

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:

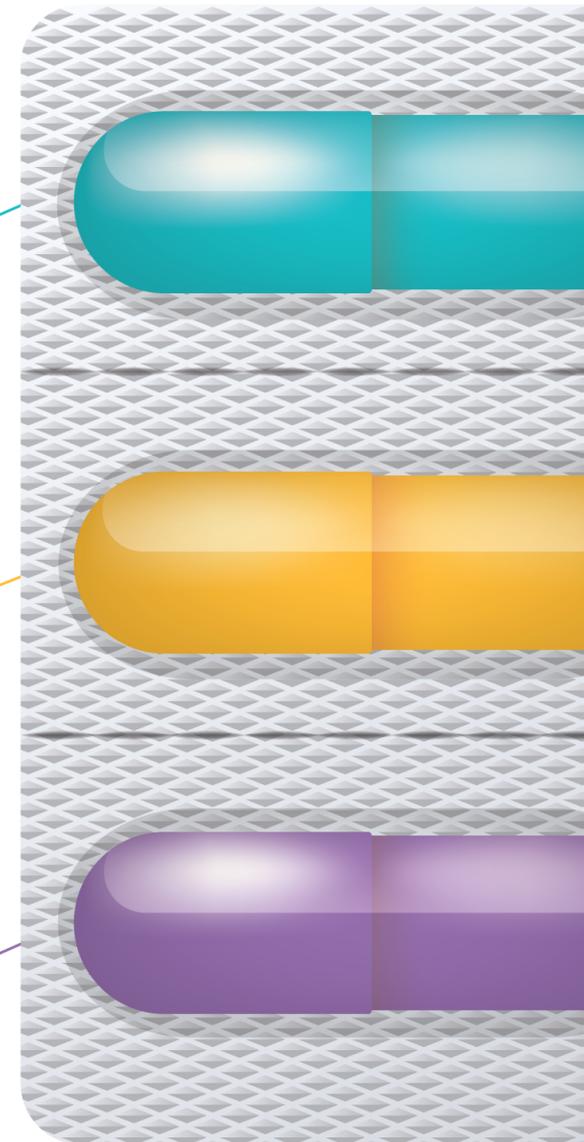
- role in economy
- investment
- manufacturers
- clinical trials
- registration of medicines

### PHARMACEUTICAL MARKET OF UKRAINE:

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

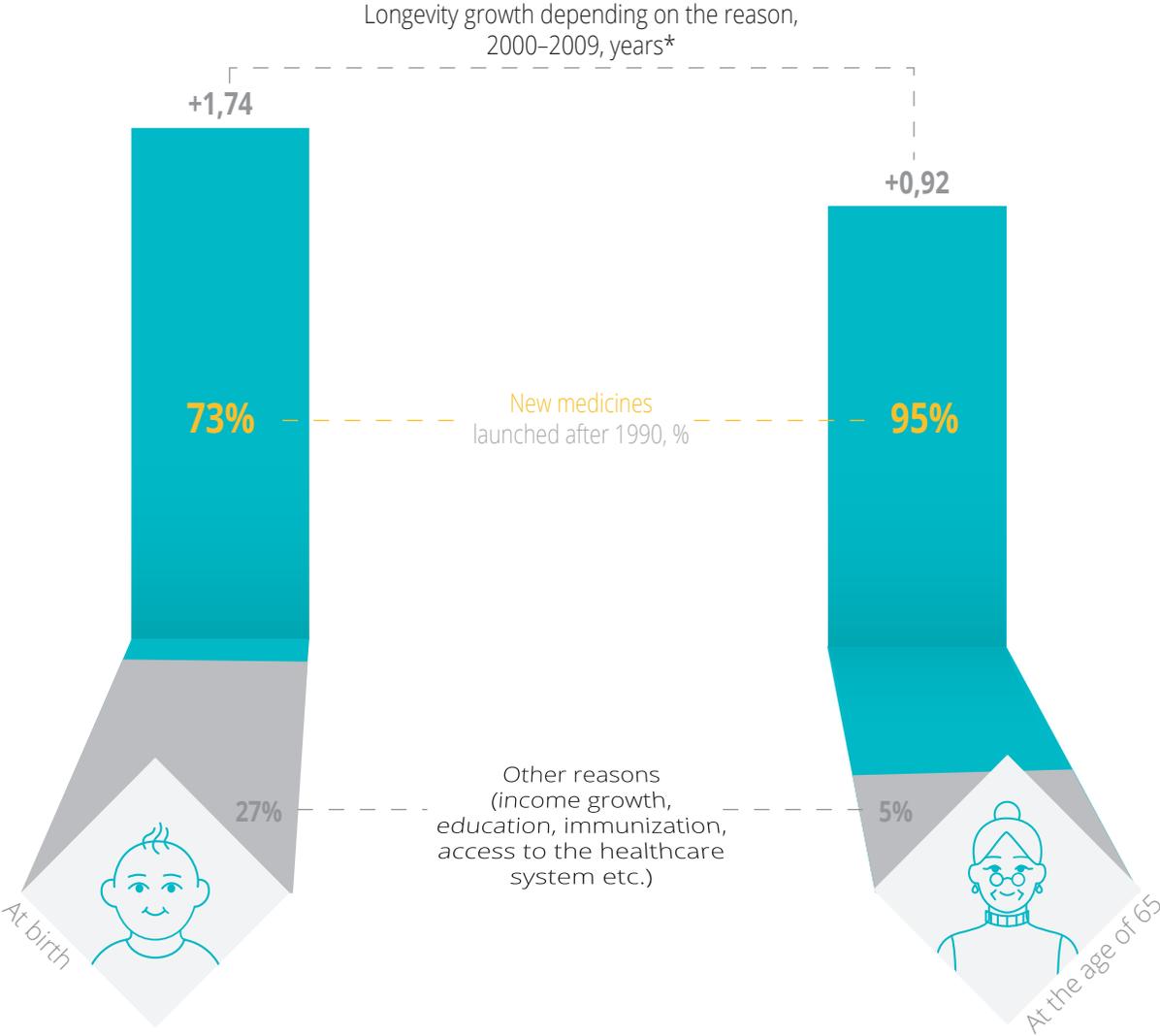
### GLOBAL PHARMACEUTICAL MARKET AND INTERNATIONAL TRADE

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



# PHARMACEUTICAL INNOVATIONS AND LONGEVITY

## New medicines are the basis for life expectancy increase

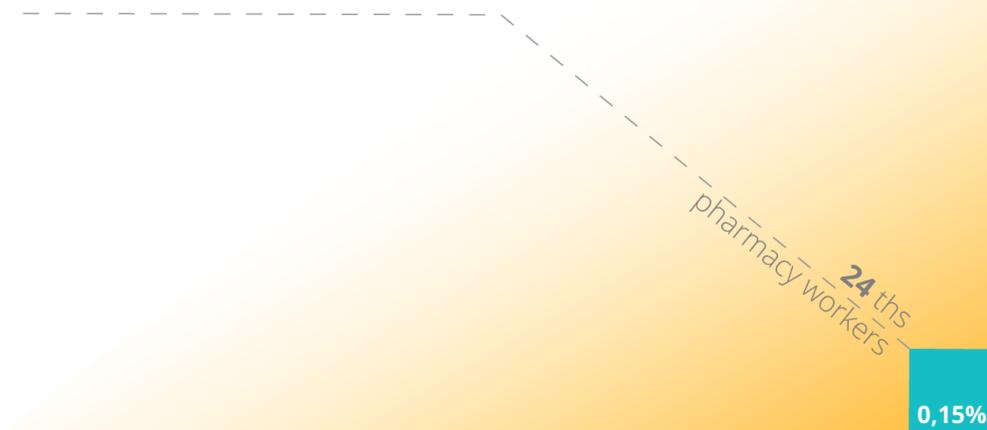


Source: Lichtenberg F. R.

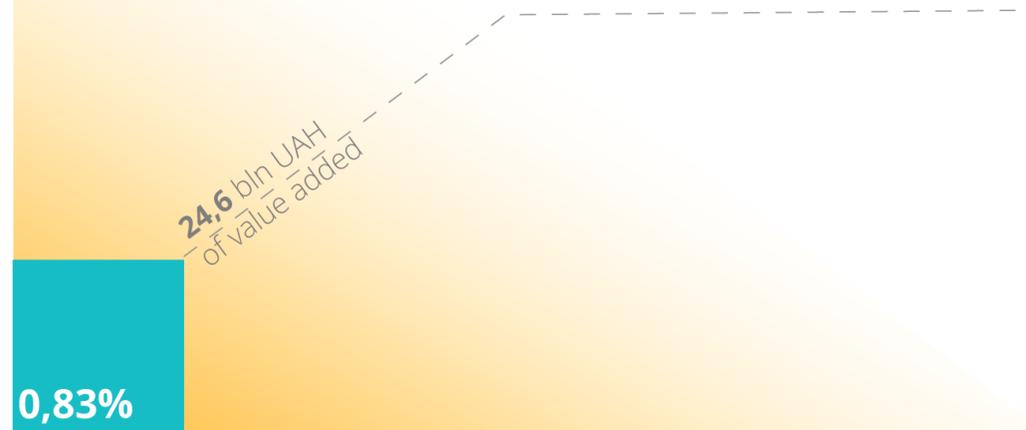
\*the research was committed in 30 developed and developing countries

# ROLE OF PHARMACEUTICAL INDUSTRY IN ECONOMY

**In Employment,**  
2018, % of the total employees



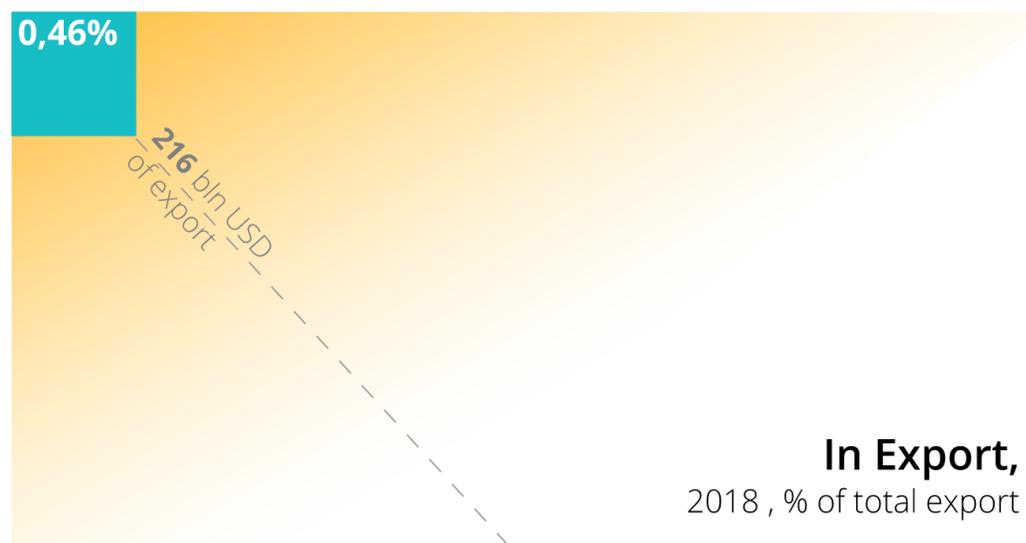
**In GDP,**  
2017, % of GDP



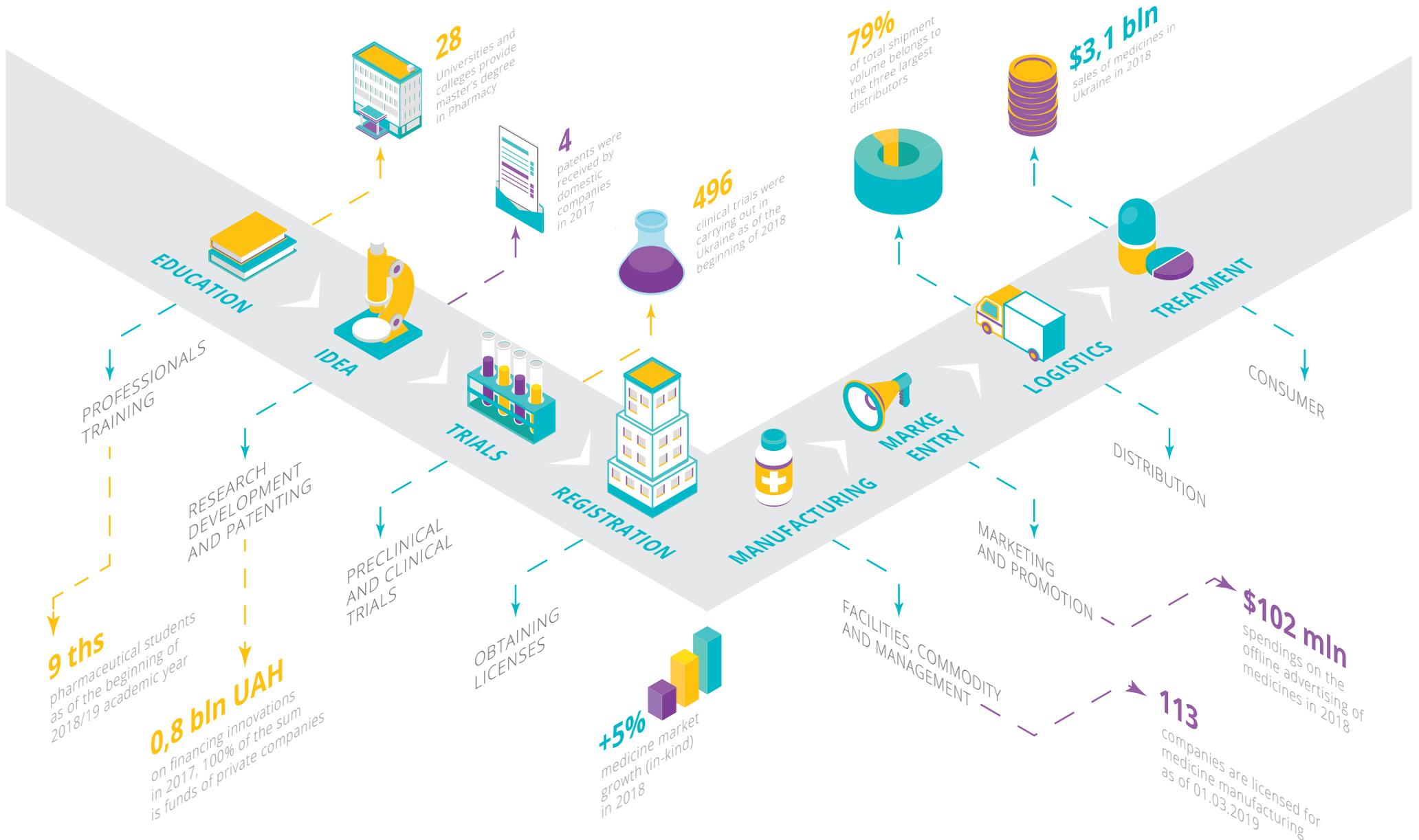
**In Import,**  
2018, % of total import



