PHARMACEUTICAL INDUSTRY IN UKRAINE 2022
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.
Medical reform implementation is underway in Ukraine. The next step is a mandatory electronic prescription for all prescription drugs. eHealth results are:

- **3 Ukrainian pharmaceutical companies** have made it to the TOP 1000 most expensive pharmaceutical companies in the world*

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

- **+43 thousand** patients joining monthly the programme “Affordable medicines”

- **more than 32 million** patients have registered in the system

- **395 thousand** doctors have registered in the system

- **12.9 thousand** pharmacies have been included to the system

*Sources: Apteka, a weekly online media, National Service of Health of Ukraine, Torreya

*as of 2021
MEDICINES: FROM EDUCATION TO TREATMENT

- 2.9 thou.: students of pharmaceutical higher education institutions began 2019-2020 study year
- 587: medicines have received a registration certificate in 2020
- 120: medicines have received a registration certificate in the 1Q 2021
- 12%: reduction of medicines market in USD terms, in 2022
- 33%: reduction of medicines market in 2022
- 4.5 thou.: medicines have an ongoing clinical trial in the 1Q 2021
- 20%: reduction of medicines market in 2022

EDUCATION

IDEA

STUDY, DEVELOPMENT AND PATENTING

PRECLINICAL AND CLINICAL TRIALS

TESTING

REGISTRATION

PRODUCTION

ENTERING THE MARKET

LOGISTICS

DISTRIBUTION

TRAINING

SPECIALISTS

END CONSUMER

When do medicines start on scientific research in 2019...
PHARMACEUTICAL PRODUCTION OF UKRAINE: HISTORY OF FORMATION

Founding

1907
The first pharmaceutical factory producing galenic, chemical and pharmaceutical products "Galenica" (now "Zdorov'ia")

1910s
Herbal products were manufactured in pharmacies' labs, the synthetic medicines were imported

1925
The first manufacturing of synthetic drugs - M.V.Lomonosov Kyiv chemical pharmaceutical plant (now "Farmak")

1932
Start of production at the Kyiv branch of Kyiv Experimental Endocrinology Institute (now "Darnitsa")

1937
Start of drug manufacturing at the predecessor of Kyiv vitamin plant

Recovery and development

1990s
Crisis and gradual reopening of manufacturing beginning 1995

1970s
Active construction of new facilities

1968
Launch of medicines manufacturing at Cherkasy dairy factory (now "Yuriia-Pharm")

1954
Creation of Darnitsa chemical pharmaceutical plant. Construction of new production facilities

1947
Launch of Kirov cooperative workshop, a predecessor of Borshchahivskyi chemical pharmaceutical plant

MID 2000s
Leaders of GMP certification

Borshchahivskyi chemical pharmaceutical plant, "Darnitsa", "Farmak"

2007
The first in Ukraine fully automated logistics complex ("Darnitsa")

2009
Introduction of mandatory compliance with the good manufacturing practices (GMP) in accordance with EU standards

2013
Ukrainian medicine export made a quarter of a billion of dollars

2022
Two out of Top 5 companies in Ukraine's market are domestic pharma companies

Sources: Pharmaphorum, "Farmak", "Darnitsa"
MARKET OF MEDICINES
Key differences between the segments are in consumers’ financial capability to purchase drugs and mechanisms used in making a decision about the purchase.

**Pharmacy (retail) segment** consists of mainly pharmacy chains. 89% of the retail market is financed directly by the consumers of the medicines. Consumers are numerous but have comparatively low purchasing power.

**In the hospital segment** medicine sales occur at medical and preventive healthcare institutions of Ukraine, which depend on state funding.

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

<table>
<thead>
<tr>
<th>Segment</th>
<th>In monetary terms</th>
<th>In physical terms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital</strong></td>
<td>$3.2 billion</td>
<td>82 million</td>
</tr>
<tr>
<td><strong>Pharmacy</strong></td>
<td>$0.4 billion</td>
<td>845 million</td>
</tr>
</tbody>
</table>

89% 90% 11% 10%

Source: Proxima Research
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.
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.

