

**PHARMA
CEUTICAL
INDU
STRY**

**IN UKRAINE
2020**

INTRODUCTION

Aim of this study

The responsibility of pharmaceuticals is to provide quality medicines to prolong life and improve its quality. The development of this industry contributes to the overall growth of the economy and wealth.

Now pharmaceuticals are actively developing. Technological changes allow improving approaches to treatment and improve life itself, regulatory – to accelerate the introduction of new effective medicines.

We researched the pharmaceutical industry in Ukraine to show how it works – becoming more technological, modern and innovative. The introduction of European standards in production, together with high investment intensity makes pharmaceuticals one of the most dynamic industries in the economy with high added value. The market size continues to expand; the share of expensive and prescription medications is growing. The pharmaceutical industry is increasing the availability of advanced medicines and making a significant contribution to economic development.

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INDUSTRY IN UKRAINE**

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PHARMACEUTICALS ARE CHANGING ALONG WITH UKRAINE

Robotics

Production automation
minimizes errors and
maximizes efficiency



Computer simulation

Used to model the behaviour of
molecules in the process of
creating medicines



Cloud technologies

No need to buy servers, all
in the cloud



Blockchain

Fixed and transparent
system for the supply chain



Serialisation Manufacturing

Labelling of medications to
confirm their originality



Data analytics, BI

Analysis of a large amount
of data for decision making



Artificial Intelligence

Can with high probability predict the results of
the interaction of a new molecule with protein
structures before its creation



Industrial Internet of Things

A system of sensors and controllers
that allows you to receive data and
control production remotely



PHARMACEUTICAL INDUSTRY IN UKRAINE

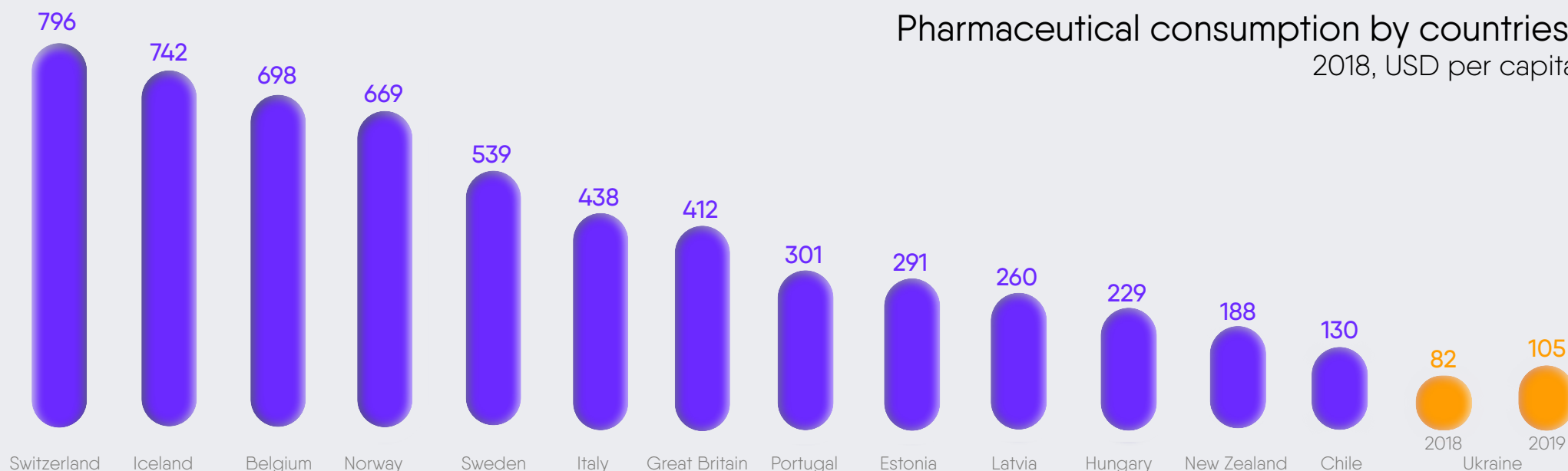
PHARMACEUTICAL CONSUMPTION

Pharmaceutical consumption structure, % (money term)

Pharmaceutical consumption in Ukraine, 2010–2019*, USD per capita



Pharmaceutical consumption by countries, 2018, USD per capita



Source: Apteka Weekly¹⁻⁹, OECD

*Excluding the Crimean Autonomous Republic and the territories of Donetsk and Luhansk Oblasts (in 2015–2019)

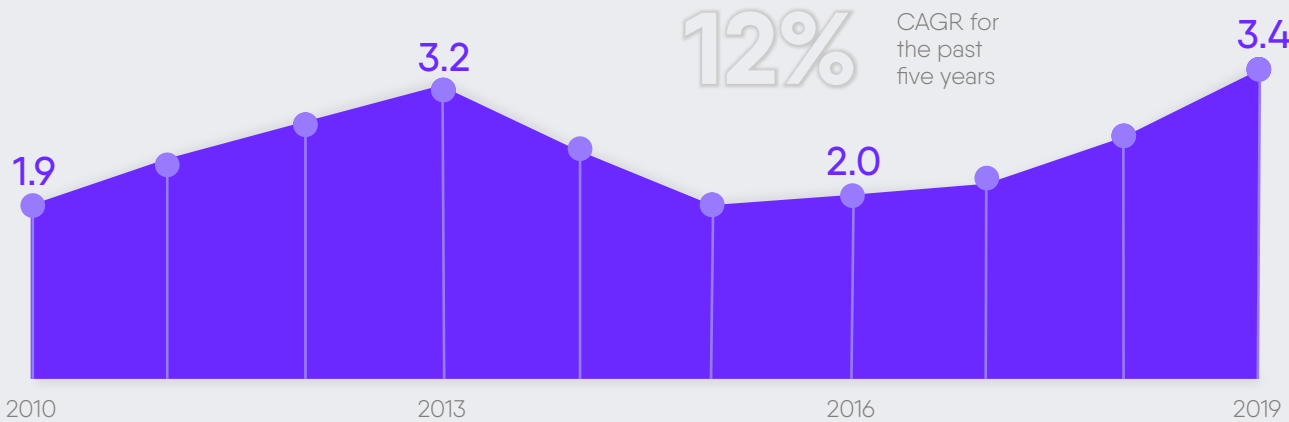
MOST POPULAR MEDICINES IN UKRAINE

Pharmacy sales leaders,
2019, ranked by sales (relative to previous year)

Place in the ranking	Brand	Area of application	Is a prescription required?
1 ⁺¹⁰	XARELTO	 Blood and blood forming organs	+
2 ⁻¹	NUROFEN	 Musculo-skeletal system	-
3 ⁻¹	NIMESYL	 Musculo-skeletal system	+
4 ⁺¹	SPAZMALHON	 Alimentary tract and metabolism	-
5 ⁻²	NATRIIU KHLORYD	 Blood and blood forming organs	+
6	SYNUPRET	 Respiratory system	-
7	REOSORBILAKT	 Blood and blood forming organs	+
8	NO-SHPA	 Alimentary tract and metabolism	-
9 ⁺¹	TSYTRAMON	 Nervous system	-
10 ⁻⁶	AKTOVEHIN	 Alimentary tract and metabolism	+

PHARMACY MARKET DYNAMICS

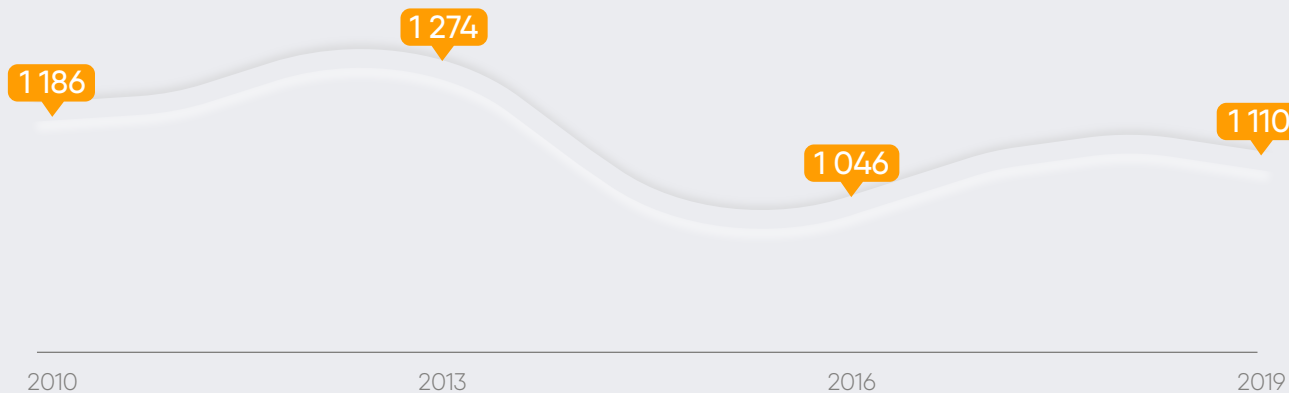
Pharmacy market,
2010–2019, bln USD



Share of pharmacy segment
in pharmaceutical market,
2019 p., % (money term)



Pharmacy sales,
2010–2019, mln pc



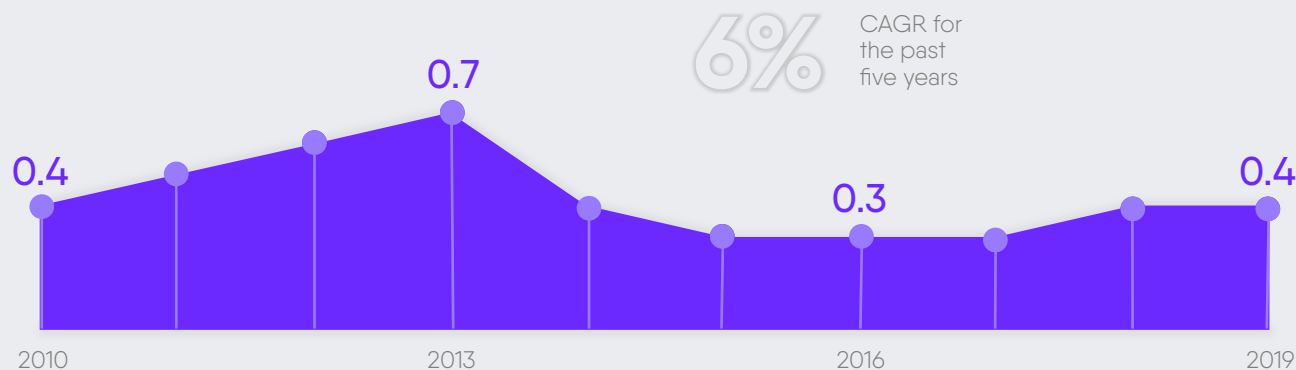
The pharmacy sector is the basis of Ukraine's pharmaceutical market

There is a tendency of the share of foreign manufacturers decrease in in-kind term and increase in money term

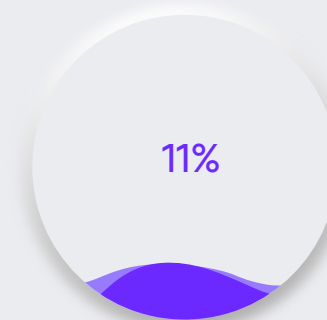
Source: Apteka Weekly^{1,2,3,4,5,6}

HOSPITAL MARKET DYNAMICS

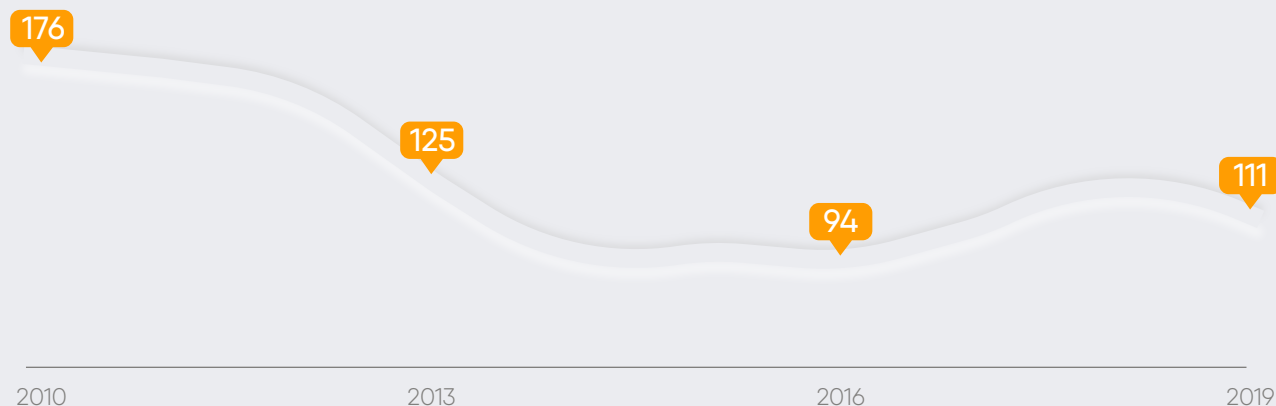
Hospital market, 2010–2019, bln USD



Share of hospitals in pharmaceutical market 2019 p., % (money term)



