CHAPTER III

STRUCTURE, GROWTH, PRICING POLICY AND R&D OF INDIAN PHARMACEUTICAL INDUSTRY

3.1 Structure of the pharmaceutical industry

The growth of the pharmaceutical industry was almost nil before 1954. The Hindustan Antibiotics Limited (HAL) was the trendsetter, which commenced operations in 1954, joined later by Indian Drugs and Pharmaceutical Limited (IDPL) in 1961. In the 1970s, the Government took certain important measures like legislating of the 1. Indian Patent Act (IPA) 1970, 2. Drug Price Control Order (DPCO), 3. FERA and 4. Increasing the import tariff to promote the domestic industry, so as to enable the industry to meet the requirements of the Indian population.

FIGURE III.1

TREND SHOWING NUMBER OF UNITS IN PHARMACEUTICAL INDUSTRIES

Source: OPPI Annual report 2003
(It is reported that there are around 24,000 pharmaceutical units in India, but the actual number of operating units is estimated to be, around 6000 - 8000)

Now the Indian pharmaceutical industry consists of around 24,000 units as on 2002 - 03. Of these 250 are in the organised sector, out of which 5 are in the public sector, 7 in the joint sector and the remaining in the private sector. Of the private sector, nearly 100 units manufacture only bulk drugs and the remaining units manufacture both bulk drugs and formulations. Nearly 5000 units are "small scale units" and the remaining units belong to "very small scale units".

3.1.1 Highly Fragmented Industry

The Indian pharmaceutical industry is a highly fragmented one. The industry is divided into two, viz organised and unorganised sectors. In the organised sector there are about 100 manufacturers controlling the total market share of more than 90%. None of them control more than 7% of the total retail formulation market. The top 20 manufacturers in the domestic industry possessed 48% of the market share in 1998 as against the market share of 35% in 1991. Despite the large number of units, their share is less than 2% of the global market. This is due to low product prices. The low prices are the result of fragmented market with severe price competition and the presence of government price control measures. However in the last 5 years there have been many mergers and acquisitions in the pharmaceutical industry resulting in the increase in market shares among the leading units, which account for 48 percent during 1998. Some companies have focused on brand acquisition rather than company acquisition. Companies are also establishing market joint ventures to increase their distribution
network. The investments required to increase the marketing network of large manufacturers has increased considerably in the 1990s.

3.1.2 Raising of small-scale units

The share of small-scale units in the pharmaceutical industry in terms of number of units is considerable. While the 250 units constituted the organised sector, the small-scale units numbering about 6000 formed part of the unorganised sector. The remaining units are very small and have a negligible role in the pharmaceutical industry. The number of units in small scale and tiny sector has been increasing because of low capital cost, government encouragements, incentives in the form of licenses, excise duty, sales tax and price control order and Government subsidiary for setting up of units. Most of the small units are involved in the manufacture of unbranded formulations and act as suppliers to large organised manufacturers.

FIGURE III.2

SECTOR WISE SHARE OF PHARMACEUTICAL UNITS IN THE INDUSTRY

Source: Chemical Weekly January 21, 2003
3.1.3 Indian Pharmaceutical Industry and WTO

The Indian situation in connection with Indian Patent Act 1970 will be a different one after 2005. Because India has became a signatory of the GATT (now known as WTO) in 1994 and thereafter a signatory to the TRIPS under the TRIPS agreement. The country is now under compulsion to introduce a product patent by 2005 after a transition period of ten years. That is India should shift from process patent to product patent from January 1st, 2005 onwards. With product patent by 2005 in mind, pharmaceutical companies have to transform themselves from re-engineering (process patent) to innovation (product patent). They should move from production to competition and should think globally and act globally.

After 2005, there will be a wide scope for the Indian Pharmaceutical manufacturers in the world market. Obviously, the manufacturers who have their own strong R&D activities as well as significant domestic and international business will have an edge over others.

3.1.4 Pharmaceutical Industry: Archetype

Worldwide, the Pharmaceutical industry operates in two categories namely, innovative and generic. Innovative companies are those that create knowledge and spend a lot of money on R&D to develop new medicines. These types of companies are found only in the developed countries where product patent has already been adopted. Generic companies are adoptive in nature and permit copying of medicines only after the expiry of the patent or for unpatented drugs. They copy the knowledge already created by innovative companies and charge low prices since they do not incur any basic research cost.
But both types of companies are essential in any country. Without innovative companies, no innovation will take place and without generic companies, the prices of medicines will remain high even after the expiry of patents. In India, there had been only the generic companies since there had been no product patent law. Obviously, there has been no incentive or protection to create knowledge and therefore the Indian Pharmaceutical companies did not concentrate on innovation. Scientific development has been intellectually sacrificed via drug policy even though Indian players had more potential resources for innovations. A few companies such as Ranbaxy, Dr Reddy's Laboratories, Orchid Chemicals, and Lupin Chemicals have already shifted their focus and taken active measures for innovation of medicines since 1994, as India have signed in WTO. They will be outperformed after 2005 when product patent is introduced.
3.1.5 Growth of generic industry:

The growth of generic industry will depend upon the growth rate of the pharmaceutical market, which in turn, will be driven by the rate of urbanization, pace of economic development, income level, and per capita GDP. In India, only 40 percent of the population relies on allopathic medicines. With every one percent rise in GDP, there should be a corresponding 1.4 percent increase in healthcare.

The Indian Pharmaceutical units have tried to produce drugs valued at Rs.30814 crores (both bulk drugs and formulations) as on March 2003 and has been growing at a rate of 15 percent per annum. For the last three decades, generic drugs consistently account for 70 to 80 percent of the total sales. The remaining 20 to 30 percent of drugs is based on research.

The generic market will increase to 90 percent in the period 2005-10, after the introduction of product pattern in 2005 and it will fall from 90 percent to 75 percent of the pharmaceutical market in 2015. Ultimately, the rates are estimated to settle at around 65 percent of generic versus 35 percent of patent drugs by the year 2020. The reason is that patent will apply only to totally new discoveries where patent filing is done after 1st January 1995. There is no impact on whatever is already available. A new pharmaceutical product generally enters the market 11 to 12 years after and therefore these products will have an effective patent life of 8 to 9 years.

3.1.6 Generic drugs for exports

Indian companies flock to tap Brazil's generic market. With a $ 4-billion pharmaceutical market, Brazil is enticing many Indian Pharmaceutical companies. At least half a dozen Indian companies including big ones such as Ranbaxy, Cadila Pharma,
and Lupin Pharma are investing in manufacturing facilities in Brazil. Interestingly, Indian companies a year ago were considering joint ventures with local players as a more strategic route, are now planning to go alone, even if that needs substantial capital investment. The reason is Brazil is a gateway to other potential Latin American markets, Mexico, Argentina, and Chile. Statistics reveal that the number of generic companies has increased from 4 in 2000 to 36 in 2002. The product registration for generics during this period has grown from 13 to 634, while registration for bulk drugs has increased from 13 to 232. Hence, generic drugs account for 6 percent of the total market and are growing at 70 percent every year. In fact, in the forthcoming year, it is estimated that generic drugs will account for 50 percent of the total pharmaceutical market.

Ranbaxy, which is already the fifth largest generic company in Brazil, started another manufacturing plant by the end of 2003. Cadila Pharmaceutical Companies also set up a plant in December 2003. Acrolab also began work on a green field project in Brazil in the forth quarter of 2003. The US generic market is considered to provide golden opportunities for the Indian companies. The market is very large. The size of the market was $16 billion by the year 2004.

