

INFOGRAPHIC REPORT

PHARMACEUTICAL INDUSTRY IN UKRAINE

INTRODUCTION

Why did we create this Report?

Citizens' health is one of the key indicators of the state's success. High-quality medicines are one of the main factors of a long and healthy life. The steady development of technologies in this area can radically transform the process of the treatment itself and improve the general standards of living.

We designed this guide in order to explain how the pharmaceutical industry in Ukraine functions — an innovative, dynamic, non-monopolized industry that creates high value-added products. Over the past three years, this industry has made significant progress: companies have received European manufacturing certificates, the intensity of investment remains one of the highest among other industries, while investment itself is increasing. The structure of the market also changes, the share of prescription and high-priced medicines increases, while the overall market volume is growing.

The pharmaceutical industry of Ukraine increases the availability of advanced medicines for citizens and serves as the booster of technological development of the economy.

Content

PHARMACEUTICAL INDUSTRY IN UKRAINE:

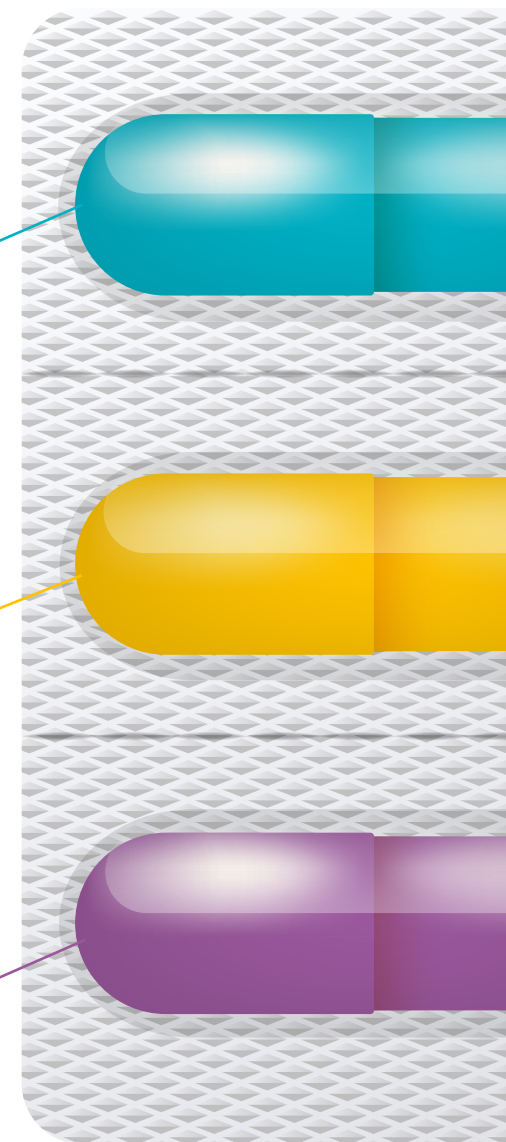
- role in economy
- investment
- manufacturers
- clinical trials
- registration of medicines

PHARMACEUTICAL MARKET OF UKRAINE:

- pharmaceutical consumption
- market dynamics
- market structure
- leading companies
- launches
- pharmaceutical retail chain

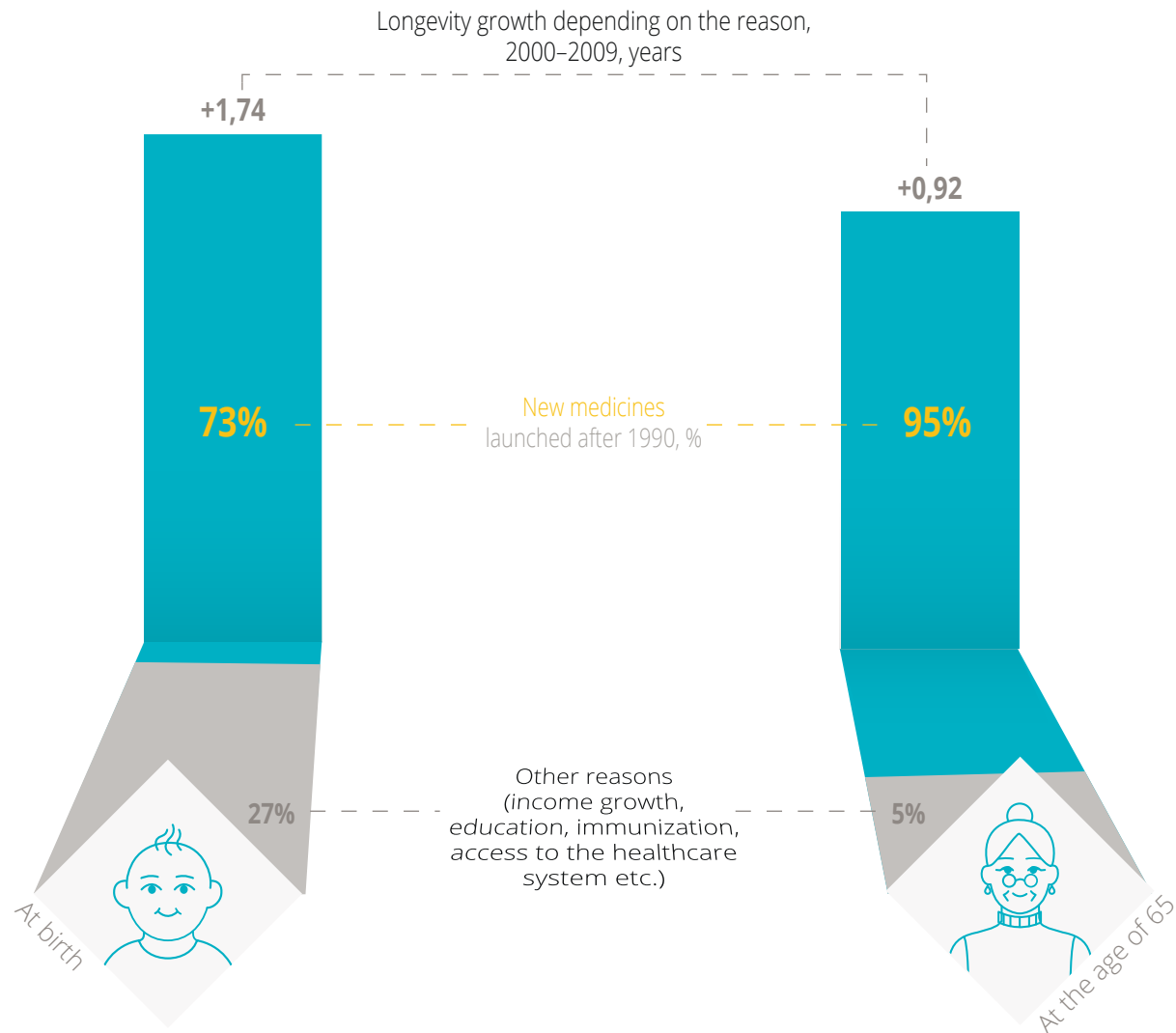
GLOBAL PHARMACEUTICAL MARKET AND INTERNATIONAL TRADE

- global market dynamics
- biopharmaceutics
- markets regulation
- healthcare system
- international trade



PHARMACEUTICAL INNOVATIONS AND LONGEVITY

New medicines are the basis for life expectancy increase





HARMACEUTICAL INDUSTRY **IN UKRAINE**

ROLE OF PHARMACEUTICAL INDUSTRY IN ECONOMY

In Employment,

2018, % of the total employees

pharmacy workers
24 ths

0,15%

In GDP,

2017, % of GDP

24,6 bln UAH
of value added

0,83%

In Import,

2018, % of total import

1 947 bln USD
of import

3,4%

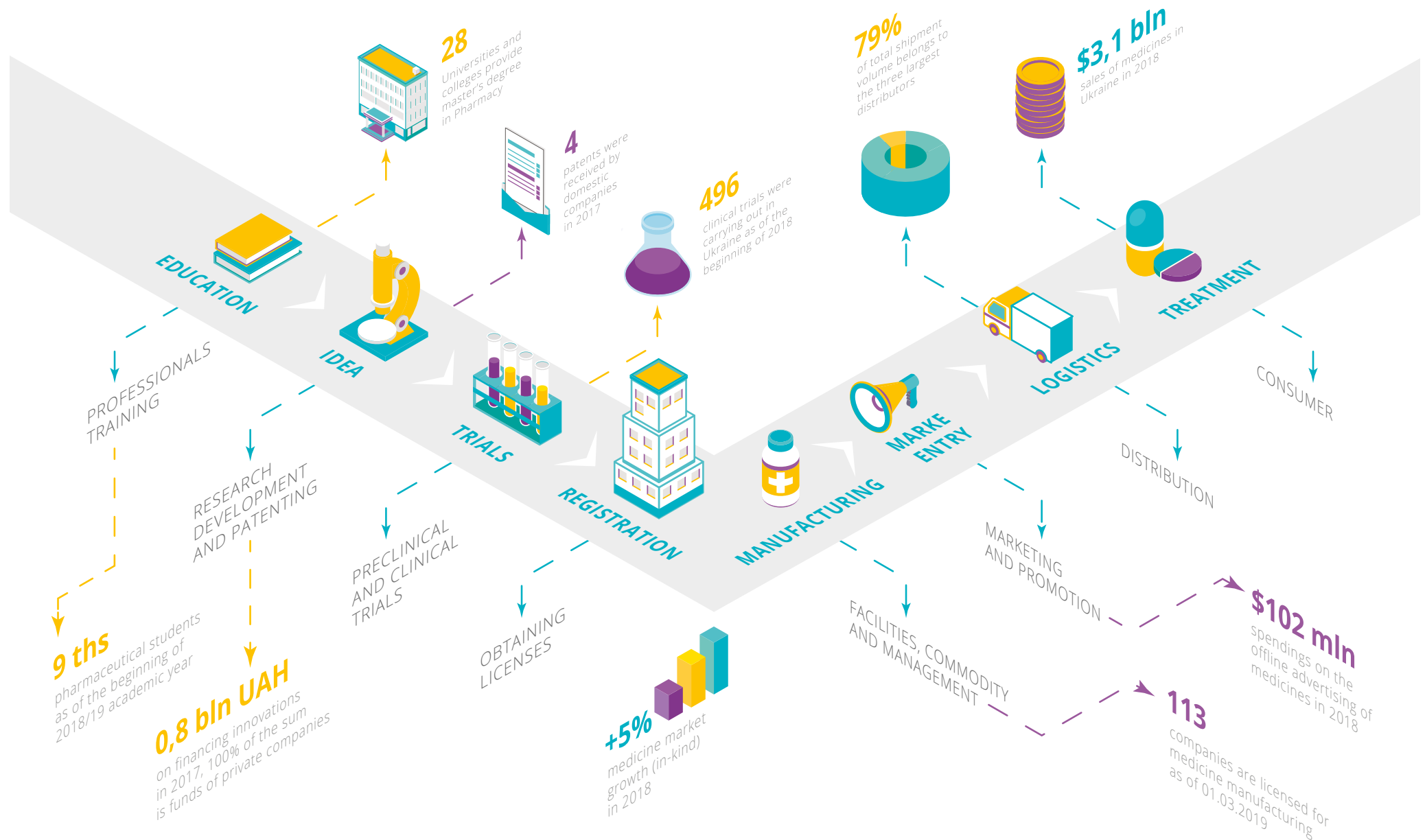
In Export,

2018, % of total export

216 bln USD
of export

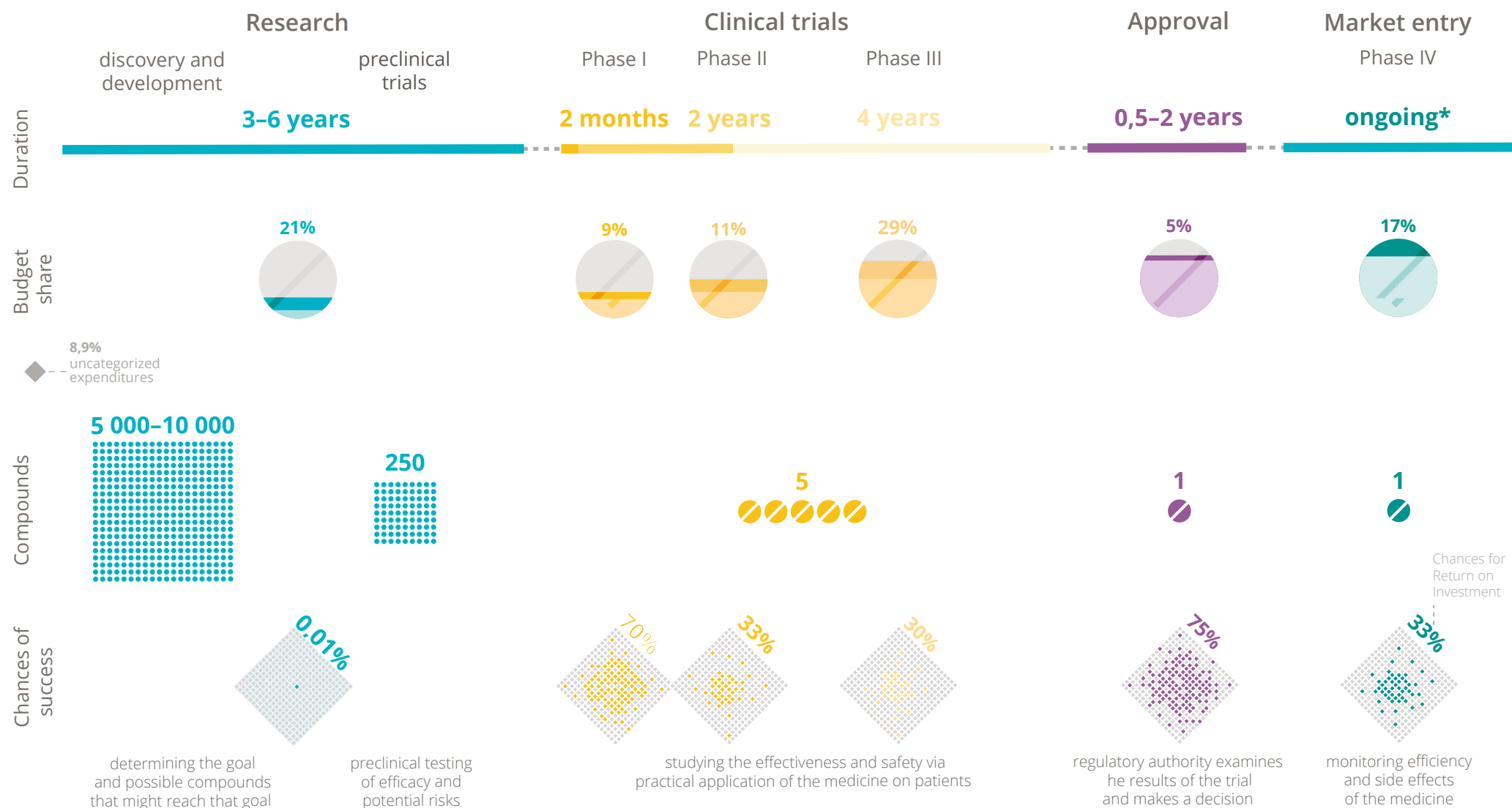
0,46%

MEDICINES: FROM EDUCATION TO TREATMENT



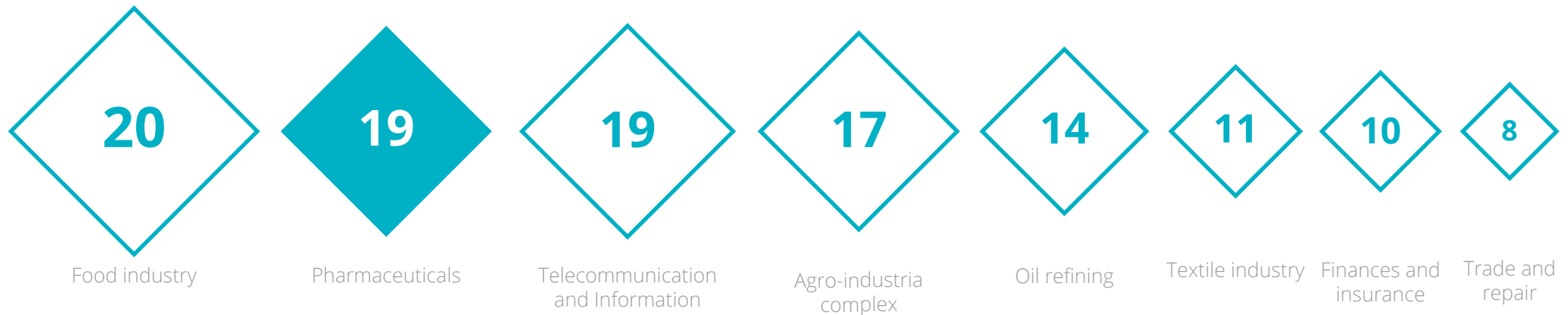
HOW ARE NEW MEDICINES DEVELOPED

Innovative medicines research and development process

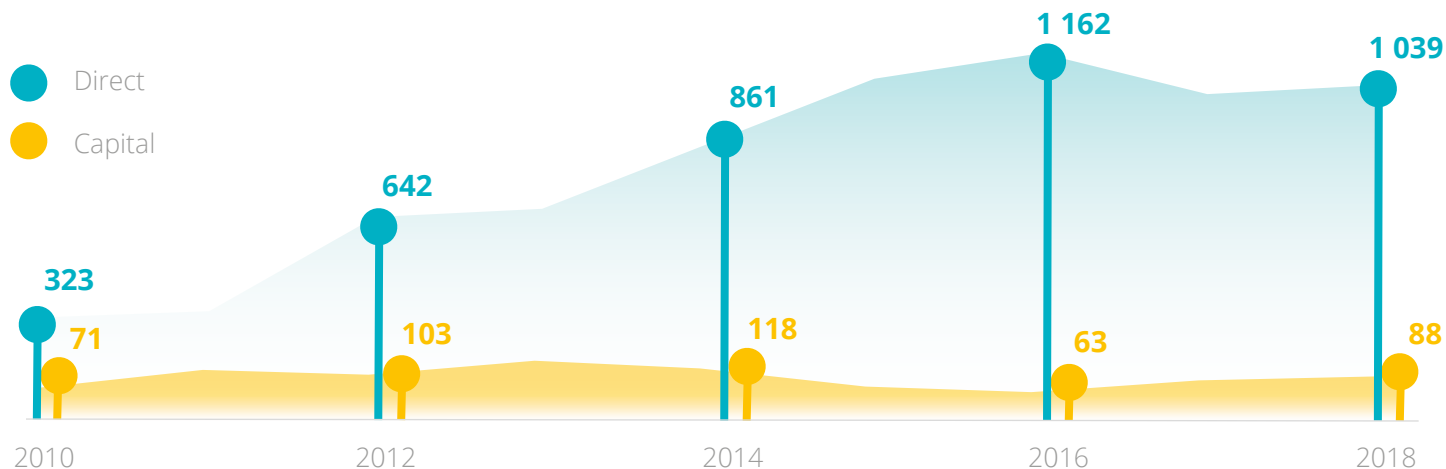


INVESTMENT IN PHARMACEUTICAL INDUSTRY

Average investment intensity by industries,
2015–2017, kopyok of capital investments per 1 UAH of value added



