Max Planck Institute
for Innovation and Competition

Max Planck Institute for Innovation and Competition Research Paper No. 24-02

Rebuilding Ukraine

The Case of the Health Sector

Max Planck Institute for Innovation and Competition Research Paper Series

Rebuilding Ukraine

The Case of the Health Sector

Editor

Daria Kim, M.A., LL.M., Dr. iur.
Senior Research Fellow, Max Planck Institute for Innovation and Competition, Munich

Language editor

Allison Felmy
Translating and Editing, Max Planck Institute for Innovation and Competition, Munich

Imprint

2024
Max Planck Institute for Innovation and Competition
Marstallplatz 1, 80539 Munich, Germany

ISBN 978-3-00-075746-4

DOI: 10.17617/2.3564369

Foreword

Immediately after the outbreak of the war in Ukraine, the Max Planck Institute for Innovation and Competition announced its commitment to support Ukrainian researchers. Both the legal and economic departments of the Max Planck Institute for Innovation and Competition reached out to invite Ukrainian researchers to the Institute, whether they were fleeing the war in their home country or looking for a way to continue their research outside Ukraine.

Since then, we have experienced an intense and very enriching period of integration of our Ukrainian guests at the Institute. Team members have supported the new Ukrainian colleagues in organising their lives in Germany. Researchers at the Institute have been active in establishing the initiative #ScienceForUkraine. A large online survey on the needs and problems of Ukrainian researchers was conducted and revealed interesting results.

The Ukrainian researchers have been able to continue their academic work in Munich, and they have taken an increasingly active role in research and life at the Institute, for which we are grateful. A comprehensive work on Ukrainian Competition and Intellectual Property Law, already begun in 2020, appeared in 2023. It is impressive how quickly and resolutely our guests have set their focus on preparing and supporting the rebuilding of Ukraine after the war by means of their research and engagement, as well as facilitating Ukraine's integration into the EU.

After an initial explorative online roundtable on 1 December 2022, the Institute hosted the roundtable 'Rebuilding Ukraine' on 21 March 2023, which was organised in a hybrid format and featured Ukrainian guests and speakers. The overall goal of this lively exchange was to help lay the groundwork for a rebuilding of the Ukrainian health sector.

The pharmaceutical industry has had great importance for Ukraine in the past, and it holds promise for its reconstruction in the aftermath of the war. Even most economists will be surprised to learn that Ukraine was the dominant producer of pharmaceutical products in the Soviet Union. How such a historical strength can be revived and built upon is an important topic in the contributions collected in this volume.

Munich — Dietmar Harhoff
15 January 2024

This collection is based on the presentations given at the roundtable 'Rebuilding Ukraine: The Case of the Health Sector' held on 21 March 2023 at the Max Planck Institute for Innovation and Competition in Munich. Several Ukrainian scholars were able to attend in person and more participants, including representatives from patient organisations, government bodies, and the pharmaceutical industry in Ukraine, joined remotely. The objective was to facilitate an exchange of views between Ukrainian researchers and the Institute's research fellows on both immediate and strategic issues within the Ukrainian health sector.

The reasons for organising this exchange are apparent. Even during times of peace, access to healthcare, as a basic necessity, is vulnerable in many nations. In wartime, it becomes a matter of survival on a national scale. Overcoming multiple challenges requires a concerted effort and a comprehensive approach to the regulatory framework in the health sector. The compilation features contributions by experts from specialised domains, including intellectual property law, regulation of drug research and development, safety regulation, and the regulation of pharmacy activity. While not meant as an all-encompassing policy proposal, this collection contains valuable insights and suggestions that, cumulatively, can show a way forward in addressing the imminent and long-term consequences of war.

This collection is a tribute to Ukrainian scholars, their dedication and resilience. Despite the challenging conditions, they carry on their work uncovering the imperfections of governance structures and seeking pathways to their improvement. As any publication takes time, the factual information inevitably becomes outdated. Whenever feasible, sources with relevant dates are provided for checking more up-to-date statistics. However, the primary intent was not to provide a list of facts but rather to explore the economic, institutional, and legal factors that are foundational for a sustained and sustainable health sector.

Munich
27 December 2023

Daria Kim

Contents

The Pharmaceutical Market as a Part of National Security

Oleksii Soloviov

The contribution examines the potential of the Ukrainian pharmaceutical market in the economic, technological, scientific, production, investment and regulatory contexts, its readiness for technology transfer, and the role that pharmaceutical activities play for the healthcare system and the state and patients, in particular during the war.

The year beginning in February 2022 was, both for the country and for the healthcare sector, the most difficult year in the entire history of Ukraine's independence due to the full-scale aggression of the Russian Federation. The consequences of the war include temporary loss of territories; destruction or damage to infrastructure; loss of assets; complication of logistics; fluctuations in the exchange rate; inflation; a rise in the price of raw materials; and migration of staff and consumers.

The war in Ukraine has had devastating consequences on the healthcare system and the pharmaceutical sector. As of March 2023, buildings housing 574 healthcare facilities in Ukraine have suffered damage or destruction. Most of these facilities are primary, emergency and specialised care facilities. According to preliminary estimates, the cost of reconstruction will be about 1 billion dollars. More than two thousand specialist doctors have been internally displaced. According to confirmed information alone, 33 healthcare workers have been killed and 86 injured. Additionally, the losses of the pharmaceutical market of Ukraine in 2022 compared to 2021 amounted to 22.4% in kind (from 1.2 billion product units to 930 million product units); 26.7% in monetary terms (the market decreased by 1.3 billion US dollars, from 5 to 3.7 billion US dollars); and 19.2% among pharmacies (almost 4 thousand pharmacies were closed). As a result, public access to medicines has been disrupted throughout Ukraine.

In response to various shortages and delays affecting the availability of medicines and/or raw materials required for their production, the government of Ukraine has taken a number of administrative measures to ensure the rapid registration, import and distribution of new drugs and, thus, to ensure the availability of at least essential medicines for patients who need them. Such measures include monitoring the availability of essential medicines in retail chains and hospitals; simplifying the mechanisms for financing healthcare institutions; simplifying the rules for working with medicinal products and their import; accelerating registration or even temporary cancellation of requirements for the import of medicinal products and active pharmaceutical ingredients; simplifying prescription drug dispensing procedures;

issuing permits for direct negotiations on the conclusion of contracts between healthcare institutions and manufacturers without tender procedures; and introducing the pharmaceutical industry into the priority areas of the economy.

During a full-scale invasion, these measures have made it possible not only to ensure reliable access of the population to medicines and to sustain domestic pharma but also to begin the process of recovery. The healthcare system has demonstrated its resilience and also achieved certain positive results. Among them were the second stage of medical reform and the digitalization of the healthcare system and pharmacy (eHealth). Every month, more than 40 thousand patients join the 'Affordable Medicines' program. The training of specialists has not stopped in the country, the systems of scientific research and patent protection are developing, clinical trials are being conducted, pharmaceutical production and distribution continue, and the amount of medicines sold in Ukraine was valued at more than 3.2 billion US dollars in 2022.[1]

In the context of national security, the pharmaceutical sector is considered a backbone component that ensures physical access to medicines throughout the unoccupied territory, the effective operation of the healthcare system, and the preservation of human life and health. Currently, it is expanding its production and technological, research and development, and export potential, thereby creating jobs and generating tax revenue. This improves the prospects of victory in the war and contributes to building the foundations for the post-war restoration of Ukraine.

History and current status

Ukrainian pharma has more than one hundred years of history. The first industrial pharmaceutical production appeared in Kharkiv in 1907. During Soviet times, about 70% of the industrial pharmaceutical and research capacities of the Soviet Union were concentrated on the territory of Ukraine.

After the illegal annexation of a part of Ukraine's territory in 2014, where 6.4 million people lived, the pharmacy market has shown almost 10% annual growth since 2017, and a similar uptick has been observed in the hospital segment.[2] Over the past 10 years, the market has seen a positive trend in the increasing consumption of prescription drugs. Although the average drug consumption per person is valued at 98 US dollars per year, which is low in a global comparison, its growth rate is quite significant.[3] This shows the potential for further growth of the entire pharmaceutical market of Ukraine.

[1] The entire pharmaceutical market of Ukraine amounted to more than 3.6 billion US dollars, with the pharmacy segment accounting for 3.2 billion and the hospital segment comprising 0.4 billion US dollars.
[2] Editor's note: As clarified in the process of editing, this sentence combines two time frames: the occupation of a part of Ukraine's territory in 2014 and a separate statement that the pharmacy segment has been growing since 2017. In other words, it does not imply a causal link between the two.
[3] That is, from 54 US dollars per year in 2016.

A decrease in the volume of public procurement was observed in 2021-2022. The reasons for this included a reduction in state funding, a decrease in the number of surgical interventions and hospitalisations (in 2021 due to COVID-19, and in 2022 due to hostilities), as well as a large influx of humanitarian assistance in 2022. In 2022, the entire pharmaceutical market of Ukraine amounted to more than 3.6 billion US dollars. Of this, the pharmacy segment contributed 3.2 billion, and the hospital segment 0.4 billion US dollars.

According to anatomical and therapeutic classification, the largest segments of consumption in Ukraine are drugs for diseases of the digestive, cardiovascular, nervous, respiratory, and musculoskeletal systems. As can be seen from a comparison with other countries, Ukraine is a generics country: 78% of sales in monetary terms are generics. This can be explained by the low level of income and the low purchasing power of the population, as generic drugs, while identical to the original drugs, are available at a lower cost and therefore expand the availability of treatment.

Today, the pharmaceutical industry contributes to key areas of the country's economy. It provides employment for many related industries: advertising, engineering, energy, chemical and construction industries, banking, logistics services, and others. Since 2012, the share of the pharmaceutical market in the GDP of the processing industry, with some fluctuation, has averaged 2.2%, while the percentage of healthcare costs has been 7.6% of the GDP. The pharmaceutical industry accounts for 3.5% of investments in the processing industry, 3.4% of imports, and 0.5% of exports of goods.

The share of domestic production in monetary terms shows a positive trend: it has increased from 30% in 2012 to 36% in 2022. As for the share of products in packages, it is almost double that of imports. It is also positive to note that four Ukrainian companies are among the top 10 companies in the Ukrainian pharmaceutical market, led by Farmak and Darnitsa. In 2020, three Ukrainian pharmaceutical companies were ranked among the one thousand most valuable pharmaceutical companies in the world.[4]

An equally important component of the pharmaceutical industry's activities for national security is innovation. Despite the fact that the share of pharmaceutical products in the country's GDP structure is 13 times lower than in the food industry and almost 8 times lower than in the metallurgical and some other industries, 48% of pharmaceutical enterprises are active in innovation. This indicator is 3.2 times higher than in the metallurgical sector and 3 times higher than in the food industry. Among the processing industries, the pharmaceutical sector demonstrates one of the highest indicators of capital investment stability. This underscores the industry's focus on long-term growth.

[4] According to the Pharma 1000 Top Global Pharmaceutical Company Report prepared by Torreya Capital LLC, USA in 2021.

In terms of productivity, pharmaceutical production is among the leaders of the country's economy. This creates resources for investment in the recruitment and development of skilled personnel: pharmaceutical production demonstrates an increase in its human resources with twice the average wage level compared to the average for the processing industry. Some medicines, especially innovative medicines, vaccines, and certain radiopaque drugs that are not produced by the domestic industry, are imported to Ukraine. The top 10 importers are Germany (imported medicines amount to a total of 368 million US dollars), India (173), France (131), Italy (125), Slovenia (110), USA (101), Spain (79), Ireland (74), China (66), and Poland (57). An equally important component in the context of national security is the export of pharmaceutical products. In particular, exporting pharmaceutical products opens up new markets for Ukrainian products (after Ukrainian producers left the Russian market starting from 2014), generates foreign exchange earnings, creates additional jobs, etc.

Regulatory norms for Ukrainian pharmaceutical production are constantly being improved. In particular, in July 2022, the Parliament of Ukraine adopted a new law 'On Medicines' designed to regulate the circulation of medicines and fully align Ukrainian legislation in this area with EU regulations and practices. The primary task in this area is to eliminate barriers between Ukraine and the EU in terms of the mutual recognition of good manufacturing practice (GMP) certificates. Now Ukraine needs to develop and adopt bylaws provided for by the new version of the law.[5]

That is why the assistance of our European partners in the formation of a modern regulatory framework in the field of the circulation of medicines in Ukraine is and will remain extremely relevant.

Challenges

Despite the considerable production, technological, scientific, export and investment potential of Ukrainian pharmaceutical production, challenges persist for its further development. The volume of the national market is small (by international standards), it is not integrated into the EU regulatory field, and it sometimes displays technological lag. These as well as imperfect regulatory norms are among the key challenges to increasing Ukrainian pharmaceutical exports. Serious issues that need to be addressed include the lack of a government strategy for industry development, the low purchasing power of the population, and legislative barriers to affordable medicines (in particular, those related to patent protection, bioequivalence research, and the need to undergo double checks for compliance with GMP requirements in Ukraine and at the level of EU member states).

However, the digitisation and continuous improvement of the regulatory framework have become clear evidence of positive transformations in these areas. In recent years

[5] Formally, the old law with the same name loses its effect, and a new one is adopted to replace it. In the Ukrainian legal system, it is referred to as new version of the law.

alone, the ecosystem of healthcare and pharmaceutical production has undergone significant changes: instruments like e-health, e-prescription, e-commerce and the digitisation of business processes in production have been introduced. The reimbursement program 'Affordable Medicines', introduced in 2017, has expanded every year. According to the implementation plan of the EU-Ukraine Association Agreement, measures are being taken to align Ukrainian with EU legislation.

The government plans to digitise about 70% of the current instruments of state regulation (permits, licenses, declarations, approvals, etc.) in manufacturing industries. This unprecedented decision aims to significantly expand civil and economic freedoms in Ukraine by ensuring transparency in management decision-making, reducing corruption, increasing the accessibility of public services for manufacturers and patients, and stimulating the development of production and entrepreneurship.

Outlook

As a general trend, the volume of public procurement is growing. The decline in volume in 2022 occurred due to a reduction in public funding, a decrease in the number of surgical interventions and hospitalisations in general due to hostilities, and a large influx of humanitarian aid. The reimbursement program is financed from both state and local budgets, with the amount of funding increasing. The variety of drugs for the reimbursement program is also growing. This indicates that Ukraine is gradually approaching the reproduction of the reimbursement standards that apply in most European countries.

The second trend is further healthcare system reform, particularly in terms of health insurance. Compared to other countries, Ukraine obviously needs to rebuild the healthcare system to change the general financing scheme and stimulate the development of voluntary medical insurance for the population. Another emerging trend is the development of contract manufacturing. Current obstacles include the lack of a state strategy for industry growth, obviously unfavourable conditions for foreign investment, distrust in the operations of domestic producers who are not well-known enough in the global market, and limited opportunities for investing in technological innovation compared to larger markets.

Oleksii Soloviov, Dr. Pharm., Doctor of Medical Sciences, Professor, is Deputy Secretary of the National Security and Defence Council of Ukraine and a lecturer at the Interregional Academy of Personnel Management. He has authored more than 100 scientific publications in periodicals and co-authored a monograph and 9 textbooks. He is actively working to improve the legal regulation of the pharmaceutical market of Ukraine. E-mail: a.soloviov71@gmail.com.

