

# Industry Insights

*The facts for your business*

## Pharmaceutical Industry in Russia, Ukraine, Belarus and Kazakhstan

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March 2017

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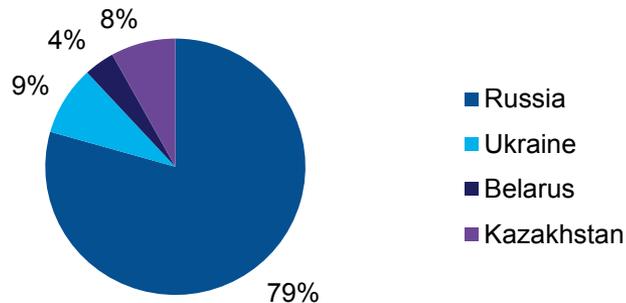
This report is an overview of the pharmaceuticals sector in Russia, Ukraine, Belarus and Kazakhstan rather than an exhaustive report. We would be happy to provide a more detailed report on a specific subject.

Financial indicators in this report cover mostly drugs. They do not include medical devices or other pharmaceutical goods.

This document contains rankings of top pharma producers in their respective economies. Upon request, you can **obtain an extended version** of our report in which you can find rankings of top pharma wholesale distributors and pharmacy chains, drug registration statistics in one of the countries and other important information.

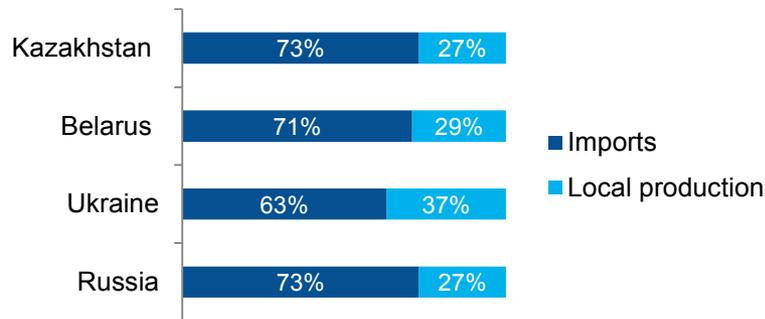
# Executive Summary (1)

Relative market size by country from a total of USD 22.1bn based on sales in 2015, %



Sources: DSM, AIPM Russia, BMI

Pharma imports vs. local production in USD terms in 2015, %



Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

## Market size

- Combined size of the pharma markets of Russia, Ukraine, Belarus and Kazakhstan totaled **USD 22.1bn** in 2015.
- The **Russian market**, with sales at c. **USD 17.5bn** in 2015 or **79%** of the combined market size, is the largest.
- This proportion is broadly repeated in the allocation of population among these countries.

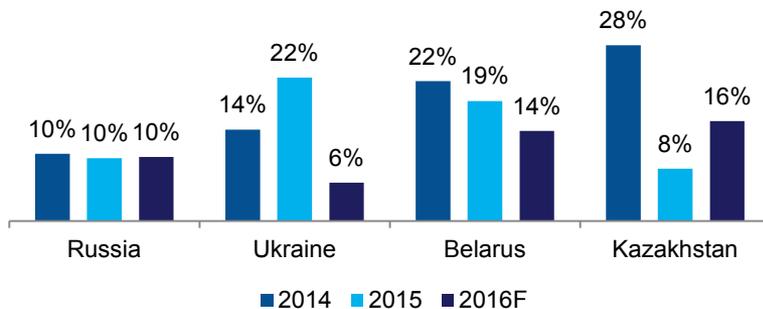
## Imports vs. local production

- Imports dominate all the markets in value terms but not in unit terms.
- **Imports are between 63% and 73%** in value terms, with a striking similarity of import shares in Russia, Kazakhstan and Belarus (70% vs. 30% range).
- Measured in **units, the proportion is quite the opposite**: e.g., imports account for 39% in Russia.
- Sectors are similar: imports are represented by expensive patented medicines whereas local pharma companies predominantly produce more inexpensive generics.

# Executive Summary (2)

## Development of pharma sales

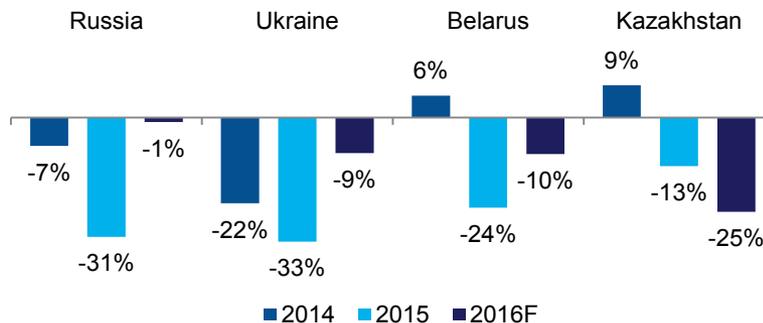
in local currencies, %



Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

## Development of pharma sales

in foreign currency terms, %



Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

## Local market performance

- All **pharma markets grew over the last three years** despite the difficult economic environment.
- **Russia's** pharma market has grown **10%** on average in RUR terms and is expected to grow by approximately another **10%** in 2016.
- **Ukraine's** market has grown by **18%** on average in UAH terms. It is forecast to show slower growth of **6%** in 2016.
- The market in **Belarus** was a strong **20%** on average in BYR terms, and its growth is seen to slow down to **14%** in 2016.
- **Kazakhstan's** pharma market has grown at **18%** on average in KZT terms. It is expected to grow **16%** in 2016.

## Effect of currency devaluation

- Devaluation of local currencies has significantly affected sales in foreign currency terms. However, they are expected to start to recover in 2016 in some countries.

# Executive Summary (3)

## Role of pharma in the national economies

- Pharma accounts for a relatively **small share in each economy**: between **1.0%** of GDP in Kazakhstan to **2.1%** in Ukraine. Russia and Belarus are pretty close, at **1.3%** and **1.5%** respectively.
- This can be partially explained by the structure of some of the economies.
- **Spending on drugs** per capita (**USD 50 to USD 165 a year**) is low compared to the EU. For example, Poland (with its USD 330) spends twice as much on drugs per capita as the biggest of the four spenders does.
- This shows that the combined **market of more than 210m consumers** has yet to realize its **potential**.

## Regulation and state involvement

- Governments pay a lot of attention to their markets.
- Certification lead times are usually lengthy but regulations are changed to improve this.

- **Ukraine introduced a fast track registration** process for drugs registered in countries with strong regulatory regimes.
- Drugs holding international patents should be registered by national authorities before they can be sold in local markets.
- In view of the economic difficulties, governments establish **'essential drug lists'** and regulate prices.
- Russia, Belarus and Kazakhstan have **national import substitution policies** which set different targets for the share of locally produced drugs, provide incentives for localization and impose market access restrictions.
- **Public tenders** are performed in relation to drugs covered by government-funded programs.
- **Local regulations have replicated GMP** and compliance has become mandatory.
- In November 2016, the Eurasian Economic Union's members (Ukraine is not part of the EEU) agreed all key regulations in order to establish **the EEU Single Drug Market**.

# Executive Summary (4)

## Key consumers and markets

- **Consumers are getting older**: the share of those who are 35 y.o. and above will increase by about 4 percentage points by 2025.
- **Cardiovascular diseases and cancer** are the leading causes of death in all the four countries.
- Markets demonstrate **different consumption behaviors**, e.g., Russia displays disproportionate spending on drugs compared to its share of population.
- **Governments finance drug purchases** for hospitals. They account for between **10% to 40%** of total market volumes, while the rest is covered by the consumer.
- **Distribution is highly concentrated**: usually there are **5-7 leaders** controlling **40%-90%** of the market.
- **Retail is less consolidated**: this is more pronounced in the larger markets (Russia and Ukraine).

- A comparison of prices for five drugs for very common conditions revealed that they are probably twice as expensive in Ukraine and Kazakhstan as in Russia and Belarus.

## Market overview and segmentation

- **Prescription drugs** account for **up to 68%** of sales in value terms depending on the market.
- **Patented drugs** claim a usually low share of sales (**11%-29%**) as they are most expensive.
- **Rx generics** provide a less expensive alternative and are the core of state healthcare programs (**39%-50% of sales**).
- **OTC drugs** are traditionally strong because of more affordable prices, better customer awareness and tendency for self-treatment (**32%-41% of sales**).

## Leading manufacturers

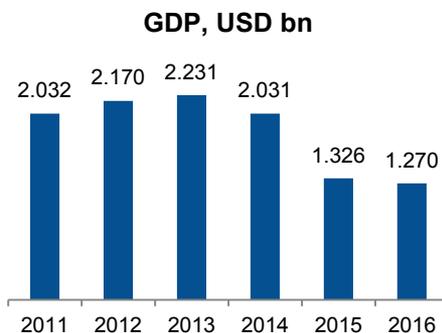
- **Governments create attractive conditions** for investors and invest themselves.
- **Many successful examples** of investment projects to produce innovative drugs and improve overall prospects of the industry.

# Chances and Opportunities (1)

## Russia

*Significant opportunities offered by the large market*

Indicators	2016
Govt debt, USD bn	158
Govt debt to GDP, %	12.4%
Consumer credit, USD bn	156
Consumer credit to GDP, %	12.3%
Human Development Index (HDI)	0.798
Unemployment, %	5.3



*\*Average exchange rates were used.  
Sources: Tradingeconomics.com, IMF, UNDP.*

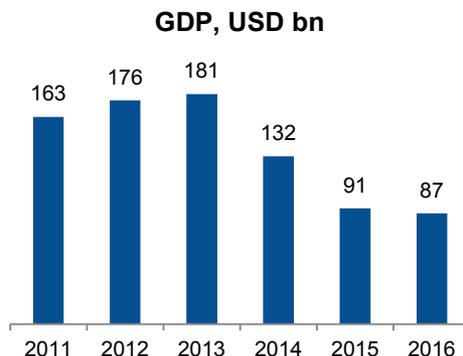
- Russia is a major market with **144m** inhabitants, of which **74% live in urban areas**.
- **77m** people are working age (aged 15-72).
- Average life expectancy at birth: **70.1** years.
- Number of state-owned hospitals: **5,600**.
- **Good education system** with a strong technical/science heritage.
- **100%** of population is **literate** with **95%** with at least **upper secondary education**.
- **950** state and private **universities** produce **1.2m graduates** a year (almost double from 2000).
- According to OECD, **54%** of those aged 25-64 have attained a **university degree**.
- **12<sup>th</sup> largest economy in the world** in 2016 measured by GDP in real terms: **USD 1,270bn**.
- **6<sup>th</sup> largest economy in the world** in 2016 measured by GDP based on PPP valuation: **USD 3,745bn**.
- **GDP per capita** in 2016 at current prices: **USD 8,840** (and **USD 26,110** based on PPP).
- **Annual progress** in World Bank's 'Ease of Doing Business' 2017 ranking: **40<sup>th</sup> place in 2016 (2015: 51<sup>st</sup>)**.
- **Corruption Perceptions Index** score (Transparency International): **29 in 2016 (2015: 29)**.

