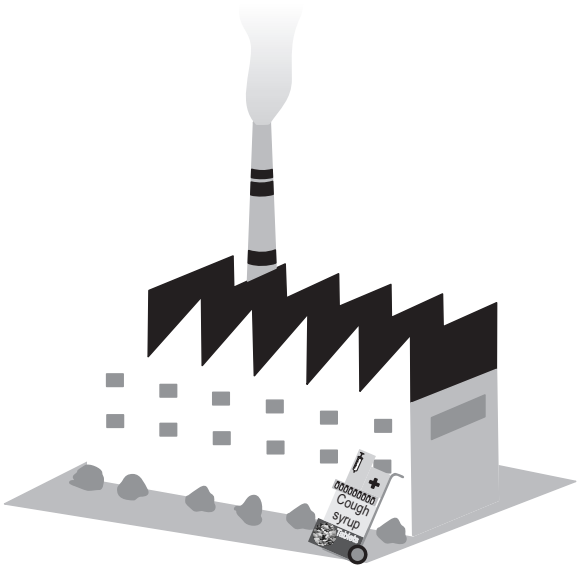
CHAPTER

1

Indian Pharmaceutical Industry



Chapter Overview

- Introduction
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- Present status
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- Future perspective

INTRODUCTION

Health is both the cause and the effect of economic development. Therefore, the pharmaceutical industry is specifically recognized in the UN Millennium Development Goals as an actor that can contribute to the economic development. In addition, the pharmaceutical industry provides significant socio-economic benefits to the society through the creation of jobs and supply chains, and through community development. The industry also plays an important role in the technological innovations that may reduce the cost of economic activity elsewhere in the economy. Various players in the pharmaceutical industry include branded drug manufacturers, generic drug manufacturers, firms developing biopharmaceutical products, nonprescription drug manufacturers and firms undertaking contract research. In addition, there are also enablers of the industry such as universities, hospitals and research centres that play an important role in the research and development (R&D) activities.

EVOLUTION OF THE INDIAN PHARMACEUTICAL INDUSTRY

Evolution of the Indian pharmaceutical industry can be classified into the following three periods:

1. Pre-1970s
2. 1970–95
3. 1995 onwards

Pre-1970s

During this period, the size of the Indian pharmaceutical industry was small, in terms of both the number of firms and the volume of production. Multinational companies (MNCs) dominated the market, in terms of both the volume of production and the patent holdings in India. The patent regime based on the Indian Patents and Designs Act, 1911, recognized both product and process patents. Due to the monopoly status enjoyed by the MNCs, the drug prices remained high during this period.

1970–95

The Government of India introduced a new patent act that came into effect in 1972, but it recognized only process patent and not product patent. The act enabled Indian firms to use the 'reverse engineering process' to manufacture drugs without paying royalty to the original patent holder. The act, along with the Drug Price Control Order, provided little incentive to the MNCs to introduce new pharmaceutical products in India. During this period, the number of domestic pharmaceutical firms increased considerably, from around 2000 units in 1970 to 24 000 units in 1995. The production of bulk drugs increased from Rs 18 crore in 1965–66 to Rs 1518 crore in 1995, while that of formulations increased from Rs 150 crore to Rs 7935 crore during this period. The increase in production was more pronounced in case of formulations due to large-scale production of generic drugs by domestic firms. Low-cost and high-volume production has helped the Indian pharmaceutical industry in opening the export channels to many developed and developing countries. The share of exports as a percentage of total production has shown a significant increase—from 3.22% in 1980–81 to 24% in 1994–95.

1995 Onwards

The year 1995 recorded another milestone for the Indian pharmaceutical industry. One of the agreements under the World Trade Organization (WTO) was complying with the provisions of the Trade Related Intellectual Property Rights (TRIPS). The TRIPS agreement reintroduced product patent in India. Further, during this period, tariff and nontariff measures have come down. Such developments have worked in favour of the Indian pharmaceutical industry to undertake activities such as clinical research and new drug development. Indigenous producers dominated the market accounting for more than 70% of the market share. Exports also continued to increase during this period, due to strong R&D processes and low manufacturing cost.

