

**REALIZING THE TRUE POTENTIAL OF THE PHARMACEUTICAL
MARKET IN INDIA**

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ABSTRACT

The pharmaceutical industry's main markets are under serious pressure. North America, Europe and Japan jointly account for 82% of drug sales. Annual growth in the European Union (EU) has slowed to 5.8%, and sales are increasing at an even more sluggish rate in Japan (2.1%) and North America (1.4%). Impending policy changes, promoting the use of generics in these key markets are expected to further dent the top- and bottom-line of global Pharma Majors. Further, higher R&D costs, a relatively dry pipeline for new drugs, increasing pressure from payers and providers for reduced healthcare costs and a host of other factors are putting pressure on the global pharmaceutical companies. Pharma companies are looking for new ways to boost drug discovery potential, reduce time to market and squeeze costs along the whole value chain. The industry is bracing itself for some fundamental changes in the marketplace and is looking at newer ways to drive growth. The main objective of the paper is to explore as to how the industry leaders can best face these challenges. In this paper we shall examine the opportunities available in India and the role played by the Government.

Key Words: *Markets, Growth, Generic manufacturing, Reverse engineering, Patents*

Introduction and Review of Literature:

India's population is growing rapidly, as is its economy – creating a large middle class with the resources to afford Western medicines. Further, India's epidemiological profile is changing, so demand is likely to increase for drugs for cardio-vascular problems, disorders of the central

nervous system and other chronic diseases. Together these factors mean that India represents a promising potential market for global pharmaceutical manufacturers.

More than that, India has a growing pharmaceutical industry of its own. It is likely to become a competitor of global pharma in some key areas, and a potential partner in others. India has considerable manufacturing expertise; Indian companies are among the world leaders in the production of generics and vaccines. As both of these areas become more important, Indian producers are likely to take a large role on the world stage – and potentially partner with global pharma companies to market their wares outside of India.

Indian companies have also started entering into the realm of R&D; some of the leading local producers have now started conducting original research. India has the world's second biggest pool of English speakers and a strong system of higher education, so it should be well-positioned to serve as a source for research talent. A new patent regime provides better protection of intellectual property rights, although some issues remain. Clinical trials can also be conducted here much more cost effectively than in many developed nations, and some local companies are beginning to develop the required expertise. All of these factors add up to a strong case for partnering with Indian companies around R&D, including clinical testing.

Further, healthcare has become one of the key priorities of the Indian Government and it has launched new policies and programmes to boost local access and affordability to quality healthcare. Global players in the pharma industry cannot afford to ignore India. The country, many predict, will be the most populous in the world by 2050. India will make its mark as a growing market, potential competitor or partner in manufacturing and R&D, and as a location for clinical trials

With the above background, the main objectives of this paper could thus be classified as:

- *To understand the factors that fuel the growth of Pharmaceutical Market/Industry in India*

- *To explore the role been played in the Pharmaceutical Market/Industry by the Government*

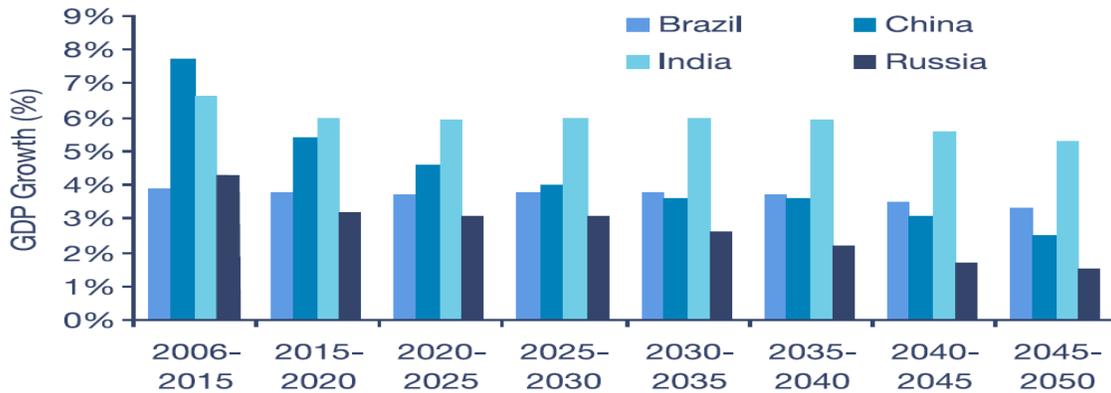
Understanding the Factors which are Responsible in fuelling of Growth:

