU in 2023, with a total value exceeding €1 billion. India imported these goods worth €800 million. The largest exports from the EU were to the United States (€61.1 billion) and Switzerland (€13.6 billion). Among the high-tech goods exported to these countries, pharmaceuticals accounted for about 50%. In the structure of high-tech goods exports to countries such as Canada, Japan, and Brazil, pharmaceuticals also held significant positions: 36.4%, 39.2%, and 44.3%, respectively (Fig. 5, constructed by data from [23]).

In 2023, russia ranked 6th after Japan among the largest EU partners for the import of medicinal products, medical and pharmaceutical goods. The EU exported medicaments, medicinal, and pharmaceutical products to Russia worth €8.8 billion (–12.1% compared to 2022). Goods from groups 541 and 542 became the leaders in exports from the EU to russia in 2022-2023 (Fig. 6, constructed by data from [23]). Many leading international pharmaceutical companies have decided to minimize their presence in the aggressor country, halting investments, clinical research, and expenditures unrelated to the supply of essential and life-saving medications. Nevertheless, in russia, several global pharmaceutical companies continued to operate in 2023: Stada (Germany), Servier (France), KRKA (Slovenia), Berlin-Chemie (Germany), Menarini Group (Italy), and Gedeon Richter (Hungary) and supplies from the EU remained at a high level.

