Kazakhstan: pharmaceutical market overview

KHIDI CIS

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1. Kazakhstan: country overview

Country description

The Republic of Kazakhstan is an upper-middle income country (according to the World Bank's classification) located predominately in Central Asia. Kazakhstan is the world's largest landlocked country and the 9th largest country in the world by land area. At the same time, Kazakhstan is the 227th country in the world by population density. Kazakhstan's economy is the largest one in Central Asia while about half of the country's GDP is contributed by industries based on raw materials. According to BP's estimates, Kazakhstan possesses 3.2% of the world's oil reserves and 1.7% of the world's gas reserves. Since 2000, Kazakhstan's economy has begun to grow sharply as oil prices at the world market had started to increase together with the country's other leading exports – metals and grain. At the same time, the government has been developing diversification programs aiming to decrease Kazakhstan's economy rely on extractive industries. Among the sectors, which are expected to strengthen the economy, are transport, pharmaceuticals, telecommunications, petrochemicals and food processing. Supporting small and medium business is also seen as an important strategic mission regarding economic development. After in 2006 the Kazakhstan's GDP had grown significantly by (10.6%) in a virtue of boost of trade relations with Russia, China, and the CIS countries, in 2008 the economy was affected by the global financial crisis. In 2010, Kazakhstan joined Russia and Belarus to establish the Customs Union (CU) to boost foreign investment and improve trade. The CU evolved into a Single Economic Space (SES) in 2012 and the Eurasian Economic Union (EEU) in January 2015. In 2014, due to the consequences of the Ukrainian crisis and oil prices fall, the GDP growth in Kazakhstan slowed down, while the country's currency devaluated by 19% in February 2014. Further economic issues continued in 2015, when Kazakhstan faced the fall in export of oil prices, slowing growth in China and continuation of ressecion in Russia. The economic growth and fiscal stability were under the threat, so in August the National Bank announced a floating exchange rate, which provoked drastic devaluation of tenge by 37% by the year's end. Since March 2016, the exchange rate has stabilized, appreciating by around 10% in February to June 2016, with short-term liquidity gradually returning to the market. GDP growth reached 1.2% in 2015, and 1.0% in 2016, reflecting the challenging external environment. In 2016, Kazakhstan's real GDP growth continued to slow and real wages declined further, adversely affecting poverty rates. The authorities reacted by extending additional spending measures and loosening monetary policy during the year. Medium -term growth is projected to pick up slowly as oil prices recover and oil production gradually expands. To improve Kazakhstan's growth prospects, and to enhance the sustainability and inclusiveness of growth, the authorities will need to deepen structural reforms designed to facilitate economic transformation.

Table 1. Key statistic indicators for 2018

18.2
158.2
8,711.8
2.7
26.5
110.7
70.8

Source: KazStat, UPharma Consulting

Economic situation

As Kazakhstan's economy started to recover from the crisis caused by the fall of global oil prices, real GDP grew by 4.0% y-o-y in 2017, compared to 1.1% in 2016. The oil sector was the main driver of economic growth, as oil output increased by 12.5% y-o-y in 2017 due to the launch of

production at the long-awaited off-shore oil field Kashagan in October 2016. The inflation rate in annual terms was 7.1%, remaining within the limit corridor established by the National Bank of 6-8%. More favorable terms of trade – as oil prices increased by 27% y-o-y 2017 – also contributed to better performance of the oil sector. Additionally, the construction sector rebounded due to new large capacity expansion projects in the oil sector. The non-oil economy also expanded, on the back of more dynamic activity of the manufacturing, agriculture, transport, and trade sectors. The large-scale exhibition "Expo-2017" attracted a significant number of tourists, which increased demand in the domestic market, expanding the opportunities for SMEs in the retail segments, restaurant and hotel business and the whole service industry. In 2017, investments in fixed assets increased by 5.5% y-o-y. The main surplus in investments was directed to agriculture, where growth was 29.3% y-o-y, trade - 21.8% y-o-y, construction - 11.8% y-o-y, communications - 9.5% y-o-y and industry - 3.8% y-o-y. Meanwhile, contrary to expectations, the weakening of the tenge had not become a driver for export and import substitution. Despite the importance of foreign exchange support for exports, it can be concluded that transport costs, the level of demand, the quality of a product have become more significant factors.

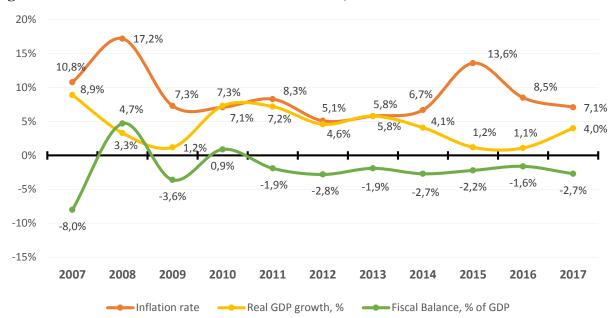


Figure 1. Macroeconomic indicators of Kazakhstan, 2007-2017

Source: National Bank of the Republic of Kazakhstan, KazStat

a) GDP

According to the KazStat, 2017 production of goods made 36.5% of GDP, production of services – 57%. Non-oil sector contributed to 60% of the GDP growth. In general, the real sector recorded a synchronous increase in production in almost all sectors of the economy.

b) Industrial Production

Among the main industrial sectors, the biggest growth was in industry -7.1% y-o-y, transports -4.8% y-o-y, communications -3.3% y-o-y and trade -3.2% y-o-y. Accelerated pace was demonstrated by the mining industry due to growth in oil production. Industry made 26.5% of the total GDP, trade -16.4%, transport -8%. The manufacturing industry shows a five-year maximum growth rate of 5.1% y-o-y, which is mainly promoted by the implementation of projects within the Industrialization Map. The increase in demand gave an additional impetus to chemistry, metallurgy, oil refining, and the food industry, where growth was 7.2%, 5.9%, 5.1% and 4.1%, respectively.

c) Export/Import

In 2017, foreign trade balance increased 25% y-o-y to USD 77.6 bn, export grew by 31.6% y-o-y to USD 48.3 bn, import – 15.5% y-o-y to USD 29.3 bn. Exports to the EEU countries increased by 30.2% y-o-y. Russia and China were the main trade partners in terms of imports, making 39.2% and 16% of total imports respectively. Main external markets for Kazakhstan were Italy (17.9% of exports), China (12%), Netherlands (9.8%) and Russia (9.3%). Kazakh export is dominated by mineral products, which made 70.5% of it.

d. Currency Exchange Rates

The exchange rate of the Kazakhstani tenge was saltatory during 2017, which was connected with pessimistic expectations of some experts and currency speculation. Intensification of anti-Russian sanctions also had impact. However, at the year's end the tenge's rate was almost the same compared to U.S. dollar as at its beginning. The National Bank did slight interventions to affect the rate of tenge. In 2017 the parity between currency and tenge deposits was achieved, and the level of dollarization in last 8 months was in the range between 48-50%.



Figure 2. Kazakhstan tenge (KZT) exchange rate dynamics, 2015-2019

Source: XE Currency statistics

Social-political situation

Kazakhstan was the last of the Soviet republics to declare independence following the dissolution of the Soviet Union in 1991. Former Communist Party chief Nursultan Nazarbayev has been the country's leader since 1989; in 2015, he won his sixth presidential term for five years with 97.8% support. Nazarbayev is described as an authoritarian politician; he is criticized for the poor observance of human rights and freedom of speech in Kazakhstan, as well as high corruption level. After 29 years in power the first president of Kazakhstan – Nursultan Nazarbayev has announced his resignation in March 2019. Nazarbayev has passed over his presidential powers immediately to Kassym-Jomart Tokayev, the speaker of the upper house of the parliament, which always approves Nazarbayev's actions. Despite the resignation, Nazarbayev will remain the chairman of the country's powerful security council, the leader of the Nur Otan party, which dominates parliament, and sustain his legal title as "leader of the nation". Kazakh national security council is responsible for establishment of guidelines for foreign and security policies, which indicates that Nazarbayev will remain in the power of the country. To mark the accomplishments of Nursultan Nazarbayev, the government has announced the change of the capital name from Astana to Nur-Sultan, in respect to the "leader of the nation". In June 9, the presidential election took place, where Kassym-Jomart Tokayev has been officially elected as the president. Kazakhstan can be called a patriarchal society, committed to the traditional way of life. Experts remain calling corruption the main problem in the path of development and integration of Kazakhstan. In 2012, the World Economic Forum listed corruption as the biggest problem in doing business in the country, while the World Bank listed Kazakhstan as a corruption hotspot, on a par with Angola, Bolivia, Kenya, Libya, and Pakistan. Ethnically the former Soviet republic is as diverse, with the Kazakhs making up nearly two thirds of the population, ethnic Russians just under a quarter, and smaller minorities the rest. Suppressed under Soviet rule, the main religion, Islam, is undergoing a revival. According to the official data, Kazakhstan has the lowest poverty level in Central Asia at about 2.7%. However, the low incomes in rural areas make people to actively migrate to cities. The unemployment level is also low – about 5% of economically active population.

Political trends and forecasts

The government of Kazakhstan has emphasized that reducing dependence on oil and facilitating the development of a well-functioning nonoil economy are high priorities. In 2015, under the President's initiative, an ambitious agenda for 2015-2019 called Nurly Zhol (The Path to the Future) has been introduced. The agenda is financed by the National Fund (\$3 bn a year) and aimed at modernizing the country's economy through supporting infrastructure development, SMEs, and banking sector. If the implementation of structural reforms is successful, it will assist in the diversification of the economy and would raise Kazakhstan's growth potential. The ongoing structural and institutional reforms under the 100 Concrete Steps program and the privatization agenda aim to reduce the role of the state in the economy and facilitate the development of a vibrant, modern and innovative tradable non-oil sector. Furthermore, efforts to restructure and privatize state-owned enterprises (SOEs) would be expected to seek raising efficiency in public administration and reducing fiscal risks. Prudent fiscal and monetary policies would support economic and price stability and encourage investments in the non-oil economy. Higher incomes will also have positive spillovers on poverty reduction. According to the EBRD outlook, oil prices will be held at the level of more than \$60 per barrel. This is a fairly favorable international environment, that will lead to an increase in the growth rate of the economy of Kazakhstan, namely real GDP – by 3.5-4%. The EBRD also forecasts the growth of exports and investments in the economy of Kazakhstan as well as a slight decrease in inflation.

