Indian Pharmaceuticals: Getting Back on Track

MIRAE ASSET LENS

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Executive Summary

India's pharmaceutical industry has weathered some challenging conditions since 2015 but better times are ahead.

As India's key export market, the US has seen an increased competition and channel consolidation culminating in price deflation in generic pharmaceuticals. A reduction in the number of products going off-patent resulted in a significant decline in US sales for most Indian players. Numerous regulatory red flags raised by the US Food & Drug Administration (FDA) related to failures to comply with Current Good Manufacturing Practice (cGMP) at key manufacturing plants added more woes for some Indian manufacturers. Regulatory and statutory developments in the domestic market, such as channel destocking prior to GST implementation, demonetization, expansion of drugs under government price control and increasing government initiatives for low-cost generics only heightened the sector's suffering.

Despite all of these short-term disruptions, generic drugs remain a vital pillar of affordable healthcare globally. Indian drug manufacturers, on the back of their proven prowess, will remain key beneficiaries of structural demand for affordable medicines. The headwinds which have impacted sales and profitability for Indian generics are abating, improving conditions in both export and domestic markets.

In the US, the declining price of generics is showing signs of stabilization with little room for further consolidation in the distribution chain. Pending FDA cGMP issues are being resolved and the industry has now factored in regulatory audits as a part of business. Indian manufacturers will soon begin to benefit from R&D investments in complex generics and specialty products, resulting in sales and profitability growth. At home, regulatory concerns have subsided and we predict the Indian pharmaceutical industry will soon return to double digit growth.

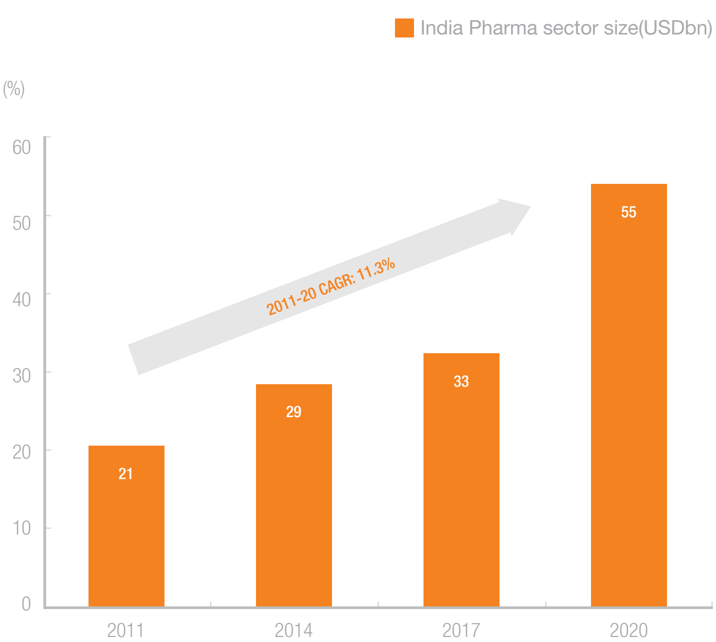
India's Clout in the Global Pharmaceutical Market

India is the world's largest supplier of generic drugs - Indian pharmaceutical manufacturers meet more than 50% of global demand volume for vaccines, up to 35% of demand volume for generics in the US, 25% of all medicines in the UK and more than 80% of the antiretroviral (ARVs) drugs used globally to combat Acquired Immune Deficiency Syndrome (AIDS). As per India Brand Equity Foundation (IBEF), the Indian pharmaceutical sector was valued at USD 33 billion as of the end of 2017 and is expected to reach as high as USD 60 billion by 2020, implying a CAGR of 18% to 21% between 2017 and 2020. The value of India's domestic pharmaceutical market is almost USD 18 billion, accounting for 55% of total pharmaceutical sales by Indian players.

India is a pharmaceutical powerhouse which remains well-placed to benefit from the global structural demand for low-cost generic medicines. The industry is supported by strong chemistry skills, a low cost manufacturing base and a large number of global cGMP-compliant manufacturing plants. India has up to 350 FDA-approved plants, the largest number of facilities with FDA cGMP compliance outside the US. An even greater number of India's plants are compliant with World Health Organisation and other Good Manufacturing Practices regulations.