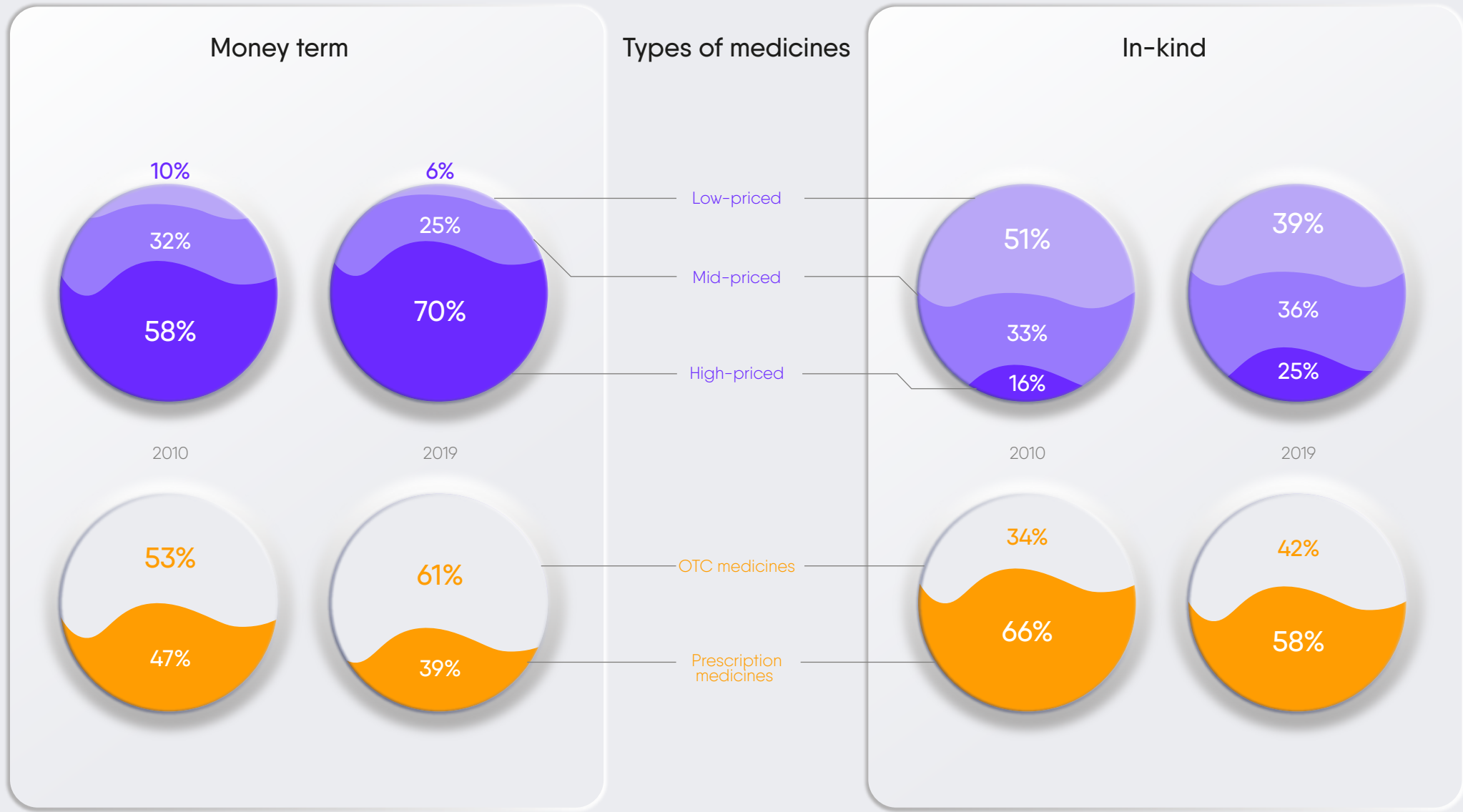
Hospital procurements, 2010–2019, mln pc



The growth rate of the hospital market is much lower than the market

Source: Apteka Weekly^{1,2,3,4,5,6}

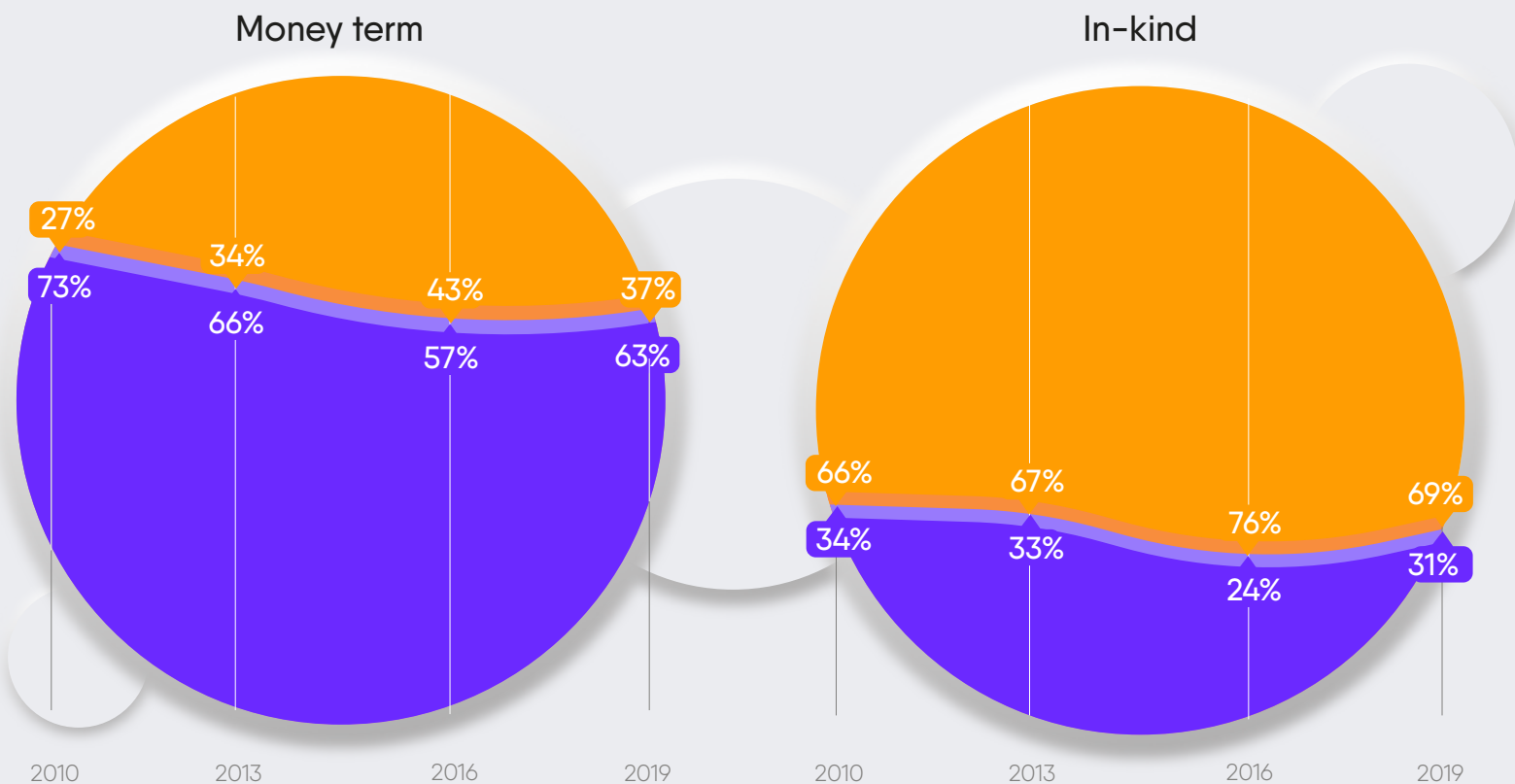
PHARMACY SALES SEGMENTATION



Source: Apteka Weekly⁶

PHARMACY MARKET STRUCTURE

Pharmacy sales split by origin, %



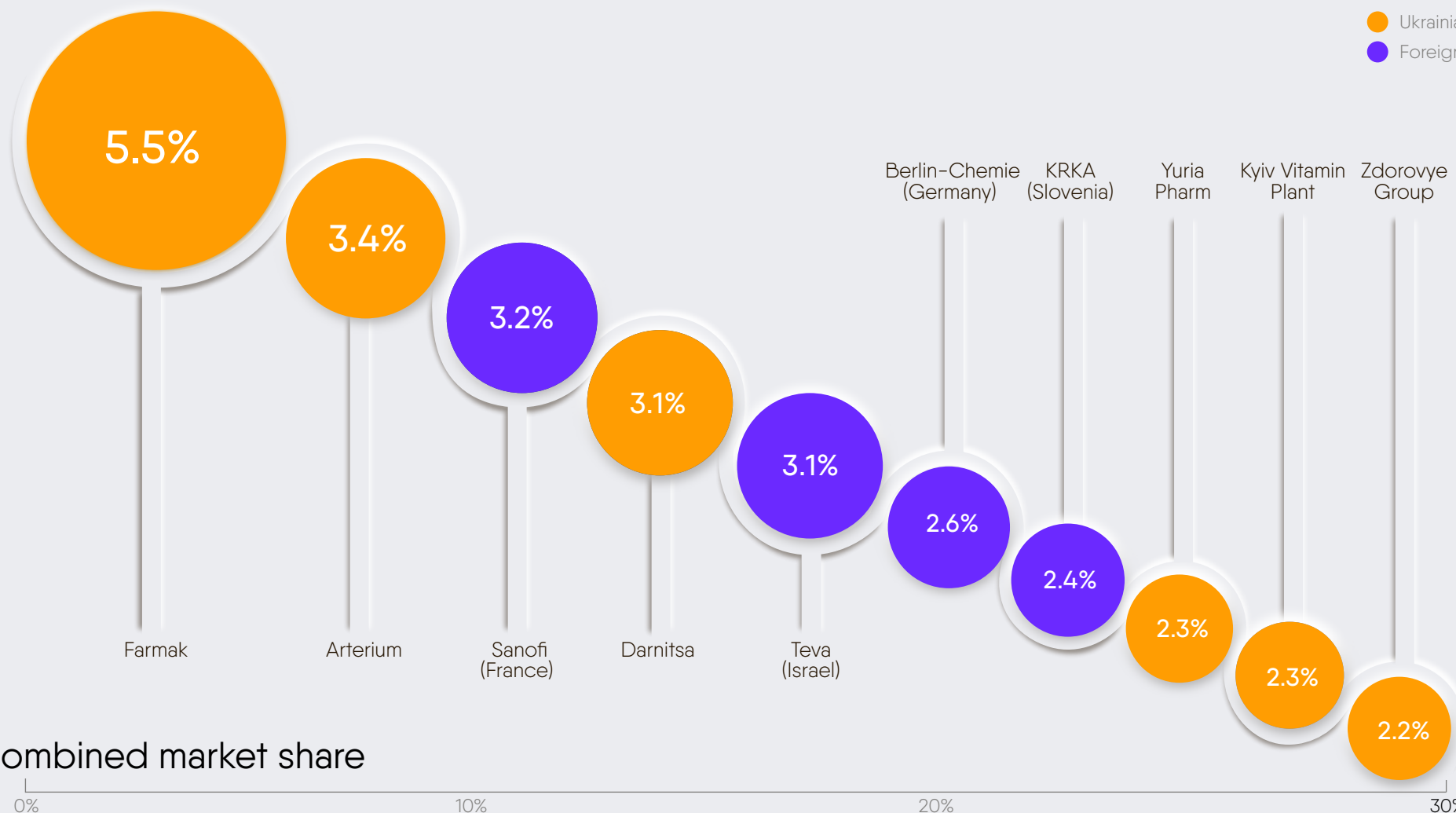
● Ukrainian
● Foreign

In in-kind terms, the market is dominated by Ukrainian medicines, but in money terms, more expensive foreign goods have a larger share