# Chances and Opportunities (2)

## Ukraine

*A large market with great potential*

Indicators	2016
Govt debt, USD bn	21
Govt debt to GDP, %	24%
Consumer credit, USD bn	3.9
Consumer credit to GDP, %	4%
Human Development Index (HDI)	0.747
Unemployment, %	9.2



*\*Average exchange rates were used.  
Sources: Tradingeconomics.com, IMF, UNDP.*

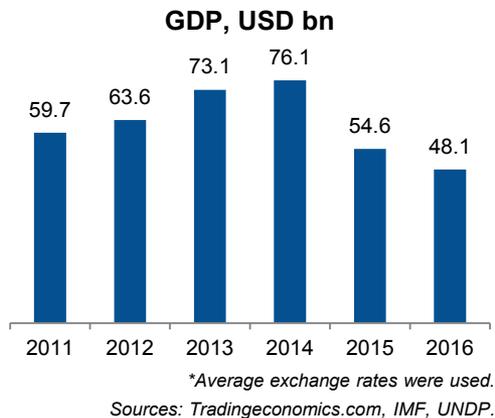
- Ukraine is a big market with **42.7m** inhabitants, of which **70% live in urban areas**.
- **23m** people are working age (aged 15-70).
- Average life expectancy at birth: **71** years.
- Number of state-owned hospitals: **1,800**.
- **Good education system** with a strong technical/science heritage.
- **100%** of population is **literate** with **94%** with at least **upper secondary education**.
- **439** state and private **universities** produce ca. **900,000 graduates** a year.
- According to the Ukrainian Institute of Demographics and Sociological Research, **76%** of those aged 25-64 have attained a **university degree**.
- **64<sup>th</sup> largest economy in the world** in 2016 measured by GDP in real terms: **USD 87.2bn**.
- **50<sup>th</sup> largest economy in the world** in 2016 measured by GDP based on PPP valuation: **USD 349.8bn**.
- **GDP per capita** in 2016 at current prices: **USD 2,050** (and **USD 8,230** based on PPP).
- **Annual progress** in World Bank's 'Ease of Doing Business' 2017 ranking: **80<sup>th</sup> place in 2016 (2015: 83<sup>rd</sup>)**.
- **Corruption Perceptions Index** score (Transparency International): **29 in 2016 (2015: 27)**.

# Chances and Opportunities (3)

## Belarus

*Belarus – a bridge between the EU and the EEU*

Indicators	2016
Govt debt, USD bn	18.3
Govt debt to GDP, %	38%
Consumer credit, USD bn	0.9
Consumer credit to GDP, %	2%
Human Development Index (HDI)	0.786
Unemployment, %	1%



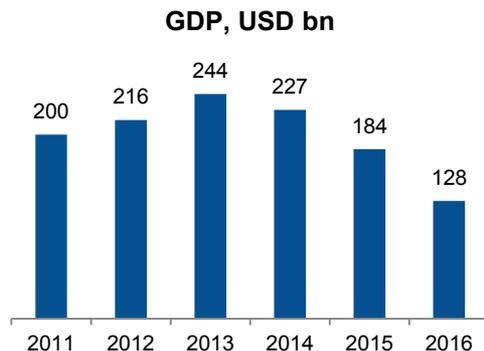
- Belarus is a major market with **9.5m** inhabitants, of which **77% live in urban areas**.
- **6.7m** people are working age (aged 15-72).
- Average life expectancy at birth: **71.3** years.
- Number of state-owned hospitals: **636**.
- **99.6%** of population is **literate** with **82%** with at least **upper secondary education**.
- **53** state and private **universities** produce ca. **420,000 graduates** a year.
- According to OECD, **19%** of those aged 25-64 have attained a **university degree**.
- **80<sup>th</sup> largest economy in the world** in 2016 measured by GDP in real terms: **USD 48.1bn**.
- **72<sup>nd</sup> largest economy in the world** in 2016 measured by GDP based on PPP valuation: **USD 165.4bn**.
- **GDP per capita** in 2016 at current prices: **USD 5,090** (and **USD 17,500** based on PPP).
- **Annual progress** in World Bank's 'Ease of Doing Business' 2017 ranking: **37<sup>th</sup> place in 2016 (2015: 44<sup>th</sup>)**.
- **Corruption Perceptions Index** score (Transparency International): **40 in 2016 (2015: 32)**.

# Chances and Opportunities (4)

## Kazakhstan

*Kazakhstan – the Central Asian tiger*

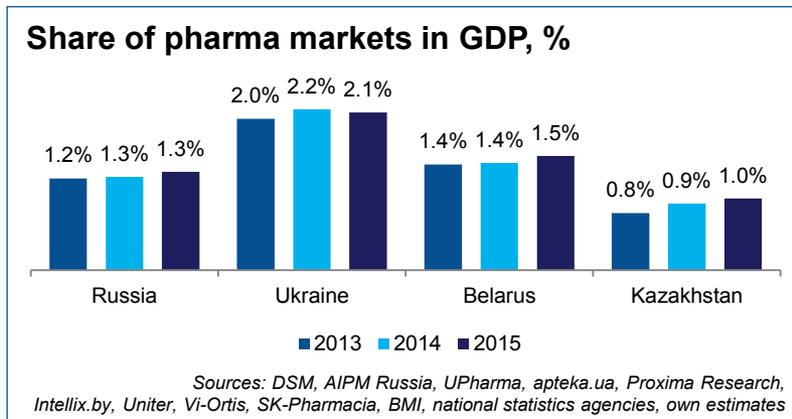
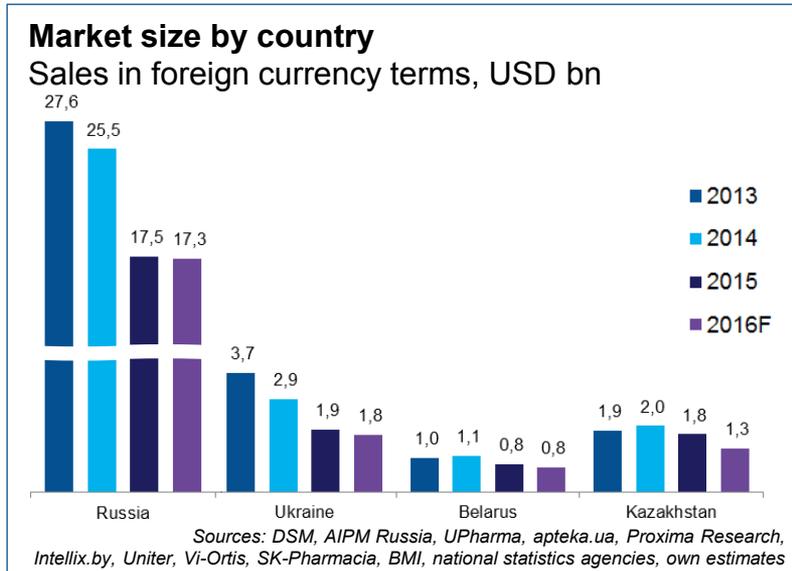
Indicators	2016
Govt debt, USD bn	12.9
Govt debt to GDP, %	10%
Consumer credit, USD bn	11.7
Consumer credit to GDP, %	9%
Human Development Index (HDI)	0.762
Unemployment, %	5%



*\*Average exchange rates were used.  
Sources: Tradingeconomics.com, IMF, UNDP.*

- Kazakhstan is a major market with **17.7m** inhabitants, of which **43.2% live in urban areas**.
- **12.5m** people are of working age (aged 15-64).
- Average life expectancy at birth: **69.4** years.
- Number of state-owned hospitals: **900**.
- **100%** of population is **literate** with **87% (91% M, 83% F)** with at least **upper secondary education**.
- **146** state and private **universities** produce **600,000** graduates a year (compared to 400,000 in 2001).
- According to the CIS Interstate Statistics Committee, **34%** of those aged 25-64 have attained a **university degree**.
- **55<sup>th</sup> largest economy in the world** in 2016 measured by GDP in real terms: **USD 128.1bn**.
- **42<sup>nd</sup> largest economy in the world** in 2016 measured by GDP based on PPP valuation: **USD 460.7bn**.
- **GDP per capita** in 2016 at current prices: **USD 7,140** (and **USD 25,670** based on PPP).
- **Annual progress** in World Bank's 'Ease of Doing Business' 2017 ranking: **35<sup>th</sup> place in 2016 (2015: 41<sup>st</sup>)**.
- **Corruption Perceptions Index** score (Transparency International): **29 in 2016 (2015: 28)**.

