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UKRAINIAN PATH TO EUROPEAN UNION. THE POLISH EXPERIENCE

2024

REPORT

UKRAINIAN PATH TO THE EUROPEAN UNION. POLISH EXPERIENCE

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PHARMACEUTICAL SECTOR

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Introduction

A full-scale Russian invasion in February 2022 accelerated Ukraine's efforts to join the European Union. The Association Agreement, which came into force in 2014, except for the Deep and Comprehensive Free Trade Area (DCFTA) enacted in 2016, formed the basis of Ukraine's preparations to join the EU. In June 2022, Ukraine was granted candidate status. In December 2023, EU leaders decided to start accession negotiations. Given Ukraine's intention to join the European Union, we would like to consider the experience of Poland and Polish entrepreneurs in practically implementing this membership. European Union regulations for new members are both a challenge and an opportunity. We believe that Poland's experience will be of great value to Ukraine due to the two countries' historical, social, and cultural proximity. The potential of the Polish economy, the Polish experience from the economic transition, and the construction of modern communications, energy, and logistics infrastructure are undoubtedly additional assets, also in the context of support for the implementation of EU regulations in Ukraine. Another issue is assessing Ukraine's ongoing economic integration with the Polish and EU market and the expected post-accession effects for both countries. Opportunities and challenges for cooperation and competition will be discussed, preparing partners for much closer economic ties soon.

This report was prepared as part of the project "Ukrainian Path to European Union. Polish experience.", carried out jointly by the Warsaw Enterprise Institute (Poland) and the Institute for Economic Research and Policy Consulting (Ukraine).

A key element of the project is expert seminars and sectoral reports. We want to focus on sensitive sectors of the economy that, on the one hand, may pose significant challenges as potential areas of competition and disputes between Polish and Ukrainian entrepreneurs, and, on the other hand, discuss those areas that can become a place of cooperation and mutual complementarity between the economies:

- energy;
- food and agriculture;
- road transportation;
- pharmacy;
- construction and building materials;
- timber and furniture industry.

Each sectoral report consists of two parts. The first deals with the Polish perspective on a respective sector of the economy, the impact of European regulations on transforming the sector, and recommendations for the Ukrainian side. The second part deals with the current state of the sector in Ukraine, the challenges posed by European integration, and prospects for cooperation between companies from both countries.

We strongly believe that our reports and the project as a whole will be an important voice in the discourse on Ukrainian integration into the European Union, provide the right knowledge, and help overcome mutual conflicts and misunderstandings. We want to convince everyone that entrepreneurs of both countries can and should work together to build the economic strength of our countries based on economic freedom and liberty.

Executive summary

This report on the pharmaceutical sectors in Poland and Ukraine highlights the characteristics, challenges, and opportunities within both countries' industries, particularly in the context of Polish-Ukrainian cooperation and European Union (EU) alignment.

The Polish pharmaceutical sector significantly contributes to the national economy, with a revenue of over PLN 15 billion to Poland's GDP and contributions of PLN 4 billion to the State budget in 2022. The sector is dominated by major players like Polpharma, Roche Polska, and Lek S.A., which collectively drive much of the market. The industry is characterized by a high concentration in pharmaceutical wholesalers and pharmacies, with three wholesalers controlling 70% of the market. Poland's aging population and the influx of Ukrainian immigrants are expected to drive continued demand for pharmaceutical products.

Ukraine's pharmaceutical sector is also crucial, supplying 63% of domestic demand by volume and showing significant export potential, primarily to post-Soviet countries. The sector has been resilient despite challenges from the ongoing war, including infrastructure damage and disruptions to logistics. Ukraine has a dense pharmacy network, comparable to that of Germany, despite having a significantly smaller population. The war has accelerated concentration in the wholesale market, with the top two wholesalers controlling 85% of the market.

Poland's pharmaceutical sector operates under a comprehensive legal framework aligned with EU regulations, covering drug reimbursement, clinical trials, and pharmaceutical law. Key legislation includes the Act on the Reimbursement of Medicines, the Pharmaceutical Law, and the Statute on Clinical Trials, all of which ensure high standards for drug safety, efficacy, and quality. The EU's pharmaceutical framework is integral to Poland's regulatory landscape, with ongoing reforms aimed at improving access to affordable medicines and fostering innovation.

Ukraine's pharmaceutical sector is governed by the Law on Medicines, with the Ministry of Health and the State Service on Medicines and Drug Control playing key roles in regulation and oversight. While Ukraine's current alignment with EU legislation is limited, significant efforts are being made to implement EU standards, particularly in the areas of Good Manufacturing Practices (GMP) and the registration of medicines. A new edition of the Medicines Law has been approved, which will bring Ukrainian regulations closer to EU standards, although full implementation is expected only after martial law is lifted.

Poland has successfully harmonized its pharmaceutical regulations with EU standards since its accession in 2004, with significant improvements in drug reimbursement transparency and access to innovative therapies. The Polish experience highlights the importance of aligning with EU regulations to enhance market access and ensure high standards for drug safety and efficacy.

Ukraine is in the process of aligning its pharmaceutical sector with EU standards, although challenges remain, particularly in gaining EU recognition for Ukrainian GMP certificates. The war has complicated these efforts, increasing costs and necessitating regulatory adjustments to maintain market stability. Cooperation with Poland offers valuable lessons and opportunities for Ukraine, particularly in areas like drug safety, price negotiations, and regulatory alignment.

Both countries have strategic opportunities for cooperation in the pharmaceutical sector, particularly in drug production and supply chain integration. Poland's strong regulatory framework and experience in negotiating drug prices with global pharmaceutical companies can provide valuable support to Ukraine as it aligns with EU standards. Joint ventures and cross-border cooperation could strengthen both countries' positions in the European pharmaceutical market, with Ukraine potentially serving as an alternative supplier of active pharmaceutical ingredients (APIs) to the EU.

Ukraine should focus on strengthening its pharmaceutical sector by increasing domestic production, enhancing drug safety, and improving access to innovative therapies. Continued alignment with EU regulations is crucial, with a focus on implementing the new Medicines Law and establishing a regulatory authority that meets EU standards. Cooperation with Poland should be deepened, particularly in areas like supply chain partnerships, regulatory alignment, and clinical trials.