Table 2. Kazakhstan in the key international ratings, 2016-2018

Table 2. Razaklistan in the key international ratings, 2010-2010					
Index		Organization	Year	Rank	y-o-y change
Global competitiven	ess	The World Economic Forum	2017-18	57	-4
Doing business		The World Bank	2018	36	-1
Economic fr	eedom	Heritage Foundation	2018	41	+1
snapshot					
Human development		UNDR	2016	56	0
Global innovation index		Johnson Cornell University 2017		78	-3
Global gender gap		The World Economic Forum	2016	51	-4
Human capital		The World Economic Forum	2017	29	0
Inclusive develo	pment	The World Economic Forum	2018	44	+2
index					
Corruption perceptions		Transparency International	2017	122	+9
World press freedom		Reporters Without Borders	2018	158	-1

2. Pharmaceutical Industry in Kazakhstan

General overview

Pharmaceutical market of Kazakhstan is the biggest and the most structured one in Central Asia. However, it is weaker compared to the CEE market in terms of business environment and its amount. Kazakhstan pharmaceutical market started its formation in the middle 1990s. In 1994, the provision of drugs in the country was carried by the State Joint Stock Holding "Pharmacia" owning 1832 pharmacies. After the de-monopolization of the Holding and privatization of its pharmacies. the national drug provision system was destroyed. In 1996, transformation processes allowed developing a drugs provision system based on market relationships. Since the USSR Kazakhstan was considered as a prospective supplier of medical raw materials. Kazakhstan obtains 243 types of medical herbals 20 of them are unique. Currently, the pharmaceutical market of Kazakhstan is among the most developed ones in the CIS region. Consolidation and evolution of vertically integrated companies can be seen in local producers, distributors, and pharmacies together with the improvement of service culture. In the virtue of the growth of purchasing power of the population, a significant boost in pharmaceutical sales and healthcare expenditures in Kazakhstan started since 2010. In 2017 Kazakh pharmaceutical industry has become the fastest growing sector in Kazakhstan. Production of vital pharmaceutical products significantly boosted growing by 41.8% y-o-y in KZT. However, the pre-crisis level of KZT 240.1 mio in 2013 wasn't reached. Despite considerable growth dynamics, the contribution of the pharmaceutical industry in the country's GDP remains quite low -0.13% in values in 2017. The main reason for this is a relatively low base of local pharmaceutical industry. The unbalanced regional structure of the pharmaceutical industry, which creates problems for supply and distribution, is also seen as its weak point. In South Kazakhstan region and Almaty about 81% of local pharmaceutical production is produced, while the share of other regions is insignificant. Moreover, poorly developed infrastructure in Kazakhstan creates additional hurdles for pharmaceutical distributors. Kazakhstan leads the EEU by reimbursement of medicines, but funds of the population is still the main source for funding pharmaceutical consuming. Foreign companies have settled a dominant position on the market due to poor technologies and productive capacities of local producers. The weakness of local manufacturing makes a big threat for the country regarding strategic security, as according to the WHO recommendation, local producers should provide at least 20% of pharmaceutical production in a country.

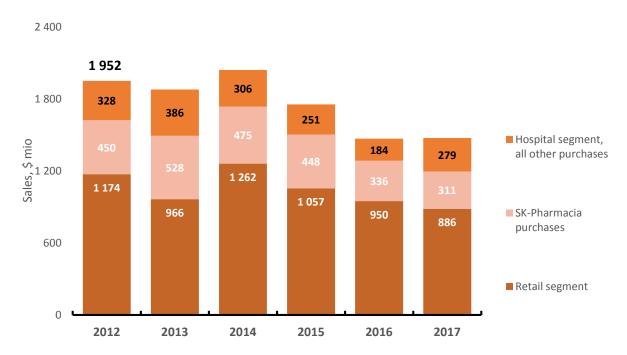


Figure 3. Total value of the Kazakhstan pharmaceutical market, values (USD mio)

Source: Vi-ORTIS: UPharma Consulting

Pharmaceutical market structure

Commodity supply chain of the pharmaceutical market of Kazakhstan includes foreign companies, local manufacturers, wholesalers/distributors of pharma related products, public and private hospitals, and the retail segment. Standard pharmacy assortment in the country comprises four categories: drugs, medical goods and cosmetics and hygiene products. Kazakh pharmaceutical market is conventionally divided into retail and hospital segments. In 2017, total pharmaceutical market of Kazakhstan grew by 0.4% y-o-y in values to USD 1,476.1 mio after two years of significant decrease (-14% in 2015 and -16.3% in 2016). Retail market made 60% of the total market, the share of hospital purchases was 40%. Foreign companies held about 86.2% of the market in values. The market share of drugs on the total market was 90.1%, medical devises – 5.3%, food supplements – 4.6%.

Pharmaceutical market supply chain

a) Manufacturers

There are more than 80 pharmaceutical producers in Kazakhstan employing about 2.6 the specialists. However, TOP-10 biggest local producers in the country manufacture 95% of all local drugs. Within the industrialization program Kazakhstan managed to attract notable investments in the pharmaceutical industry. In 2010, 51% of shares of local company Chempharm were acquired by Polish company Polpharma. The investments of over USD 100 mio allowed the emerged Santo company to become a leader of the Kazakh pharmaceutical market. In the same way Turkish companies Nobel and Abdi Ibrahim created competitive production companies in Kazakhstan. 7 local and 4 foreign production sites in Kazakhstan are GMP certified.



Figure 4. Domestic production of essential drugs in Kazakhstan, values (USD mio)

Source: Vi-ORTIS: UPharma Consulting

b) Export and Import

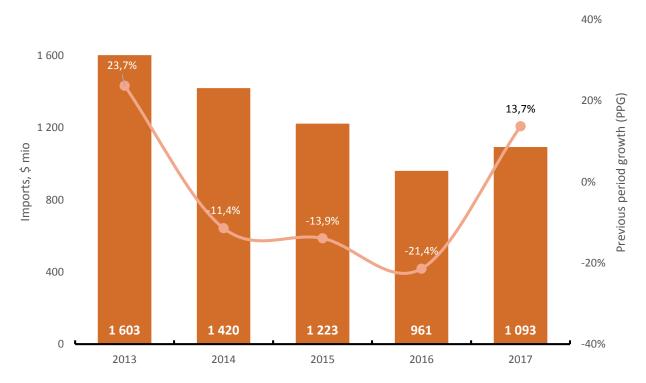
In 2017 exports of pharmaceuticals from Kazakhstan increased 20.6% y-o-y to USD 26.9 mio after almost analogic decrease in 2016. As compared to 2016 imports of pharmaceuticals to Kazakhstan rose 13.6% y-o-y to USD 1,093 mio in 2017. Among the main pharmaceutical importers in 2017 were Germany, Russia, France, India, Italia, Slovenia and Hungary. The share of importers from the CIS is declining over the years while the EU countries increase export volumes in Kazakhstan.

30 40% 29,3% 20% Previous period growth (PPG) 20 Exports, \$ mio 0% -19,8% 10 -20% 23,5 21,5 27,8 22,3 26,9 0 -40% 2013 2014 2015 2016 2017

Figure 5. Export of pharmaceuticals from Kazakhstan, values (USD mio)

Source: Vi-ORTIS: UPharma Consulting

Figure 6. Import of pharmaceuticals to Kazakhstan, values (USD mio)



Source: Vi-ORTIS: UPharma Consulting

c) Wholesalers and Distributors

TOP-10 distribution companies of Kazakhstan possess 95% of wholesale trade on the market. All TOP-10 pharmaceutical distributors have national status as they operate within several regions of the country, other pharmaceutical distributors are smaller and possess a low share of the market. The biggest distributors in Kazakhstan are Amanat, Medservice, Inkar, Stopharm and Akniet.

According to the President of AIPM in Kazakhstan, distributors establish the average margin on drugs at the level of 7-15%, while pharmacies – at the level of 12-25%.

Table 3. Top-10 Pharmaceutical distributors in Kazakhstan

#	Distributors	Share 2017
1	Amanat	20%
2	Medservice	17%
3	Inkar	17%
4	Stopharm	15%
5	Akniet	11%
6	Emiti	6%
7	Zerde	5%
8	Rauza	2%
9	AktubPharmCenter	1%
10	Medikus	1%
	Other	7%

d) Pharmacies

As on Jan 1, 2018, there were 8,597 pharmacies operating in Kazakhstan. Pharmacies are massively concentrated in big cities – Almaty (870), Astana (442) and Shymkent (440). On average, there are 53 pharmacies per 100,000 population in large cities in Kazakhstan (cities with less than 50 pharmacies are not considered). About 95% of Kazakh pharmacies are private. Private pharmacies in the country operate as individual entrepreneurships with a simplified taxation regime, where the amount of corporate income tax and the social tax together makes up 3% of the amount of income excluding expenses. Biggest pharmacy chains in Kazakhstan are Amanat, Europharm, RauzaADE, Sadykhan and Pharmakom, which possess about 25% of the market. The GPP compliance will become obligatory for pharmacies since 2023. As on the end of 2017, there were only 255 pharmacies in Kazakhstan, which implemented the GPP standards.