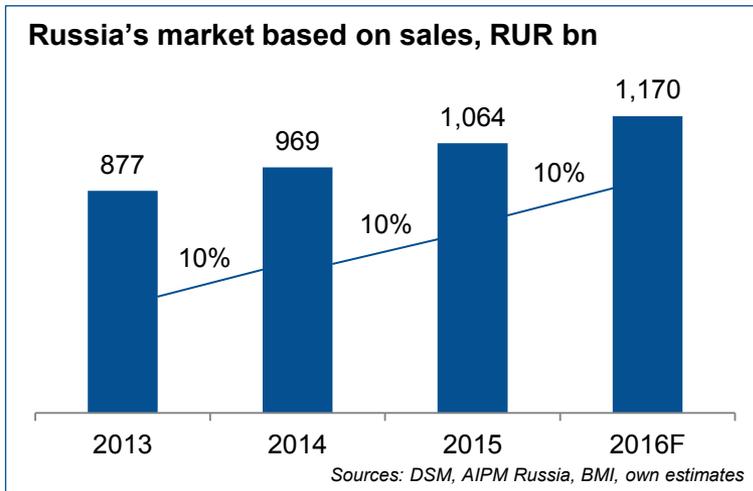
# Role in the National Economies (1)



- This chart shows the relative size of each market in 2013-15. The overall reduction is a result of the local currencies' devaluation seen across the board. In local currency terms, the markets have been growing.
- These countries have inherited their pharma sectors from the Soviet Union. Each former republic had a different economy structure, with pharma being well-represented in Ukraine, Russia and Belarus, and probably less so in Kazakhstan.
- While natural resources are key in Russia and Kazakhstan, pharma's share in their GDP numbers is lower than in Ukraine and, marginally, Belarus. This is as a result of a stronger role played by pharma in the economies with less dependence on natural resources.
- In light of the special nature of the industry (need for highly skilled employees and a greater degree of automation), the industry's headcount is not significant: 70,000 in Russia, 40,000 in Ukraine, 10,000 in Belarus and approximately 15,000 in Kazakhstan.

# Role in the National Economies (2)

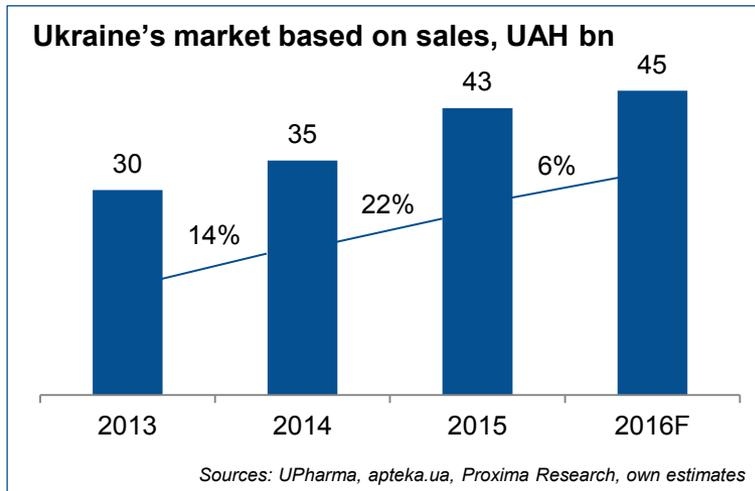
## Russia



- Russia's pharma market has grown 10% on average in RUR terms and is expected to grow by approximately another 10% in 2016.
  - Russians spend c. USD 165 a year on medicines, which is a long way to Poland's USD 330 or Germany's USD 680 a year.
  - This market is very significant in value terms and is the largest market in Central Europe in terms of its consumer base of some 145m people.
- Russians' preference for western quality and brands, together with its demographic trends (ageing population) and untapped growth potential, make it one of the most attractive emerging markets for international pharma manufacturers.
  - Local laws require that clinical trials should be carried out in Russia before drugs are registered and authorized for sale.

# Role in the National Economies (3)

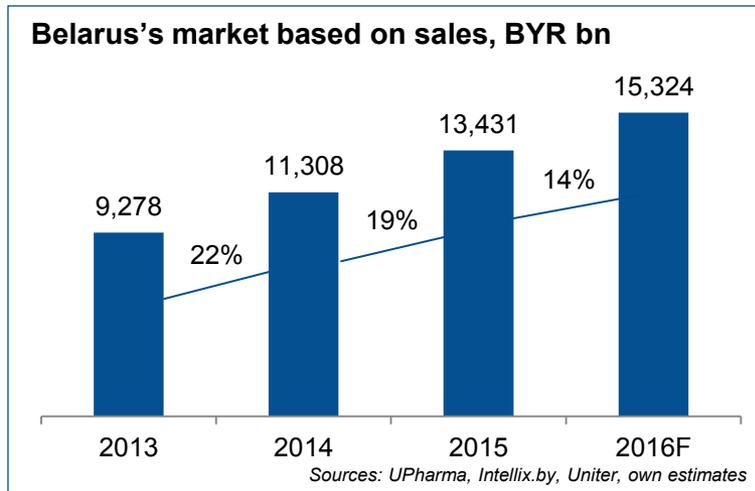
## Ukraine



- Ukraine's market has grown by 18% on average in UAH terms. It is forecast to show slower growth of 6% in 2016.
  - Ukrainians spend c. USD 50 a year on medicines (USD 330 in Poland or USD 680 in Germany).
  - This market is the 14<sup>th</sup> largest market in value terms in Central and Eastern Europe and is the second largest market in the region with some 42m people.
  - Government's funding of healthcare is reduced, most of drugs and other health related expenses are paid for by individuals.
- The market is under pressure resulting from the economic and political difficulties, devaluation of the local currency, falling incomes and growing tariffs.
  - However, the government is pushing for serious reforms of the sector. Recent positive changes have seen the introduction of reference pricing and simplified registration of drugs which have already been registered in certain countries.

# Role in the National Economies (4)

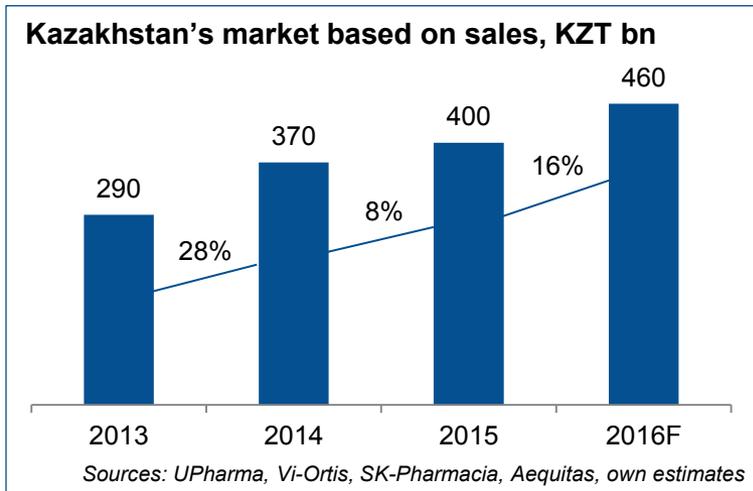
## Belarus



- The market in Belarus was a strong 20% on average in BYR terms, and is seen to slow down to 14% in 2016.
- Belarussians spend c. USD 80-95 a year on medicines (USD 330 in Poland or USD 680 in Germany).
- The government has increased its expenditures on the country's healthcare system, which resulted in significant improvements in such key indicators as child immunization rate and incidence of infectious diseases.
- The healthcare sector is dominated by the government. It contributes about 70% of total health costs. The government controls top five drug producers.
- Prices for the essential drugs acquired for the state hospital system are regulated by the state.
- There is no strong voluntary health insurance yet, but the government is considering whether this system should be introduced on a large scale.
- Drugs produced locally are given preference in state tenders: 80% of drugs purchased via tenders are of local origin.
- About 40% of drugs produced locally are exported.
- Approximately 50% of drugs are prescribed.

# Role in the National Economies (5)

## Kazakhstan



- Kazakhstan's pharma market has grown at 18% on average in KZT terms. It is expected to grow 16% in 2016.
  - Kazakhstan's citizens spend c. USD 90 a year on medicines (USD 330 in Poland or USD 680 in Germany).
  - The government increased funding of the healthcare sector several years ago, which led to positive results in the incidence of infectious diseases.
  - Favorable taxation: no VAT on drugs and APIs.
  - The government is pushing for reforms of the sector to make it attractive to investors.
- One of such reforms is implementing a public health insurance system.
  - Import substitution policies are aimed at reducing the dependence on imported drugs and making the country a drug exporter.
  - State procurement of drugs is run via one powerful procurer (SK Pharmacia) while the private distribution is fragmented.
  - Out-of-pocket expenses on drugs are significant.

# Regulation and State Involvement (1)

## Russia

Question	Answer
Who certifies drugs?	The Ministry of Health of the Russian Federation and its subsequent body the Department of state regulation of pharmaceutical product circulation.
How long does certification take?	18 months for a product that requires a clinical study, 9 months for a product that does not require a clinical study. Only drugs which have been registered in Russia more than 20 years ago can be registered without a clinical study.
How can patent protection for pharmaceuticals be achieved in Russia?	Russia is no party to the European Patent Convention, but party to the Patent Corporation Treaty (PCT). Therefore a national patent is required. It can be applied for locally in Russia or within the framework of the PCT through the patent office of the applicant and the World Intellectual Property Organization (WIPO).
Does an “essential drug list” exist?	Yes, currently (2017 list) there are 649 international non-proprietary names (INN) listed, of which c. 70% are manufactured domestically.
Are prices regulated?	A direct regulation takes place for drugs on the essential drug list, whose prices are regulated once a year and are based on a reference pricing system (prices in the EEU). Indirect regulation takes place through regulation of participation in public tenders and rules governing maximum prices and obligatory discounts.
Are their import substitution laws in place?	Yes, they include: <ul style="list-style-type: none"> <li>• Creation of incentives for localization of production facilities by foreign manufacturers in the Russian Federation, including granting of subsidies for organization of clinical trials and manufacturing of medicines and medical devices</li> <li>• Restriction of the procurement of foreign goods for state and municipal needs</li> <li>• Pharma 2020 strategy aims to reduce the share of imported drugs in public procurement tenders to 10% by 2020 (see Investment section).</li> </ul>
Are public tenders performed?	Yes, but under the regime of the import substitution law, foreign companies either produce locally to participate in these tenders, are generally punished with a 15% mark-down for offers, or banned from participation in public tenders. Draft regulations propose that only the drugs produced from substances of Russian origin (molecule created in Russia) should be allowed access to state tenders.
Do public buyers exist?	Yes, the Federal Ministry of Health as well as the regional Ministries of Health purchase items for state hospitals collectively.

