

A Case Study

on

**A case study on Pharmaceutical Industry
of ABC Pvt. Ltd.”**

By

Prof. Kiran Khatri (Assistant Professor) with following students of MBA

AchwalaBurhanJakirHussain
QureshiM.KalimM.Akbar
VajaVikaskumarNandkishorbhai
AkashThakkar
Shah Navin
Sitarambhai
TripathiUtkarshPankajkumar
SaiyedMohamadSelan
SiddharthIyer
TopiyaUjashChandubhai
PrajapatiDhwaniDilipkumar
Tariq Parmar
GoswamiYashGulabgiri
KherRahulkumarJesingbhai

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Introduction to the Pharmaceutical Sector:

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value. Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 per cent of the market. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 percent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented.

India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immuno Deficiency Syndrome) are supplied by Indian pharmaceutical firms. The UN-backed Medicines Patent Pool has signed six sub-licences with Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs, allowing them to make generic anti-AIDS medicine TenofovirAlafenamide (TAF) for 112 developing countries.

Market Size

The Indian pharma industry, which is expected to grow over 15 per cent per annum between 2015 and 2020, will outperform the global pharma industry, which is set to grow at an annual rate of 5 per cent between the same period. The market is expected to grow to US\$ 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally by absolute size. India has also maintained its lead over China in pharmaceutical exports with a year-on-year growth of 7.55 per cent to US\$ 12.54 billion in 2015, according to data from the Ministry of Commerce and Industry.

Overall drug approvals given by the US Food and Drug Administration (USFDA) to Indian companies have nearly doubled to 201 in FY 2015-16 from 109 in FY 2014-15 an increase of 84 per cent as per analysis by USFDA.

India's biotechnology industry comprising bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics is expected to grow at an average growth rate of around 30 per cent a year and reach US\$ 100 billion by 2025. Biopharma, comprising vaccines, therapeutics and diagnostics, is the largest sub-sector contributing nearly 62 per cent of the total revenues at Rs 12,600 crore (US\$ 1.9 billion).

Investments

The Union Cabinet has given its nod for the amendment of the existing Foreign Direct Investment (FDI) policy in the pharmaceutical sector in order to allow FDI up to 100 per cent under the automatic route for manufacturing of medical devices subject to certain conditions. The drugs and pharmaceuticals sector attracted cumulative FDI inflows worth US\$ 13.85 billion between April 2000 and March 2016, according to data released by the Department of Industrial Policy and Promotion (DIPP).

Some of the major investments in the Indian pharmaceutical sector are as follows:

- International Finance Corporation (IFC), the investment arm of the World Bank, plans to invest upto US\$ 75 million in Glenmark, which is looking to raise around US\$ 200 million for expansion and the launch of several new products in India and other emerging markets over the next three years.
- Cipla Limited, one of India's leading pharmaceutical firms, plans to invest around Rs 600 crore (US\$ 88.94 million) to set up a biosimilar manufacturing facility in South Africa for making affordable cancer drugs and growing its presence in the market.
- RusanPharma, a firm which specialises in de-addiction and pain management products, plans to invest Rs 100 crore (US\$ 14.82 million) in a Research and Development (R&D) centre and a manufacturing unit in Kandla, located in Kutch District in Gujarat.
- Pink Blue Supply Solutions Pvt. Ltd, a clinical supplies provider, has raised Rs 1.5 crore (US\$ 0.22 million) in a seed round of funding from TermSheet.io, a transaction-focused service provider for start-ups and investors.
- The Medicines Patent Pool (MPP) has signed a licencing agreement with six Indian drug makers for the generic manufacturing of four antiretrovirals (ARV) and hepatitis C direct-acting antiviral drug Daclatasvir.
- Dr Reddy's Laboratories, one of the major pharmaceutical companies of India, has entered into a strategic collaboration agreement with Turkey-based TR-Pharm, to register and subsequently commercialise three biosimilar products in Turkey.
- Lupin has completed the acquisition of US-based GAVIS Pharmaceuticals in a deal worth US\$ 880 million, which is expected to enhance its product pipeline in dermatology, controlled substances and high-value speciality products.
- Cipla Ltd, one of the major pharmaceutical and biotechnology companies in India, has acquired two US-based generic drug makers, InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc., for US\$ 550 million, which is expected to strengthen Cipla's US business.
- Emcure Pharmaceuticals has acquired Canada's International Pharmaceutical Generics Ltd and its marketing arm Marcan Pharmaceuticals in order to boost its global expansion drive.
- Cipla announced the acquisition of two US-based companies, InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc., for US\$550 million.
- Glaxosmithkline Pharmaceuticals has started work on its largest greenfield tablet manufacturing facility in Vemgal in Kolar district, Karnataka, with an estimated investment of Rs1,000crore (US\$ 148.24 million).
- Lupin has acquired two US based pharmaceutical firms, Gavis Pharmaceuticals LLC and Novel Laboratories Inc, in a deal worth at US\$ 880 million.
- Several online pharmacy retailers like PharmEasy, Netmeds, Orbimed, are attracting investments from several investors, due to double digit growth in the Rs 97,000 crore(US\$ 14.38 billion) Indian pharmacy market.
- StelisBiopharma announced the breakthrough construction of its customised, multi-product, biopharmaceutical manufacturing facility at Bio-Xcell Biotechnology Park in Nusajaya, Johor, Malaysia's park and ecosystem for industrial and healthcare biotechnology at a total project investment amount of US\$ 60 million.
- Strides Arcolab entered into a licensing agreement with US-based Gilead Sciences Inc to manufacture and distribute the latter's cost-efficient TenofovirAlafenamide (TAF)

