PHARMACEUTICAL INDUSTRY INDUKRAINE • •



This is why we did this study

Covid-19 pandemic and full-scale Russia's invasion of Ukraine have clearly shown the importance of a strong pharmaceutical industry as a part of the healthcare system and a factor that strengthens national security.

Pharma in Ukraine is the industry which combines a long history of development with innovation and orientation to the future. This is the industry that is among the leaders in terms of investment and productivity. This is the industry which, in addition to economic growth, has a significant social component and directly affects living standards.

In this study, we showed the main changes in the market, the position of domestic and foreign players, we considered development trends, opportunities, problems and achievements of the Ukrainian pharmaceutical production, and demonstrated the impact of Covid-19 and full-scale Russia's invasion of Ukraine have on the industry



UKRAINE'S Pharmaceutics in 2022



3 Ukrainian pharmaceutical companies

1000 most expensive pharmaceutical companies in the world*



-6.1% decrease in sales of medicines in pharmacies, UAH terms



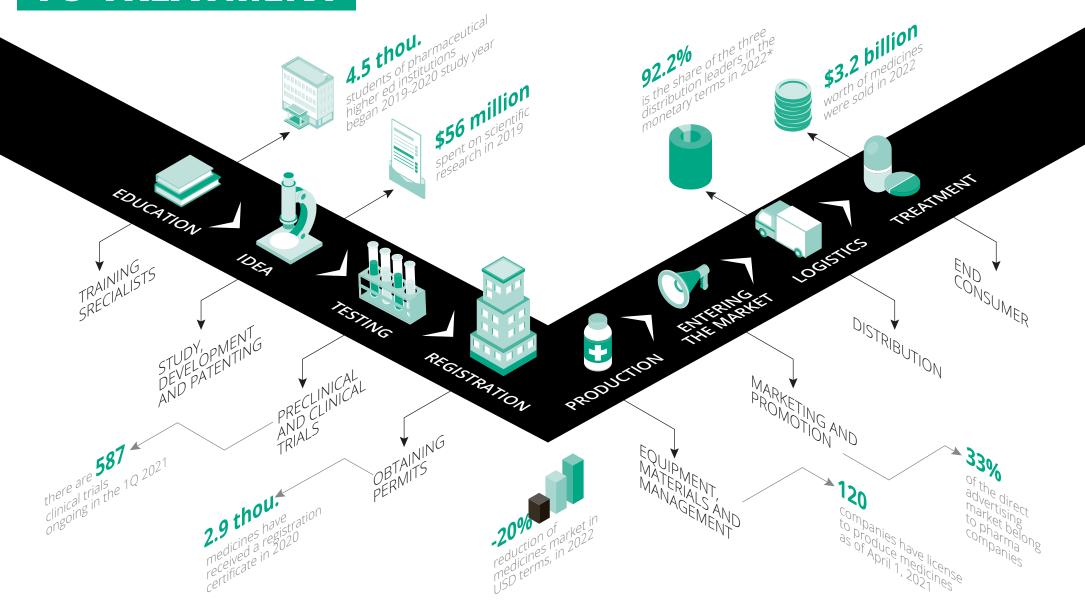


patients joining monthly the programme "Affordable medicines"

Medical reform implementation is underway in Ukraine. The next step is a mandatory electronic prescription for all prescription drugs. eHealth results are:



MEDICINES: FROM EDUCATION TO TREATMENT



PHARMACEUTICAL PRODUCTION OF UKRAINE: HISTORY OF FORMATION

Founding

Founding				
1907	1910s	1925	1932	1937
The first pharma factory producing galenic, chemical and pharmaceutical products "Galenica" (now "Zdorov'ia ")	Herbal products were manufactured in pharmacies' labs, the synthetic medicines were imported	The first manufacturing of synthetic drugs - M.V.Lomonosov Kyiv chemical pharmaceutical plant (now "Farmak ")	Start of production at the Kyiv branch of Kyiv Experimental Endocrynology Institute (now "Darnitsa ")	Start of drug manufacturing at the predecessor of Kyiv vitamin plant
Reco	overy and development			Growth
1990 s	1970 s	1968	1954	1947
Crisis and gradual reopening of manufacturing beginning 1995	Active construction of new facilities	Launch of medicines manufacturing at Cherkasy dairy factory (now "Yuriia-Pharm ")	Creation of Darnitsa chemical pharmaceutical plant. Construction of new production facilities	Launch of Kirov cooperative workshop, a predecessor of Borshchahivskyi chemical pharmaceutical plant
MID 2000s	2007	2009	2013	2022
Leaders of GMP certification Borshchahivskyi chemical pharmaceutical plant, "Darnitsa ", "Farmak"	The first in Ukraine fully automated logistics complex ("Darnitsa ")	Introduction of mandatory compliance with the good manufacturing practices (GMP) in accordance with EU standards	Ukrainian medicine export made a quarter of a billion of dollars	Two out of Top 5 companies in Ukraine's market are domestic pharma companies

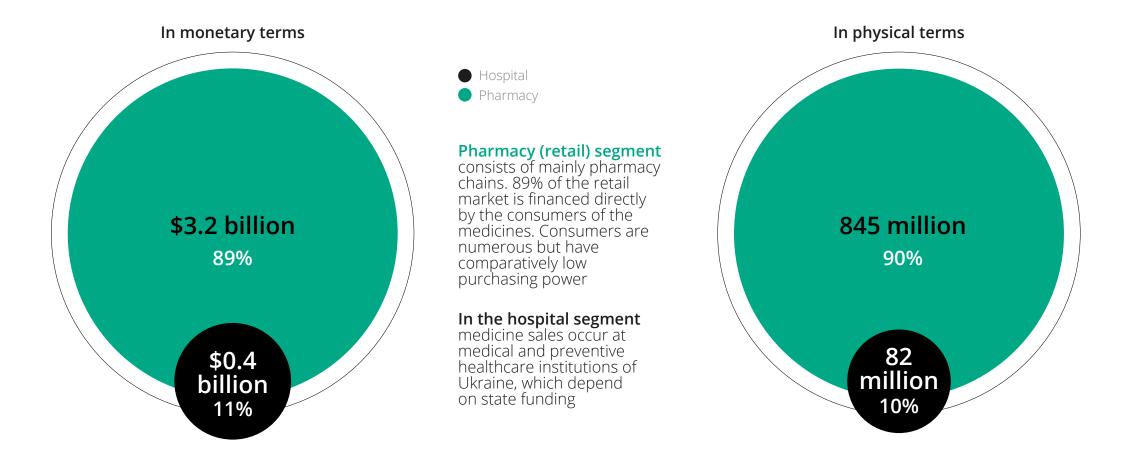
MARKET OF MEDICINES



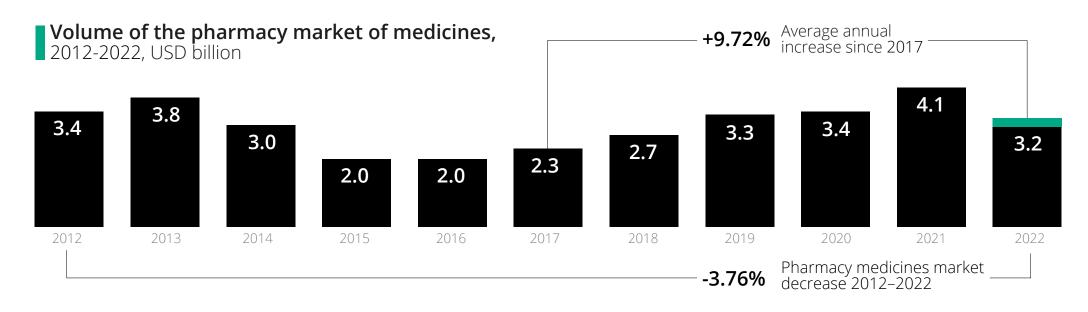
MARKET OF MEDICINES

Structure of the medicine market, 2022, USD billion and millions of packages

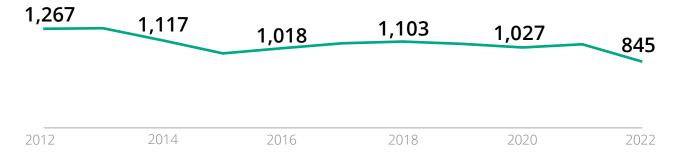
Key differences between the segments are in a consumers' financial capability to purchase drugs and mechanisms used in making a decision about the purchase



