UDC 339.564:615.1(100)
DOI https://doi.org/10.32782/2077-6594/2025.3/11

Zayats O.I.[1], Myronyuk I.S.[1], Mulesa O.Yu.[1, 2]

Risks to the supply of quality medicines to the population of Ukraine under conditions of transformation in international pharmaceutical trade and digitalization

[1] State Higher Educational Institution
"Uzhhorod National University",
Uzhhorod, Ukraine
[2] University of Prešov in Prešov,
Prešov, Slovakia

Заяць О.І.[1], Миронюк І.С.[1], Мулеса О.Ю.[1, 2]

Ризики забезпечення якісними ліками населення України в умовах трансформації міжнародної фармацевтичної торгівлі та цифровізації

[1] Державний вищий навчальний заклад
«Ужгородський національний університет»,
м. Ужгород, Україна
[2] Пряшівський університет у Пряшеві,
м. Пряшів, Словакія

olena.zayats@uzhnu.edu.ua, ivan.myronyuk@uzhnu.edu.ua, Oksana.mulesa@unipo.sk

Introduction

Human health during times of war, large-scale emergencies, and prolonged psycho-emotional stress presents a significant challenge for a country's healthcare system. Ensuring timely, equitable, and safe access to essential medicines is fundamental to population survival and recovery. Currently, Ukraine is highly dependent on the import of pharmaceutical products – active pharmaceutical ingredients, finished dosage forms, as well as components and equipment for their production. This reliance on imports creates risks of supply disruptions and reduced quality control, particularly in the context of full-scale war, trade uncertainty, and global supply chain crises.

This article examines how transformations in the global pharmaceutical market affect the availability of quality medicines in Ukraine. Particular attention is given to the role of digitalization – specifically, traceability systems, electronic prescriptions, and digital medicine passports – in increasing supply chain transparency and protecting patients.

The **purpose** of this study is to analyze the risks associated with the decreased availability of quality medicinal products and medical devices for the population of Ukraine in the context of transformations in international pharmaceutical trade, socio-humanitarian crises, and the digitalization of healthcare systems.

Object, materials and research methods

The object of the study is the system of supplying the population of Ukraine with medicinal products and medical devices under conditions of transformation in global supply chains.

The research methods are comprehensive and aimed at ensuring both scientific validity and practical applicability of the results. At different stages of the study, the following methods were used:

− **Comparative analysis** was applied to assess the adaptation strategies of leading countries – EU member states, the USA, India, and China.

− **Case analysis** was used to illustrate the approaches of companies such as Pfizer, Novartis, Polpharma, the HERA initiative, and Ukrainian clusters Biosynth and Enamine.

− **Statistical analysis** was based on selective data from official sources (2021–2024) regarding import dynamics, investment programs, and the market shares of key active pharmaceutical ingredient (API) producers.

The research materials include official reports from international organizations, such as the World Trade Organization (WTO), the World Health Organization (WHO), the European Fine Chemicals Group (EFCG), the State Statistics Service of Ukraine, the European Business Association (EBA), as well as analytical studies conducted by IQVIA and McKinsey. Program documents from the HERA (EU), ACAA (Ukraine–EU), and PLI (India) initiatives were also examined. This allowed for the formation of an objective understanding of pharmaceutical trade transformations and the prospects for Ukraine's participation in regional cooperation frameworks.

Research results

Global pharmaceutical supply chains have undergone significant transformations as a result of the COVID-19 pandemic, the full-scale military aggression of the Russian Federation against Ukraine, and increasing trade uncertainty. These shocks have exposed the vulnerability of the current supply system for both active pharmaceutical ingredients (APIs) and finished pharmaceutical products. Consequently, governments and pharmaceutical companies have been

forced to revise their production, logistics, and international trade strategies.

Disruptions in logistical chains, the intensification of tariff and non-tariff barriers, and excessive production concentration in a few countries directly affect patients' access to quality and timely medical care, particularly its pharmaceutical component.

According to the World Trade Organization (WTO), in a report published in 2024 [1], the concentration of API production in specific regions, high logistical costs, and regulatory trade barriers create significant obstacles for low- and middle-income countries. These challenges threaten the functioning of national healthcare systems, especially in countries critically dependent on medicine imports.

The COVID-19 pandemic reaffirmed this vulnerability: many countries faced shortages of essential medicines due to API supply interruptions caused by transportation restrictions, border closures, and export bans [1; 2].

Furthermore, rising trade tariffs have only exacerbated the issue. For example, the increase in U.S. import duties on Chinese products by 145 percentage points has already led to negative consequences: global trade in goods is projected to decline by 0.2% in 2025 (after an increase of 2.9% in 2024) [3]. This is especially critical for API supplies, a large share of which is produced in China.

Such an environment generates new risks for global and national pharmaceutical supply, particularly for vulnerable population groups requiring continuous pharmacological support.