product to treat HIV patients in developing countries. The licence to manufacture Gilead's low-cost drug extends to 112 countries.

- CDC, the UK's development finance institution, invested US\$ 48 million in NarayanaHrudayalaya hospitals, a multi-speciality healthcare provider, with an aim to expand affordable treatment in eastern, central and western India.
- Cadila Healthcare Ltd announced the launch of a biosimilar for Adalimumab - for rheumatoid arthritis and other auto immune disorders. The drug will be marketed under the brand name Exemptia at one-fifth of the price for the branded version-Humira. Cadila's biosimilar is the first in class and an exact replica of the original in terms of safety, purity and potency of the product, claims the company.
- Torrent Pharmaceuticals entered into an exclusive licensing agreement with Reliance Life Sciences for marketing three biosimilars in India — Rituximab, Adalimumab and Cetuximab.
- Indian Immunologicals Ltd plans to set up a new vaccine manufacturing facility in Pondicherry with an investment of Rs 300 crore (US\$ 44.47 million).
- SRF Ltd has acquired Global DuPont Dymel, the pharmaceutical propellant business of DuPont, for US\$ 20 million.
- Intas Pharmaceuticals is the first global company to launch a biosimilar version of Lucentis, the world's largest selling drug for treatment of degenerative eye condition called Razumab.

Government Initiatives

The Addendum 2015 of the Indian Pharmacopoeia (IP) 2014, published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, is expected to play a significant role in enhancing the quality of medicines that would in turn promote public health and accelerate the growth and development of pharmaceutical sector. The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments. Further, the government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines.

Some of the major initiatives taken by the government to promote the pharmaceutical sector in India are as follows:

- Government of India's decision to increase Foreign Direct Investment (FDI) in existing pharmaceuticals companies to 74 per cent is expected to boost Mergers and Acquisitions (M&As) and Private Equity (PE) investments in the pharmaceuticals sector in the country.
- Indian Pharmaceutical Association (IPA), the professional association of pharmaceutical companies in India, plans to prepare data integrity guidelines which will help to measure and benchmark the quality of Indian companies with global peers.
- The Government of India plans to incentivize bulk drug manufacturers, including both state-run and private companies, to encourage 'Make in India' programme and reduce dependence on imports of Active Pharmaceutical Ingredients (API), nearly 85 per cent of which come from China.

- The Department of Pharmaceuticals has set up an inter-ministerial co-ordination committee, which would periodically review, coordinate and facilitate the resolution of the issues and constraints faced by the Indian pharmaceutical companies.
- The Department of Pharmaceuticals has planned to launch a venture capital fund of Rs 1,000 crore (US\$ 148 million) to support start-ups in the research and development in the pharmaceutical and biotech industry.
- Indian and global companies have expressed 175 investment intentions worth Rs 1,000 crore (US\$ 148 million) in the pharmaceutical sector of Gujarat. The memorandums of understanding (MoUs) would be signed during the Vibrant Gujarat Summit.
- Telangana has proposed to set up India's largest integrated pharmaceutical city spread over 11,000 acres near Hyderabad, complete with effluent treatment plants and a township for employees, in a bid to attract investment of Rs 30,000 crore (US\$ 4.48 billion) in phases. Hyderabad, which is known as the bulk drug capital of India, accounts for nearly a fifth of India's exports of drugs, which stood at Rs 95,000 crore (US\$ 14.08 billion) in 2014-15.
- At the launch of Cluster Development Programme of pharmaceutical sector, Mr Ananth Kumar, Minister of Fertilizer and Chemicals, announced that six pharmaceutical parks will be approved and established this year which will have sufficient infrastructure and facilities for testing and treatment of drugs and also for imparting training to industry professionals.

