Farmak

Caring for your health and you

Spotlight on Ukrainian Pharmaceutical Market with Focus on Biosimilars

Dr. Oleh Syarkevych
PhD in Pharma, MBA
Member of the Supervisory Board
JSC Farmak

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Pharmaceutical Market Overview
Ukraine

Ukraine vs Poland in figures

Indicator	Ukraine	Poland
Total population	42,177,600 (2017)	38,224,000 (2016)
Area	603 500 sq km (46th)	312,685 sq km (70th)
Urban population (of total population, 2015)	69,7%	60,5%
GDP	$ 112, 1 billion (2017)	$1.201 trillion (2018 est.) (Source: International Monetary Fund. IMF.org)
GDP per capita	$2 639 (2017)	$31,647 (2017) (Source: International Monetary Fund. IMF.org)
Total expenditure on health per capita (2014)	$584	$1570
Total expenditure on health % from GDP (2014)	7,1%	6,3%
Life expectancy at birth M/F (years, 2016)	68/77	74/82
Pharmaceutical market	$3,12 B (2018) (Source: Proxima Research)	€ 7,58 B (2018) (Source: IQVIA)
Pharmaceutical market (billion units)	1,3 (2018) (Source: Proxima Research)	1,3 (2018) (Source: IQVIA)

Source of other information: World Health Organization

Pharmaceutical market in Ukraine: 2018

Pharm. market (retail and hospital segments): 85,0 B UAH (3,12 B $);

General growth: +21,5% by value;

Retail growth: +21,8% by value;

Hospital segment growth: +19,3% by value;

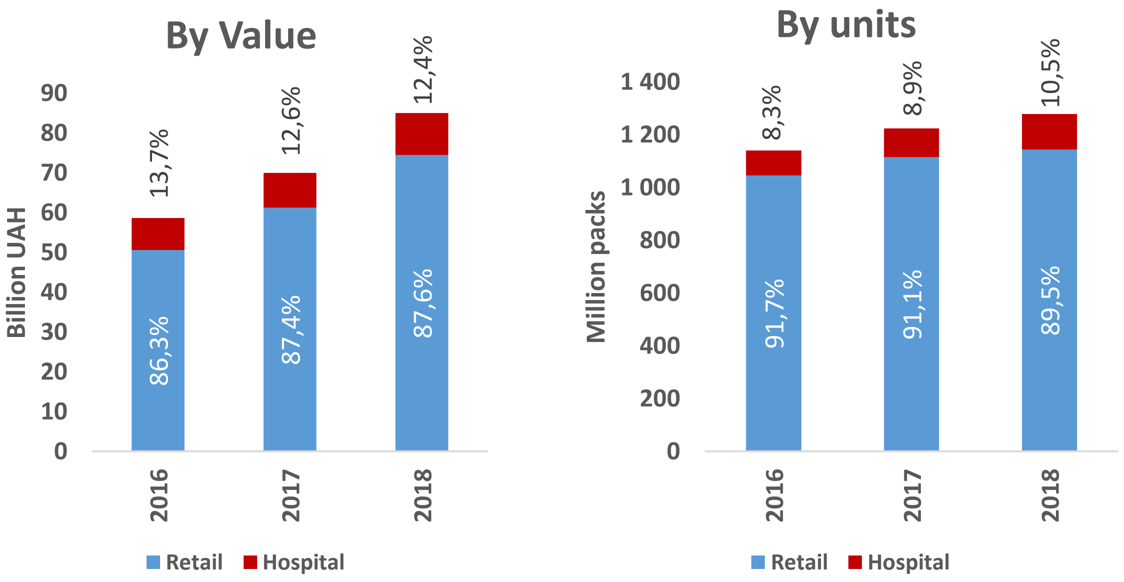
Pharm. market (retail and hospital segments): 1,3 B packs;

General growth: +4,5% by units;

Retail growth: +2,6% by units;

Hospital segment growth: +23% by units;

Dynamics of retails sales and hospital supply of medicines in value and units in 2016 – 2018 with the indication of share of each segment



Source: Proxima Research

TOP-10 companies in retail and hospital market

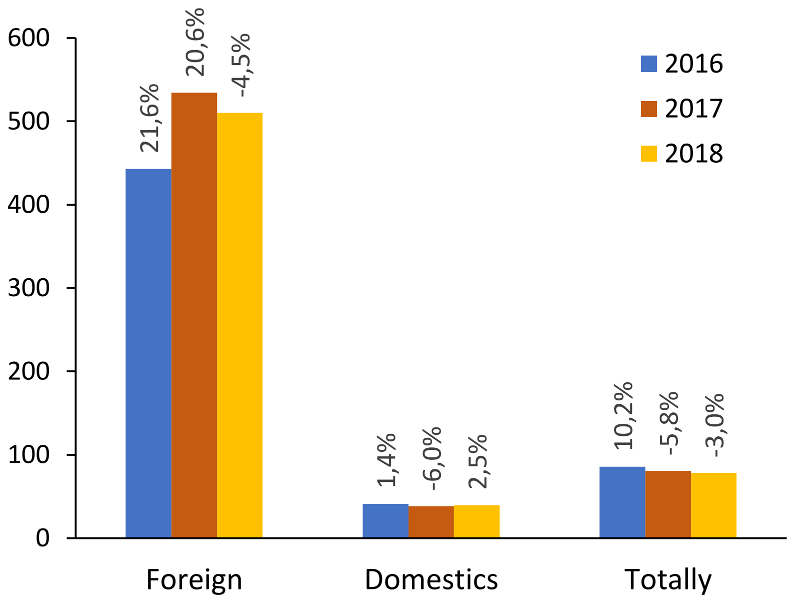
№	Company Name	Sales, 2018 (ths. UAH)	Growth (by value in UAH), %	Market share 2018,%
1	**Farmak**	**5 017 767**	**17,1%**	**5,9%**
2	Arterium	3 703 667	19%	4,4%
3	Darnytsya	3 370 828	20%	4,0%
4	Sanofi	3 235 587	15%	3,8%
5	Teva	3 022 016	23%	3,6%
6	Yuria-Pharm	2 998 752	36%	3,5%
7	Berlin-Chemie	2 614 209	11%	3,1%
8	Zdorov’ya	2 609 960	11%	3,1%
9	KRKA	2 023 580	32%	2,4%
10	Kyiv Vitamin Plant	1 965 739	21%	2,3%
	Total (retail+hospital)	85 012 769	21,5%	

