India Pharma Inc.: Capitalising on India's Growth Potential









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Foreword



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The global Pharma industry is under serious pressure from a large number of innovator molecules facing patent expiration, a thin pipeline of new drugs, regulatory challenges and pricing pressures. This has led to a directional shift towards the emerging markets of Asia, Australia, Africa and Latin America, which are growing three times faster than the current growth rates experienced in the industry's leading markets of North America, Japan and Europe. We expect over 40% of the global Pharma industry's incremental growth over the next decade to come from the emerging markets.

The Indian Pharma industry is on the threshold of becoming a major global market by 2020. Many experts believe that the Industry has the potential to grow at an accelerated 15 to 20% CAGR for the next 10 years to reach between US\$49 billion to US\$74 billion in 2020.

The Indian pharmaceuticals market is witnessing dynamic changing trends such as large acquisitions by multinational companies in India, increasing investment by domestic and international players in India, deeper penetration into the rural markets, growth and availability of healthcare and incentives for setting up special economic zones (SEZ's). We believe these trends combined with increased purchasing power and access to good quality medical care will continue to propel the domestic pharmaceutical industry to new heights.

Indian Pharma companies are already major outsourcing partners of global Pharma companies. Research & Development in India is getting more innovative. Domestic companies have strengthened their position in the world for supplying solutions across the pharmaceutical value chain. They are likely to become a competitor of global Pharma in the areas of manufacturing and R&D, and a potential partner in others.

In this report, we look at developments in the branded generics market, over-the-counter products (OTC), vaccines and rural markets, and analyse what lies ahead for the industry as it aims to capitalise on the promise of the domestic market place. We believe that the domestic Indian pharmaceutical market has a positive growth trajectory but will also face major transformational challenges in the next decade. We address some of these challenges and identify key imperatives to accelerate the domestic market's growth.





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Executive Summary

The global pharmaceutical market is undergoing rapid transformation. As blockbuster drugs come off patent, there are fewer new products in the pipeline to replace them. This is due to declining R&D productivity and rising regulatory costs. In PwC Pharma 2020 series of reports, we have examined in detail the challenges faced by Big Pharma in this regard. There has been a dramatic shift towards emerging markets as western markets slow down. Global Pharma multinational corporations are looking at new growth drivers such as the Indian domestic market to capitalise on the growing opportunity.

The paradigm faced by the leading economies of the US, Europe and Japan are significantly different from those in the emerging markets of India, China, South America and Russia. According to IMS Health, the emerging markets of Asia/Africa/Australia grew at a rate of 15.9% in 2009, as compared to much slower growth rates in North America (5.5%), Japan (7.6%) and Europe (4.8%).⁽¹⁾ Emerging markets will be the next major growth drivers for the global Pharma industry, with more than 40% of incremental growth of the industry coming from emerging economies in the next decade.⁽²⁾

In our report, "Capitalising on India's growth potential", we analyse the immense potential of India's domestic Pharma market, which was valued at approximately US\$12 billion in 2010, and showed a strong growth of 21.3% for the twelve months ending September 2010.⁽³⁾ PwC estimates that over the next 10 years, the domestic market will grow to US\$49 billion - a compounded annual growth rate (CAGR) of 15%, with the potential to reach US\$74 billion – a CAGR of 20%, if aggressive growth drivers kick in.

One of the reasons behind this expected growth rate is that India's pharmaceutical

industry has a favourable macroenvironment to grow in. The Indian economy has rebounded from the global economic downturn, with real gross domestic product (GDP) growth reaching 9.66% in 2010.⁽⁴⁾ The Indian middle class is also expanding rapidly, with affordability of medicines increasing, and an increased percentage of disposable income being spent on healthcare. The government has made public healthcare one of its top priorities by launching policies and programmes that are aimed at making healthcare more affordable and accessible, especially in rural markets.

The industry is witnessing trends such as acquisition activity, increasing investment, deeper penetration into the tier I to tier VI and rural markets, growth in insurance coverage and innovation in healthcare delivery. Taken together, these trends are leading to increased affordability of services to patients and access to quality medical care. We believe these trends, along with the favourable macro environment will propel the industry to the next level of growth.

At the moment, approximately 90% of India's pharmaceutical market is made up of branded generics.⁽⁵⁾ We estimate that this segment will grow at a CAGR of 15% - 20% for the next five years.⁽⁵⁾ Generic generics' and patented products' contributions to the market as a whole is currently very low. Although this is the expected model of the future, we do not foresee a significant increase in the next five years; the market is expected to remain comprised predominantly of branded generics. By 2020 though, patented drug sales are expected to increase, owing to an improvement in the implementation of patent laws and spread of health insurance. We also expect the OTC segment to be a strong growth driver for the industry.

Currently, around 67% of India's population, or 742 million people live in rural areas ⁽⁶⁾, but rural markets contribute to only 17% ⁽⁷⁾ of the overall market's sales. This represents a huge opportunity for pharmaceutical companies, as we expect these markets to be the future growth drivers for the industry. The rural market has several challenges, and in order to tap the full potential of this opportunity, companies should:

- create demand by increasing awareness and education;
- work with the government through public-private partnerships (PPP), in order to improve hygiene and infrastructure conditions;
- mobilise primary care givers and paramedics through health and diagnostic camps;
- bring specific product solutions to the market and use local languages;
- improve accessibility of medicines by innovative distribution channels and
- make products affordable, through appropriate pricing and packaging.

Top Indian and foreign companies will look to increase their market share by entering into strategic alliances, strengthening their sales forces and increasing penetration into newer markets.

The potential that the Indian Pharma industry holds is unquestionable. India is home to approximately 1/6th of the world's population, and is expected to become the most populous nation in the world by 2050.⁽⁸⁾ Demand for pharmaceuticals will grow decidedly. Government must continue to invest in healthcare and medical infrastructure in rural markets, raise healthcare spending, encourage innovation, contain healthcare costs and work with private players to take the market to the next level.

Background

Strong macroeconomics over the next decade

The Growing Indian Economy Growing Middle Class With Higher Purchasing Powe Changing Disease Profile Government Policies Healthcare Insurance Large numbers of forthcoming patent expiries, a dry pipeline of new drugs, regulatory challenges and pricing restrictions have collectively contributed to low growth rates for prominent global pharmaceutical markets. As global markets such as North America, Europe and Japan continue to slow down (See figure 1), pharmaceutical companies are scanning markets for new growth opportunities to boost drug discovery potential, reduce time to market and squeeze costs along the value chain. The Industry is beginning to realize that some of the most promising opportunities will come from emerging markets (Asia/ Australia/Africa & Latin America).

IMS Health and other sources suggest that emerging markets (China, India, Brazil, Russia, Turkey, Mexico and South Korea) will contribute to over 40% of the incremental growth of the global Pharmaceutical industry over the next decade.⁽²⁾ In this report, we will look at the domestic Indian Pharma market, and the opportunities it holds.

The huge potential of the Indian pharmaceutical industry is impossible for global Pharma companies to ignore, given that India will be one of the top 10 sales markets in the world by 2020. Some of the largest Pharma companies in the world have been in the Indian market since the 1970s, and 5 out of the top 10 domestic Pharma companies are already foreign owned, with a consolidated share of 22 - 23%.

India's domestic pharmaceutical market has recorded a CAGR of 13.5% over the past five years.⁽⁵⁾ With considerable expertise in manufacturing of generics and vaccines, Indian companies have now also started significant research and development (R&D). India has the world's second biggest pool of English speakers and a strong system of higher education, all this has well-positioned

Figure 1: Emerging markets (Asia/Australia/Africa & Latin America) growing faster than developed markets



Source: IMS Health market prognosis, March 2010



Figure 2: Emerging markets drive industry growth

Source: IMS Health, Market Prognosis, October 2009

India to become an outsourcing partner in manufacturing and R&D, and as a location for clinical trials.

The Indian economy is growing strongly and healthcare is expanding to meet the needs of a growing population with a changing disease profile. Increase in insurance coverage, aggressive market creation, growth in the income of the Indian population and steady government investment into medical infrastructure has further propelled the growth of the industry, such that it is on the threshold of becoming a competitor of global Pharma companies in some key areas, and a potential partner in others.

