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The Government Policy for the Ukraine's Pharmaceutical Industry: Economic and Statistical Aspect

Among the priorities for the Ukrainian government during the country's recovery period after the war should be ensuring national security, establishing an effective healthcare system, creating jobs, achieving stability and economic growth. The development of the pharmaceutical industry plays a crucial role in achieving these goals. The pharmaceutical industry, as revealed by the study, despite increasing production and value added over the years of independence, remains vulnerable and dependent on external resources. The Covid-19 pandemic and the russian military aggression exposed the industry's unpreparedness for new challenges and threats, casting doubt on the effectiveness of Ukraine's policy for national pharmaceutical production. The aim of this article is to show initiatives and political decisions made since the early 2000s, as well as economic and statistical assessments of their consequences for the pharmaceutical industry in Ukraine. Study found, that the government's policy in the process of European integration primarily focused on harmonizing legislative and regulatory frameworks for pharmaceutical activities, rather than on enhancing the domestic manufacturers through a variety of activities: the implementation of a deliberate policy for the technological product and process innovation based on domestic R&D, strengthening competitive advantages for to meet growing domestic needs and increase exports. Lack of policy for increasing the innovative and scientific and technological potential of pharmaceutical industry has led to the growth of imports. It is proven that in 1996, the import of pharmaceutical products per capita in the country was $4,98 and at the end of 2021 (before the start of the war), it was $71.78. The research revealed that Ukrainian pharmaceutical industry, primarily manufactures products for the domestic market and relies largely on imported intermediate goods (as there is no domestic production of fine chemicals, active pharmaceutical ingredients and their intermediates); the industry does not generate foreign currency earnings even to cover the expenses for purchasing necessary ingredients in foreign markets. The article substantiates the necessity of a multi-aspect policy. The formulation of such policies should be based on both the results of statistical analysis from official statistics and surveys of professional associations' members associated with the pharmaceutical industry (developers and manufacturers of biological and chemical substances, pharmaceuticals, and medical devices, as well as providers of fillers and packaging materials and equipment for pharmaceutical production). This approach will allow for a comprehensive and adequate assessment of the current state and future prospects of the industry.

Key words: *pharmaceutical industry, government policy, value added, exports, imports, pharmaceutical products, national security.*

Introduction. Among the top priorities for the Ukrainian government today and during the country's recovery period after the war are ensuring national security, establishing an effective healthcare system, achieving financial stability, creating jobs, attaining social stability, and economic growth. The development of the national pharmaceutical industry plays a crucial role in achieving these goals. In countries where the growth of pharmaceutical assets is a priority of state policy, the following effects are demonstrated: progress in healthcare (improvement of health, quality, and life expectancy, influencing the ability to learn, educational and professional levels of the workforce); economic efficiency (increase in employment, added value, labor productivity, exports, and reduction in imports); and ensuring national security (reducing dependence and vulnerability from external influence; mitigating threats in economic and social spheres). The Ukrainian industry, despite its long history, scientific schools, and educational institutions that train specialists in chemistry, biology, and pharmaceuticals, has not accumulated sufficient technological and production resources to respond to new threats. As a result, the country was unprepared for both the COVID-19 pandemic and the russian military aggression, and continues to depend from the supply of strategic pharmaceutical products, both finished and intermediate, from abroad. These new

challenges and threats cast doubt on the effectiveness of Ukraine's policy for national pharmaceutical production.

Literature review. A number of research studies have been undertaken that examine issues related to the strategic directions of the pharmaceutical industry's development in Ukraine, challenges in achieving EU membership, and nuances in the legal implementation of EU pharmaceutical legislation [1–3]; statistical assessments of high-tech pharmaceutical production and foreign trade were carried out [4; 5]. Studying the legal aspects of pharmaceutical activity in Ukraine, V. Khomenko [6] points out that over the years of independence in Ukraine, significant problems have emerged in public administration, and as a result, the loss of a coherent management structure has had a negative impact on the organization of healthcare services for the population. One of the main reasons for this situation, according to the scientist, is the lack of a systematic approach to defining the principles and mechanisms of public administration in the pharmaceutical sector. Several authors explored the challenges facing the pharmaceutical industry during wartime, analyzing the state of the pharmaceutical goods market [7; 8]. Notably, V. Pashkov, & Ye. Gnedyk remark, "Attempts by government bodies, including the Ministry of Health of Ukraine, to take measures to improve the situation in the pharmaceutical market only create the illusion of improvement while simultaneously creating new problems." [8, p. 80]. The aim of this article is to show initiatives and political decisions made since the early 2000s, as well as economic and statistical assessments of their consequences for the pharmaceutical industry in Ukraine.

Results and discussion. Based on the results of the all-Ukrainian referendum in 1991 and the Act of Declaration of Independence of Ukraine, the appeal of the Verkhovna Rada of Ukraine on December 5, 1991 "To the Parliaments and Peoples of the World" [9] indicated Ukraine's self-identification as a European state that intends to become a direct and full-fledged participant in the pan-European process and participate in other European structures. This intention of cooperation with the EU and seeking future EU membership received legislative consolidation in the resolution "On the Main Directions of Ukraine's Foreign Policy" of July 2, 1993. The resolution states that "The prospective goal of Ukraine's foreign policy is Ukraine's membership in European communities, as well as in other Western European or pan-European structures, provided that it does not harm its national interests" [10].

The Association Agreement between Ukraine and the EU has conditioned transformative processes in the pharmaceutical industry. According to the current Ukrainian legislation [11], the Ministry of Health is the main body in the system of central executive authorities responsible for the formation and implementation of state policy in the field of healthcare and ensures the formation and implementation of state policy in the following areas: creation, production, quality control, and distribution of medicinal products. Since Ukraine is not a member of the EU, EU norms cannot be applied automatically in Ukraine, and therefore, national legislation must be brought into line with EU legislation in accordance with the Association Agreement and its appendices. And to that end, the regulatory and technical framework of Ukraine and new measures to regulate activities related to the pharmaceutical industry (a series of laws and resolutions of the Cabinet of Ministers of Ukraine, as well as orders of the Ministry of Health of Ukraine) have been adopted. This is primarily associated with the necessity to use the same terminology on medicinal products, uniform rules for regulating the pharmaceutical market, and consolidating the procedures for implementing the requirements of good practices – GMP, GDP, GCP, GSP (Good Manufacturing Practice, Good Distribution Practice, Good Clinical Practice and Good Storage Practice respectively). However, as the analysis of adopted documents shows, the European integration processes in Ukraine over the past 20 years have primarily focused on harmonizing legislative and regulatory provisions regarding the production of pharmaceuticals and medical equipment rather than boosting the scientific potential and endogenous innovations of national producers in this crucial industry for the economy, healthcare system, and national security.

As early as the beginning of the 2000s, representatives of the pharmaceutical industry in Ukraine, appealing to Ukrainian politicians and public administrators, substantiated the necessity of "finding ways to access the leading pharmaceutical markets in the world and developing a strategy for the prosperity of domestic pharmaceutical manufacturers in conditions of intense competition" [12]. At the initiative of the business community during the VI National Congress of Pharmacists of Ukraine in 2005, the Concept for the Development of the Pharmaceutical Industry of Ukraine was presented (2005 Concept) [13]. The practical implementation of this concept envisaged the creation and implementation of not just pharmaceutical policy, but a policy that, in the EU in the 1990s, was referred to as "an industrial policy for the pharmaceutical sector". For information, in 1994, a Resolution on the Communication from the Commission to the Council and the European Parliament on the principles of industrial policy for the pharmaceutical sector in the European Community was adopted. The resolution emphasized that innovation and industrial investments are crucial factors for progress in the interests of patients and society as a whole; "an

industrial policy for the pharmaceutical sector should have as its first priority a guaranteed supply of safe, effective drugs for the public and it cannot therefore be separated from aspects of public health and social security on the one hand, and support for industrial development and employment in the Union on the other hand" [14].