DYNAMICS **OF THE PHARMACY MARKET**

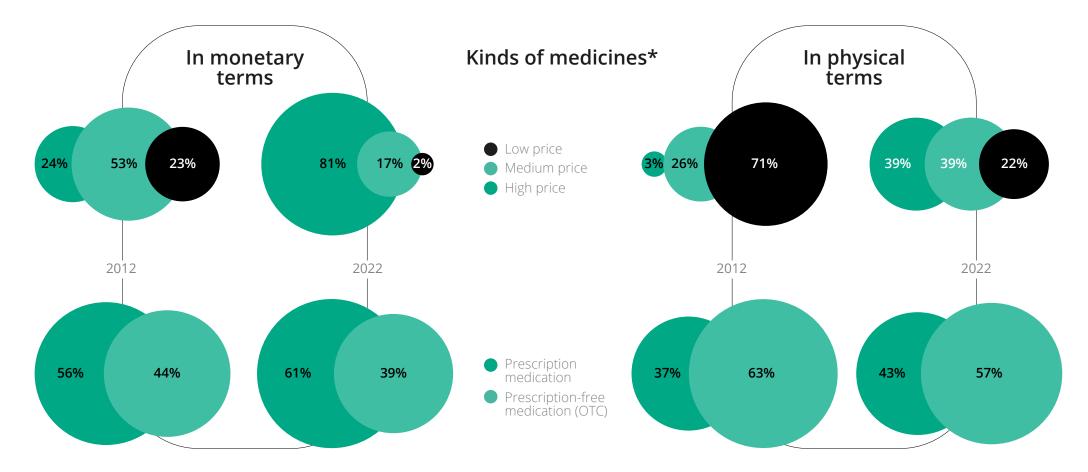


Volume of pharmacy sales of medicines, 2012–2022, millions of packages



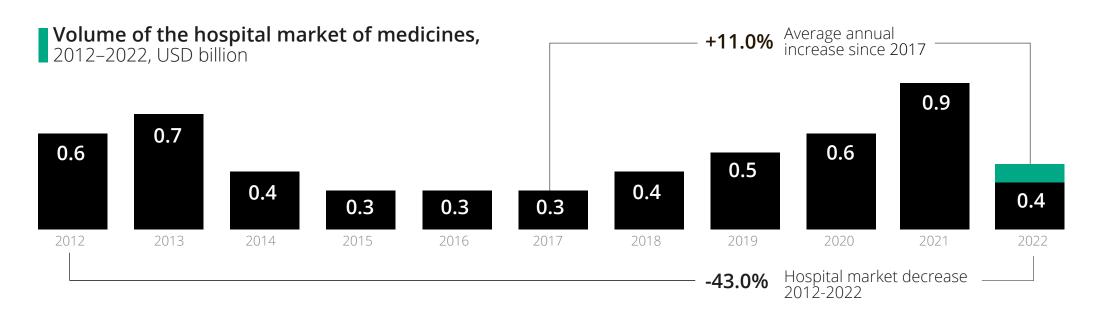
One can see a decrease in volume of sales in physical terms and, at the same time, an increase in monetary terms, which is caused by the price increases and increase in the share of more expensive medicines as a result of the growing number of foreign manufacturers in the market

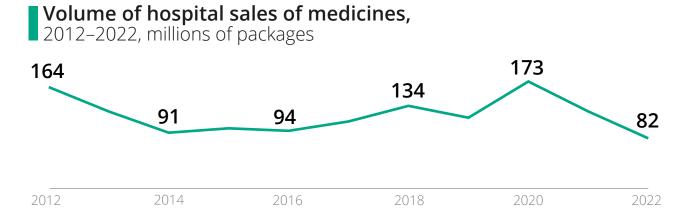
SEGMENTATION OF THE PHARMACY SALES



In spite of the stringent quarantine limitations, in 2022, the key market trends of the recent years have kept their place. Thus, the growth of the share of prescription and high-price medicines compensated for considerable market decrease in physical terms

DYNAMICS OF THE HOSPITAL MARKET





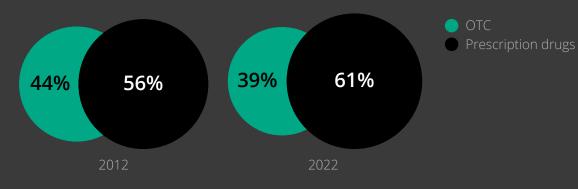
Public procurement of medicines decreased in physical terms in 2021-2022 due to a reduction in state funding, a decrease of operative interventions and hospitalizations in general (due to COVID-19 in 2021, and a full-scale Russia's invasion in Ukraine in 2022), and large volumes of humanitarian aid that arrived to Ukraine in 2022.

The increase in monetary terms for public procurement of medicines in 2021 is caused by the purchase of expensive medicines, primarily specific ones, vaccines against COVID-19, and antibiotics

MEDICINE CONSUMPTION

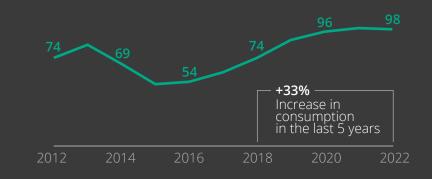
Structure of medicine consumption,

2012 and 2022, in monetary terms



Volumes of medicine consumption

in Ukraine, 2012–2022, USD per person



Medicine consumption in the world,

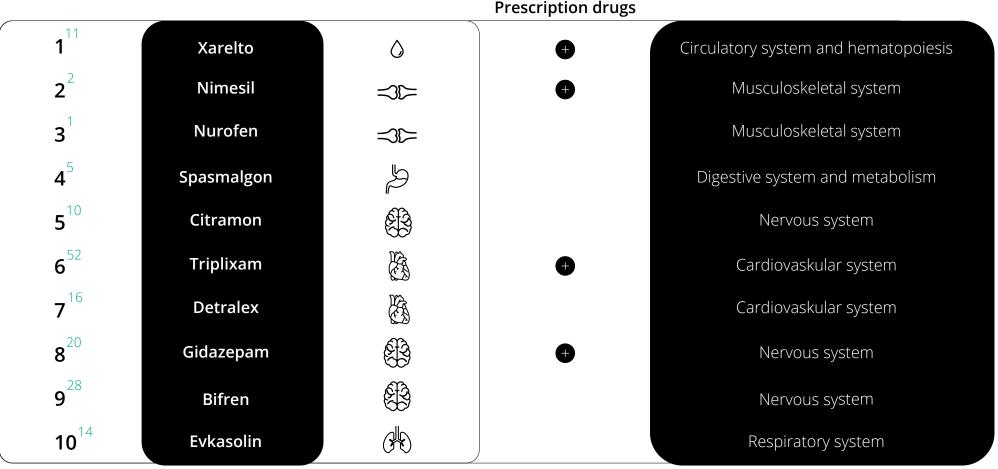
2021, USD per person

Though medicine consumption level in Ukraine is lower than in other countries, it's been steadily rising



