# 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



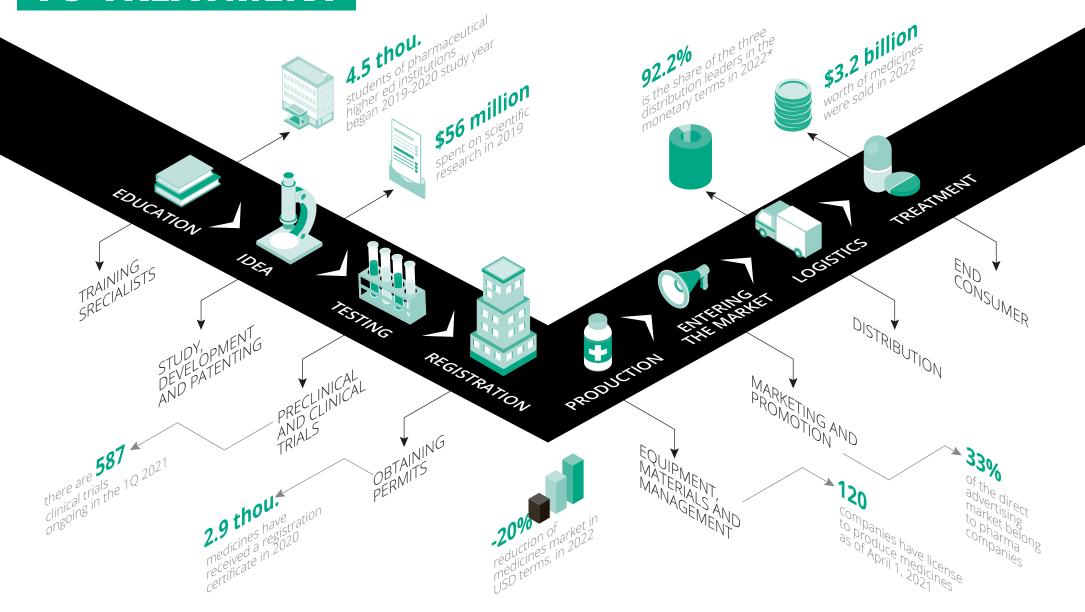


patients joining monthly the programme "Affordable medicines"

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	<b>1910s</b>	1925	1932	1937
The first pharma factory producing galenic, chemical and pharmaceutical products "Galenica" (now <b>"Zdorov'ia</b> ")	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 <b>"Farmak</b> ")	Start of production at the Kyiv branch of Kyiv Experimental Endocrynology Institute (now <b>"Darnitsa</b> ")	Start of drug manufacturing at the predecessor of Kyiv vitamin plant
Reco	overy and development			Growth
<b>1990</b> s	<b>1970</b> 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 <b>"Yuriia-Pharm</b> ")	Creation of <b>Darnitsa</b> chemical pharmaceutical plant. Construction of new production facilities	Launch of Kirov cooperative workshop, a predecessor of <b>Borshchahivskyi</b> chemical pharmaceutical plant
MID 2000s	2007	2009	2013	2022
Leaders of GMP certification <b>Borshchahivskyi</b> chemical pharmaceutical plant, <b>"Darnitsa</b> ", <b>"Farmak"</b>	The first in Ukraine fully automated logistics complex ( <b>"Darnitsa</b> ")	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	<b>Two out of Top 5</b> companies in Ukraine's market are domestic pharma companies

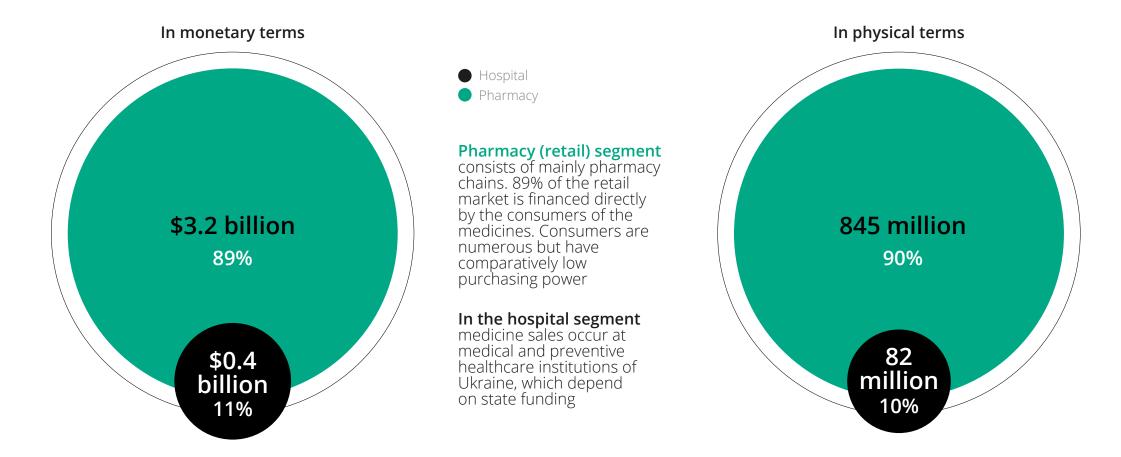
## MARKET OF MEDICINES



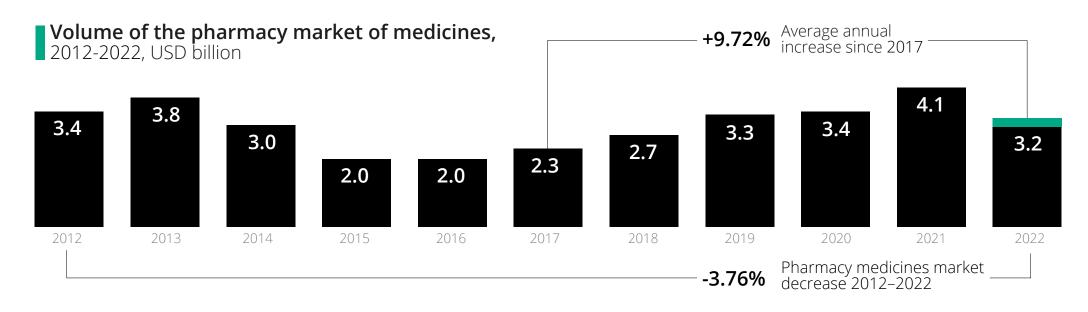
# MARKET OF MEDICINES

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

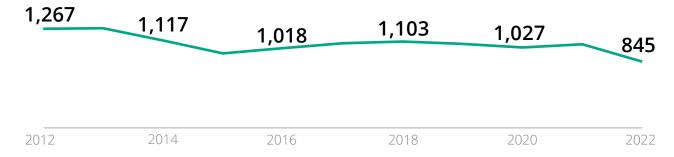
Key differences between the segments are in a consumers' financial capability to purchase drugs and mechanisms used in making a decision about the purchase



