

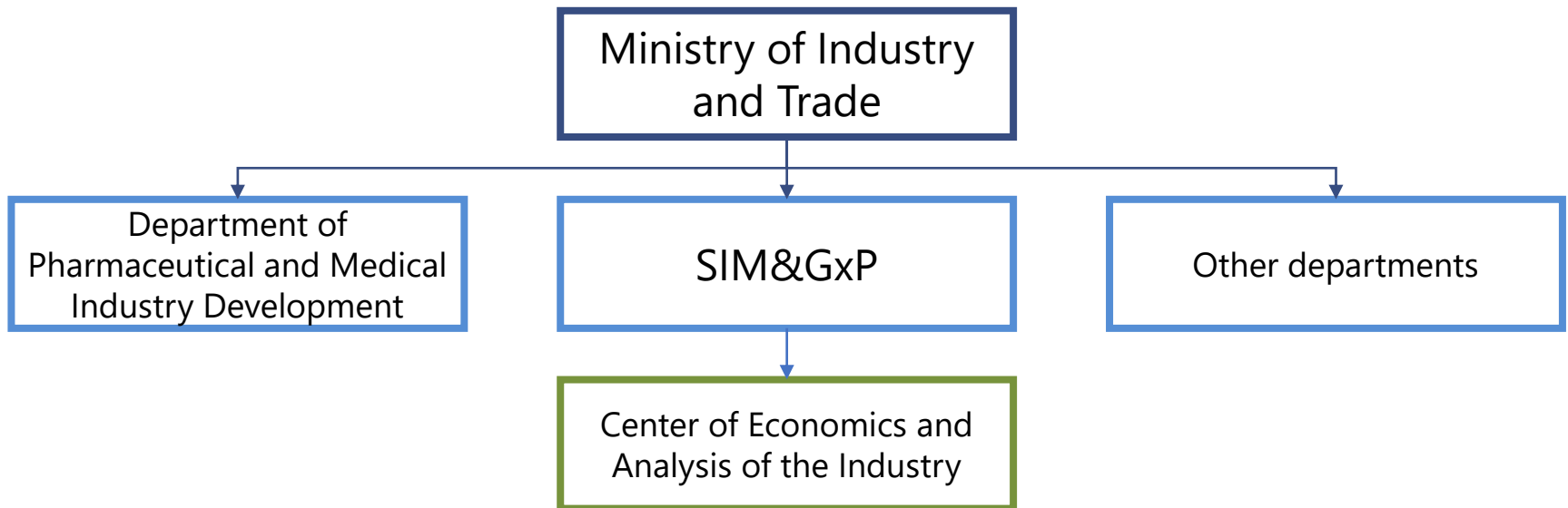


# Russian pharma industry: collaboration and competition

Stanislav Livanskiy  
Head of economics and analytics  
St Petersburg May 17, 2017



# SIM&GxP: Center of Economics and Analysis of the Industry



## Role and Responsibilities

- Analytical research of the Russian pharmaceutical market and medical devices for Ministry of Industry and Trade. Participation in the development and implementation of federal targeted program
- Collection and maintenance of data on production and shipment of drugs and medical devices in 2 lek (prom) and 1 mediz forms
- Risk assessment and analytical support of the Inspectorate department of SIM&GxP
- Consulting services

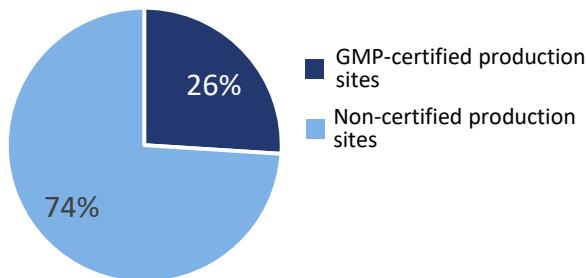
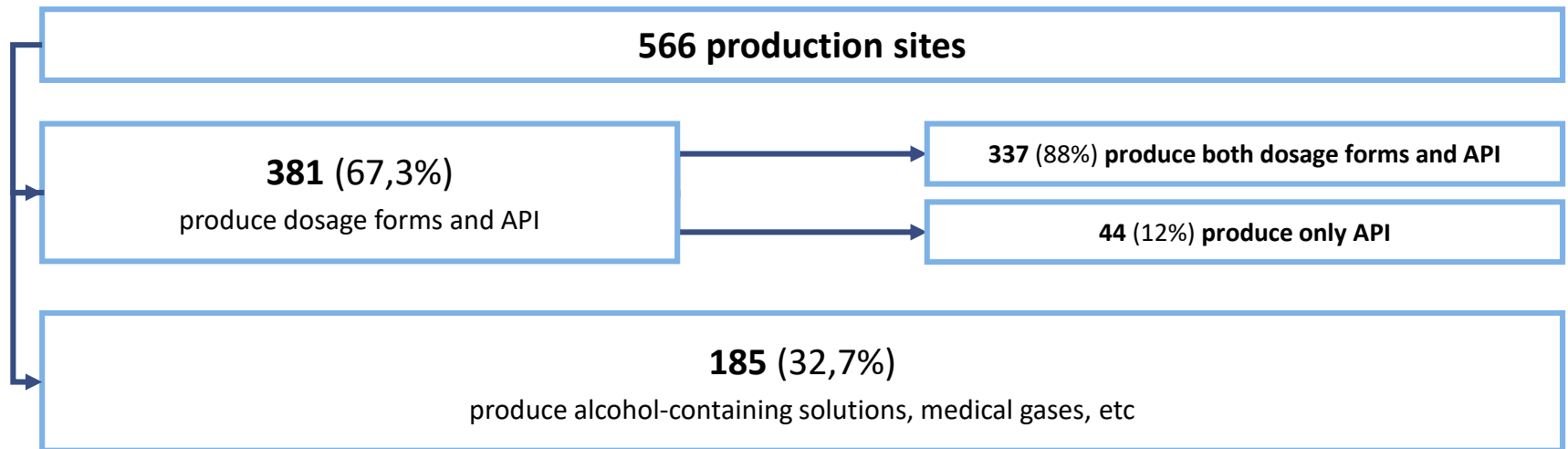
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## Local Pharma Industry overview

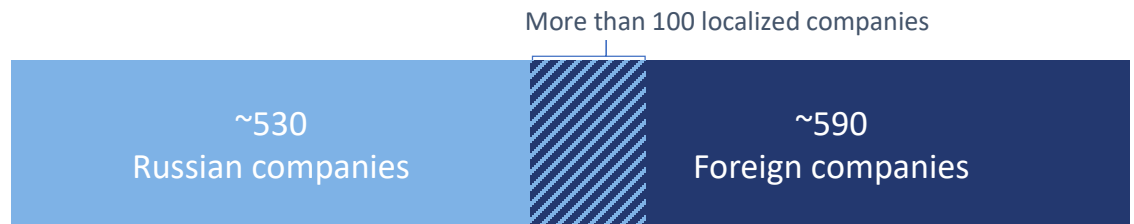


# Active production sites in 2016

In 2016 there were 527 active production licenses granted by the Ministry of Industry and Trade, which corresponds to **566 production sites across 71 federal subjects:**