* 1 USD ~ 26,76 UAH

Source: ProximaResearch

Weighted average cost per pack in hospital segment

Weighted average cost of one pack of medicine in hospital segment with the indication of its growth for the equivalent period of previous year



Source: Proxima Research

The **weighted average cost** of one pack of medicine in hospital segment is 78,3 UAH (**2,9 USD**).
The weighted average cost of **domestic** medicine is 39,4 UAH/pack (**1,45 USD/ pack**) and **foreign** one is 510,3 UAH/pack (**18,8 USD/pack**)

Tender purchases were carried out through state budget (MOH of Ukraine and other state authorities) and local budgets.
For some medicines (for example, vaccines, antiretroviral, rare disease, children oncology and primary immunodeficiencies, hemophilia in adults therapies) purchase was conducted through international organizations.
ProZorro – e-system for state purchases

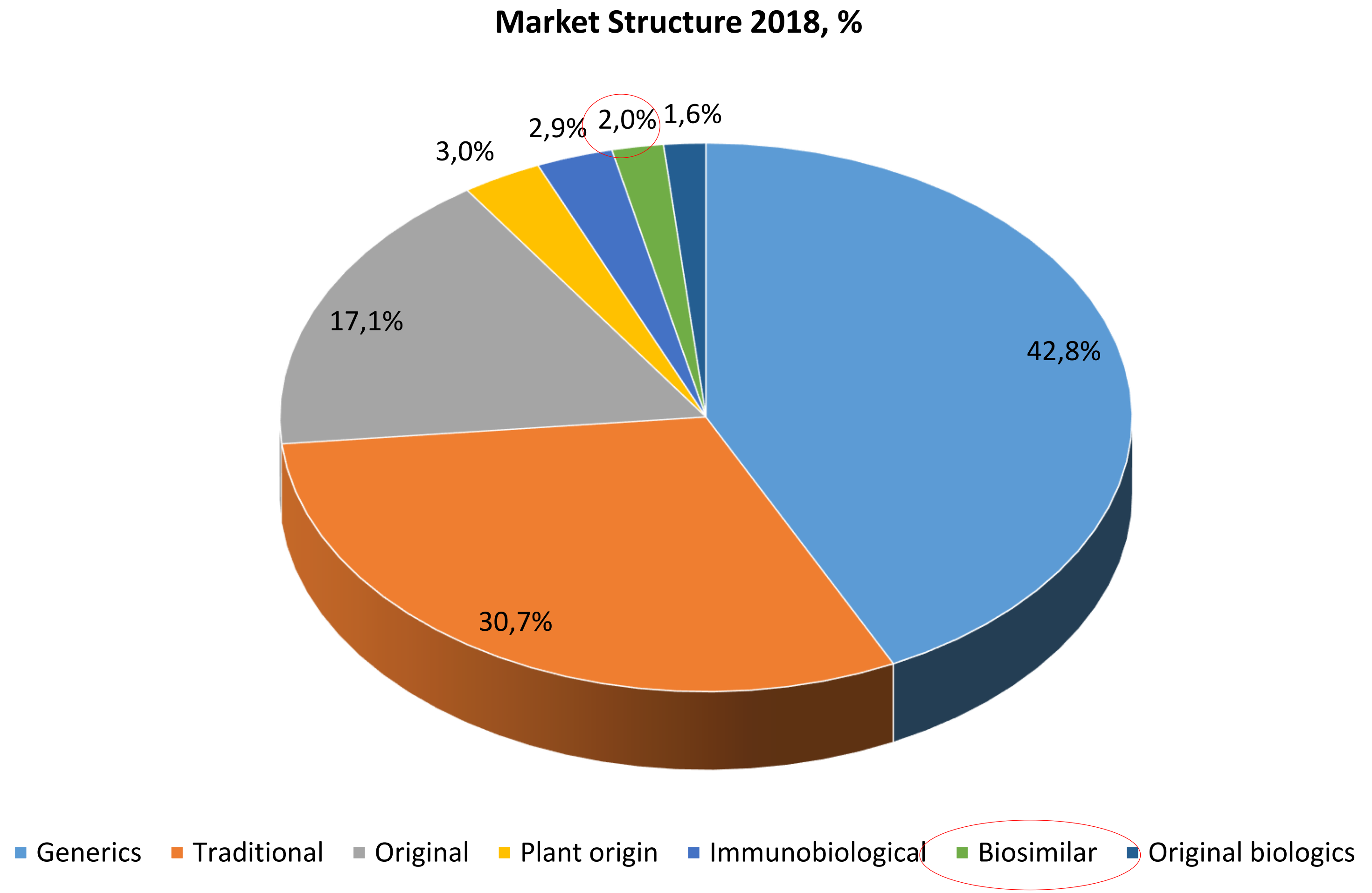
Top ATC groups, Ukraine vs Poland, hospital+retail