### DYNAMICS **OF THE PHARMACY MARKET**

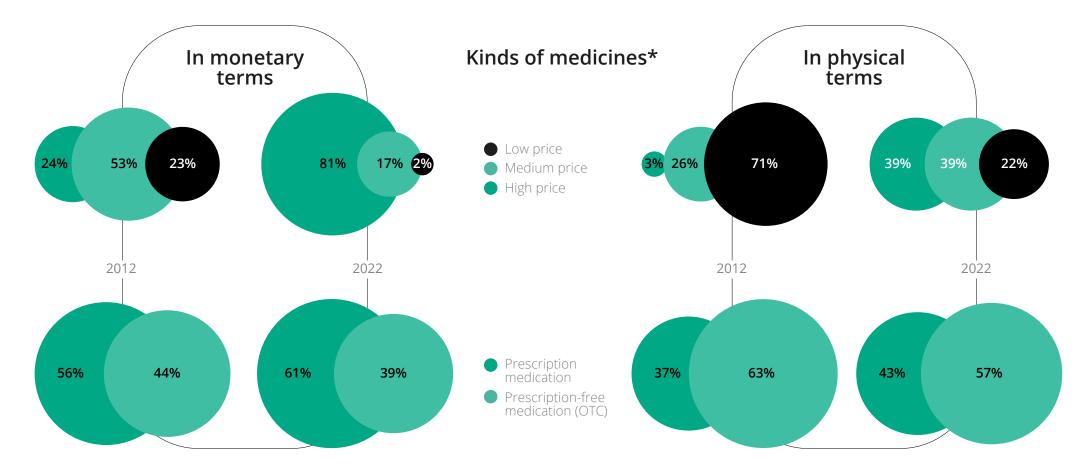


### **Volume of pharmacy sales of medicines,** 2012–2022, millions of packages



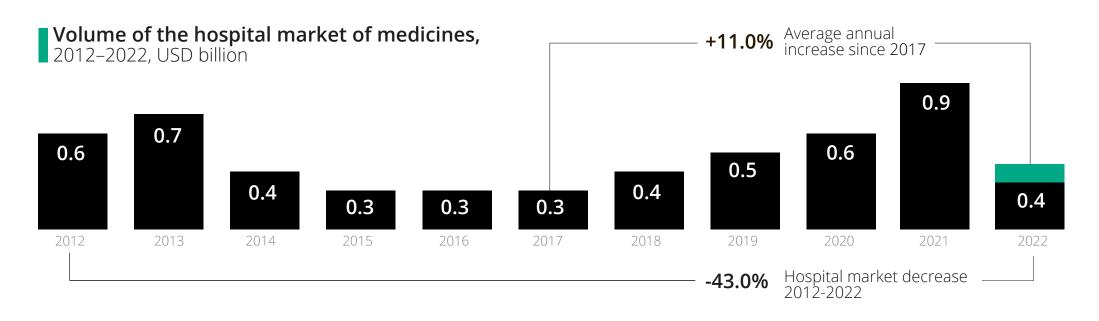
One can see a decrease in volume of sales in physical terms and, at the same time, an increase in monetary terms, which is caused by the price increases and increase in the share of more expensive medicines as a result of the growing number of foreign manufacturers in the market

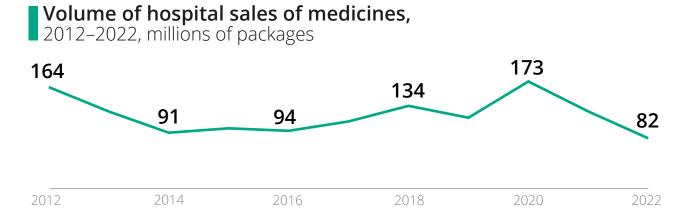
### SEGMENTATION OF THE PHARMACY SALES



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





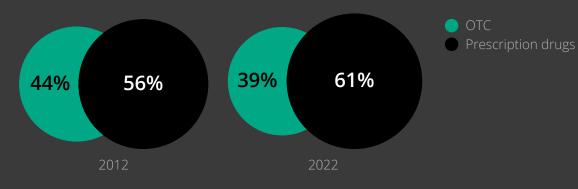
Public procurement of medicines decreased in physical terms in 2021-2022 due to a reduction in state funding, a decrease of operative interventions and hospitalizations in general (due to COVID-19 in 2021, and a full-scale Russia's invasion in Ukraine in 2022), and large volumes of humanitarian aid that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

