

Swot analysis indian pharmaceutical industry



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Strengths

1. India is regarded as having an edge over China in terms of qualified, English-speaking manpower and fair protection of intellectual property rights supported by well-developed judicial system. (Appendix IV gives more information on IPR status in India).
2. India has skilled scientists/technicians/management personnel at affordable cost leading to low cost of innovation/ manufacturing/capex costs/ expenditure to run cGMP compliance facilities and high quality documentation and process understanding.
3. The country has well developed chemistry, R & D and manufacturing infrastructure with proven track record in advanced chemistry capabilities, design of high tech manufacturing facilities and regulatory compliance.
4. The healthy domestic market with rising per capita expenditure is another significant strength enabling achievement of economies of scale. The country also has a strong marketing & distribution network.
5. India is considered a desirable destination for off shoring of data management functions for clinical trials and also due to its rich biodiversity and strength in Chemistry which are essential for drug discovery.
6. The country has significant ability to circumvent API Patents. India has filed a number of non-infringing process patents. The country has a recent success track record in circumventing formulation patents. Proven Legal skills to evaluate IP and commercial strategies are available at least in select top companies.

7. The present domestic regulatory environment though in need of further improvement has been conducive to the growth of an emerging pharmaceutical industry.

Weaknesses

1. Low investments in innovative R&D continue to be a major weakness of Indian pharmaceutical industry.
2. Diffused nature of the Indian pharmaceutical industry means that only about 20 to 30 companies are large enough to bear the transactions costs associated with sustained exports to and compliance with entry regulations of the developed markets.
3. Majority of companies lack the ability to compete with MNCs for New Drug Discovery, Research and commercialization of molecules on a worldwide basis due to lack of resources.
4. Strong linkages between industry and academia which are essential for growth of the industry is lacking in India.
5. Comparatively small domestic market size due to low medical and healthcare expenditure in the country.
6. The country has at times shown inadequate regulatory framework or compliance and enforcement regime, reflected in occurrences such a production of spurious or low quality drugs.
7. Competency in API/Formulation, intellectual property creation, facility design and maintenance, global regulatory affairs, legal intricacies, and

managing international work force is limited to a few players among the big players.

8. Rapidly increasing costs of skilled manpower such as scientists/ regulatory compliance personnel / pharmaceutical lawyers/ international business development personnel is pushing up the cost of innovation. Ability to evaluate contracts/alliances etc., is available only in top companies.

Significant lacuna in this area exists and companies are falling into traps created by the competitors. Institutionalisation of learning in the following areas is restricted:

Regulatory affairs knowledge for different countries and continents

Process and product patents procedures knowledge for different countries and continents.

9. Sales and marketing knowledge is inadequate due to lack of understanding of international Pharmaceutical marketing/pricing practices and market environment in various countries.

10. Inadequate manufacturing practices in comparison to those accepted in developed world such as change of API source, change of manufacturing locations, equipment etc, with out proven stability/ bioequivalence may be creating inadequate technical work force for exports. The national drug regulatory system though evolved substantially, has been in the need of strengthening its manpower and systems requirements.

11. Inadequate emphasis on Biosciences in education system leading to slower development in areas related to Biology giving away advantage to China.

Opportunities

India is faced with significant export opportunities, such as:

i. US\$40 billion worth of drugs in the U. S. A and US\$25 billion worth of drugs in Europe are expected to go off patent soon. Assocham estimates that Indian manufacturers may capture 30 percent of that market. This translates to an opportunity of US\$19. 5bn which is significant considering the country's current exports of approx. US\$7. 25bn. However the figures need to be appropriately deflated since Indian opportunity will lie in generics equivalent of branded or patented drugs, which would be cheaper.

ii. Generic launches by Indian manufacturers have increased in the United States from 93 in 2003 to 250 by 2008.

iii. Compulsory licensing provisions negotiated in the Doha Round, allows for countries to import cheaper generic versions of patented drugs in the interests of public health. Thailand and South Africa have already started such initiatives from which Indian firms have benefited.

2. Due to the cost advantage in contract manufacturing & Research multi-national companies find it compelling to shift their production bases to countries offering such cost advantage. Typical of the industry which requires approval of manufacturing facilities by various drug regulatory

agencies of the world involving a very high cost, once such business finds base in India it would continue with it for at least one & half to two decades.

3. Licensing deals with MNCs for NCEs (New Chemical Entities) and NDDS (New Drug Delivery Systems) offer new opportunities for Indian manufacturers.

4. Marketing alliances for MNC products in domestic and international market is another emerging opportunity.

5. Contract manufacturing arrangements with MNCs is estimated at 10% of patented markets estimated at US\$450bn which is approx. US\$45bn.

