CHAPTER II

INDUSTRY OVERVIEW*

This chapter, through sections 1.0 to 9.0, covers the nature of demand for pharmaceutical products, a brief history of the Indian Pharma industry, the industry's evolution as a net forex earner, its market potential and health infrastructure, the therapeutic segment structure of the pharmaceutical market, the legal and regulatory environment of the Indian pharma industry, a brief profile of technological achievements, the strategic issue of India's patent regime, the controversial pricing regulations and finally, the historical profitability profile for the industry Requisite industry statistics are presented at the end of the chapter.

1.0 Nature Of Demand For Ethical Drugs

In terms of value chain, industry is divided into two categories . bulk drugs and formulations. Drug intermediates are used as raw materials for the production of bulk drugs which are either sold directly or meant for captive consumption for production of formulations. This study restricts itself to the universe of firms predominantly manufacturing formulations (refer Chp.V, Sec. 1.0). The formulations can further be subdivided into proprietary drugs and generic drugs Proprietary drugs are those

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* Relevant references are listed at the end of this chapter.

manufactured under either a product patent or process patent and are marketed as a separate brand Generic drugs are those that have gone off patent and can also be marketed as a separate brand in which case it is called branded generics Moreover, both proprietary and generic drugs are further divided majorly into 'prescription drugs' and 'over-the-counter' (OTC) drugs. Prescribed drugs (also called ethical drugs) are those which require a physician's prescription before they can be purchased by the consumer. OTC drugs are certified to be safe for self-medication when the consumer follows the directions that accompany the product, and hence can be purchased without a prescription These interpretations are based upon popular nuances prevailing in industry and hence may not match strict technical criteria in medical research The OTC market is only 18 % of the total global pharma market and in India too is restricted mainly to the cough/cold, antacid, rub, balm, and analgesic areas only Thus, the nature of demand for pharmaceuticals is largely addressed to the ethical/prescription drugs sector

Under extant laws governing the dispensing of ethical (prescription) drugs, a consumer can enter a particular ethical drug market only after he has received a physician's prescription for the drug. Once in possession of a prescription, the typical, though not inevitable, consumer response is to regard the consumption of the drug as essential to his health and comfort, and possibly even imperative for the maintenance of life itself. Thus, once a physician has prescribed a drug, the preference structure of the patient may become such that there is no possibility of substitution between the drug and any other commodity; in such a case, the marginal utility derived from the consumption of the required dosage of the drug approaches infinity

In writing a prescription, the physician almost invariably specifies the quantity that the patient is to consume Larger quantities consumed in the same period of time will, generally, confer no additional therapeutic benefits, in many cases, consumption of larger quantities than those recommended would be harmful The relationship between improved health and drug inputs is relatively rigid In general, improvement in health cannot be shifted to a higher level or made to occur at a faster rate by an increased rate of drug consumption

This implies that the patient is unlikely to purchase greater quantities of a particular drug if prices decline - even by substantial amounts Given the restrictions upon consumer choice in the ethical drugs market, a decrease in the price of drugs is not in itself likely to increase the quantity demanded by bringing new consumers in the market Thus, since price decreases are expected to have insignificant effects in the direction of increasing quantity demanded, the demand function for drugs is expected to be highly inelastic for price reductions. Similarly, demand is expected to be highly price inelastic for price increases as well

Much the same type of argument holds with respect to the influence of consumer income upon quantity demanded. Changes in income would be expected to have a negligible influence upon the demand for almost all drugs. The marginal utility derived from a prescribed drug will be higher than the marginal utility of expenditures on other goods and services for any level of income. Examples of low-income groups going without food for several days to purchase medicines abound. For a consumer to buy a drug which has been prescribed for him, it is sufficient, except in very rare cases, that he

have money to make the purchase Higher income groups, more likely to more often visit a physician, purchase more different types of drugs Finally, most standard economic theory suggests that the demand for drugs would be highly inelastic in relation to price as well as income

2.0 A Brief History

The exact date on which the Allopathic system of medicine made its entry into the country is not available but it is generally estimated that it happened sometime during the early part of the 19th century. Medicines were first imported into India by the Britishers for their personal use and then gained popularity among the people in urban areas. Indigenous production of these medicines, however, was started in 1901 with the establishment of the Bengal Chemical and Pharmaceutical Works, due to the pioneering efforts of Acharya P.L Ray. Between 1904 and 1907 four research institutes, namely, The Haffkine Institute, King Institute, Central Research Institute and Pasteur Institute, were established. Scientists in India, then, undertook research in tropical diseases like malaria, typhoid and cholera The first world war resulted in a drastic cut in imports and this gave domestic manufacturers a boost However, after the war resumption of imports discouraged domestic production rendering it uncompititive. Yet during this period significant drugs like aspirin and barbiturates, caffeine and surgical dressings were made available By 1941 the industry took up the manufacture of new drugs like iodochlorohydraxy quinolone, a variety of alkaloids like ephedrine and codeine,

chemotherapeutic drugs, anti-leprotic drugs, colloidal preparations, and glandular products like liver extracts. The production of several formulations based on imported drugs also showed a significant expansion during the period. Post-war developments in the west resulted in a high degree of product obsolescence as new age antibiotics made much headway At the time of independence, with the small production base the then nascent industry had an estimated production value of Rs 10 crores in 1947