# Regulation and State Involvement (2)

## Ukraine

Question	Answer
Who certifies drugs?	The Ministry of Health is responsible for state registration of drugs. The State Administration on Pharmaceutical Products and Drugs Control Service of Ukraine is charged with certification of drugs and licensing of activities in pharmaceutical manufacturing.
How long does certification take?	When a drug is registered for the first time, the registration procedure takes no more than 210 working days. This registration is valid for 5 years. Re-registering a drug takes no more than 90 working days. To have a drug certified takes no more than 15 working days. A new fast-track registration procedure was adopted for drugs registered in the U.S., Switzerland, Japan, Australia, Canada and the EU. The Ministry of Health should take a decision to register a drug within 7 working days and registration materials should be reviewed within 10 working days.
How can patent protection for pharmaceuticals be achieved in Ukraine?	Ukraine is no party to the European Patent Convention, but party to the Patent Corporation Treaty (PCT). Therefore a national patent is required. It can be applied for locally in Ukraine or within the framework of the PCT through the patent office of the applicant and the World Intellectual Property Organization (WIPO).
Does an “essential drug list” exist?	Approximately 70% of drugs on the WHO’s list on essential medication appear on the essential drug list. The latest version is dated 01.02.2012 and can be seen on the webpage of the Ministry of Health.
Are prices regulated?	Semi-regulated. Mark-up caps exist for wholesalers (max. +10% on registered price) and for retailers (max. 25% on the wholesale price). There is a list of registered drugs, including mark-up prices. In November 2016, the government decided to adopt reference pricing for drugs based on the API.
Are there import substitution laws in place?	Yes, similar to the Russian version. It is called “The Concept of the National Targeted State Program for the Development of Import-Substituting Manufacturing Industries in Ukraine and Substitution of Imported Medicinal Products with Domestic Products, Including Biotechnological Medicinal Products and Vaccines, for 2011-2021”. In the middle of 2016, the Cabinet of Ministers of Ukraine said that it would develop a new concept.
Are public tenders performed?	Yes, though the tendering process is currently undergoing changes to reflect the currency volatility while still enabling sufficient quantities to be purchased/delivered.
Do public buyers exist?	Yes, the procurement department within the Ministry of Health purchases medicines (once a year) from a list of medicines allowed to be purchased with public funds. The Ministry buys drugs from those specialized international organizations (public buyers) which it had pre-selected. This list, however, covers about 80% of the available medicines in the market. There are various drugs (with varying prices) to treat the same condition, which can lead to budgetary increases. The tendering process is currently undergoing changes to reflect the currency volatility while still enabling sufficient quantities to be purchased/delivered.

# Regulation and State Involvement (3)

## Belarus

Question	Answer
Who certifies drugs?	The Ministry of Health oversees certification of drugs. There is a two-tier “certification” procedure for drugs and pharma substances in Belarus supervised by the Health Ministry: (1) clinical trials and (2) state registration of drugs at the State Enterprise “Center for healthcare expert evaluation and trials”.
How long does certification take?	Full cycle of drug registration takes about 18 months, while pharmaceutical substance registration takes about 6 months.
How can patent protection for pharmaceuticals be achieved in Belarus?	Belarus is no party to the European Patent Convention, but party to the Patent Corporation Treaty (PCT). Therefore a national patent is required. It can be applied for locally in Belarus or within the framework of the PCT through the patent office of the applicant and the World Intellectual Property Organization (WIPO).
Does an “essential drug list” exist?	The latest list is approved by the Health Ministry (regulation dated 16.07.2007 #65 (latest update of 04.04.2014)).
Are prices regulated?	Regulation #137 of the Ministry of Health regulates the maximum selling price for some drugs manufactured by domestic producers. In 2012, there were 161 such drugs on the list. Furthermore, selling price limits are set when the drug is registered. Relevant legislation: (i) Wholesale and trade mark-ups for drugs are provided for in the Belarus President’s Decree dated 11.08.2005 #366 (last updated on 21.06.2016) (ii) Prices for certain locally produced drugs are governed by the Health Ministry: Regulation dated 19.01.2012 #56 (last updated on 11.07.2014). (iii) Regulation #137 (updated on 24.06.2016).
Are there import substitution laws in place?	Regulation #174 deals with improving the exportability of Belarus’ pharmaceutical companies. It also pursues a policy of reducing its reliance on imported drugs (50% of drugs sold locally in value terms should be produced in Belarus).
Are public tenders performed?	Yes.
Do public buyers exist?	Belpharmacia State Company, Pharmacia group companies are authorized procurement agencies for all state purchases of medicines. In certain cases hospitals are entitled to purchase drugs for own internal needs as well.

# Regulation and State Involvement (4)

## Kazakhstan

Question	Answer
Who certifies drugs?	The National Expertise Center, a Ministry of Health agency.
How long does certification take?	< 1 year for drugs and up to 1.5 years for medical devices.
How can patent protection for pharmaceuticals be achieved in Kazakhstan?	Kazakhstan is no party to the European Patent Convention, but party to the Patent Corporation Treaty (PCT). Therefore a national patent is required. It can be applied for locally in Kazakhstan or within the framework of the PCT through the patent office of the applicant and the World Intellectual Property Organization (WIPO).
Does an “essential drug list” exist?	There is a list of drugs and medical devices that will be used within the free medical program and must be bought by SK Pharmacia as an official distributor. It is adopted every year.
Are prices regulated?	The Minister of Healthcare signs a decree every year. It caps the prices for the drugs used for the state free medical program. SK-Pharmacia purchases the drugs and medical devices within the capped prices set in the Decree. It then distributes products to hospitals under the state free medical program. SK-Pharmacia is a state owned distribution enterprise with 67% market share.
Are there import substitution laws in place?	Kazakhstan’s laws support national producers and require that national producers should be given preference in government procurement. There are three government programs which cover the development of the industry. Specific incentives include a) concluding long-term drug purchase contracts thus making production levels predictable; b) reimbursing expenses related to achieving compliance with GMP; c) reimbursing expenses associated with promoting locally produced drugs overseas. The government plans to increase the share of local production to 50%.
Are public tenders performed?	Yes, SK-Pharmacia organizes public tenders for purchasing drugs and medical devices as part of the free medical program.
Do public buyers exist?	Yes, the major public buyer of drugs for the free medical program is SK-Pharmacia.

# Regulation and State Involvement (5)

## GMP Certification

### Russia

- Russia requires that foreign manufacturers obtain a 'Russian GMP' certificate (based on 'global' GMP) for their sites in Russia in addition to international GMP certifications they may have already obtained.
- Russian manufacturers can obtain a 'Russian GMP' during the process of product registering.
- To be able to participate in government tenders, foreign companies exporting to Russia should have their overseas sites audited by the Ministry of Industry and Trade.
- Realizing that a GMP certification is a must-have for contract manufacturing partnerships with international producers, Russian companies are stepping up efforts to obtain it.

### Ukraine

- In Ukraine, all manufacturers are required to have either a local or international GMP certificate.

- Drugs imported into Ukraine should be compliant with GMP.
- Manufacturers should also ensure that active ingredients they use in producing their drugs are in compliance with GMP.

### Belarus

- Most pharmaceutical manufacturers have already obtained national GMP certificates.
- In 2015, the Ministry of Health introduced mandatory audits for compliance with GMP.
- A plan of audits is approved annually.

### Kazakhstan

- Imported drugs cannot be registered if they are not in compliance with GMP.
- There are plans to deny registration to drugs produced locally at sites which are not compliant with GMP.
- Only companies whose sites are compliant with GMP can have access to the government's long-term drug supply contracts for the government's free healthcare program.

# Regulation and State Involvement (6)

## EEU Single Drug Market

- Creating a single drug market within the Eurasian Economic Union (EEU) was mandated by Heads of State of the EEU Members as a key focus of integrating the Union.
- The Union brings together Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia.
- All key regulations governing the EEU Single Drug Market were adopted in 2016 and are expected to come into effect in 2017 (decisions of the Council of the Eurasian Economic Commission); they are in line with all best practices and can be found in the Appendix of this paper.
- They cover manufacturing, registration, all types of clinical trials, sales and control of drugs.
- In 2017-2018, so-called ‘third tier’ regulations will be developed: they will deal with implementation of the above regulations.
- Transition periods are adopted – both for manufacturers and regulators.
- Manufacturers can choose the rules – national or single-market – which they will follow in registering drugs and medical devices. They can do it until 31 December 2020.
- Trials will be held in a reference country. Trial results should be acknowledged by and applicable to the Union’s five members.
- Given all procedures are followed, it can be expected that the first product which will be registered in accordance with the new rules will be available on the market in the middle of 2018.

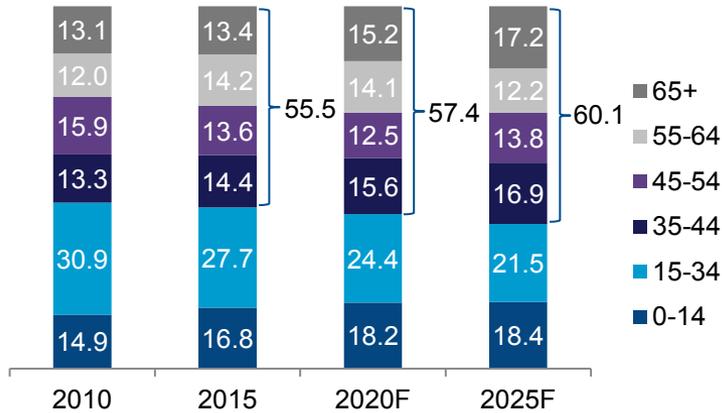


***From today’s perspective, starting from 2018 pharmaceutical drugs and medical equipment registered in one country of the EEU can be sold in any other country of the EEU without the need for re-registration in this country.***

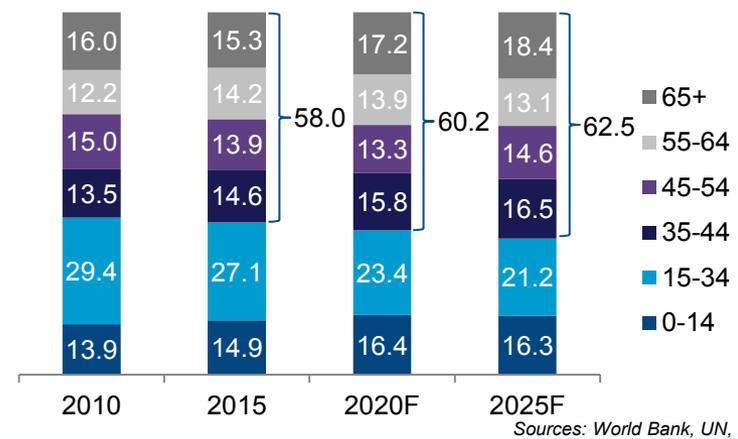
# Key Consumers and Markets (1)