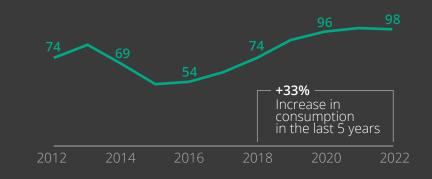
#### Structure of medicine consumption,

2012 and 2022, in monetary terms



### Volumes of medicine consumption

in Ukraine, 2012–2022, USD per person



### Medicine consumption in the world,

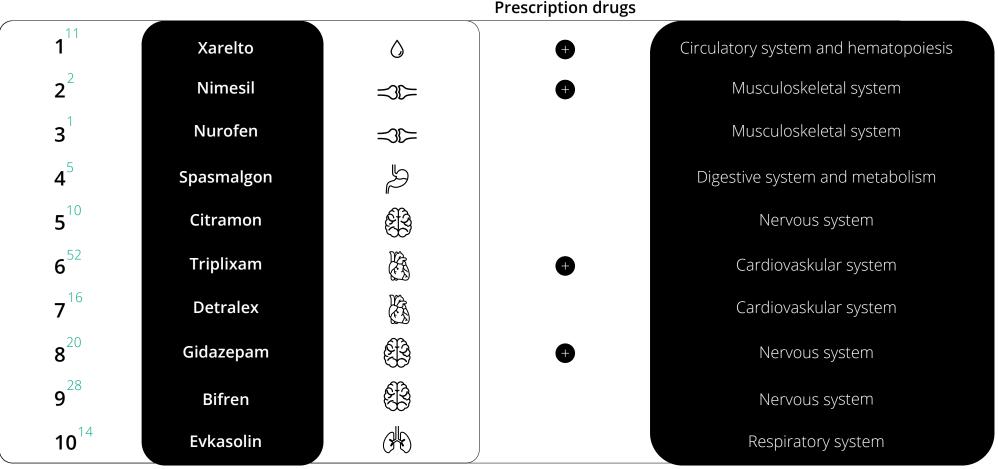
2021, USD per person

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



### THE MOST POPULAR MEDICINES IN UKRAINE

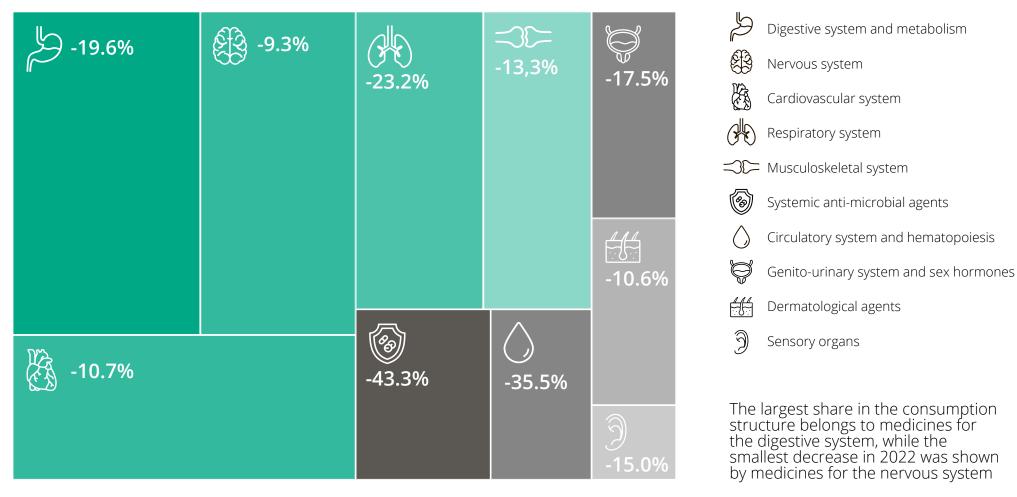
**Leaders of pharmacy sales of medicines,** by volume, in monetary terms in 2022 and their position in 2018