Till the second plan period, 1956-61, India concentrated on formulations but, often even, these were being made under agreement with foreign firms Bulk drugs were imported and then processed into tablet and capsule form It was war again which forced this aspect of the Indian drugs and pharmaceuticals industry to change The Indo-China war and the price hike in critical drugs by foreign firms made the government realise the urgency to produce antibacterials indigenously However, no foreign firm was forthcoming with the necessary investments With no foreign firms willing to invest because of little business potential, or to part with technology, the government of India had little option but to seek Soviet help for producing critical life-saving drugs In September 1958, the Soviet Union offered India technical and financial assistance including credit to buy machinery and equipment. This Russian connection culminated in the establishment of Indian Drugs and Pharmaceuticals Ltd (IDPL) and its five branches At Rishikesh for the manufacture of antibiotics, at Hyderabad for manufacture of synthetic drugs, at Madras for manufacture of surgical instruments and formulations and at Muzaffarpur for the manufacture of drugs and chemical intermediates Hindustan Antibiotics Ltd., Pune, was later set up in collaboration with IDPL to manufacture

penicillin and its derivatives, vitamin C and other formulations These companies were to provide the first trained Indian scientists who later turned technocrats and helped set up wholly Indian pharmaceutical companies

The Indian Patents Act, 1970, and stiff import tariff structures next provided the protection that gave Indian firms the much needed fillip. Upto 1970, multinational companies controlled over 90 % of the Indian market They had a stranglehold on pricing and availability of drugs Industry was completely dependent on imports for meeting bulk drug and formulation requirements. Often, the raw materials imported were not brought in at market rates, but at higher transfer prices These supplies were coming from other inter-group companies outside India. The higher material costs were passed on to the Indian public resulting in domestic drug prices being among the highest in the world In 1970 the Indian Patents Act, the drug price control order, high tariffs (over 80 %), ban on imports of later stage raw materials, the draconian provisions of the Foreign Exchange Regulation Act (FERA), and the insistence that multinationals would have to ensure that at least 10 % of their sales would consist of bulk drugs which had been locally produced, arrested the growing clout of the multinationals Under these new legal restrictions, the Indian pharmaceutical industry blossomed More and more Indian companies began learning to copy the molecular structure of pharmaceutical compounds and further mastered the installation of highly cost effective manufacturing processes. At the center of this resurrection was the entrepreneurial flair of scores of scientists who were trained at IDPL and HAL Today, Indian pharmaceutical companies have made inroads in the very territories foreign companies once believed to be their exclusive markets

Currently, local players dominate the sector - they account for 70 % of India's formulations market, 85 % of the bulk drugs market, and 85 % of the industry's exports Six of the ten largest (in retail formulation sales) pharmaceutical companies are locals compared to two local players in the top ten a decade ago Domestic production meets 70 % of bulk drug requirement (350 bulk drugs out of 500 consumed in India) and 90 % of its formulations requirement (about 20,000 formulations) Domestic production has grown 12 % annually in the last 13 years In a few drugs (like sulphamethosazole and ethambutol) current production accounts for about 50 % of world production. Table 2 1 presents industry production statistics from 1980-81 to 1994-95 Today cost-efficient processes ensure that domestic prices of Indian medicines are amongst the lowest in the world. A comparison of prices of select Indian drugs with other countries is presented in Table 2 2 By the 1980s, most new drugs introduced internationally could be produced in India within four years of their international launch Table 2 3 presents the time lag in the introduction of patented drugs. As per the estimates of the Organisation of Pharmaceutical Producers of India (OPPI), the total number of licensed manufacturing units in India has increased from around 6,000 in 1980-81 to about 23,790 registered units in 1994-95, making this sector of the Indian economy the most competitive one, indicating very low entry barriers Currently, foreign companies account for around 38 %, the Indian private sector for 61 % and the public sector for 1 % of the market The top 10 companies account for around 30 % of the market. Other facets of the industry are taken up in subsequent sections of this chapter.

3.0 Exports Profile

For the past few years, the exports of the pharma industry have been increasing and the industry has been a net forex earner. From around Rs. 112.54 crore in 1980-81, imports have increased to about Rs 1,800 crore in 1994-95. Exports on the other hand have increased from a mere Rs. 46.38 crore in 1980-81 to about Rs 2,185 crore in 1994-95 (Refer Table 2.4)

The increase in exports has been mainly because of the cost effectiveness of the products in India. The cheap cost of both technically skilled and unskilled labour has been the major reason due to which the pharma firms have been able to maintain lower costs Also the image of India as a quality producer of medicines has helped boost exports. Moreover, intense domestic competition and government price controls keep domestic profitability low. Exports are more profitable than domestic sales. In some drugs/markets margins on exports are twice that of domestic margins.

Finally, many emerging Asian, Eastern European, Latin American and African markets are exhibiting terrific growth and offer great opportunities. The Chinese market for Western drugs is estimated to grow at 26 % compound over the rest of the decade to around $ 20 billions - bigger than the current value of the French and German markets combined, the world's 3rd and 4th largest markets. The existence of global pricing pressures, emergence of cost-conscious consumers, patent erosion, and an erupting generics market make India's cost competitive players ideally positioned to reap handsome gains in the near future.