Both countries should facilitate cross-border cooperation by streamlining regulations and encouraging joint ventures between Polish and Ukrainian pharmaceutical companies. Continued dialogue and collaboration are essential to optimize cooperation, reduce potential disputes, and ensure both countries benefit from their integration into the broader European pharmaceutical market.

This joint report emphasizes the importance of strategic alignment, regulatory cooperation, and investment in innovation to strengthen the pharmaceutical sectors in both Poland and Ukraine. Through collaboration, both countries can enhance their competitiveness in the European market, ensuring better access to medicines and driving economic growth.

1. Characteristics of the pharmaceutical sector in the Polish economy

The key elements of the pharmaceutical sector are manufacturers of medicinal products, wholesalers, and pharmacies

Manufacturers of medicinal products

Economic Freedom Forum prepared an analysis of the Polish pharmaceutical manufacturers' sector and published it in Wprost on May 23, 2024, under the title "20 largest pharmaceutical companies in Poland."[1]

The Polish pharmaceutical sector contributed PLN 4 billion to the State budget in 2022, generating over PLN 15 billion to Poland's GDP. According to estimates by the Employers' Union of Innovative Pharmaceutical Companies INFARMA, which associates foreign entities operating in Poland, innovative pharmaceutical companies contributed over PLN 10 billion to the State budget and employed over 82,000 Poles.

In turn, the Polish Union of Employers in the Pharmaceutical Industry presented data showing that Polish pharmaceutical companies operating within Poland employ over 100,000 people.

It should be noted that in the last several years, the volume of pharmaceutical industry production has more than doubled across the European Union. In Poland, these increases have been smaller, and the industry's share of processing value added in recent years has even declined from 2.6 to 1.6 percent. The industry's development has been adversely affected in recent years, particularly by rising energy costs and high wage dynamics.

The outlook for the pharmaceuticals industry is optimistic, mainly due to the demand for the drugs themselves, which is linked to the rapidly aging Polish society and the influx of a significant number of immigrants to Poland, mainly from Ukraine.

In addition, it is essential to emphasize the state's activities aimed at easing the development of generic and biological medicines, rebuilding the production of active ingredients in Europe, and providing preferences for companies that decide to produce medicines in Poland.

According to Wprost magazine, the largest Polish pharmaceutical companies in terms of revenue in 2022 are:

- PLN 3.6 billion ZAKŁADY FARMACEUTYCZNE POLPHARMA
- PLN 2.6 billion ROCHE POLSKA
- PLN 2.5 billion LEK S A
- PLN 1.9 billion TEVA OPERATIONS POLAND
- PLN 1.8 billion GSK SERVICES
- PLN 1.8 billion BAUSCH HEALTH POLAND
- PLN 1.5 billion ADAMED PHARMA
- PLN 1.2 billion SANOFI AVENTIS
- PLN 1.1 billion USP ZDROWIE
- PLN 1.0 billion BOEHRINGER INGELHEIM

Pharmaceutical wholesalers

In 2020, PEX PharmaSequence Sp. z o.o, commissioned by the Association of Employers of Pharmaceutical Wholesalers, published a report, "The role of pharmaceutical wholesale distribution in ensuring Poland's drug security.[2]

[1] https://eff.wprost.pl/11697211/te-firmy-trzesa-polskim-rynkiem-lekow-oto-20-gigantow-z-branzy.html
[2] http://zphf.pl/raporty

Key data and analyses on financial and organizational aspects of the operation of pharmaceutical wholesalers in Poland are presented below.

In Poland, 488 wholesalers listed in the Register of Pharmaceutical Wholesalers had active status at the beginning of 2020.[3]

The three largest players (Neuca, Pelion Farmacol) account for as much as 70 percent of the value of pharmaceutical sales to pharmacies in Poland. International concerns do not play a significant role in this sector, which is a phenomenon on a European scale

There is a significant degree of concentration on the pharmaceutical wholesale market. The 10 largest entities concentrate almost 90 per cent of the turnover of the entire pharmaceutical distribution market, according to the PEX PharmaSequence report of 2020.

Depending on the product group, concentration in the manufacturer market reaches up to 25 per cent. Such disparity causes disproportionality in trade contacts and prevents pharmacies from exerting real downward pressure on the prices of non-refundable medicines. Subsequently, suppliers have been taking advantage of market fragmentation for years.

The largest wholesalers and manufacturers dictate terms of trade through partnership and marketing programs: they reward pharmacists for selling a specific range at a certain quantity and make the availability of medicines and their prices dependent on the sales volumes.

The country's largest distributor, controlling a third of the wholesale market, brings together over 6,500 pharmacies representing 44 percent of the retail market through partnership and marketing programs.

Pharmacies

According to the Central Statistical Office, at the end of 2023, there were 11.5 thousand pharmacies (public and company pharmacies) and 1.1 thousand pharmacy points, in which 57.8 thousand master pharmacists and pharmacy technicians worked.[4]

At the end of the period in question, 11,500 general pharmacies (down 1.6% year-on--year) and 1,100 pharmacy points (down 2.5% year-on-year) were operating. In addition, there were 24 company pharmacies (similar to 2022).

17 chain pharmacies (50+ pharmacies) accounted for 36% of the market, with 3,054 outlets.