Macro factors pushing the industry

The Growing Indian Economy

The Indian economy is growing fast, and is valued at US\$1.430 trillion in 2010.⁽⁴⁾ GDP growth, calculated on a Purchasing Power Parity basis has reached 9.66% in the year 2010, and the International Monetary Fund (IMF) expects it to remain consistently above 8% till 2015. Furthermore, India's share in the world GDP has been steadily increasing, and is expected to reach 6.28% in 2015, up from 4.17% in 2005.⁽⁴⁾



Source: International Monetary Fund, World Economic Outlook, (October 2010)

Figure 4: Growing global share of India's GDP (%)



Source: International Monetary Fund, World Economic Outlook, (October 2010)

Growing middle class with higher purchasing power

India's population is currently just over 1.1 billion and is projected to rise to 1.6 billion by 2050 – a 45.5% increase that will see it outstrip China as the world's most populous state.⁽⁹⁾ Besides, India has a huge middle class population (households with annual incomes of US\$4762 to US\$23,810 at 2001-02 prices), which has grown rapidly, from 25 million people in 1996 to 153 million people in 2010.⁽¹¹⁾ If the economy continues to grow fast and literacy rates keep rising, around a third of the population (34%) is expected to join the middle class in the near future. The middle class population is rapidly acquiring the purchasing power necessary to afford quality western medicine due to an increase in disposable income. The Indian population spent 7% of its disposable income on healthcare in 2005; this number is expected to nearly double, to 13%, by 2025.⁽¹²⁾



Figure 7: Indian population's expenditure break up as a % of overall disposable income



Source: IDFC Institutional Securities, Indian Pharma (June 2010)

Changing Disease Profile

The Indian population is experiencing a shift in disease profiles (Figure 8). Traditionally, the acute disease segment held a significant share of the Indian pharmaceutical market. This segment will continue to grow at a steady rate, due to issues relating to public hygiene and sanitation. But, with increase in affluence, rise in life expectancy and the onset of lifestyle related conditions, the disease profile is gradually shifting towards a growth in the chronic diseases segment. India has the largest pool of diabetic patients in the world, with more than 41 million people suffering from the disease; this is projected to reach 73.5 million in 2025.⁽¹⁰⁾

IMS Health indicates that some of the fastest growing therapeutic segments in the Indian Pharma space today are chronic disease-related therapeutic segments. The anti-diabetic segment grew 29% in the 12 months ending July 2010. Cardio-vascular medication and nervous system disorder medication grew at 22% for the same period of time, indicating rapid growth.⁽¹³⁾

The growing size of the Indian geriatric population will be a key factor in influencing the growth of the chronic segment. By 2028, an estimated 199 million Indians will be age 60 or older, up from about 91 million in 2008.⁽⁹⁾ Along with chronic, in the last year there has been a rebound in sales in the acute diseases segment. This trend is likely to continue over the next few years, as we see companies widening their reach into newer markets, which have a relatively higher number of treatment naïve patients requiring basic treatment, thus, creating new demand for drugs of the acute therapies segment.





Source: IDFC Institutional Securities, Indian Pharma (June 2010)

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Government policies

The Indian government has been making efforts to improve nationwide provision of healthcare. It has launched policies that are aimed at:

- building more hospitals,
- boosting local access to healthcare,
- improving the quality of medical training,
- increasing public expenditure on healthcare to 2-3% of GDP, up from a current low of 1%.⁽¹⁴⁾

Some of the significant government allocations on healthcare spend include a five year tax break for opening hospitals anywhere in India, with an added focus on tier II and tier III markets, both in the 2008-09 Union Budget. plans to spend US\$293 million on the promotion of healthcare through programmes for the prevention and cure of diseases such as cancer, diabetes, heart ailments and stroke in 2011-12. Diabetes, hypertension and noncommunicable disease patients will be screened under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS). The programme is likely to cover more than 70 million adults across 100 districts in 15 states and union territories of the country.⁽¹⁵⁾

Healthcare Insurance

India's healthcare insurance industry is currently very small and limited, but is expected to grow at a CAGR of 15% till 2015. Around 80% of India's healthcare expenditure is financed out of pocket. This limits the propensity of Indians to spend on healthcare, particularly in lower and middle income groups which comprise around 95% of population.⁽⁸⁾

The small percentage of Indians who do have some insurance, the main provider is the Government-run General Insurance Company (GIC). Private insurance only came into the market post 2007, when the Insurance Regulatory and Development Authority (IRDA) eliminated tariffs on general insurance. Apollo was the first private healthcare insurance provider in the country; other private entrants are ICICI Lombard, Tata AIG, Royal Sundaram, Star Allied Health Insurance, Cholamandalam DBS and Bajaj Allianz Apollo.









Source: ISI Analytics, Healthcare Industry (2010), General Insurance Council of India (2010)

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"In terms of factors that could drive the market up, I think insurance would be a major factor. Insurance penetration numbers should go up dramatically, because out of pocket payment for medications is not a model anywhere in the world, as it cannot drive a large part of the market. A lot of countries have gone through this change; it is imperative to take us to the next level."

- Achin Gupta, Sr. V.P, Corporate Strategy, Glenmark

The government runs a programme called the National Rural Health Mission (NRHM), for the development of the poor, allocating US\$2920 million in the 2008-09 budget, under the NRHM.⁽¹⁶⁾ A health insurance scheme called Rashtriya Swasthya Bima Yojna (RSBY) that provided US\$745 worth of cover for every worker was also included. The total allocation of this inclusion was US\$51 million⁽¹⁷⁾, which was then increased in the subsequent budgets. The latest budget, 2010-11, incorporated a further 20% of the population covered under the NREGA (National Rural employment Guarantee Act).(18)

The government, along with many in the industry believes that increase in insurance coverage is essential to take the market forward. But, other experts believe that the spread of health insurance could lead to a market wherein there is minimal differentiation between branded generics. An important success factor for generic makers is differentiation of their products. While increased health insurance coverage may benefit generic drug manufacturers by increasing the market's affordability for medicines, it may, in combination with increased institutional sales cause a reduction in prices, owing to the rising influence of insurance companies.

Overall, lack of insurance coverage still remains a challenge. Widespread use of health insurance could take many years, not least because insurance companies lack the data they require to assess health risks accurately and the only products they sell work on an indemnity basis – that is, they reimburse the patient after he or she has paid the healthcare provider's bill, making such policies less attractive.

Key takeaways

- 1. The Indian economy is growing strongly, and will continue to provide a conducive macro-environment for the industry to grow in.
- 2. The government is increasing spend on healthcare; and the Indian population is spending an increased amount of money on healthcare as a percentage of disposable income.
- 3. The disease profile is changing with an increase in acute diseases along side growth of chronics.
- 4. Health insurance is growing.

The Indian Domestic Pharma market Set for robust growth

Key Players Industry SWOT Key Recent Trends

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According to IMS Health, in September 2010, on a Moving annual total (MAT) basis, the Indian Pharma market grew at 21.3%, reaching a size of US\$10.9 billion.⁽³⁾ Taking into account generic medicines sold directly to institutions and OTC drugs sold through non-pharmacy retailers, PwC and IMS Health estimate the domestic market size to be US\$12 billion. We estimate that by 2020, it will grow to US\$49 billion - a conservative CAGR of 15%, with the potential to reach US\$74 billion – at an aggressive CAGR of 20%, if growth drivers kick in.

Key Players

There is a high level of market fragmentation. As of 2009, there were more than 10,000 firms in the market, of which, around 200 of them collectively controlled about 70% of the market share.⁽¹⁹⁾

Most of the top 10 players in the market had growth rates of over 18% for the 12 months ending July 2010. Of these, Cipla continued to have the largest market share of 5.2%, followed by Ranbaxy (now a subsidiary of Daiichi-Sankyo), with a 4.7% share.⁽¹³⁾ Figure 11: India Pharma top 10 players: 12 month growth rate ending July 2010 (09/10 Revenues in US\$ millions)



Source: Business Standard (October 2010), IMS Health, Capitaline

Industry SWOT

Figure 12: Indian Pharma Industry SWOT analysis

Strengths

- Higher GDP growth leading to increased disposable income in the hands of general public and their positive attitude towards spending on healthcare
- Cost Competitiveness
- Low-cost, highly skilled set of English speaking labour force
- Growing treatment naive patient population

Opportunities

- Global demand for generics rising
- Rapid OTC and generic market growth
- Increased penetration in the non metro markets
- Large demand for quality diagnostic services
- Increase in healthcare insurance coverage
- Significant investment from MNCs
- Public-Private Partnerships for strengthning infrastructure

Source: PwC analysis, Industry & Company interviews

Key Recent Trends

Figure 13: Industry trends and implications



Source: PwC analysis, Industry & Company interviews

Poor all-round infrastructure is a major challenge Stringent price controls

Weaknesses

- Lack of data protection
- Poor health insuracnce coverage

Threats

- Labour shortage
- Wage inflation
- Government expanding the umbrella of the Drugs Price Control Order (DPCO)
- Considerable counterfeiting threat
- Competition from other emerging economies

Investment Scenario

The Indian Pharma industry has attracted US\$1707.52 million worth of foreign direct investment (FDI) in the period between April 2000 and April 2010.⁽²⁰⁾ This FDI is exclusive of investments in shares of Indian firms. Acquisitions of local players by large MNCs illustrate the increasing level of interest that they have shown in the Indian market.

MNC acquisitions in the Indian Pharma space took off in 2008 with the acquisition of Ranbaxy by Japanese drug maker, Daiichi Sankyo for US\$4.6 billion.⁽²¹⁾ This deal was valued at five times Ranbaxy's sales.⁽¹²⁾ Since then, there has been a trend of higher valuations of Indian Pharma companies, culminating with a new benchmark: in 2010, Abbott bought Piramal Healthcare in a deal worth US\$3.7 billion⁽²²⁾, a valuation that was nine times the value of Piramal's sales revenue.⁽¹²⁾

Partnerships and Licensing deals

Although long-term supply deals between innovators and genericproducers have been taking place for a while now, the frequency of these deals has been growing at an increasingly rapid rate in the recent past. Deals between Pfizer and Aurobindo, and GlaxoSmithKline and Dr. Reddy's Labs are recent examples of out-licensing deals where generic makers are signing distribution and marketing contracts, so their products reach foreign regulated and developing markets. Due to the large number of drugs going off-patent in the next few years, this trend is expected to increase even further.