#### **Prescription drugs**

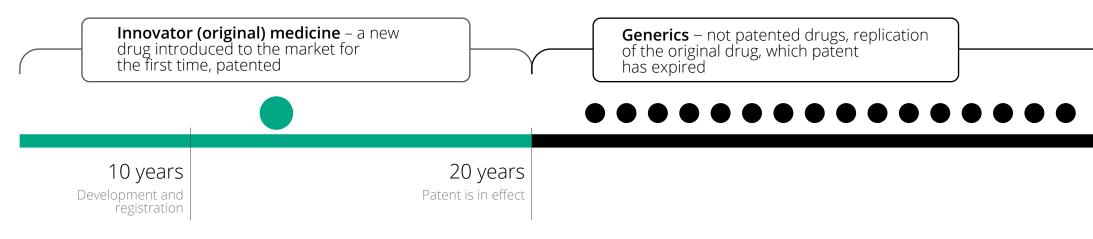
### STRUCTURE OF MEDICINE CONSUMPTION

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, %



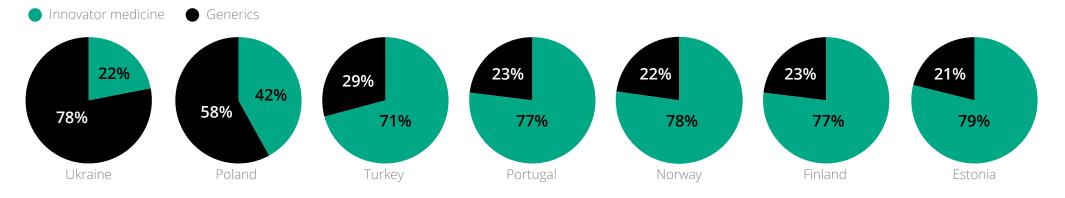
### INNOVATOR MEDICINES AND GENERICS

#### Life cycle of medicines

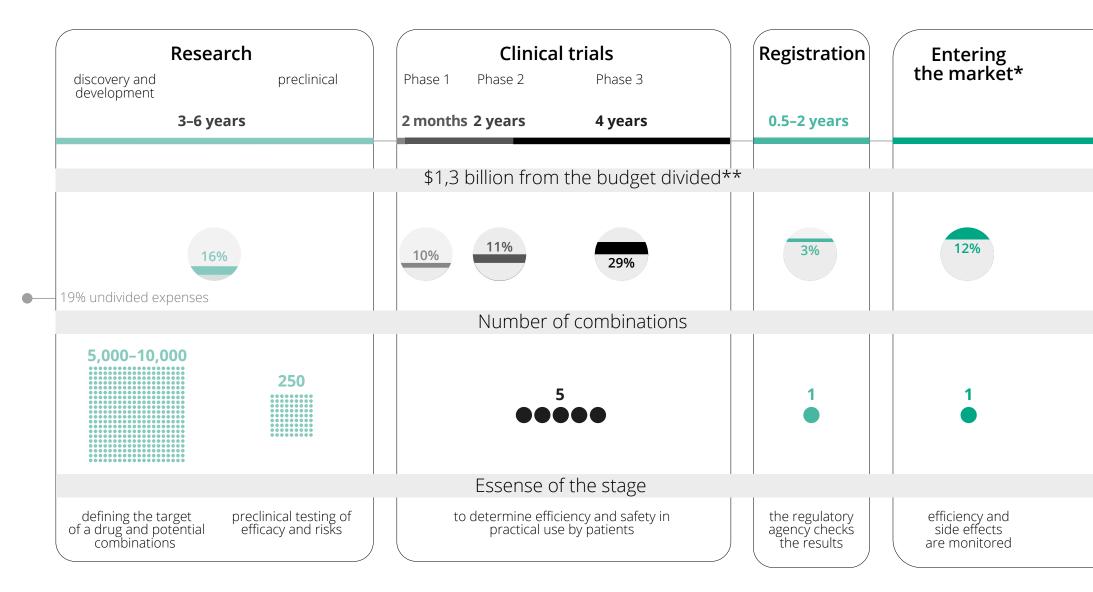


### **Structure of medicine market by country,** based on sales in monetary terms, 2021, %

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

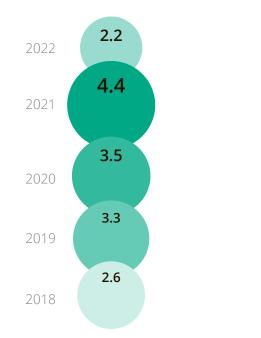


### INNOVATOR MEDICINE DEVELOPMENT PROCESS



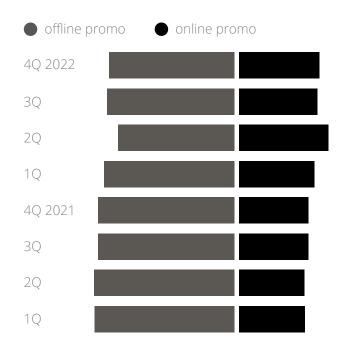
### ADVERTISING MEDICINE IN THE PHARMA MARKET

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



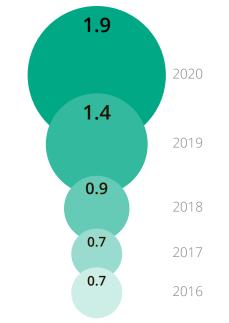
Investments of pharmaceutical companies in TV advertising grew annually until 2022. The decrease in 2022 was 50% vs. 2021. This was due to a significant decrease in sales of most pharmaceutical companies, considerable emigration and unemployment

#### 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 \*

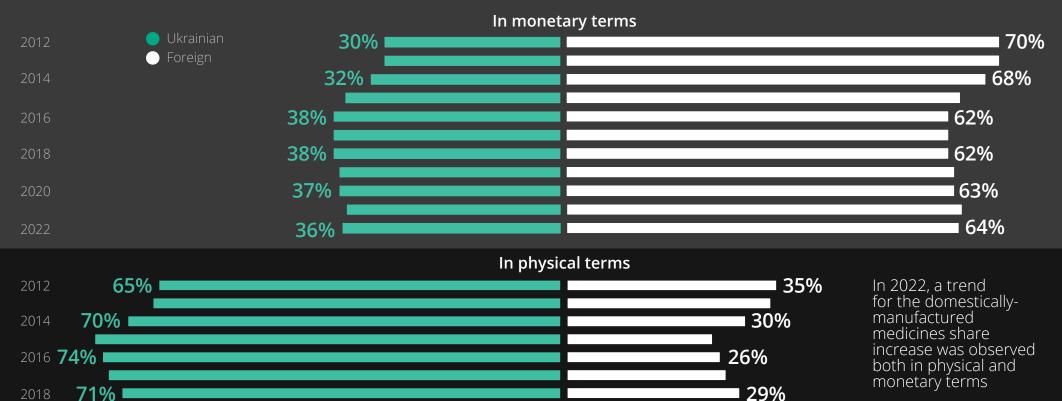


With every year pharmaceutical brands are getting bigger and more active in online promotion. Especially in the last 2 years