Number of GMP-certified production sites



Number of foreign and localized companies



# Production and market dynamics

Production growth rate in Russia is far beyond pharmaceutical market growth rate

**394** **bln RUB**  
Total production\*  
by value

CAGR for 2014-2016

**9,7%**

Total market  
[Market data]

**20,4%**

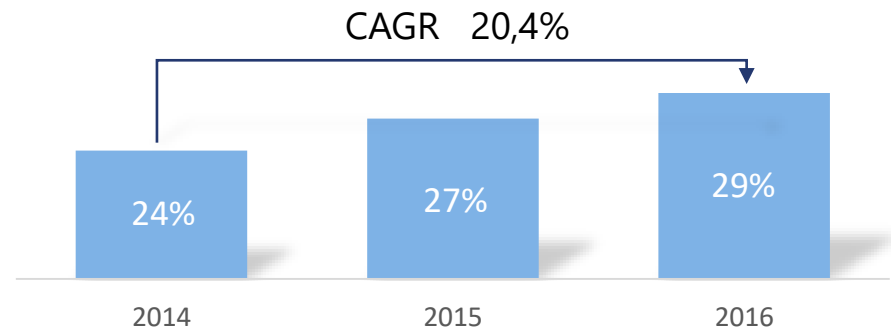
Local manufacturers  
[Market data]

**29,7%\***

Sales (shipment)  
[Production data]

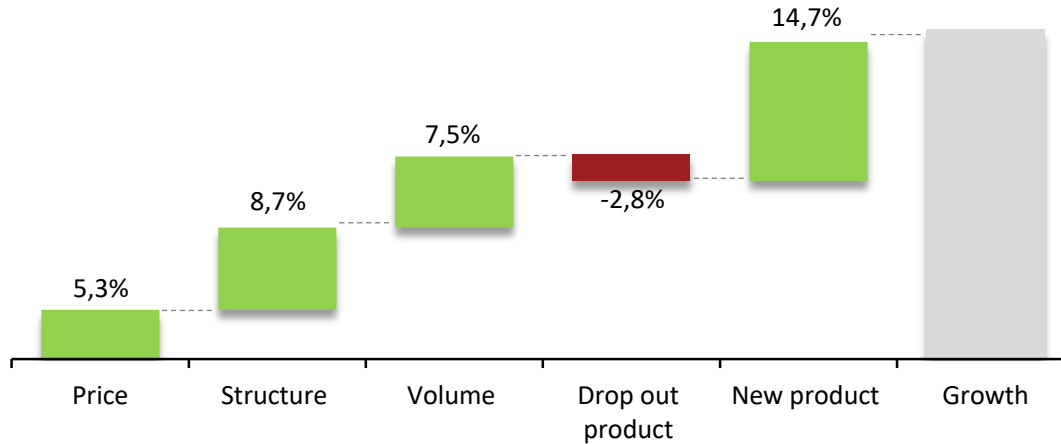
**29%** Local companies  
market share  
in 2016

Local manufacturers, sales by value

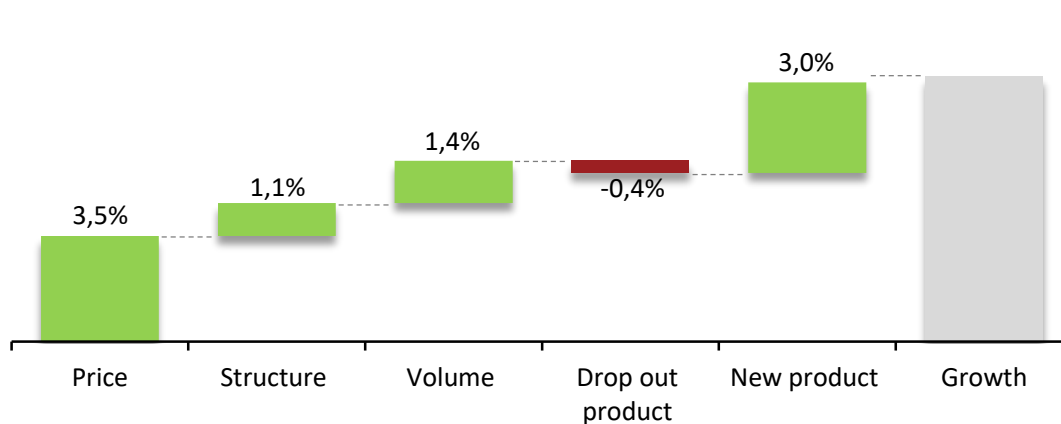


# Production drivers in 2016

## Production



## Total market sales

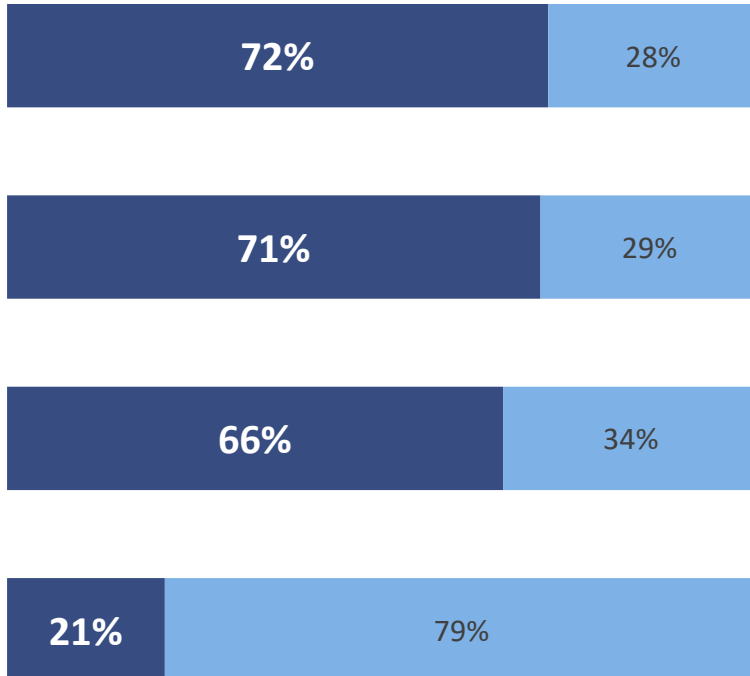


- Production volume is growing due to new products\* and shift in assortment towards more expensive products
- High contribution of new products is largely achieved due to two elements of state policy:
  - Import substitution in state procurement
  - Stimulating localization of production at Russian sites