Table 4. Top-10 Pharmacy Chains in Kazakhstan

#	Pharmacy chains	Share 2017
1	Amanat	8,1%
2	Europharm	6,3%
3	Rauza ADE	4,8%
4	Sadykhan	3,1%
5	Pharmakom	2,5%
6	AktubPharmCenter	1,8%
7	Hippokrat	1,2%
8	Ot A do Ya	1,2%
9	Tsvetnaya	1,2%
10	Zerde	0,9%
	Other	68,9%

Pharmaceutical market segments

a) Retail segment

In 2017 retail market decreased 6.8% y-o-y in values, after falling by 16% y-o-y in 2015 and by 10.4% y-o-y in 2016. Retail sales contributed 60% to the total amount of pharmaceutical market in values in 2017. Foreign companies dominated the market with about 92.4% market share. Most

of them operate through representative offices and local distributors. On the retail drug market products from Germany made 16.5% of sales, Russia – 13.6%, India – 7.4%. As of 01.05.2018, there were 8,007 product names of drugs registered in Kazakhstan. About 14% of them were of Indian origin, 10% –Kazakh, and 9.8% – Russian. 41% of registered drugs had solid forms while 23% were in liquid dosage forms. In 2017, Rx segment embraced about 59.9% of the market in values and 38.25 in volumes. It is expected that further growth of the market will be provided through Rx segment's annual 10% growth in values. However, OTC segment will likely rise in volumes and exceed the share of Rx segment due to lower prices of OTC drugs. Low price segment (with the price below USD 1), which conventionally belongs to local producers, possessed 66.3% of the market in volumes. Drugs priced in a range of USD 1-5 made 25% of sales. The share of drugs from high price segment (above USD 50) was insignificant, however it grew to 0.05% vs 0.03% in 2016. Japanese company Takeda increased its retail sales by 18.7% y-o-y and became a leader of the retail drug market surpassing Santo company, that decreased its sales 1.7% y-o-y. German companies Bayer, STADA and Berlin-Chemie showed significant sales growth, increasing by 20.3%, 19.2% and 15.5% in values, respectively. Russian drug based on recombinant human interferon alpha-2b Viferon was the best-selling drug on market with USD 7.8 mio sales. It was followed by Takeda's Actovegin and Novartis' Theraflu. Antibacterials for systemic use (ATC_2 code – J01) was the most selling ATC_2 category providing 8.6% of sales of the retail market.

20% Retail segment Retail segment PPG, % 13,1% Previous period growth (PPG) 400 Sales, mio units 0% -6,8% -7,3% 200 536 494 458 427 483 0 -20% 2016 2012 2013 2014 2015

Figure 7. Retail segment of the Kazakh pharmaceutical market, values (USD mio)

Source: Vi-ORTIS: UPharma Consulting

Table 5. TOP-15 pharmaceutical companies by retail drug sales in the Kazakh pharmaceutical market, 2016-2017

No	Company	Origin	Values (US\$, mio)				
			Sales		Shares		Growth
			2016	2017	2017	2017	2017 vs 2016
1	Takeda	JPN	28.9	34.3	4.0%	4.3%	18.7%
2	Santo	KAZ	30.5	30.0	4.3%	3.8%	-1.7&
3	Bayer	GER	23.7	28.5	3.3%	3.6%	20.3%

4	Sanofi-Aventis	FRA	27.1	28.4	3.8%	3.6%	5.1%
5	Gedeon Richter	HUN	26.9	26.6	3.7%	3.4%	-1.0%
6	STADA	GER	21.7	25.9	3.0%	3.3%	19.2%
7	Teva	ISL	25.1	25.7	3.5%	3.3%	2.6%
8	Berlin-Chemie	GER	21.3	24.6	3.0%	3.1%	15.5%
9	GlaxoSmithKline	UK	26.9	24.5	3.7%	3.1%	-9.1%
10	Abbott	USA	20.6	24.3	2.9%	3.1%	18.0%
11	World Medicine	USA	20.8	22.5	2.9%	2.8%	8.1%
12	Sandoz	GER	22.0	21.2	3.1%	2.7%	-3.5%
13	Dr. Reddy's	IND	15.5	15.8	2.2%	2.0%	2.3%
	Laboratories						
14	KRKA d.d.	SLO	17.1	14.5	2.4%	1.8%	-15.2%
15	Nobel	TUR	14.0	13.9	1.9%	1.8%	-0.4%
	Top-15		342.2	361.0	47.6%	45.6%	5.5%
	Other		376.1	431.2	52.4%	54.4%	14.6%
	TOTAL market		718.3	792.1	100.0%	100.0%	10.3%

Source: Vi-ORTIS: UPharma Consulting

Table 6. TOP-15 drug brands by retail sales in the Kazakh pharmaceutical market, 2016-2017

№	Product	INN	Company	Values (US\$, mio)				
				Sales		Shares		Growth
				2016	2017	2017	2017	2017 vs 2016
1	Viferon	Interferon alfa-2b	Feron	6.7	7.8	0.9%	1.0%	17.0%
2	Actovegin	Calf blood	Takeda	5.4	6.8	0.8%	0.9%	25.0%
3	Theraflu	Paracetamol	Novartis	5.2	6.3	0.7%	0.8%	23.0%
4	Canephron	Comb drug	Bionorica	5.2	6.3	0.7%	0.8%	21.0%
5	Cerebrolysin	Cerebrolysin	Ever Pharma	4.2	5.7	0.6%	0.7%	35.0%
6	Creon	Multienzymes	Abbott	5.2	5.5	0.7%	0.7%	7.0%
7	Essentiale	Mono	Sanofi- Aventis	5.2	5.3	0.7%	0.7%	3.0%
8	Hylac	Comb drug	Ratiopharm	4.4	4.8	0.6%	0.6%	8.0%
9	Anaferon	Comb drug	Materia Medica	4.6	4.6	0.6%	0.6%	-1.0%
10	Ceraxon	Citicoline	Takeda	3.7	4.4	0.5%	0.6%	21.0%
11	Concor	Bisoprolol	Takeda	3.2	4.3	0.4%	0.5%	34.0%
12	Cardiomagnil	Acetylsalicylic acid + Magnesium hydroxide	Takeda	3.1	4.3	0.4%	0.5%	39.0%
13	Mucaltin	Althea root	Santo	3.4	4.2	0.5%	0.5%	24.0%
14	Ekvator	Lisinopril + Amlodipine	Gedeon Richter	4.7	4.1	0.7%	0.5%	-13.0%
15	Heptral	Ademetionine	Abbott	2.4	3.9	0.3%	0.5%	64.0%
	TOP-15			66.5	78.3	9.3%	9.9%	17.8%
	Other			651.8	713.8	90.7%	90.1%	9.5%
	TOTAL market			718.3	792.1	100.0%	100.0%	10.3%

Source: Vi-ORTIS: UPharma Consulting

Table 7. TOP-10 ATC-2 categories of drugs by retail sales on the Kazakh pharmaceutical market, values, 2016-2017

No	ATC-2	ATC-2 Name		Values (US\$, mio)				
	code		Sales		Shares		Growth	
			2016	2017	2017	2017	2017 vs 2016	
1	TO 1	A (11 (1 C () 1	(()	60.1	0.20/	0.60/		
1	J01	Antibacterials for systemic use	66.8	68.1	9.3%	8.6%	2%	
2	M01	Anti-inflammatory and antirheumatic products	35.7	39.6	5.0%	5.0%	11%	
3	R05	Cough and cold preparations	39.6	36.4	5.5%	4.6%	-8%	
4	N02	Analgesics	32.3	33.3	4.5%	4.2%	3%	
5	G04	Urologicals	24.2	28.5	3.4%	3.6%	18%	
6	N06	Psychoanaleptics	22.6	26.9	3.2%	3.4%	19%	
7	S01	Ophthalmologicals	23.5	26.1	3.3%	3.3%	11%	
8	G03	Sex hormones and modulators of the genital system	19.8	25.3	2.8%	3.2%	28%	
9	C09	Agents acting on the reninangiotensin system	26.1	24.6	3.6%	3.1%	-6%	
10	A11	Vitamins	23.3	23.8	3.2%	3.0%	2%	
	TOP-10		313.9	332.7	43.7%	42.0%	6.0%	
	Other		404.4	459.4	56.3%	58.0%	13.6%	
	TOTAL market		718.3	792.1	100.0%	100.0%	10.3%	

Source: Vi-ORTIS: UPharma Consulting

b) Hospital segment

Governmental support is among the key drivers of growth of the pharmaceutical industry, as public procurements amount 40% of the pharmaceutical market. However, in 2014, due to national currency devaluation, hospital expenditures started to fall, and the market decreased by 14% y-o-y and in 2015 – by 7.6% y-o-y. In 2016, the fall was even more drastic – 35.4% y-o-y in values. Economy stabilization allowed increasing hospital sales by 13.5% y-o-y in 2017. The major part (52.7% in values in 2017) of hospital market is related to Single distributor SK-Pharmacia, which was created in 2009 to procure drugs and medical devices and provide them to medical organizations within guaranteed volume of free medical care. In 2013, the 100% of the company's capital were transferred to the Ministry of Healthcare and Social Development of Kazakhstan. The main activity directions of the Single distributor are:

- carrying public tenders within public procurement of drugs;
- organization of storage of drugs by GDP (good distribution practice);
- organization of distribution of drugs and medical devices in medical organizations;
- creation of information system to integrate logistic processes of the Single distributor, contracting authority and suppliers.

Besides the Single distributor as national operator, there is funding through regional budgets of outpatient, hospital and price tenders as well as Healthcare Department, which forms an outpatient sector of the market (30% of hospital market). Priority for local producers is among the main principles of public procurement in Kazakhstan. In 2017, 23.2% share of hospital market in values

belonged to local producers being followed by companies from France (15.8%), Germany (14.8%), Austria (5.9%) and USA (5.8%).