## PHARMACEUTICAL COMPANIES

### STRUCTURE OF THE PHARMACY MARKET

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



2020

2022

**69%** |

65%

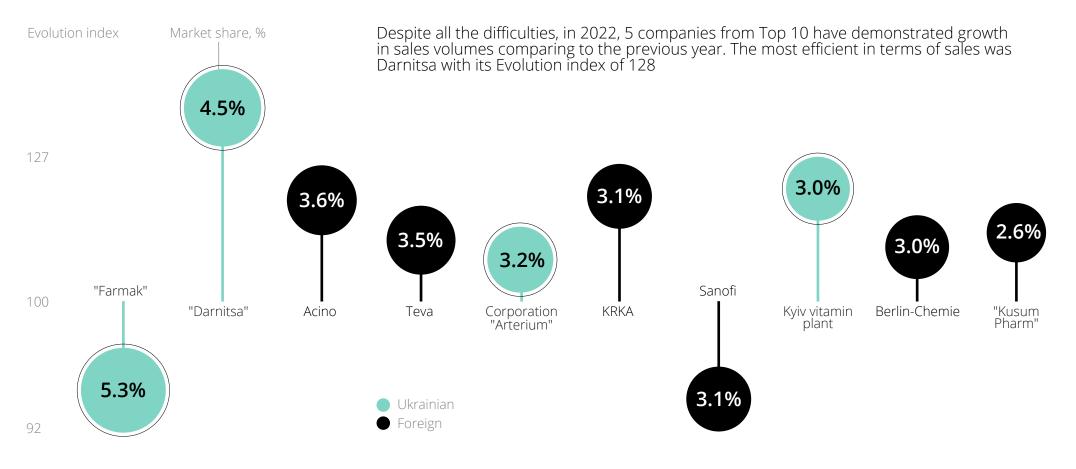
31%

35%

### LEADERS OF THE PHARMACY MARKET

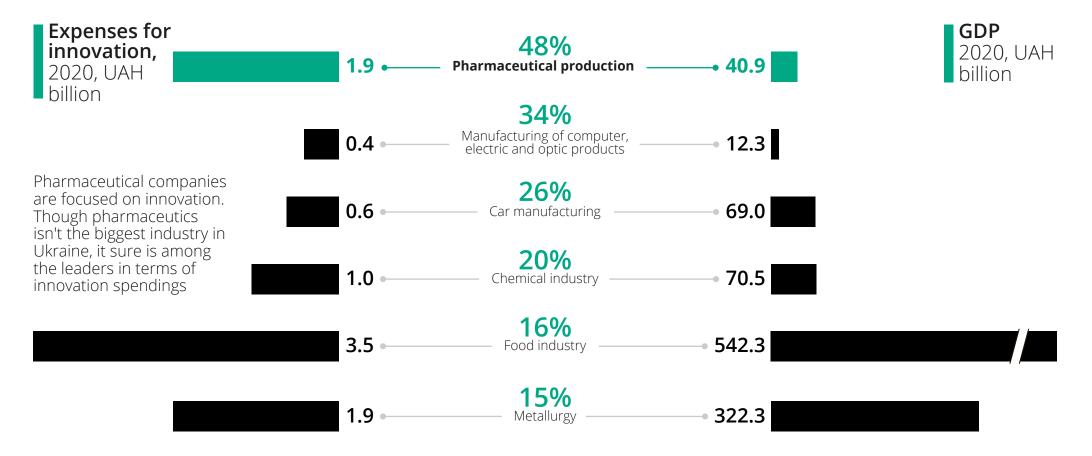
#### Top 10 companies by volumes of pharmacy sales of medicines and dietary supplements,

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



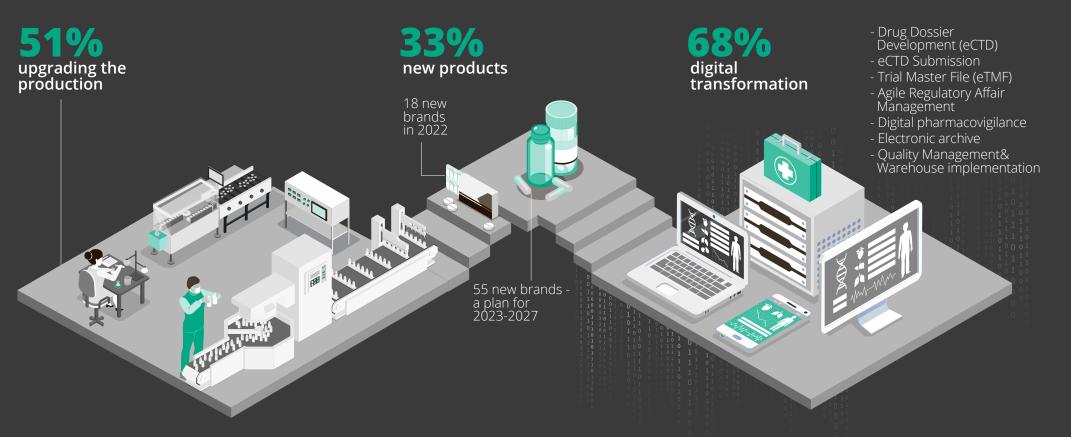
### INNOVATIONS IN THE PHARMACEUTICAL MANUFACTURING

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



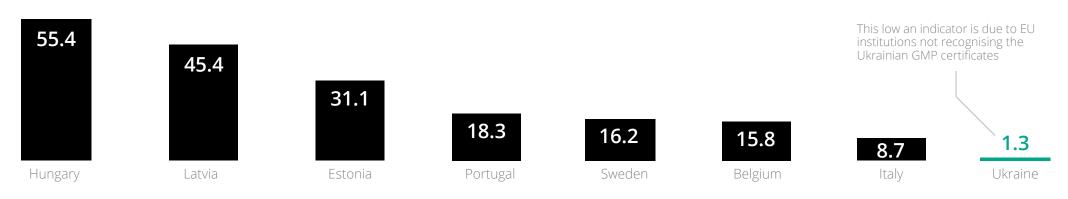
### CERTIFICATION OF PHARMACEUTICAL MANUFACTURERS

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

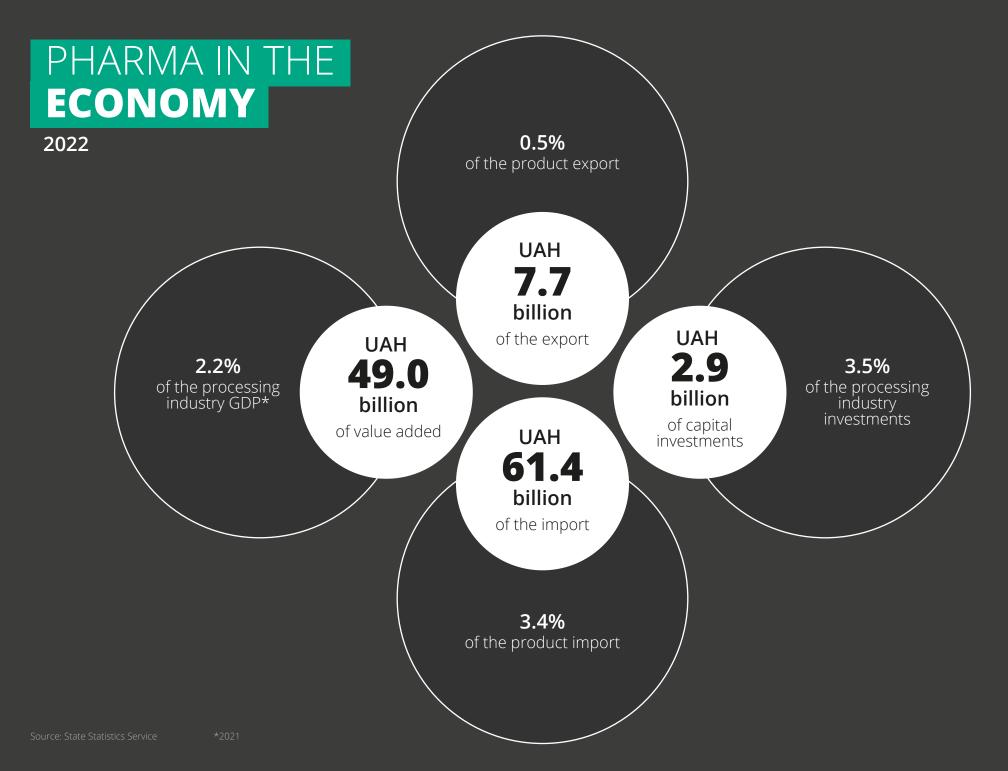
Borshchahivskyi ChPhP	"Darnitsa"	"Pharma Start"	"Farmak"
12.04.2019	05.07.2019	06.09.2019	24.05.2021
GMP – a set of rules and requirements to a production process and quality control of medicines		Currently, the EU regulatory institutions don't recognise the certificate issued by the Ukrainian regulatory 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\*

