

A pest analysis of pharmaceutical industry



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The environment under which the Indian pharmaceutical industry is operating is changing very slowly at present, but is likely to change significantly – and significantly faster – in the future.

The Indian pharmaceutical industry grew at a very slow pace from 1947 to 1970, largely due to the lack of incentives and the failure of the government to set-up a concrete regulatory framework.

Today, the industry is characterized by numerous governmental regulations and policy changes, stifling price controls, rigorous controls on formulations, and an absence of international patent protection. During 1970, the Indian Patents Act (IPA) and the Drug Price Control Order (DPCO) were passed. Although the DPCO acted as a buffer against pharmaceutical companies making free pricing illegal, it fulfilled the goal of providing quality drugs to the public at reasonable rates.

The introduction of the IPA – which did not recognize product patents but only process patents – provided a major thrust to the industry and its companies, which, through the process of reverse-engineering, began to produce bulk drugs and formulations at lower costs. This led to high fragmentation in the industry, due to the emergence of a number of small firms.

The Indian Pharma Industry

Thus, there are today about 24, 000 companies – big, medium and small – fighting for a USD 3. 9 Billion market. The Indian pharmaceutical market is ranked 12th worldwide. About 300 firms are in the organized sector, about

15, 000 are in the small scale sector, and the rest are very small without any economies of scale.

India manufactures over 400 bulk drugs and around 60, 000 formulations, which are distributed by 5, 000, 000 chemists all over the country.

The Indian pharmaceutical industry is passing through a wave of consolidation, with the objective to strengthen their brand equity and distribution in what is essentially a branded-generics market.

The Indian pharmaceutical sector has come a long way, being almost non-existent before 1970 to a prominent provider of healthcare products, meeting almost 95% of the country's pharmaceuticals needs. The domestic pharmaceutical sales have increased from Rs. 4 bn in 1970-71 to Rs. 214 bn in 2002, at a CAGR (Compound Annual Growth rate) of 13. 7% per annum. The total Indian production constitutes about 1. 3% of the world market in value terms and, 8% in volume terms. The per capita consumption of drugs in India, stands at US\$ 3, is amongst the lowest in the world, as compared to Japan - US\$ 412,

Germany - US\$ 222 and USA - US\$ 191.

Climbing the value chain

Indian pharmaceutical industry is mounting up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving towards basic research driven, export oriented global presence, providing wide range of value added quality products and services. Government policies will play an important role in defining the

future of the pharmaceutical industry. The product patent regime which has come into effect from January 2005 will lead to long-term growth for the future.

In the present scenario, the growth of a domestic pharmaceutical company is critically dependent on its therapeutic presence. The old and mature categories like anti-infective, vitamins, and analgesics are de-growing while; new lifestyle categories like Cardiovascular, Central Nervous System (CNS), Anti-AIDS, Anti-Cancer and Anti Diabetic are expanding at double-digit growth rates.

The new trends

Increased generic penetration, intense competition, fragmentation of the industry has negatively impacted the overall value growth of the domestic pharmaceutical market. In this scenario, to grow in the domestic market, pharmaceutical companies are constantly eyeing for innovation, introduction of new value added products, product life cycle management and enlarging their market reach.

Indian companies are putting their act together to tap the generic drugs markets in the regulated high margin markets of the developed countries. The US market will remain the most lucrative market for the Indian companies led by its market size and the intensity of blockbuster drugs going off patent. An estimated US\$ 45bn of drugs expected to go off patent by 2007 in US alone.

Outsourcing in the fields of R&D and manufacturing is the next best event in the pharmaceutical industry. Spiraling costs, expiring patents, low R&D cost

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and market dynamics are driving the MNCs to outsource both manufacturing and research activities. India with its apt chemistry skills and low cost advantages, both in research and manufacturing coupled with skilled manpower will attract a lot of business in the days to come.

Indian companies have started investing more and more into R&D activity at home which is bound to one day give birth to new products invented in India and patented worldwide. This will enhance the bottom-line of Indian Pharma companies. Contract R&D is another offshoot of this phenomenon where MNCs set Indian companies to undertake research in the specified areas of their large Research projects. India offers cost advantages and skilled manpower for the purpose.

The Fields of Bio-technology and stem-cell Research has already produced wonderful results. Humuno-insulin and Hepatitis-B vaccines are producing wealth for India although in its infancy.

FMHG (Fast Moving Health Goods) is a new term introduced into the advertising world. Many a company has taken the direct route to the consumer's home just like consumer product. This has led to an increase in the incidence of self-medication and rising sales volumes for the industry.

