Indian Pharma Sector -

A Strategic Shift

Q S Consultants India Pvt. Ltd.

INTRODUCTION

Q S Consultants is a Strategic Business Advisory company. Our bouquet of services includes Mergers & Acquisitions, Financing Services, Sustainable development practices & Corporate Restructuring. We bring dedicated expertise and a imaginative approach to meet the demands of an industry in the midst of rapid transition and offer well defined and executable strategies to achieve business objectives.

Helping you make the

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Indian Pharma Industry - A Snapshot

- India is the world's 4th largest producer of pharmaceuticals by volume, accounting for around 8% of global production and ranks 13th in value terms.
- The domestic formulation segment accounted for almost 48%, the formulation export market accounted for about 25%, while the bulk drug exports segment constituted for the balance 27%.

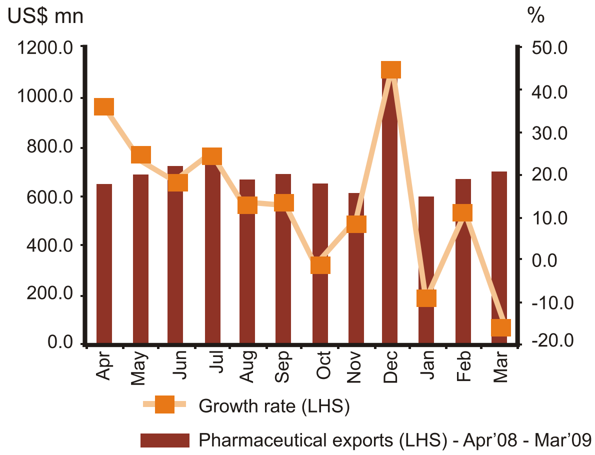


Figure 1: Indian Pharma Exports FY 2009

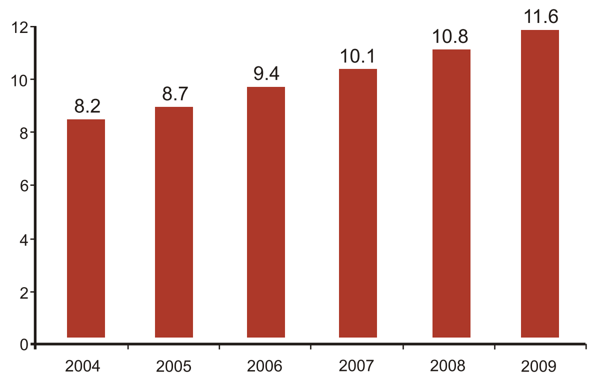
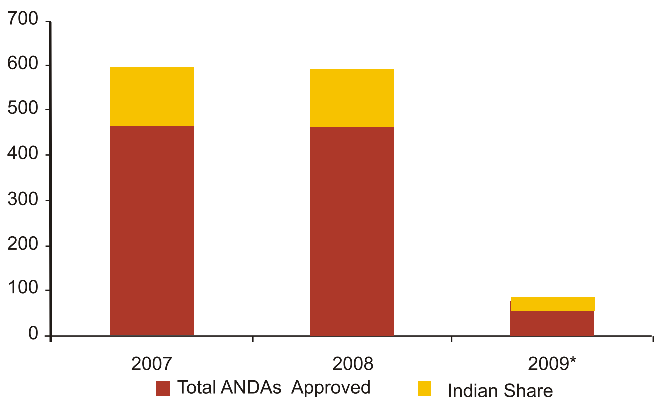
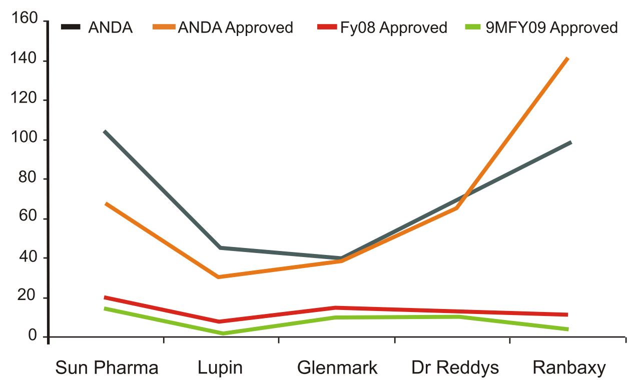


Figure 2: Growth in Indian Pharma Industry (US$ bn.)