Source: Proxima Research

*a low price - less than UAH20/ a package, medium price - UAH20-100/ a package, high price - above UAH100/ a package
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.
Structure of medicine consumption, 2012 and 2022, in monetary terms

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.

Sources: Proxima Research, UN, State statistics, OECD
**THE MOST POPULAR MEDICINES IN UKRAINE**

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

<table>
<thead>
<tr>
<th>Position</th>
<th>Medicine</th>
<th>System</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Xarelto</td>
<td>Circulatory system and hematopoiesis</td>
</tr>
<tr>
<td>2</td>
<td>Nimesil</td>
<td>Musculoskeletal system</td>
</tr>
<tr>
<td>3</td>
<td>Nurofen</td>
<td>Musculoskeletal system</td>
</tr>
<tr>
<td>4</td>
<td>Spasmalgan</td>
<td>Digestive system and metabolism</td>
</tr>
<tr>
<td>5</td>
<td>Citramon</td>
<td>Nervous system</td>
</tr>
<tr>
<td>10</td>
<td>Triplixam</td>
<td>Cardiovascular system</td>
</tr>
<tr>
<td>52</td>
<td>Detralex</td>
<td>Cardiovascular system</td>
</tr>
<tr>
<td>16</td>
<td>Gidazepam</td>
<td>Nervous system</td>
</tr>
<tr>
<td>20</td>
<td>Bifren</td>
<td>Nervous system</td>
</tr>
<tr>
<td>28</td>
<td>Evkasolin</td>
<td>Respiratory system</td>
</tr>
<tr>
<td>14</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sources:** Proxima Research, Medicines Kontrol
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, %

- Digestive system and metabolism: -19.6%
- Nervous system: -9.3%
- Cardiovascular system: -23.2%
- Respiratory system: -13.3%
- Musculoskeletal system: -17.5%
- Systemic anti-microbial agents: -10.7%
- Circulatory system and hematopoiesis: -13.3%
- Genito-urinary system and sex hormones: -43.3%
- Dermatological agents: -35.5%
- Sensory organs: -15.0%

The largest share in the consumption structure belongs to medicines for the digestive system, while the smallest decrease in 2022 was shown by medicines for the nervous system.

Source: Proxima Research

*ATC classification - an international system of medicine classification
INNOVATOR MEDICINES AND GENERICS

Life cycle of medicines

_INNOVATOR (ORIGINAL) MEDICINE_ – a new drug introduced to the market for the first time, patented

_GENERICS_ – not patented drugs, replication of the original drug, which patent has expired

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.

Sources: Proxima Research, OECD, EFPIA, MO3
## INNOVATOR MEDICINE DEVELOPMENT PROCESS

<table>
<thead>
<tr>
<th>Stage</th>
<th>Duration</th>
<th>Research</th>
<th>Clinical trials</th>
<th>Registration</th>
<th>Entering the market*</th>
</tr>
</thead>
<tbody>
<tr>
<td>discovery and development</td>
<td>3–6 years</td>
<td>preclinical</td>
<td>Phase 1 Phase 2 Phase 3</td>
<td>0.5–2 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 months 2 years 4 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of combinations</td>
<td></td>
<td>5,000–10,000 250</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Essense of the stage</td>
<td></td>
<td>defining the target of a drug and potential combinations</td>
<td>to determine efficiency and safety in practical use by patients</td>
<td>the regulatory agency checks the results</td>
<td>efficiency and side effects are monitored</td>
</tr>
</tbody>
</table>

- **Sources:** EFPIA, FDA, IFPMA, JAMA Network
- "*" during a certain period of time the right to manufacture a drug belongs only to its developer
- "**" estimated average costs 2009-2018 in the USA