3.1.7 Generic market after 2005

The Indian pharmaceutical market continues to remain largely a generic market and the share of patented products is quite small. This is likely to be the case after 2005 also. The largest change in the post 2005 scenario will be the unprecedented number of drugs going off patent (refer to the table) as the patent rights in USA expires. This basically implies a huge potential in national and international generic markets. Hence, most of the Indian pharmaceutical companies will continue to focus on off-patent
products. Local companies with no R&D skills will continue to be local, regional players, as there will always be a large and growing market available to them. Companies having world-class manufacturing practices, approved by many developed countries, including US, FDA will try to tap the international market.
<table>
<thead>
<tr>
<th>Chemical ingredient</th>
<th>Category</th>
<th>Manufacturer /Marketer</th>
<th>US patent expiration</th>
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<tbody>
<tr>
<td>Glimepiride</td>
<td>Diabetes</td>
<td>Horizont-Ag</td>
<td>06.04.2005</td>
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<td>Ondanatetron</td>
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<td>Clarithromycin</td>
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<td>25.05.2005</td>
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<td>Pamidronate disodium</td>
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<td>Zidovudin</td>
<td>HIV/AIDS</td>
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<td>Zilevton</td>
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<td>09.12.2010</td>
</tr>
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</table>

Source: IDMA Annual Report 2004
3.1.8 Reduced Capital Investment

The investment in the Pharmaceutical units was almost negligible in the early years of Independence. The total investments in the industry have grown at an annual rate of 8.8 percent between 1952 and 1962. In 1965-66 the total investment in the pharmaceutical industry was Rs.140 crores. This amount has increased to Rs.3900 crores in 2001-02 with a growth rate of 10.61 percent. The increase in investments has been encountered only after the 1970s. This is because of the domestic companies rather than the MNCs.

FIGURE III.4

TRENDS IN THE INVESTMENTS IN PHARMACEUTICAL INDUSTRY IN INDIA

Source: OPPI Annual report, 2003

The domestic company's contribution to the increased investments is more important when compared to the MNCs. This is evident from the fact that, the market share of the domestic company's has increased from 10 percent in 1970 to 75 in 2002,
whereas that of the MNCs has decreased from 80 percent in 1970 to 25 percent in 2002. Also, the growth rate of the domestic company' were 12.3 percent, 11.7 percent and 13.8 percent in the years 2000, 2001 and 2002 respectively as against the low growth rate of 6.1 percent, 4.7 percent and 5.5 percent in the same years of the MNCs.

**FIGURE III. 5**

**GROWTH RATES 2000 – 2002**

Source: AC Nielsen ORG-MARG (Economic times dated 2nd Oct, 2002)

Further, the dominance of the MNCs in the Indian drug market has diminished to such an extent that the MNCs are slipping out of the list of top 20 pharmaceutical companies in the country. According to ORG-MARG, the number of MNCs in the top 20 has reduced from eight to five during 2001-2002 namely, Glaxo, Aventis, Knoll, Novartis and Pfizer.

The investments of the MNCs were more before 1970. In future, by 2005 the scope for the investments of MNCs may increase, which will result in increased inflow of Foreign Direct Investments (FDI). There has been a significant shift in the recent past.
The MNCs reduced its production facilities while increasing their market infrastructure. On the other hand the large Indian Companies have concentrated on the production of both bulk drugs and formulations as they have been concentrating on marketing infrastructure both in the domestic and international market.

3.2 Growth of the pharmaceutical industry

Since independence, the Indian Pharmaceutical Industry has improved significantly. It is, nearly a century old. First, Prof. P.C. Roy started Bengal Chemical and Pharmaceutical around 1901, through indigenous production of drugs. From a mere 800 formulators and 125 bulks drug manufacturers in 1965-66, the industry had grown to over 16,000 formulators and 350 bulk drug manufacturers in 2002³. A similar increase in the growth of Indian pharmaceutical industry in various parameters is shown in the Table III.1.

3.2.1 Growth Indicators

TABLE III.2

GROWTH INDICATORS OF PHARMACEUTICAL INDUSTRY IN INDIA

<table>
<thead>
<tr>
<th>Particulars</th>
<th>1965-66 (Crores)</th>
<th>2001-02</th>
<th>Annual Compound Growth Rate (%)</th>
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<tr>
<td>Capital Investment</td>
<td>140.00</td>
<td>3900</td>
<td>10.61</td>
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<tr>
<td>Production</td>
<td></td>
<td></td>
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<tr>
<td>Formulations</td>
<td>150.0</td>
<td>24273</td>
<td>16.66</td>
</tr>
<tr>
<td>Bulk Drugs</td>
<td>18.00</td>
<td>6528</td>
<td>19.55</td>
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<tr>
<td>Import</td>
<td>820.00</td>
<td>3640</td>
<td>4.62</td>
</tr>
<tr>
<td>Export</td>
<td>305.00</td>
<td>11760</td>
<td>11.70</td>
</tr>
<tr>
<td>R&amp;D Expenditure</td>
<td>3.00</td>
<td>550</td>
<td>17.11</td>
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<tr>
<td>Bulk Drug Manufacturers</td>
<td>125.00</td>
<td>350</td>
<td>3.17</td>
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<tr>
<td>Formulation Manufacturers</td>
<td>800.00</td>
<td>16000</td>
<td>9.50</td>
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The capital investment which was just Rs.140 crores in 1965-66 shot up to Rs.3900 crores in the year Rs. 2001-2002 with an annual compound growth rate of 10.61 percent. Similarly formulations have shown an increase from Rs.150 crores to Rs.24273 crores recording an annual compound growth rate of 16.66 percent, the bulk drugs have grown from Rs.18 crores to Rs.6528 crores recording an annual compound growth rate of 19.55 percent.

The exports have grown from Rs.305 crores to Rs.11760 crores having an ACGR of 11.7%. The imports also have increased from Rs.820 crores to Rs.3640 crores during the same period. The import growth rate (4.62%) is less than half of the export growth rate (11.70%) and the R & D expenditures have shown an increased rate of 17.11 percent. The number of bulk drug manufacturers has increased from 125 to 350 and has recorded a growth rate of 3.17 percent. Similarly formulation manufacturers have increased from mere 800 to 16000 recording a 9.50 percent. A decrease in the imports growth rate and an increase in the export growth rate have shown a positive sign of the pharmaceutical industry in the global market. Now an attempt has been made to trace the growth rate under different phases.

3.2.2 Pre-independence period

During this period the existence of Indian pharmaceutical industry was almost nil. Although there was a high level of need for medicines, the demand from the public was very low due to low income and the lack of access to medicines. Consequently, the government of India had to take some important initiatives to develop the Indian Pharmaceuticals Industry in the post independent period. The value of the production of drugs and formulations accounted for only to Rs.10 crores in 1947.
3.2.3 Period from 1947 to 1970

At the dawn of independence, the pharma manufacturers in India were merely engaged in producing formulations based on imported bulk drugs. Though a few bulk drugs were produced in the country in late 1960s, the progress achieved in the production of fine chemicals and synthetic drugs was less. Since the country suffered from many epidemics, all the anti-infectives had to be imported. Therefore, in 1954, laid foundation for the Hindustan Antibiotics Ltd (HAL) in Pune followed by Indian Drugs and Pharmaceuticals Ltd in 1961 in West Bengal for manufacture of bulk drugs such as penicillin and other anti-infectives, which were otherwise imported. Government’s policy emphasized the need for foreign participants in the area of technology for accelerating the tempo of industrialization. The Industrial Policy Statement 1948 made a specific mention of this in the following words: "It should be recognized that participation of foreign capital and enterprise, particularly of industrial technique and knowledge will be the value in the rapid industrialization of the country." Consequently, the Government of India encouraged the MNCs to set up their manufacturing units in India. Subsequently, the MNCs brought in technology and international manufacturing practices in India. As a result, in 1970-71 the industry attained a size of Rs 4,000 million, and the MNCs dominated with a market share of 80%.
3.2.4 Period from 1970 to 1979:

Four significant developments have taken place during this period in shaping the domestic industries. Namely,

- Drug Price Control Order (DPCO)
- The Indian Patent Act (IPA)
- FERA (1973)
- Import Tariffs

The year 1970 is considered as a landmark year in the growth of Indian Pharmaceutical Industry. With a view of developing the domestic companies, the Government enacted the Indian Patent Act (IPA) in 1970. It was one of the single most important factors to spur the domestic pharmaceutical units into action. Under the IPA 1970, substances used in foods and pharmaceuticals could not be granted product patents.
The process patent was allowed for a period of 5 years from the date of grant of patent or 7 years from the date of filing for patent, whichever is earlier. With the objective of making important drugs available to the consumers at a reasonable price, the Government of India also introduced the drug price control order.

**Drug Price Control Order (DPCO)**

The Drug Price Control order (DPCO) was introduced in 1970 by the Indian Government. The DPCO effectively put a ceiling on prices of certain mass usage bulk drugs and their formulations, so as to prevent any undue profiteering. This further deterred the MNCs selling their products at much lower prices in India. Hence MNCs decreased launching of new products giving further scope to Indian companies.