Ukraine*, 2018	Poland**, 2018
A - 18,0% Alimentary tract and metabolism	N - 14,2% Nervous system
N - 13,2% Nervous system	C - 13,7% Cardiovascular system
C - 12,5% Cardiovascular system	A - 13,4% Alimentary tract and metabolism
R - 12,1% Respiratory system	R - 11,6% Respiratory system
J – 10,8% Anti-infective for systemic use	L – 11,1% Antineoplastic and immunomodulating agents

*Source: Proxima Research "PharmXplorer"

**Source: IQVIA "Midas"

Structure of pharmaceutical market in Ukraine by type of product

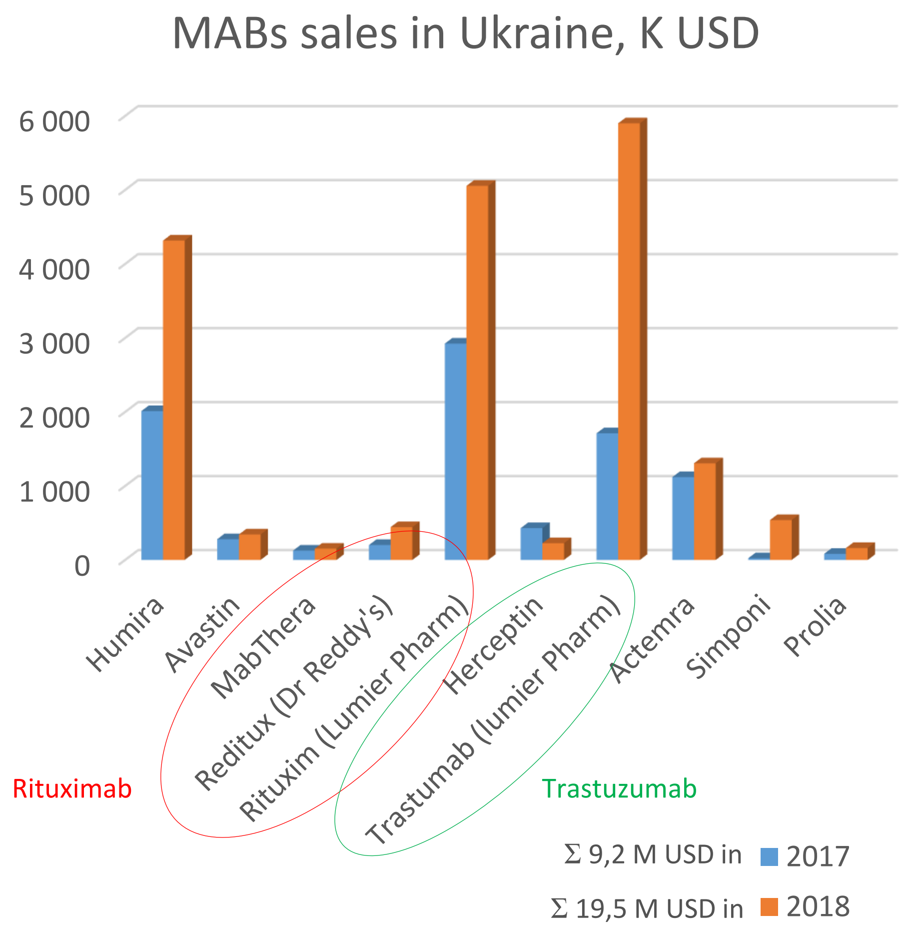


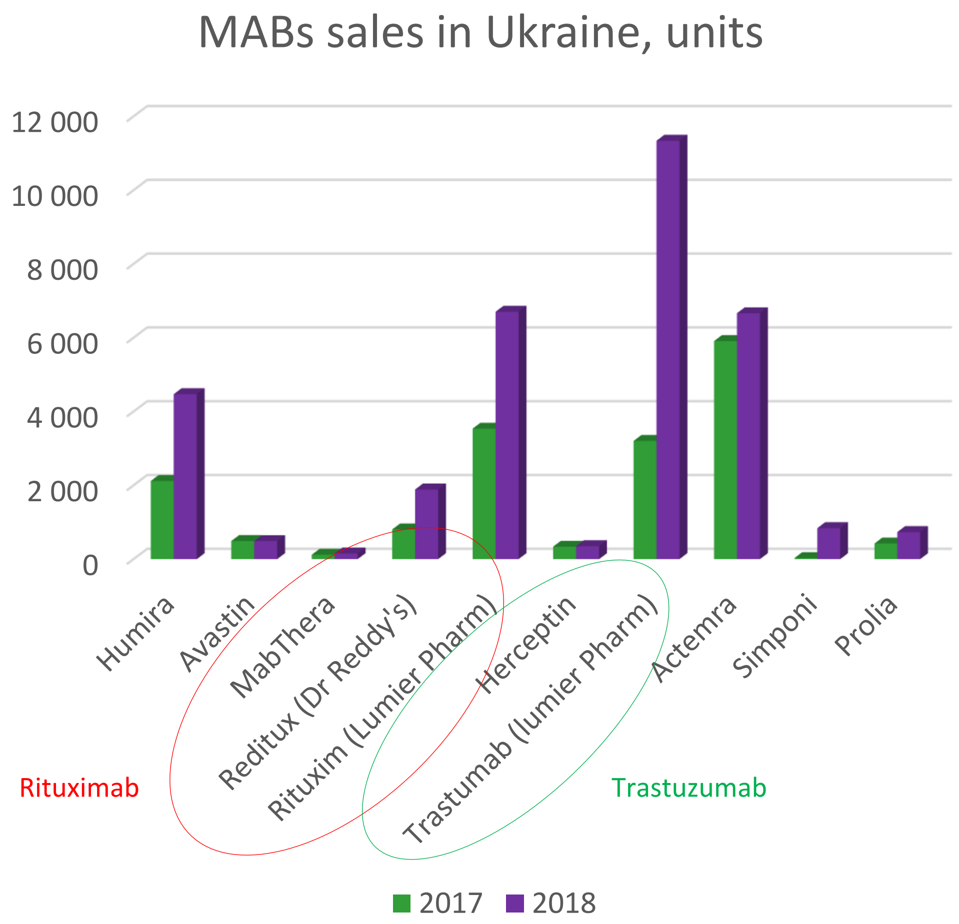
Biosimilars in Ukraine

INN	Manufacturer
Insulin Glargine	Farmak
Pegfilgrastim	Biopharma (Ukraine)
Rituximab	Celltrion

Source: Proxima Research "PharmXplorer"