INDIA'S PHARMACEUTICAL INDUSTRY IN THE SPOTLIGHT

In 2001, India's pharmaceutical industry became the focus of public debate when Cipla, the country's second-largest pharmaceutical company, offered an AIDS drug to the African countries for USD 300, while the same preparation cost USD 12 000 in the United States. This was possible because the Indian company produced an all-in-one generic pill containing all the three substances required for the treatment

of AIDS. This kind of production is much more difficult in other countries because there the patents for these three substances are held by three different companies. In the final analysis, the price slump was a result of India's lax patent legislation.

PRESENT STATUS OF THE INDIAN PHARMACEUTICAL INDUSTRY

The annual turnover of the Indian pharmaceutical industry is over USD 11 billion. Globally, it ranks fourth in terms of volume, with an 8% share in the world pharmaceutical market. In terms of value, it ranks 14th. The key therapeutic segments of the Indian pharmaceutical industry include anti-infective, gastrointestinal and cardiovascular drugs. Acute therapies make about 60% of the market. However, it is expected that with the changing lifestyle and aging population, sales of chronic therapies (i.e. diabetes, cardiovascular) are growing rapidly. The pharmaceutical industry is showing good performance in terms of exports also. It is one of the top export items from India, accounting for more than 4% of India's total exports in 2006–07. Exports that constitute around 50% of the industry's total production have grown at a compound annual growth rate (CAGR) of 14% in the last decade. Major export markets include the highly regulated markets such as the USA, Germany, the UK and Canada. Europe is the biggest export destination for Indian pharmaceuticals, accounting for more than 30% of the total exports, followed by the American region (25%). Government policies, viz. Drugs and Cosmetics Act (1940), Drugs Policy (1986), Indian Patents Act (1970), Drug Price Control Order (1995), Pharmaceutical Policy (2002) and the Indian Patents (Amendment) Act (2005) have played a major role in the growth of the Indian pharmaceutical industry. The government has also formulated a Draft National Pharmaceutical Policy (2006) that will be finalized after consultations with the stakeholders. Besides, the government has also facilitated the growth of the Indian pharmaceutical industry through institutional framework and by encouraging investments in R&D.

DISPROPORTIONATELY HIGH SALES GROWTH

Between 1996 and 2006 the nominal sales of pharmaceuticals on the Indian subcontinent were up 9% per annum (p.a.) and thus expanded much faster than the global pharmaceutical market as a whole (+7% p.a.). The Indian companies strongly expanded their capacities, making the country by and large self-sufficient. Nonetheless, with the total sector sales of roughly EUR 10 billion, India commands less than 2% share in the world's pharmaceutical market (1.5%). This puts the country in the twelfth place internationally—behind Korea, Spain and Ireland; and before Brazil, Belgium and Mexico. Among the Asian countries, India's pharmaceutical industry ranks fourth, at 8%, but has lost market share to China, as the sales growth there was nearly twice as high and the sales volume nearly four times higher than that of India. India's pharmaceutical industry currently comprises about 20 000 licensed companies employing approximately 5 00 000 staff. Besides many small firms, these also include internationally well-known companies such as Ranbaxy, Cipla and Dr. Reddy's. With sales of roughly EUR 1 billion, Ranbaxy is currently the world's seventh largest generic-drug manufacturer. Currently, the most important segment on the domestic market is the anti-infectives; they account for one quarter of the total turnover. Next in line and accounting for one-tenth each are cardiovascular preparations, cold remedies and pain killers. By contrast, medicines against civilization diseases (such as diabetes, asthma and obesity) or so-called lifestyle drugs (antidepressants, drugs to help smokers to quit and antiwrinkle formulations) are of little significance at present. All in all, the Indian pharma industry produces about 70 000 different drugs, which is higher than the number produced in Germany (60 000).