Acknowledgement

The following sources of materials and data were used in preparing this contribution: The State Statistics Service of Ukraine (https://www.ukrstat.gov.ua/), The State Customs Service of Ukraine (https://customs.gov.ua/en/), The National Bank of Ukraine (https://bank.gov.ua/en/), The Ministry of Health of Ukraine (https://en.moz.gov.ua/), The Ministry of Foreign Affairs of Ukraine (https://mfa.gov.ua/en), The National Health Service of Ukraine (https://nszu.gov.ua/); Proxima Research (https://proximaresearch.com/ua/en/), and Apteka, an online trade weekly (https://www.apteka.ua/).

The Resilience of the Ukrainian Pharmaceutical Industry during the 2022-2023 War Years

Liudmyla Petrenko

Market and industry resilience in wartime is poorly understood in the literature. The Ukrainian pharmaceutical industry is an illustrative case of resilience during the war, as against a GDP decline of 30% in 2022, in the first half of 2023 the pharma industry already returned to pre-war production rates. As the study shows, the shock and panic in the market lasted only for the first two weeks of the war. The industry's resilience is positively affected by the concentration of the full cycle, from drug development to production, geographically mainly in the Kyiv region, which is relatively sheltered from bombing. Its resilience is also influenced by the specialisation of pharmaceutical companies in the production of generics, which do not require huge investments in development and are oriented towards the affordability of medicines. Patients are responsible for more than 85% of the market's demand, which has made pharmaceutical companies' sales insensitive to war-related cuts in government support for healthcare. The high level of resilience is also attributed to the relative stability of the market demand for generics produced in Ukraine, which even increases as the population becomes poorer, and the expansion of pharmacy activities in safe regions following population migration. This study is based on recent data from pharmacy market operators as well as national statistics.

The availability of a country's own pharmaceutical manufacturing facilities is critical in wartime. In the case of Ukraine, without diminishing the importance for the Ukrainian people of external assistance with medicines from Western partners and volunteers, it is important to talk about internal resilience of the Ukrainian pharmaceutical industry during the 2022-2023 war years.

Two major 'physical' factors have complicated the resilience of industrial and social development during the war, namely the damage caused by bombing (supply side) and the loss of population, including those killed and those who have become refugees (demand side). In addition to physical factors, the current political situation also reduces resilience, since uncertainty and the risks of war negatively affect the investment attractiveness of the industry and the introduction of innovations. However, in this study, we will take these risks for granted

Since 2014, a significant part of the territory of Ukraine has been under temporary occupation by the Russian Federation, namely, as of 20 March 2023, approximately

110,000 square kilometres, or 18% of the country's area. Population losses have come to about 15 million people or 33% of the total population. All this has led to a loss in the network of 5,000 pharmacies, or 25%, of pharmacy outlets (which are now in occupied territory or were physically destroyed), as a result of which some 37 billion UAH, or 27%, of the potential annual consumption of medicines, was lost.[1]

The current war in Ukraine has caused tremendous damage to the public health system, reducing the availability of medical drugs and healthcare. As of September 2022, the total direct loss[2] to the health industry was 1.6 billion USD, with 953 health facilities affected, of which 127 were destroyed.[3] Indirect losses of the industry are almost twice as high as direct losses and have been estimated by experts at 2.7 billion USD, of which 100 million USD are a result of the reduction of budget expenditures for selected programs. The remaining 2.6 billion USD is associated with a decrease in the income of the private sector of medicine due to the suspension of the activities of institutions because of destruction, threats to the safety of workers and patients, lack of access to critical resources (electricity, water, gas) and occupation.[4] In addition, the market has also been affected by the migration processes of Ukrainians to other regions and abroad.

The war has forced about one-third of Ukrainians to leave their homes, creating the greatest refugee surge in OECD countries since World War II.[5] In particular, about 10 million Ukrainians were forced to become internally displaced persons (IDPs), while at the same time 6.5 million refugees from Ukraine were registered throughout Europe.[6] In addition, the demand for medicine was negatively affected by citizens' loss of a significant part of their income. Because of the war, some Ukrainians have lost the

---

[1] Russian-occupied territories of Ukraine, https://www.wikiwand.com/en/Russian-occupied_territories_of_Ukraine accessed 1 July 2023. S Ischenko, 'Pharmaceutical market of Ukraine at the beginning of the war: analytics and forecasts', presentation at the conference 'Pharmapoglyad-2023: on the way to recovery' on 16-17 February 2023 in Kyiv (on file with the author). The presentation was based on data collected by Proxima Research International.

[2] Direct losses result from the destruction of buildings and structures; indirect losses are a reduction in the volume of medical services provided by both the public and private sectors.

[3] Report on direct damage to infrastructure destroyed because of Russia's military aggression against Ukraine as of 1 September 2022, https://kse.ua/wp-content/uploads/2022/10/Sep22_FINAL_Sep1_Damages-Report.pdf accessed 1 July 2023.

[4] Report on direct infrastructure damage, indirect losses of the economy destroyed as a result of Russia's military aggression against Ukraine, and a preliminary assessment of Ukraine's needs for financing reconstruction, https://kse.ua/wp-content/uploads/2022/07/NRC_CLEAN_Final_Jul1_Losses-and-Needs-Report.pdf accessed 1 July 2023.

[5] OECD, 'The Ukrainian Refugee Crisis: Support for teachers in host countries' (2022) https://www.oecd.org/ukraine-hub/policy-responses/the-ukrainian-refugee-crisis-546ed0a7/ accessed 1 July 2023; UNHCR, 'Ukraine-Fastest Growing Refugee Crisis in Europe since WWII' (2022) https://www.unhcr.org/hk/en/73141-ukraine-fastest-growing-refugee-crisis-in-europe-since-wwii.html accessed 1 July 2023.

[6] Ukraine refugee situation – UNHCR data portal, https://data2.unhcr.org/en/situations/ukraine accessed 1 July 2023. The number of refugees abroad fluctuates, as some individuals return to Ukraine while others leave.

ability to take their prescribed medicines: 27% of the population and 32% of IDPs have relatives who have stopped taking their prescribed medication. 9% of the population and 30% of IDPs have problems accessing necessary medical care.[7]

Despite the objective difficulties, the Ukrainian pharmaceutical industry continues to develop, confirming its investment attractiveness and fulfilling an invaluable social function in the warring country.[8] The roots of these processes lie in the pre-war development of this industry and its accumulated potential. Also, the pharmaceutical market in Ukraine, despite the outflow of population, has sufficient internal resilience. Accordingly, this research aims to explore both of these reasons for the resilience of the Ukrainian pharmaceutical industry.

To explain the potential of the industry, as well as the market development, data from Ukrainian statistics, Proxima Research International IQVIA Market Prognosis and the United Nations were used.

Background and main problems

The analysis of the main problems is structured as follows: First, it is necessary to give estimated losses on the supply side, namely pharmaceutical production, as well as on the side of demand for medicines, due to the war. This is the starting point for the next step. We will review the pre-war development of the Ukrainian pharmaceutical industry and its accumulated potential and move on to analyses of the pre-war pharma market development. On 24 February 2022, there was a shock in the market and production. Accordingly, we will discuss the short-term and long-term impact of this shock based on available data on the Ukrainian market, including by region. In the end, we turn to forecasts for the development of the situation in the near future.

The state of the pharmaceutical industry and the market as of August 2023

During the war production and storage facilities and infrastructure were physically destroyed. The 160 pharmaceutical companies that operated until 24 February 2022 were reduced to 113 operating after this date.[9] Also, some Ukrainian partner enterprises of pharmaceutical companies ceased to exist,[10] which complicated the supply of resources and the sale of finished medicines. The destruction of infrastructure (electricity, water supply, roads, etc.) breaks the supply chain of both raw materials and finished medicines. As a result, there was an increase in prices for energy carriers, fuel, raw materials, etc. All of the above inevitably led to an increase in

[7] Ukraine — Internal Displacement Report — General Population Survey Round 8 (17-23 August 2022), https://dtm.iom.int/reports/ukraine-internal-displacement-report-general-population-survey-round-8-17-23-august-2022 accessed 1 July 2023.
[8] See also the contribution by Yevgeniya Piddubna and Viktoriia Popovych in this collection.
[9] Data for February 2023. The State Statistics Service of Ukraine, https://ukrstat.gov.ua accessed 1 July 2023.
[10] The supply chains for inputs and finished products have been disrupted by the cessation of operations and even physical destruction of partner companies in Ukraine.

the cost of finished medicines, both for sale and for humanitarian purposes. In particular, this reduces the ability of pharmaceutical companies to provide humanitarian assistance.

The first factor determining the development of the market was the 'outflow' of consumers, many citizens had to seek refuge abroad. As mentioned above, approximately 6.2 million Ukrainians,[11] mostly women and children, have gone abroad, which is 15% of consumers.[12] Note that it is women who usually decide to visit a pharmacy for family needs. Most of the refugees were middle- and upper-middle-income people, suggesting a greater loss of demand than just a percentage of the population. The second factor was internal migration and income decline. About 10 million people have been displaced internally from dangerous regions to areas far from the war zones. This has affected their lifestyle and consumption patterns, and most importantly, their income. A decrease in the level of consumer income directly causes the need for savings, including on medicines: cheaper analogues are preferred, even at the expense of quality.

Pre-war development of the Ukrainian pharmaceutical industry and its accumulated potential

Until February 2022, Ukrainian pharmaceutical manufacturers were fully self-sufficient, making up 4.1% by volume of Ukraine's total processing industries. The high macro potential of the pharmaceutical industry prior to the war in Ukraine is reflected in the industry's outperformance compared to the average for all industries in the country. In 2020, the index of production growth in the pharmaceutical industry reached +3.0%, while the index of the entire processing industry of the country fell to -4.5%.[13] The years before the war in Donbas and the annexation of Crimea were even more promising: in 2013, the pharmaceutical industry's production index reached 11.8% growth over the previous year.

It should be noted that the investment attractiveness of pharmaceutical production is also reflected in its high profitability compared to other sectors in Ukraine. The fast payback of investments in the pharmaceutical industry is influenced by the specialisation of Ukrainian pharmaceutical companies in the production of generics that do not require huge investments in development and are focused on the availability of affordable medicines.

[11] Ukraine refugee situation – UNHCR data portal, https://data2.unhcr.org/en/situations/ukraine accessed 23 August 2023.
[12] Calculated by the author on the basis of UNHCR refugee data and State Statistics of Ukraine data on population as of 1 January 2022. The State Statistics Service of Ukraine, https://ukrstat.gov.ua/operativ/operativ2021/ds/kn/arh_kn2021_u.html accessed 23 August 2023.
[13] The index is calculated as the ratio of the current year's production growth to the previous year's production volume. The State Statistics Service of Ukraine, https://ukrstat.gov.ua accessed 1 July 2023.

From a broader perspective, the profitability trend of the pharmaceutical industry looks as if it is evening out the profitability failures of the total economy during the crisis of 2014-2015.[14] For example, in the worst economic year in recent memory, 2014, operating profitability[15] in pharma production was 3.1%, while in the economy as a whole, it was -14.2%. In the most successful pre-COVID year, 2019, the average profitability of the Ukrainian economy as a whole reached 7.6%, and in the pharmaceutical industry even 12.5%.

The pharmaceutical industry attracts talent and retains human capital. Employees of the pharmaceutical industry earn 80-90% more than the average salary in the economy, according to the state statistics of Ukraine 2018-2020.[16] It should be added that salaries in the Ukrainian pharmaceutical industry are low compared to the European Union, at an average of 608.5 euros per month.[17] All this speaks in favour of the attractiveness for foreign investors to develop pharmaceutical production in Ukraine.

The industry is attractive for investment; however, it should be noted that the sources of financing for the innovation activities of industrial enterprises are mainly their own funds.[18] The peak years for investment in innovative technologies in the last 10 years were 2015 and 2016,[19] due to the creation of pharmaceutical production capacities in mainland Ukraine to compensate for the loss of such capacities in Donbas and the annexed Crimea. Export potential also speaks for the investment attractiveness of the industry. Ukrainian pharmaceutical products are popular in many countries around the world, and over the past five years, the export of medicines from Ukraine has increased by 64%.[20] The largest trading partners are Uzbekistan (26.9% of total imports), Kazakhstan (9.1%) and Azerbaijan (8.5%).[21]

Pre-war pharma market development

In the USSR, Ukraine was the second largest producer[22] of pharmaceutical products, accounting for about 30% of the total market share and 800 medicinal products. However, Ukraine was a leader in the USSR in the production of vitamins, antibiotics, antipyretics and anti-inflammatory drugs, some cardiovascular drugs, plant extracts,

[14] The crisis in the Ukrainian economy was provoked by the war in Donbas and the annexation of Crimea in 2014 by the Russian Federation. In 2014, Ukraine's real GDP declined by 6.8% compared to 2013 (in constant 2010 prices); in 2015, GDP fell by 10.4%, according to the State Statistics Service of Ukraine.
[15] Operating profitability is the ratio of operating profit to operating costs.
[16] The State Statistics Service of Ukraine. https://ukrstat.gov.ua accessed 1 July 2023.
[17] The State Service of Statistics of Ukraine, 'Labour of Ukraine in 2020', https://ukrstat.gov.ua/druk/publicat/kat_u/2021/zb/08/zb_Pracia2020.pdf accessed 1 July 2023.
[18] State Statistics Service of Ukraine. https://ukrstat.gov.ua accessed 1 July 2023.
[19] ibid.
[20] Ischenko (n 1).
[21] The State Statistics Service of Ukraine, https://ukrstat.gov.ua accessed 1 July 2023.
[22] V Chernykh, 'Pharmaceutical Industry during the Years of Independence of Ukraine' (2002) 3(31) Pharmacy Bulletin 3, https://dspace.nuph.edu.ua/bitstream/123456789/1341/1/3-12(1).pdf accessed 1 July 2023.

sterile bandages and first aid kits. The pharmaceutical industry in Ukraine was mainly engaged in the production of finished medicines, while the synthesis of chemical substances and the production of excipients and raw materials were carried out in other Soviet republics. Moreover, throughout the entire thirty-year post-Soviet period, Ukrainian producers owned the majority of the domestic market. In the pre-war period, Ukrainian companies held the majority of the market in consumption, about 65%, and produced 61% of medicines from the National List of Medicines.[23]

The pharmaceutical market is dominated by domestic companies. During periods of relative economic prosperity, the share of foreign manufacturers usually grows: as consumers' incomes rise, they can accordingly afford more expensive imported medicines. This was the case as of January 2022, when the market shares of domestic and foreign manufacturers were 63% and 37%, respectively, in physical terms.[24] But during periods of economic crises, the impoverishment of the population leads to a relative increase in the share of domestic companies in consumption: for example, in July of the crisis year of 2015,[25] this ratio was 77% to 23% in favour of the domestic producer.[26]

For a long time, the Ukrainian pharmaceutical market has been constantly growing.[27] This growth is illustrated by the figures of the last pre-war years. Thus, the volume of the pharmaceutical products market in 2019, 2020 and 2021 amounted to 116,675.2 million UAH, 133,824.5 million UAH and 169,920 million UAH, respectively. At the same time, the share of the Ukrainian market in the global market of pharmaceuticals as of 1 January 2022 was only 0.35%, and at the end of 2022, it fell to 0.25%.[28]

As we have already noted, domestic producers are the largest in terms of sales volume on the Ukrainian market: Farmak holds 5.5% of the market, Darnytsia 2.8%, Arterium 2.7%, Kyiv Vitamin Plant 1.9% and Zdorovya (1.6%). The main production facilities of all plants, except for the last one (located in Kharkiv), are located in Kyiv. This is due to the historical concentration of pharmaceuticals in these two largest cities of Ukraine, where there are pharmaceutical research institutes, as well as university pharmaceutical faculties.