Table 1: Key recent mergers & acquisitions

Year	Indian Player	MNC	Nature of deal	Details
2010	Piramal Healthcare	Abbott	Sale of domestic branded formulations	Abbott acquired Piramal's domestic branded formulations division, along with its 350 brands, Baddi facility and about 5,200-strong sales force for US\$3.72 billion
2010	Strides Acrolabs	Pfizer	Licensing and supply arrangement	To supply 40 off patent products, mainly oncology ingestables that would be commercialised by Pfizer
2009	Shantha Biotech	Sanofi- Aventis	Acquisition	Acquired for about US\$820mn and got access to Shantha's vaccines pipeline and access to emerging markets
2009	Aurobindo	Pfizer	Dossier licensing & supply contract	Formulations and injectables for US,EU and ROW markets on exclusive and co-exclusive basis
2009	Biocon	Mylan	Development & supply contract	To develop, manufacture, supply and commercialise many high-value generic biologic compounds for the global markets.
2009	Dr. Reddy's Labs	GSK Pharma	Supply contract	To develop and market more than 100 branded products on an exclusive basis across an extensive number of emerging markets, excluding India.
2008	Strides-Aspen JV	GSK Pharma	Upfront milestone & supply contract	To manufacture and supply branded generics to GSK which would be marketed in about 80 emerging markets.
2008	Ranbaxy	Daiichi Sankyo	Acquisition	Daiichi acquired Ranbaxy and got access to Ranbaxy's diversified product portfolio and vast geographical presence.

India's domestic market is poised for strong growth on the back of increased foreign investment in the region, an increased reach in non-metro markets, the implementation of GST, growing insurance coverage, a change in the population's disease profile and increase in healthcare innovation, in combination with growth of key segments branded generics, OTC, rural markets and vaccines.

Source: Centrum. Pharmaceuticals update, (June 2010).

Indian Pharma Market Segments

A market dominated by branded generics

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Branded Generics

Generic Generics

Over-The-Counter Products

Patented Products

Retail vs. Institutional sales

Road ahead

It is difficult to track and estimate the exact composition of India's domestic Pharma market; but industry experts believe that this market is largely dominated by branded generics. This segment contributes around 90% of total sales, and represents one of the key strengths of the market, encompassing the OTC segment as well. Only about 10% of the market constitutes commodity generics sold through institutional sales and innovator products.⁽⁵⁾ The branded generics segment is expected to grow at a CAGR of 15% - 20% for the next decade.⁽⁵⁾

Figure 14: Indian Pharma market is predominantly a branded generics market



Branded generics

In the global context, IMS Health, which began tracking and reporting on branded generics in 2002, defines the category as including "prescription products that are either novel dosage forms of off-patent products produced by a manufacturer that is not the originator of the molecule, or a molecule copy of an off-patent product with a trade name." This definition is used by both the United States of America's Food and Drug Administration (FDA) and the United Kingdom's National Health Service (NHS). It does not include authorized generics, which are drugs made by or under license from the innovator company and sold without a brand name.

In India, any non patented molecule with a brand name other than the innovator's name is termed as a branded generic. Chemically, branded generics are identical, or bioequivalent to innovator drugs. It is the share of voice the brand commands by getting repeatedly prescribed by the physicians, due to some degree of recall and preference over the other brands. In the global context, substitution – when an innovator product goes off-patent is the key driver for generics. In India, it's about driving a difference using the core equity of a brand, over a competitor's product.

> Any non patented molecule with brand name, which is other than the innovator's name, is termed as a branded generic.

"India has a very large acute segment growing at strong double digits, which is expected to continue. While the chronic market is relatively small, it is on a rapid growth path due to an ageing population and changing lifestyles. Therefore, both markets will be attractive."

- Vivek Mohan, MD, Abbott India

Top Brands

Table 2 gives the top 20 brands in the Indian market, as tracked by IMS Health. The leading brand, according to September 2010 sales (MAT) is Corex[®], followed by Phensedyl[®] both of which are cough preparations.⁽²³⁾ Figure 15 shows a direct correlation between the age of a brand and its ranking - 19 of the top 20 brands are over a decade old. The last few years has seen aggressive new brand launches. However, not many of these have made it to the top 20 ranking, indicating that some of the older brands have created a strong equity, enabling them to maintain market share. Older brands have been creating newer opportunities in the tier II to tier VI and rural markets, where demand is mainly for acute therapies. In addition, an increasing level of awareness is leading to a greater propensity to self medicate, thus further increasing the uptake of these brands. Finally, many of the classic chronic brands are finding a wider prescription base from general physicians.

An example of this is pain management brand Aspirin, which is over a 100 years-old and still enjoys strong sales.

Table 2: Top 20 Brands

Rank	Top Brands MAT 2010	Company	Year of launch	Market Share (%)
1	COREX (CRX)	Pfizer	1993	0.5
2	PHENSEDYL COUGH (PHNSL)	Piramal Healthcare	1996	0.4
3	VOVERAN (VVR)	Novartis	1986	0.4
4	HUMAN MIXTARD (HMIX)	Abbott	1994	0.4
5	AUGMENTIN (AUG)	GlaxoSmithKline	1992	0.4
6	REVITAL (REV)	Ranbaxy	1989	0.4
7	ZIFI	FDC	1999	0.3
8	MONOCEF (MCF)	Aristo Pharma	2001	0.3
9	DEXORANGE (DEX)	Franco Indian	1990	0.3
10	TAXIM (TAX)	Alkem	1990	0.3
11	BECOSULES (BEC)	Pfizer	1989	0.3
12	LIV-52 (LIV)	Himalaya	1989	0.3
13	MOX	Ranbaxy	1997	0.3
14	ASTHALIN (ASN)	Cipla	1993	0.3
15	BETADINE (BET)	Win Medicare	1990	0.3
16	TAXIM-O (TAX-O)	Alkem	1998	0.3
17	AZITHRAL (AZL)	Alembic	1994	0.2
18	CALPOL (CAL)	GlaxoSmithKline	1995	0.2
19	ZINETAC (ZNC)	GlaxoSmithKline	1986	0.2
20	STORVAS (SVS)	Ranbaxy-Stancare	1999	0.2

Source: IMS Health, MAT, (August, September 2010)

Figure 15: Older brands are higher ranked



Source: PwC Analysis.

Brand Premium

Brands have always been synonymous with quality. This often makes leading brands command a price remium over the next ranked brands in their categories. This premium can be negligible or as high as 300%.⁽⁵⁾ For example, in figure 16, the number 1 ranked brand for the molecule Amoxicillin clavulanate, Augmentin, commands a premium as high as 260% over the next-in-line brand, Moxikind-CV, and 101% over the third ranked brand, Clavam A.K. But, in the case of the molecule Cefixime, the leading brand, Zifi, commands a price premium of just 2% over the second ranked, and 24% over the third-ranked brand.

"Brand premium differs from therapeutic area to therapeutic area. There are instances where the price of the brand leader is 3 times the price of the cheapest brand, and others where there is a 30% increase."

– Dr. Hasit Joshipura, MD, GSK





Source: IMS Health, MAT, (August 2010)

Premium charged by innovator brands

Innovator brands can command high premiums over branded generics. For example, in table 3, Risperdal, an innovator brand, commands a 1048% premium over Risdone (generic brand).

Figure 16: Leading brands command a price premium

Drug	Brand	Manufacturer	Quantity	Price (US\$)
Risperidone	Risperdal	Johnson & Johnson (Innovator)	2 mg, 10 tablets	6.54
	Risdone	Intas Pharma	2 mg, 10 tablets	0.57
Risedronate	Actonel	Sanofi Aventis (Innovator)	35 mg, 4 tablets	50.28
	Risofos	Cipla	35 mg, 4 tablets	2.97
Clopidogrel	Plavix	Sanofi Aventis (Innovator)	75 mg, 10 tablets	38.45
	Noklot	Zydus	75 mg, 10 tablets	2
Pregabalin	Lyrica	Pfizer (Innovator)	75 mg, 10 tablets	18.28
	Pregabit	Intas Pharma	75 mg, 10 tablets	1.76
Levofloxicin	Tavanic	Sanofi Aventis (Innovator)	500 mg, 5 tablets	11.48
	Leevoflox	Cipla	500 mg, 5 tablets	2.07

Table 3: Innovator brands command a large price premium

Source: PwC Analysis, Primary Research

Brand premium is dependent on

1. First mover advantage

First mover brands always have an advantage over late entrants. If a brand is built over 3 to 5 years before competition intensifies, it can command a price premium of close to 100% over the later entrants.⁽⁵⁾ Once competition increases, it will have to cut prices to sustain market share.

2. Creating a value proposition

Creating a value proposition can help build brand names, thus increasing the brand's longevity. This value proposition is created by:

- offering value added services, such as backing up the brand with scientific data, continuous medical education and a strong portfolio of products,
- doctor representative relationship: continuous improvement in sales

representative quality by improving their interpersonal skills for customer targeting and maintaining a strong doctor-rep relationship,

- strong life-cycle management programme by launching line extensions,
- quality of formulation,
- attractive packaging,
- cost competitiveness,
- company name and reputation.

3. Being the innovator drug

Industry experts believe that if a company launches an innovator drug in the market late, it can still enjoy a price premium, and it will not lose out to the first mover brand. The reason being there will always be a certain percentage of the population that would be willing to pay a premium for innovator drugs.

4. Appropriate pricing strategy

India is a price sensitive market. Pricing strategies for both the rural and tier II to tier VI markets, should be based on market affordability.