6. India has a very high potential for developing as a centre for international clinical trials due to its rich diversity.

7. India can become a niche player in global pharmaceutical R&D and possibilities exist for expansion of biotechnology generics (also known as bio-similars) and biopharmaceuticals.

8. There is a possibility of greater returns from an Indian entry into mature and more remunerative markets like Brazil, Japan, CIS, Russia, etc.

9. The Work Programme for the European Medicines Agency 2007 identifies greater co-operation with India - especially in the field of traditional and herbal medicines and remedies. Emerging preference for traditional medicines and herbs in the developed markets including lifestyle products and food supplements also presents an opportunity for the country in traditional medicinal systems & Herbal based products.

10. A rise in life expectancy generally, and increase in the population of the old, particularly in the developed world is causing higher expenditure from respective national health budgets compelling them to move to cheaper APIs and formulations which are India's forte.

11. Unleashing of a plethora of preferential trading arrangements, both bilateral and regional, offers opportunities for India to negotiate preferential access to partner markets for Indian pharmaceuticals in the long term and in a sustainable manner.

Threats

1. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.

2. R&D efforts of Indian pharmaceutical companies are hampered by lack of enabling regulatory requirement.

3. Drug Price Control Order puts unrealistic ceilings on product prices and profitability.

4. Export effort is hampered by procedural hurdles in India as well as non-tariff barriers imposed abroad. For example:

i. Indian manufacturers are prevented from bidding for government contracts as US permits bidders only from countries that are signatories to WTO Agreement on Government Procurement.

ii. Indian manufacturers have to submit separate state level applications for marketing drugs in the United States as there is no nation-wide system of application even where FDA approval has been received.

5. Lowering of tariff protection has increased competition in domestic markets resulting in erosion of profitability.

6. Mergers and acquisitions by foreign companies particularly multinational corporations of a few Indian generic leaders may completely change the direction of India's pharmaceutical movement neutralising its thrust on generics and cost competitiveness.

7. The generics market in developed countries may be affected by a number of factors:

i. The release of authorized generics by major drug manufacturers.

ii. New mid-sized players, establishing themselves in the generics market.

iii. Increased competition due to newer Chinese and East European manufacturers. (E. g. there has been massive state level investment by China in the biotechnology sector - though at present India still has the edge due to IP laws.)

iv. TA's entered into by the United States of America with third countries (e. g. the Morocco-U. S. A FTA) may be harmful to Indian pharmaceutical exports because of provisions for increases in patent terms, etc. The United States enters into a number of FTA's with different countries and while the exact text of these agreements differ from country to country, each of these

agreements contains provisions which can be damaging to Indian exporters of pharmaceuticals partly also because of their provisions on patents. These FTA's contain a large number of provisions which increase patent terms for pharmaceuticals by allowing for patentability of new uses of discovered inventions and by increasing patent terms by taking into account the time taken to process claims (evergreening). These provisions go beyond TRIPS and hence it may not be possible to challenge these under the WTO Dispute Resolution process. However, the compatibility of these provisions with Article XXIV of the GATT needs to be examined.

8. Specific non-tariff and para-tariff barriers being increasingly adopted by other countries such as long transaction time taken for registration of drugs, insistence on completing long process for registration when the drug may actually have gone through the most rigorous process of registration such as the USFDA; insistence on allowing imports of only those drugs which are registered in some developed countries, etc.

PORTER'S FIVE FORCES MODEL

(a) INDUSTRY COMPETITION

The Indian Pharmaceutical Industry is highly fragmented with around 250-300 manufacturing and formulation units in organized sector which contribute to only 70% of the market share of the total sales in the country. The concentration ratio (proportion of total industry output by the largest firm in the industry) for the industry is very low. Also government subsidies have led to the proliferation of many small players. Since the Product Patents were not valid in the country till 2005, the differentiation in the product is very low. The key driver in this industry is the cost-competitiveness. After

2005, major MNCs like Pfizer & GSK started introducing newer products in the market thereby increasing competition in the industry.

Many small players that are focused on a particular region have a better hand on the distribution channel, making it easier to succeed, albeit in a limited way.

An important fact is that, pharmaceutical is a stable market and its growth rate generally tracks the economic growth of the country with some multiple (1.2 times average in India). Though volume growth has been consistent over a period of time value growth has not followed in tandem.

Earlier it was easy for Indian pharmaceutical companies to imitate pharmaceutical products discovered by MNCs at a lower cost and make good profit. But today the scene is different with the arrival of the patent regime 2005 which has forced Indian companies to rethink its strategies and to invest more on R&D. Also contract research has assumed more importance now.