Shock for the pharma market at the beginning of the war

[23] Ischenko (n 1).
[24] Market shares are reported here in terms of volume of medicines (in units, litres, kilograms, etc.).
[25] Crisis provoked by the annexation of Crimea and the war in Donbas in 2014.
[26] Ischenko (n 1).
[27] ibid. See also IQVIA Institute for Human Data Science, 'The Global Use of Medicines 2022' (2022) https://www.iqvia.com/-/media/iqvia/pdfs/library/publications/the-global-use-of-medicines-2022.pdf accessed 1 July 2023.
[28] IQVIA Institute for Human Data Science, 'The Global Use of Medicine in 2019 and Outlook to 2023. Forecasts and Areas to Watch' (2019) https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023 accessed 1 July 2023.

The beginning of the war was accompanied by a panic demand for medicines. On 24 February, on the first day of the large-scale invasion by the Russian Federation, drug consumption amounted to UAH 707 million against UAH 412 million the day before. The panic purchasing led to a drop in drug inventory, namely from 36 days' to 14 days' worth. This forced pharmacies to limit sales; in some cases, drugs and ampoules were sold by parts of the pills' packaging. However, the increased daily dynamics of drug consumption lasted only the first two weeks after the start of the war. By mid-March, the situation had stabilised.[29]

In the first six months of 2022, the market dynamics showed two trends. Thus, at the beginning of 2022, the pharmaceutical market[30] grew at an enormous pace: 31% in January and 45% in February compared to the same months of the previous year, which was also due to panic demand in the first days of the war. However, already in March, the decline began. Thus, in March the market decreased by 11%, in April it decreased by 32%, in May by 24% and in June by 26% compared to the corresponding period of the previous year.[31]

It was the loss of pharmacy presence that significantly reduced the availability of medicines for the population: as of 31 January 2023, there were 17,021 pharmacies or 82% of the pre-war total number – 3,834 pharmacies were closed. Not only the quantity but also the quality of work of pharmacies has changed: refugee emigration of women has led to an acute shortage of personnel, forcing many of the remaining pharmacies to work on a reduced schedule.[32]

The development of the Ukrainian pharmaceutical market depends almost entirely on consumer welfare. By the end of 2022, government spending covered 13%[33] of total drug consumption, including programs of the Ministry of Health of Ukraine with 5.2%, COVID-19 vaccines accounting for 1.0%, reimbursement[34] 2.0%, and local and departmental budgets 5.0%. 87% are drugs that are bought directly by patients, of which: retail consumption of drugs makes up 86.3%, public hospitals 13.2% and private hospitals 0.5%. The ability of patients to buy medicines is negatively affected by the fall in both nominal and real wages. For comparison, nominal wages in the fourth quarter of 2022 fell by 2.7%, and real wages by 23.1%[35] compared to the

[29] Excluding the temporarily occupied territory of the Autonomous Republic of Crimea, the city of Sevastopol and parts of the territory of Donetsk and Luhansk oblasts as of 24 February 2022. Ischenko (n 1).
[30] Sales in monetary terms, in UAH.
[31] Ischenko (n 1).
[32] ibid.
[33] ibid.
[34] Head of the National Health Service of Ukraine (NHSHU) Natalia Husak: The planned budget for reimbursement of medicines in 2023 is UAH 4.7 billion, this amount is sufficient (in Ukrainian): https://interfax.com.ua/news/interview/885860.html accessed 1 July 2023.
[35] The birth and death rates for 2022 are estimates. They do not include figures from the temporarily occupied and newly liberated areas, where data cannot be collected in full; nor do they include data on the births of Ukrainians abroad.

corresponding period of the previous year. According to available forecasts, the unemployment rate in 2023 will reach 26.1% and the inflation rate will reach 28.0%.[36]

Potential solutions: resilience of both the pharmaceutical market and pharmaceutical industry

Geographically, the resilience of the Ukrainian market is manifested in the compensatory growth of drug consumption where there is no active combat, including the Western region, with a decrease in the regions close to the war front.

The Eastern region was by far the most affected, where the market fell by 23% in 2022 compared to 2021.[37] At the same time, the largest relative decrease in sales is observed in the regions of Donetsk (67%, from 3 trillion to 1 trillion UAH) and Luhansk (75%, from 1 trillion to 250 billion UAN). At the same time, the largest absolute decrease in monetary terms is in the Kharkiv region: from about 10 trillion to 6 trillion UAH (39%), significantly in Zaporizhzhia, from 7 trillion to 4.5 trillion UAH (33%). In the south, the most affected market was in the Khersonska region, which fell by 67%, from approximately 3 trillion to less than 1 trillion UAH.

Compensatory growth is taking place over 2022 in the whole Western region and is 14% in total. The biggest absolute growth is in Lviv, from 7 trillion to 8 trillion UAH, i.e. by 15%. The biggest relative increase was in Zakarpattia, by 28%, that is, from 2.5 trillion to 3.2 trillion UAH. Of interest is the growth of consumption in the regions directly neighbouring the regions of military operations, which is explained by the movement there of the civilian population relocating nearby, as well as by the activity of hospitals.

Intense competition in the supply of medicines to pharmacy chains continues even in wartime. The war contributed to increased concentration in the pharmacy market while strengthening the positions of two leading distributors of medicines in Ukraine, Optima-Pharm and BaDM, which essentially control the market. For comparison, the share of these companies in December 2022 amounted to 44.9% and 40.2%, respectively (vs. 41.5% and 42.8% in December 2021[38]).

Market resilience becomes clear from analysis of media mentions of drug promotions tracked in the PharmXplorer research system, including POS materials, promotions, marketing events, mailing lists, sales force visits, sales force calls, internet advertising, trade press advertising, TV advertising, and remote communication. The greatest promotional failure was in March 2022, the first month of the war, when the market promotion amounted to 16.14% of the number of mentions in March of the previous

[36] Ischenko (n 1).
[37] The estimates do not take into account the data on pharmaceutical sales in the territories occupied on a certain date.
[38] Excluding the temporarily occupied territory of the Autonomous Republic of Crimea, the city of Sevastopol and parts of the territory of Donetsk and Luhansk oblasts as of 24 February 2022.

year. However, already in April, the market started to recover from the shock, that month reaching 56.86% of the comparative period of the previous year, in June 74.51% and in August already 85.34%.

Despite such a significant reduction in the country's population and pharmacy network, the drop in market volume in 2022 was relatively small,[39] at -6.10% (103.9 billion UAN). Recall that before the war, the market had been growing steadily, doubling between 2016 and 2021, and growing 19.1% in 2021 (reaching 110.6 billion UAN). Despite the war, in 2022, some Ukrainian companies continued to increase exports to Central Asian markets: the corporation Arterium increased its sales to Uzbekistan and Kazakhstan by 40% and 30%, respectively.[40]

The development of pharma production during the war is also connected with investments outside Ukraine. For example, the largest Ukrainian drug manufacturer, Farmak, is investing more than €20 million[41] in a new plant to produce its own medicines in the suburbs of Barcelona, where a closed-cycle production facility is scheduled to open in early 2024.

The forecast for the development of the retail pharmaceutical market in Ukraine under war conditions for 2023 is positive.[42] It is realistic to assume the recovery to pre-war market growth rates and even slightly above, 21.5% relative to the 2022 market volume, which in monetary terms may amount to 126 billion UAH. Even the pessimistic scenario, according to Proxima Research International, projects that growth in the amount of 6.8% (111 billion UAH) will be achieved; the optimistic scenario projects 30.6% (136 billion UAH).

One way to facilitate pharmaceutical production is by technology transfer to Ukraine. The ability of the Ukrainian pharmaceutical industry to absorb new technologies, as well as the internal potential of Ukraine for development and reverse engineering, is evident from the multiple research findings[43] of the Ukrainian Academy of Sciences,

[39] Again, this is excluding the temporarily occupied territory of the Autonomous Republic of Crimea, the city of Sevastopol and parts part of the territory of Donetsk and Luhansk oblasts as of 24 February 2022. Ischenko (n 1).

[40] 'Near Europe and Distant Australia. Where do Ukrainian pharmaceutical companies export their products' (*New Voice*, February 2023) https://biz.nv.ua/markets/farmkompanii-ukrainy-s-kem-rabotayut-i-kuda-idet-eksport-vo-vremya-voyny-poslednie-novosti-50299564.html accessed 1 July 2023.

[41] Y Tarasovsky, 'Farmak invests more than €20 million in a new plant in Spain' (*Forbes*, 23 November 2023) https://forbes.ua/ru/news/farmak-investue-ponad-20-mln-u-noviy-zavod-v-ispanii-23112022-9973 accessed 1 July 2023.

[42] Excluding Crimea, Sevastopol, and portions of Donetsk and Luhansk oblasts as of February 24, 2022. Ischenko (n 1).

[43] R.E. Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology of the National Academy of Sciences of Ukraine, 'Innovative and Patent Activities', https://www.iepor.site/?page_id=254 accessed 1 July 2023.

and the specialised Academy of Medical Sciences. Ukraine's pharmaceutical industry leaders Farmak, Darnitsa and Biopharma develop dozens of generics[44] every year.[45]

Outlook

The resilience of Ukrainian pharmaceuticals is based on the following factors:

- The production capacities and research potential of the main pharmaceutical enterprises have not been destroyed (113 enterprises operate, the largest located in Kyiv). The capacity of Ukrainian pharmaceutical production is sufficient to supply the domestic market with necessary and high-quality generics produced in Ukraine. There is a request[46] from pharmaceutical enterprises for the transfer of modern production technologies needed by the military front and the civilian population of Ukraine;
- Qualified personnel has been retained since the wages in the industry remain attractive. At the same time, relative to the West, the level of salaries is low (about 600 euros per month), which, together with the cost of other resources, increases the investment attractiveness of the industry;
- Foreign markets have been preserved, including the former socialist republics (except for Russia and Belarus), where exports are growing;
- The transfer of capacities and new construction are developing in safe areas, including outside of Ukraine, for example, in Spain;
- Drug distribution networks have been preserved, the reduction in sales in the south and east of the country is offset by growth in the west and centre and partially by the opening of new pharmacies;
- The impoverished population of Ukraine increases the share of consumption of affordable medicines by domestic consumers; however, there is a negative forecast for the growth of unemployment for the current war year.

In conclusion, we note a generally positive forecast for the development of pharmaceutical production in the near future, provided there are no critical bombings and damage to infrastructure.

Liudmyla Petrenko holds a Doctor of Science degree and a Ph.D. in Economics; Kyiv National Economic University named after Vadym Hetman (KNEU) Professor of Business Economics and Entrepreneurship; Coordinator of Technology and Innovation Transfer Centre (TISC) in the framework of the cooperation of the KNEU with WIPO; Head of Research Project on the commercialisation of an

[44] On the patent regime in Ukraine, see the contribution by Oksana Kashyntseva in this collection.
[45] Above (n 41).
[46] '"Time to become international": How Ukrainian business sees 2023' (*Farmak*, 15 February 2023) https://farmak.ua/en/publication/time-to-become-international-how-ukrainian-business-sees-2023/ accessed 1 July 2023.

anticancer autoimmune vaccine (within the framework of cooperation between KNEU and the R.E. Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology of National Academy of Sciences of Ukraine, 2019-2021); member of several research projects for the Ministry of Education and Science of Ukraine on innovative development based on the commercialisation of intellectual property and technology transfer. E-mail: liudmyla.petrenko.3@kneu.edu.ua.

The Problem of Concentration of the Pharmacy Market in Ukraine and Potential Solutions

Vitalii Pashkov

The article deals with the formation of the pharmaceutical market in Ukraine in the pre-war period and at present. Analysis of pharmaceutical legislation leads to the conclusion that its application, with the tacit support of the state, contributes to the monopolisation of pharmacy activities. The monopolisation of the pharmacy market minimises pharmaceutical manufacturers' competition and negatively affects pharmaceutical product availability. No pharmaceutical products are supplied to pharmacies without remuneration of the latter. The basis for this is a marketing transaction, with a marketing agreement between a pharmaceutical manufacturer or importer and a pharmacy. Consequently, to ensure competitiveness, pharmaceutical manufacturers and importers are forced to inflate the cost of final products. Another negative factor is the unofficial recommendation of doctors that patients take dietary supplements under the guise of medicines. The uncontrolled use of marketing contracts facilitates the spread of this practice, i.e., paid promotion of pharmaceutical products regardless of their effectiveness and quality. This factor contributes to the widespread use of medicines without proven efficacy in Ukraine. In Ukraine, medical professionals widely recommend such products to patients without including them in the official prescription. Another factor is the spread of Internet pharmacies. With the growth of the digitalisation of pharmaceutical marketing, there is an increase in the number of illegal Internet pharmacies, which pose a threat to patient health. The activities of Internet pharmacies are a problem not only for Ukraine but also for countries of the European Union. Online sales of pharmaceutical products by illegal Internet pharmacies often occur outside the national jurisdiction of particular countries. In contrast, the jurisdiction of national regulatory authorities usually ends at their countries' borders.

In Ukraine, pharmaceutical market activity is regulated by the Constitution and by several legal acts. First of all, these are the Fundamentals of Health Legislation of Ukraine and the laws 'On Medicines', 'On Licensing of Economic Activities', and 'On Technical Regulations and Conformity Assessment', as well as the resolutions of the Cabinet of Ministers 'On Approval of the Technical Regulations for Medical Devices' and 'On Approval of the Licence Terms of Economic Activities for the Production of Medicines, Wholesale and Retail Trade of Medicines, Import of Medicines (Except Active Pharmaceutical Products)'.

According to Art. 7 of the Law 'On Licensing of Economic Activity', activities related to the production, wholesale and retail trade, and import of medicines (except for active pharmaceutical ingredients) shall be subject to licensing, taking into account the specifics defined by the Law of Ukraine 'On Medicinal Products'. Although the legislature uses the term 'pharmaceutical activity', it does not define it. Thus, most experts use the concept of 'pharmaceutical activity' to refer to the circulation of medicines only, overlooking the circulation of medical devices, which have a completely different legal status and procedure for admission to the market of medical services. Meanwhile, part 2 of Art. 19 of the Fundamentals of Health Legislation of Ukraine uses the concept of 'pharmaceutical industry', and part 1 of the same article mentions medical apparatus, instruments, equipment, laboratory reagents, medicines, medical devices (medical products), technical and other rehabilitation, prosthetic and hygienic materials.

For the purposes of our discussion, we will consider as falling under the concept of pharmaceutical products 1) medicines, immunobiological preparations; 2) disinfectants, antiseptics, and disinfection equipment; 3) medical products and medical equipment; 4) dietary supplements that can be used for patient rehabilitation.

Analysing the above legislation, we can conclude that the activity of pharmacies, as healthcare institutions, is left outside the legislature's attention. Regarding retail sales of pharmaceutical products, this segment of the pharmaceutical market is regulated only by the procedure for retail sales of medicines. At the same time, the pharmacy as a healthcare institution has not only medicines in its assortment but also other pharmaceutical products with specific storage conditions, terms of realisation, and requirements for the qualification of personnel. Also, the organisation of pharmacy activities is currently neglected, which leads to some distortions in the pharmaceutical market. These include: 1) the gradual elimination of state and municipal pharmacy institutions, which in the last several years has led to the deterioration of access to medicines that contain narcotic drugs and psychotropic substances (this has become especially noticeable during the war); 2) tacit government support (including local government) for the monopolisation of pharmaceutical activities and the creation of monopolistic pharmacy associations on both the interregional and regional level, which has led to a minimisation of economic competition in pharma.