Under these circumstances, the implementation of digital tools for monitoring medicine availability, analyzing logistical risks, and managing pharmaceutical stockpiles in real time becomes especially relevant.

The full-scale military aggression of the Russian Federation against Ukraine, launched in 2022, has significantly exacerbated the fragmentation of global supply chains, which had already been affected by the COVID-19 pandemic. According to WTO data, trade growth between geopolitical blocs in 2023–2024 was 4% slower than within the blocs themselves [3], indicating a weakening of global interdependence.

For Ukraine, which depends on imports of APIs and finished medicines by more than 70% [4], these risks pose a direct threat to the continuity of treatment for chronic conditions and to emergency care for acute illnesses, particularly in regions close to the front line.

For Ukraine's healthcare system as a whole, this may have immediate local-level consequences: in many communities, the supply of medicines for patients with chronic diseases will become more difficult, vaccination schedules and childhood immunization calendars may be disrupted, and dependence on humanitarian aid will increase. This situation could not only undermine the resilience of the medical system but also potentially endanger the health of the most vulnerable population groups – namely, persons with disabilities, patients with chronic illnesses, the elderly, and children. It may also exacerbate social tensions in regions experiencing shortages of medicines and, consequently, medical care in general.

In response to new challenges, global pharmaceutical companies are adapting their approaches to logistics and investment. For example, in 2022, Pfizer ceased investments in Russia, halted recruitment for clinical trials, and relocated them to other countries. The company maintained drug supplies to the Russian Federation solely for humanitarian reasons, and the profits received were redirected to support Ukraine [5]. This example illustrates how a responsible position, based on universal ethical values, can influence access to treatment for populations in crisis regions.

In response to market instability, the leading countries in the global pharmaceutical industry are pursuing strategies of regionalization and supply diversification. In particular, India exported pharmaceutical products worth over USD 21 billion in 2023, actively promoting API production through government programs [1; 5]. Such a shift also creates opportunities for low-income countries – for example, Bangladesh, where pharmaceutical exports are expected to grow by 4.8% in 2025 [3]. This lays the groundwork for more equitable access to medicines globally, provided that countries can overcome regulatory and logistical barriers.

Special attention should be given to the digital transformation of pharmaceutical logistics, which is becoming a tool for enhancing transparency and traceability in supply chains. For instance, the use of blockchain technologies to monitor API supply chains has already proven effective in ensuring medicine quality. This not only increases the reliability of supplies but also helps prevent counterfeit drugs – an issue particularly relevant for countries experiencing war or other socio-humanitarian crises. However, the digital divide remains a critical challenge – especially for countries with limited infrastructure. In Ukraine, some communities, particularly in temporarily occupied territories and areas near active combat zones, lack stable access to digital services, making it impossible to implement modern medicine supply monitoring systems, especially in rural areas.

According to WTO estimates, trade in digital services grew by 8.3% in 2024, reaching USD 4.64 trillion, creating new opportunities to optimize logistics for healthcare systems. This is particularly important for small and medium-sized pharmaceutical operators, who play a vital role in supplying essential medicines to regional areas [3].

The rise in global trade uncertainty may reduce global GDP by more than 1% in 2025, directly affecting the availability of healthcare in resource-limited countries such as Ukraine [3]. Pharmaceutical trade flows remain highly concentrated in a few regions, increasing risks for countries lacking their own production capacities. For Ukrainian communities, this means a risk of potential disruptions in the supply of essential medicines, particularly

Table 1

Major Exporters and Importers of Pharmaceutical Products in 2023

Country/Region	Export, USD billion	Share of Global Export, %	Import, USD billion	Share of Global Import, %
EU (*excluding intra-EU trade*)	299.60	–	128.71	–
Germany	120.99	15.01	74.72	9.02
Switzerland	99.01	12.29	58.47	7.05
USA	90.31	11.21	177.85	21.47
Ireland	71.56	8.88	13.45	1.62
Belgium	60.47	7.50	53.73	6.48
India	21.30	2.64	2.60	0.31
China	11.28	1.40	43.08	5.20
Ukraine	0.28	0.03	2.14	0.25

Source: Compiled by the authors based on [5; 6].

during emergencies, threatening the continuity of treatment and deepening dependence on unstable humanitarian aid.

According to data from 2023, pharmaceutical trade remains concentrated among several major exporters – namely the EU, Germany, Switzerland, and the United States. Such concentration creates structural vulnerability, which is especially dangerous for countries with low levels of self-sufficiency. For Ukraine, which accounts for only 0.03% of global pharmaceutical exports while importing more than 0.25% of global volume, this means increased risks of disruptions in the supply of essential medicines and vaccines, particularly during global crises [5; 6].

A 3.5% decrease in EU exports and a 6.1% increase in imports further emphasize the ongoing shifts in global logistics and the need for countries like Ukraine to seek more stable sources of supply to prevent threats to public health, especially among vulnerable patient populations.