Direct and capital investments,
2010–2018, mln USD*



The volume of investment in the pharmaceutical industry has not recovered to the pre-crisis level yet

However, the intensity of investment is higher than the average in other industries of the Ukrainian economy

PHARMACEUTICAL MANUFACTURERS

Ukrainian companies holding GMP certificate for manufacturing sites from an EU-member state regulatory authority, 2016–2018

2016

- ◆ Borshchahivskiy CPP
- ◆ Farmak
- ◆ Yuria-Pharm

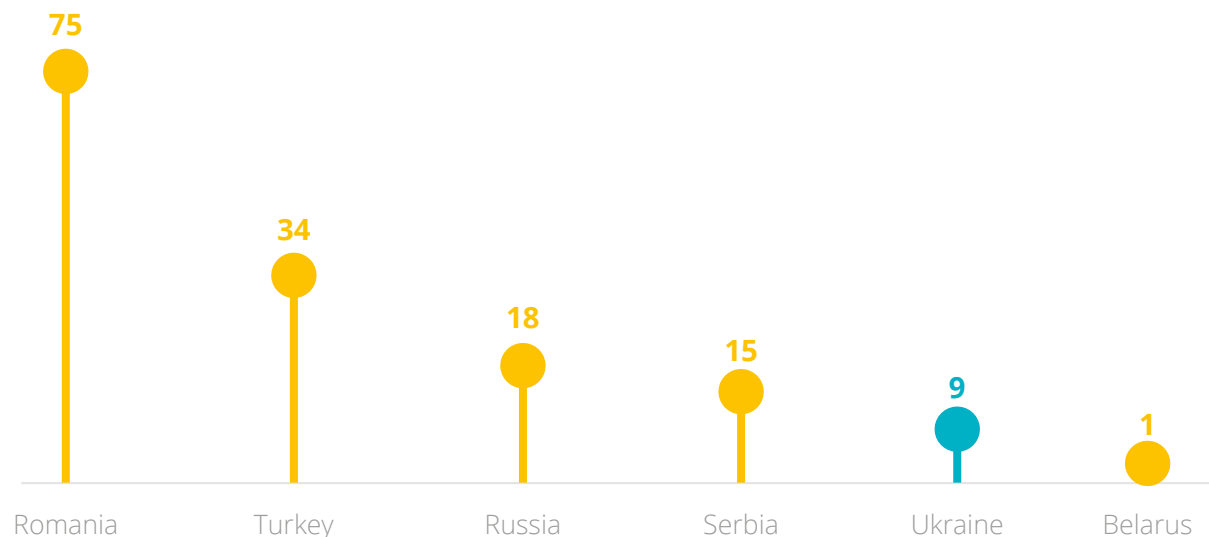
2017

- ◆ Darnitsa
- ◆ Technolog
- ◆ Farmak

2018

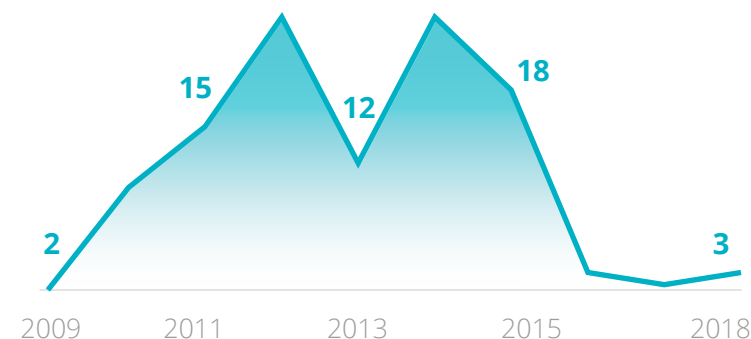
- ◆ Borshchahivskiy CPP
- ◆ Synbias Pharma
- ◆ Ukrvetprompostach

Issued GMP certificates for manufacturing sites from an EU-member state regulatory authority by countries, 2016–2018, pcs



Issued licenses for medicine manufacturing, 2009–2018, pcs (excluding cancelled and expired licenses)

113
valid licenses
for medicine
manufacturing



GMP establishes quality-control standards for medicine manufacturing. GMP certificate, received from an EU member state regulatory authority, is necessary if a company wants to enter the European market

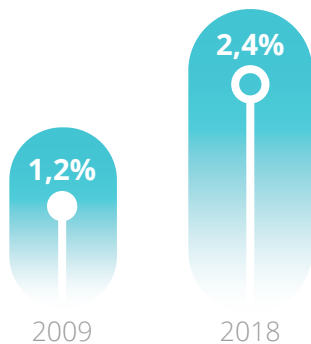
PHARMACEUTICAL MANUFACTURING DEVELOPMENT

Road to innovative pharmaceutical industry in Ukraine

TOP-20 global pharmaceutical companies by origin*, pcs



Share of India in global export of pharmaceutical products, 2009 and 2018, %



Switzerland is a leader in productivity in the life sciences sector, 2016, ths CHF of income per workplace



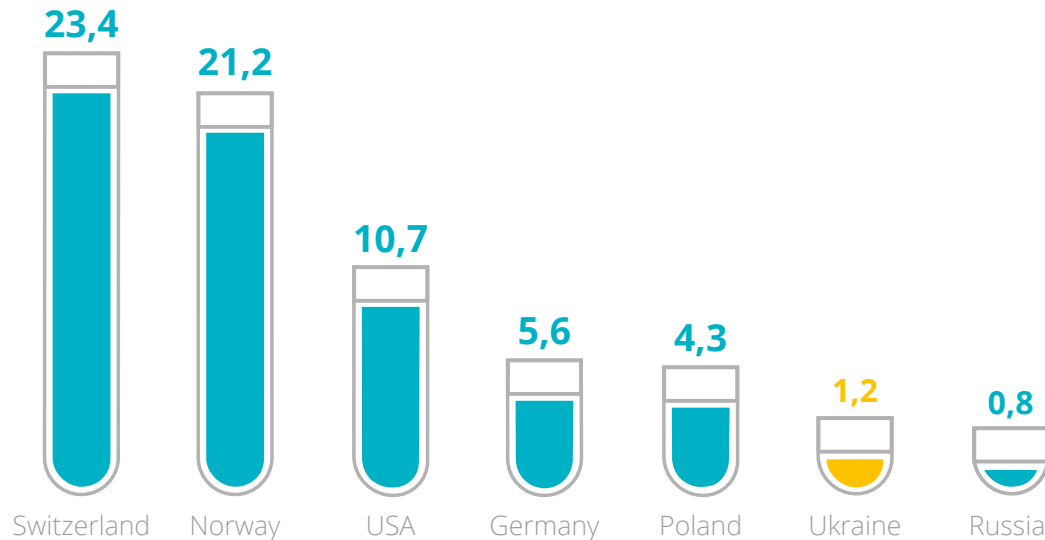
*in terms of prescription medicines sales



CLINICAL TRIALS

Clinical trials,

as of 26.02.2019, pcs per 100 ths of population

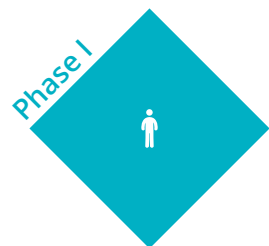


Opportunities provided by clinical trials

- get a free treatment via the newest, yet not registered medicines
 - to patient
 - contribute to scientific progress
- understand the nature of a disease better and find safe ways to treat it
 - to society
 - confirm the effectiveness and safety of a new drug
- implement the best international practices and standards
 - to MOH
 - get investments for technical re-equipment, reduce expenditures

Phases of clinical trials

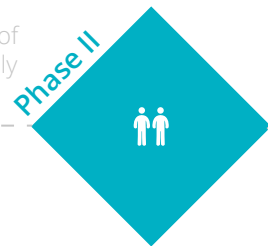
20–80 healthy volunteers



studying of bioavailability, testing safe dose

In Ukraine, participants of clinical trials are paid only during the Phase I

100–300 patients



determination of effective dose, assessment of treatment safety

Thousands of patients with specific diseases



confirmation of the efficacy and safety of a medicine

In Ukraine, 65% of ongoing clinical trials are in Phase III

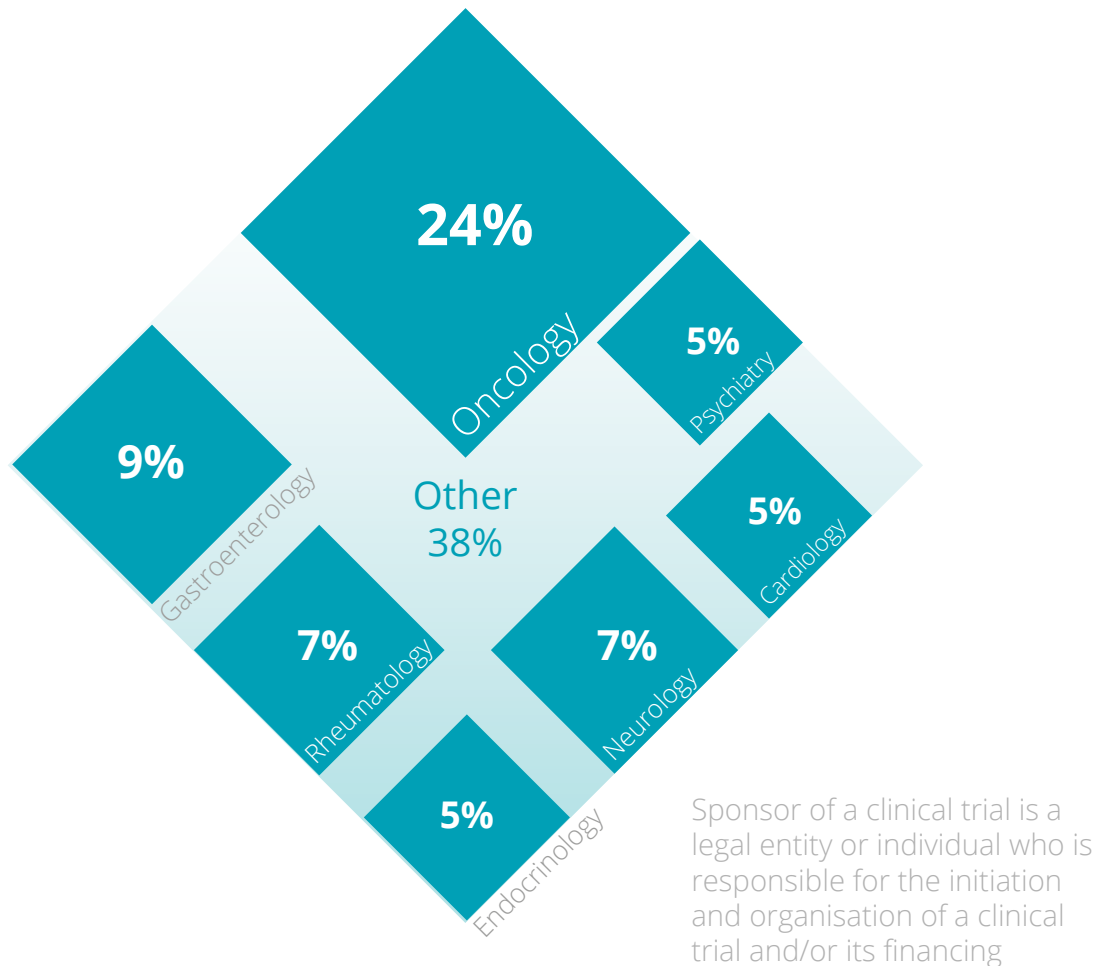
Postmarketing surveillance



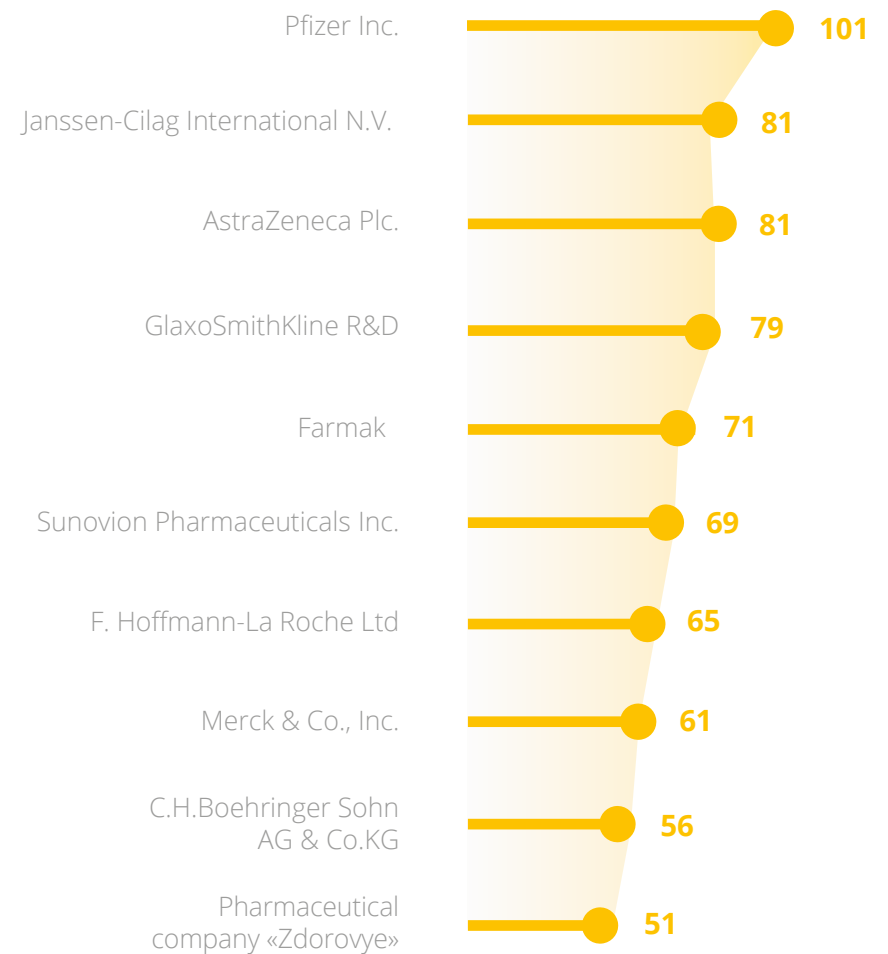
getting additional information about medicine effectiveness, usage and its safeness

CLINICAL TRIALS IN UKRAINE

Structure of clinical trials in Ukraine by the field,
ongoing as of 26.02.2019, %

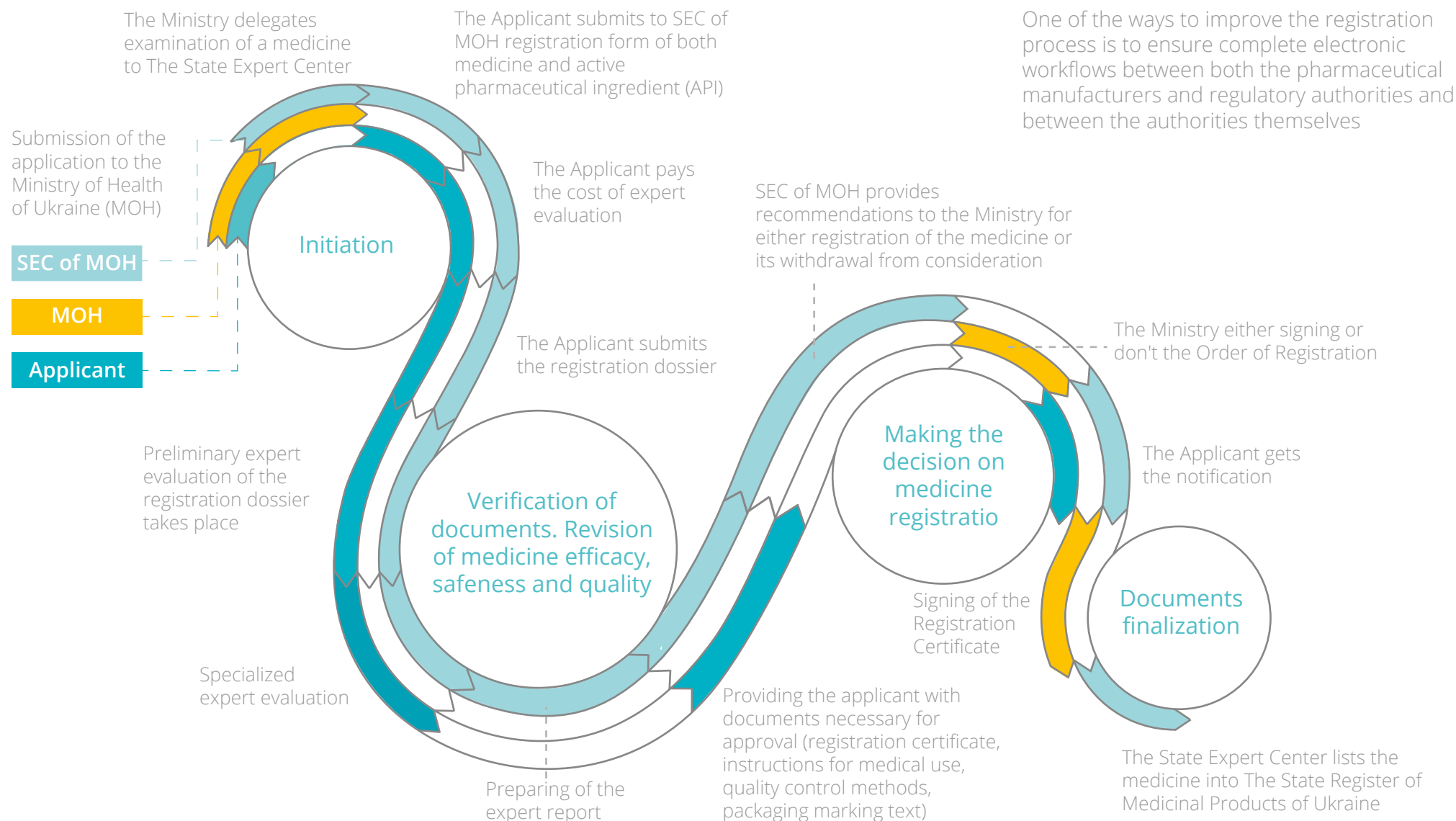


Main sponsors of clinical trials in Ukraine, as of 26.02.2019, the number of approved, initiated, closed, and completed clinical trials *

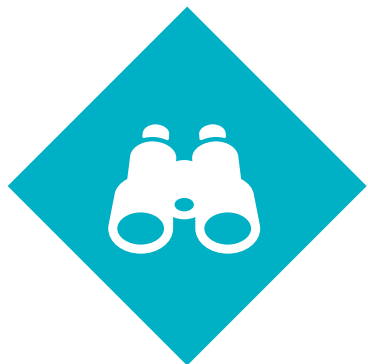


REGISTRATION OF MEDICINES

Process of registration in Ukraine



DISTRIBUTION OF MEDICINES



Why should pharmaceutical companies be concerned about the distribution system?