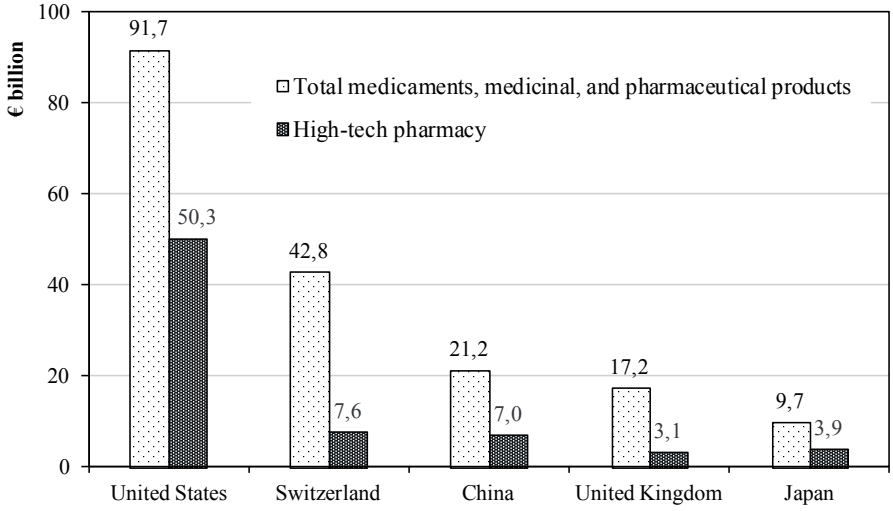



**Figure 4. TOP-5 countries importing medicaments, medicinal, and pharmaceutical products from the EU, 2023**

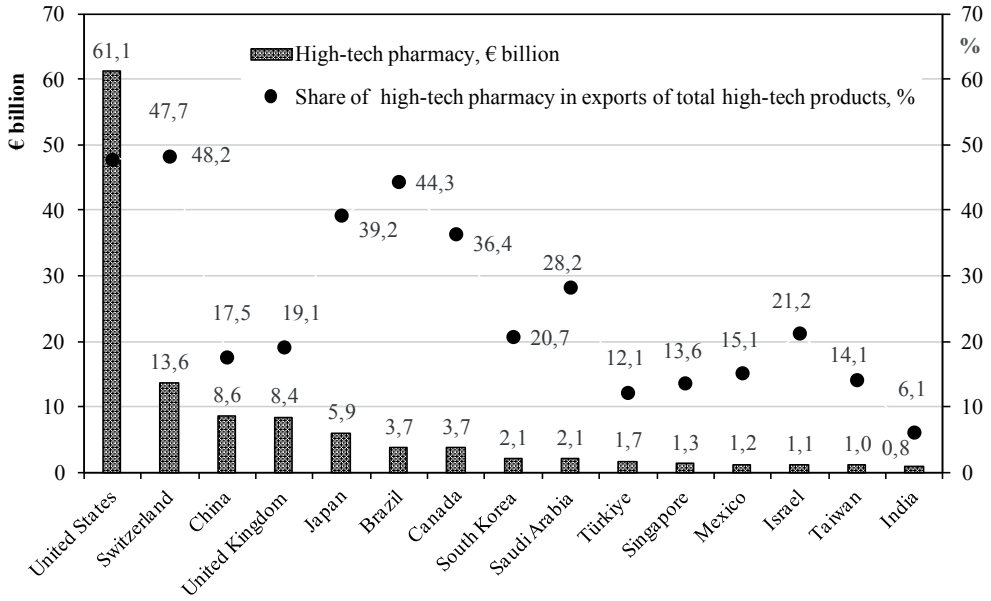



**Figure 5. TOP-15 countries importing high-tech pharmacy from the EU, 2023**

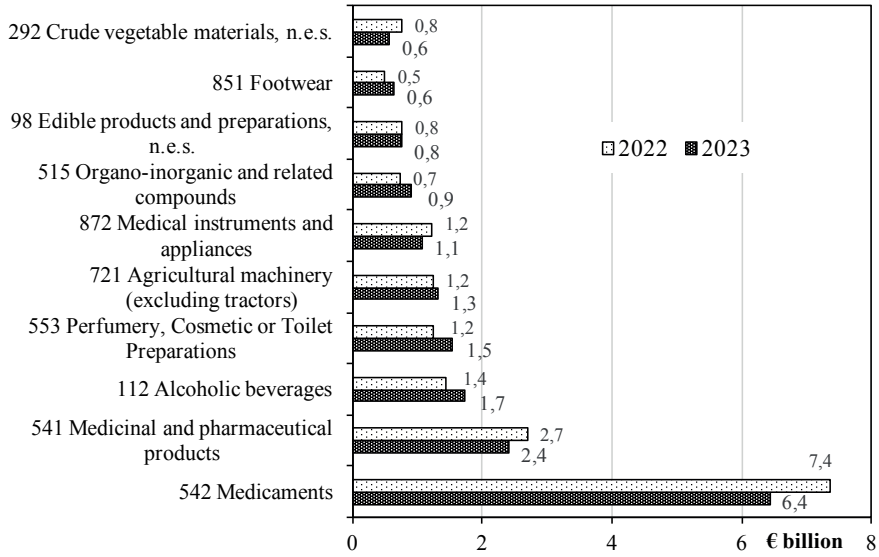



**Figure 6. TOP-10 EU exported goods to Russia, 2022–2023**

The issue of high import dependency in the russian pharmaceutical market has been well-known for a long time (the share of foreign medicines in the overall consumption structure is overwhelming). European analysts have pointed out that in 2020, 1.716 product categories (out of 4,385) worth €57 billion (28% of russia's total import volume) were identified, where at least half of the imports came from the EU and the US [25]. Among the most important product categories, medicines were highlighted. Russians interpret the situation regarding the high dependence on medicine imports from abroad in the way. The investment attractiveness of russian pharmaceutical enterprises remains at a low level, and local companies find it much more profitable to invest in the procurement and promotion of existing products, primarily imported, rather than in long-term and costly innovations and production modernization. At the same time, the current level of pharmaceutical science development in russia significantly lags behind developed countries, which determines the low competitiveness of domestically produced medicines compared to foreign ones. As a result, import dependency is a serious problem not only within the pharmaceutical market but also on a national scale, as it has a significant impact on russia's national security [26]. It is difficult to assess what portion of the €8.8 billion worth of goods from European companies in groups 541 and 542 were purchased for the needs of russian security forces and defense, either as finished products from European brands or as russian products (manufactured from European pharmaceutical ingredients). However, it is evident that, in the context of the war with Ukraine, this portion has increased since 2022. Among the EU countries, the largest exporters of pharmaceuticals, medical, and pharmaceutical products to russia in 2023 were [26]: Germany – $2.498 billion, Netherlands – $718.9 million, Slovenia – $657.1 million, Austria – $602.5 million, Belgium – $530.6 million, France – $500.1 million, Hungary – $499.1 million, Poland – $333.8 million (Fig. 7, constructed by data from [24]). In 2023 Germany exported $555 million in commodity group 541 and $1943 million in commodity group 542 (Fig. 8–9, constructed by data from [24]).

In the conclusions of the European Council on Ukraine, May 30, 2022, it is stated [27]: "The European Council resolutely condemns russia's war of aggression against Ukraine. It urges russia to immediately stop its indiscriminate attacks against civilians and civilian infrastructure, and to immediately and unconditionally withdraw all its troops and military equipment from the entire territory of Ukraine within its internationally recognized borders. The atrocities being committed by russian forces and the suffering and destruction being inflicted are unspeakable. ... The European Council is committed to intensify pressure on Russia and Belarus to thwart Russia's war against Ukraine".