4.0 Market Potential And Health Infrastructure

India, with its huge size and large population, has the promise of an excellent potential market for any industry. With an annual per capita drug expenditure which is one of the lowest at $ 3 (compared to $ 5 in Indonesia, $ 7 in China and Pakistan, and $ 16 in Brazil and $ 28 in Mexico) and with the Government declaring a 'Health for All' status by AD 2000, the industry is poised for rocketing growth

Today, India's expenditure on health care as a proportion of GDP is only around 0 8 %, compared to 12.4 % in the US, 9 % in Canada, 8 9 % in France, 8 1 % in Germany, around 6 5 % in Japan, 6.2 % in the UK, and 7.7 % in Italy Another measure of the sweeping potential can be gauged by the size of the population compared with the volume of drug production Whereas India has around 16 % of the world population, it produces only around 1.2 % of the world pharma production (see Table. 2.5). There are around 4 lakh doctors in the country (CAGR from 1955-56 around 5 %), around 3 5 lack nurses (8%), around 12,000 hospitals (CAGR from 1960, 3 1 %), around 8 25 lack hospital beds (5%); around 22,250 primary health centres (9 4 %), and around 150 medical colleges (3.3 %) With the government committed to make 'Health for All' a reality and with the process of reversing the brain-drain almost started, all the above ancillaries, which are critical to the growth of the pharmaceutical industry, are expected to grow exponentially. One estimate (of NCAER) puts total domestic demand for drugs at around Rs. 16,000 crores by Ad 1999-2000, reflecting a compounded growth of around 18 % per annum. In addition to the above, the same estimate puts export demand at

around Rs 5,000 crores by the end of the century (CAGR of 23 %) finally, a glance at Table 2 6 also presents a historical profile of the governments commitment to building a health infrastructure from the first five-year plan till the current one

5.0 Therapeutic Segments

Like other industries, the pharmaceutical industry too is segmented along therapeutic lines. In India, like in other countries, the total pharmaceutical market is divided into 'Anatomical classifications' as per the criteria of World Health Organisation These anatomical classifications are also alternatively called therapeutic categories or segments. Each therapeutic segment would then have within it a number of products Thus, the pharma market consists of many sub-divisions, within divisions, each involving a variety of drugs for different usages.

Choosing a product segment in the pharmaceutical market represents a strategic decision issue and is far more complex than it appears. Market segmentation here involves dividing a given therapeutic segment demographically, geographically, by age group, by severity of disease, by acute/chronic/recurrent, by nature of disease, by doctor speciality, by place of use, prescription, etc An illustration of the same is presented in Fig 2.1 for a non-steroidal anti-inflammatory compound to highlight the complexity of the issue. The Indian pharmaceutical market is made up of 77 therapeutic categories catered to by 6,526 products (IDMA Bulletin - 1996) Table 2 7 presents a breakdown of the market by top therapeutic groups

Selection of a product segment, in the domestic market, plays a key role in influencing profitability. Success of a firm is dependent on its presence in a segment which is lucrative not only in terms of growth, but also whether it offers enough margins to sustain profitability Some product segments may offer high volume sales but low margins while others may represent specialised niches but handsome margins Finally, in the Indian market, the segment selection decision is also influenced by whether it falls under the price control order or not.

Given the above character of the pharmaceutical market, nature of demand for its products, and extremely fragmented make up of units (23,790 totally); the structure of this industry may reasonably be claimed to be a monopolistic competitive one

6.0 Legal And Regulatory Framework

The current legal and regulatory environment of the pharmaceutical industry in India is a result of several statutes enacted over a period of more than a hundred years. These statutes or enactments can broadly be categorised into two areas:

1. Those pertaining to quality control of the pharmaceutical industry such as quality control, safety and standards of all the drugs manufactured and marketed in the country and those imported into the country All these are under the purview of the Union Ministry of Health (Directorate General of Health services).
2. Those pertaining to other aspects of manufacture and marketing of drugs such as investment, foreign collaboration, licensing of production facilities, pricing,

trademarks, patents, import of capital equipment, raw materials and technology All these aspects come under the purview of different departments like the Ministries of Petroleum, Chemicals and Fertilisers, Industry, Finance, Law, Commerce and Labour of the Central Government

In addition to the central laws and regulations, there are controls and regulations at the state level also A detailed list of the major laws that govern the industry's conduct is presented in Table 2.8

7.0 Current State Of Capital Investments

As of 31 December 1995, there were 126 drugs and pharmaceutical projects envisaging a total investment of Rs 3,830 crore Majority of the projects envisaged are by the Indian companies. Of the 126 projects, 97 projects are in various stages of implementation and are expected to be completed by 1997-98. Further, most of these companies have succeeded in raising money from the capital market to part finance their respective projects Table 2.9 presents a detailed picture of the public issues of pharma based ventures From the modest capital investment of Rs. 24 crores in 1952-53 till today the industry can claim to have made immense progress