- *i*. For drugs that are not under the government's price control mechanism, companies can charge any amount as base price, and can increase it annually by up to 10%.⁽²⁴⁾
- *ii*. For drugs covered by the Drugs Price Control Order (DPCO), National Pharmaceutical Pricing Authority (NPPA) norms must be adhered to.
- iii. Another pricing strategy is the differential pricing of Merck's diabetes drug Januvia, which is priced at approximately US\$1 per dose in India – a fifth of its price in the US.⁽²⁵⁾

Maximising the focus on branded generics - For example: Abbott-Piramal deal for branded generics

An excellent example of a deal that was carried out on the back of the value of branded generics is the Abbott acquisition of Piramal Healthcare. Abbott was looking to increase its stake in the Indian branded generics sector, and agreed to pay US\$3.72 billion, a valuation that was 9-times that of Piramal's sales. The deal included Piramal's domestic formulations business, including its branded formulations business and its manufacturing facility at Baddi. The valuation of the deal was unprecedented in the Indian Pharma market, and is a signal of interest that large Pharma companies have in the Indian branded generics market.

Maximising focus on branded generics

Both multinational companies and domestic firms are taking steps towards maximising potential returns from branded generics. For example, Abbott acquired Piramal Healthcare for its strong sales force and branded generics portfolio (Refer pull out). Domestic firms are also looking to increase their share of the branded generics market, with some of the leading pharmaceutical companies adding to their sales forces by nearly 50% in 2010 (Figure 17).⁽²⁶⁾

Figure 17: Leading Indian firms are ramping up sales forces



Sales forces numbers 2010 (% increase from 2009)

Source: Emkay research (August, 2010)

Generic generics

Currently, the market share of generic generics is very low. We see two main hurdles to pure genericisation of the Indian market:

1. Lack of generic generics regulations and guidelines for the establishment of bio-equivalence, for example the Abbreviated New Drug Application (ANDA) guidelines that exist in the U.S.

2. Doctor comfort derived from prescribing medications on the basis of brand name.

A good example of a generic generics programme in India is the government-

run 'Jan Aushadi'. This programme provides no-name generic drugs at subsidized prices in 24-hour pharmacies that are located all over the country.

Over-the-counter products

The OTC segment has been identified as one of the potential growth drivers for the Indian Pharma industry, as the sale of OTC drugs in India has been increasing over the years. The OTC market was worth about US\$1.8 billion in 2009⁽²⁷⁾, and PwC estimates that by 2020, it will grow to US\$11 billion - a CAGR of 18%, with the potential to reach US\$13 billion – at an aggressive CAGR of 20%.

'OTC Drugs' means drugs legally allowed to be sold 'Over The Counter' by pharmacists, i.e. without the prescription of a Registered Medical Practitioner. Although the phrase 'OTC' has no legal recognition in India, all the drugs not included in the list of 'prescription-only drugs' are considered to be nonprescription drugs (or OTC drugs).

"The OTC segment is going to grow faster. We are looking at a growth rate of around 25%, more than that of the overall market growth of around 15%."

– Sanjeev I. Dani, Sr. V.P.& Regional Director (Asia, CIS & Africa), Ranbaxy

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Key drivers behind the growth of the OTC segment:

Figure 18: OTC segment growth drivers



The above factors have meant that there are a large number of Indian companies that manufacture and sell OTC products. Cipla, Ranbaxy and Zydus Cadila are examples of Indian companies that have done well in the OTC segment. The attractiveness of the Indian OTC market has extended to MNCs as well. Novartis, Pfizer and Johnson & Johnson are examples of MNCs that have a strong presence in the Indian OTC segment.

Patented Products

The market size for patented drugs as of today is very small. Only about 1-2% of the market is made up of patented drugs, which are being sold by multinational innovators. There are multiple Indian companies that have drugs in the pipeline, with a greater focus on R&D, but estimates suggest that it would be at least 7 to 10 years before these begin to have a serious impact on the industry. Industry experts believe that the current size of the patented drug market is estimated at US\$120-130 million.⁽⁵⁾

Due to weak patent laws in the past, and multiple, cheap generic versions of drugs present in the market, multinational players were hesitant to introduce their patented products. In the future, with growing affordability, deepening of health insurance and steady improvement in Intellectual Property Rights (IPR), patented product launches should increase.

Retail vs. Institutional sales

Currently, majority (91%) of drug sales is through the retail markets, while institutional sales are very low (9%).⁽⁵⁾ We believe that the increase in institutional sales will be marginal in the next 5 years, and will only show significant impact between 2015 and 2020. Increased institutional sales will be driven by the increase in the penetration of insurance, and the growing number of government and private hospitals.

Figure 19: Institutional sales increase marginally over the next 5 years



Road ahead

The branded generics segment has been the key driving force behind the growth of the pharmaceutical market. In the next 5-10 years, the market is expected to remain comprised predominantly of branded generics. We also expect the OTC segment to be a strong volume driver for pharmaceutical companies. Generic generics' and patented products' contributions to the market as a whole is expected to rise. Although this is the expected model of the future, we do not foresee a significant challenge to the domination of branded generics in the next 5 years. By 2020, improvement in the implementation of patent laws, spread of health insurance, rising affluence, decreasing generic launches, increasing number of patented product launches from foreign companies, and potential releases of novel drugs will impact the share of branded generics significantly.

Rural Markets The next frontier

Market Sizing

Key Challenges

The Government's Role

Pharmaceutical companies entering rural markets

Novartis Arogya Parivar Case Study

Road ahead

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Figure 20: Geographical split of the Indian population

Source: Novartis, Arogya Parivar: Health for the poor (April 2010)

Market Sizing

Majority of the Pharma market's growth is driven by the urban markets, that is, areas that are classified as metros or tier I cities (Refer figure 20). Tier II to tier VI is classified as peri urban, while rural is the bottom of the pyramid, which constitutes 67% of India's population (600,000 villages). As per IMS Health, peri-urban markets account for 38% of total industry sales, being valued at US\$3.4 billion⁽²⁸⁾, while, rural markets account for 17% of total industry sales, being valued at US\$2 billion, in 2010.⁽⁷⁾ PwC estimates that over the next ten years, rural markets will grow at a CAGR ranging from a conservative 15% to an aggressive 20%, reaching an expected valuation of between US\$8 billion and US\$12 billion, depending on the implementation of growth drivers.

The opportunity

Around 742 million people reside in rural areas.⁽⁶⁾ There is a significant gap between the number of people residing

in villages that require treatment, and quality treatment and medicines reaching these villages. Accessibility of medication in rural areas is very poor, with less than 20% of the population having access.⁽⁶⁾ This gap represents a huge opportunity for pharmaceutical companies to expand, and we believe that these markets will be the future volume drivers of the industry.

Key challenges of the market

Low government spend on healthcare

India has a low level of government spending on healthcare, at 1% of the GDP, putting the country in the lowest 20% of those that contribute significantly low levels of public spending to health.⁽¹⁴⁾ Business Monitor International forecasts that healthcare expenditure in India will increase from US\$49.7 billion to US\$86.9 billion between 2009 and 2014, a rise of 75%.⁽²⁹⁾

Poor Infrastructure

Healthcare infrastructure is poor, compared to urban areas. The doctor patient ratio in rural areas is 1:20,000, versus the urban ratio of 1:2000 [India requires 600,000 doctors in order to meet the statutory 1:250 ratio that is a World Health Organisation (WHO) norm].⁽⁶⁾ Doctors are not qualified, as most of them in villages have Bachelor of Health Sciences (BHS) & Bachelor of Ayurvedic Medicine and Surgery (BAMS) degrees. The quality and availability of medicines in rural areas is dubious, as there are many cases of counterfeiting and spurious drugs that have been exposed. Majority of the patients earn a basic daily wage, and affordability is very low.

Table 4: Healthcare penetration in rural areas is significantly lower than in urban areas

Population	Rural (72%) 742 Million Population	Urban (28%) 285 Million Population
Hospital %	31	69
Hospital Bed %	20	80
Doctors %	08	92
Doctors/100,000 people	05	50
Spurious Pharma sales %	75-80	20-25

Source: Novartis, Arogya Parivar: Health for the poor (April 2010)

Limited affordability

Healthcare is a low priority when it comes to income allocation, with average consumer expenditure on healthcare at just 7%.⁽⁶⁾ 80% of the rural population is on a daily wage, income levels are as low as <US\$1.78 per day.⁽⁶⁾

Low awareness of diseases and possible treatment

People here have lower literacy levels and lack awareness about various diseases & their treatment option. They rely mainly on alternative forms of treatment such as Ayurvedic medicine, Unani and Acupuncture.

Poor basic hygiene and living conditions

33% of the diseases in rural areas are related to unsafe drinking water & poor sanitation. This is because 80% of rural inhabitants lack adequate sanitation, and 70% don't have safe drinking water.⁽⁶⁾ This has led to a market dominated by acute illnesses.



The Government's role

- Providing universal access to health including water, sanitation, nutrition, primary education, communication and employment are essential to balanced development.
- Incentives for setting up hospitals anywhere in India, especially in tier II and tier III towns.
- The NRHM 2005 2012 aims to provide effective healthcare to rural population throughout

the country, especially in the 18 special focused states, which have weak public health indicators or weak infrastructure (details discussed in chapter 1).

 Further, the NRHM emphasizes on provision of a female health activist in each village, strengthening of rural hospitals for effective curative care and making this measurable and accountable to the community through Indian Public Health Standards (IPHS), integration of vertical Health & Family Welfare Programmes, optimal utilization of funds and infrastructure and strengthening the delivery of primary healthcare. It also targets to improve access of rural people, especially poor women and children, to equitable, affordable, accountable and effective primary healthcare.