Current regulatory changes in the pharmaceutical sector are tightening requirements for quality, safety, and the resilience of supply chains, directly affecting medicine availability – particularly in importing countries. In 2023, the EU adopted an updated regulatory framework (replacing Regulation 726/2004, Directive 2001/83/EC, among others), with a focus on equitable access to quality medicines, supply reliability, and support for innovation [6].

At the same time, in 2025, the United States introduced tariffs on pharmaceutical imports – ranging from 10% to 245% for APIs from China. This has complicated the global supply of generics, most of which depend on API imports [10; 12], and may increase the cost of medicines for patients, especially in countries that rely on re-export.

EU GMP requirements have become critically important for entering the EU market [7]. For countries like Ukraine, the absence of Mutual Recognition Agreements (MRAs) means delays and additional certification costs. This hampers the rapid supply of medicines in emergency situations, which can directly affect patient health. Simultaneously, intensified FDA inspections in the United States [11] are driving up generic drug prices, which also affects vulnerable population groups both in America and in importing countries.

India, as a key manufacturer of generic medicines, faces price pressure from China, which accounted for over 43% of India's pharmaceutical imports in 2023–2024 [9]. The decrease in prices of active ingredients (e.g., atorvastatin – down 33%) [8] complicates the development of domestic production, even despite government support (the USD 5.1 billion PLI program).

In 2025, the U.S. imposition of tariffs up to 245% on APIs from China and 25% on equipment [12] further disrupts global supply chains, jeopardizing treatment access for millions of patients, particularly in countries like Ukraine, where the absence of a domestic production base increases dependence on unstable supplies.

The main barriers hindering the stability of supply chains include:

− price competition without proper quality standardization;

− limited access to GMP certificates for new manufacturers;

− trade protectionism and tariff barriers;

− delays due to complex logistical and customs procedures.

These factors require a coordinated policy to ensure that the Ukrainian population has access to affordable, high-quality, and safe medicines, even under conditions of global disruption.

The key regulatory and trade barriers that hinder the effective functioning of pharmaceutical supply chains are presented in Table 2.

As shown in Table 2, regulatory and trade barriers – such as strict EU GMP requirements, U.S. customs restrictions in 2025, and price pressure from China –significantly complicate the stable supply of medicines. These challenges underscore the need to harmonize standards, diversify suppliers, and localize the production of essential medicines.

The European Union, through HERA (established in 2021), is investing over €1.3 billion in strategic stockpiles of vaccines and antibiotics [13; 14]. Regulation (EU) 2021/953 facilitates access to quality medicines [17].

The United States, which imports up to 90% of APIs (including 17% from China), introduced 2025 tariffs (up to 245%) and the "Buy American" program [10; 12;

Table 2

Key Regulatory and Trade Barriers in Pharmaceutical Supply Chains, 2023–2025

Barrier	Description
EU GMP Certification Requirements	Mandatory compliance with EU GMP standards for manufacturers and API importers into the EU requires lengthy inspections and certifications, limiting market access.
Enhanced Import Inspections	New U.S. regulations (2025) involving FDA inspections and customs procedures, as well as EU GMP requirements for importers from third countries, increase costs and delays.
U.S. Import Tariffs	U.S. tariffs in 2025 (up to 245% on Chinese APIs) increase API and equipment import costs, escalating generic drug production expenses.
Price Competition	Price reductions on Chinese APIs (up to 50% for some products) exert pressure on local manufacturers, particularly in India, hindering self-sufficiency development.
Regulatory Inconsistency	Differences in regulatory standards between the EU, U.S., and other countries complicate mutual recognition of API quality and certification.

Source: Compiled by the authors based on [6; 7; 8; 9; 10; 11; 12].

16]. Investments by BARDA, along with enhanced FDA inspections, aim to strengthen pharmaceutical security and improve access to generic medicines for the population [11; 16].

China, which holds 80% of the global API market, is investing in biotechnological ingredients through its five-year plan, forecasting market growth to USD 347.9 billion by 2029 [20].

India is investing over USD 1.8 billion in API production (PLI program) to reduce dependence on imports from China [9; 15; 18]. Additionally, 36 critical drugs have been exempted from duties to reduce the burden on patients [15; 18].

These measures confirm a global trend toward strengthening pharmaceutical autonomy, which has direct implications for countries with import-dependent healthcare systems, such as Ukraine, where the absence of local production complicates the stable supply of critical medicines. To reduce the risk of supply disruptions, Ukraine needs a systematic state policy focused on production localization, support for GMP certification, and integration into international regulatory frameworks.

The main adaptation strategies of key players in the global pharmaceutical market are presented in Table 3.

To evaluate the effectiveness of the adaptation strategies of key players in the pharmaceutical sector, the following factors were taken into account:

− **EU (4.5):** HERA ensures rapid response and coordination, supported by a €1.30 billion budget and Regulation (EU) 2021/953. However, dependence on external API suppliers persists.

