UZBEKISTAN PHARMA REPORT

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Introduction

Improving access to healthcare will remain a policy priority for the Uzbek government. International aid also helps uzbek govt in this direction. The expanding and ageing population, as well as increased income from a low base, are the possible drivers of the market. However, due to high levels of out-of-pocket spending onhealthcare and pharmaceuticals, access to high-end and costly health products will remain predominantlylimited to affluent population segments, while making the overall market sensitive to economic growth andconsumer confidence.

Uzbekistan is highly reliant on pharmaceutical imports, given the nascent nature of its domestic industry. As such, the extreme change in exchange rate in September 2017, when the Central Bank of Uzbekistan (CBU)'s devaluation of the soum (UZS), has made imports significantly more expensive. This has been incorporated into forecasts, and it is to be noted that access to medicines remains limited and largely confined to non-branded generics and over-the-counter medicine sectors.

Uzbekistan Government's efforts are in the direction of improving domestic pharmaceutical business environment through proper regulations, privatisations and also to consider FDI.

Pharma market was of the size $ 640 million in 2017 andis expected to touch $424 billion negatively growing during 2018. Market is expected to touch $ 888 million by 2022 with a cagr of 6.6%

Key Trends

In May 2018, new social pharmacy regulations came into effect, as the Cabinet Decree No 334, which stipulated a smaller recommended distance between pharmacies and approved the public-private partnership parameters.

In May 2018, Uzbekistani and Kazakhstani delegations discussed mutual trade and partnerships, looking to build on the strength of the established joint trading platforms that already cover key sectors, such as pharmaceuticals, agriculture and petrochemicals.

In April 2018, the residents of Boz and Qorgontepa districts of Andijan region were examined free of charge by Indian oncologists, cardiologist and nephrologists, as part of the GM Uzbekistan initiative. The company had fitted out a number of Clinic Pro clinics with modern diagnostic equipment

Also in April 2018, a new insulin producing plant, built at a cost of UZS28bn, operated by Zamin Bio Health and with the annual capacity of 10 million vials, came into operation in the Andijan Oblast. Around 30% of its output is reportedly earmarked for exports to Kyrgyzstan, Kazakhstan and other countries.

Uzbekistan's healthcare system will continue to suffer from human resource constraints, impedingimprovements in healthcare outcomes. While non-communicable diseases are on the rise, creating longtermopportunities for drugmakers, pharmaceutical firms focused on infectious and communicablediseases can also expect to see revenue growth given the burden of diseases such as HIV/AIDS,tuberculosis and respiratory diseases. However, the low affordability of pharmaceuticals and the limitedfunding capacity of the Uzbek healthcare system will moderate the level of access to certain therapies.

Strengths:

- Strong and Sustained market but of a low base.
- Government's commitment to increase access to health care
- Emerging State finance primary care centre.
- Well-developed state developed immunisation program

Weaknesses:

- Poorly enforced intellectual property rights and deficient regulations.
- Low per capita spending and low purchasing power

Opportunities for India

- Opportunities for Generic drug makers. As India has wide range and can offer at affordable prices.
- Growing relationship between the governments.
- Donor Organisations are modernising Hospitals and health care.
- Their Local infrastructure & technology being of Inferior quality, India's entrepreneurs are likely to have good opportunities for investment and/or offering technical assistance.

Market Overview:

Pharmaceutical expenditure in Uzbekistan reached 640 USDmn in 2017,(Estimates put the size in 2018 as $ 424 million) which compares as aslightly smaller pharmaceutical market than Slovenia's, standing among the five smaller pharmaceuticalmarkets within 20 countries in the Central and Eastern Europe region. Per capita pharmaceuticalconsumption is low, and was calculated at USD20.1 in 2017.

The market is expected to reach $888 million by 2022 with a Cagr of 6.7%. The per capita Pharma consumption by 2021 is expected to reach $26.1

Foreign companies have traditionally dominated via imports. Around 300 producers have some degree of presence in Uzbekistan's pharmaceutical market, and there are around 125 licensed producers. The 19th Tashkent International Healthcare Exhibition (TIHE) in April 2014 attracted around 150 companies from 22 countries, including both pharmaceutical and medical device manufacturers, providing some additional rough indication of interest in the sector. Most exhibitors (70%) were from foreign countries, including Austria, Belarus, Belgium, the UK, Germany, India, China and Italy, among others.**Approximately 12% were imported from India**. As of 2015, Uzbekistan remains dependent on imported pharmaceuticals, and multinational drugmakers continue to show caution prior to entering the market due to operating challenges and weak patent protection, despite ongoing marginal improvements in the regulatory environment.