Non-allopathic medication is another field which is showing good promise in terms of people's acceptance. With new and modern technology and standardization in the manufacturing and formulating practices, the therapeutic results with alternate systems of medicine are becoming more predictable. This has led to the emergence of a totally new field of

therapeutics. Many MNCs have also adopted these forms and reaped the benefit of a ready market.

Exports of bulk-drugs, formulations and API (Active Pharma Intermediates) have of late become the fashion. A company worth its salt has an export unit. The Government provides many fiscal incentives for exports such as Excise duty exemption, Exports subsidy, packing credits; export Financing, IT advantages, exemptions from Local laws etc. There are a number of examples where the companies started as a 100% EOUs (Export Oriented Units) and later diversified into local sales.

The Key Players

The Key Players in the Indian Pharmaceutical Industry are:

- Aarti Drugs
- Abbott India
- Ajanta Pharma
- Alembic
- Alkem
- Anglo-French Drugs
- Aristo
- Astrazeneca Pharma
- Aurobindo Pharma

- Aventis Pharma
- Cadila Health
- Cipla
- Concept
- Dr. Reddy
- Elder Pharma
- Franco-Indian
- Fulford India
- FDC
- German Remedies
- Glaxo Smithkline
- Ind Swift Lab
- Ipca Laboratories
- J B Chemical
- Jagson Pharma
- K D L Biotech
- Kopran

- Krebs Biochem

- Lupin

- Lyka Labs

- Maker

- Medicorp Tech

- Merck

- Natco Pharma

- Nicholas Piramal

- Novartis

- Orchid Chemicals

- Organon

- Panacea Bio

- Pfizer

- Pharmacia

- Ranbaxy

- Raptakos Brett

- R P G Life Sciences

- Shasun Chemicals

- Siris Limited

- Sterling Biotech

- Strides Arcolab

- Sun Pharma

- Suven Life Sciences

- Torrent Pharma

- Unichem Lab

- Wockhardt

- Wyeth Ltd

- Zandu Pharma

The future

In India, medicines represent between 10 to 15% of total health care costs. This will not rise substantially when product patents are introduced, for two reasons. First, over 90% of the medicines in the Indian market are now off-patent globally. Second, for most of those that would be patentable, there are close alternatives available which provide effective competition.

The real reason for the lack of access to medicines and other forms of healthcare is the prevailing stranglehold of Governmental regulation of the Healthcare sector.

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This dismal picture can, however, change dramatically if the Government takes prudent steps such as easing the DPCO and other regulations, provide adequate budgetary provision for Healthcare (Govt. spends a miserly 1% of GDP on healthcare), allow Indian companies to buy technology, allows Indian companies to buy finance, set up subsidiary companies abroad, allows FDI into the sector, freely allows tie-ups with MNCs, takes away restrictions on exports to some countries.

The industry on its own must take steps to increase its commitment to R&D, quality, manpower development, exports, market development and consolidation for economies of scale. The development of traditional system of medication like Ayurveda, Herbal and other systems of treatment must be researched into and standardized. Documentation on their therapeutic benefits must be generated and put open for one and all to study and analyze. Ayurveda can give India the cutting edge that the Pharma industry needs against a Patented regime dominated by MNCs.

The industry has a bright future.

PEST ANALYSIS

To understand the implications of the environment on any industry it is imperative to study the four cardinal influencers on the industry namely Political, Economic, Social and Technological factors. It is rather unfortunate that in India these factors have a rather disproportionate influence on the functioning of a commercial organization. From the days of independence the business environment has been overly regulated by a handful of bureaucrats, middlemen, businessmen and politicians. Its only a decade

since the country has seen an emergence of a political thought that encourages free enterprise. A welcome change indeed!

Political Factors

1. Today there is political uncertainty in the air. A combination of diverse political thought have got together to cobble together a rag-tag coalition, that is riddle with ideological contradictions. Therefore, any consistent political or economic policy can not be expected. This muddies the investment field.
 2. The Minister in charge of the industry has been threatening to impose even more stringent Price Control on the industry than before. This is throwing many an investment plan into the doldrums.
 3. DPCO which is the bible for the industry has in effect worked contrary to the stated objectives. DPCO nullifies the market forces from encouraging competitive pricing of goods dictated by the market. Now the pricing is determined by the Government based on the approved costs irrespective of the real costs.
 4. Effective January, 2005 the country goes in for the IPR (Intellectual Property Rights) regime, popularly known as the Patent Act. This Act will impact the Pharmaceutical Industry the most. Thus far an Indian company could escape paying a patent fee to the inventor of a drug by manufacturing it using a different chemical route. Indian companies exploited this law and used the reverse-engineering route to invent a lot of alternate manufacturing methods. A lot of money was saved this way. This also encouraged competing company to market their versions of the same drug. That meant
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that the impurities and trace elements found in different brands of the same substance were different both in qualification as well as in quantum.