40% Hospital segment, all other purchases 26,7% SK-Pharmacia purchases 1 000 17,4% Hospital segment total PPG, % 20% Previous period growth (PPG) 13,5% Sales, \$ mio 0% 500 -14,59 -10,5% -20% 25,6% 450 **528** 475 448 336 311 -40% 2012 2013 2014 2015 2016 2017

Figure 8. Hospital segment of the Kazakh pharmaceutical market, values (USD mio)

Source: Vi-ORTIS: UPharma Consulting

Major domestic pharmaceutical manufacturers

1. SANTO Member of Polpharma Group



FULL NAME	SANTO MEMBER OF POLPHARMA GROUP,
	JSC
HQ LOCATION	Shymkent, Kazakhstan
RANK (2017)	2
SALES (2017)	\$ 30.0 mio
MS (2017)	3.8%
STAFF (2018)	>1,300 employees
PORTFOLIO	246 brands
WEB	santo.kz
PRODUCTS	Infusions, Antibacterials, Cardiology, Analgesics and
FOCUS	Anesthetics

In 2011, Chimpharm pharmaceutical plant had become a part of the Polpharma Group of Companies and was renamed to Santo Member of Polpharma Group. The company exports its production to Russia, Kyrgyzstan, Tajikistan, Mongolia and Turkmenistan. Most sales of the company belong to the hospital segment.

Santo's facilities allow manufacturing 1.2 bn tablets, capsules and granules, 300 mio ampoules, 40 mio bottles of antibiotics and 6 mio packages of infusions annually.

The company is implementing an investment project on modernization of APIs productions worth USA 100 mio.

<u>Address:</u> 160019, Republic of Kazakhstan, Shymkent city, Rashidova, 81 Telephone: +7 (7252) 610120, +7 (7252) 561342, +7 (7252) 560533 (fax)

E-mail: santo@santo.kz

Almaty branch address: 050013, Republic of Kazakhstan, Almaty, Al-Farabi17/1, Business

Center "Nurly-Tau", 5B block, floor 19

Telephone: +7 (727) 3121833 Webiste: www.santo.kz

2. "Nobel" Almaty Pharmaceutical Factory



FULL NAME	NOBEL ALMATY PHARMACEUTICAL PLANT
HQ LOCATION	Almaty, Kazakhstan
RANK (2017)	15
SALES (2017)	\$ 13.9 mio
MS (2017)	1.8%
STAFF (2018)	400 employees
PORTFOLIO	180 brands
WEB	nobel.kz
PRODUCTS	Antibiotics, Antihypertensive, NSAIDs, Lipid-
FOCUS	lowering agents

In terms of the National Program for Import Substitution in Kazakhstan in 2003 the "Nobel Pharmaceuticals" company has invested in Almaty Pharmaceutical Factory. The investor – "Nobel Pharmaceuticals" is a Turkish company, founded in 1964, which has more than 2700 employyes in 18 countries. In 2002-2016 about \$ 65 mio were invested in the Nobel Almaty. Nobel exports 30% of its production in the CIS countries. Annual production capacity amounts 350 mio tablets, 150 mio capsules, 20 mio bottles of syrup and suspension and 10 mio tubes of creams and pomades. The company has a GMP certificate and is one of the best contractors in Kazakhstan.

<u>Address:</u> Republic of Kazakhstan, Almaty, Shevchenko 162E Telephone: +7 (727) 399-50-50, +7 (727) 399-60-60 (fax)

E-mail: nobel@nobel.kz
Website: www.nobel.kz

3. ABDI IBRAHIM GLOBAL PHARM



FULL NAME	ABDI IBRAHIM GLOBAL PHARM, LLC
HQ LOCATION	Almaty, Kazakhstan
STAFF (2018)	>400 employees
PORTFOLIO	108 brands
WEB	aigp.kz
PRODUCTS	Neurology, Antibacterials, Respiratory
FOCUS	

The company was founded in 2000 within import substitution policy of Kazakh government in cooperation with Korean Han Seo Pharm company. In 2012, 60% of Global Pharm was acquired by Turkish Abdi Ibrahim company. In 2015, the construction of the new GMP-complying plant was finished.

Abdi Ibrahim Global Pharm's portfolio includes over 70 preparations. The company's main export markets are Azerbaijan, Uzbekistan, Tajikistan and Kyrgyzstan. Reaching Russia, Belarus, Turkmenistan, Moldavia and Armenia is in plans.

Contacts:

Registered address: Republic of Kazakhstan, Almaty, Zhandosova 184 G

Telephone: +7 (727) 232-44-80, +7 (727) 232-44-81 (fax)

E-mail: info@aigp.kz

Plant address: Almaty region, Ili district, Ashibulak village district, Mukhametzhan Tuimebayev,

Industrial Zone space No. 282

Webiste: www.aigp.kz

4. KELUN-KAZPHARM



FULL NAME	KELUN-KAZPHARM, LLC
HQ LOCATION	Kokozek, Kazakhstan
STAFF (2018)	>450 employees
PORTFOLIO	10 brands
WEB	kelun-kazpharm.kz
PRODUCTS	Infusion solutions, oncology
FOCUS	

The company is part of Chinese Corporation Kelun, one of the biggest producers of pharmaceuticals in China. GMP-complying plant of Kelun-Kazpharm was launched in 2014. The plant includes two sites, which produce injection and infusion solutions. The company has

become one of the biggest suppliers of infusion solutions in Kazakhstan. It plans to expand the assortment and open the site for the production of antibiotics and cancer drugs.

Address:

Almaty region, Karasay district, Eltay village - Kokozek

Sales department telephones: +7(727)312-14-04, +7(727)312-16-45, +7(727)312-16-46

Registration department: +7(727)312-14-01

E-mail: 3131404@mail.ru – Sales department Almaty

<u>bauken1971@bk.ru</u> – manager Baurzhan Kaptagayev (Moscow)

rusian.86@mail.ru – manager Ruslan Kameshev (Moscow)

kelunrussia@gmail.com - manager Anderi Duan (Moscow)

saniya.kelun@mail.ru – manager Russia Sania Bektasova

Website: www.kelun-kazpharm.kz

5. KARAGANDA PHARM COMPLEX



FULL NAME	KARAGANDA PHARM COMPLEX, LLC
HQ LOCATION	Karaganda, Kazakhstan
STAFF (2018)	150 employees
PORTFOLIO	154 brands
WEB	kphk.kz
PRODUCTS	Oncology, Endocrinology, Immunology
FOCUS	

The company was created under the Order of the President of the Republic of Kazakhstan Nursulan Nazarbayev for the manufacturing of original, competitive injectable preparations. In 2015, the workshop for manufacturing of lyophilized injections and solutions for injections as well as quality control laboratory were put into operation. Project capacity of the Complex is 4 mio packs per year in 2017.

Details of the complex:

- Physio-chemical laboratory
- Microbiology laboratory
- Biochemistry laboratory
- Central warehouse
- Engineering infrastructure
- 4,291 hectares territory
- Project capacity: 4 million packs per year
- 150 employees

Address:

Republic of Kazakhstan, Karaganda region, 100009 Kazybek Bi district, Botanixheskaya street

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Telephone: +7 (7212) 90-80-51, +7 (7212) 90-80-51 (fax)

E-mail: kphk@kphk.kz
Website: www.kphk.kz

6. DOSPHARM



FULL NAME	DOSPHARM, LLC
HQ LOCATION	Almaty, Kazakhstan
STAFF (2018)	130 employees
PORTFOLIO	17 brands
WEB	dosfarm.kz
PRODUCTS	Respiratory, Sensory organs
FOCUS	

DOSPHARM was founded in 2001 in Almaty. The company's main specialization is drops and sprays in bottles. Currently, there are 18 preparations on the company's portfolio. DOSPHARM is actively implementing modern equipment at the manufacturing; in Feb 2016, it received international GMP certificate for the production of eye, nasal and ear dosage forms.

Address:

Republic of Kazakhstan, Almaty, Chaplygina 3

Reception telephone: +7 (727) 253 03 88, +7 (727) 248 31 81, +7 (727) 377 91 21

Quality control telephone: +7 (727) 253 03 88

Manufacturing: +7 (727) 377 91 20

E-Mail: dosfarm@dosfarm.kz

Sales department telephones: +7 (727) 253 07 07, +7 (727) 253 07 08

Sales department e-mail: gulshat@dosfarm.kz

Website: www.dosfarm.kz

7. ZERDE KZ



FULL NAME	ZERDE GROUP, LLC
HQ LOCATION	Shymkent, Kazakhstan
STAFF (2018)	220 employees
PORTFOLIO	27 brands
WEB	zerdegroup.kz

PRODUCTS Herbal, Phyto teas FOCUS

Production company Zerde-Phyto is a part of Zerde Group, which also includes retail and distribution departments. It produces herbal preparations by proceeding about 1 thousand tons of herbal raw materials annually. In 2015, Zerde Group started the construction of the joint plant in Shymkent in cooperation with Russian company Pharmasyntez. The plant will produce medicines against cancer, cardio diseases and HIV.

<u>Address:</u> Republic of Kazakhstan, Shymkent city, Tamerlanovskoe shosse Telephone: +7 (7252) 45 51 84 reception, +7 (7252) 39 12 77 sales department

E-mail: <u>okzerde@mail.ru</u>
Website: <u>www.zerdegroup.kz</u>

8. KYZYLMAY



HQ	Almaty, Kazakhstan
LOCATION	
STAFF (2018)	>50 employees
PORTFOLIO	96 brands
WEB	kyzylmay.kz
PRODUCTS	Herbal, Food supplements, Cardio
FOCUS	

Kyzylmay Complex, which includes manufacturing, marketing, trade, construction, and planning groups, was founded in 1994. The company produces over 100 herbal and natural preparations. Company's assortment includes herbal teas, herbal capsules, syrups, honey composition, suppositories, herbal balsams, contraceptives, oils and ointments.

Address: Republic of Kazakhstan, 050016, Almaty, Ippodromnaya street, 6

Telephones: +7 (727) 382-17-14, +7 (727) 382-17-13

Website: www.kyzylmay.kz

9. EIKOS PHARM



FULL NAME	EIKOS PHARM, LLC
HQ LOCATION	Almaty, Kazakhstan

STAFF (2018)	>50 employees
PORTFOLIO	9 brands
WEB	eikos-pharm.kz
PRODUCTS	Respiratory, Antiinfectives
FOCUS	

Eikos Pharm was founded in 1998 and was designed for the manufacturing of influenza drugs. In 2015, the company received international GMP certificate. The company produces 80 mio tablets annually.