Road Ahead

The Indian pharmaceutical market size is expected to grow to US\$ 100 billion by 2025, driven by increasing consumer spending, rapid urbanization, and raising healthcare insurance among others.

Going forward, better growth in domestic sales would also depend on the ability of companies to align their product portfolio towards chronic therapies for diseases such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers that are on the rise.

The Indian government has taken many steps to reduce costs and bring down healthcare expenses. Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies. In addition, the thrust on rural health programmes, lifesaving drugs and preventive vaccines also augurs well for the pharmaceutical companies.

Gujarat's Pharmaceutical Giants

Gujarat has a lion's share in the development of both the pharma and the pharma machinery industry in India. Today both the industries are flourishing industries in Gujarat according to Rajesh Shah, President of Indian Pharma Machinery Manufacturers Association (IPMMA).

Gujarat's pharma industry has a well-developed ecosystem with strong building blocks that have helped the industry grow at a phenomenal pace. Over the last few years, Gujarat has made a significant contribution in the growth of India's pharmaceutical industry. Gujarat commands 42 per cent share of India's pharmaceutical turnover and 22 per cent share of exports.

Approximately 52,000 people are employed in Gujarat's pharmaceutical sector, which has witnessed 54 per cent CAGR (Compounded Annual Growth Rate) in capital investments over the last three years. Valued at US\$ 4.4 billion in 2005-06, Gujarat's pharma industry has grown at a CAGR of almost 88 per cent between 2002-03 and 2005-06, as against the 18 per cent growth registered by the pharma industry of India as a whole, in the corresponding period, he said.

Gujarat, an established manufacturing base for bulk drugs and formulations — with its inherent competitive advantages— is poised to capture emerging global opportunities to become a global pharmaceuticals hub. Emergence of SEZs is likely to create a pharma behemoth- with scale and infrastructure on par with international standards that will enable it to compete in the global market place. The availability of a well-developed chemicals industry, which has strong linkages with pharma API (active pharmaceutical ingredient)/intermediates can be utilised to boost the high growth of CRAMS (contract research and manufacturing sector). This could make Gujarat a strong sourcing base for global pharma companies, he added

Evolution of pharma machinery industry

According to him, the roots of today's vibrant and flourishing pharma and pharma machinery industry are old and strong. Alembic Chemical Works Co. Ltd., one of the oldest pharma companies in India, was set up in Vadodara in 1907, just six years after India's first domestic pharmaceutical unit- Bengal Chemical and Pharmaceutical Works was set up in Kolkata. Sarabhai Chemicals was started soon thereafter. Also the industry had received strong support from the academic field. In 1940, a drugs laboratory was established in Vadodara and this was followed by setting up of the LM College of Pharmacy in Ahmedabad. In the early sixties Cadmach was set up in Ahmedabad and further in 1989, the B. V. Patel Education Trust, Ahmedabad and Gujarat Branch of Indian Pharmaceutical Association (IPA) - established the B.V. Patel Pharmaceutical Education and Research Development (PERD) Centre in Ahmedabad.

Also in the last few decades, the invested capital to labour ratio has risen significantly. The employment almost doubled between 1979-80 and 1997-98. Over the years, the industry has developed strong linkages with related sectors and industries. Today there about 3,500 drug manufacturing units in Gujarat and the state houses several established companies such as Torrent Pharma, ZydusCadila, Alembic, Sun Pharma, Claris, Intas Pharmaceuticals and Dishman Pharmaceuticals, which have operations in the world's major pharma markets.

Pharma industry performance

In the exports segment too, Gujarat's pharmaceutical industries' performance has been exemplary. Exports, valued at US\$ 1.1 billion in 2005-06, have grown at an impressive CAGR

of nearly 78 per cent between 2002-03 and 2005-06 as against the 28 per cent growth in India's total pharma exports during the same period. Of the state's total exports, bulk drugs constituted for 40 per cent, while formulations accounted for the remaining 60 per cent.