**FERA 1973 (Implemented from late 70’s)**

MNCs are forced to reduce their holdings in the Indian ventures to 40%, otherwise to comply with the export obligations to retain a maximum stake of 51%. Due to this, some of the MNCs reduced their scope of operations. This further strengthened the position of the domestic drug and formulation manufacturing companies.

**Tariffs:**

The MNCs dominated with a market share of 80% at the end of 1970. This is due to the fact that MNCs imported bulk drugs from their parent companies in other nations and manufactured only formulations in India. Under this situation the Govt. of India increased the tariff for importing bulk drugs. As a result, the market share of MNCs decreased while that of the domestic companies increased. All these factors produced a favorable climate to develop the indigenous pharmaceutical manufacturers.
The international norms recognized the product patent but the Indian Patent Act provided for process patents, which recognizes the "process" to manufacture a medicine and not the end product. Indian Companies took advantage of the Indian Patent Act and succeeded in producing molecules, which were under patent protection elsewhere, at a cost that was a fraction of the original research cost. By taking the cost advantage, the Indian pharmaceutical companies fixed their prices lower than the MNCs.

3.2.5 Period from 1979 - 1995

The most important factor that has contributed to the growth of domestic pharmaceutical units is the absence of product patent. By this the Indian manufacturer could come out with a highly efficient method of producing drugs by reverse engineering of various drugs and by focusing on process based research. Most Indian drug manufactures are backward integrated and go into the manufacture of bulk drugs. On the other hand some Indian drug manufactures are forward integrated and go into the manufacture of formulations. This will enable them to benefit from economies of scale. These advantages together with lower R & D expenses enabled them to price their drugs at levels far below than that of the MNCs. Thus Indian manufacturers were competing on the basis of low price, dominating the domestic market in both bulk drugs and formulations.

In addition to the above measures, in order to enhance the attractiveness of the pharmaceutical industry the Government made some amendments to the DPCO in 1979. They were 1. Reduced number of drugs under DPCO from 347 to 163, 2. High margins permitted on the production cost and 3. Export incentives given by the Government of India. All these advantages jointly provided a substantial boost to the domestic players.
for exports (especially of bulk drugs). The DPCO was again amended in 1987, resulting in a reduction in the number of drugs under price control from 163 to 146.

FIG. III.7

PERCENTAGE SHARES IN OWNERSHIP OF INDIAN PHARMACEUTICAL MARKET (1982)

Since the Indian government recognized the process patent, the Indian pharmaceutical units were not encouraged to spend much on R & D and subsequently the new products developed were quite less. Since the success of pharmaceutical companies in the developed world depends on the success of their new molecules, the Indian players were unable to succeed in the developed countries.
3.2.6 Period 1995 - 2001

In 1995, the Govt. of India further reduced the number of drugs under the price control from 146 to 74. In the same year, the Government of India also signed in the General Agreement on Tariffs and Trade (GATT) now known as World Trade Organization (WTO). Since, India is a signatory to the GATT, it is under compulsion to introduce the product patent by 2005 and provide legal protection to Trade Related Intellectual Property Rights (TRIPS). The signing of the GATT agreement induced a series of changes in the business strategy of the Pharmaceutical Industry. The attention of the companies has experienced a shift and research has emerged as an inevitable drive for the growth in the long run. Therefore all the companies are undergoing restructuring exercise and a lot of mergers and acquisitions are being witnessed during this period.
3.2.7 Pharma Policy, 2002 (From Controlled to Monitoring Regime – 2002).

On 15th February 2002, the government of India outlined the details of the new pharmaceutical policy that envisages a shift from a "Controlled" to a "Monitoring" regime for the pharmaceutical industry. The new policy has been formulated with an aim of promoting the indigenous drug industry through reduction of the span of the price control regime, and at the same time ensuring abundant availability of quality drugs at reasonable prices. While moving away from a "Controlled Regime", the policy proposes to introduce a new monitoring system, which would be based solely on the market price data and to apply controls selectively on those cases, in which either profiteering or monopoly profit seeking was noticed.

**FIG.III.9**

PERCENTAGE SHARE IN THE INDIAN PHARMACEUTICAL MARKET IN 2002

<table>
<thead>
<tr>
<th>Private sector</th>
<th>75%</th>
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<tbody>
<tr>
<td>MNCs</td>
<td>25%</td>
</tr>
</tbody>
</table>

Source: AC Nielsen, Director, ORG-Marg

Further, it envisages that the Health Ministry would progressively bench-mark regulatory standards on par with international standards, harmonize standards for clinical
testing with global practices, streamline the procedures and steps for quick evaluation and clearance of new drug applications developed indigenously and set up a world class "central drug standard control organisation" by modernising, restructuring and reforming the existing system.

3.2.8: 2002 – a major success to Indian manufacturers

The year 2002 turned out to be a major success for Indian pharmaceutical majors. Ranbaxy and Dr. Reddy's Laboratories have already made significant breakthrough in the US generic market this year. The year began with Ranbaxy getting approval to manufacture and market Cefuroxime axetil, a generic equivalent of Glaxo's Ceftin, after a prolonged legal battle. This generic has already cornered nearly 60 percent of its total sales in the US drug market. Early in the month of August 2002, the company received final approval from the US Food and Drug Administration to manufacture and market Lisinopril and Lisinopril + Hydrochlorothiazide tablets, the bio-equivalent and therapeutical equivalent of Zestril and Prinizide tablets with sales of over $1,000 million in 2001 in the US market. On the same day, Dr. Reddy's Laboratories received approval for Tizanidine hydrochloride, the generic equivalent of Elan Corporation's Zanaflex, with sales of $160 million in 2001 in the US. The latest in the generics success story is the US FDA Dept.'s, approval for Dr. Reddy's Ciprofloxacin tablets, generic equivalent of Bayer's $1.2 billion Cipro. These successes have reinforced the view that for the pharmaceutical industry, especially for the generics the key to growth is the US market. Already, for Ranbaxy the US has become a bigger market than India in the quarter ended 31st March 2002. Its US operations had sales of $51 million against $40 million from Indian operations. Dr. Reddy's is also close to achieving the same in 2001-02. Its US
sales accounted for 34% of revenues against 39% from India. In fact, with 29 generics awaiting approval for Ranbaxy and 14 abbreviated new drug applications pending with the US FDA Dept. for Dr. Reddy's, these companies could soon rank alongside Infosys and Wipro in terms of foreign earnings.\textsuperscript{6}

3.2.9 Public Sector undertakings in Pharmaceutical Industry

Among 250 units in the organised sector, five of them are public sector units, seven are joint sector units and the remaining are in the private sector. Of these more than 100 are engaged in the production of bulk drugs only.

The five public sector units are:

1. Hindustan Antibiotics Limited (HAL)
2. Indian Drug and Pharmaceutical Limited (IDPL)
3. Smith Stand Street Pharmaceuticals Ltd. (SSPL)
4. Bengal Chemicals and Pharmaceuticals Ltd. (BCPL)
5. Bengal Immunity Ltd. (BIL)

The seven joint sector units are:

1. Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)
2. Uttar Pradesh Drugs and Pharmaceuticals Ltd. (UPDPL)
3. Orissa Drugs and Pharmaceuticals Ltd. (ODPL)
4. Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL)
5. Maharashtra Antibiotics and Pharmaceuticals Ltd. (MAPL)
6. Manipur State Drugs and Pharmaceuticals Ltd. (MSDPL)
7. SPIC Pharmaceuticals Ltd.
Development of Public Sector

Hindustan Antibiotics Limited incorporated in March 1954, with support and collaboration of USSR at Pumpari was the first public sector undertaking in the field of pharmaceuticals. The company had the primary objective of manufacturing penicillin and other antibiotics. It also produced streptomycin, hyamycin and aurefimgin. HAL has three subsidiary companies, promoted in collaboration with the respective state governments, viz. Karnataka Antibiotics and Pharmaceuticals Ltd. (KAPL) in Bangalore, Maharashtra Antibiotics and Pharmaceuticals Ltd. (MAPL), in Nagpur and Manipur State Drugs and Pharmaceuticals Ltd (MSDPL) in Impal. In addition to these it had one more joint venture unit with Max GB Limited (Private Sector) called Hindustan Max GB Ltd. for production of penicillin.