THE MOST POPULAR MEDICINES IN UKRAINE

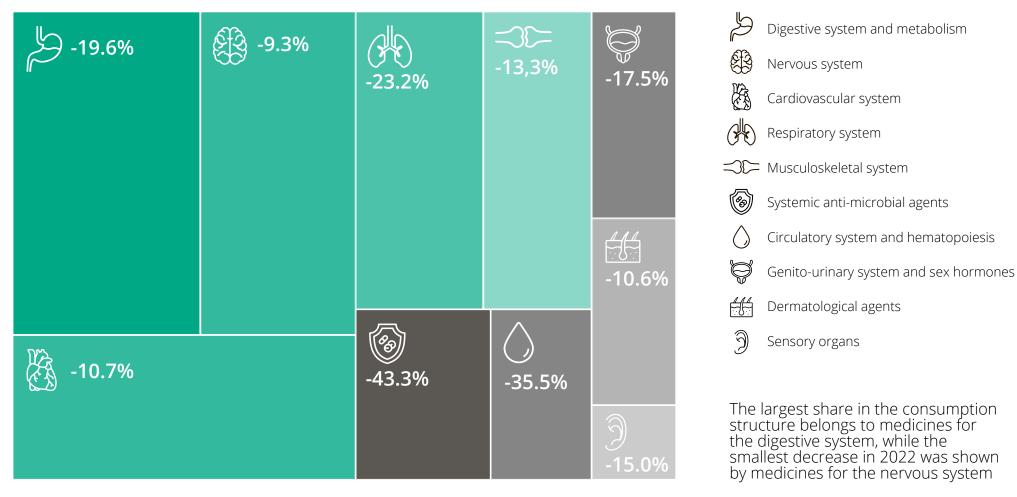
Leaders of pharmacy sales of medicines, by volume, in monetary terms in 2022 and their position in 2018



Prescription drugs

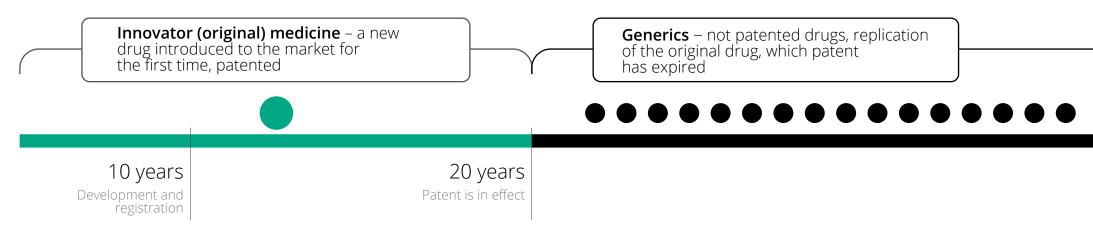
STRUCTURE OF MEDICINE CONSUMPTION

Top 10 groups of medicines on the pharmacy market and dynamics of their sales by ATC classification*, structure in monetary terms in 2022 and increase in sales comparing with 2021, %



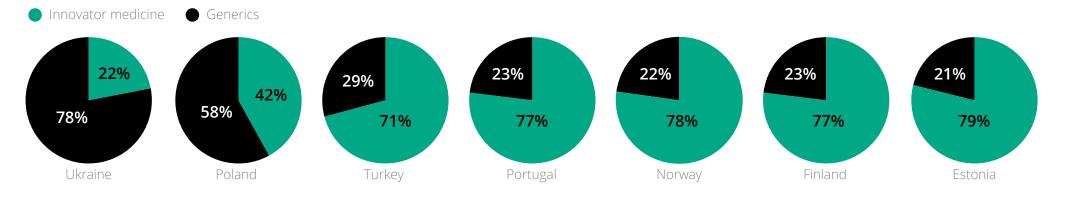
INNOVATOR MEDICINES AND GENERICS

Life cycle of medicines

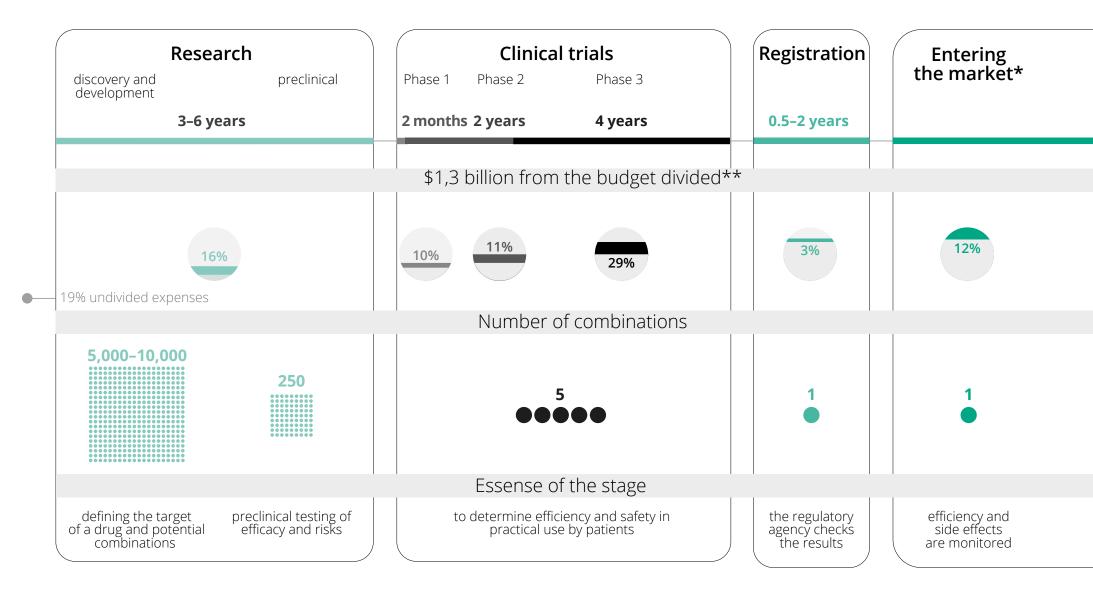


Structure of medicine market by country, based on sales in monetary terms, 2021, %

The majority of medicines in Ukraine are generics. It's been justified by consumers' low income level and purchasing power. Generics cost less and are identical to original drugs, thus make treatment affordable

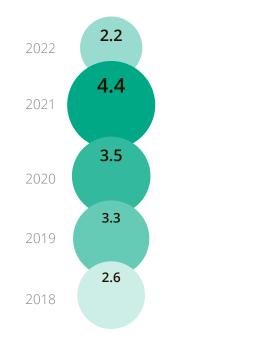


INNOVATOR MEDICINE DEVELOPMENT PROCESS



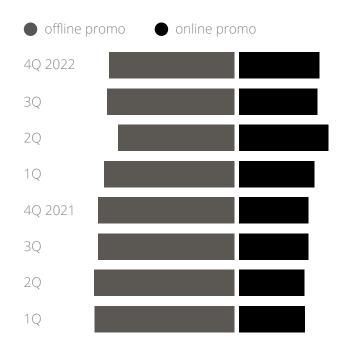
ADVERTISING MEDICINE IN THE PHARMA MARKET

Pharmaceutical companies invest in TV advertising, 2018–2022, UAH billion



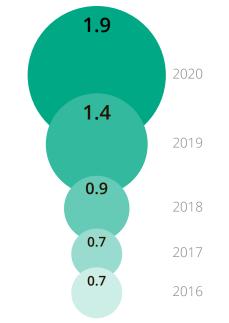
Investments of pharmaceutical companies in TV advertising grew annually until 2022. The decrease in 2022 was 50% vs. 2021. This was due to a significant decrease in sales of most pharmaceutical companies, considerable emigration and unemployment