## Population Age Structure (1)

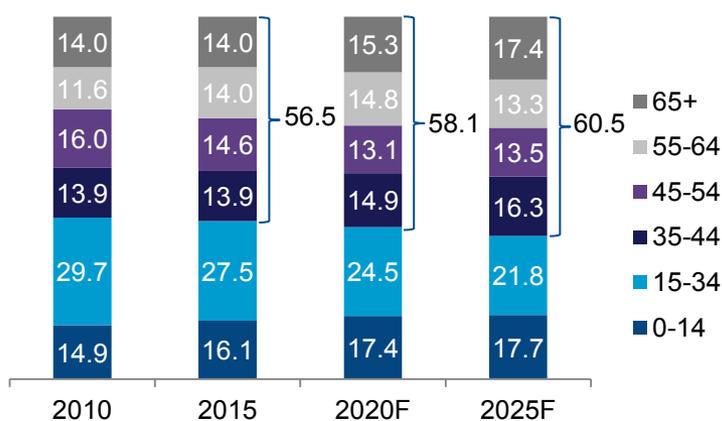
Russia's population age groups, % of population



Ukraine's population age groups, % of population



Belarus's population age groups, % of population

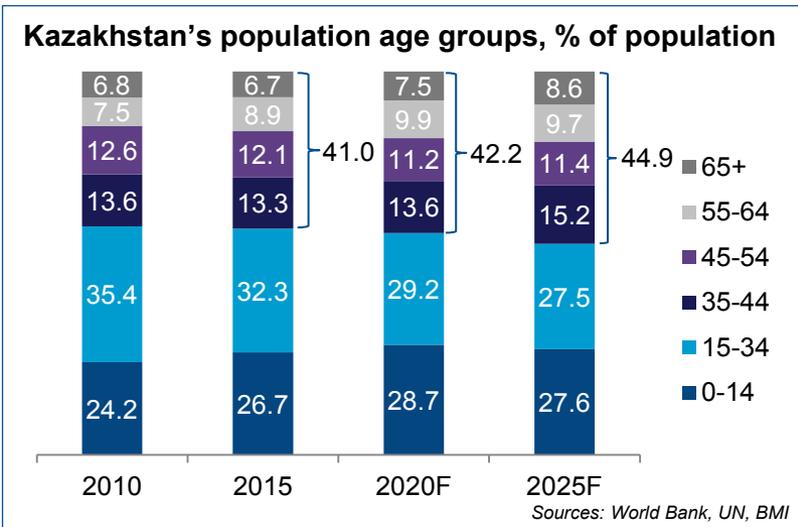


— By 2025, the share of those who are in the 35+ year-old bracket will increase by approximately 4-4.6 percentage points from 2015 to 2025:

- From 55.5% to 60.1% (4.6 pp) in Russia
- From 58% to 62.5% (4.5 pp) in Ukraine
- From 56.5% to 60.5% (4 pp) in Belarus

# Key Consumers and Markets (2)

## Population Age Structure (2)

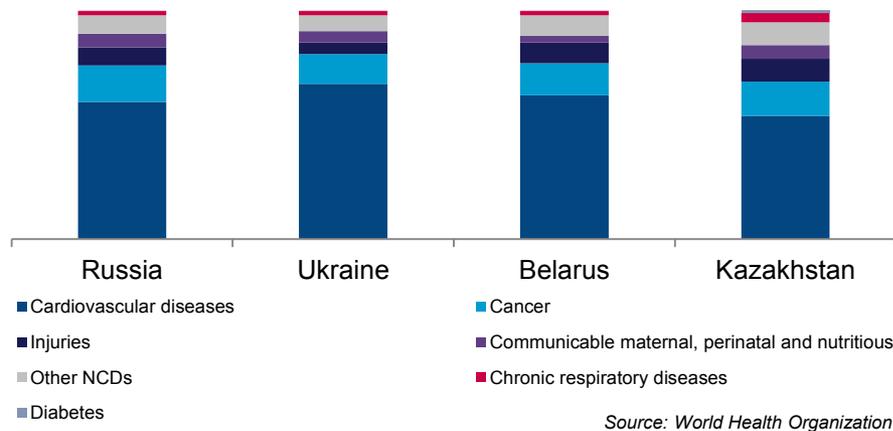


- A similar trend is observed in Kazakhstan (3.9 pp) but there the percentage of people in this group is lower (from 41% in 2015 to c. 45% in 2025).

# Key Consumers and Markets (3)

## Causes of Death and Lifestyle Choices

**Leading causes of death**  
due to non-communicable diseases, %



- As can be seen from the graph, cardiovascular diseases and cancer are the leading causes of death in all the four countries. AIDS is a very significant concern.
- Poor environmental conditions, massive smoking and stress are the main reasons for these diseases.
- All the countries provide access to costly treatments through various financial aid programs but the current funding hardly covers the demand.

Lifestyle choices	Russia	Ukraine	Belarus	Kazakhstan
<b>Consumption of alcohol</b> Liters	<b>M 23.9</b> <b>F 7.8</b>	<b>M 22.0</b> <b>F 7.2</b>	<b>M 27.5</b> <b>F 9.1</b>	<b>M 15.7</b> <b>F 5.5</b>
<b>Obesity</b> % of population	<b>M 18.6</b> <b>F 32.9</b>	<b>M 15.9</b> <b>F 25.7</b>	<b>M 20.0</b> <b>F 27.8</b>	<b>M 19.1</b> <b>F 27.6</b>
<b>Consumption of tobacco</b> % of population	<b>M 59.0</b> <b>F 25.0</b>	<b>M 49.0</b> <b>F 14.0</b>	<b>M 50.0</b> <b>F 11.0</b>	<b>M 40.0</b> <b>F 9.0</b>

Source: World Health Organization

# Key Consumers and Markets (4)

## Overview of Consumption

	Distribution of sales	Distribution of population	Prescription drugs	Patented drugs	Generics drugs	OTC drugs
Russia	79%	68%	78%	82%	76%	80%
Ukraine	9%	20%	10%	6%	13%	10%
Belarus	4%	4%	3%	2%	4%	4%
Kazakhstan	8%	8%	8%	10%	7%	6%

Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

- Russia displays disproportionate overspending on drugs compared to its share of population.
- Ukraine, on the other hand, underspends on medicines compared to its share of population.
- While patented drugs in Russia claim a higher share of the market than expected, usage of generics has not yet reached its potential.
- In Ukraine, patented drugs are not widely used, which is compensated for by a higher usage of generics. That is why the share of local production in the domestic market is higher than in the rest of the region.
- Similar to Russia, Kazakhstan consumes more patented drugs than its share of sales would suggest.

# Key Consumers and Markets (5)

## Distribution Channels – Russia

### **Public healthcare system**

- Patented drugs are prohibitively expensive for private consumers and hence the major buyer is the public health care system through state tenders.
- Drugs acquired by the government, which are included in the Essential Drugs List (hospitals and low-income groups) and Seven Nosologies Program (rare and severe diseases requiring expensive treatment), account for c. 25% of the market in value terms.

### **Wholesalers**

- Everything else is done through wholesalers that either a) act on behalf of the manufacturer or b) are independent.
- Generally 1-3 wholesalers are involved from manufacturer to user.
- The wholesalers' concentration is medium with the top 10 national wholesalers making up 84% of the market and the top 5 about 60% of the market.
- The leader (Katren) has a market share of about 20%.

### **Pharmacies**

- 37,000 pharmacies of different kinds serve customers in Russia.
- Top 20 chains account for approximately 30% of the market.
- Most businesses owning pharmacies purchase from <5 wholesalers, only 1/3 of businesses purchase from more than 9 wholesalers.
- The share of private pharmacies was at 75%, about 15% are state owned and the remaining 10% are municipality owned.
- Online pharmacies exist though their legal status is dubious.

# Key Consumers and Markets (6)

## Distribution Channels – Ukraine

### Public healthcare system

- 80%-90% of drug expenses are borne by the customer while the hospital segment accounts for only 10%-20% of the market in value terms. This is as a result of severe underfinancing of the public healthcare system.
- Healthcare services are provided to the public via state medical centers, private medical centers and private doctors. Public centers dominate. Services provided by the state-owned centers are officially free, however, unofficial payments are wide-spread.
- The government is trying to implement ambitious reforms in the healthcare sector but they are stalling because of the economic problems.
- Plans include privatizing a portion of state hospitals and introducing voluntary medical insurance.

### Wholesalers

- The most consolidated segment of the market.
- Top 5 players control about 90% of the market in value terms. BaDM is the market leader enjoying a 33% market share.

### Pharmacies

- There are about 20,000 pharmacies of different formats in Ukraine, which translates into 1 point of sale (POS) per 2,150 people whereas 1 POS in Russia serves about 3,900 people.
- A very low degree of consolidation in pharma retail: there are more than 100 retail chains with the top 100 of them controlling slightly more than 60% of sales in value terms.

# Key Consumers and Markets (7)

## Distribution Channels – Belarus

### Public healthcare system

- Approximately one quarter of the market is represented by the hospital sector. Retail sales are responsible for 75% of the market.
- Hospital purchases include expensive foreign drugs and domestic drugs. Sometimes the price differential can be 10 times.
- The government reimburses treatments provided in hospitals, whereas drugs are reimbursed depending on the patient's income level.

### Wholesalers

- Belpharmacia, the largest drug wholesaler, is owned by the state.
- Top 7 distributors account for c. 40% of the market.
- Dominantpharm (about 10% of the market) is owned by Russia's leading distributor Katren.

### Pharmacies

- There are about 3,000 pharmacies in Belarus, of which 58% are owned by the state.
- 37% of state-owned pharmacies belong to Belpharmacia.
- Apteka-Group Holding, the largest private chain, owns approximately 7% of pharmacies.
- Private pharmacies tend to be located in the capital and regional centers.
- Pharmacies are divided into five categories, with private ones either in the second or fifth categories.
- Private pharmacies sell about 75% of imported drugs.