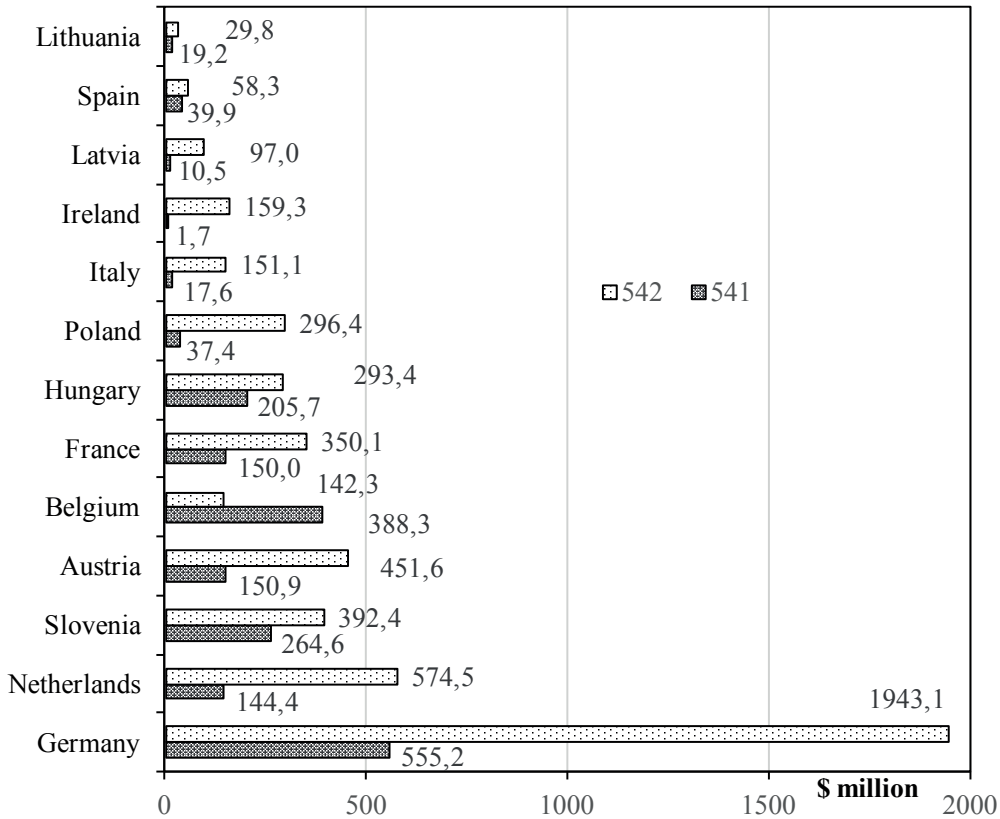



**Figure 7. TOP-10 EU exported medicaments, medicinal, and pharmaceutical products to russia, 2022–2023**

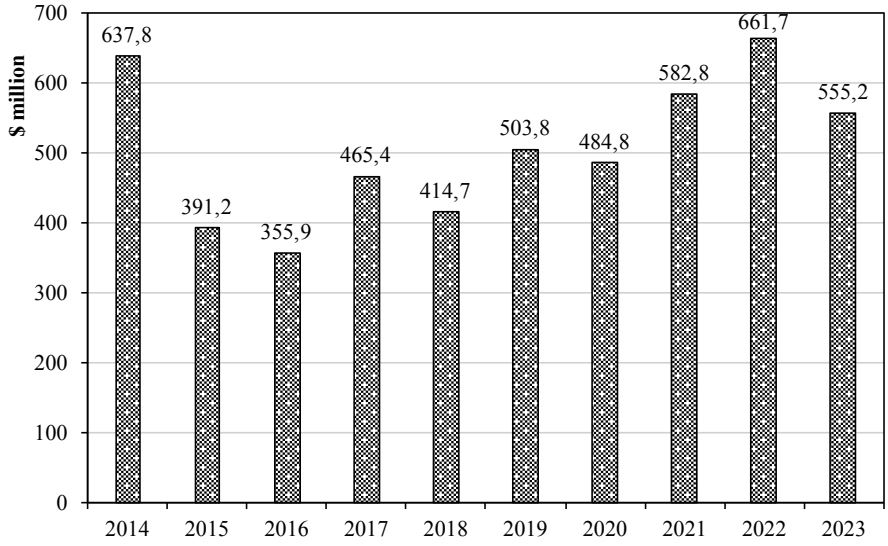



**Figure 8. The dynamics of exports of commodity group 541 from Germany to russia**

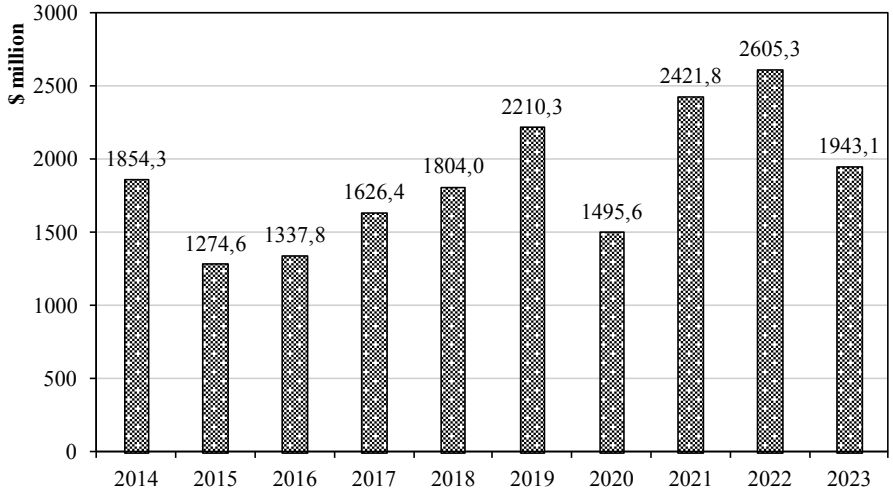



**Figure 9. The dynamics of exports of commodity group 542 from Germany to russia**

Nevertheless, the EU and other countries continue to supply medicines and active ingredients to Russia. Such supplies among others contribute to reducing Russia's national security threats (this compensates for the lack of local production of necessary goods) and meeting the needs of Russian military. And as a result, the threats to Ukraine's national security and sovereignty increase.

At the same time, Ukraine, having a domestic pharmaceutical industry, was significantly dependent on imported supplies of medications and their ingredients even before the war. Ukraine imports medicaments from the EU. In 2023, €1.17 billion were spent on commodity group 542. Medicaments are among the top export categories from the EU to Ukraine, ranking 5th after Petroleum oils other than crude, Arms and ammunition, Motor cars and motor vehicles, and Telecommunications equipment (Fig. 10, constructed by data from [23]).

Before the beginning of the war in Ukraine (in December 2021), the author of the article noted: "Today, the pressing question is whether allies will provide Ukraine with lethal weapons to counter Russian aggression. However, the issue of whether military personnel and civilians will be supplied with the necessary medications, and how this will be done (in the event of restrictions or a complete halt in supply from foreign companies), is not even raised. Clearly, the problem of scaling up the production of medicines and their components is complex. Its solution lies within the responsibilities not only of the Ministry of Health but also the Ministry of Strategic Industries, Ministry of Economy, Ministry of Education, Ministry of Finance, and Ministry of Environment. A roadmap for the development of domestic pharmaceutical production, including APIs, fillers, packaging materials, equipment, and other industry-related goods, is needed. Since the stakes involve reducing threats to national security, it is likely that the development of such a roadmap should take place on the platform of the National Security and Defense Council of Ukraine" [28]).