**In Export,**  
2018, % of total export

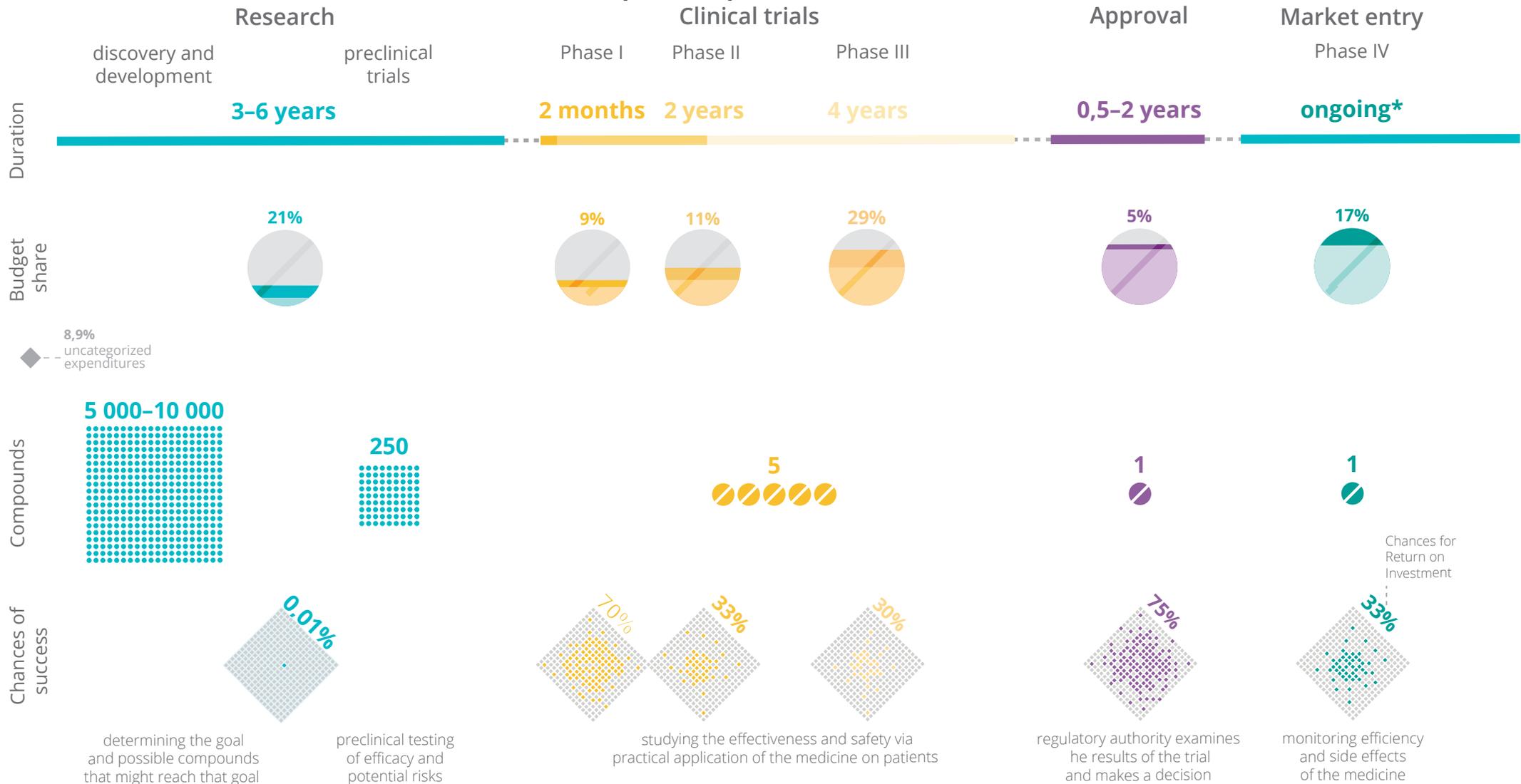


# VALUE CREATION IN PHARMA



# HOW ARE NEW MEDICINES DEVELOPED

## Innovative medicines research and development process

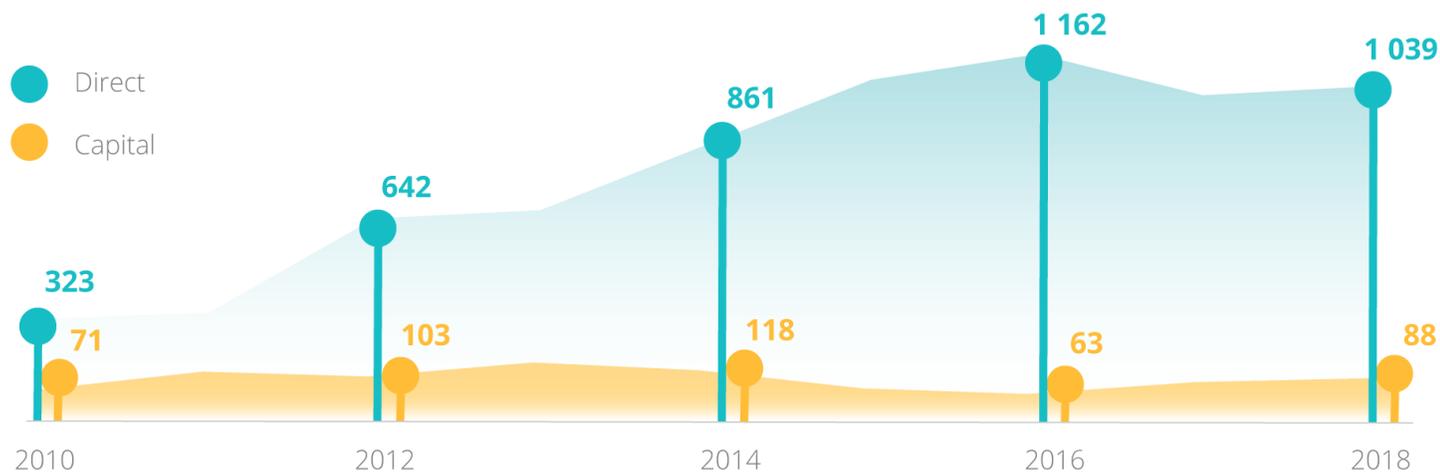


# INVESTMENT IN PHARMA INDUSTRY

**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

Source: SSC of Ukraine

\*capital investments are indicated over the year, direct - as of 01.01 of each year

# PHARMACEUTICAL MANUFACTURERS

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

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

## 2016

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

## 2017

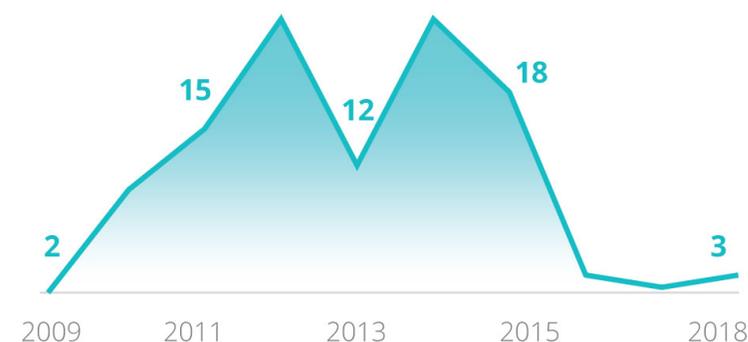
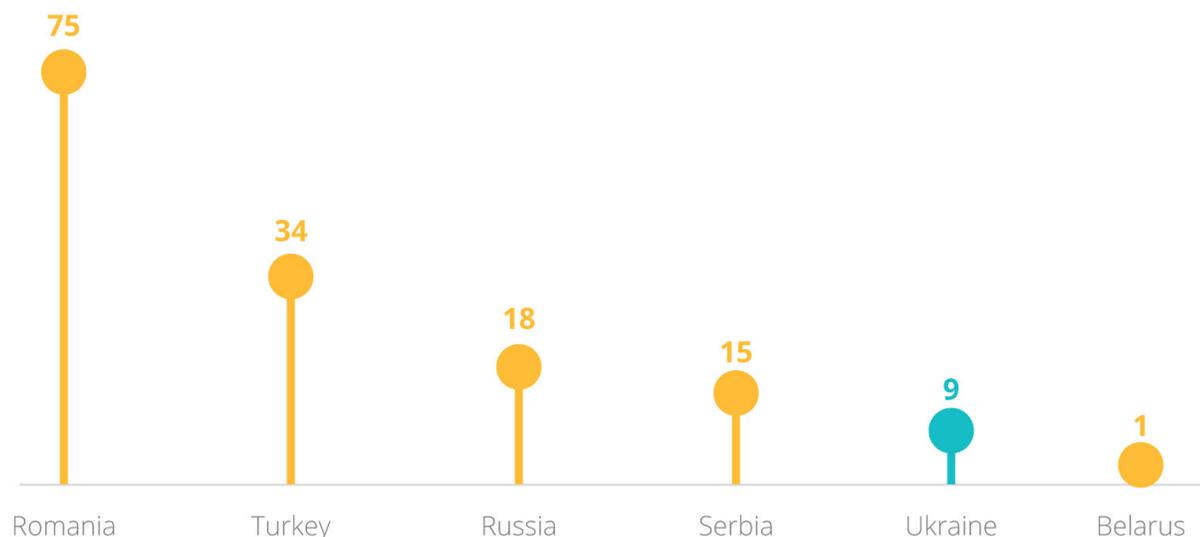
- ◆ Darnitsa
- ◆ Technolog
- ◆ Farmak

## 2018

- ◆ Borshchahivskiy CPP
- ◆ Synbias Pharma
- ◆ Ukrvetprompostach

**113**  
valid licenses  
for medicine  
manufacturing

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



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

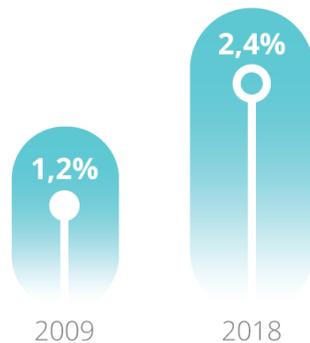
# MANUFACTURING DEVELOPMENT

## 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



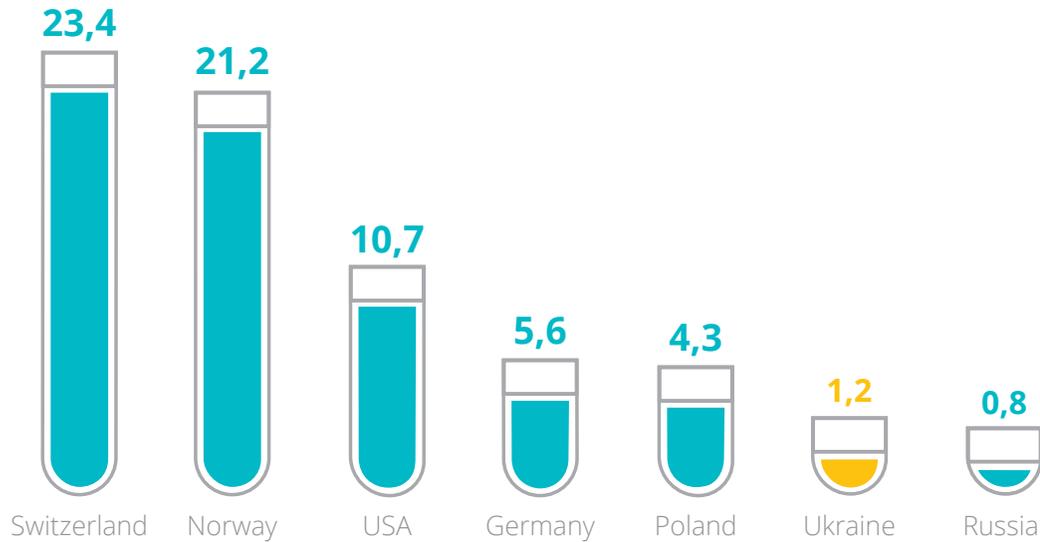
Source: open source analysis, ITC, Interpharma

\*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

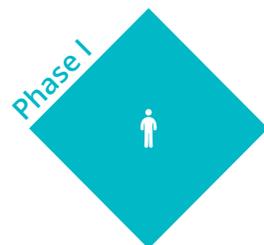
## Phases of clinical trials

20–80 healthy volunteers

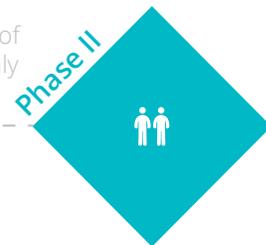
100–300 patients

Thousands of patients with specific diseases

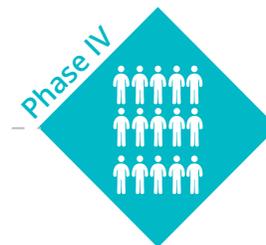
Postmarketing surveillance



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



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



studying of bioavailability, testing safe dose

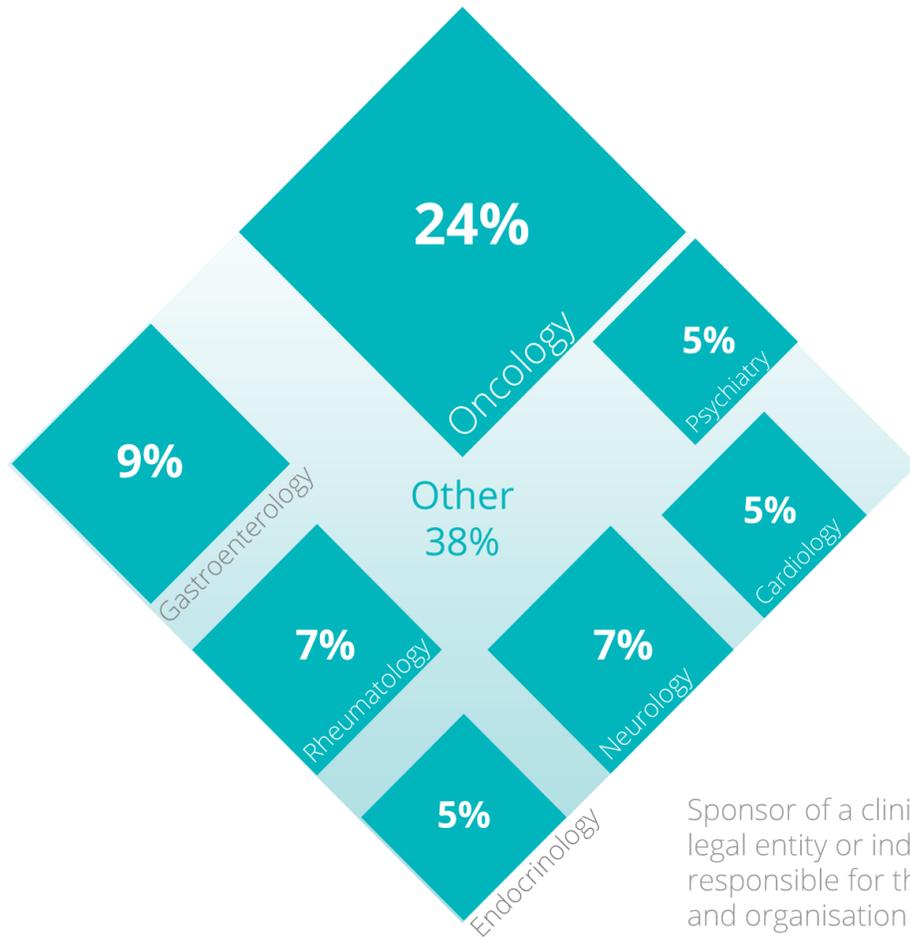
determination of effective dose, assessment of treatment safety

confirmation of the efficacy and safety of a medicine

getting additional information about medicine effectiveness, usage and its safeness

