RUSSIA MARKET REPORT

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Contents

Introduction

Russia's economic recovery has returned the market to its former position as a key emerging growth driver. Innovative drugmakers will remain averse to the high levels of risk within the market and as such generic medicine sales, in house manufactured, will be the major beneficiary of this growth.

In November 2016, a report was published by the Russian government outlining plans to subsidizethecost of producing medicines on the Vital and Essential drugs list.

According to Russian market research firm DSM, 56% of all medicines sold in September 2016 weredomestically produced, with a market share of 28% in value terms.

Russia Pharma market has recorded a negative growth of 27% and reached $ 15.9 bn in 2015. However the market has grown by 3.14% in 2016 and has touched $ 16.4 bn. The size of the market in 2017 is $ 20.1 billion with a growth of almost 22.4%. Forecast for 2018 speak of2.8% growth and the size touching $ 20.7 bn.

Latest Updates

- In August 2018, the Russian Ministry of Industry and Trade prepared the draft Pharma 2030 strategy, which aims to increase Russian medicine exports by 10 times by 2030, relative to 2017.
- Reflecting the increased localisation of multinational drugmakers' products in Russia, AbbVie and Takeda completed the localisation of production of a number of products with two domestic drugmakers in July and August 2018 respectively.
- In July 2018, the Russian government announced plans to increase VAT from 18% to 20%, with additional revenues set to be funneled towards financing infrastructure, healthcare and education. While the exact allocation of additional funds between these sectors is unknown, it is reported that this increase will generated annual revenues of RUB600bn (USD8.79bn).

Protectionist Measures

On December 29 2015, President Vladimir Putin signed Federal Law No. 389-FZ 'On Amendments toCertain Legislative Acts of the Russian Federation', which came into effect at the turn of the year. The new legislation, which amends the Law on Circulation of Medicines, allows foreign drugmakers to be defined as domestic players if their drugs are packaged in Russia, even if they are produced outside of the country.

However, this concession will last only until the end of 2016; from 2017 onwards medicines must be produced in their finished dosage form in Russia to be considered as domestic. The government already applies a domestic bias to the medicine tendering process; if two domestic drugs are available for tender no foreign products may be considered. The new legislation will severely impact multinational pharmaceutical firms given this bias.

In November 2017, it was announced that the government had finalized a draft resolution updating the regulations for state medicine tenders amending the above law. **The new regulations stipulate a price preference of 25% for products produced in a full cycle (from production of the active pharmaceutical ingredients to formulation of the product) in a country in the Eurasian Economic Union. This resolution is set to enter force on January 1 2019.**

The government has isolated certain segments of the market for sole-supply contracts given to Russian companies and in 2017 also ammended a number of regulations regarding subsidies to localdrugmakers; both of these discriminate against multinational pharmaceutical firms.

Strengths:

- Largest market among Central and east European countries.
- Long-term growth in pharmaceutical consumption for the industry, due to the absolute population size, demographic trends and economic development.
- Strong market growth for generic drugs will continue as low purchasing power and a desire to moderate government pharmaceutical expenditure persist.
- Pharmacy chains account for 65-70% of the pharmacy market, thereby providing drug makers with volume purchasers for their products.
- Amongst the highest disease burden per capita of non-communicable diseases, providing a significant demand for chronic disease medicines.

Weaknesses:

- The government's drug pricing, reimbursement and purchasing policies are complex and opaque, with a history of sudden changes in policy without consulting manufacturers.
- The enforcement of patent laws and other regulations will likely remain weak, while the courts are a costly and unreliable last resort.
- Plans designed to increase the share of domestically produced pharmaceuticals pose risks for firms exporting to Russia.

Market Overview

The Russian pharmaceutical market is one of the largest globally and is the largest market on an absolute basis in the Central and Eastern European (CEE) region. Russia's pharmaceutical expenditure per capita, at USD 140 in 2017. It is 17th highest among 32 CEE countries.