PHARMACY MARKET LEADERS

TOP-10 companies based on sales of «pharmacy basket» products, 2019, share of market, % (money term)

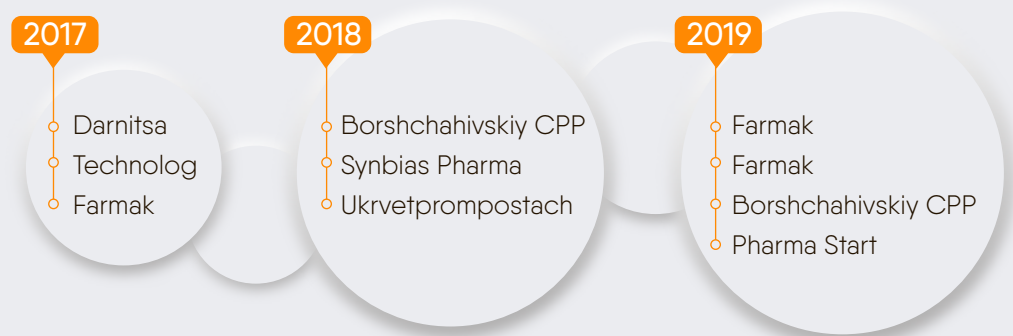
● Ukrainian
● Foreign



The combined market share

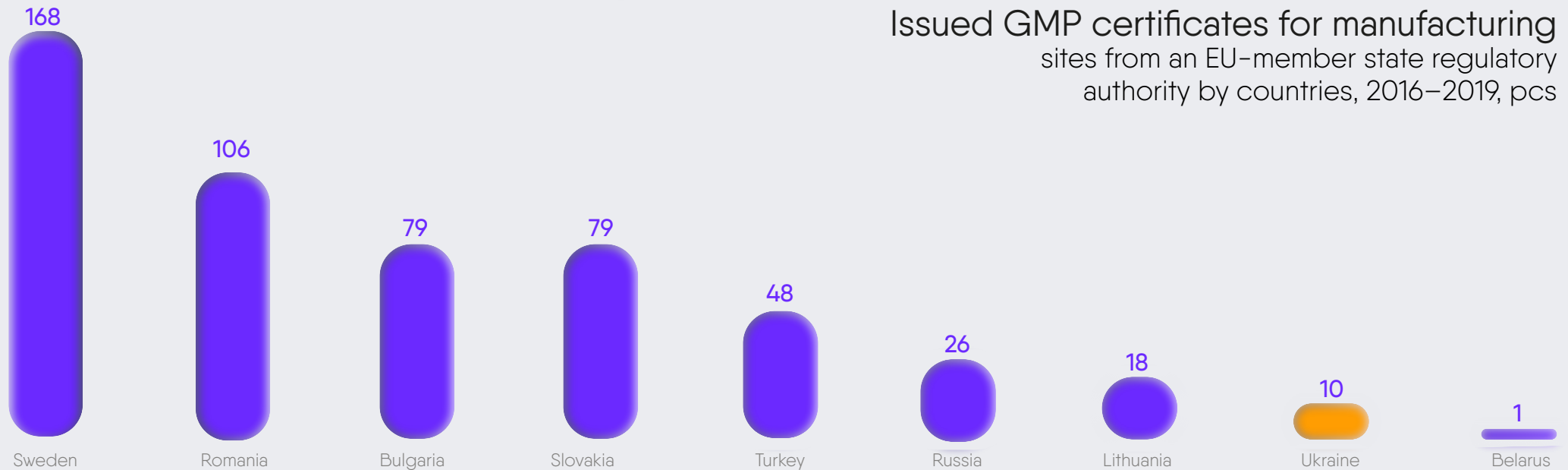
PHARMACEUTICAL MANUFACTURERS

Ukrainian companies holding GMP certificate for manufacturing sites from an EU-member state regulatory authority, 2016–2019



GMP is a set of rules and requirements for the organization of production and quality control of medicines

Obtaining a GMP certificate is a mandatory requirement for registration and sale of a medicinal product on the European market



Issued GMP certificates for manufacturing sites from an EU-member state regulatory authority by countries, 2016–2019, pcs

PHARMACEUTICAL INDUSTRY IN THE ECONOMY

ROLE OF PHARMACEUTICAL INDUSTRY IN ECONOMY

Output of pharmaceutical products, 2018, bln UAH (at consumer prices)

0.8%

of GDP is created by Pharmaceutical industry

Value added

Salary

7

Profit

6

Taxes

17

Domestic production

92

Cost of production

62

Total pharmaceutical products output
152

Consumption

100

10%

share of pharmaceutical products in retail turnover

Pharmacies and hospitals

88

Pharmacy sales

5.1

Local budgets

4.6

MOH through international organizations

0.9

State budget

0.9

Affordable Medicines Program

7

Export

1

Stock growth

44

Consumption by other industries

Imports

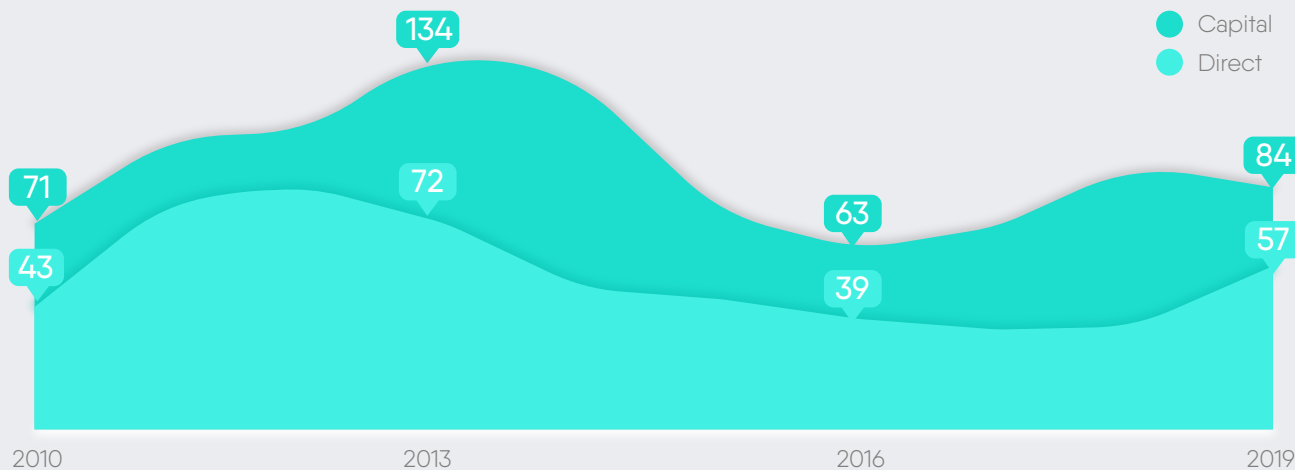
60

INVESTMENT IN PHARMACEUTICAL INDUSTRY

Average investment intensity by industries,
2018, kopiyyok of capital investments per 1 UAH of value added



Direct and capital investments,
2010–2019, mln USD

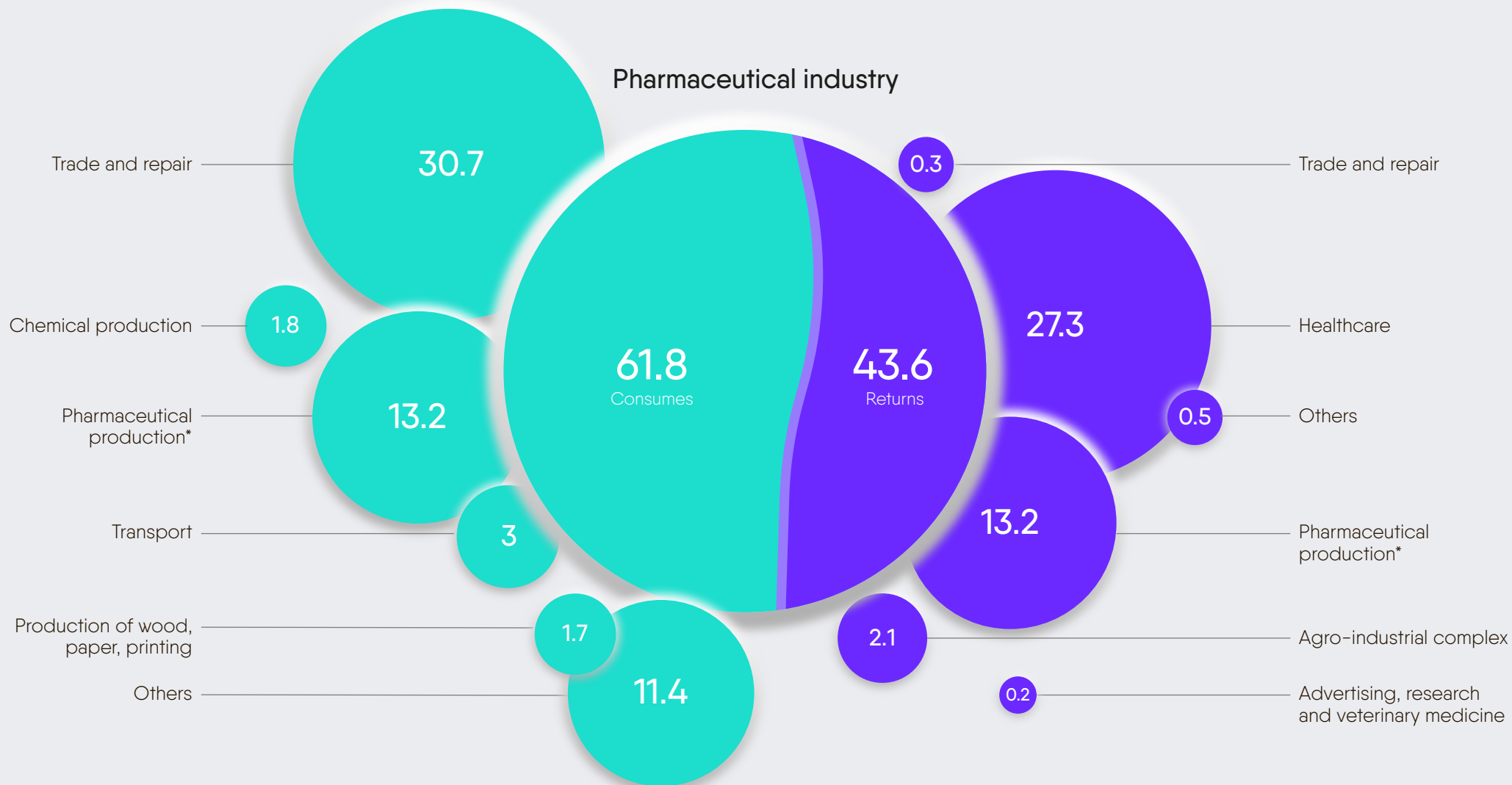


The volume of investment in the pharmaceutical industry has not recovered to the pre-crisis level yet. However, the intensity is higher than the average in other sectors