8.0 Technology

Pharmaceutical production in India is broadly planned by the Government and every project is rigidly controlled at every stage of licensing import collaboration and execution The product and process technology in the west are private assets and have been attempted to be transferred to India through private commercial enterprises like foreign subsidiaries, joint ventures and by pure technical collaboration arrangements, and also through public sector undertakings. As mentioned earlier, from socialist countries (mainly USSR) government had bought technology through inter-government contracts, with loan assistance for purchase of capital equipment as also technical assistance without any financial participation. However, by the eighties, scores of scientists trained at HAL and IDPL turned technocrats designing and commissioning indigenous technology

One criterion for measuring the adaptation of imported technology and indeginisation of such technology would be the progressively quicker introduction of products of foreign technology, in other words, the time lag between the introduction of a new drug in the developed countries and India should gradually shorten. Given that till recently India followed a process patent regulation, and as earlier mentioned in sec. 2 of this chapter, such new product introduction time lag has been today reduced to four years Currently, the ability of Indian firms in the industry to innovate and find new methods of manufacturing that can substantially alter their costs, is demonstrated by the cost leadership enjoyed by Indian firms not only in India but in global markets as well Indian firms have, over the years, groomed manufacturing process competencies that result in

high yields and lower costs, new methods in drug storage and drug delivery systems Events have turned full circle for the Indian pharmaceutical companies They have graduated to the status of multinationals themselves by setting up joint ventures in Canada, China, Hong Kong, Nigeria, Thailand, Vietnam, Russia, and the Middle East This itself, is ample proof of the Indian pharmaceutical Industry's technological self-reliance

9.0 India, Research And Development, And Intellectual Property Rights

Intellectual property, as the name suggests, is basically a concept, an idea or thought leading to the actual invention of a product or process. Intellectual property right, therefore is a legal protection for inventions which are the results of the individual's ideas resulting in new products and processes The World Intellectual Property Organisation (WIPO) defines and clarifies what exactly should be the nature of 'intellectual property' Currently about 140 countries give legal protection to both product patents as well as process patents as per the Paris Convention on International Patents and Intellectual Property Rights Recently, Mexico, Brazil and China too, have agreed to provide protection to international patents.

India recognises only 'process patents' and not product inventions, since the amendment of the Indian Patents Act in 1970 According to the Act, a patent once granted for an 'intellectual property' remains in force for a period of 7 years In the case of countries which have signed the Paris convention on Patents and Intellectual Property Rights, it is 20 years As product patents were not recognised, Indian companies have

mainly concentrated on research and development to develop cost-effective processes, so that a product can be made available at a substantially lower cost (without compromising on effectiveness). Not much attention has been paid to research and development to develop altogether new products The expenditure on research and development was a mere 1 8% of the sales in 1994-95 (Refer Table 2.10) This is not surprising, as Indian companies were not capable of investing in such research and development, nor did there seem much need. With limited turnover and low profitability, they did not have the funds to invest in research and development, which requires Rs 50-100 crores over a period of 5-10 years to introduce just one product (Ref Fig. 2.2) Moreover, since product patents were not recognised in India, there was no guarantee of covering even the investment in such research and development. The simple solution was to focus on reverse engineering and produce inexpensive versions of products developed by MNCs

The process patent regime fostered a climate for the industry to manufacture internationally patented drugs independent of the patent holder and free of royalties by developing alternative processes Since, most of these drugs are outside price controls (and are often new drugs), they retail at higher prices and are more profitable than their substitutes. Further, government support - via high tariffs (Over 80 %) and ban on imports of later stage raw materials - has been crucial in allowing local players to develop critical competencies in reverse and re-engineering patented drugs in a most cost-effective manner By the 1980s, most new drugs introduced internationally could be produced in India within four years of their international launch

Succumbing to international pressure, India finally became a signatory to the World Trade Organisation by accepting the Uruguay Final Act, signed on 15 April by 123 countries Post-GATT India will amend its patent laws by 1st January 1995 The main impact on pharmaceutical patents will be

1 Full cover for pharmaceutical products, as opposed to only processes earlier.

2 A patent term of 20 years from the date of filing against the earlier 5-7 years.

3 Government powers in enforcing compulsory licensing to be confined to special circumstances; like abuse of patent rights or national emergencies.

4. Reversal of the burden of proof in infringement actions relating to process patents - obliging the defendant to prove that the process is non-infringing

However, India is entitled (under GATT) to a transitional moratorium period of 10 years (1995-2004) before having to adopt product cover for drugs, giving Indian patent infringing manufacturers shelter for 10 years Thus, as the time frame for this study extends only to March 1995 - the implications of a post-GATT product patent regime will not affect its results and findings. Nevertheless, its role in policy formulations for the purpose of projecting future scenarios is taken up in the final chapter of this thesis.

10.0 Drug Price Policy

Government control on sale prices of drugs was instituted in 1963 when government pegged the prices of drugs at levels prevailing as on April 1st, 1963. In 1970, the Drug (price control) Order (DPCO) was passed Under this, prices of bulk drugs and

of selected formulations were controlled and a ceiling on the overall profits of pharmaceutical industries was introduced

As mentioned earlier (Refer sec 2 0 of this chapter), the dominance of multinationals in the Indian pharma market was immense They not only had the lion's share of the market but also possessed monopoly status in a variety of drugs This led to exorbitant prices being charged from Indian consumers In a bid to loosen the MNCs' strangle hold and protect consumers from high prices, the Government instituted a regulatory policy, the Drug Price Control Order (DPCO) in 1970.