Pharmaceutical companies entering rural markets

In the future, healthcare conditions in rural areas are going to improve, rural consumers will have more disposable income than they did in the past. The rationale behind this argument is that food, shelter and primary education are virtually free in rural areas, whereas a substantial chunk of income in urban areas is spent on these necessities. According to estimates of the planning commission, village dwellers have started spending 12% of their household income on healthcare. This has resulted in a spurt of Pharma companies targeting this market.

Figure 21: Multinational Pharmaceutical companies are looking to enter rural markets

Company	Rural Penetration Strategy	
Novartis	Arogya Parivar is Novartis' rural marketing initiative, wherein it markets a portfolio of drugs for common ailments such as diarrhoea. Women and children's nutrition is sold in smaller packs, in line with rural affordability. Novartis also organises camps to increase healthcare awareness.	
Pfizer	Pfizer runs project Sanjeevani so that it can reach out to Tier II and below areas. The project is mainly for its mature portfolio, thereby extending the product life cycle of these well known brands.	
Novo Nordisk	They have set up mobile clinics all over Goa to diagnose people with diabetes.	
Eli Lilly	Has a tie up with Self Employed Women's Association (SEWA) in Ahmedabad to educate, diagnose and treat people for tuberculosis	
Sanofi Aventis	Launched Prayas, aimed at bridging the diagnosis - treatment gap through a structured continuing education program for rural doctors across India.	

Source: IDFC India research, MNC Pharma: New Avatar (2010)

Novatis Arogya Parivar Case Study

Arogya Parivar is a social innovation to improve healthcare for the poor in rural areas by promoting disease prevention through a healthy lifestyle and laying focus on Community Education & not 'sell-in' to stockists. It also aims to form partnerships with NGOs & healthcare companies to implement a complete healthcare program. *Works on 4 principles:* Arogya uses the 4 A's: awareness, affordability, availability (access), and adaptibility.

1. Awareness

- Community Education meetings
- Physician knowledge sharing [BAMS/BHMS]

"Novartis has improved access to healthcare for 42 million underserved people in rural India through Arogya Parivar (Health Family), a sustainable social business model."

- Ranjit Shahani, Country President, Novartis India

2. Adaptability

- Rural specific solutions [oral rehydration solutions (ORS)/Zinc]
- Vernacular communication [local dialect]

3. Availability

- Linkages to city supply points
- Mobile Health camps

4. Affordability

Custom small packs

Arogya Parivar's Business Model





Source: Novartis, Arogya Parivar: Health for the poor (April 2010)

Road Ahead

The rural markets are the next volume drivers for the pharma companies. However, the next 2 to 5 years will see a larger focus on the metros and tier II to tier VI markets, rather than the rural markets. Rural markets are currently growing slower than the metros and the tier II to VI markets due to infrastructure bottlenecks, affordability related challenges and a high cost of operation.

In order to realise the full potential of the rural markets, pharma companies must:

- create demand by increasing awareness and education,
- work with the government through PPP models in order to improve hygiene and infrastructure conditions,
- mobilize primary care givers and paramedics through health and diagnostic camps,
- bring specific product solutions to the market, and use local languages,
- improve accessibility of medicines
 - by use of technology
 - innovative distribution channels
- make products affordable through appropriate pricing and packaging.

An example of how technology can be used for the increase in accessibility in medicines is telemedicine. Only about 3% of medical care professionals practice in rural areas, meaning that access to healthcare and medications is very limited. A potential solution for this is the remote diagnosis, monitoring and treatment of patients using telecommunication technologies. This will allow the rural population to call upon the consultancy expertise of medical professionals on a more regular basis.

Vaccines Shift towards prevention

The Indian Market for Vaccines Vaccine Market Drivers Players and Deals

Trends

Overview and Global Scenario

Globally, the vaccines sector is growing rapidly; there are now 245 pure vaccines and 11 combination vaccines in clinical development, and some industry experts estimate that the market could be worth as much as US\$42 billion by 2015.⁽³⁰⁾ Five major players – GlaxoSmithKline, Merck, Sanofi-Aventis, Wyeth and Novartis (via its acquisition of Chiron) – have traditionally dominated the field, but a number of smaller pharmaceutical companies have also entered the fray.

Even though governments may have to invest more, there is a global shift in attitudes in the Pharma industry toward disease prevention, rather than treatment. This will enable the industry to enter the realm of health management with wellness programmes that supplement what governments and employers already provide. It will also boost demand for vaccines. This could ultimately generate new business opportunities for Pharma companies.

The Indian Market for Vaccines

The Indian vaccine industry - human as well as animal vaccines - registered sales of US\$ 524 million in 2009-10. This accounted for about 25% of the total BioPharma market, which is valued at US\$2.1 billion for the same period.⁽³¹⁾

PwC estimates that the vaccine industry will continue to drive the growth of the biopharma segment, growing at a CAGR in the range of 10-13% over the next 10 years to reach a size of between US\$1.4 billion and US\$1.8 billion by 2020.⁽³¹⁾



Figure 23: Indian vaccine market sales, 2010 (US\$ Millions)

Source: Biospectrum (June 2010)

Table 5: Increased vaccine sales in 2009-10

		2008-09 (US\$ millions)	2009-10 (US\$ millions)	Growth rate
Human Vaccines	Export	155	179	15.5%
	Domestic	215	238	10.7%
	Total	370	417	12.7%
Animal Vaccines	Total	102	107	4.9%

Vaccine Market Drivers

Figure 24: Factors driving the vaccine market forward



Players and Deals

India is the one of the largest producers of measles, DPT (diphtheria, pertusis and tetanus) and BCG (bacille calmetteguérin) vaccines in the world. It produces about 40-70% of the WHO demand for DPT and BCG, and almost 90% of the demand for measles. Indian vaccines are produced and exported to 150 countries worldwide. The largest vaccine producer in India is the Serum Institute of India, it is the world's largest producer of measles and DPT vaccines.⁽³²⁾

- Serum Institute 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 does the potential market for new vaccines.⁽³³⁾
- Panacea Biotec is associated with the WHO for supplying polio vaccines throughout the world.
- Serum Institute has an agreement with the Global Alliance for Vaccines and Immunization (GAVI) to develop, manufacture and sell meningitis vaccines.
- Shantha Biotechnics was taken over by Sanofi Pasteur (the vaccine division of Sanofi-Aventis) and was awarded a contract by the United Nation (UN) to supply pentavalent vaccines worth US\$340 million over the period 2010-12.⁽³⁴⁾

Vaccine	Company	Status of Development	
Rotavirus vaccine	Bharat Biotech	Bharat Biotech, in collaboration with the Indo-American vaccine action programme, is developing a rotavirus vaccine for the prevention of diarrhoea. The vaccine will be entering phase III shortly.	
Rotavirus vaccine	Shantha Biotechnics	Has entered phase II trials.	
Cadi-05	Cadila Pharmaceuticals	Cadi-05 is a Mycobacterium cancer vaccine for the treatment of hormone-refractory prostate cancer.	

Table 6: Vaccines currently under development by Indian players
Influenza vaccine	Cadila Pharmaceuticals; Bharat Biotech	Bharat Biotech and Cadila entered into a licensing agreement with Novavax in 2006 and 2009 respectively for the development of prophylactic influenza vaccine containing recombinant, functional influenza virus-like particles.		
Malaria vaccine	Bharat Biotech; ICGEB	Bharat Biotech, in collaboration with the Malaria Vaccine Initiative (MVI) at Program for Appropriate Technology in Health (PATH), the US, and the International Centre for Genetic Engineering and Biotechnology, India, is developing a malaria vaccine.		
H1N1 influenza (Swine flu) vaccine	Bharat Biotech	Bharat Biotech is developing a cell culture-based influenza vaccine. Will be entering phase-III.		
H1N1 influenza (Swine flu) vaccine	Panacea Biotec	It is an inactivated, split virion monovalent vaccine.		
H1N1 influenza (Swine flu) vaccine	Zydus Cadila	Zydus Cadila is developing an egg-based, inactivated vaccine against the H1N1 strai of influenza. It is the first Indian company to get Drug Controller General of India (DCGI) approval for conducting clinical trials of H1N1 vaccine in January 2010. The plan to launch the vaccine by mid-April		
H1N1 influenza (Swine flu) vaccine	Serum Institute of India	It is an indigenous live attenuated H1N1 virus intranasal vaccine for the prophylaxis o pandemic H1N1 influenza. Has started phase II/III.		
H1N1 influenza (Swine flu) vaccine	Biological E	Biological E entered into a licensing agreement with VaxInnate Inc for clinical development and commercialization of its swine flu vaccine in India in January 201		
H5 N1 (Avian flu) vaccine	Serum Institute of India	The company received the contract for developing the avian flu vaccine in 2006 and later in August 2009, Serum has prioritized the development of swine flu vaccine.		
Malaria vaccine	Bharat Biotech; ICGEB	Entering phase-I.		
Conjugated typhoid vaccine	Bharat Biotech	Conjugated typhoid vaccine is entering phase-III, will be ready by end of this year.		

Trends

Figure 25: Vaccine Industry Trends



Changing Tax Environment

Increased efficiencies expected



Direct Tax Code (DTC)

Goods and Services Tax (GST)

Goods and Services Tax (GST) has become a constant talking point today. The entire industry is watching the developments in and around this front. The attention is well deserved as GST is the largest indirect tax reform India has ever had, post -independence.