Follow the spirit, not just the letter European principles, the pharmaceutical professionals in Ukraine argued in favor of implementing policy measures to strengthen and develop the potential of the domestic pharmaceutical industry. In the 2005 Concept were encouraged to establish domestic production of vaccines and other medical immunobiological products (especially those included in the schedule of preventive vaccinations); develop and introduce into production immunodiagnostics and next-generation immunotropic drugs; expand the production of domestic blood products, blood substitutes, and preservative solutions; stimulate the development and implementation of new technological directions in drug creation, such as genetic engineering and molecular biology; broaden the range and volumes of pharmaceutical production. The recommendations included initiating a mechanism of state orders for the production and supply of essential medicines and drugs for the treatment of socially dangerous diseases in accordance with the then-existing Law of Ukraine "On Supplies of Products for State Needs". The 2005 Concept notes that "the issue of further development of domestic pharmaceutical production is a matter of national security" [13].

These issues were addressed by the National Security and Defense Council. In connection with the decision of the National Security and Defense Council [15], the Cabinet of Ministers of Ukraine (in particular the Ministry of Health of Ukraine) was tasked with developing and presenting to the Verkhovna Rada of Ukraine by June 1, 2006, draft laws on the principles of state policy in the field of pharmaceuticals and medical devices production. This included the launch of state program for the development of immunology, genetic engineering, and immunobiotechnology in Ukraine, which was supposed to promote the creation of relevant scientific and production enterprises by 2007–2010 for the production of modern medical and veterinary immunobiological products of a new generation (vaccines, sera, diagnostics, etc.) for the prevention, diagnosis, and treatment of the most common infectious diseases in Ukraine and the world among humans and animals; also to promote their production in volumes necessary to ensure epidemic safety in Ukraine. A draft of the Concept of the State Target Program for the Development of Domestic Immunobiological Preparations "Ukrainian Vaccine" for 2011–2015 was developed; and in March 2010 [16], the Ministry of Health of Ukraine presented it for public discussion, justifying the need for adopting this regulatory act for several reasons, including the absence of a powerful modern biotechnological center in Ukraine capable of meeting urgent needs in medicine and pharmacology, as well as the lack of a scientific laboratory base for the development of modern vaccines, new antibiotics, and much more. However, despite its importance and relevance, the "Ukrainian Vaccine" program was never launched.

In 2011, the Ministry of Health presented a draft of the Concept of the State Targeted Program "Development of Import-Substituting Industries in Ukraine and Replacement of Imported Pharmaceuticals with Domestic Ones, Particularly Biotechnological Medicines and Vaccines for 2011–2021" [17]. The developers of the Import Substitution Program, while advocating for Ukraine's national interests, drew attention to the issues of the domestic pharmaceutical market and provided statistics on the growth of pharmaceutical imports, with the majority being generic drugs. The share of imported drugs was 73.5% of all medicinal products registered in Ukraine, and significant opportunities for import substitution exist, especially in drug groups used in cardiology (63%), anesthesiology and intensive care (61%), rheumatology (60%), and antimicrobials (59%). This means that in these groups, it is possible to replace 59–63% of imported drugs. This program outlined specific steps related to the development and production of new pharmaceuticals, including: ensuring the complete production cycle of essential drugs in Ukraine, from the synthesis (biosynthesis) of substances to, if possible, the finished dosage form, and reducing dependence on the supply of imported substances; financing from the state budget for the acquisition of licenses for the production of innovative drugs, with further development of their production at leading pharmaceutical enterprises in Ukraine. It was anticipated that the implementation of this program would increase the market share of domestic pharmaceuticals, biotechnological drugs, especially vaccines and sera, in the Ukrainian market. The medicines produced in Ukraine were expected to be as effective, safe, and high-quality as imported drugs. Additionally, due to the reduced cost, domestic medicines would become more affordable for citizens. The developers of the program justified that its launch would allow for the prompt production of many essential drugs, would also elevate domestic research and development (R&D) to a modern level, and that it would allow having to the creation of original pharmaceutical products based on endogenous innovations. In particular, in point 5.4, it was indicated that in the field of pharmaceutical production, it is necessary to: ensure the complete production cycle of essential drugs in Ukraine: from the synthesis (biosynthesis) of substances to the finished pharmaceutical form, where possible, and reduce dependence on the supply of imported

substances; finance the acquisition of licenses for the production of innovative drugs intended for the treatment of socially dangerous diseases (tuberculosis, AIDS, etc.), with subsequent placement of their production at leading pharmaceutical enterprises; introduce new preferences for domestic pharmaceutical manufacturers in the development of competitive innovative and non-patented import-substituting drugs, as well as in state procurement of domestic drugs; prioritize state procurement of domestic drugs developed with budgetary funds. In 2011, the developers of the program warned that ignoring the issues of increasing imports negatively impacts not only Ukraine's balance of trade but also the development of the domestic pharmaceutical industry and science; it also increases dependence on foreign pharmaceutical products, posing serious threats to Ukraine's national security in the event of global or local emergencies.

Despite the relevance and compelling arguments in favor of the program, the Healthcare Committee of the European Business Association (EBA), along with several associations, appealed to the Ukrainian government not to allow its adoption, as they believe it will lead to a power imbalance and the disappearance of innovative medicines [18]. The EBA noted that Ukraine is concluding negotiations on the creation of a free trade zone, taking on certain commitments, and, therefore, the EBA "draws attention to the risk of unequal competitive conditions for domestic and foreign manufacturers in Ukraine if the draft Concept is approved by the government. Moreover, since 2008, Ukraine has been a full member of the World Trade Organization (WTO), and the proposed concept of «import substitution» may raise questions about the country's adherence to WTO principles and norms regarding the possibility of discriminating against imported goods". As a result, under pressure from lobbyists of foreign companies, the Import Substitution Program aimed to promote the development of domestic pharmaceutical production and reduce Ukraine's reliance on imported medicines and active substances was not adopted by the successive Governments.

In 2016, the Ukrainian government portal posted a message stating that the Ministry of Health, with the involvement of representatives from the public, professional community, and the pharmaceutical market, was starting the process of developing a Concept for a state program to promote import substitution in Ukraine [19] (causes a feeling of deja vu). The goal (like the previous draft document) was to increase the share of domestically produced pharmaceuticals in the country's market, support domestic manufacturers, and develop import-substituting production of pharmaceuticals and medical devices. However, a new final document has not been presented. The question has arisen again: is Ukraine really dependent on the import of pharmaceutical products today?

In 2010, the Concept of the Program for the Development and Conduct of Preclinical Trials of Domestic Medicines was adopted [20], with the goal of establishing a system for developing and purposefully producing pharmaceutical substances, vaccines, next-generation antibiotics, and other medicinal products. The concept also was aimed to create specialized laboratories with corresponding scientific and technical equipment for conducting preclinical trials of new chemical compounds. In June 2011, the Ukrainian government approved the State Target Scientific and Technical Program for 2011–2015 [21], with planned funding of 2,7 billion UAH, including 1,2 billion UAH from the state budget, with up to 300 million UAH – for research related to the development of molecular and cellular technologies for creating domestic drugs and biologically active substances. However, after the first year of program implementation, it became evident that it was not a priority for the government, as it did not receive adequate funding. In 2014, both the Concept and the Program were canceled.

The Ministry of Health approved the Concept for the Development of the Pharmaceutical Sector in the Healthcare Sector of Ukraine for 2011–2020 [22]. This document outlined prospective directions and tasks for the pharmaceutical industry, aiming to create the necessary regulatory framework regulating pharmaceutical activities and developing national policies in the pharmaceutical field. One of the tasks was to stimulate the development, production, and export of essential pharmaceuticals. According to the Pharmaceutical Development Concept, an Action Plan was adopted. However, adopted assumptions was no provision for state financial assistance to business in implementing projects for the development of new drugs and their prompt production on existing capacities; and thus the tasks outlined in the Pharmaceutical Development Concept were not implemented.