According to PEX Pharma Sequence data, the entire pharmacy market's sales amounted to PLN 50.42 billion at the end of 2023, 9.5 percent more than in 2022. In turn, reimbursements amounted to PLN 11.47 billion, an increase of 12.6 percent compared to 2022.[5]

Drug reimbursements cover four categories:

- medicines dispensed free of charge
- medicines issued with a lump sum payment of PLN 3.2
- medicines with a 30% co-payment
- medicines with a 50% co-payment

According to the National Health Fund (NFZ) data presented in the Activity Report for 2022, the structure of drug reimbursement expenditures in 2022 by type of reimbursement (free, 30%, 50% lump sum) showed that more than half (61%) of the total reimbursement amount was spent for patients

[3] http://rhf.rejestrymedyczne.csioz.gov.pl
[4] https://stat.gov.pl/obszary-tematyczne/zdrowie/zdrowie/apteki-i-punkty-apteczne-w-2023-roku,15,8.html
[5] https://forsal.pl/artykuly/9406883,2023-byl-dobry-dla-aptek-o-ile-wzrosl-rynek.html

paying a lump sum. PLN 6,126 million was spent for this purpose.[6]

The following groups, in terms of the value of funds spent, constitute:

- medicines dispensed at 30% reimbursement - 29% (amount of reimbursement PLN 2 963 million.
- medicines issued free of charge - 5% (reimbursement amount PLN 544 million).
- medicines issued with 50% payment - 5% (reimbursement amount PLN 485 million).

The pharmaceutical industry in Poland should see fairly significant revenue growth in the coming quarters, with cost pressures still elevated, according to Bank Pekao's report 'In anticipation of a breakthrough. Potential and prospects for the pharmaceutical industry in Poland" („W oczekiwaniu na przełom. Potencjał i perspektywy przemysłu farmaceutycznego w Polsce"). Not only 2024 but the entire current decade should be favorable regarding sales growth opportunities.[7]

"We assume that the dynamics of domestic pharmaceutical production volumes in the following quarters should continue in a slight upward trend. Volumes have grown by 1.4% on average every quarter since H2 2022, although Q3 itself performed rather poorly in this respect (up 0.2% vs. Q2 2023 after adjusting for seasonal and calendar factors). Combined with an increase in drug prices, driven by cost factors (in particular, an increase in the price of imported raw materials and materials, which may be compounded by an exchange rate factor related to the weakening of the PLN against the major currencies after the Monetary Policy Council, started a cycle of interest rate cuts), this should translate into fairly pronounced increases in the industry's value of production sold and revenues in the coming quarters."

Bank Pekao's analysts cautioned that price trends in the global drug market remain an essential factor of uncertainty, particularly the prices of substances used in the production of medicines and imported into Europe from Asia. Their further increase could negatively reflect domestic production volumes through the prism of their profitability.

The second uncertainty factor is the industry's possible adjustments to the new regulations introduced by the reimbursement law amendment. The amendment adds new eligible groups for the free drugs system, expands the catalog of free drugs, and incentivizes domestic drug production.

Assuming that EU and national policies improve the operating conditions of the EU pharmaceutical industry, it can be expected that the industry's financial situation will at least not deteriorate in the current decade.

The industry development strategy declared by the state, aimed to a large extent at supporting the development of innovative activity and expanding the product portfolio of the Polish pharmaceutical industry, should theoretically have an impact in the direction of increasing activity in the field of research and development. In turn, the assumption of sales growth should be associated with the need to expand production capacity, especially if the product portfolio of the Polish pharmaceutical industry were to be significantly extended due to ongoing development activities.

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6 https://www.nfz.gov.pl/gfx/nfz/userfiles/_public/bip/dzialalnosc_nfz/sprawozdania_z_dzialalnosci_nfz/zal._do_uchwaly_nr_16_sprawozdanie_z_dzialalnosci_nfz_2022_rok-sig.pdf

7 https://www.pekao.com.pl/analizy-makroekonomiczne/publikacja.html?id=d815dd15-f785-40c1-9f9b-2683184be2f0

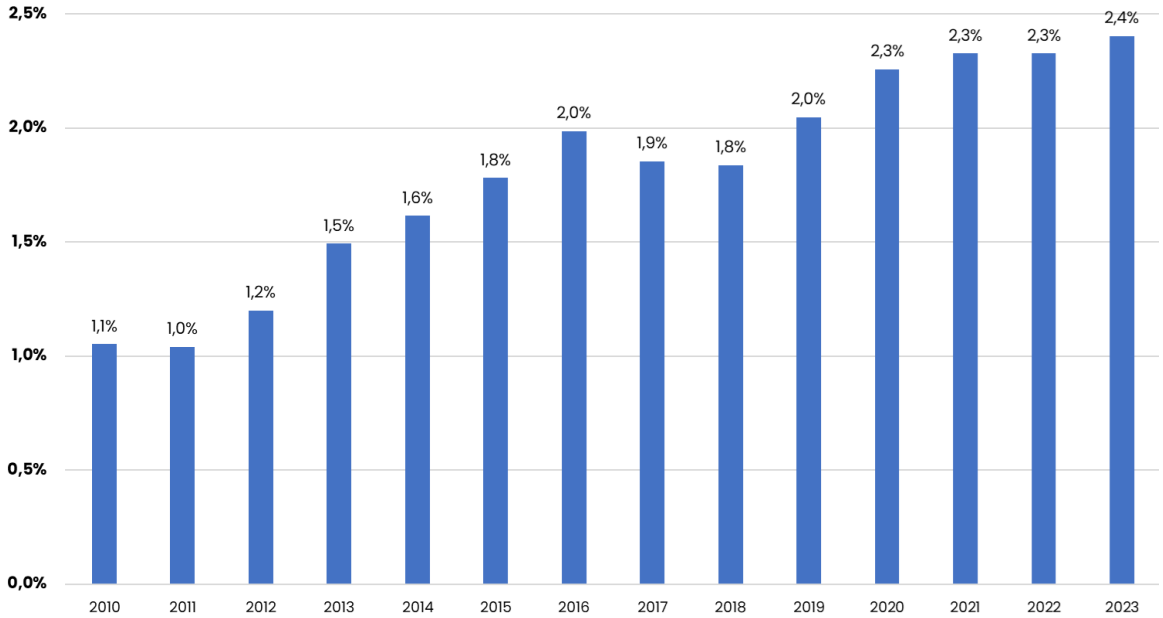
2. Characteristics of the pharma sector in Ukraine

The Ukrainian healthcare system is primarily publicly funded, with a modest share of private facilities. However, most medical products and pharmaceuticals are purchased using private funds: Government and local authorities fund the in-hospital supply of key products and reimburse most of the purchase cost for around 500 products needed to treat cardiovascular diseases, asthma, diabetes, and psychiatric disorders under "Accessible pharmaceuticals" program under a recipe from a treating physician. However, public funding accounted for less than 13% of the Ukrainian market in 2023[8].