- The domestic pharma industry is going through a transformation, led by strong underlying growth drivers. The industry has grown at CAGR of 13% from 2002-2007 and is expected to grow at a CAGR of 16% over 2007- 2011.
- The domestic pharmaceutical market recorded a growth of 18% in 2009 and is the 2nd largest market in terms of consumption.
- India's pharmaceutical market has the potential to grow to US$20 bn. by 2015, maintaining 13% CAGR, growing more than 300% from US$6 billion in 2005. This incremental growth of around US$14 bn. will make India the third largest market after the US and China in value terms in 10 years.
- Drug approvals given to Indian firm were 30% of total generic medicine approvals given by USFDA during 2008. The trend is likely to continue, as Indian companies account for 35% of all ANDA (Abbreviated New Drug Application) approvals given by the USFDA in the first two months of 2009.[1]





- The Indian pharmaceutical market grew 15% in 2008, largely driven by volume and new products, with the domestic market touching Rs 32,095 cr. Tier II cities (with population less than 1 lakh) and rural areas currently account for 40% of the market, and are expected to grow much faster than the rest of the country.
- More than 85% of the formulations produced in the country are sold in the domestic market. India is largely self-sufficient in case of formulations. Overall, the size of the domestic formulations market is around Rs. 160 billion and it is growing at 10% per annum.

[1] US, regardless of competition and pricing pressure, remains the largest generic market in the world with a projected size of $52.3 billion in 2011.

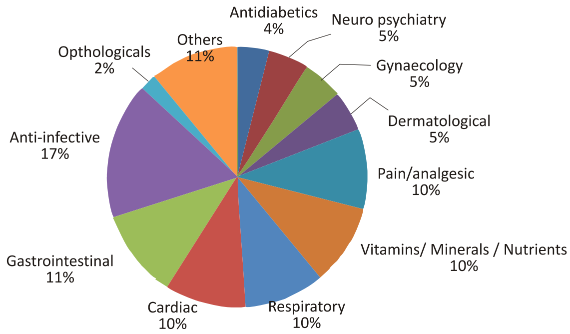
Key Industry segments

Generics

- The Indian pharma industry is a leading producer of high quality, low cost generic drugs. It has a significant market share in the US$80 billion world generic market and is expected to increase it to 50% by 2010.
- India is conveniently placed, with the advantage of cost competitiveness, ability and experience in reverse engineering, availability of skilled scientific and engineering personnel and the capability to produce raw materials for a wide range of drugs from the basic stage.
- The Indian generic manufacturers are expected to grow at a faster rate as drugs worth approximately US$ 20 bn in annual sales will face patent expiry in 2011. Nearly US$ 80 billion worth of patent-protected drugs will go off-patent (including 30 of the best selling US patent-protected drugs) by 2012.
- The generic penetration in Europe has increased manifold over last 7 years. UK which is second largest market in EU has grown by 2 times during last 7 years. Europe's generics market is expected to grow from an estimated US$18.7 billion in 2006-07 to over US$30 billion in 2011-12.

Category	Value (Rs bn)	Value Market Share (%)	Value growth (%)	Volume Growth (%)
Anti-infective	32.8	16.4	4	11
Gastrointestinal	21.8	10.9	8	9
Cardiac	20.7	10.3	18	15
Respiratory	20.4	10.2	9	6
Vitamins/ Minerals / Nutrients	19.3	9.6	5	5
Pain/ Analgesic	19.1	9.5	8	9
Dermatological	10.8	5.4	8	4
Gynaecology	10.7	5.3	3	-1
Neuro psychiatry	10.6	5.3	10	6
Antidiabetics	8.8	4.4	11	16
Opthologicals	3.5	1.7	18	16
Others	22.0	11.0	-	-

Market Share of Different Pharmaceutical Product Categories



- Generic drugs interest pharma manufacturers because they are cheaper than the originator due to lower costs. The price advantage coupled with quality determines the market share of the generic companies. Consumers in this market enjoy the advantages of price and quality competition as they get better products at lesser prices.
- The only threat the generic drug face is the intensity of competition and with globalization this threat assumes huge proportions.
- Antibiotics, anti hypertensives anti ulcerants, and non steroidal anti-inflammatory drugs (NSAIDs) are the most commonly registered generics.
- Strict government regulations coupled with the high cost of new introductions have favored the growth of the generic drugs.
- The global market for generic drugs is expected to grow at a CAGR of 13-14% in the decade 2000-2010. The size of the generic market open for imports is huge. The US and Germany are the two largest markets for generic products in the world at present.
- Generic drugs account for a major part of all prescriptions. In emerging markets, big multinationals are seeking to exploit global scale economies by catering to the big volume generic market.
- The manufacture of sophisticated drugs in India within a short period of their introduction by their inventors abroad and the practice of cost-efficient process technology to produce these drugs at prices much lower than those overseas are the major strengths of the Indian industry. India's already established position of acceptance in international pharmaceutical markets, and the ability to produce bulk drugs of high quality and low cost and with a number of its manufacturing plants already approved by the USFDA, offers substantial export potential.

