Chapter 2
An Overview of the Indian Pharmaceutical Sector

2.1 Introduction

Over the past 40 years or so the Indian pharmaceutical sector witnessed rapid growth and transformation. From a mere volume of just Rs. 10 core in 1947, the industry registered a sales turnover of about US $ 5.5 billion in 2004 with an annual growth rate of about 17%. The flexible provisions of the Patent Act of 1970 and other supportive policies of the Government of India played an instrumental role in the growth and development of this industry. Given the importance of public policies in influencing the present structure of the industry this chapter, reviews in brief the important policy changes that have taken place in this sector and also examines the current changes in the structure of the industry and the changing behavior of firms in responding to policy changes.

2.2 The Evolution of the Indian Drug and Pharmaceutical Industry

The history of the evolution of the Indian pharmaceutical industry can be divided into four principal epochs. The first epoch is from 1850 to 1945. The second epoch spans from 1945 to the late 1970s. The third epoch for development is from the early 1980s to the early 1990s, and the fourth epoch spans from the early 1990s to the present time.

2.2.1 The Early Stage of Pharmaceutical Evolution

For convenience, the early stage of Pharmaceutical evolution has been divided into two distinct phases viz., the pre-independence and the post independence scenarios.

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2.2.1.1 Pre-independence Scenario

Before the advent of British Rule, the indigenous forms of medicine were in use (Ayurrvedic or Unani) in India. The Central Government of British India first introduced the allopathic form of medicine in the country. However, there were no production units in the country. Instead, the foreign companies exported raw materials from India, transformed it into finished products, and imported it back to India (Chaudhuri 1984). In spite of sincere efforts by a handful number of entrepreneurs[1] to establish indigenous companies, drug production in the country was low and could hardly meet only 13% of the total medicinal requirement of the country.[2] The indigenous industry, however, received impetus during the Second World War due to the fall in the supply of drugs from foreign companies and many more Indian companies like Unichem, Chemo Pharma, Zandu Pharmaceutical Works, Calcutta Chemicals, Standard Chemicals, Chemical Industrial and Pharmaceutical Laboratories (now known as Cipla), East India Pharmaceutical Works and others were established. With the entry of new firms in the market the production of drugs increased rapidly and indigenous firms were able to satisfy about 70% of the country's medicinal requirement.[3] During this period, foreign companies across the globe as well as Indian companies were engaged in production related activities and the importance of R&D was unknown to them (Temin 1979). Whichever new inventions of drugs were made were mainly due to the individual efforts of scientists and the drug companies were not involved in it (Chaudhuri 2005).

2.2.1.2 Post Independence Scenario

The period spans from 1945 to approximately the mid 1970s. A major breakthrough known as therapeutic revolution marked the beginning of this period and resulted in a phenomenal growth of the global pharmaceutical industry located mainly in Germany, Switzerland, the UK and also to some extent in the US (Gambardella 1992, 1995). A noteworthy achievement during this period was a shift in drug therapy from treating the symptoms to treating the disease itself (Temin 1979). At the same time there was a significant shift in the structure of the industry mainly because the global pharmaceutical industry instead of being mere production units

[1] Concerned about the lack of domestic manufacturing facilities and the unequal pattern of trade, few scientists like Prafulla Chandra Ray, TK Gajjar and AS Kotibhaskar laid the foundation of Bengal Chemical and Pharmaceutical Work in Calcutta (BCPW) in 1892 (see, BCPW 1941 for its activities in the early days) and Alembic Chemical Works by in 1907 in Baroda. The establishment of the Bengal Immunity in 1919 by a group of notable scientists and physicians, namely Nilratan Sircar, Kailash Chandra Bose, Bidhan Chandra Ray etc was yet another landmark in the history of the evolution of the Indian pharmaceutical industry. The company was established with the sole objective of attaining self-sufficiency of the production of synthetic medicine and of sera and vaccines.

[2] See Pharmaceutical Enquiry Committee 1954, pp 17–18.

[3] See Pharmaceutical Enquiry Committee 1954, p 75.

Table 2.1 Selected indicators of the pharmaceutical industry in 1952

				Employment	
Sector	No. of units	Investments	Sales value (Rs Cores)	Technical	Non technical
Public	11	1.48	1.16	181	1,492
Foreign	28	6.9	13.14	354	3,126
Large	54	9.26	13.38	1,076	15,896
Small	1,550	6.00	7.00	1,700	8,300
Total	1,643	23.64	34.68	3,311	28,814

Source: Narayana P.L. (1984)

also embarked on the path of massive investment in R&D (Temin 1979). The commercialization of newly invented pharmaceutical products like penicillin and other synthetic drugs also turned out to be a lucrative business. As noted by Statman (1983), the accounting rate of returns from a newly invented drug between 1954 and 1978 averaged at around 20.9 for global pharmaceutical companies. This encouraged firms to conduct more R&D to tap the potential emerging markets by inventing new drugs in a scientific manner. Further, the public sector also extended its unprecedented support for health related research (see Cockburn and Henderson 1996). In comparison Indian companies were however, not influenced by the wave of therapeutic revolution. The lack of technology, capital and support from the government were the principal hindrances for Indian companies to embark on the new trajectory of drug development.

Concerned about the lack of manufacturing facilities and guided by the perception that 'foreign technology' was an important component for the growth of the pharmaceutical sector, the Government of India in its Industrial Policy Statement of 1948 decided to take a liberal attitude towards MNCs and allowed them to establish plants without facing the hurdle of licensing agreements. Such liberal attitude of the government towards MNCs led to a free flow of foreign capital and the sector witnessed rapid growth. As noted by the Pharmaceutical Enquiry Committee of 1954, the drug production of India witnessed a 3.5 times growth in the production from just Rs. 10 core in 1947 to about Rs. 35 core by the end of 1952 (see Table 2.1).

However, in spite of the progress made by the sector, it was observed that foreign companies did not establish any production unit in India, but were engaged in assembling bulk drugs[4] (imported from their country) for manufacturing the final product (Pharmaceutical Enquiry Committee 1954). MNCs were not keen to establish production units in the country because the production of bulk drugs required investment in plant and machinery whereas importing bulk drugs and

[4] Drug manufacturing in India has two important vertically linked processes: (1) production of bulk drug; and (2) the production of formulation. The Bulk drug production is essentially the production for the raw material or active pharmaceutical ingredients (API) for drugs, whereas production for formulation is achieved by synthesizing the bulk drug into final products like tablets, ointments, capsules etc.

processing them into the formulation was an easier and more profitable business (Pharmaceutical Enquiry Committee 1954).

To overcome the structural weakness that the sector was suffering from, the government in its industrial licensing policy of 1956 made it mandatory for foreign multinational companies to establish their production unit in the country and produce drugs from the basic stage. The pharmaceutical industry was also included in the core group of industries for the purposes of licensing because of the 'high social value' content of medicinal products. Accordingly, the license was granted under the supervision of the Director General of Technical Development (DGTD) for setting up a new unit or expansion of the existing units keeping into account the medicinal need for the country.

In order to fulfill regulatory requirements many foreign companies started their production in India. During this period, a large number of domestic companies also entered the market mainly due to government support under the Industrial Licensing Act and started producing a wide range of products. Between 1952 and 1962, drug productions in the industry increased from Rs. 35 crore to about Rs. 100 crore. Besides, the capital investment for the sector was about Rs. 56 crore in 1962 as compared to its value of Rs. 23 crore in 1952.

2.2.1.3 Role of Public Sector Units and Research Institutes

Another note-worthy achievement of this period was the establishment of two public sector units (PSUs) the Hindustan Antibiotics Ltd (HAL) in 1954 and the Indian Drugs and Pharmaceuticals Ltd (IDPL) in 1961 to start the production of drugs from its basic stage. HAL was established to produce antibiotic with the assistance of WHO and UNICEF. It was the first company in India to manufacture a number of antibiotic drugs like penicillin, streptomycin, Sulfate, ampicillin, anhydrous, gentaminin from the basic stage (Sahu 1998). The technology required to produce these drugs were imported mainly from a large number of foreign companies which were then adapted to the local condition assisted by the in-house R&D wing of the company (see Sahu 1998 for details). The IDPL was established with the support and assistance of the Soviet Union to produce antibiotics, synthetic drugs, and surgical instruments. The technology acquired for the production of drugs was transferred to IDPL by the Soviet Government and was upgraded and adapted to local conditions by Indian scientists.[5]

Apart from PSUs, the public funded research institute also played a pivotal role in the growth of the sector. The government created a number of research institutes under the guidance of the Indian Council of Medical Research (ICMR) and the

[5] IDPL has three major plants – the Rishikesh plant, which was established to produce a majority of the basic drugs and their product mix. The Hyderabad unit was established to produce 16 synthetic vitamins, analgesics, antipyretics and other varieties of drugs, and the Madras unit produced the surgical instruments. Subsequently, two more plants were established at Gurgaon and Muzaffarpur to produce nicotinamide and acetic acid manufacturing (Chaudhuri 2005).