### Notes
- 19% undivided expenses
- $1.3 billion from the budget divided
- 16% 10% 11% 29% 3% 12%
ADVERTISING MEDICINE IN THE PHARMA MARKET

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

- 2018: 2.6
- 2019: 3.3
- 2020: 3.5
- 2021: 4.4
- 2022: 2.2

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, %

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Offline Promo</th>
<th>Online Promo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1Q 2022</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2Q 2022</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3Q 2022</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4Q 2022</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1Q 2021</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2Q 2021</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3Q 2021</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4Q 2021</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 *

<table>
<thead>
<tr>
<th>Year</th>
<th>1Q</th>
<th>2Q</th>
<th>3Q</th>
<th>4Q</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
<td>1.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2021</td>
<td></td>
<td>1.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td></td>
<td></td>
<td>0.9</td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td></td>
<td></td>
<td></td>
<td>0.7</td>
</tr>
<tr>
<td>2018</td>
<td></td>
<td></td>
<td></td>
<td>0.7</td>
</tr>
<tr>
<td>2017</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Source: Apteka, a weekly online media

* share of medicines in the “pharmacy basket” is approx. 80%
PHARMACEUTICAL COMPANIES
 STRUCTURE OF THE PHARMACY MARKET

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

In monetary terms:
- 2012: 30% Ukrainian, 70% Foreign
- 2014: 32% Ukrainian, 68% Foreign
- 2016: 38% Ukrainian, 62% Foreign
- 2018: 38% Ukrainian, 62% Foreign
- 2020: 37% Ukrainian, 63% Foreign
- 2022: 36% Ukrainian, 64% Foreign

In physical terms:
- 2012: 65% Ukrainian, 35% Foreign
- 2014: 70% Ukrainian, 30% Foreign
- 2016: 74% Ukrainian, 26% Foreign
- 2018: 71% Ukrainian, 29% Foreign
- 2020: 69% Ukrainian, 31% Foreign
- 2022: 65% Ukrainian, 35% Foreign

In 2022, a trend for the domestically-manufactured medicines share increase was observed both in physical and monetary terms.

Source: Proxima Research
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)

Despite all the difficulties, in 2022, 5 companies from Top 10 have demonstrated growth in sales volumes comparing to the previous year. The most efficient in terms of sales was Darnitsa with its Evolution index of 128

Source: Proxima Research
*Evolution index - an indicator that shows growth of the company in regards to the whole market
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

Expenses for innovation, 2020, UAH billion

<table>
<thead>
<tr>
<th>Sphere</th>
<th>Expenses, UAH billion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical production</td>
<td>1.9</td>
</tr>
<tr>
<td>Manufacturing of computer, electric and optic products</td>
<td>0.4</td>
</tr>
<tr>
<td>Car manufacturing</td>
<td>0.6</td>
</tr>
<tr>
<td>Chemical industry</td>
<td>1.0</td>
</tr>
<tr>
<td>Food industry</td>
<td>3.5</td>
</tr>
<tr>
<td>Metallurgy</td>
<td>1.9</td>
</tr>
</tbody>
</table>

GDP 2020, UAH billion

- Pharmaceutical production: 40.9 billion
- Manufacturing of computer, electric and optic products: 12.3 billion
- Car manufacturing: 69.0 billion
- Chemical industry: 70.5 billion
- Food industry: 542.3 billion
- Metallurgy: 322.3 billion

Pharmaceutical companies are focused on innovation. Though pharmaceutics isn’t the biggest industry in Ukraine, it sure is among the leaders in terms of innovation spendings.