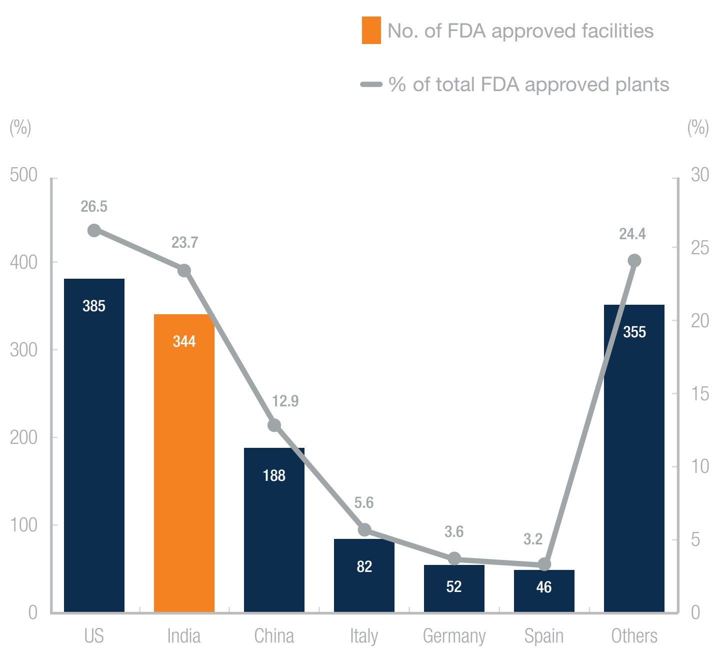
Indian Pharmaceutical Sector Growth Outlook Remains Robust

Source: IBEF, HSBC



India Has the Highest Number of US FDA Compliant Facilities after US

Source: FDA, HSBC

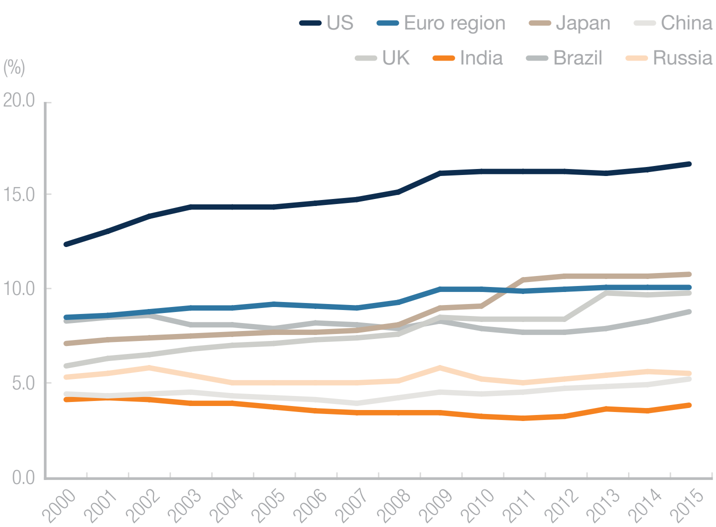


Demand Driven by Demography Trends and Healthcare Budgets

Demand for low-cost generic medicines worldwide is supported by demographic trends and healthcare budget constraints. Healthcare costs as a percentage of GDP have risen consistently in all developed countries and are expected to keep rising as their populations age further. In the US, which is the largest pharmaceutical market in the world, healthcare expenditures rose to nearly USD 3 trillion in 2015, or 17% of GDP. Costs are forecast to reach 20% of GDP by 2025 as per The Centers for Medicare and Medicaid Services (CMS). Governments in developing countries are increasingly focused on affordable, universal healthcare coverage with reduced out-of-pocket spending for patients. As developing countries gradually catch up with developed countries in terms of healthcare spend, a greater share of their expenses will be borne by the government.

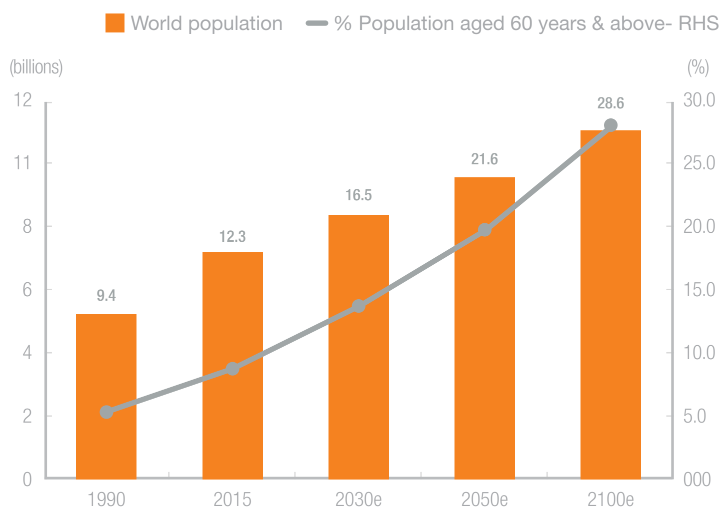
Healthcare Expenditure as % of GDP is Rising Globally

Source: World Bank data



The World Population is Ageing

Source: United Nations data



This demand for generic medicines is supported by the increasing focus on value in healthcare provision and greater price sensitivity from patients. Healthcare systems worldwide have achieved great savings from the usage of generics. In the US, generic drugs cost 75% to 90% less than their branded equivalents and account for around 85% of all prescriptions dispensed by volume. The FDA expects that competition will be crucial to bringing down the exorbitant costs of some prescription drugs. US President Donald Trump supports reducing the cost of prescription medicines promoting more affordable alternatives such generics and biosimilars. This should play significant role in lowering drug prices.