Therefore different brands of the same medicine were truly different. Here Branding actually meant quality and a purer brand actually had purer active ingredient and lesser or less toxic impurities.

Product patent regime will eliminate all this. Now, a patented drug would be manufactured using the same chemical route and would be manufactured by the inventor or his licentiates using the chemicals with same specifications. Therefore, all the brands of the same active ingredient would not have any difference in purity and impurities. The different brands would have to compete on the basis of non input-related innovations such as packaging, color, flavors, Excipients etc.

This is the biggest change the environment is going to impose on the industry. The marketing effort would be now focused on logistics, communications, economy of operation, extra-ingredient innovations and of course pricing.

5. In Pharma industry there is a huge PSU segment which is chronically sick and highly inefficient. The Government puts the surpluses generated by efficient units into the price equalization account of inefficient units thereby unduly subsidizing them. On a long term basis this has made practically everybody inefficient.

6. Effective the January, 2005 the Government has shifted from charging the Excise Duty on the cost of manufacturing to the MRP thereby making the

finished products more costly. Just for a few extra bucks the current government has made many a life saving drugs unaffordable to the poor.

7. The Government provides extra drawbacks to some units located in specified area, providing them with subsidies that are unfair to the rest of the industry, bringing in a skewed development of the industry. As a results Pharma units have come up at place unsuitable for a best cost manufacturing activity.

Economic Factors

1. India spends a very small proportion of its GDP on healthcare (A mere 1%). This has stunted the demand and therefore the growth of the industry.

2. Per capita income of an average Indian is low (Rs. 12, 890), therefore, spending on the healthcare takes a low priority. An Indian would visit a doctor only when there is an emergency. This has led to a mushrooming of unqualified doctors and spread of non-standardized medication.

3. The incidence of Taxes are very high. There is Excise Duty (State & Central), Custom Duty, Service Tax, Profession Tax, License Fees, Royalty, Pollution Clearance Tax, Hazardous substance (Storage & Handling) license, income tax, Stamp Duty and a host of other levies and charges to be paid. On an average it amounts to no less than 40-45% of the costs.

4. The number of Registered Medical practitioners is low. As a result the reach of Pharmaceuticals is affected adversely.

5. There are only 50, 00, 000 Medical shops. Again this affects adversely the distribution of medicines and also adds to the distribution costs.

6. India is a high interest rate regime. Therefore the cost of funds is double that in America. This adds to the cost of goods.

7. Adequate storage and transportation facilities for special drugs is lacking. A study had indicated that nearly 60% of the Retail Chemists do not have adequate refrigeration facilities and store drugs under sub-optimal conditions. This affects the quality of the drugs administered and of course adds to the costs.

8. India has poor roads and rail network. Therefore, the transportation time is higher. This calls for higher inventory carrying costs and longer delivery time. All this adds to the invisible costs. Its only during the last couple of years that good quality highways have been constructed.

Socio-cultural Factors

1. Poverty and associated malnutrition dramatically exacerbate the incidence of Malaria and TB, preventable diseases that continue to play havoc in India decades after they were eradicated in other countries.

2. Poor Sanitation and polluted water sources prematurely end the life of about 1 million children under the age of five every year.

3. In India people prefer using household treatments handed down for generations for common ailments.

4. The use of magic/tantrics/ozhas/hakims is prevalent in India.

5. Increasing pollution is adding to the healthcare problem.

6. Smoking, gutka, drinking and poor oral hygiene is adding to the healthcare problem.
7. Large joint families transmit communicable diseases amongst the members.
8. Cattle-rearing encourage diseases communicated by animals.
9. Early child bearing affects the health standards of women and children.
10. Ignorance of inoculation and vaccination has prevented the eradication of diseases like polio, chicken-pox, small-pox, mumps and measles.
11. People don't go in for vaccination due superstitious beliefs and any sort of ailment is considered as a curse from God for sins committed.

Technological Factors

1. Advanced automated machines have increased the output and reduced the cost.
2. Computerization has increased the efficiency of the Pharma Industry.
3. Newer medication, molecules and active ingredients are being discovered. As of January 2005, the Government of India has more than 10, 000 substances for patenting.
4. Ayurveda is a well recognized science and it is providing the industry with a cutting edge.
5. Advances in Bio-technology, Stem-cell research have given India a step forward.

6. Humano-Insulin, Hepatitis B vaccines, AIDS drugs and many such molecules have given the industry a pioneering status.

7. Newer drug delivery systems are the innovations of the day.

8. The huge unemployment in India prevents industries from going fully automatic as the Government as well as the Labor Unions voice complains against such establishments.