Source: State Statistics Service

*innovations: scientific and research papers, purchase of new machines, equipment, acquiring new knowledge.
INNOVATIVE GROWTH ON THE EXAMPLE OF THE NATIONAL MANUFACTURER

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

51% upgrading the production

33% new products
18 new brands in 2022

68% digital transformation

55 new brands - a plan for 2023-2027

- Drug Dossier Development (eCTD)
- eCTD Submission
- Trial Master File (eTMF)
- Agile Regulatory Affair Management
- Digital pharmacovigilance
- Electronic archive
- Quality Management & Warehouse implementation

Source: "Darnitsa"
**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**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Certification Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Borschchahivskyi ChPhP</td>
<td>12.04.2019</td>
</tr>
<tr>
<td>&quot;Darnitsa&quot;</td>
<td>05.07.2019</td>
</tr>
<tr>
<td>&quot;Pharma Start&quot;</td>
<td>06.09.2019</td>
</tr>
<tr>
<td>&quot;Farmak&quot;</td>
<td>24.05.2021</td>
</tr>
</tbody>
</table>

GMP – a set of rules and requirements to a production process and quality control of medicines

GMP-certification by EU institutions – a mandatory procedure for a company entering the medicine market

Currently, the EU regulatory institutions don't recognise the GMP certificate issued by the Ukrainian regulatory institution. That is why domestic pharma companies undergo double inspection which complicates entering the EU market and increases costs.

**Relative number of pharmaceutical productions GMP certified by EU regulatory institutions, by country, company per USD 1 billion worth of drug sales**

<table>
<thead>
<tr>
<th>Country</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hungary</td>
<td>55.4</td>
</tr>
<tr>
<td>Latvia</td>
<td>45.4</td>
</tr>
<tr>
<td>Estonia</td>
<td>31.1</td>
</tr>
<tr>
<td>Portugal</td>
<td>18.3</td>
</tr>
<tr>
<td>Sweden</td>
<td>16.2</td>
</tr>
<tr>
<td>Belgium</td>
<td>15.8</td>
</tr>
<tr>
<td>Italy</td>
<td>8.7</td>
</tr>
<tr>
<td>Ukraine</td>
<td>1.3</td>
</tr>
</tbody>
</table>

This low an indicator is due to EU institutions not recognising the Ukrainian GMP certificates.

Source: EudraGMDP

*according to EudraGMDP and certification validity during 3 years, not considering a possible increase of the term due to Covid-19
PHARMACEUTICAL PRODUCTION IN THE ECONOMY
PHARMA IN THE ECONOMY

2022

0.5% of the product export

UAH 7.7 billion
of the export

UAH 49.0 billion
of value added

UAH 61.4 billion
of the import

2.2% of the processing industry GDP*

3.4% of the product import

UAH 2.9 billion
of capital investments

3.5% of the processing industry investments

Source: State Statistics Service

*2021
**ADDED VALUE AND INVESTMENT IN PHARMA**

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wood processing and paper</td>
<td>72</td>
<td>74</td>
<td>98</td>
<td>119</td>
<td>116</td>
<td>75</td>
<td>65</td>
<td>69</td>
<td>88</td>
<td>96</td>
<td>99</td>
<td>106</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Furniture and assembly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rubber and plastic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Machine manufacturing**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The arrows show the direction during crisis years.

*Based on data in USD million

Sources: State Statistics Service, NBU

**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**

**not taking into account electronics and electrical equipment**
Pharmaceutical manufacturing – is one of the most productive industries of the economy, GDP per employee, 2021, UAH thousand

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

Number of workers in the pharmaceutical manufacturing, 2015–2021, thousand people

The salary is almost twice as high as in the processing industry, 2021, UAH thousand

Source: State Statistics Service
IMPORT OF MEDICINES IN UKRAINE

Import dynamics, 2012–2022, USD million

Structure of medicine import, 2022, USD million

Top 10 countries where Ukraine imports medicines from, 2022, USD million

Sources: State Statistics Service, State Customs Service
UKRAINIAN MEDICINE EXPORT

Export dynamics, 2012–2022, USD million

Structure of medicine export, 2022, USD million

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

Sources: State Statistics Service, State Customs Service
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.