In pursuance of the provisions of the drug policy announced in December, 1986, the DPCO of 1979 was replaced by a new order, the DPCO, 1987 Under the revised DPCO of 1987, the then existing three categories of drugs, were reclassified into two categories Drugs under category -I are those required for National Health Programme There were 27 items in this list. Drugs under category-II were called other essential drugs and were 139 in number Formulations of the first category would be entitled to 75 percent maximum allowable post-manufacturing expenses (MAPE) and those of the second category to 100 percent MAPE

While fixing the price of a bulk drug, the government may take into consideration a post-tax return of 14 percent on net worth or a return of 22 percent on capital employed or in respect of a new plant an internal rate of return of 12 percent based on long term marginal costing depending upon the option for any of the specified rates of return that may be exercised by a manufacturer of a bulk drug The government has also worked out a formula for calculation of retail price of formulations The formula allows maximum

post manufacturing expenses of 75 percent in the case of category I formulations and 100 percent in category II formulations.

In July, 1989, the Government removed 26 bulk drugs from price control as their turnover was marginal In August, 1989, drug price increased on the basis of new conversion and packaging norms were approved for companies which had submitted price revision applications for their entire range of products and price adjustments based on maximum allowable post manufacturing expenses in case of formulations were announced price of 164 pharmaceutical formulation packs were reduced by the centre on March 9, 1990 based on prices of 21 bulk drugs which were brought under drug price control in February 1990 With the extension of drug control to 21 more drugs, the market share of controlled formulations increased to about 70 percent. The government set up in Feb. 1990 a permanent 12 members standing committee under the chairmanship of the Secretary, Department of Chemicals and Petrochemicals to review the Drug (price Control) Order, 1987.

In July 1990, five more bulk drugs were brought under Drug (Price Control) Order 1987 thereby raising the number of controlled drugs from 145 to 150. Again August 1990, all bulk drugs used to make formulations for the national health programme were declared to be category I bulk drugs under the Drug (Price Control) Order 1987. All formulations containing category I or II bulk drugs were to be considered category I or II formulations respectively. The Government also allowed price increases for 400 drug formulations based on 1979 packaging norms In October 1990, the government ordered a five percent increase in pharmaceutical prices regardless of actual cost increases against

the industry's demand for a 15 percent across the board hike to absorb the cascading impact of the hike in petroleum prices

The Drug Policy, 1986, was modified in September, 1994, with regards to the price control on drugs At this time there were 143 drugs (and the thousands of formulations based on these) which came under the price control order and accounted for 72 % of the turnover of the organised sector To support domestic industry, the DPCO exempts new drugs (most being drugs under international patents) manufactured with indigenous technology from price controls for 5 years from production date In addition, all formulations with new indigenously-developed delivery systems are exempt from price control for 3 years from the date of government approval

On 6th January 1995, the government notified the DPCO 1995 This amended DPCO has identified 76 drugs to kept under price control The new DPCO, discarding the two different categories of drugs identified by the DPCO, 1987, has a notified list of drugs under price control with a MAPE of 100 % The government has also further announced new criteria for identifying drugs to be kept under price control The impact of these changes will accure to formulations only in 1995-96 because of the time it will take for the government to carry out the necessary amendments As the cut off point for the time period is March, 1995, for this study, the implications of the new DPCO 1995 is in any case not relevant.

Intense competition, domestic as well as from imports, and availability of substitutes have however ensured that the DPCO eventually loses its relevance While the DPCO does not include within its preview patented products developed with indigenous

research and development, currently most generic bulk drugs sell at below government notified prices. Bulk drug margins continue to be under pressure as competition increases and due to lower protection following reduction in tariffs In recent years the dynamics of competition has to an extent reduced the efficacy of the DPCO, in general

11.0 Profitability

Subjected for over two decades to an increasingly stringent system of price controls covering about four-fifths of its production of drugs and formulations, the industry's profitability track record is abysmal The Table 2.11 profitability trends, demonstrates the industry's profitability decline from an acceptable 15 47 % in 1969-70 to a pathetic 2 0 % in 1990-91. Pricing control policies more often than not, have been influenced by political, and other extraneous (populist) considerations Between 1989 and 1992 even legitimate price revisions based on documented cost increases were often not permitted. Historically, drug prices have not even kept pace with inflation Rigid controls, coupled with inadequate government administrative machinery to revise prices in line with cost increases, have also adversely affected industry profitability.