Indian Drugs and Pharmaceuticals Ltd., Pune was incorporated under the Companies Act, 1956 on 5th April 1961. The company has five plants including two wholly owned subsidiaries located at Rishikesh (U.P.), Hyderabad, Gurgaon, Haryana, Chennai and Fugaffapur (Bihar). IDPL has also setup three subsidiaries in collaboration with the respective state governments for production of quality pharmaceutical formulations. They are 1. Rajasthan Drugs and Pharmaceuticals Ltd, Jaipur. 2. Uttar Pradesh Drugs and Pharmaceuticals Ltd., Lucknow 3. Orissa Drugs and Pharmaceutical Ltd., Bhuvaneswar.

There are other three public sector undertakings engaged in the manufacture of drugs and formulations located at Kolkata. These were actually private sector companies,
pioneers in their field, but had been ailing over the years for various reasons. The management of these companies were taken over by the Government of India as per Industrial Development and Regulations Act, 1951 and subsequently, they were nationalised and the new public sector companies namely 1. Bengal Immunity Ltd. (BIL), 2. Bengal Chemicals and Pharmaceuticals Ltd. and 3. Smith Standstreet Pharmaceuticals Ltd. (SSPL) came into existence. Their main manufacturing activities were concentrated in West Bengal.

Performance

IDPL is a major producer of Vitamin B$_1$ and B$_2$ and folic acid. IDPL and HAL are major producers of penicillin. A number of downstream units, both in the organised and in the small-scale sectors depend upon the bulk drugs produced by these companies. Bengal Immunity Ltd (BIL) used to be one of the largest producers of sera and vaccine toxoids. It also produces other pharmaceuticals like anti-snake venom, some home products like hair oil, perfumes etc. Bengal Chemicals and Pharmaceuticals Ltd. (BCPL) produces, some herbal products also in addition to the above. Smith Standstreet Pharmaceuticals Ltd. (SSPL) is engaged in the manufacturing of pharmaceutical formulations. IDPL and other public sector units except HAL and joint sectors have incurred loss for the past many years while the private sector companies have been making huge profits.

3.3 Price Regulations

Drugs are required to relieve the patients from pain, suffering and other disabilities arising out of sickness. Due to this factor, the demand for drugs is relatively inelastic which provides ample opportunity to any manufacturer or seller of drugs to
manipulate the prices for his own benefit. This is the reason, which warrants the price regulation in the pharmaceutical industry.

There are various ways of controlling prices. In most of the developed countries, the control is indirect. A typical example is the Health Management Organisations (HMOs) of the United States. Most of the countries in Europe have direct price controls for different products.

3.3.1 Pricing of Drugs in India

As the drugs of the pharmaceutical companies in India are mostly dominated by the MNCs, the prices of drugs are strongly linked with the role of these companies in the Industry. Kefauver Committee of USA has given a very bold comment on drug prices charged by MNCs in India. "India which does grant patents on drug products, provides an interesting example. Prices in India for the broad spectrum of antibiotics, Aureomycin and Anchromycin, are among the highest in the world. As a matter of fact, India ranks among the highly priced nations of the world - a case of inverse relationship between per capita income and the level of drug prices". This bold comment worked as an eye-opener for the Indian public and motivated the joint committee of Indian Parliament on Patent Bill in 1965 to go into a detailed investigation of drug prices. The evidences testified before the joint committee about high prices of drugs in India is given below in a summarized manner.
TABLE III.3

HIGH PRICES OF DRUGS IN INDIA IN COMPARISON TO INTERNATIONAL PRICES

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>International prices (Rs./Kg)</th>
<th>Prices in India (Rs.)</th>
<th>Increase in prices in India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin B₆</td>
<td>Much-Sara</td>
<td>206</td>
<td>800</td>
<td>4 times</td>
</tr>
<tr>
<td>Vitamin B₁₂</td>
<td>M.S&amp; Dohme</td>
<td>32</td>
<td>215</td>
<td>7 times</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>Park Davis</td>
<td>100</td>
<td>410</td>
<td>4 times</td>
</tr>
<tr>
<td>Tolbutamide</td>
<td>Hoechest</td>
<td>20</td>
<td>0.75</td>
<td>4 times</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>Glaxo</td>
<td>54</td>
<td>421</td>
<td>8 times</td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>Hoechest</td>
<td>16</td>
<td>21</td>
<td>2.6 times</td>
</tr>
</tbody>
</table>

Source: IDMA Annual Bulletin

3.3.2 Government's Control on Drug Prices

Prices of drugs were brought under statutory control for the first time in 1962 in the wake of Indo-China war and declaration of emergency. Prior to that there was no comprehensive control on the prices of drugs. By promulgating the Drugs (Display of prices) Order 1962 and the Drugs (Control of Prices) Order 1963 under the Defence of India Act, the prices of the drugs were frozen as on April 1963. The drug industry took a very critical stand on price-freeze and government had to replace these orders by a new order, under the Essential Commodities Act, viz. Drug Prices (Display & Control) Order, 1966. As per this order, it was made obligatory for the manufacturers to take prior approval of the government for increasing prices.
3.3.4 Tariff Commission's Investigation in cost-structure

In the early seventies the pharmaceutical industry led by foreign firms vigorously campaigned for abolition of price control. Its active lobby created constant pressure in official circle and consequently the government asked the Tariff Commission in August, 1966 to investigate the cost structure of 17 essential drugs so that the pricing scheme may be rationalized. The Tariff Commission submitted its report in August, 1968 and presented the first detailed enquiry into the cost structure and pricing pattern of the pharmaceutical industry. It recommended fair selling prices for 17 bulk drugs and 34 single drug formulations. The following were the two broad conclusions of the commission:

1. "The domestic prices of the selected drugs are very much lower in most cases than in other countries."

2. "By and large the prices in the Indian market for formulations compare favorably with the prices of similar formulations in the domestic markets of other countries."

The Tariff Commission also went into the factors responsible for higher prices of essential drugs as compared to those in developed countries and presented three important factors as given below:

1. The high cost of equipment, intermediates and raw materials, which were mostly imported,

2. The small size and lower capacities of production as compared to other countries,

3. The patent law and related conditions for the transfer of know-how.
3.3.5 The Drugs (Price Control) Order, 1970

Based on the report of the Tariff Commission, the government promulgated the Drugs (Price Control) Order on 16th May 1970. The major objectives of this order were to rationalise the prices of drugs, to curb excessive profits and to provide sufficient incentive to the industry to facilitate its growth. The salient features of DPCO, 1970 were as follows:

1. Selling prices for 16 essential bulk drugs were fixed by the government taking into account the recommendations of the Tariff Commission,

2. Selling prices of other bulk drugs were frozen at a level prevailing immediately prior to promulgation of the order. Prices of these drugs were required to be notified to the government within two weeks of the commencement of the order and thereafter no manufacturer was permitted to increase the prices without the prior approval of the government.11

Regarding the prices of formulations, two schemes of pricing were provided by DPCO in 1970, a general scheme and an alternative scheme. Under the general scheme all formulations were allowed to mark up 74 percent of the total ex-factory cost with no ceiling on profit. The mark-up was supposed to cover all post factory expenses like outward freight, trade commission, distribution costs, promotional expenses and the margin for the manufacturers. In the case of formulations involving original work and research, a higher mark-up of up to 100 percent was permitted.

Some flexibility in fixation of prices was provided under the alternative scheme. In this scheme formulations based on essential drugs were allowed a mark-up of up to 75 percent and other formulations were allowed a mark-up of not exceeding 150 percent.
subject to an overall profitability ceiling of 15 percent pre tax on sales turnover. Profit Before Tax (PBT) in excess of 15 percent on sales turnover, was required to be funded separately to be utilized with the prior approval of the government for certain purposes.\textsuperscript{12}

Under the DPCO 1970 the government had to do the lengthy exercise of scrutiny of detailed cost data. The Ministry of Petroleum & Chemicals constituted a Drug Price Review Cell (DPRC) and the cell examined the cost structure of 11,732 packs of formulations. As a result of this examination, prices of about 44.9 percent of the formulations/packs were lowered, 36.15 percent were kept at the earlier level and permission for price increase was given only for 11.45 percent packs of total finished formulations. The whole exercise resulted in large benefits to the society by way of price reduction, which amounted to about Rs.20 crores in a total turnover of about Rs.220 crores in 1970 themselves.