The Association for Accessible Medicine (AAM) estimates that the US healthcare system saved USD 253 billion in 2016 through the usage of generics, and cumulatively saved USD 1.67 trillion over the last decade. Medicines for Europe reports that the European healthcare system saved EUR 100 billion between 2014 and 2015 through the usage of generics.

All in all, demand for pharmaceutical products will rise in both developed and developing markets. In developed markets it will be spurred by an ageing population, increased incidence of chronic ailments, coupled with demand for affordable new specialty medicines. Developing markets will be impacted by a higher incidence of chronic ailments, rising disposable income, aspiration for better healthcare and increasing penetration of healthcare insurance coverage.

Medical Spend Growth will Continue to be Fastest in Emerging Markets

Source: IQVIA, HSBC

	2017 Spending (USDbn)	2013-17 CAGR (constant USD)	2022 Spending (USDbn)	2018-22 CAGR (constant USD)
Global	**1,135.1**	**6.2%**	**1,415-1,445**	**3-6%**
Developed	**753.2**	5.8%	**915-945**	**2-5%**
US	466.6	7.3%	585-615	4-7%
EU	154.4	4.4%	170-200	1-4%
Japan	84.8	2.0%	85-89	(-3)-0%
Emerging	**269.6**	**9.7%**	**345-375**	**6-9%**
China	122.6	9.4%	145-175	5-8%
Brazil	33.1	11.5%	38-42	5-8%
India	19.3	11.0%	26-30	9-12%
Russia	14.9	10.8%	20-24	7-10%
Rest of World	**112.3**	**2.0%**	**125-155**	**2-5%**

Affordable Medicine Under the Limelight

The global generics market is valued at USD 200 billion (17% to 18% of the total global pharmaceutical market) and it is expected to reach USD 250 billion by 2022 as countries continue to focus on increasing the availability of affordable medicines.

The primary driver of the volume growth over the past three decades has been the increasing penetration of generics in developed markets. This was supported by a wave of patent expirations on blockbuster primary care drugs in the US between 2007 and 2012, a period the industry refers to as the “Patent Cliff”. At present, generics account for 14% to 16% of total US sales but more than 80% of total prescription volume. In Europe, generic penetration is between 55% and 60% by volume. In emerging markets such as India, Brazil and Russia, many off-patent drugs are available as branded generics under a trade name and consumers are often willing to pay a premium for the brands they trust.

Indian Domestic Market Recovery

India has a vibrant market for pharmaceutical products and there are structural growth drivers in place for further development. India's population of 1.3 billion people, while young by global standards, is ageing, and thus more vulnerable to diseases. Rapid urbanization and lifestyle changes are leading to a higher incidence of chronic diseases. Sustained economic growth is making a larger section of population richer, thus better able to afford healthcare services. The government is increasing its focus on affordable, universal healthcare coverage and has recently announced the Aayushman Bharat scheme or offering quality medicines at affordable prices.

The Indian pharmaceutical market has increased in size from INR 310 billion (USD 9 billion) in FY08 to about INR1.2 trillion (USD 18 billion) in FY18, implying CAGR of 14.4% as per AIOCD (All Indian Origin Chemist & Distributors Ltd.). Branded generic drugs, referring to off-patent medicines sold under a trade name, account for nearly 80% of the market by sales. Through active marketing by sales representatives, companies try to create brand recall and product preference among doctors and patients.