# Key Consumers and Markets (8)

## Distribution Channels – Kazakhstan

### **Public healthcare system**

- Approximately 40% of the market is represented by the hospital sector and public procurement.
- Two thirds of drugs for the public healthcare system are purchased through Single Distributor SK-Pharmacia which is 100% owned by the state. It is responsible for buying drugs at public tenders, storing and delivering them to hospitals.
- Another third of drugs in the public sector is funded by regions and is primarily targeted at outpatient care hospitals.

### **Wholesalers**

- According to Vi-Ortis, a local pharma consulting firm, top 7 distributors are responsible for about 60% of the market.
- The largest of them, Amanat, controls approximately 15% of the segment.
- Average margins level set for drugs is 7%-15%.

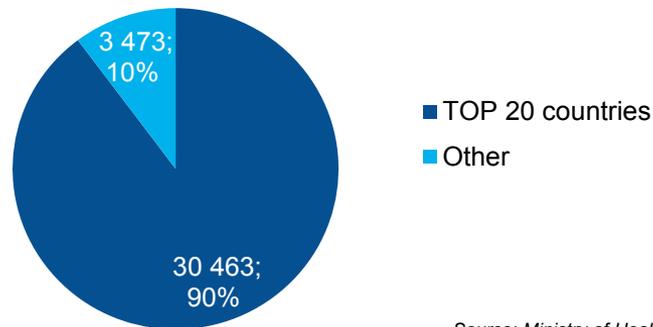
### **Pharmacies**

- Pharma retail accounts for 60% of the total market.
- Top 6 pharmacy chains control approximately 35% of the market.
- Amanat, which is also the leading distributor, holds a 10% share.
- Average margins earned by pharmacies range between 12% and 25%.

# Key Consumers and Markets (9)

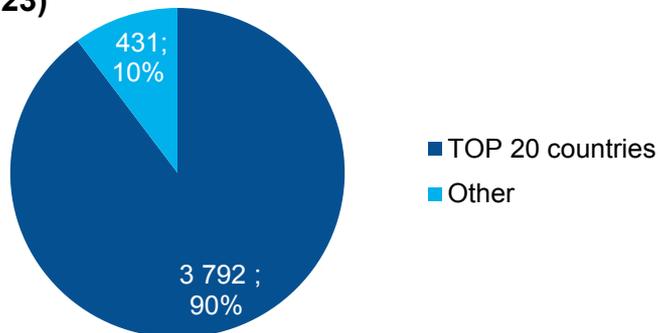
## Drug Registrations – Russia in Focus (1)

**Number of drug registrations in Russia (total = 33,936)**



Source: Ministry of Health

**Number of registrants (entities holding drug registration certificates) in Russia (total = 4,223)**



Sources: AIPM, AESGP, BMI, Central Banks

### Drug registrations in Russia

- According to the State Register of Medicines, there are approximately 34,000 drug registration certificates issued in Russia.
- Out of them, 90% of certificates are held by companies originating from 20 countries (see details on the next slide).
- Russia leads with 56% of registrations, followed by India, Germany, Switzerland and Slovenia.
- About 15% of drugs are wholly imported into Russia.
- Approximately 2% of foreign drugs have a production stage in Russia.
- There are a further 63 countries below the top 20 grouping.

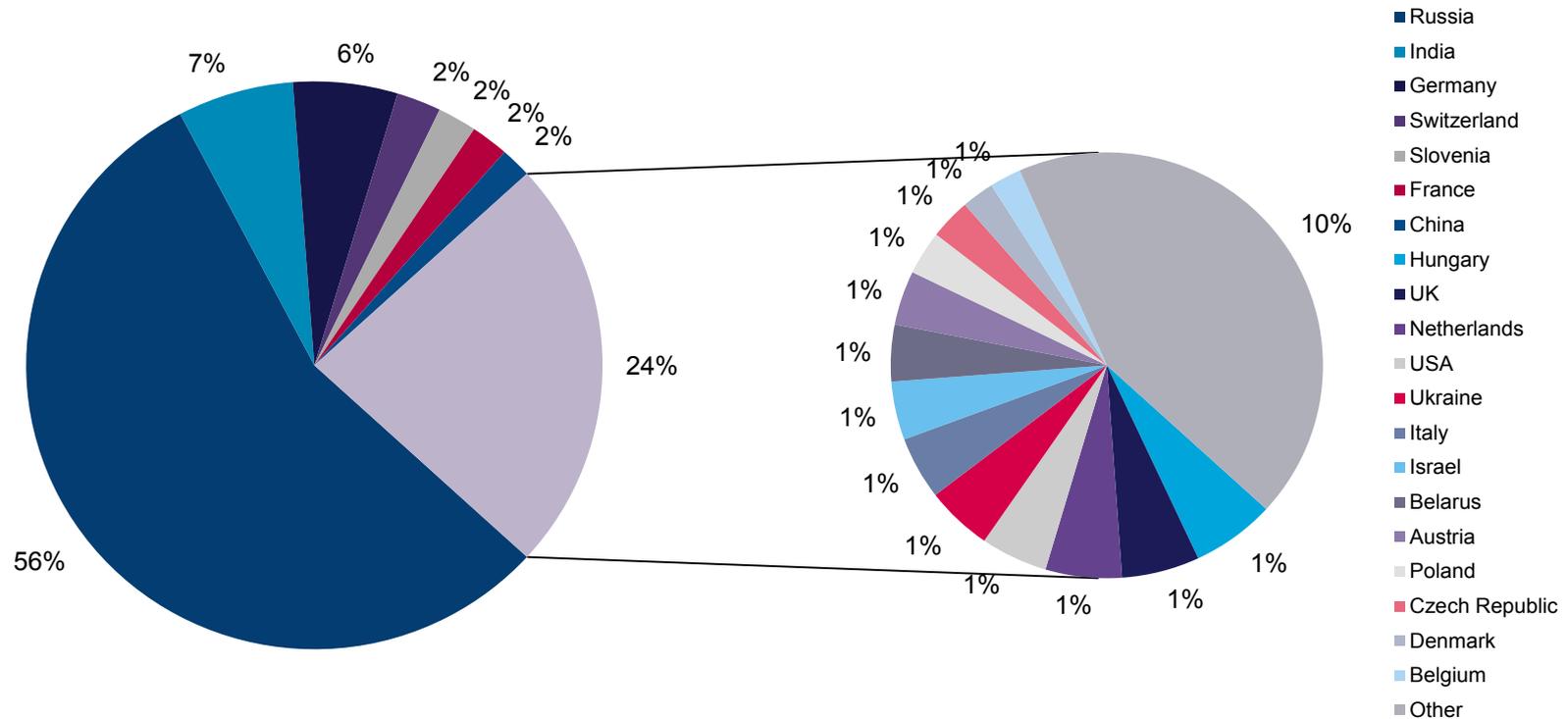
### Registrants (pharma companies) in the Russian market

- Out of the 4,223 entities whose products are sold in the market, 90% of them come from 20 countries (the number of corporate groups is estimated at c. 1,100).

# Key Consumers and Markets (10)

## Drug Registrations – Russia in Focus (2)

Number of drug registrations in Russia by country of origin  
(top 20 and other, total = 33,936)



Source: Ministry of Health

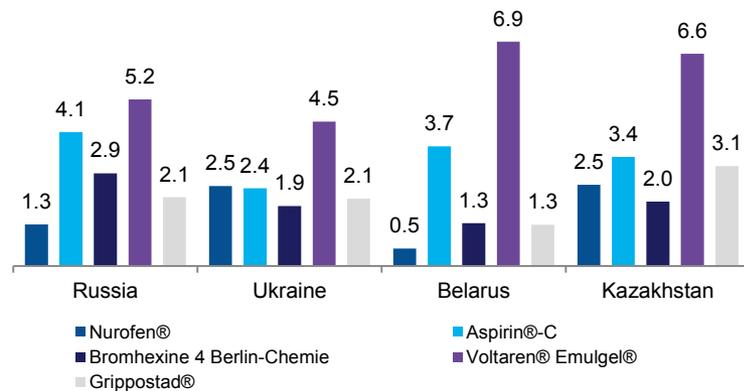
– Details of top manufacturers by country of origin are provided in the extended version of this report.

# Key Consumers and Markets (11)

## Prices for 5 Drugs Compared

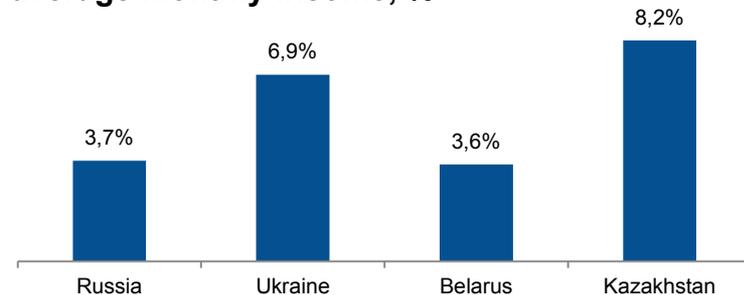
### Comparison of drug prices by country, USD

Based on a random sample of 5 popular drugs



Sources: DSM Group, local pharma retailers

### Cost of combined basket as a percentage of average monthly income, %



Source: DSM, local pharma retailers, national statistics agencies

- To get a feeling of the market from the consumer's perspective, we compared prices for five popular drugs and medicines.
- They are OTC and designed to treat very common conditions:
  - High fever
  - Cold/flu
  - Cough
  - Back pains.
- We have converted prices in local currencies into USD at average annual exchange rates to obtain USD prices.
- The cost of these drugs combined into one 'basket' is the highest in Kazakhstan and Ukraine.
- Russia and Belarus are very similar in terms of combined cost.
- For this sample, costs in these countries are half those in Kazakhstan and Ukraine.