Gujarat holds a dominant position in India's pharma industry. The state has successfully captured a share of over 42 per cent of India's total turnover in 2005-06. This is a steep increase from the mere 10 per cent market share in 2002-03. As a precursor to growth, capital investment in the pharma industry in Gujarat has also increased at an astounding CAGR of about 54 per cent between FY'03 and FY'06 – reflected in the increase of number of units (both own as well as loan) from 1,964 in 2003 to 3,462 in 2007, he explained.

Opportunities galore

Similarly in the pharmaceutical machinery sector, there is a strong local and global opportunity for Gujarat, given its strong and well established engineering sector. Over the years with the rise of the pharma industry, the pharma machinery industry also made giant strides catering to various segments like tableting, powder processing, capsulation, R&D equipment & instrumentation, material handling, coating, bulk drug plant installation & packaging. The pharmaceutical machinery manufacturers of Gujarat have huge potential and as such many international companies have collaborated with many such companies. This has enabled Gujarat pharma industry to procure machineries at a price almost one third or one fourth of the imported technology.

The pharma machinery industry is growing 15-20 per cent annually. A basic advantage of using machineries made in the domestic market is that the foreign machines are five times more expensive than locally manufactured machines, for the same products and in the same capacity. People still look to the Gujarat market for those products because Gujarat pharmaceutical machineries provide value for money. No wonder then the Gujarat pharma machinery industry has earned the reputation of being the hub for low-cost manufacturing. The reasons behind this is the availability of cost-efficient man power, highly skilled and experienced engineers and low capital investment on plant and machinery.

Going global

Gujarat pharma machine makers and their foreign counterparts are increasingly exploring various collaborations and partnerships with each other to share new technology, to innovate and develop new technology. Together, they are targeting more price conscious developing countries. Gujarat is becoming an integral part of the global pharmaceutical value chain and many Indian companies are participating in this global growth potential through their organic as well as

inorganic initiatives. Pharma companies from Gujarat have also contributed significantly to this process through acquisitions of foreign assets or by having export-led business models – reflected in Gujarat’s increasing share in India’s pharma exports as well as industry turnover.

Going forward, as India further increases its dominance in the world pharma market, Gujarat with its growth enablers and strong building blocks can become a global pharmaceutical hub. However, this would call for an enormous change in mindset and transformation to attract global capital and talent. The path to globalization is full of opportunities but also fraught with risks. Companies which would develop the right framework that would help them capitalize on this opportunity and mitigate risks will benefit the most, he opined.

Pharma SEZs

Also we need to focus our attention on the proposed pharma SEZs which are expected to further boost India’s pharmaceutical exports segment. And Gujarat, which is witnessing a vibrant growth in this segment, will be one of the major beneficiaries of this development. SEZs are instrumental in bringing in globalization at a faster pace, due to their inherent outward looking foreign trade focus by establishing close global contacts. SEZs, therefore, offer distinct advantages to export oriented pharma companies who are present in these zones. SEZs— which have good infrastructure facilities and technology— can help these pharma companies develop a global mindset, he emphasized.

Gujarat is set to witness tremendous benefits from the development of SEZs, as it already has an established pharma ecosystem with excellent infrastructure facilities. Through these SEZs, pharma companies in Gujarat will further facilitate India's integration in the global pharma industry. Also there is a strong local and global opportunity for Gujarat in the manufacturing of pharmaceutical machinery, given its strong and well established engineering sector.

According to industry estimates, approximately 35-40 per cent of India’s pharmaceutical machinery is produced in Gujarat. The strong growth prospects of the pharmaceutical exports segment and growing demand from the domestic market, will further fuel growth in the pharmaceutical machinery sector. However, Gujarat’s engineering sector is highly fragmented, especially the pharma machinery manufacturing segment. Due to the highly fragmented nature, there is a dearth of pricing power and critical scale. This in turn restricts the ability to produce the technology-driven products required for operating in global markets. The pharma machinery manufacturing industry in Gujarat needs to consolidate and synergise the skills and complementarities available in the broader engineering sector (like the CNC machine tools industry) to be able to create world-class players with the scale and resources required, to tap the global as well as local demand. As such Gujarat’s dominant position in India’s pharmaceutical sector is well known. The next logical step is to aspire for global leadership in the

pharmaceutical industry.

Need for new strategies

Pharmaceutical sales in India grew at an average annual rate of 9.6 per cent in 2000-04, faster than growth in GDP and real private consumption. As so many of India's healthcare requirements are being met by private expenditure, rising personal incomes should push pharmaceutical sales steadily higher. This is already being reflected in rising revenue for pharmaceutical companies. In the pharmaceutical sector, comparisons are now being drawn between India's increasingly successful drug companies—whose exports are growing rapidly—and its well-known information technology (IT) companies. Indian firms such as Ranbaxy Laboratories and Dr Reddy's Laboratories, which derive more than 50 per cent of their revenue from international sales, should grow steadily, he informed.