In order not to violate the competition law, which violation may result in the necessity to change the business model of relations with contractors and in substantial penalties (one of the fines imposed by the AMCU totalled almost UAH70 million)

Who is subject to liability?

producer or importer 
distributor 








Preventive measures to avoid violations:

pharmaceutical companies have an opportunity to have their distribution systems approved by the AMCU by means of obtaining its opinion in the form of informative clarifications

Drugs pricing mechanisms that may constitute a violation

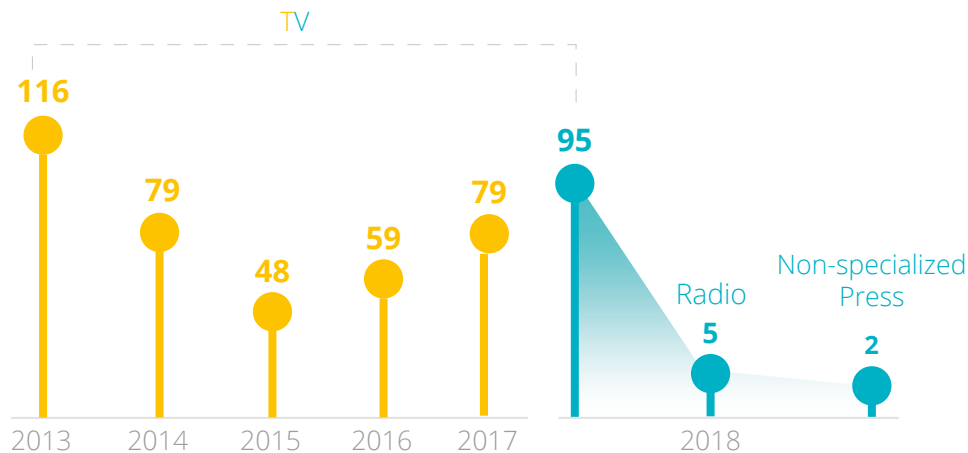


Involving a higher risk level

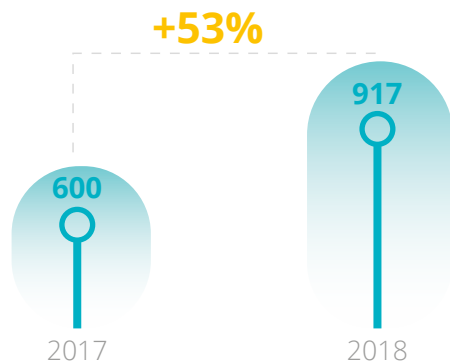
-  Retrospective discounts
-  Individual discounts for certain purchasers
-  A target level for a discount to be granted, which level is specified in monetary indicators
-  Significant purchase volume and a long period of time for granting a discount
-  Combination of several types of discounts or when discounts are granted on specific drugs provided that some other drugs are purchased

ADVERTISEMENT IN PHARMACEUTICAL INDUSTRY

Advertisement by offline channels, mln USD, excluding taxes*

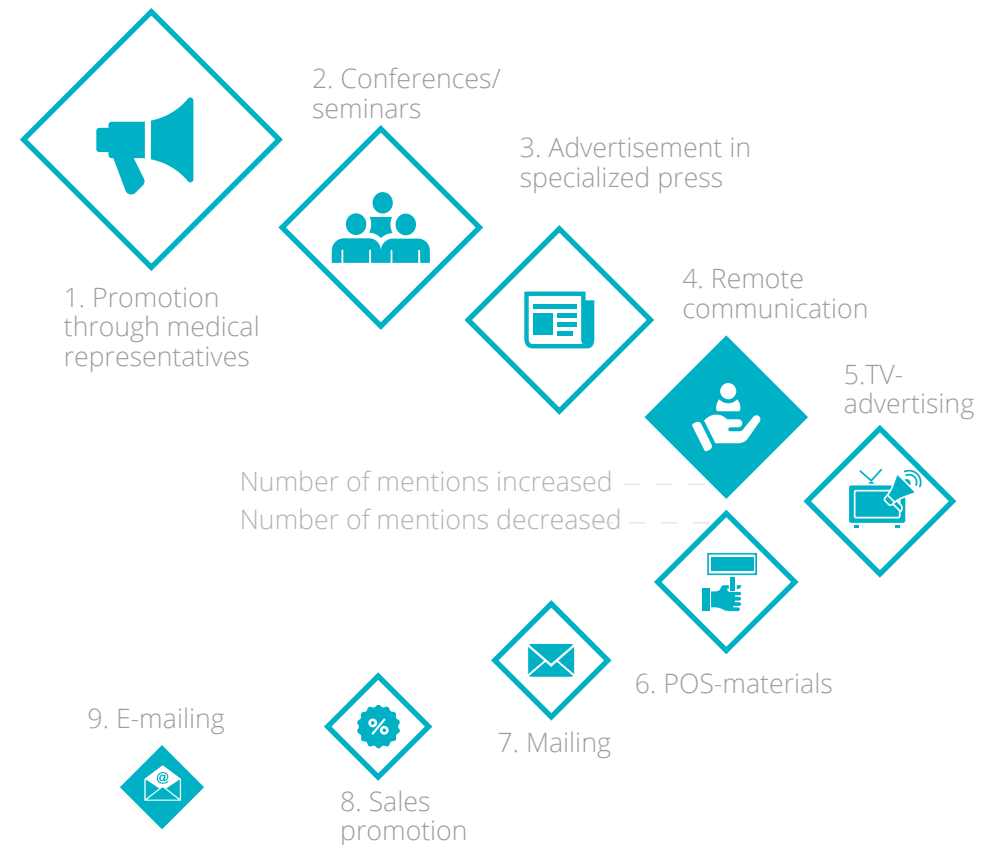


Growth of online advertising, graphics and video, mln appearances**



The multichannel promotion of medicines is actively developing in the pharmaceutical industry. Pharmaceutical companies continue to invest in TV advertising. The main trend is the development and increase of the share of digital channels of promotion

Promotion among experts, based on a survey of former experts in the field of healthcare



ADVERTISING OF MEDICINES: THE ANTITRUST ASPECT

Why should pharmaceutical companies be concerned about the advertising of medicines?

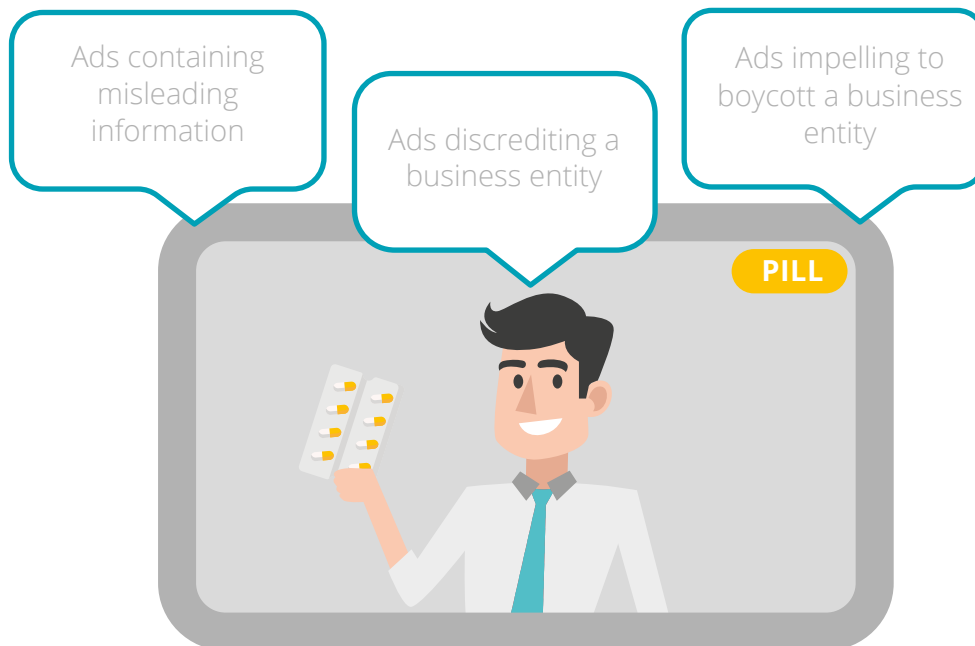
Own medicines

In order not to violate the competition law, which violation may result both in substantial fines and other expenses

Medicines of competitors

In order not to allow the competitors to obtain undue preference on the account of unfair competition

What advertising of medicines is prohibited?



Mechanisms for the protection of rights against unfair competitors

Detection of violations



Filing an application regarding the violation of the laws on protection against unfair competition:

company / consumer / other persons
whose rights are being violated
Initiation of an investigation
by the AMCU on its own initiative



Consideration of the application by the AMCU:

Within 1 year

Expert knowledge and/ or questioning of consumers may be required to confirm/ refute certain arguments



The offence has not been established by the AMCU, the proceedings in case shall be terminated

The offence has been established:

imposition of obligation to stop the violation
imposition of a fine



MANUFACTURING AND MARKET

Value Added

Output of pharmaceutical products

2017, bln UAH (at consumer prices)

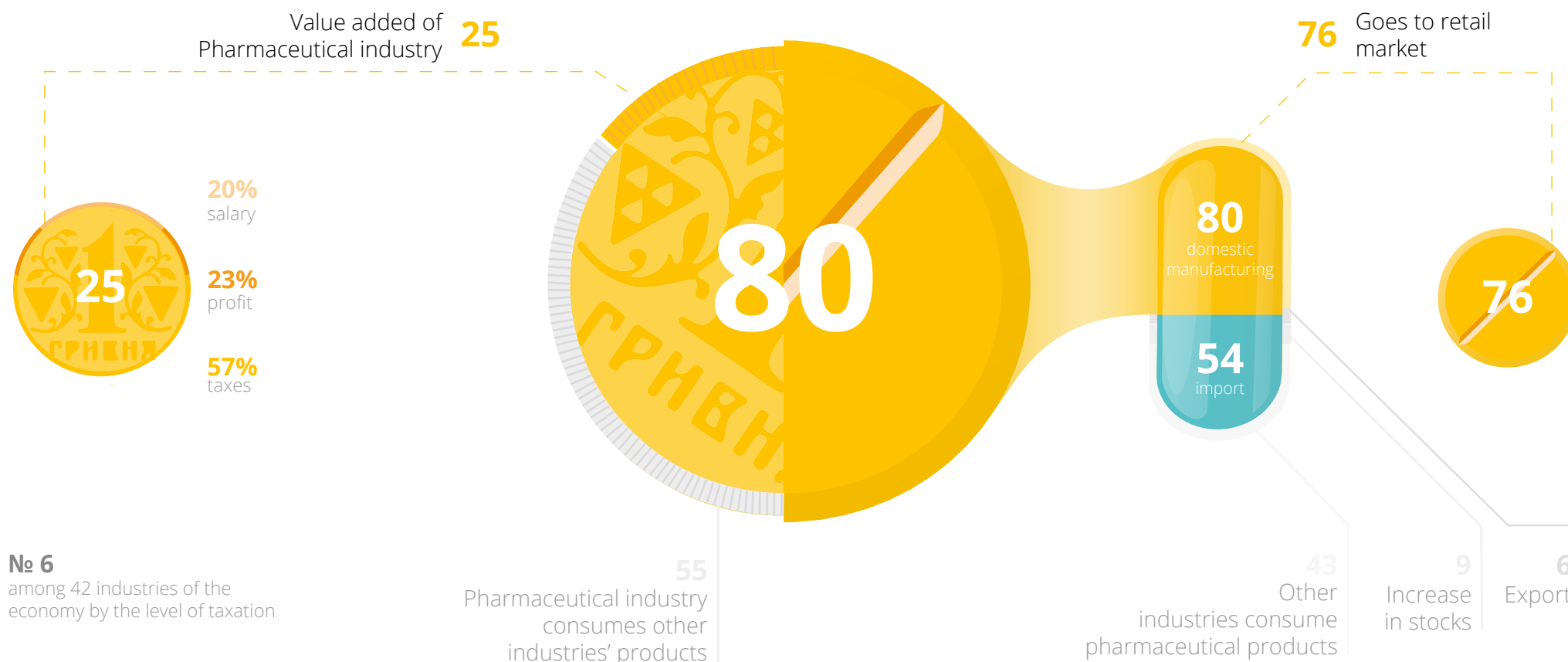
Market

0,8% of GDP

is created
by Pharmaceutical industry

9%

share of pharmaceutical
products in retail turnover



№ 6

among 42 industries of the
economy by the level of taxation

PHARMACEUTICAL MARKET OF UKRAINE

PHARMACEUTICAL CONSUMPTION

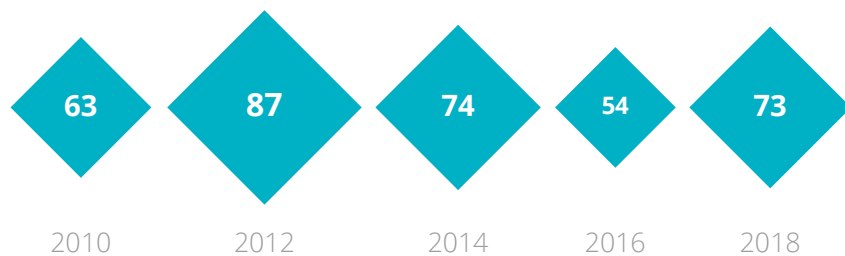
Pharmaceutical consumption by countries,
2017, USD per capita



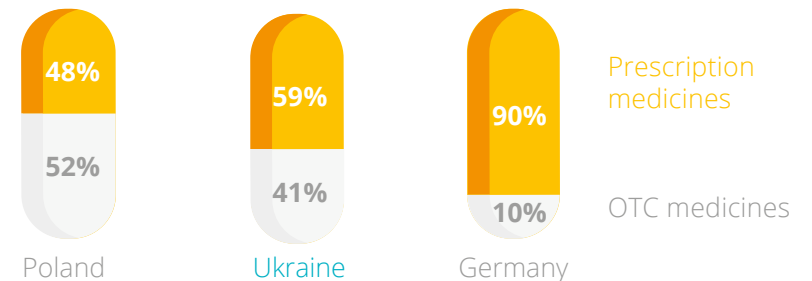
99%

of pharmaceutical expenditures in Ukraine (in the pharmacy retail segment) is out-of-pocket expenditure. In Europe, a significant share of costs is covered by health insurance and government programs*

Pharmaceutical consumption in Ukraine,
2010–2018, USD per capita

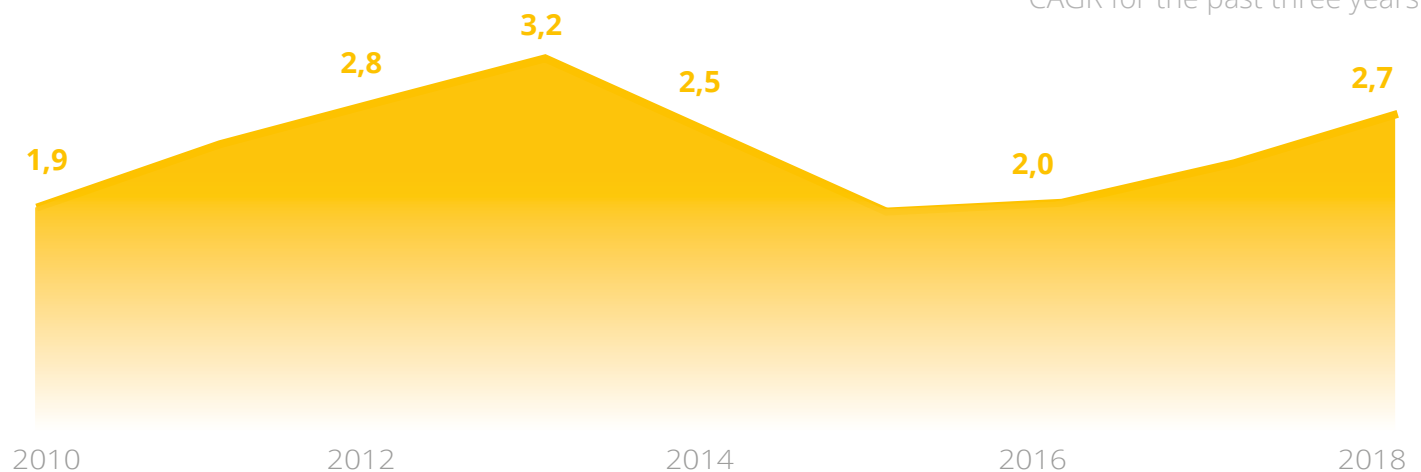


Pharmaceutical consumption structure,
% (money term)**



PHARMACY MARKET DYNAMICS

Pharmacy market,
2010–2018, bln USD



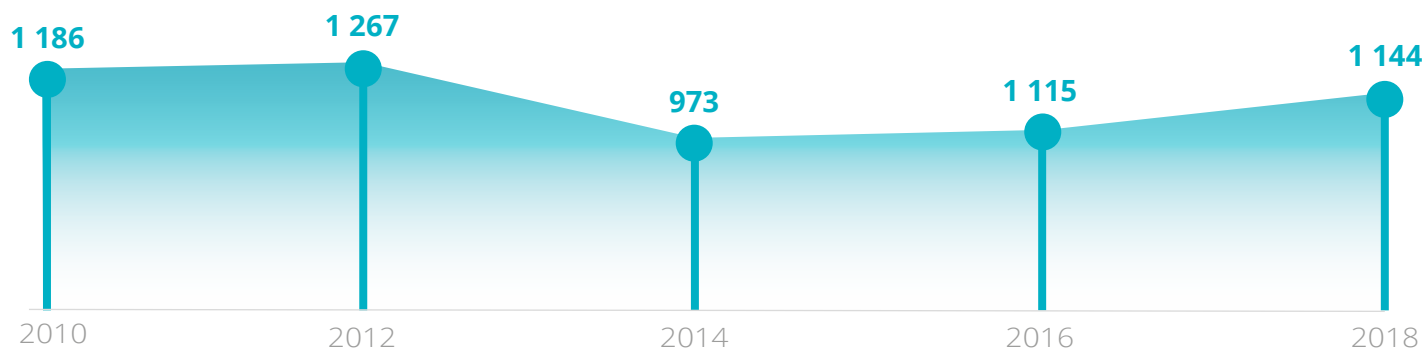
+11%

CAGR for the past three years

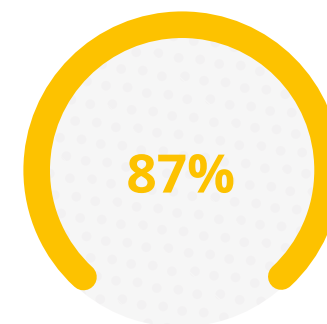
The pharmacy sector is the basis of
Ukraine's pharmaceutical market