API

- Indian bulk drugs market was US$4.1 billion, witnessing a CAGR growth of 18.8% during 2003-2007. India ranks 4th in the world in terms of API output.
- Bulk Drug exports accounts to 80-90% of the total bulk drugs production in India, which accounted for about 28% of overall pharmaceutical demand. The Indian API export market is expected to increase to US$12.75 billion in 2012 from US$3.75 billion in 2007 (a CAGR of 28%).
- Indian companies have the distinction of developing cost-effective technologies for manufacturing bulk drugs and intermediates, conforming to global standards.
- India has over 80 US FDA approved plants, the second highest in the world. India currently has about 3000 API factories and 5,000 reagent factories, the key API producers including the Ranbaxy, Dr. Reddy, Cipla Ltd, Cadila Healthcare and Matrix. They are producing more than 400 sorts of API and around 10,000 kinds of reagents, satisfying over 90% of Indian domestic demand.

MNC Pharma

Indian market has emerged as a key destination for global pharma companies, thanks to its high growth prospects and conducive regulatory environment. MNC pharma companies are likely to witness a sea change in their strategy and are aggressively scouting for growth options. The MNCs have embarked on a multi-pronged strategy to establish their stronghold in Indian market by introducing patented products, divesting non-core businesses, going in for acquisitions, strengthening sales and distribution network as well as developing India-centric portfolios.

Key Industry risks:

Delay in the ANDA approvals by USFDA

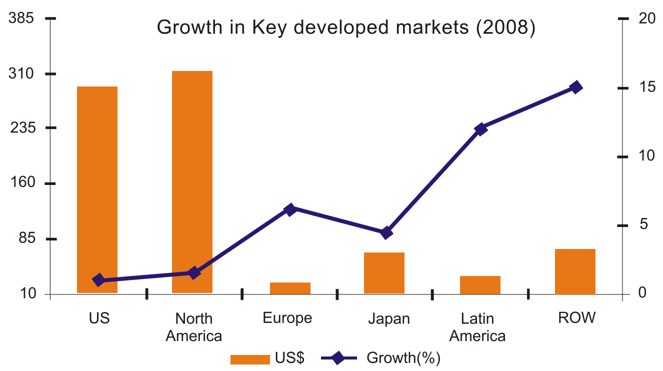
US, not only being the largest market but also the biggest growth driver for most of the pharma companies in India as well as globally. Any delay in product approvals from the USFDA would have severe impact not only on the revenues as well as margins of the company. Therefore we see this as a key risk to the business of the companies.

The US Trade pact

This has raised concerns for the domestic pharma companies as certain clauses would cause significant reduction in exports. The Indian companies would experience a hit in revenues as cheaper generic versions would take longer to reach markets across the world due to patent extensions. However, as the under developed as well as developing countries witness supply shortages due to unavailability of cheap generic drugs, their dependence on expensive innovative drugs would increase. It is estimated that around $123 billion of generic products could go off patents by 2012 across the globe. This would amount to an $18.4 billion opportunity for the Indian pharma industry if we conservatively estimate 15% of this market for India.

Global Pharma Industry

- The global pharma industry poised a growth of 5%-6% in 2008 and touched the level of US$ 770 billion. The global pharmaceutical market would grow at about 5% in 2009 to US$820 billion and over US$1 trillion by 2013.
- North America, Europe and Japan turned out to be the key contributor to the growth and accounted to nearly 85% of the global pharma sales in 2008. In terms of growth, the Latin American market, which constitutes 5% of the total market, grew by 13%. Asia, Africa and Australia collectively account for 8.5% of the market and achieved the second highest growth rate of 9.8%.
- Approximately 31 new molecules were launched in key global markets and with over 2,075 molecules under development; the global R&D pipeline has grown by over 35%.
- The pharma industry across the globe recorded a slower growth due to the factors like increased volume for generic drugs, drying up of the new patented products in the market and economic downturn.