Pharmaceutical sales in 2017 was at USD20.1bn, and is said to have grown over 22.42%. By 2022, it is forecast to reach USD24.1bn, with a five-year compound annual growth rate (CAGR) of 3.7%.

Russia's epidemiological profile resembles that of other CEE states, with non-communicable diseases such as heart disease, stroke and cancer the leading causes of mortality and morbidity in the country. The largest contributor to the country's disease burden was cardiovascular diseases; however, the high incidence of HIV in the country results in communicable diseases being the second largest contributor to the country's disease burden, ahead of cancers. Russia has recorded the highest number of new cases during 2014-2016 in the region says many reports are not properly documented by the government. It is also reported that only 34% of HV positive cases are on Anti-retroviral therapy.

Like many European and middle-income markets, pharmaceutical sales in Russia are currently dominated by foreign players such as Roche, Sanofi, Johnson & Johnson and Bayer Healthcare who sell high-value, innovative therapies at steep mark-ups and run effective monopolies on those products through patent protection. Domestic players such as Pharmstandard, Veropharm and Pharmsynthez are focused primarily on generics, which provide stable returns but do not offer the returns that enable ascension through the value chain of pharmaceuticals. These companies have also entered partnerships with multinationals to licence production of their patented products for sale in the Russian market, in order to circumvent protectionist policies.

However, recent legislative changes make access difficult for companies particularly those without a physical manufacturing presence in the country, given legislative changes in line with the country's Pharma 2020 vision; the market share of domestic medicines continues to rise.

Russia has taken several initiatives to increase domestic production. One such initiative is the amendment to the law governing the registration of medicines, effective since January 1 2016. As of this amendment, from 2017, medicines must be produced locally in their final dosage form to be registered as a domestic medicine. This is a key development given the country already applies a very harsh domestic bias in state medicine tenders, whereby a non-domestic product will not be considered for tender if there are two-such domestic products available.

Generic Drug market:

Government initiatives to encourage generic use will drive generic drug sales over the long term. Generic drugs will become increasingly important in total drug sales, driving growth in the pharmaceutical market. Posing risks are the increasingly competitive environment given the heavy amount of investment within the domestic generic industry.

The generic market size is estimated at $ 8.2bn in 2017 and is said to have grown by 27% accounting for 41% of the total market. By 2022 the market is expected to touch $ 11.2bn with a Cagr of 6.3%.

India's exports ofGenerics to Russia during 2017 has grown by 21% less than the generic domestic sector size(27%as describedabove) indicates domestic production is fact catching up and India's exports may not be able to retain the present share.

This is principally because the technical expertise and infrastructure in the country is not up to WesternEuropean standards and the patent protection landscape still leaves much to be desired. Low-cost drugs andself-treatment represent the only access to healthcare for a large segment of the population, and governmentpolicies that aim to initiate reimbursement over the medium term involve purchasing cheaper generics in large procurements.

The Kremlin's Pharma 2020 initiative has led to a significant investment into the country'sdomestic pharmaceutical market. This has been exacerbated by the depreciation of the rouble, makingforeign imports prohibitively expensive. However, currently, the majority of the investments made bymultinational pharmaceutical firms in Russia have been focused on the generic medicines segment; According to the country's Minister of Health Veronika Skvortsova, 70 medicinefactories for the packaging and production of medicines have been built since the start of 2014. This rapidincrease in medicine production facilities, often aided by the state, will create an increasingly competitivemarket; some of the lax patent laws also benefit the generic industry.

Longer-Term Export Opportunities

While in the short-to-medium term, Russia's domestic market is expected to provide significantopportunities to drugmakers, there are also secondary benefits from forming a generics manufacturing basein the country. The Eurasian Economic Union (EAEU) single medicines market will provide longer-termexport potential; also circumventing EU and US sanctions and the pitfalls of the acrimonious relationshipwith the West. The single medicines market aims to have a singular code for drug registration andregulation, as well as to allow the free trade of medical products among Armenia, Kazakhstan, Kyrgyzstan and Russia.