CHANGES IN DRUG PATENT LAW LEAD TO DEVELOPMENT OF ORIGINAL DRUGS

Since 2005 India's pharma sector has no longer been protected by the country's lax patent legislation. Hence innovation must come before imitation now. Large manufacturers, who already began to adjust their business models some time ago, put greater emphasis on drug research. In the long term, they do not want to limit themselves to the production of low-cost generic drugs. Even though a number of companies are well positioned in the generic-drug market, many of them are seeking to turn into research-based firms. However, they are facing fierce international competition in this segment, so it will take many years for India to become a serious competitor for the western pharmaceutical companies in the field of patent-protected drugs. According to the company's own information, approximately 40% of the turnover at the drugs manufacturer Ranbaxy stems from drugs developed in house that would still be about one-tenth lower than at similarly large western companies. In order to increase the speed of development and share the financial risk, there are likely to be more strategic alliances between the Indian and the foreign companies. India's leading pharmaceutical companies are currently spending nearly one-tenth of their revenues on research and development. At the large western companies, however, the R&D expenditure comes to 20%. Already in 1994, Dr. Reddy's launched a basic research programme, which was followed by Ranbaxy and Wockhardt in 1997. Last year, as many as 12 companies were engaged in the research for new pharmaceutical substances. The focus here is on drugs against malaria and AIDS, as the demand potential in these segments is particularly high. Malaria is the most common tropical disease, with about 300 to 500 new infections per year, according to the WHO. The number of people infected with HIV adds up to about 40 million worldwide.

However, compared with the large international players, the volume of research at the Indian pharmaceutical companies—especially basic research—is still very small. The average R&D spending of the Indian pharmaceutical companies comes to just under 4% of the total turnover, compared with 9% in Germany. However, one must bear in mind the different sizes of the pharmaceutical industries in the two countries. In this context, the Indian companies are likely to benefit from the liberalization process on the domestic capital market that began in the early 1990s and is not yet complete. The loosening of the financial market regulations has until recently led to an increasing presence of foreign investors, with the interest focusing mostly on the equity market. Since the early1990s, Indian companies can also be listed on the foreign stock exchanges.

INCREASING R&D ACTIVITIES

Pharmaceutical industry is knowledge intensive and R&D investment plays a crucial role in the growth of this industry. R&D in pharmaceutical industry includes, directional search for solutions to existing medical problems and unmet medical requirements. In addition, pharmaceutical R&D may also be aimed at improving the existing solutions to improve the efficiency or safety of medicines. Thus the pharmaceutical R&D may be concentrated in the New Chemical Entities (NCEs), Novel Drug Delivery Systems (NDDS) or in generic products. Historically, research in Indian pharmaceutical firms was concentrated mainly on process engineering of bulk drugs and development of NDDS for formulations. Although research in the area of discovery of NCE has taken place, due to the heavy investment required in the clinical trial phase many companies have either licensed the molecules to players abroad or collaborated with the overseas players to conduct clinical research. However, the post-WTO patent regime has introduced new challenges for the Indian pharmaceutical industry. Now the pharmaceutical companies are increasingly becoming innovative rather than imitative. The industry is changing its R&D strategy from reverse engineering to patent-driven research. Although the product patent was

introduced in 2005, many pharmaceutical companies have realized the need of increasing their R&D efforts only recently.

R&D EXPENDITURE OF SELECTED INDIAN PHARMACEUTICAL COMPANIES

Table 1.1 contains a list of pharmaceutical companies and their R&D expenditures:

Table 1.1. Pharmaceutical Companies and Their R&D Expenditures

Company name	R&D expenditure (in Rs crore)
Ranbaxy Laboratories Ltd.	639.33
Dr. Reddy's Laboratories Ltd.	253.95
Sun Pharmaceutical Industries Ltd.	161.49
Cipla Ltd.	155.40
Cadila Healthcare Ltd.	118.70
Nicholas Piramal India Ltd.	91.15
Torrent Pharmaceuticals Ltd.	87.36
Wockhardt Ltd.	81.08
Aurobindo Pharma Ltd.	77.01
Orchid Chemicals & Pharmaceuticals Ltd.	61.36
Panacea Biotec Ltd.	49.02
Glenmark Pharmaceuticals Ltd.	46.69
Jubilant Organosys Ltd.	39.38
Ipca Laboratories Ltd.	37.86