Structure of doctors' references to kinds of medicine promotion, 2021–2022, %



Covid-19 and full-scale Russia's invasion of Ukraine became the impetus for the growth of promotion in digital channels. In the nearest future the main task for the market will be to find an effective balance between offline and online communication

Number of demonstrations of "pharmacy basket" product ads on the Internet, 2016–2020, demos billions *

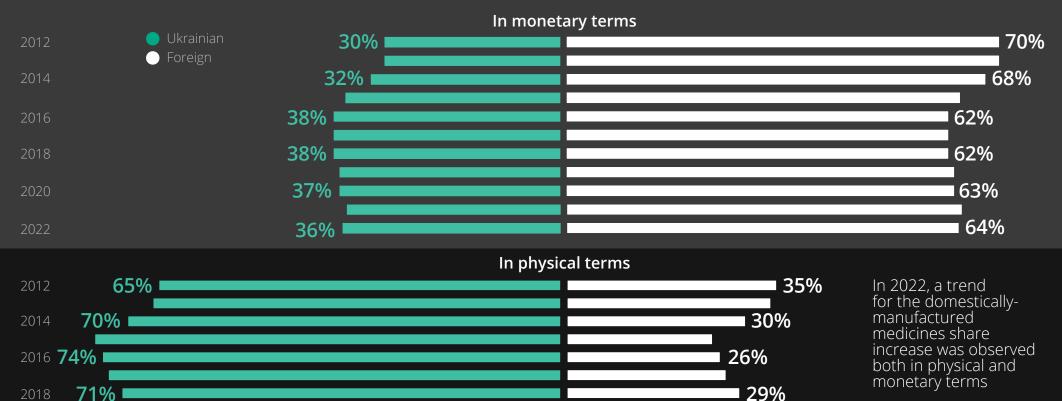


With every year pharmaceutical brands are getting bigger and more active in online promotion. Especially in the last 2 years

PHARMACEUTICAL COMPANIES

STRUCTURE OF THE PHARMACY MARKET

Structure of pharmacy sales by the place of manufacturing, 2012–2020, %



2020

2022

69% |

65%

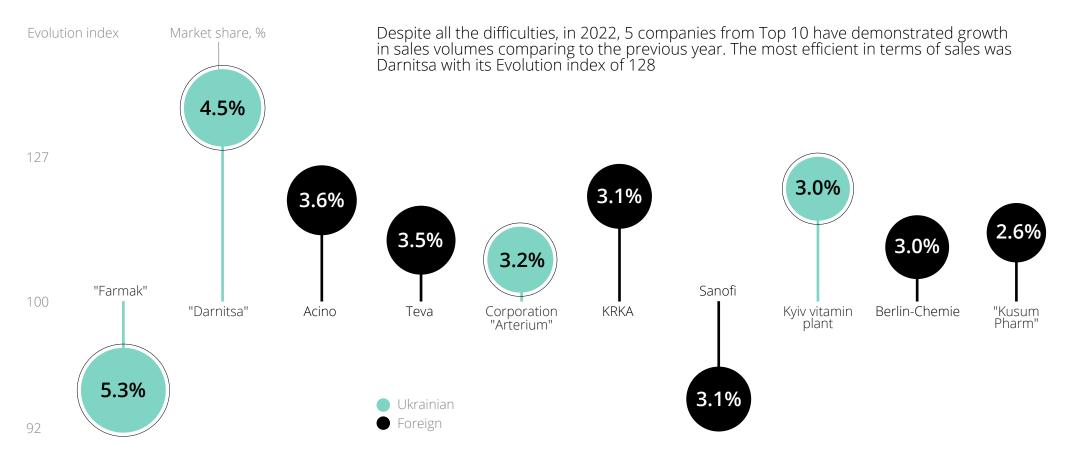
31%

35%

LEADERS OF THE PHARMACY MARKET

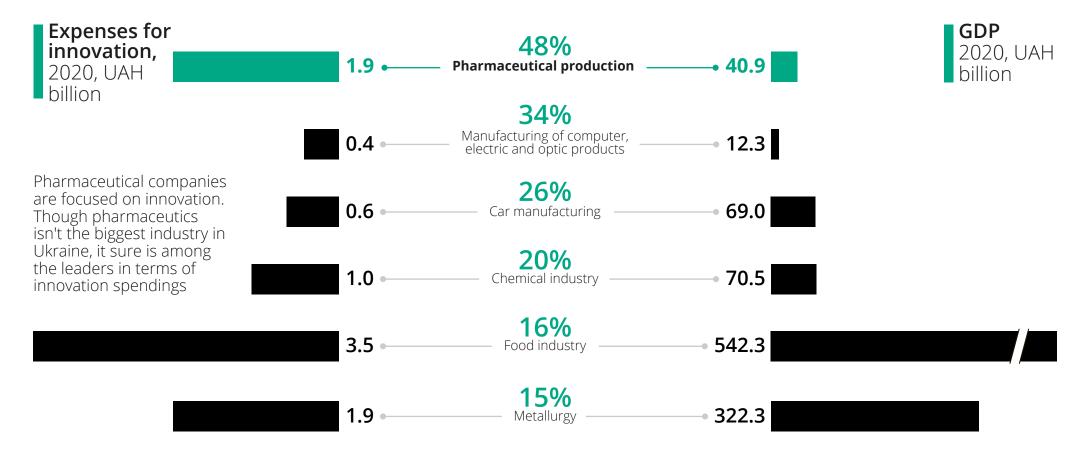
Top 10 companies by volumes of pharmacy sales of medicines and dietary supplements,

2022, % of the whole pharma market and Evolution index* (based on sales in monetary terms)



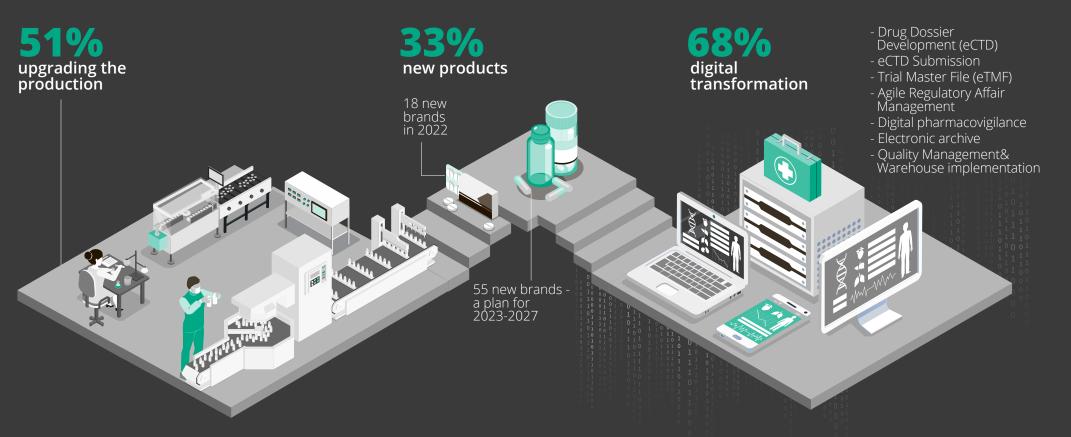
INNOVATIONS IN THE PHARMACEUTICAL MANUFACTURING

Share of actively innovating enterprises in the spheres of processing industry*, 2020, % of the total number of enterprises in the sphere



INNOVATIVE GROWTH ON THE EXAMPLE OF THE NATIONAL MANUFACTURER

\$33.6 MILLION "Darnitsa" - the leader of the market, invested in development in 2019-2021