Foreign investments grow steadily in recent years

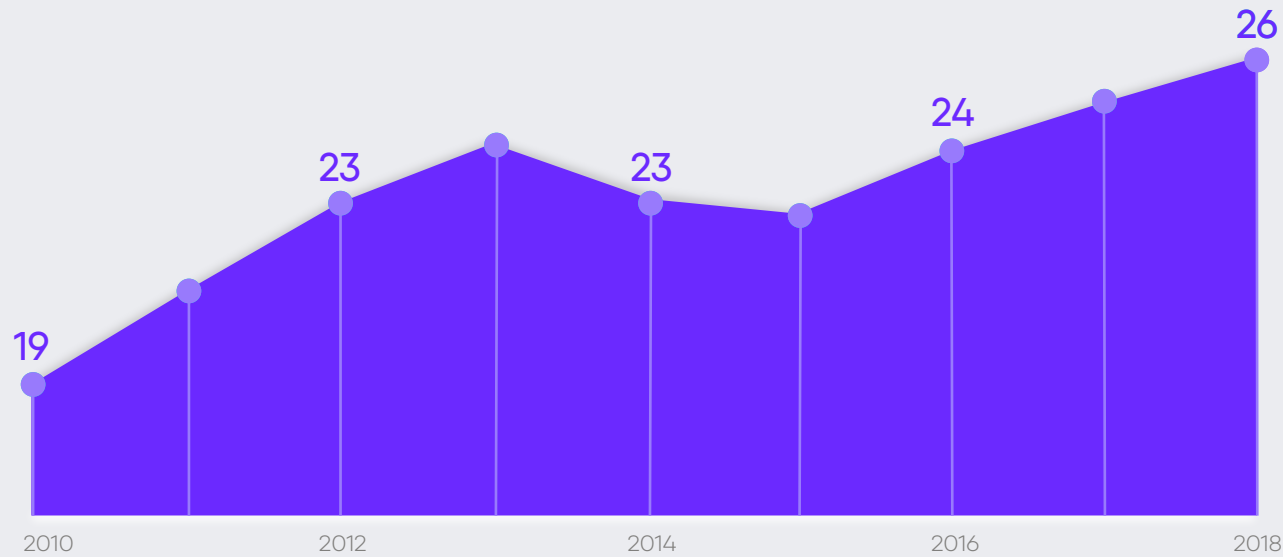
IMPACT ON OTHER INDUSTRIES

Interaction of pharmaceutical production with other industries,
2018 bln UAH

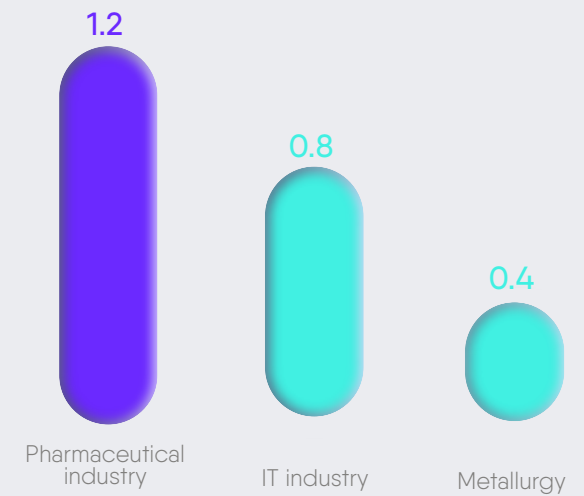


WORKFORCE

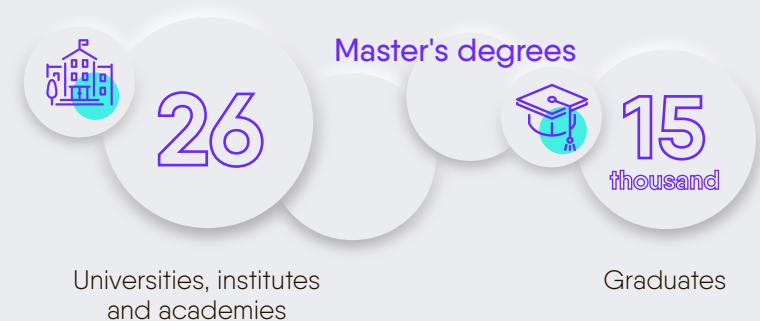
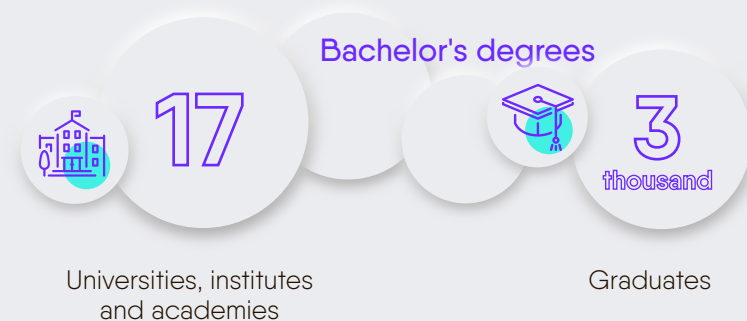
Number of employees,
2010–2018, ths



Value added created by
one employee
mln UAH, 2018

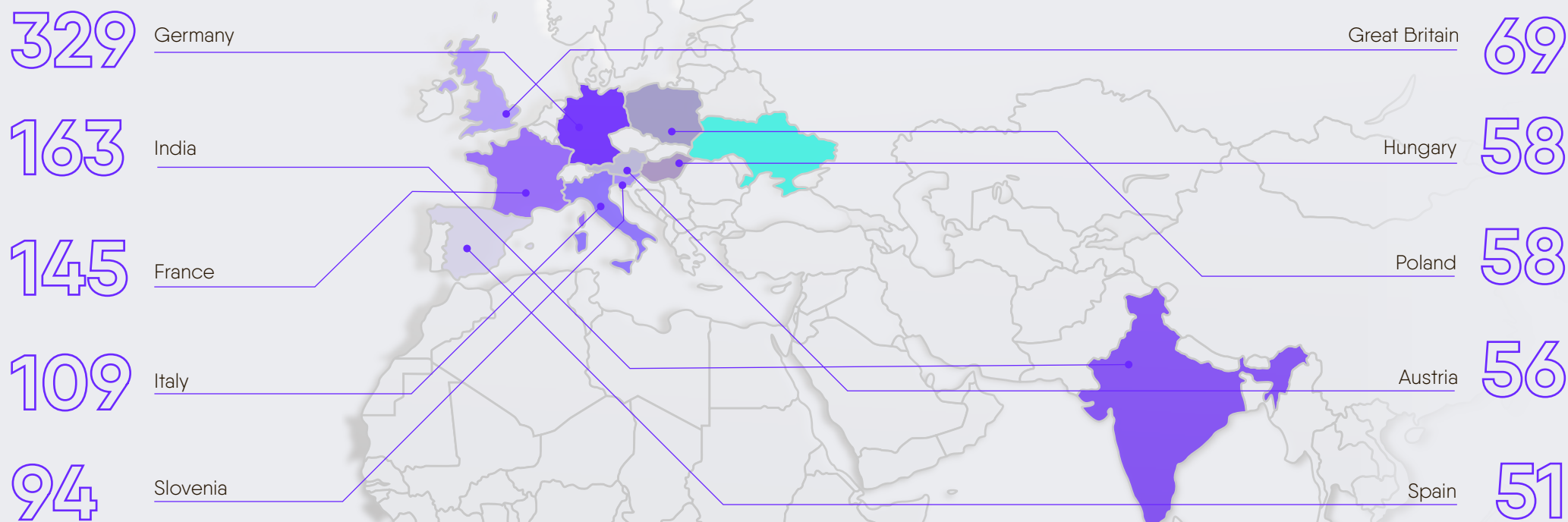


Pharmacy educational institutions,
number of institutions and students in the 2019/20 academic year