Council of Scientific and Industrial Research (CSIR) to promote the technological advancement of the country. Some of the CSIR institutes, which have played a significant role in boosting up the knowledge base in the pharmaceutical sector of India, are the Central Drug Research Institute (CDRI) of Lucknow, the Indian Institute of Chemical Technology (IICT) of Hyderabad, the National Chemical Laboratory (NCL) of Pune and the Regional Research Laboratories (RRL) of Jammu and Jorhat. Among the few innovative drugs developed in India, the CDRI has made a major contribution (Chaudhuri 2005). However, in spite of the achievement, what was really missing among the research institutes was commercial orientation. Therefore, most of the new and 'Novel Drugs' developed could not be profitably introduced in the market. However, CDRI[6] had invented more than 100 new process technologies, which were successfully commercialized. Besides CDRI, the technologies developed by NCL and other RRL were also transferred effectively from laboratories to industries. The success of the CSIR laboratories in fostering the technological environment of the Indian pharmaceutical sector is also evident when we find that almost all the top pharmaceutical companies like Lupin, Ranbaxy, Cipla, Nicholas Primal, Wockhardt, Unichem, Torrent, J.B chemical, Neuland, Sun Pharmaceutical, Orchid, S O L Pharmaceuticals Ltd and Aurobindo Pharma Ltd have benefited from the services of the research institutes in India in some way or the other (Chaudhuri 1997a).

The Public enterprises and research institutes also played a key role in enriching the human capital endowment that was necessary for the pharmaceutical sector of the country to flourish. Almost all the entrepreneurs of the big companies (about one-third of the 200 large companies) have worked in IDPL production or the R&D wing at some point of time or the other (Chaudhuri 1997). The necessary skill that is required for reverse engineering was acquired by entrepreneurs of the pharmaceutical industry through their long-term associations with public sector units, which is fundamental to the product and process development for this industry.

By early 1970s due to favorable government policies, the domestic industry had grown considerably from a state of non-existence. In 1952, the total turnover for the sector was around Rs. 32 crore. This increased to approximately Rs. 75 crore for bulk drugs and Rs. 370 crore for formulation production in 1970. However, the industry was still dominated mostly by foreign MNCs with a share of about 68% (see Tables A.1 and A.2 in Appendix A). It is interesting to note that during this period the public sector and indigenous companies contributed to a significant share of the bulk drug production, whereas the contribution of MNCs was less than 12% of the total bulk drug production in India. It was also noted that out of the 66 foreign companies that operated in India, only 19 were engaged in bulk drug production (Hathi Committee Report 1974). Most of the companies were engaged in high-payoff formulation production in which they had monopolistic position for certain life saving drugs like Metholdopa, Indomethacin, etc. MNCs even misused the

[6] Source CDRI website: www.cdriindia.org

provision of Product Patent in the Patent Act of 1911 to maintain their monopolistic position in India,[7] which resulted in prices for formulations in India becoming as high as in developed nations (Tariff Commission Report 1968).[8] In contrast, the prices for bulk drugs were the lowest because of the significant presence and contribution of public sector units and indigenous players (see Tariff Commission Report 1968).

2.2.2 *The Amendment of Patent Law and the Implementation of the New Drug Policy (The Second Epoch of Development)*

Concerned by the high price of medicines and the lack of domestic infrastructure, the government constituted the Hathi Committee in 1974 'to probe into the problems and suggest a rational drug policy that would meet the medicinal needs of the country'. Recommended by the Committee's report, the government amended the Patent Act of 1970 and enacted the Foreign Exchange Regulation Act (FERA) 1973 in its New Drug Policy (NDP) of 1978.

The Patent Act of 1970 recognized only process patents. The life of the patent was also reduced significantly from 16 to 5 years from the date of sealing or 7 years from the date of filling a complete application, whichever is shorter; in other words, the maximum period of patent was 7 years. Further, in the amended Act an MNC could patent only one process. FERA was implemented to compel MNCs to manufacture high technology bulk drugs. It was laid down in Section 29 that FERA companies, i.e., foreign companies with an equity holding of more than 40% and engaged in the production of only formulation products or bulk drugs not involving 'high-technology', should reduce their equity holding to 40% or below. For FERA companies licenses would be granted only when the companies provide 50% of bulk drugs to non-associated formulators, and the ratio of value of bulk drugs used in own manufacture to the value of total formulation production would not exceed 1:5. The corresponding figures for domestic firms were about 1:10. In addition, the NDP of 1978 had reservation for the domestic manufacturer for the production of various categories of drugs. Economies of scale, technology and pricing of products are the deciding factors for the production of drugs. The Patent Act of 1970 and the changes in domestic regulation virtually curbed the monopoly of MNCs. Adopting the flexible provisions of the amended patent act, indigenous companies started imitating the patented product and could eventually come out with better processes for the same product. The FERA and the NDP of 1978 also restricted the activities of MNCs. It is, therefore, not surprising to find that the share of MNCs dropped from 70% to about 50% by the late 1980s (see Table A.1

[7] For further details, see Chaudhuri (1999, 1997).

[8] The Kefauver Committee of US in 1950 (see Jordan 1999), also noted that India was among the high priced nations in the world.

in Appendix A). The industry also embarked on the path of high growth during this period. The other significant outcomes were fall in the prices of the medicines and the introduction of a large number of generic versions of patented products.

The drug policy of 1978 was, however, revised in 1986 to dilute the mechanism of check and control with respect to the production of certain categories of drugs. NDP 1986 also regularized the production of a large number of drugs that were earlier questionable on regulatory grounds. This was done to encourage greater participation of private players in the production of drugs, because the public sector started to suffer from industrial sickness due to the lack of proper commercial orientation (See Sahu 1998).

2.2.3 The Phase of Liberalization, De-Control and Product Patent (The Third Epoch of Development)

The growth impetus that the sector received during the 1980s continued even in the 1990s. The pharmaceutical sector witnessed a consistent growth of around 16% from 1995 onward. The bulk drug and the formulation sector also experienced a growth rate of between 15% and 20% during this period (see Table A.3 in Appendix A). Because of the competence gained by the Indian pharmaceutical companies in process engineering, the Indian companies also emerged as the major players in the domestic market. This resulted in a further fall in the share of MNCs in the country (see Table A.1 in Appendix A). The country also gained reputation in the international market as low cost producer.[9] The number of production units in the Indian pharmaceutical sector also increased from 1,752 in 1952–1953 to 20,053 in the year 2000–2001(see Table A.2 in Appendix A).

However, there was a shift in the regulatory framework under which the sector was operating. As part of the liberalization policy, the Government of India in the New Drug Policy of 1994 and 2002 abolished the licensing requirement for entry and expansion of firms. Further, 100% inward foreign direct investment has been allowed under the automatic approval of RBI and automatic approval for technological collaboration has been approved. Further, free import of formulations, bulk drugs and intermediaries are allowed.

The government also implemented certain rules in its New Drug Policy for producers to follow good manufacturing practices and produce quality products. Concern about quality medicine was high on the agenda of the government, because the WHO study reported (2007)[10] that about 35% of fake drugs produced in the

[9] India has gained fame as a low-cost producer and supplier of anti-retroviral and supplier to international organizations and to needy patients in Africa. In a recent case of supplying anti-retroviral drugs to South Africa, the price quoted by Indian firm was the lowest at US $ 350 per year per person compared to $ 1679 quoted by US MNCs.

