



BELARUS PHARMA MARKET REPORT



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Introduction

Belarus' pharmaceutical market is expected to grow at a rate above average. The introduction of a basic reference pricing methodology will improve transparency of the market, but may also result in downward price revision. The country's domestic pharmaceutical industry continues to expand rapidly, driven by contract manufacturing agreements and joint ventures.

In 2018 market touched \$ 1.18 billion and is expected to touch \$ 1.19 bn with a growth of 5.8% in 2019.

Latest Updates

- In January 2019, BelTA also reported that the incidence of HIV infections in the Minsk region fell by 15.8% in 2018, to 28.3 cases per 100,000, quoting figures from the Regional Center for Hygiene, Epidemiology and Public Health, which further revealed that men account for almost 60% of all HIV-positive individuals.
- According to BelTA reports, at the start of 2019 general practitioners (GPs) accounted for 60.8% of the total number of primary care doctors, as the authorities launch the Caring Clinic initiative, which aims to make GPs gatekeepers to other medical services and also provide more personalised medicines.
- In the month of Jan 2019, it is reported that Belarusian and Indian delegations met to discuss further avenues for cooperation in the field of pharmaceuticals,

Strengths

- Continued double-digit local currency growth over a number of years with some accounted for by genuine demand increase.
- Extensive universal healthcare system supports a significant state drug purchasing sector yet it leaves a lot of room to improve.
- Government commitment to providing incentives to attract contract manufacturing.
- Pharmacies sell more of foreign-made medicines as they earn better margins.

Weaknesses

- Low per capita spending on pharmaceuticals with healthcare funding also negatively impacted by recent recession.
- Poor access to treatment in rural areas.

Opportunities

- Government's commitment to modernising the healthcare system.
- Increased demand for high-end products in urban environments.
- Authorities' support for local manufacturing could provide investment opportunities.
- Future potential for economic liberalisation and opening of economy as EU ties increase.
- Introduction of pilot reference pricing system increasing transparency.

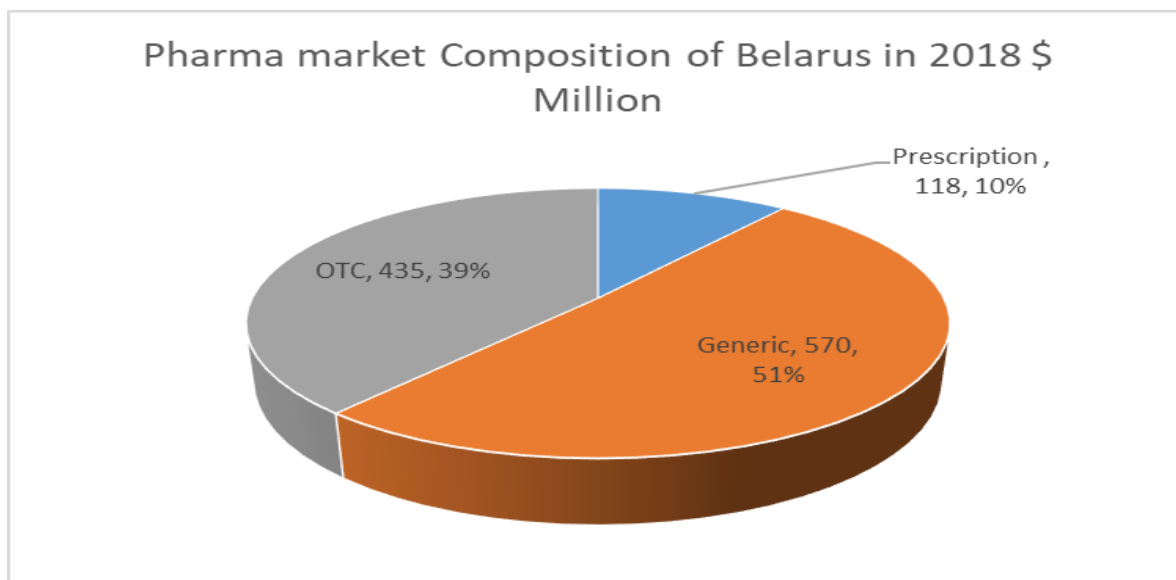
Market Overview

Belarus pharma market is set to touch \$ 1.19 million in 2019. It is expected that it would grow at cagr of 5% in the next five years and touch \$ 1.43bn by 2023. The pharmaceutical market in Belarus is likely to continue to lag behind due to the impact of Belarus' unstable currency and its faltering economic outlook in the short-term, with the majority of growth driven by inflation.