(b) BARGAINING POWER OF BUYERS

The unique feature of pharmaceutical industry is that the end user of the product is different from the influencer (read doctor). The consumer has no choice but to buy what doctor says. However, when we look at the buyer's power, we look at the influence they have on the prices of the product. In pharmaceutical industry, the buyers are scattered and they as such do not wield much power in the pricing of the products. Due to the extremely fragmented nature of industry & government policies like DPCO (Drug Price Order Control), 1970 under which the power to control prices is with the

NPPA (National Pharmaceutical Pricing Authority) the low power of buyers does not have much effect on the manufacturers. Except in generic & OTC medicines, the buyer does not normally switch medicines.

(c) BARGAINING POWER OF SUPPLIERS

The pharmaceutical industry depends upon several organic chemicals. The chemical industry is again very competitive and fragmented. The chemicals used in the pharmaceutical industry are largely a commodity. The suppliers have very low bargaining power and the companies in the pharmaceutical industry can switch from their suppliers without incurring a very high cost. However, what can happen is that the supplier can go for forward integration to become a pharmaceutical company. Companies like Orchid Chemicals and Sashun Chemicals were basically chemical companies who turned themselves into pharmaceutical companies. The fragmented nature of the organic chemicals industry prevents it from having much bargaining power over the manufacturers as the switching cost is low for the manufacturers.

(d) BARRIERS TO ENTRY

Threat of new entrants in the Indian Pharmaceutical sector during pre-2005 era used to be low as the capital requirement for the industry used to be very low from 1970s - till 2005 because of the absence of product patents and heavy dependence on reverse engineering or Process Patent phenomenon but post 2005 it has become a huge burden on the part of new entrants to establish Manufacturing facilities of International Regulatory standards to tap the potential of generic exports and domestic consumption demand . That major barriers to entry are :

The presence of economies of scale in manufacturing, R&D, marketing, sales etc capital requirement & financial requirements. The existing companies have advantage in terms of costs involved in launching new drugs & formulations. The new companies would find it difficult to achieve this.

Differentiation of products from the existing products in the market & creating brand awareness in the minds of doctors & pharmacists. New entrants will face difficulties in gaining trust of doctors/patients and they also need to develop efficient distribution channels & preferred arrangements with doctors/pharmacists.

Regulatory policies including patents, regulatory standards. The Indian Patent Act, 1970 recognized process but not product patents. The introduction of Product Patent 2005 of TRIPS part of WTO agreement has led to huge barriers for potential entrants. But to be noted it is unlikely to discourage new entrants, as market for generics will be huge in the near future as the demand for generics by all the developed economies has increased by leaps and bounds as their governments are drawing plans to effectively manage the health expenditure budget by switching from branded drugs to generic versions.

(e)THREAT OF SUBSTITUTES

This is one of the great advantages of the pharmaceutical industry.

Whatever happens, demand for pharmaceutical products continues and the industry thrives. One of the key reasons for high competitiveness in the industry is that as an ongoing concern, pharmaceutical industry seems to have an infinite future. However, in recent times the advances made in the

field of biotechnology, can prove to be a threat to the synthetic pharmaceutical industry. Also in developing countries like India, the traditional medicines also play a major substituting role.

CONCLUSION

This model gives a fair idea about the industry in which a company operates and the various external forces that influence it. These five forces of competition interact to determine the characteristics and the attractiveness of an industry. The strongest forces become dominant in determining profitability and become the focal points of strategy formulation. However, it must be noted that any industry is not static in nature. It's dynamic and over a period of time the model, which we have used to analyse the pharmaceutical industry may itself evolve.

Going forward, we foresee increasing competition in the industry but the form of competition will be different. It will be between large players (with economies of scale) and it may be possible that some kind of oligopoly or cartels come into play. This is owing to the fact that the industry will move towards consolidation. The larger players in the industry will survive with their proprietary products and strong franchisee.

In the Indian context, companies like Cipla, Ranbaxy and Dr. Reddy's are likely to be key players. Smaller fringe players, who have no differentiating strengths, are likely to either be acquired or cease to exist.

The barriers to entry will increase going forward. The change in the patent regime has made sure that new proprietary products come up making imitation difficult. The players with huge capacity will be able to influence

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substantial power on the fringe players by their aggressive pricing thereby creating hindrance for the smaller players. Economies of scale will play an important part too. Besides government will have a bigger role to play.

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!

(P)olitical 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
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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 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.

(E)conomic 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.

(S)ocio-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.

(T)echnological 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.