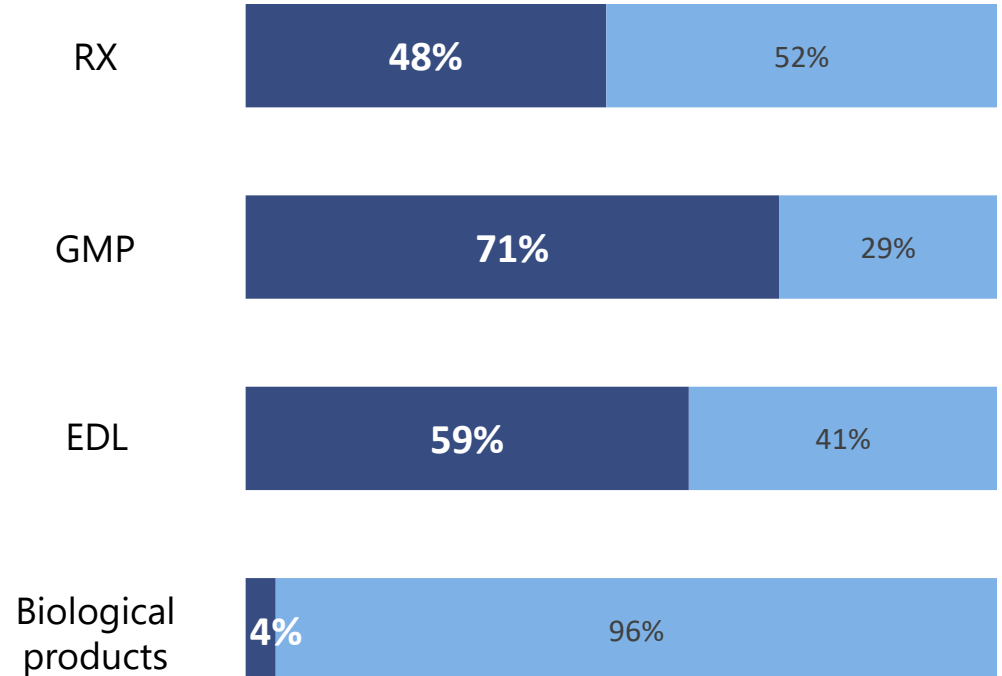


# Production structure in 2016

Share by value, %



Share by volume, %



■ Yes   ■ No

2

## Collaboration and Competition

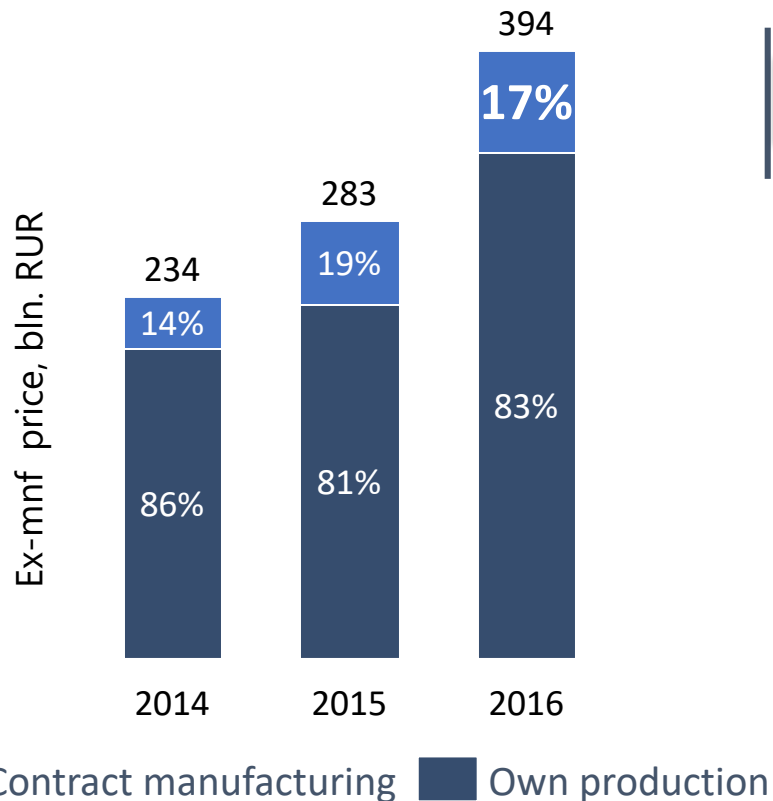




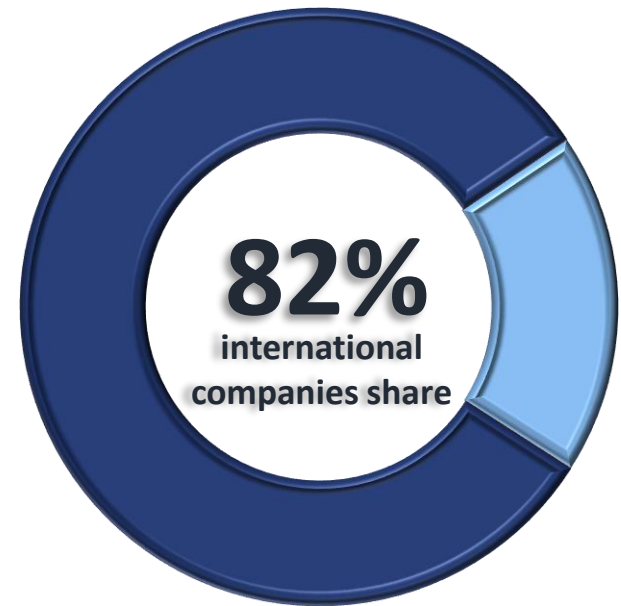
# Contract manufacturing in Russia

CM is estimated at 68\* Bln. RUR in 2016, where 82% is a share of orders placed by international companies

## Production structure



## CM structure



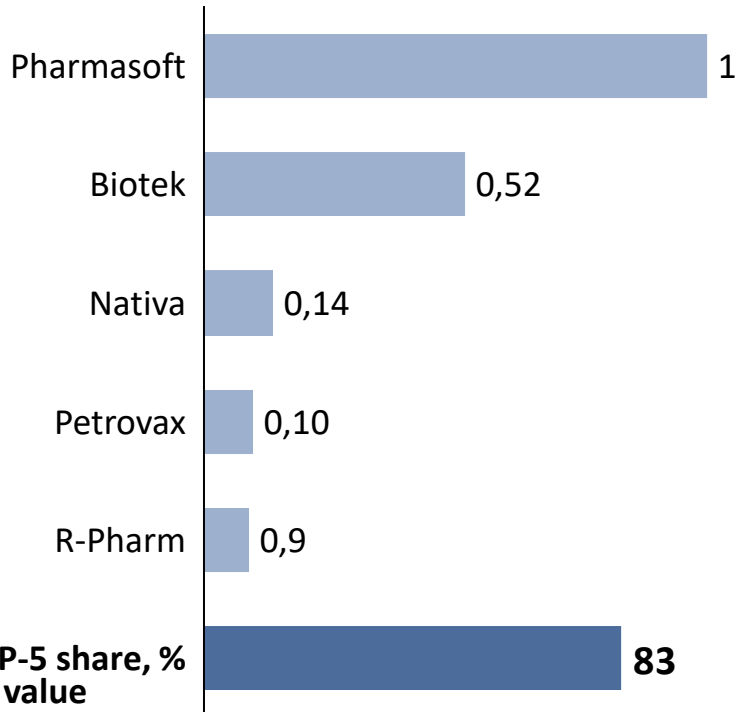
- "Ru-Ru" collaboration
- "International -Ru" collaboration