# Key Consumers and Markets (12)

## Average prices for 5 popular drugs

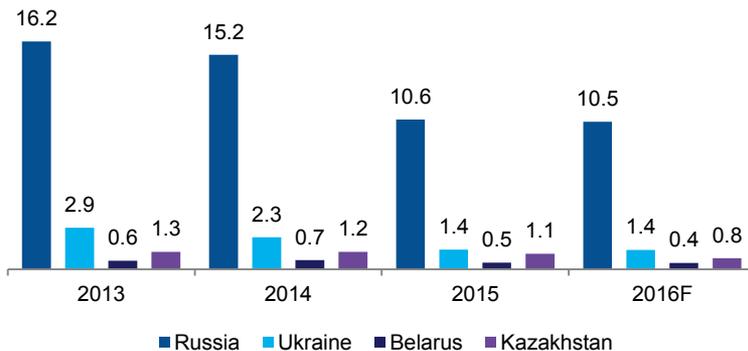
Brand	Active substances	Dosage forms	Manufacturer	Reference link	Russia, USD	Ukraine, USD	Belarus, USD	Kazakhstan, USD
Nurofen®	Ibuprophenum	10 coated tablets of 200 mg / 12 coated tablets of 200 mg	Reckitt Benckiser		1.3	2.5	0.5	2.5
Aspirin®-C	Acetylsalicylic acid + Ascorbic acid	10 effervescent tablets, carton pack	Bayer AG		4.1	2.4	3.7	3.4
Bromhexine 4	Bromhexinum	Oral solution, 60 ml / drops, 20 ml	Berlin-Chemie AG / Krewel Meuselbach GmbH		2.9	1.9	1.3	2.0
Voltaren® Emulgel®	Diclophenacum	Emulgel for external application 1 % tube of 50 g	Novartis		5.2	4.5	6.9	6.6
Grippostad®	Paracetamolum + Acidum ascorbinicum	The blisters of 10 capsules per pack	Stada		2.1	2.1	1.3	3.1

Sources: DSM, local pharma retailers

# Market Overview and Segmentation (1)

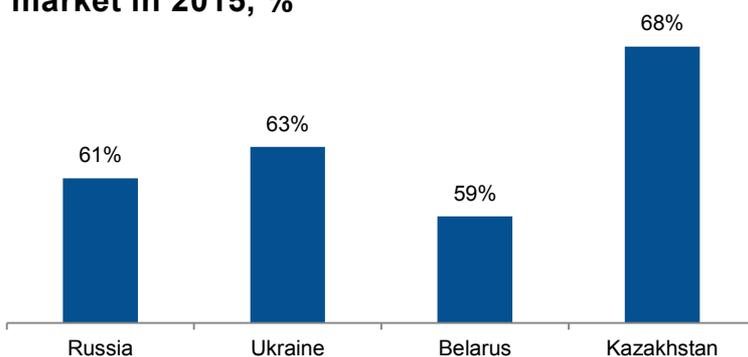
## Prescription Drugs

**Sales of prescription drugs, USD bn**



Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

**Percentage of prescription drug sales by market in 2015, %**



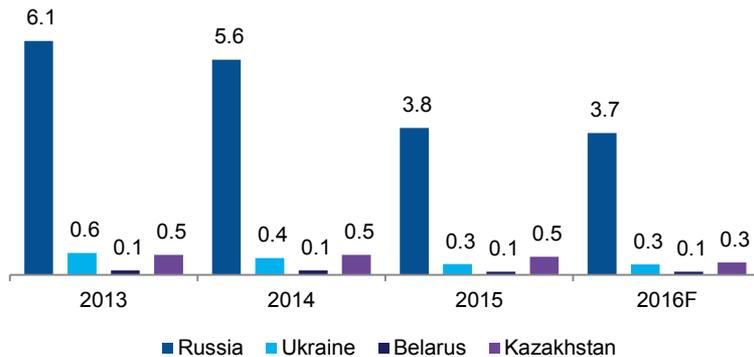
Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

- Prescription drugs are represented by patented drugs and generics.
- Prescription drugs account for 59% to 68% of sales depending on the market.
- Many drugs are imported, hence prices are subject to local currency fluctuations.
- The market for prescription drugs will feel pressure from declining purchasing power of the population and reduced government spending on patented drugs.
- As a result, generics will show greater growth potential than patented drugs in the short term in view of strained government spending.
- Although governments have established a list of drugs which can be sold only for a prescription in their respective country, drugs are fairly easily available in pharmacies without a prescription.

# Market Overview and Segmentation (2)

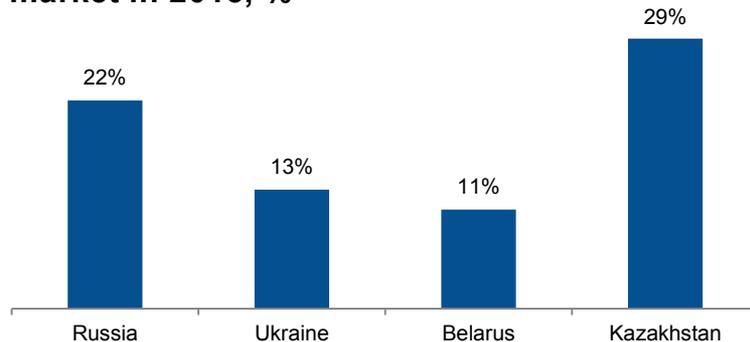
## Patented Drugs

**Sales of patented drugs, USD bn**



Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

**Percentage of patented drug sales by market in 2015, %**

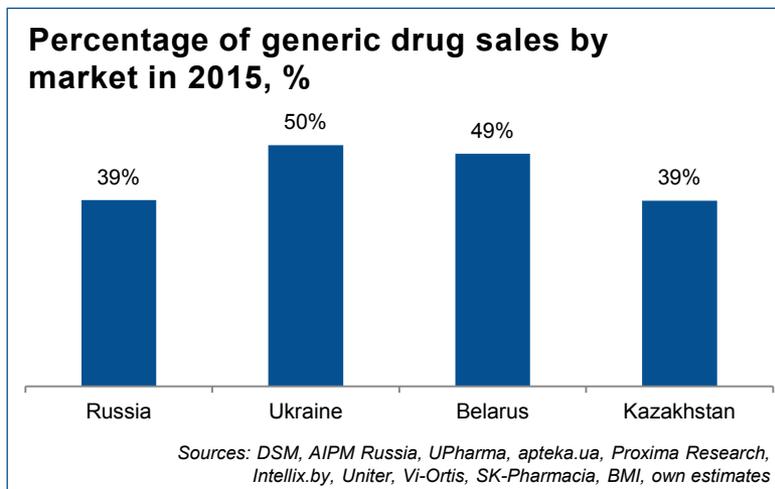
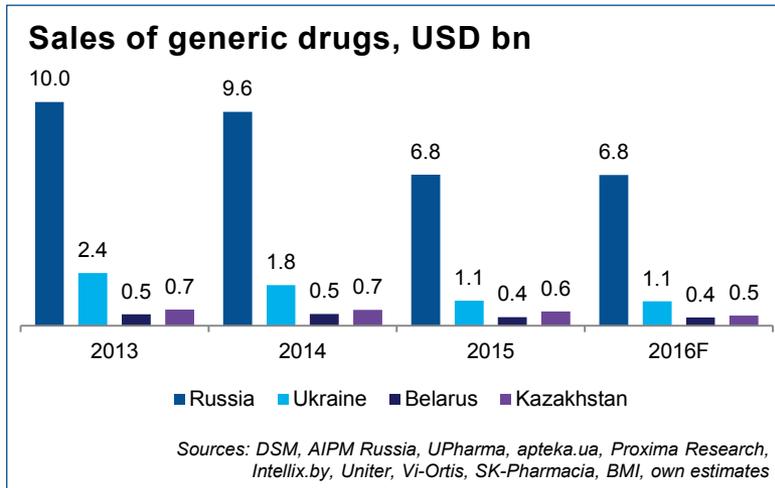


Sources: DSM, AIPM Russia, UPharma, apteka.ua, Proxima Research, Intellix.by, Uniter, Vi-Ortis, SK-Pharmacia, BMI, own estimates

- Patented drugs are mostly imported from abroad, which makes prices for them very vulnerable to local currency fluctuations.
- The four countries represent very difficult markets for patented drugs in the short- to medium-term. This, however, can improve as the economies perform better.
- These drugs account for a very low 11% of total sales in Belarus to a relatively high 29% in Kazakhstan.
- Prices for these drugs are too high for the majority of consumers and funding provided by local governments is not sufficient.
- For example, the Russian government restricts its spending on patented drugs to orphan diseases and cancers.
- Generic and OTC drugs erode the share of patented drugs as national governments are focused on developing historically strong generics segments.

# Market Overview and Segmentation (3)

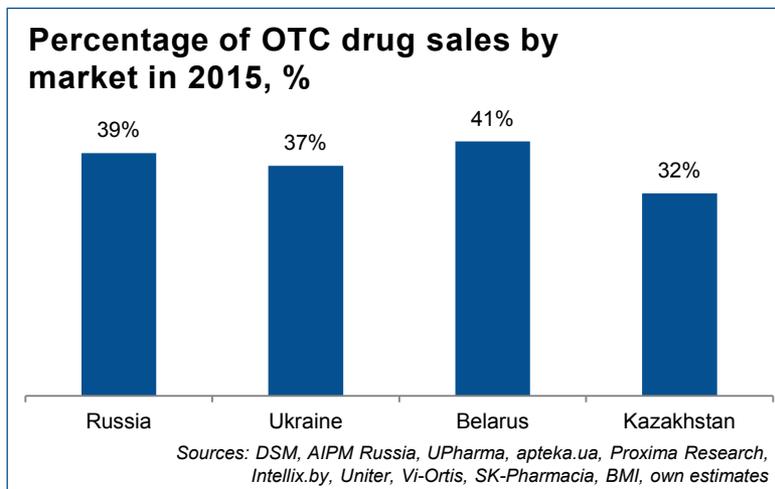
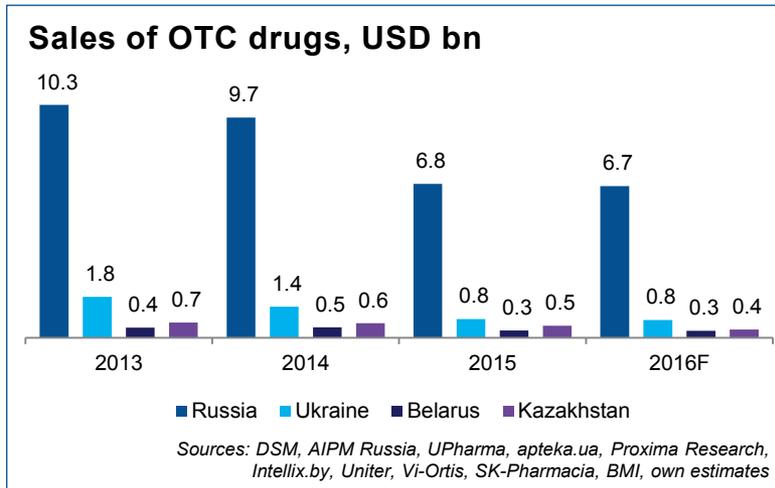
## Generics



- Generic drugs have been the strongest segment of national pharma sectors historically, accounting for between 39% to 50% of total pharma sales.
- Generic drugs are viewed as the only source of hope in the current economic environment.
- Indeed, they appear to be the main beneficiary of reduced purchasing power of consumers and government spending, as well as government import substitution and pharma industrial policies.
- Generics are and will continue to be the key growth segment of local pharma markets.
- Building new facilities to produce generic drugs and biosimilars attracts most of investment.