Belarus is seeking to boost its domestic pharmaceutical industry to reduce its reliance on foreign-made drugs given their increased price due to a weakened currency. The government of Belarus set a target for local production to account for 55% of the market by the end of 2020 - a significant rise from the 25-30% seen in 2012. According to government reports in January 2018, domestic production accounts for over 50% of the market. There has been significant investment into the country's domestic drug production industry, with particular focus on generic medicines, over the past year.

Domestically-produced product bias is shown through the tendering process, where they account for about 80% of the market share. This has led to growth within domestic firms but has limited opportunities for multinational drugmakers. Pricing control legislature, which was passed in May 2015, has also reduced the attractiveness of the Belarusian market.

The domestic pharmaceutical industry currently accounts for approximately 25% of local demand in value terms. There are currently 26 companies operating in Belarus, five of which are state-owned enterprises. The single biggest domestic player is Belmedpreparaty. Multinationals with a considerable presence in Belarus include Roche, Novartis, Sanofi, Nycomed, Gedeon Richter and Bayer Healthcare. The government's tendering system for pharmaceuticals is based on a reimbursement list heavily biased towards domestically produced generic pharmaceuticals.



Generic Drug market overview

Due to its economic issues a greater emphasis will be placed on generic medicines with expanding access to healthcare. This will be boosted by increasing domestic production. Moreover, the country's challenging business environment, highlighted by poor IP laws and large amounts of state intervention, will limit growth in the patented medicines sector.

Belarus is well positioned geographically to provide a manufacturing base for such products to serve both Central Europe and the Central Asia/Commonwealth of Independent States region.

In 2018 generic market in which India is interested constituted 49% of the total market touching \$ 569 million. By 2023 it is expected that it would touch \$ 767 mn with a cagr of 6.2%.

Generic products dominate Belarus's pharmaceutical market and will also continue to steadily increase their market share within prescription sales, from 82.6% in 2018 to 84.1% by 2028, with low prices precluding faster growth. Owing to the economic problems in the country that are limiting the purchasing power of Belarusian consumers and the public healthcare system for high valued drugs - as well specific measures aiming to decrease import dependence – may support this trend for foreseeable future

As government has very ambitious plans for developing generic industry to raise local production by 2023 to an extent of 60% will leave an opportunity of \$ 220- 230 for generic exporters to Belarus.

Pharmaceutical Trade

Local manufacturing improvements and government support will serve to correct the negative trade balance to an extent and also reduce import reliance. However, over the coming five years, major changes may not be seen as, innovative medicines continue to be supplied through imports. At the same time, however, expanding domestic capacities should be able to take advantage of the rising regional demand for generics.

Pharma imports reached \$ 694 million in 2018. At a CAGR of 3.5 imports may touch USD 825mn by 2023.

Belarus is also well positioned to become a pharmaceutical export hub within the CEE region, given its proximity to some of the largest pharmaceutical markets in the region - Russia, Poland, Romania, and Ukraine. Furthermore, it has strong economic and trade ties to the former Soviet CIS countries further to the East

Eurasian economic union

The proposal for a Eurasian Economic Union (EAEU) medicine market aims to increase accessibility to safe, effective and quality healthcare and medicines, through the elimination or minimisation of administrative barriers between the member states. Talks have been ongoing for many months with a view to initiating a single medicine marketplace for Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia; however, there have been constant delays and disagreements over the regulations. In November 2016, the Eurasian Intergovernmental Council agreed on a package of documents to launch the single medicines market. Discussions regarding common legislation are on, this development greatly increases the possibility of a fully functional single market in the short term.

It is this formation that might pose difficulties for India's exporters as it would be difficult to compete with fast developing Russian industry which will gain local status and may shrink the available generic opportunity.

India's exporters need to necessarily setup units in the Eurasian economic union either independently or in JVs.

Regulatory Review

Drug registration should take place within 180 days but in the past has reportedly taken up to 12 months. A company seeking to enter the market must register with the Ministry of Health and it receives a certificate valid for five years. Registration of pharmaceutical substances must be renewed every year. Information supplied with drugs such as the summary of product characteristics (SPC) must be written in either Russian or Belarusian.

The main regulatory body - the Department of Pharmaceutical Inspectorate, which operates under the Ministry of Health, is not independent like most similar bodies in the region. The inspectorate ensures legal entities and individual entrepreneurs comply with national legislation and certify good manufacturing practice (GMP) compliance.