Population explosion: Indian population is growing. India is the second most populous country in the world, with over 1.27 billion people (2014), more than a sixth of the world's population. Already containing 17.5% of the world's population, India is projected to be the world's most populous country by 2025, surpassing China, its population reaching 1.6 billion by 2050. Its population growth rate is 1.2%, ranking 94th in the world in 2013. The Indian population had reached the billion mark by 1998. This results in more probable people getting sick and hence demands of different kinds of drugs increase.

A fast growing economy: India flourished as one of the world's fastest-growing economies for much of the last decade. This has resulted in growing incomes of members of the population. With the growing income levels, the demand for the drugs is bound to increase.

The Indian economy is worth about US\$ 1,243 billion and rapidly getting bigger. Real GDP growth reached 9% in the year to March 2008. The rate of increase has since slowed down due to the global financial crisis; in the year to March 2009, growth eased to 6.7%. Even so, most forecasters believe that India will continue to show robust growth over the long-term; a survey of Professional forecasters performed for the Reserve Bank of India (RBI) anticipates robust growth of 7.8% p.a for the next ten years. Previous forecasts such as those of Goldman Sachs suggest that India will be the only emerging economy to maintain such an outstanding pace over the longer term, i.e. to 2050.

Figure 1: India is forecast to grow by at least 5% a year for the next 41 years



Source: BRICs and Beyond, Goldman Sachs, November 2007.

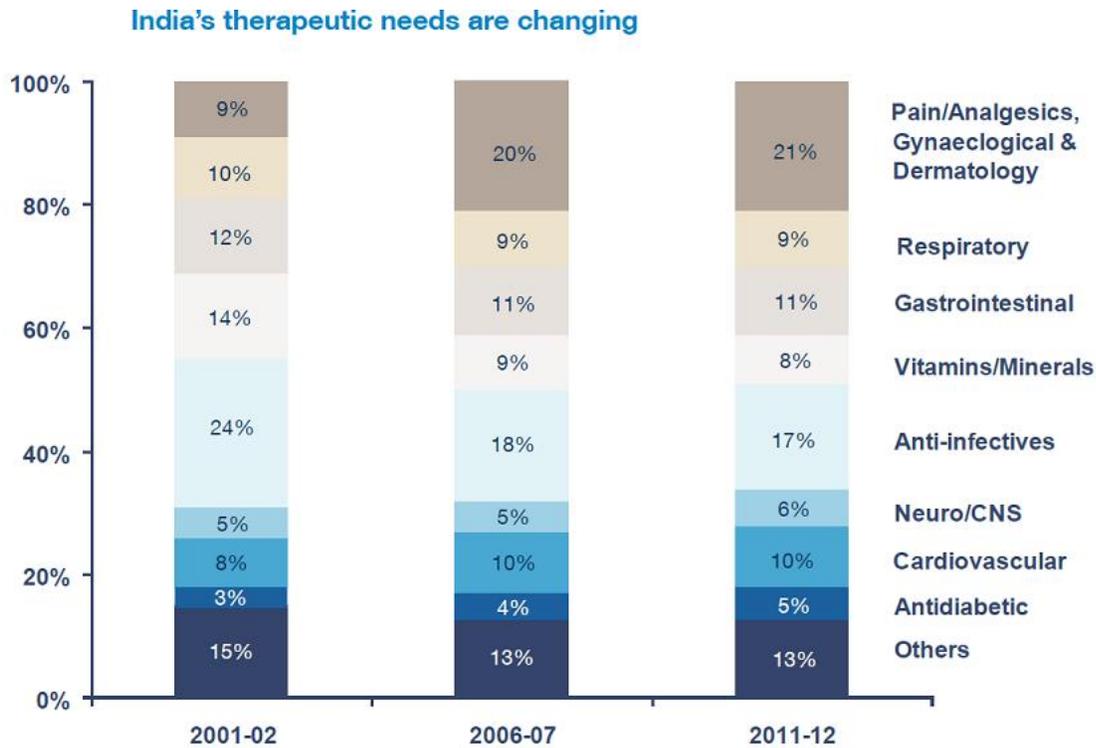
An expanding pharmaceuticals market: India's pharmaceuticals industry looks set for a solid long-term growth. It already ranks fourteenth in the global league table, with sales of almost US\$ 19 billion in March 2009. This growth will be driven by the expanding economy and increasing per capita GDP. In 2008, India's middle class constituted 13% of the population, according to the National Council of Applied Economic Research. While this remains a fairly small proportion of the total population, it represents a substantial increase from a mere 3% in 1995. If the economy continues to grow faster than those of the developed world and the literacy rate keeps rising, around a third of the population (34%) is expected to join the middle class in the near future. While these consumers still earn substantially less than their US or European counterparts, they are rapidly acquiring the buying power necessary to afford modern healthcare, particularly if purchasing power parity is considered. One source estimates that at least 60 million Indians – a market as big as the UK – can already afford to buy Western medicines.