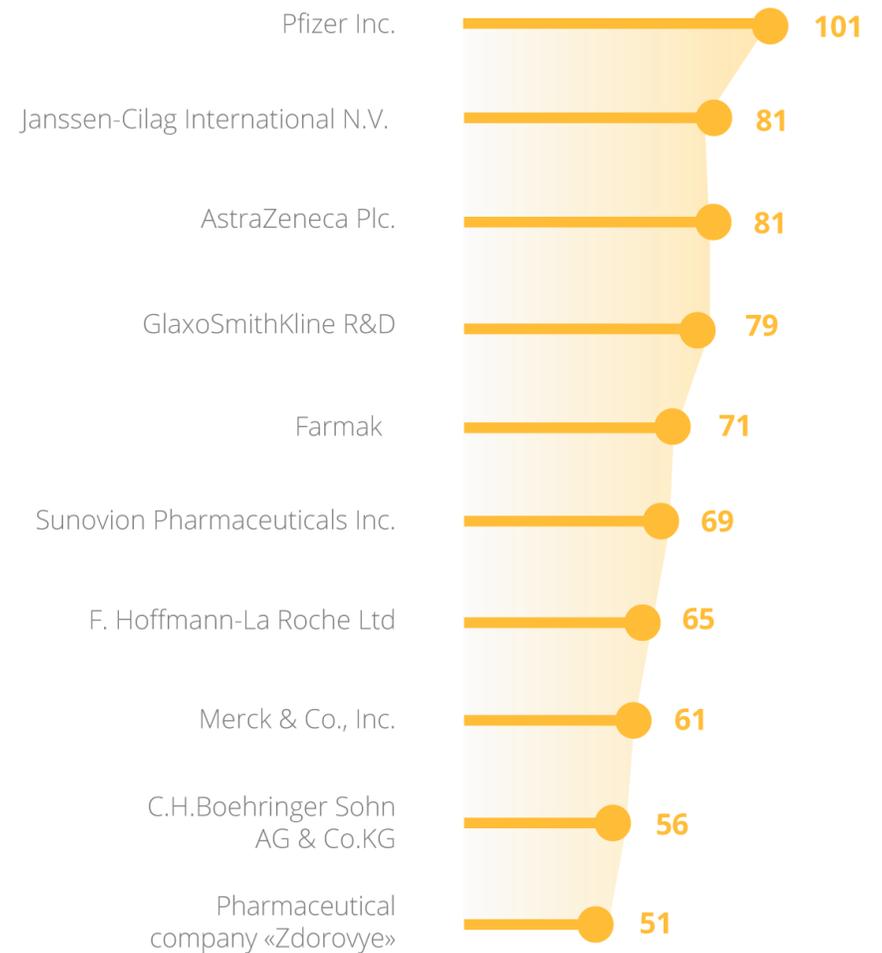
# CLINICAL TRIALS IN UKRAINE

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



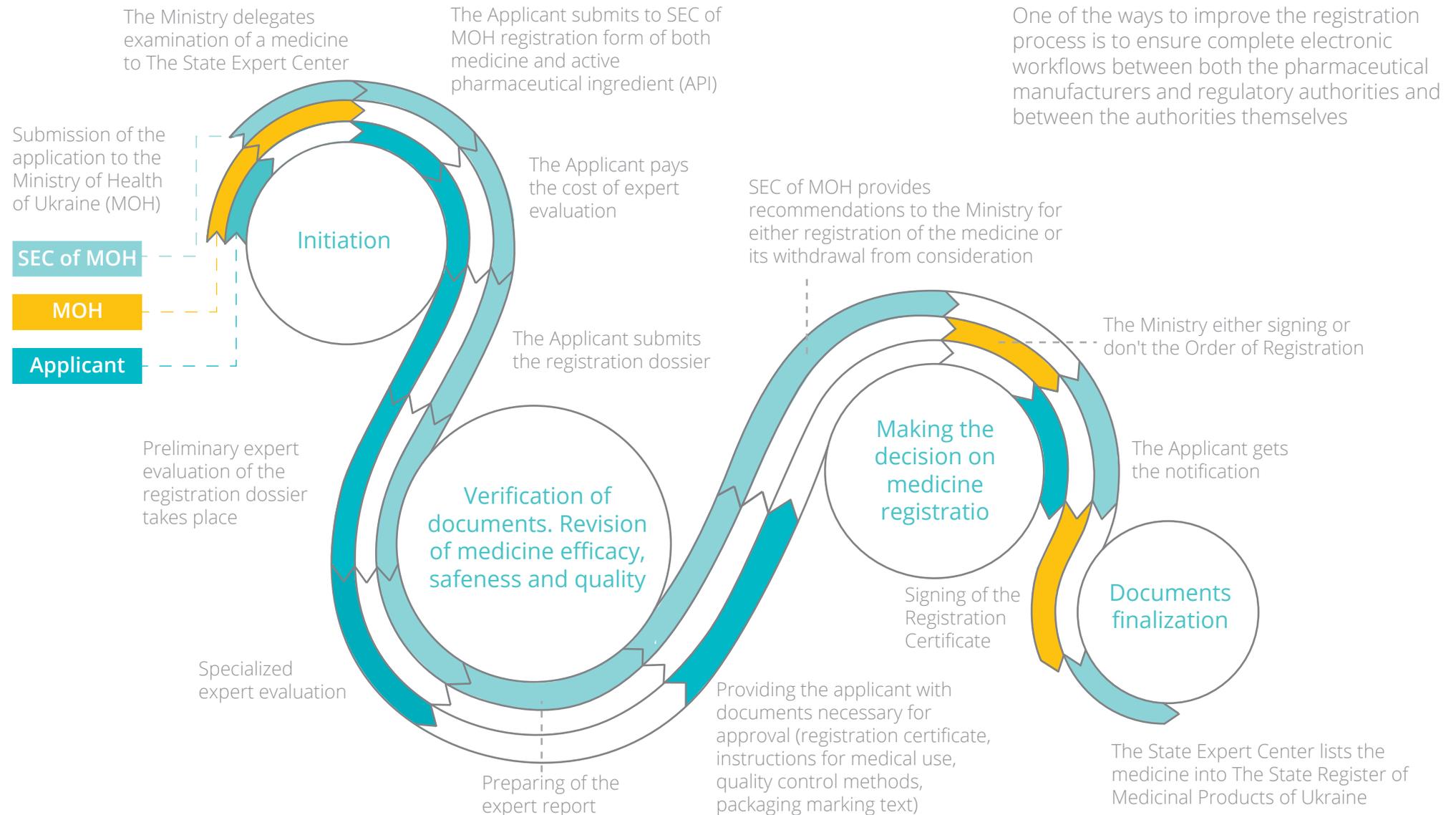
Sponsor of a clinical trial is a legal entity or individual who is responsible for the initiation and organisation of a clinical trial and/or its financing

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



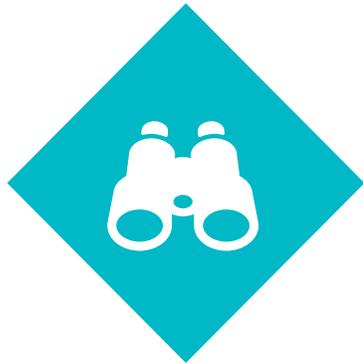
# REGISTRATION OF MEDICINES

## Process of registration in Ukraine



One of the ways to improve the registration process is to ensure complete electronic workflows between both the pharmaceutical manufacturers and regulatory authorities and between the authorities themselves

# 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

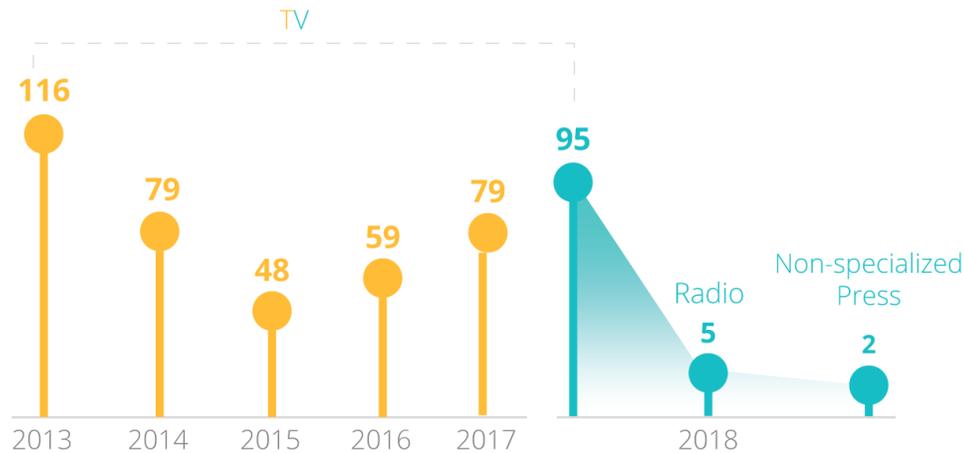


### Involving a higher risk level

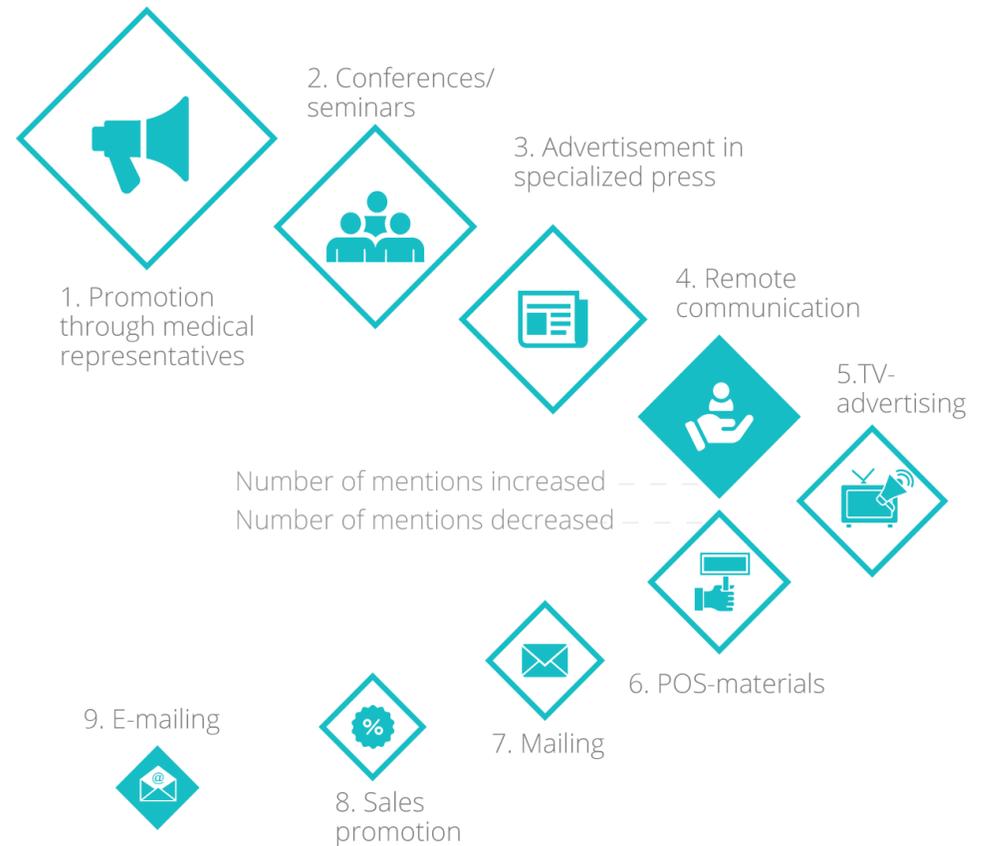
-  Retrospective discounts
-  Individual discounts for certain purchasers
-  A target level for a discount to be granted, which level is specified in monetary indicators
-  Significant purchase volume and a long period of time for granting a discount
-  Combination of several types of discounts or when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

# ADVERTISEMENT IN PHARMA INDUSTRY

**Advertisement by offline channels,**  
mln USD, excluding taxes\*



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



**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

# ADVERTISING: THE ANTITRUST ASPECT

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

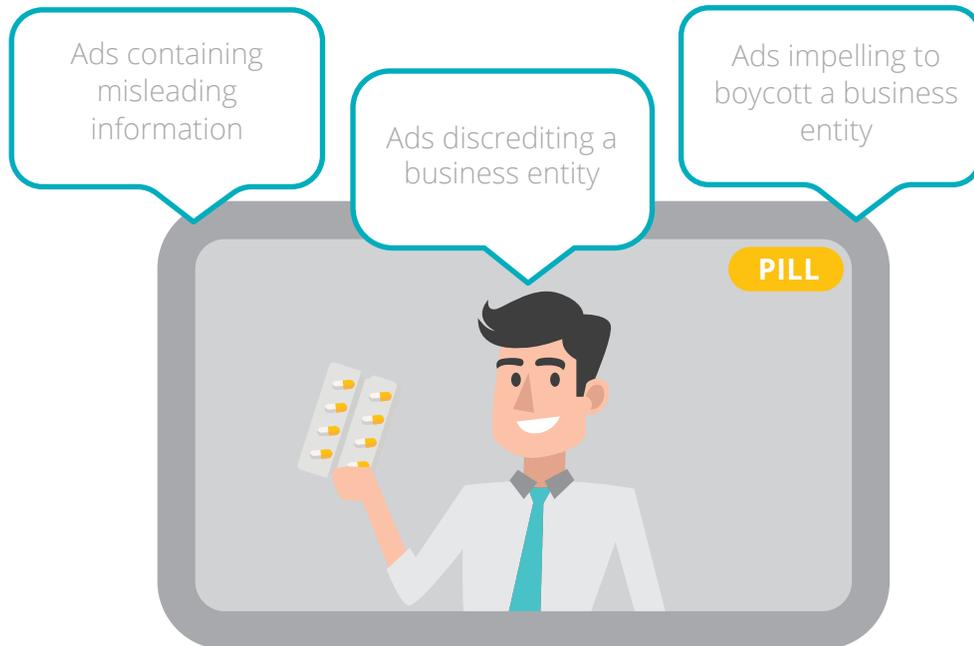
### Own medicines

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

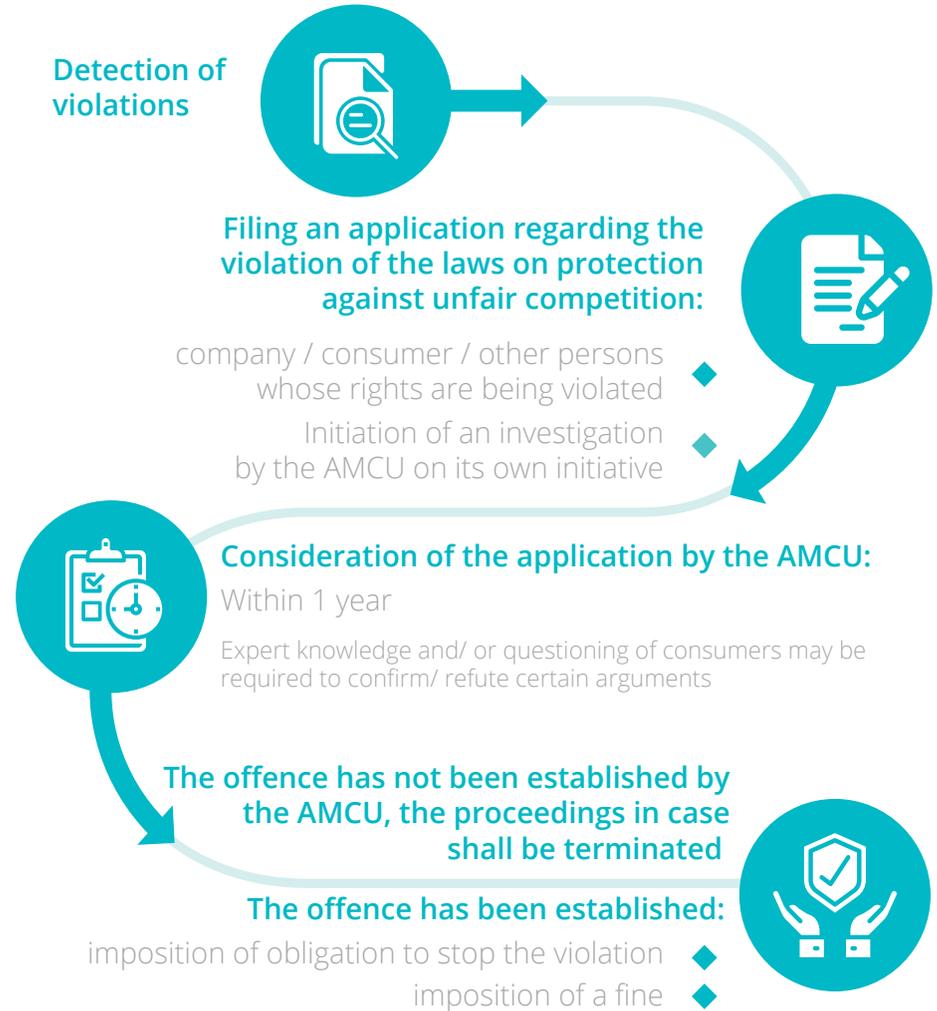
### Medicines of competitors

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



# MANUFACTURING AND MARKET

## Value Added

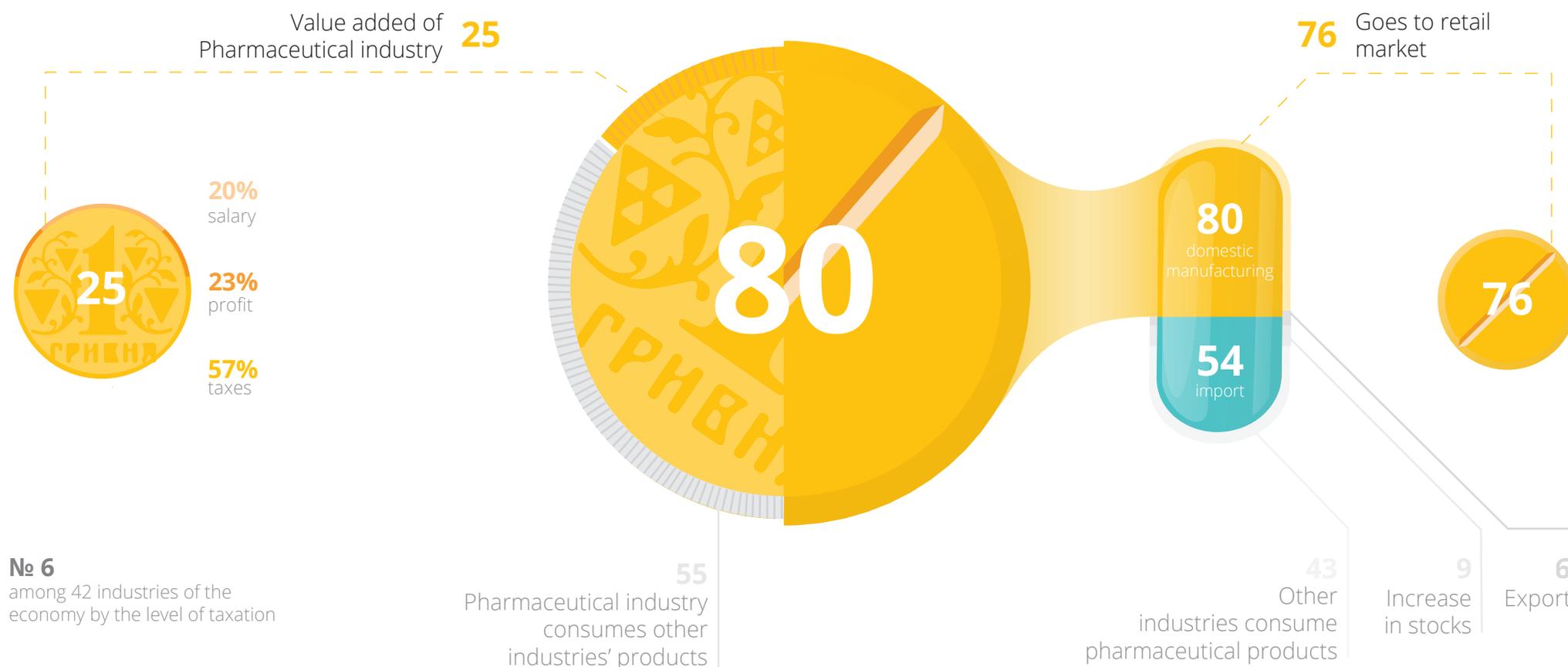
**0,8% of GDP**  
is created  
by Pharmaceutical industry

## Output of pharmaceutical products

2017, bln UAH (at consumer prices)