Pharmacy segment has been growing four
years in a row, both in-kind and
money term

Pharmacy sales,
2010–2018, mln pc



Share of pharmacy segment
in pharmaceutical market,
2018 p., % (money term)

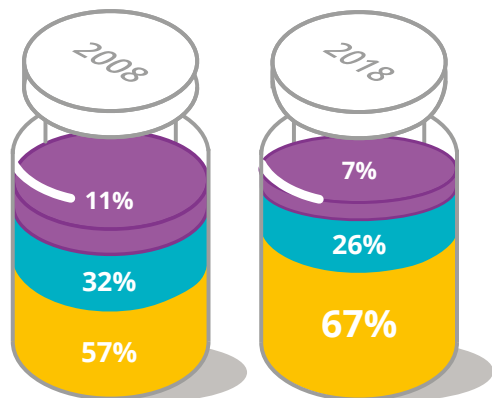


PHARMACY MARKET STRUCTURE

Pharmacy sales split by origin, %



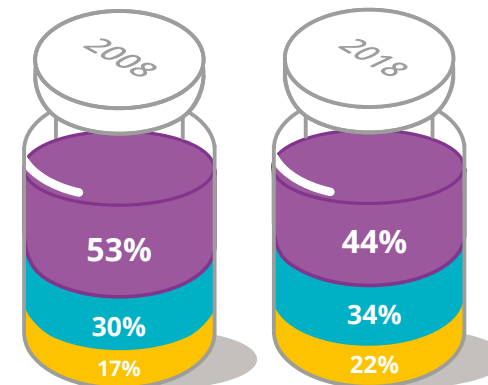
PHARMACY SALES SEGMENTATION



Low-priced

Mid-priced

High-priced

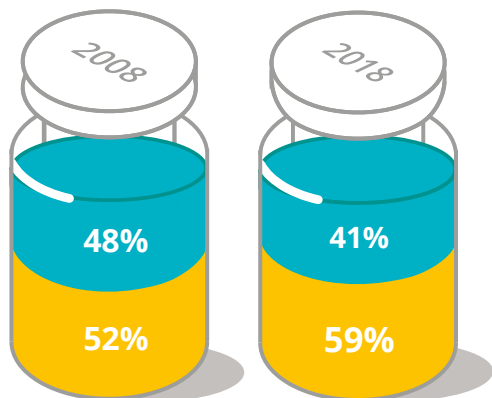


Money term

2008 and 2018

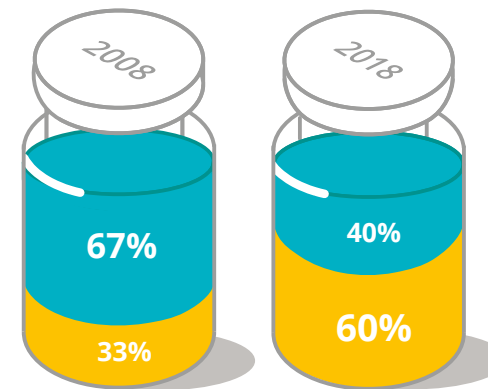
In-kind

2008 and 2018



Prescription medicines

OTC medicines



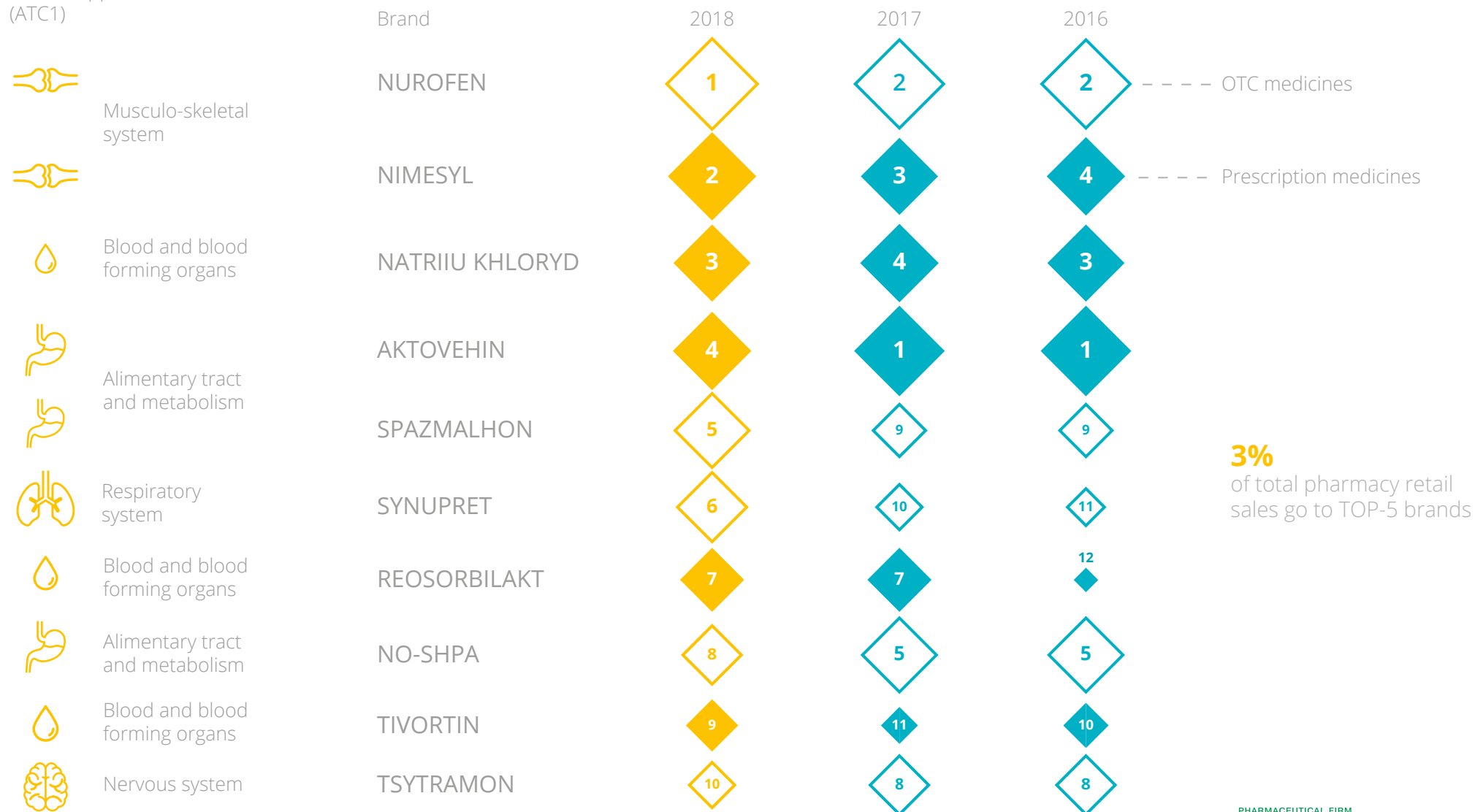
The market has a tendency towards an increase
in the share of prescription and high-priced medicines

MOST POPULAR MEDICINES IN UKRAINE

Pharmacy sales leaders,

2016–2018, ranked by sales (money term)

Area of application
(ATC1)



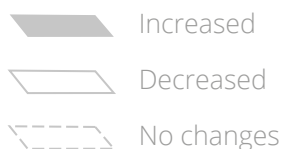
3%
of total pharmacy retail
sales go to TOP-5 brands

PHARMACY MARKET LEADERS

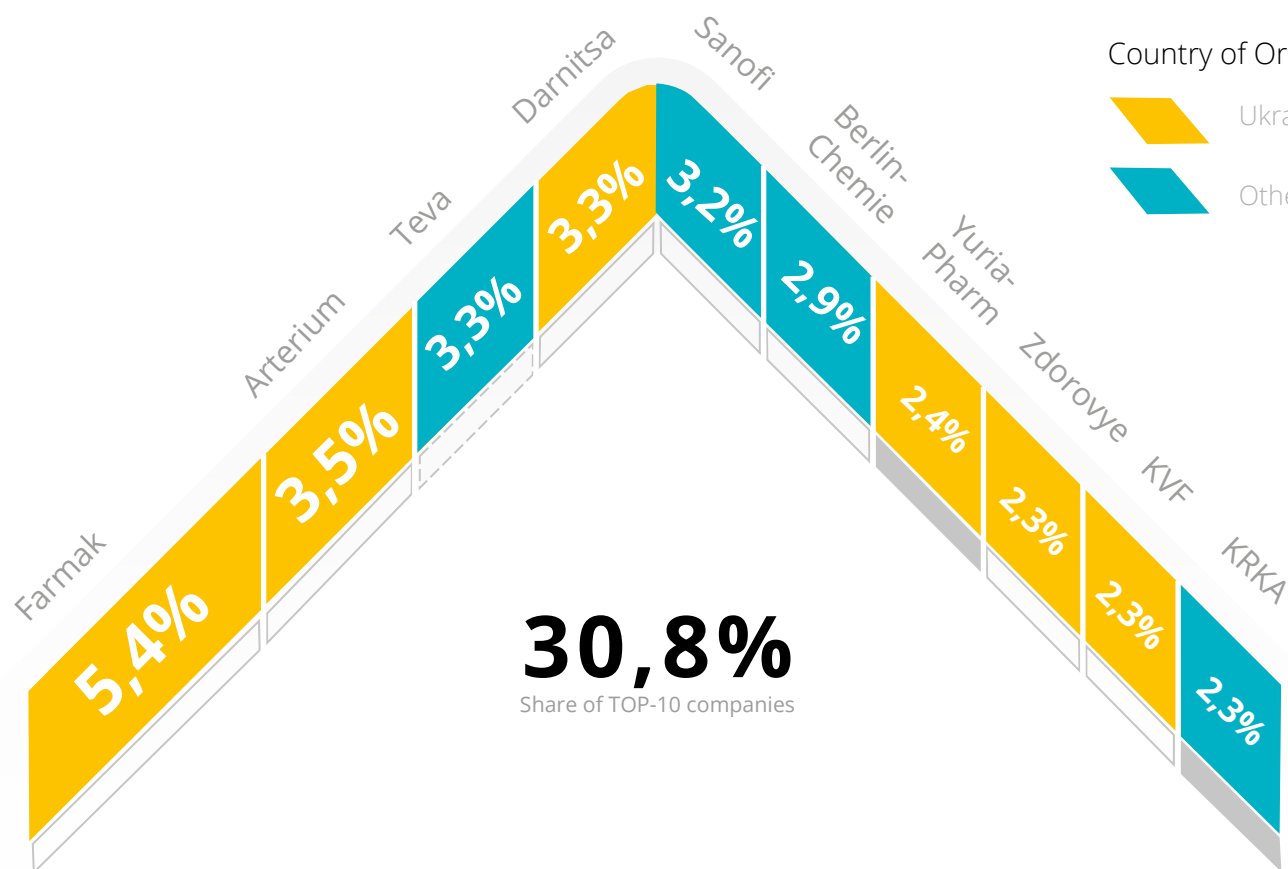
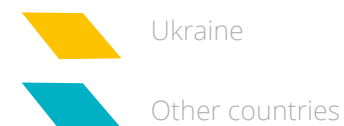
TOP-10 companies based on sales of «pharmacy basket» products,
2018, share of market, % (money term)

The pharmacy sales market is highly competitive, the share of TOP-20 companies is 47%, and it is almost equally distributed among Ukrainian and foreign manufacturers

Market share shift relative to previous year



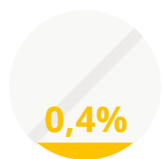
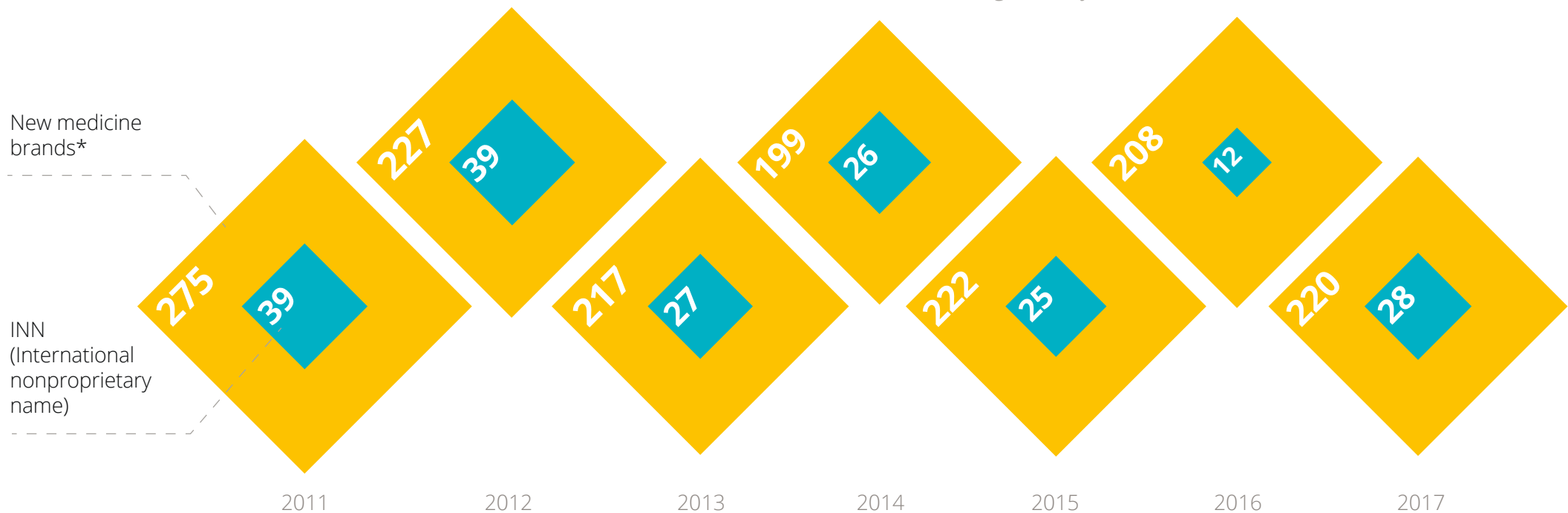
Country of Origin



LAUNCH OF NEW MEDICINES

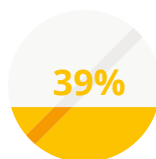
Dynamics of launches,
2011–2017, pcs.

The number of new brands launched by pharmaceutical companies on the Ukrainian market has not changed much over the last years, but the number of new INNs dropped significantly



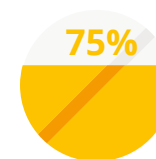
**Share of launches in
pharmacy market,**
2017 (money term)