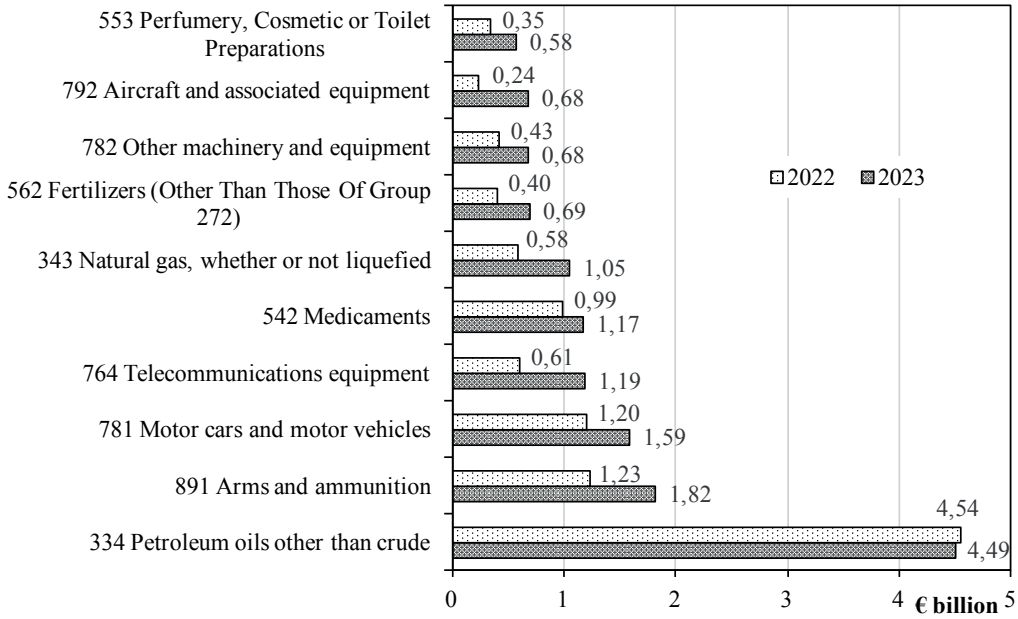



**Figure 10. TOP-10 EU exported goods to Ukraine, 2022–2023**

In 2022, amid russia's aggression and military invasion of Ukraine, a significant portion of medicines was delivered as humanitarian aid. This was in response to critical needs for medications to treat the wounded and to meet the basic medical needs of the population, which was under threat due to the war. Since the supply of medicines from abroad was complicated by disruptions in logistics chains and other restrictions, humanitarian organizations, governments of Western countries, and international institutions provided vital support to Ukraine in the form of medications, medical supplies, and equipment. At the same time, Ukraine paid $1960.21 million for the import of goods (group 541+542) in 2022. In 2023, the expenses increased to $2206.21 million (close to the amount paid in 2019, which was $2236.76 million), despite a significant decrease in Ukraine's population due to migration, casualties, and the temporary occupation of Ukrainian territories. It should be noted that the growth in the import of medicaments, medicinal, and pharmaceutical products (2016–2021) occurred against the backdrop of an increase in the Consolidated Budget of Ukraine's expenditure on health (Fig. 11, constructed by data from [24; 30]). Figure 12 (constructed by data from [24; 29]) demonstrates a noticeable correlation between the import of medicaments, medicinal, and pharmaceutical products into Ukraine and the Consolidated Budget of Ukraine's expenditure on health during the period 2014–2023.

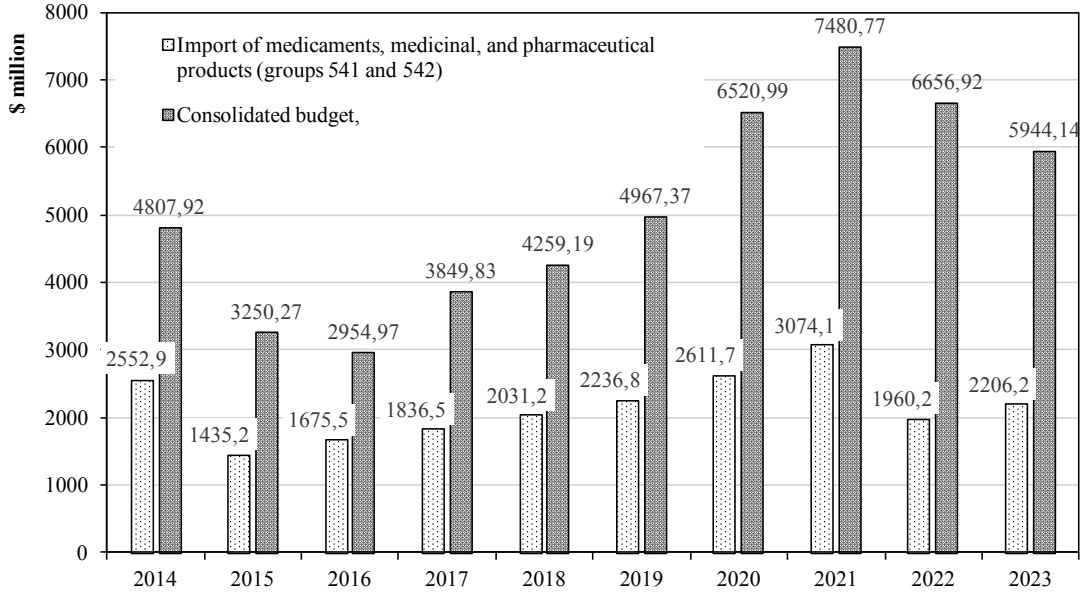



**Figure 11. The import of medicaments, medicinal, and pharmaceutical products into Ukraine and the Consolidated Budget of Ukraine's expenditure on health**