In December 2020, in response to the challenges of the global pandemic, the Ministry of Health proposed for discussion another project – the Concept of the State Target Program for the creation and development of domestic production of Quality Medicines [23]. This essentially, it was a yet another reproduction of "Ukrainian Vaccine" program from 2010. In the explanatory note for the project, the ministry pointed out the problem that needs to be solved: "Current problems in ensuring the epidemiological well-being of the country's population are primarily due to the lack of domestic production of vaccines, serums, and other vital drugs for the treatment of particularly dangerous infectious diseases. Due to the loss of domestic production of immunobiological drugs and almost complete dependence of the state on imported

supplies of such drugs, considering the aggravation of the epidemiological situation in Ukraine, the question of national security as a whole arises" [23]. Therefore, 15 years after announcing of the provisions of the 2005 Concept, the decision of the National Security and Defense Council, and the implementation of the Concept for the development of pharmaceuticals 2011–2020, the ministry stated not about the creation but "the loss of domestic production", "the lack of domestic production of vaccines, serums, and other vital drugs for the treatment of particularly dangerous infectious diseases", and once again emphasizes that these are "issues of national security as a whole". But disagreements on issues such as government intervention and Ukraine's commitments under the Association Agreement with the EU and the WTO once again blocked the adoption of the draft document and stunted the development policy of the Ukrainian pharmaceutical industry.

But the Ministry of Health was not the only one with initiatives. In 2011, on the initiative of the Ministry of Economic Development and Trade the State Program for the Development of Domestic Production [24] was adopted. The program indicates that the pharmaceutical industry occupies a leading position in the national economy as an important segment of the domestic market, ensuring the country's national and defense security. The Program includes the implementation of several organizational and economic mechanisms, including state orders for scientific and technical products and subsidizing R&D; the provision of tax, credit, customs, tariff, and other incentives; creating attractive conditions for private industrial capital to develop technologies and enhance the connections between science and production, etc. An action plan was developed, which envisaged support for the establishment of industrial clusters, particularly in the pharmaceutical industry, for the years 2012–2015. The Ministry of Finance and the Ministry of Economic Development and Trade were instructed to ensure the allocation of funds necessary for the implementation of tasks and measures outlined in the Program during the development of the state budget of Ukraine. However, such allocations had not been included in the budget. The Program remains in effect to the present day, but the mechanisms for implementing the announced measures are not being realized by the executive authorities.

Today, such a document that would determine the state's policy (the priorities, development objectives) for the Ukrainian pharmaceutical is missing in the country. However, despite the absence of state support, and the problems that inhibit growth, the industry has demonstrated significant achievements over the last 25 years; and the statistics illustrate these results. In order to estimate major trends in the Ukraine's pharmaceutical; and to outline the specific characteristics of industry therein the author have used the data from the jointly prepared by the OECD and the WTO "Trade in Value Added" (TiVA) database for industries D21 Pharmaceuticals, medicinal, chemical and botanical products [25].

The value added in the pharmaceutical industry during the period 1995–2020 is characterized by an overall upward trend (Fig. 1–5, constructed by the authors using information from [25]). But the global financial crises 1998 significantly impacted the economic performance of the pharmaceutical industry in Ukraine – in 1999, the value added by the industry decreased by 23.7%; this indicator fell by 43% by the financial crisis 2009.

The Ukrainian crisis of 2014 (the annexation of Crimea and the direct military invasion of russian troops in the east of the country) has had greatest negative effect for the pharmaceutical industry. The "Styrol" Concern (Horlivka, Donetsk region),

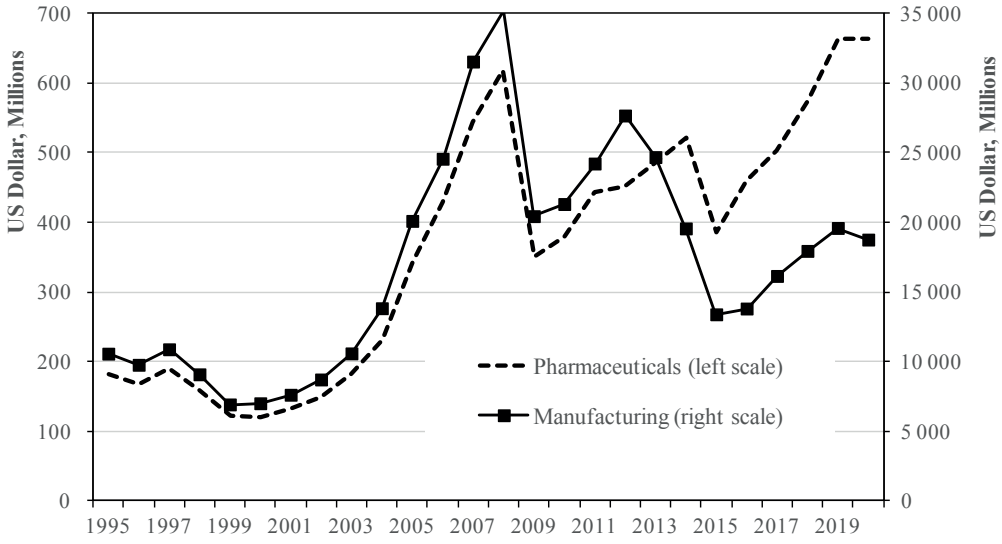


Fig. 1. Dynamics of value added: C21 Manufacture of pharmaceuticals, medicinal chemical and botanical products and C Manufacturing of Ukraine

which was a huge chemical complex with 12 plants employing nearly 4000 people, found itself in an uncontrolled territory after the russian occupation in 2014. This resulted in a significant loss for the national pharmaceutical industry. The product range of PJSC "Concern Styrol" included dozens of solid dosage forms (tablets and capsules), injectable solutions for urgent use, as well as solutions for ophthalmology. Additionally, "Concern Styrol" was the sole producer of medical nitrous oxide in Ukraine, which is used for inhalation anesthesia. The assortment of medications, in the form of tablets and capsules, included both prescription and over-the-counter drugs in various pharmaceutical groups.

Despite new challenges, the pharmaceutical industry began a rapid recovery and further development from 2015 onwards, even in difficult economic conditions. After the decline in the added value of Ukraine's pharmaceutical industry by 25.9% in 2015, the sector managed to return to an upward trend, ensuring significant annual growth rates: in 2016 – 19.2%; in 2017 – 9.4%; in 2018 – 14.5%; in 2019 – 15.1%; in the pandemic year of 2020 – 0.1% (the value added by the manufacturing decreased by 4.3%). In 2019, the added value indicator of Ukraine's pharmaceutical industry reached a historical maximum – $663 million (in 2008 – $619 million). At the same time, according to the database TIVA, Ukraine stimulated the creation of value added abroad. The foreign value added embodied in domestic final demand on pharmaceuticals industry (Domestic Final Demand is equivalent to total Household Final Consumption, Non-Profit Institutions Serving Households expenditures, General Government Final Consumption) reached $660–680 million during peak periods (Fig. 2).