Exports have become a major growth area for Indian drug manufacturers. Domestic pharmaceutical companies have thrived by using their low labour and research costs to export generic drugs to developed-country markets, especially the US. Exports are likely to maintain strong growth in the coming years. Opportunities in the developing world are also expanding rapidly.

But to maintain the growth momentum, the Indian pharma industry at large will have to focus on the emerging techniques and work out new strategies to overcome the dependability on obsolete technologies. The local production of copycat pharmaceuticals, patented in other countries, is widespread. Several multinational drug companies import bulk drugs from the parent company and process them for the local market. India is self-sufficient in terms of formulation technology, including those for sulpha drugs, vitamins, hormones and a number of new synthetic drugs. Also India is home to the largest number of pharmaceuticals plants approved by the USFDA outside the US.

But driven by the change to a product patent regime and the opportunities offered in the international market, the mindset of Indian companies towards research has altered. Indian companies are shifting their focus to innovative research that is, developing non-infringing processes, New Chemical Entities (NCEs), Novel Drug Delivery Systems (NDDS), Biopharmaceuticals etc. Thus Indian drug companies have started to invest more in research and development to produce their own patented products.

The Indian industry at large has developed good R&D skills through reverse engineering. But adoption of product patent regime has forced industry to acquire product development skills. While investments in R&D may be lower than global standards but now growing at 32 per cent per annum as Indian companies surge for intermediate level of technology competence or to affiliate themselves with large Western pharmaceutical companies and become outsourcing centres for some of those firms' activities, such as clinical trials.

The better-financed companies are already attempting to develop their own drugs—to become innovators instead of just copiers. This is an expensive process, and will not yield results quickly,

if ever. As an alternative, Indian firms are expanding their overseas sales of existing generic drugs. To that end, some have already established production facilities and equipment that meet regulatory standards in the US and elsewhere. Some Indian companies have also begun purchasing foreign pharmaceutical firms to improve their access to overseas markets and develop new profit streams.

Also the Indian firms have begun collaborating with Western drug companies on back-office clinical trials and other research-oriented activities, which Indian companies can often perform at a fraction of the developed-country cost, he informed.

Challenges and solutions

If one were to do a SWOT analysis of the Gujarat pharma sector then I would rate the strengths of the industry as modern infrastructure facilities, backward linkages with raw material suppliers, established pharma industry, entrepreneurial mindset, well-developed allied industries and a benign regulatory environment. As far as the weaknesses are concerned then it is definitely the low level of spend in the R&D sector, relatively inadequate technical manpower and skilled workforce and limited international exposure for most small to medium scale companies.

Amongst the opportunities are SEZ-led significant export opportunities and high growth segments such as CRAMS, R&D and generics. As far as threats are concerned for Gujarat then announcement of tax holidays from governments of other Indian states, emergence of other alternative pharma destinations abroad, inadequate emission norms and waste disposal facilities may hinder growth. Gujarat's dominant position in India's pharmaceutical sector is well known. The next logical step is to aspire for global leadership in the pharmaceutical industry.

However, global dominance would require continuance of current growth-oriented policies that have helped Gujarat achieve this mark, and acquisition or development of capabilities required for operating in the global market place. Many pharma companies in Gujarat have adopted the inorganic route to participate in the global markets. However, operating in the world markets is not just about acquiring global assets but also about having a global mindset. In order to benefit from the on-going integration of the world pharma markets, the pharma industry and companies have to change internal mindsets to think and compete globally, and create an environment of innovation. Companies would have to imbibe a culture that enhances its efficiency while responding to the global challenges in different geographies. Having a world-class management team, reflective of the diverse global markets in which they operate, would be a start in this direction. The use of global IT solutions is another area that needs to be addressed, he concluded.

SWOT Analysis of the Industry

The SWOT analysis of the industry reveals the position of the Indian pharmaceutical industry in respect to its internal and external environment.

a) Strengths

- Higher GDP growth leading to increased disposable income in the hands of general public and their positive attitude towards spending on healthcare.