Ukraine had several pharmaceutical producers in the Soviet times with production capacity that matched domestic demand. Following independence in 1991 pharma producers survived mostly intact due to steady domestic demand even during economic depression of 1990s. Ukrainian pharma industry accounted for 2.4% of sales in manufacturing in 2023 according to the Ukrstat. This share is relatively small but increased significantly and steadily over the last decade and a half as can be seen on a chart below.

[8] Due to limited statistics available in the wartime in this paper we rely primarily on numbers provided in the Proxima Research/TopLead report on the pharmaceutical market in Ukraine in 2023 found at the-infographics-report-pharmaceutical-industry-of-ukraine-2023.pdf (toplead.com.ua)

Chart 1. Share of pharmaceuticals industry in manufacturing sales, 2010–2023



Source: Own calculations based on Ukrstat data

However industry supplied critical needs for medical treatment accounting for 63% of domestic supply by volume and 37% in money terms. According to the Ukrstat pharmaceutical producers sent almost 15% of their sales as exports. Exports went primarily to post-Soviet countries in Europe and Central Asia.

The Pharma industry suffered from Russian attacks on infrastructure, displacement of consumers and workers, and disruption of supplies in line with the economy as a whole. Some companies in the sector suffered direct damage from Russian occupation and attacks on their logistics capacity. production capacity was not concentrated near the frontline, and damage from attacks was limited. There are a lot of pharmacies in areas close to frontlines. This included pharmacies in Nothern Ukraine before Russian retreat in 2022. Demand for pharmaceuticals remained robust as healthcare needs remained stable or even increased due to the war. Sales of pharmaceutical in US dollar terms dropped by around 20% between 2021 and 2023 to USD 4.0 bn from USD 5.0 bn.[9] Considering displacement and occupation of the parts of Ukraine per capita spending probably increased.

Some companies in the sector suffered direct damage from Russian occupation and attacks on their logistics capacity.

Ukraine has fairly dense pharmacy network at 17800 pharmacies in controlled part of Ukraine in 2023. This is comparable to 17571 pharmacies in Germany, which has over twice the population.[10]

[9] Ibid.

[10] https://www.abda.de/fileadmin/user_upload/assets/ZDF/Zahlen-Daten-Fakten-24/ABDA_ZDF_2024_Brosch_english.pdf

3. Legal foundations and organization of the pharmaceutical sector in European law

The European Union's legal framework for medicines for human use sets standards to ensure a high level of protection of public health and the quality, safety, and efficacy of authorized drugs.

The EU legal framework promotes the functioning of the internal market through measures to encourage innovation. It is based on the principle that a medicinal product requires a marketing authorization from the competent authorities before it can be placed on the market.

To a large extent, the impetus for the adoption of the legal framework stemmed from a determination to prevent a repeat of the thalidomide disaster that occurred in the late 1950s, when thousands of children were born with limb deformities as a result of their mothers taking thalidomide during pregnancy.

To protect public health, no medicinal product should ever again be placed on the market without prior authorization.

This experience, which shocked public health authorities and the general public, made it clear that, to protect public health, no medicinal product should ever again be placed on the market without prior authorization. Since then, a great deal of legislation has been developed around this principle, including the progressive harmonization of requirements for marketing authorization and post-marketing monitoring, implemented across the European Economic Area (EEA).

In the EU, a medicinal product for human use may be authorized by the European Commission through the centralized procedure or by national competent authorities through the mutual recognition procedure, the decentralized procedure, or national.

Marketing authorization requirements and procedures, as well as rules on the monitoring of authorized products, are primarily set out in Directive 2001/83/EC and Regulation (EC) No 726/2004. They also include harmonized rules on the manufacture, wholesale or advertising of medicinal products for human use.

In addition, EU legislation provides common rules for the conduct of clinical trials (to test the safety and efficacy of medicines under controlled conditions) in the EU. Different rules have also been adopted to consider the specificities of certain types of medicinal products and to promote research in specific areas:

- Regulation (EC) No 141/2000 on orphan medicinal products
- Regulation (EC) No 1901/2006 on medicinal products for pediatric use
- Regulation (EC) No 1394/2007 on advanced therapy medicinal products

All EU legislation in the area of medicinal products for human use is listed in Volume 1 'Pharmaceutical legislation for medicinal products for human use.

Numerous regulatory and scientific guidelines have been adopted to facilitate the interpretation of the legislation and its uniform application throughout the EU. A detailed

explanation of the marketing authorization procedures and other regulatory guidance can be found in Volume 2 (The Notice to Applicants).

The authorization of medicines is based on three key criteria, namely quality, safety and efficacy, to ensure that products administered to patients are of adequate quality and provide a positive benefit/risk ratio.

Quality of medicines

When applying for marketing authorization, companies must provide documentation demonstrating that the product is of sufficient quality. This is assessed according to the criteria set out in EU legislation (Annex 1 of Directive 2001/83/EC) and the guidelines (EudraLex volume 3).

If the medicinal product's qualitative and quantitative composition does not meet these standards, the marketing authorization will be refused or, if the medicinal product has already been authorized, suspended or revoked. In such a case, all appropriate steps will be taken to ensure the prohibition of supply and the withdrawal of the medicinal product from the market.

A manufacturing or import authorization is required for medicinal products, including investigational medicinal products.

Due to the impact of manufacturing and distribution practices on the quality of medicinal products, including their starting materials, a set of good practice principles and guidelines provides safeguards against deviations from product specifications and inappropriate manufacturing and distribution practices.

As the production of medicines and the sourcing of pharmaceutical ingredients are often global activities, the European Commission has intensified global cooperation with international organizations and other countries at various levels.

Safety and efficacy of medicines

The safety and efficacy of medicines are essential. For new medicines, companies must demonstrate safety and effectiveness based on the results of clinical trials. For established compounds, companies may refer to data on drugs already authorized (generic marketing authorization) or to published literature (well-established medicinal use).