Aggressive pricing strategies will be necessary, however, to make in-roads into India's price sensitive market. Some multinational pharma companies are already taking measures to reach a larger patient population by reducing drug prices and increasing affordability. One example: **Merck & Co.** has launched differential pricing through **Januvia**, its anti-diabetic drug, which is priced at approximately US\$ 1 per dose in India – a fifth of its price in the US. Indian companies like **Biocon** have also followed a similar pricing strategy. Biocon has launched its monoclonal antibody **BIOMAb EGFR** at one-fourth of its price in the global markets.

Tropical Climate: India is a tropical country. Hence the presence of mosquitoes and flies can never be ruled out. These result in various kinds of water and food borne diseases. In other words in results in creation of a huge patient base in India. This too results in increase in demand of medicines, which result in growth of the Pharmaceutical Industry in India.

Changing Disease Patterns and Patient Demographics: Many regions have diseases which are not fully understood and may have different medical needs because differences in genetics, diet, climate or other factors which are unique to their environment. It is important that companies recognize that they need to invest in clinical trial and other investigative work before they attempt to introduce their portfolio of current products to the region. This again can be seen as a huge growth potential especially in the Indian context. In India we have a huge middle class. The middle class suffers from various diseases like hypertension, diabetes etc. The root cause of the problem is the higher levels of stress faced by the middle class due to its high aspirations. This again will result in high demand of drugs which will result in higher growth rate.

It's also likely that India will require different types of drugs in the future. Like almost every other emerging economy, India is experiencing epidemiological changes. Thanks to greater affluence and better hygiene, the population is ageing; by 2028, an estimated 199 million Indians will be 60 or older, up from about 91 million in 2008. Besides that, it has the largest pool of diabetic patients, for example, with more than 41 million people suffering from the disease. The pattern of demand for medicines is shifting accordingly. In 2001, anti-infective and gastrointestinal drugs and vitamins accounted for 50% of the domestic market. By 2012, they accounted for just 36%. Conversely, drugs for cardio-vascular problems, disorders of the central nervous system and other chronic diseases have accounted for 64% of total sales, up from 50% in 2001.