− **China (4.3):** Dominance in 80% of generic API production and investments in biotechnology strengthen its position, but geopolitical risks and deglobalization pressures reduce the overall score.

− **USA (4.0):** Tariffs and the "Buy American" initiative support domestic market strengthening, but localization remains limited (<15% of APIs are produced domestically), and strict tariff measures may reduce access to critical medicines.

− **India (3.7):** PLI and PRIP stimulate localization, but bureaucratic barriers and underdeveloped infrastructure hinder implementation (43.45% of API imports still come from China).

These results indicate that even the strongest systems face adaptation challenges that impact not only their internal markets but also importing countries.

For states with a high level of import dependency, such as Ukraine, the effectiveness of the adaptation strategies of key players directly determines the resilience of pharmaceutical supply during crises, the price level of medicines, and access to essential drugs for vulnerable population groups.

In 2024, the volume of pharmaceutical imports to Ukraine rose to USD 2.89 billion, accounting for 4.54% of the country's total imports [21–24]. This represents a 35% increase compared to 2023, and a 52% increase compared to 2022. The growth is driven by strengthened cooperation with the EU and India amid the ongoing war, as well as temporary trade preferences granted by the EU (ATM until 2025).

Despite positive dynamics, structural dependence on imports remains high, which increases the vulnerability of the healthcare system to external risks.

Table 3

Adaptation Strategies of Key Players in the Pharmaceutical Sector

Country/Region	Instruments	Budget	Effectiveness (1–5)
EU	HERA, Regulation (EU) 2021/953	€1.30billion (2023)	4.5
China	14th Five-Year Plan, biotechnological APIs	–	4.3
USA	Tariffs, "Buy American," BARDA, FDA inspections	–	4.0
India	PLI, PRIP, duty exemptions	USD 0.29 billion (2025–2026)	3.7

Source: Compiled by the authors based on [9; 11; 13; 14; 15; 16; 17; 18; 19; 20, authors' own research].

Investments in local production – particularly in the Lviv cluster (Biosynth and Enamine, €100 million in 2023) – are an important step; however, this accounts for less than 10% of domestic demand. The main reasons are infrastructural limitations and the need to modernize production in accordance with EU GMP standards.

Table 4 illustrates the main medicine suppliers to Ukraine in 2023 and highlights the concentration of supply sources, emphasizing the need for diversification strategies and the development of domestic capacities.

Table 4

Structure of Pharmaceutical Imports to Ukraine in 2023

Country	Share (%)	Volume (USD million)
Germany	19.30	414
India	8.61	184
France	8.28	177
Italy	6.89	147
USA	4.70	100
Spain	4.65	99
Slovenia	4.39	94
Ireland	4.16	89
Switzerland	3.23	69
Hungary	3.18	68

Source: Compiled by the authors based on [21; 23; 24].

Analysis of Table 4 shows that in 2023, the top 10 supplying countries accounted for 53.5% of Ukraine's pharmaceutical imports, totaling USD 1.14 billion [21]. The largest supplier was Germany (USD 414 million, 19.3%), focusing on generics, branded vaccines, and oncology drugs, which corresponds to the import structure: 80% are medicines for retail sale (HS 3004), and 13.7% are immunological products and vaccines (HS 3002) [21].

India (USD 184 million, 8.6%) ranks second due to its substantial share of generics and antibiotics, explained by its role as a key supplier of active pharmaceutical ingredients (APIs) [21; 23]. France, Italy, and other European countries supply highly specialized medicines, including hormonal drugs, oncology treatments, and biologics, which are critical under conditions of armed conflict [21; 24].

Poland (USD 128 million, 6.0%) and Turkey (USD 113 million, 5.3%) show steady growth in supply (+33.3% and +25.0%, respectively, in 2022–2023), but remain limited by smaller production capacities [21; 23].

These data indicate an excessive concentration of imports from a few countries, creating risks in the event of supply chain disruptions. In this context, Ukraine's integration into regional logistics networks (through ACAA, IMEC) and the development of domestic clusters become strategically important [24; 31; 33].

Discussion of research results

The research results confirm that global pharmaceutical trade is undergoing profound transformation under the influence of a number of systemic factors – geopolitical conflicts, energy shocks, increased regulatory protectionism, and structural shifts in value chains. The global model, which for decades was based on centralized production in China and India, is giving way to regional trade configurations. These changes are not only economically significant – they directly affect the availability, timeliness, and safety of medicines for millions of people, especially vulnerable population groups.

The formation of regional blocs, restricted access to the global API market, and the development of strategic corridors (such as the India–Middle East–Europe Economic Corridor) by 2030 are processes that are reshaping the very architecture of global medicine supply. In this context, the role of intermediary countries such as Ukraine may be strengthened – provided domestic issues are addressed, including the lack of certified production facilities, weak logistics digitalization, energy instability, and regulatory fragmentation.