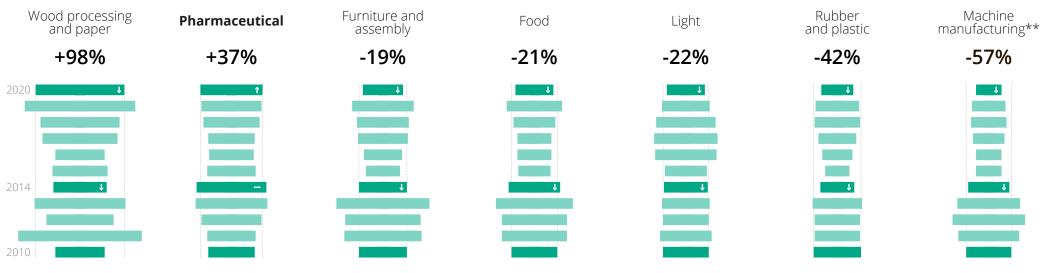


## PHARMACEUTICAL PRODUCTION IN THE ECONOMY



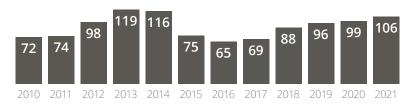
### ADDED VALUE AND INVESTMENT IN PHARMA

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



The arrows show the direction during crisis years

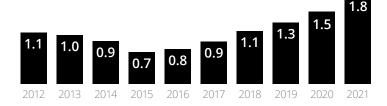
### **Capital investment in pharmaceutics,** 2010–2021, USD million



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

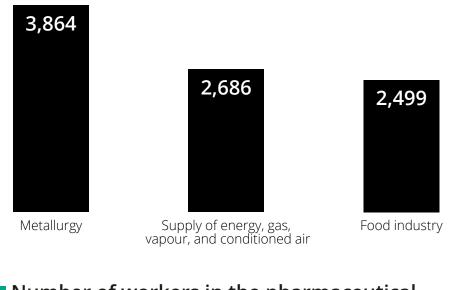
#### GDP of the pharmaceutical sector,

2012–2021, USD billion



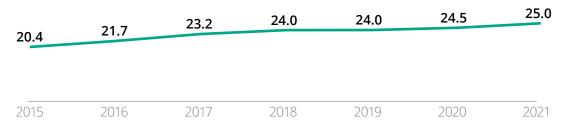
### PRODUCTIVITY AND EMPLOYMENT **IN PHARMACEUTICS**

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



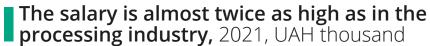
### Number of workers in the pharmaceutical

manufacturing, 2015–2021, thousand people

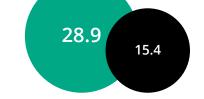


Productivity-wise the pharmaceutical manufacturing is among the leaders of the economy. High productivity level creates resources for investment in development and recruting the best highly paid specialists