Some reports suggest currently (months of April & May of 2017) has seen domestic **production meeting more than 50% of generics required.** Government aims at meeting 90% of essential medicine's to be produced locally by 2020.

Pharma Trade:

Russia's Pharma 2020 policy will continue the expansion of domestic pharmaceutical manufacturing, reducing the reliance on imported medicines especially generics. While much of the increased domestic production will serve the Russian population, the high-growth markets of neighboring CIS States will provide opportunities for exports. This policy will continue over the long-term as increasing pharmaceutical exports is a key part of the Pharma 2030 policy, currently under development.

Pharmaceutical imports reached USD 10.4bn in 2017, posting y-o-y increase of 22.1%(mostly due to Ruble Devaluation). Forecasts for 2018, show imports might touch USD11.2bn. In the next five years imports might grow at a compound annual growth rate (CAGR) of 5% to reach USD12.89 bn by 2022.

Regulatory

The main healthcare regulatory agency in Russia is Roszdravnadzor, under the Ministry of Healthcare and Social Development, which replaced the previous Ministry of Health as part of wide-ranging ministerial and agency restructuring in 2004.

The new legislationestablished a state pharmacopoeia and introduced legislation relating to the import and export of medicine, as well quality control and labelling. Itfocuses on setting up a precise and transparent process for registering medicines, with a detailed descriptionof all the requirements for the state approval of drugs and registration procedures. The maximumregistration time for new drugs has been set at 210 business days, equivalent to around 10 months,compared to 18 months or more in the past.

The Medicines law ends the practice of open-ended registration certificates for pharmaceuticals, with approvals limited to a validity period of five years for a first registration. An open-ended registrationcertificate may be issued in the event of a subsequent successful state re-registration. Notably, medicinesdesignated exclusively for export will not be subject to state approval. Furthermore, the new registration andre-registration regulations allow the government to determine the prices of medicines on its List of Vital andEssential Drugs List. The law states that the drug may not be sold at without the registration of a price, andit cannot be sold at a price higher than it was registered at.

Russia has also made moves to more closely align its legislation with EU norms. Russia has officiallyincorporated EU Directive 2001/83/EC and its amendments into national law, as well as Regulation (EC)726/2004.

Legislation maintains that imported medicines are required to undergo clinical trials in labs recognized under Mutual recognized treaties. If the clinical trials are held outside of Russia, butfall under the international clinical trials mutual recognition treaties and/or the reciprocity principle, or if theforeign manufacturer included Russia in the international, multi-centre clinical trials, then the drug isaccepted. However, there are few countries that hold reciprocity agreements with Russia. Some observers claim that Russianregulation of clinical trials still falls short of international standards, particularly those regulating patient care.

The above law might pose difficulties to some Generics also in the categories of Dermatology, Ophthalmology, Respiratory inhalers and insulins as Russia intends to amend their regulations to fall in line with some advanced agencies like USFDA. However the date of those amendments are yet to be finalized.

Risk/Reward

The country is considered a high-risk, high-reward market, with significant growth opportunities partiallyoffset by the challenging operating environment, notably from the high degree of protectionism and the weak enforcement ofintellectual property rights.

Local Industry

The Pharma 2020 plan was split into three stages:

- Stage 1 (2009-2012): Localisation of pharmaceutical production and development in Russia; investment into new production facilities.
- Stage 2 (2013-2017): Development of domestic pharmaceutical production; implementation of import substitution policies for generic medicines; progress towards medical self-sufficiency.
- Stage 3 (2018-2020): Expansion of pharmaceutical exports; development of innovative medicine analogues to replace imported products; development of novel medicines.