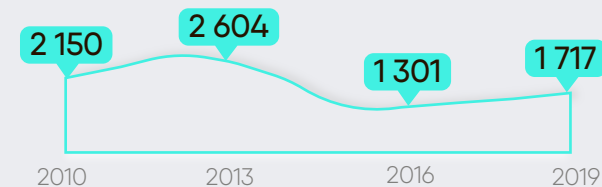
MEDICINE IMPORT IN UKRAINE

TOP-10 Medicine Import Directions in Ukraine,
2019, mln USD



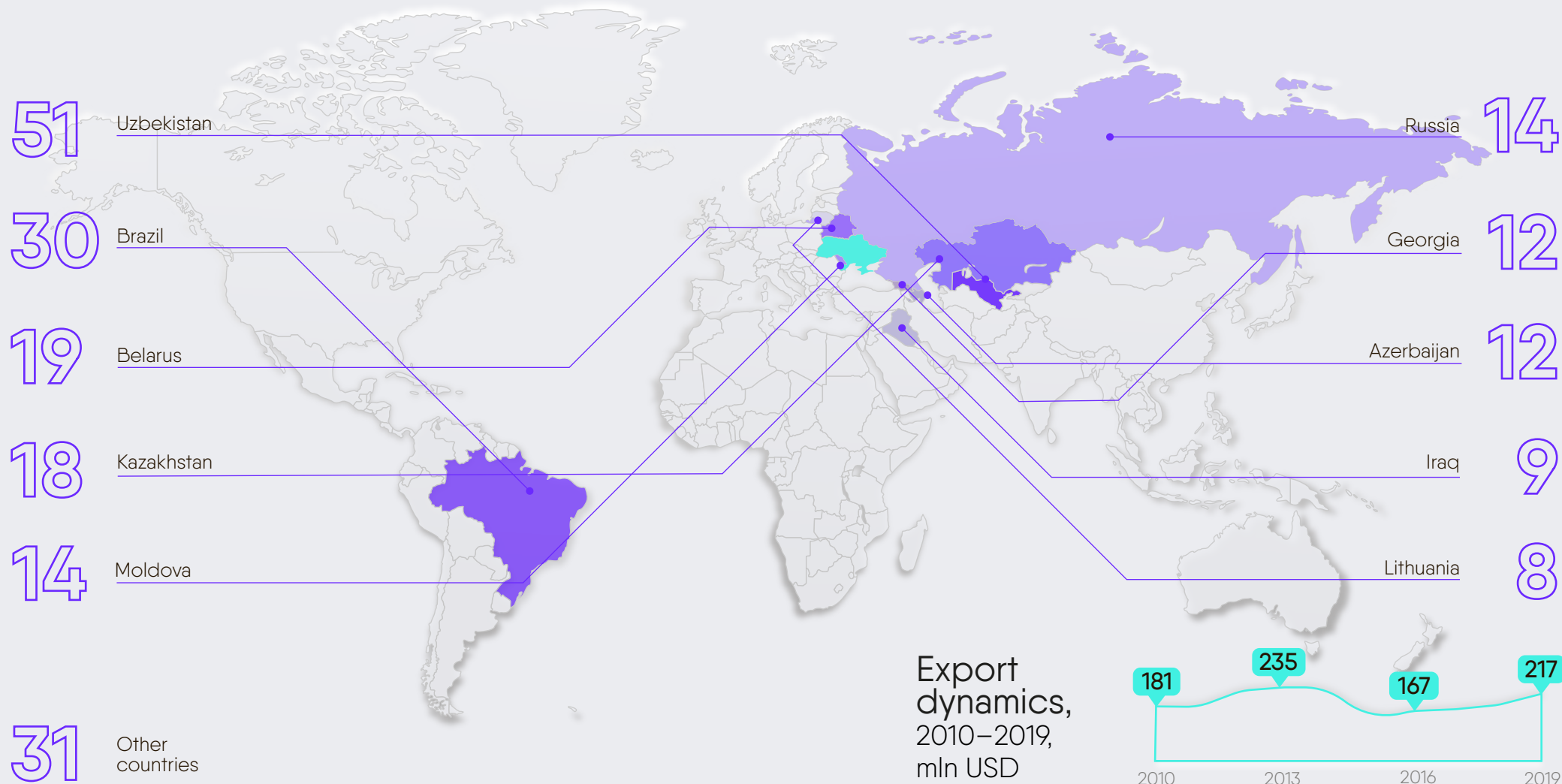
584 Other countries

Import dynamics,
2010–2019,
mln USD

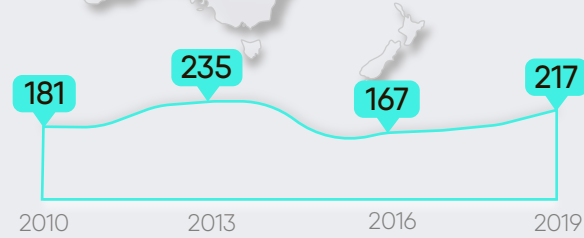


MEDICINE EXPORT FROM UKRAINE

TOP-10 Medicine Export Directions from Ukraine,
2019, mln USD



Export dynamics,
2010–2019,
mln USD



Source: SSC of Ukraine

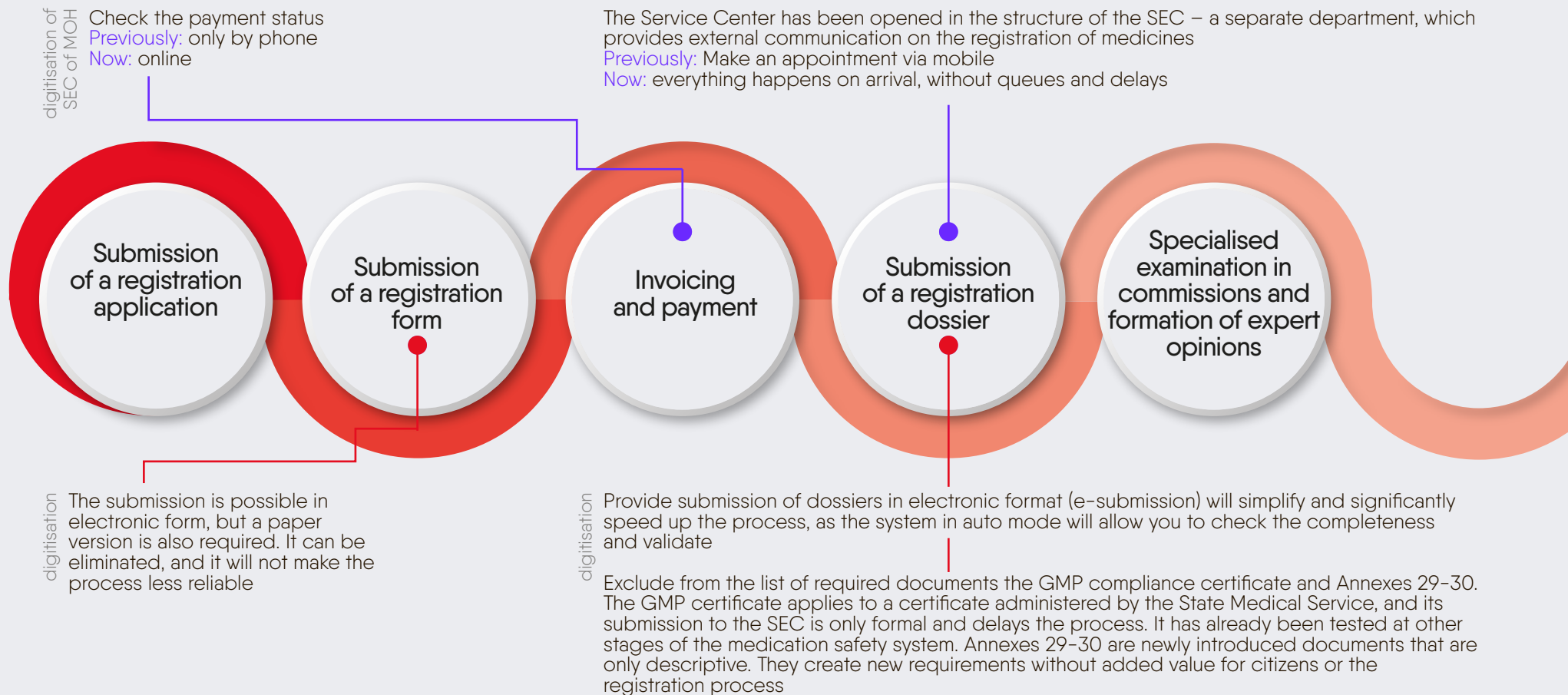
PHARMACY REGULATION

REGISTRATION OF MEDICINES – CONTINUOUS IMPROVEMENTS

Medicine registration is an essential component of the medication safety system. At the same time, it is a complicated and time-consuming process that has recently been simplified and accelerated

Process of registration in Ukraine

● Improvements that have already taken place ● What can be improved in the future



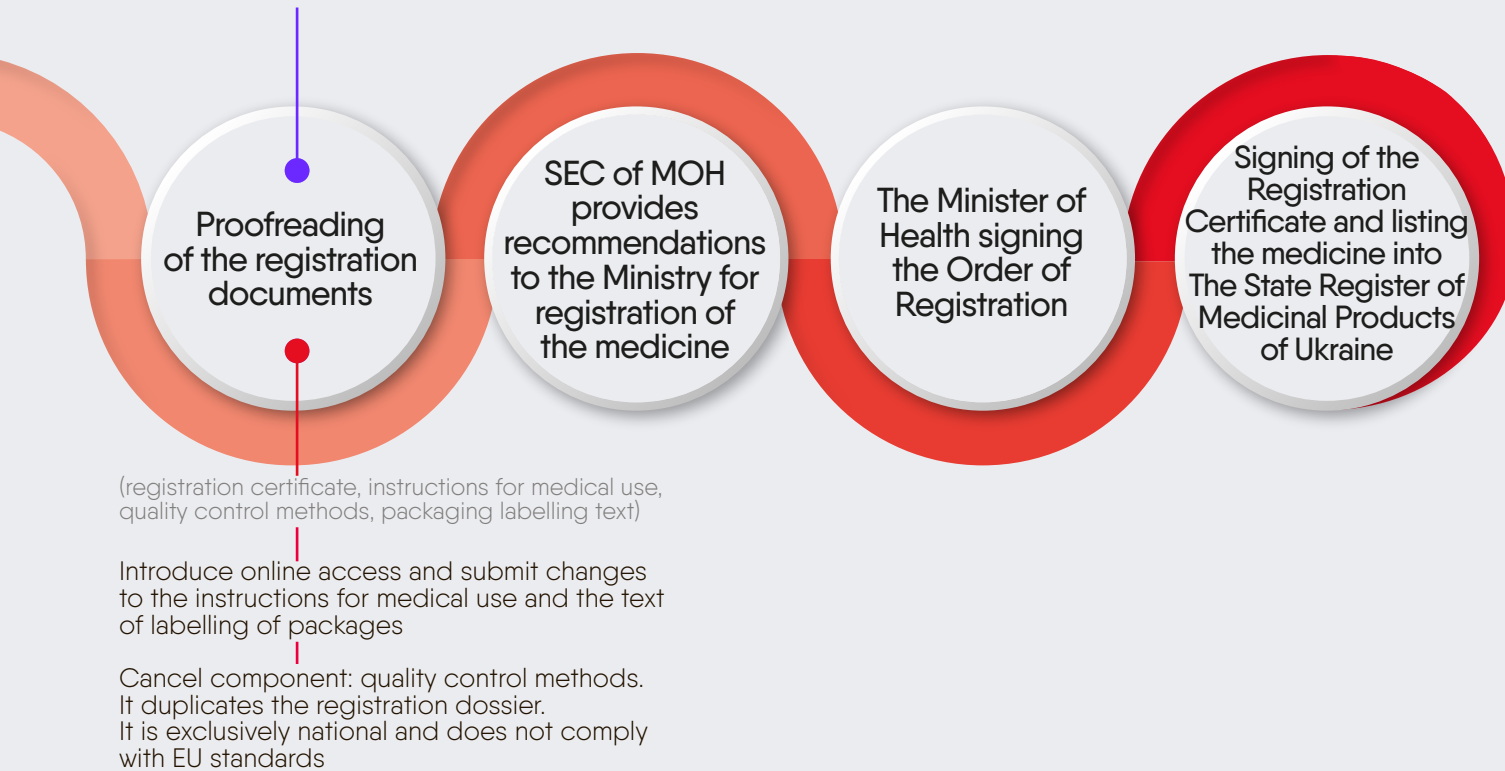
COVID-19 Case Study

The State Expert Center (SEC), as one of the central bodies of the registration process, has successfully switched to remote operation and ensured the continuity of the medicine registration process

digitisation Proofreading and submission of changes to the registration certificate.
Previously: only in paper form
Now: online

Improvements that have already taken place

What can be improved in the future



General trends and necessary changes in the process of medicine registration

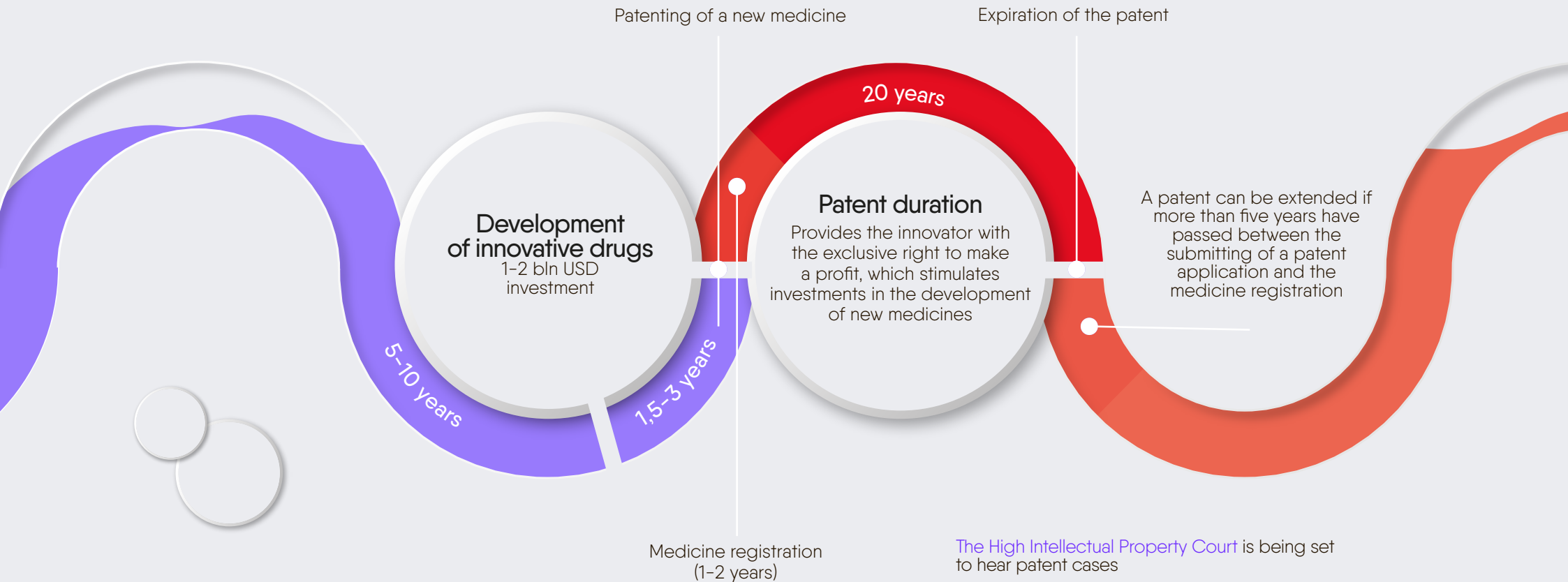
- Digitisation of some registration processes over the last two years has **accelerated** the registration process by one month on average digitisation
- Complete** the digitisation of the entire registration process that will speed it up for another three months. Accordingly, it will accelerate citizens' access to new medicines
- Improving the visualisation system, informativeness of the SEC website and launching new communication channels (Telegram) has significantly **simplified** the process of medicine registration digitisation of SEC of MOH
- Continue to develop and improve the **visualisation** system that will allow the applicant to monitor the entire registration process remotely and respond quickly if necessary
- Digitisation of the re-registration process allowed to achieve a significant **reduction** in the process by speeding it up by two months digitisation
- Introduce a fully **digital** medicine re-registration mechanism and simplify it to two primary documents: adverse reaction reports and periodic safety reports

PHARMACEUTICAL PATENTS

A pharmaceutical patent is a document certifying the authorship and ownership of a medicinal product

Patent regulation is based on the balance of public interests and the interests of the right holder

Patenting of medicines in Ukraine

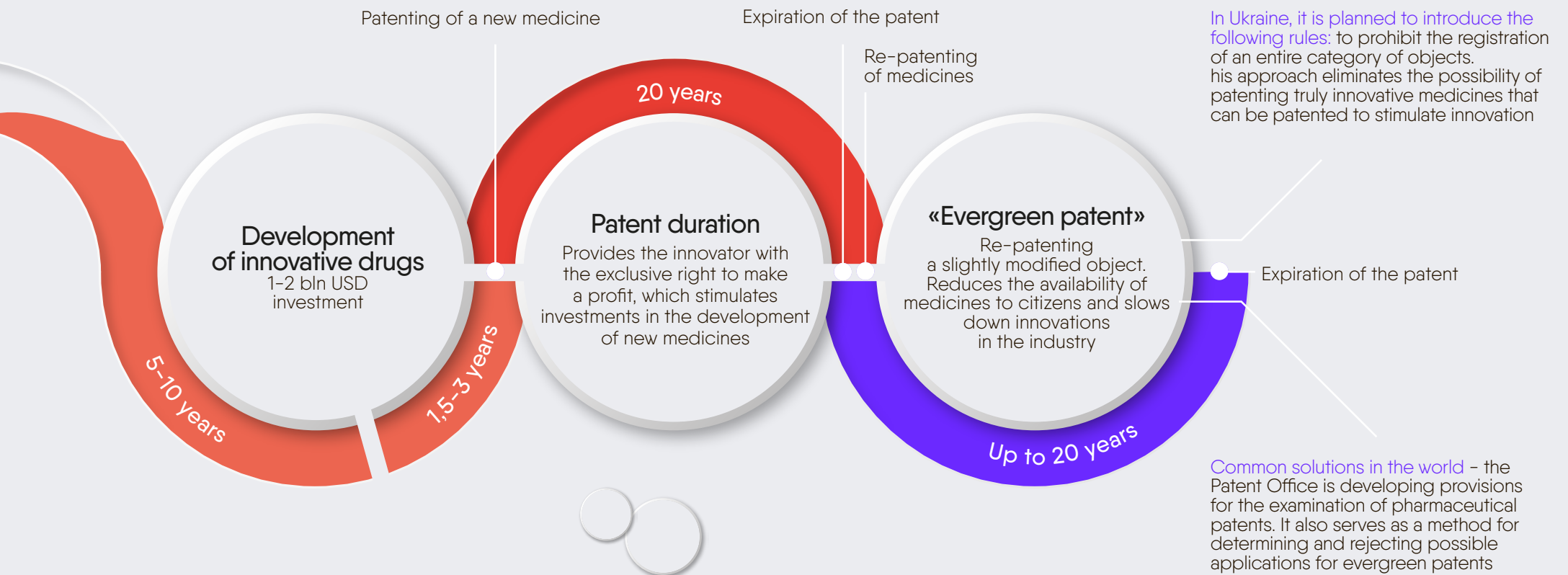


CHALLENGES IN PATENTING OF MEDICINES

The term «**evergreen patents**» refers to the problem of re-patenting similar medicines