The competent authorities carefully assess safety and efficacy data before a product is granted marketing authorization. For centrally authorized products, the European Medicines Agency (EMA) carries out this assessment.

Safety and efficacy continue to be monitored after marketing authorization through pharmacovigilance activities or risk-benefit ratio reviews.

EMA continues to monitor products' safety and effectiveness after receiving market authorization through pharmacovigilance activities and benefit-risk ratio reviews.

4. Impact of European regulation and practice on the sector in Poland

Poland has three laws that regulate all issues concerning the pharmaceutical and pharmacy market. Extensive consultations and legal analyses of compliance with EU law preceded the introduction of the laws.

- Act of May 12, 2011, on reimbursement of medicines, foodstuffs for special nutritional purposes, and medical devices
- Statute of September 6, 2001. Pharmaceutical Law
- Statute of March 9, 2023, on clinical trials of medicinal products for human use

The Statue of May 12, 2011, on the reimbursement of drugs, foodstuffs for particular nutritional purposes, and medical devices specifies:

1. The rules, conditions, and procedure for making an administrative decision on the reimbursement coverage of a drug, foodstuff for particular nutritional purposes, medical device, and the revocation of this decision.
2. Terms of financing of the drug, foodstuff for particular nutritional use, and medical device covered by the decision.
3. Criteria for the creation of payment levels and limit groups of drugs, foodstuffs for particular nutritional purposes, and medical devices covered by the decision;
4. Terms and procedures and criteria for determining official selling prices for drugs, foodstuffs for particular nutritional purposes, medical devices, and the amount of official wholesale and retail margins.
5. The terms for determining the prices of drugs and foodstuffs for particular nutritional purposes are used to provide guaranteed benefits.
6. The terms of public financing of medical devices available to recipients on the order of an authorized person.
7. The obligations of pharmacies arising from the circulation of drugs, foodstuffs for particular nutritional purposes, medical devices, covered by the decision, as well as the principles of control of pharmacies.
8. Obligations of persons authorized to issue prescriptions for drugs, foodstuffs for particular nutritional purposes, and medical devices covered by the decision

Statute of September 6, 2001. The Pharmaceutical Law specifies:

1. The terms and procedures for authorizing the marketing of medicinal products, considering, in particular, the requirements for quality, efficacy and safety of their use.
2. Conditions for conducting clinical trials of veterinary medicinal products.
3. Conditions for manufacturing medicinal products.
4. Rquirements for advertising medicinal products.
5. Conditions for the marketing of medicinal products.
6. Requirements for pharmacies, pharmaceutical wholesalers and non-pharmacy trading establishments.
7. Organization and principles of operation of the system of supervision and monitoring of the safety of use of medicinal products.
8. Tasks of the Pharmaceutical Inspectorate and powers of its bodies.

The Statute of March 9, 2023, on clinical trials of medicinal products for human use specifies

1. The procedure for issuing an authorization for a clinical trial of a medicinal product for human use
2. The tasks of the Supreme Bioethics Committee for Clinical Trials
3. Rules and procedures for entry into the list of bioethics committees authorized to make ethical evaluations of clinical trials,
4. Terms and procedures for conducting an ethical evaluation of a clinical trial.
5. Responsibilities of the sponsor, principal investigator and investigator.
6. Rules of civil and criminal liability of the investigator and sponsor.
7. Terms of organization and operation of the Clinical Trial Compensation Fund,
8. The amount and method of payment of fees related to the clinical trial.
9. Terms of financing health care services related to the clinical trial.
10. Terms and procedures for conducting inspections of the clinical trial.

It should be noted that on April 26, 2023, the European Commission presented drafts of two pieces of legislation - a directive and a regulation - to amend and replace current EU pharmaceutical legislation.

The goal of EU pharmaceutical law reform is to provide patients with better access to affordable medicines and security of supply, as well as encourage research in areas of unmet medical need. All this while striving to increase the competitiveness of the pharmaceutical industry in Europe, create incentives for innovation, and improve the legal framework for its development.

The European Commission's proposal to reduce the period of legal protection of data from the current 8 to 6 years, which makes up the above incentive system, is a major opportunity for the development of the pharmaceutical market in Poland and in the future in Ukraine.

Fulfillment of the expected conditions, including the introduction of a product to the market in all member states within two years of the product's registration by the European Medicines Agency, will be beyond the influence and control of current manufacturers and will depend on the vast majority on system-administrative solutions in individual countries.

However, a shorter data protection period could potentially discourage European research and development, including Poland. The European Commission's proposed changes may have the unintended consequence of weakening the motivation of innovative industry.

5. Legal and organizational basis of the pharma sector in Ukraine

The Ukrainian pharma market is governed by the specialized law "On Medicines" and regulatory rules approved by Ukrainian agencies, the Health Ministry, and the State Service on Medicines and Drug Control. The Ministry of Health is responsible for policy-making within the bounds of the law and proposing changes to the primary legislation, while the State Medicines Service executes policy on medicine registration and supervision. Legislation on intellectual property (primarily Law protecting rights for inventions[11] and law on trademark protections[12]) and valuable is also relevant for marketing of patented drugs and generic copies of trademarked drugs after patent protection ends.

Government also applies price regulation for medicines and medical products[13] on the National List of key medicines and medical products. It limits price margin for wholesalers to 10% and for retail pharmacies to 10-25% depending on its price.