Digitalization plays a critical role in ensuring pharmaceutical supply resilience. The underdevelopment of digital infrastructure – such as electronic medicinal product registries, automated batch tracking systems, eHealth platforms, and blockchain-based logistics integration – complicates quality control, supply chain transparency, and responsiveness during crisis situations. While leading players are actively investing in digital analytics tools, shortage prevention, and demand forecasting, these elements in Ukraine are not yet systematically integrated into medical-pharmaceutical planning.

At the same time, existing initiatives – such as the creation of clusters in Lviv (Enamine, Biosynth), pilot partnerships with EU countries, and international assistance for modernization of production capacities – demonstrate potential for the gradual formation of pharmaceutical hub elements in Ukraine. Combined with expanded logistics connectivity (ACAA, IMEC, development of border infrastructure), these factors may strengthen Ukraine's position as a key transit and manufacturing player in the region.

Therefore, today's challenge lies not only in the transformation of trade models, but in ensuring a fundamental human right – the right to health and access to quality medicines. Despite the strategic importance of manufacturing and logistics integration, it is critically important to maintain the primary objective of the pharmaceutical system in focus – the protection of public health. Any disruptions in supply or restrictions in access to essential medicines may have immediate consequences in the form of treatment complications, deterioration in quality of life, or even increased premature mortality among various population groups. Thus, the effectiveness of reforms and adaptations should be assessed not only in economic or logistical terms, but also through the lens of their impact on patients' lives and well-being.

Prospects for further research

The prospects for further research lie in exploring Ukraine's potential integration into regional pharmaceutical supply chains, with a focus on quality improvement, production localization, and digital transparency. Particularly relevant is the analysis of development scenarios positioning Ukraine as a transit and manufacturing pharmaceutical hub for the EU and MENA markets amid global transformations.

Conclusions

Global trade in pharmaceutical products is undergoing a phase of strategic reconfiguration, driven by the simultaneous influence of several powerful factors -geopolitical tensions, deglobalization trends, inflationary pressure, API supply instability, and the rising role of regional blocs. The regionalization of supply chains, technological modernization of logistics, and the implementation of adaptive security policies are shaping a new paradigm in which universal solutions give way to flexible, localized, and resilient pharmaceutical supply models.

Despite the strategic and economic dimensions of these transformations, the human being must remain at the center of the system – their right to timely, safe, high-quality, and affordable access to medicines, especially in times of crisis, war, or humanitarian threats.

The health of the population cannot be subordinated to logistical, tariff, or customs decisions. On the contrary, trade and industrial policy in the healthcare sector must be patient-oriented, anticipate risks, reduce system vulnerabilities, and enhance autonomy in critical segments – from API production to medicine distribution.

In this context, the development of a national pharmaceutical strategy for Ukraine should be based on three key principles:

1. Economic efficiency – support for local production, optimization of logistical costs, attraction of investment, and promotion of exports.
2. Geopolitical flexibility – expansion of cooperation with reliable partners, integration into European supply chains, and reduction of dependence on monopolistic suppliers.
3. Social justice – ensuring access to essential medicines for all population groups, with a particular focus on vulnerable categories.

Only by combining these vectors is it possible to ensure the resilience, strategic autonomy, and human-centered nature of Ukraine's pharmaceutical system in the post-crisis world.