Thus the government with elaborates provisions and vigorous efforts implemented the DPCO (1970), but it could not fulfill the promises as the order contained so many loopholes. The government had to amend it many times within a short span. In spite of reduction in drug prices to some extent, it could not "restructure the industry in favour of the Indian sector or curb the excessive profits and prices of foreign firms" \textsuperscript{13}. Even the Hathi Committee, which was appointed for price regulation in the year, had to admit that it "had less impact on the structure and level of prices of drugs, and formulations than one would have expected".

3.3.6 Hathi Committee on Pricing of Drugs

The Hathi Committee was appointed to examine the measures taken so far to reduce prices of drugs for the consumer and to recommend such further measures as may
be necessary to rationalise the prices of basic drugs and formulations". The Committee studied in detail the performance of various price control orders issued by the government in a decade since 1962 and then submitted its report in 1975. The Committee was of the opinion that the price control "had not succeeded fully in bringing about equity between units or contributed to socially desirable structure of prices". The committee found that the price control could not prevent wide variations in prices and had tended to be distorted both in relation to the original intentions of the DPCO 1970 and also in terms of any rational criteria for evolving a pricing policy in respect of drugs and formulations". The Hathi Committee recommended a broad scheme based on regulations, surveillance and selectivity in pricing of earlier schemes based on adhocism and comprehensive control on all products of each firms. All these circumstances led to the declaration of a new order.

3.3.7 The Drug: Price Control Order, 1979

When Janata party came to power at the center, it announced its New Drug Policy on 29th March 1978, which partially accepted the recommendations of the Hathi Committee. The new Drugs (Price Control) Order came into force from 31st March 1979 and it included the pricing perspective contained in the New Drug Policy.

(a) Pricing of Bulk Drugs. The DPCO 1979 subjected to price control all the bulk drugs, which are used in the production of price-controlled formulations. Prices of bulk drugs were to be fixed largely on the basis of the average cost of the relatively more efficient firm, which account for a large percentage of the production of such drugs. Under this order bulk drugs were divided into two groups for pricing. The first group consists of bulk drugs used in the manufacture of category I and II formulations for
which a return of 14 percent (post tax) on net worth was to be allowed in computing the approved prices. The second group included bulk drugs under the category III formulations. For this category a return of 12 percent post tax on net worth is allowed.

(b) Pricing of Formulations. Regarding the formulations, the DPCO, 1979 brought three categories for price control. The ceiling on mark-up of category I formulations was 40 percent, on category II formulations 55 percent and on category III formulations 100 percent. The remaining formulations, which were not covered by these categories, were exempted from price-control. The order also envisaged a ceiling on pre tax profit on sales turnover of formulations, which ranged from 8 percent to 13 percent as against 15 percent profit allowed under DPCO, 1970.

The pharmaceutical industry made howls of protest against this order (DPCO, 1979). Their opposition to the order was based on two points. Firstly, the pricing scheme outlined in the DPCO, 1979 was unrelated to targets of the industry’s growth envisaged in the New Drug Policy (1978). Secondly, the mark-up provided for category I and II formulations were not remunerative and would adversely affect the profitability of the drug manufacturing companies.

Effects of DPCO, 1979

The profitability of many concerns fell sharply due to this order. MNCs investment in this sector got reduced and they discontinued many products especially in the life saving segments. The MNCs with industrial licensing requirements reeled under the severe decline in profitability. On the other hand, the local players were granted licences relatively easily and their ability to introduce new drugs led to their prosperity. Overall profit wise, the Indian Pharmaceutical companies passed through its worst phase
from 1979 till the DPCO was revised in 1987. Because of these factors the overall fall in business in most of the companies has been estimated to be about 2-4%

3.3.8 DPCO, 1987

Both the strict control of DPCO, 1979 and the strict profitability curbs proved to be a hurdle to the growth of pharmaceutical concerns in India. Therefore, the number of drugs under DPCO was reduced from 370 to 143. Secondly, the number of control categories was reduced to two. Thirdly, the higher Maximum Allowable Post Manufacturing Expenses (MAPE) was given in each of these two categories:

1) Category I - 75% MAPE
2) Category II - 100% MAPE

In addition to the above steps, the industrial licensing norms were also made less stringent during this period. Due to this effect, though 75% of the pharmaceutical concerns were under price control, the profitability improved due to a higher MAPE.

3.3.9 DPCO, 1995

The latest DPCO was passed in January 1995. In this, the government introduced a number of significant changes in it. Under the new order the number of drugs covered reduced from 143 to 76. It was further reduced to 74 in 1997. Any formulation using any one of these bulk drugs came automatically under the cover of price control. Further, to bring any particular drug under the purview of the Price Control Order, the pricing methodology to be followed was as below:

1) Annual turnover calculation based as on 31 March 1990
2) Inclusion of a bulk drugs if turnover exceeds Rs.40 million
3) Inclusion of a bulk drug if turnover is over Rs.10 million with any single formulator having a 90% plus market share.

4) Exclusion, if at least 5 bulk drug manufacturers and 10 formulation manufacturers exist, none having more than 40% market share.

5) Exclusion from price control for five years, if the drugs are manufactured indigenously for the first time.

6) All annual turnover calculations are made including sales tax but excluding excise duty and other local taxes.

7) Government introduced a single MAPE of 100% for all drugs under price control.

8) Small-scale units were subjected to the price control of drugs.

9) The new regulation removed the compulsory ratio of bulk drugs and formulations for producers in different categories.

Most of the above changes or amendment as stated above are based on the Hathi Committee Report of 1995.

The other features of the Drug Price Policies are:

1) Industrial licensing was abolished for all bulk drugs except for five drugs reserved for public sector namely Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxytetracycline.

2) Automatic approval has also been introduced for proposals envisaging up to 51 percent foreign equity holding. Proposals for foreign investment above 51 percent are to be considered on case-by-case basis. Thus the companies with foreign equity holding up to 51 percent have been brought on par with Indian companies.
Pricing Mechanism for Bulk Drugs

The price of a drug is fixed by the government based on the study of the cost audit reports of the major manufacturers of that drug. Once the government fixes it, then it is binding on all manufacturers, irrespective of their actual cost of production. This has an inherent disadvantage to small manufacturers. Companies who manufacture the bulk drugs can adopt any of the following options to calculate the cost of production:

1) A post tax return of 14 percent on net worth or
2) A return of 22 percent on capital employed
3) In respect of a new plant an Internal Rate of Return (IRR) of 12 percent based on long term marginal costing will be allowed. Where production is from basic stage, a post tax return of 18 percent on network or a return of 25 percent on capital employed will be allowed. However the choice of the method is left to the company and not to the product, but should cover the entire range of products.

Formulations:

The maximum prices fixed by the government covers all formulations using any of the bulk drugs specified in the DPCO. In fixing the price, the government continued to advocate profitability ceiling. In the case of formulations the retail prices of controlled products were decided by applying the concept of MAPE. It marks up on the ex-factory cost provided to cover all selling and distribution costs, including the retail and wholesale trade margins.

The formula used for pricing was as below:

Retail price = (MC+CC+PM+PC) x (1+MAPE) + Excise duty.

MC = Material cost including bulk drugs.
CC = Conversion Cost, as per the dosage.

PM = Cost of packing materials (suitable to dosage)

PC = Packing charges.

Regarding the commonly manufactured formulations, ceiling price is notified in the official gazette. However, if a new formulation is developed using any drug under DPCO, the company has to work out the price using government prices as benchmark along with the standard costing procedures and other norms specified in the official gazette. After this the manufacturer should inform the government about the proposed price and the government has the power to revise the price. However this price is applicable only to a particular company's brand. If the other companies are making the same formulations, they should also seek the government's permission. For imported formulations, the landed cost along with the selling and distribution expenses, which cannot exceed 50% of the landed cost, forms the basis for price fixation.

3.3.10 DPCO 2002

Maximum Allowable Post – Manufacturing Expenses (MAPE) will be 100 percent for indigenously manufactured formulations. For imported formulations, the margin to cover selling and distribution expenses including interest and importers’ profit shall not exceed 50 percent of the landed cost.