An Introduction to GST

So what is GST all about? Simply put, Goods and Service Tax (GST) is a comprehensive value added tax (VAT) on the supply of goods or services. GST is collected on the value added at each stage of sale or purchase in the supply chain. The tax on value addition is ensured through a tax credit mechanism throughout the supply chain. GST paid on the procurement of goods and services is available for set off against the GST payable on the supply of goods or services. The idea is that the final customer will bear the GST charged to him by the last person in the supply chain.

Many countries in the world have a single unified GST system i.e. a single tax applicable throughout the country. However, in federal countries like Brazil and Canada, a dual GST system is prevalent whereby GST is levied by both the Federal and the State or provincial governments. In India, a dual GST is proposed whereby a Central Goods and Services Tax (CGST) and a State Goods and Services Tax (SGST) will be levied on the taxable value of every intra-State transaction of supply of goods or services. In case of inter-State transactions, an Integrated Goods and

Services Tax (IGST) is proposed to be levied. The rate of IGST is expected to be the aggregate of the CGST and SGST rate.

Dual GST in India

The CGST and SGST will be based on a common tax code. While, each State will legislate its own enactment to levy and collect the SGST, it is expected that a majority of the provisions of the SGST will be uniform across the States.

It is proposed that the taxes to be subsumed under CGST will include Central Excise Duty (CENVAT), Service Tax, Countervailing Duty (CVD) and Additional Duties of Customs and the taxes to be subsumed under the SGST will include Value Added Tax, Central Sales Tax, Purchase Tax, Entertainment Tax, Luxury Tax, Lottery Taxes, and State surcharges relating to supply of goods and services.

Customs duties will remain outside the GST regime. Thus, the applicable basic custom duty will continue to be levied on import of goods. In addition, both the CGST and the SGST are expected to be levied on imports of goods.

Similarly, importation of services will be taxed and both the CGST and SGST will apply on such imports. The tax will be payable on a reverse charge mechanism and the importer of services will hence need to self declare and pay the tax.

There would be a paradigm shift in the "taxable event" under the GST regime.

It is expected that the taxable event will be the 'supply of goods' and the 'supply of services'. Hence, the current taxable events such as 'manufacture of goods', 'sale of goods' and 'rendition of services' will become redundant.

It should be noted that a transaction of 'supply of goods' will attract both the CGST and SGST as applicable on goods. Similarly, a 'supply of service' will attract both the CGST and SGST as applicable on services. Furthermore, inter-depot transfers (stock transfers) will also be subjected to levy of GST.

Impact on the Pharmaceutical Industry

The GST brings with it a host of challenges. It also brings with it opportunities to realise efficiencies and related benefits.Some of the key tax challenges, benefits and opportunities for the Pharmaceutical industry are highlighted below.

Procurement

On the procurement front, the pharmaceutical industry has been enjoying host of concessional rate of excise duties and State VAT. This may not continue in the GST era. Further, certain States like Himachal Pradesh and Uttaranchal offer excise duty exemptions. Thus, goods procured from these exempt units are free of excise. Moreover, there is a reduced rate of 1% CST on inter-States sales of these products. It is expected that the aforementioned exemptions/ concessional rates may no longer be available in the GST regime and that they could be converted to cash refund schemes.

Clearly, this would have an impact on the cost of procurement. However, due to availability of credit of taxes paid, the GST charged by the suppliers may not be a real cost and would be available as a set-off against the GST liability.

Another beneficial impact of the GST is the expected discontinuance of Central Sales Tax (CST) charged on inter-State sales. CST is a cost to pharma manufacturers whenever they procure goods from outside the State and sell the same on inter-State basis. This is on account of the fact that CST is not creditable. Although, over the last couple of years CST rates have reduced from 4% to 2%, it still continues to be a cost for the dealers, having inter-State transactions. The phasing out of CST will save the sticking tax cost.

Another expected benefit of the GST is with regard to the discontinuance of refunds in relation to the Special Additional Duty (SAD) of Customs. At present, the SAD is paid upfont on imports and is thereafter refunded through an elaborate valedictory mechanism. It is expected that the GST on imports would be fully creditable and hence there ought not to be any refunds on this count.

As mentioned earlier, the proposed GST regime also offers numerous opportunities. One such opportunity is with respect to flexibility in selection of vendor. Up till now, the selection of vendor has been dependent primarily on location of the vendor to take advantage of the lower tax cost. Post-GST, with a single market concept, this criterion of selection will no longer be relevant and the procurement can be done based on other logistics/quality related aspects.

Manufacture

As opposed to the current taxable events of manufacture and sale, the taxable events under GST regime would be supply of goods and services.

As explained earlier, certain units located in the States of Himachal Pradesh, Uttaranchal enjoy an excise tax holiday on their manufacturing activities. Since their output is exempted, the tax paid on inputs/capital goods by such units is a cost to the entities located in such areas. Under GST, such area based exemption may not continue.

The abolition of taxable event of manufacturing & the excise benefits in backward areas would give flexibility to the entities to set up their units at a place most convenient from a logistic standpoint.

Abolition of the taxable event for excise purposes from GST ambit will also take away the archaic concept of MRP based payment of excise duty. At present, the manufactures of drugs and medicines are required to pay excise duty (sans abatement) on the maximum retail price (MRP) of the said product. Thus, even if the assessable value of such product works out to be different, the manufactures are compelled to compute and pay the excise duty on the MRP of such product. This also restricts the manufacturers from having multiple sales prices for different set of buyers say institutional customers. However, all of the above is expected to end in the GST era and hence the manufacturer will have the flexibility to price the products.

Furthermore, many pharma companies get their goods manufactured on loan licensing or on a contract manufacturing basis. The job charges do not attract service tax unless excise duty is exempted. It will be important to ascertain whether job work will be considered as transaction of supply of goods or supply of services in GST. The categorisation may not only have a bearing on the rate of GST applicable to such transactions but also may necessitate separate provisions for arriving at valuation for levying GST.

Sales & Distribution

One of the biggest changes relating to sales and distribution would be taxability of stock transfers. At present, the biggest challenge for a pharma distribution company is movement of goods across India, to cater to the need of each State locally and thus save the CST payable otherwise on such inter-State movement. Also, quite a few entities set up warehouses in thus far attractive locations like Daman as the CST rate at such locations was previously lower than the rates prevalent in other states. This logistical challenge and the added cost of compliance would become a focal point of attention post the GST. The distribution team needs to reascertain the warehousing locations from a commercial/logistic point of view rather than from a pure tax saving perspective. Reduction in such warehouses would reduce the cost of distribution.

Pricing

The pharma industry has been enjoying series of product specific exemptions, be it for research, life saving devices etc. It is expected that the said exemption list will be pruned substantially, leaving only a handful of products with exemptions. Companies will have to re-think the pricing strategy of such products.

Physician samples are on one hand subject to excise duty, however on the other hand, since they are not 'sold', there is no VAT payable. This scenario may well be a thing of the past as in the GST regime, all such 'supplies' of samples might well be taxable.

Sales promotional schemes are very common for the pharma industry. Hitherto, different States have adopted different approach for allowing a deduction of such schemes from the VAT liability. It is expected that the SGST model will be common across India and a parity in law is expected for allowing this deduction paving the way for companies to plan uniform pricing policies.

Few States have imposed VAT on the Maximum Retail Price (MRP) of the product, exempting the subsequent dealers from payment of VAT. While this defeats the very intent of VAT, it remains to be seen whether in the GST regime, similar MRP based taxation would prevail or not. Clearly, this area would also require adequate attention from a pricing perspective.

Services

Research-based pharma companies currently enjoy exemption on testing and analysis services. It is likely that the said exemption might be withdrawn in the GST regime. On one hand, it would mean the services will become costly and it would also mean that the CENVAT credit hitherto lost on providing these services would be recouped and thus the overall cost of providing these services would come down.

Similarly, an impact will be seen on those set of services which are considered exempt from service tax at the moment. R&D organizations undertaking such services will have to take a close look at their input tax credit pool to determine whether they are eligible to claim the taxes paid on their inputs / input services availed in providing such services.



IT changes

The GST will require lot of changes to be made in the existing IT system. The Government is expected to put lot of thrust on the documentation and records to plug the unwanted revenue leakage. Further, the tax administrations are gearing up to be technology savvy and this will mean that the industry will have to re-visit the existing Enterprise Resource Planning (ERP)/accounting system and make suitable changes to put into effect change in rate of tax, change in format of invoice, for correct and timely tracking, computation and payment of tax obligations and compliance in the GST era.

As can be seen from the above, GST should not be viewed not only as a change in tax system but also a change impacting almost every business function like finance, logistics, procurement, IT etc. Hence, a cohesive effort from every business vertical would be required to study the impact of the changes and a concrete roadmap would have to be put in place well in advance.

The Pharma industry (including FMCG) is significantly impacted by the GST since the classic manner of concentrated manufacturing and disaggregated distribution across a national level C&FA / warehousing mechanism is significantly disadvantaged. Consequently, it is imperative for the Pharma sector to understand the implications and the challenges arising out of the dual GST and to ensure that the business model / supply chains are re-engineered so as to maximise the benefits.



Direct Tax Code (DTC)

India has witnessed numerous developments in the corporate tax regime, including in the pharmaceutical sector. The Corporate Tax regime is on the threshold of change with the imminent onset of the Direct Taxes Code (DTC). The DTC is intended to come into effect from Financial Year 2012-13.