As the full-scale war started in 2023 several measures were passed to ensure smooth functioning of the pharma sector. This included[14] documentation for registration in electronic form and in English, simplified extensions of medicine registration. Medicines can be sold without packing in Ukrainian if usage manual is in Ukrainian. Also to alleviate potential shortage of pharmacists, senior pharma and medical students were allowed to work as assistant pharmacists.[15]

11 https://zakon.rada.gov.ua/go/3687-12
12 https://zakon.rada.gov.ua/go/3689-12
13 https://zakon.rada.gov.ua/go/955-2008-%D0%BF
14 https://www.dls.gov.ua/for_subject/набула-чинності-постанова-яка-спрощу/
15 https://zakon.rada.gov.ua/go/v0429282-22

6. Impact of European regulation and practice on the pharmaceutical sector in Ukraine

EU-Ukraine Association Agreement does not call for implementation of the key EU legislation on the pharma sector including Directive 2001/83/EU introducing Community Code on medicinal products.[16] Association Agreement contains Chapter 22 dealing with the issues of public health and related annex XLI covering acquis approximation commitments related to tobacco control, infection surveillance and handling of human blood but pharma issues are not covered there. However full range of the EU rules will need to be transposed into Ukrainian legislation under EU accession process.[17] Also, Ukraine implemented some of the EU rules unilaterally: EU GMP (General manufacturing practice) rules for pharma industry were adopted as national standard with some adaptations (mostly to reflect Ukrainian legislation) in the early 2000s and are regularly updated to reflect changes in the base document.[18] However, EU does not currently recognize GMP certificates issued by State Medicines Service under Ukrainian legislation. In Thus Ukrainian pharma producers need to be certified again in the EU countries where their products will circulate.[19] As of August 2024, EudraGMDP[20] database listed 10 EU GMP certificates for Ukrainian producers. 6 out of 10 certificates covered Farmak JSC production sites certified in Poland and Croatia. 4 others were issued to 4 other companies by authorities in Lithuania, Latvia and Bulgaria.

> ***Full range of the EU rules will need to be transposed into Ukrainian legislation under EU accession process.***

In 2022 Parliament approved new edition of the Medicines law[21] that is supposed to implements EU directive 2001/83/EU and the related legislative acts. New law if not amended will mostly become effective 30 months after martial law is repealed. Under new law it is planned to create new regulatory authority that will provide marketing authorizations for medicines in Ukraine in line with the EU standards including using eCTD (Common Technical Document) international standard for medicine registration submissions.

16 http://data.europa.eu/eli/dir/2001/83/oj
17 https://zakon.rada.gov.ua/go/v0095282-09
18 https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
19 Medicines authorized by the EU Commission for the whole EU can be distributed in all EU countries.
20 https://eudragmdp.ema.europa.eu/
21 https://zakon.rada.gov.ua/go/2469-20

7. Challenges in aligning Ukraine's pharma sector with EU standards

Ongoing war added to the costs of most companies operating in Ukraine, including pharma producers. This made the added burden related to approximation to the EU rules heavier for producers. However, domestic demand and Ukrainian producers seem to be resilient so far, and adjustment to the EU rules comes with expected expanded access to the EU market.

Under war policy changes, Ukraine extended the validity of all patents for the duration of martial law and 6 months afterward. This prevented marketing of some generic medicines that can be sold in the EU.[22]

War also accelerated the concentration of the pharma wholesalers and pharmacy networks. According to Ukraine's competition regulator (Anti-monopoly Committee or AMC), the two largest pharmaceutical wholesalers controlled 85% of the Ukrainian market in 2022, and they maintained a dominant share in 2023, according to market research. This happened as the third largest wholesaler lost market share due to links to Russia. On the retail side, concentration was lower, and a relatively high density of pharmacies from different networks helped preserve a degree of competition. Still, four largest pharmacy networks controlled over 50% of the market by sales.[23]

[22] https://zn.ua/ukr/ECONOMICS/ukrajintsi-platili-rosijskomu-miljarderu-za-liki-chastku-odnoho-z-najbilshikh-farmatsevtichnikh-distribjutoriv-peredano-derzhavi.html

[23] https://rau.ua/novyni/top-10-aptechnih-merezh-2023/

Table 1. Top 4 pharmacy networks

Carriage of goods EU	Number of pharmacies	Market share in sales, %
Magnolia (АНЦ)	1143	16.3
Podorozhnyk	1744	15.5
Gamma-95 (911, Аптека оптових цін)	1532	13.0
Sirus-95 (Бажаємо здоров'я)	1002	10.6
Total	5421 (30% of the total)	55.4

Source: Proxima Research via Forbes Ukraine and RAU

This sharply contrasts with the situation in 2015, where AMC found a regional concentration of the market but a relatively low role in the national pharmacy networks. Increased concentration allows economies of scale, and, e.g., adapting to the EU rules may thus be easier. However, large players potentially gain market power at the consumers' expense, which may lead to rent-seeking behavior. In November 2023, AMC issued semi-binding recommendations to pharma producers and importers to sell their products to smaller wholesalers in line with demand in response to complaints about reduced or refused supplies from producers to wholesalers.[24]

EU Commission in the Ukraine 2023 Enlargement report noted that Ukraine will be partly aligned with the EU acquis after the new Medicines Law is implemented. Implementing the new law is an important next step but not the end of the road. Ministry of Health stated several times that it is working on implementing the Medicines law, including preparing for the new regulatory agency.[25] It suggested that when preparations are complete, the effective date for the latest Law may be moved forward. The goal of these efforts is for the pharma sector to be included in the future ACAA agreement that is likely to be concluded before Ukraine's accession to the EU. This will allow mutual recognition of product authorizations between the EU and Ukraine. According to the Health Ministry, prerequisites for this decision include adopting the EU pharma acquis and effectively implementing it by forming a new regulatory authority and removing a large share of falsified medicines from the market.[26]

[24] https://amcu.gov.ua/news/amku-nadav-rekomendaciyi-virobnikam-ta-importeram-likarskih-zasobiv

[25] Eg https://moz.gov.ua/uk/moz-stvorjue-edinij-reguljatornij-organ-schob-maksimalno-integruvati-standarti-ta-pidhodi-es-; https://moz.gov.ua/uk/moz-inicijue-prishvidshennja-vvedennja-v-diju-zakonu-pro-likarski-zasobi

[26] https://moz.gov.ua/uk/marina-slobodnichenko-schob-otrimati-farmacevtichnij-bezviz-z-evrosojuzom-mi-maemo-vikonati-domashne-zavdannja

8. The experience of Polish companies regarding the EU accession and EU membership – lessons for Ukraine and Ukrainian entrepreneurs – WEI

After Poland acceded to the EU in 2004, work began aligning pharmaceutical law and reimbursement issues.