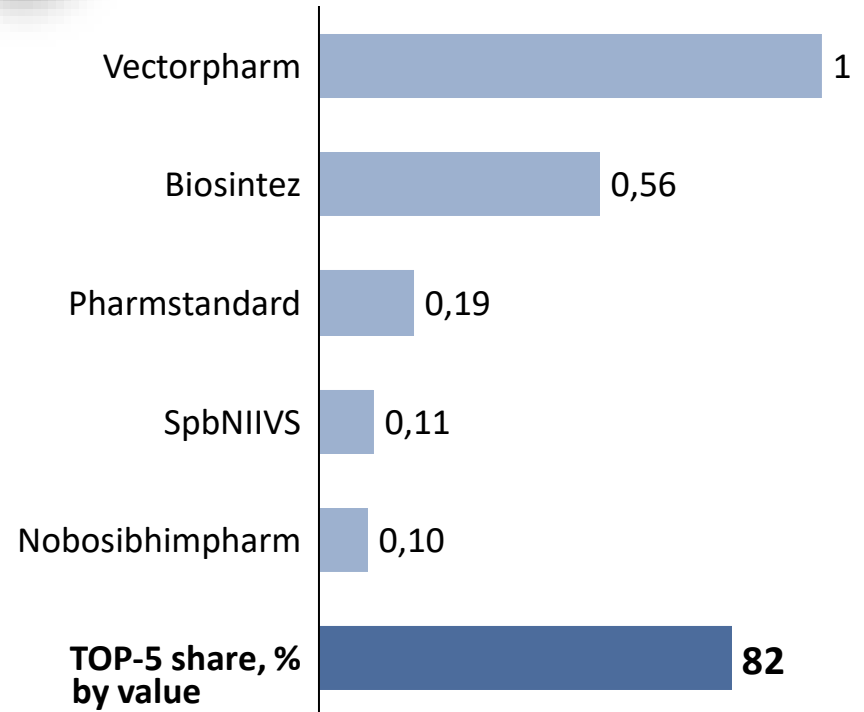
# "Ru-Ru" contract manufacturing players