Tax Structure

Under the DTC, the corporate tax rate for Indian companies is intended to be maintained at 30% as against current effective tax rate of 33.2175% under the Income-tax Act, 1961 ('the Act'). MAT is intended to be levied at 20% which is more or less equal to the current effective MAT rate of 19.93%. Noticeably, the period for carry-forward of MAT credit is intended to be increased from 10 years to 15 years.

Incentives available to the pharmaceutical sector

It is intended to do away with area-based profit-linked tax benefits and move towards investment-based tax benefits. Accordingly, various area-based incentives linked to profits available under the current tax regime are intended to be done away with. An exception has been made for units set-up in Special Economic Zones (SEZ). Units set up before March 31, 2014 will continue to enjoy tax benefits. The benefit would not be available beyond the period for which the deduction was allowable under the Act. Scientific research and development expenses related to the business will continue to enjoy a deduction against business profits. Assets used in scientific

research (other than land) would be permitted 100% depreciation. An approved in-house R&D Facility will continue to enjoy 200% deduction of scientific research expenditure (other than expenditure on land and building) on scientific research under the DTC.

Road Ahead

It remains to be seen whether DTC is implemented by April 1, 2012 and the form it takes when implemented. Certain benefits available under the Act to pharmaceutical companies have been done away with but the focus on encouraging in-house scientific research remains.





Price Controls

Price controls are broadly cited as the most critical challenge that companies face in the Indian market. India is one of the most price-controlled markets in the world, as under the DPCO, prices and margins are monitored carefully. The DPCO is being supervised by the NPPA.

There were originally 347 price controlled drugs included in 1979, which were then reduced to 143 in 1987⁽³⁵⁾ and currently, there are 76 bulk drugs under the DPCO.⁽³⁶⁾ Price controlled drugs are essential medicines, such as antibiotics and painkillers, and drugs used for the treatment of diseases such as cancer and asthma. Such medicines contain bulk drugs, or raw materials, whose prices are controlled by the NPPA - manufacturers cannot hike prices on their own. However, 90% of drugs are currently outside of any price controls in India.

Consumer organisations maintain their stance of urging the government to continue to expand the umbrella of the DPCO, but the industry believes that there is enough competition for the prices to be modulated by the market itself. They believe that price caps would inhibit the development of R&D in the country as companies would be less inclined to invest in R&D without the possibility of high returns.

Infrastructure

Infrastructure has always been mentioned as a barrier to growth of the Pharma industry in India. Poor energy and transport infrastructure has traditionally posed a problem for companies. Some areas lack basic hotel facilities, preventing reach and penetration. With the government gradually increasing investment in infrastructure, the situation is improving, but it is still seen as an investment opportunity in India.

Example of government investment in infrastructure expansion

The government is keen to include PPP's in order to finance infrastructure growth. A good example of this is a coalition between the Union Ministry of Health and Family Welfare, the pharmaceutical industry and private airport developers, GVK and GMR to set up specialized cargo zones for pharmaceutical products import and export. This was taken a step further, and the CDSCO has taken up the initiative to form these zones all over Indian airports, the first being at Indira Gandhi International airport, New Delhi. Currently the government has budgeted US\$6 million for the formation of these zones. These projects could help towards spurring infrastructure development in the medium term.

Counterfeiting

Counterfeiting of drugs has been a major issue in the Indian Pharma space. The inherent nature of the Indian market makes it difficult for a systematic study that quantifies the extent of counterfeiting, to be carried out. There have been multiple reports suggesting various figures as the rate of counterfeiting. A good indicator may be a large scale survey that was published in December 2009 by the health ministry that reported that spurious drug prevalence is much lower than otherwise suggested. The report found that only 0.046% of all medicines sold contained evidence of being spurious. This is in contrast to other reports, for example one conducted by the International Pharmaceutical Federation and financed by the WHO that said 3.1% of all drugs sold in India were spurious.⁽³⁷⁾

These reports suggesting lower numbers than earlier ones may be encouraging, but leading players are still weary of the threat of spurious drugs. Steps taken by the industry to counter the threat of counterfeiting include investing in innovative packaging, using authenticity markers and sponsoring programmes to increase awareness amongst patients and healthcare workers. The Organisation of Pharmaceutical Producers of India (OPPI) has also carried out various initiatives to combat the situation like organising seminars and working with the Ministry of Health towards the development of policies against spurious drugs.

Labour

There is an increasing concern in the domestic industry regarding a shortage of skilled labour in critical areas. This causes a demand-supply imbalance, and has led to an increased rate of wage inflation.



Intellectual Property

India has accepted and made a commitment to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, and keeping with this commitment, implemented the Patent (Amendment) Act in 2005. Although this act does not apply for drugs patented before 1995, it is a major step forward on the earlier patent scenario. Since then, recommendations have been made to the government regarding improvement and expansion of the Patent (Amendment) Act, by the Satwant Reddy committee and the Mashelkar report. These reports highlighted the need for data exclusivity and the prevention of 'evergreening'.

Domestic and global Pharma companies are showing an increased confidence in the patent laws, and we expect an increase in the number of launches of patented products in the Indian market in the future. Resolution of data exclusivity laws and capacity building at patent offices will help in increasing confidence among foreign companies.

Overcoming the challenges that exist in the market is a key imperative for future growth.



Road Ahead: Imperatives for Growth – Realising India's potential

The Pharma Industry Scenario in 2020 Critical success factors, requirements for Indi to go forward

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The Pharma Industry Scenario in 2020

	 Size in 2010	CAGR over 10 years		Estimated size in 2020	
Key opportunities and growth areas		Base growth	Aggressive growth	Base valuation	Aggressive valuation
Total domestic market	US\$12 billion	15%	20%	US\$49 billion	US\$74 billion
Rural market	US\$2 billion	15%	20%	US\$8 billion	US\$12 billion
OTC market	US\$1.8 billion	18%	20%	US\$11 billion	US\$13 billion
Vaccines market	US\$524 million	10%	13%	US\$1.4 billion	US\$1.8 billior

Table 7: Strong growth in key areas

Source: PwC Analysis

The Critical success factors that are required for the next level of growth

1. Increasing public spend on healthcare

The government should step up it's spend on healthcare from a current low of 1% of total GDP, to 3%.

2. Health Insurance

The focus of the government should be on the increase in penetration and access of health insurance.

3. Improvement in infrastructure

All forms of infrastructure, medical, educational and physical, need improvement through PPP programmes.

4. Innovation

Work towards the launch of 'made in India' novel drugs.

5. Creating enabling policies and regulatory framework for the launch of innovator products

Focus on price monitoring rather than price control, along with resolution of data exclusivity laws will help in increasing confidence among foreign companies.

6. Out of the box thinking

Expansion into the high potential rural and peri-urban markets will require an out of the box thinking to tailor strategies to fit these markets. Companies will be required to build a networked operational model with various stakeholders in order to squeeze costs and improve efficiencies across the value chain.

7. Using technology to increase efficiency

Technology capabilities can be used to increase efficiency across the value chain, and increase medical services accessibility. An example of this is the 'Telemedicindia' project that has been set up by the School of Telemedicine and Biomedical Informatics, SGPGIMS, Lucknow, India, and Sony.

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- Achin Gupta Senior Vice President, Corporate Strategy, Glenmark Pharmaceuticals Limited
- Dr. Hasit Joshipura Vice President, South Asia and Manging Director, GlaxoSmithKline India
- Dr. Prakash Mody Chairman & Managing Director, Unichem Laboratories Limited
- Ramesh Swaminathan President (Finance and Planning), Lupin India Limited
- Ranjit Shahani Country President, Novartis India Limited
- Sanjeev I Dani Senior Vice President & Regional Director (Asia, CIS & Africa), Ranbaxy Laboratories Limited
- Vivek Mohan Managing Director, Abbott India Limited

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The views expressed herein are personal and do not reflect the views of the organisations represented by the individuals concerned.

Profiles



Achin Gupta

Achin Gupta Senior Vice President, Corporate Strategy, Glenmark Pharmaceuticals Limited.

Achin Gupta is Sr. Vice President, Corporate Strategy at Glenmark Pharmaceuticals, which is one of the leading Indian pharmaceutical companies engaged in NCE/NBE research. He currently leads the group's M&A and licensing strategy and heads Project management of R&D assets. As part of this role, he has been closely involved in portfolio planning for R&D and optimizing the return on investment for the same.

Achin joined Glenmark at its Swiss office in 2004 and was responsible for setting up Glenmark's presence in Switzerland to enter biologics research. Since then, he has been involved in acquisition of antibody products, licensing-in technologies, entering various manufacturing collaborations as well as out-licensing of Glenmark's NCE assets. Prior to joining Glenmark, he worked for nearly five years with management consulting firm, A.T. Kearney, based out of New Delhi office. Achin holds an M.Tech. in Biochemical Engineering & Biotechnology from IIT Delhi and an M.B.A from IIM, Ahmedabad in India.



Dr. Hasit Joshipura

Dr. Hasit Joshipura Vice President, South Asia and Managing Director, GlaxoSmithKline, India.