Pricing of formulations

For scheduled formulations, prices shall be determined as per the present practice. The time frame for granting price approvals will be two months from the date of the receipt of the complete prescribed information.
Pricing of bulk drugs

For scheduled bulk drugs, the rate of return in case of basic manufacture would be higher by 4 percent over the existing 14 percent on net worth or 22 percent on capital employed. The time frame for granting price approvals will be 4 months from the date of the receipt of the complete prescribed information. The Government shall however retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest.

3.3.11 National Pharmaceutical Pricing Authority (NPPA)

As per the DPCO (1995), the government announced its plan to set up an independent body, called the NPPA, in order to improve the speed and transparency of the process of fixing prices of bulk drugs and formulations. This apex body has been made functional since 1st September, 1997. The NPPA has the power both to determine and notify the prices of drugs. Due to the functioning of this, it is expected that the time lag between the price revisions will be reduced and thereby provide stable margins for formulations. The NPPA has been fairly active on that front, coming in with extremely frequent price revisions.

The functions of the National Pharmaceutical Pricing Authority:

1. To implement and force the provisions of Drug Prices Control Order, 1995 in accordance with the powers delegated to it.
2. To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
3. To monitor the availability of drugs, identify shortage, if any, and to take remedial steps.
4. To collect/maintain data on production, exports, imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.

5. To deal with all legal matters arising out of the decision of the authority.

6. To render advice to the central government on changes/revision in the drug policy.

7. To render assistance to the central Government in parliamentary matters relating to drug pricing.

Performance since inception and upto 15th November 2002

The National Pharmaceutical Pricing Authority (NPPA), since its inception has fixed/revised the prices of scheduled bulk drugs in 96 cases, which includes 63 bulk drugs, 33 derivatives of scheduled bulk drugs and 1968 formulations. Of these, the prices of 7 scheduled bulk drugs (2 bulk drugs and 5 derivatives) and 57 formulations were fixed/ revised during the period between 1st April 2002 to 15th November 2002.

Price Behaviour

<table>
<thead>
<tr>
<th>Year</th>
<th>Price increase in controlled products</th>
<th>Price increase in decontrolled products</th>
<th>Total price increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>1.7</td>
<td>2.8</td>
<td>2.4</td>
</tr>
<tr>
<td>1996</td>
<td>2.2</td>
<td>4.2</td>
<td>3.6</td>
</tr>
<tr>
<td>1997</td>
<td>1.1</td>
<td>4.7</td>
<td>3.2</td>
</tr>
<tr>
<td>1998</td>
<td>-0.4</td>
<td>3.9</td>
<td>2.1</td>
</tr>
<tr>
<td>1999</td>
<td>2</td>
<td>4</td>
<td>3.2</td>
</tr>
<tr>
<td>2000</td>
<td>NA</td>
<td>NA</td>
<td>2.5</td>
</tr>
<tr>
<td>2001</td>
<td>NA</td>
<td>NA</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Source: ORG- MARG Study

The prices of drugs and pharma products have not increased on par with the general increase in price level because, the drug prices faced a downward pressure in the
early 1990s due to the development of domestic companies, supply conditions, price control and increased competition. As a result of this the wholesale price index decreased from 7.7% in 1995 to 3.5% in 2001. Similarly the total price decreased from 2.4% in 1995 to 0.9% in 2001.

**FIGURE III.10**

**DRUG PRICE CHANGES VS WHOLESALE PRICE INDEX**

![Graph showing drug price changes vs wholesale price index from 1995 to 2001. The graph indicates that the pharmaceutical price index is always at a lower level compared to the wholesale price index from the year 1995 till 1998. Only during the year 1999 there is a gradual increase in pharmaceutical price index. During the same year the wholesale price index has fallen from the previous value. But still after 1999 the pharmaceutical price index has again decreased when compared to the wholesale price index.]

Figure III.10 shows the trend in pharmaceutical price and whole price index between the years 1995 to 2001. From the figure it is evident that the pharmaceutical price index is always at a lower level when compared to the wholesale price index from the year 1995 till 1998. Only during the year 1999 there is a gradual increase in pharmaceutical price index. During the same year the wholesale price index has fallen from the previous value. But still after 1999 the pharmaceutical price index has again decreased when compared to the wholesale price index.
According to the ORG study (Table III.5), in 8.7% of the medicines the prices have decreased and in 41.7% of the medicines there was no change in price. Therefore in approximately 50% of medicines, there was no increase in prices. Moreover about 20.9% of the medicines had experienced only less than 5% increase in price. Even when comparing the prices of drugs with developed country (UK), the prices in India are less. This is evident from the table III.6.

**TABLE III.5**

<table>
<thead>
<tr>
<th>% Price Change</th>
<th>No. of Medicines</th>
<th>No. of Medicines (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price Decreases</td>
<td>18</td>
<td>8.7</td>
</tr>
<tr>
<td>No Change</td>
<td>86</td>
<td>41.7</td>
</tr>
<tr>
<td>&lt;5%</td>
<td>43</td>
<td>20.9</td>
</tr>
<tr>
<td>5%-10%</td>
<td>31</td>
<td>15.1</td>
</tr>
<tr>
<td>10%-20%</td>
<td>20</td>
<td>9.7</td>
</tr>
<tr>
<td>20%-50%</td>
<td>8</td>
<td>3.9</td>
</tr>
</tbody>
</table>

Source: ORG. Marg. study.

Table III.6 shows the comparison between prices of drugs in India and U.K. As is seen from the table, all ten drugs which are compared are sold at a lesser price in India when compared to U.K. For example considering Erythromycin, the price of 250 mg capsules is Rs.9.25 in UK whereas only Rs 3.57 in India. Similarly Norfloxacin 400 mg tabs are only Rs.4.7 in India whereas they are Rs 32.64 in U.K. Thus the price reduction between U.K. and India ranges from three times to eight times. The prices of bulk drugs in the domestic market experienced a downward trend in the past because of excessive supply conditions. But, the prices of formulations did not face a declining trend because the formulation price was varying according to the brand equity and marketing strength.
of the companies. Hence many large companies have changed the product mix in favour of formulations.

TABLE III.6

PRICE - COMPARISON WITH U.K

<table>
<thead>
<tr>
<th>Molecules</th>
<th>Strength</th>
<th>Per Capsule/Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>UK (Rs.)</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>250 mg Caps</td>
<td>9.25</td>
</tr>
<tr>
<td>Cephalexin</td>
<td>250 mg Caps</td>
<td>10.4</td>
</tr>
<tr>
<td>Cefixime</td>
<td>200 mg Caps</td>
<td>116.96</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>0.50 mg tabs</td>
<td>2.18</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>250 mg Caps</td>
<td>51</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>50 mg tabs</td>
<td>10.95</td>
</tr>
<tr>
<td>Amoxycillin</td>
<td>250 mg Caps</td>
<td>13.06</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>150 mg Caps</td>
<td>31.62</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>300+150 mg caps</td>
<td>51.95</td>
</tr>
<tr>
<td>Norfloxacin</td>
<td>400 mg tabs</td>
<td>32.64</td>
</tr>
</tbody>
</table>

Source: UK MIMS and Indian Drug Index (Drugs Today)

Profit behaviour

Profit behaviour in pharmaceutical industry is related to the price behaviour. In 1969 – 70, the profit before tax as a percentage of sales was 15.4% which was the highest profit margin in the period between 1969 and 1998, upto 1970, only the MNCs were ruling and the market share was 70%. Hence they were enjoying the monopolistic market and there was no competition. But after 1970 the domestic companies took an upper hand.
Further the DPCO was imposed. Hence the profit before tax was 1 percent in the year 1991 - 1992. Thereafter, the profit started increasing steadily from 2.6 percent to 8 percent in the years 1992-93 to 1997-98 respectively. Subsequently it increased to 10 percent in 2002-2003. This was possible because DPCO was diluted and globalisation came into existence.