Though there are many of collaboration cases, still contract amounts are not big

## Top-5 Companies placed CM orders



## Top-5 Russian contract manufacturers

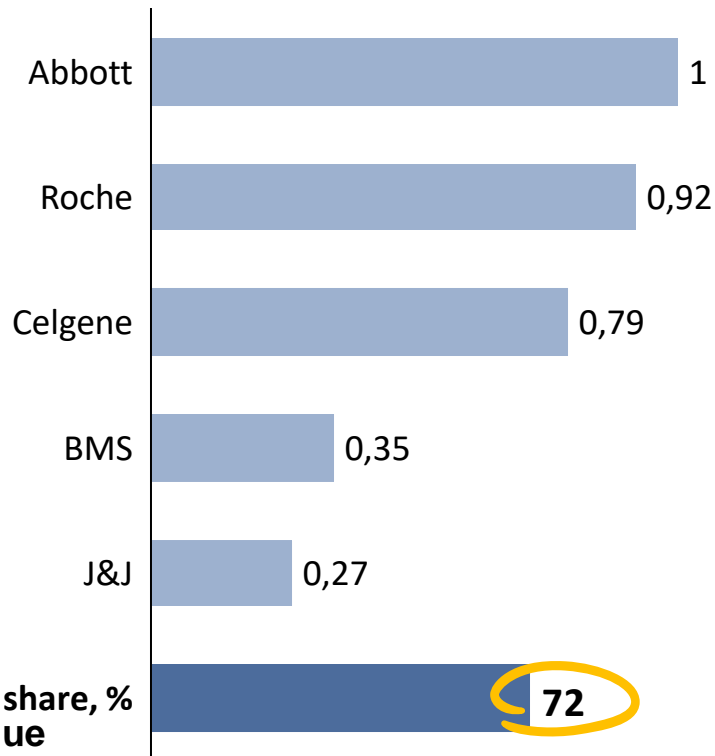




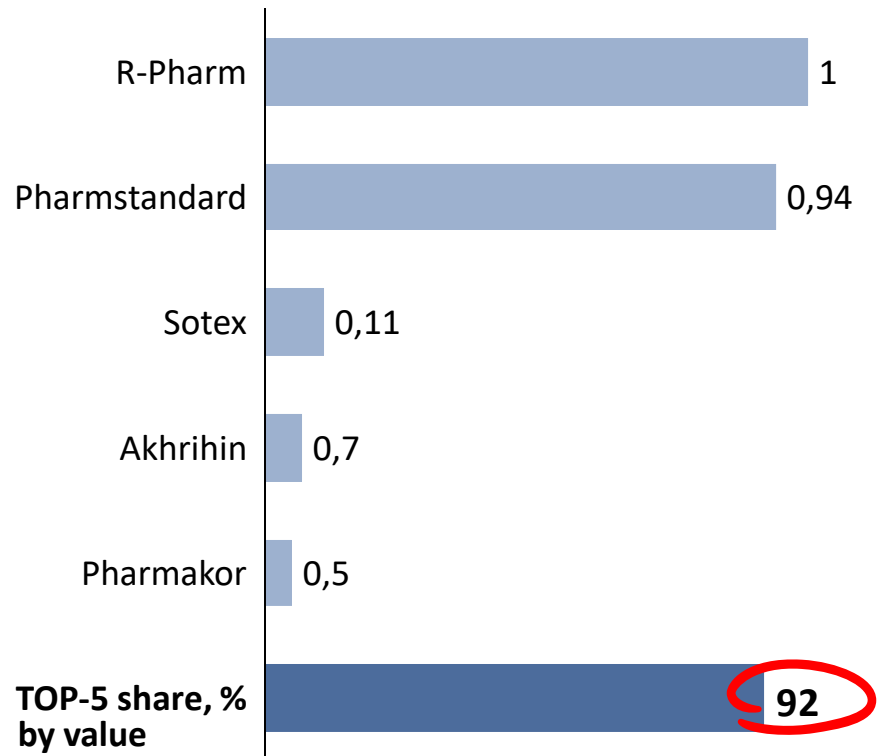
# “International – Ru” CM players

This type of cooperation is highly concentrated

### Top-5 Companies placed CM orders



### Top-5 Russian contract manufacturers

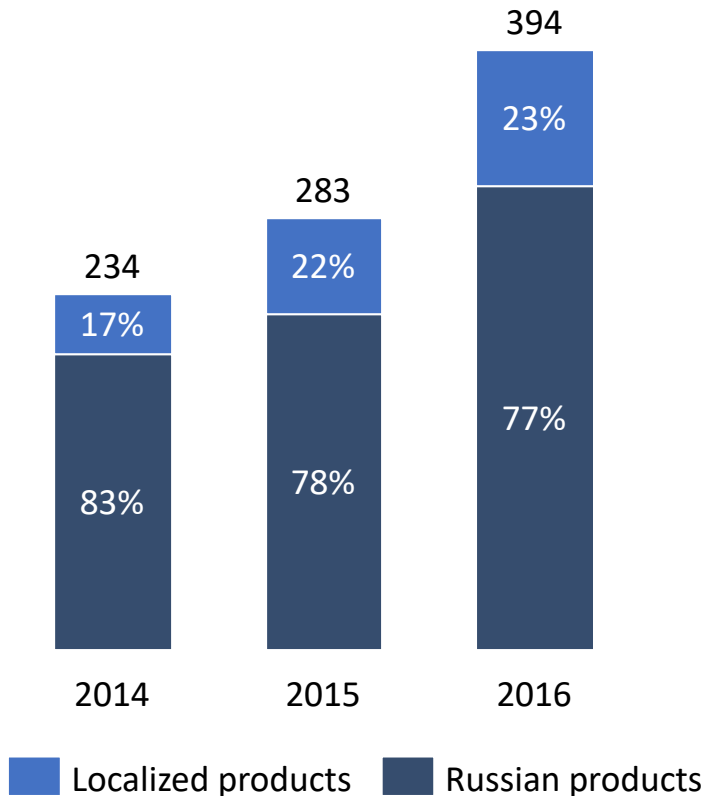




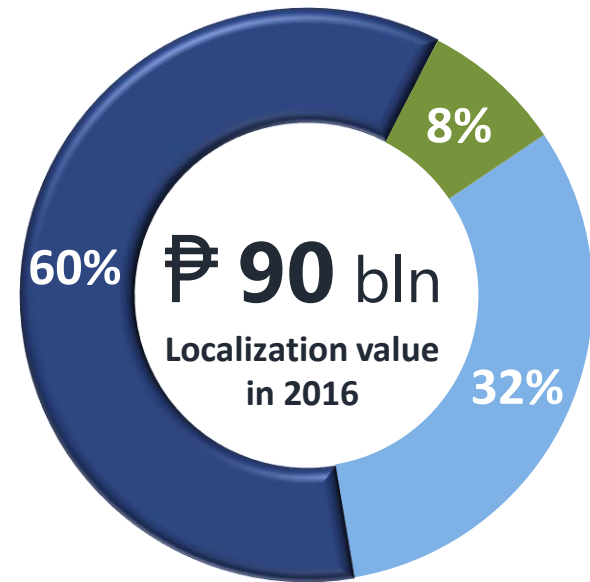
# Localization on Russian market

Localized products accounted for almost ¼ of total production by value

## Production structure



## Localization models



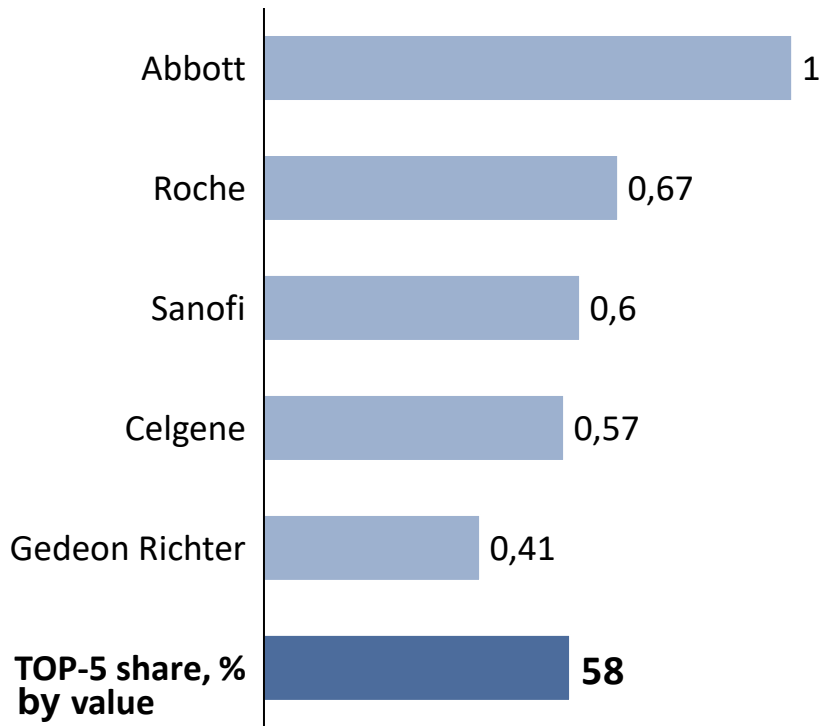
- Own production site
- Contract manufacturing
- Merged manufacturer



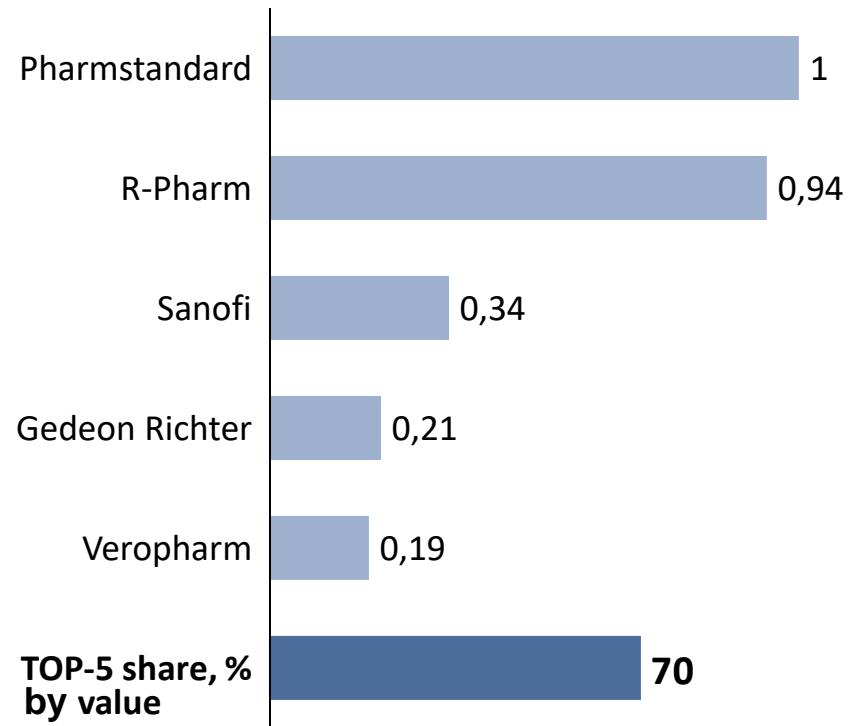
# Localization leaders

Pharmstandard and R-Pharm are key partners for international companies

## Top-5 localized companies



## Top-5 Russian localization sites





# State support initiatives

**State programme:**  
Development of the  
Pharmaceutical and Medical  
Industry 2013 - 2020

## Goals

- Organization of local production of generic and innovative drugs for treatment of socially significant diseases, as well as high-tech medical products
- Technological re-equipment of domestic production capacities to reach exportable level
- Personnel training for staffing of domestic pharmaceutical and medical industries

## Measures

- Subsidizing development of improved analogues of innovative drugs
- Funding projects involving production of drugs, API or medical products
- Subsidizing clinical trials
- Subsidizing production of export-oriented products

**Special economic zones**

- Special tax regime: reduction of taxes on profits, property, transport and land
- Access to a well-established infrastructure
- Tax preference