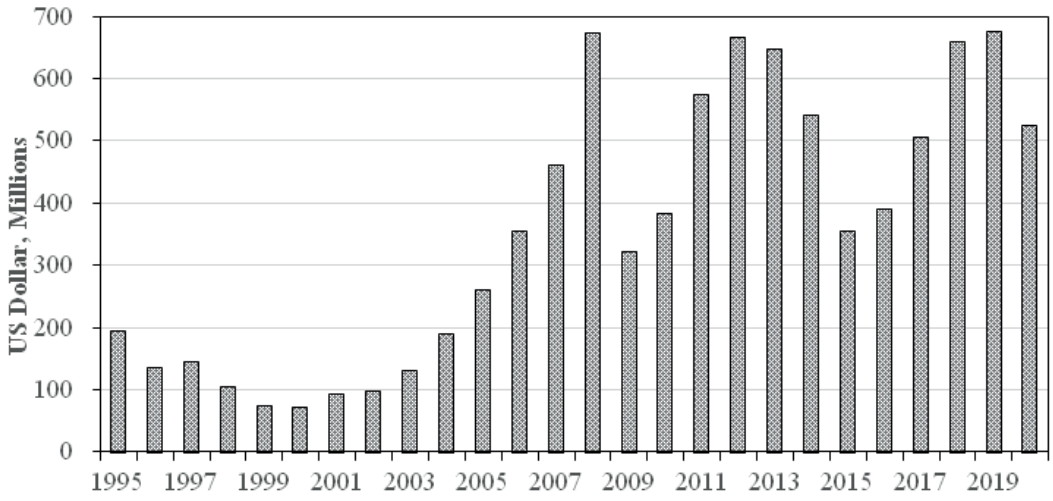


Fig. 2. Dynamics of foreign value added embodied in domestic final demand: pharmaceuticals industry of Ukraine

The positive dynamics of value-added Ukraine's pharmaceutical industry are driven by the upward trend in output. However, both indicators are closely related to the import of the Gross imports of intermediate products and Re-exported intermediate imports. The Fig. 3, 4 show a high functional dependence between the Gross imports of intermediate products and Production, also Value added of Ukraine' pharmaceuticals industry.

In the work the ratio of gross exports and the gross imports of intermediate products by pharmaceutical industry was calculated. Based on these calculations, one could argue that the Ukrainian pharmaceutical industry, primarily manufactures products for the domestic market and relies largely on imported intermediate goods (as there is no domestic production of fine chemicals, active pharmaceutical ingredients and their intermediates); the industry does not generate foreign currency earnings even to cover the expenses for purchasing necessary ingredients in foreign markets. Starting from 2017, pharmaceutical exports cover only 30–40% (on average) of the industry's expenditures on imported intermediate goods (Fig. 5).

Statistics indicate a steady growth not only of intermediate pharmaceuticals. According to data UN Comtrade [26], since 1996, Ukraine has significantly increased its pharmaceutical imports (code 30 HS). By 2005, the volume reached $1 billion, and by 2008 – $2.4 billion (Fig. 6, constructed by the authors using information from [26; 27]). After the global financial crisis 2009, there was a slight reduction in imports, but in 2012, a historical maximum of $3.3 billion was reached. The events of 2014, resulting from russian military aggression, occupation, and the illegal annexation of part of the territory, led to a significant reduction in imports. However, by 2021, imports had almost reached the levels of 2013 – $3.1 billion. Taking into account the dynamics of Ukraine's population provided by the State Statistics Service of Ukraine (since 2015, excluding the temporarily occupied territories of the Autonomous Republic of Crimea,

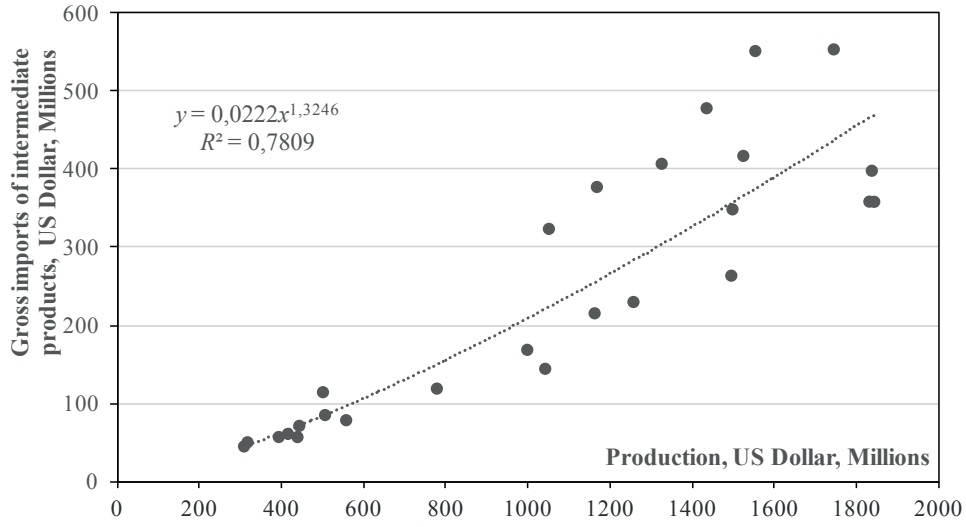


Fig. 3. The functional dependence between the Gross imports of intermediate products and Production: pharmaceuticals industry of Ukraine

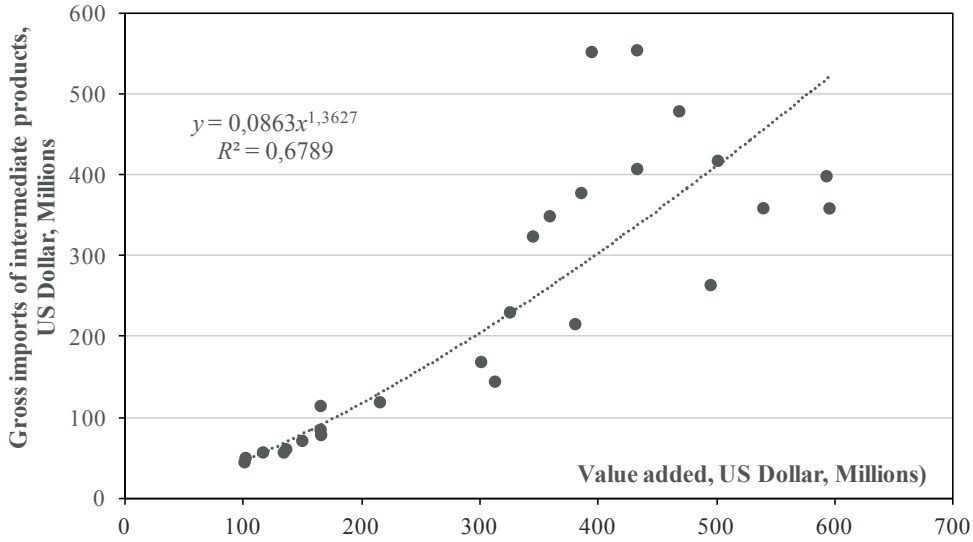


Fig. 4. The functional dependence between the Gross imports of intermediate products and Value added: pharmaceuticals industry of Ukraine

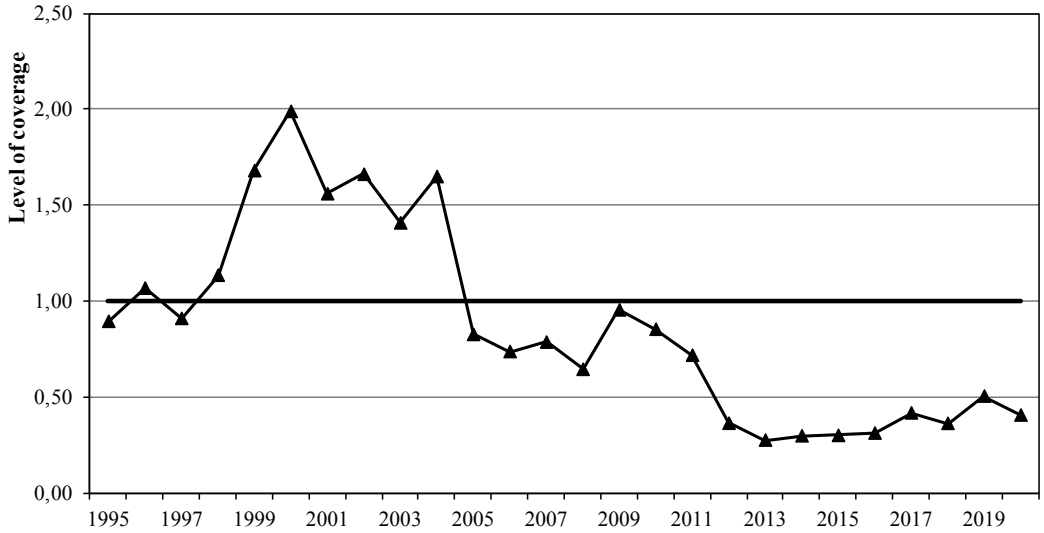


Fig. 5. The coverage of Gross imports of intermediate products with Gross exports: pharmaceuticals industry of Ukraine