Bibliography

1. World Trade Report 2024: Trade and Inclusiveness – How to Make Trade Work for All. World Trade Organization. Geneva: WTO, 2024. Available from: https://www.wto.org/english/res_e/booksp_e/wtr24_e.htm (date of access: 14.07.2025).
2. Pfizer Updates Company Position in Russia. Pfizer. 2022. Available from: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-updates-company-position-russia (date of access: 14.07.2025).
3. Global Trade Outlook and Statistics April 2025. World Trade Organization. Geneva: WTO, 2025. Available from: https://www.wto.org/english/res_e/booksp_e/trade_outlook25_e.pdf (date of access: 14.07.2025).
4. Rizzi D, Ciuffo G, Landoni M, Mangiagalli M, Ionio C. Psychological and environmental factors influencing resilience among Ukrainian refugees and internally displaced persons: a systematic review of coping strategies and risk and protective factors. Frontiers in Psychology. 2023;14:1266125.
5. Pharmaceutical products | Imports and Exports | 2023. TrendEconomy. 2024. Available from: https://trendeconomy.com/data/commodity_h2/30 (date of access: 14.07.2025).
6. EU trade in medicinal and pharmaceutical products in 2023. Eurostat. 2024. Available from: https://ec.europa.eu/eurostat/en/web/products-eurostat-news/w/ddn-20240426-3 (date of access: 14.07.2025).
7. Regulatory Considerations for API Manufacturing in the EU. DrugPatentWatch. 2024. Available from: https://www.drugpatentwatch.com/blog/regulatory-considerations-for-api-manufacturing-in-the-eu-ensuring-compliance-and-supply-chain-resilience/ (date of access: 14.07.2025).
8. China now fighting a losing battle in India's bulk drugs market. Financial Express. 2025. Available from: https://www.financialexpress.com/business/industry/china-now-fighting-a-losing-battle-in-indias-bulk-drugs-market/ (date of access: 14.07.2025).
9. India struggling to free pharma industry from dependence on Chinese APIs. Policy Circle. 2025. Available from: https://www.policycircle.org/industry/apis-import-depencence-on-china (date of access: 14.07.2025).
10. Study Finds Over 90% of All Generic Drugs Dependent on Imports. Prosperous America. 2025. Available from: https://prosperousamerica.org/study-finds-over-90-of-all-generic-drugs-dependent-on-imports/ (date of access: 14.07.2025).
11. How U.S. Import Regulations Are Changing for Pharma and Biotech in 2025. EAW Logistics. 2025. Available from: https://www.eawlogistics.com/how-u-s-import-regulations-are-changing-for-pharma-and-biotech-in-2025/ (date of access: 14.07.2025).
12. How 2025 U.S. Tariffs Are Reshaping Global Pharma Supply Chains. Cognitive Market Research. 2025. Available from: https://www.cognitivemarketresearch.com/blog/how-2025-u-s-tariffs-are-reshaping-global-pharma-supply-chains (date of access: 14.07.2025).
13. HERA: A new era for health emergency preparedness in Europe. European Commission. 2021. Available from: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_4672 (date of access: 14.07.2025).
14. HERA presents a 1.3 billion euros budget to prevent health emergencies in 2023. FASI. 2022. Available from: https://fasi.eu/en/articles/in-evidence/25280-hera-presents-a-1-3-billion-euros-budget-to-prevent-health-emergencies-in-2023.html (date of access: 14.07.2025).
15. India's 2025-26 Budget: A Game Changer for APIs & Pharma Exports. LinkedIn. 2025. Available from: https://www.linkedin.com/pulse/indias-2025-26-budget-game-changer-apis-pharma-exports-chetan-ghatge-zbzde (date of access: 14.07.2025).

16. The US is relying more on China for pharmaceuticals – and vice versa. Atlantic Council. 2023. Available from: https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/ (date of access: 14.07.2025).

17. Regulation (EU) 2021/953. EUR-Lex. 2021. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX-%3A32021R0953 (date of access: 14.07.2025).

18. Schemes. Department of Pharmaceuticals, India. 2025. Available from: https://pharma-dept.gov.in/schemes (date of access: 14.07.2025).

19. The Role of China in the Global Generic Drug API Market. Available from: https://www.drugpatentwatch.com/blog/the-role-of-china-in-the-global-generic-drug-api-market/ (date of access: 14.07.2025).

20. The Role of China in the Global Generic Drug API Market. DrugPatentWatch. 2025. Available from: https://www.drugpatentwatch.com/blog/the-role-of-china-in-the-global-generic-drug-api-market/ (date of access: 14.07.2025).

21. Ukraine | Imports and Exports | World | Pharmaceutical products | Value (US$) and Value Growth, YoY (%) | 2012–2023. TrendEconomy. 2024. Available from: https://trendeconomy.com/data/h2/Ukraine/30 (date of access: 14.07.2025).

22. Digitalization of Customs Procedures: Current State and Prospects. Journals PNU. 2024. Available from: https://journals.pnu.edu.ua/index.php/jpnu/article/view/8231/8335 (date of access: 14.07.2025).

23. Ukraine Import Data for 2023. Tendata. 2024. Available from: https://www.tendata.com/blogs/import/5726.html (date of access: 14.07.2025).

24. Ukraine Imports of Pharmaceutical products. Trading Economics. 2025. Available from: https://tradingeconomics.com/ukraine/imports/pharmaceutical-products (date of access: 14.07.2025).

25. Harnessing the power of AI in distribution operations. McKinsey. 2024. Available from: https://www.mckinsey.com/industries/industrials-and-electronics/our-insights/distribution-blog/harnessing-the-power-of-ai-in-distribution-operations (date of access: 14.07.2025).

26. How AI in freight forwarding drives efficiency and reduces costs. Sedna. 2024. Available from: https://sedna.com/resources/how-ai-in-freight-forwarding-drives-efficiency-and-reduces-costs (date of access: 14.07.2025).

27. Support the establishment of the state control authority for medicines and medical devices. Twinning Fiche. 2025. Available from: https://ncp-twinning.de/wp-content/uploads/2025/05/Twinning-Fiche-Ukraine-UA-24-UF-HE-01-25-1.pdf (date of access: 14.07.2025).