**Regulatory**

## Current

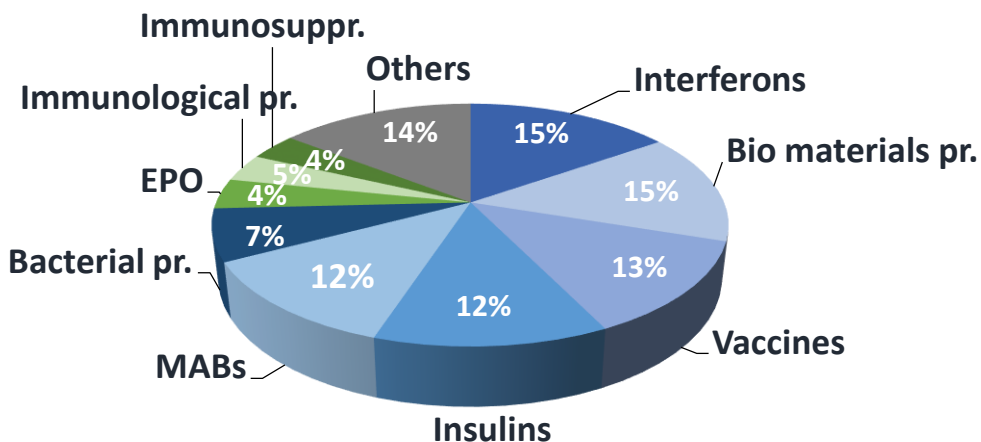
- Preference for locally manufactured drugs and medical products during public procurement
- Criteria for classifying pharmaceutical and medical products as locally manufactured
- Sectoral plan of measures for import substitution of drugs and medical products

## **Planned - 3-step procurement system giving preference to locally produced products based on level of localization. There are several possible ways of implementation**

- This system is going to be implemented for all federal-level state procurement
- In 2018, system is going to be implemented for **biological products**
- In 2019, system is going to be implemented for all other products

# Biological market structure

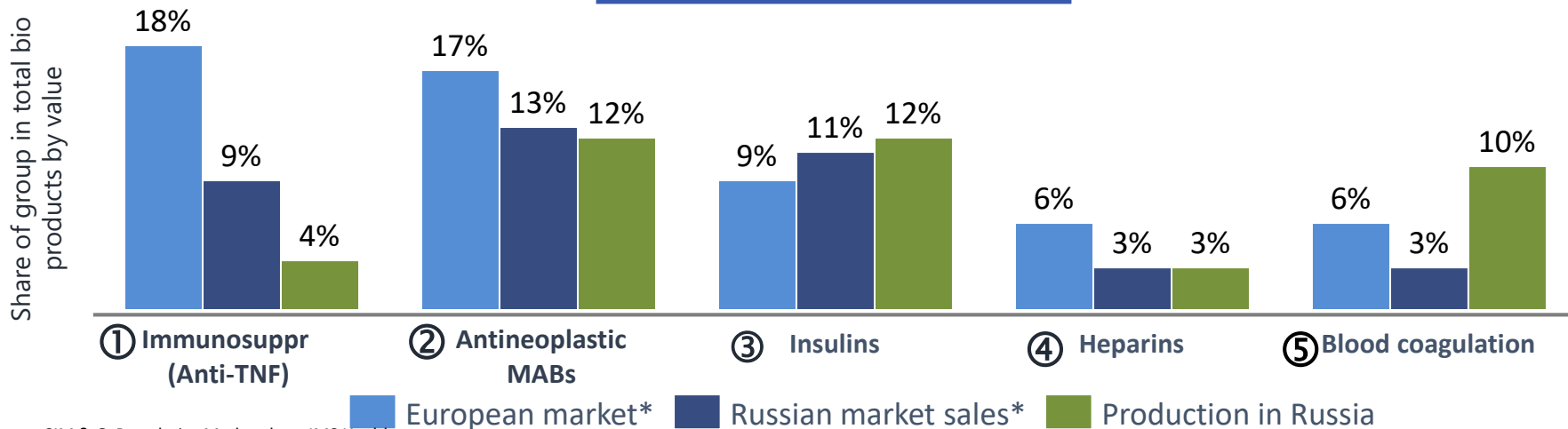
## Production structure



**Bio products** definition is based on Federal Law N61-FZ «On the circulation of medicines»

**Biological medical products** – medical products that contain active ingredient produced or extracted from a biological source and that require a combination of biological and physicochemical methods to determine their properties and quality