Top three therapeutic category	
Therapeutic Area	Market Size
CNS	US$ 118 billion
Cancer drugs	US$ 70 billion
CVS	US$ 105 billion

- The global generic industry witnessed a marginal growth of 3.6% in 2008 to touch US$ 80 billion. The growth was adversely impacted due to the low growth rates in developed markets primarily due to price erosion. The emerging markets reported an overall growth of 14%.
- US, regardless of witnessing intense competition and pricing pressure remains the largest generic market in the world with a projected size of US$52.3 billion in 2011 (14% of the total drug market in
- The generic industry globally would record a healthy CAGR of 10% over the five years 2007-2012 with major contribution from emerging markets.

Major International Markets:

There are four major international destinations within the global pharma industry as follows:

US Market– expected to contract

The pharmaceutical market in the US witnessed a slowdown in the growth in the year 2008 mainly due to high level of generic penetration, economic climate, and less than expected demand for the recently introduced drugs. We expect that going forward the contraction in the demand for pharmaceutical drugs would continue resulting in the US market experiencing a continued slow down in the growth rate. The US market with a mammoth size of $312 Bn is the largest pharma market across the globe.

Europe – next big market for the players

Europe, the 2nd largest pharma market contributes around US$ 247 billion to the world's pharmaceutical market. It recorded a growth of around 5-6% in the year 2008, with the top 5 markets (France, Germany, the UK,, Italy and Spain) in Europe together grew at 4%-5% in 2008 (up from 3%-4% in 2007). Going forward we expect these market to continue with its growth trend of 5%-6% led by increased demand from ageing population, rising need of preventive care.

Japan – 3rd largest market

Japan turned out to the 3rd largest market after US and Europe. It recorded a growth rate of 1%-2% a sharpest fall in the growth compared to 5%-6% in the year 2007. The Japanese pharmaceutical market generated total revenues of US $65.3 billion in 2008, representing a compound annual growth rate (CAGR) of 2.4% for the period spanning 2004-2008. According to IMS Health, the Japanese market is expected to increase to US $ 79 billion by 2013 and nearly US $ 105 Bn by 2023. Japan is one of the most lucrative destinations for pharma players mainly because of the rapidly ageing population, increasing incidence of western life style diseases and also increasing scope of growth in obesity, metabolic diseases, cancers, central nervous system diseases, type II diabetes and cardiovascular disease.

Emerging market – taking the centre stage

The pharma MNCs globally are targeting emerging markets mainly to overcome to slow growth recorded in the developed nations. According to the IMS Health Inc, the seven emerging pharmaceutical markets of India, China, Brazil, Mexico, South Korea, Turkey and Russia grew by 12% in the year 2008 mainly due to the expanding economies, increasing affordability and broader access to health care. In 2008 the seven emerging markets are expected to contribute nearly 25% to the global pharma sales whereas moving ahead we estimate this share to spurt up to 40%. China which is sixth largest market in the world at present is expected to become the 3rd largest market by 2011. According to the forecast by IMS, the revenue contribution from emerging markets by 2017 would be between US $ 290 Bn to US $ 320 Bn, a CAGR of 12%-15%.

Key Market Trends

Key market trends emerging on a global platform are as follows:

Declining R&D productivity

Even though the global R&D pipeline has grown at an attractive rate, the industry is facing severe pressure on account of reducing number of blockbuster drugs coming into the market coupled with declining R&D productivity on the back of steeply rising drug discovery and development costs, as well as increasing sales and marketing expenses.

Increasing spread of generics

There is global shift towards use of generics as governments worldwide are under tremendous pressure to curtail steeply escalating healthcare budgets. The global generics market was valued at $ 77 billion in 2006, split 60:40 between emerging and regulated markets. The US market has a share of over 28% of the world's generics market and is still by far the largest generics market. In Europe, Germany and UK have the highest generics penetration rate by value, of around 23% and 20% respectively, whereas in Japan, generics accounts for only 5% of the total market by value

Increasing outsourcing

Multinationals are increasingly outsourcing activities such as drug development and manufacturing to low cost destinations and are increasing their focus on core functions of drug discovery, sales and marketing and brand management.

Opening new doors of opportunity for you...

Q S Consultants India Pvt. Ltd.

Q S Consultants India Pvt. Ltd. ,
A20, Nakshatra Apartments, Wd no7, Mehrauli, New Delhi-110030 India email: info@qsconsultants.in, www.qsconsultants.in

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