Non communicable diseases like cardiovascular & Neuropsychiatric are a major concern. 5% of the population is estimated to be Diabetic.

Infectious diseases like parasitic infections, respiratory and T.B. are also a problem.As of2014, WHO's latest available data reports HIV prevalence at 104 per 100,000 population (compared toWHO Europe

Domestic Industry caters to 32% of the requirement in terms of Volumes.

In 2012, major FDI operations in the pharmaceutical industry in Uzbekistan were dominated by the UK(60%), Turkey (26%), India (12.5%) and Germany (1.5%).

Generic Market

Sales of generic drugs reached a calculated value of USD316 mn in 2017, and are expected todecreaseto USD209 mn in 2018. In 2017 generic medicines accounted forjust under half ofthe market (49.5%) in value terms and an overwhelming share in volume terms. Generic drugs dominate thepharmaceutical market due to cost considerations and availability, and also account for virtually all ofdomestic production. Generic market is expected to touch $ 437 million by 2022 with a cagr of 6.2%

Several multinational generic drug manufacturers make up the top 10 rankings according to sales,specifically Berlin Chemie/Menarini Pharma, Sandoz-Lek, Krka and Gedeon Richter, underlining thedominant role of the non-patented prescription medicine sector. industry in Uzbekistan were dominated by the UK (60%), Turkey (26%), India (12.5%) and Germany (1.5%)

Pharmaceutical Trade

In September 2017, the Central Bank of Uzbekistan (CBU) devalued the local currency by 50% to UZS8,100/USD, in addition to removing currency controls and abolishing the country's dual exchange rate as part of the President's pledge to liberalise the economy and attract foreign direct investment.

Uzbekistan is highly reliant (over 90%) on pharmaceutical imports given the nascent development of its domestic industry. As such, this extreme change in exchange rate will significantly alter market growth as imports are made significantly more expensive.

In 2017, Uzbek imports reached a value of USD382mn, and this is expected to increase to USD657mn in 2022, growing at a CAGR of 11.5%.

The leading sources for imported medicines are Russia, Germany, Ukraine, India and Hungary.Commonwealth of Independent States (CIS) countries supply around 28% of the total registered drugs inthe country, ahead of Asian destinations (23%), but behind that of other European sources (30%). USimports account for less than 1%, with domestic producers accountable for the remainder.

Most of the imports are designed for retail sale (to the tune of almost 83% in 2010, according to officialsources). Of this figure, 54% by value were finished drugs, with a focus on antibiotics (around USD38mn),alkaloids (USD27mn), vitamins (USD28mn) and vaccines (USD17mn).

Chinese imports(Almost entire requirement of Bulk drugs of Uzbekistan is met by China) could receive a significant boost from the development of a free-enterprisezone near Khorgos in Xinjiang focused on chemicals and pharmaceuticals. This zone would have excellentgeographic access to Central Asian markets, including Uzbekistan.

Pharmaceutical companies in the country produced more than 1,320 types of medicines in 90 pharmacotherapeutic groups and 30 dosage forms, reports Turkiston press. Uzbekistan's pharmaceutical companies attracted a total investment of USD300mn, of which USD100mn was foreigninvestment from the early 1990s. Pharmaceutical products manufactured in Uzbekistan are exported toArmenia, Azerbaijan, Afghanistan, Georgia, Kazakhstan, India, Mongolia, Turkmenistan, China, andRussia, amongst others.

Regulatory Development

The Policy Centre for Medicines and Products for Medical Purpose controls the regulation ofpharmaceuticals in Uzbekistan, under the auspices of the Ministry of Health. It is not an independent body.The Centre is organised according to Order No. 570, which was implemented in December 2001. Theprimary legislation governing the sector is the law 'On Medicines and Pharmaceutical Activity'.