INORGANIC GROWTH STRATEGY—ACQUISITIONS OR JOINT VENTURES ABROAD

The global pharmaceutical industry has been undergoing, on the one hand, the consolidation mode driven by increasing competition and pressure on pricing and margins, while on the other, a desire for geographical diversification and growth in the market share. Indian companies have also adopted the inorganic growth strategy since recent times and have undertaken several mergers-and-acquisition (M&As) activities. There are various reasons that motivate companies to go for M&As or setting up of joint ventures abroad. These include the following:

1. A company may have a strong product portfolio, but it may lack access to the overseas distribution network. In such cases, a firm may acquire a foreign company to have a sound distribution network. Thus, acquisition helps the acquirer to explore new markets.
2. The reason for acquisition can also be firm specific. Acquisition can be made to gain control over new products, brands, technology and skills. Companies can acquire strong research expertise and boost their capabilities through consolidation.
3. The recent trend in acquisitions also shows an attempt for vertical integration by many firms that are specializing in generic-drug production to get into active pharmaceutical ingredients (API) production. This has been driven by sharp erosion of margins in the finished dosage products and the intense pressure on pricing experienced by generic-drug manufacturing.

Although the acquisition trend started in 1995, Indian firms have aggressively started acquiring foreign firms after the beginning of the decade. The year 2005 witnessed the highest number of overseas acquisitions by the Indian pharmaceutical firms. Ranbaxy, one of the largest Indian pharmaceutical firms, made 12 acquisitions during this period, in different countries like the USA, Germany, the UK, Japan and France. Other firms that have made considerable number of overseas acquisitions include Glenmark and Nicholas Piramal (five each); Dr. Reddy's Laboratories; Sun Pharmaceuticals and Jubilant Organosys (four each); Strides Arcolab and Matrix Laboratories (three each); and Wockhardt, Alembic and Aurobindo Pharma (two each).

The number of acquisitions by each company is listed in Table 1.2.

Table 1.2. Pharmaceutical Companies and Their Acquisitions

Company name	Number of acquisitions
Ranbaxy	12
Glenmark Pharmaceutical Ltd.	5
Nicholas Piramal	5
Dr. Reddy's Laboratories	4
Sun Pharmaceuticals	4
Jubilant Organosys Ltd.	4
Strides Arcolab	3
Matrix Laboratories	3
Aurobindo Pharma	2
Wockhardt	2
Alembic	2
Dishman Pharmaceuticals	1
Enzyme Technologies	1
Indegene Life systems	1
Ipca Laboratories	1
Lupin Ltd.	1
Malladi Drugs	1
Marksans Pharma	1
Natco Pharma	1
Solvay Pharma India	1
Suven Pharmaceuticals	1
Torrent pharmaceuticals	1
Wanbury Ltd.	1
Zydus Cadila	1

OUTLOOK FOR INDIA'S PHARMACEUTICAL INDUSTRY UP TO 2015

All in all we expect India to see a rise in the sale of drugs by an annual 8% to nearly EUR 20 billion between 2006 and 2015. To be sure, this growth rate is higher than those seen for Germany (+5% p.a.) and the entire world (+6% p.a.). Nonetheless, India's share in the world pharmaceutical sales will rise only marginally, to a good 2%. Growth of India's pharmaceutical industry and thus its share in the global

drugs manufacturing could even be slightly higher if the infrastructure problems could be remedied quickly. While the pharmaceutical industries of China and Singapore will likely continue to show much higher growth, India looks set to lose market share even in Asia. Mainly affected by this development will be smaller Indian companies, with sales of up to EUR 10 million, that focus on traditional Indian medicines. It is likely that many of these companies will merge or altogether disappear from the market. By contrast, large pharmaceutical companies, with sales volumes of over EUR 50 million, will be able to increase their sales, as they will be better equipped to adjust their product ranges to the demands of the international markets. These firms will expand their capacities in India—mostly in the sector's clusters surrounding Delhi and Mumbai—but will also take over firms in the industrial countries. Medium-size businesses will benefit from increasing contract production for western firms.

All in all the share of pharmaceuticals in the total chemicals industry in India will come down to roughly 17% in 2015 (from 18% in 2006), compared with 28% in Germany (from 24% in 2006). For the world as a whole the ratio will likely be only slightly lower than the German level (25%).