3.4 Research and Development

The Pharmaceutical Industry is considered as one of the most research-based industry in the world. The rate of obsolescence and scientific innovations in the case of drugs is so rapid that it is difficult to imagine a modern pharmaceutical industry without
massive efforts on Research and Development (R & D). In contrast to other industries, research and development function of the Pharmaceutical industry has some special characteristics. The scope for conducting research in the Pharmaceutical industry is huge. It is not just the medicines are developed to treat new diseases or improve upon the existing treatment, but even the existing medicines need to be upgraded constantly. The upgrading becomes necessary since the known ailments develop resistance to the existing medicines. For this, in depth understanding of the human physiology and disease mechanism is a pre requisite. Thus research in the Pharmaceutical industry refers to the directional search for solutions to existing medical problems and medical needs which are not yet met. It is also to be aimed at improving the effectiveness of the existing medicines, so as to minimize the treatment time, cost of treatment and improving the efficiency in containing side effects.

Therefore to facilitate the research in industry, companies usually focus on select therapeutic areas such as anti ulcers, anti-cancer drugs etc. Continuous research is being conducted globally for major diseases such as AIDS, Alzheimer's disease, arthritis cancer, depression, diabetes, heart disease osteoporosis and stroke etc. Research was the major boost for growth of pharmaceutical industry after Second World War. This is due to two reasons:

1) Emergence of new diseases, which call for development of new medicines.

2) Upgradation of existing medicines, as the known ailments develop resistance to the existing medicines.
3.4.1 Importance Of Research And Development

1) With the coming of the product patents regime as a consequence of India signing in the WTO agreement implied, accepting the TRIPS clause development of the new product and launching it will become absolutely vital for survival in the domestic market,

2) Indigenously developed new drugs do not come under the purview of the DPCO and are thus going to enjoy higher margins,

3) A study conducted by ORG-MARG shows that the rate at which products are going off patent in the global market is higher than the rate at which new drugs are coming into the final stages, thus creating a gap and

4) To ensure long-term growth, the nature of this industry is such that one needs to have a few cash cows and a few stars at the same time. This can be possible only via extensive R & D capabilities.

3.4.2 Types of R & D

Four categories of researches are being conducted for development of new medicines globally today. They are:

Fundamental or Basic research:

This involves discovering molecules from Scratch. It is highly capital intensive in nature, as it relies on a great deal of automation. Only a few of Indian manufacturers are capable of conducting this type of research. E.g. Ranbaxy and DRL.

Most Indian manufacturers do not have the sort of resources to conduct this type of research due to their low profit margins.
Process research or reverse engineering

Under this type of research, a company typically copies the molecule of another company and develops a cost-effective method of producing that molecule. It is less expensive than the former because this type of research need not carry out any discovery or clinical trials. Maximum numbers of Indian manufacturers are focusing on this type till now.

Analogue or Discovery Research

Under this method companies will access the international database and will take away an existing molecule and develop one that has not yet been commercialized. This is modified to produce another molecule. In India, Ranbaxy, DRL and Sun Pharma are getting into this type of research and business.

Genetic Research

It aims at establishing the link between one’s genes and the disease that he/she may have and could one day determine the best drug for that individual genetic-based makeup. Some Government institutions like the National Institute of Immunology, JNU, Delhi; Centre for microbiology, Hyderabad; the IISc, Bangalore etc. are conducting this type of research. But there is an opportunity for both the Indian and foreign manufacturers to work in alliance with these institutes for conducting further advanced researches.

3.4.3 Scientific Infrastructure:

India has the third largest quantity of scientific and technically qualified manpower. Its premier educational & research institutions in Gujarat and Maharashtra have profited immensely. The Chemical Industry in India has grown stronger and
become internationally competitive. But somehow, it is felt, that the ground rules set by
the Government are not sufficient to stimulate the will to conduct innovative research. If
proper ground rules are provided for, probably many of the top class Indian expatriates in
R & D would be persuaded to return to the country and train junior scientists. Also,
multinational companies would be induced to set up R & D units in India, with a
subsequent "trickle down" effect. It is seen that multinationals in India have reduced
their presence in Pharmaceutical industry from 80 percent in 1970 to 25 percent in 2002.

Research in Indian players

After India had signed the TRIPs clause of WTO some of the Indian companies
realised the need for the basic research. Hence a few prominent Indian companies with
strong research skills have conducted basic drug research and discovered a few
molecules. These companies find it difficult to conduct the clinical trials and other tests
required thereof. This is because; it comprises the most capital-intensive step in the
process of basic research, which account for around 60-70% of the total research cost.
Therefore the major Indian players either sells off their molecule at the pre clinical stage
itself or the clinical trials are conducted in collaboration with the multinational patents.

High cost process with long lead-time

The average cost of developing a new molecule in the international market is
estimated at US $ 350 million requiring a time frame of 12-15 years. However the
average drug development time has increased. This is mainly because of the tightening
of the regulations associated with drug approval in different countries. The total drug
development time has increased from an average of 8.1 years in the 1960s to 11.6 years in
the 1970s and further from 14.2 years in the 1980s to 14.9 years for the drugs approved during the 1990s.

**High-risk proportion**

Pharmaceutical research is not only an expensive venture but also a risky one. The rate of failure is relatively high. Typically, out of 10,000 compounds synthesized, only about 20 reaches the final testing stage, of which only about 10 reached clinical trials and the drug regulatory authorities approved just about 1. Moreover, only about 2 to 3 out of every 10-drug product recover their R&D costs. Therefore, companies have to rely on highly successful products to fund their R&D activities.

After India had signed the TRIPS, clause of WTO, some of the Indian companies realized the need for basic research. Hence a few prominent Indian companies like Ranbaxy, Dr.Reddy's Laboratories, Sun Pharma and Cipla with strong research skills have conducted research on basic drugs and discovered a few molecules. These companies find it difficult to conduct technical trials and other tests required. Therefore the major Indian players, either sell their molecules at the pre clinical stage itself or the clinical trials are conducted in collaboration with the multinational partners.

Research and Development seems to be the new buzz word not only for the 1st class Indian Pharmaceutical companies but also for the domestic pharmaceutical companies; especially, the second rung pharmaceutical companies have to upgrade their research and development (R&D) facilities to increase their share in the emerging market of contract research and to gain a foot hold in the US generics market. The second set of companies that are planning to make fresh investments for the purpose upgrading is presented in the Table III.7.
TABLE III.7
SECOND SET OF COMPANIES SHOWING INTEREST IN R&D

<table>
<thead>
<tr>
<th>Name of the company</th>
<th>Base</th>
<th>Subsidiary company</th>
<th>Investment in R&amp;D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torrent Pharmaceuticals</td>
<td>Ahmadabad</td>
<td>Torrent Research Center</td>
<td>Rs.14 crores</td>
</tr>
<tr>
<td>Alembic Limited</td>
<td>Baroda</td>
<td>Bio Arc Research solution</td>
<td>Rs.15 crores</td>
</tr>
<tr>
<td>Shasun Chemicals</td>
<td>Chandigar</td>
<td>-</td>
<td>Rs.25 crores</td>
</tr>
<tr>
<td>Ind-Suift Laboratories</td>
<td>Chennai</td>
<td>-</td>
<td>Rs.40 crores</td>
</tr>
</tbody>
</table>


The Indian pharmaceuticals companies are eyeing at the US generic market, in which many block-buster drugs are going to be off-patented by 2005. The size of this market is estimated around $40 billion. Looking at the huge opportunities, most of the Indian pharma companies have started the process of filling Drug Master Files (DMFs) and Abbreviated New Drug Applications (ANDA) for their bulk drugs and formulation business in the US. As part of this, R&D and other manufacturing facilities are being developed as per the international regulatory norms.

Indian pharmaceutical companies register 25% of DMFs in US FDA between March-June 2003. Out of the total DMFs of around 148 filed with US FDA, 34 DMFs, which received the approval, were for Indian companies. Incidentally, Cipla, Dr.Reddy’s and Ranbaxy represent a little less than 20 percent of the total approved DMFs of Indian companies. Second rung companies such as Ajantha Pharma, Torrent Pharma, Alembic Limited, Shasun Chemicals and Ind-Suift Laboratories file the rest of the 80 percent of DMFs.
Reasons for low investments in R & D:

1. Low level of profits since the products prices are regulated by DPCO from 1970.
2. Indian companies have been concentrating on applied research rather than basic research as a consequence of Indian regulatory system.
3. Indian companies do not have the financial capacity to fund basic research, which is a capital-intensive process.
4. R&D investment by MNCs in India is almost insignificant in the past due to absence of product pattern.
5. New drug development is time consuming (10 – 12 years) and risky.