- Low-cost, highly skilled set of English speaking labourforce and proven track record in design of high technology manufacturing devices.
- Growing treatment naive patient population.
- Low cost of innovation, manufacturing and operations.

b) Weaknesses

- Stringent pricing regulations affecting the profitability of pharma companies.
- Poor all-round infrastructure is a major challenge.
- Presence of more unorganized players versus the organized ones, resulting in an increasingly competitive environment, characterized by stiff price competition.
- Poor health insurance coverage.

c) 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.
- Significant investment from MNCs.
- Public-Private Partnerships for strengthening Infrastructure.
- Opening of the health insurance sector and increase in percapita income - the growth drivers for the pharmaceutical industry.
- India, a potentially preferred global outsourcing hub for pharmaceutical products due to low cost of skilled labour.

d) Threats

- Wage inflation.
- Government expanding the umbrella of the Drugs Price Control Order (DPCO).
- Other low-cost countries such as China and Israel affecting outsourcing demand for Indian pharmaceutical products
- Entry of foreign players (well-equipped technology-based products) into the Indian market.

PESTEL Analysis

Political

There is now growing political focus and pressure on healthcare authorities across the world. This means that governments will be looking for savings across the board. Some of the questions the industry should ask are:

- What pressures will be put on pricing?
- What services will be cut?
- Will the same selection of drugs be available to everyone?

In addition to this, could there be more harmonization of healthcare systems across Asia? What impact will reforms have on insurance models?

Economic

The global economic crisis still exists yet government reports still show that the spending on the healthcare per capital continues to grow. Will the current healthcare models exist tomorrow? The growth in homecare (as seen in the Nutrition sector) demonstrates how nursing services have moved to the private sector and have become a key business offering.

The reduction in consumer disposable income will have an impact on those countries using health insurance models particularly where part payment is required.

These economic pressures are seeing an increased growth in strategic buying groups who are forcing down prices.

Increased pressure from shareholders has caused a consolidation of the industry: more mergers and acquisitions will take place over the coming years.

Social / Culture

The increasing aging population offers a range of opportunities and threats to the pharmaceutical industry. The trick will be to capitalise on the opportunities.

There is also the problem of the increasing obesity amongst the population and its associated health risks.

Patients and home careers are becoming more informed. Their expectations have changed and they have become more demanding. Public activism has also increased through the harnessing of new social networking technologies. How can pharmaceutical companies get closer to consumers without over stepping the regulatory boundaries?

Technological

Technological advancements will create new business prospects both in terms of new therapy systems and service provisions. The online opportunities will see the growth in:

- New info and Communications technologies.

- Social Media for Healthcare.
- Customized Treatments.
- Direct to Patient Advertising.
- Direct to patient communications.

Legislation

The pharmaceutical industry has many regulatory and legislative restrictions. There is also a growing culture of litigation in many countries. The evolution of the internet is also stretching the legislative boundaries with patient's demanding more rights in their healthcare programmes.

Environmental

There is a growing environmental agenda and the key stake holders are now becoming more aware of the need for businesses to be more proactive in this field. Pharma companies need to see how their business and marketing plans link in with the environmental issues. There is also an opportunity to incorporate it within their Corporate Social Responsibility programmes. Marketing and new product development should identify eco opportunities to promote as well.

Conclusion

Overall growth outlook for the Indian drugs and pharmaceutical industry appears positive. Pharma manufacturers are likely to benefit from rise in demand for generic products. Some of the factors that would drive growth in the domestic pharma industry are: 1) low cost operations 2) research-based processes 3) improvements in API and 4) availability of skilled manpower. The domestic formulations and bulk drugs markets are currently facing price pressure as benefits of cheaper drugs have been shifted to end-users and trade channels. Hence, consolidation, partnership and alliances are expected to gather momentum in the near future. Off patenting of branded drugs would increase demand for generic drugs. This provides immense opportunities to the Indian pharmaceutical companies especially given their prior experience in generic drug development. Some other factors such as high penetration in the global markets and increase of share in Abbreviated New Drug Application (ANDA) filings are likely to power growth of the formulations market. Major growth drivers for the Indian bulk drug industry include rise in demand for contract manufacturing, increase of share in Drug Master Files (DMF) filings and process innovation. Furthermore, initiatives of the Government will act as a backbone for growth. Some such initiatives include: 1) allowing 100% FDI under the automatic route in drugs and pharmaceuticals including those involving use of recombinant technology 2) increasing weighted tax deduction on expenditure in in-house R&D activities to 200% in the Budget 2010 and 3) setting up a US\$ 639.56 mn venture capital fund to support drug discovery and strengthen pharmaceutical infrastructure

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