MABs market in Ukraine



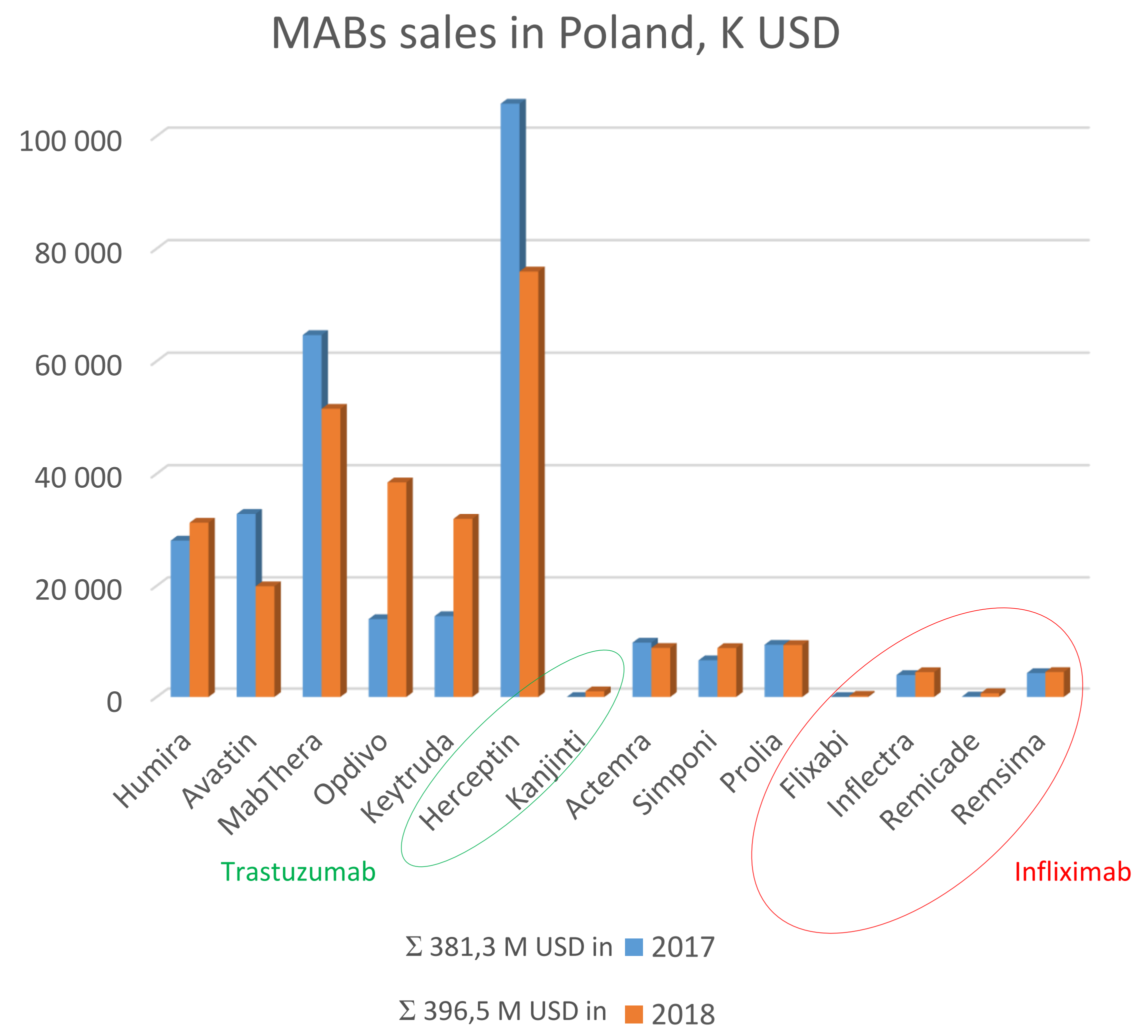


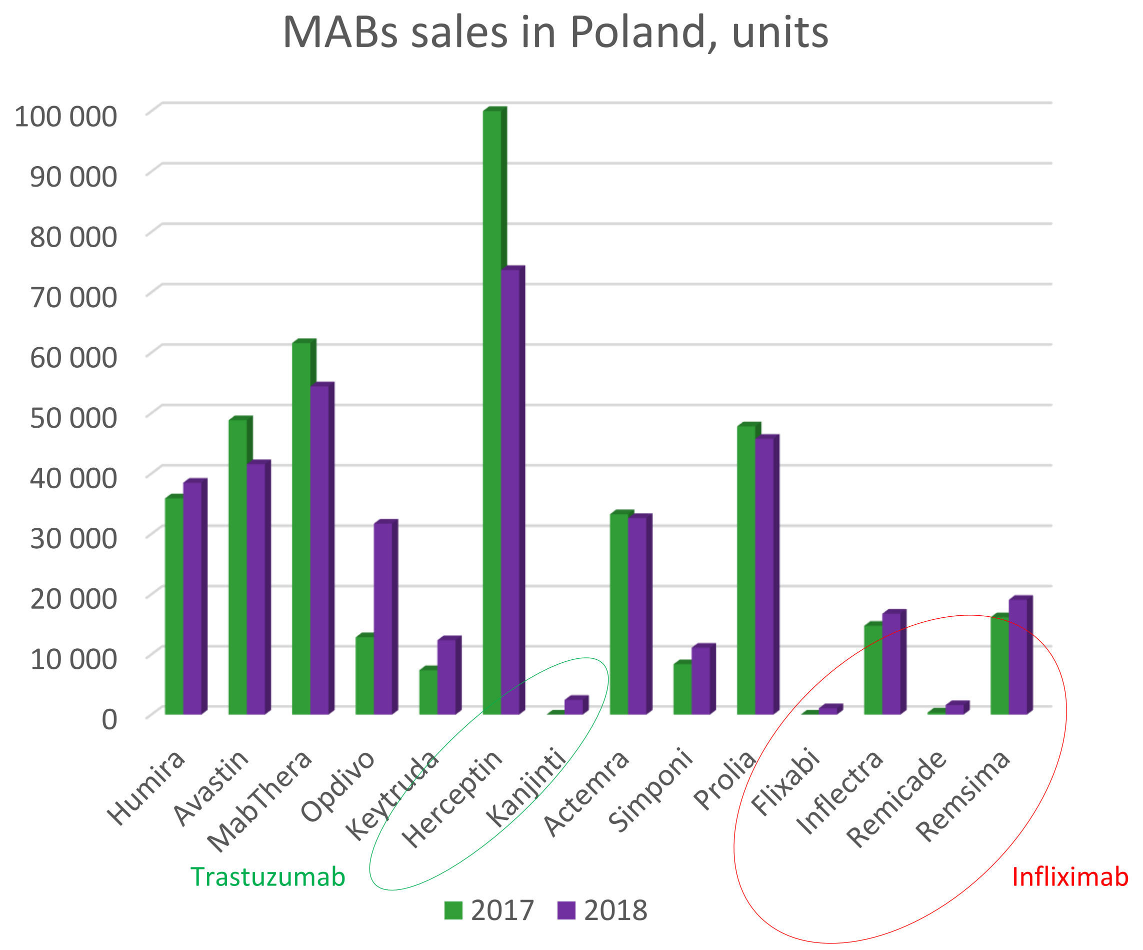
- Reditux is **Dr Reddy's** biosimilar to Rituximab marketed in Ukraine for several years, but currently its' MA in Ukraine has expired.
  - **Tocilizumab, Rituximab** are included into National list of medicines.
    - **Celltrion** has registered Rituximab biosimilar in Ukraine via simplified procedure.

Source: Proxima Research "PharmXplorer"