The most important task was the harmonization of medicines. Any drug to remain on the market had to undergo a marketing authorization procedure, which involved harmonizing product documentation with EU requirements. The procedure was time-consuming and costly if it also required supplementing the registration dossier with bioequivalence studies.

The cut-off date was December 31, 2008. After that date, a drug without harmonized documentation could not remain on the market. The process required a considerable mobilization of the Ministry of Health.

The EU main objection to the drug reimbursement system in Poland was its lack of transparency.

The second task was developing and implementing the reimbursement law. The European Union's main objection to the drug reimbursement system in Poland was its lack of transparency.

Evaluating this law with the hindsight of the last few years, one has to admit that its enactment was a real milestone in the approach to drug reimbursement rules in Poland and opened up greater access to innovative patient therapies. The definition of an administrative framework for the reimbursement process and the implementation of HTA assessment have increased transparency and introduced a scientific criterion in decision-making based on Evidence-Based Medicine.

The balance of benefits of EU membership for Polish drug policy and patients is favorable. The challenge facing policymakers in Poland and the EU today is to continue streamlining and simplifying administrative processes, giving a strong impetus to the further development of innovative therapies and increasing Europe's global competitiveness.

In the case of the Clinical Trials Act, it was essential to ensure that the application of the EU regulation is one of the critical steps on the road to eliminating the many administrative and legal barriers to conducting clinical trials.

The European Parliament's regulation implemented in the Polish national legislation directly required the regulation of specific areas, including the system of ethical evaluation of clinical trials, the language requirements for documentation, the introduction of solutions to ensure the protection of participants in clinical trials in terms of the compensation system, the level of fees for research applications, the division of funding between the sponsor and the public payer, or the support mechanism for non-commercial clinical trials.

All these solutions have significantly increased the chances of further development of clinical trials in Poland, which is essential not only for the industry and research centers but also for patients who are already benefiting from research or will benefit from it in the future.

9. Prospects for cooperation between Polish and Ukrainian companies in the pharmaceutical sector in the European market

Ukraine has consistently been working towards accession to the European Union and has a significant place in European health policy. Drug independence and drug availability problems, which were already substantial during the COVID-19 pandemic or active substances from Asia, provide an opportunity for the Polish-Ukrainian partnership to be a production leader for the Old Continent. Strategically, Poland and Ukraine are leaders in European drug and API production.

The challenge for the Ukrainian industry is the quality of drug production required to register and sell drugs in the European Union. Ukraine must meet European certifications and implement appropriate safety procedures. On the other hand, Poland has the best drug safety control system in Europe; in this area, Ukraine should take advantage of Polish experience and good practices.

It should also be emphasized that innovative medicinal products are limitedly available in Ukraine. Poland has excellent experience obtaining good results in price negotiations with global pharmaceutical companies; therefore, Ukraine can use Polish solutions as a best practice.

Poland is currently cooperating with Ukraine in many areas. The effectiveness of their actions can be evidenced, for example, by the fact that a law dedicated to the Ukrainian system KOWAL, i.e., the system of control of drug supply chains, is already underway in the Ukrainian parliament.

10. Strengthening ties between Poland and Ukraine in the pharma sector

Ukraine and Poland already have some relations in the Pharma sector. For example, Polish authorities issued 5 out of 10 GMP certificates received by Ukrainian producers. In April, EBRD announced a EUR 22 m loan to Ukraine's largest pharma producer to fund the acquisition of a Polish pharmaceutical company and the expansion of the IT systems.

There is also potential for supply chain cooperation and joint ventures between Ukrainian and Polish producers. This is eased by the proximity of the two countries and a large shared border, at least if the border is not blocked (as was the case in 2023 and the beginning of 2024). Ukrainian producers may provide an alternative to China as the supplier of active ingredients for medicines to the EU producers. Supplying active ingredients has a lower barrier to entry at the price of providing intermediate rather than final product. Still, cooperation in this area is likely to create value for both sides: more secure and responsive supplies on the Polish side and an expanded market for Ukrainian producers.

EU or other donors may fund training and consulting opportunities for Polish experts to help prepare the Ukrainian side for the new regulatory environment. There is a knowledge sharing with the potential for a win-win for both sides. There is also potential for similar cooperation on the private sector side on a more commercial basis. Clinical trials are another area for cooperation between Poland and Ukraine.

11. Recommendations for Ukraine and Ukrainian companies related to EU accession

The critical task for the Ukrainian authorities should be to ensure drug security, increase citizens' access to innovative therapies, and protect and develop the domestic pharmaceutical industry. The EU accession process and ACAA negotiations to reduce non-tariff barriers will take some time. Therefore, it is essential to continue working on implementing the new drug law on time. In parallel, dialogue should continue with the EU side to determine what is needed to achieve full compliance with the EU acquis in the pharmaceutical sector. The best outcome would be a mutually agreed roadmap that clearly defines the steps necessary for mutual recognition of EU and Ukrainian regulatory authorities in the pharmaceutical sector. This will allow the pharmaceutical sector to benefit from alignment with EU regulations before EU accession is completed.

In particular, we should recommend:

1. To ensure drug safety for Ukrainian citizens, regulations should be introduced to increase pharmaceutical production by Ukrainian companies. Ukrainian manufacturers will need external financing to comply with the new regulations;
2. Expenditures on pharmacy reimbursement should be increased;
3. Establish a new pharmaceutical regulatory body responsible for issuing licenses to market medicines in Ukraine following EU standards. Establishing such a body, which will obtain mutual recognition with EU bodies and individual EU countries, can be based on the Polish experience adapting to the EU acquis.
4. A list of drugs critical to Ukraine's drug security should also be developed, as well as incentives for those willing to invest in their production
5. The legal environment for drug policy should be shaped in dialogue with drug manufacturers who produce drugs in Ukraine and have a tangible impact on the economy,
6. Tax breaks or other forms of financial support should be considered to encourage pharmaceutical companies to invest in research and development. This would allow the industry to become more innovative and stimulate competition.
7. Companies should also focus on developing medical technologies like telemedicine or health-enhancing mobile applications.