Although India's pharmaceutical sector is growing strongly, the demand for drugs for the population cannot be met by the country's own production in all segments. At EUR 1.5 billion, India's total drug imports are comparable in size to Norway's entire pharmaceuticals market. Imports look set to continue to rise strongly. On a medium-term horizon, one-fifth of the world's pharma sales will be accounted for by the emerging markets. China will then be among the group of five largest manufacturers, while India will join the group of the ten largest suppliers.

The following figure depicts the rate of growth for Indian pharmaceutical industry as compared to the world till 2015:

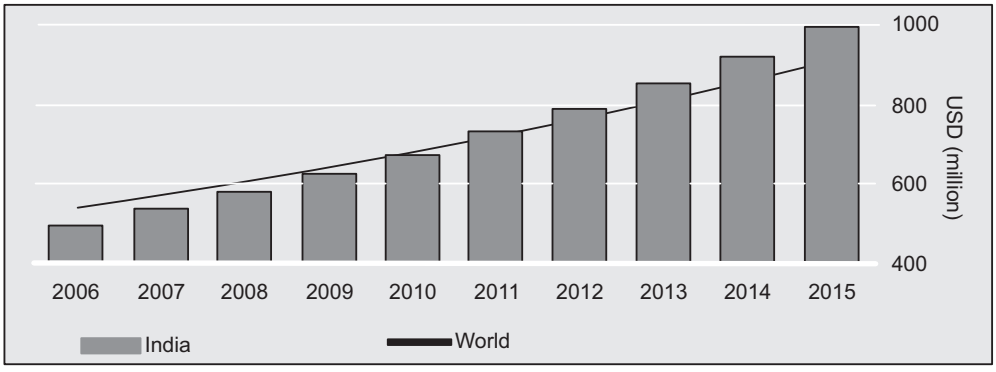

Figure 1.1. India's Pharmaceutical Industry up to 2015

HIGH EXPORT GROWTH OF INDIAN DRUG MAKERS

In the course of increasing contract production and low-cost manufacture of proprietary medicines, exports are expected to receive a major boost in future. However, Germany's very high export ratio of currently 55% will hardly be achieved by 2015, as this would imply more than trebling of total exports. In this context it should be considered that takeovers of foreign companies will lead to a strong increase in foreign production by Indian manufacturers and will have a dampening effect on exports, a positive impact on exports is expected from foreign investment in India, though. The competition between the Indian firms and western drug makers will probably be much fiercer as the companies from Asia are

increasingly seeking to tap the global markets. The generic-drug market will grow in both the developed countries and the emerging markets. Most vital medicines are already exempt from patent protection today. The manufacture of generic drugs in that segment is growing strongly. In addition, patents for high-turnover drugs with a volume of EUR 100 billion will expire in the next few years. Of these drugs roughly one-third will likely be produced by Indian companies.

Points to Ponder

1. Good health leads to the economic development of the society and vice versa.
2. The Indian pharmaceutical industry has evolved over three phases namely
   a. Pre-1970s,
   b. 1970–1995 and
   c. 1995 onwards.
3. India has emerged as a production source of drugs at very low costs.
4. The current turnover of the Indian pharmaceutical industry is over USD 11 billion.
5. The important government regulatory policies include the Drugs and Cosmetic Act (1940), Drug Policy (1986), Indian Patents Act (1970), Drug Price Control Order (1995), Pharmaceutical Policy (2002) and Indian Patent Amendment Act, and the latest is the Draft National Pharma Policy (2006).
6. R&D is required in NCE, NDDS and the generic products for discovering new drugs to combat diseases.
7. Acquisition is the latest trend that drives the Indian and the global pharmaceutical industry.

Self-Assessment Exercises

1. Briefly describe the development of pharmaceutical industries in India dating back to 1970.
2. Write a short note on the present status of the Indian pharmaceutical industry.
3. Describe how the changes in the drug patent law led to the development of the Indian pharma industries.
4. Describe the role of the R&D activities in the export market of pharma industries.