The peculiarity of the pharmaceutical price control system is that while the prices of raw materials as well as finished products are controlled, there is no control on the input cost, that keeps increasing. As a result, the mark-ups provided in the essential product categories are lower than the breakeven points. Not only is the price control policy paradoxical but it is irrational as well. Under the system of retention and pooled prices for bulk drugs, different prices for different manufacturing units are fixed for the

same product based on direct costs and actual yields of the respective companies But a 'pooled price' is fixed for the bulk drug. The more efficient manufacturer who produces the drug more cost-effectively, deposits the difference between the 'pooled price' and the 'lower retention price' into the Drug Price Equalisation Account (DPEA) administered by the government This amount is used to meet the claims made by the manufacturers (who could not achieve cost-effectiveness due to manufacturing inefficiency) whose retention prices are higher than the 'pooled prices' Such a policy can only help deter research and development for designing cost-effective manufacturing processes and promote inefficiency Not only is the costing structure regulated, but there is a ceiling on the profitability of the manufacturing unit (Refer sec 10 of this chapter) However, over the five year period, 1991-95, ever since the country formally embarked on a course of economic liberalisation, the performance of the industry has been encouraging Table 2 12 represents on aggregate financial profile of a sample of 75 drugs and pharmaceutical companies. Although, it is a comparative performance statement bringing out the superior results of Indian companies vis.a.vis multinationals, the overall pharma industry statistics are telling. The industry witnessed a sales growth of 119 % over the five years, expenses climbed by to 109 %, and operating margins had grown at a reasonable 34 %. Note should be taken of the Indian performers for whom sales grew by 151 %, expenses by 133 % and operating margins by an astonishing 279 %. These figures, although specific to the CMIE sample, are a vindication of the liberalised regulatory climate fostered by the government, and more importantly proof of the competitive advantage enjoyed by Indian players in cost-effective manufacturing-process technologies

Table 2.1 : Production Trends (Value-Wise)

Years	Bulk drugs	Formulations
1980-81	240	1,200
1981-82	289	1,434
1982-83	345	1,660
1983-84	355	1,760
1984-85	377	1,827
1985-86	416	1,945
1986-87	458	2,140
1987-88	480	2,350
1988-89	550	3,150
1989-90	640	3,420
1990-91	730	3,840
1991-92	900	4,800
1992-93	1,150	6,000
1993-94	1,320	6,900
1994-95	1,518	7,935

Note Figures in Rs. crore
Source OPPI

Table 2.2 : Comparison of Indian Drug Prices

Therapeutic Category	Times costlier in		
	Pakistan	USA	UK
Anti-bacterials			
Cefadroxil	2 76	10 86	3 49
Ciprofloxacin	4 60	5 98	6.20
Anti-inflammatories			
Diclofenac	9 84	42.23	16 90
Piroxicam	5.63	43 54	12.04
Anti-ulcerants			
Ranitidine	8 97	25 65	16 58
Famotidine	9.92	27 67	19 07
Cardiovasculars			
Atenolol	11 55	30 45	13 76
Diltiazem	3 68	8 16	3 90
Anti-virals/fungals			
Acyclovir	10 77	10 57	17 12
Ketoconazole	3 16	15 67	5 82
Anti-cancer			
Carboplatin	-	-	4 84
Vincristine	11 22	37 10	18 85

Source Capital Market (Nov., 1995-23).

Table 2.3 : Time Lag in Introduction of Patented Drugs

Drug	Introduced in the world market by inventor	Introduced in India by Indian Companies
Salbutamol	1973	1977
Mebendazole	1974	1978
Rifampicin	1974	1980
Naproxen	1978	1982
Bromhexin	1976	1982
Ranitidine	1981	1985
Captopril	1981	1985
Norflaxacin	1984	1988

Source : Capital Market (Nov , 1995, pg - 23)

Table 2.4 : Industry As Net Forex Earner

Years	Exports	Imports	Net exports
1980-81	46 38	112.54	(-) 66 16
1981-82	84.79	136.33	(-) 51 54
1982-83	65.94	148 48	(-) 82 54
1983-84	79 92	163 34	(-) 83.42
1984-85	128.75	215 63	(-) 86.88
1985-86	139 95	267 39	(-) 127 44
1986-87	189 28	287 59	(-) 98 31
1987-88	227.96	349.44	(-) 121 48
1988-89	400.16	446 91	(-) 46 75
1989-90	664 70	652.12	12.58
1990-91	784 80	604 00	180 80
1991-92	1,347.40	807.38	540.02
1992-93	1,375 00	1,100 00	275 00
1993-94	1,848.00	1,440 00	408 00
1994-95	2,184.70	1,800.00	384 00

Note : Figures in Rs. crore
Source : OPPI

Table 2.5 : The Global Pharmaceutical Industry

Country	% of world production (by value)	% of world population
US	28 2	4 7
Japan	17 9	2 3
Germany	7 7	1 5
Italy	7 4	1 1
France	7 1	1 1
UK	3.4	1.1
Spain	2 7	0 7
Canada	2 4	0 5
Brazil	1.7	2.8
South Korea	1.5	0 8
India	1 2	16 1

Source . Capital Market (Nov. 1995-25)

Table 2.6 : Outlay on Health of the Five-year Plan

Plan	Years	Outlay (Rs cr)	As % of total plan
1st	1951-56	65.2	3 3
2nd	1956-61	140.8	3.0
3rd	1961-66	225 9	2 6
Annual	1966-69	140.2	2 1
4th	1969-74	335 5	2 1
5th	1974-79	760 8	1 9
Annual	1979-80	223.1	1 8
6th	1980-85	1821.1	1 9
7th	1985-90	3392.9	1 9
8th	1992-97	7575 9	1 7

Source · Capital Market (Nov. 1995-25)

Table 2.7 : Major Therapeutic Groups and their Market Share

Antibiotics	17 40 %
Vitamins	6 00 %
Cough Preparation	6 00 %
Anti-Inflammatory	4 80 %
Antibacterial	4 70 %
Antacid	4 50 %
Cardiac Theraphy	3 40 %
Tuberculosis	3 00 %
Antiparaitic	2 80 %
Antianaemic	2 80 %
Others	44 60 %