In Ukraine, it is planned to introduce rules to avoid the problem of the bill № 2259 dated 11.10.2019

The mechanism of functioning of evergreen patents



INNOVATIVE MEDICINES AND GENERICS

Generic is an unpatented medicine, a copy of the original medication, the active substance of which has expired patent protection

23%

of medicines in Europe are generics in 2016

Advantages of generics

High-quality

Same as the original medicine

Affordable price

Are 20-70% cheaper than the original medicine

Initiation of innovations

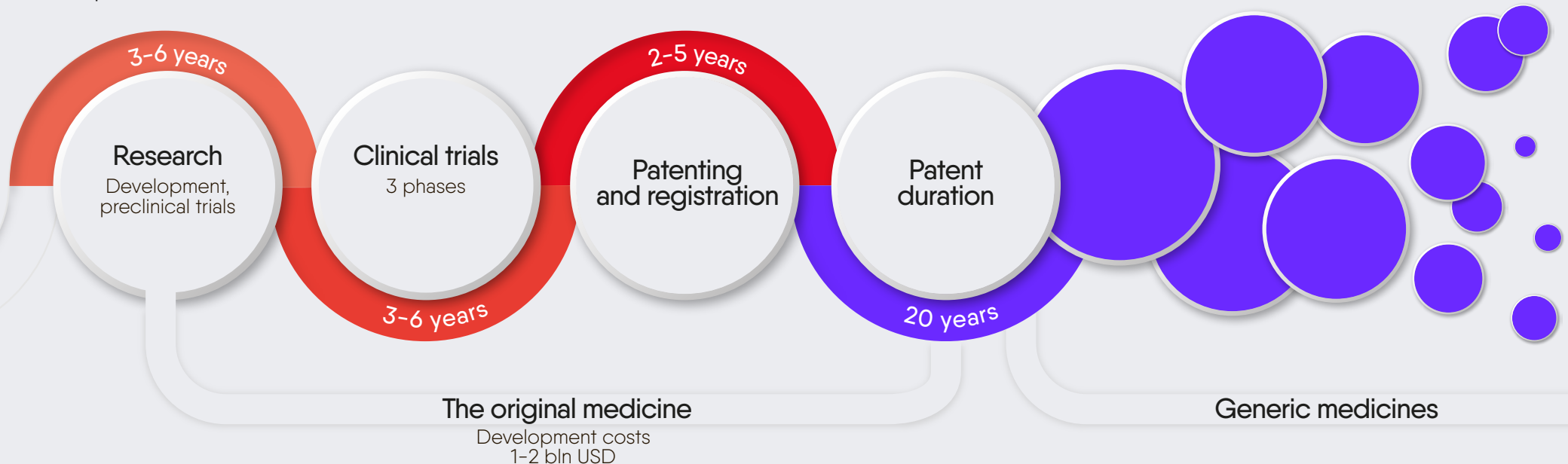
Introduce the latest developments in clinical practice

Stimulate to developments

They force pharmaceutical companies to implement promising innovations more actively

After the expiration of the patent, other companies can produce and sell similar to the original medicine, i.e. **generics**

The life cycle of new medicines, development and sale of a new medicine



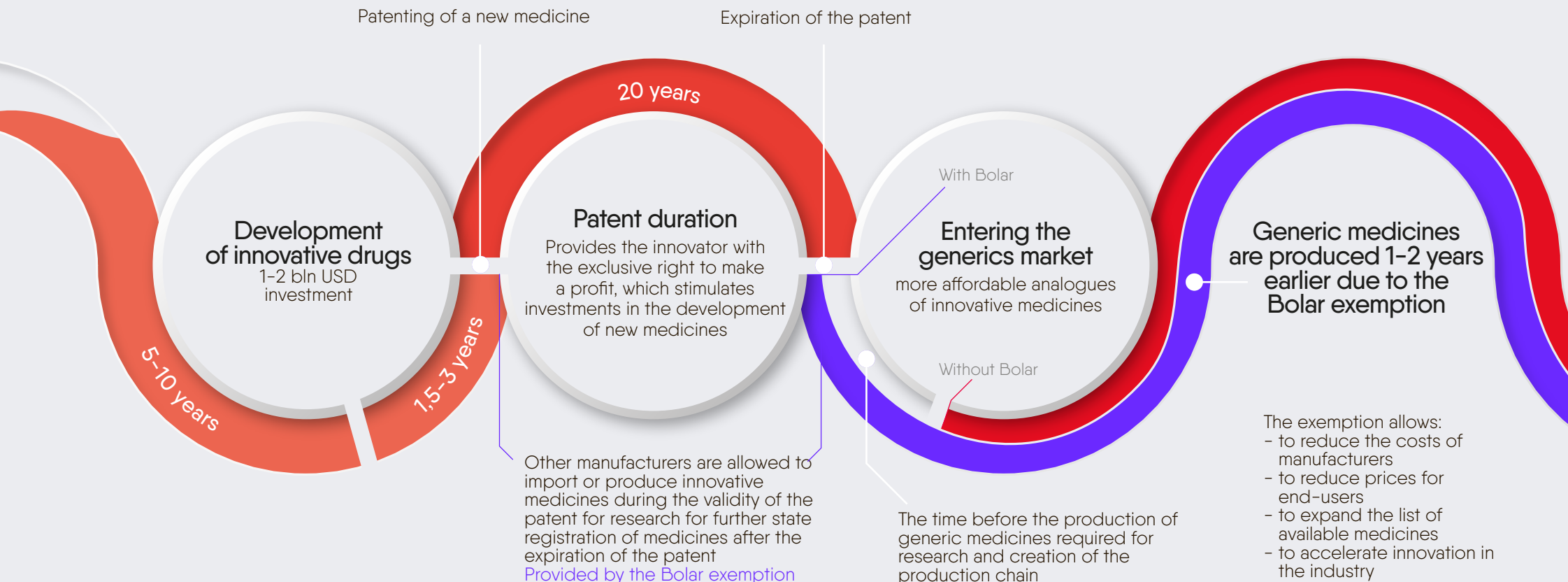
ACCELERATION OF GENERIC PRODUCTION

The **Bolar** exemption accelerates the market entry of generic medicines while protecting the rights of innovative companies

The US Congress first approved it in 1984

Introduced in Ukraine by Bill №2429 of **November 13, 2019**

The mechanism of functioning of the Bolar exemption



GENERICS – THE FIRST STEP OF PHARMACEUTICAL INDUSTRY DEVELOPMENT

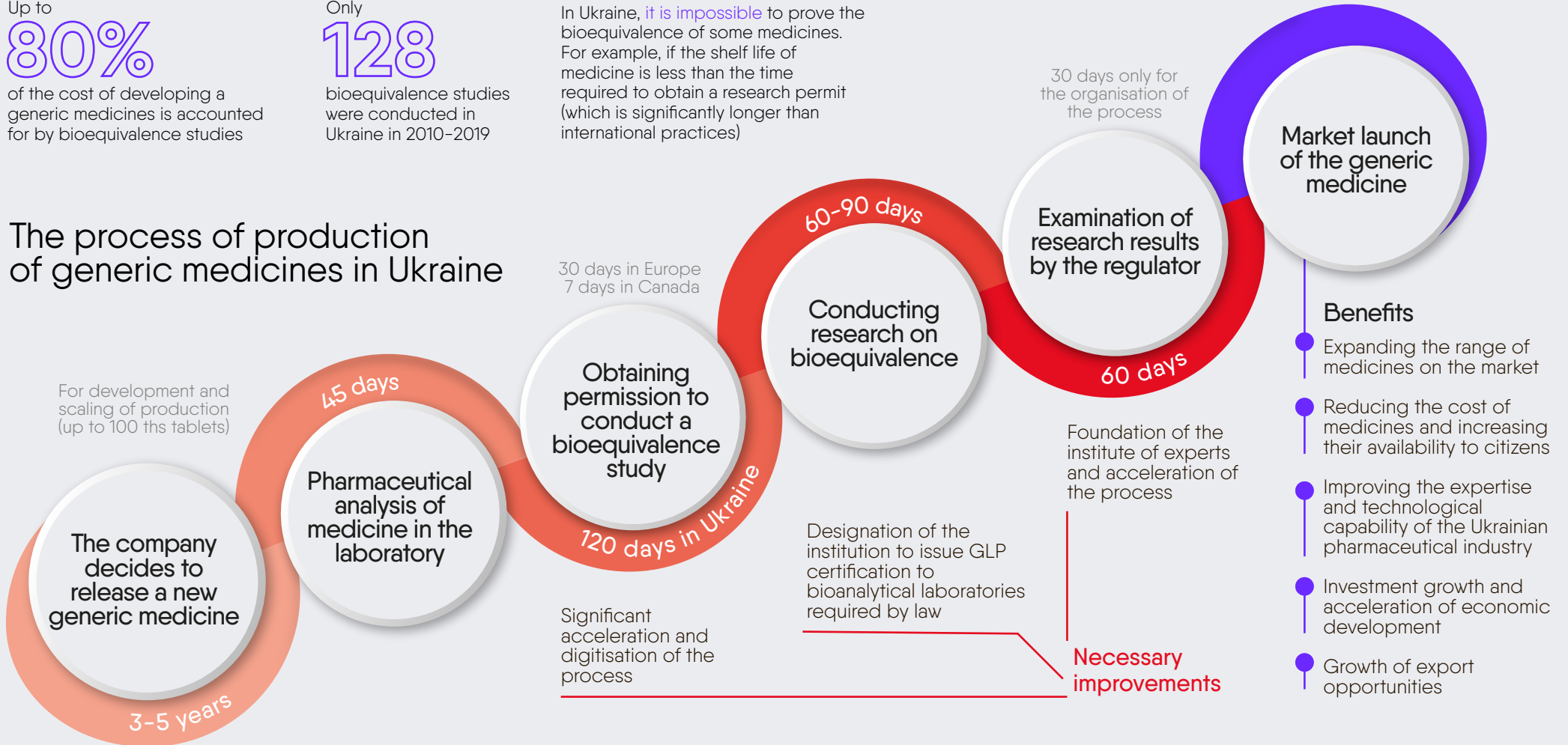
The market of generic medicines is a highly competitive segment of pharmaceutical production, where the speed of permitting processes is vital for development. The only way to enter the market of generic medicines is to prove bioequivalence with innovative medicines

Up to
80%
of the cost of developing a generic medicines is accounted for by bioequivalence studies