Contacts:

Correspondence address: 050016, Republic of Kazakhstan, Almaty, Nusupbekova 32

Production plant address: Republic of Kazakhstan, Almaty region, Ili district, Boralday, junction

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Registered address: 040700, Republic of Kazakhstan, Almaty region, Ili district, Otegen Batyr,

Titov street 8, apartment 2

Telephone: +7 727 397 64 29; +7 727 397 64 14

E-mail: pharm@eikos.kz, mail@eikos.kz

Website: www.eikos-pharm.kz

10. Pharmaceutical Manufacturing Company «Sultan» LLP



LLP "Sultan" is a domestic manufacturer of pharmaceutical products since 1999. In connection with the Decree of the President of the Republic of Kazakhstan of September 13th 2004 year, N 1438 "On State program of reforming and development of healthcare of the Republic of Kazakhstan for 2005-2010" the company has built pharmaceutical production in Talgar district, Almaty region during 2006-2012. Project LLP "Sultan" Construction of a pharmaceutical production included by Akimat of Almaty region in the Governmental Program of the Republic of Kazakhstan" Business Road Map 2020 ". Over 3 years, the company launched the first in Kazakhstan production of medical devices for trauma. At the moment, a modern production facility was constructed in accordance with ISO standards, advanced metal processing equipment purchased from a Swiss provider, and continually training was conducted by technology provider with 120 years of experience. All products that are authorized for issue, are registered and certified.

Address: Almaty region, Talgar district, village Erkin, street B.Momyshuly, 5

Phone: +7 (727) 305-48-65/(80)

E-mail: toosultan@list.ru

Web-site: www.sultanpharm.kz

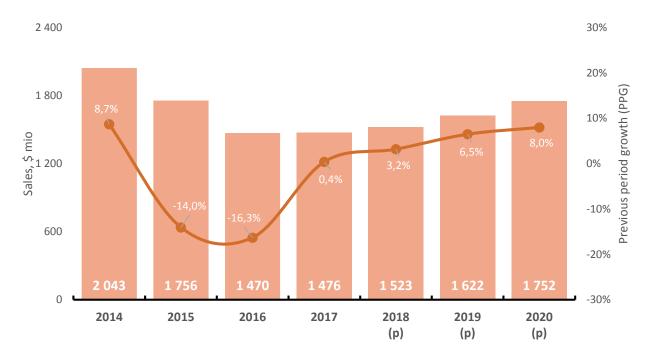
EEU integration of the pharmaceutical market

The agreement on common principles and rules for the circulation of medicines within the framework of the EEU, signed as early as 2014, opened new opportunities for the pharmaceutical

industry. After Kazakhstan's accession to the EEU, the state has vastly increased the chances of attracting large foreign players to the industry. If earlier it was unprofitable to place pharmaceutical enterprises in Kazakhstan, in particular, due to a small sales market, the market of the EEU countries opened new prospects, since its total volume is more than USD 20 bn. The Kazakhstan pharma market is particularly attractive to the countries with the most stable economies: the USA, the EU countries (Germany, Denmark, France), as well as Eastern Europe states like Poland, Slovenia and Turkey. Investors' interest in Kazakhstan is explained by the fact that the pharmaceutical market is growing and it has not reached its limit yet. Formation of a common market of drugs and medical devices within the EEU, which had been launched on May 6, 2017, will create favorable opportunities for Kazakh pharma producers, which plan to enhance the export of pharmaceuticals to the EEU states to USD 360 mio per year. The common market foresees harmonization of rules for drugs circulation and registration as well as quality standards for drugs. Moreover, all drugs registers of member states will also be harmonized, so the drugs registered in other member-states will be available in Kazakhstan. The prices are expected to fall due to introduction of the parallel import. However, the process of the market's integration and harmonization will take time.

Kazakhstan is also committed to improving the quality standards under the interstate documents, which were adopted to ensure the launch of the common market of the EEU. These documents define the general requirements for drugs production, storage and sale, which meet the highest quality standards (GMP, GCP, GDP, GLP, etc.). Since 2020, the government plans to launch the system of compulsory medical insurance (SCMI), which aims to increase the public's access to medical aid and medicines provision. Also, the government continues implementing measures on price regulation. The MOH proposed to establish limiting prices as well as reference pricing in retail sale of drugs; the adoption of the corresponding legislation is expected by the end of 2018. The market is expected to grow gradually – we forecast the 3.2% y-o-y increase in values in 2018. Attraction of investments and growth of the purchase power of the population will allow to see 6.5% y-o-y growth in 2019 and 8% y-o-y growth in 2020. By 2020, Kazakhstan plans to implement 15 investing projects in pharmaceutical sphere allocating about \$29.2 mio investments. Experts see the biggest opportunities in the therapeutic sectors of antituberculosis, cardiovascular, oncology, diabetic preparations as well as vaccines and other immunobiological products. The share of Gx is likely to rise in following years, as in crisis conditions customers continue to prefer cheaper analogs of drugs. Similarly, low price segments (<\$2 and <\$5) are expected to continue growing.

Figure 9. Forecast of the total pharmaceutical market of Kazakhstan for 2020, values (USD mio)



Source: Vi-ORTIS: UPharma Consulting

3. Regulation of the pharmaceutical sphere

National healthcare regulation

Healthcare issues in Kazakhstan are regulated through more than 12,000 legislative acts. Main aspects of doing pharmaceutical activities are defined in the Code on Health, but detailed regulation of the market contained in Resolutions of the government, Orders of the Ministry of Healthcare of the Republic of Kazakhstan (MOH), etc. In 2014, the process of improvement of the national pharmaceutical legislation had started. The features of integration within the EEU were considered. Particularly, the conceptual apparatus was substantially developed to comply it with international standards; contracts on supply and storage of drugs and medical devices are now defined as long-term contracts; such long-term contracts commits the contractor to comply the GDP and GMP standards; Pharmaceutical Inspectorate was created to develop an integrated system of inspection and control over the quality of drugs within the EEU as well as harmonizing the legislation on Kazakhstan with international demands in inspection to join The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S).

Introduction of the new "Committee for Quality Control and Safety of Goods and Services of the Ministry of Healthcare of the Republic of Kazakhstan"

On the Government resolution of April 10, 2019 "On some issues of the Ministry of Health of the Republic of Kazakhstan" Ministry has made restructurings¹. The following reorganizations were made: the republican state enterprise "Committee of Public Health Protection of the Ministry of Health of the Republic of Kazakhstan" and the republican state institution "Committee of Pharmacy of the Ministry of Health of

¹ http://dsm.gov.kz/ru/news/v-minzdrave-sozdan-novyy-komitet-kontrolya-kachestva-bezopasnosti-tovarov-i-uslug Accessed on: 02/09/2019

the Republic of Kazakhstan" were merged into the republican state enterprise "Committee of quality control and safety of goods and services of the Ministry of Health of the Republic of Kazakhstan".

The Committee of quality control and safety of goods and services will control the following activities:

- Quality and safety of goods and services, which have an effect on human health;
- Quality of medical services;
- In the field of distribution of medicines, including control on the retail price limits;
- In the field of sanitary-epidemiologic wellbeing of the population.

The newly formed Committee comprises 250 territorial departments and administrative units. It will also control 9 antiplaque stations and 2 national centers - republican state enterprise on the right of economic management "National Center for Expertise of Medicines and Medical Devices" and "National Centre of Expertise".

Source: Ministry of Healthcare of the Republic of Kazakhstan (http://dsm.gov.kz), Committee of quality control and safety of goods and services (http://kkkbtu.dsm.gov.kz)

Regulation and registration of pharmaceuticals

All pharmaceuticals, products of medicinal use and medical equipment with active registration in the Republic of Kazakhstan can be found at the State Register of the National Center for Medicines and Medical Devices².

Registration of pharmaceuticals is a two-step process:

1) Examination of drugs - carried by monopoly organization "National Center for Expertise of Drugs, Medical Devices and Medical Equipment" (hereinafter Expert Center). Examination of pharmaceuticals is regulated by the Order of the Ministry of Health of the Republic of Kazakhstan of 18.11.2009 No. 736 "About the approval of Rules of conducting examination of medicines, products of medical appointment and medical equipment".

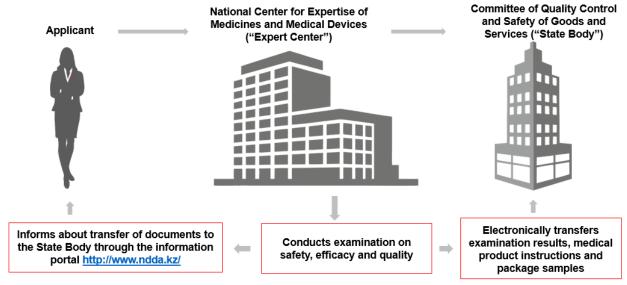
The examination of drugs includes following phases:

- 1. Primary examination
- 2. Analytical expertise
- 3. Specialized pharmaceutical expertise
- 4. Specialized pharmacological expertise
- 5. Safety, efficacy and quality confirmation

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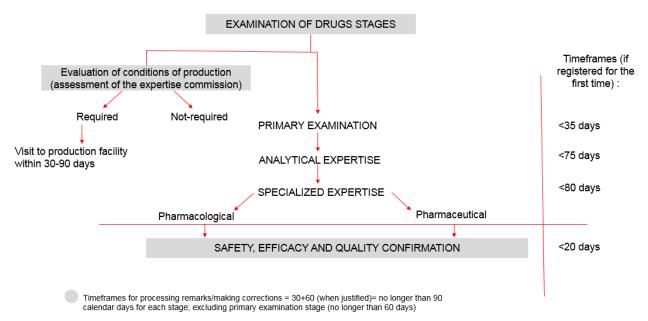
² http://www.ndda.kz/category/search_prep Accessed on: 02/09/2019

Figure 10. Pharmaceutical product examination procedure scheme



Source: MedExpert Company

Figure 11. Pharmaceutical product examination detailed procedure and timeframe



Source: MedExpert Company

2) State registration, reregistration, and amendments to registration dossier of a drugunder the field of circulation of drugs and medical devices is conducted by the "Committee of quality control and safety of goods and services of the Ministry of Health of the Republic of Kazakhstan" (hereinafter State Body). Pharmaceutical registration issues are controlled by the Order of the Ministry of Health of the Republic of Kazakhstan of 18.11.2009 No. 735 "About the approval of Rules of the state registration, re-registration and modification of the registration file of medicine, products of medical appointment and medical equipment". The applications have to be made through the portal of the electronic licensing of the Republic of Kazakhstan (elicense.kz).