Source: ORGIMS Data, Crisil Research, Pharmaceuticals: Review Indian formulation market (2008)

Penetration of Health Insurance: Health is always a priority in India. While India has made significant gains in terms of health indicators - demographic, infrastructural and epidemiological, it continues to struggle with newer challenges. The country is now in the midst of a dual disease burden of communicable and Non-communicable diseases. In light of the fiscal crisis facing the government at both central and state levels, in the form of shrinking public health budgets, escalating health care costs coupled with demand for health-care services, and lack of easy access of people from the low-income group to quality health care, health insurance is emerging as an alternative mechanism for financing of health care. This alternative mechanism for financing creates demand for quality health care which in turn results in further growth of Pharmaceutical companies due to higher access of health care by people.

Alliances with the Generic firm: India's manufacturing clout has made it a massive threat to established generics firms – India now produces more than 20% of the world's generics. Moreover, around US\$ 70 billion worth of drugs are expected to go off patent in the US over the

next three years, and India is well-positioned to take a substantial share of the resulting new generics markets. Indian companies today account for 35% of the Abbreviated New Drug Application (ANDA) approvals granted by the US Food and Drug Administration (FDA) until February 2009. India's generic houses are now entering into strategic alliances with global pharma companies to strengthen their generic portfolio and jointly market these drugs globally. E.g. Pfizer has entered into alliances with Aurobindo and Claris to market their drugs in offshore markets. Similarly, GlaxoSmithKline (GSK) has acquired exclusive rights for Dr. Reddy's Laboratories' (DRL) pipeline of over 100 generics for sale in emerging markets. In addition to partnering with global pharma, some Indian companies are also setting up their own marketing subsidiaries abroad.

The recent economic downturn, healthcare reform in many countries and less disposable income for customers have made the generic option more attractive to payers, insurance companies and consumers concerned with managing their costs. As a result the generic drug makers have been making inroads in the product sales of the branded products and this along with patent expiration has led to increase in generic sales.

Contract manufacturing: Contract manufacturing is a strong segment of the domestic market. Indian firms have several advantages over their Western rivals. The expertise gained in manufacturing generics through reverse engineering has helped some companies streamline the process for getting manufacturing up and running. Costs are very competitive; indeed, they are only two-fifths of those involved in setting up and running a new manufacturing facility in the West. They can operate on significantly lower margins, given their low development and labour costs. Currently their key area of strength in outsourcing is the manufacture of APIs. Some Indian pharma companies could probably benefit significantly by moving towards specialty APIs in the future.

Vaccines: Vaccines are another prominent area of growth. India is one of the largest vaccine producers in the world, with many new vaccines set to be launched in the next five years. The vaccines segment was around US\$ 780 million in March 2008, growing at a compounded annual

growth rate (CAGR) of 15%. India currently exports vaccines to about 150 countries. It also meets around 40-70% of the World Health Organisation (WHO) demand for the DPT (diphtheria, pertussis or whooping cough, and tetanus) and the BCG (bacille calmette-guérin) vaccine against tuberculosis, and almost 90% of its demand for the measles vaccine. The Serum Institute of India, founded in 1966, is a leading player which produces and supplies low-cost, lifesaving vaccines for children and adults. It has been commissioned by the WHO to develop vaccines against the latest strain of H1N1. An estimated two out of every three immunised children in the world have received a vaccine manufactured by the Serum Institute. As the risk of global pandemics grows, so do potential markets for new vaccines.

The untapped rural market: Although urbanization continues, around 60% of India's population still resides in rural areas. As already noted, the population residing in villages has significantly reduced access to quality treatment and medicines. Many pharma companies are thinking beyond larger cities and targeting rural sectors.

While urban markets are currently more lucrative and will continue to represent a focus for the industry, the untapped potential of Indian rural markets is now seen as the next volume driver. Rising income levels leading to more affordability, improving health infrastructure, and increasing incidence of lifestyle diseases along with the use of health insurance are fuelling the growth in rural areas.