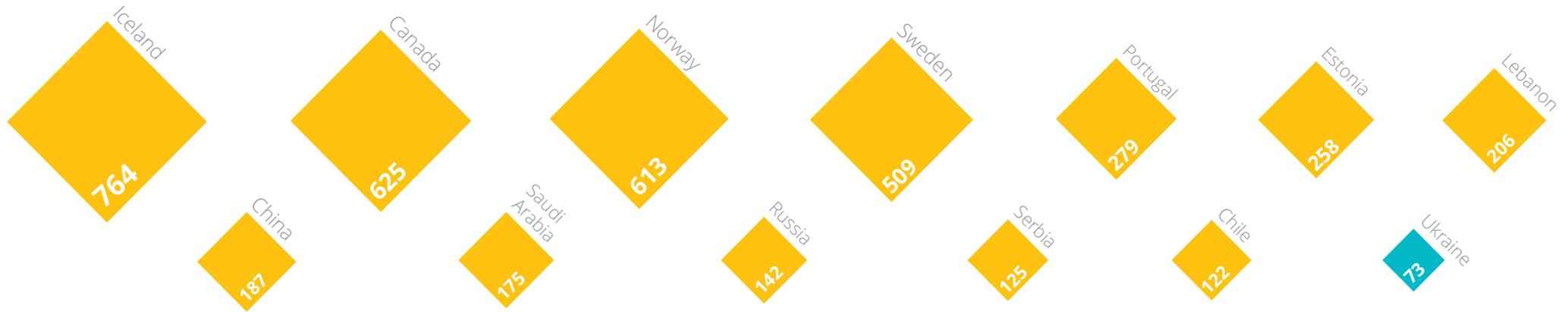
## Market

**9%**  
share of pharmaceutical  
products in retail turnover



# 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\*

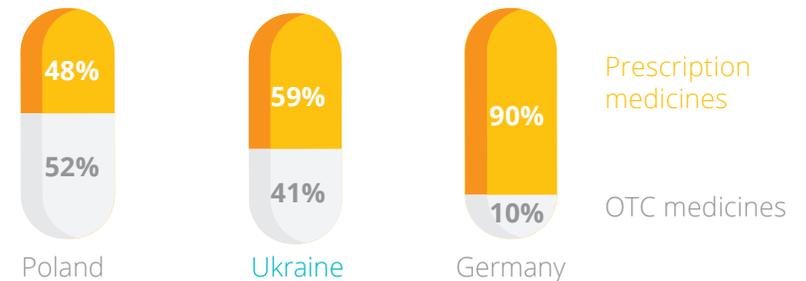
Pharmaceutical consumption in Ukraine, 2010–2018, USD per capita



Source: Apteka Weekly <sup>1-12, 14-15, 18, 21</sup>, Export.gov, OECD, DBS

\* expenditures on pharmaceuticals and medicines

Pharmaceutical consumption structure, % (money term)\*\*

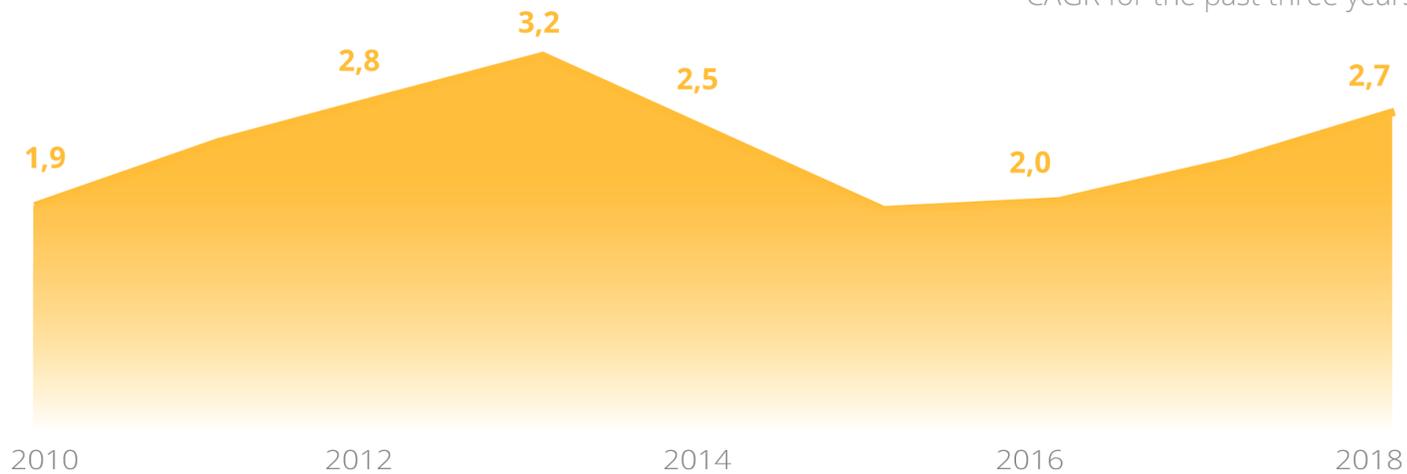


\*\* the structure includes only pharmacy retail sales, Poland and Germany - costs in Euros for PPPs

# PHARMACY MARKET DYNAMICS

Pharmacy market,  
2010–2018, bln USD

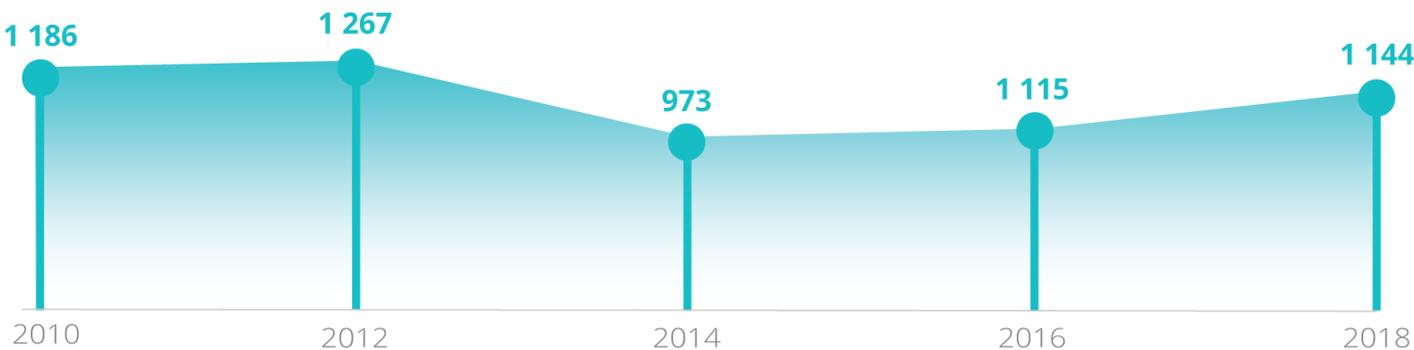
**+11%**  
CAGR for the past three years



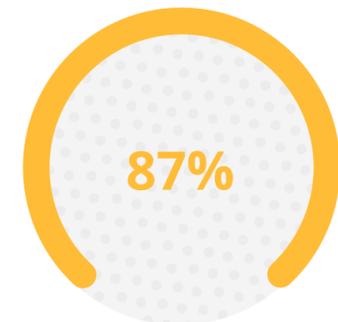
The pharmacy sector is the basis of Ukraine's pharmaceutical market

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

Pharmacy sales,  
2010–2018, mln pc

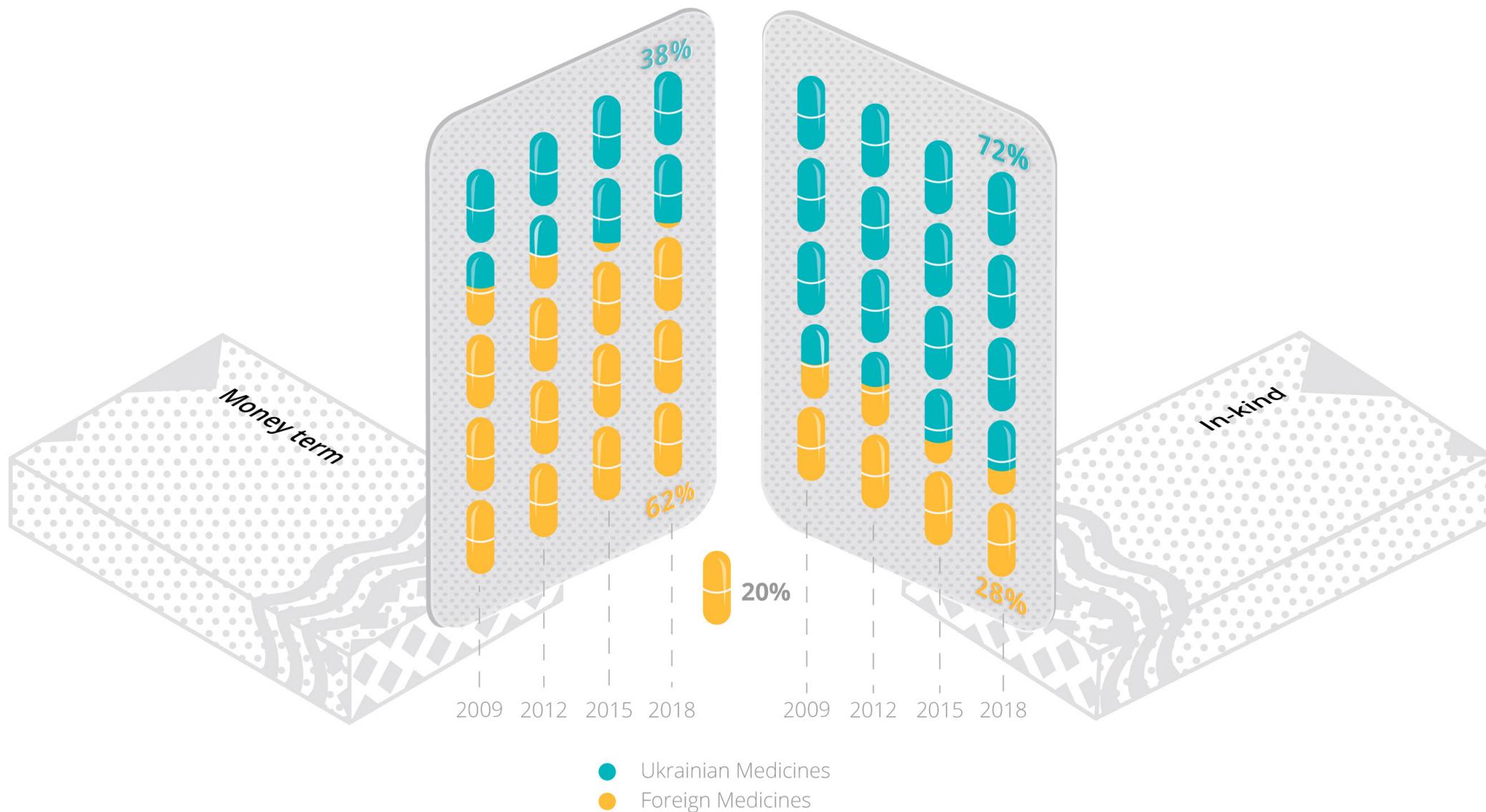


Share of pharmacy segment  
in pharmaceutical market,  
2018 p., % (money term)

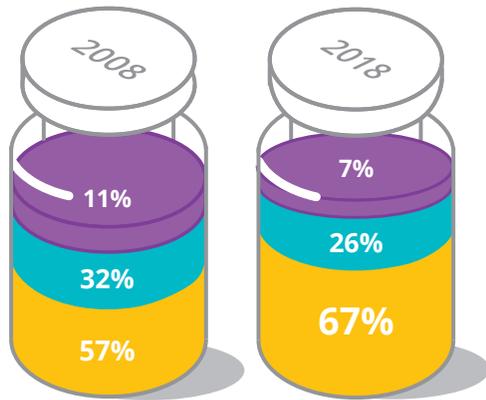


# PHARMACY MARKET STRUCTURE

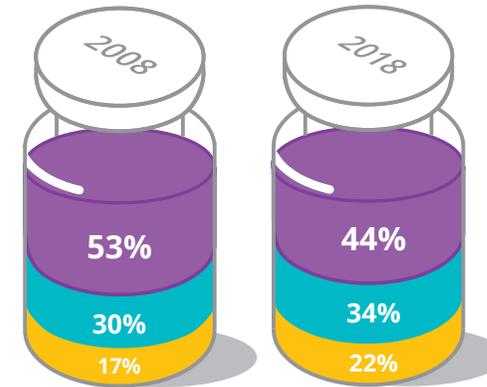
Pharmacy sales split by origin, %



# PHARMACY SALES SEGMENTATION

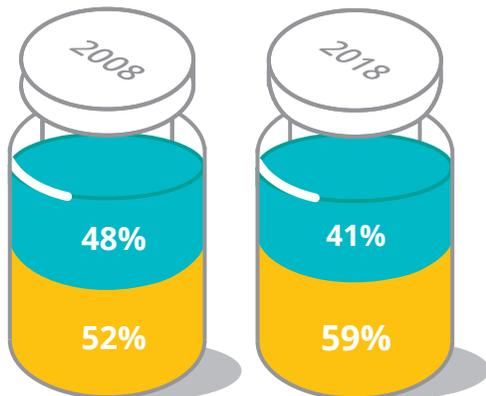


Low-priced  
Mid-priced  
High-priced

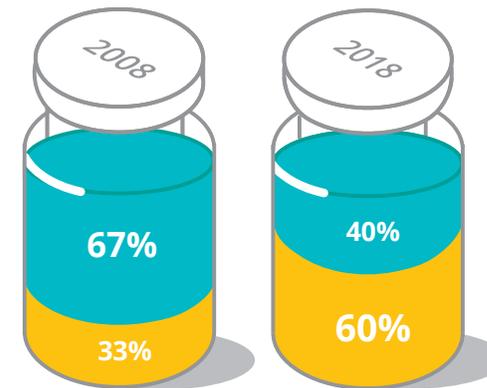


In-kind  
2008 and 2018

Money term  
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

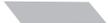
Source: Apteka Weekly <sup>18</sup>

# PHARMACY MARKET LEADERS

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

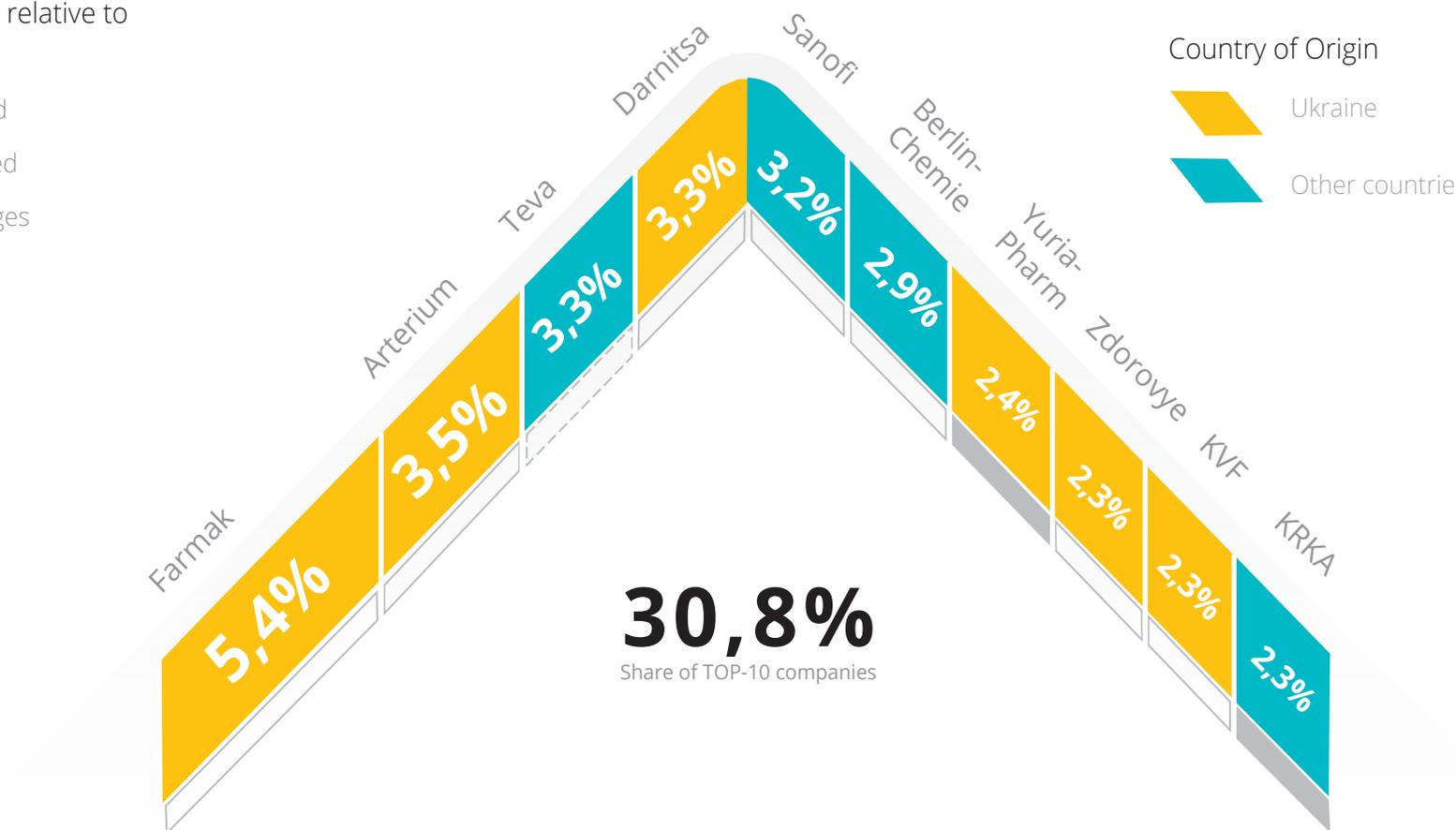
The pharmacy sales market is highly competitive, the share of TOP-20 companies is 47%, and it is almost equally distributed among Ukrainian and foreign manufacturers