[10] See *The Hindu*, September 2007.

world come from India, which also had a spurious drug market worth Rs. 4,000 crore.[11] Thus, while, on the one hand, India has shown its competence in manufacturing high quality products that also have demand in the international market, paradoxically, the Indian market is also flooded with spurious drugs to a large extent. To control spurious drugs, the government incorporated Schedule M in the Drugs and Cosmetic Act in 1995 that lays down Good Manufacturing Practices (GMP) at par with WHO standards.[12]

Apart from the changes in domestic policies, perhaps the most controversial and debated regulatory changes relate to the amendment of the Patent Act of 1970. To recall the Patent Law was amended under the WTO compulsion to recognize product patent from 2005 onward. This was implemented in three successions. The first version of it was implemented in 1995 in which the 'mail-box' system was recognized. On January 1, 2000, a Second Amendment was introduced. Its key issues re-defined patentable subject matter, extended the term of patent protection to 20 years and amended the compulsory licensing system. A third amendment of patent law was made on January 1, 2005 to introduce product patent regime in areas, including pharmaceuticals that were hitherto covered by process patents only.

To summarize, we notice that there is a gradual shift in public policy from the regime of control and process patents to a regime of decontrol and product patents. It is expected that such changes in policy will have a far-reaching effect on the industry. In the following section, we, therefore, discuss certain indicators pertaining to the industry.

2.3 Market Structure and Firm Behavior

Market structure of an industry is determined by the degree of competition and the collusive behavior among firms.[13] This, in turn, is determined by the number of firms in an industry and by their relative size distribution. A crude way of

[11] About 20% of medicines in the country are fake or substandard, of these, 60% does not contain any active ingredient, 19% contain wrong ingredients and 16% have harmful and inappropriate ingredients.

[12] It is worth mentioning here that many small scale units in India do not have adequate resources to upgrade their facilities at par with the GMP standard which requires investment worth 25 million for plants and machinery. Consequently, these companies might have to exit the market or may merge and grow in size.

[13] The data relevant for the analysis has been collected from the financial balance sheets of the companies provided by the Prowess and the Capital-online data sources. The other sources of data are the ORG-MARG data on the pharmaceutical sector of India, the Annual Survey of Industries (ASI) and the annual balance sheets of the Bulk Drug association of India, Organization of Pharmaceutical Producer of India (OPPI), Ministry of Chemical and Petro-Chemical of India.

Table 2.2 Concentration index over the years

Year	C4	C25	H-Index
1991	0.32	0.80	0.041
1992	0.27	0.71	0.032
1993	0.25	0.87	0.029
1994	0.29	0.76	0.037
1995	0.27	0.70	0.033
1996	0.22	0.86	0.024
1997	0.23	0.85	0.027
1998	0.22	0.87	0.028
1999	0.24	0.85	0.030
2000	0.23	0.86	0.030
2001	0.27	0.90	0.036
2002	0.32	0.84	0.046
2003	0.31	0.85	0.044
2004	0.30	0.86	0.042
2005	0.29	0.89	0.049

Source: Calculated from the annual balance sheet of companies

measuring the degree of competition in an industry is its four firm concentration ratios[14] and the Herfindahl index of concentration.[15] Table 2.2 summarizes the concentration level computed for the Indian pharmaceutical sector from the year 1991 to 2005.[16]

Whether calculated in terms of the C (4) or Herfindahl index, it is observed that the extent of concentration is low. This also implies that the level of competition is high for the Indian pharmaceutical sector. Figures in Table 2.2 also indicate that on an average the top four firms capture about 30% of the total market for the industry. Since there is no reason to believe that one has to consider only four firms to

[14] The four firm concentration ratio C4 is computed by ranking firms with respect to their market share in the industry. It is the industry sale accounted for by the four largest firms in the industry. Values of the C4 may range from Zero (0) to the limit, to one (1). The selection criteria of "Four – firm" in determining the concentration of the industry is done on an ad hoc basis and there is no reason to believe that one has to consider only four firms to determine the concentration in the industry. A better measure of concentration is the Herfindahl index for concentration.

[15] The Herfindahl index (H) is measured as the sum of the square of each firm's market share; thus $H = \sum_{i=1}^{n} s_i^2$ where $S_i =$ share of the i^{th} firm. H index utilizes the size distribution as well as the total number of firms in the industry and is therefore a more appropriate measure of concentration. Moreover, the H Index is constructed from a theoretical framework under the assumption of the Cournot – Nash equilibrium (see Stigler 1964, pp 201–220) and satisfies all the criteria of the good measure of concentration (see Stephen 1979, pp 67–75). The range of the value of H is from 1 (monopoly case) to 1/n (for n equal sized firm).With perfect competition when $n \rightarrow \infty$ the value of H is zero. The general norm is that the H-index with a value of less than 0.1, between 0.1 and 0.18 and above. Eighteen indicates an un-concentrated to moderately concentrated to highly concentrated market structure.

[16] These ratios are computed using information about firms as per CMIE data base.

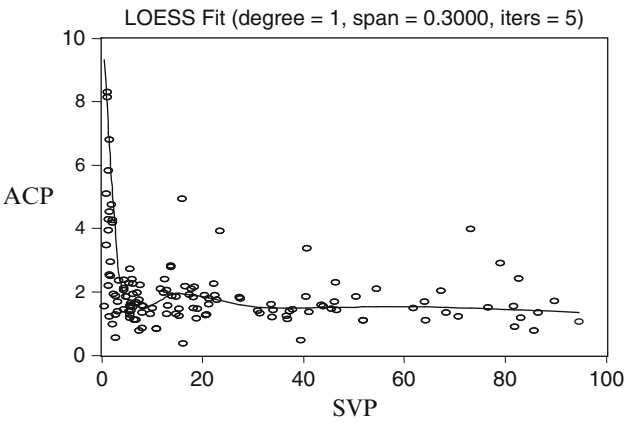

Fig. 2.1 Average cost of production (ACP) by sales volume of firms (SVF) (Source: Computed from the information provided by CMIE data base)

determine the concentration in an industry, the concentration among the top 25 companies has also been calculated for the Indian Pharmaceutical industry. The figures for C (25) also indicate that about 85% of the total pharmaceutical market is captured by the top 25 companies.

The figures for C (4) or the H-Index calculated over the years indicate some degree of fluctuation. It is noticed that from 1991 to 2000 the level of concentration has reduced in the Pharmaceutical industry by around 26%[17] which is, relatively, a large change for such a short time period. However, from 2001 to 2005 the level of concentration has increased by about 8 per centage points for an even shorter period of just 4 years. On the whole, it can be inferred that the top 25 companies, dominate the Indian pharmaceutical industry, which captures about 85% of the total market, and the rest of the firms (the total number of small to tiny firms are around 200–250) operate at a very low level of output. In recent years, the concentration in the industry has increased to some extent.

2.3.1 Economies of Scale in the Indian Pharmaceutical Industry

Economies of scale capture the effect of increased production on the average cost of production of a firm. To get an idea about the extent of the scale economies in the

[17] The figure is arrived at by calculating the percentage change in the concentration indices from 1991 to 2000.

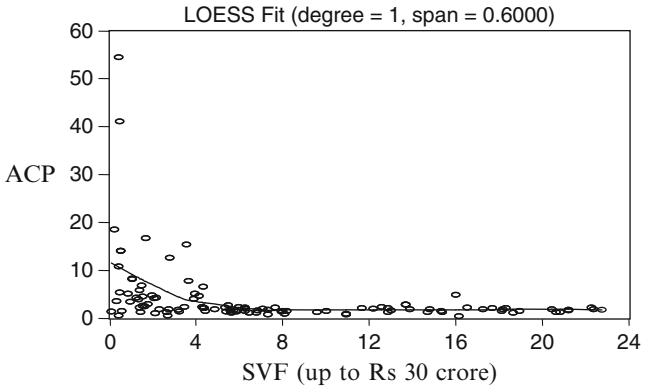

Fig. 2.2 Average cost of production (ACP) by the sales volume of firms (SVF)

Indian pharmaceutical industry the average cost of production[18] is plotted against the *sales volume* for a sample of 280 firms for the year 2002.[19] In the presence of scale economies, the average cost of production exhibits a non-linear relationship with the level of output. Ideally, it initially falls and then rises exhibiting a U–shaped relationship. To capture the non-linear relationship between the output and the cost of production, the nonparametric local curve fitting technique has been applied (loess fit, see Cleveland 1979). The loess fit is shown in the diagram below (Fig. 2.1).

The vertical axis measures the average cost of production and the horizontal axis the total revenue of the firms. The diagram indicates the presence of scale economies for the industry within a range of about Rs. 10 crore of sales volume, beyond which the average cost curve takes a flat shape. This indicates the industry cost curve to be L shaped which implies that there are no significant *diseconomies of scale* for large sized firms. To get a clear idea about the approximate size of the Minimum Efficient Scale (MES)[20] in the industry the loess fit is also done separately for firm size up to the sales volume of Rs. 30 crore. This is illustrated in Fig. 2.2.