0,4%



**Share of domestic
manufacturers in
launches structure,**
average for 2013-2017
(money term)

39%

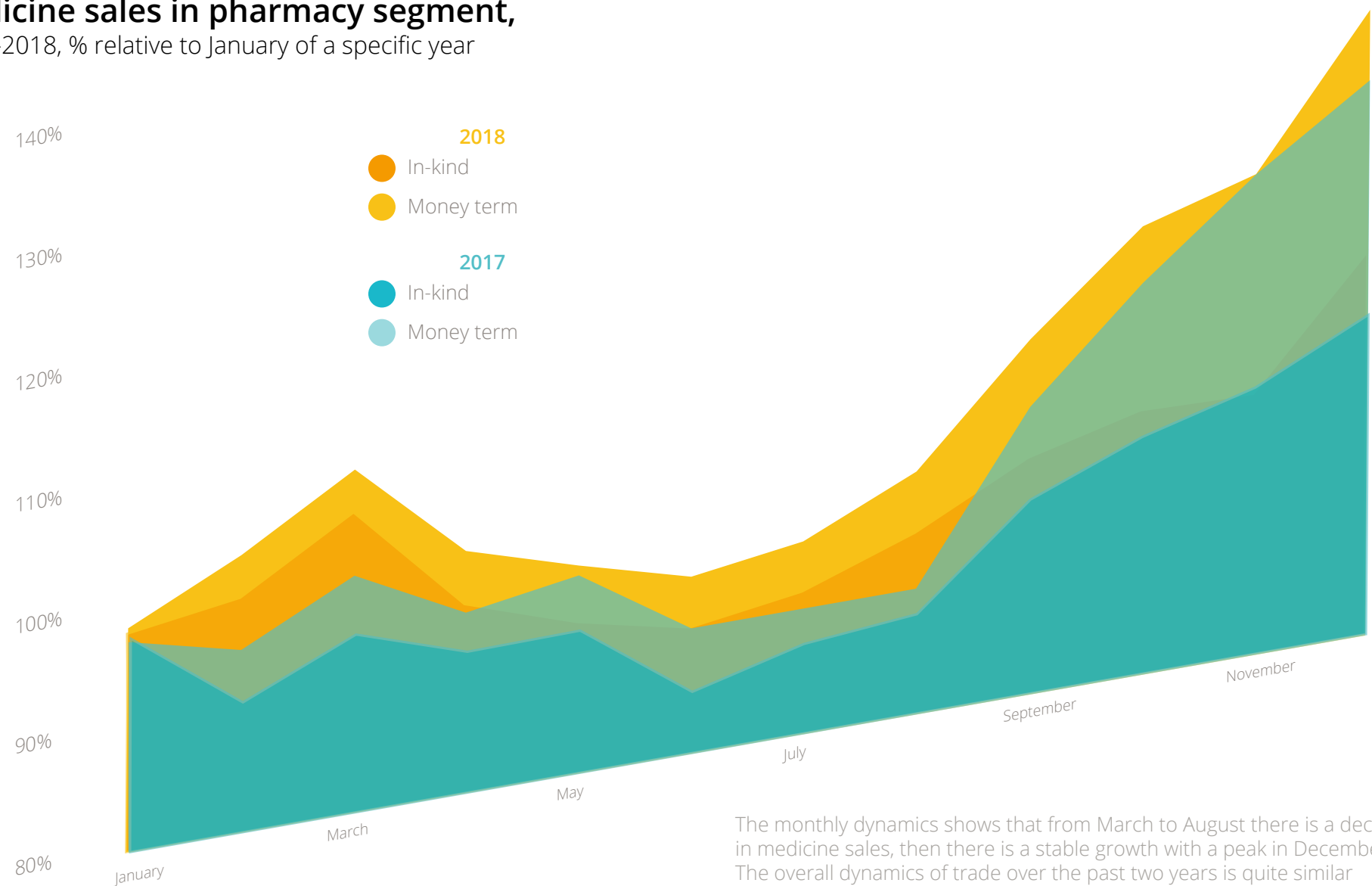


**Share of prescription
medicines in
launches structure,**
average for 2013-2017
(money term)

75%

PHARMACY SALES SEASONALITY

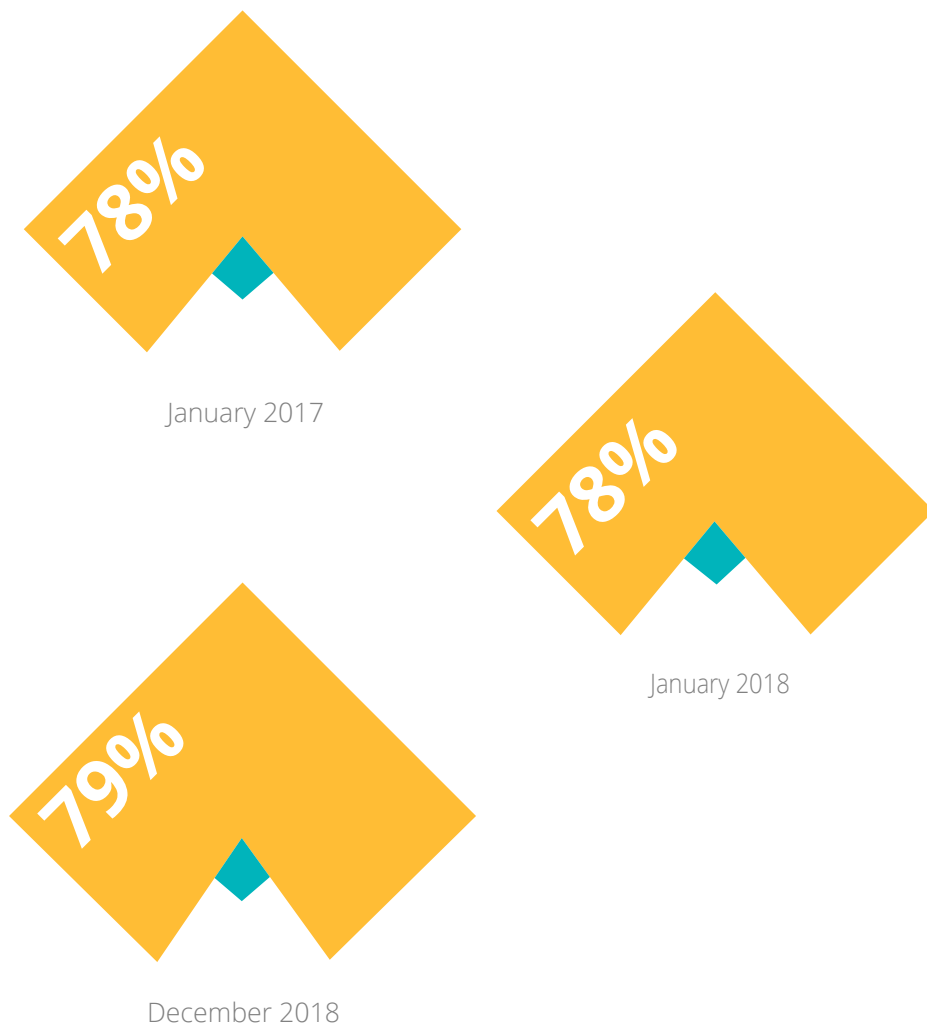
Medicine sales in pharmacy segment,
2017–2018, % relative to January of a specific year



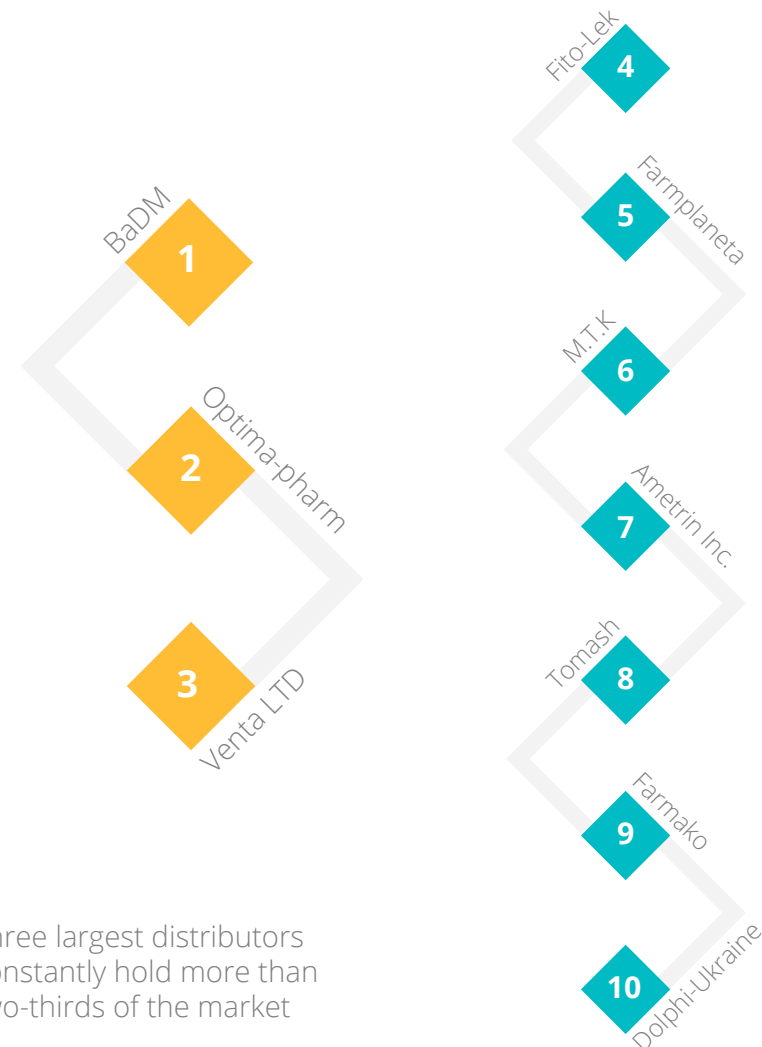
The monthly dynamics shows that from March to August there is a decline in medicine sales, then there is a stable growth with a peak in December. The overall dynamics of trade over the past two years is quite similar

PHARMACY MARKET WHOLESALE CHAIN

Share of TOP-3 distributors in «pharmacy basket» products shipment, January 2017 – December 2018, %



TOP-10 distributors of «pharmacy basket» products, December 2018



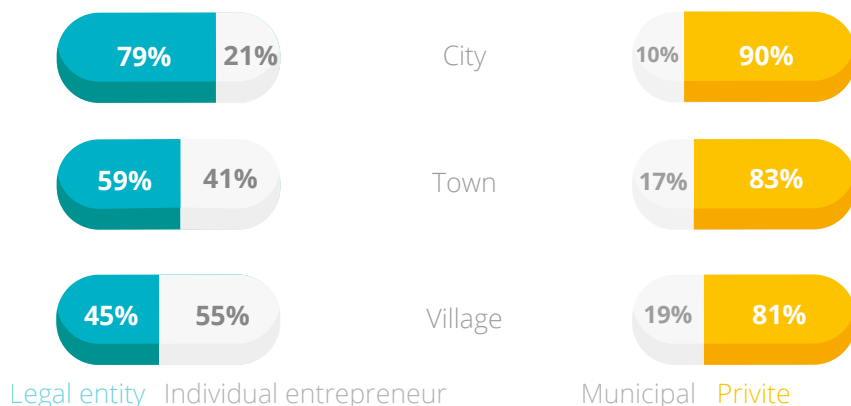
Three largest distributors constantly hold more than two-thirds of the market

PHARMACY RETAIL STRUCTURE

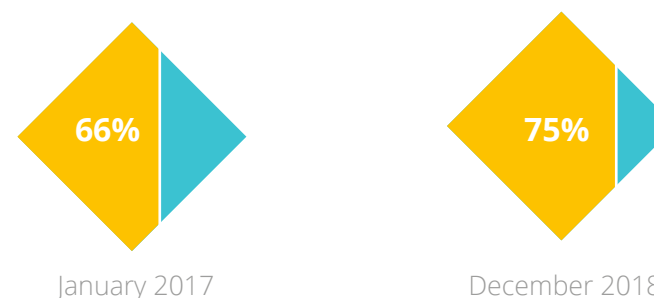
Breakdown of pharmacy chains by size,
2015 and 2018, as of 01.01, %



Structure of pharmacy shops by type of settlement, as of 01.01.2019, %

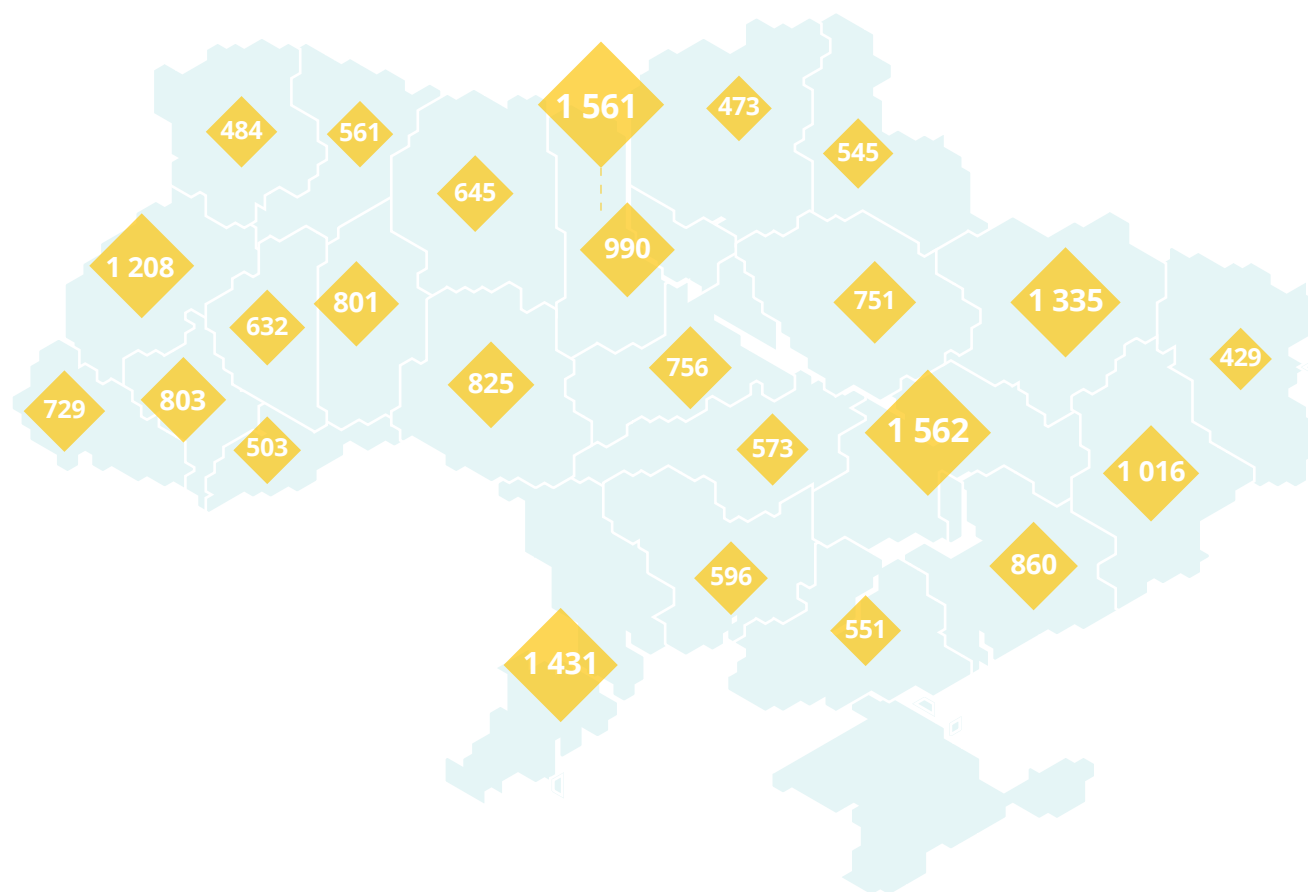


Share of TOP-100 pharmacy chains,
2017–2018, % (money term)



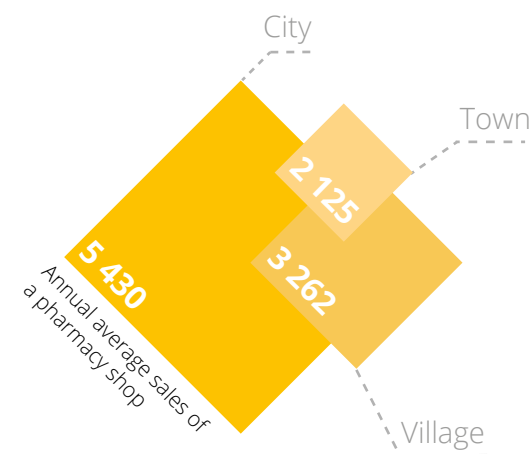
PHARMACY TRADE INFRASTRUCTURE

Number of pharmacy shops in regions,
as of 01.01.2019



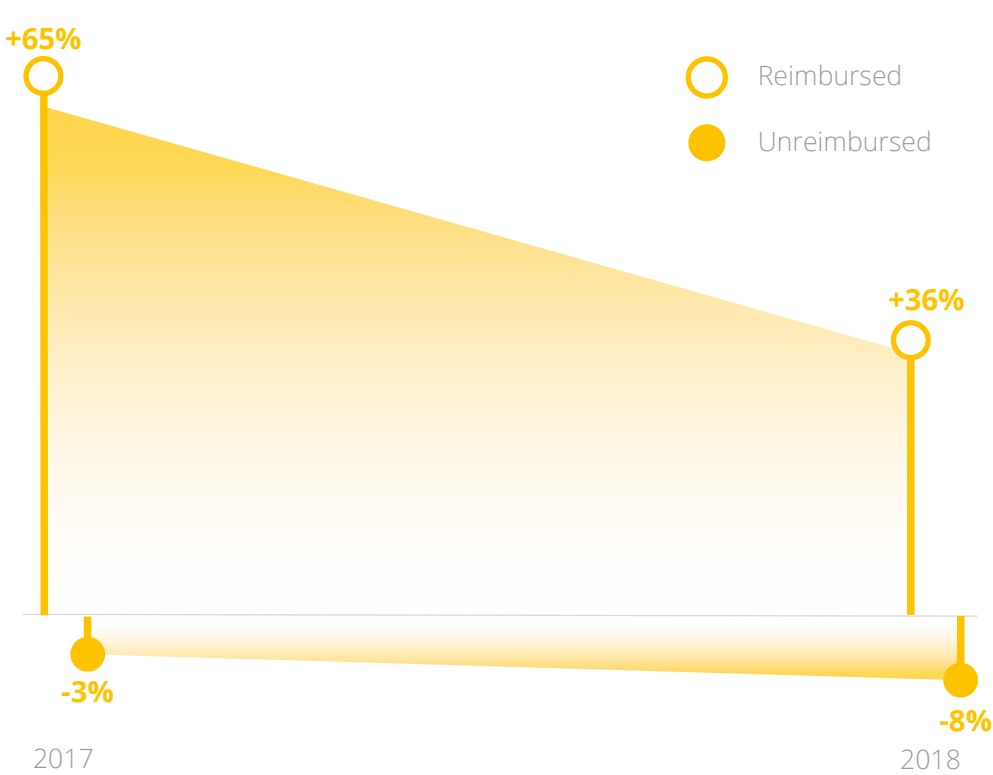
Sales per pharmacy shop in the city are the largest, as expected. Meanwhile, sales per pharmacy shop in the town are lower than in the village

Pharmacy retail sales by type of settlement, 2018, ths UAH



AFFORDABLE MEDICINES PROGRAM

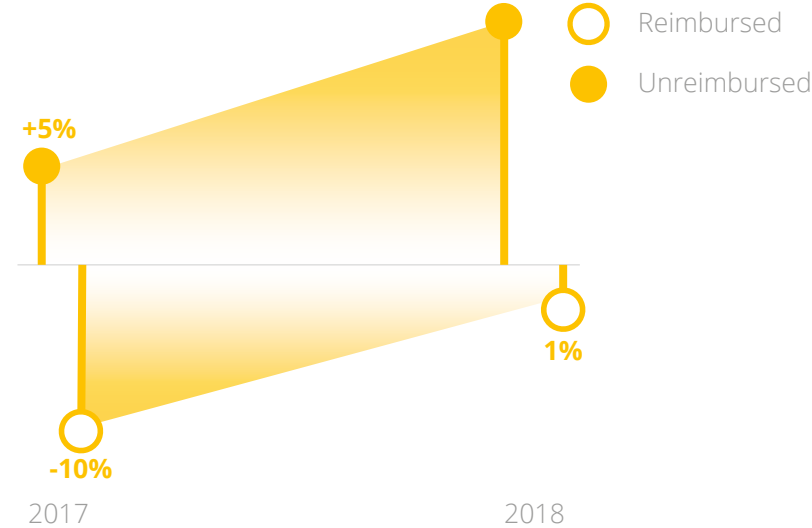
Dynamics of pharmacy sales of medicines from the INN list, 2017–2018, % relative to previous year (In-kind, DDD*)