Indian companies are devising a number of strategies to increase rural penetration. For instance, Lupin has a strong brand franchise in the anti-infective, pain management, and gastrointestinal segments – these three areas account for 40% of domestic formulations sales. The company has a dedicated rural field force of more than 300 people and is rapidly expanding it. Piramal Healthcare has also announced a new initiative to target the mass market, focused on general practitioners, to cater to rural markets. Piramal plans to employ a field-force of approximately 800 people.

Companies looking to access rural markets face many hurdles, including lack of communication, language barriers, high penetration of spurious drugs, lack of adequate infrastructure, such as marketing and distribution channels for niche therapeutic segments in particular, poor storage facilities, and insufficient sales personnel deployment. Global pharma companies eyeing rural markets will need to forge alliances and partnerships to overcome these obstacles.

To explore the role been played in the Pharmaceutical Market/Industry by the Government:

The Indian Government is currently in the throes of a much needed programme to reform the health care system. After years of under-funding, most public health facilities provide only basic care. Moreover, three quarters of medical facilities are located in urban areas, leaving the majority of rural workers without access to hospitals or pharmacies. Many of the poor rely exclusively on alternative forms of treatment such as Ayurvedic medicine, Unani and Acupuncture.

India healthcare facilities

Doctors	60 per 100,000 people ²⁹
Nurses	80 per 100,000 people ³⁰
Pharmacies	367,000 (urban), 183,000 (rural) ³¹
Hospitals	30,000 (67% public, 23% private) ³²
Hospital beds	1.7 million (one per 1,000 people) ³³
Health centers	171,687 (including 145,272 sub-centres with basic facilities) ³⁴

Source : World Health Organisation (2008)

The Indian Government has made the provision of healthcare as one of its key priorities. It launched a new policy to build more hospitals, boost local access to healthcare and improve the quality of medical training, and promised to increase public expenditure on healthcare to 2-3% of GDP, up from the Existing levels. The 2008-09 Union Budget highlighted a five year tax holiday

for setting up hospitals anywhere in India, especially in tier-2 and tier-3 towns. The Government further allocated US\$ 51 million for a new health insurance scheme to provide a health cover of US\$ 745 for every worker (including his/her family) in the unorganised sector falling below poverty line (BPL), which was increased to US\$ 76 million in 2009-10 budget. The budget (2010-11) extended the coverage to another 20% of the Indian population covered by the NREGA (National Rural employment Guarantee Act) programme, who have worked for more than 15 days during the preceding financial year. Budget 2010-11 also allocated US\$ 2,920 million under the National Rural Health Mission (NRHM), an increase of 15% over the previous year.

However, critics suggest that the authorities are doing too little too late, and those who can afford it have turned to the private sector instead.

The recent (2006–2010) economic downturn has in many situations intensified and refocused people's attention on regulation in the Pharmaceutical Market/Industry. Some of the arguments in the fall of 2009 healthcare debate in the United States are a prime example. The debate has been driven both by the need for the improvement in the regulatory process to meet the current needs of all the stakeholders as well as the stated and in some cases implied need to ensure that the expected benefits are aligned with the cost for the insurance, products and services.

FDI: India had thrown open the sector to foreign investments up to 100% on the automatic route in 2002 under the previous NDA regime. However, the subsequent United Progressive Alliance government imposed certain restrictions after an intense debate following a spate of acquisitions of Indian companies by global drug makers including the takeover of biggest domestic company Ranbaxy by Daichi Sankyo. The government then introduced distinct norms for FDI in green field or new projects and brown field projects amid fears that consumers in India will be denied cheap medicines if foreign multinational companies continued to buy large domestic Pharmaceutical companies. In year 2014, foreign direct investment (FDI) in Pharmaceutical sector was back in the spotlight, with the finance ministry pitching for a review of the policy that

was tightened for brown field investments, or investments in existing Indian companies, following fears of large-scale takeover by multinational companies.