# Market Overview and Segmentation (4)

## OTC Drugs



- OTC drugs traditionally play a very important role because consumers have better access to medical information, prices are lower compared to prescription (patented) drugs, national reimbursement programs are limited and people have a tendency for self-treatment.
- They account for between 32% to 41% of total pharma sales.
- Most common OTC drugs are vitamins, dietary supplements, cough/cold treatments, analgesics and digestives.
- According to MarketLine, Russia is the third largest market in Europe for OTC drugs in value terms, preceded only by Germany and Britain.

# Investments (1)

## Russia

- Approximately USD 2.5bn (at 2015 rates) was invested by Russian and foreign pharma manufacturers in 2011-2015.
- Almost a quarter of this amount was invested by the state.
- In 2015, six new sites were launched.
- Nineteen sites were launched between 2013 and 2014 (seven of them have foreign investors).
- The Pharma 2020 program (2009) and the Federal program for the pharma and medical industry by 2020 (2011) have been the key drivers for investments by local and international investors.
- Local companies, in partnership with their international peers or alone, started to build high-tech production facilities for complex drugs to treat serious conditions.
- International players, such as Novartis, AstraZeneca, Takeda, Novo Nordisk and Sanofi, have built their plants.
- Approximately 100 international players have been localizing their production in Russia. A number of examples are provided in the Appendix.
- Several notable projects were implemented by Russian manufacturers, including Biocad, R-Pharm, Polysan, Nanolek, Nearmedic, Generium, Geropharm and Fort.
- According to Expert, a well-known local business weekly, a third of the national companies which built new facilities, see their revenues and number of units produced go up. Growth of units produced was 30% on average in 2015.
- F-Syntez, Biocad and R-Pharm launched biosimilars for cancer treatment and continue building their pipelines.
- Microgen launched a new flu vaccine and Ozon launched a new antibiotic – they saw their revenue grow several times.
- Generium is developing 3 drugs for treatment of hemophilia.

# Investments (2)

## Ukraine

- Investments in the pharma industry are estimated to have reached approximately USD 200 million over the last 5 years.

## Belarus

- 13 investment projects for a total of USD 126 million were completed in 2015 while another 5 projects, valued at USD 25 million, will come on stream in 2016.

## Kazakhstan

- There are plans to invest approximately USD 220m in new production facilities between 2016 and 2020, with approximately 15% of the funds coming from the government.
- Polpharma (PL), Pharmstandard (RU), Abdi Ibrahim (TR) and Farea (CZ) are building local facilities.



# Leading Manufacturers (1)

## Russia – Top 10

#	Company name	Revenue in 2015, RUR bn	Specialization	HQ location
1.	OTCPharm	15.2	Wide range, incl. antiviral, CNS, digestive and intestinal, etc.	Moscow
2.	Pharmstandard	11.1	Wide range, incl. cardiovascular, diabetes, cancer, etc.	Moscow
3.	Biocad	9	Cancer, HIV, hepatitis, MS, etc.	St. Petersburg
4.	F-synteZ (new name: Nativa)	8.7	MS, cancer, pancreas, etc.	Moscow Region
5.	Sotex (part of Protek Group)	8.7	Anemia, cardiovascular, CNS, rheumatology, gastroenterology, etc.	Moscow Region
6.	Valenta	7.9	CNS, urology, gastroenterology, immunology, antiviral and antibacterial therapy, etc.	Moscow Region
7.	Servier (FR)	7.3	Cardiovascular, cancer, CNS, diabetes, rheumatology, psychiatry, etc.	Moscow
8.	Ozon Pharmaceuticals	6.5	Wide range, incl. allergies, antibacterial, vitamins, gastroenterology, cardiology, neurology, cancer, etc.	Samara Region
9.	KRKA (SI)	6.4	Wide range, incl. cough and cold, pain killers, vitamins, CNS, cardiovascular, gastroenterology, etc.	Moscow Region
10.	PharmasynteZ	6.3	TB, HIV, cancer, antibiotics, antibacterial, etc.	Irkutsk Region

Sources: Expert.ru, company information

- Pharma clusters: Moscow and Moscow Region, St. Petersburg, Kaluga, Yaroslavl, and others. A new cluster will be built in 2017-2018 in Grozny, it will come on stream in 2019.

# Leading Manufacturers (2)

## Ukraine – Top 5

#	Company name	Revenue in 2014, UAH m	Specialization	HQ location
1.	Farmak	1,700	Alimentary, respiratory, sensory, cardiology, dermatology, etc.	Kiev
2.	Darnitsa	1,300	Pain, dermatology, respiratory, neurology, alimentary, cardiology, etc.	Kiev
3.	Arterium Corporation	1,100	Neurology, antibacterial, alimentary, cardiology, dermatology, veterinary, etc.	Kiev
4.	Zdorovie	900	Respiratory, cardiology, ophthalmology, neurology, antibacterial, antifungal, etc.	Kharkiv
5.	Kiev Vitamin Factory	600	Vitamins, alimentary tract, cardiology, neurology, etc.	Kiev

Sources: UPharma, apteka.ua, company information

- Pharma clusters: Kiev, Kharkiv, Lviv, Sumy and Vinnitsa.

# Leading Manufacturers (3)

## Belarus – Top 10

#	Company name	Ownership	Revenue in 2014, USD m	Specialization	HQ location
1.	Belmedpreparaty	State	88	Cardiology, dermatology, neurology, metabolism, etc.	Minsk
2.	Borisovskiy ZMP/ Borimed	State	49	Bacteriology, cardiology, etc.	Minsk Region
3.	Lekpharm	Rompharm (BG)	34	Cardiology, gastroenterology, respiratory system, etc.	Minsk Region
4.	Pharmland	Holden- Medicalbv (NL)	30	Blood system, infections, testing systems	Minsk
5.	Minskintercaps	State	25	Cardiology, alimentary tract, allergies	Minsk
6.	Nesvizh Plant of Medical Preparations	State	15	Blood system	Minsk Region
7.	Ekzon	Mixed	6	Dietary supplements, syrups, etc.	Brest
8.	Nativita	Private (IN, LT, RU)	N/A	Monoclonal antibodies, lungs/breathing	Minsk/Vitebsk
9.	Pharmtechnology	Private	N/A	Dermatology, musculoskeletal system	Minsk
10.	Triplepharm	Mixed	N/A	Antibiotics	Minsk Region

Sources: UPharma, Uniter, Ministry of Health, company information

- Important players on the market without local production: Sanofi-Aventis, Novartis, Bayer Healthcare, Takeda, Roche, Gedeon Richter, GSK.
- Pharma clusters: Minsk and Minsk Region (Belpharm and BelBiograd).

# Leading Manufacturers (4)

## Kazakhstan – Leading Companies

#	Company name	Ownership	Revenue in 2014, USD m	Specialization	HQ location
1.	Santo/Chimpharm	Polpharma Group (PL)	55	Infusions, antibacterial preparations, cardiology, analgesics and anesthetics, etc.	Shymkent
2.	NOBEL AFF	Private	22	Antibiotics, antihypertensive, pain killers, lipid-lowering agents, etc.	Almaty
3.	Dosfarm	Private	7	Respiratory, sensory organs, etc.	Almaty
4.	Abdi Ibrahim Global Pharm	Abdi Ibrahim (TR)	5	Neurology, antibacterial preparations, respiratory, etc.	Almaty
5.	Kyzyl-May	N/A	5	Herbal, food supplements, cardiology	Almaty
6.	Lecos LLC	N/A	4	Sensory organs	Almaty
7.	Eikos Pharm LLC	N/A	2	Respiratory, infections, etc.	Almaty
8.	Karaganda Pharmaceutical Complex	N/A	N/A	Injection preparations	Karaganda
9.	Romat LLC	Private	N/A	Nervous system, cardiology, respiratory, etc.	Pavlodar

Sources: UPharma, AEQUITAS, company information

- Sanofi-Aventis is the only international manufacturer with local production: it has fully localized one of its drugs working together with Santo/Chimpharm.
- Important players on the market without local production: Akrikhin, GlaxoSmithKline, Nycomed/Takeda, Bayer Healthcare, Roche, Sanofi-Aventis, Teva, Pfizer, Johnson & Johnson and Menarini.

# Market Strategies (1)

## Possible ways of servicing a market:

- Distribution contract with a local entity.
- Licensing agreement with local manufacturers and/or distributors.
- Greenfield investments.
- Brownfield investments.
- Contract manufacturing (CMO).

## CMO Overview

- First CMO partnerships were established in the late 1990s and early 2000s.
- Based on publicly available information, **17** Russian companies have established CMO partnerships with **38** international manufacturers.
- A major international manufacturer can work with several Russian CMO partners, e.g., Bayer, Actavis, AstraZeneca and Pfizer use more than one provider.
- In addition, **15** Russian pharma producers claim they are capable of contract manufacturing but do not provide details of any partnerships – so the list can be potentially longer.
- CMO partnerships, along with building a plant and acquiring a local business, are pursued by foreign manufacturers that want to obtain access to Russian public tenders.

# Market Strategies (2)

## Things to consider in CMO agreements

- Rights and obligations of the local CMO Partner.
- Quality requirements of the manufactured product with indication of technical conditions or state standards.
- Price and payment conditions.
- Acceptance of works results or services.
- Delivery of APIs, its list, and quality requirements.
- Reports on use of raw materials (forms, terms of providing).
- Terms for product manufacturing.
- Production schedule.
- Requirements on packaging and labeling.
- Guaranties.
- Complaint procedure, settlement of disputes, etc.



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