Farmak JSC

MABs market in Poland



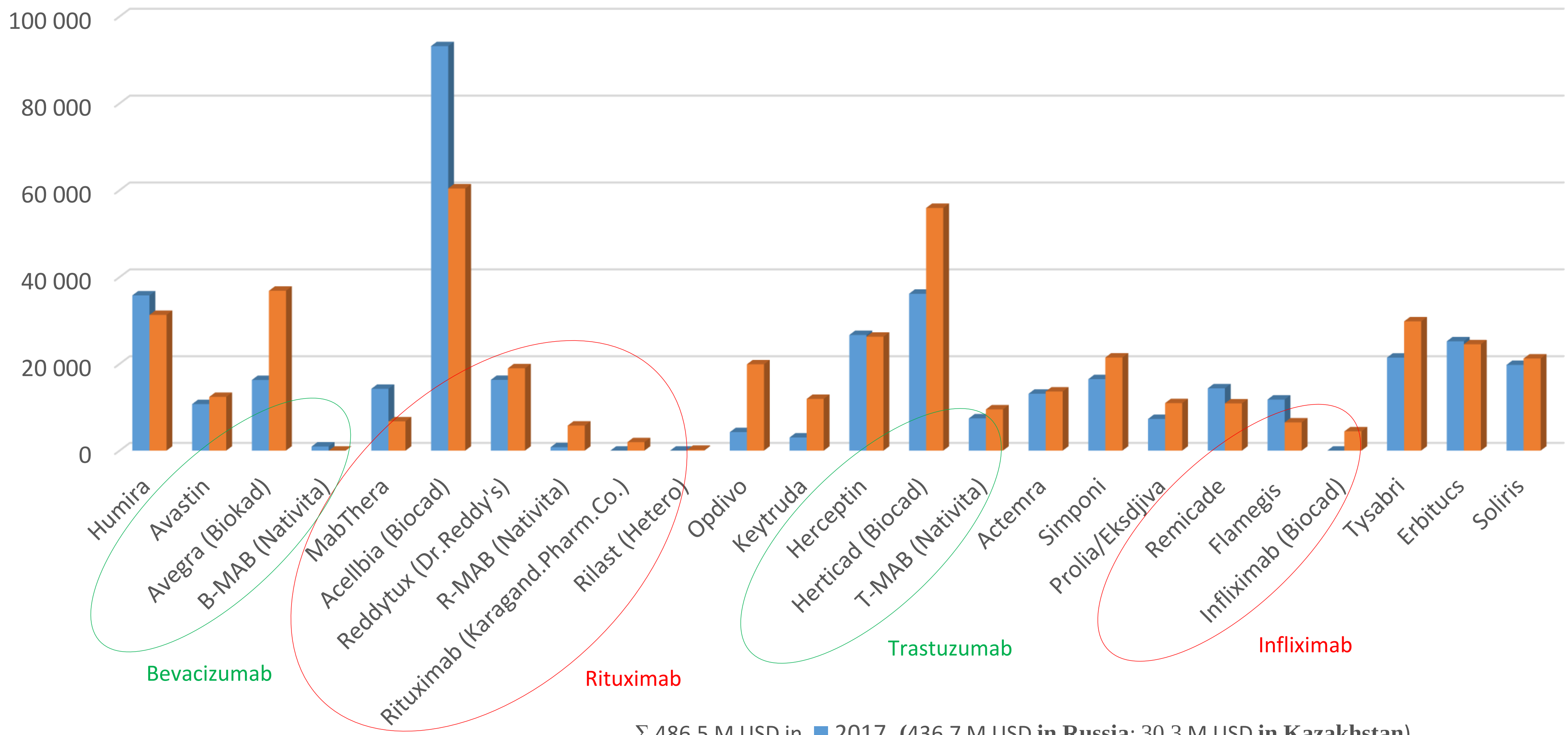


Source: IQVIA "Midas"

Biosimilar MABs registered by EMA

INN	Company name
Adalimumab	Boehringer Ingelheim
Adalimumab	Amgen
Adalimumab	Sandoz
Adalimumab	Samsung Bioepis
Adalimumab	Mylan/Fujifilm Kyowa Kirin Biologics
Bevacizumab	Amgen
Etanercept	Samsung Bioepis
Etanercept	Sandoz
Infliximab	Celltrion
Infliximab	Sandoz
Infliximab	Hospira
Infliximab	Samsung Bioepis
Rituximab	Celltrion
Rituximab	Sandoz
Trastuzumab	Celltrion Healthcare
Trastuzumab	Biocon/Mylan
Trastuzumab	Samsung Bioepis
Trastuzumab	Pfizer
Trastuzumab	Amgen/Allergan

MABs market in CIS (Belarus, Russia, Kazakhstan, Kyrgyzstan, Moldova, Uzbekistan), K USD