In order to apply for a State registration of a pharmaceutical drug, the manufacturer has to have a representative body in Kazakhstan (resident company), who will be listed in the State

registration certificate. Applications for examinations of drugs can be done directly from the manufacturer.

The Expert Center approves or rejects state registration, reregistration or amendments to registration dossier of a drug based on the conclusion of the expert organization regarding the safety, efficacy, and quality of a drug. In case of a positive decision on registration or reregistration of a drug, the Expert Center issues the Order on registration/re-registration and provides the applicant with:

- registration certificate to the registered drug with an indication of the period during which the medical use of it is allowed in the Republic of Kazakhstan;
- approved instructions for medical use of a drug in Kazakh and Russian;
- agreed regulatory document on quality and safety control of a drug with the assigned number;
- approved layouts of the package, labels, and stickers.

Source: Committee of quality control and safety of goods and services (http://kkkbtu.dsm.gov.kz), National Center for Expertise of Drugs, Medical Devices and Medical Equipment (http://www.ndda.kz/)

Manufacturing policy

According to the state program for the development of the pharmaceutical industry, the government's priority task is to supply 50% of the market with locally produced medicines and healthcare products by 2025. To meet this goal, modernization of existing and construction of new pharmaceutical production facilities are planned. In January 2014, Kazakhstan adopted international GMP (Good Manufacturing Practice) standards for drug manufacturing.

All pharmaceutical manufacturing enterprises are obliged to adopt GMP certificates in order to facilitate in Kazakhstan.

Amendments were made to the uniform distribution system of medicines and the definition of the term "long-term supply agreement" to the Code on Public Health and the Healthcare System were introduced. Supply agreements of up to 10 years will are available to domestic pharmaceutical companies or other companies that have agreed manufacturing arrangements with local plants (contract production). As of February 2019, the uniform distributor (SK-Pharmacy) has signed 15 long-term agreements with domestic pharmaceutical manufacturers on 2668 types of medicines³. Up to date there are 64 long-term contracts with domestic manufacturers.

In Kazakhstan, pharmaceutical activity including manufacturing and sale of drugs and medical devices belongs to the ones that need licensing. The licensing authority is Supervising Committee over Medical and Pharmaceutical Activities of the MOH. The licensing process requires submission of the statement, payment of license fee copies of documents confirming the ownership or lease of room or building and the building's plan approved by the Head of the organization. Submission of the documents is allowed in electronic form on the portal elicense.kz.

Source: SK-pharmacy (http://sk-pharmacy.kz)

³ http://sk-pharmacy.kz/rus/sotrudnichestvo/podderzhka_otech_proizvoditele/dolgosrochnye_dogovora/ Accessed on: 03/09/2019

Retail policy

Retail sale of drugs, medical devices and medical equipment is carried by entities, which had obtained the license. The process of obtaining the license for retail sale requires submission of same documents as in licensing manufacturing activity. The retail unit is required to have signboard indicating the name of the subject, its organizational and legal form and work schedule in Russian and Kazakh. The law also obliges the pharmacy to conduct systematic staff training and retraining at least once every five years. The share of counterfeit drugs in Kazakhstan is quite high (10-12%). This is explained by the fact that Kazakhstan pharmacies only pay a penalty for selling counterfeit drugs – there is no criminal responsibility for such violations in the country.

To fight the counterfeit production, the government plans to introduce compulsory labeling of drugs and tracking system by 2023.

Source: Ministry of Healthcare of the Republic of Kazakhstan (http://dsm.gov.kz)

Prescription regulation

Prescription drug retail in the Republic of Kazakhstan is regulated by the Rules of prescribing, control and account of prescriptions approved by the Order of the Minister of health and social development of the Republic of Kazakhstan of May 22, 2015 No. 373. Although, this regulation is not a new requirement, the Committee for Quality Control and Safety of Goods and Services of the Ministry of Healthcare of the Republic of Kazakhstan has strengthened control over retail of pharmaceuticals under prescriptions. As of May 21, 2019, 7748 drugs were registered in the Republic of Kazakhstan, 6114 of which require doctor prescriptions (77% of total number), without the prescription 1634 drugs are sold⁴. The full list prescription drug retail and non-prescription drug retail is released systematically in the official website of the Committee for Quality Control and Safety of Goods and Services, MOH⁵. The list of the medicines sold under prescriptions include: antimicrobial and hormonal medicines; the medicines containing drugs and psychotropic substances; medical medicines for treatment of cardiovascular diseases; medicines for treatment of diseases of digestive tract, etc. Without the doctor's prescription Kazakh citizens can purchase: vitamins, nose drops, syrups, herbal teas, pain-killers, cold & flu relief.

As of May 2019, Committee for Quality Control and Safety of Goods and Services, MOH has strengthened the control on drug prescriptions. The list of prescription drug retail and non-prescription drug retail is released systematically on the website of the Committee. By 2020, drug prescriptions will be done electronically and tracked by the information systems of the Ministry of Healthcare of the Republic of Kazakhstan.

Source: Ministry of Healthcare of the Republic of Kazakhstan (http://dsm.gov.kz), Committee of quality control and safety of goods and services (http://kkkbtu.dsm.gov.kz)

Price regulation

Ministry of Health is vested with the competence to set prices for medicines and has assigned uniform prices for drugs to be set in all pharmacies across the country⁶.

⁴ https://government.kz/ru/press/news/vipisivanie-retseptov-sposobstvuet-ratsionalnomu-primeneniu-lekarstv-i-predotvrashcheniu-samolecheniya-l-burabekova Accessed on: 02/09/2019

⁵ http://kkkbtu.dsm.gov.kz/ru/kategorii/reestry-1_Accessed on: 02/09/2019

⁶ http://dsm.gov.kz/ru/news/v-kazahstane-ceny-na-lekarstva-vo-vseh-aptekah-strany-mogut-byt-nizhe-chem-ustanovlennye Accessed on: 02/09/2019

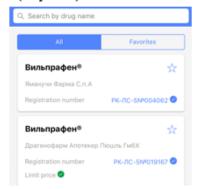
Retail and wholesale prices of pharmaceutical drugs, as well as their limits are regulated by the Ministry of Healthcare of the Republic of Kazakhstan by the Order of the Minister of health and social development of the Republic of Kazakhstan of June 15, 2019 No. 104, registered in the Ministry of Justice of the Republic of Kazakhstan on June 16, 2019 No. 19037. Retail and wholesale markups, as well as their limits are available through the website Committee for Quality Control and Safety of Goods and Services⁷ and through the mobile application <u>Dari.kz</u>. This measure is aimed to secure maximum economic availability of medicines for the whole population of Kazakhstan.

Figure 12. DariKZ app and its containing information on registered drugs in Kazakhstan

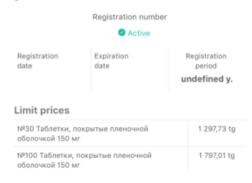
a) DariKZ app logo



b) Example of registered drug (Vilprafen)



b) Information of the drug and limit prices



The price regulation mechanism is based on established retail price margin, which is added to the actual price of the pharmaceutical product. The lower is the cost of a medicinal drug, the higher a price surcharge can be. For example, if the price of a medicinal drug is less than 350 KZT, then the retail price margin can be up to 68%. If the price of a medicinal drug is more than 200 000 KZT, then the retail price margin cannot exceed 3%.

In addition, the price regulation initiative includes a medicine supply request that can now be completed electronically for state medical enterprises (united with SK-Pharmacy single pharmacy information system). The action will help avoid under- and over-supply of certain medicines, as the needs of those with illnesses will become part of the same database. In terms of the initiative, treatment plans by regions will become a part of the SK-Pharmacy single pharmacy information system, where the total request of the state of the necessary medicine with an amount by regions and clinics will be published. After that, the total request will be sent to the budget commission for budget forming and the distribution of corresponding budget resources.

⁷ http://kkkbtu.dsm.gov.kz/ru/pages/reestr-svidetelstv-o-gosudarstvennoy-registracii-produkcii-tovarov-rk-0 Accessed on: 02/09/2019

Source: Ministry of Healthcare of the Republic of Kazakhstan (http://dsm.gov.kz), Committee of quality control and safety of goods and services (http://kkkbtu.dsm.gov.kz)

Advertising policy

Legislation of Kazakhstan on drug advertising is harmonized with the EU legislation in the field, particularly with Directive 92/28/EEC "On the advertising of medicinal products for human use". Advertising of drugs is regulated by the Order of the MOH #105 "On Approval of Rules of doing advertising of drugs, medical devices and medical equipment dated 27.02.2015. Permission for the advertising of a drug is issued after the examination of advertising materials by the Expert Center.

- The advertisement should be reliable and recognizable without special knowledge;
- it should exclude comparisons, not mislead consumers regarding the characteristics, composition and consumer properties, cost, application of the results;
- contain complete and accurate information, the exclusion of which may lead to inappropriate use of drugs or undue risk to the consumer.

Advertising in Kazakhstan could be performed in both Kazakh and Russian languages. Advertising of Rx drugs is allowed only in specialized periodicals for medical and pharmaceutical workers.

Sources: Dari.kz, Aequitas.kz, "Doing business in Kazakhstan 2017", Baker McKenzie.