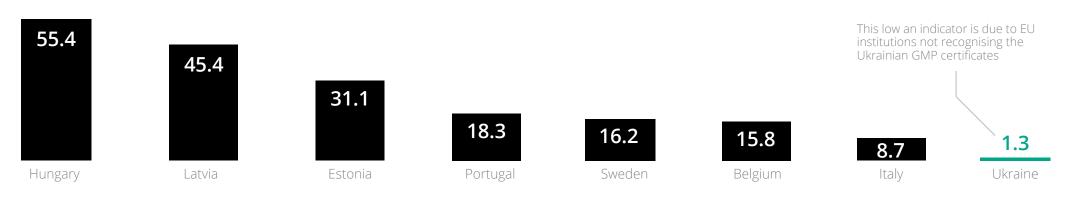
CERTIFICATION OF PHARMACEUTICAL MANUFACTURERS

Valid GMP certification of Ukrainian manufacturers by the regulatory institutions of the EU, as of May 24, 2021 and date of certification*

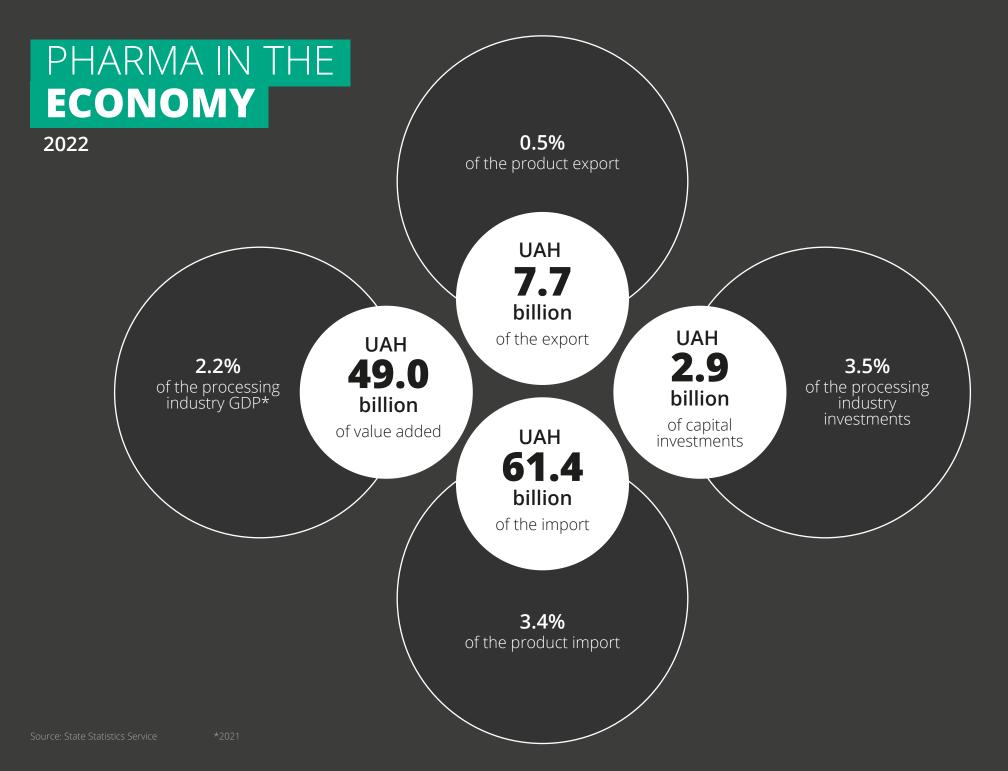
Borshchahivskyi ChPhP	"Darnitsa"	"Pharma Start"	"Farmak"
12.04.2019	05.07.2019	06.09.2019	24.05.2021
GMP – a set of rules and requirements to a production process and quality control of medicines		Currently, the EU regulatory institutions don't recognise the certificate issued by the Ukrainian regulatory institution. Tha domestic pharma companies undergo double inspection wh complicates entering the EU market and increases costs	
GMP-certification by EU institutions – a mandatory procedure for a company entering the medicine market			

Relative number of pharmaceutical productions GMP certified by EU regulatory institutions, by country,

company per USD 1 billion worth of drug sales*

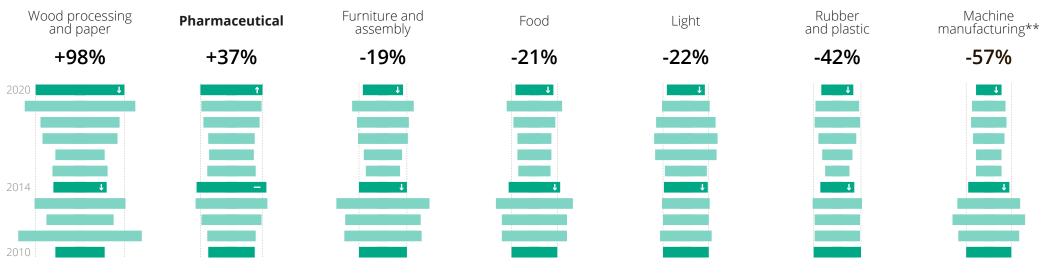


PHARMACEUTICAL PRODUCTION IN THE ECONOMY



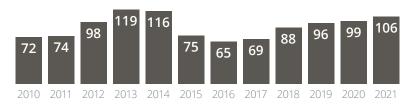
ADDED VALUE AND INVESTMENT IN PHARMA

Change of capital invesment of processing industry spheres in regards to 2010, 2010–2020, %*



The arrows show the direction during crisis years

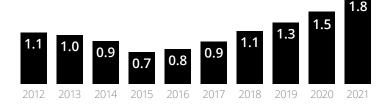
Capital investment in pharmaceutics, 2010–2021, USD million



Consistency of the capital investment, which is easy to see in crisis years of 2014 and 2020, shows the long-term focus of the industry on growth

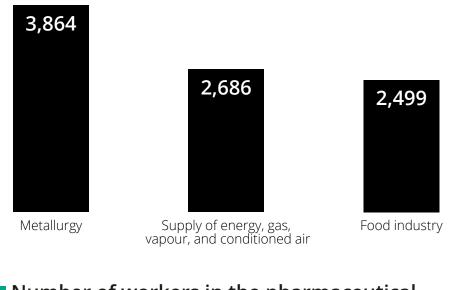
GDP of the pharmaceutical sector,

2012–2021, USD billion



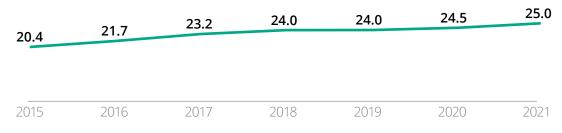
PRODUCTIVITY AND EMPLOYMENT **IN PHARMACEUTICS**

Pharmaceutical manufacturing – is one of the most productive industries of the economy, GDP per employee, 2021, UAH thousand



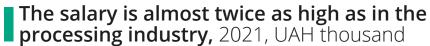
Number of workers in the pharmaceutical

manufacturing, 2015–2021, thousand people

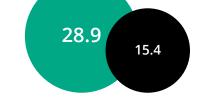


Productivity-wise the pharmaceutical manufacturing is among the leaders of the economy. High productivity level creates resources for investment in development and recruting the best highly paid specialists