Market share shift relative to previous year

-  Increased
-  Decreased
-  No changes

Country of Origin

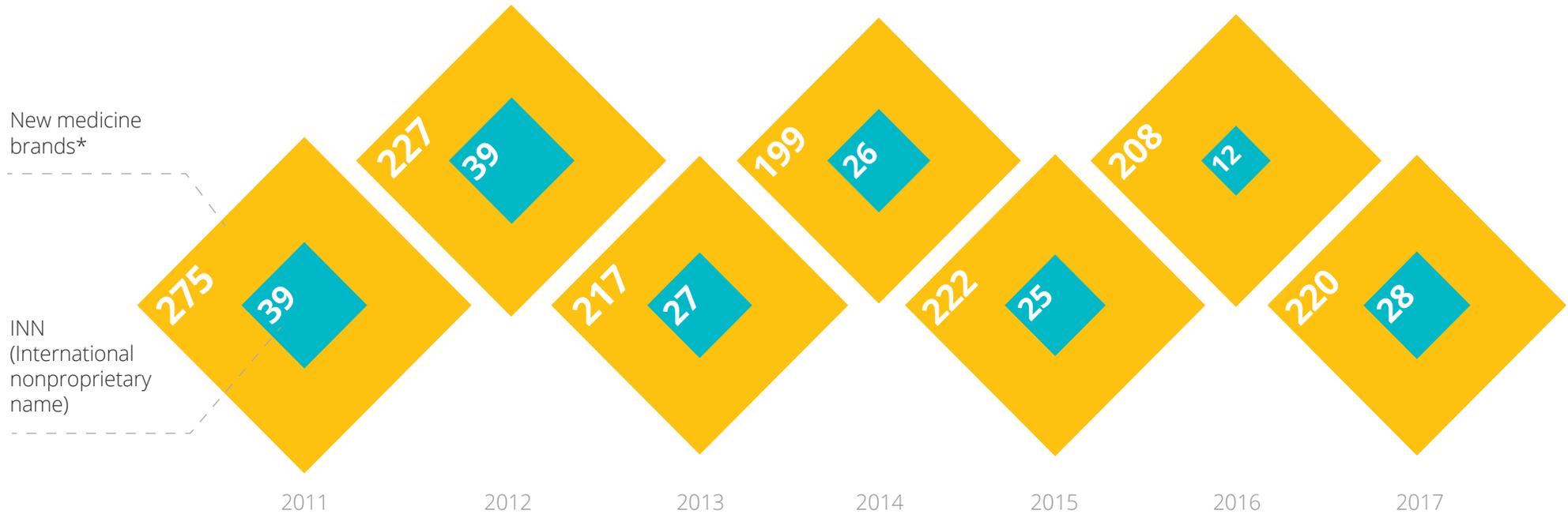
-  Ukraine
-  Other countries



# LAUNCH OF NEW MEDICINES

## Dynamics of launches, 2011–2017, pcs.

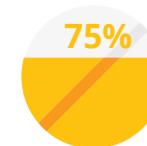
The number of new brands launched by pharmaceutical companies on the Ukrainian market has not changed much over the last years, but the number of new INNs dropped significantly



**Share of launches in pharmacy market, 2017 (money term)**  
0,4%



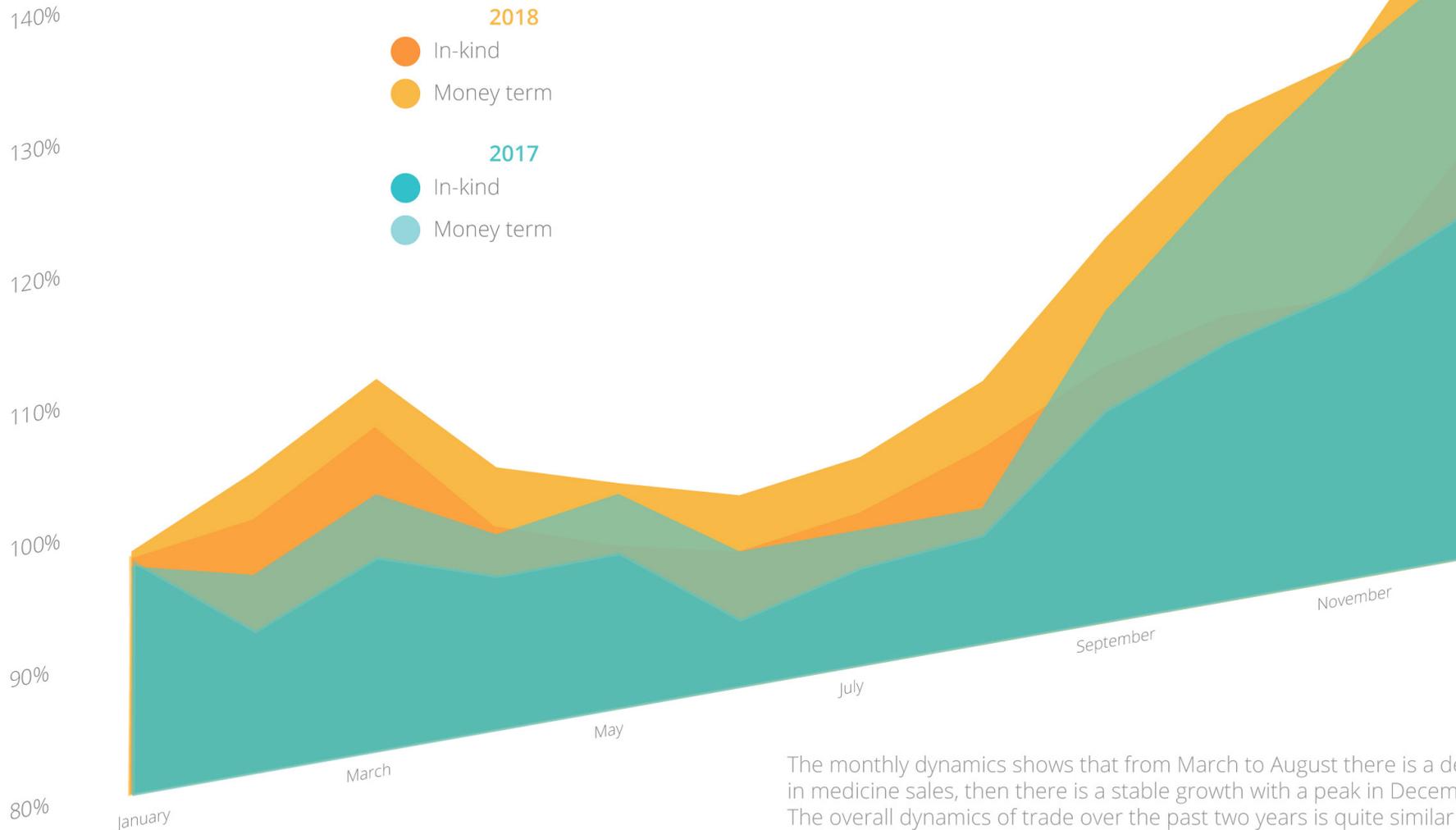
**Share of domestic manufacturers in launches structure, average for 2013-2017 (money term)**  
39%



**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



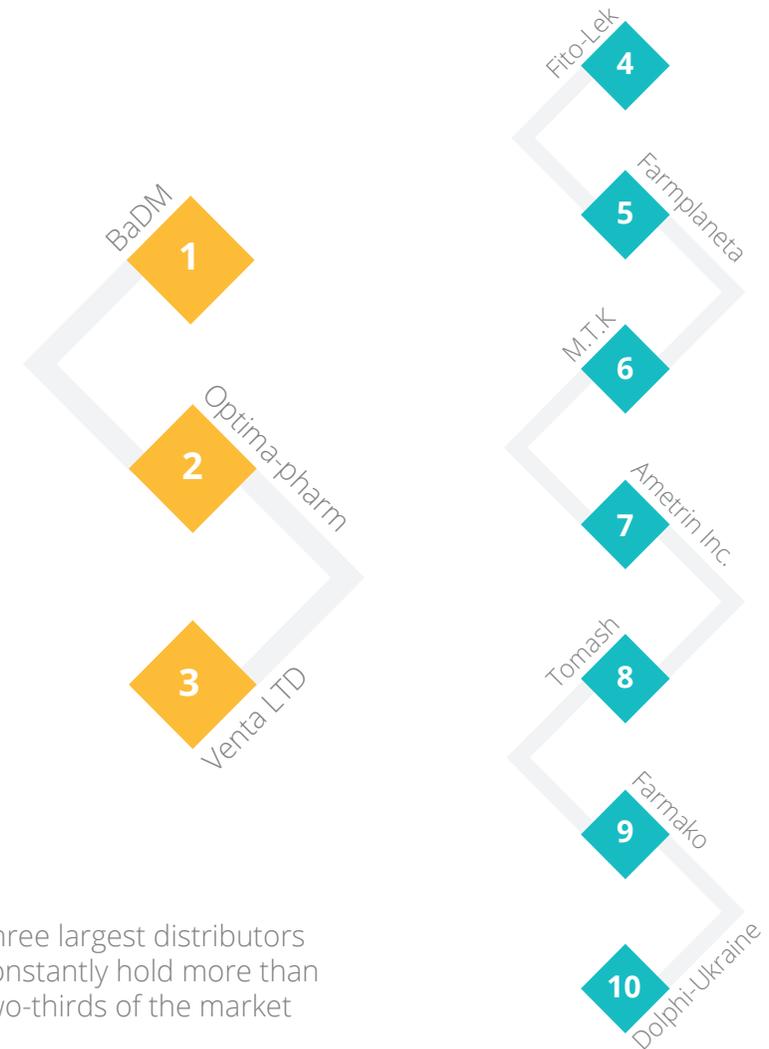
The monthly dynamics shows that from March to August there is a decline in medicine sales, then there is a stable growth with a peak in December. The overall dynamics of trade over the past two years is quite similar

# PHARMACY MARKET WHOLESAL 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

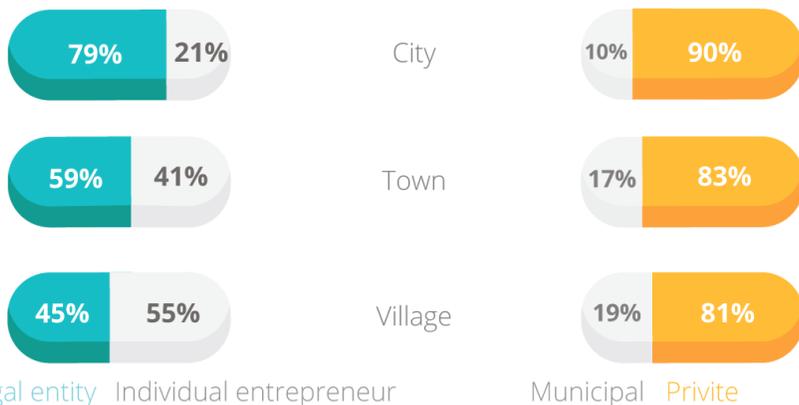
# PHARMACY RETAIL STRUCTURE

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

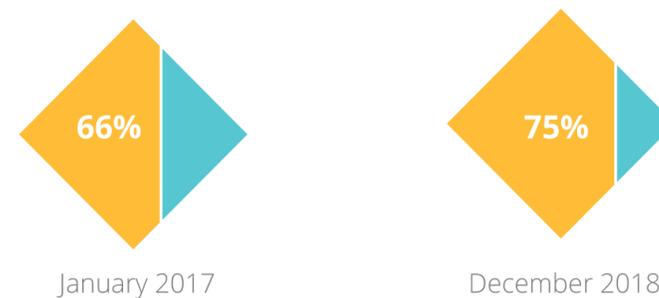


We can see a steady consolidation of business in the pharmacy segment. The share of mega pharmacy chains has been increased by 13.6% over the past four years

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

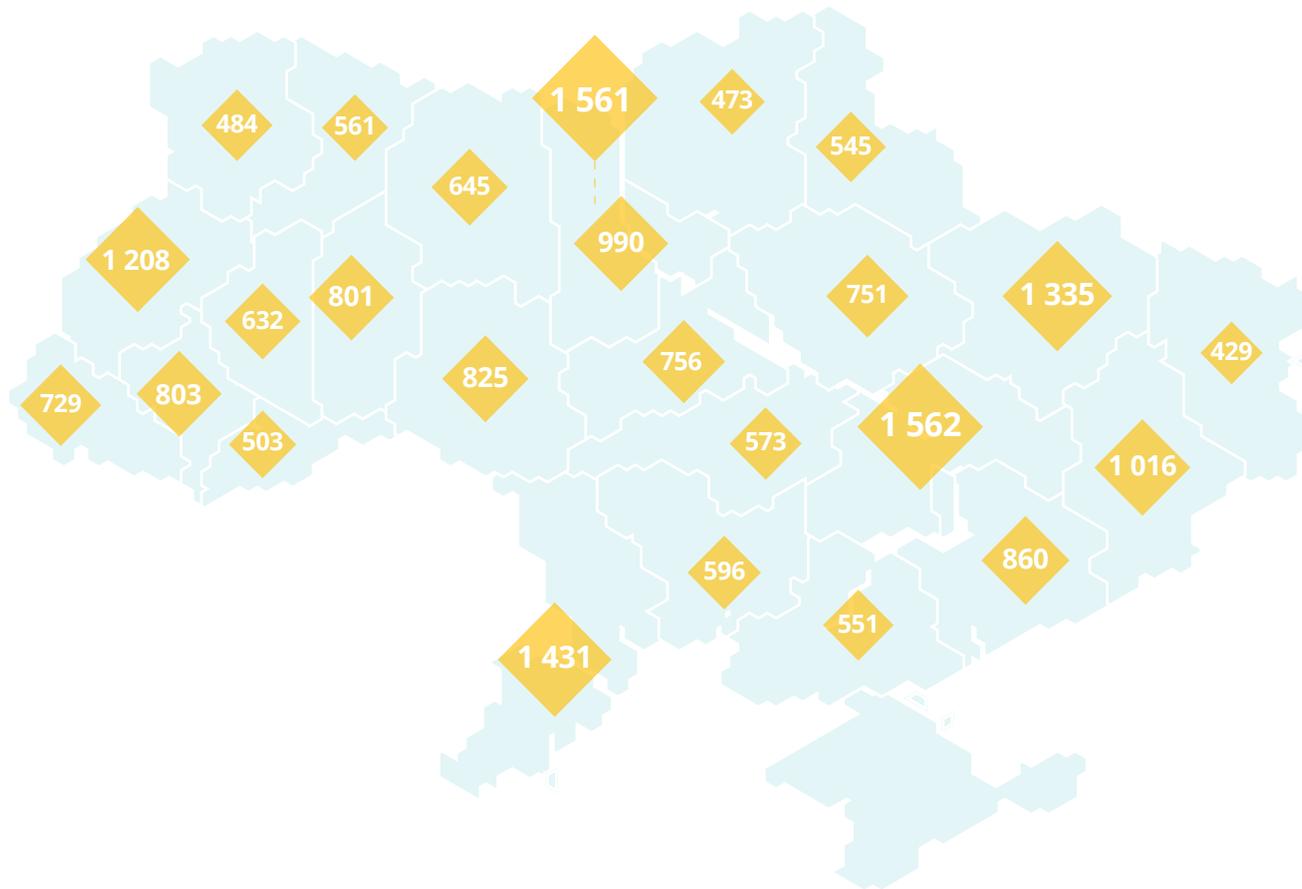


**Share of TOP-100 pharmacy chains,** 2017–2018, % (money term)



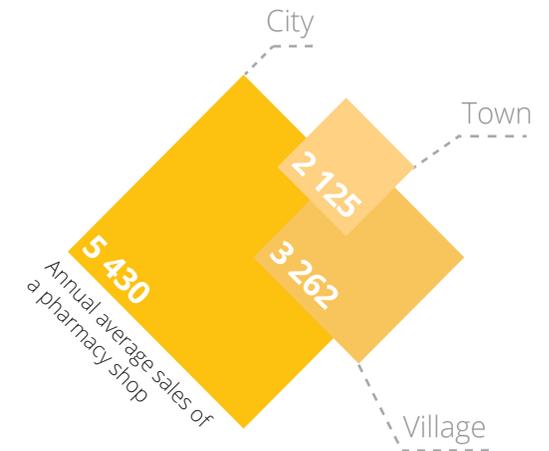
# PHARMACY TRADE INFRASTRUCTURE

Number of pharmacy shops in regions,  
as of 01.01.2019



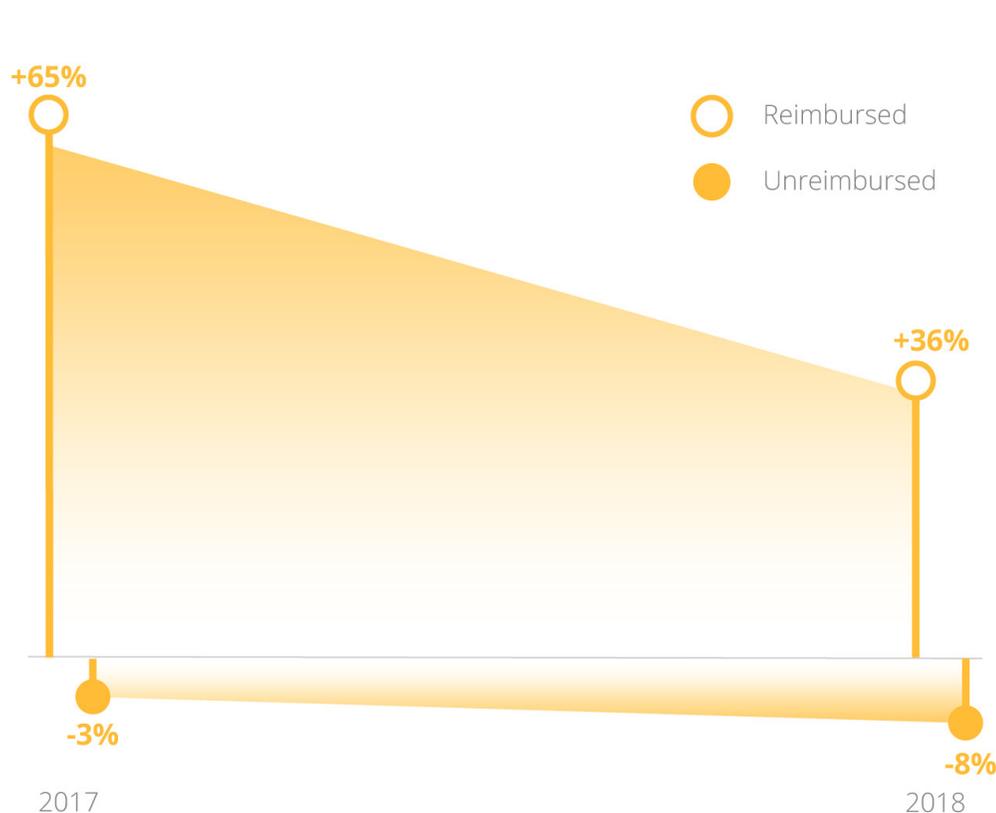
Sales per pharmacy shop in the city are the largest, as expected. Meanwhile, sales per pharmacy shop in the town are lower than in the village