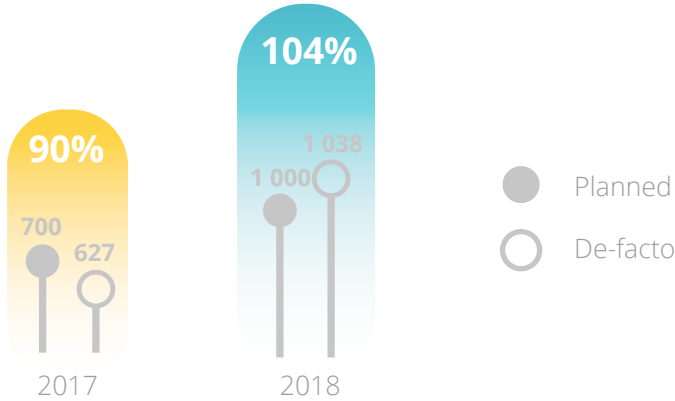
In 2018, the program contributed to the increase in consumption of medicines, the cost of which is fully or partially reimbursed by the state

Prices for reimbursed medicines have been stabilized, while prices for unreimbursed medicines continue to grow

Dynamics of weighted average cost of one DDD, medicines from the INN list, 2017–2018, %



Financing of the program, 2017–2018, % (mln UAH)

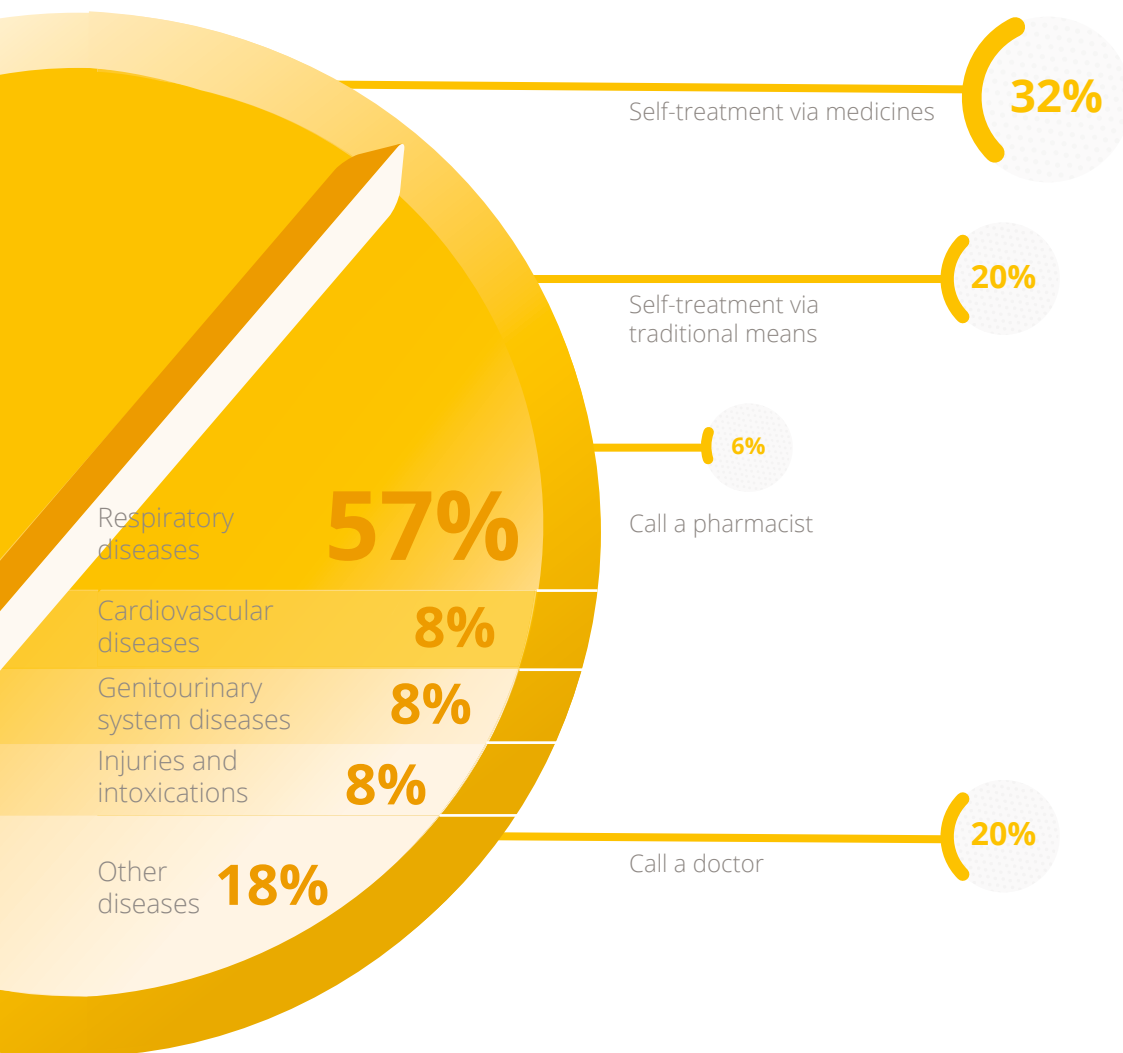


MEDICAL TREATMENT IN UKRAINE

Common diseases,
2017, % of the total number of
newly registered cases of disease

Ways of treatment,
probability, %

**TOP-10 medicines by
importance,** pharmacy market, I-III
quarter 2016, % (money term)



Why people avoid doctors?

Have a positive experience of self-treatment
Expect the disease cured of itself
Too expensive
Queues in medical facilities

58%
26%
25%
13%

Do people buy all the medicines prescribed by a doctor? (Outpatient treatment)

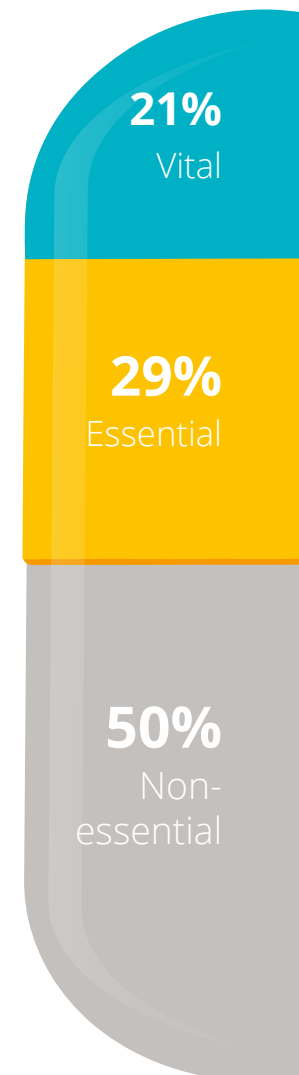
Yes, all of them
Yes, some of them
No, don't buy

78%
17%
6%

Decisive,
save lives

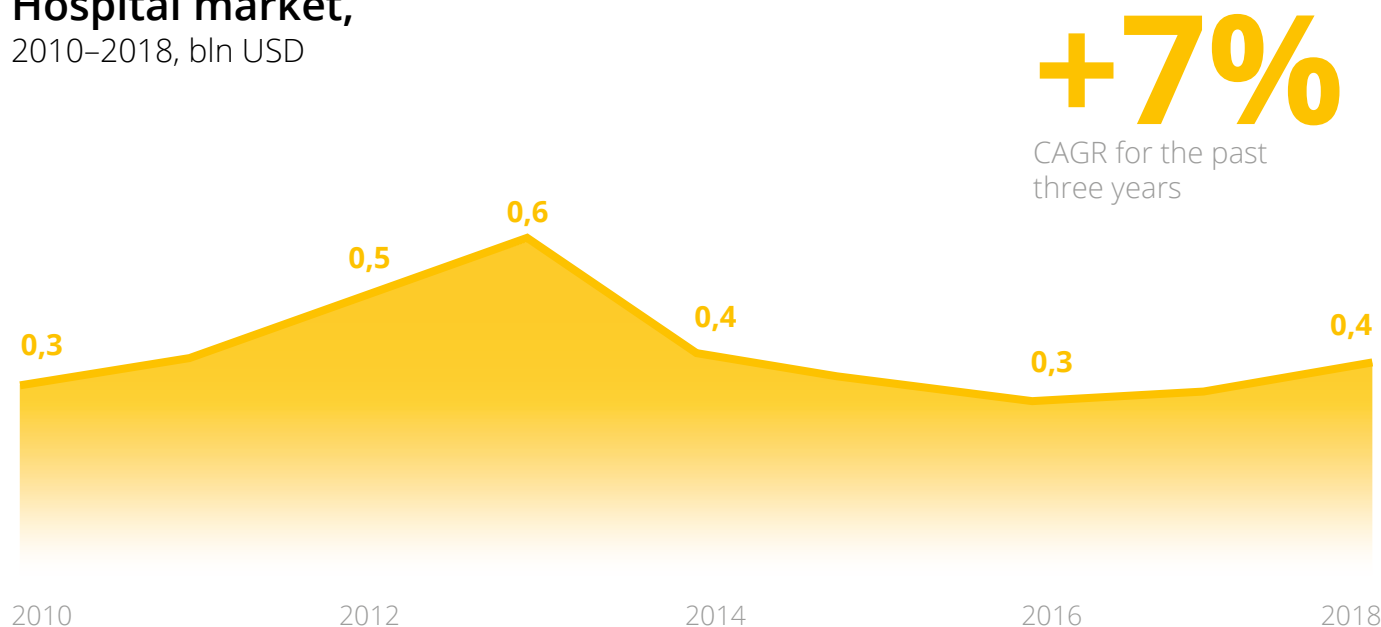
Effective,
not decisive

Subsidiary,
can be
abandoned



HOSPITAL MARKET DYNAMICS

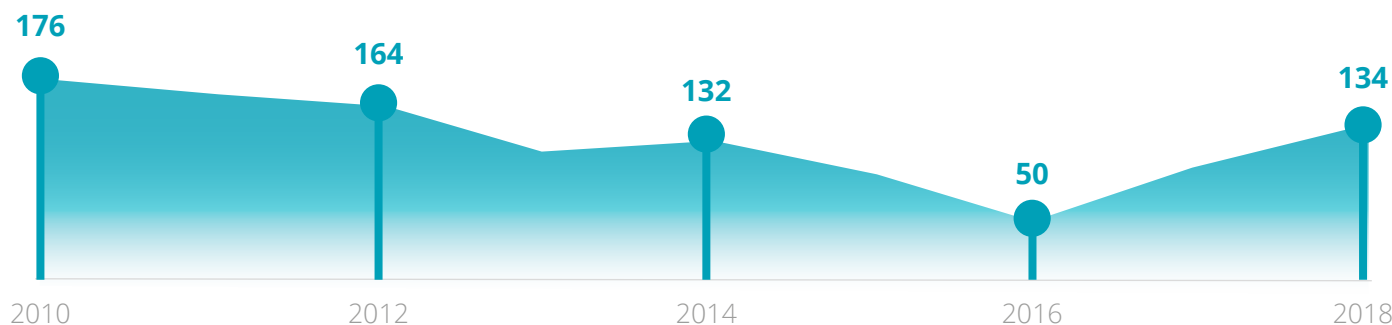
Hospital market,
2010–2018, bln USD



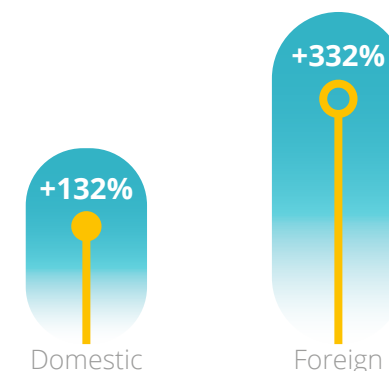
The main reason for the decrease in the procurement of medicines is the devaluation of the hryvnia, which led to an increase in the cost of medicines, especially foreign ones

Currently, the development of hospital market largely determines the dynamics of tender procurement in the electronic trade system ProZorro

Hospital procurements,
2010–2018, mln pcs

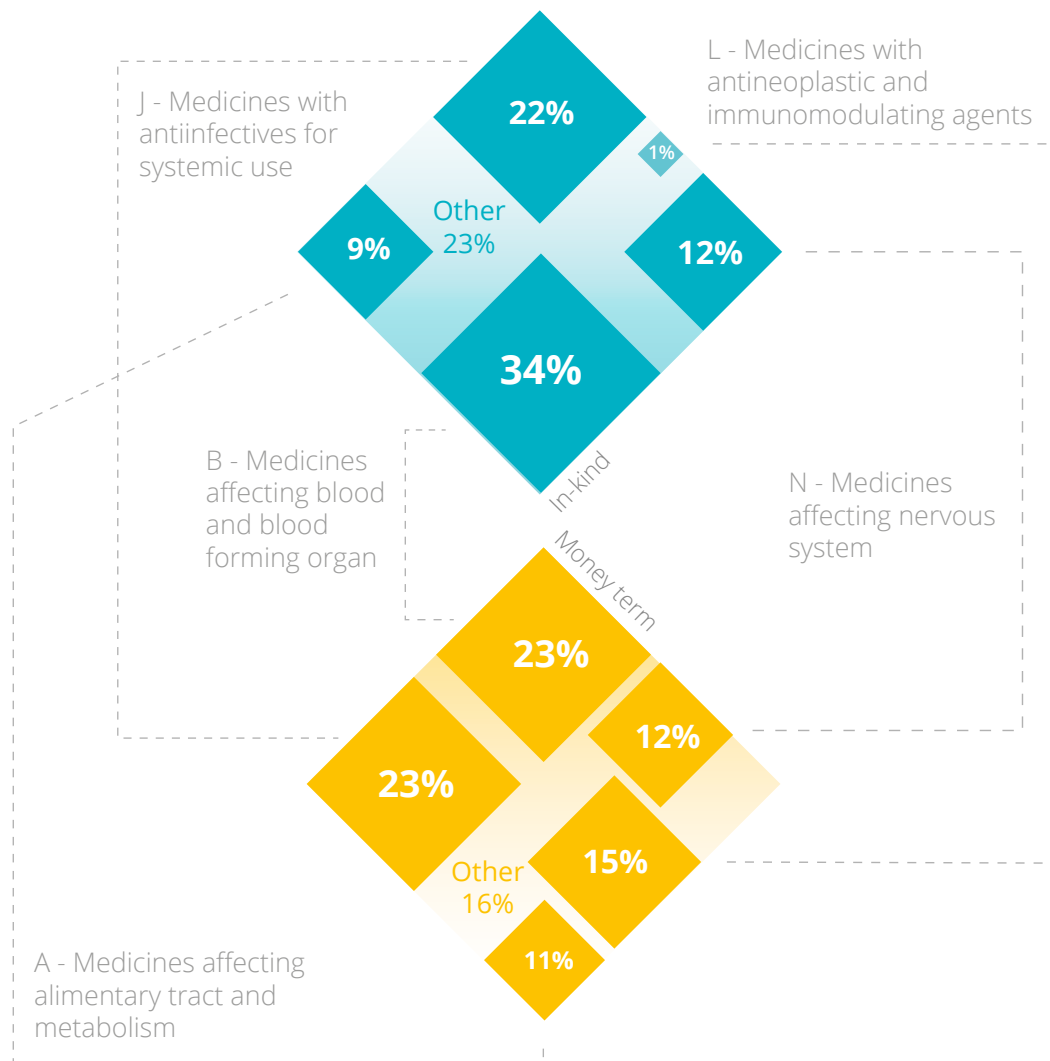


Dynamics of weighted average cost of medicines, 2012–2018, %

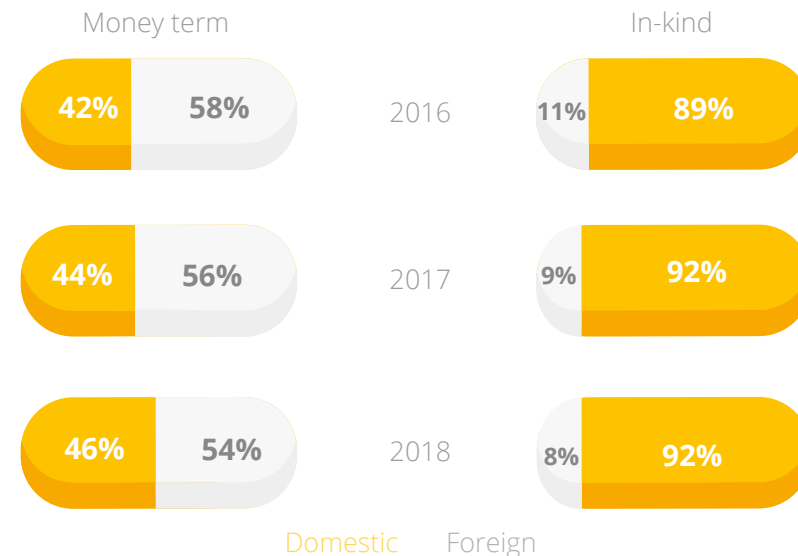


HOSPITAL MARKET STRUCTURE

Structure of medicines in the context of ATC-groups, 2018, %*

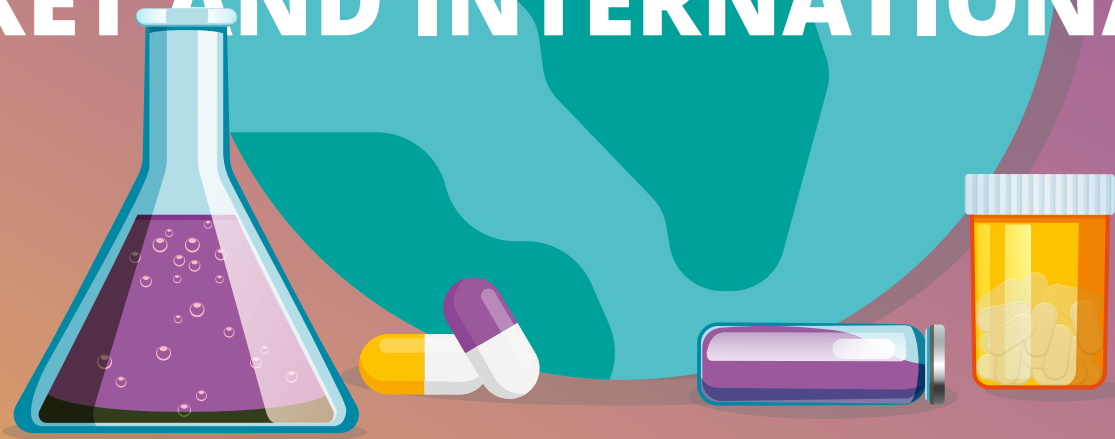


Structure of hospital supplies, 2016–2018, %



In the structure of hospital supplies, there is a tendency of the share of domestic medicines increase both in money term and in-kind