The resolution 'On Additional Measures To Improve The System Of Providing The Population With Medicines and Medical Products' was signed by President Mirziyoyev in August 2017, outlining a number of basic regulations to be put in place. This included the setting of maximum mark-ups for the wholesale and retail sector for medicines placed on the List of Socially Significant Medicines, and exemption from VAT for domestically-produced medicines. Compounding this development, two additional Presidential Decrees were signed in late 2017, further expanding on proposals put forward in the August resolution. Decrees UP-5216 (October 30 2017) and UP-5229 (November 7 2017) outlined a significant shift in market regulation in Uzbekistan. Firstly, the Agency for Development of the Pharmaceutical Industry (the agency) was created as a semi-independent subdivision of the Ministry of Health. The agency will be responsible for the following tasks:

- Developing and implementing a strategy for the sustainable development of the country's pharmaceutical industry, including the implementation of public-private partnerships.
- Coordinating the activities of pharmaceutical firms in implementing programmes to increase access to medicines for the population and public health institutions.
- Carrying out state registration and certification of medicines, including on imported medicines.
- To monitor pharmaceutical firms for compliance with international good manufacturing practice (GMP) standards

In addition, the State-owned firm Uzfarmsanoat, which was responsible for monitoring the country's pharmaceutical industry, overseeing state-owned pharmaceutical firms and coordination of major investment projects, was liquidated and its responsibilities were transferred to the agency. Other changes outlined in the Decrees include:

The reorganisation of the state-owned Uzmedexport Foreign Trade Association. The organisation has been renamed Uzmedimpex, which will be under the control of the agency. Through Uzmedimpex, the agency will perform centralised procurement of socially significant medicines for state medical establishments. Uzmedimpex will be exempt from paying all taxes, mandatory payments and customs duties until 2023.

The Ministry of Health will become responsible for the setting of prices of medicines on the List of Socially Significant Medicines.

The agency will also be responsible for the creation of a network of social pharmacies (for socially significant medicines) which is due to be fully functional by December 1 2018. Registration of domestic products must be supported by locally conducted clinical trials, with some exceptions (e.g.

if the drug is registered in several other countries, including the source country). A regulation passed in March 2012 reportedly bans 'multi-level' marketing of pharmaceuticals and other products, suggesting that this practice, which exists at the margins of the industry, may have emerged as a problem

Differing lengths of time have been reported for registering medicines already approved in other markets,from six months to significantly longer. Imported medicines are subject to centralised batch-testing by theDori-Darmon testing centre, controlled by the state-backed pharmaceutical wholesale company, inTashkent, which can lead to delays. In the past, some sources have suggested that the regulator lackssufficient skilled personnel and equipment, although it claims to have 18 working laboratories. Industry Sources mention regular delays in bringing goods through border checkpoints.

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Uzbekistan has more than 6,000 registered medicines and medical devices, of which around 70-80% are imported, although not all are marketed. The registry of medicines contains the brand, as well as generic names of the drug, and includes both domestically produced pharmaceuticals and imports.

Another tariff issue is the World Trade Organisation (WTO) accession of Russia, approved in late 2011, and Kazakhstan's accession in November 2015. This follows the previous implementation of the Customs Union of Russia, Belarus and Kazakhstan since mid-2010, which included common external tariffs on medicines entering this free trade area. These developments were likely to push foreign investors to focus on Russia and Kazakhstan. Uzbekistan has been a traditional market for Kazakh pharmaceutical producers, although even before the customs union, imports from the country had been falling due to Uzbekistan's import substitution policy, as well as broadly similar product portfolios among Kazakh and Uzbek producers. In July 2014 the Uzbek president signed a decree that provides for measures to assist in Uzbekistan's joining the WTO. The measures include making the national legislation correspond to WTO rules, obtaining support from key WTO members and conducting training and conferences on Uzbekistan's joining of the WTO, among others. The decree states that these measures are under consideration and have yet to be approved.

On July 1 2016, the Ministry of Health published a list of 129 approved drugs, specified in terms of international non-proprietary names, for the treatment of orphan diseases. In addition, Article 24 of the recently amended law 'On Medicines and Pharmaceutical Activity' determines that imports of orphan drugs can be carried out without state registration, thus simplifying access to such treatments.

Pharmaceutical Sector Reforms

The pharmaceutical development programme has aimed to increase domestic production ofpharmaceuticals to 50% of market volume by 2015. The programme envisages the involvement of foreign partners to supply partial investment and expertise, with the total value of the programme at about USD1bn. It could only touch 32% by 2016.

Foreign Pharmaceutical Industry

In 2012 the country took a decision not to allow foreign made formulations for Government procurement. Imports were reduced only to out of pocket expenditure. Between 1993 and 2013 September, FDI in pharma sector adds up to only $ 50 million.