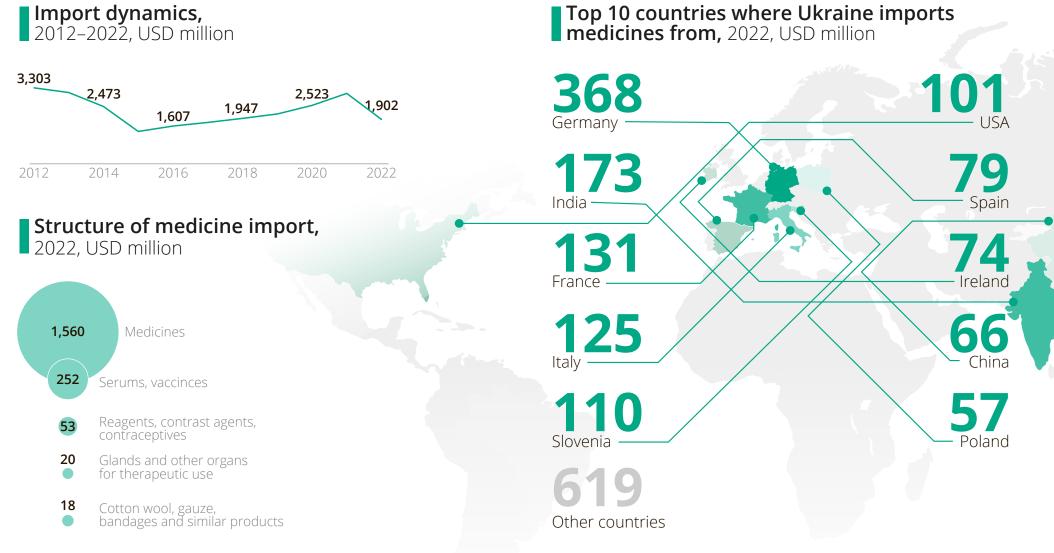




Pharmaceutical manufacturing Processing industry

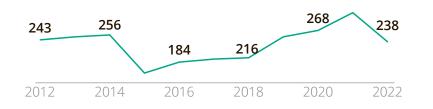


## IMPORT OF MEDICINES

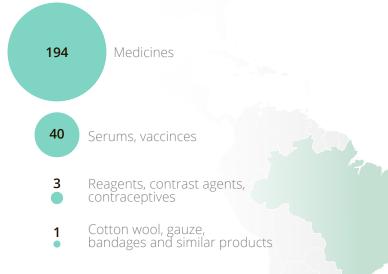


### UKRAINIAN MEDICINE EXPORT

**Export dynamics,** 2012–2022, USD million

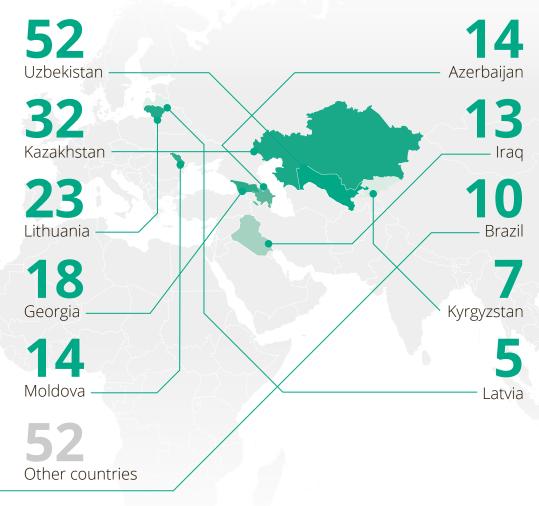


**Structure of medicine export,** 2022, USD million



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

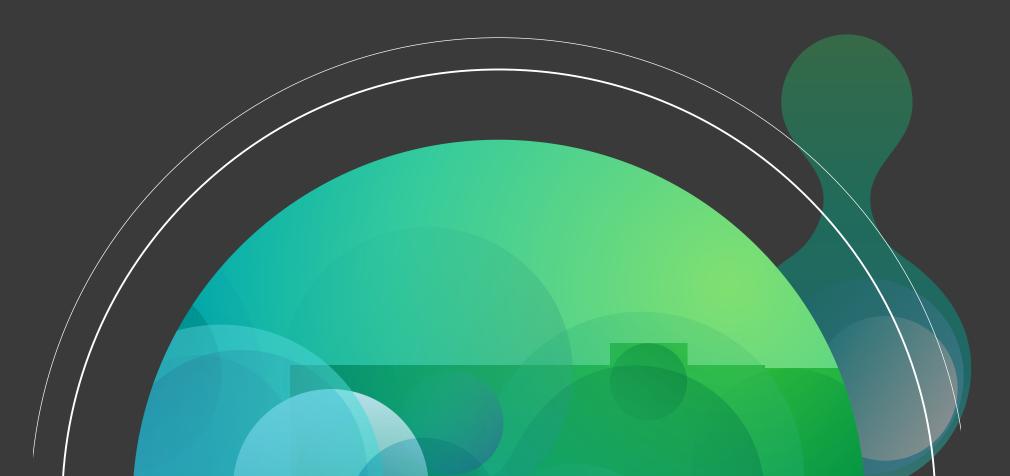
The consequences of the country's economical weakness are a smaller number of domestic innovations and slower implementation of foreign technologies



### 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

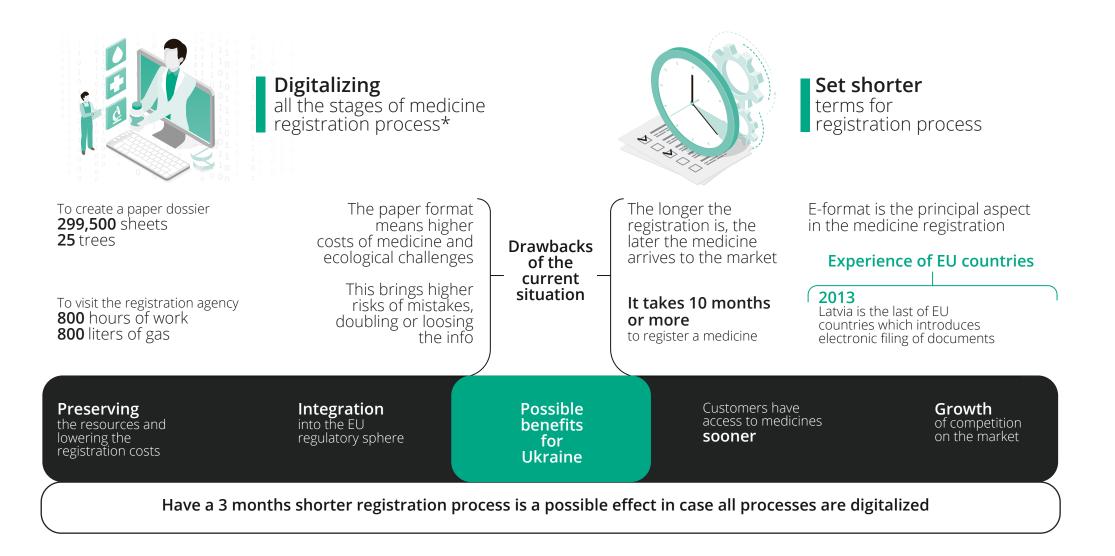
#### Make changes to the patent legislation

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

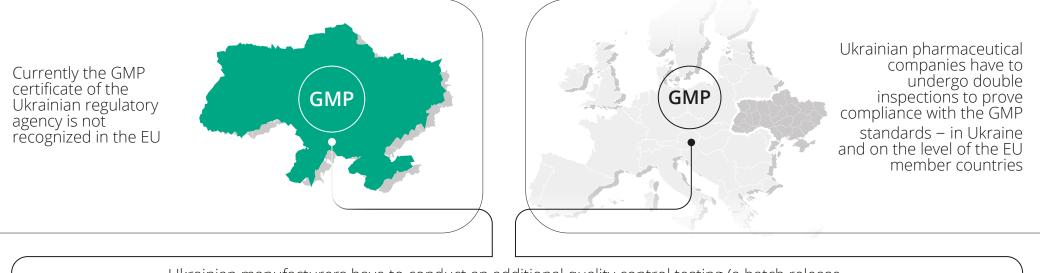
This will improve competitiveness of the national pharmaceutical manufacturers. Currently this process may last ten times more than abroad