Figure 2.2 indicates the presence of scale economies at a Minimum Efficient Scale size (M.E.S) of Rs. 8 crore. The above diagrammatic representation indicates that the industry exhibits a certain degree of economies of scale at a low level of

[18] The average cost is measured by the total expenses for production which is the sum of the cost of labor, capital, raw material and fuel and also the total operating expenses, which includes the administration and selling cost, and other manufacturing expenses divided by the sales volume of the companies (all units measured in Rs crore).

[19] Scale economies is a phenomenon that is observed for a cross-section of firms. Hence, the analysis is done for the year 2002, which has the maximum number of observation (280 firms) for all the years considered in the study.

[20] M.E.S is defined as the output level at which the average cost curve attains the minimum value. If M.E.S is achieved for a large plant size or larger value of output then a company can enter the market only after investing heavily in plant and machinery.

Table 2.3 Estimate of n for the industry, large, medium and small sized firms in 2002

	a	n	R-Square Adjusted R Square	t-Statistics for a	t-Statistics for n
Industry	1.104[a]	0.850[a]	0.897, .895	8.332	26.947
Size wise top 25% of the firms	0.219	1.021[a]	0.843, .835	0.219	1.021
Size wise middle 25% of the firms	0.277	1.031[a]	0.432, .417	0.389	7.718
Size wise bottom 50% of the firms	1.203[a]	0.777[a]	0.762, .760	11.673	20.979

[a]Significant at 1% level
White Heteroskedasticity-Consistent Standard Errors & Covariance

output value of Rs. 8 crore. We next estimated the magnitude of scale economics using the following functional form[21]

$$C = aq^n \tag{2.1}$$

Here C is the total cost of production, q is the total output and ***a*** is the technological parameter. Suppose q increases t times, if now n is greater than unity we have decreasing returns to scale (DRS), if n is less than unity we have increasing returns to scale (IRS) and for n equal to unity we have constant returns to scale (CRS). Taking the log form of the above equation we get

$$LnC = lna + nlnq \tag{2.2}$$

$dlnc/dlnq = n$, is the measure of the elasticity of cost with respect to output and captures the economies of scale in the industry. The above equation is estimated using the simple ordinary least square technique (OLS) taking into consideration all the observation in the sample to get the industry wise measure of economies of scale. Further, firms are also classified into different groups based on their size[22] and the equation is re-estimated for each group of firms to capture the variation in the scale economies for different firm size. The main findings from the estimation are summarized in Table 2.3.

The above table indicates the presence of scale economies for the overall industry as well as for all groups of firms. The estimated value of the scale

[21] The following functional form was used by **Silberston Aubrey** (1972) to measure scale economies of the industry in the U.K. We have also applied the same form to measure scale economies for a cross-section of 280 pharmaceutical firms in 2002. We have conceptualized the size of the firms in terms of the sales volume (value of output).

[22] Firms with a sales volume of Rs. 8 crore is defined as: tiny firm, firm within the range of Rs. 9–100 crore as small sized firm, firm within the range of Rs. 100 crore to 300 crore as medium sized firms and firms with sales volume of more than Rs. 300 crore as large firms. The classification of firms as tiny, small, medium and large-sized is arrived at by dividing the sales distribution into four groups: firms with sales up to 25th percentile are taken as tiny firms, firms having sales greater than 25th percentile and up to 50th percentile are classified as small firms, firms having sales greater than 50th percentile and up to 75th percentile are classified as medium sized firms and those having sales greater than 75th percentile are designated as large-sized firms.

parameter ***n*** is 0.85 for the industry and .77 for the small sized firm. This implies that if output rises by one unit then cost rises by 0.85 units for the industry and .77 for the small – sized firms, indicating the presence of IRS in the industry as well as for the small sized firm. The magnitude for ***n*** is 1.02(>1) and 1.03 (>1) for large and medium sized firm, which implies the presence of DRS for both these groups of firms. However, the magnitude is close to one. In order to test the robustness of the above results Wald[23] test has been conducted for the estimated scale parameter ***n*** by imposing the restriction that $n = 1$ for the industry as well as for the other groups of firms. The result indicate the presence of IRS in the industry with a magnitude of $n = .85$ and for small sized firms the magnitude of $n = .77$. The Wald Test however, accepts the null hypothesis (Ho) that $n = 1$ for large and medium sized firms.

The pattern and the estimate of scale economies in the pharmaceutical sector exhibit certain interesting phenomenon. First, simple computation of scale economies shows that for reasonably small-sized firm (size of Rs 8 core in sales volume) economies of scale exists. Since there has been a dense clustering of small firms with a sale volume of less than Rs .1 core on the falling part of the AC curve (see Figs. 2.1 and 2.2) it is advisable that firms enlarge in size and reap the benefit of scale economics. It is easy to calculate that small firms can save on their cost front by around 29% by increasing their scale of operation. The near presence of CRS type production structure for large scale of production, however, indicates that medium and large firms do not gain additional benefit by simply enlarging their size of operation. Scale economies also achieved a low level of sales volume of Rs. 8 crore. This implies that the Minimum Efficient Scale (MES) size is achieved at about Rs. 8 crore and thus it does not pose entry barrier in the pharmaceutical industry from the production point of view. This explains to an extent the presence of such a large number of firms (approx. 10,000) in this industry.

2.3.2 Capital Intensity of the Indian Pharmaceutical Sector

To understand the extent of capital intensity in the Indian pharmaceutical industry a cross comparison of capital intensity of pharmaceutical firms reported in the CMIE database is made with the total manufacturing and chemical firms.

Table 2.4 summarizes the mean capital intensity of the pharmaceutical, chemical and manufacturing sectors. Table 2.4 suggests that the trend in capital intensity is rising after 1995. On an average, the capital to sales ratio is around 55 % for the

[23] The Wald test computes the test statistic by estimating the unrestricted regression without imposing the coefficient restrictions specified by the null hypothesis. The Wald statistic measures how close the unrestricted estimates come to satisfying the restrictions under the null hypothesis. If the restrictions are in fact true, then the unrestricted estimates should come close to satisfying the restrictions.

Table 2.4 Cross comparison of capital intensity across industries[a]

Year	Pharmaceutical	Chemical	Manufacturing
1989	0.28	0.39	0.53
1990	0.28	0.40	0.52
1991	0.35	0.41	0.54
1992	0.33	0.41	0.55
1993	0.35	0.44	0.57
1994	0.36	0.47	0.59
1995	0.41	0.43	0.56
1996	0.47	0.45	0.56
1997	0.50	0.47	0.60
1998	0.56	0.54	0.66
1999	0.55	0.52	0.68
2000	0.57	0.51	0.66
2001	0.57	0.46	0.60
2002	0.55	0.52	0.66
2003	0.55	0.49	0.62
2004	0.55	0.46	0.58
2005	0.64	0.43	0.52

Source: Compiled from the annual balance sheet prowess data base
[a]Capital intensity = Total value for pant and machinery and building/total revenue

pharmaceutical sector. This implies that as the market size of the pharmaceutical industry is increasing due to growth in this sector by about 16 % in recent years, the capital investment is also rising over the years. However, on the whole the sector is less capital intensive compared to the manufacturing sector.

2.3.3 Labor Intensity in the Pharmaceutical Sector

After measuring capital intensity, the labor intensity in the Indian pharmaceutical sector is also computed and compared with the chemical and the manufacturing sector to get an idea about the employment potential of the sector. Table 2.5 summarizes the mean labor intensity for the pharmaceutical, chemical and manufacturing sectors.

It is observed from the figures in Table 2.6 that the pharmaceutical sector (on an average) spends more on wages and salaries compared to the chemical and manufacturing sectors. However, there has been a marginal fall in the potential to absorb labor in the pharmaceutical sector in the early 1990s though it again picked up from 1997. Since the industry is growing at an annual rate of 16%, it can be inferred that the potential to absorb labor and generate employment in the pharmaceutical sector is also rising over the years.