3.4.4 Present condition

Both Indian companies and MNCs are gearing themselves, towards contributing to investments in the R&D since 1995 after Govt. of India has signed the WTO. It will be further accelerated after 1st Jan 2005 once India starts implementing the product patent.

**TABLE III.8**

**COST-ELEMENT IN R&D IN INDIAN PHARMACEUTICAL INDUSTRY**

<table>
<thead>
<tr>
<th>Item</th>
<th>Developed countries</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of developing a molecule</td>
<td>$250–500 million</td>
<td>140 - 200 crores</td>
</tr>
<tr>
<td>Hiring of Chemist with Ph.Ind.</td>
<td>$1,00,000</td>
<td>$15,000</td>
</tr>
<tr>
<td>Pre clinical</td>
<td>$100–150 million</td>
<td>40 – 60 crores</td>
</tr>
<tr>
<td>Clinical</td>
<td>$150 – 350 million</td>
<td>100– 150 crores</td>
</tr>
</tbody>
</table>

India’s research and development facilities represent good opportunities both for Indian’s and MNC’s. Experience has led multinationals to cast a jaundiced eye over India’s research facilities. India’s strength in R&D is rich scientific base and low cost are
more apparent from table III.8. Further India has the second largest English speaking scientific base in the world with more than 200 Universities and 2000 research institutions including up to ten leading biological chemistry institutes. India is also an a attractive site for pre clinical and clinical development activities and they have almost developed world class skills, as well having low costs advantages that multinationals can use to conduct pre clinical and clinical trials in India. India could be a competitive source of clinical research for use in international drug dossiers. There are three reasons for this, first, vast pool of patients and faster enrolment rates; second, India’s low costs – even after accounting for additional investments required to meet good clinical practices (GCP) and finally the prevalence of certain diseases – notably malaria and hepatitis – which makes the country an attractive clinical research location.

From Table III.8, it is evident that the cost of hiring a chemist, cost element of pre clinical and clinical trial is ten times more in developed countries when compared to India as a result the difference in the cost of developing a molecule in developed countries and in India is also ten times more in developed countries.

In general R&D expenditure played an important role in the Indian industry after implementations of economic reform. This can be witnessed particularly in the pharmaceutical industry. The survival of the pharmaceutical industry depends upon how for the industry is concentrating on investment in R&D. Table III.9 clearly indicates the trend of expenditure in R&D as percentage of production. From the table it is apparent that prior to economic reforms the expenditure was from 1.5% as percentage of production in 1980-91 to 2.05% in the year 1990-91, and after the economic reforms the expenditure ranged from 3.0 to 3.35 which clearly shows that the pharmaceutical industry
have realized the importance of R&D investment in the post globalisation period. Though there is an increasing trend between these two periods, the increase expenditure is not at par with international expenditure, which is 10% as percentage of sales to production.

TABLE III.9

R&D EXPENDITURE IN INDIAN PHARMACEUTICAL INDUSTRY

<table>
<thead>
<tr>
<th>Years</th>
<th>R&amp;D expenditure (Rs. in crores)</th>
<th>% Increase over Previous year</th>
<th>Production (Rs. in crores)</th>
<th>R&amp;D expenditure as % of production</th>
</tr>
</thead>
<tbody>
<tr>
<td>80-81</td>
<td>21.0</td>
<td>-</td>
<td>1440.00</td>
<td>1.5</td>
</tr>
<tr>
<td>81-82</td>
<td>29.3</td>
<td>68.6</td>
<td>1723.00</td>
<td>1.7</td>
</tr>
<tr>
<td>83-84</td>
<td>40</td>
<td>36.5</td>
<td>1925.00</td>
<td>2.1</td>
</tr>
<tr>
<td>84-85</td>
<td>48</td>
<td>20.0</td>
<td>2115.00</td>
<td>2.3</td>
</tr>
<tr>
<td>86-87</td>
<td>50</td>
<td>4.0</td>
<td>2204.00</td>
<td>2.3</td>
</tr>
<tr>
<td>90-91</td>
<td>55</td>
<td>15.0</td>
<td>2361.00</td>
<td>2.05</td>
</tr>
<tr>
<td>91-92</td>
<td>80</td>
<td>60.0</td>
<td>2665.00</td>
<td>3.0</td>
</tr>
<tr>
<td>92-93</td>
<td>95</td>
<td>19.0</td>
<td>2830.00</td>
<td>3.4</td>
</tr>
<tr>
<td>93-94</td>
<td>125</td>
<td>31.0</td>
<td>3700.00</td>
<td>3.4</td>
</tr>
<tr>
<td>94-95</td>
<td>140</td>
<td>12.0</td>
<td>4060.00</td>
<td>3.4</td>
</tr>
<tr>
<td>95-96</td>
<td>160</td>
<td>14.0</td>
<td>4570.00</td>
<td>3.5</td>
</tr>
<tr>
<td>96-97</td>
<td>185</td>
<td>15.6</td>
<td>5700.00</td>
<td>3.2</td>
</tr>
<tr>
<td>97-98</td>
<td>220</td>
<td>19.0</td>
<td>7150.00</td>
<td>3.1</td>
</tr>
<tr>
<td>98-99</td>
<td>260</td>
<td>18.0</td>
<td>8220.00</td>
<td>3.2</td>
</tr>
<tr>
<td>99-2000</td>
<td>320</td>
<td>23.0</td>
<td>9453.00</td>
<td>3.4</td>
</tr>
<tr>
<td>2000-01</td>
<td>370</td>
<td>16.0</td>
<td>10947.00</td>
<td>3.4</td>
</tr>
<tr>
<td>2001-02</td>
<td>460</td>
<td>24.0</td>
<td>12680.00</td>
<td>3.6</td>
</tr>
<tr>
<td>2002-03</td>
<td>550</td>
<td>20.0</td>
<td>14991.00</td>
<td>3.35</td>
</tr>
</tbody>
</table>

Source: OPPI annual report.
3.4.5 Swot analysis of R&D of Indian pharmaceutical industry

This section delves into the assessment of R&D in the pharmaceutical sector, as this is needed to emerge as a global player. The strategic assessment is succinctly brought out in the following swot analysis.

Strengths

- Mature industry with strong manufacturing base with capacity to produce quality drugs at a relatively low cost.

- A very rich base of traditional knowledge in therapeutics like Ayurveda, Sidha and Yunani.
➢ Well-developed engineering base to produce wide range of pharmaceutical equipments and machinery.

➢ Abundance of Science and Technology (S&T) talent and infrastructure.

➢ Successful experience in innovative process/chemistry.

➢ Access to brain bank internationally.

➢ Acclaimed NRI, S&T professionals.

Weaknesses

➢ Sub-critical R&D investments

➢ Lack of innovative R&D culture in industry

➢ Poor networking among constituents in the innovation chain

➢ Inadequate framework for clearance of new drug investigation and registration

➢ A policy framework for testing on animals and their import that is not facilitative

➢ Inadequately trained manpower in emerging areas

Opportunities

➢ Greater tendency towards outsourcing by the foreign companies and networking due to rising casts of revenue and expenditure overseas.

➢ Expertise to blend knowledge of traditional medicines with modern science

➢ Increasing competency in molecular biology, immunology and biotechnology

➢ Early R&D wins boosting confidence (Reddy's, Ranbaxy's, Dabur's, Shanta Biotech's)

➢ Large number of patients covering wide range of diseases

➢ Potential for clinical research and initiating clinical trials

➢ Opportunity to improve quality standards
Contract research including clinical and preclinical work

Selective Biotech R&D and production of cost-effective products such as anti-cancer products, vaccines, etc.

**Threats**

- Inability to cope-up with the rapidly changing new drug discovery technologies and process at the global level
- Rapidly changing standards of quality and manufacturing at the international level
- Lack of clearly articulated and facilitative national IPR policies
- Lack of strategy to bring convergence between aspirations of the 'small' and 'big' players
- Distortion in priority and public concern on health and pharma issues
- Reducing tariff levels and dumping can be a threat to survival of products and industry.

It is apparent that Indian pharma R and D has several scientific techno-economic advantages that outweigh the few inherent weaknesses. The opportunities are appealing and attractive and the threats are manageable. Thus if the proper policy support and direction is given, the Indian pharmaceutical industry can carve out a niche for itself in the global pharmaceutical market.

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