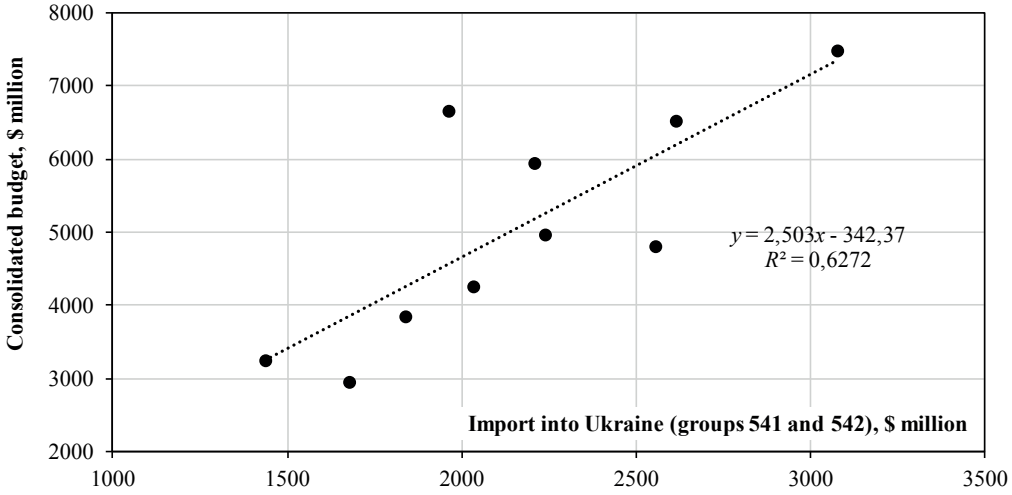



**Figure 12. The relationship between the dynamics of Ukraine's Consolidated budget of Ukraine expenditure on health by economic budget classification, total expenditure, and the import of medicaments, medicinal, and pharmaceutical products into Ukraine, 2014–2023**

Over the past years, Ukraine has established a legal framework for the licensing, registration, standardization, certification, and control of pharmaceutical products, which is largely based on the guidelines set by the EU and WHO. International standards for good manufacturing practices have been implemented, creating a foundation for improving the quality, efficiency, and safety of medicines and their manufacturing and packaging processes. These measures have enhanced the technical and economic parameters of the Drug Research and Development (R&D) stages, promoted the adoption of advanced technologies, modernized production, increased labor productivity, and fostered international cooperation, as well as reducing technical barriers to trade. At the same time, the European integration processes over the years have primarily focused on harmonizing the legislative and regulatory framework for pharmaceutical and medical device production rather than on expanding the innovative development potential of this sector. While Ukraine has aligned its industry practices with EU standards, it does not have access to EU funds, which cover a portion of the expenses for pharmaceutical companies in EU member states to develop research infrastructure and implement scientific, technological, and innovation-driven investment projects. This creates a competitive disadvantage for Ukrainian companies compared to European producers, for whom the Ukrainian market has become a promising market for pharmaceutical sales.

**Conclusions.** In the context of the war and post-war economic recovery of Ukraine, in order for the pharmaceutical industry to gain maximum benefits from the process of European integration (in particular, strengthening technological potential, increasing production efficiency and product competitiveness, establishing sustainable ties with European producers) and to enter the EU market, the development of the industry must take into account both European guidelines and national interests. The state's task is to remove eliminate barriers and launch development incentives of the pharmaceutical industry and promote its growth. This necessitates the development and implementation of a Pharmaceutical Production Development Strategy in Ukraine (hereinafter referred to as the Strategy), the goal of which should be to build a stable and efficiently functioning industry with high added value. This industry should rely on endogenous innovations as a guarantee for increasing the competitiveness of existing and new substances, ready-made medicines, and medical devices, maintain a high level of localization within Ukraine, ensure the fulfillment of internal needs, and expand its share in the global market of high-tech products. Based on this, the key priorities of the Strategy should include: technological innovations, cooperation and partnerships, international collaboration, quality and effectiveness, import substitution, stability of supplies to the domestic market and access to foreign markets, ecology and green pharmaceuticals, smart manufacturing.

The realization of these goals and priorities requires addressing the following tasks:

1. Improvement of regulatory and institutional foundations for the development of the pharmaceutical industry.
2. Creation of high-quality human capital for state management of the industry's development, as well as for scientific, innovative, and manufacturing activities.
3. Strengthening cooperation between the government, academia, educational institutions, the private sector, and civil society in the interest of developing the national pharmaceutical industry and bringing it to an international level.
4. Creation of stable funding sources for programs based on public-private partnerships, which will allow the implementation of scientific, technical, innovative, and investment projects.

5. Implementation of the State Scientific and Technical Program for the Development of Pharmaceutical Production in Ukraine, which will comprehensively cover: the development of new biological and chemical substances and medicines; medical products; new excipients and packaging materials, as well as equipment for pharmaceutical production.

6. Implementation of the State Program for Technological Innovations and Digitalization of Pharmaceutical Production in Ukraine, which will contribute to increasing the efficiency of existing and the creation of new business processes, improving product quality, and bringing new substances and medicines to the market based on endogenous innovations with high localization, added value, and export potential.