Table 2.5 Cross comparison of labor intensity accross industries[a]

Year	Manufacturing	Chemical	Pharmaceutical
1989	0.075	0.036	0.121
1990	0.073	0.036	0.115
1991	0.071	0.036	0.110
1992	0.068	0.036	0.102
1993	0.069	0.036	0.096
1994	0.066	0.037	0.090
1995	0.061	0.034	0.093
1996	0.062	0.038	0.088
1997	0.060	0.034	0.089
1998	0.062	0.035	0.092
1999	0.064	0.035	0.088
2000	0.059	0.032	0.092
2001	0.055	0.028	0.094
2002	0.055	0.030	0.091
2003	0.052	0.028	0.093
2004	0.048	0.026	0.096
2005	0.043	0.024	0.101

Source: Computed from the CMIE data base
[a]Labor intensity = Industry expenses for wages and salaries/total revenue

Table 2.6 Profitability[a] and productivity[b] of large and small sized firms

	Large firms		Small firms	
Year	Profitability	Productivity	Profitability	Productivity
1991–1995	0.514	2.298	0.368	1.977
1996–2000	0.440	2.175	0.274	1.824
2001–2005	0.543	3.232	0.398	2.545

[a]Profitability = Total Revenue – (expenses for wages and salaries + for raw-material + for power and fuel + rental rate of capital)/total Revenue
[b]Productivity = Total revenue/(Total expenses for wages and salaries + raw-material + power and fuel + rental rate of capital)
See Chap. 6 for details about the construction of the rental rate of firms

2.3.4 *Extent of Diversification in the Pharmaceutical Industry*

The pharmaceutical industry is also diversified and most of the firms produce multiple products. The degree of differentiation in the pharmaceutical industry is measured in terms of the Herfindahl Index of Diversification.[24] Table A.4 in

[24] The Herfindahl index (H_D) for diversification for a firm is measured as the sum of square of the share for the *i*th commodity in the total revenue earned by a firm. Thus, $H = \sum_{i=1}^{n} s_i^2$ where s_i = share of the *ith* commodity in the total revenue earned by a firm. The Herfindahl index takes a value of one (1) for firms producing single output and for a highly diversified firm the value of H-Index of Diversification falls.

Appendix A summarizes the mean H-index of diversification.[25] The figures in the Table suggest that instead of producing too many products, pharmaceutical firms in India are gradually becoming specialized over the years. To confirm the above statement firms are also classified into different groups based on their degree of diversification. A close look at the figures in Table A.4 indicate that there is a fall in the proportion of highly diversified firms (with a value of less than .25) from 37% to around 12–11%. A rise in the proportion of firms in the highly specialized to specialized group (1 to .75) is also evident from figures in Table A.4. On the whole, it thus appears that instead of producing too many products, pharmaceutical firms are gradually specializing in certain core product groups.

There can be few possible reasons for such a rise in the proportion of specialized firms in the industry. First, in recent years a large number of new firms have entered the industry with new technology. Generally, the new firms bring in specialized products in which they have competence. Second, there has been a spurt in R&D activities of the pharmaceutical firms. If firms have a focused product basket, chances of success will be high for its R&D effort. Finally, if firms are more specialized in their production, it is easier to differentiate its product and establish a good brand name in the domestic as well as the international market.

2.4 Examining the Performance of Indian Pharmaceutical Firms

The analysis of the data reveals that the pharmaceutical industry is one of the most profitable industries in India. The average profit earning (profit as a percentage of sales) of the pharmaceutical industry stands at around 8.8% in the year 1995 as against the 5.8% of the chemical industry, 4.8% of the food and the beverage industry, 5.5% of the machinery industry and 5.8 % of the transport and equipment industry.[26] Further, there has been a rise in the profitability of firms from 8.8% to about 15.4 % in a short span of only 10 years from 1995 to 2005. In the pharmaceutical industry the extent of concentration is low. However, the co-existence of low levels of concentration and ever-increasing rise in profit earning stands against the conventional economic wisdom and a feature which is peculiar to this industry.[27]

We next compare the performance of firms on the basis of their R&D, marketing and export related activities as well as size. We first take up the case of the size of firms. We have classified the firms into two groups based on their size

[25] H_D is estimated for registered pharmaceutical companies based on the information provided by the CMIE database.

[26] Computed from the prowess database using the aggregated data of the industries.

[27] The co-existence of high profit and low concentration for the pharmaceutical industry is also observed in other parts of the globe see for example the studies by Santerre and Stephen 2004, p 467; Viscusi et al. 2000, p 820; Schweitzer 1997, p 25.

Table 2.7 Profitability and productivity of firms with and without R&D units

	Firms with R&D units		Firms without R&D units	
Year	Profitability	Productivity	Profitability	Productivity
1991–1995	0.435	2.054	0.350	2.096
1996–2000	0.401	2.069	0.247	1.773
2001–2005	0.492	2.871	0.305	1.487

Companies that have reported positive outlays for R&D have been clubbed together as firms with R&D units and the rests as firms without any R&D units

distribution. Thus, firms that jointly capture sevent 5% of the sales volume of the industry are classified as large sized firms and the rest as small-sized firms. Table 2.6 summarizes the performance differences for large and small-sized firms.

It is evident from the figures in the Table that large sized firms have earned higher profit and also have higher productivity compared to small firms. In the pharmaceutical industry, the benefits of higher profitability accrue to large sized firms not because of economies of scale in production but because of other factors like ability to undertake R&D or do more of marketing activity at large scale (Santerre and Stephen 2004; Viscusi et al. 2000; Schweitzer 1997). Consider now the case of firms with R&D related outlays.

It is noticed from Table 2.7 that, on an average, firms with R&D units have earned higher profit compared to firms without any R&D unit. The productivity difference also reveals similar trends. This indicates that investment in R&D is an effective action for firms to perform better. Since most of the firms in India have embarked on R&D related activity quite recently, we also explain in brief the emerging R&D trends of the Indian pharmaceutical industry.

2.4.1 Patterns of R&D Investment in the Indian Pharmaceutical Industry

Research and Development (R&D) is a comparatively recent phenomenon for Indian pharmaceutical firms, which gained momentum only after 1995. R&D spending by the pharmaceutical industry has increased from a mere 1.5% of the total sales turnover in 1981–1982 to almost 4% in 2004. A rise in the total actual R&D expenditure in the Indian pharmaceutical sector is also evident from Fig. 2.3, which plots the aggregate actual R&D expenditure by the Indian Pharmaceutical industry over the years.

A cross comparison of R&D (see Fig. 2.4a) spending by the Indian pharmaceutical sector with respect to other industry groups also indicates a rise in the share of R&D expenditure by the drugs and pharmaceutical sector of India.

Figure 2.4b, which plots the contribution of R&D by the Indian pharmaceutical sector in the total R&D pool of the manufacturing and the chemical sectors shows two noticeable trends: (1) the pharmaceutical industry is one of the major

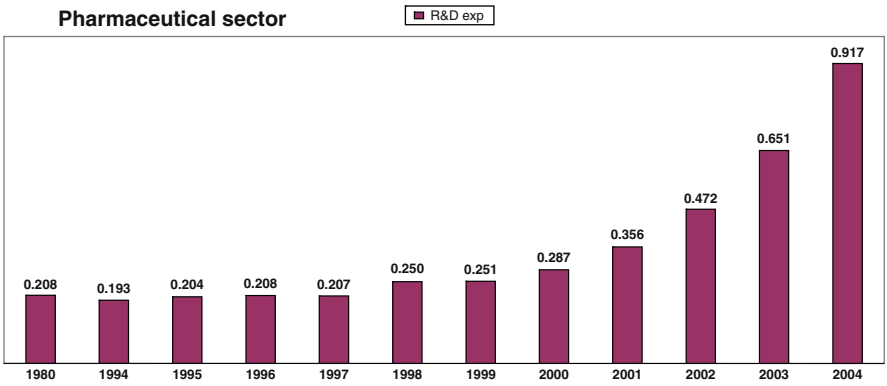

Fig. 2.3 Real R&D expenditure (Crores and dollars) in the Indian pharmaceutical sector (Source: Computed from the Bulk Drug Association of India)

contributors of R&D in the chemical and manufacturing sector; and (2) the share of pharmaceutical R&D in the total manufacturing and chemical sectors is rising over the years. This indicates that the pharmaceutical industry plays a leading role in R&D activities in the country.

Figure 2.5 indicates that from 1995 onwards, the total number of new generic products introduced in the Indian pharmaceutical market has increased substantially. This is an outcome of R&D initiatives of the Indian pharmaceutical firms and could be an important strategic move of firms to deter the entry of foreign firms into various product groups.