Only
128
bioequivalence studies were conducted in Ukraine in 2010–2019

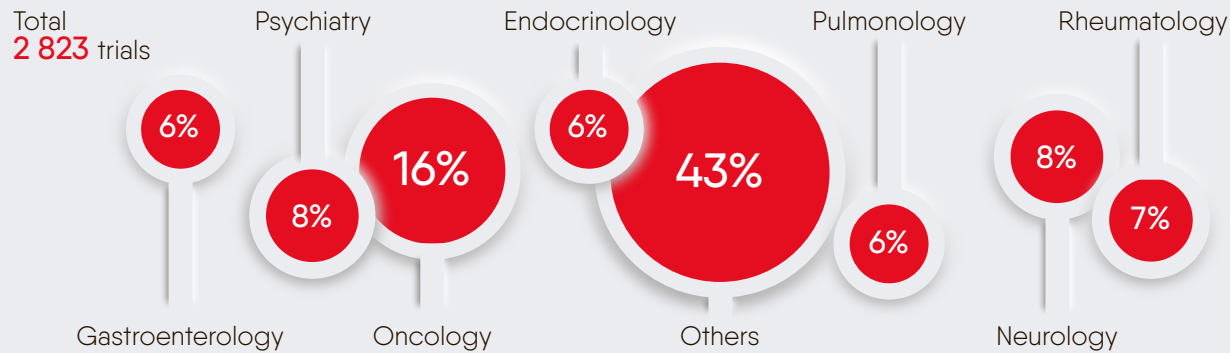
In Ukraine, *it is impossible* to prove the bioequivalence of some medicines. For example, if the shelf life of medicine is less than the time required to obtain a research permit (which is significantly longer than international practices)

The process of production of generic medicines in Ukraine



CLINICAL TRIALS

The structure of clinical trials in Ukraine by profile
as of 03.06.2020, %



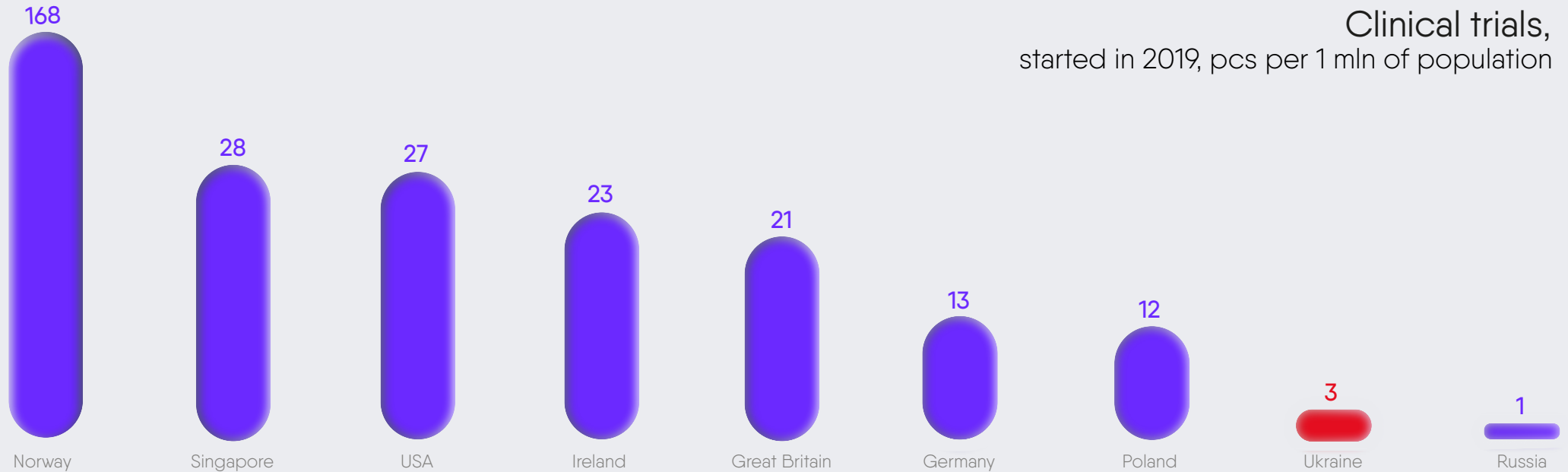
Clinical trials are



the opportunity to receive innovative treatment free of charge for patients



the opportunity to confirm the effectiveness and safety of a new medicine for manufacturers



PHARMACY TRENDS

HEALTHCARE SYSTEMS

Healthcare funding schemes and amounts, 2017, ths USD PPP per person



The role of insurance mechanisms in the healthcare system

Insurance mechanisms are fundamental in the healthcare systems of developed countries

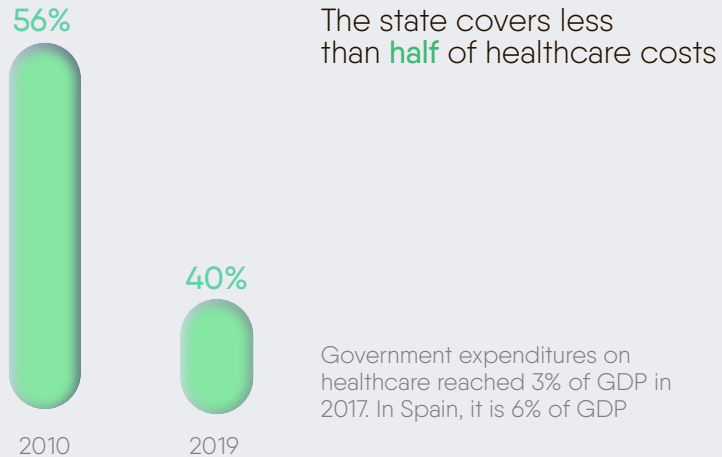
Insurance allows you to meet the two main requirements of the healthcare system simultaneously:

to accumulate the necessary resources, rationally distributing them

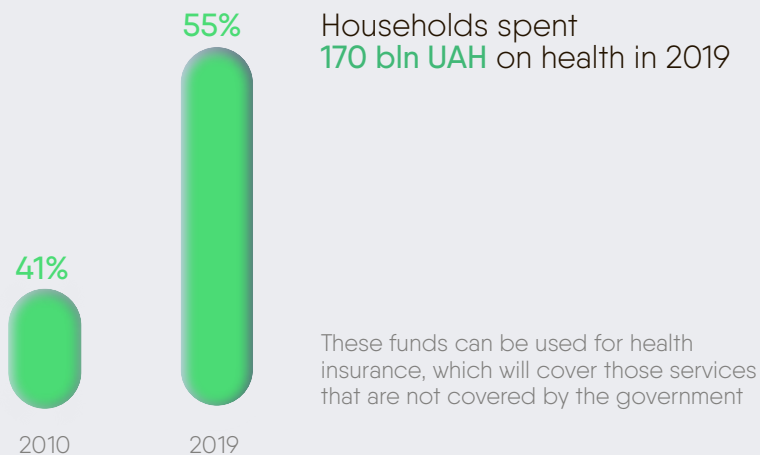
ensure the highest quality and efficiency of services at the expense of available resources (by increasing competition)

HEALTHCARE IN UKRAINE

Share of government expenditures on healthcare

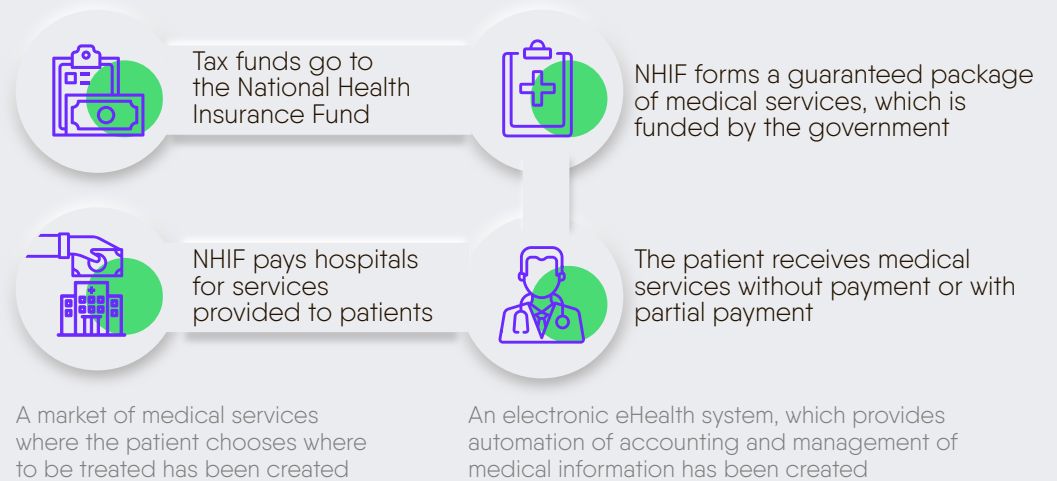


Share of household expenditures on health

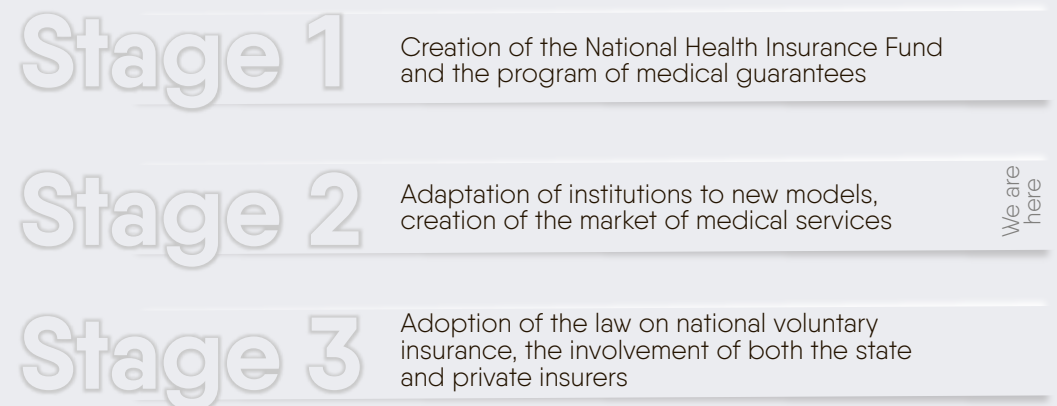


Source: SSC of Ukraine, Cabinet of Ministers of Ukraine, Alexander Torgun, Worldb

Medical reform in Ukraine



3 stages of reform if Ukraine leaves by Spanish medicine



AVAILABILITY OF MEDICINES

10.7
bln UAH

Hospital supplies, 2019
Procurement of medicines
for medical institutions

111
mln pcs

Since 2016, procurement under all centralised programs has been transferred to international organisations

The structure of supplies of medicines to medical institutions

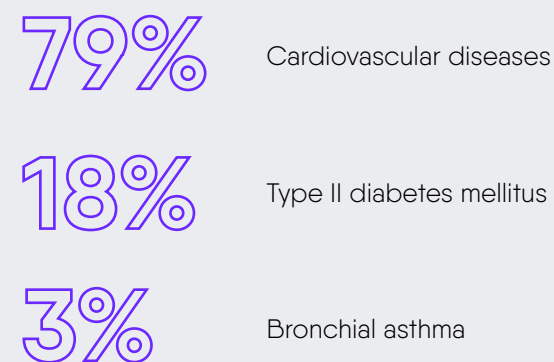


Affordable Medicines Program Reimbursement, bln UAH

«Affordable Medicines» is the government's program for full or partial reimbursement of the cost of medicines



Distribution of paid prescriptions according to the program, 2019



SERIALISATION MANUFACTURING

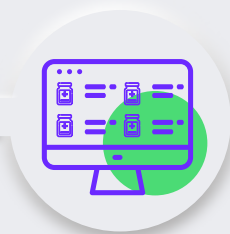
Uncontrolled medicine trafficking
leads to counterfeit

According to the WHO, every tenth medicine
in developing countries is a counterfeit

Serialisation Manufacturing is



Labelling of medicine
packaging



Inclusion of them in the state system
of monitoring the circulation of medicines

It will help



The consumer

To get original and safe medicine



The manufacturer

To protect products from counterfeiting
and increase exports



The State

Monitor medicine circulation and increase
public confidence in medicines

The concept of implementation of the state policy on prevention of falsification of medicines

Legislative regulation

Creation of a state system for
monitoring medicine circulation

10 companies label medicines
approved by the Ministry of Health

Expanding the list of
medicines that are labelled

Mandatory labelling and monitoring
of all types of medicines

I. Pilot project

II. Expansion

III. Implementation

CONTRACT MANUFACTURING

Contract manufacturing is an agreement under which the production line of a pharmaceutical company produces products of another company

What's in it

Company-tenant

Produces medicines without creating production facilities

Rents production facilities at a lower cost

Leases production facilities with unique technologies

Manufacturer

Earns on capacity without developing new medicines

Produces medications without a cycle of development and research

The role of the contract production in the total production of medicines in the world, % and bln US