Source : ORG

Table 2.8 : Industry Regulatory Environment

1	Opium Act, 1978
2.	Poisons Act, 1919
3	The Dangerous Drugs Act, 1930
4.	The Drugs and Cosmetics Act, 1940
5	The Pharmacy Act, 1948
6	The Industrial Development & Regulations Act, 1951
7.	The Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954
8.	The Trade & Merchandise Marks Act, 1958
9.	The MRTP Act, 1969
10.	The Drug Price Control Order, 1969
11.	The Patents Act, 1970
12.	The Foreign Exchange & Regulation Act, 1973 (Now scrapped)

Source · Rao 1993

Table 2.9 : Industry Related Public Issues in the Last 4 Years

Category	*1995-96		1994-95		1993-94		1992-93		1991-92	
	No.of issues	Amount (Rs cr)	No of issues	Amount (Rs. cr)	No of issues	Amount (Rs cr)	No of issues	Amount (Rs. cr)	No of issues	Amount (Rs cr)
Bulk Drugs	8	178 5	37	246.65	19	85.98	8	35 99	2	6 02
Formulations	11	37 85	19	98.98	12	46 76	4	15 72	1	4 37
Bulk Drugs/ Formulations	2	5 99	15	205.36	6	261.81	3	130 60	-	-
IV Fluids	-	-	5	20.40	1	3 00	-	-	1	16 15
Total	21	258.34	76	571.39	38	397 55	15	182 31	4	26 54

* Till Aug'95.

Source . Capital Market (Nov , 1995)

Table 2.10 : Expenditure on Research and Development (value-wise)

Years	Amount
1976-77	10 50
1978-79	12 00
1979-80	14 75
1981-82	29 30
1983-84	40.00
1985-86	48.00
1986-87	50.00
1993-94	125.00
1994-95	140.00

Note : Figure in Rs crore
Source OPPI

Table 2.11 : Profitability Trends

Year	Profit before tax as % of sales	Agency/source
1969-70	15 47	Hathi Committee Report
1974-75	10 7	
1977-78	11 7	RBI Bulletin
1980-81	8 8	
1982-83	7 5	
1983-84	6 7	NCAER study
1984-85	5 8	A.F. Ferguson study
1985-86	4 5	OPPI estimate
1986-87	3.4	
1987-88	3 5	
1988-89	1 7	OPPI Surveys
1989-90	2 5	
1990-91	2 0	
1991-92	1 0	
1992-93	2 6	
1993-94	4 4	

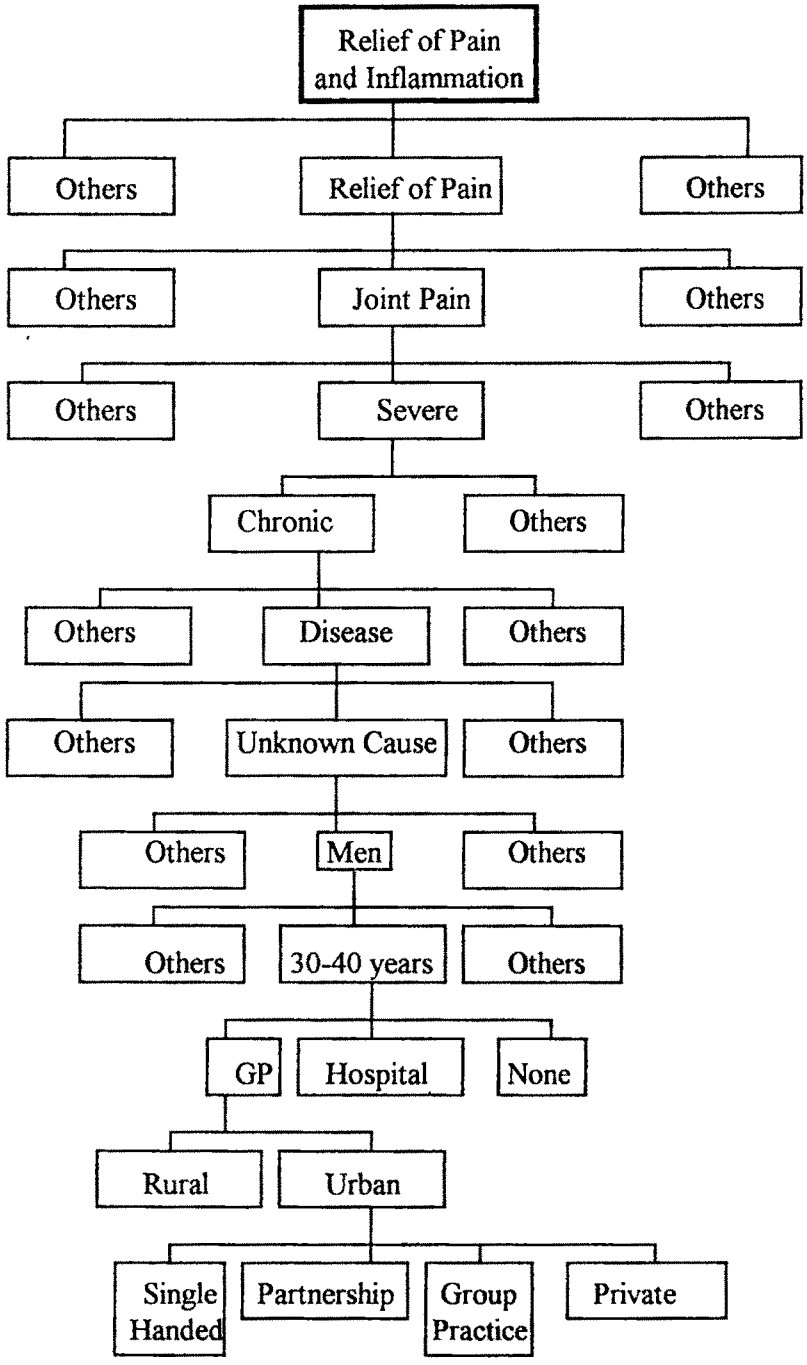
Source Rao 1993.