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



# AFFORDABLE MEDICINES PROGRAM

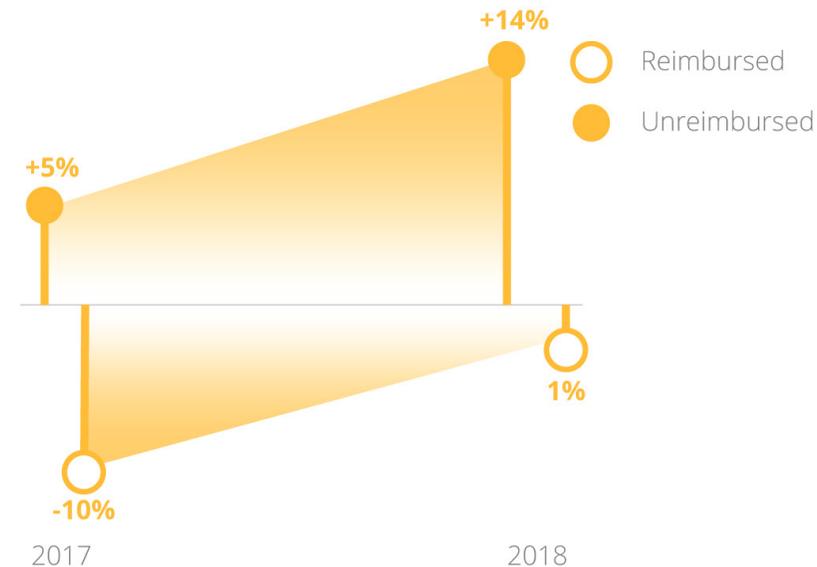
Dynamics of pharmacy sales of medicines from the INN list, 2017–2018, % relative to previous year (In-kind, DDD\*)



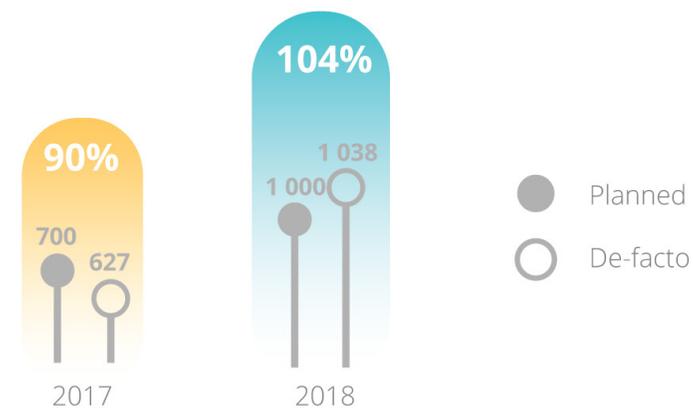
In 2018, the program contributed to the increase in consumption of medicines, the cost of which is fully or partially reimbursed by the state

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)

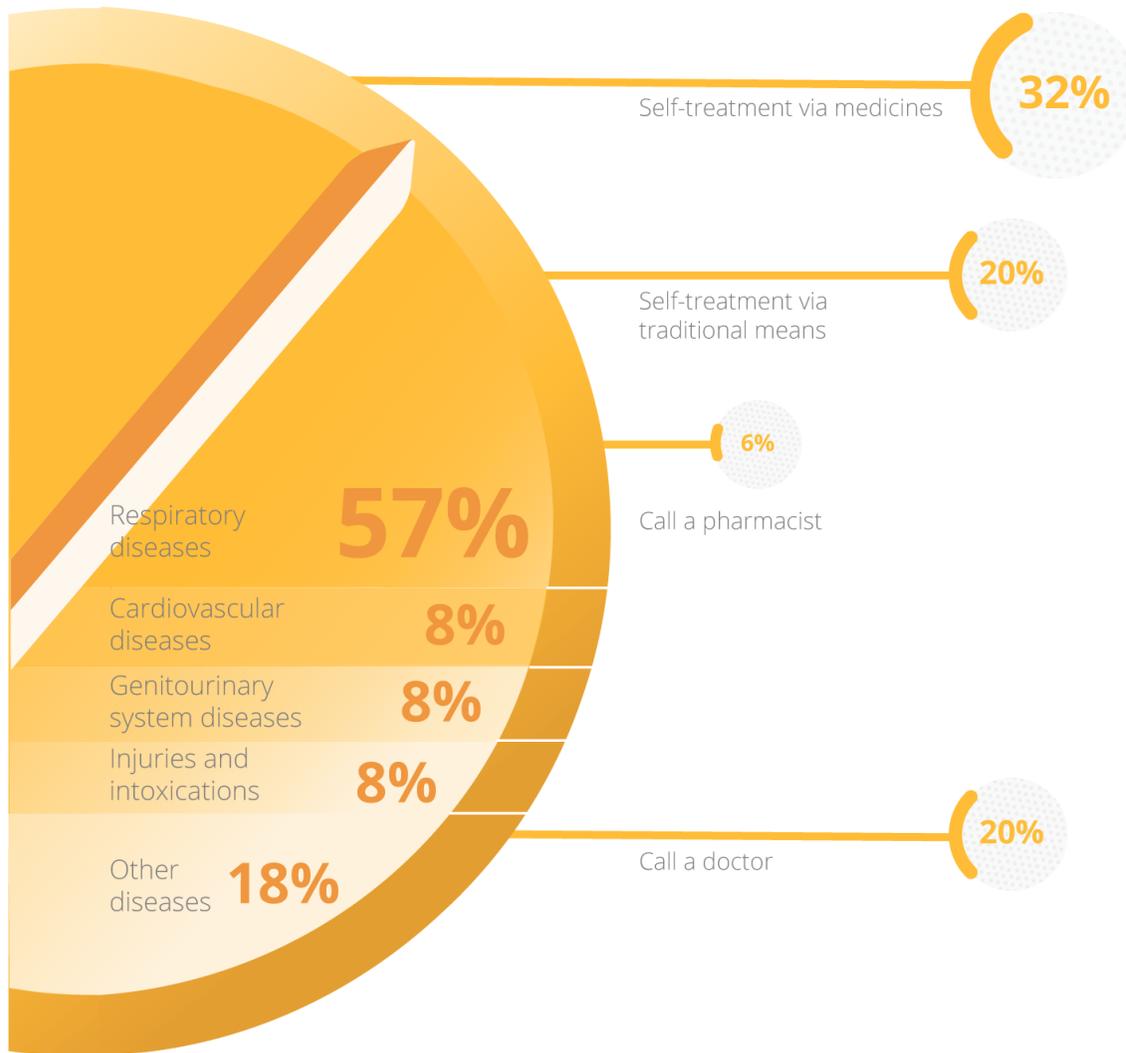


# MEDICAL TREATMENT IN UKRAINE

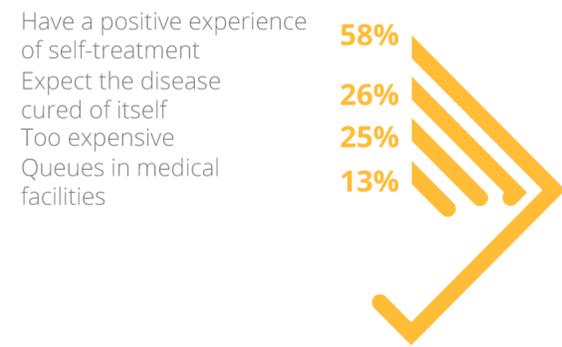
**Common diseases,**  
2017, % of the total number of newly registered cases of disease

**Ways of treatment,**  
probability, %

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



**Why people avoid doctors?**



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



Decisive, save lives



Effective, not decisive

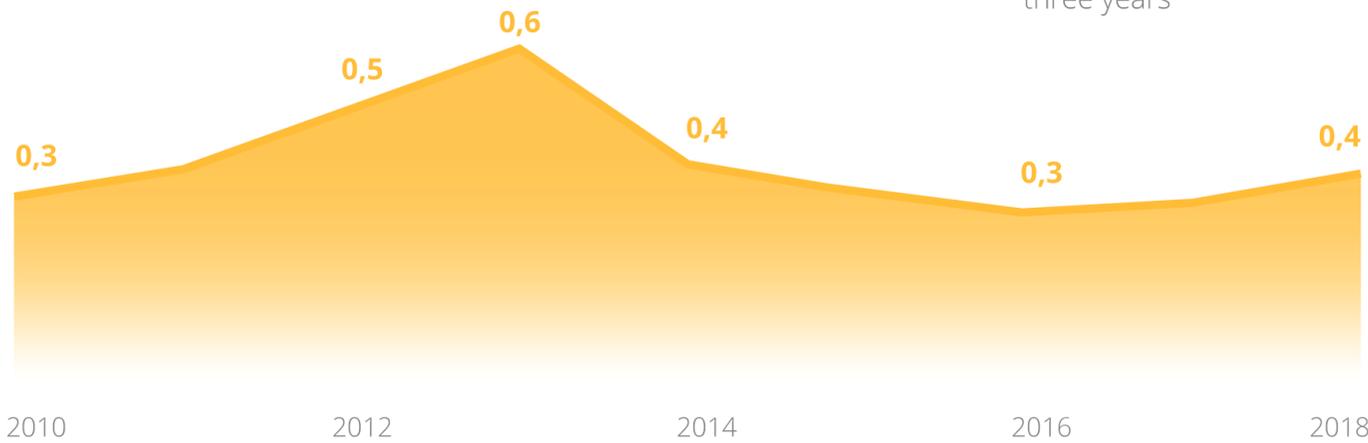
Subsidiary, can be abandoned

# HOSPITAL MARKET DYNAMICS

Hospital market,  
2010–2018, bln USD

**+7%**

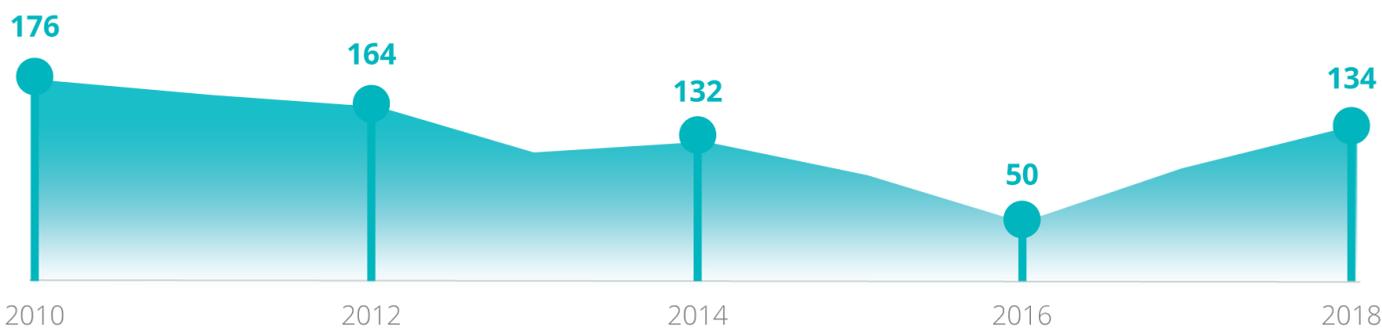
CAGR for the past  
three years



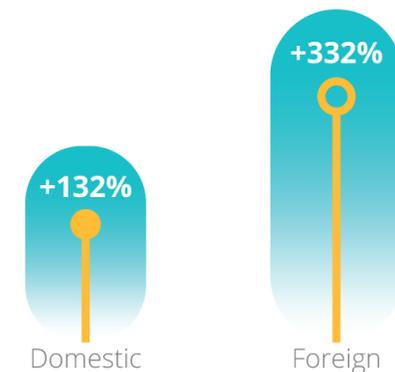
The main reason for the decrease in the procurement of medicines is the devaluation of the hryvnia, which led to an increase in the cost of medicines, especially foreign ones