Dr. Hasit Joshipura is a graduate in Electrical Engineering from VJTI -Bombay University and a Post Graduate from Indian Institute of Management - Ahmedabad. He has completed his Doctorate programme at the School of Management at IIT Mumbai. After having spent about three years with the Tata Administrative Services, Hasit has spent about 16 years with the Unilever Group of companies in India and held positions of increasing responsibility in commercial, sales, marketing and business management functions. He joined the pharmaceutical business of Johnson & Johnson Ltd., as President & Executive Director in October 2001, a position he held until August 2006. Hasit was also the Chair person for the Corporate Contributions Programme, as well as the lead for Government Affairs for the Johnson & Johnson group of businesses in India.

In October 2006, Hasit was appointed Vice President, South Asia and Managing Director India with GlaxoSmithKline Pharmaceuticals Ltd. (GSK). He is also Chairman of the boards of GSK Bangladesh and GSK Sri Lanka. Hasit formally took over on 1st January, 2007.

Dr. Joshipura is a member of the Board of Governors of VJTI and is also on the Board of Governors of the Indian Institute of Management, Ahmedabad.



Jai Hiremath

Jai Hiremath Chairman – CII Pharma Summit 2010 & Vice Chairman and Managing Director, Hikal Limited

Mr. Jai Hiremath is the Vice Chairman and Managing Director of Hikal Ltd. Hikal specializes in Contract Manufacturing in the areas of Crop protection chemicals, Active Pharmaceutical Ingredients and also Contract Research and development.

He was awarded "Chemtech Business Leader of the Year Award (Chemicals) 2005". He completed the "Owner President Management Program" at Harvard University, Boston, USA. He was nominated as a finalist for the Ernst & Young Entrepreneur of the Year award in 2000

Mr. Jai Hiremath is currently holding the following positions :

- Chairman of Chemicals Committee, FICCI.
- Member of the Executive Committee of the Indian Chemical Council (ICC). Mr. Hiremath has served as the President of ICC for a period of 2 years from October 2008 to September 2010.
- Member of the National Committee on Drugs & Pharmaceuticals and National Committee on Chemicals & Petrochemicals of the Confederation of Indian Industry (CII).
- Member of CII's Western Regional Council.
- Board Member of the National Safety Council (NSC) of India
- Board Member of Novartis (India) Ltd.



Dr. Prakash Mody

Dr. Prakash Mody Chairman & Managing Director, Unichem Laboratories Limited

Dr. Mody is a doctorate (Ph.D) in Organic Chemistry from the University of Bombay.

He has done his Marketing Management from Jamnalal Bajaj Institute of Management Studies, University of Bombay.

Dr. Mody is a Graduate Alumni of Harvard Business School having undergone the Owner Presidents' Management Program.

- Professional Experience: Dr. Prakash Mody is the Chairman and Managing Director of Unichem Laboratories Limited, a globally-operating, integrated pharmaceutical company.
- Other/Achievements: Dr. Mody is the Vice President of the Indian Pharmaceutical Alliance (I.P.A.) and also on the Executive Committee of the industry association viz. Indian Drug Manufacturers Association (I.D.M.A.)

He is a member of the National Committee on Drugs & Pharmaceuticals of the Confederation of Indian Industry.

In addition to the above Dr. Mody is also associated with other philanthropic activities.



Ramesh Swaminathan

Ramesh Swaminathan President (Finance and Planning), Lupin India Limited

S.Ramesh, aged 44, is President (Finance and Planning) of Lupin Ltd, a top tier Pharma company based in Mumbai. Lupin, in its last fiscal year ended 31 March 2009, recorded a turnover of Rs 3838 crores and a Profit after tax of Rs 501 crores.

Ramesh has over two decades of work experience and has worked in firms of international repute. He has been with Lupin for the past two years driving our Financial strategy and Corporate Planning endeavours. Prior to joining Lupin, he was with Henkel KGaA (Sept 2004 to June 2007) at Dusseldorf Germany as the Regional Financial Controller for the Eastern Europe and Middle East region, a region comprising of over seventeen countries encompassing a turnover of over Euro 2 billions. Whilst at Henkel Germany he was involved in several international projects including several M&A transactions for the Henkel group. Prior to his transfer to Germany, Ramesh was CFO of their operations in India. (2000-2004)

Ramesh has also served with VST Ltd, Hyderabad, (1996-1999) part of the British American Tobacco group as CFO of their operations. Prior to this assignment, Ramesh was with Standard Chartered Bank (1988-1996) in several capacities. He was articled as with A F Ferguson, Chartered Accountants for his CA apprenticeship.(1985-1988)

Ramesh has impeccable academic credentials as well. Besides being a rank holding Chartered Accountant from India, he is also a member of the Chartered Institute of Management Accounting, London, The Institute of Company Secretaries of India as well as the Institute of Cost and Works Accountants of India. He is a graduate in commerce form the Madras University. He was awarded the Lord Chevening Scholarship by the Foreign and Commonwealth office UK in 1996 for Management training with London Businesses. He has also done an Advanced Management Programme at the Insead Business school.

Ramesh is married and has two children. Reading and music would be his other interests.



Ranjit Shahani

Ranjit Shahani Country President, Novartis India Limited

Ranjit Shahani is Country President Novartis India responsible for the overall operations of the Novartis AG Companies in India

He started his career with ICI in India in their businesses of Fibres & Speciality chemicals. Later, he rose to the position of General Manager with ICI / ZENECA in the U.K., overseeing their Asia Pacific and LatAm operations for their Petrochemicals and Plastics division.

This was followed by a period as CEO at Roche Products Limited, after which he moved to Novartis in India in 1997, following the merger of Sandoz and Ciba-Geigy.

Mr Shahani is President, Organisation of Pharmaceuticals Producers of India (OPPI), an organization he also lead earlier from 2001-2007, is

Past President of the Bombay Chamber of Commerce and Industry, President, Swiss Indian Chamber of Commerce, and was on the Council of the International Federation of Pharmaceuticals Manufacturers Associations (IFPMA, Geneva). He is a thought leader in the Pharmaceutical Industry and has been actively involved in lobbying for a strong Product Patent law in the country and Data Protection and liberalization of the price control mechanism for Pharmaceuticals. He has also strongly canvassed for deterrent legislation against counterfeit drugs.

A Mechanical Engineer from IIT Kanpur and MBA from JBIMS, Bombay, was born in Kanpur, India, is married and his wife is a well known educationist and currently also the Sheriff of Mumbai - they have one son - who works with McKinsey in London.



Sanjeev I. Dani

Sanjeev I. Dani Senior Vice President & Regional Director (Asia, CIS & Africa), Ranbaxy Laboratories Limited.

Sanjeev I. Dani is the business head responsible for P&L for Asia, CIS (ex-USSR) & Africa Regions of Ranbaxy. In these markets, Ranbaxy has major business interests in South Africa, Russia, ASEAN countries and UAE/GCC countries apart from India. Sanjeev I. Dani has over 25 years of experience in Pharmaceutical Industry, both in India and Overseas. He is also a Member of the Board, Daiichi-Sankyo Espha Co Ltd, Tokyo, Japan.

Sanjeev I. Dani has previously worked in various capacities in Sales & Marketing functions of Companies such as Johnson & Johnson India, Xian-Janssen China (a J&J affiliate) based at Beijing, China and G.D Searle India. He joined Ranbaxy in March 2001.

He is a pharmacy graduate with an MBA post-graduate degree from Ahmedabad, Gujarat University. Sanjeev I. Dani is an alumni of Columbia University, USA having completed its General Management course.



Vivek Mohan

Vivek Mohan Managing Director, Abbott India Limited

Vivek Mohan is Managing Director of Abbott India Ltd, a publicly traded company in India. He has held this role since November 2004. He was earlier General Manager for Abbott Indonesia based in Jakarta.

Vivek has been with Abbott for 18 years and started his career with Abbott in May 1992 as a scientist for the Diagnostics Division in the US. Since then he has held various international roles with Abbott including pharmaceutical sales management for Abbott UK and nutritional marketing roles for Abbott in the Middle East.

Vivek has successfully strengthened organizations and operations in several international markets through focused revitalization initiatives and implementation of new commercial models.

Vivek has an MBA in International Business from the University of Illinois, and a B.Sc. in Microbiology from the University of Michigan.

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The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.

CII is a non-government, not-for-profit, industry led and industry managed organisation, playing a proactive role in India's development process. Founded over 115 years ago, it is India's premier business association, with a direct membership of over 8100 organisations from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 companies from around 400 national and regional sectoral associations.

CII catalyses change by working closely with government on policy issues, enhancing efficiency, competitiveness and expanding business opportunities for industry through a range of specialised services and global linkages. It also provides a platform for sectoral consensus building and networking. Major emphasis is laid on projecting a positive image of business, assisting industry to identify and execute corporate citizenship programmes. Partnerships with over 120 NGOs across the country carry forward our initiatives in integrated and inclusive development, which include health, education, livelihood, diversity management, skill development and environment, to name a few.

CII has taken up the agenda of "Business for Livelihood" for the year 2010-11. Businesses are part of civil society and creating livelihoods is the best act of corporate social responsibility. Looking ahead, the focus for 2010-11 would be on the four key Enablers for Sustainable Enterprises: Education, Employability, Innovation and Entrepreneurship. While Education and Employability help create a qualified and skilled workforce, Innovation and Entrepreneurship would drive growth and employment generation.

With 64 offices and 7 Centres of Excellence in India, and 8 overseas in Australia, China, France, Germany, Singapore, South Africa, UK, and USA, and institutional partnerships with 223 counterpart organisations in 90 countries, CII serves as a reference point for Indian industry and the international business community.

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