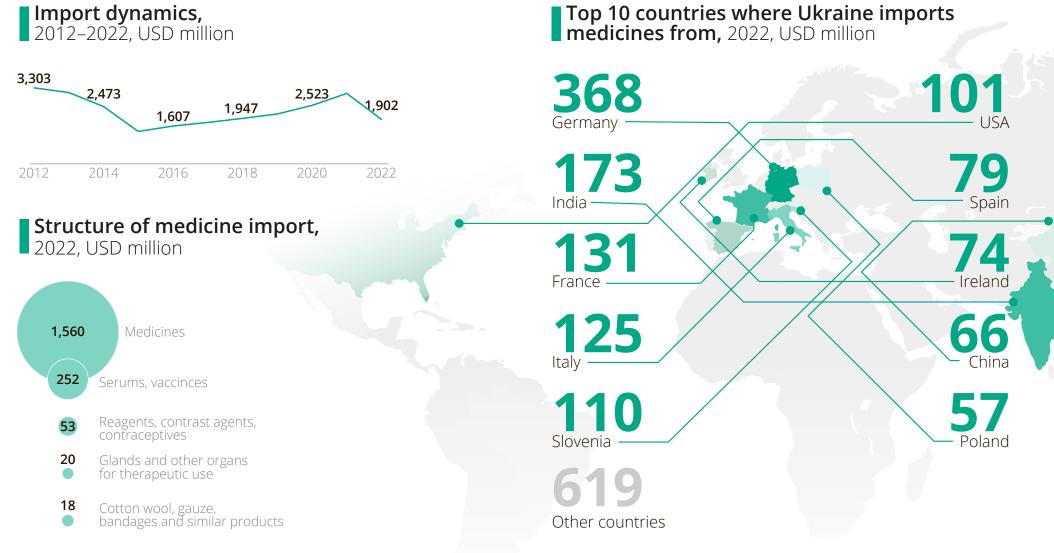




Pharmaceutical manufacturing Processing industry

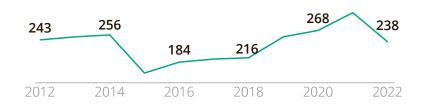


IMPORT OF MEDICINES

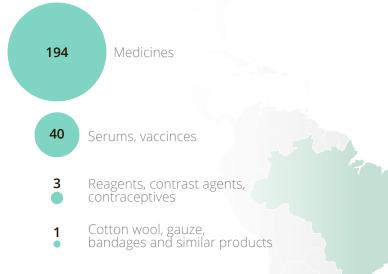


UKRAINIAN MEDICINE EXPORT

Export dynamics, 2012–2022, USD million

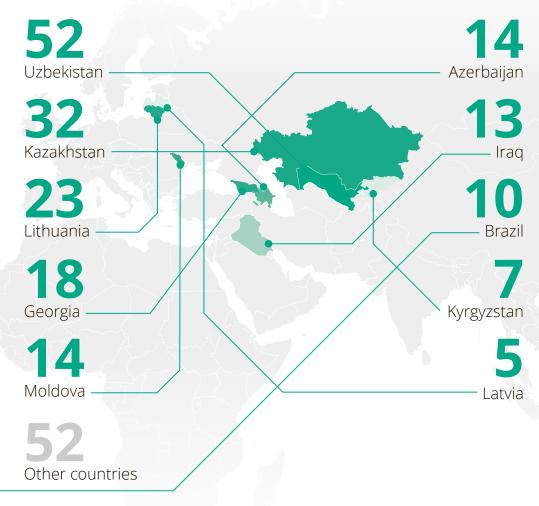


Structure of medicine export, 2022, USD million



Sources: State Statistics Service, State Customs Service

Top 10 destinations Ukraine exports medicines to, 2022, USD million



OBSTACLES TO INCREASING THE EXPORTS



Scant domestic market

Being plentiful, the domestic market stimulates primary growth and provides means for entering foreign markets



Not being integrated into the EU regulatory sphere

Ukrainian manufacturers face additional obstacles on the way to the European market because Ukrainian manufacturing quality certificates are not recognised in the EU



Technological lagging

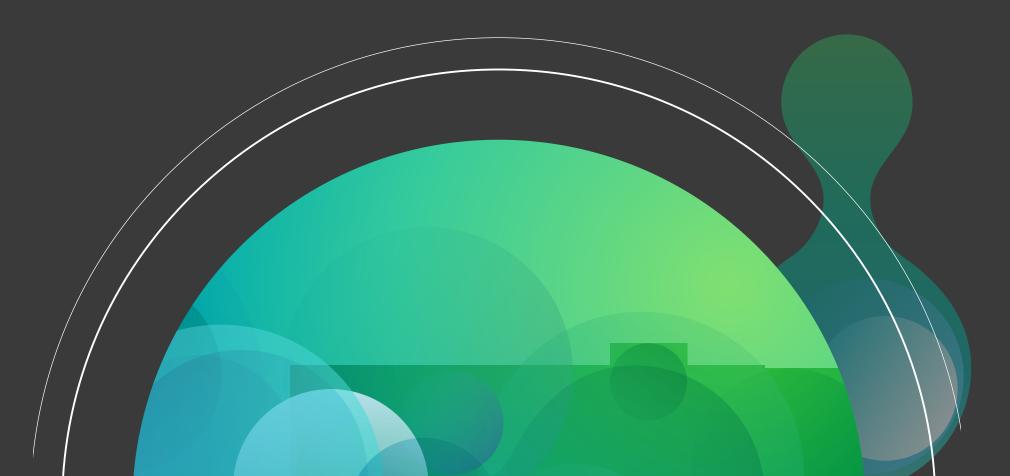
The consequences of the country's economical weakness are a smaller number of domestic innovations and slower implementation of foreign technologies



Imperfect regulatory standards

Current regulatory standards significantly slow down the work of medicine manufacturing companies

REGULATIONS • FOR PHARMACEUTICS



CRUCIAL CHANGES OF REGULATIONS

The changes that are being implemented



The majority of them harmonize regulatory standards of Ukraine and EU countries

- adoption of the new version of the Law "On Medicines"

- launch of the Applicant's e-office in 2020, which facilitates the exchange of info between the applicant and the regulatory agency

- digitalizing certain elements in regulating of the clinical trial sphere in Ukraine

- introduction of audits in the system of pharmacovigilance. The concentration of regulatory and controlling functions in one agency remains an important issue

- the first in Ukraine guidlines for state assessment of medical technologies for medicines

- the first in Ukraine guidlines for rules for conducting bioanalytical part of pharmakinetic and toxicokinetic studies

The changes that are yet to implement

Develop and adopt the regulations provided for by the new version of the Law "On Medicines"

This will harmonize Ukrainian legislation with the European one, and open the way to mutual recognition of GMP certificates

Regulate distributors' and pharmacy chains' activities

This will create a transparent, competitive market for other players in the pharmaceutical industry

Provide for mutual recognition of GMP certificates between Ukraine and EU

This will push back the limits for Ukrainian companies entering the EU market and will let them develop medicine sales

Digitalizing and accelerating the medicine registration process

This will allow to lower the costs of entering the medicine market and make products accessible sooner

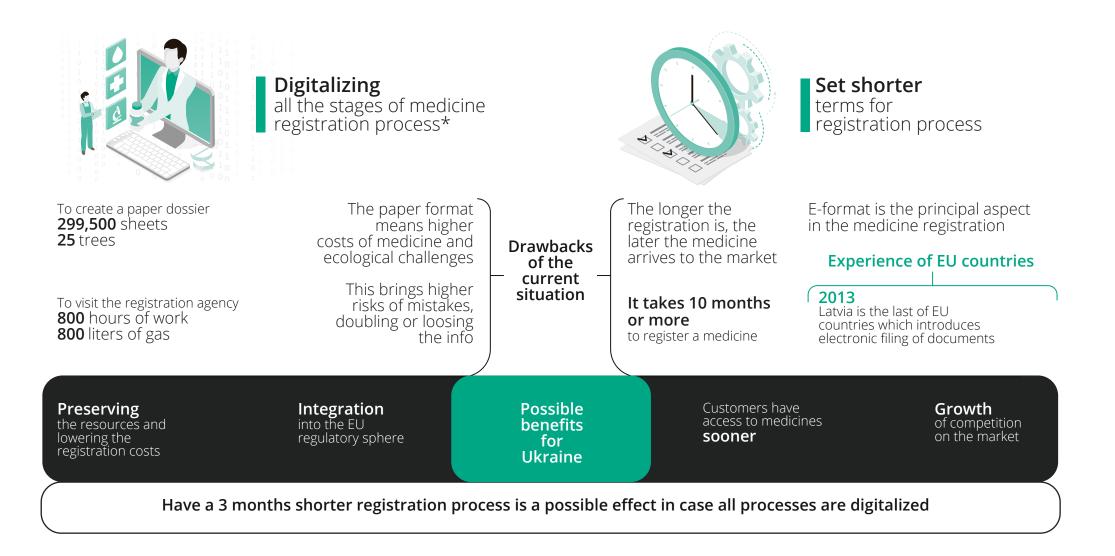
Make changes to the patent legislation

This will allow to speed up the entry to the market of high-quality generic medicines at an affordable cost