28. Global consumer health trends 2023: Impact of pricing. IQVIA Institute for Human Data Science. 2023. Available from: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/global-consumer-health-trends-2023-impact-of-pricing.pdf (date of access: 14.07.2025).

29. Health financing in Ukraine: Reform, resilience and recovery. World Health Organization. 2024. Available from: https://iris.who.int/bitstream/handle/10665/379548/WHO-EURO-2024-10570-50342-75964-eng.pdf (date of access: 14.07.2025).

30. Industry allies with EBA to speed Ukraine's integration with EU market. Medicines for Europe. 2024. Available from: https://insights.citeline.com/GB152797/Industry-Allies-With-EBA-To-Speed-Ukraines-Integration-With-EU-Market/ (date of access: 14.07.2025).

31. One step closer to the European market for Ukrainian manufacturers with the preparations on an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA). European External Action Service. 2023. Available from: https://eu4ukraine.eu/whats-happening-ua/news-ua/one-step-closer-to-the-european-market-ua.html (date of access: 14.07.2025).

32. McKinsey on Semiconductors 2024. McKinsey & Company. 2024. Available from: https://www.mckinsey.com/~/media/mckinsey/industries/semiconductors/our%20insights/mckinsey%20on%20semiconductors%202024/mck_semiconductors_2024_webpdf.pdf (date of access: 14.07.2025).

33. The Infinite Connection: How to Make the India-Middle East-Europe Economic Corridor Happen. European Council on Foreign Relations (ECFR). 2024. Available from: https://ecfr.eu/publication/the-infinite-connection-how-to-make-the-india-middle-east-europe-economic-corridor-happen/ (date of access: 14.07.2025).

34. OECD Economic Surveys: Ukraine 2025. Organisation for Economic Co-operation and Development (OECD). 2025. Available from: https://www.oecd.org/en/publications/oecd-economic-surveys-ukraine-2025_940cee85-en.html (date of access: 14.07.2025).

Purpose of the Study. The purpose of this study is to analyze the risks associated with the declining availability of quality medicinal products and medical devices for the population of Ukraine under the conditions of transformation in international pharmaceutical trade, socio-humanitarian crises, and the digitalization of healthcare systems.

Materials and Methods. The object of the study is the medicine supply system in Ukraine under disrupted global supply chains. The research methodology is based on a comprehensive approach that includes comparative analysis of international strategies, case studies of practices used by leading pharmaceutical companies, and statistical analysis of official data on imports, investment programs, and API market structure. The sources of information include official reports from international organizations (WTO, WHO, EFCG), national statistics, regulatory initiative documents (HERA, ACAA, PLI), and analytical research by companies such as IQVIA and McKinsey.

Research Results. It was found that the transformation of the global pharmaceutical market is accompanied by trade regionalization, rising tariff barriers, price pressure on APIs, and stricter GMP certification requirements. Ukraine, which depends on imported medicines for more than 70% of its supply, faces increased risks of supply disruptions, especially in wartime conditions. The critical importance of implementing digital tools for monitoring the circulation of medicinal products is emphasized. International adaptation strategies (EU, USA, China, India) were analyzed, and the need for Ukraine to localize production and integrate into regional logistics platforms was identified.

Conclusions. The global pharmaceutical system is shifting toward a new paradigm – from centralized global production to resilient regional models. For Ukraine, key priorities include the development of local manufacturing, digitalization of logistics,

harmonization with European standards, and the formation of a national pharmaceutical security strategy. Ensuring access to quality medicines for the population must remain a core objective of national health policy in the context of global crises.

Key words: pharmaceutical security, import dependence, supply chains, regionalization, API, digitalization, GMP certification, healthcare, production localization, strategy, Ukraine.

Мета наукового дослідження. Метою дослідження є глибокий аналіз ризиків, пов'язаних із зниженням доступності якісних, безпечних та ефективних лікарських засобів і виробів медичного призначення для населення України в умовах трансформації глобальної фармацевтичної торгівлі, загострення геополітичних конфліктів, тривалих соціогуманітарних криз і зростання значущості цифрових технологій у сфері охорони здоров'я. Особлива увага приділяється вивченню чинників, що ускладнюють функціонування ланцюгів постачання, та пошуку стратегій зменшення критичної залежності від імпорту. Крім того, дослідження орієнтоване на розробку пропозицій щодо зміцнення національної фармацевтичної безпеки України з урахуванням нових глобальних і регіональних тенденцій.

Матеріали та методи. Об'єктом дослідження є система забезпечення лікарськими засобами в Україні на тлі трансформацій міжнародної фармацевтичної торгівлі та регіоналізації ринку. У дослідженні використано міждисциплінарний підхід, що поєднує елементи міжнародної економіки, фармацевтичної політики, логістики, регуляторного аналізу та цифрового управління. Методологічно застосовано:

– порівняльний аналіз стратегій адаптації фармацевтичного сектору в ЄС, США, Китаї, Індії;

– кейс-аналіз дій провідних компаній (Pfizer, Novartis, Polpharma), а також українських кластерів (Biosynth, Enamine);

– кількісний статистичний аналіз на базі офіційних даних WTO, WHO, EFCG, Євростату, Державної служби статистики України та аналітичних звітів компаній IQVIA, McKinsey. Вивчено програмні документи стратегічних ініціатив (HERA, ACAA, PLI) щодо регіональної інтеграції та локалізації виробництва лікарських засобів.