4. Kazakhstan Healthcare System

Healthcare system overview

The first Constitution of independent Kazakhstan of 1993 allowed the provision of paid medical care and promised to promote the development of a private health care system on the part of the state. The market has been growing considerably and by 1999, 369 commercial outpatient clinics were registered in the country. In 2016, state organizations included 69% (2,300) of all medical institutions, while private – 31% (1,033). The dynamics show the growth of private medical organizations over the years. Medical organizations do not pay taxes (VAT and Corporate income tax). However, the share of shadow private medicine is big. Investors are actively investing in polyclinic services, where the return on investment is much faster. Stationary care is provided by the state and it is difficult to compete with it. The payback period of private medical projects is usually hard to calculate, as this indicator is very individual, as well as the cost of the projects themselves. They can range from several million to several tens of millions of dollars. Local investors are much more inclined in contributing to Kazakhstan's medical market. There are few foreigners, which opened medical chains here, among them are Health City (South Korea) and Sema (Turkey). The quality of services provided by local private medical clinics do not considerably differ from the ones provided by foreigners, while the prices in Kazakh clinics are much lower. After the introduction of the Single National Healthcare System (SNHS), the cooperation with the government started to actively promote the development of private healthcare industry. State project on the development hemodialysis services, caused that 2/3 of hemodialysis centers in Kazakhstan are now private organizations. In 2016, 36.7% of private medical organizations provided services within the guaranteed volume of free medical care. In some private clinics (e.g. Sema), public contracts bring more than 50% of the overall revenues.

Financing

- Public health care is funded by a single insurer for each region: the regional health departments.
- Role of voluntary health insurance (supplementary) is minor and is estimated to account for approximately 2% of Total health expenditure. (WHO)

• Private health expenditure is predominantly via OOP.

Delivery

- The private sector is well integrated with the public health system.
- Primary, secondary and tertiary care are mixed, as are clinical support services and long-term care.
- The private health sector is small but growing.

Key challenges and/or reform agenda

- The trend has been towards decentralization of health care organization and financing.
- The current reform program prioritizes the remodeling of the health finance system and introduction of a mandatory insurance fund by 2018.

Healthcare infrastructure

As of Jan 01, 2017, there were 840 medical institutions (secondary care) in Kazakhstan: 670 public hospitals and 170 – private ones. The primary care consists of 2,718 outpatient clinics (1,856 of them are public, and 862 – private). Healthcare for the rural population is being provided by 143 central and district hospitals, 142 rural district hospitals and rural hospitals, 198 rural and rural district outpatient clinics, 1,328 medical and family medical dispensaries, 20 centers of the PHC, 3,987 paramedic and medical posts. The total number of hospital beds has declined in 2016 to 87,287 from 89,962 in 2015 or by 3%. Hospital beds coverage decreased by 4% for the same period: from 50.9 to 48.7 per 10,000 of the population. The total number of hospitalized patients in Kazakhstan in 2016 reached 2,727.2 ths vs 2,645.8 ths in 2015 or by 3% more. Preliminary reports by the Kazakh MOH indicated the increase of the physician's force in the country in 2016 vs 2015. The total number of physicians in Kazakhstan grew from 52,398 in 2015 to 53,682 in 2016 or by +2.4%. The coverage of the population by physicians has grown for the same period by +2.4% from 29.7 to 30.4 per 10,000 of the population. The nursing staff number grew by +2.8% in 2016 compared with 2015: from 138,851 to 142,734 workers. The coverage of the population by the nursing staff increased from 78.6 in 2015 to 79.7 per 10,000 of the population or by +1.4%. Average monthly salary of a physician in Kazakhstan in 2017 was KZT 139 ths (USD 428). Physisians from Aqtobe region have the lowest salary – KZT 110.2 ths, the highest salary KZT 170.5 ths in Astana.

Healthcare state budget

State public funding of the healthcare sector in the Republic of Kazakhstan traditionally is among top priorities for the government. In 2017 the total public spending on the healthcare in the country decreased by 2.6% vs 2016 and reached KZT 1.075 trln or USD 3.30 bn. The structure of total public spending on the healthcare will significantly change in 2017 as well. Previous years on average 64% of all public spending had been sourced from the local budgets, while starting from 2017 republican budget spending rose by +82% making the republican budget the key source of funding the healthcare in the country. The total republican budget spending for 2017 was at KZT 717 bn (USD 2.08 bn) and the local budget accumulated KZT 386 bn (USD 1.12 bn). About KZT 599 bn (USD 1.75 bn) were allocated for the provision of healthcare services and products for the population of Kazakhstan in 2016 within the framework of the Single system of the healthcare. These funds were allocated for the treatment of seriously ill patients, purchase of medicines, surgical operations, medical infrastructure enhancement. For 2017 the financing of the system was increased by +29% to KZT 771 bn (USD 2.23 bn). The total public financing of oncology patients in 2017 was at KZT 35.7 bn, not changing notably vs 2016. The government has allocated KZT 1.88 bn (USD 5.45 mio) for the treatment of TB and HIV patients in the country in 2017.

6 000 5 000 4 000 Local budgets 3 435 2 852 3 164 2 449 3 000 2 574 ■ Republican 2 000 (central) budget 2 199 1 000 2 049 1 823 1 792 1 614 1 323 1 148 0 2011 2012 2013 2014 2015 2016 2017

Figure 13. Kazakhstan national healthcare budget 2011-2017, USD mio

Source: Vi-ORTIS: UPharma Consulting

Provision of pharmaceuticals through state budget

Public provision of pharmaceutical products for the funds of the State budget in Kazakhstan is being provided by a single distributor – SK-Pharmacy, and directly by regional healthcare bodies and hospitals. SK-Pharmacy was founded in February 2009 by the Order of the Government of Kazakhstan. In 2013 the distributor was transferred into the 100% ownership of the Ministry of Healthcare of the Republic of Kazakhstan. The main function of SK-Pharmacy is to purchase and deliver medicines and medical devices for the healthcare institutions across the country in the framework of GVFMC. Public purchases and provision for the GVFMC are not subject to the scope of legislation on public procurement in Kazakhstan but are carried out in accordance with special rules for the procurement of medicines, preventive (immunobiological, diagnostic, disinfectant) medicines, medical products and medical equipment, pharmaceutical services for the provision of GVFMC. Pricing control during the public purchases for GVFMC is done by the Committee for Control of Medical and Pharmaceutical Activities of the MOH of Kazakhstan. In 2017 the GVFMC increased 4.1% y-o-y to KZT 924 bn (USD 2.83 bn). The cost of provision of drugs and medical devices within the GVFMC increased in 2017 to KZT 192.5 bn (USD 590 mio). Outpatient drugs coverage (drugs and medical devices), which is a part of the GVFMC, reached KZT 96 bn (USD 294 mio) in 2017, growing by +5% in KZT vs 2016.

Social health insurance scheme

In 2017 the government once again postponed the launch of the compulsory medical insurance (CMI) system to 2020. However, since July 1, 2017 some employers started making monthly premiums for insurance of their employees. If in 2017 they paid 1% of the salary of the employee, then in 2018 and 2019 this amount will be 1.5% of the salary, 2% – in 2020, 3% – after 2022. If a citizen belongs to a preferential category the state covers the insurance expenses for him/her. In total there are 14 categories of citizens who have the right to free insurance from the state – among them children, unemployed, unemployed pregnant women, nonworking people who raise a child under three years old, disabled and others. An individual who does not have a permanent income and does not enter into a preferential category will pay for himself 5% of one minimum wage monthly since January 1, 2020. The government strives to implement a mixed model of medical

insurance, considering best world practices. The Mandatory Social Health Insurance Fund will manage two financing flows. The first is the guaranteed amount of medical insurance, which will be presented regardless of the availability of insurance premiums and will be available for every citizen of the Republic of Kazakhstan. It will include preventive vaccinations, ambulance, ambulance, emergency medical services, inpatient and inpatient medical care for socially significant diseases (oncology, psychiatry), as well as for diseases that pose a danger to others (tuberculosis). The second flow will cover the expenses on insurance package, which will include: outpatient medical care, hospital treatment, nursing care, rehabilitation treatment, high-tech medical services and palliative care. The government will sign agreements with some (but not all) state and private hospitals and medical clinics. The Mandatory Social Health Insurance Fund will cover a treatment based on a list of medical services approved by the Health Ministry, drawn up on the advice of healthcare workers.

Epidemic statistics

The Head of the MOH has reported about positive natural population growth in the country in 2016 compared with 2015 at +2.6% (from 15.2 in 2015 to 15.6 in 2016). The birth rate in the country grew up by +1.4%: from 22.7 in 2015 to 23.0 live births per 1000 of the population in 2016. According to the official data issued by the MOH the mortality rate in the country in 2016 has declined compared with 2015 by 1%: from 7.5 to 7.4 deaths per 1000 of the population. North Kazakhstan, Kostanay, East Kazakhstan, Akmola, Qaraghandy, Pavlodar and West Kazakhstan regions are those with the highest mortality rates in the country. The major causes of deaths in the country are DCS (acute cerebrovascular insufficiency, myocardial infarction), malignant neoplasms, accidents, injuries and poisoning, which make about 50% of the total deaths in Kazakhstan. The incidence rate of the entire population in Kazakhstan was 56,823 per 100 ths of the population compared to 52,410 in 2015. Incidence rate of DSC in 2016 slightly decreased to 2,413 from 2,430 cases per 100 ths of the population in 2015. The highest incidence rates were registered in the Almaty city (3180), North Kazakhstan (3137), East Kazakhstan (2999), South Kazakhstan (2808), Zhambyl (2704) and Qyzylorda (2683) regions.