Accelerate the process of harmonization of clinical research protocols

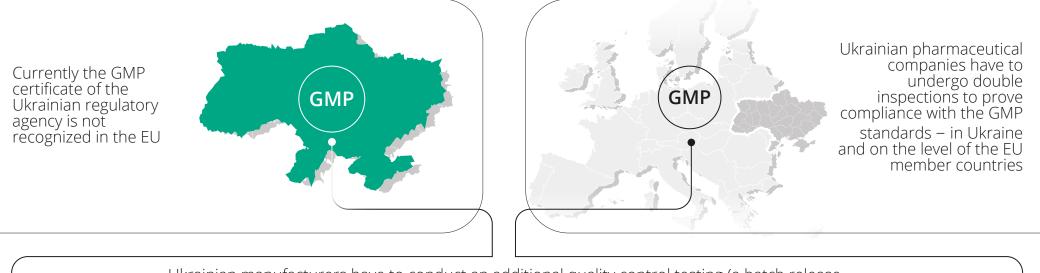
This will improve competitiveness of the national pharmaceutical manufacturers. Currently this process may last ten times more than abroad

WAYS TO IMPROVE REGULATIONS TO DEVELOP PHARMACEUTICAL MANUFACTURING



GMP CERTIFICATION: ELIMINATING BARRIERS BETWEEN UKRAINE AND THE EU

Each pharmaceutical manufacturer that wishes to work in the market of any country has to be certified according to the GMP standards



Ukrainian manufacturers have to conduct an additional quality control testing (a batch release testing) during a certain procedure, which puts one more burden upon the exporters

Goal: achieve recognition of Ukrainian GMP certificates in the EU

In 2020, a reconsideration of the Ukraine-EU Association Agreement was announced with an aim to ameliorate the trade conditions for Ukrainian manufacturers. The Ukrainian side strives to include medicines and products of medicinal purpose into the Agreement on assessment of compliance and acceptance of manufactured goods (ACAA).

In 2022, a new version of the Law "On Medicines" was adopted, which harmonizes Ukrainian legislation with the European one. This is an important step towards the mutual recognition of GMP certificates but Ukraine still needs to develop and adopt the by-laws provided for by the new version of the law

PHARMACEUTICAL MANUFACTURING IN UKRAINE: OBSTACLES TO DEVELOPMENT



Low purchasing power of the population

Small market influences the volumes of investment and growth of manufacturing capacities. As a result, the technologies are implemented much later and costs are higher in the conditions of small volumes of manufactured goods



Complicated regulatory requirements

The developed countries intensify the regulatory requirements, which fuel the costs. Ukraine simultaneously implements the international standards into the national legislature and this creates even more pressure for the manufacturers



Legislative barriers on the way to affordable medicines

 The possibility for patents to have longer term of action comparing to foreign countries hinders the introduction of Ukrainian generics, while they are the basis of pharmaceutical manufacturing
Currently the regulation of bioequivalent studies slows them significantly and encourages to have them done abroad



Absence of state guidance on the development strategy

Absence of an effective system of state-private partnership and unstable government economic policy hamper the speed of business investment activities

DEVELOPMENT TRENDS

POSITIVE TRANSFORMATIONS **OF LAST YEARS**

Digitalization of heathcare



Introduction of the e-system of healthcare, which acts as a digital medical record and makes the whole patient's history of treatment accessible

Electronic prescriptions in "Affordable medicines" programme. In future all the patients may receive e-prescriptions

Internet shopping for medicines that makes remote delivery possible

Digitalization of manufacturing



Digitalizing the manufacturing:

beginning storage spaces to manufacturing lines and distribution and promotion

Electronic document flow and digitalizing coordination with partners and suppliers

Development of regulation



Reimbursement programme "Affordable medicines" that returns

citizens cost of some categories of medicines

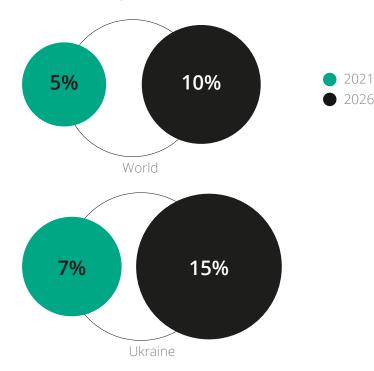
Start of digitalizing the cooperation manufacturer – government, aimed at making it smoother, easier and more efficient

Update of legislative standards to

boost the market development and enable harmonization with the EU standards

E-COMMERCE IN THE PHARMACEUTICAL MARKET

Share of e-commerce in the pharma market will grow rapidly, 2021-2026, %



The pandemic has significantly accelerated the development of e-commerce in the pharmaceutical sphere. The adoption of law in September 2020 legalising the remote trade and delivery of medicines in Ukraine is the best confirmation of this fact

Structure of the pharmaceutical e-commerce market includes 3 main parts:







Pharmacy chain sites

The main place of cooperation where patients can buy medicines directly from the pharmacy and pick them up in any trade point, or order their delivery

Landing pages

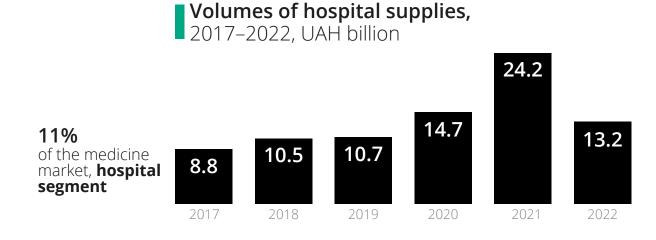
Sites filled with info about medicines and aimed at promoting them. Normally they allow finding a product in the pharmacy, book it and pick it up or have it delivered. The pandemic has sped up the growth of this channel.