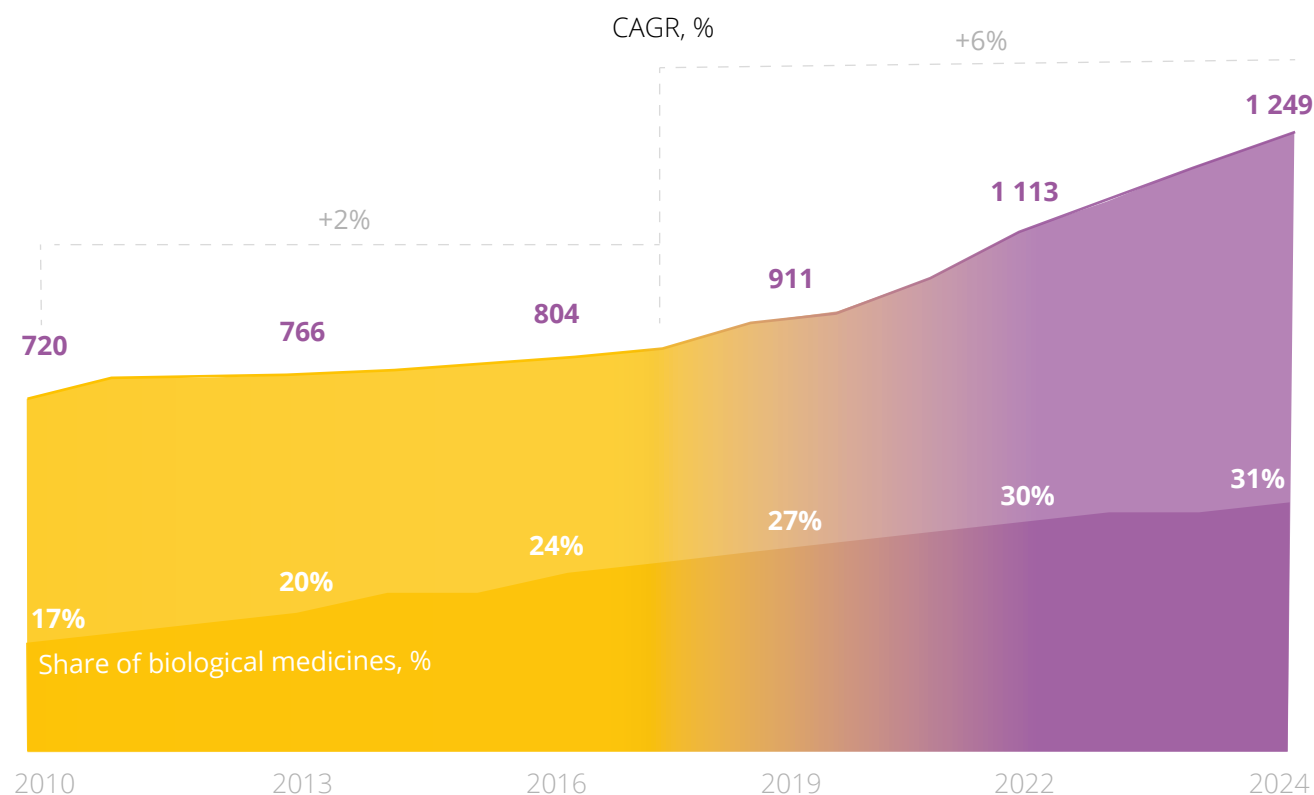
GLOBAL PHARMACEUTICAL MARKET AND INTERNATIONAL TRADE



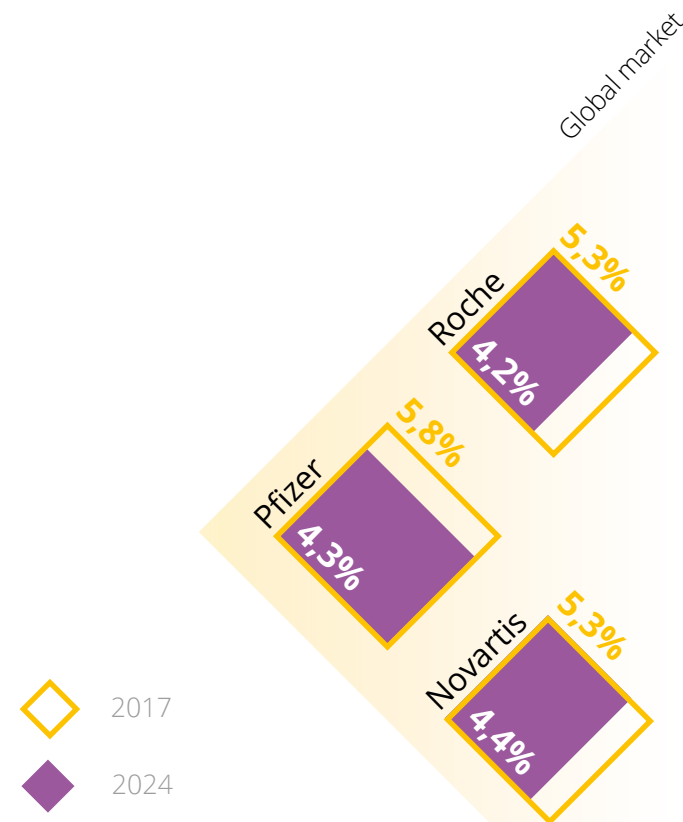
GLOBAL PHARMACEUTICAL MARKET

Global sales of medicines, 2010–2024, bln USD*

It is expected that CAGR for 2017-2024 will be significantly higher than for the equivalent previous period. The basis for growth will be the increase in sales of prescription medicines



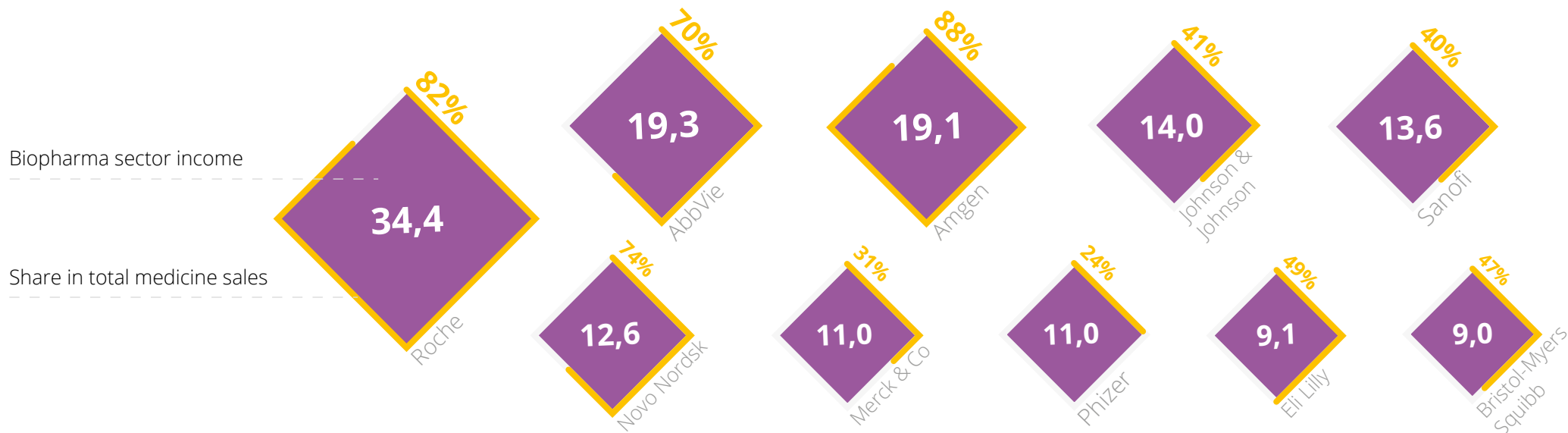
The Biggest market participants, share of global sales, 2017 and 2024, %**



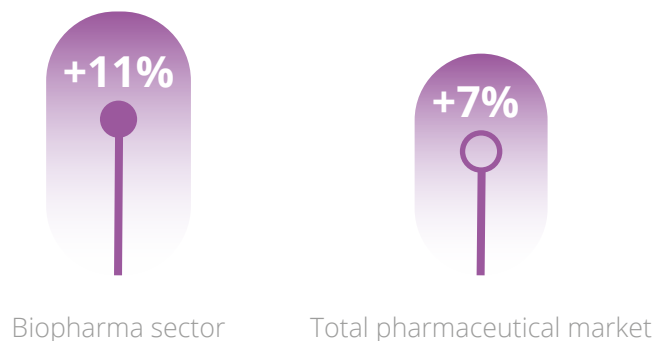
The role of market leaders is expected to decrease, competition will continue to grow

GROWTH OF BIOPHARMACEUTICS

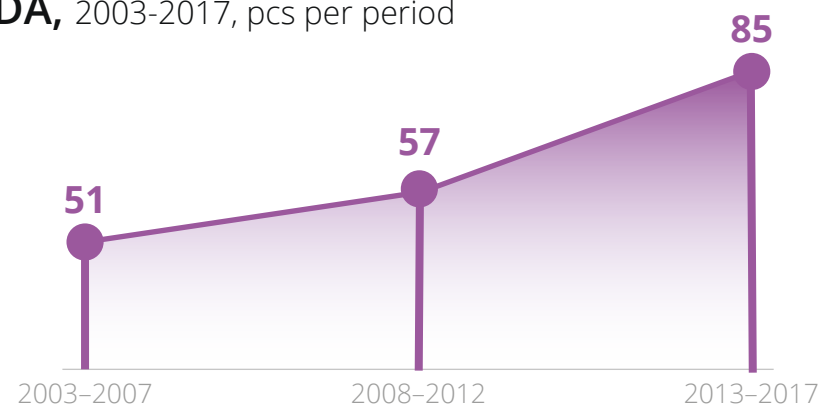
Global biopharma leaders, 2017, bln USD, %*



CAGR forecast, 2018-2024, %



Number of biological medicines approved by FDA, 2003-2017, pcs per period



R&D INVESTMENT IN PHARMACEUTICAL INDUSTRY

Cost-effectiveness of R&D expenditures by pharmaceutical companies,

the number of new medicines per one billion dollars of private R&D investments (2014 prices)

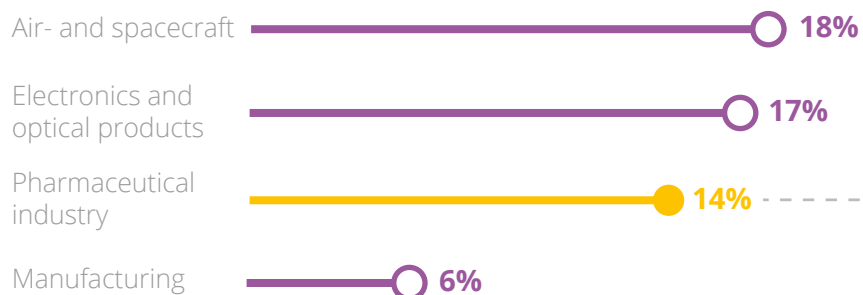


Due to the increase in the cost of new medicines developing the productivity of R&D expenditures has been reduced

Pharmaceutical companies of the US and Japan spend the most on R&D

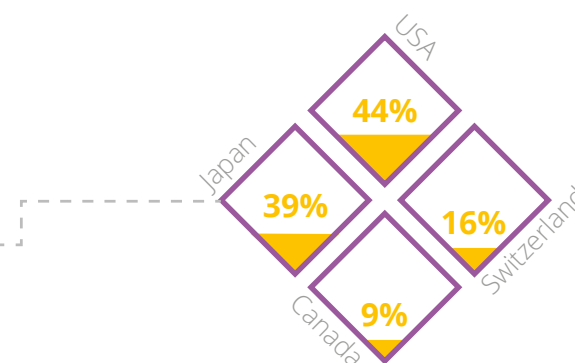
R&D intensity by industries,

share of R&D in value added, 2014 or nearest one, %*



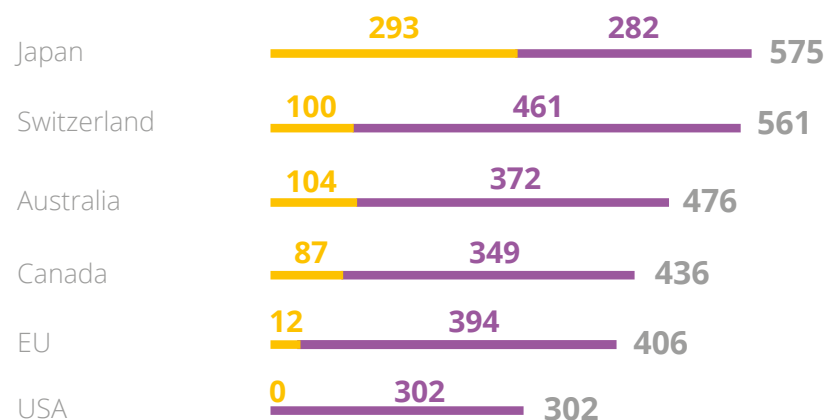
R&D intensity in pharmaceutical industry,

share of R&D in industry value added, 2014 or nearest one, %

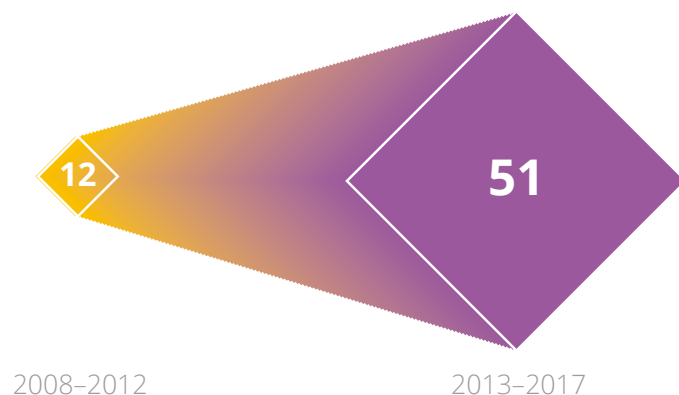


MEDICINES APPROVALS

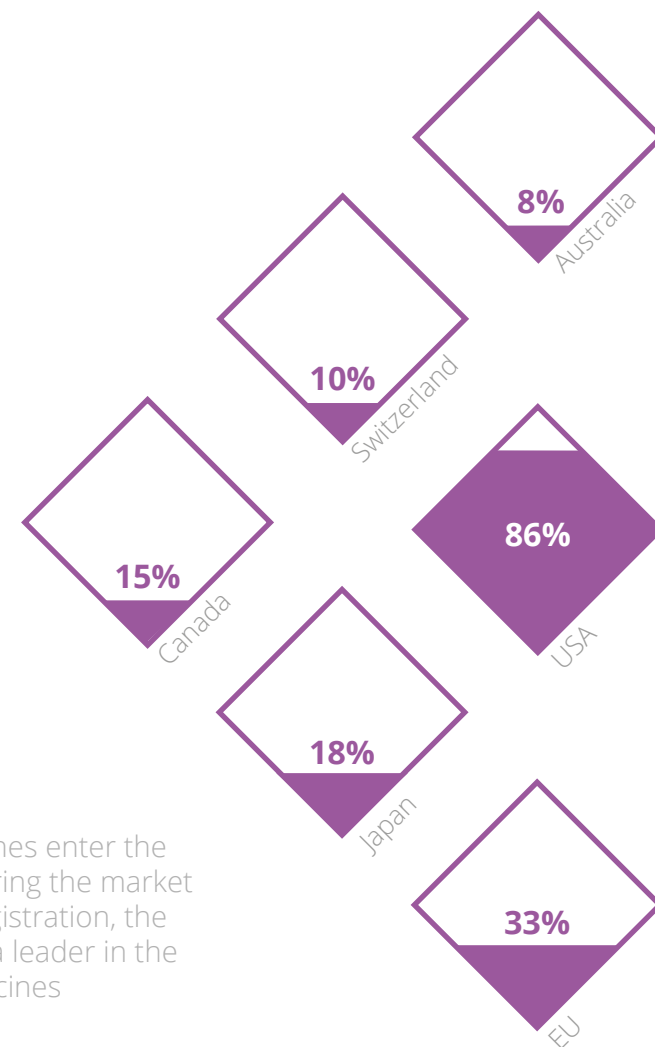
Medicines median approval time, 2017, days



Number of new medicines, new active substance approved in above-mentioned states, 2008-2017, pcs



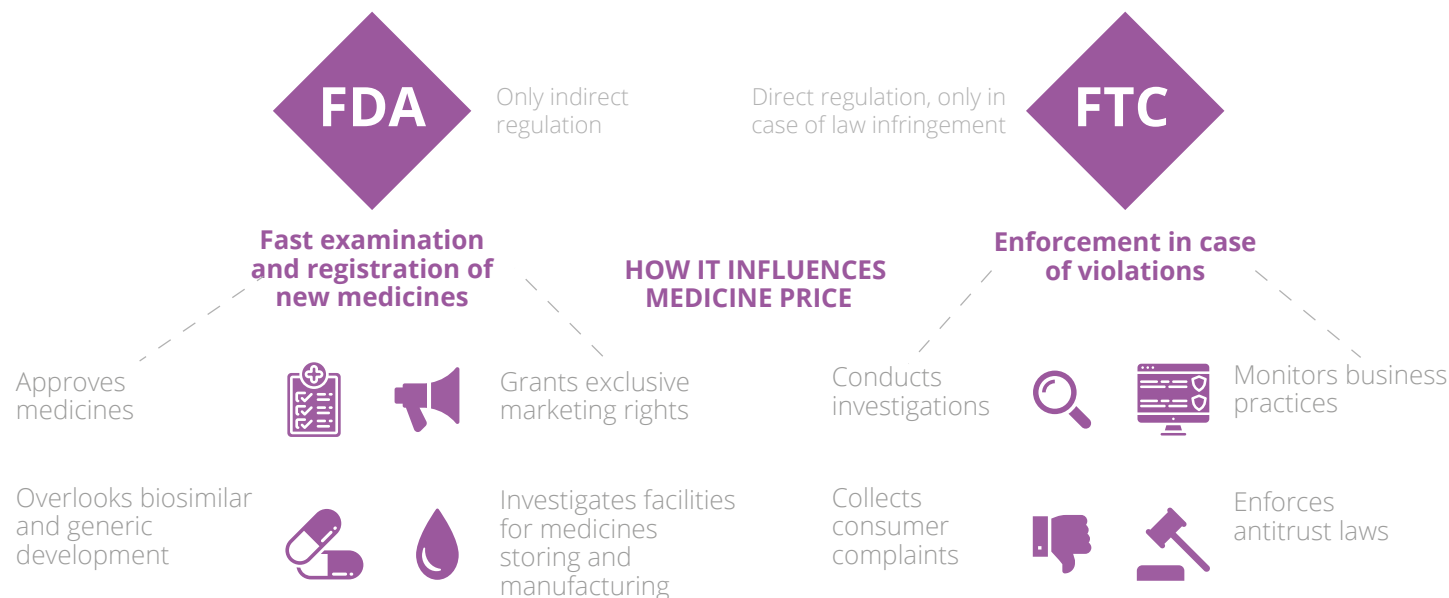
Availability of medicines by countries, medicines approved for the first time or within one month of their approval in another country from the total number of approved, 2017, %