By 2020, the plan outlines ambitious aims to increase the market share of domestically-produced medicines to 50% by value (up from 22% in 2010) while Russian-made medicines should account for 90% of the Vital and Essential drugs list. Moreover, the plan envisages medicine exports to reach USD1.3bn, up from RUB8.6bn (USD284mn) in 2010.

The strategic goal of import substitution was the principal initiative in the country's 'Pharma 2020' policy and is being accelerated with pressure from the highest levels of government, as Russia seeks to reduce its reliance on western countries for essential goods and move away from a purely hydrocarbon-driven economy.

The implementation of this vision has led to significant upheaval in the regulatory environment, with the introduction of adomestically-biased medicine tendering system and heavy-handed state intervention into the industry. As a result, domesticmedicine manufacturing capacity has risen significantly. According to the Minister of Industry and Trade of the Russian Federation,Denis Manturov, by September 2017 the share of Russian-made medicines was 32% (and 69% in volume terms) while the share ofdomestic medicines on the VED list was 83%

Generic drugmakers have a significant presence in the Russian pharmaceutical market, owing to the overwhelming reliance of the market on consumer spending. With most medicines purchased out-of-pocket (including prescription drugs), generics are the biggest single segment of the Russian pharmaceutical market. Indeed, in volume terms, generic medicines accounted for 85.5% of medicine demand in 2016. Almost all large global and regional generic drug makers are present in Russia such as Teva, Novartis (via subsidiary Sandoz), Gedeon Richter, Krka, Stada and Abbott Laboratories. Moreover, the majority of the investments made by multinational pharmaceutical firms in Russia have been focused on the generic medicines segment.

Statistics:

India's Exports Of Pharmaceuticals to RUSSIA in $ mn							
Category	**2014-15**	**2015-16**	**GR%**	**2016-17**	**Gr%**	**2017-18**	**GR%**
Bulk drugs	14.46	17.43	20.54	29.17	38	55.15	89
Formulations	399.12	343.54	-13.93	339.31	Nil	394.7	16.35
Ayush	9.44	9.23	-2.13	10.53	13	12.03	14
Herbal products	0.26	0.59	131.29	0.77	40	0.88	14
Surgicals	1.53	3.23	0.00	3.67	11	6.0	63.47
Total	424.80	374.02	-11.95	384	3	468.74	22.24
Source: DGCIS							

India's Pharma Exports to Russia during April-September $ Mn				
Category	Fy-18	Fy-19	Change%	change in Revenue
Bulk Drugs & Drug Intermediates	24.18	39.04	61.45	14.86
Drug formulations & Biologicals	201.69	192.48	-4.57	-9.21
Ayush	4.70	4.55		-0.14
Herbal Products	0.47	0.50		0.03
surgicals	4.29	5.19	20.92	0.90
Vaccines	0.00	0.00	-100.00	0.00
Total	235.33	241.76	2.73	6.43
Source: DGCIS				

Imports of Russia

Russia's Top ten formulation Importing partners $ Million						
Rank	**Country**	**2015**	**2016**	**2017**	**Gr%**	**Share%**
1	Germany	1742.34	1792.44	2272.61	26.79	20.82
2	France	700.27	817.84	951.43	16.33	8.72
3	USA	683.91	693.04	794.67	14.67	7.28
4	Italy	498.71	550.91	659.97	19.80	6.05
5	United Kingdom	429.15	414.19	594.72	43.59	5.45
6	India	468.12	455.26	561.10	23.25	5.14
7	Switzerland	477.10	487.09	560.83	15.14	5.14
8	Hungary	397.68	377.14	431.56	14.43	3.95
9	Netherlands	372.51	360.24	394.93	9.63	3.62
10	Slovenia	312.48	317.35	377.38	18.91	3.46
	World	8679.50	8978.41	10915.70	21.58	100.00
Source:UNcomtrade						

India is the sixth largest importing partner of Russia and the largest exclusive generic importing partner.