In September 2011 Nova Pharm, an Indian-Uzbek JV, opened a small, USD2mn production line at a new plant in Termez in the far south of the country. A second line was planned. Initial reports did not specify the types of products to be made by the generic drugs plant. The facility was intended for both the local and export markets - ideally situated for exporting to Afghanistan, as well as Tajikistan; both countries with substantial demand, often funded by international aid organisations.

As of July 2015, Uzbekistan's pharmaceutical industry includes 146 local producers (132 manufacturers of medicines, seven manufacturers of diagnostic tools and seven manufacturers of medical supplies) - as reported by Uzbekistan's authorities at the bilateral Swiss-Uzbek business forum held on July 1, 2015 in Zurich, Switzerland. Despite the challenging business environment, foreign firms are present in Uzbekistan's pharmaceutical market. The government has tried to push through localisation; however, domestically manufactured medicines cater to only 32% of total drug demand by volumes. According to data reported in July 2015 by Uzbekistan authorities, out of the 7,214 registered drugs in the country, only 1,446 are produced domestically.

Official sources suggest that investments in the sector stood at around USD300mn in November 2014. Turkish and Indian firms have been leading foreign investors. Investments in the pharmaceutical industry are estimated to rise to around USD317mn in 2015, according to the UN Development Programme and Uzpharmasanoat. Investments between 2007 and 2012 under the Uzpharmasanoat holding stood at USD127mn (87.8% based on local bank loans and the companies own resources, with foreign direct investment accounting for the remainder). Foreign capital has a 69% share in the structure of pharmaceutical companies in the country, with local investors accounting for the remainder. In 2012, major FDI operations in the pharmaceuticals industry in Uzbekistan were dominated by the UK (60%), Turkey (26%), India (12.5%) and Germany (1.5%)

According to local media, Indian generic drugmaker Sharon Bio-Medicine announced plans to build a USD37mn antibiotics plant in the Navoi Free Industrial and Economic Zone, in partnership with Uzpharmsanoat. Uzbekistani banks were to provide loans of USD10mn for the project costs. Local media reported in Q412 that another Indian player, Medicamen Biotech, had signed a memorandum of cooperation for the country's first plant specialised in making oncology drugs. The new plant was due to be built in Tashkent with a budget of USD12mn.

Statistics:

India's exports to Uzbekistan $ million				
Category	2016-17	2017-18	2018-19	Change%
Bulk Drugs & Drug Intermediates	0.51	1.44	1.07	-25.73
Drug Formulations & Biologicals	36.97	44.23	58.78	32.92
Ayush	1.77	1.52	1.58	3.87
Herbal Products	0.03	0.03	0.05	80.98
surgicals	1.11	0.84	1.88	122.93
Vaccines	4.27	6.29	2.68	-57.35
Total	44.66	54.35	66.04	21.52

Imports of Uzbekistan

Top Ten Importing Partners of Uzbekistan $ Million						
Rank	Country	2015	2016	2017	Gr%	Share%
1	Russian Federation	75.06	66.69	72.04	8.02	12.69
2	Germany	55.62	54.89	70.79	28.97	12.47
3	Latvia	40.10	70.16	55.58	-20.78	9.79
4	Georgia	92.71	64.91	55.22	-14.93	9.73
5	Ukraine	38.00	47.04	52.65	11.93	9.28
6	India	49.44	42.86	44.84	4.62	7.90
7	Switzerland	23.97	34.55	34.85	0.88	6.14
8	Hungary	27.62	28.39	34.23	20.58	6.03
9	Belgium	18.94	13.03	33.40	156.43	5.88
10	Slovenia	40.14	20.87	23.30	11.66	4.11
	World	₹ 635.67	₹ 571.39	₹ 567.64	-0.66	100.00

India’s share in Uzbekistan Imports of formulations is 8.1%.

Issues & Suggestions:

1) In 2012 the country took a decision not to allow foreign made formulations for Government procurement.

   Suggestion: Uzbek authorities may be persuaded for India’s participation in Government procurement tenders at least by the Indian companies present in Uzbekistan irrespective of the range of products being produced locally.

2) Imported medicines are subject to centralised batch-testing by theDori-Darmon testing centre, controlled by the state-backed pharmaceutical wholesale company, inTashkent, which can lead to delays.

   Suggestions: India can suggest that Uzbek may designate quality testing centers available in Indiaof their choice and India's exports may get accredited through these centers which will help the products reaching the market fast, without losing precious shelf life waiting to be tested.