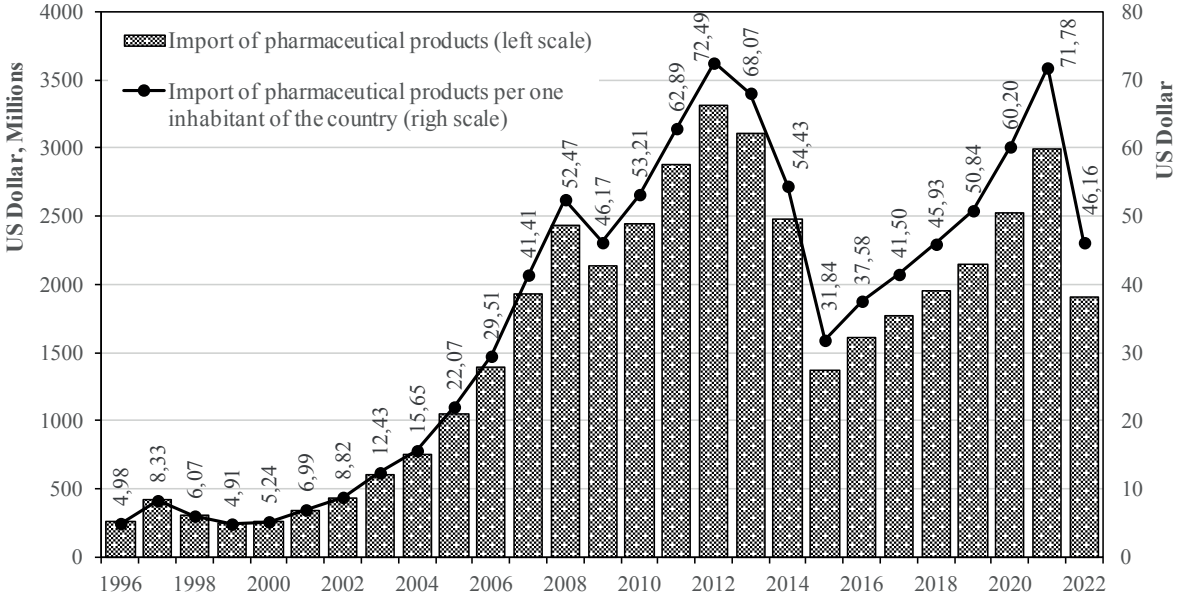


Fig. 6. Dynamics of Ukrainian' import of pharmaceutical products

and the city of Sevastopol) it can be observed that in 1996, the import of pharmaceutical products per capita in the country was $4.98. By 2012, this figure had risen to $72.49, and at the end of 2021 (before the start of the war), it was $71.78.

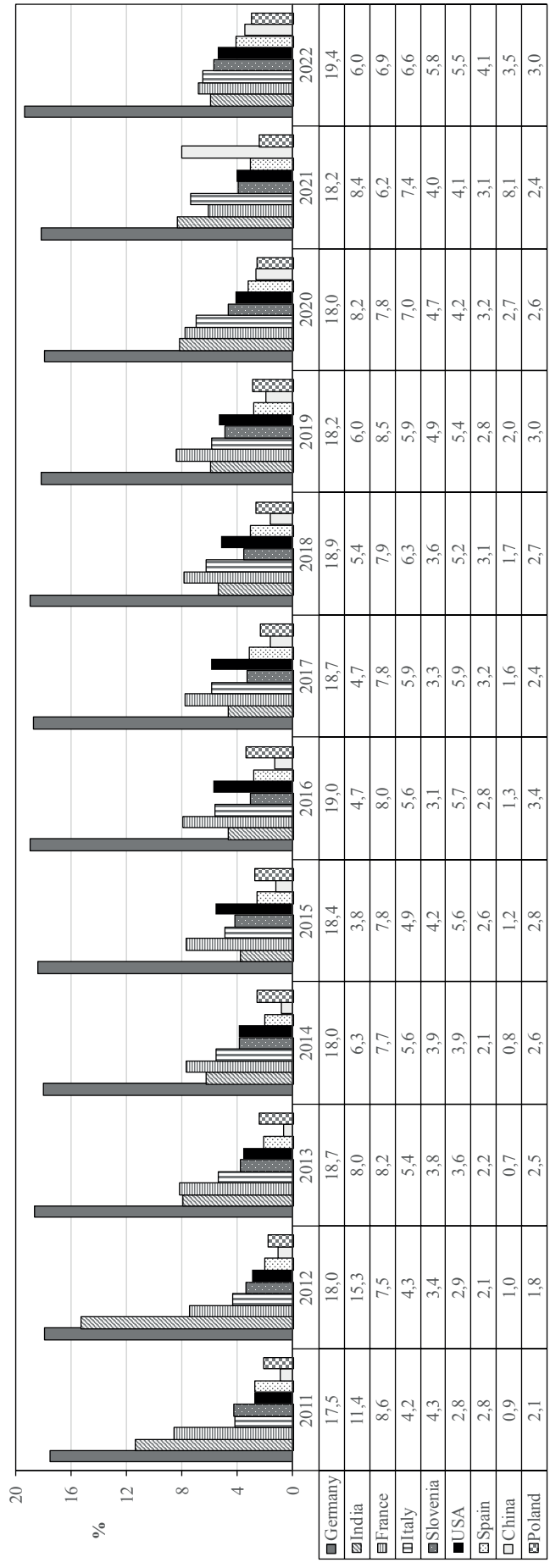
Although according to statistics the reduction of pharmaceutical imports in 2022, amid the war, amounted to 36,3%; and the import of pharmaceutical products per capita fell to $46.16, one can assume that these data do not reflect the real scale of foreign-made medicines and its consumption, because of the foreign humanitarian assistance received. According to the official government website [28], in 2022 during the period of martial law, Ukraine received a total of 10,500 tons of humanitarian medical aid amounting to 12.85 billion hryvnias. This included 480559363 pcs of medicines, consumables and personal protective equipment – 133020948 pcs, and so on. In addition to the influx of humanitarian aid, several other factors influenced the reduction in the import of pharmaceutical products to Ukraine in 2022. These factors include the destruction and blockade of infrastructure (affecting the operation of warehouses and retail networks), complications and increased costs in logistics (due to rising fuel prices, disruption, and changes in production-distribution chains), and a lack of purchasing power (resulting from changes in currency exchange rates, loss of income for citizens, high inflation, population migration, and a reduction in the number of consumers).

On the import side, Germany is the leader in supplying pharmaceutical products to Ukraine (consistently accounting about 18–19% of the annual share). Other European Union countries, including France, Italy, Slovenia, Poland and Spain also involved in the supply of pharmaceuticals to Ukraine. In 2021, these 6 countries represented more than 40% of the imported goods under code 30 HS (Ukraine paid them for deliveries worth $1.3 billion) (Fig. 7, constructed by the authors using information from [26]).

The statistical analysis of the structure of Ukrainian pharmaceutical imports based on HS codes shows that products under code 3004 HS predominate (Table 1, constructed by the authors using information from [26]). These are pharmaceutical products, consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses or packed for retail sale – in other words, finished medicines (1996 – 88,53%; 2019–2020 – about 80%).

After 2005, in the import structure there is an observed increase in imports of products under HS code 3002, in which antisera, other blood fractions, immunological products (modified or obtained by biotechnological processes) and vaccines predominate (in particular code 300220 Vaccines for human medicine, 300230 Vaccines for veterinary medicine, 300210 – Blood, human or animal, antisera, other blood fractions and immunological products; whether or not modified or obtained by means of biotechnological processes). Statistics have changed since 2020 [29]: code 300210 (HS, 2012) corresponds to the following codes 300211, 300212, 300213, 300214, 300215, 300219 (HS, 2017). In this study considering these changes, using aggregated data for the new codes after 2020, a time series for code 30210, was compiled for the period 2002–-2022 (Fig. 8, 9, constructed by the authors using information from [26]).