## TOP-5 Bio groups in Europe

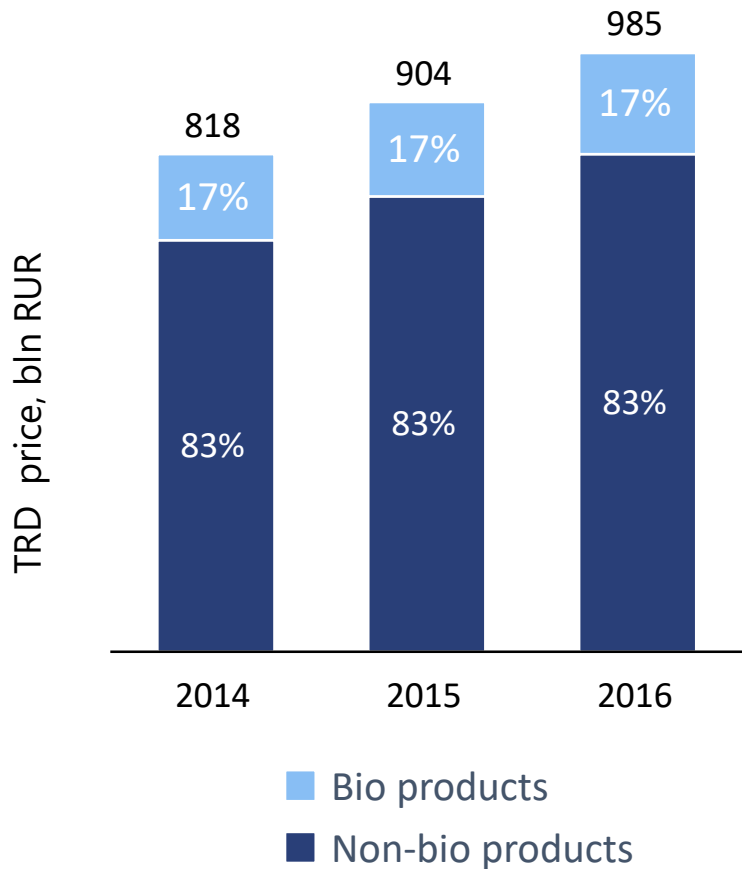




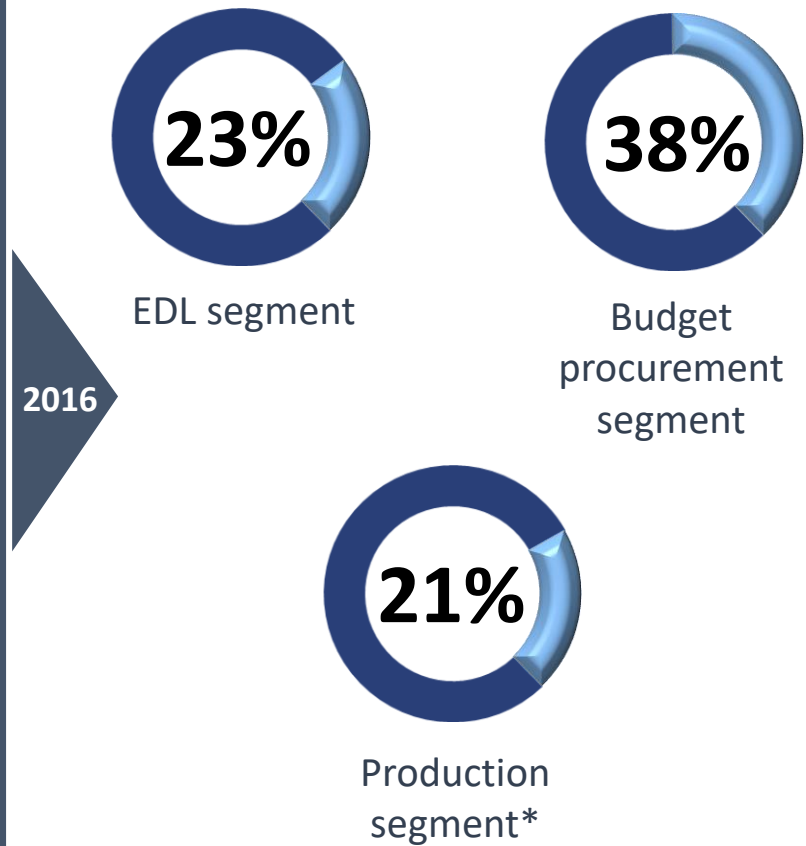
# Russian biological market

Share of biopharmaceuticals in state procurement is nearly 40%

## Market sales



## Bio products share



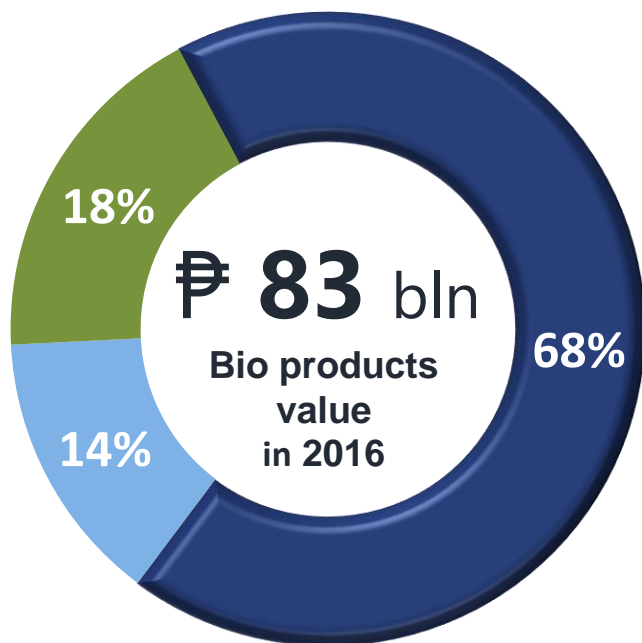




# Bio production domestic leaders

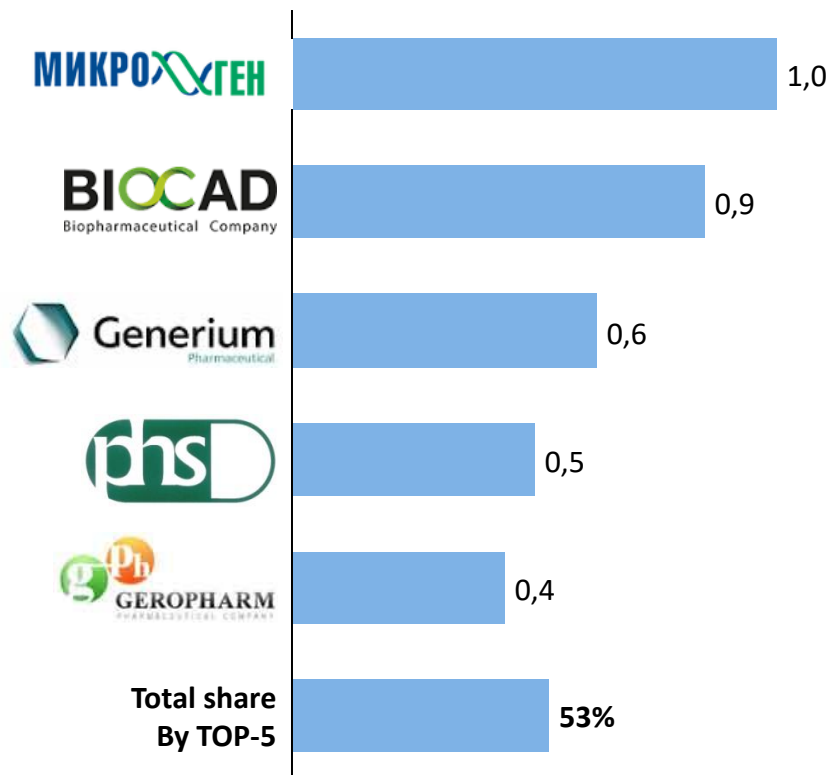
Domestic companies hold 2/3 of the total bio production by value