In Ukraine, pharmaceutical marketing has its national peculiarities. The task of pharmaceutical marketing is to promote pharmaceutical products, primarily those of manufacturers that have concluded a 'marketing agreement' with the relevant pharmacy. Under such agreements, pharmacists receive a fee for promoting certain products. When dispensing pharmaceutical products to patients, the pharmacist offers the patient the product for the promotion of which he or she has received a fee. Sometimes, this may be a dietary supplement. Doctors are also actively involved in promoting such products, recommending to patients exactly the products for which they receive remuneration from medical representatives of pharmaceutical companies.

This includes prescription medications, the promotion and advertising of which are prohibited by law.[1] This practice violates the balance of public and private interests in the pharmaceutical market.

Another area that needs attention is the uncontrolled activities of Internet pharmacies. The main distribution of counterfeit medicines occurs precisely through online pharmacies.[2] Another practice to pay attention to is paid promotion of pharmaceutical products regardless of their effectiveness and quality, which contributes to the widespread use of medicines without proven efficacy in Ukraine. In pharmacies of all EU countries, there are medicines without proven efficacy among the pharmacy assortment, and no doctor will prescribe such medicine, because the patient will not be reimbursed by insurance funds for its purchase, and such products are not included in the clinical protocol.

Background and main problems

Most medicines produced domestically in Ukraine are generics and biosimilars. To be fair, about 70% of prescription medicines in Europe are also generics and biosimilars,[3] which have the advantage of being much cheaper than the original drugs. However, Ukrainian drug manufacturers depend on imports of active pharmaceutical ingredients; domestic substances account for only 30% of the total, with the rest imported from China, Germany, India, and the United States.[4] In fact, pharmaceutical manufacturers in most countries depend on the importation of active pharmaceutical ingredients.

For drugs of foreign companies, the production of which is located in the member countries of the Pharmaceutical Inspection Cooperation System (PIC/S), the State Service for Medicinal Products and Drug Control confirms GMP (Good Manufacturing Practice) certificates issued by the regulatory authorities of these countries through recognition. The only part of this system where the risk of corruption is possible is the timing of document review.

The pharmaceutical market of Ukraine features products from 116 domestic manufacturers, among which only 22 have been producing medicines since the USSR

[1] The Law of Ukraine 'On Advertising', https://zakon.rada.gov.ua/laws/show/270/96-%D0%B2%D1%80#Text.

[2] V Pashkov, O Soloviov, A Harkusha, 'Digital Marketing: Problems of Internet Pharmacies Legal Regulation' (2021) 3 (21) Socrates 191, https://dspace.rsu.lv/jspui/bitstream/123456789/7132/1/Socrates-21-14_Pashkov-Soloviov-Harkusha_191-203.pdf accessed 28 December 2023.

[3] 'New Pricing Models for Generic Medicines to Ensure Long-term Healthy Competitiveness in Europe' (2022) https://www.medicinesforeurope.com/wp-content/uploads/2022/06/New-pricing-models-for-generic-medicines.pdf accessed 28 December 2023.

[4] A Vasyuta, M Miroshnik, 'Konkurentosposobnost otrasli kak sostavlyayushaya effektivnosti nacionalnoj ekonomiki' (2014) 2 Biznesinform 160.

era,[5] and the rest are newly formed pharmaceutical market players. These newly formed subjects of the pharmaceutical market typically produce one or two pharmaceutical products, such as medical ethyl alcohol and gas-like pharmaceuticals.

Ukraine has taken steps toward harmonisation of its pharmaceuticals market with the EU. In the last 10 years, Ukraine has implemented the requirements of good manufacturing practice (GMP), good distribution practice (GDP), and good storage practice (GSP) of medicines into the national legislation, harmonised procedures for inspection of manufacturing facilities, and created GMP and GDP inspectorates, which are successfully operating. An important step for Ukraine is its accession to the Pharmaceutical Inspection Cooperation System (PIC/S), which includes EU countries. Theoretically, it implies the possibility of importing pharmaceutical products to these countries. At the same time, pharmaceutical products from EU countries can be freely exported to Ukraine, with no additional examinations required, provided that the products are registered in the EU countries and the packaging and instructions for use are in Ukrainian.

One of the main requirements of the EU countries for the import of medicines into developed countries is a permanent national system of state control of manufacturers to ensure compliance with GMP conditions in the importing country. Despite the implementation of the pharmaceutical legislation of Ukraine in harmony with the EU legislation, most of the relations between the pharmaceutical market players remained at the level of developing economies of the world. As already mentioned, the area at issue here is the organisation of pharmacy activities. While the issue of circulation of medicines in the Law of Ukraine 'On Medicines' is in compliance with EU law, the organisation of pharmacy activities in Ukraine is not and has been left out. As an example of the type of legislation needed, we can cite the German Pharmacy Act (ApoG).[6]

According to estimates of the Antimonopoly Committee of Ukraine since 2015, there has been a concentration of market power in the pharmaceutical sector, with the largest market operators fully establishing their own rules on the market and preventing the development of competition.[7] Trends in the development of the pharmacy segment in Ukraine indicate a market consolidation, with a risk of larger pharmacy chains absorbing weaker competitors. Pharmacy chains, having the ability

[5] P Bagrij, 'Звернення Асоціації "Виробників ліків України" до Міністра охорони здоров'я України Мусія О.С.' (*InterFax-Ukraina*, 12 March 2014) http://ua.interfax.com.ua/news/press-release/195572.html accessed 28 December 2023.

[6] Gesetz über das Apothekenwesen (Apothekengesetz – ApoG) https://www.gesetze-im-internet.de/apog/BJNR006970960.html accessed 28 December 2023.

[7] Antimonopoly Committee of Ukraine, 'Звіт за Результатами Дослідження Фармацевтичних Ринків' (2016) https://amcu.gov.ua/news/zvit-za-rezultatami-doslidzhennya-farmacevtichnih-rinkiv accessed 28 December 2023.

to influence the market supply of medicines, may limit consumer choices to categories of pharmaceutical products that yield the highest profitability.

The current state of capital concentration in the pharmaceutical retail market, based on both formal and informal ties, is significant and shows a clear upward trend. Groups of business entities with a large number of pharmacies (pharmacy chains) act in public relations under a unifying name and are managed either by common controllers or related persons (which is facilitated by an overly simplified procedure for establishing business entities in Ukraine).[8] Such entities implement economic strategies unfavourable for consumers solely for maximising income (with an emphasis on the quick sale of the most commercially 'interesting' medicines, with an aggressive advertising policy and simultaneous limitation of the offer of the most affordable drugs or those intended for the treatment of orphan diseases). At the same time, pharmacies operated by individual entrepreneurs are discriminated against by large pharmacy chains when supplying medicines. Moreover, large pharmacy chains dictate the terms of purchasing products from pharmaceutical manufacturers, forcing them to enter into marketing contracts to promote goods.

Given that the founders (participants, shareholders)[9] of business entities, due to their corporate rights, can have a decisive influence on the activities of pharmacies, whose functions are primarily social – the protection of human health and life, and the safeguarding of patient rights – rather than commercial, it is necessary for the founders of pharmacies to be professional participants in pharmaceutical activities. This ensures the professional management of pharmacies, as they are the primary source of information for the public. Compliance with this approach will not only protect human rights to life and health but also guarantee consumer rights, quality control, and product safety.

Today, however, the vast majority of pharmacies in Ukraine are not managed by pharmacists but by ordinary entrepreneurs, trying to maximise profits (even at the expense of the life and health of consumers) and to create as many pharmacies for this purpose as possible. Unprofessional owners do not follow the rules of pharmacist ethics and professional deontology, and they extend the standard of 'unprofessionalism' to their employees.

Simplification of pharmacy activities and less monitoring have led to an increase in Internet pharmacies. Meanwhile, researchers estimate that the spread of counterfeit medicines through illegal online pharmacies constitutes approximately 50% of the

[8] Pursuant to the Law of Ukraine 'On Joint Stock Companies', affiliated persons are defined (clause 1, part 1, Art. 2) as legal entities – provided that one of them exercises control over the other or both entities are controlled by a third party; family members of an individual – husband (wife), as well as parents (adoptive parents), guardians (trustees), brothers, sisters, children and their husbands (wives); an individual and a member of his/her family and a legal entity, if such individual and/or his/her family members exercise control over the legal entity.

[9] Founders can have different statuses according to the legal entity type under the legislation of Ukraine.

total counterfeit market.[10] At the same time, patients are unaware of the potential danger associated with purchasing medicines through Internet pharmacies and cannot distinguish between legal and illegal establishments.

Internet pharmacies began to emerge in the late 1990s. As of 2020, the global Internet pharmacy market was estimated to be worth about $68.2 billion, according to cybersecurity experts. It is projected to grow to $202.2 billion by 2027.[11] This indicates that health-related innovative technology is experiencing an evolution driven by the digitalisation of healthcare and the proliferation of Internet use in daily life.[12] The new direction of pharmaceutical services associated with digitalisation is attractive to most patients, especially those with disabilities. This includes the ability to order online within 24 hours, the affordability of most pharmaceutical products, and privacy issues. For example, online pharmacies have seen increased demand for contraceptives.[13] But the Internet differs from other media in at least one crucial respect: it allows shoppers worldwide to shop with relative anonymity on a 24/7 shopping site.[14]

Another aspect that warrants scrutiny is the increase in retail sales of dietary supplements through pharmacies, including Internet pharmacies. In 2022, the growth in retail sales of dietary supplements exceeded the increase in sales of medicines by more than 2.5 times and the growth in sales of medical products by 1.5 times.[15] Joint research with the Laboratory of Medicinal Products at the Research Institute of Public Health of the National Academy of Medical Sciences of Ukraine identified instances of the sale of dietary supplements in pharmacies, including online pharmacies, containing therapeutic doses of active pharmaceutical ingredients far exceeding those contained in medicines. The study also established that dietary supplements containing substances prohibited for sale via Internet pharmacies had in fact been sold.[16]

Potential solutions and outlook

To address the identified shortcomings, it would be advisable to reform the organisation of pharmacy activities in Ukraine drawing on the experience of Germany. First, Germany's ApoG establishes that one licensed pharmacist has the right to

[10] T Katsuki, TK Mackey, R Cuomo, 'Establishing a Link between Prescription Drug Abuse and Illicit Online Pharmacies: Analysis of Twitter Data' (2015) 17(12) J Med Internet Res, doi:10.2196/jmir.5144.
[11] AlltheResearch, 'Online Pharmacy Market Is Expected to Reach USD 202.3 Billion by 2027 (*Yahoo*!*finance*, 8 September 2021) https://finance.yahoo.com/news/online-pharmacy-market-expected-reach-140000853.html?guccounter=1 accessed 28 December 2023.
[12] TK Mackey, BA Liang, 'Pharmaceutical Digital Marketing and Governance: Illicit actors and challenges to global patient safety and public health' (2013) 9(45) Globalization and Health, https://doi.org/10.1186/1744-8603-9-45.
[13] ibid.
[14] ibid.
[15] D Kyrsanov, 'Війна і ліки: аптечний продаж за підсумками I півріччя 2022 р' (*Аптека.ua*, 25 July 2022) https://www.apteka.ua/article/641331 accessed 28 December 2023.
[16] European Directorate for the Quality of Medicines & HealthCare, European Pharmacopoeia (Ph. Eur.) https://www.edqm.eu/en/european-pharmacopoeia accessed 28 December 2023.

establish no more than four pharmacies. At the same time, the legislature imposes stringent qualifications on individuals seeking to establish pharmacies, which does not contradict European practice. Introducing professional requirements for those wishing to open pharmacies will effectively eliminate the aforementioned drawbacks. It should be considered that there are dynamic requirements for pharmaceutical workers to ensure their professionalism and systematic improvement of professional skills. By the way, this approach is widely used in many professions of public trust (audit and law firms, insurance companies), where it has proven to be an effective mechanism for ensuring a high level of professional behaviour of legal entities.

To reform pharmacy activities, it is necessary to develop and implement the draft Law of Ukraine 'On the Organisation of Pharmacy Activities'. The draft law could provide for a reduction in the concentration of pharmacies on a territorial basis. This approach will create balanced financial conditions for all market players so that each pharmacy can become profitable and can focus on accomplishing public tasks and improving customer service.

Vitalii Pashkov is the Head of the Laboratory for the Study of National Security Problems in the Sphere of Public Health of the Research Institute for the Study of Crime Problems of the National Academy of Sciences of Ukraine, Professor of Civil, Economic and Financial Law of the Poltava Law Institute at Yaroslav Mudryi National Law University.

Legal Instruments Against Illicit Medicine Markets in Ukraine

Nataliya Gutorova

The article raises awareness of the need to develop and apply effective legal measures against illegal activities in the pharmaceutical market in Ukraine. It focuses on the most significant threats to public health: the counterfeiting of medical products and their distribution, illegal sale of medicines, including e-commerce, unfair competition in the pharmaceutical market, and improper healthcare marketing, including bribery of medical professionals by pharmaceutical companies. It proposes legal instruments to combat such crimes, including the improvement of both legislation and its application in practice.

Modern healthcare is only possible with high-quality and effective pharmaceuticals, on which a person's health and sometimes life largely depend.

Any abuses in the pharmaceutical market are extremely dangerous. At the same time, the high profitability and rapid development of the pharmaceutical market increase the risks of unfair and irresponsible activities to obtain high incomes. The other factors contributing to the increase in these risks are the high and constantly growing demand for pharmaceutical products, which are basic necessities, and the specificity of drug consumption where the choice of drugs is determined not by the consumer but by medical professionals.[1]

This situation is typical for the majority of countries, but the danger of such activities increases significantly in countries with transitional economies, including Ukraine. Several factors, such as a high level of corruption, a weak law enforcement system, and a lack of traditions of honesty in business, cause this. All of this necessitates developing and applying effective legal instruments against illicit medicine markets in Ukraine.

Background and main problems

A major challenge for the pharmaceutical sector is corruption, which is used both to increase the profitability of the legitimate pharmaceutical market and to cover up criminal activities related to the production and distribution of counterfeit and substandard medicines. This is confirmed by data from Transparency International's

[1] Schoonveld Ed. The Price of Global Health: Drug Pricing Strategies to Balance Patient Access and the Funding of Innovation. 2nd edition (2015). doi.org/10.4324/9781315553993.

study 'Corruption in the Pharmaceutical Sector. Diagnosing the Challenges',[2] as well as academic research in the field.[3]

Improvement of criminal law regulation of the pharmaceutical sphere in Ukraine is important in view of European integration. Ukraine, which on 17 June 2023 received the conclusion of the European Commission recommending that it be granted candidate status for accession to the European Union,[4] today is painstakingly working to bring its national legislation into line with the acquis communautaire.

For EU member states, the safety of their own health sector from counterfeit and substandard drugs and their illegal sale and distribution will depend on the effectiveness of such Ukrainian statutory regulation. According to Europol monitoring, the results of which were presented in 2020, Ukraine, along with Turkey, was one of the transit countries through which, using complex illegal chains, counterfeit pharmaceutical products of Asian origin were distributed to the EU countries. In addition, as of March 31, 2020, Ukrainian nationals ranked third after Poles and Romanians in percentages of suspects who had been detained in connection with the illegal distribution of pharmaceutical products (12.3% were Polish nationals, 11.3% Romanian, and 8.1% Ukrainian).[5]

Among the crimes committed in the pharmaceutical sector of Ukraine are the following: spread of falsified and substandard medical products, such as medicines, active substances, medical devices, and software for medical devices; unfair competition in the wholesale and retail sale of medicines, which leads to artificial price increases and squeezes out of the market small and medium-sized, but highly professional companies; corrupt cooperation of doctors with legal and illegal pharmaceutical companies and pharmacies; and violations of established rules for the conduct of clinical trials, the establishment of bioequivalence of generic drugs, and the registration of medicines.