7. Creation of preclinical platforms for obtaining preliminary information about the effectiveness, toxicity, and pharmacokinetics of new drugs; standardization of clinical trial databases for drugs and medical products with proper clinical practice; improving the quality of clinical trials and responsibility in the development of innovative products.

8. Directing the resources of medical institutions toward innovations, improving the level of clinical research on new drugs, and promoting the transformation and application of medical science achievements in pharmaceutical production.

9. Creation and support of platforms to promote startups and small businesses, such as business incubators and open laboratories; creating publicly accessible databases for pharmaceutical R&D and improving the level of open information exchange.

10. It is proposed to launch a state program to stimulate the production of new Ukrainian medicines and medical devices, within which the identification and certification of products based on domestic developments will be created and endogenous innovations will be initiated, along with providing preferences in their procurement.

11. Creating conditions for expanding the use of Ukrainian medicines by raising awareness among civil servants, doctors, pharmacists, and patients about the high quality and effectiveness of domestically produced drugs, and the connection between consuming domestic products and the well-being of the nation; implementing a program to promote the national pharmaceutical industry.

12. Encouraging the implementation of waste-free production and rational consumption of pharmaceutical products; when developing an innovative product – focusing on a closed life cycle, reuse, recovery, and recycling of waste.

In the implementation of these tasks, the focus should be on key areas of scientific, technical, and innovative activity in the interests of the development of the pharmaceutical industry. Based on modern global trends in technology development, the pharmaceutical sector in Ukraine should prioritize a comprehensive approach that encompasses the development and production of:

1. Biological products (development of therapeutic drugs based on antibodies; medicinal products based on recombinant proteins; vaccines; nucleic acid-based products and products for cell therapy);

2. Chemical products (development of new synthesized chemical drugs; chemical generics; highly effective drugs);

3. Medical devices - medical equipment and devices for medical purposes (development of medical imaging equipment; medical devices for in vitro diagnostics; therapeutic equipment; medical devices for interventional procedures; mobile medical devices);

4. Pharmaceutical excipients and packaging systems (development of pharmaceutical excipients and functional materials; systems for packaging and delivery of medicines);

5. Pharmaceutical manufacturing equipment and apparatus (development of modern equipment; Improvement of manufacturing technologies, focusing on higher levels of integration, continuity, automation, digitalization, and the use of smart technologies).

In the context of growing dependence on pharmaceutical imports and national security threats, Ukraine needs to develop a targeted scientific, technological, innovative, and industrial policy aimed at the development of the pharmaceutical industry, capable of meeting domestic needs and increasing exports. The concretization of the author's proposals and recommendations requires professional discussions in expert and scientific circles, as well as further research on the assessment of resources and prospects for the development of this industry in Ukraine under the conditions of European integration (these issues can be the subject of future studies).

Since the responsibility of governments lies in efforts to care for the nation's health, ensure the efficiency of the economic system and social stability, it is advisable to initiate negotiations with European partners regarding the construction of pharmaceutical enterprises (relocate from Asia), particularly for the production of pharmaceutical and biological ingredients within Ukraine. Such measures are a rational and politically justified decision. This will help reduce the EU and Ukraine's external strategic dependence on supplies (including from unfriendly countries) and ensure the regulation and management of the industry's development in national interests. In case of threats, this will allow measures to influence the structure and volume of production, which, as the 2020 lockdown showed, turned out to be impossible with the placement of production capacities in countries where the free flow of goods becomes difficult in crisis situations.

**References**

1. Dependency of the EU pharmaceutical industry on active pharmaceutical ingredients and chemical raw materials imported from third countries. (12 March 2020). European Commission. Pharmaceutical Committee. *ec.europa.eu*. Retrieved from https://health.ec.europa.eu/document/download/d6871c01-b30a-49d9-a780-6396e094e1f5_en

2. Exposing the Risks of America's Dependence on China for Medicine. Testimony of Rosemary Gibson Before the Senate Committee on Small Business and Entrepreneurship. (March 12, 2020). *www.sbc.senate.gov.* Retrieved from https://www.sbc.senate.gov/public/_cache/files/1/c/1c39a1bc-f22c-4178-951e-29b92dcb2182/3AD9C94FB267763A83913E2303A6A772.gibson-testimony.pdf

3. Vidkryte zvernennia asotsiatsii "Vyrobnyky likiv Ukrainy" do prezydenta, premier-ministra, inshykh vysokoposadovtsiv [Open Appeal of the Association "Pharmaceutical Manufacturers of Ukraine" to the President, Prime Minister, and Other High-Ranking Officials] (April 02, 2020). *Interfax-Ukraine. News Agency.* Retrieved from https://ua.interfax.com.ua/news/press-release/651870.html [in Ukrainian].

4. Shukar, S., Zahoor, F., Hayat, K., Saeed, A., Gillani, A, H., & Omer, S. et al. (2021) Drug Shortage: Causes, Impact, and Mitigation Strategies. *Frontiers in Pharmacology,* 12:693426. https://doi.org/10.3389/fphar.2021.693426

5. Garattini, S., Natsis, Y., & Banzi, R. (2021) Pharmaceutical Strategy for Europe: Reflections on Public Health-Driven Drug Development, Regulation, and Policies. *Frontiers in Pharmacology,* 12:685604. https://doi.org/10.3389/fphar.2021.685604

6. Blanc, L. (2015). The European Pharmaceutical Industry in a Global Economy: what drives EU exports of pharmaceuticals? *Bruges European Economic Research Papers 31.* Retrieved from https://core.ac.uk/download/pdf/148890074.pdf