However, in spite of its investment in R&D, the mean R&D-sales ratio of the Indian pharmaceutical companies is only 4% in 2005, which is far below the global figures of around 10–15%. R&D spending in India is low because most of the firms either do process R&D or the thrust for R&D is targeted mainly for minor product improvement. The thrust of R&D activities of firms also differs according to the size of firms.

Size-wise differences in the R&D intensity (R&D by sales ratio of firms (see Table 2.9)) reveal that on an average, large sized firms spend more on R&D activities, followed by medium and small sized firms.[28] The trend in R&D also indicates that R&D intensity has also been steadily rising for all groups of firms though the rise is much higher for large and medium sized firms.

[28] Presentation of such data cannot establish a causal relation. However, such data no doubt provides certain indicators. Relations have been examined in subsequent chapters in a statistically rigorous manner.

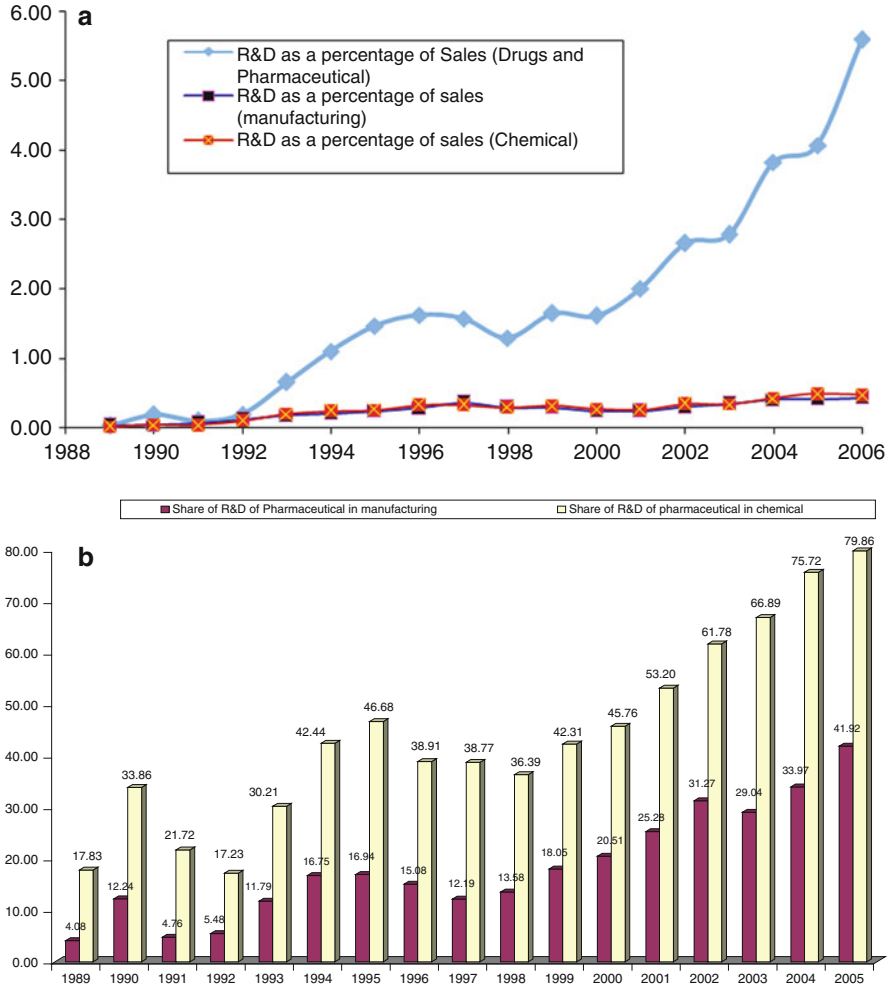

Fig. 2.4 (**a**) R&D intensity in the manufacturing, chemical and pharmaceutical sectors. (**b**) Share of Pharmaceutical in Total Manufacturing and Chemical Sector R&D spending (Source: Computed on the basis of information provided by CMIE prowess data base)

2.4.2 Pattern of R&D Spending in the Indian Pharmaceutical Industry and the Emerging R&D Models

In recent years, there has been a shift in the R&D emphasis of firms from imitative to innovative R&D. Further, even in imitative R&D the transition is towards advanced process R&D. With respect to the product and process R&D, Indian pharmaceutical companies are gradually adopting different models depending upon their capability and long-term vision. Some of the important models followed by Indian pharmaceutical companies are as follows (see Fig. 2.6).

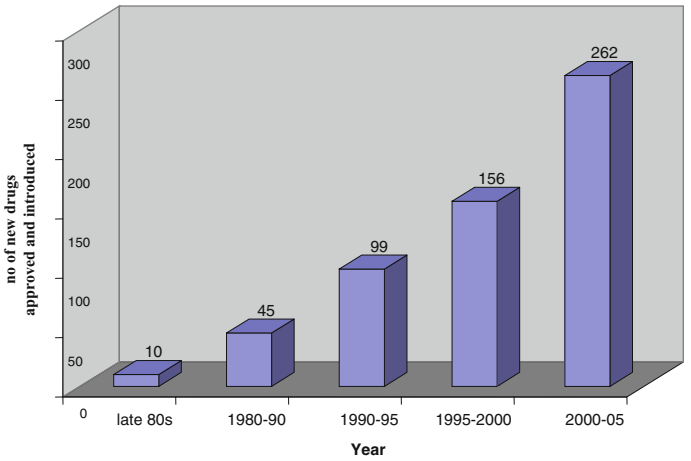

Fig. 2.5 New drug introduced by R&D (Source: Constructed form the Pharmabiz data base)

Table 2.8 R&D intensity for different sizes of firms

Year	Large	Medium	Small
1995	2.224	0.988	0.663
1996	2.314	1.053	0.585
1997	3.309	2.993	0.617
1998	1.628	0.900	0.979
1999	2.191	0.953	0.639
2000	2.478	1.099	0.850
2001	3.065	1.374	0.877
2002	3.606	2.021	0.694
2003	3.879	2.020	0.608
2004	5.364	2.881	0.859
2005	7.776	4.157	1.718

Broadly speaking, R&D activities adopted by the Indian Pharmaceutical companies are of two types: in-house R&D effort and contract R&D. Let us first take the case of the in-house R&D effort of firms.

The in-house R&D effort of firms can be for (1) novel product (2) advanced process and (3) bio-pharmaceutical products. Firms following the above strategies are mainly large sized firms with sales turnover of more than Rs. 300 crore (at least from the years 1995) and earn about 50–60 % of their revenue from the international market of the US, Europe, Japan, and Australia.

2.4.2.1 Product R&D

Few firms from these groups have also ventured into product R&D. It was first started by Dr. Reddy's laboratory and Ranbaxy as early as 1995 and today there are almost 15 companies engaged in product R&D and many of them have also

Table 2.9 Profitability and productivity of firms pursuing marketing

Year	Marketing high ≥ 25%		Marketing low <25%	
1991–1995	0.553	2.547	0.386	1.980
1996–2000	0.468	2.516	0.297	1.816
2001–2005	0.538	3.587	0.402	2.468

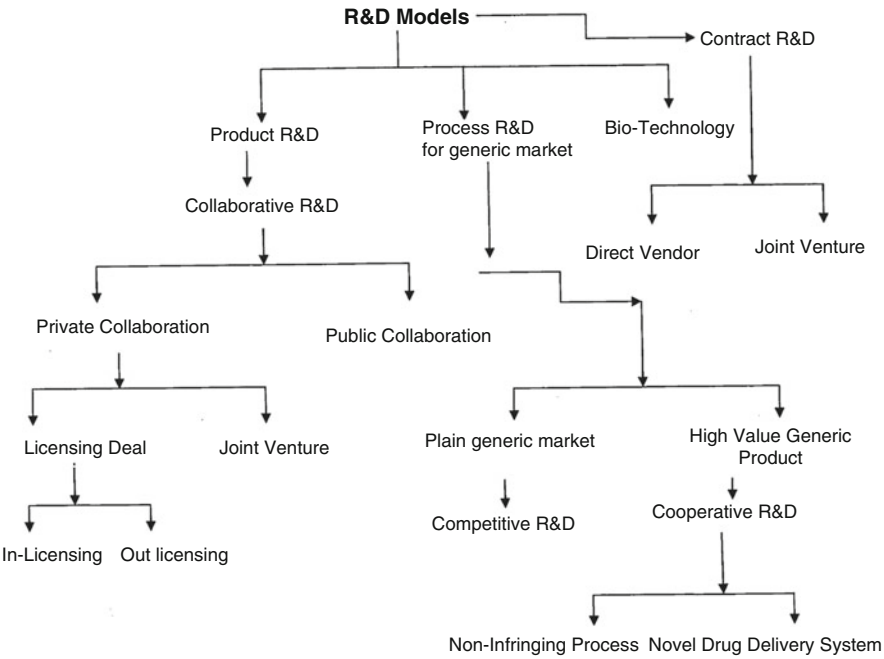

Fig. 2.6 Alternative R&D models followed by Indian pharmaceutical companies (Source: Author's own classification from the balance sheet of the companies)

reported some success (see Table A.5, Appendix A). However, none of these firms is fully engaged in the whole process of R&D for product innovation because of the lack of appropriate skills. Since most of these firms have competence in the manufacturing stage of drug development, but lack the necessary skills for the initial stage of drug discovery, they are adopting various forms of collaborative strategies to make up for their deficiency in resources and skills. Two most important forms of collaborative activity noticed in the context of the Indian pharmaceutical industry are (1) Joint Venture (JV), and (2) Licensing Deal. In JV schemes, the risk is shared with foreign MNCs and in licensing arrangements, a firm licenses out the molecule to foreign MNCs, and gets a royalty from the deal.