In 2002, Ukraine imported pharmaceutical products under codes 300210–300230 HS worth about $18 million. By 2008, these imports had increased nine-fold to $166.32 million. After the global financial crisis in 2008–



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Germany	17,5	18,0	18,7	18,0	18,4	19,0	18,7	18,9	18,2	18,0	18,2	19,4
India	11,4	15,3	8,0	6,3	3,8	4,7	4,7	5,4	6,0	8,2	8,4	6,0
France	8,6	7,5	8,2	7,7	7,8	8,0	7,8	7,9	8,5	7,8	6,2	6,9
Italy	4,2	4,3	5,4	5,6	4,9	5,6	5,9	6,3	5,9	7,0	7,4	6,6
Slovenia	4,3	3,4	3,8	3,9	4,2	3,1	3,3	3,6	4,9	4,7	4,0	5,8
USA	2,8	2,9	3,6	3,9	5,6	5,7	5,9	5,2	5,4	4,2	4,1	5,5
Spain	2,8	2,1	2,2	2,1	2,6	2,8	3,2	3,1	2,8	3,2	3,1	4,1
China	0,9	1,0	0,7	0,8	1,2	1,3	1,6	1,7	2,0	2,7	8,1	3,5
Poland	2,1	1,8	2,5	2,6	2,8	3,4	2,4	2,7	3,0	2,6	2,4	3,0

Fig. 7. The TOP 9 countries-exporters of pharmaceutical products to Ukraine

Table 1

The structure of Ukraine' import of pharmaceutical goods

Code HS	1996	2000	2005	2010	2015	2019	2020	2021	2022
3001	0.35	0.02	0.02	0.14	0.26	0.45	1.07	1.41	1.04
3002	2.93	5.18	8.78	9.75	16.05	16.18	17.42	23.80	13.22
3003	1.67	0.33	0.42	0.23	0.57	0.41	0.72	0.44	0.38
3004	88.52	88.34	86.54	87.05	79.94	79.69	78.05	71.33	81.61
3005	5.26	3.21	1.13	0.89	0.99	0.68	0.61	0.63	0.96
3006	1.27	2.92	3.11	1.94	2.19	2.59	2.13	2.39	2.79

2009, Ukraine more than doubled its purchases of these products on external markets. There was a slight reduction in imports in 2014–2015 due to russian aggression and the annexation of part of Ukrainian territory. However, by 2019, volumes exceeded the historical maximum in 2013, reaching around $295.1 million.

The pandemic in 2020 and related issues led to a reduction in shipments. Still, by the end of 2021, Ukraine paid foreign manufacturers and suppliers of vaccines, serums, and other products a record amount of $651.3 million (code 300220 HS – $311.9 million, code 300230 HS – $53.8 million, code 300210 HS – $285.63 million), as these products, despite long-term initiatives are not produced in the country.

From 1996 to 2021, exports of pharmaceutical products increased 4-fold to $301.38 million; however negative trade balance expanded from $183.06 million to $2683.69 million which naturally affects on money supply and inflation (Fig. 10–12, constructed by the authors using information from [26]).

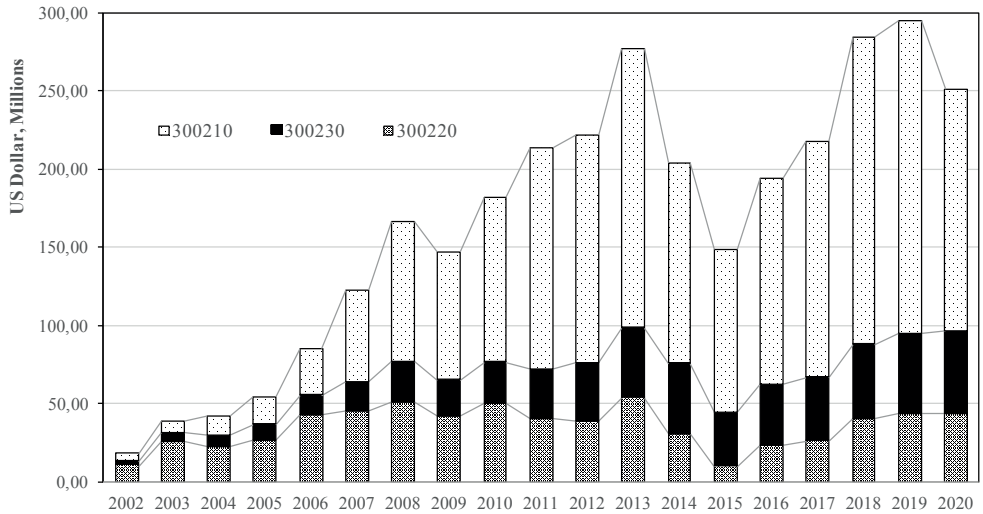


Fig. 8. Dynamics of Ukrainian' import pharmaceutical products: codes 300210, 300220, 300230 HS (2002–2020)

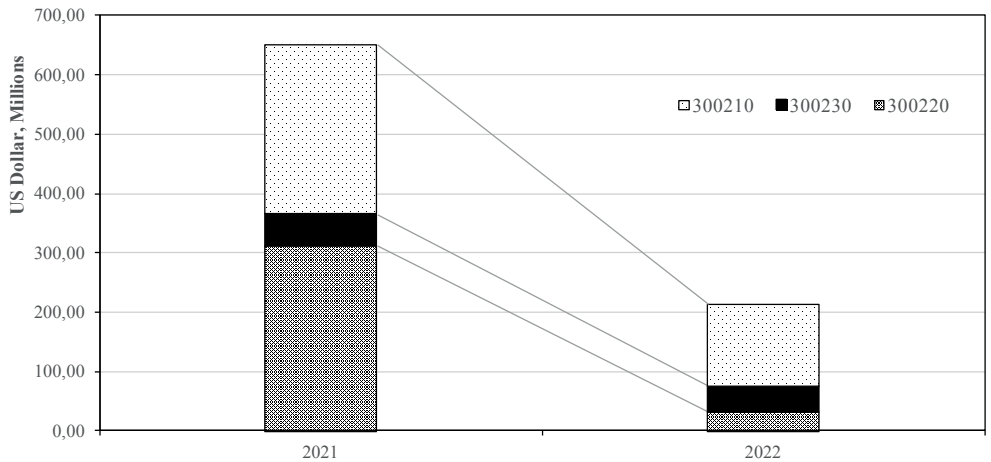


Fig. 9. Dynamics of Ukraine's import pharmaceutical products: codes 300210, 300220, 300230 HS (2001–2022)