A 2002 decree requires batch testing of imported and domestically produced pharmaceuticals. The Republican Centre for Examination and Tests in Healthcare verifies bioequivalence tests and results of clinical studies in order to avoid the necessity for retesting of pharmaceuticals entering the market. Drug manufacturing facilities do not need to be checked if inspections have recently been made by other recognised, competent authorities such as the US Food and Drug Administration (FDA). It is understood that this exception is being extended to manufacturing facilities in Russia and Kazakhstan under the customs union, although the timetable for harmonisation is uncertain. In June 2012, the testing centre received WHO prequalification, allowing it to conduct testing on medicines for UN and other international bodies.

India's investments :

- In January 2017, the Chairman of the Republic of the National Assembly announced that at least three pharmaceutical plants will be established in Belarus with Indian cooperation in the next two to three years.
- Construction of a pharmaceutical plant for a joint venture between Indian Lok-Beta Pharmaceuticals and Belarusian Belmedpreparaty, Novalok, began in January 2017. According to the Chairman of the Council of the Republic of the National Assemble, at least three Indian-Belarusian pharmaceutical plants will be built in the coming years.

- A joint Belarusian-Indian public-private partnership (PPP) pharmaceutical firm, DzhivaFarm, began construction of its production facility in August 2016, with an expected start date for commercial production in 2018. The facility will be focussed on the local production of generic medicines to treat diseases such as cancer and hepatitis, with the aim of producing drugs at as much as five-to-seven times less than current market value.
- The construction of a new generic drug factory specializing in treatments for cancer, autoimmune diseases and severe infectious diseases will be completed by the end of 2016. The newly-formed NatiVita is building the plant at a cost of USD15mn, and has received investment from pharmaceutical firms Natco Pharma (India), Biocad (Russia), Belarusian medicine distributor VitVar, as well as Lithuanian investment company ZIA Valda.

Advantages of Belarus as an investment center:

In January 2012, plans were unveiled to create a pharmaceutical cluster in the country aimed, partly, to attract contract production of innovative pharmaceuticals for foreign companies without an existing production presence in the CIS. This is something of a new approach for the authorities, which have previously emphasised import substitution, production of primarily generic medicines and vaccines. The project envisages guaranteed government purchases of medicines produced in the country. Given the limited size of the country's pharmaceutical market, Belarus' domestic industry will provide opportunities for exports to neighbouring markets. Belarus is well positioned geographically to exploit the growing demand for medicines in the CEE region. It is surrounded by some of the largest pharmaceutical markets in the region - Russia, Poland, Romania, and Ukraine are all in the top eight in the region for sales in 2016. Furthermore, it has strong economic and trade ties to the former Soviet Commonwealth of Independent States (CIS) countries further to the East. Every single one of these countries is highly reliant on pharmaceutical imports due to a lack of scientific expertise and domestic pharmaceutical manufacturing infrastructure. Moreover, the impending formation of the Eurasian Economic Union (EAEU) single medicines market – joining Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia - will provide a lucrative market.

Statistics:

India's Imports

India Pharma exports to BELARUS by Category \$ Million					
Category	2015-16	2016-17	2017-18	2018-19	Change%
Bulk Drugs & Drug Intermediates	3.67	6.28	3.28	4.24	29.46
Drug Formulations & Biologicals	11.55	9.85	8.67	11.54	33.06
Ayush	0.35	0.08	0.45	0.16	-64.76
Herbal Products	0.00	0.00	0.01	0.00	-66.63
surgicals	0.28	0.32	0.45	0.40	-11.38
Vaccines	0.07	0.00	0.00	0.00	
Total	15.92	16.54	12.86	16.34	27.11

Belarus Imports

Top Ten Importing Partners of Belarus \$ Million						
Rank	Country	2015	2016	2017	Gr%	Share%
1	Russian Federation	68.83	86.82	100.06	15.25	13.84
2	Germany	72.83	69.60	79.66	14.45	11.02
3	France	38.00	38.09	49.16	29.06	6.80
4	India	40.24	40.26	47.03	16.79	6.51
5	USA	39.63	28.28	35.04	23.91	4.85
6	Hungary	33.42	29.56	31.18	5.48	4.31
7	Italy	27.55	30.13	29.75	-1.26	4.12
8	Canada	1.77	4.23	27.37	547.65	3.79
9	Poland	25.81	20.85	26.93	29.19	3.73
10	Austria	25.85	21.69	22.93	5.74	3.17
	World	609.71	606.63	722.93	19.17	100.00

Source: UN comtrade