Table 2.12 : Comparative Performance Indicators

Pharma formulation	1990-91	1991-92	1992-93	1993-94	1994-95	1995/94*
PBDIT	100 00	119 83	115 87	131 24	142 81	108 82
Total income	100 00	115 23	136 90	153 11	158 98	103 84
Total expenses	100 00	114 67	139 44	155 75	160.94	103 33
Pharma multinational firms						
PBDIT	100 00	104 83	128 89	170.74	185 37	108 57
Total income	100 00	115.31	135 79	153.23	173 69	113 35
Total expenses	100.00	116 54	136 60	151 19	172 33	113 98
Pharma Indian firms						
PBDIT	100 00	129 07	192 64	252.77	379.78	150 25
Total income	100 00	130.19	166 85	201 63	251.39	124 68
Total expenses	100.00	130.35	163 16	194.32	233 02	119 92
Pharma top firms						
PBDIT	100 00	140 72	228 27	315 03	469 69	149 10
Total income	100.00	134 61	180 59	223.68	254.23	113.66
Total expenses	100 00	133 81	174 39	211.80	226.21	106 81
Pharma industry						
PBDIT	100.00	97 38	107 78	117 69	134 19	135 51
Total income	100.00	122.73	151 51	184.48	219 23	118 84
Total expenses	100 00	123.17	149 90	180.02	208.99	116.09

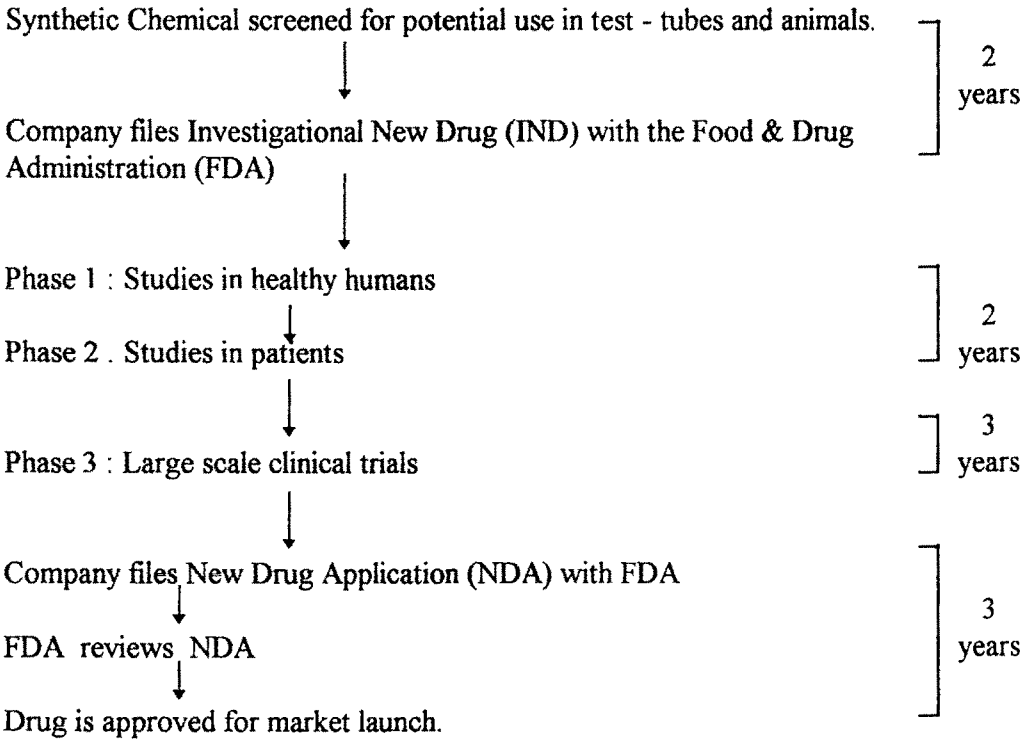
Note . Figures indicate indexed figures; * indicates change in 1995 over 1994 figures
Source CMIE

Fig 2.1 : Therapeutic Segmentation cascade for non-steroidal anti-inflammatory compound



Source . Lidstone 1989

Fig. 2.2 : Regulatory Hurdles (United States)



Source . The Economist (Feb 7, 1987).

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