---

[2] Corruption in the Pharmaceutical Sector. Diagnosing the Challenges. Transparency International (2016) https://apps.who.int/medicinedocs/documents/s22500en/s22500en.pdf/ accessed 14 June 2023.

[3] J Lexchin et al., 'Combating Corruption in the Pharmaceutical Arena' (2018) Indian Journal of Medical Ethics, doi: 10.20529/IJME.2018.022/; MA Gagnon, 'Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health' (2013) 41(3) J Law Med Ethics 571.

[4] Communication from the Commission to the European Parliament, the European Council and the Council. Commission Opinion on Ukraine's application for membership of the European Union. Brussels, 17.6.2022 COM(2022) 407 final (2022) https://neighbourhood-enlargement.ec.europa.eu/opinion-ukraines-application-membership-european-union_en/ accessed 14 June 2023.

[5] Viral marketing counterfeits, substandard goods and intellectual property crime in the COVID-19 pandemic. Europol, April 17, 2020 (2020). https://www.europol.europa.eu/publications-documents/viral-marketing-counterfeits-substandard-goods-and-intellectual-property-crime-in-covid-19-pandemic/ accessed 14 June 2023.

The global trade in illegal pharmaceuticals is a vast and lucrative area of criminal activity, estimated at $4.4 billion, involving organised criminal groups around the world.[6] Much of this activity consists of illegal sales through online pharmacies. Interpol targets this activity with its international Operation Pangea, conducted each year in collaboration with national pharmaceutical regulators and law enforcement agencies. In 2022, the operation took place from June 23 to 30 in 94 Interpol member countries. As a result, in just one week, law enforcement agencies made more than 7,800 confiscations of illegal and substandard drugs and medical products, totalling more than 3 million individual items with a value exceeding $11 million. Nearly half (48 per cent) of the packages inspected by law enforcement during the operation were found to contain either illicit or falsified medicines.[7]

Even though Ukraine has ratified the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention),[8] the country still has not implemented some provisions in criminal legislation. Thus, the Criminal Code of Ukraine[9] does not contain provisions on falsifying medical devices (articles 5 and 6 of the Convention) or the illegal sale of medicines (article 8 of the Convention).[10] The analysis of court decisions shows that Ukrainian judges have a very liberal attitude toward punishment for the falsification of medicines. As our research shows, all persons convicted of such crimes were released from punishment with probation.[11]

The next problem is poor statutory regulation of online trade in medicines, which was legalised during the COVID-19 pandemic. During the same period, many illegal Internet pharmacies appeared in Ukraine, operating under cover of drug delivery services and often selling illegally imported or falsified medicines. There has been an unprecedented development of the illegal trade in smuggled medicines, including falsified and substandard medicines, which occurs with virtual impunity due to the lack of effective legislation. Illegally obtained medicines are freely sold to consumers through a network of dozens of Internet sites, such as https://one-apteka.com.ua/,

---

[6] OECD/EUIPO (2020), Trade in Counterfeit Pharmaceutical Products, Illicit Trade, OECD Publishing, Paris, https://doi.org/10.1787/a7c7e054-en.

[7] INTERPOL. From fake COVID-19 tests to hazardous erectile dysfunction tablets, the 94-country Operation Pangea XV targeted illicit pharmaceuticals and medical products traded online. (2022) https://www.interpol.int/News-and-Events/News/2022/USD-11-million-in-illicit-medicines-seized-in-global-INTERPOL-operation/ accessed 14 June 2023.

[8] Council of Europe Convention CETS No. 211 on the counterfeiting of medical products and similar crimes involving threats to public health. Moscow dated 28.10.2011 (2011) https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/ accessed 14 June 2023.

[9] The Criminal Code of Ukraine (1960) https://zakon.rada.gov.ua/laws/show/2341-14?lang=en#Text/ accessed 14 June 2023.

[10] Gutorova, N., Zhytnyi, O., & Soloviov, O. (2019). Falsification of medical products: criminal law mechanism combating threats to public health. *Wiadomosci lekarskie (Warsaw, Poland : 1960)*, *72*(5 cz 1), 856–861.

[11] ibid.

https://a24.com.ua/, https://farmalad.com/about, etc., but no measures are taken to stop such activities.[12]

The next problem is unfair competition and monopolisation of the wholesale and retail drug market, which leads to artificial price increases and drives small and medium-sized but highly competent companies out of the market.

Patients in Ukraine are increasingly being denied access to affordable and quality medicines due to rampant corruption in the sector. Attempts by the state to prevent unreasonable price increases for medicines and medical devices through state regulation, on the one hand, and the high degree of monopolisation of the pharmaceutical market in Ukraine, on the other hand, have only contributed to the aggravation of this problem. Undoubtedly, it became possible against the background of the lack of effective institutional mechanisms to counteract such a phenomenon.

The corrupt influence on the promotion of medicines in Ukraine 'begins' with the heads of hospitals and clinics (mostly municipal or state-owned) who, for a fee from pharmaceutical companies, bribe medical representatives of pharmaceutical companies, doctors who, for the amount of 5 to 10% of the cost of medicines, prescribe or recommend them to patients when they are not needed, or even force such action on subordinates. The statutory regulation of medical representatives of pharmaceutical companies in Ukraine is extremely insufficient.[13] Due to the contradictions and gaps in the legislation, as well as society's lenient attitude toward the receipt of illegal payments by medical professionals, such activities remain unpunished.[14]

In contrast to the situation in Ukraine, we can observe a completely different reaction of the state to such actions in Germany. For several years there was a practice called 'prescription management', under which doctors received a percentage of the selling price of the relevant manufacturer as a bonus for prescribing certain drugs of that manufacturer. These payments were claimed as honoraria for fictitious scientific lectures.[15] This practice was criminalised in Germany in 2016 as healthcare corruption, such as taking bribes in the healthcare sector (Criminal Code §299 a) and giving bribes in the healthcare sector (Criminal Code §299 b).[16]

---

[12] N Gutorova, 'Chornyy onlayn rynok likarskykh zasobiv pid chas pandemiyi COVID-19: pravovi zasoby protydiyi [Legal Remedies against Black Online Market of Medicines during COVID-19 Pandemic]' (2021) 68(3) Forum Prava 15, http://doi.org/10.5281/zenodo.5075677.

[13] On the problem of marketing agreements in the Ukrainian pharmaceutics market, see the chapter by Vitalii Pashkov in this collection.

[14] N Gutorova, O Soloviov, D Olejnik, 'Improper Healthcare Marketing: German and Ukrainian experience in prevention' (2019) 72(12 cz 2) Wiadomosci lekarskie (Warsaw, Poland: 1960) 2404.

[15] Strafsenat für Strafsachen des BGH Beschluss vom 11.10.2012, Aktenzeichen 5 StR 115/11, http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=d704cebcfcf3fa46c7a52ef4f7343096&nr=62012&pos=0&anz=2/ accessed 14 June 2023.

[16] German Criminal Code (Strafgesetzbuch – StGB), https://www.gesetze-im-internet.de/englisch_stgb/englisch_stgb.html accessed 14 June 2023.

Another corrupt influence is the conclusion of pseudo-marketing contracts between manufacturers (distributors) of medicines and national pharmacy networks, as a result of which, contrary to the maximum mark-up established by the state, the cost of medicines increases by an average of 40-60%, and professionals who have performed pharmaceutical activities in one or more pharmacies are eliminated from the pharmaceutical market.[17]

Corrupt influence on the representatives of the authorities in Ukraine has led to a situation in which the state regulatory body – the State Service of Ukraine on Medicines and Drugs Control – de facto has no competences and is deprived of the authority to collect evidence on the illegal promotion of medicines and to bring the perpetrators to justice.

As a result, reputable participants in the pharmaceutical market find themselves in a situation where their activity becomes uncompetitive due to the existing corruption mechanisms in Ukraine, which leads to the outflow of foreign investments and the filling of the market with products of lower quality but higher price. All this, in the end, has a negative impact on the performance of individuals, threatens the lives and health of Ukrainians, causes great damage to the country's economy, and deprives more and more Ukrainians of the opportunity to obtain affordable and quality medicines.

The situation is aggravated by the problems caused by the full-scale invasion of Ukraine by the Russian Federation, which began on February 24, 2022. It should be noted that the population's access to medical services in the occupied territories and areas of active hostilities is deteriorating and a significant part of the medical infrastructure is destroyed, while the number of people in need of medical care – due to injuries on the front lines, shelling of civilians by the aggressor state and other negative consequences of the war on human health – is increasing. Under such conditions, there is a growing need for the population to have access to quality and affordable pharmaceutical products.

Potential solutions and outlook

In order to improve the legal instruments against illegal medicine markets in Ukraine, it is necessary to improve both the legislation of Ukraine and its application in practice. This should be done through:

a) improving the statutory regulation of liability for counterfeiting and trafficking of medical products through full implementation of the Medicrime Convention in the national legislation of Ukraine, increasing the training of law enforcement officers, and changing the attitude of judges and the public to the punishability of such crimes;

[17] N Gutorova, V Pashkov, O Soloviov, 'Legal Means of Ensuring Competition in Pharmaceutics' (2020) 73(12 cz 2) Wiadomosci lekarskie (Warsaw, Poland: 1960) 2701.

b) legal measures, following the example of Germany, Poland, and other EU countries, against monopolism and unfair competition in the pharmaceutical market, and towards transforming it into a professional activity of pharmaceutical professionals providing services in the healthcare sector;
c) strict regulation of the activity of medical representatives of pharmaceutical companies, the establishment of liability for bribery of medical professionals for illegal promotion of medical products;
d) legal restriction of internet sales of medicines, establishment, and application of criminal liability for illegal trafficking of such medicines, as well as their use by medical professionals in medical services.

Legislative solutions to the issues mentioned above require profound scientific substantiation, using the best practices of the European Union states and, above all, Germany. In this connection, conducting joint research in this area at the institutional level with the Max Planck Institute for Innovation and Competition (Munich) would be very useful.

In addition to the above issues, promising for further research is the statutory regulation of the market of dietary supplements in Ukraine, where today, sales of products that contain API and are, in fact, counterfeit medicines, are uncontrolled.

Another area of pharmaceutics that requires improvement of the legal framework is the establishment of bioequivalence of generic drugs and their subsequent state registration. Corruption risks in this area are very high, and statutory regulation is insufficient.

Prof. Dr. Nataliya Gutorova is Professor at the Yaroslav Mudryi National Law University (Ukraine), Chief Researcher of the Laboratory for the Study of National Security Problems in the Field of Public Health of the Academician Stashis Scientific Research Institute for the Study of Crime Problems of the National Academy of Law Sciences of Ukraine. She is a Full Member of the National Academy of Law Sciences of Ukraine, a member of the working groups on Criminal Law Reform of the Commission on Legal Reform under the President of Ukraine and the development of proposals for implementation in the national legislation of the provisions of the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health under The National Security and Defence Council of Ukraine. E-mail: natalygutorova@gmail.com.

Success and Failure of the Healthcare Patent Reform in Ukraine: Keeping Balance in Wartime and Demands of EU Membership

Oksana Kashyntseva

The article explores the main challenges to the patent reform in healthcare faced by Ukraine before and during wartime. The high prices for medicines and the inability to treat patients with life-threatening diseases have necessitated a search for international legal instruments to ensure access to medicines in Ukraine. After the first shock of Russia's full-scale invasion, Ukrainian experts began considering the need for IP exceptions in the context of the war. This has been pursued through the key ministries and working groups of the Ukrainian Parliament. However, there are still significant shortcomings that require policy attention and further legislative action. This article argues that in the circumstances of the war and, at the same time, during Ukraine's process of incorporating EU legislation into national law as a candidate for EU membership, the IP legislation in the healthcare sector requires liberalisation in compliance with international legal principles.

The 21st century shows a global trend toward liberalising intellectual property rights in healthcare. It came about even before COVID times and for Ukraine increased in wartime. The United Nations Millennium Development Goals (MDGs)[1] identify the need to encourage the development of the generic pharmaceutical industry in order to provide access to affordable essential medicines in developing countries. Under the WHO Global Strategy and Action Plan on Public Health, Innovation and Trade, the organisation has a key role in balancing public health, innovation and intellectual property.[2] The legal aspects of balancing public and private interests in healthcare by intellectual property mechanisms gained significance after the proclamation of the UN Millennium Declaration and became even more relevant in the context of the COVID-19 pandemic.

[1] World Health Organization, 'Millennium Development Goals (MDGs)' (2018), https://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-(mdgs) accessed 9 September 2023.

[2] See 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property – WHA68.18' (26 May 2015) https://www.who.int/publications/i/item/global-strategy-and-plan-of-action-on-public-health-innovation-and-intellectual-property---wha68.18 accessed 11 June 2023.

For Ukraine, the problem of access to treatments is an urgent concern and has always been intertwined with political challenges. When fulfilling the strategic task of acquiring membership in the WTO, Ukraine introduced instruments for the protection of intellectual property in the field of medicine without considering the experience of the EU countries, specifically, as regards the significance of the human right to access to treatment, and without taking into account the experience of low- and middle-income countries in implementing the flexible provisions of the TRIPS Agreement.[3]

Even though the TRIPS Agreement only sets minimum requirements for the legal protection of intellectual property in a WTO member state, Ukraine made additional commitments (TRIPS-plus provisions) already during its accession process. This was not mandatory for WTO member states. However, Ukraine introduced legal protection in the field of medicine, allowing patenting of therapeutic and surgical methods of treatment and diagnostics, patenting of a previously known product or method for a new purpose and introducing a patent linkage within the framework of the marketing authorisation of medicines, etc. The countries of Eastern Europe did not undertake such obligations and made their way into the EU much faster than Ukraine, which is under pressure from the side of the Russian Federation due to integration into the economic and political area of the EU. To join the WTO, Ukraine had to outperform Russia because, as a member of the WTO, Russia would never allow Ukraine to join it.

The Association Agreement between the EU and Ukraine[4] and the political will of key stakeholders made it possible to implement the Patent Reform in the field of medicine and pharmacy based on Article 219 'Patent and Public Health' of the Association Agreement in 2020. As a result, the government and patients received effective mechanisms to ensure a balance between public and private interests in healthcare. Even though some experts consider the impact of patent reform to be remote, the significance of legal instruments such as patent opposition and the exclusion of treatment methods from patentable subject matter in mitigating the misuse of IP rights in the healthcare sector should not be underestimated.

Today, the war as a tragedy and Ukraine's acquisition of the status of an EU candidate state as a historic opportunity have created new challenges for reforming IP legislation.

Patent reform in brief and persisting challenges

Before the patent reform in 2020, the prices of medicines in Ukraine were much higher than in European countries. It created great pressure on the state budget, and patients had to pay for vital medicines out of their own pockets.

[3] In Ukrainian: http://zakon3.rada.gov.ua/laws/show/981_018 accessed 10 September 2023.
[4] The Association Agreement between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and their Member States, on the other hand. In Ukrainian: https://zakon.rada.gov.ua/laws/show/984_011 accessed 11 June 2023.