7. Bown, Ch. P. (January, 2022). How COVID-19 Medical Supply Shortages Led to Extraordinary Trade and Industrial Policy. *Asian Economic Policy Review, 17 (1),* 114–135. doi: 10.1111/aepr.12359

8. Pisani-Ferry, J., Weder, B., & Zettelmeyer, J. (2024). How to derisk: European economic security in a world of interdependence. Research Report. *Bruegel Policy Brief, 7.* Retrieved from https://www.econstor.eu/bitstream/10419/302287/1/1900628155.pdf

9. Lionello, L., Stranges, D., Karki, T., Wiltshire, E., Proietti, Ch., Annunziato, A., & et al. (2022). Non-pharmaceutical interventions in response to the COVID-19 pandemic in 30 European countries: the ECDC–JRC Response Measures Database. *Eurosurveillance, 27 (41)*:2101190. https://doi.org/10.2807/1560-7917.ES.2022.27.41.2101190

10. Honcharenko, D. O. (2021). [The Theoretical Approaches and Methodological Principles for Development of Ukrainian Pharmaceutical Production in the Conditions of European Integration]. *Biznes Inform – Business Inform, 5,* 194–201. https://doi.org/10.32983/2222-4459-2021-5-194-201 [in Ukrainian].

11. Budnikevych, I., & Honchar, V. (2020). Regulatory Mechanisms of Ukrainian Pharmaceutical Market Competitiveness in the Context of European Integration. *Three Seas Economic Journal, 1 (3),* 1–8. https://doi.org/10.30525/2661-5150/2020-3-1

12. Popova, I. A., Demchenko, N. V., & Shved, A. B. (2023). Tendentsii rozvytku farmatsevtychnoho rynku Ukrainy v umovakh voiennoho stanu [Trends in the Development of the Pharmaceutical Market of Ukraine in the Conditions of Martial Law]. *Biznes Inform – Business Inform, 4,* 203–209. https://doi.org/10.32983/2222-4459-2023-4-203-209 [in Ukrainian].

13. Yanchuk, A. O. (2024). Stymuliuvannia rozvytku farmakolohichnoho sektoru yak odyn z klyuchovykh elementiv zabezpechennia natsionalnykh ekonomichnykh interesiv v umovakh povoiennoho vidnovlennia Ukrainy [Stimulating the Development of the Pharmaceutical Sector as One of the Key Elements of Ensuring National Economic Interests in The Context of Post-War Recovery of Ukraine]. *Vcheni zapysky TNU imeni V. I. Vernadskoho. Seriia: Publichne upravlinnia ta administruvannia – Scientific notes of V. I. Vernadsky Taurida National University. Series: Public Management and Administration, 35 (74), 5,* 110–117. https://doi.org/10.32782/TNU-2663-6468/2024.5/17 [in Ukrainian].

14. Salikhova, O. B., & Honcharenko, D. O. (2020). The Conceptual Foundations of the Strategy of Development of the High-Tech Industry of Pharmaceuticals and Medical Products in Ukraine till 2030. *Biznes Inform – Business Inform, 7,* 28–35. https://doi.org/10.32983/2222-4459-2020-7-28-35 [in Ukrainian].

15. Outlines of an industrial policy for the pharmaceutical sector in the European Community. Communication from the Commission to the Council and the European Parliament. (2 March 1994). COM (93) 718 final. EUR-Lex. Access to European Union law. *eur-lex.europa.eu*. Retrieved from https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:1993:0718:FIN

16. Towse, A. (Ed.). (1995). *Industrial policy and the pharmaceutical industry.* The Proceedings of a Symposium held on 22nd June 1994. London: Office of Health Economics. Retrieved from https://trove.nla.gov.au/work/23267703

17. European Parliament. (1996). *Verbatim report of proceedings*. Part 3. Industrial policy for the pharmaceutical sector. Debates Tuesday, 16 April 1996. Strasbourg. Retrieved from https://www.europarl.europa.eu/doceo/document/CRE-4-1996-04-16-ITM-003_EN.html

18. Council Resolution designed to implement the outlines of an industrial policy in the pharmaceutical sector in the European Union. (23 April 1996). *Publications Office of the European Union*. Retrieved from https://op.europa.eu/ga/publication-detail/-/publication/bf15f43c-6a8b-4953-8155-04fc004a1be3/language-en

19. Pharmaceutical Industry: A Strategic Sector for the European Economy. (22 October 2014). *European Commission*. Retrieved from https://ec.europa.eu/newsroom/growth/items/47862

20. IMI is the world's largest public-private partnership in health. (2020). *European Federation of Pharmaceutical Industries and Associations (EFPIA)*. Retrieved from https://www.efpia.eu/about-medicines/development-of-medicines/public-private-partnerships/

21. Affordable, accessible and safe medicines for all: the Commission presents a Pharmaceutical Strategy for Europe. (November 25, 2020). *ec.europa.eu*. Retrieved December 17, 2024 from https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2173

22. Salikhova, O. B., Honcharenko, D. O. (2021). Challenges of the COVID-19 pandemic to pharmaceutical manufacturing: the EU and Ukraine's response. *Ekonomika i prohnozuvannia – Economy and forecasting, 3,* 93–117. https://doi.org/10.15407/eip2021.03.093

23. International trade in goods. Database. Eurostat. *ec.europa.eu*. Retrieved October 19, 2024 from https://ec.europa.eu/eurostat/web/international-trade-in-goods/database

24. Free access to detailed global trade data. UN Comtrade Database. *comtradeplus.un.org*. Retrieved October 19, 2024 from https://comtradeplus.un.org