Table 8. Population increase by regions as on Jan 1, 2018

Region		Population increase		
		Overall	Natural	Migratory
The Republic of Kazakhstan	18 157 337	55 439	58 817	-3 378
Akmola region	738 942	660	814	-154
Aktobe region	857 711	2 755	3 196	-441
Almaty region	2 017 277	4 327	7 901	-3 574
Atyrau region	620 684	3 227	3 300	-73
West Kazakhstan region	646 927	1 312	1 655	-343
Zhambyl region	1 117 220	1 299	4 419	-3 120
Karaganda region	1 380 538	-25	1 841	-1 866
Kostanay region	875 616	-933	376	-1 309
Kyzylorda region	783 156	3 084	3 515	-431
Mangistau region	660 317	4 386	4 044	342
South Kazakhstan region	2 929 196	14 640	15 000	-360
Pavlodar region	754 854	-146	978	-1 124
North Kazakhstan region	558 584	-956	3	-959
East Kazakhstan region	1 383 745	-902	1 373	-2 275
Nur-Sultan city	1 030 577	9 027	5 905	3 122
Almaty city	1 801 993	13 684	4 497	9 187

a) Diseases of the Circulatory System

The highest mortality rates of DCS in Kazakhstan were registered in Qaraghandy (331), Aqmola (269), North Kazakhstan (250), West Kazakhstan (218), Pavlodar (217) and West Kazakhstan (218) regions. These steps allowed to decrease the overall mortality of the DCS in 2016 by 7%, including acute myocardial infarction – by 10%, acute cerebrovascular insufficiency – by 9%. DCS hospitalized incidence increased by 3% to 226.6 in 2016 compared with 220.2 in 2015. Three new Stroke centers, Percutaneous coronary intervention center, were opened in the country in 2016. The number of cardiac surgery operations in Kazakhstan has increased in 2016 (36,027) by 10% vs. 2015 (32,604), including 11862 open-heart surgeries (CABG; vs 11,193 in 2015) and 24165 (vs 21,411 in 2015) interventional surgical procedures.

b) Malignant neoplasms

Incidence rate of malignant neoplasms in Kazakhstan in 2016 slightly decreased compared with 2015: from 207.7 to 199.1 per 100 000 of the population. The highest incidence rates of these diseases were registered in North Kazakhstan (338), Pavlodar (302), Qostanay (300), East Kazakhstan (298), Qaraghandy (290) regions. Kazakh State Statistics Committee had registered an insignificant decrease of the mortality rate from malignant neoplasms in the country in 2016 compared to 2015: from 92.0 to 88.8 deaths per 100 000 of the population. The highest mortality rates were in Pavlodar (143), East Kazakhstan (131), North Kazakhstan (126) and Aqmola (122) regions. The overall number of oncology patients on the dispensary treatment and a number of newly diagnosed cases of malignant neoplasms in the country has grown from 156,280 of patients in 2015 to 163,080 of patients in 2016 or by +4%. There are 3,950 of specialized oncology beds in the country or 2.3 per 10,000 of the population. Oncology mortality rate in Kazakhstan is the second highest after the DCS mortality rate. There were 15,763 oncology deaths registered in the country in 2016, of which – 48.3% persons of working age. Early diagnosis rate for oncology diseases has grown from 49.5% in 2011 to 58.5% in 2016. This had led to decrease in the proportion of neglected cases (late diagnosis) of oncology diseases from 14.4% in 2011 to 11.1% in 2016. The proportion of patients with the diagnosed stage I oncology diseases from newly diagnosed diseases increased in 2016 to 21.8% from 19.9% in 2015. In 2016 there were 36,998 patients identified with primary malignancies. The proportion of malignant neoplasms in the early stages is increasing:

breast cancer (stages I-II): from 92.9% in 2015 to 94.6% in 2016; colorectal cancer (stages I-II): from 81.6% in 2015 to 82.9% in 2016.

The annual coverage of screening in Kazakhstan for early detection of cancer is conducted for more than 2 million men and women of target groups aged 30 to 70 years. The screening has identified 2,204 neoplasms cases in the country in 2016:

- breast cancer total 895 cases (of which I stage 39.1%);
- cervical cancer total 189 cases (of which I stage 54%);
- colorectal cancer total 475 cases (of which I stage 21.1%);
- prostate cancer total 412 cases (of which I stage 38.8%);
- esophagus and stomach cancer total 221 cases (of which I stage 22.6%);

Yearly reimbursement of cancer treatment for patients in Kazakhstan has allowed to cover 86% of all patients with the specialized treatment. Accidents, poisoning, injuries in the structure of total mortality, mortality from accidents, injuries and poisoning ranks fourth, from which an average of 15,000 persons die every year. The total number of accidents, poisonings and injuries in the country decreased slightly in 2016 (3,224 cases per 100,000 of the population) compared to 2015 (3,270). The highest incidence rates were registered in Qaraghandy (5,923), Pavlodar (5,560), East Kazakhstan (4,473), North Kazakhstan (4,141), Qostanay (4,026) and West Kazakhstan (3,838) regions. The highest mortality rates from accidents, poisoning, injuries were registered in North

Kazakhstan (124), East Kazakhstan (121), Qostanay (110), Aqmola (104) and Pavlodar (99) regions. The total coverage of population by traumatologists in the country is 0.6 per 10,000 of the population.

c) Tuberculosis

Tuberculosis incidence rate in the country decreased in 2016by 9.9% to 52.7 per 100000 of the population from 58.5 in 2015. Incidence rate has decreased in all regions. The highest incidences rates in 2016 were registered in North Kazakhstan (73), Aqmola (71), Atyrau (66), Qyzylorda (65), Qostanay (62) and Mangghystau (59) regions. Mortality rate from tuberculosis has decreased by 17% in 2016 vs. 2015: from 4.1 to 3.4 deaths per 100,000 of the population. The total number of first diagnosed persons with tuberculosis has decreased from 10,255 in 2015 to 9,383 in 2016 or by 9%. Number of tuberculosis induced deaths for the same period declined by 16% from 721 in 2015 to 609 in 2016. In 2016, Kazakhstan has improved its position in The Global Competitiveness Report 2016–2017 by the World Economic Forum in the "Tuberculosis incidence" section by 9 positions: from 101 out of 140 countries in 2015 to 92 out of 138 countries in 2016.

d) Transplantology

Transplantology services are being provided in Kazakhstan by 10 medical centers (6 of them republican hospitals, and 4 – regional and city hospitals). There were conducted 1,034 transplantology surgical operations during 2012-2016 (including 65 in 2012, 164 in 2013, 224 in 2014, 275 in 2015 and 306 – in 2016). As of Dec 31st, 2016, there were 3,414 people in line for a transplantology operation in Kazakhstan (vs 3,054 as of Dec 31st, 2015).

Demographic statistics

As on Jan 1, 2018, the population of Kazakhstan grew by 231.2 ths persons or 1.3% y-o-y as compared to Jan 1, 2017. At the beginning of 2018, the population of the country amounted was 18,157.1 thousand people, including urban population - 10,426.5 ths persons (57.4%), rural population – 7,730.6 ths persons (42.6%). The number of births in Jan-Dec of 2017 amounted 390.5 ths persons, which is 4.7% less than in the corresponding period of 2016. The total fertility rate per 1,000 people was 21.65 births. The natural increase in the population of the Republic in 2017 vs 2016 decreased by 17 ths persons or by 6.1% y-o-y and amounted to 260.5 ths persons. The natural increase per 1,000 population was 14.44 persons. In the reporting period, the number of deaths amounted to 130 ths persons, which is 1.8% less than in 2016. The overall death rate was 7.21 deaths per 1,000 persons. In 2017 in Kazakhstan there were 3,150 infant deaths (under the age of one year) registered, 10.6% less than in 2016. The main cause of infant mortality is the conditions that arise in the perinatal period, which caused 1,586 infant deaths in 2017 or 50.3% of the total number of deaths among infants. The number of infants died from congenital anomalies was 731 (23.2%), respiratory diseases – 195 (6.2%) and from accidents, poisonings and injuries – 168 (5.3%). In 2017, the infant mortality rate amounted 8.07 cases per 1,000 births. As a result of the processing of information provided by the migration service, the number of migrants registered in the country in Jan-Dec 2017 increased by 20.5% y-o-y and amounted to 16,081 persons compared to the corresponding period in 2016, the number of migrants who left the country increased by 7.8% y-o-y and amounted to 37,704 persons, the balance of migration was 21,623 persons. The main migration exchange of the country was with the CIS countries: the share of arrivals from the CIS countries made up 72.1% of total; the share of those who moved to the CIS countries was 89.4% of total. The share of interregional migrants was 35.4% of the country's total internal migrants. The labor force as on Jan 1, 2018 amounted 8,976.8 persons, employed population – 8,541.3 persons (47% of the population). In 1Q2018, the average salary of one employee in Kazakhstan was KZT 152,442 (USD 477.6), growing by 2% vs 1Q2017. The unemployment was stable throughout 2017 and 1Q2018 amounting 4.9%. The youth unemployment was 4.1%

Abbreviations

ADB Asian Development Bank

AIPM Association of international pharmaceutical manufacturers

ATC Anatomical Therapeutic Classification of a drug

CABG Coronary artery bypass grafting CEE Central and Eastern Europe

CIS The Commonwealth of Independent States

CMI Compulsory Medical Insurance

CU Customs Union

DCS Diseases of the Circulatory System

EBRD European Bank for Reconstruction and Development

EEU The Eurasian Economic Union

GDP Gross Domestic Product

GMP Good Manufacturing Practice

GVFMC State Guaranteed Volume of Free Medical Care

IMF The International Monetary Fund

KazStat Committee on Statistics of the Republic of Kazakhstan

M&A Merger and Acquisition

Mio Million

MOH Ministry of Healthcare of the Republic of Kazakhstan

MOLSPP The Ministry of Labor and Social Protection of Population of the Republic of

Kazakhstan

NBK National Bank of Kazakhstan

OOP Out-of-pocket payment
OTC Over-the-counter drugs
PHC Primary Healthcare

RK The Republic of Kazakhstan SES Single Economic Space SHC Secondary Healthcare

SHIF Social Health Insurance Fund
SHIS Social Health Insurance Scheme

SOE State-owned Entreprises
THC Tertiary Healthcare
WB The World Bank

WHO World Health Organization y-o-y Year Over Year Growth

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