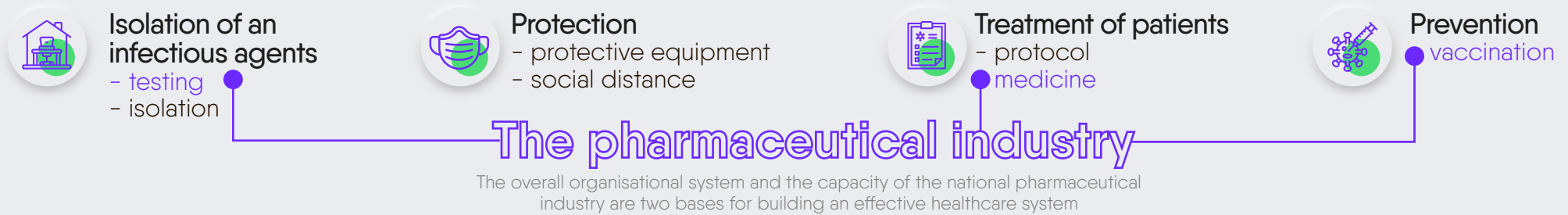


Conditions for the development of contract manufacturing in Ukraine:

- growth of the national market
- improvement of legislation in the field of pharmaceutical production
- government orientation on the development of national pharmaceutical production
- development of unique technologies in the production of medicines

COVID-19 CHALLENGE AND THE ROLE OF THE PHARMACEUTICAL INDUSTRY

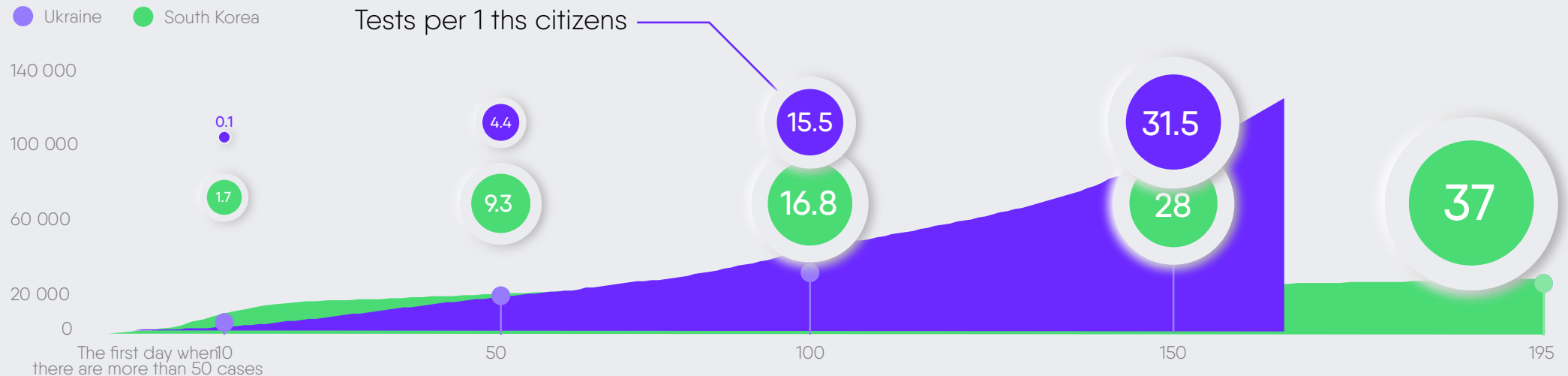
An infectious disease control system



Distribution of COVID-19 and its detection, the number of reported cases from the first day when there are more than 50 cases

Rapid detection and isolation of the disease. The first and most effective step in the spread of infection. The ability of the pharmaceutical industry is the basis for the rapid setup and scaling of test production

Testing in Ukraine was significantly delayed at the beginning due to both inefficient management and legislative barriers to the development of the pharmaceutical industry in Ukraine



INNOVATIONS IN A PANDEMIC CONDITION

The pandemic has prompted innovations

Before



You go to the hospital



You stand in line for a doctor

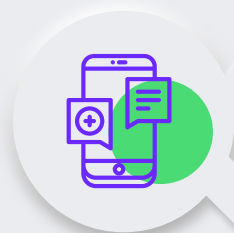


You get a prescription



You go to the pharmacy and buy prescription medicines

Now



Telemedicine

Consultations without visits

On the website of the electronic medical system, you consult a doctor online or make an appointment



Electronic queue

You come to the doctor for a particular time and get a prescription



E-prescription

Helps to stay at home

You receive an electronic prescription for the «Available Medicines» program



Delivery of medicines by post became possible in quarantine

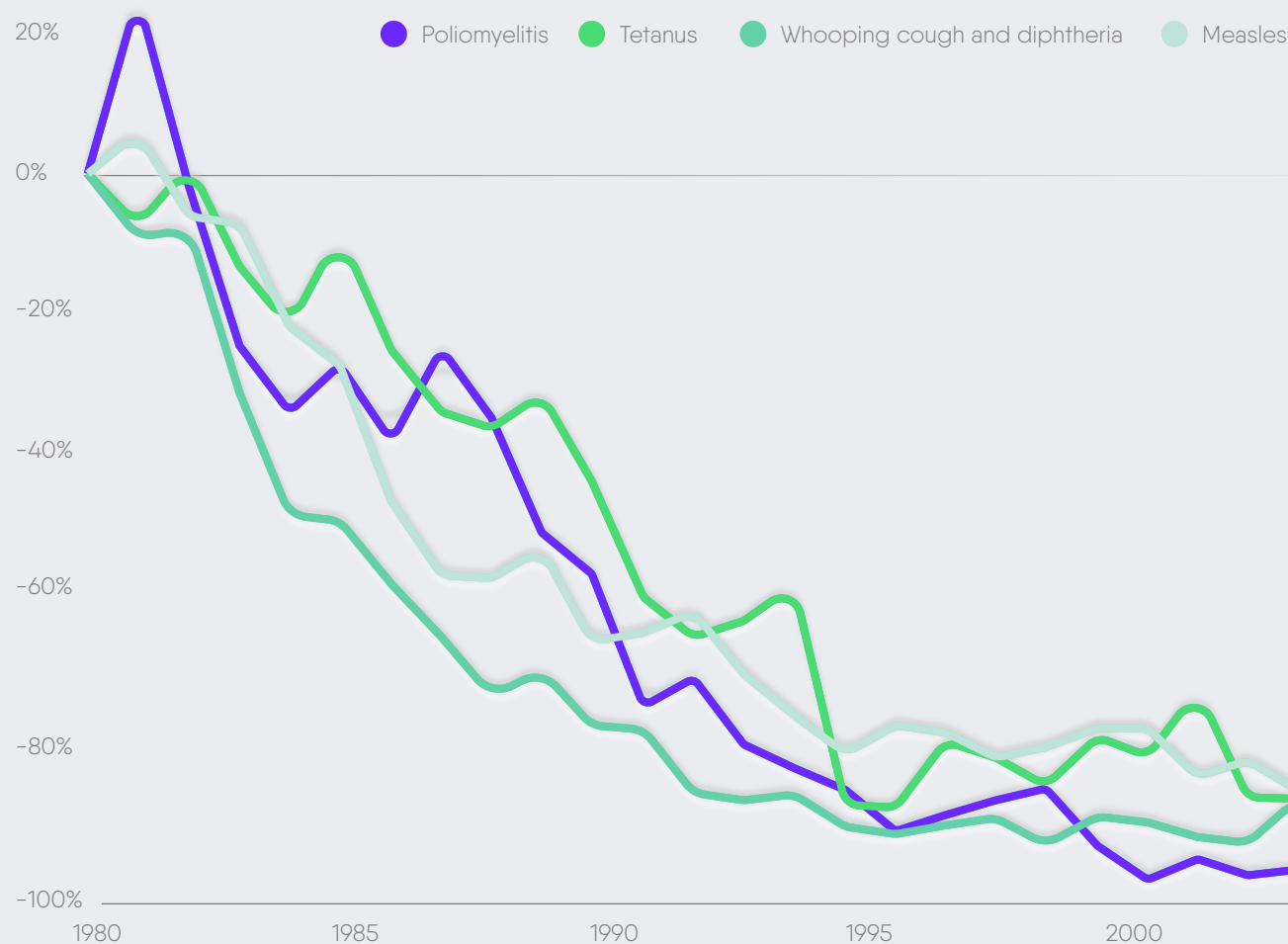
You order medicine online



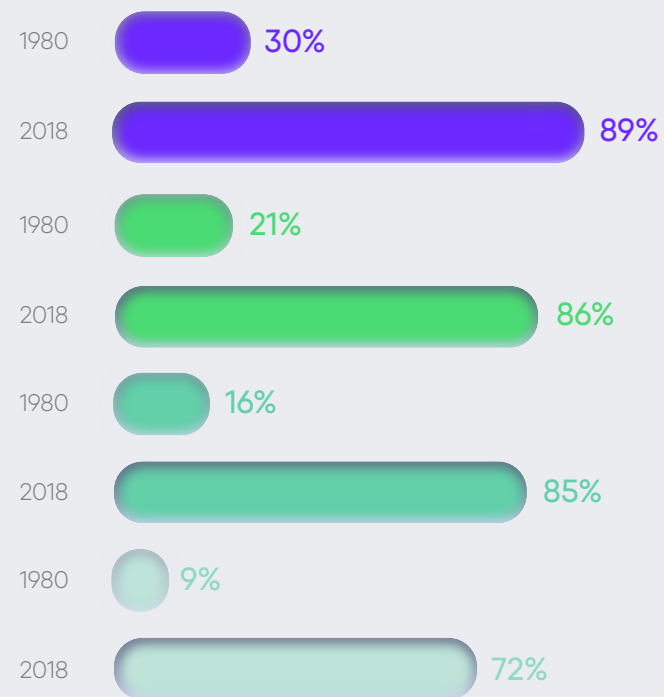
You go to the pharmacy and buy prescription medicines

VACCINATION - THE BASIS OF FIGHTING INFECTIONS

Change in the number of cases compared to 1980, %



Vaccination of the target group*, %



Source: WHO

*a group of people to be vaccinated with a specific vaccine

SOURCES

- BOO3
- World Health Organization (WHO)
- Darnitsa
- State Statistics Service of Ukraine (SSC of Ukraine)
- The State Expert Center of the Ministry of Health of Ukraine, PE (SEC of MOH)
- The Law of Ukraine "On medicinal products"
- Cabinet of Ministers of Ukraine
the Ministry of the Healthcare of Ukraine
- Order of the Ministry of Health of Ukraine, No. 690 "About approval of the Procedure for carrying out clinical testing of medicines and examinations of materials of clinical testing and Standard regulations on the commissions on questions of ethics"
- Order of the Cabinet of Ministers of Ukraine №301-p "On approval of the Concept of implementation of the state policy on prevention of falsification of medicines and approval of the plan of measures for its implementation"
- Order of the Ministry of Health of Ukraine of 26.08.2005, No. 426 "On approval of the procedure for the examination of the materials for medicinal products which are submitted for the state registration (re-registration), as well as for the examination of materials on changes to registration materials during the validity of the Registration Certificate"
- Order of the Ministry of Health of Ukraine, No. 460 "About modification of the Procedure for conducting examination of registration materials on medicines which move on state registration (re-registration), and also examinations of materials about modification of registration materials throughout action of the registration certificate and approval of the Procedure for test of the materials enclosed to the application for state registration of separate medicines concerning their amount"
- the National Health Insurance Fund
- Alexander Torgun
- Decree of the Cabinet of Ministers of Ukraine of 26.05.2005, No. 376 "On approval of the procedure for state registration (re-registration) of medicines and fees for their state registration (re-registration)"
- School of evidence-based medicine
- Apteka Weekly
 1. Apteka Weekly № 3 (824) January 23, 2012
 2. Apteka Weekly № 8 (829) February 27, 2012
 3. Apteka Weekly № 4 (875) January 28, 2013
 4. Apteka Weekly № 5 (926) February 3, 2014
 5. Apteka Weekly № 13 (1034) April 11, 2016
 6. Apteka Weekly № 2 (1073) January 23, 2017
 7. Apteka Weekly № 2 (1173) January 21, 2019
 8. Apteka Weekly № 4 (1225) February 3, 2020
 9. Apteka Weekly № 6 (1227) February 17, 2020
 10. Apteka Weekly № 9 (1230) March 9, 2020
- Aequo
- ClinicalTrials.gov
- ECDC
- EFPIA
- EudraGMDP
- Evaluate
- FTC
- IFPMA
- OECD
- Our World In Data
- Statista
- Results Healthcare
- WEF

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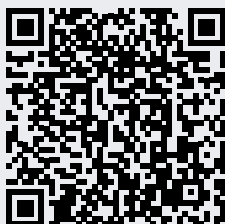
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