Source: "Darnitsa"
REGULATIONS
FOR PHARMACEUTICS
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 guidelines for state assessment of medical technologies for medicines
- the first in Ukraine guidelines for rules for conducting bioanalytical part of pharmakinetic and toxicokinetic studies

CRUCIAL CHANGES OF REGULATIONS

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

Sources: State Expert Center, "Darnitsa", open sources
WAYS TO IMPROVE REGULATIONS TO DEVELOP PHARMACEUTICAL MANUFACTURING

Digitalizing all the stages of medicine registration process*

- The paper format means higher costs of medicine and ecological challenges
- This brings higher risks of mistakes, doubling or loosing the info

Set shorter terms for registration process

- E-format is the principal aspect in the medicine registration
- Experience of EU countries
  - Latvia is the last of EU countries which introduces electronic filing of documents
  - 2013

Drawbacks of the current situation

- It takes 10 months or more to register a medicine

Preserving the resources and lowering the registration costs

Integration into the EU regulatory sphere

Possible benefits for Ukraine

- Customers have access to medicines sooner

Growth of competition on the market

Have a 3 months shorter registration process is a possible effect in case all processes are digitalized

Sources: State Expert Center, "Darnitsa" *based on the example of yearly expenses of "Darnitsa"

To create a paper dossier
- 299,500 sheets
- 25 trees

To visit the registration agency
- 800 hours of work
- 800 liters of gas

*Have a 3 months shorter registration process is a possible effect in case all processes are digitalized.
Each pharmaceutical manufacturer that wishes to work in the market of any country has to be certified according to the GMP standards.

Currently the GMP certificate of the Ukrainian regulatory agency is not recognized in the EU.

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.

Ukrainian pharmaceutical companies have to undergo double inspections to prove compliance with the GMP standards – in Ukraine and on the level of the EU member countries.

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.

Sources: MFA, "Darnitsa"
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
1. 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
2. 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 healthcare

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

Sources: Apteka, a weekly online media, "Darnitsa", Ministry of Health
E-COMMERCE IN THE PHARMACEUTICAL MARKET

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

- **World**
  - 2021: 5%
  - 2026: 10%

- **Ukraine**
  - 2021: 7%
  - 2026: 15%

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 number of orders: x6
  - Increase in volume of traffic: x8

- **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.

Source: Apteka, a weekly online media
Sources: Proxima Research, Ministry of Health of Ukraine, National Health Service

**Volumes of hospital supplies, 2017–2022, UAH billion**

- 2017: 8.8
- 2018: 10.5
- 2019: 10.7
- 2020: 14.7
- 2021: 24.2
- 2022: 13.2

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

- State budget: 7.3
- Local budgets: 5.9
- Foreign suppliers from Top 10 in terms of volumes: 10/10
- Local budgets: 3/10

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

- April 2017, launch: 627
- 1Q 2Q 3Q 4Q: 1,038
- 1Q 2Q 3Q 4Q: 887
- 1Q 2Q 3Q 4Q: 940
- 1Q 2Q 3Q 4Q: 1,350
- 1Q 2Q 3Q 4Q: 2,360

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

- 83% Cardiovascular-diseases
- 15% Diabetes Type 2
- 2% Bronchial asthma

"Affordable medicines" is a governmental programme of total or partial reimbursement of medicines cost.
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.

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.

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

<table>
<thead>
<tr>
<th>Country</th>
<th>State financing</th>
<th>Citizens’ financing</th>
<th>Voluntary medical insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ukraine</td>
<td>49%</td>
<td>4%</td>
<td>47%</td>
</tr>
<tr>
<td>Portugal</td>
<td>26%</td>
<td>30%</td>
<td>9%</td>
</tr>
<tr>
<td>Germany</td>
<td>35%</td>
<td>12%</td>
<td>8%</td>
</tr>
<tr>
<td>Switzerland</td>
<td>49%</td>
<td>28%</td>
<td>9%</td>
</tr>
<tr>
<td>Poland</td>
<td>69%</td>
<td>21%</td>
<td>15%</td>
</tr>
<tr>
<td>Canada</td>
<td>69%</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>84%</td>
<td>10%</td>
<td>7%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Sector</th>
<th>Premiums</th>
</tr>
</thead>
<tbody>
<tr>
<td>KASKO car insurance</td>
<td>19%</td>
</tr>
<tr>
<td>Mandatory car insurance</td>
<td>16%</td>
</tr>
<tr>
<td>Medical insurance</td>
<td>16%</td>
</tr>
</tbody>
</table>