Pressure by the most significant Ukrainian patients' charitable organisation (CO) '100% Life – People living with HIV'[5] and the Ukrainian Ministry of Health resulted in a precedent (the *Sovaldi* case) which should be recognised as a turning point to start the patent reform in healthcare. In that case, Gilead had registered Sovaldi (a medicine to treat hepatitis C) and offered it at a price of almost 35,000 USD for a 3-month treatment course. The mentioned public pressure and patent opposition promoted by CO '100% Life' led to the denial of the patent. The denied patent opened the market for registration of a generic (a cheaper alternative of the same medicine) at the price of about 60 USD instead of 35 000 USD per same 3-month treatment.[6] This case and others highlight the problems in the examination procedure (low patentability criteria) of medicines in Ukraine in pre-reform time.

Esteemed international organisations that have become leaders in procuring life-saving medicines for Ukrainian patients have also shed light on the problem of patenting in Ukraine. UNDP, UNICEF, and Crown Agents have identified specific patents that had expired in all countries except Ukraine.

In 2012, the National Academy of Legal Sciences of Ukraine, in cooperation with CO '100% Life – People living with HIV', launched the research project Harmonisation of Human Rights and Intellectual Property Rights in the Field of Medicine and Pharmacy. In 2014 the Strategy of Harmonisation of Human Rights and Intellectual Property Rights was approved. The Centre for Harmonisation of Human Rights and Intellectual Property Rights was established under the umbrella of the Scientific-Research Institute of Intellectual Property of the National Academy of Legal Sciences of Ukraine.[7]

According to statistical data from 2001 to 2017, the highest number of patents granted in Ukraine were in medicine and pharmacy.[8] Until 2020, medicines were patented even as utility models or as a part of treatment methods, and the criteria for patentability were extremely low.[9] Before 2020 Patent Office experts lacked the legal expertise to prevent patent trolling. It was a time of prosperity for evergreening patents.[10]

---

[5] Website: https://network.org.ua/en/.

[6] 'Ukraine Signs Settlement Agreement with US Hepatitis Drug Maker' (*LB.ua*, 22 February 2017) https://lb.ua/society/2017/02/22/359426_ukraina_podpisala_mirovoe.html accessed 11.06.2023.

[7] O Kashyntseva, 'Human Rights and Patenting of Methods of Human Diagnosis and Treatment in the Context of Health Care Reform' (2014) 4 Journal of Theory and Practice of Intellectual Property 5.

[8] O Kashyntseva, 'Key Points of the Ukrainian Patent Reform in the Health Care Sphere' (2018) 3 Journal of Theory and Practice of Intellectual Property 46.

[9] Law of Ukraine 'On Protection of Inventions and Utility Models' of 5 December 2012. In Ukrainian: https://zakon.rada.gov.ua/laws/show/3687-12/ed20121205#Text accessed 11 June 2023.

[10] 100% LIFE, aidsfonds, ITPC, the Scientific Research Institute of Intellectual Property at the National Academy of Law Sciences of Ukraine, 'Evergreening Patents in Ukraine' (2020) https://makemedicinesaffordable.org/resource/evergreening-patents-in-ukraine accessed 11 June 2023.

In 2012, under the auspices of patients' organisations and the National Academy of Legal Sciences of Ukraine, the Centre for Harmonisation of Human Rights and Intellectual Property Rights joined the main stakeholders (including the Ministry of Health, its State Expert Centre, and the Ministry of Economic Development and Trade) and started advocating for patent reform in healthcare. Upon request of the Ukrainian Government, the international organisations (UNDP, WHO, UNITAID and ITPC) began providing expert and technical support for patent reform in healthcare.

The main legal basis for the patent reform was Article 219 'Patents and Public Health' of the Association Agreement between Ukraine and the EU:

1. The Parties recognise the importance of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 (hereinafter referred to as the 'Doha Declaration') by the Ministerial Conference of the WTO. In interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with the Doha Declaration.
2. The Parties shall contribute to the implementation of and shall respect, the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration.

The following were the stated goals of the patent reform, some of which were reached, and some of which were postponed for the future due to political compromises:

- Excluding from patentability diagnostic methods, treatments and surgery and introducing stringent patentability criteria regarding pharmaceutical products (medicines), including, where needed, with the expert support of the Ministry of Health of Ukraine (this is intended to help Ukraine to grant patents based on high-level examination in accordance with the principles and rules of the European Patent System);
- Implementing supplementary protection for inventions on pharmaceutical products based on the same principles as in EU legislation, establishing additional rules such as prolonging only the protection covering the basic patent for products (active pharmaceutical ingredient), linking the application for market authorisation in the national market with the first appearance of the product in the world market, etc.;
- Implementing pre- and post-grant patent opposition procedures in the National Patent Office, as in other European countries;
- Allowing the state examination body (State Expert Centre of the Ministry of Health) to use the information from a patented invention for the examination of the pharmaceutical product with the purpose of its further registration immediately from the date of patent rights expiration;
- Implementing clearly determined provisions allowing the non-commercial use of the patented pharmaceutical product without the permission of the

patent holder in the case when such pharmaceutical product is not affordable because of the high price;

- Harmonising the intellectual property and unfair competition legislation with the right to health and life as laid down in the Charter of Fundamental Rights of the European Union;
- Implementing the international principle of exhaustion of intellectual property rights based on international legislation which allows each country to choose the principle of exhaustion of intellectual property.[11]

The advocacy efforts met resistance from the biopharmaceutical industry, which was unhappy to lose the possibility of obtaining evergreen patents in Ukraine.[12] The allies of patent reform were national generic manufacturers ready to fill the Ukrainian market with cheaper but still effective medicines and patients' organisations looking for effective and cheaper medicines. Foreign generic manufacturers were also looking forward to the patent reform on pharmaceutical products, and they were ready to supply cheaper generics.

In hindsight, it should be noted that this list of reform allies sheds light on one of the key reasons for the failure of patent reform. The domestic industry was not ready to support compulsory licensing or government use. Such legal instruments for expanding access to medicines involve imports. The Ukrainian manufacturer is not willing to compete with Indian generic companies, and this is the main challenge and the main stumbling block to the patent reform in Ukraine.

In drafting the amendments to the patent legislation, the Ukrainian team[13] had significant expert support from Professor Carlos María Correa, Head of the South Centre.[14] Professor Correa visited Ukraine and provided step-by-step consultations on drafting the Law 'On Amendments to Certain Legislative Acts of Ukraine on Reform of Patent Legislation'. The Parliament of Ukraine adopted the mentioned draft in June 2020.[15]

[11] The goals were presented in a Parliament hearing on 'Building an Effective System of Intellectual Property Protection in Ukraine' (16 December 2019) https://www.rada.gov.ua/news/Novyny/186120.html accessed 9 September 2023.

[12] 'Evergreening Patents in Ukraine' (n 10).

[13] Based within the Ministry of Economic Development and Trade of Ukraine, the Ukrainian team included scientists and practical lawyers from the IP sphere, representatives of international and domestic pharmaceutical companies and patients' organisations.

[14] The South Centre serves as the intergovernmental organisation for developing nations, facilitating the collaboration of these countries to pool their efforts and expertise in advancing shared interests on the global stage. The Centre supports developing countries in formulating national policies and participating effectively in international negotiations to achieve Sustainable Development Goals (SDGs), particularly poverty eradication, while respecting diverse national interests and priorities. For further details: https://www.southcentre.int/about-the-south-centre/ accessed 11 June 2023.

[15] In Ukrainian: https://zakon.rada.gov.ua/laws/show/816-20#n9 accessed 11 June 2023.

Ultimately, Ukraine reached the following achievements beyond the abovementioned strategic goals:

- Exclusion from patent protection of methods and techniques of treatment and surgical interventions;
- Pre-grant opposition for any person who recognises the violation of their rights in the case of granting the patent (which gives a standing to NGOs to oppose patent applications covering medicines);
- Bolar exception;
- Implementing strong patentability criteria for medicinal products in accordance with UNDP's Guidelines for the Examination of Patent Applications relating to Pharmaceuticals.[16]

However, there were also some failures of patent reform in healthcare. In particular, the legal provisions of compulsory licence (CL) and government use (GU) have not been reformed. As a member of the Working Group drafting changes and amendments to the Patent Law of Ukraine and part of the advocating company for the mentioned reform on behalf of patients' organisations, I am allowed to mention that it was a political compromise not to reform the sector of CL and GU. The opponents proposed to postpone such changes for the future. Likewise, patent linkage also has not been removed from the Law of Ukraine 'On Medicines'.[17] That future has come today due to the war and European integration agenda of Ukraine.

During the preparation of this contribution, an explosion occurred at the Kakhovka hydroelectric power station, which was under the control of the Russian occupation forces.[18] The dam's subsequent collapse has created the danger of environmental disaster. Flooding and pollution could cause some of the worst infectious diseases in history, including typhoid fever and cholera, to spread. Long forgotten in Europe, their threat is again looming. Infectious diseases know no borders. Therefore, the European Union is facing an environmental catastrophe. The improvement of the system of IP exceptions and limitations in Ukraine is also crucial for the EU as regards two key points: 1) control of infectious diseases in Ukraine through access to generic medicines, which saves partners' funds provided to Ukraine by the EU; and 2) consideration of Ukraine as a potential source of generic products for the EU market and EU refugees.

Potential solutions and outlook

[16] CM Correa, 'Guidelines for the Examination of Patent Applications Relating to Pharmaceuticals' (2016) https://www.undp.org/publications/guidelines-examination-patent-applications-relating-pharmaceuticals accessed 09 September 2023.

[17] In Ukrainian: https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80#Text accessed 11 June 2023.

[18] 'Ukraine Dam: What We Know about Nova Kakhovka Incident' (*BBC*, 8 June 2023) https://www.bbc.com/news/world-europe-65818705 accessed 11.06.2023; D Peleschuk, 'Evidence Grows of Explosion at Collapsed Ukraine Dam' (*Reuters*, 9 June 2023) https://www.reuters.com/world/europe/ukraine-security-service-says-it-intercepted-call-proving-russia-destroyed-2023-06-09/ accessed 11 June 2023.

Today is the time to continue the reform of patent law in the areas of CL and GU, not only based on the Doha Declaration but also from the perspective of EU membership of Ukraine and, unfortunately, through the prism of the most significant environmental disaster in Europe in the 21st century.

Therefore, Ukraine needs to study the tendencies in developing EU legislation in the field of CL and GU in healthcare. For this research, it is also important to focus on the definitions of legal grounds for CL and GU in EU member states and consider their relevance for Ukraine.

At the same time, Ukraine should also consider the provisions of Article 73 'Security Exceptions' of the TRIPS Agreement as grounds for IP waivers in healthcare. The numerous publications of Dr Olga Gurgula provide the most significant input in the field.[19]

Ukrainian experts and key stakeholders have a clear vision that such changes and amendments to the Patent Law of Ukraine should fully comply not only with the Association Agreement between Ukraine and the EU but also with the legislation of the EU. During the discussion at the online Round Table which was held in cooperation with the Max Planck Institute in December 2022, it became apparent for Ukrainian participants that the experience of the international experts of the Max Planck Institute is invaluable for Ukraine.

Therefore, the following efforts should be made:

1. On the part of the National Office of IP and Innovation, to work out and implement the changes to Patent Law in the sector of CL and GU.
2. To work out the Guidelines on the granting of CL, which should be formalised in the Order of the Cabinet of Ministers of Ukraine.
3. To examine potential solutions for aligning the grant of CL with test data protection and trade secrets protection.
4. To draft amendments which clearly define the legal grounds for CL and GU considering the EU experience, which is the most applicable for Ukraine.

Oksana Kashyntseva holds a Ph.D. in Law and is Head of the Department of Intellectual Property Rights and Human Rights in Healthcare of the Science and Research Institute of Intellectual Property at the National Academy of Legal Sciences of Ukraine; Head of the Centre for Harmonisation of Human Rights; member of several working groups on reforming the legislation in healthcare at the

[19] O Gurgula, 'Saving Ukrainian Lives During the Russian War: Ukraine Must Waive IP Rights under Article 73 TRIPS to Provide Access to Essential Medicines' (2022) 71(8) GRUR International 719; O Gurgula, 'Ukraine Medicine IP Waiver Becomes "Matter of Life or Death"' (*Financial Times*, 16 June 2022) https://www.ft.com/content/6f30e0e4-3f36-4961-a85f-2dfcd58dbc50 accessed 11 June 2023.

Parliament of Ukraine and National Office of IP and Innovations. E-mail: kashyntseva@ukr.net

International Experience with Compulsory Licensing during the COVID-19 Pandemic and Lessons for Ukraine

Sergiy Kondratyuk

The COVID-19 pandemic demonstrated many weaknesses of the existing global R&D system for medical products based on intellectual property (IP) protection. The mechanism of compulsory licensing, though perceived by many countries as most instrumental in ensuring access to needed health technologies during the pandemic, was not as widely used as could be expected in such an emergency situation. This demonstrates a weakness of the current TRIPS flexibilities framework that could be problematic for future pandemics' response. Ukraine did not manage to amend or use compulsory licensing to improve its response to the COVID-19 pandemic.

Global inequity in access to vaccines and COVID-19 antivirals has remained one of the defining features of the COVID-19 pandemic. Attempts by low- and middle-income countries (LMICs) to obtain a comprehensive waiver of IP protections on COVID-19 health technologies at the World Trade Organization (WTO) have resulted in a weak compromise. Manufacturers of vaccines and antiviral medicines in the United States (US) and Europe have used multiple techniques to limit and control the supply of their medical products to the developing world. The mRNA vaccine producers Moderna and Pfizer-BioNTech have refused to share the technology and know-how for local production in LMICs.[1] Viral-vector vaccine producers AstraZeneca and Johnson and Johnson (J&J)[2] and antiviral medicine producers Gilead,[3] Merck and Pfizer[4] have entered into restrictive, sometimes secret, voluntary licensing agreements with a limited number of LMIC producers. These vaccine and antiviral producers along

[1] S Nolen, SG Stolberg, 'Pressure Grows on U.S. Companies to Share Covid Vaccine Technology' (*The New York Times*, 22 September 2021) https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html accessed 31 May 2023.

[2] Developing Countries Vaccine Manufacturers Network (DCVNM), Towards Vaccinating The World Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible "Solution Space": a Discussion Document, Appendix, *Global COVID-19 Supply Chain & Manufacturing Summit* (March 8th and 9th, 2021) p. 6 https://dcvmn.org/wp-content/uploads/2020/04/landscape_of_current_c19_supply_chain_manufacturing_capacity_appendix_embargo_9march20.pdf accessed 31 May 2023.

[3] E Silverman, 'Gilead signs licenses for generic companies to make and sell remdesivir in 127 countries' (*Stat News: Pharmalot*, 12 May 2020) https://www.statnews.com/pharmalot/2020/05/12/gilead-generics-remdesivir-covid19-coronavirus-licenses/ accessed 31 May 2023.

[4] Medicines Patent Pool, Progress and Achievements: Licenses https://medicinespatentpool.org/progress-achievements/licenses accessed 28 May 2023.

with the US and European governments have cited donations of vaccine doses and not-for-profit pricing as proof of fulfilment of their international obligations.

Main problems

In May 2020, when the first truly promising COVID-19 antiviral medicine, remdesivir, was approved for emergency use by the US FDA,[5] the initial three-month supply was hoarded by the US government.[6] Later on, when additional supply became available, the pricing of the drug by Gilead, its originator (patent owner) – and by Gilead's licensees for generic manufacturing – was significantly higher than the estimated cost of manufacturing ($386-$2,340[7] versus $9[8] per treatment course). Similarly, when molnupiravir showed very promising results for COVID-19 treatment, it was initially priced at $700 per treatment course, as opposed to the $19.99 estimated cost of manufacturing.[9] It is well known that IP monopolies regarding medicinal products reduce physical and economic availability during the term of such monopolies,[10] as the number of potential manufacturers and suppliers of such products is limited in order to allow the company that developed the medical product to obtain increased profits to recoup alleged R&D investments. This contribution argues that granted patents and pending patent applications on remdesivir and molnupiravir[11] were the main contributing factors to such low availability and high pricing.