## Bio production



- Domestic products
- Localized: own mnf site
- Localized:contract mnf

## Russian Bio companies, %

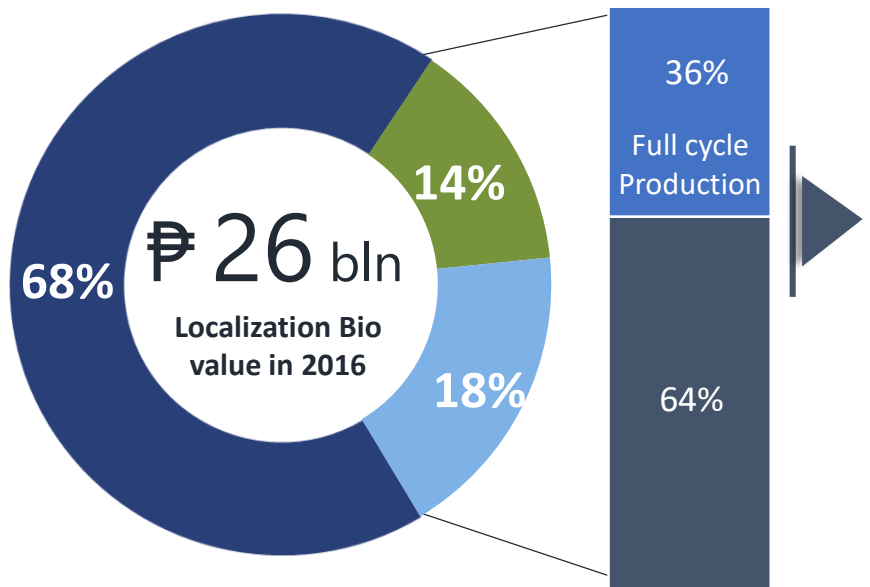




# Bio production localization

About 1/3 of biopharmaceuticals produced in Russia are localized products

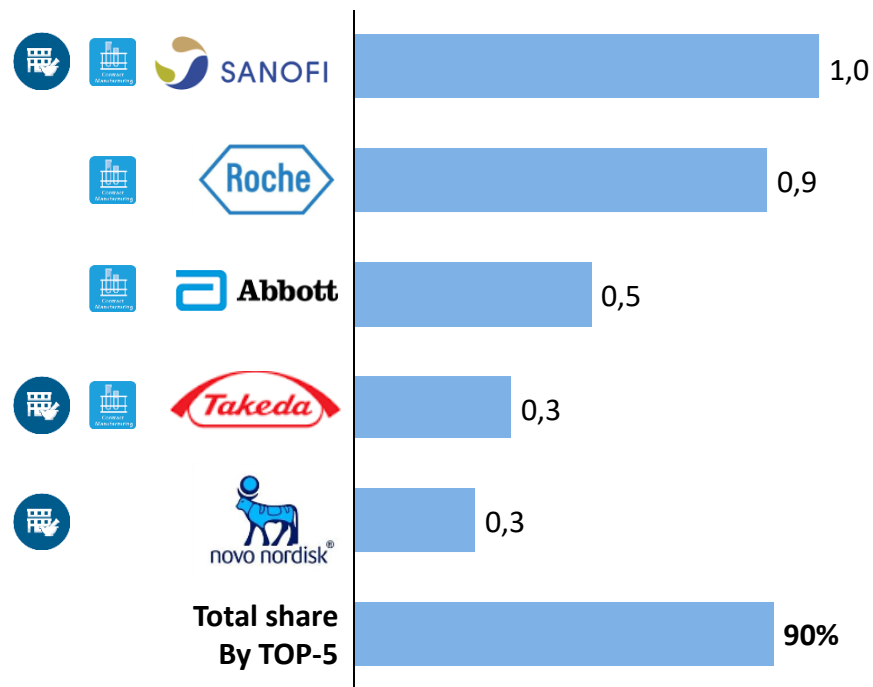
## Bio production



- Domestic products
- Localized: own mnf site
- Localized: contract mnf

- Full cycle
- Packing and QC

## Localized Bio companies, %





# Import substitution program on API

Case study: HIV, TB, Hepatitis

## New initiative

3-step procurement system

✓ Products based on **local API** have priority

We calculate effect for 3 nosologies only



20 local APIs market authorized plus new 13\* APIs are planned to submission:

	2017 - 2018	2019 - 2021
HIV	9 INNs	1 INNs
Hepatitis	-	2 INNs
Tuberculosis	-	1 INNs

planned changes could affect

# 76%

of the market, where main foreign players are

TOP-5 Companies

- Abbvie
- Bristol-Myers Squibb
- Johnson & Johnson
- GlaxoSmithKline
- Hetero Drugs

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Forecast



# Macroeconomic environment in 2017

No factors for rapid growth

	<u>2009</u>		<u>2010</u>
Oil prices	61\$		78\$
GDP growth,%	-7,8%		4,5%
Population income, %	3,0%		5,9%
	<u>2016</u>		<u>2017</u>
Oil prices	42\$		46\$
GDP growth,%	-0,2%		2,0%
Population income, %	-5,9%		1%



# Outlook for 2017 and beyond

Local and generic companies are going to benefit from current situation

## Key forecast assumptions

### Economic outlook

Russia suffered a deep crisis in 2015. But the economy has already adapted to the changed external conditions and a slow recovery has begun. At the same time, the potential for growth under current conditions is limited.

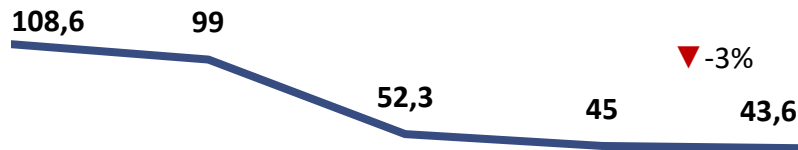
### OOP market

Slow recovery in solvent demand is expected. The population will continue to look for cheaper alternatives from the "relatively expensive options" offered by the supply chain.

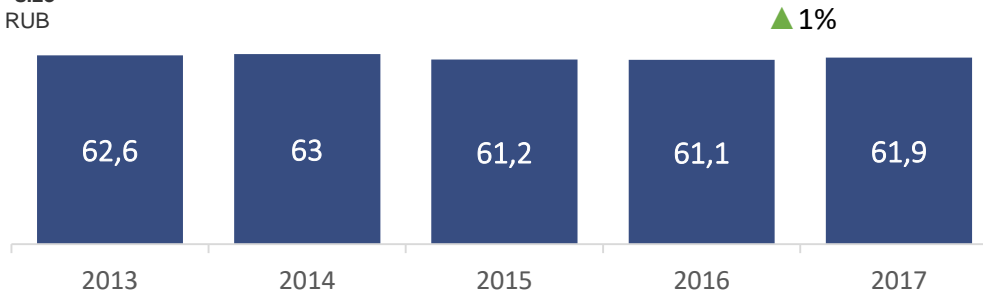
### Budget procurement

In the next 2-3 years the "resource limitation" model is expected to prevail. The state will try to reduce the costs of public procurement in every way. All other goals, including market access for new original products, will be set depending on the financial capabilities.

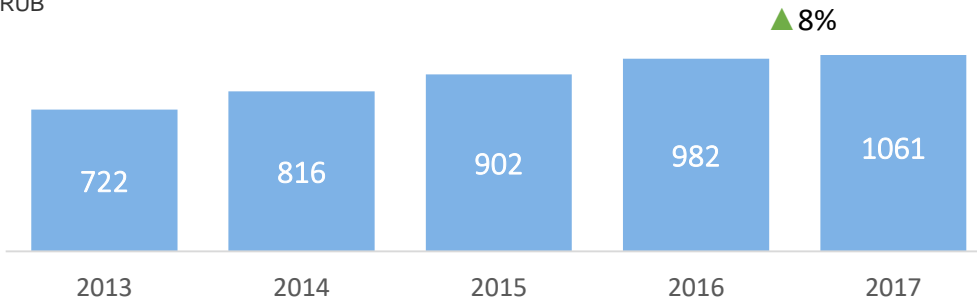
Brent oil Price  
In USD per barrel



GDP size  
Trln RUB



Pharmaceutical market size  
Bln RUB





# Investigating different alternatives

Production will keep outpacing pharmaceutical market growth rate

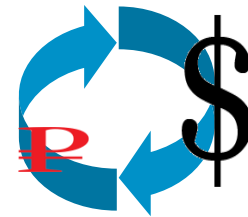
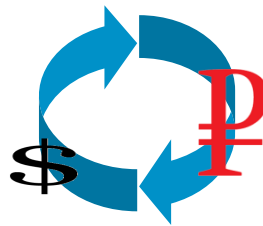
2010 - 2015

2015 - 2020

Commodities' prices



Affordability



Pharma market growth

10%-15%

5%-10%

Local production growth

12%-16%

15%-25%



Moscow, Lavrov lane, 6

Phone: +7 (495) 676-43-60, Fax: +7 (495) 911-31-93

E-mail: [info@gilsinp.ru](mailto:info@gilsinp.ru)

Regarding of GMP inspection consulting, please, contact us:

+7 (495) 911-39-64

+7 (495) 676-43-60 (ext. 120)

Working hours: Monday-Friday from 9.00 till 17.45