Ukrainian and Polish pharmaceutical manufacturers would benefit from cross-border cooperation, such as supply chain partnerships and joint ventures. Ukrainian manufacturers would benefit from their Polish counterparts' know-how and market connections. In contrast, Polish pharmaceutical companies would be best positioned to exploit the Ukrainian pharmaceutical sector's accession to the EU market.

Cooperation with Poland can help the Ukrainian sector on its way and is likely to benefit the Polish partners as well.

The Warsaw Enterprise Institute (WEI) is a leading Polish think tank originating from the Union of Entrepreneurs and Employers. Established to enhance Poland's prosperity, WEI focuses on four critical areas: State and Law, Security, Economy, and Demographics. WEI provides solutions for state institutions and independent social or commercial entities through rigorous research, analysis, educational projects, and publication of commentaries, stances, memoranda, and reports.

WEI believes that Poland's security and the prosperity of its citizens depend on their rights and freedoms, including the right to choose their way of life, equality before the law, and the right to accumulate wealth. WEI advocates for a strong and efficient state to protect against injustice and external threats but emphasizes that the state's role should be minimal to foster entrepreneurial energy and spirit.

WEI's key areas of focus are:

State and Law. WEI is dedicated to improving the quality of laws, the legislative process, and their application and enforcement in court proceedings. WEI supports a legal framework based on simplicity and the natural order, advocating for minimal regulation and emphasizing voluntary agreements and contracts. The organization promotes a strong but limited state focused on ensuring security and justice for its citizens.

Security. Learning from historical experiences, WEI supports Poland's participation in defense pacts and international organizations while emphasizing self-reliance, with the Polish Army as the key guarantor of national independence. WEI advocates for a professional army capable of effectively countering potential threats and stresses the importance of energy security by diversifying energy sources and supply routes. The institute supports Poland's presence in the EU as an economic community but opposes the concept of a single European state dominated by bureaucracy. Poland's foreign policy, according to WEI, should prioritize national political and economic interests.

Economy. WEI asserts that a robust economy is essential for funding national defense, improving living standards, and halting depopulation. The institute calls for straightforward business regulations, low and simple taxes, and an efficient judiciary. WEI opposes harmful taxes and bureaucratic barriers, advocating for equal conditions for business competition and focusing on small and medium-sized enterprises (SMEs), the backbone of the Polish economy. Educational reform to align with job market needs and limited state participation in the economy, except in military and energy sectors, are also crucial economic policies WEI promotes.

Demography. Addressing unfavorable demographic trends is crucial for achieving WEI's goals. The institute supports policies to increase birth rates, curb emigration, and implement sensible immigration policies. Strengthening families' legal and social position to encourage higher fertility rates is a priority. WEI believes in allowing citizens to retain more earnings to support child-rearing and advocates for localized social support policies targeting only those in need.

WEI maintains a nonpartisan stance, supporting beneficial national solutions regardless of political origin. WEI collaborates with Polish authorities through professional analysis and active public engagement in strategic planning, policy development, and implementation, contributing to Poland's development and prosperity.

INSTITUTE
FOR ECONOMIC RESEARCH
AND POLICY CONSULTING

The Institute for Economic Research and Policy Consulting (IER) is the leading Ukrainian independent think tank focusing on economic research and policy advice. It has more than 20 years of experience in economic policy analysis and the development of policy recommendations. Since 2016, the IER actively supports regional civil society organizations in Ukraine through re-granting, mentoring, training, and awareness-raising campaigns.

IER's mission is to provide alternative solutions to key problems of social and economic development in Ukraine based on the rule of law, democracy, and market economy principles. The IER's special focus is on promoting the EU-Ukraine Association Agreement.

The IER aims to:

1. provide top-quality expertise in the field of economy and economic policy-making and developing strategic and instrumental components of the economic policy;
2. formulate a public opinion through the organization of public debate, facilitation of public dialogue and spreading knowledge;
3. contribute to the development of economic and social sciences and promote the development of the Ukrainian research community.

Since its establishment in 1999, the IER has focused on economic research and policy advice in macroeconomic policies, business climate, small and medium entrepreneurship (SME) development, international trade, financial markets, and regional and sectoral development. Since the early 2010s, the IER has been extensively focused on promoting the European integration of Ukraine.

The IER's particular strength is monitoring business attitudes and expectations towards various aspects of the business environment and regulation, including policy impacts, by conducting regular and ad-hoc business tendency surveys. Since July 2002, the IER has held a regular quarterly survey of 450 industrial enterprises in Ukraine to monitor, forecast, and analyze business activity based on the information received "from the ground up" judgments and economic agents' anticipations. Since May 2022, the survey has been conducted monthly and covered 500+ from all controlled by GOU oblasts. The IER has developed an Annual Business Climate Assessment – a policy tool for monitoring and assessing business climate and SME development based on firms' perceptions and attitudes. Annually the IER has conducted 1000+ enterprises regarding trade facilitation issues and customs work assessment.

After 24 February 2022 year, the IER focused on supporting Ukrainian resistance to full-scale military aggression. Our activities are repurposed according to stakeholder needs. Since May 2022, the IER has run the Program "Analytics and Information of the Countries' Economy during the War Time." The IER produces and promotes monthly the analysis and forecast of the Ukrauaianin economy, including monthly surveys of 500+ enterprises. The IER is a member of the public initiatives RISE (a coalition of Ukrainian and international organizations working for Ukraine's Reconstruction Integrity, Sustainability, and Efficiency). Also the IER is the founder of the RRR4Ukiraine think tank initiative, which aims to promote honest and visionary recovery based on the principles of openness and accountability.

The IER successfully combines professional analysis with active involvement in public dialogue and advocacy and actively cooperates with Ukrainian national and regional authorities in strategic planning and policy development, and policy implementation. The IER has the capacity for grant management and provides re-granting for capacity development to regional civil society organizations and media.

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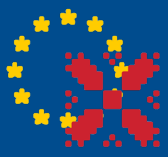

UKRAINIAN PATH TO
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