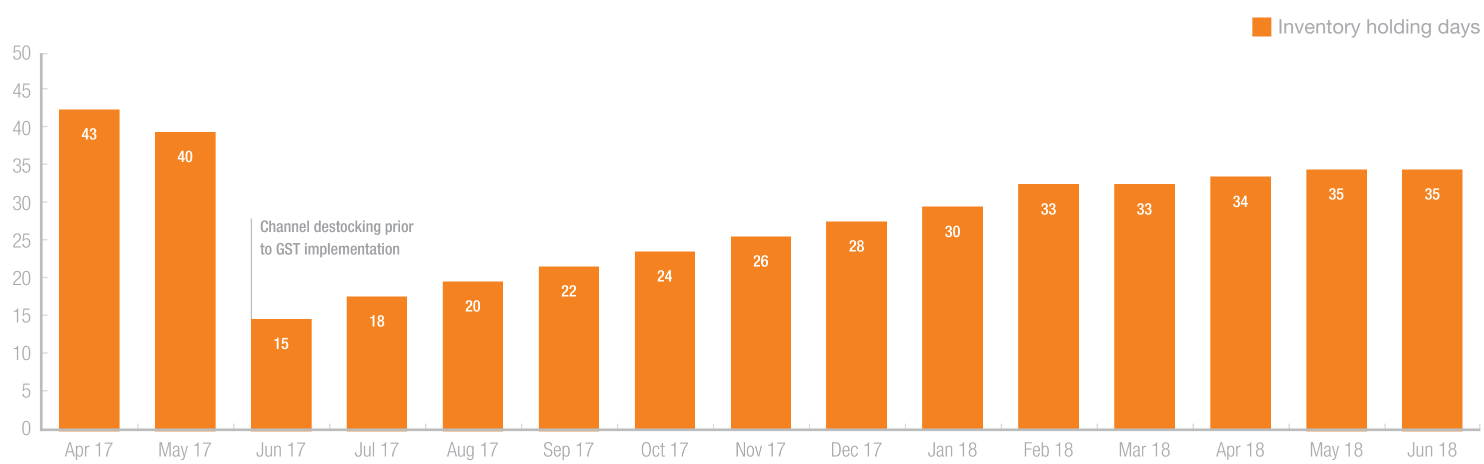
For example, Augmentin, the largest selling brand in India, is the brand name used by GSK for an amoxicillin and clavulanic acid combination drug. India is one of the cheapest market in the world for drugs where simple as well as complex and patented-drugs are available at prices that are 50% to 90% less than they would cost in a developed market.

Government's Involvement in the Market

While the long-term market outlook is positive, several recent government measures to make healthcare more affordable have caused jitters in the market. When India introduced its unified Goods and Services Tax (GST) regime in July 2017, limited clarity around tax credits available on existing stocks led to a drastic reduction of inventory holdings by trade channels. This equaled a loss of nearly one month of sales for most manufacturers and most of them reported double digit sales declines on a yoy basis in the 2nd-3rd quarter of last fiscal year.

Channels Drastically Reduced Inventory Holding Before GST Implementation

Source: AIOCD, HSBC



Similarly, government announcements regarding higher controls on drug pricing as well as a push for generics over branded-generics have kept companies on their toes. Under national drug policy, certain drugs on India's National List of Essential Medicine (NLEM) are subject to price controls.

In May 2013, the government released the Drugs Price Control Order (DPCO) 2013, revised from the earlier DPCO 1995, increasing the scope of price controls to 348 drugs from 74 drugs. With continuous expansion, 376 drugs currently are under price control, representing about 10% of the market value. The mechanism of price control was changed from a cost plus model to an average of price of brands with a market share of more than 1%. The price of NLEM drugs was also linked to annual changes in the wholesale price index (WPI).

The market was further agitated when the Indian Prime Minister Narendra Modi in a public meeting in April 2017 mentioned government plans to make it mandatory for doctors to prescribe pure-generics instead of branded generics to make medicines more affordable.

The industry is also waiting for an update on the proposed pharmaceutical draft policy of 2017 in which the government sought opinion on proposed measures to improve the quality of drugs, encourage R&D to develop new drugs, improve access to affordable medicines and provide a long-term stable policy environment for the pharmaceuticals sector. It proposed making India self-reliant by promoting local manufacturing and reducing dependency on Chinese APIs (Active Pharmaceutical Ingredients) while curbing unfair trade practices by restricting loan-licensing (or third party manufacturing) and fixing trade margins.

The government has also recently announced a ban on the manufacturing, sale and distribution of 328 fixed dose combination drugs (FDCs), concluding a legal battle between the government and the manufacturers that has gone on since 2016.

In our view government and regulatory concerns will remain an influential factor but the worst issues have been resolved. The impact of the GST transition has been absorbed and most of the manufacturers have indicated they expect revenue growth of 10% to 12%, up from the approximately 6% growth seen in FY18.

While further price controls cannot be ruled out, we believe the government is now more cognizant of the fact that such controls could stifle innovation by making companies hesitate to invest capital to introduce new drugs in the market. The government must balance the need to improve healthcare affordability with a business environment that encourages companies to spend on innovation.

Besides, the government has not issued any further signals regarding their push for generics over branded generics drugs since the initial announcements. Also, Jan Aashushadi, the government scheme for offering quality medicines at affordable prices, has been a limited success so far. It is over-dependent on state support and has suffered from poor supply chain management and is therefore seen as less of a threat to the traditional sales channels of the generic manufacturers.

In conclusion, most Indian pharmaceutical market participants believe that 10% to 12% annual sales growth will continue for the foreseeable future, driven by the inherent strengths of the market. India's pharmaceutical has weathered significant storms and is now poised for a period of strong growth and innovation.

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