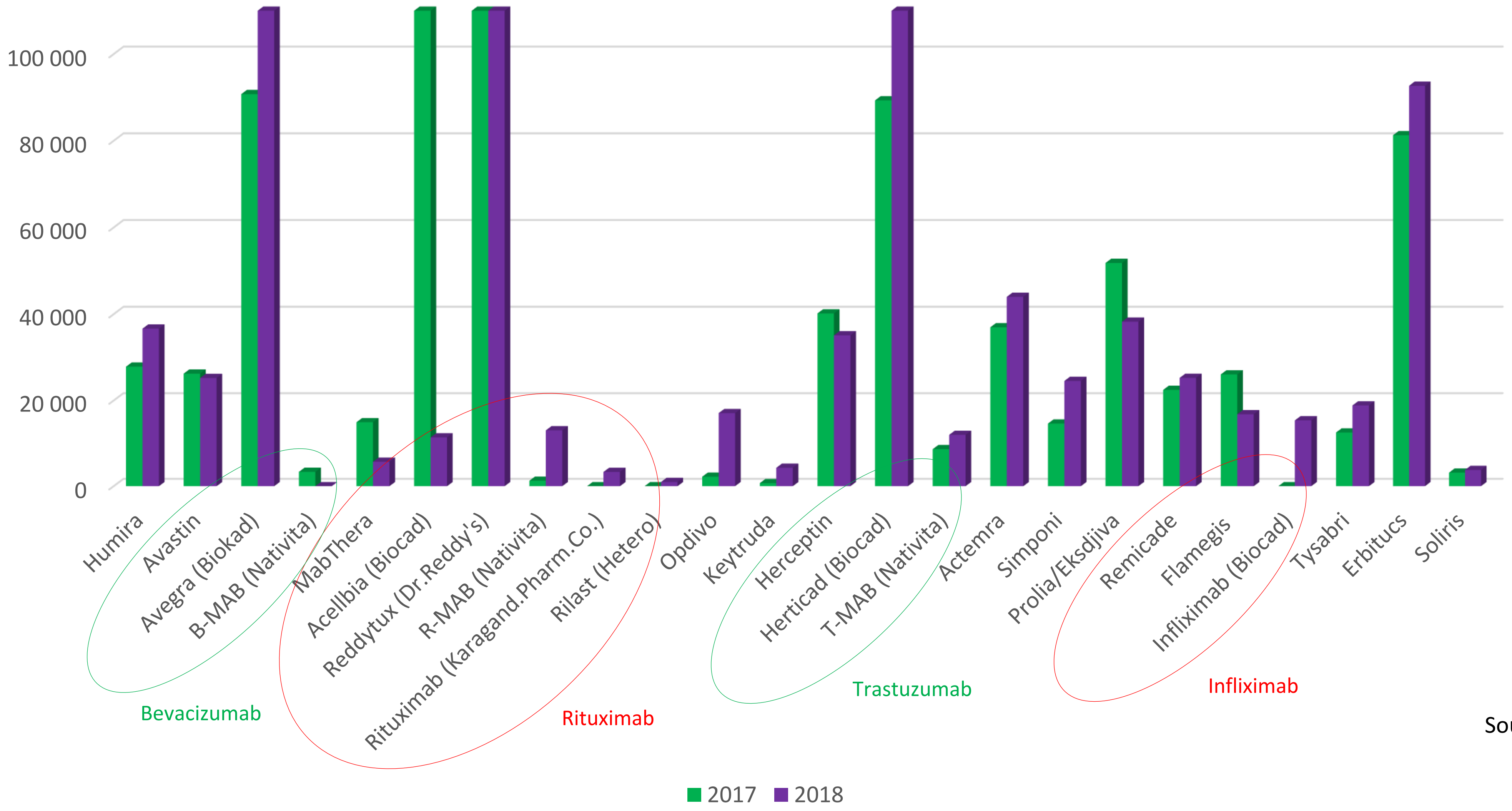


Σ 486,5 M USD in 2017 (436,7 M USD **in Russia**; 30,3 M USD **in Kazakhstan**)

Σ 584 M USD in 2018 (515 M USD **in Russia**; 43 M USD **in Kazakhstan**)

Source: IQVIA CIS

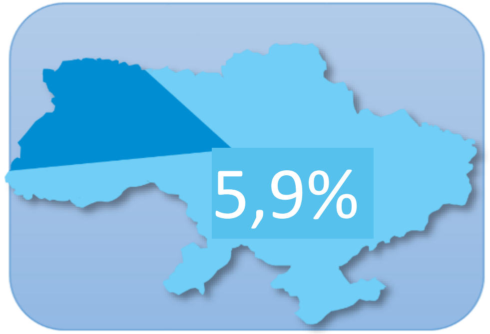
MABs market in CIS (Belarus, Russia, Kazakhstan, Kyrgyzstan, Moldova, Uzbekistan), units



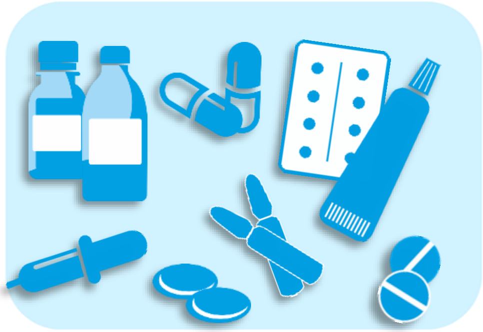
Source: IQVIA CIS

Farmak Overview

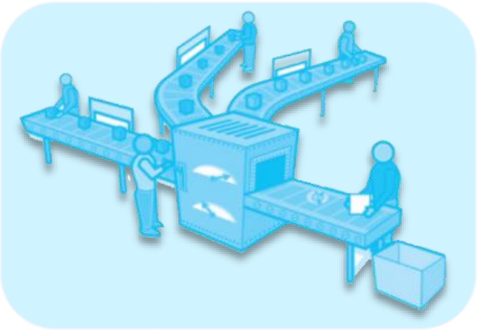
Farmak – leader in the Ukrainian pharmaceutical market



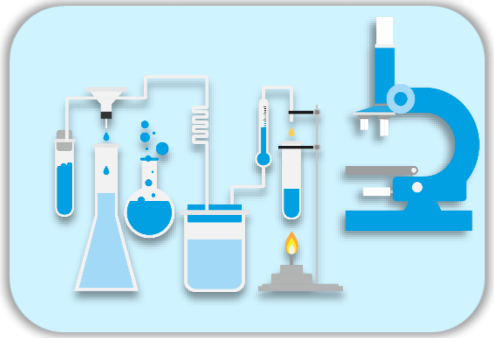
№ 1 Ukrainian producer and exporter of pharmaceuticals*