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

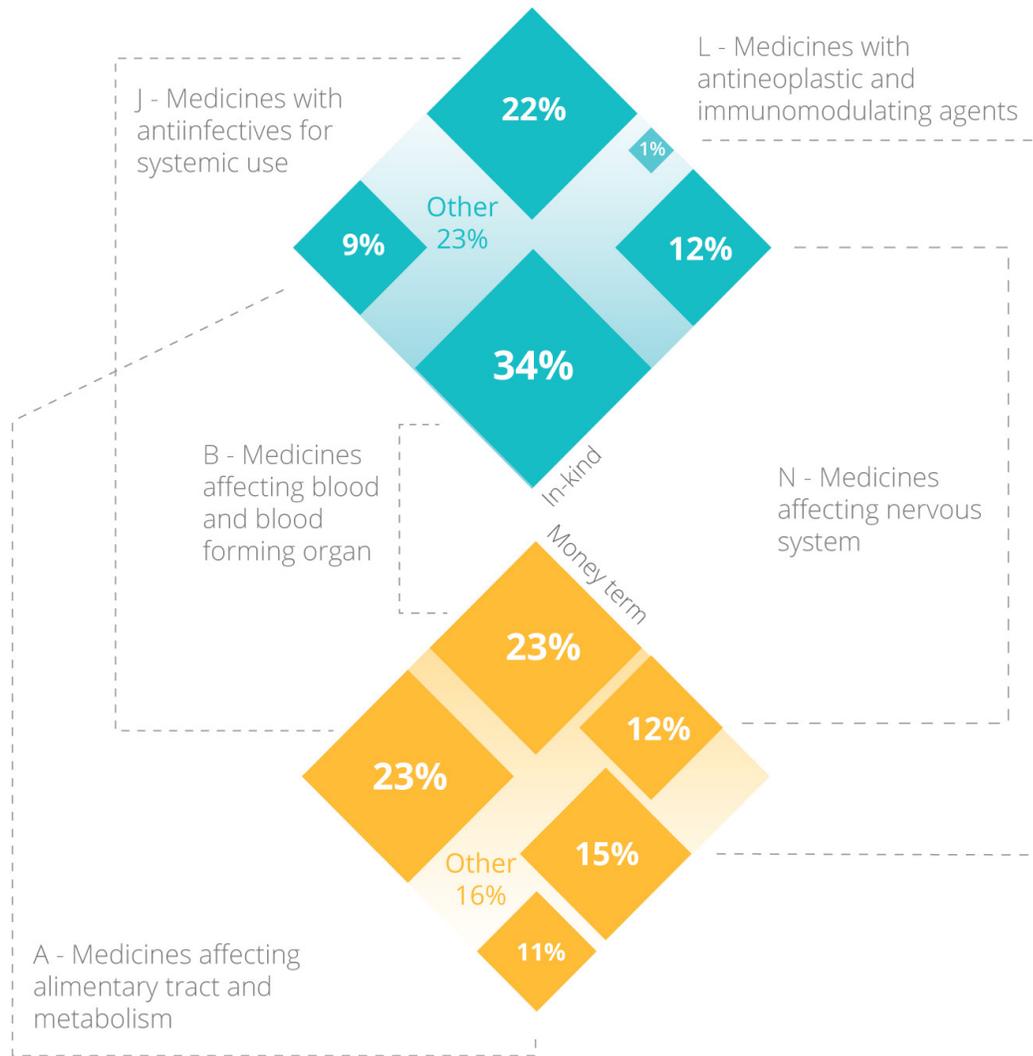


Dynamics of weighted average  
cost of medicines, 2012–2018, %

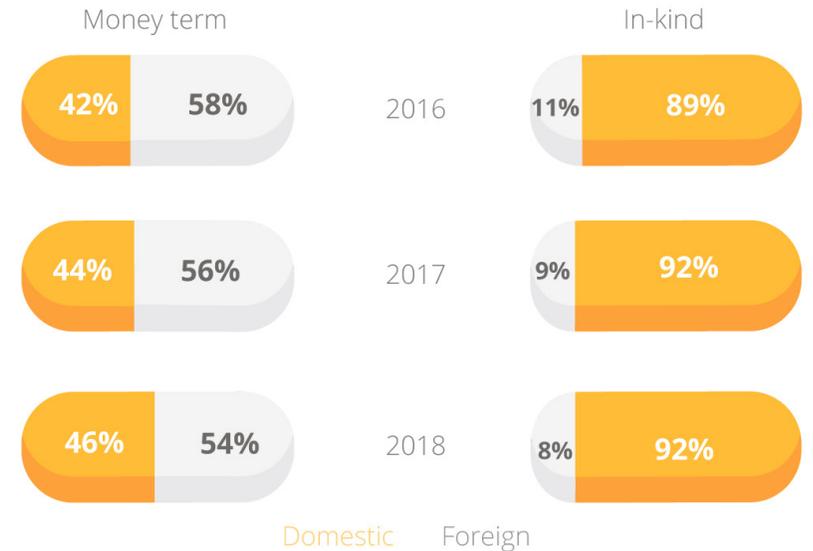


# HOSPITAL MARKET STRUCTURE

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

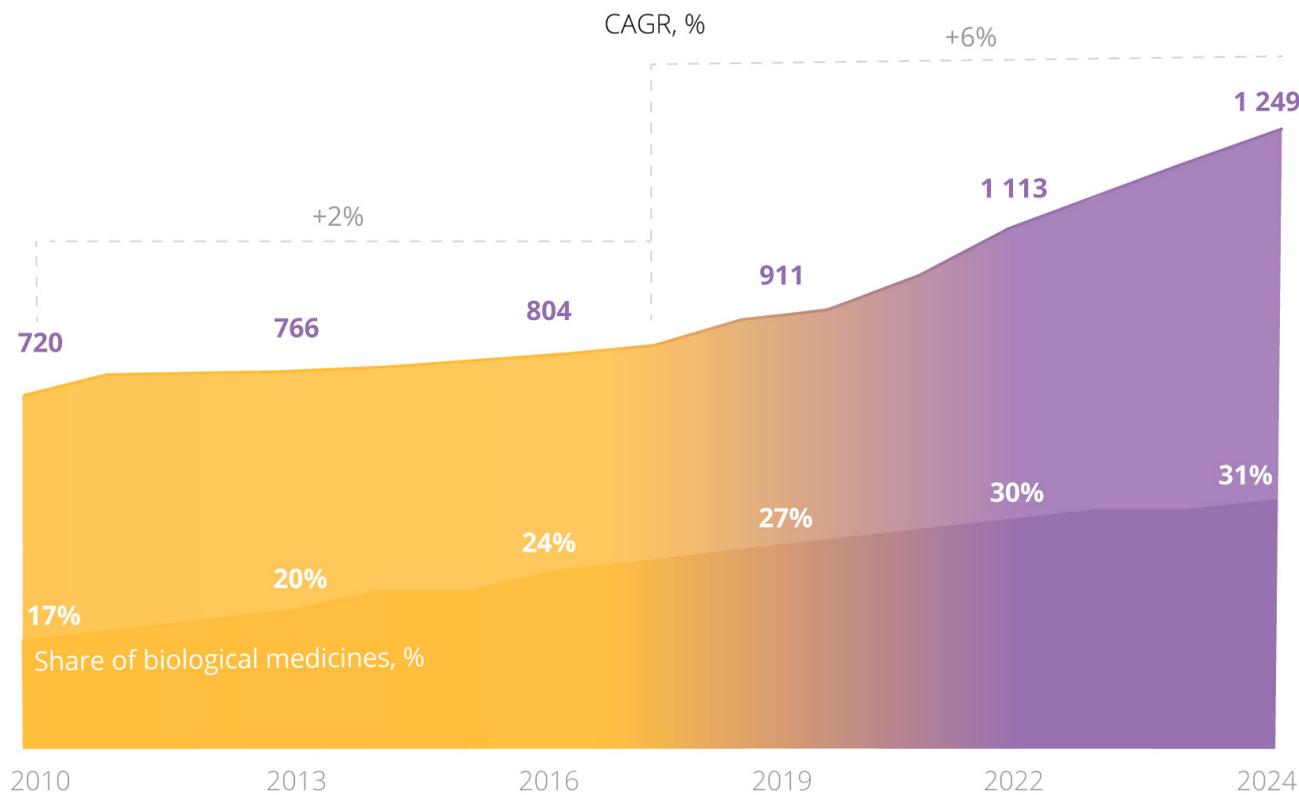
Source: Apteka Weekly <sup>21</sup>

\*ATC - The Anatomical Therapeutic Chemical Classification System

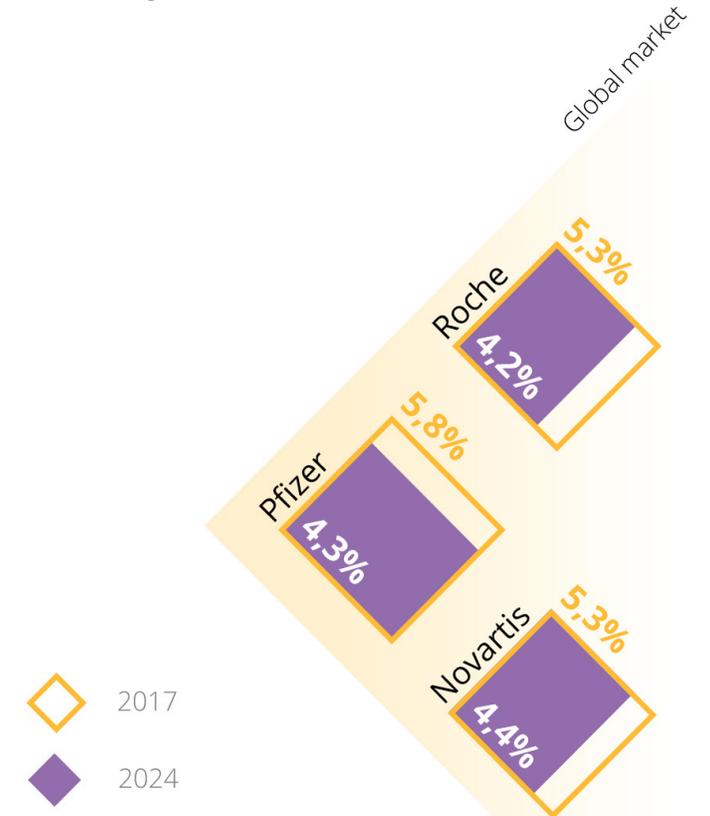
# GLOBAL PHARMACEUTICAL MARKET

## 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, %\*

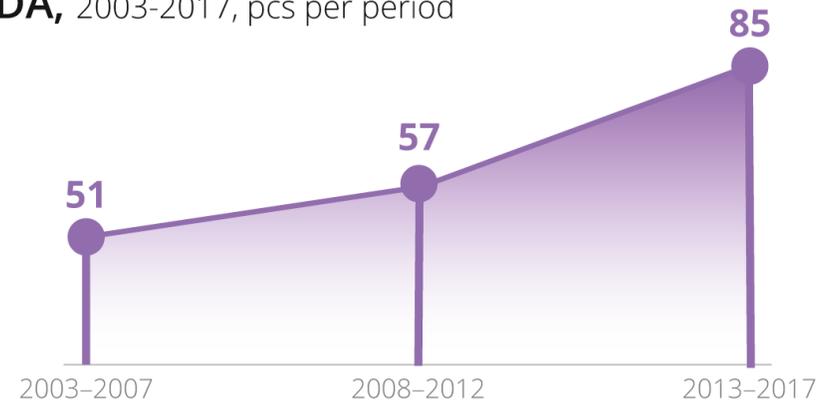
Biopharmaceutics is the way of medicine manufacturing by obtaining complex macromolecules, identical to those found in living organisms. Biopharmaceutics makes a significant impact on the incomes of leading pharmaceutical manufacturers



## CAGR forecast, 2018–2024, %



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



# R&D INVESTMENT IN PHARMA INDUSTRY

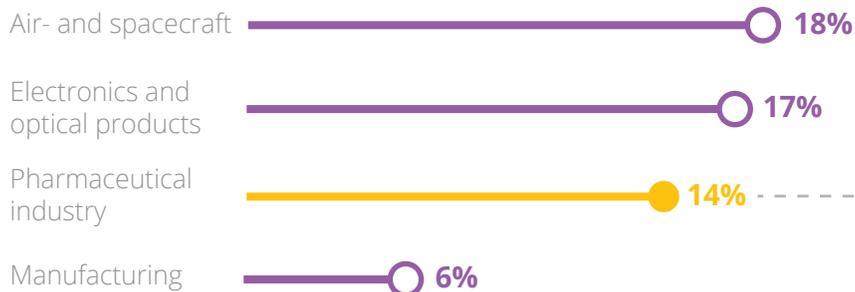
**Cost-effectiveness of R&D expenditures by pharmaceutical companies,**  
the number of new medicines per one billion dollars of private R&D investments (2014 prices)



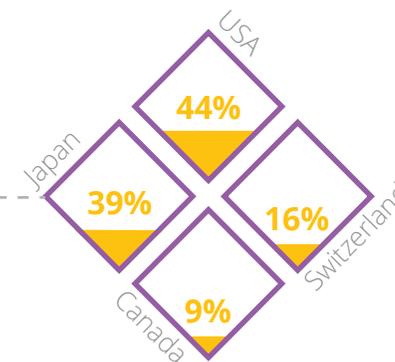
Due to the increase in the cost of new medicines developing the productivity of R&D expenditures has been reduced

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, %\*

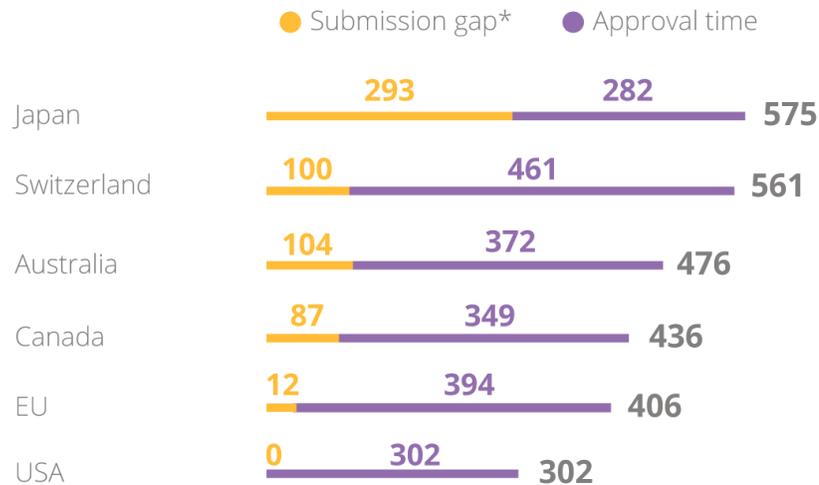


**R&D intensity in pharmaceutical industry,**  
share of R&D in industry value added, 2014 or nearest one, %

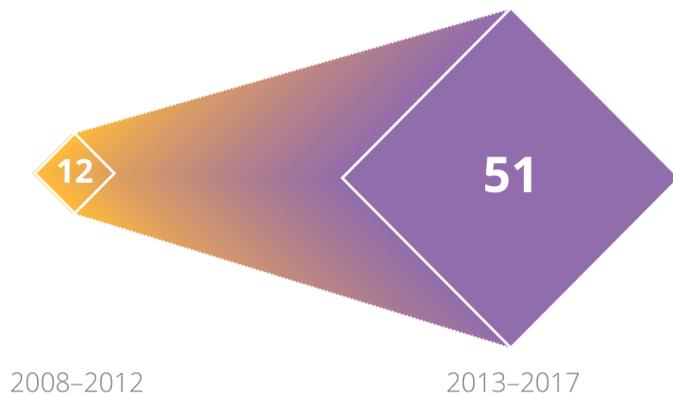


# MEDICINES APPROVALS

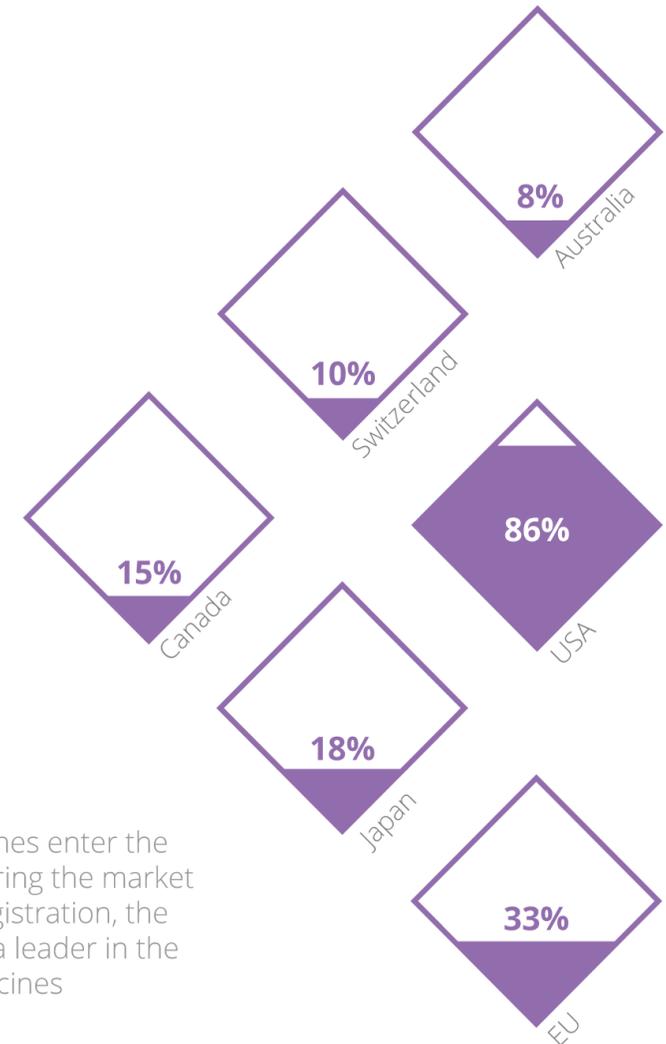
## Medicines median approval time, 2017, days



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



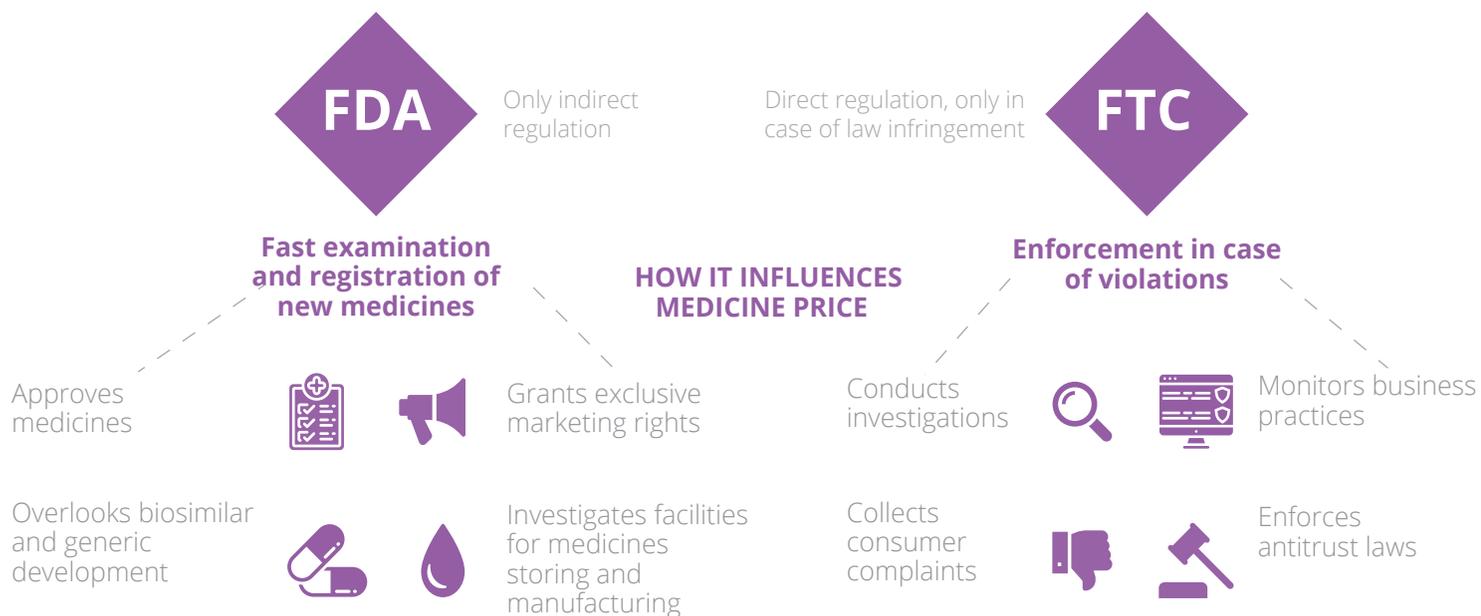
## Availability of medicines by countries, medicines approved for the first time or within one month of their approval in another country from the total number of approved, 2017, %