More and more medicines enter the global market. Considering the market size and the ease of registration, the United States remains a leader in the availability of new medicines

PHARMACEUTICAL MARKET REGULATION

The authority of the U.S. Government in medicine price regulation, 2018*

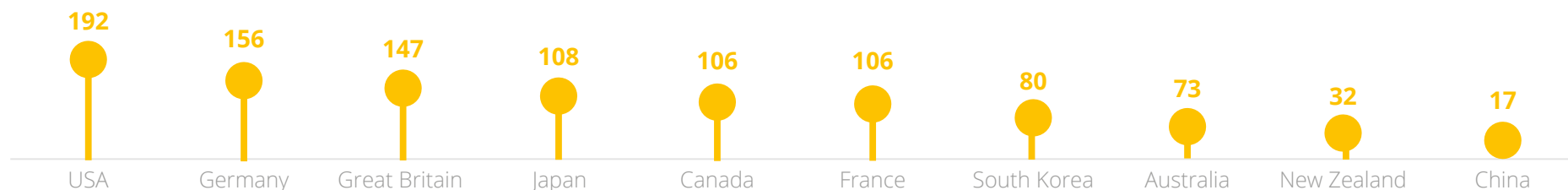


To a great extent, medicine prices in the US are not regulated

U.S. antitrust law allows lawful monopolists, and a fortiori other market participants, to set their prices as high as they choose

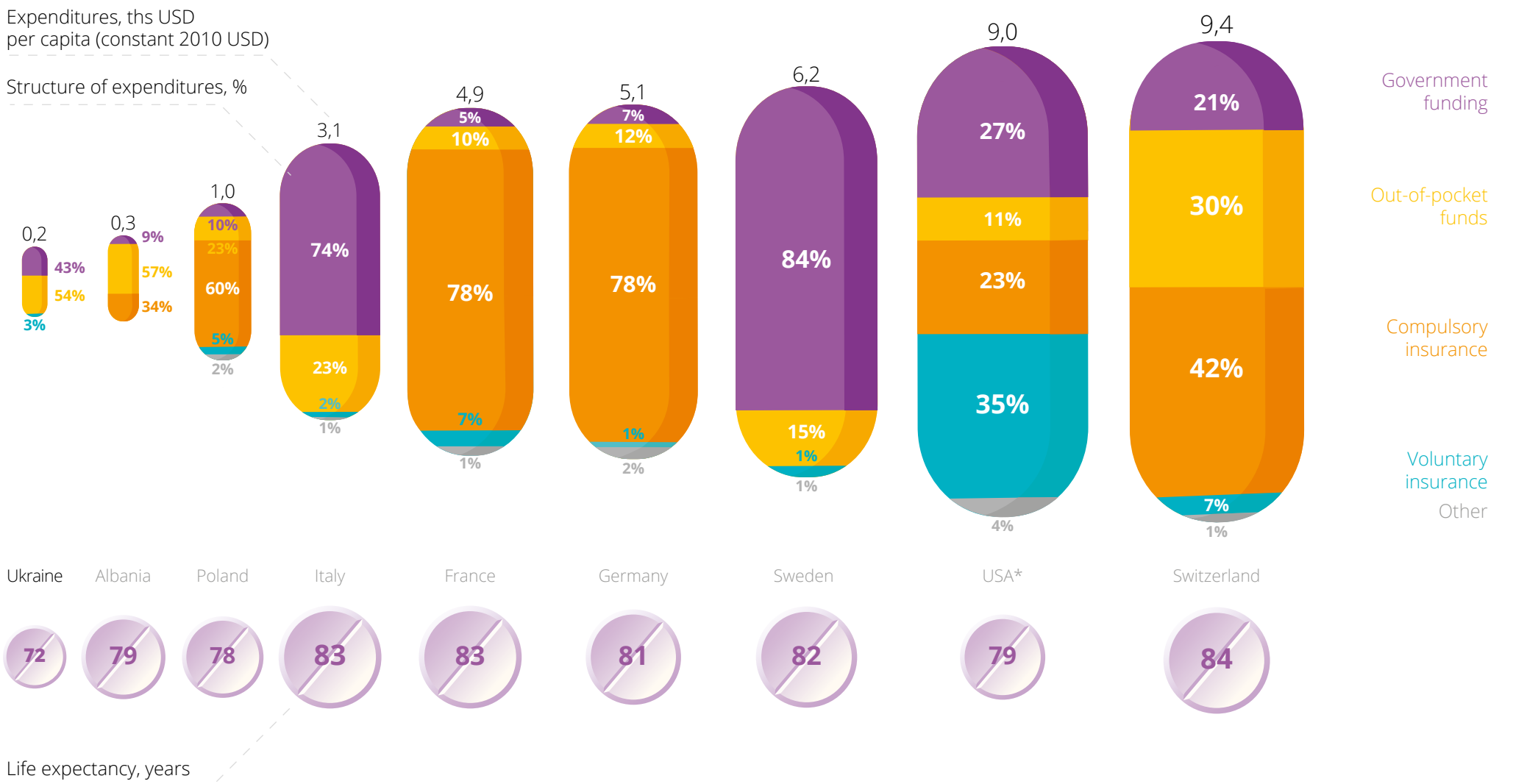
Legislators believe that regulation reduces incentives for competition and innovation. As a result, the number of new medicines in the United States is significantly higher than in other countries

Number of new medicines available by country, new medicines registered for the first time, 2011–2017, pcs



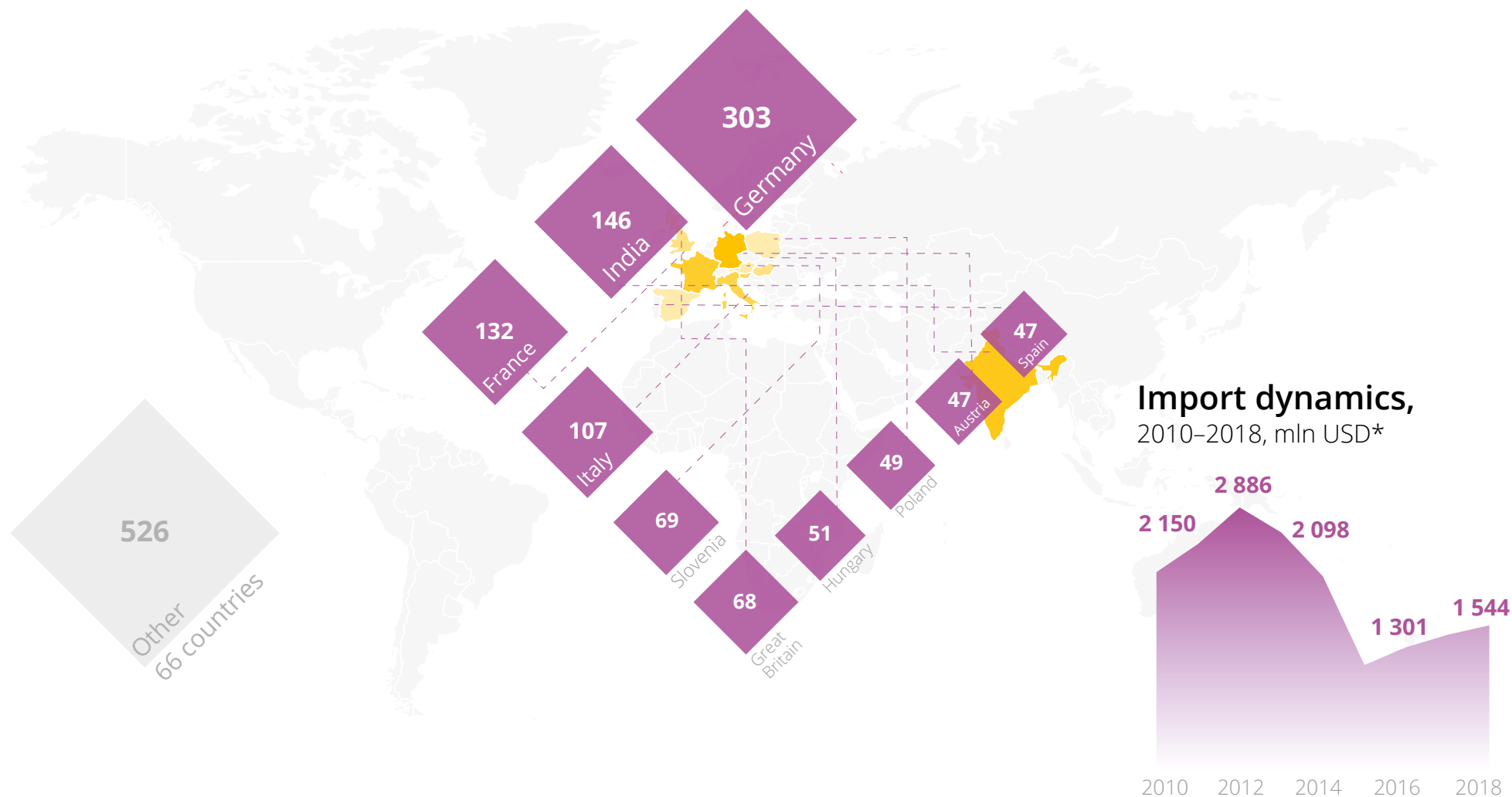
HEALTHCARE SYSTEM

Breakdown of healthcare financing and life expectancy, 2016 or nearest one



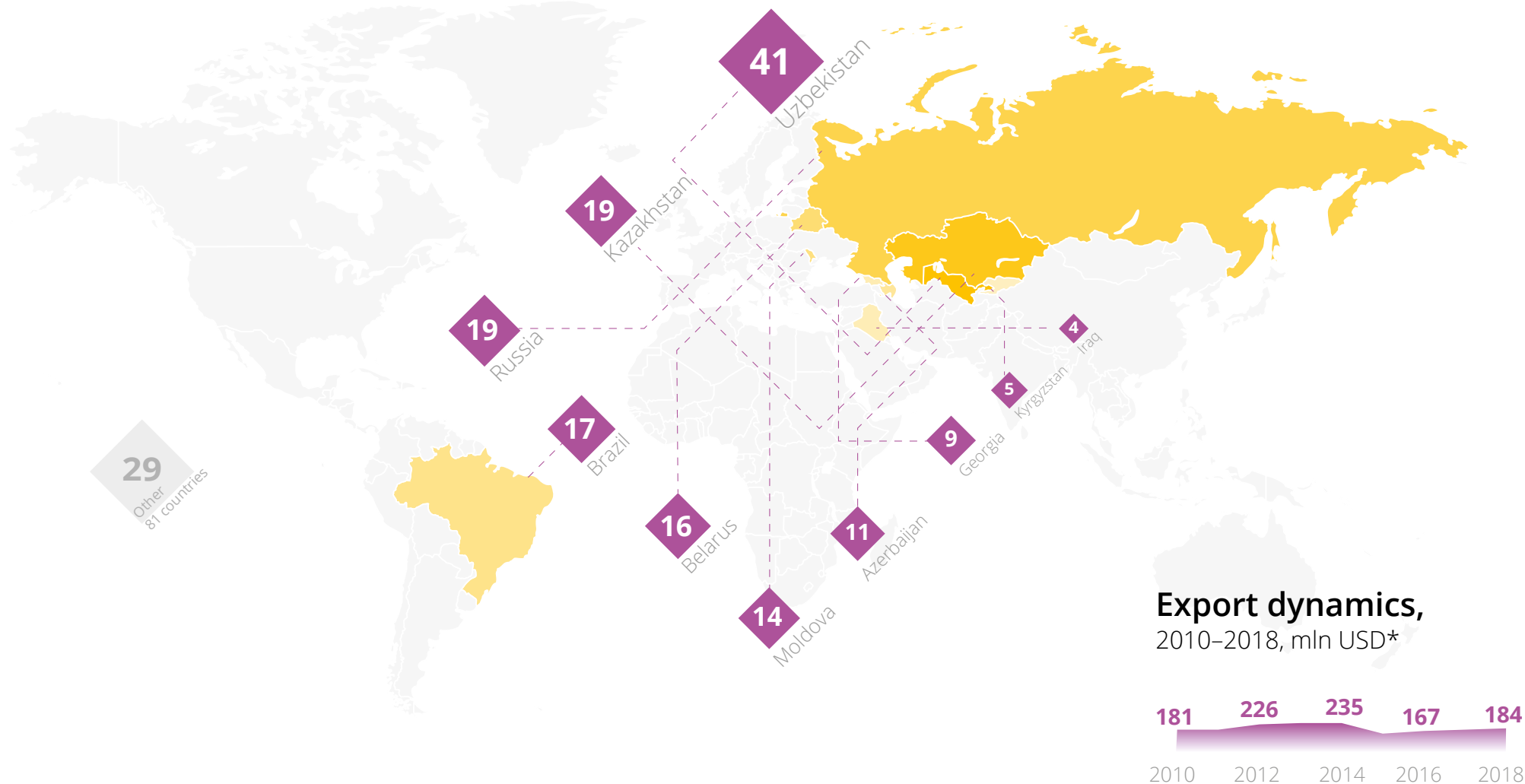
MEDICINE IMPORT IN UKRAINE

TOP-10 Medicine Import Directions in Ukraine,
2018, mln USD



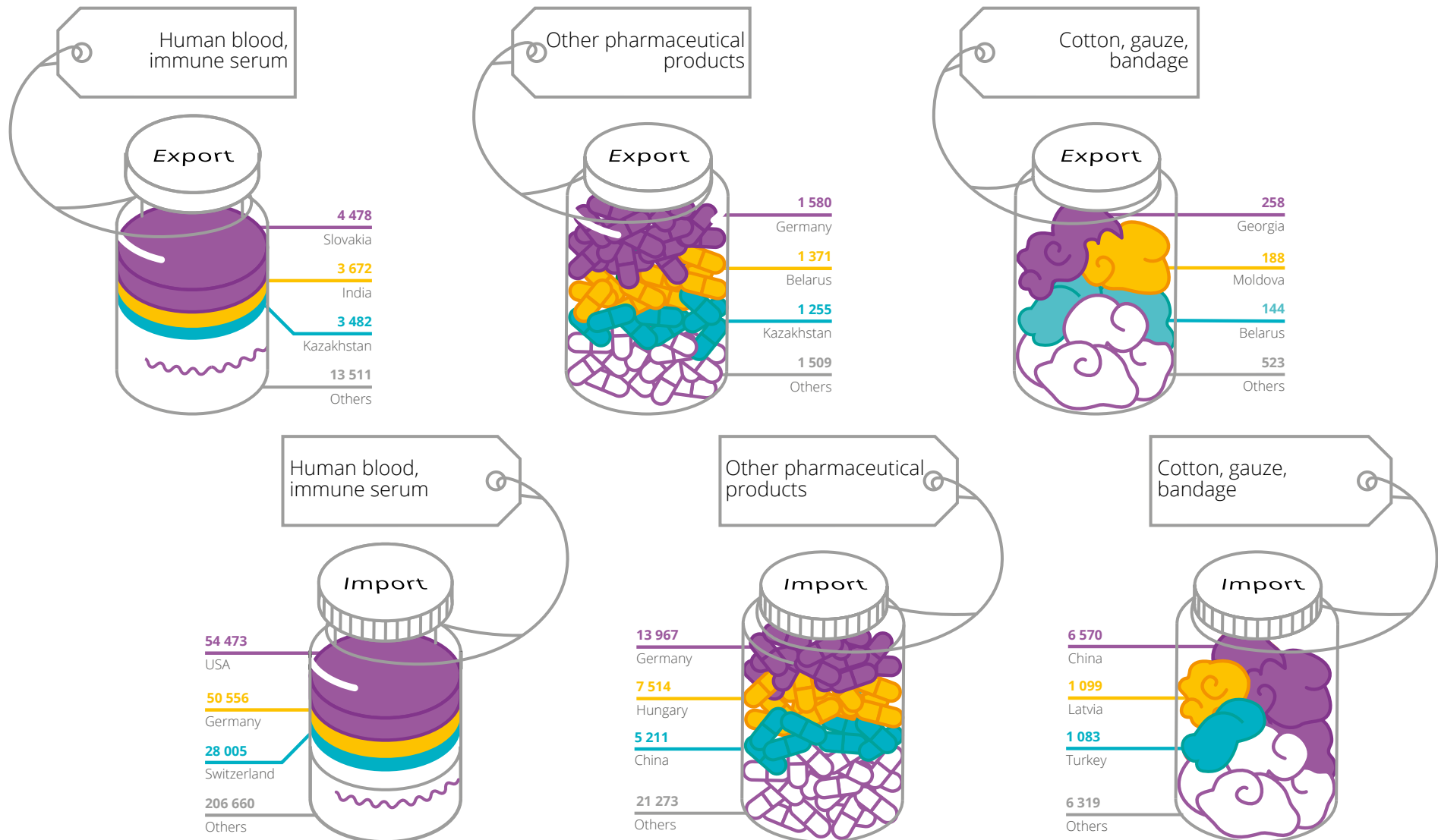
MEDICINE EXPORT FROM UKRAINE

TOP-10 Medicine Export Directions from Ukraine in 2018,
mln USD



OTHER PHARMACEUTICAL PRODUCTS TRADE

Main state-partners, 2018, ths USD



SOURCES

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- State Statistics Service of Ukraine (SSC of Ukraine)
- State Service of Ukraine on Medicines and Drugs Control (SMDC)
- The State Expert Center of the Ministry of Health of Ukraine, PE (SEC of MOH)
- The Law of Ukraine “On medicinal products”
- 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"
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- The Centre for Innovation in Regulatory Science (CIRS)
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