### 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

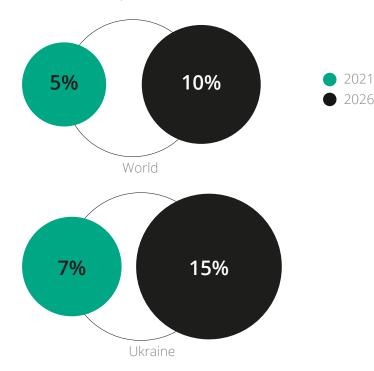
Start of digitalizing the cooperation manufacturer – government, aimed at making it smoother, easier and more efficient

#### 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

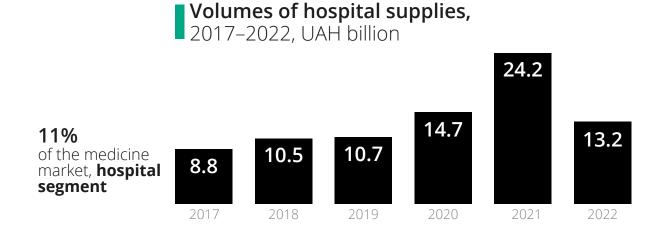
Sites filled with info about medicines and aimed at promoting them. Normally they allow finding a product in the pharmacy, book it and pick it up or have it delivered. The pandemic has sped up the growth of this channel.

For example, <b>"Liki24.com</b> " in 2020					
increase in	increase in				
<b>x6</b> number	<b>x8</b> 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

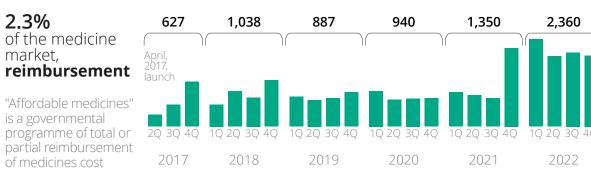
### AFFORDABILITY **OF MEDICINES**



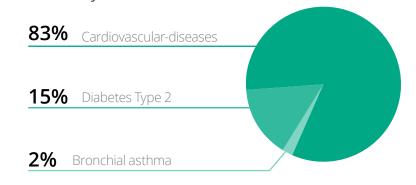
### **Structure of hospital supplies,** 2022, UAH billion



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

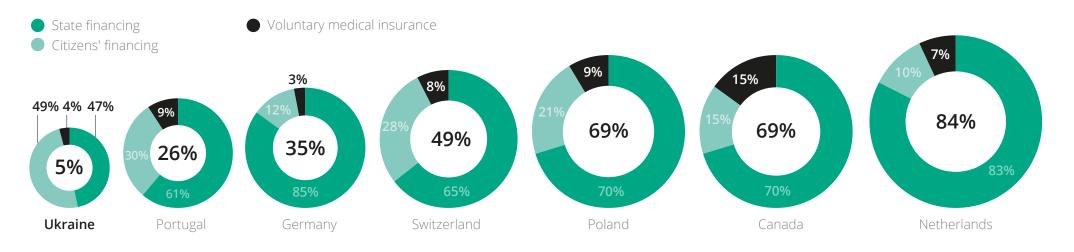


#### **Structure of the medicine register in the programme "Affordable medicines",** February 2023



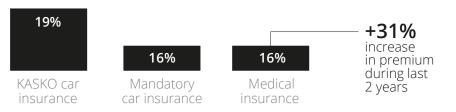


## Share of population that has a voluntary medical insurance, by country, with a healthcare financing structure mentioned, 2019



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

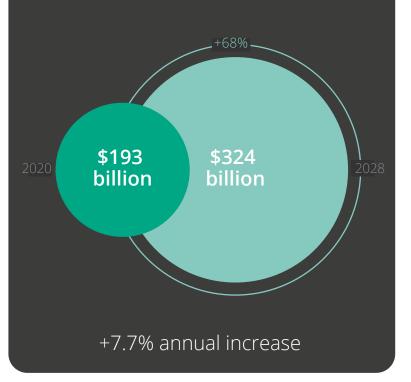
Enter the market sooner

#### 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

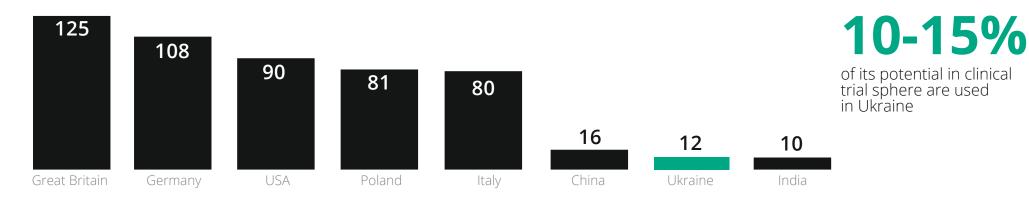
#### Pharmaceutical manufacturers

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

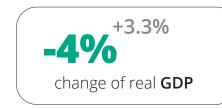
# COVID-19 INUKRAINE

### 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



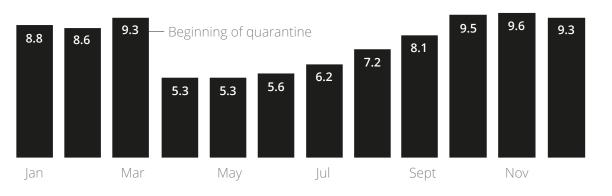
What was happening to pharma at the beginning of the crisis?\*

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

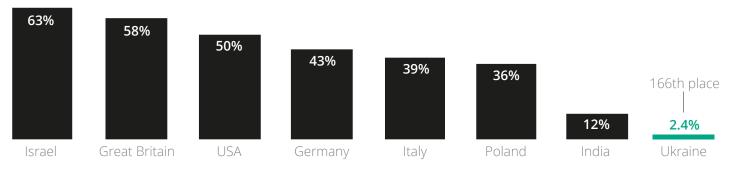
The volumes of vaccines brought in Ukraine and their efficacy, thousand doses as of June 1, 2021



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



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- State Service of Ukraine on Medicines and Drug Control
- State Statistics Service
- State Expert Center
- Medicines Control
- Ministry of Foreign Affairs
- Ministry of Health
- National Bank of Ukraine
- National Security and Defense Council of Ukraine
- National Health Service
- "Farmak"
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