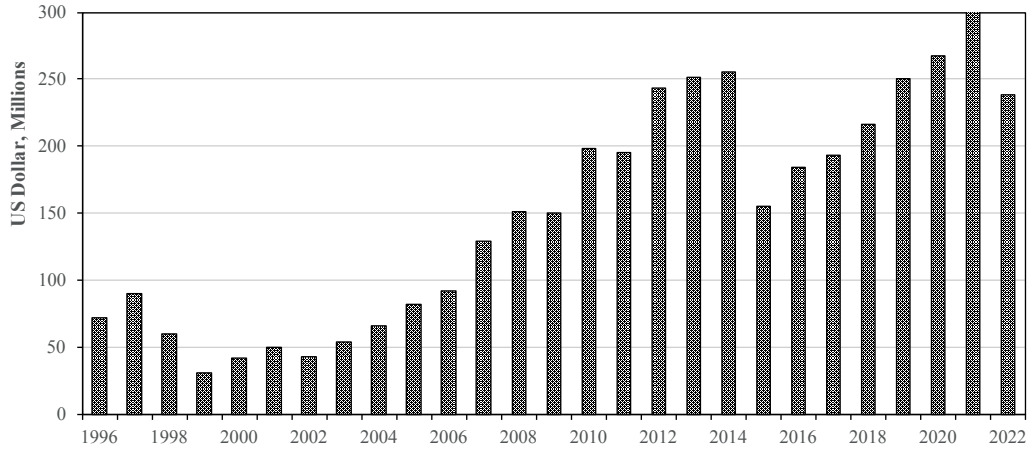


Fig. 10. Dynamics of Ukraine's export of pharmaceutical goods

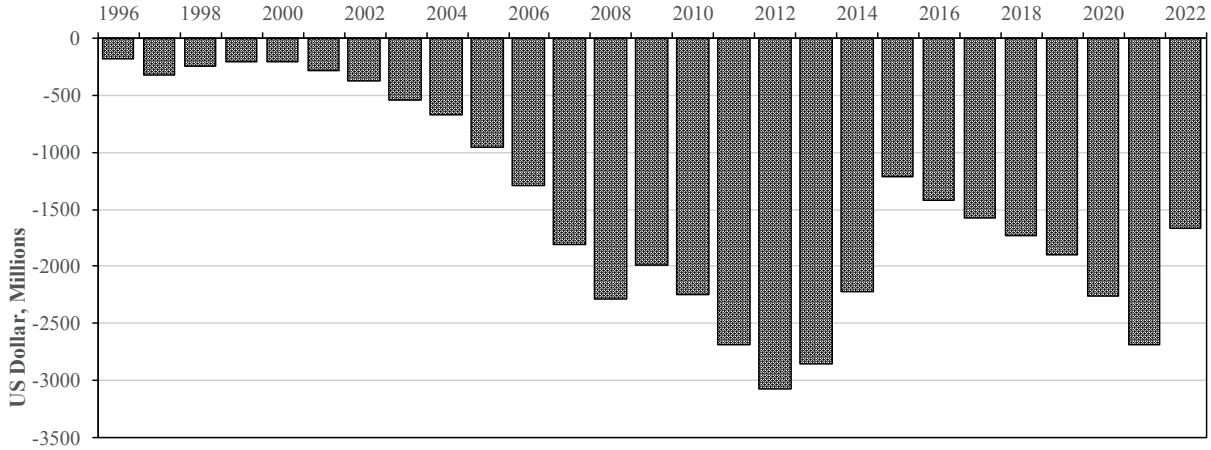


Fig. 11. Ukraine's trade balance of pharmaceutical goods

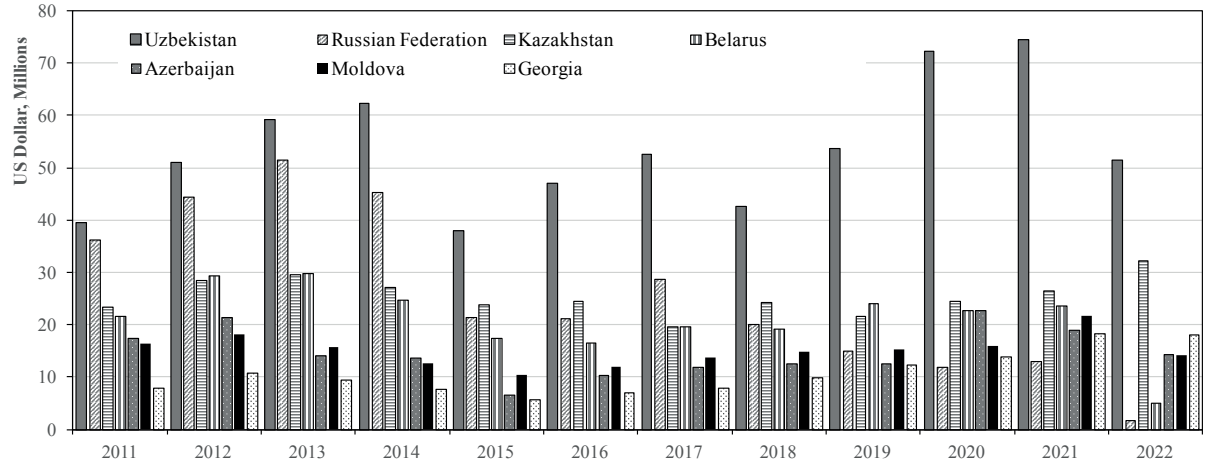


Fig. 12. The TOP 7 countries-importers of Ukrainian pharmaceutical products

Analysis of Ukrainian pharmaceutical exports by world countries (see Fig. 12) showed that in 2011, 83,13% of the shipments were to 7 countries – Uzbekistan, Russian Federation, Kazakhstan, Belarus, Azerbaijan, Moldova, Georgia (former Soviet republics). Uzbekistan became the largest market (in 2011 – $39.6 million, in 2021 – $74.1 million). In 2021, russia and Belarus still held a significant place in exports. However, after the start of the war in 2022, deliveries to these countries ceased (deliveries amounted to russia – $1.61 million, Belarus – $4.89 million. Total, according to the results of 2022, top 5 countries (Uzbekistan, Kazakhstan, Azerbaijan, Moldova, Georgia) accounted for 54,5% of Ukrainian pharmaceutical industry exports. Despite the challenges, Ukrainian manufacturers

are making efforts to expand the geography of their exports, considering European countries among their potential markets [30], but the EU market is still out of reach (with the exception of certain deliveries, for example, an export to Lithuania grew to $22.5 million in 2022).

As noted earlier, one of the main problems affecting the competitiveness of the Ukrainian pharmaceutical industry is the weak innovation activity of local companies due to a lack of sufficient funds to implement scientific and technical projects (Table 2, constructed by the authors using information from [31]).

The analysis of the Input-Output table for 2015–2021 (at consumer prices) [31] for the pharmaceutical industry confirms this. Wholesale and retail trade; repair of motor vehicles and motorcycles (G45–G47, NACE Rev.2) in dominate in the structure of intermediate consumption of pharmaceutical Industry (2015 – 53.11%, 2021 – 56.18%). Scientific research and development (M72, NACE Rev.2) cover less than 1 per cent of the intermediate consumption. Due to the absence of mechanisms for government support in scientific, technological, innovative, and investment projects, as well as the lack of cheap long-term loans and working capital, and given the current circumstances (such as the lack of instruments for insurance against military risks) pharmaceutical companies have difficulty creating innovative products. Even with ready developments for launching production and entering highly competitive markets, significant financial resources are required, which are lacking in the conditions of war.

The main task is to maintain production and achieved positions. According to industry representatives, it would be easier to plan the production of the necessary amount of medications for new challenges "in collaboration with the government" [32]. Summarizing different points of view on the development of industry in the current situation, we can distinguish the following factors: collaboration of the healthcare system exactly with domestic manufacturers; increase in state funding for the healthcare system and procurement of pharmaceuticals, including state initiatives such as the drug reimbursement program; consolidation of stakeholders, increased investments and innovation, development of clinical trials, and the establishment of an "industrial visa-free regime" with the European Union, which requires implementing EU standards and norms, intensifying the fight against counterfeiting, and creating a unified regulatory body in the pharmaceutical business, and recognition of Ukrainian GMP certificates in Europe; State stimulation of pharmaceutical production in Ukraine, and encouragement of companies to invest in R&D, particularly in the development of new vaccines through a mechanism of public-private partnership; provision of state orders for R&D with a requirement for a certain level of production localization of innovative products, and Conclusion of contracts for 5–10 years for state procurement.

Conclusions. As the study showed, from the early years of Ukraine's independence, the foundation was laid for the adoption of legislative acts that defined the European integration vector of the national economy's development and triggered transformation processes in various industries, including the pharmaceutical industry. The implementation of international standards has indeed contributed to the modernization of the pharmaceutical industry and the removal of technical trade barriers. However, the government's leadership in European integration processes primarily focused on harmonizing legislative and regulatory frameworks for pharmaceutical activities with the European Union, rather than on enhancing the local pharmaceutical manufacture's potential: the implementation of a deliberate policy for the technological product and process innovation based on domestic R&D, strengthening competitive advantages for to meet growing domestic needs and increase exports. At the same time, while Ukraine has aligned its industry activities with EU requirements, it does not have access to the billions of EU funds that partially cover the expenses of European companies for the development of R&D infrastructure and the implementation of scientific, technological, innovative, and investment projects. This places Ukrainian companies in a non-competitive position compared to European manufacturers, for whom the Ukrainian market has become a promising sales market for pharmaceutical products.