+31% increase in premium during last 2 years

Sources: State Statistics Service, OECD, WHO, Forinsurer

*KASKO - voluntary insurance
**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 market

### 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

---

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

- **$193 billion** (2020)
- **$324 billion** (2028)
- +68%
- +7.7% annual increase

---

Sources: “Darnitsa”, Grandviewresearch
Amount of clinical trials by country,
2020, unit per 1 mln population

- Great Britain: 125
- Germany: 108
- USA: 90
- Poland: 81
- Italy: 80
- China: 16
- Ukraine: 12
- India: 10

10-15% of its potential in clinical trial sphere are used in Ukraine.

Clinical trials in Ukraine,
as of June 1, 2021

- Concluded*: 2,232
- In action: 527

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**.

Sources: Apteka, a weekly online media, WHO, State Expert Center *since Ukraine became independent.
COVID-19 IN UKRAINE
Imposing an all-Ukrainian lockdown. Increase of medicine sales in the first week, then a rapid fall (-18% in April)

Introduction of adaptive quarantine. Pharmaceutical market is still in decline, however the fall slows down

Pharma market has reached the last year numbers and enters the growth phase

Pharma market has quickly adapted to the new reality and showed an increase in 2020

+9.7% in monetary terms
+2.2% in packages

Sources: Apteka, a weekly online media, National Security and Defense Council of Ukraine, Johns Hopkins University & Medicine
PANDEMIC INFLUENCE
ON THE MARKET

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

-4% change of real GDP
+3.3%

5% level of inflation
4.1%

9.9% level of unemployment
8.6%

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

71.4% of pharmacies have noted a decline in sales volumes

40% of manufacturers have noted a decline in sales

69.2% of pharma companies were anxious

Pharmacy medicine sales dynamics, 2020, UAH billion

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.

8.8 8.6 9.3
Beginning of quarantine
5.3 5.3 5.6
5.6 6.2 7.2
7.2 8.1 9.5
9.5 9.6 9.3
8.6
Jan Mar May Jul Sekt Nov

+68% of antivirus drug sales
+32% antibacterial drug sales

Sources: Apteka, a weekly online media, State Statistics Service, robota.ua

*based on a survey of pharmaceutical companies in May
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

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Doses</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoronaVac</td>
<td>1,915</td>
<td>84%</td>
</tr>
<tr>
<td>Comirnty (Pfizer)</td>
<td>758</td>
<td>95%</td>
</tr>
<tr>
<td>Covishield</td>
<td>500</td>
<td>63%</td>
</tr>
<tr>
<td>AstraZeneca-SKBio</td>
<td>367</td>
<td>63%</td>
</tr>
<tr>
<td>Janssen</td>
<td>0.5</td>
<td>67%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Israel</td>
<td>63%</td>
</tr>
<tr>
<td>Great Britain</td>
<td>58%</td>
</tr>
<tr>
<td>USA</td>
<td>50%</td>
</tr>
<tr>
<td>Germany</td>
<td>43%</td>
</tr>
<tr>
<td>Italy</td>
<td>39%</td>
</tr>
<tr>
<td>Poland</td>
<td>36%</td>
</tr>
<tr>
<td>India</td>
<td>12%</td>
</tr>
<tr>
<td>Ukraine</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

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.

Sources: Our World in Data, Ministry of Health
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