Apart from private collaboration, Indian companies are also availing of the benefit from research institutes of CSIR, ICMR, and around 30 universities funded by the government in their endeavor for product R&D. However, compared to the

global level the extent of public spending in India is still low. Internationally, the public sector has played a significant role in the development of new drugs. An investigation of the 21 block buster and top 50 drugs from 1965 to 92 and 1992–1997 respectively indicate that almost all the drugs (almost 95%) received government funding at some stage or the other (Cockburn and Henderson 1997, 2000; NIHCM 2000, 2002[29], p 2). In contrast, public spending of the Indian drug and pharmaceutical sector was only Rs. 559.78 lakh or US dollars 1.24 million in 1998. Though the situation has improved in recent years, it is not adequate compared to the global level. The need of the hour is to enhance public spending to boost up the R&D environment for pharmaceutical companies.

R&D targeted for process development: Very few companies have ventured into the business of product R&D because of the high costs and risks involved therein. Instead, most of them are targeting the ever-emerging generic market because of their age long competence in process engineering.

The global generic market is of two types (1) the plain generic market and (2) the niche generic market. The R&D endeavor of medium and small sized firms is mainly targeted for the plain generic market. A few ambitious medium sized firms and large firms are also targeting the niche generic market of developed nations. The entry barrier in the niche segment of the generic market is high because of strict regulatory requirements, but the returns are also high.

Two forms of strategies are adopted by the Indian pharmaceutical companies to enter the generic market viz., the competitive and the cooperative strategy. The competitive strategy is adopted mainly for the plain generic market. There are almost no entry barriers for such a market and a firm's R&D is targeted for product improvement. Generally, the small or medium sized firms follow this strategy.

Few large firms also target the high-end generic market by following co-operative strategies. Since the cost of entry is high, because of strict regulatory requirements, firms enter into various forms of collaboration with foreign multi-nationals. To cite a few examples, Glenmark Pharmaceutical has entered into various forms of partnership with Merk Generics to capture the Dermatology market of Europe. Zydus Cadila has entered into partnership with Mayne Pharma to market their anti-cancer product in Australia. To capture the high-end generic market, firms either come out with a non-infringing process or a novel drug delivery system (NDDS). In non-infringing processes,[30] companies come out with a new process which does not infringe upon the existing process patent of the innovative company and enjoy the benefit of early mover advantage with the patent expiry of

[29] Available at http://www.nihcm.org/~nihcmor/pdf/innovations.pdf

[30] Generally, innovating companies not only obtain patent on the NCE in the drug invented but also "ring-fence" their product with other secondary sources of patent. These secondary sources of patent are obtained (1) on specific formulation (2) for methods to cure the diseases and (3) process of manufacturing the product. The presence of the secondary sources of patent assists the company to extend the monopoly period of the product even after its patent expiry (Chaudhuri 2005). In such cases, generic companies cannot enter the market even with patent expiry.

the product. Another route for capturing the generic market is by inventing a new delivery system for the familiar drug.[31]

Indian pharmaceutical companies are also leveraging themselves to tap the potential emerging market of contract research.[32] It is estimated (Grace 2004) that the overall cost of clinical trials in India is 46 % lower than that in developed countries. Hence, foreign innovative firms are also outsourcing their clinical trial activities in India an opportunity which many Indian firms are availing.

2.4.3 The Role of 'Detailing' or Marketing for Indian Pharmaceutical Companies

The pharmaceutical industry also spends a large proportion of its revenue on marketing or detailing activities. As compared to the manufacturing and chemical industry, which spends around 4% of its revenue (in the year 2000–2005) on marketing, the pharmaceutical industry spends 7% of its revenue on it. In recent years, there has been a spurt in such activities because of an increased focus of companies on sales for formulations, which requires investment in setting up sales infrastructure. Further, the domestic market is over saturated with a large number of branded products, with similar therapeutic benefits.[33] Consequently, companies spend heavily on marketing activities to maintain brand loyalty for its products and keep its market share.

How effective is the marketing effort of firms? To examine this question we have classified firms into two groups: (1) firms that spend 25% or more of their revenue on marketing related activities and (2) firms that spend less than 25% of their revenue on marketing. Figures in Table 2.9 indicate that spending more on marketing enables firms to earn a higher profit and maintain higher productivity.

In this regard, we have also examined whether the extent of marketing expenditure of a firm has any relation to its size. A simple computation reveals that in the early 1990s large sized firms spent around 7–8% of their revenue on detailing

[31] In NDDS a commonly quoted example is the noteworthy success of Ranbaxy. The firm has come up with an improved version of antibiotic ciprofloxacin which is developed by the American company Bayer AG. The Ranbaxy formulation proved to be much more effective with better patient – compliance. Recognizing the potential benefit of the product, Bayer entered into a licensing agreement with Ranbaxy and agreed to market the product world-wide against a payment of US $ 65 million. Other Indian companies like Dr.Reddys Laboratory, JB Chemicals, Cadila Healthcare, Zydus Cadila, Morepen Labratories, FDC Limited are also in this NDDS business.

[32] The Boston Consulting Group estimated that the contract research market for global companies in India would touch US$ 900 million by 2010 and industry estimates suggest that the Indian companies bagged contract research worth US$ 75 million in 2004.

[33] For example, the Amoxicillin groups have 100 and 36 brands in the market. But this is available at different prices and the price differences can be as high as Rs. 308.50 through use of brand name and advertising.

activities; whereas, medium and small sized firms spent around 5% of their sales on marketing related outlays. The differences in the average marketing to sales ratio among the different group of firms, however, dropped significantly in the late 1990s or early 1920s and the average marketing to sales shot up to 7% for the years 1997–2005. However, the average marketing to sales ratio remained constant at around 7% for all those years. A possible reason for such change could be as follows. Large sized firms were already spending a substantial amount of their revenue on establishing a brand name for their products. Given the large scale of operation, it is expected that by spending heavily on marketing activities from the early days of its operation, large sized firms have already contributed to the stock of goodwill of the company (Nerlove and Arrow 1962a). However, with the rise in the total number of players in the mid of 1990s many medium and small sized firms faced difficulties in maintaining their competitiveness. Thus, they have also started spending on marketing related activities to maintain competitiveness. Besides the new entrants (which are mainly medium sized firms) also have to spend heavily on marketing activity to get a share of the market. On the whole, we, therefore find that the average spending for marketing expenditure has increased for all firms including small and medium sized firms in the recent year.

2.4.4 Exploring the Global Market

The wave of globalization and the liberalization policy[34] of the government have opened up new opportunities for the industry and large numbers of firms[35] are also competing at the global level. Evidence of increased internationalization is noticed among Indian pharmaceutical companies from Fig. 2.7, which plots the average export and import intensity[36] of the Indian pharmaceutical sector.

With respect to outward orientation, figures in Table 2.10, reveal that firms exposed to international market perform better compared to firms that target the domestic market alone.

Pharmaceutical exports are destined for around 175 countries which include the highly regulated markets of the US, the European Union and Australia, the semi-regulated markets of Singapore, Taiwan, Brazil etc to markets of lower regulation such as that of Sri-Lanka and African countries. The bulk of India's export of pharmaceutical products are however, destined toward the US and other European

[34] Apart from removing the trade barrier for the free flow of medicinal products the Government of India also relaxed the limit for outward investment from a meager US $ 4 million in 1993–1994 to any amount up to the net worth of US $ 199 million in 2003–2004. In other words, firms have more flexibility to export their product and also to establish any overseas production unit.