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



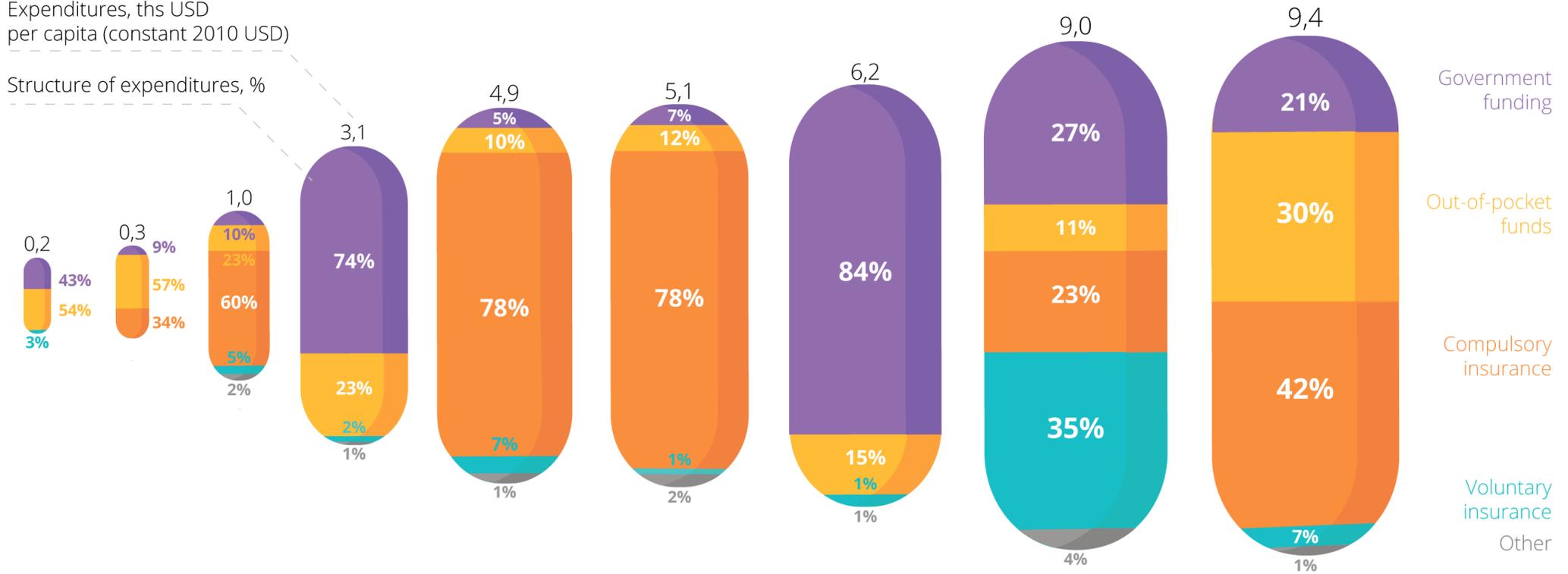
# HEALTHCARE SYSTEM

## Breakdown of healthcare financing and life expectancy,

2016 or nearest one

Expenditures, ths USD  
per capita (constant 2010 USD)

Structure of expenditures, %



Ukraine

Albania

Poland

Italy

France

Germany

Sweden

USA\*

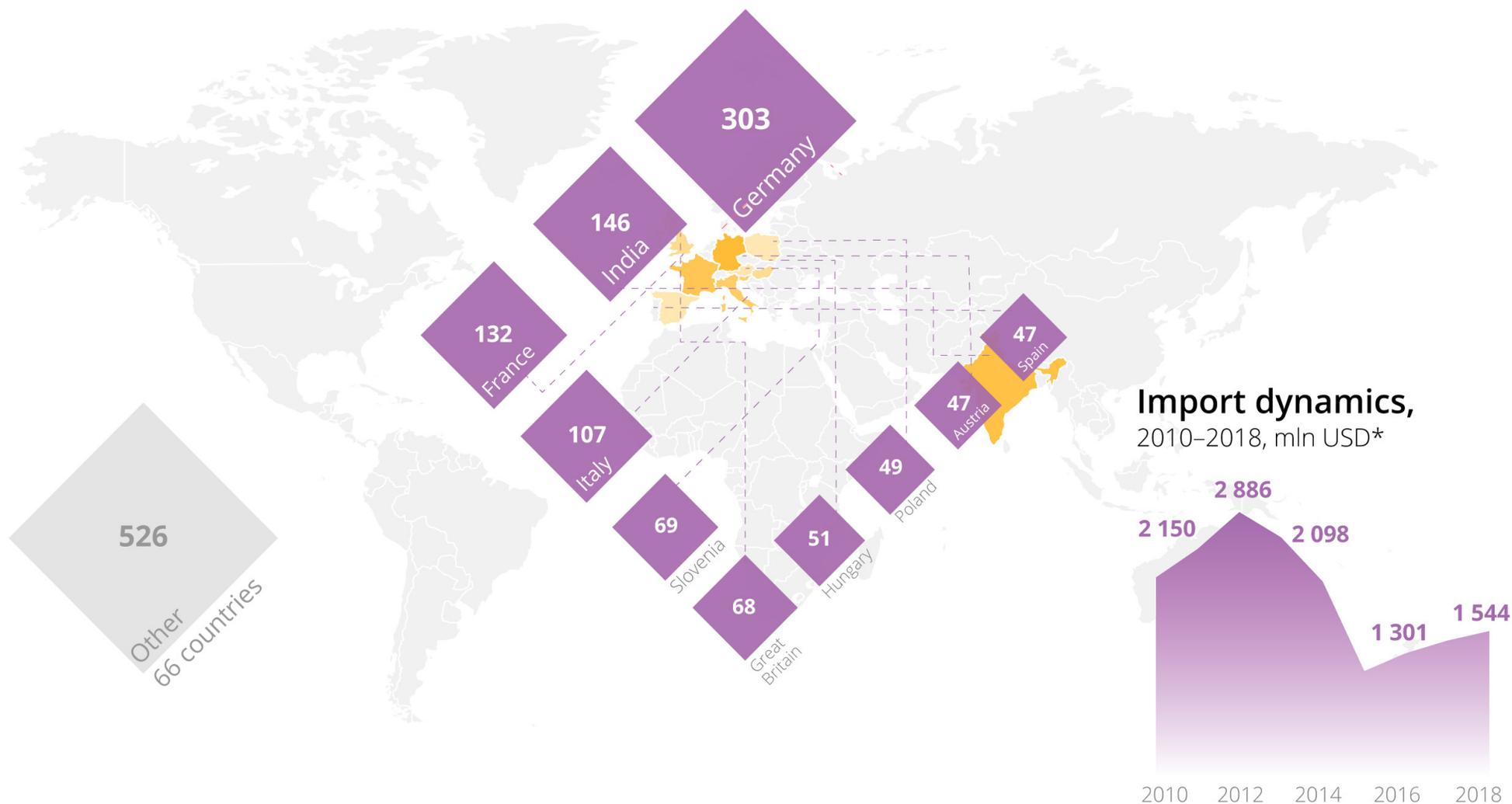
Switzerland



Life expectancy, years

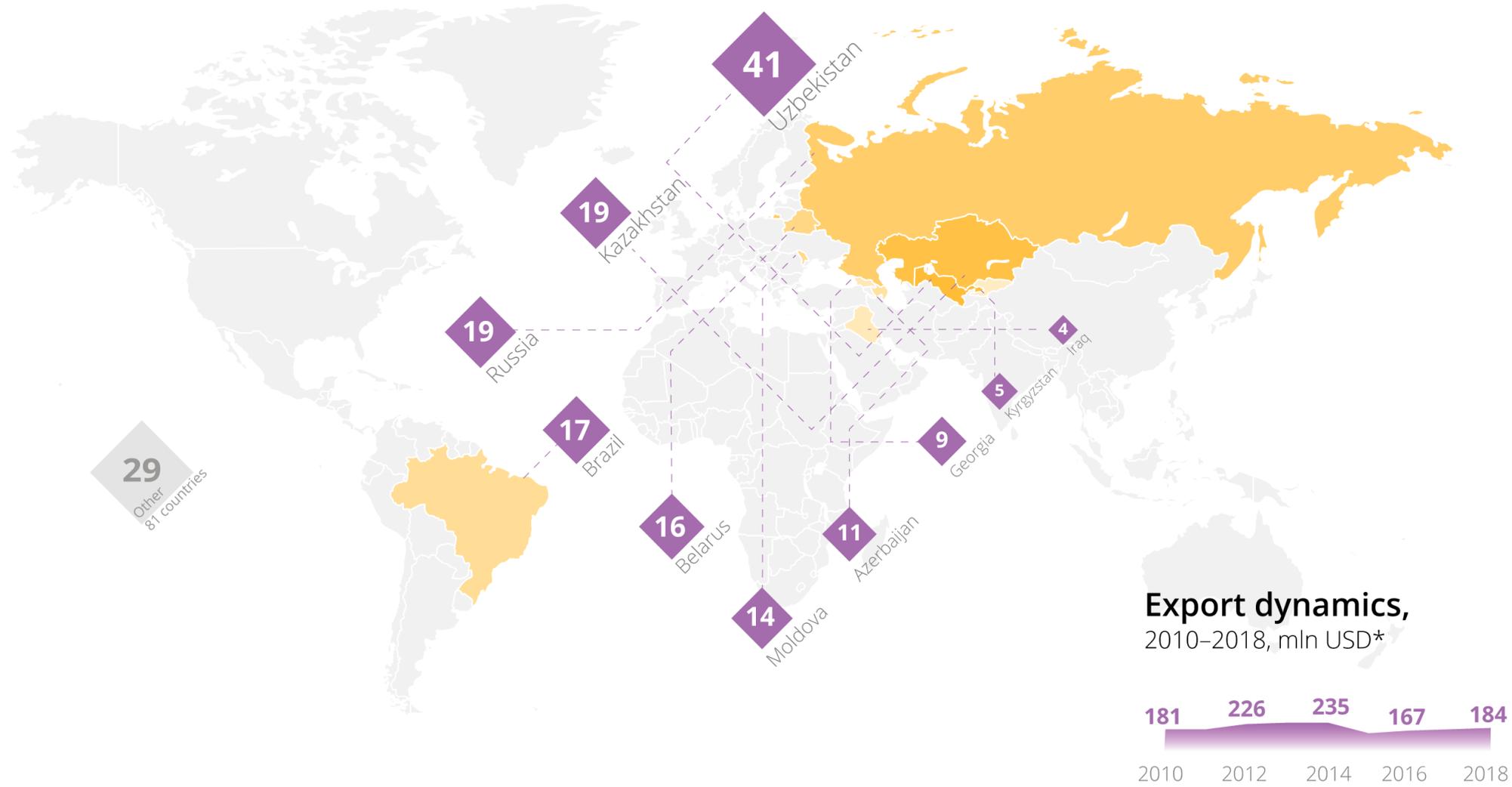
# MEDICINE IMPORT IN UKRAINE

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



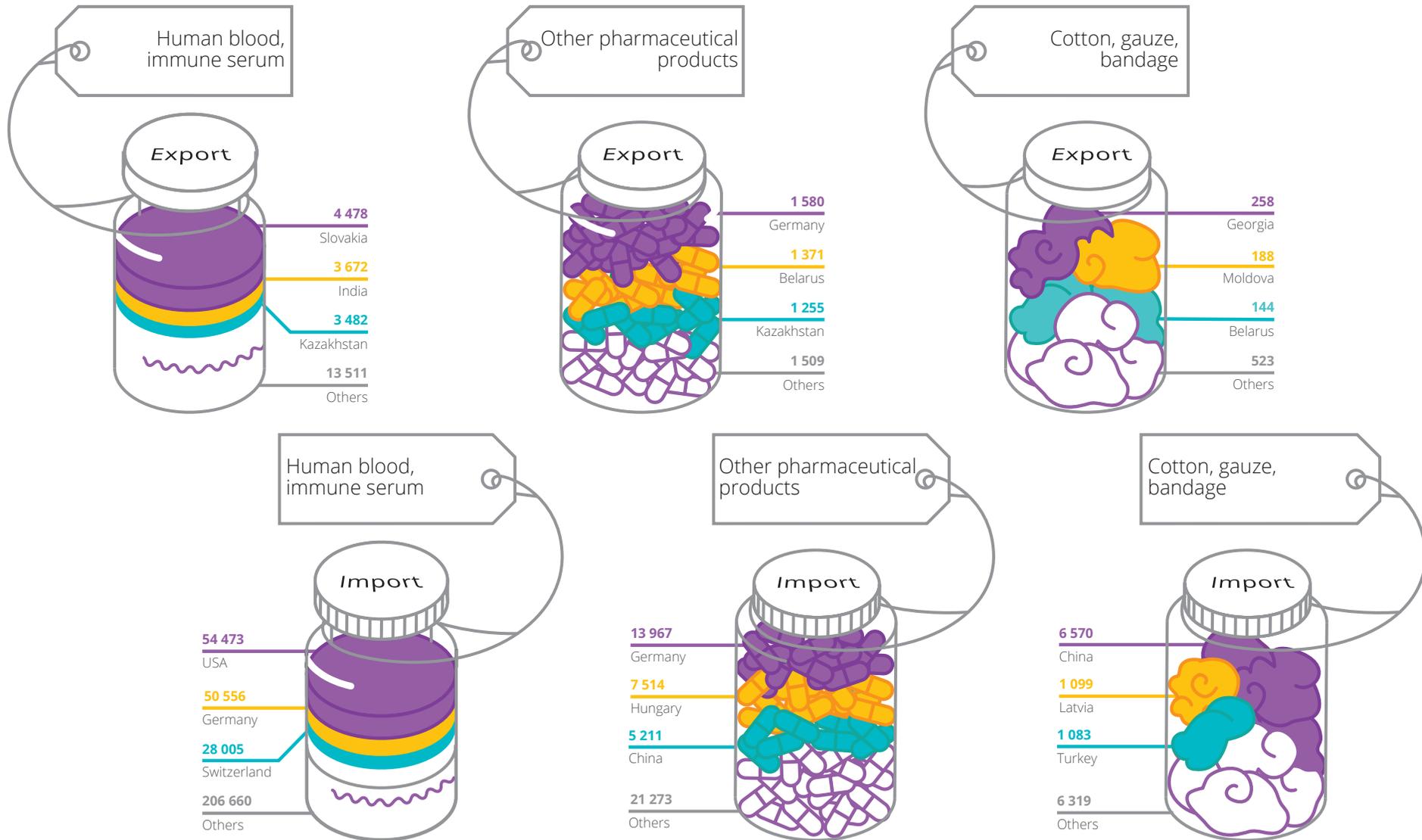
# MEDICINE EXPORT FROM UKRAINE

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



# OTHER PHARMACEUTICAL PRODUCTS TRADE

Main state-partners, 2018, ths USD



- CF «Patients of Ukraine», Research “Cost(less) Medicine”
- World Health Organization (WHO)
- 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"
- Order of the Ministry of the Healthcare of Ukraine of 15.04.2015, No. 220 “On cooperation between the Ministry of the Healthcare of Ukraine and the State Expert Center of Ukraine”
- 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)"
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  1. Apteka Weekly № 3 (824) 23 January 2012
  2. Apteka Weekly № 8 (829) 27 February 2012
  3. Apteka Weekly № 4 (875) 28 January 2013
  4. Apteka Weekly № 10 (881) 11 January 2013
  5. Apteka Weekly № 5 (926) 3 February 2014
  6. Apteka Weekly № 11 (932) 17 March 2014
  7. Apteka Weekly № 3 (974) 26 January 2015
  8. Apteka Weekly № 9 (980) 9 March 2015
  9. Apteka Weekly № 2 (1023) 25 January 2016
  10. Apteka Weekly № 13 (1034) 11 April 2016
  11. Apteka Weekly № 2 (1073) 23 January 2017
  12. Apteka Weekly № 7 (1078) 27 February 2017
  13. Apteka Weekly № 22 (1093) 12 June 2017
  14. Apteka Weekly № 3 (1124) 22 January 2018
  15. Apteka Weekly № 5 (1126) 5 February 2018
  16. Apteka Weekly № 12 (1133) 26 March 2018
  17. Apteka Weekly № 27 (1148) 16 July 2018
  18. Apteka Weekly № 2 (1173) 21 January 2019
  19. Apteka Weekly № 3 (1174) 28 January 2019
  20. Apteka Weekly № 4 (1175) 4 February 2019
  21. Apteka Weekly № 5 (1175) 11 February 2019
  22. Apteka Weekly № 9 (1180) 11 March 2019
  23. Apteka Weekly № 10 (1181) 18 March 2019
- AEQUO Law Firm (AEQUO Law Firm)
- ClinicalTrials.gov
- DBS Bank (DBS)
- EudraGMDP database (EudraGMDP)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Evaluate Ltd. (Evaluate)
- Export.gov
- Federal Trade Commission (FTC)
- Food and Drug Administration (FDA)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- International Trade Centre (ITC)
- Lichtenberg F. R.: How many life-years have new drugs saved? A 3-way fixed-effects analysis of 66 diseases in 27 countries, 2000-2013 (Lichtenberg F. R.)
- Organisation for Economic Co-operation and Development (OECD)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- The Centre for Innovation in Regulatory Science (CIRS)
- Verband der forschenden pharmazeutischen Firmen der Schweiz (Interpharma)

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