Diversified product portfolio



Modern and high quality production facilities

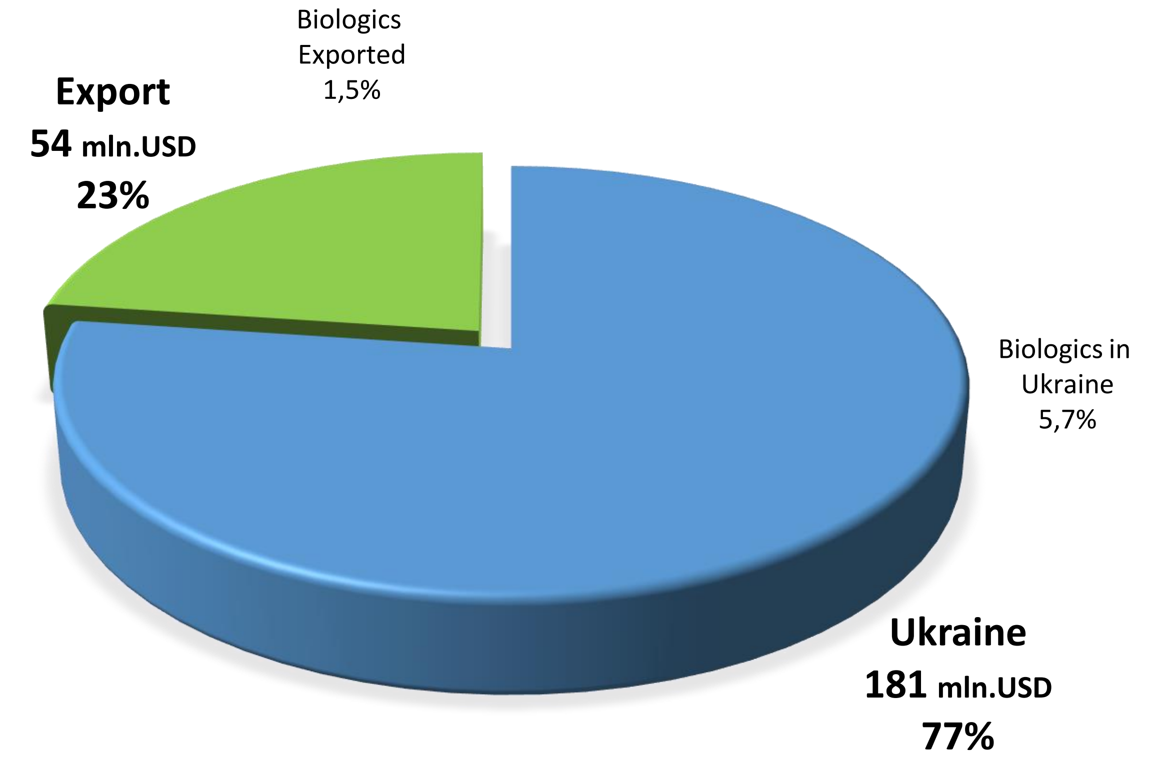


Strong research and development capabilities

Highly skilled motivated staff

Financial strength

Structure of Farmak sales in 2018



TOTAL: 235 mln.USD

* 1 USD ~ 26,76 UAH

Farmak JSC

Farmak Overview

Leader in the state reimbursement program, which is called **"Affordable medicines"**.

8 INN of 23 Which are reimbursed by the program, are presented in Farmak portfolio

26 FDF Produced by Farmak are included into the program. 19 of which are partially reimbursed, 7 are fully reimbursed

18 production lines and
1 pilot line

Comply with National GMP requirements

- 14 lines are EU GMP certified
- FDA approval of OTC and food supplements
- ISO 9001, ISO 14001 and ISO 14385

Farmak Overview

Farmak

Top 5

Innovative companies in Ukraine

184

Mln. USD

volume of investments in the production modernization in 7 years, including the investment of USD 39 million in API production in Shostka

500

thousand EUR

grants for training under the program Horizon – 2020

14.83

Mln. USD

Invested in R&D, starting from 2011

Farmak R&D Potential

Farmak

The scientific potential of Farmak JSC ensures the company's independence in the development of new medicinal products

150 Specialists work in R&D

17 out of them have a scientific degree (15 PhDs, 2 Doctoral Degrees)

114 **medicinal products** in pipeline

>20 new medicinal products are launched in the market annually

State-of-the-art R&D complex includes:

4 cross-sectional analytic laboratories

2 laboratories for biological and synthetic API

3 technological laboratories for finished products

4 pilot R&D sites

Farmak Potential

Biotechnological R&D site:

Farmak has developed manufacturing processes of insulin analogues: lispro and aspart.

Farmak Biosimilars Cases

Insulin case

INN available at Farmak
Insulin H solution for injection
Insulin H NP suspension for injection
Insulin H 30/70 suspension for injection
Insulin Glargine suspension for injection

1998	Start of cooperation with Eli Lilly (USA)	Human Insulin H, H NP, H 30/70
2000	Launch of Human Insulin in Ukraine	Human Insulin H, H NP, H 30/70
2006	Tech transfer from Eli Lilly to Farmak in vials	Human Insulin H, H NP, H 30/70
2012	Tech transfer from Eli Lilly to Farmak in cartridges	Human Insulin H, H NP, H 30/70
2013	Tech transfer agreement with Biocon	Glargine, Recombinant Human Insulin
2015	MA in Ukraine	Human Insulin H, H NP, H 30/70 (Biocon)
2016	Clinical trials in Ukraine (Phase III), 160 patients	Glargine
2017	MA in Ukraine (first biosimilar in Ukraine)	Glargine
	MA in Kyrgyzstan	Human Insulin H, H NP, H 30/70 (Biocon)
2018	MA in Kyrgyzstan, Moldova	Glargine

- 6,3 M — Revenue in 2016, USD
- 6,6 M — Revenue in 2017, USD
- 8,1 M — Revenue in 2018, USD

* 1 USD ~ 26,76 UAH

Enoxaparin Case

2006
- Start of cooperation with Hangzhou Jiuyuan Gene Engineering (China)

2009
- Enoxaparin launched in Ukraine (first enoxaparin generic in the market)

2013
- Tech transfer from Hangzhou to Farmak

2014
- Re-registration in Ukraine as a biosimilar
- Clinical trials in Russia (Phase I) in syringes, 24 healthy volunteers

2015
- Clinical trials in Ukraine (Phase III) in syringes

2016
- Clinical trials in Russia (Phase III) in syringes, 116 patients
- MAs in Uzbekistan and Turkmenistan, PFS

2017
- Clinical trials in Ukraine (Phase III) in vials (30 000 Anti-Xa IU)
- MA in Russia, PFS

2018
- MA in Georgia, PFS
- Deep characterization of molecule structure by Ronzoni Institute, Milano

4,7 M	Revenue in 2016, USD
6,3 M	Revenue in 2017, USD
8,9 M	Revenue in 2018, USD

Conclusions

Conclusions

1. The market of biotechnological products in Ukraine is not developed due to low purchasing ability and lack of state financing. The potential is equal to Poland;

2. Local biotechnologies are at the early stage of development due to high entry barriers: lack of knowledge and financing;

3. Potentially, the most effective cooperation with partners is to license-in the products followed by a transfer of complete technological cycle of the finished dosage form.

THANK YOU FOR YOUR ATTENTION!