Ukraine does not have well-regulated government use or compulsory licensing mechanisms that would allow for overcoming IP barriers during pandemics. Moreover, the EU membership aspirations of Ukraine and the fear of criticism from EU trade officials limit the potential for the political will needed to utilise such mechanisms.

---

[5] US FDA 'Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment' (News Release, 1 May 2020) https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment accessed 28 May 2023.

[6] S Boseley, 'US secures world stock of key Covid-19 drug remdesivir' (*Guardian*, 30 June 2020) https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug accessed 31 May2023.

[7] A Kumar Mitra, A Banerjee 'Mylan prices its generic remdesivir in India at $64 per 100 mg vial' *Reuters* (Bengaluru, 6 July 2020) https://www.reuters.com/article/us-health-coronavirus-mylan-india-idUSKBN2471CJ accessed 31 May2023.

[8] A Hill and others, 'Minimum costs to manufacture new treatments for COVID-19' (2020) 30(6(2)) J Virus Erad 61, doi: 10.1016/S2055-6640(20)30018-2.

[9] Melissa Barber, Dzintars Gotham, Estimated cost-based generic prices for molnupiravir for the treatment of COVID-19 infection (1 October 2021) https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_molnupiravir_for_the_treatment_of_covid-19_infection.pdf accessed 31 May 2023.

[10] Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies, 2016, 70. URL: http://www.unsgaccessmeds.org/final-report p. 8 accessed 31 May 2023

[11] MPP, Medspal database https://www.medspal.org/?product%5B%5D=Molnupiravir+200+mg&product%5B%5D=Remdesivir+100+mg%2Fvial&page=1 accessed 28 May 2023

Potential solutions

Knowing that IP monopolies would be a barrier in ensuring access to health technologies needed for the COVID-19 pandemic response, several countries, including many high-income countries, at the beginning of the pandemic quickly set about making their mechanisms of compulsory licensing applicable or more fit for purpose. For example, Canada amended its laws to make it easier to issue compulsory licences with Bill C-13, the COVID-19 Emergency Response Act, passed into law on 25 March 2020. Along with a range of powers to tackle problems caused by COVID-19, it specifies that if the federal Minister of Health decrees a public health emergency, the commissioner of patents must, on the application of the Minister of Health, authorise the government of Canada and any person specified in the application to make, construct, use and sell a patented invention as necessary to respond to that emergency. Unlike existing compulsory licensing provisions, the new law allowed the government to issue a licence without first negotiating with the rights holder or establishing its own ability to supply a product. The provision expired on 30 September 2020, after which no compulsory licence can be granted in Canada using this procedure.[12] At the same time, the Canadian government was actively investing in COVID-19 vaccine R&D and launching a local vaccine-manufacturing facility in Montreal operated by the National Research Council (NRC).[13] Notwithstanding such efforts, when the Canadian local manufacturer Biolyse requested that the government issue a compulsory licence for the export to Bolivia of the J&J COVID-19 vaccine in 2021, the government never responded.[14] Similarly, arguably due in part to IP barriers, as of April 2023 the NRC facility in Montreal had not managed to produce a single dose of COVID-19 vaccine.[15]

In Germany, on 28 March 2020, a law entered into force one day after its adoption by the Bundestag, amending the Act on the Prevention and Control of Infectious Diseases in Humans. In the event of an 'epidemic situation of national significance', this law granted powers of essentially government use of inventions to the federal Health Minister. The Minister was authorised 'to order under Section 13(1) of the Patent Act that an invention relating to one of the products mentioned in [paragraph 4 of the Act]

---

[12] A Houldsworth, 'The Key Covid-19 Compulsory Licensing Developments So Far' *IAM* (7 April 2020) https://www.iam-media.com/article/the-key-covid-19-compulsory-licensing-developments-so-far accessed 31 May 2023. Parliament of Canada, Act respecting certain measures in response to COVID-19, Bill C-13 as of March 25, 2020, Part 12 https://www.parl.ca/DocumentViewer/en/43-1/bill/C-13/royal-assent.

[13] Prime Minister of Canada, New measures to ensure the supply of future vaccines and therapies against COVID-19 (Montreal, 31 August 2020) https://pm.gc.ca/en/news/news-releases/2020/08/31/new-measures-ensure-supply-future-vaccines-and-therapies-against accessed 31 May 2023.

[14] F Bruce, 'Canadian Firm Scathing on Obstacles to Compulsory Licensing' (*Pink Sheet Citeline Regulatory*, 27 May 2021) https://pink.pharmaintelligence.informa.com/PS144384/Canadian-Firm-Scathing-On-Obstacles-To-Compulsory-Licensing accessed 31 May 2023.

[15] M Rabson, 'Canada's Pledge to Make More Vaccines at Home Is Still a Work in Progress' (*The Canadian Press*, 14 April 2023) https://nationalpost.com/pmn/news-pmn/canada-news-pmn/canadas-pledge-to-make-more-vaccines-at-home-is-still-a-work-in-progress accessed 31 May 2023.

shall be used in the interest of public welfare or the interest of the security of the Federal Republic of Germany', and that 'the Federal Ministry of Health may instruct a subordinate authority to make such an order'.[16] On 25 March 2020, the Bundestag found that due to the spread of the Coronavirus in Germany, there was an epidemic situation of national significance, which was an important pre-condition at that time for the new power to apply.[17]

France went further, amending its Public Health Code by introducing Article L.3131-15 (7, 9, 10), which empowered the Prime Minister to order by regulatory decree, upon report of the Health Minister, any measure (even limiting freedom of enterprise) to make appropriate medication available to patients for the eradication of the health disaster.[18] This could be interpreted as permitting the Prime Minister to issue compulsory licences or to set a price ceiling for the medicines needed, according to debates on this provision in the French parliament.[19]

In Brazil as well, there were several proposals during the COVID-19 pandemic aimed at improving the compulsory licensing mechanism. The unsuccessful bill 1462/2020, advocated by civil society groups such as Associação Brasileira Interdisciplinar de AIDS (ABIA), proposed automatic compulsory licensing that would be triggered by a public health emergency of national or international scale and would apply to all patents and patent applications for technologies needed to respond to that health emergency or calamity. The bill set royalty amounts at between 1.5 and 3% of sales of relevant generic products and would have obliged state authorities, the patentee, or the patent applicant to share all information necessary for the effective reproduction of the protected subject matter.[20] Another bill, which became Law 14.200/2021, added to the grounds for these measures a national state of public calamity and an international emergency. It made compulsory licensing applicable to pending patent applications and obliged public institutions to share all information necessary for the reproduction of the licensed subject matter. Though this law was a win from the perspective of access, several important provisions were vetoed by the President and some provisions

[16] WIPO Lex, Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance, 2020, https://www.wipo.int/wipolex/en/legislation/details/19754 accessed 19 November 2023.
[17] T Musmann, S Klopchinski, 'Update on Patent-Related Measures in Germany in View of Corona Pandemic' (*Kluwer Patent Blog*, 2 April 2020) https://patentblog.kluweriplaw.com/2020/04/02/update-on-patent-related-measures-in-germany-in-view-of-corona-pandemic/ accessed 31 May 2023.
[18] Public Health Code of France: article L3131-15 https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000043911599/2023-05-30 accessed 31 May 2023.
[19] F Pochart et al., 'Compulsory Licenses Granted by Public Authorities: An Application in the Covid-19 Crisis in France? Part 1' (*Kluwer Patent Blog*, 23 April 2020), http://patentblog.kluweriplaw.com/2020/04/23/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-1 accessed 31 May 2023.
[20] S van der Ploeg, C Scopel, A Rossi Silva, 'Compulsory Licensing: Brazilian Context' Presentation' ABIA/GTPI (MMA ITPC CL Workshop for Latin America on 22 May 2023) (on file with the author).

were included that made the compulsory licensing process more bureaucratic and patent monopoly-friendly in some cases.[21]

There were also several examples of countries issuing compulsory licences for COVID-19 medicines. The first country to issue compulsory licences during the COVID-19 pandemic was Israel. On 18 March 2020, the Minister of Health and attorney general issued a permit allowing the state to import a generic version of AbbVie's lopinavir/ritonavir from India for the treatment of COVID-19 patients.[22] Within five days after the compulsory licence was issued, AbbVie announced *global* non-enforcement of patents on lopinavir/ritonavir.[23]

Another example was in Hungary, where the old law contained only a provision for a compulsory licence for export, and Government Decree 212/2020 of 17 May 2020[24] included provisions on compulsory licences for health emergencies, according to which compulsory licences may be issued by the Hungarian IP Office (HIPO) based on a submission from the Hungarian pharmaceutical regulator (OGYÉI) regarding national needs to address a critical health situation. On 8 June 2020, Decree 212/2020 ceased to have effect, though similar provisions on the public health compulsory licensing system were introduced into the patent law.[25] On 7 October 2020, Reuters reported[26] that Gideon Richter had produced 3,000 treatment courses of remdesivir for domestic use, under a decision to issue a compulsory licence based on the provisions of emergency Law Decrees 283/2020 and 478/2020.[27] The Hungarian government, which owns 5.25% of Richter's shares, had approached the company during the first wave of the pandemic to investigate whether remdesivir could be produced domestically. It took five months to solve the problem of synthesis, and the government funded the development of a generic version of remdesivir.[28] However, Gilead has appealed the compulsory licence decision, arguing that there was no unmet supply need for remdesivir in Hungary, hence there was no basis for the compulsory licence, and that the company was not heard by HIPO. After losing the appeal in general courts,

[21] ibid.
[22] Houldsworth (n 12).
[23] K Blankenship, 'AbbVie Gives Up Patent Rights to HIV Med Kaletra amid COVID-19 Tests: Report' (*Fierce Pharma*, 23 March 2020) https://www.fiercepharma.com/pharma/abbvie-gives-up-patent-rights-to-hiv-med-kaletra-amid-covid-19-tests-report accessed 31 May 2023.
[24] WIPO, Government Decree 212/2020 (as in force on 17 May 2020) https://www.wipo.int/wipolex/en/text/570056 accessed 31 May 2023
[25] T Balasubramanian, 'WTO TRIPS Council (October 2020): Hungary answers queries posed by South Africa regarding Hungarian compulsory licensing provisions (*KEI*, 20 October 2020 https://www.keionline.org/34268
[26] Gergely Szakacs, 'Hungary's Richter has manufactured Remdesivir for 3,000 COVID-19 patients' *Reuters* (7 October 2020) https://www.reuters.com/article/health-coronavirus-remdesivir-richter-idUSL8N2GY465/ accessed 19 November 2023
[27] Thiru Balasubramaniam 'Hungarian compulsory license for remdesivir raises a stir with BIO, PhRMA and the US Chamber of Commerce' KEI (8 March 2021) https://www.keionline.org/35558 accessed 31 May 2023.
[28] Ibid.

the company's complaint was successful in the Constitutional Court, which annulled the HIPO administrative decisions on compulsory licence.[29]

The most recent example occurred in Indonesia, where in 2020, the Indonesian President issued Regulation 77/2020 as an implementing regulation for the provisions on compulsory licences under Indonesia's Patent Law (Law No. 13 of 2016). Regulation 77/2020 specifically recognises that government use can be authorised here if an international public health emergency exists. On 10 November 2021, two Presidential Decrees were approved on government use of four remdesivir and five favipiravir patents by the national pharmaceutical industry with remuneration at 1% of the net selling value of generic medicine to meet urgent need for COVID-19 treatment as the spread of COVID-19 has been declared by World Health Organization (WHO) as a global pandemic and the government has also established the spread of COVID-19 as a national disaster.[30]

Unlike the abovementioned countries, Ukraine took almost no steps to use the momentum created by the COVID-19 pandemic to revise the existing compulsory licensing mechanism, which has multiple flaws that make it inoperable in practice. For example, the compulsory licensing procedure requires to provide evidence that demand for the relevant medicine could not be satisfied by the patentee using conventional manufacturing capacity; also, there is no definition of the state body that is to approve the amount of remuneration, and the calculation formula of remuneration under the compulsory licensing scheme is too complicated to apply in practice.[31] The only change that was made during the COVID-19 pandemic by the Law of Ukraine № 816-IX 'On amendments to certain legislative acts of Ukraine regarding patent legislation reform' of 21 July 2020 was to delete prior negotiations requirement for government use. Previously, the requirement was to obtain from patentees an 'ungrounded refusal' to provide a voluntary licence for government use to be triggered, which was clearly a TRIPS-plus provision. However, the Ukrainian government made no other changes to fix the mechanism, nor did it make any serious attempt[32] to authorise government use.

---

[29] B Halazs, B Kovecses, 'Hungarian Constitutional Court Annuls First Public Health Compulsory License' (*Lexology*, 19 October 2023) https://www.lexology.com/library/detail.aspx?g=49f6051c-1457-4626-9343-0b43a9af15a3 accessed 20 November 2023

[30] Make Medicines Affordable campaign 'Indonesia Issues Government Use Licenses for Remdesivir and Favipiravir' (8 December 2021) https://makemedicinesaffordable.org/indonesia-issues-government-use-licenses-for-remdesivir-and-favipiravir/ accessed 31 May 2023.

[31] Regulation on the granting by the Cabinet of Ministers of Ukraine of a permit to use a patented invention (utility model) related to a medicinal product, approved by resolution of the Cabinet of Ministers of Ukraine on 4 December 2013 p. № 877; see paragraphs 2, 6, 7, 8, 13 https://zakon.rada.gov.ua/laws/show/877-2013-%D0%BF#n57.

[32] With the exception of the unfruitful discussion that was raised by the head of the parliamentary healthcare committee; see for more detail (in Ukrainian): Kateryna Khoroschak 'There is a will to permit the Ukrainian pharmaceutical industry to produce medicines that allegedly treat COVID' *Ukrainska Pravda Life* (Kyiv, 8 April 2020) https://life.pravda.com.ua/health/2020/04/8/240515/.

Outlook

The COVID-19 pandemic demonstrated the critical influence of the existing IP-centred design of the global R&D system for health products on the availability and affordability of medicines needed to respond to a public health emergency.

Several developed and developing countries, motivated by the unfolding COVID-19 pandemic, have at least introduced or adapted government-use compulsory licensing mechanisms, and some have issued government-use licences for COVID-19 medicines. Unfortunately, Ukraine did not use the opportunity to sharpen the compulsory licensing mechanism and did not resort to its use to ensure the availability and affordability of COVID-19 treatments, notwithstanding the obvious challenges that the Ukrainian public health system was facing at that time.

While compulsory licensing had the potential to be one of the most impactful instruments to address the availability and affordability of needed COVID-19 emergency response health products, its use was unreasonably limited as a catastrophic pandemic was unfolding, bringing an end to the lives of millions of people. This was a major failure of the TRIPS flexibilities framework in view of the urgent need for IP-protected products, and it revealed the need for more radical change to the TRIPS Agreement rules in relation to medical products. Current pandemic preparedness negotiations at WHO partially reflect the need for a more radical approach to waiving IP protection in times of future pandemics for IP barriers. However, it still relies on voluntary measures in place of obligations for member states concerning transparency, transfer of technology and know-how.[33]

Sergiy Kondratyuk is a PhD candidate at the Science and Research Institute of Intellectual Property at the National Academy of Legal Sciences of Ukraine. He is a project manager of the Make Medicines Affordable campaign of the International Treatment Preparedness Coalition.