For example, "Liki24.com " in 2020					
increase in	increase in				
x6 number	x8 volume				
of orders	of traffic				

Pharmaceutical companies

This channel is just starting to grow as majority of companies sell medicines via mediators. Now there is a task to develop a direct connection with the customer

AFFORDABILITY **OF MEDICINES**



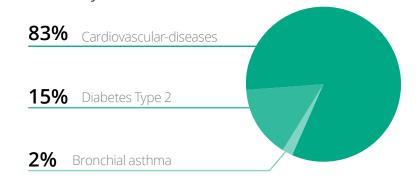
Structure of hospital supplies, 2022, UAH billion



Reimbursement according to the "Affordable medicines" programme, 2017–2022, UAH billion

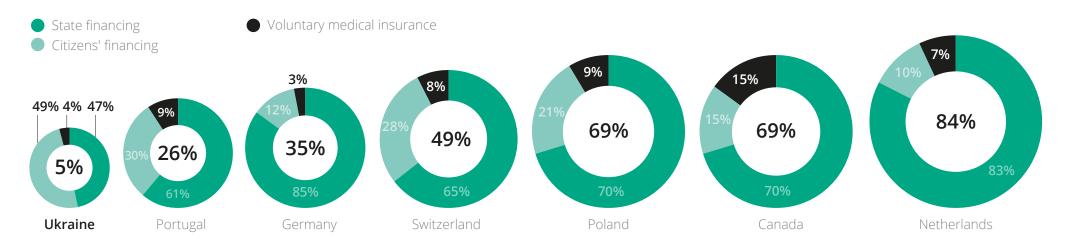


Structure of the medicine register in the programme "Affordable medicines", February 2023



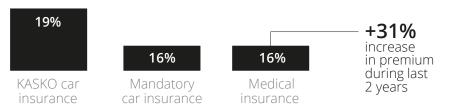


Share of population that has a voluntary medical insurance, by country, with a healthcare financing structure mentioned, 2019



Insurance – is the foundation of the healthcare system in developed countries. It allows to collect sufficient finance and provide high quality and efficacy services. In Ukraine medical insurance only starts being popular and its role is not significant yet

Top 3 sectors by insurance, % of the total volume of premiums, 2020*



Nowadays it's important to rebuild the healthcare system. Firstly, the general scheme of financing has to be changed and voluntary medical insurance of the population has to be stimulated

CONTRACT MANUFACTURING

Contract manufacturing – a type of activity when the manufacturing line of one company is used to produce a product of another company

Benefits

For the lessee

Savings on capital investment in production capacities

Opportunity to launch a drug that has a small market

Access to unique technologies

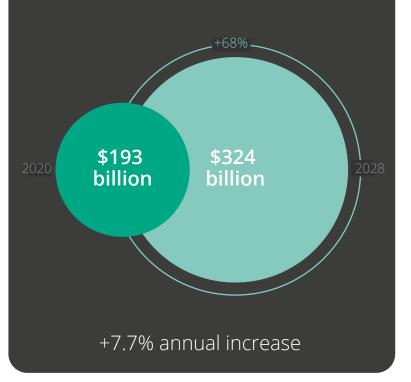
Enter the market sooner

For the manufacturer

Stable source of income

Absence of business risks from medicine entering the marke

Volume of the world market, 2021 and a prognosis for 2028



Obstacles to growth

State

Absence of growth strategy and effective regulatory standards in the economic policy. Unfavourable conditions for foreign investment

Reputation

Ukrainian manufacturers are not well-known enough in the world, this creates mistrust to their operations

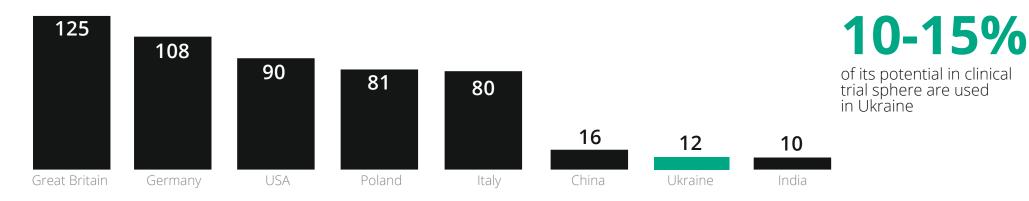
Pharmaceutical manufacturers

Insufficient volume of investment in technological innovations comparing to the foreign companies that work in more voluminous markets



Amount of clinical trials by country,

2020, unit per 1 mln population



Clinical trials in Ukraine, as of June 1, 2021



What holds back the development of clinical trials?

- Longer terms of research confirmation
- In Ukraine it is **5-6 months**,
- while in Europe up to **2 months**
- Huge delay in customs clearance of pharmaceutical products
- Absence of the **appropriate legislature** regulating the relations of a researcher and a state medical institution

Specialists deficit

COVID-19 INUKRAINE

COVID-19 DYNAMICS IN UKRAINE

Ukraine's position in the world, place and indicator per 1000 people as of June 1, 2021 Prevalence rate of SARS-CoV-2 in Ukraine, average weekly number of detected cases of infection April 1, 2020–June 1, 2021 20.341 16.294 Prevalence of Mortality from Intensity the virus the virus of testing 43 place 1.2 deceased the highest number 63 place during each wave 51 8 ill of infection 1.091 71 place 234 tests 01.10.2020 01.04.2020 01.07.2020 01.01.2021 01.04.2021 Imposing an all-Ukrainian Introduction of adaptive Pharma market has Pharma market has lockdown. Increase of medicine quarantine. Pharmaceutical reached the last year quickly adapted to the sales in the first week, then market is still in decline, numbers and enters new reality and showed however the fall slows down a rapid fall (-18% in April) the growth phase an increase in 2020 +9.7% in monetary terms +2.2% in packages 12.03.2020 22.05.2020 July 2020

PANDEMIC INFLUENCE ON THE MARKET

Key indicators of economy development in 2020 comparing with indicator for 2019



4.1% 5% level of inflation



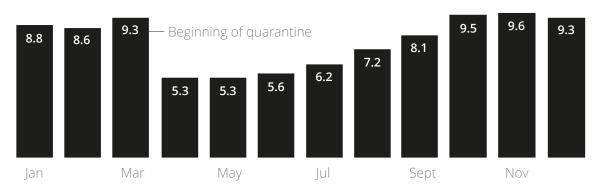
What was happening to pharma at the beginning of the crisis?*

71.4% of pharmacies have noted a decline in sales volumes



69.2% of pharma companies were anxious

Pharmacy medicine sales dynamics, 2020, UAH billion



+68% of antivirus drug sales

+32% antibacterial drug sales Despite 2020 being a crisis year, pharma was one of the industries that experienced growth. Volumes of sales grew both in monetary and physical terms

VACCINES AND VACCINATION

Prior to independence, there were a lot more immune-biotechnological institutions operating in Ukraine, which were manufacturing medical and bioactive products. One of the leaders in the sphere was the Mechnikov Institute of microbiology and immunology of **National Academy of Medical Sciences of Ukraine**, which has been operating for more than 130 years now

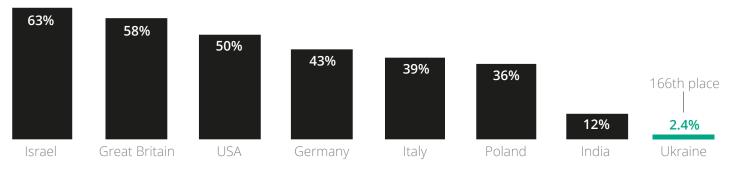
The volumes of vaccines brought in Ukraine and their efficacy, thousand doses as of June 1, 2021



60 vaccines, serums and other products were developed overal

Currently there is no vaccine production in Ukraine. However, domestic pharmaceutical companies-leaders have necessary capacities. The starting point for organising the vaccine manufacturing is the state preorder and favourable government's policy

Share of population that got at least one dose of vaccine from SARS-CoV-2 as of June 1, 2021



The first vaccination took place only on February 24, 2021, while in the USA and Europe vaccination roll-out was in full force. Slow pace of vaccination is connected with its belated start as a result of untimely deliveries of vaccines



- WHO
- "Darnitsa"
- State Customs Service
- State Service of Ukraine on Medicines and Drug Control
- State Statistics Service
- State Expert Center
- Medicines Control
- Ministry of Foreign Affairs
- Ministry of Health
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 - 1. Apteka, a weekly online media № 8 (1379) 27 February 2023
 - 2. Apteka, a weekly online media № 17 (1288) 3 May 2021
 - 3. Apteka, a weekly online media № 25 (1296) 28 June 2021
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