The government also moved medical devices sector out of the approval route even in case of brown field investments, indicating it may not be averse to dropping some restrictions. India was keen to draw investments into the sector to reduce the country's dependence on China for bulk drugs and is looking at measures to boost productivity in the sector.

Infrastructure: Insufficient energy infrastructure and inadequate transport infrastructure has historically posed challenges for companies operating in India. The situation is definitely improving, as the Government focuses attention on infrastructure needs. The Indian infrastructure sector continues to be viewed as an investment opportunity, despite the global slowdown.

Special Economic Zones (SEZs): Of particular interest for pharma companies may be the special economic zones (SEZs). In order to incentivise the country's export sector, the Government has formulated the SEZ policy, which offers cost and tax benefits. On the corporate tax front, units set up in SEZs enjoy 100% income tax exemption on export profits in the first five years of operation, 50% exemption for the next five years, and 50% exemption on the reinvested export profits in the following five years. Companies located in SEZ also benefit from various Indirect Tax benefits such as exemption from payment of Customs Duty; Excise Duty; Central Sales Tax and refund and exemption of Service Tax.

Currently, SEZs must adhere to a positive net foreign exchange obligation policy (i.e. where the total value of exports should be more than the total value of imports) under the Import Export policy, in order to retain SEZ status. A proposal has been made to exempt pharma SEZs from this requirement.

In an effort to attract companies to SEZs, some of these are located in modern industrial areas. The Jawaharlal Nehru Pharma City, India's first and largest pharma industrial estate, includes a SEZ. The facility is located near Visakhapatnam, in close proximity to many chemical

manufacturing hubs, and offers common infrastructure for resident pharma companies. There are three other pharma SEZs located in Andhra Pradesh, and four in Maharashtra, as well as one on the outskirts of Dehra Dun in Uttarakhand, so global pharma companies have a range of options.

Taxation: India is expected to implement a new Direct Tax Code, which should simplify the existing tax structure. The new tax code proposes a reduction in the corporate tax rate from the current 30% to 25% and an unlimited carry forward of business losses. A dual system GST has also been proposed. The new system would impose taxes at both federal and state levels and differentiate between goods and services. The new dual GST is designed to aggregate different indirect taxes currently levied, in order to simplify and integrate the current system of indirect taxation.

Hence the above factors highlight that the Government has an impact on the growth of the Pharmaceutical Market/Industry in India. Regulation also impacts many other issues and stakeholders concerned about issues like Global Warming (the effects of manufacturing plants on the environment, e.g. Ranbaxy in Mohali, Punjab) Animal Rights groups (resistance to testing in animals) and many other groups. These groups often have not only the monetary resources but also the political connections that can make it very difficult for Pharmaceutical companies to operate to their full potential in many countries and markets.

Conclusions:

When looking at the Market/Industry from a global standpoint it is clear that there are opportunities to address un-met medical need in many therapeutic areas and regions of India. The Indian market is impossible to ignore, given its economic prospects. Foreign companies view India as a potential significant contributor of future sales and are ramping up their investments in the country accordingly. India's domestic market looks promising for global pharma looking to launch new products. The country's growing capabilities in contract

manufacturing, R&D and clinical trials also make it a preferred outsourcing partner for global pharma at every stage of the value chain.

India's appeal is growing rapidly in a number of respects. It has long been a formidable player in pharmaceutical manufacturing, but its socio-economic strengths provide even greater grounds for optimism. If the economy outpaces that of every other emerging country for the next half century, as many commentators expect, large portions of the population will be able to afford modern medicines.

India's increasing scientific expertise will also equip it to play a significant role in researching and developing those drugs. It has a large pool of highly educated, English speaking scientists who can undertake research and conduct trials more cheaply and in some cases faster than their Western peers. These are major advantages in a world where drug development costs are soaring and getting to market fast is vital.

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