Результати. Установлено, що глобальні фармацевтичні ланцюги постачання перебувають у фазі глибокої перебудови, спричиненої пандемією COVID-19, повномасштабною війною в Україні, торговельними конфліктами та технологічними трансформаціями. Виявлено посилення залежності України від імпорту – понад 70 % препаратів завозяться з-за кордону, що створює ризики порушення безперервності лікування, зростання цін, дефіциту препаратів для хронічно хворих і порушення вакцинаційних програм. Показано, що до основних бар'єрів належать: митні обмеження, відсутність MRA-угод, нерівність у доступі до GMP-сертифікації та логістичні затримки. Результати дослідження підтверджують, що зростаюча роль таких країн, як Індія, Бангладеш і Туреччина, створює нові можливості для диверсифікації постачань.

Особливо важливою визнано роль цифрових технологій. Недостатній рівень цифрової інфраструктури в окремих регіонах України, особливо в сільській місцевості та на прифронтових територіях, значно обмежує ефективне застосування сучасних інструментів відстеження й електронного контролю лікарських засобів. У дослідженні підкреслено необхідність впровадження єдиних електронних реєстрів, цифрових логістичних платформ і систем блокчейн-верифікації як основи стійкості постачань у кризових ситуаціях. Проаналізовано вплив тарифів США (до 245 % на API з Китаю), стратегії Buy American та оновлених регламентів ЄС на глобальні потоки медикаментів.

Висновки. Дослідження доводить, що світова фармацевтична система переходить до нової парадигми: від централізованого виробництва та глобалізованої торгівлі до фрагментованих, гнучких, регіонально орієнтованих моделей. У таких умовах Україна має сформувати власну довгострокову фармацевтичну стратегію, що спирається на три основні принципи:

Економічна ефективність – підтримка внутрішнього виробництва, залучення інвестицій, оптимізація витрат на імпорт і розвиток експортного потенціалу.

1. Геополітична гнучкість – поглиблення співпраці з країнами ЄС та іншими надійними партнерами, мінімізація залежності від окремих постачальників, розвиток кластерного виробництва.

2. Соціальна справедливість – забезпечення рівного доступу до базових і спеціалізованих препаратів для всіх громадян, особливо уразливих категорій (дітей, літніх осіб, людей з інвалідністю, пацієнтів із хронічними захворюваннями).

3. З урахуванням потенціалу логістичної транзитної ролі України, розбудови фармацевтичних кластерів, цифрової модернізації галузі та міжнародної технічної допомоги країна здатна посісти важливе місце у європейському фармацевтичному просторі. Основним критерієм ефективності реформ має залишатися не лише економічна або політична вигода, а насамперед реальний вплив на доступність, безперервність і якість лікування населення.

Ключові слова: фармацевтична безпека, імпортозалежність, ланцюги постачання, регіоналізація, API, цифровізація, GMP-сертифікація, охорона здоров'я, локалізація виробництва, стратегія, Україна.

Конфлікт інтересів: відсутній.
Conflict of interest: absent.

Information about the authors

Zayats Olena Ivanivna – Doctor of Economics, Professor at the Department of International Economic Relations, State Higher Educational Institution "Uzhhorod National University"; Narodna Square, 3, Uzhhorod, Ukraine, 88000. olena.zayats@uzhnu.edu.ua, ORCID ID: 0000-0001-9904-8706 [A, B, C, D, E]

Myronyuk Ivan Sviatoslavovych – Doctor of Medical Sciences, Professor, Vice-Rector for Research of the State Higher Educational Institution "Uzhhorod National University"; Narodna Square, 3, Uzhhorod, Ukraine, 88000. ivan.myronyuk@uzhnu.edu.ua, ORCID ID: 0000-0003-4203-4447 [A, E, F]

Mulesa Oksana – Doctor of Technical Sciences, Habilitated Doctor in Applied Mathematics, Professor at the Department of Software Systems, State Higher Educational Institution "Uzhhorod National University"; Uzhhorod, Ukraine, 88000; Associated Professor at the Faculty of Humanities and Natural Sciences, University of Prešov; Prešov, Slovakia, 080 01. Oksana.mulesa@unipo.sk, ORCID ID: 0000-0002-6117-5846 [A, C, D, E, F]

Стаття надійшла до редакції 31.07.2025
Дата першого рішення 05.09.2025
Стаття подана до друку 30.09.2025