25. Erixon, F., Guinea, O., Sharma, V., Zilli, R. (March, 2022). Russia Import Dependency Problem. *European Centre for International Political Economy (ECIPE)*. Retrieved from https://ecipe.org/blog/russia-import-dependency-problem/

26. Baimakova, K. V., & Trofimova, L. A. (2020). Import Dependence of Russian Pharmaceutical Market as The Country's Economic Security Threat. *Economic and Social Trends for Sustainability of Modern Society (ICEST 2020)*. I. V. Kovalev, A. A. Voroshilova, G. Herwig, U. Umbetov, A. S. Budagov, & Y. Y. Bocharova (Eds.). Vol 90. European Proceedings of Social and Behavioural Sciences (pp. 1350–1357). European Publisher. https://doi.org/10.15405/epsbs.2020.10.03.156

27. European Council conclusions on Ukraine, 30 May 2022. (May 31, 2022). Press releases. *consilium.europa.eu*. Retrieved October 19, 2024 from https://www.consilium.europa.eu/en/press/press-releases/2022/05/31/european-council-conclusions-on-ukraine-30-may-2022/

28. Salikhova, O. (December 24, 2021). Zalezhna nezalezhnost' [Dependent independence]. *LB.ua*. Retrieved from https://lb.ua/economics/2021/12/24/501666_zalezhna_nezalezhnist.html [in Ukrainian].

29. Previous Years Budgets. Ministry of Finance of Ukraine. *mof.gov.ua*. Retrieved October 29, 2024 from https://mof.gov.ua/en/previous-years-budgets

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## Міжнародна торгівля фармацевтичною продукцією та питання національної безпеки

З пандемією COVID-19 світ увійшов у реальність, яку можна назвати "силою ліків". Закриття заводів у Китаї через жорсткий карантин, заборона на експорт певних товарів із Індії на початку 2020 р., відсутність авіаперевезень і блокування морських перевезень порушили логістику та розірвали ланцюжки доданої вартості. Стало очевидним: існує загроза залежності від імпорту активних фармацевтичних інгредієнтів, медикаментів, лікарських засобів і фармацевтичної продукції, виробництво яких зосереджено в Азії. Зрозуміло, що країни, які мають науково-технологічні, інноваційні та виробничі можливості для забезпечення потреб сектору охорони здоров'я (зокрема фармацевтичними товарами), менш вразливі та залежні від імпортних поставок (переважно з недружніх держав). Навпаки, країни, які не мають відповідних ресурсів, стикаються з загрозами національній безпеці. Ці загрози особливо загострюються під час епідемій, криз, екологічних катастроф, військових конфліктів. Метою цієї статті є аналіз політи-

ки ЄС та ключових тенденцій експорту з ЄС продукції фармацевтичної промисловості, особливо після широкомасштабного російського військового вторгнення в Україну в лютому 2022 р., що викликало рішуче засудження Європейською Радою агресивної війни Росії проти України та запровадження низки санкцій. Ідеться, зокрема, про визначення обсягів експорту до росії та України; а також розробку рекомендацій для України щодо розвитку фармацевтичної галузі та зменшення зовнішньої залежності від поставок і загроз національній безпеці. Аналіз показав, що у 2023 р. росія посіла 6 місце серед найбільших партнерів ЄС з імпорту лікарських засобів, медичних і фармацевтичних товарів. ЄС експортував до росії цих товарів на суму 8,8 млрд євро (медикаменти, лікарські засоби та фармацевтична продукція стали лідерами з-поміж товарних груп, що експортувалися з ЄС до росії у 2022–2023 рр.). Водночас Україна за імпорт цих товарів заплатила європейським постачальникам у 2022 р. 1960,21 млн дол. У 2023 р. ці витрати зросли до 2206,21 млн дол. незважаючи на значне зменшення чисельності населення України через міграцію, жертви та тимчасову окупацію українських територій. Оскільки відповідальність урядів – дбати про здоров'я нації, забезпечувати ефективність економічної системи та соціальну стабільність, у статті обґрунтовується необхідність ініціювання переговорів з європейськими партнерами щодо будівництва фармацевтичних підприємств (у тому числи переміщення з Азії) для виробництва фармацевтичних і біологічних інгредієнтів, а також готових лікарських засобів в Україні. Такі заходи є раціональними і політично виправданими, оскільки їхня реалізація сприятиме зменшенню зовнішньої стратегічної залежності ЄС та України від поставок (у тому числі з недружніх країн) та забезпечить регулювання розвитку галузі в національних інтересах. У разі виникнення загроз це дозволить органам влади вплинути на структуру та обсяги виробництва, що, як показав локдаун 2020 р., виявляється неможливим через розміщення виробничих потужностей у країнах, із яких у кризових ситуаціях ускладнюється вільний рух товарів.

***Ключові слова:*** *фармацевтична промисловість, лікарські засоби, медикаменти, фармацевтична продукція, міжнародна торгівля, високотехнологічна фармацевтика, експорт, національна безпека.*

Bibliographic description for quoting:

Salikhova, O. B. (2024). International Trade of Pharmaceutical Products and Issues of National Security. *Statystyka Ukrainy – Statistics of Ukraine, 4,* 40–53. Doi: 10.31767/su.4(107)2024.04.04

Бібліографічний опис для цитування:

Саліхова О. Б. Міжнародна торгівля фармацевтичною продукцією та питання національної безпеки (публікується англійською мовою). *Статистика України.* 2024. № 4. С. 40–53. Doi: 10.31767/su.4(107)2024.04.04