[35] There has been a phenomenal rise in the number of firms exporting their products in the international market.

[36] Export Intensity $= \frac{\text{Export earning in the Year}}{\text{Total revenue in the th Year}}$

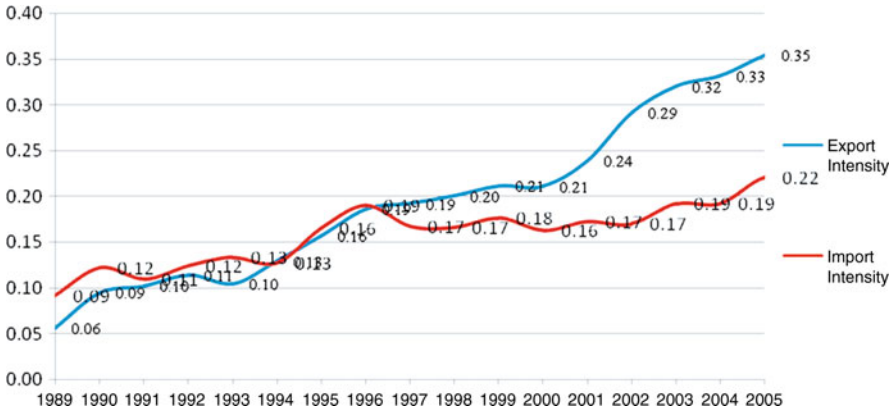

Fig. 2.7 Exports and import intensity of the Indian pharmaceutical sector (Source: Computed from the aggregated Prowess Data base)

Table 2.10 Profitability and productivity for firms with export earning

	Firms targeting the international market		Firms targeting the domestic market	
Year	Profitability	Productivity	Profitability	Productivity
1991–1995	0.5155	2.506	0.412	2.437
1996–2000	0.422	2.4825	0.271	1.966
2001–2005	0.6145	3.762	0.379	2.481

Source: Computed from the aggregated data of the Prowess Data base

nations. This shows the relative strength of Indian Pharmaceutical firms in producing high quality generic products.[37] Further, because of stringent regulatory barriers in the global regulated market, the numbers of players in the regulated market are less and therefore there is a higher price realization. However, exporting in the regulated market is not easy because it involves high cost in maintaining good manufacturing practices and quality standards at par with global norms. Very few pharmaceutical companies have adequate resources[38] to undertake such activity; we, therefore, find that only top domestic players like Ranbaxy, Dr. Reddys Laboratory, Cadila, Cipla, Lupin Laboratory and few medium sized companies like Ipca Labratories, Neuland Laboratory, Alembic Limited and a few others have targeted the global regulated market.

Large proportions (about 40%) of the companies are, however, exporting their products in the semi-regulated or unregulated market. The process of exporting products in the unregulated market started as early as the 1980s. The advantage of exporting in the unregulated market is that there is lesser of anentry barrier and

[37] Presently, India has about 75 U.S. FDA approved plants. This is the highest number of U.S. FDA approved plants outside the U.S.

[38] The cost of establishing a dedicated bulk drug facility for a simple bulk drug can be as high as US $ 3–5 million in India; most of the Indian companies have, however, invested up to US $ 10 million for bulk drug facilities (Chaudhuri 2005).

production can be started with a very low technological base. The disadvantages are low price realization and intense competition, which may result in lower profit realization as well. In recent years, for certain categories of bulk drugs the prices of the product have slashed by more than 30% and for certain cases prices have come down even below domestic market prices. (see Chaudhuri 2005, pp 188).

To pursue internalization strategy, firms are following two different routes: Direct Investment and Merger & Acquisition. Indian pharmaceutical firms embarked on the route for direct investment in the late 70s.[39] Direct investments in global market (also known as Greenfield investment) are undertaken either with production motive or with marketing motive (Pradhan 2006a). Overseas merger and acquisition is another attractive route, which has lately gained ground among Indian pharmaceutical companies. In a short spell of 6 years from 2000 to 2006 the total number of trans-border acquisition stands at around 49, which is worth US $ 1.3 billion of financial deal (Pradhan and Abhinav 2006b). Apart from the usual market share gain, access to firm-specific assets like new product portfolio with an established brand name, internationally accredited manufacturing units, R&D infrastructure, marketing synergies are some of the other motives for firms to follow the route of merger and acquisition (Pradhan and Abhinav 2006b).

2.5 Conclusions

In this chapter, we have reviewed some of the important policy changes pertaining to the pharmaceutical sector of India. We noticed that government policies played a pivotal role for the growth and development of this sector over time. Particularly, the absence of product patents, assured the market for life saving drugs, and protection from foreign competition, helped the growth of this industry. We also notice that positive externalities from the public sector and the research units enabled firms to gain competence in process engineering and maintain a competitive edge in the international market.

The recent changes in government policy from protection to competition are also evident from the review of policies. Aggregate indicators like concentration ratio, scale economies etc. also suggest that the industry is highly competitive with a low level of concentration. However, in spite of high competition, the pharmaceutical industry is one of the most profitable industries. We traced the largeness in the size of the firm, R&D, marketing and export intensity as the possible main sources for better performance of firms. However, the analyses are not statistically rigorous. In the subsequent chapters of this book, we have done an in-depth analysis of the performance of firms by examining their efficiency, productivity and profitability and the factors that influence performance.

[39] The first case of overseas investment was undertaken by Sarabhai M. Chemicals in Indonesia and Malaysia in 1976 followed by Ranbaxy. A total of 15 Greenfield investments took place by 11 companies from the late 70s to the early 1980s.

Appendix A

Table A.1 Market share of MNCs and Indian companies

Year	MNC (%)	Indian companies (%)
1952	38	62
1970	68	32
1978	60	40
1980	50	50
1991	40	60
1998	32	68
2004	23	77

Source: Chaudhuri (2005)

Table A.2 Production units in the pharma sector

Years	No. of units
1952–1953	1,752
1969–1970	2,257
1977–1978	5,201
1979–1980	5,126
1980–1981	6,417
1982–1983	6,631
1983–1984	9,000
1984–1985	9,234
1985–1986	9,540
1989–1990	16,000
2000–1901	20,053

Source: Organisation of pharmaceutical producers in India

Table A.3 Growth rate in the Indian pharmaceutical sector

Year	Growth rate of bulk drug	Growth rate of formulation	Growth rate of the sector
1975–1978	0.14	0.18	0.18
1979–1982	0.13	0.12	0.13
1983–1986	0.08	0.08	0.08
1987–1990	0.17	0.20	0.19
1991–1994	0.19	0.18	0.18
1995–1998	0.20	0.15	0. 16
1999–1903	0.20	0.15	0.16

Table A.4 Proportion of diversified firms

Year	H-Index for the Sector	Highly specialized firms (1–.75)	Specialized firms (.74–.40)	Moderately diversified firms (.39–.25)	Highly diversified firms less than (.25)
1991	0.352	0.18	0.19	0.25	0.37
1992	0.329	0.19	0.22	0.31	0.28
1993	0.359	0.20	0.23	0.33	0.23
1994	0.423	0.24	0.27	0.32	0.17
1995	0.416	0.28	0.24	0.28	0.20
1996	0.453	0.28	0.26	0.32	0.15
1997	0.449	0.28	0.30	0.27	0.15
1998	0.475	0.24	0.26	0.19	0.10
1999	0.433	0.30	0.32	0.24	0.15
2000	0.481	0.28	0.33	0.26	0.13
2001	0.472	0.31	0.33	0.24	0.13
2002	0.403	0.27	0.29	0.23	0.21
2003	0.414	0.32	0.25	0.26	0.17
2004	0.432	0.27	0.29	0.32	0.12
2005	0.482	0.28	0.31	0.30	0.11

Source: Computed from the annual balance sheets of companies from the CMIE data base

Table A.5 New chemical entities invented

Companies	New chemical entities (NCE)
Dr Reddys lab	10
Ranbaxy	12
Cadila	4
Lupin	4
Glenmark	6
Wockhardt	4
Torrent	2
Kopran	2
Dabur	4
Orchid	2
Nicholas Primal	7
JB Chemical	2

Source: Calculated from the annual balance sheets of companies