[33] Medecins Sains Frontieres 'Pandemic Accord: MSF's Comments on Equity Provisions in INB Proposal for Negotiating Text' Briefing document (3 November 2023) https://msfaccess.org/pandemic-accord-msfs-comments-equity-provisions-inb-proposal-negotiating-text accessed 21 November 2023.

Ukrainian Pharma as a Reliable Partner for the EU

Yevgeniya Piddubna • Viktoriia Popovych

This article explores certain potential benefits of integrating the Ukrainian pharmaceutical industry into the market of the European Union (EU) in light of the EU's plans to develop a Critical Medicines Act to reduce dependencies for critical medicines and ingredients, particularly for products supplied by only a few manufacturers or countries. The prerequisites for such integration are the high quality of products supplied by the local industry leaders, their research and development (R&D) capabilities and the potential for localisation of innovative technologies from international manufacturers in light of the decrease of investments in the Russian Federation and related sanctions. It also examines the barriers that the Ukrainian pharmaceutical industry faces when exporting products to the EU and, finally, summarises why such a partnership can be mutually advantageous.

The Ukrainian pharmaceutical industry has emerged as an attractive prospect for the EU member states as an alternative supplier of pharmaceutical products. European companies can leverage Ukrainian manufacturing capacities and resources to ensure an uninterrupted supply, diversify the available selection, and partially substitute the supplies from Indian and Chinese manufacturers of generic drugs and active pharmaceutical ingredients (APIs).

In the first place, we aim to dispel the myth that the Ukrainian pharmaceutical industry is underdeveloped. Despite its underappreciated potential, the Ukrainian pharmaceutical industry has much to offer. Pharmaceutical companies are among the leaders in the Ukrainian economy in terms of investments in R&D. Almost half of the leading pharmaceutical enterprises in Ukraine are investment-active; in 2019 alone, they spent up to 50 million USD to fuel innovations and studies for new generic drugs. R&D complexes of the key local manufacturers are equipped by the world's leading suppliers. The majority of domestic market leaders have their own R&D centres, as well as necessary experience in contract manufacturing and technology transfer from internationally known pharmaceutical companies. Each leading company obtains proper good manufacturing practice (GMP) certification from EU regulatory authorities and releases nearly 20 new products per year.[1]

[1] KSE Insitute. *Шляхи стимулювання R&D та трансферу технологій у фармацевтичній галузі України*, 2021.

The COVID-19 pandemic and Russia's full-scale invasion of Ukraine are pushing the EU and the whole world to restructure their healthcare systems to make them more resilient to crisis.[2] It is evident that unsustainable logistic chains from Asia impose hazards on healthcare systems, while partnerships with Russia are becoming toxic.[3] In this situation, the advantageous geographical location of Ukraine makes it possible to reduce the dependence of the EU on suppliers from India and China. Ukraine's efficient logistical channels and diplomatic ties can provide a favourable foundation for expanding exports of EU-based manufacturers to the regions of Eastern Europe, Central Asia, the Middle East and North Africa. Moreover, the country's significant potential in the chemical-pharmaceutical field provides the option of developing the production of APIs in Ukraine for further integration into the EU drug production and supply chains.

Potential collaboration in the pharmaceutical sector

Collaboration between the Ukrainian and European pharmaceutical industries can be mutually beneficial, promoting further sustainable development of both parties and ensuring the stability of the supply of quality medicines and ingredients. This can contribute to improving healthcare systems and meeting the needs of patients in the EU. Potential areas of collaboration between Ukraine and the EU include:

1. *Contract Manufacturing*: European companies can tap into Ukrainian potential for contract manufacturing, optimising production processes, and reducing costs by utilising the high-quality manufacturing capabilities of Ukrainian companies.
2. *API Production*: Ukraine has the potential for API production, a critical component of pharmaceutical products. In the USSR, the country was second in pharmaceutical production volumes, accounting for approximately 30% and producing around 800 types of medicinal products.[4] Today, some companies have full-cycle pharmaceutical manufacturing – from producing APIs to the finished dosage forms. For instance, in 2015, Farmak JSC launched its own production of APIs in Shostka, Sumy Oblast, investing over $40 million in this project. Ukraine's potential for API production stems from its skilled workforce, robust R&D capabilities, favourable geographical location, access to natural resources, a growing local pharmaceutical industry, regulatory compliance, and governmental support. Cooperation between European pharmaceutical companies and Ukrainian API manufacturers can ensure a reliable supply of high-quality components. Moreover, Ukraine has the capability to manufacture APIs, intermediate products, and generic drugs from

[2] S Fischer et al., 'Potential Measures to Facilitate the Productions of Active Pharmaceutical Ingredients (APIs)' (2023) https://www.europarl.europa.eu/RegData/etudes/STUD/2023/740070/IPOL_STU(2023)740070_EN.pdf accessed 20 December 2023.

[3] EU Commission Implementing Decision on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2023, 2022, https://hadea.ec.europa.eu/system/files/2022-11/wp2023_annex_en.pdf accessed 20 December 2023.

[4] See also the contribution by Liudmyla Petrenko in this collection.

the Critical List of Medicines of the EU in Ukraine, including antibiotics, thrombolytics, insulin, antipyretics, analgesics, etc.[5]

3. *Vaccines Production*: Ukraine possesses the potential for vaccine production for the internal market and exports. Partnerships with European companies in vaccine production and supply can ensure uninterrupted deliveries to meet the needs of Ukraine, European countries, and Central Asia.
4. *Guaranteeing Continuous Generic Supply*: Ukraine is a significant producer of generic pharmaceuticals, including those included on the Critical Medicines list recently developed in the EU in light of fighting the consequences of pandemics and related shortages of drugs in some EU member states. Collaboration with European companies can provide a stable and continuous supply of quality generics to the EU, partially substituting those from India and China.
5. *Conducting Clinical Trials of New Drugs and Medical Technologies*: Ukraine can serve as an attractive platform for replacing the Russian market, where most international companies have suspended operations due to sanctions against the aggressor country.

Overcoming barriers

Despite the potential for collaboration, several barriers need to be overcome for the successful integration of the Ukrainian pharmaceutical industry within the EU market. The very first one lies in dismantling regulatory barriers for the export of Ukrainian medicines to the EU through the mutual recognition of GMP certificates between Ukraine and the EU. Currently, all leading Ukrainian companies are certified according to these international standards. However, in practice, when exporting to the EU, they face double verifications and checks. When exporting medicines to the EU, Ukrainian manufacturers are required to undergo compliance checks for GMP requirements both in Ukraine and at the level of the EU member states. This significantly affects the final price of pharmaceutical products and, as a result, the competitiveness of Ukrainian medicines abroad. Another barrier for pharmaceutical companies entering the market is obtaining marketing authorisation. The implementation of the mutual recognition procedure for drug registration is particularly important, as it will accelerate the market entry of Ukrainian medicines.[6]

Another issue to be highlighted is that the Bolar exemption needs to be comprehensively implemented in Ukraine to bring it in line with EU practices. It would also be a crucial step towards integrating the Ukrainian pharmaceutical industry into the global market on equal terms. The Bolar regulation refers to the legal framework that allows generic drug manufacturers to conduct research and development

[5] ПА Осос, 'Потенціал фармацевтичної індустрії в умовах пандемії COVID-19' (2021) 1(235) Актуальні проблеми економіки 34, https://eco-science.net/wp-content/uploads/2022/01/1.21._topik_Osos-P.%D0%90.-34-41.pdf accessed 20 December 2023.
[6] В Костюк, 'Безвіз для ліків': чого очікує українська фарміндустрія від саміту з ЄС (2021) https://www.eurointegration.com.ua/experts/2021/10/11/7128780/ accessed 20 December 2023.

activities, including clinical trials and drug marketing authorisation (except for any marketing activities), prior to the expiration of the originator's patent protection. By adopting the EU-inspired Bolar provisions, Ukraine can attract more international investments in its pharmaceutical industry. The alignment with the EU practices will enhance the country's reputation as a reliable partner for multinational pharmaceutical companies seeking to conduct research and development activities or establish production facilities. Additionally, the harmonisation of the Bolar regulation will enhance cooperation and knowledge sharing between Ukrainian and European pharmaceutical stakeholders. International partners can indeed play a vital role in extending a helping hand to the Ukrainian pharmaceutical sector. One area where support is needed is the development and implementation of different programs that encourage cooperation with major international companies for technology transfer and localisation of drug production in Ukraine, as well as the use of the country's logistical advantages. This can involve sharing expertise, knowledge, and best practices to enhance manufacturing capabilities and improve product quality. Some potential programs that could be developed and implemented to encourage cooperation and growth in the sector include:

- Technology Transfer Programs: Collaborative initiatives with major international pharmaceutical companies to transfer innovative manufacturing technologies and expertise to Ukrainian companies. This can help to enhance the capabilities and efficiency of local drug production.
- R&D Partnerships: Facilitating research collaborations between Ukrainian pharmaceutical companies and international partners. Joint research projects can lead to the development of new and innovative drugs, benefiting both the Ukrainian and global markets.
- Regulatory Support: Assisting Ukrainian pharmaceutical companies in meeting international regulatory standards, including the requirements of the EU and other major markets. This support can streamline the export process and improve access to the international markets for both parties.
- Market Access Programs: Facilitating market access for Ukrainian pharmaceutical products in international markets. This can involve market research, trade missions, and promotional activities to increase the visibility of Ukrainian-made medicines.
- Public-Private Partnerships: Encouraging cooperation between the government, the private sector, and international organisations to address challenges and seize opportunities in the pharmaceutical industry.

Financial support programs dedicated to the development of API production in Ukraine are crucial. Assistance in funding and infrastructure development can help strengthen the domestic API manufacturing capacity, reducing dependency on imports and ensuring a stable supply chain for pharmaceutical companies both in Ukraine and in the EU.

To enhance the quality standards in line with EU requirements, international partners can support the establishment of training programs and facilitate appropriate validation processes for inspectors issuing certificates based on the EU GMP standards. This will contribute to improving the overall quality and compliance standards of Ukrainian pharmaceutical manufacturers, enabling them to meet international regulatory expectations.

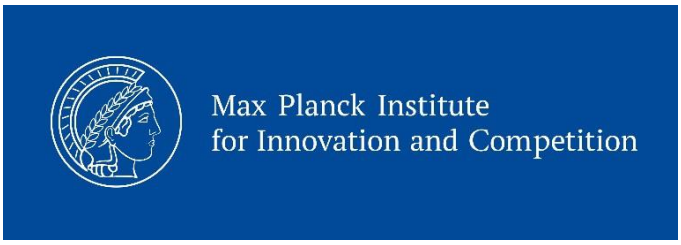
By developing and implementing these types of programs, international partners can contribute significantly to the growth and development of the Ukrainian pharmaceutical sector, ultimately benefiting both the country's healthcare system and the global pharmaceutical industry.

Conclusion

The Ukrainian pharmaceutical industry holds significant potential for partnerships with the EU. The high quality of products from industry leaders and research and development capabilities can attract European partners.

Yevgeniya Piddubna is Corporate Communications Director at Farmak JSC. Yevgeniya is a member of the Working Groups under the Ministry of Health of Ukraine and the Office of the President of Ukraine and a contributor to the development of the following documents: Draft Strategy for the Healthcare System Development 2030 in Ukraine (https://moz.gov.ua/strategija) and Draft Recovery Plan for Ukraine (Healthcare part) (https://www.urc-international.com/urc2022-recovery-plan).

Viktoriia Popovych is Manager for Corporate Social Responsibility and Government Relations Communications at Farmak JSC. She is responsible for government liaisons and implementing social and charitable initiatives within the company. She also handles the assessment of legislative documents and analysis of EU legislation related to the pharmaceutical industry.



Roundtable
'Rebuilding Ukraine: The Case of the Health Sector'

21 March 2023

Max Planck Institute for Innovation and Competition (Munich)

Room E10

1 p.m. Welcome Address

Prof. Dietmar Harhoff, Ph.D., Director at the Max Planck Institute for Innovation and Competition,Department of Innovation and Entrepreneurship Research; Honorary Professor at Ludwig-Maximilians-Universität (LMU) Munich

Panel 1: The Ukrainian Pharmaceutical Industry: Strategic and Industrial Policy Perspectives

Moderation: Prof. Dietmar Harhoff, Ph.D.

1: 10 Ukrainian Pharmaceutical Market as a Part of National Security – Volodymyr Bortnytskyi, Ph.D., Deputy Head of the Social and Humanitarian Security of the Staff of the National Security and Defence Council of Ukraine, *online*

1: 30 Production of Pharmaceutical Products in Ukraine: Before the War and Now – Prof. Dr. Liudmyla Petrenko, Department of Business Economics and Entrepreneurship, Kyiv National Economic University named after Vadym Hetman, Ukraine, *in person*

1: 45 Q&A

Panel 2: Drug Research and Development in Ukraine

Moderation: Anastasiia Lutsenko

2 p.m.	Clinical Trials Industry in Ukraine: The Contribution to the Economy and Potential for the Rebuilding of the Country – Prof. Ivan Vyshnyvetskyy, MD, Ph.D., Managing Director Ukraine at FutureMeds, President of the Ukrainian Association for Clinical Research, Associate Professor at National Medical University (Kyiv), *online*
2: 15	Insurance of Clinical Trials in Ukraine – Prof. Nino Patsuria, Taras Shevchenko National University of Kyiv, *online*
2: 30	Q&A
2: 45	Coffee break
	Panel 3: A Regulatory Framework Outlook for the Ukrainian Pharmaceutical Sector Moderation: Dr. Daria Kim
3 p.m.	The Ukrainian Pharmaceutical Market: Legal Regulation and Prospects of Development – Prof. Vitalii Pashkov, Head of the Laboratory for the Study of National Security Problems in the Field of Public Health of the Academician Stashis Scientific Research Institute for the Study of Crime Problems, National Academy of Law Sciences of Ukraine, *in person*
3: 15	Legal Instruments Against Illicit Medicine Markets in Ukraine – Prof. Nataliya Gutorova, Yaroslav Mudryi National Law University, Ukraine, *in person*
3: 30	Q&A
	Panel 4: Perspectives on Intellectual Property in the Pharmaceutical Industry in Ukraine Moderation: Prof. Dr. Dr. h.c. Reto M. Hilty
3: 45	Outline of Patent Reform in Ukraine: Legal Instruments to Ensure the Access to Medicines from the Perspective of Membership in EU – Assoc. Prof. Oksana Kashyntseva, Ph.D. Law, Head of the Department of IP rights and Human Rights in Healthcare of the SR Institute of Intellectual Property of National Academy of Law Sciences of Ukraine, Head of the NGO 'Center of Harmonization of Human Rights', *in person*
4 p.m.	International Experience on Compulsory Licensing and Patent Oppositions during COVID Pandemic – Sergiy Kondratyuk, ITPC Global IP and Access to Medicines Projects Manager, *online*
4: 15	The Need for the Further IP Reform in the Sphere of Medicines in Ukraine & Perspectives of Enhancing Cooperation between Ukrainian and the EU Pharmaceutical Sector – Dr. Yevgeniya Piddubna, Corporate Affairs Director, Farmak JSC, Chair of the Healthcare Committee at the Union of Ukrainian Entrepreneurs, in person, and Dr. Kseniia Velychko, GR Manager, Pharmaceutical Company 'Darnitsa', *in person*
4: 30	Q&A

ISBN 978-3-00-075746-4