Based on the European experience and the realities of Ukraine, the post-war recovery of Ukraine's economy should prioritize the innovative development of the pharmaceutical industry. This requires the formulation of a policy that balances the interests of consumers and pharmaceutical product manufacturers with the interests of the state, considering its goals: safeguarding the health of the nation, ensuring the efficiency of the economic system and social stability, promoting the emergence of new effective medicines based on advanced technologies, reducing dependence on imports, and addressing threats to national security. Such a policy should be based on the synergy and complementary measures of pharmaceutical and industrial policies, as well as policies ensuring national security. The development of such a policy should be based on the results of statistical analysis of official statistics data, as well as surveys of members of professional associations related to the pharmaceutical industry (domestic developers and manufacturers of biological and chemical substances and medicinal products, medical devices, new fillers and packaging materials, as well as equipment for pharmaceutical manufacturing).

Table 2

Ukraine: Manufacture of pharmaceutical products (21 NACE Rev.2), Intermediate consumption, %

Types of economic activity	2015		2016		2017		2018		2019		2020		2021	
Wholesale and retail trade; repair of motor vehicles and motorcycles	G45–G47	53,11	G45–G47	57,05	G45–G47	50,95	G45–G47	49,64	G45–G47	55,57	G45–G47	57,97	G45–G47	56,18
Manufacture of basic pharmaceutical products and pharmaceutical preparations	C21	24,93	C21	27,62	C21	21,12	C21	21,40	C21	15,51	C21	17,88	C21	21,40
Transport, warehousing	H49–H52	4,69	H49–H52	4,35	C20	7,19	H49–H52	4,88	H49–H52	4,29	H49–H52	4,30	H49–H52	4,89
Manufacture of chemicals and chemical products	C20	2,77	C20	1,84	H49–H52	4,79	C20	2,93	C20	4,07	C20	3,28	C20	3,38
Manufacture of wood, paper, printing and reproduction	C16–C18	2,34	L68	1,38	C16–C18	2,65	C16–C18	2,76	C22	3,22	C22	2,09	C23	2,69
Financial and insurance activities	K64–K66	2,09	C16–C18	1,28	L68	2,04	M72	2,07	C16–C18	2,52	C23	1,90	C22	1,40
Advertising and market research; other professional, scientific and technical activities; veterinary activities	M73–M75	2,01	M72	1,05	M72	1,63	L68	1,88	C23	1,91	C16–C18	1,67	C16–C18	1,33
Manufacture of rubber and plastic products	C22	1,48	C22	0,62	K64–K66	1,34	K64–K66	1,82	L68	1,68	M69–M71	1,36	D35	1,12
Scientific research and development	M72	0,94	D35	0,55	C22	1,10	M73–M75	1,81	D35	1,50	K64–K66	1,23	M73–M75	1,06
Manufacture of other non-metallic mineral products	C23	0,59	K64–K66	0,52	D35	0,95	C28	1,04	K64–K66	1,23	D35	1,03	L68	1,00
Electricity, gas, steam and air conditioning supply	D35	0,57	C23	0,52	C23	0,88	C23	1,02	M73–M75	1,22	L68	0,98	M69–M71	0,79
Extraction of crude petroleum and natural gas	B06	0,44	M73–M75	0,49	C28	0,84	D35	0,90	C28	0,87	M73–M75	0,88	K64–K66	0,63
Real estate activities	L68	0,39	C28	0,46	M73–M75	0,55	C22	0,87	A01–A03	0,62	C28	0,82	C28	0,53
Manufacture of machinery and equipment n. e. c.	C28	0,39	B06	0,32	A01–A03	0,44	J58–J60	0,85	J58–J60	0,62	J58–J60	0,80	A01–A03	0,40
Manufacture of refined petroleum products	C19.2	0,37	A01–A03	0,21	J58–J60	0,44	J62–J63	0,62	C19.2	0,60	M72	0,47	C24	0,39
Legal and accounting activities; activities of head offices; management consultancy activities; architectural and engineering activities; etc.	M69–M71	0,33	J58–J60	0,20	B06	0,41	C31–C33	0,55	C31–C33	0,49	N77–N82	0,44	M72	0,38
Publishing, motion picture, video, television programme production; sound recording, programming and broadcasting activities	J58–J60	0,31	C19.2	0,17	N77–N82	0,36	A01–A03	0,52	M72	0,47	A01–A03	0,43	N77–N82	0,31

The development of statistical surveys of business (to assess the problems and prospects of post-war development of the industry) is the subject of further research.

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Державна політика щодо фармацевтичної індустрії України: економіко-статистичний аспект

Серед пріоритетів українського уряду в період відновлення країни після війни мають бути: забезпечення національної безпеки; формування ефективної системи охорони здоров'я; створення робочих місць; досягнення стабільності та економічного зростання. Розвиток фармацевтики відіграє вирішальну роль у досягненні зазначених цілей. Ця галузь, демонструючи зростання виробництва та доданої вартості за роки незалежності, залишається вразливою та залежною від зовнішніх ресурсів. Пандемія Covid-19 та російська військова агресія виявили неготовність виробників лікарських засобів та медичних виробів в Україні оперативно забезпечувати потреби системи охорони здоров'я, що ставить під сумнів ефективність політики керівництва країни щодо національного фармацевтичного виробництва. Мета статті – показати ініціативи та політичні рішення, ухвалені з початку 2000-х років, а також надати економіко-статистичну оцінку їх наслідків для фармацевтичної галузі України. Дослідження показало, що політика уряду в процесі європейської інтеграції насамперед зосереджена на гармонізації законодавчої та нормативної бази фармацевтичної діяльності, а не на посиленні вітчизняних виробників через запровадження таких заходів, як стимулювання технологічних інновацій (продуктових та процесних), що базуються на здобутках вітчизняних ДіР, та посилення конкурентних переваг для забезпечення відповідності зростаючим вимогам ринку та збільшення експорту. Показано, що через відсутність цілеспрямованої політики сприяння підвищенню інноваційного та науково-технологічного потенціалу компаній фармацевтичної індустрії відбувається щорічне збільшення поставок в Україну іноземних фармацевтичних товарів. Доведено, що у 1996 р. їх імпорт на одну особу населення в країні становив 4,98 дол. США, а на кінець 2021 р. (до початку війни) – 71,78 дол. США. Виявлено, що українська фармацевтична промисловість

насамперед виробляє продукцію для внутрішнього ринку та багато в чому спирається на імпортні проміжні товари (оскільки в Україні виробництво тонких хімікатів, активних фармацевтичних інгредієнтів, субстанцій та їх напівпродуктів практичне відсутнє); галузь не генерує валютну виручку навіть для покриття витрат на закупівлю необхідних інгредієнтів на зовнішніх ринках. У статті доводиться необхідність багатоаспектної політики, яка ґрунтуватиметься на синергії та взаємодоповнюючих заходах, що відповідають цілям фармацевтичної та промислової політики, а також політики забезпечення національної безпеки. Формування багатоаспектної політики має ґрунтуватися як на результатах аналізу даних офіційної статистики, так і на опитуваннях членів професійних асоціацій, пов'язаних з фармацевтичною галуззю (розробників і виробників біологічних та хімічних речовин, лікарських засобів та медичних виробів, наповнювачів, пакувальних матеріалів, обладнання для фармацевтичного виробництва). Такий підхід дозволить дати комплексну й адекватну оцінку поточного стану та перспектив галузі, що, своєю чергою, сприятиме запровадженню дієвих заходів для її розвитку.

Ключові слова: *фармацевтична промисловість, державна політика, додана вартість, експорт, імпорт, фармацевтична продукція, національна безпека.*

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