CHAPTER 1

PHARMACEUTICAL INDUSTRY: AN OVERVIEW

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References
1.1 Introduction

India is one of the fastest-growing pharmaceutical markets in the world and has established itself as a global manufacturing and research hub. The country also has a huge pool of scientists and engineers who have the potential to take the industry to a very high level.

The Indian pharmaceutical industry ranks 14th in the world by value of pharmaceutical products. With a well-established domestic manufacturing base and low-cost skilled manpower, India is emerging as a global hub for pharma products and the industry continues to be on a growth trajectory. Moreover, India is significantly ahead in providing chemistry services such as analogue preparation, analytical chemistry and structural drug design, which will provide it ample scope in contract research and other emerging segments in the pharmaceutical industry.

The Indian Pharmaceutical Industry currently heads the list among India’s science based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It holds the distinction of being a highly organized sector, and is estimated to be worth 4.5 billion (dollars), growing at about 8 to 9 percent annually. In terms of technology, quality and the range of medicines that are manufactured, it ranks very high among all the third world countries.

The last two decades have seen wide expansion of this industry. In fact the Indian pharmaceutical sector is highly fragmented with more than 20,000 registered units. Besides, the Pharmaceutical and Chemical industry in India is an extremely fragmented market with severe price competition and government price control. The Pharmaceutical industry in India meets around 70% of the country’s demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, capsules, tablets, orals and injectibles. Considered to be a highly fragmented industry, consolidation has increasingly become an important feature of the Indian pharmaceutical market.

1.2 Terms related to the Pharmaceutical Industry

Pharmacognosy

It is the science that deals with natural drugs and their constituents.
Pharmacology

Pharmacology is the science that deals with drugs. It consists of detailed study of drugs; particularly their actions on living organisms. The actions may be beneficial or harmful.

The word is derived from the Greek word PHARMAKON (a drug or poison) and LOGOS (discourse). It broadly covers the information about the history, source, physiological actions, mechanism of action, absorption, distribution, metabolism, excretion, and therapeutic uses of drugs.

Drugs

The word drug is derived from the French word ‘drogue’, meaning herb. It is defined as any substance used for the purpose of diagnosis, prevention, relief or cure of a disease in man or animals.

Pharmacy

Pharmacy means the art of preparing and dispensing drugs.

Pharmacy is the science of identification, selection, preservation, standardization, compounding, proper utilization and dispensing of medicinal substances.

Pharmacy is the practice of compounding and dispensing drugs; also the place where such medicinal products are prepared. Pharmacy is an area of materia medica, that branch of medical science concerning the sources, nature, properties, and preparation of drugs.

Pharmaceutical

The word pharmaceutical comes from the Greek word Pharmakeia. The modern transliteration of Pharmakeia is Pharmacia.

Pharmaceutical Industry

The term pharmaceutical industry refers to the industrial scale manufacture of drugs based on the substance of vegetable organic of synthetic origin.
The pharmaceutical industry is made of hundreds of firms that discover, develop, produce and sell drug products. These products are used by health professionals to prevent and cure some diseases and relieve symptoms of other ailments. Throughout the twentieth century and especially from 1940s onwards, members of the industry have discovered new drugs, that cure previously incurable diseases, prevent diseases that are epidemic in nature, reduce the frequency and length of hospital stays, and increase life expectancy.

It is the group of firms, manufacturing and distributing medicines in finished forms, such as ointments, capsules, tablets and syrups, (based upon substances of vegetables, organic or synthetic origin). The industry performs the manufacturing and processing activities, which includes: (a) bulk manufacturer of synthetic organic chemicals, such as Vitamins, Anti-histamines, Diuretics and Sulphonamides; (b) bulk manufacture by fermentation, synthesis or both of Antibiotics such as Penicillin and Streptomycin, which are normally made by the culture of microorganisms; (c) preparation of Sera and Vaccines by microorganisms culture; (d) production from naturally occurring animal or vegetable sources of drugs such as Insulin, Hormones and Morphine; and (e) processing of bulk drugs into finished forms such as capsules, tablets and ointments.

The World Health Organisation (WHO) defines a drug or pharmaceutical preparation as “any substance or mixture of substances manufactured, sold or offered for sale, or represented for use in the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state, or the symptoms thereof in man or animal, (and for use in) restoring, correcting or modifying organic functions in man or animal.”

1.3 World History of Pharmaceutical Industry

NATURE always stands as a golden mark to exemplify the outstanding phenomenon of symbiosis. The biotic and abiotic elements of nature are all interdependent. The plants are indispensable to man for the life. The three important necessities of life – food, clothing and shelter – and a host of other useful products are supplied to him by the plant kingdom. Nature has provided a complete store-house of remedies to cure all ailments of mankind. The knowledge of drugs has accumulated over thousands of
years as a result of man’s inquisitive nature so that today many effective means of ensuring health-care are available.

The human being appears to be afflicted with more diseases than any other animal species. There can be little doubt then that he, very early, sought to alleviate his suffering from injury and disease by taking advantage of plants growing around him. In the past, almost all the medicines used were from the plants, the plant being man’s only chemist for ages. Today, a vast store of knowledge concerning therapeutic properties of different plants has accumulated. All phyla of plants viz. Thallophyta, Bryophyta, Pteridophyta and Spermatophyta, (of which conservative estimates place the total number of known species at approximately 3,35,000) contain species that yield official and unofficial products of medicinal importance. By far a number of these are derived from plants and include three hundred or more recognized families of Spermatophyta.

Most of the medicinally active substances identified in the nineteenth and the twentieth centuries were used in the form of crude extract. In China, many medicinal plants had been in use since 5000 B. C. The oldest known herbal is Pen-t’soo written by Emperor Shen Nung around 3000 B. C. It contains 365 drugs, one for each day of the year. Indians also, worked meticulously to examine and classify the herbs which they came across, into groups called Gunas. Charaka made fifty groups of ten herbs each of which, according to him, would suffice an ordinary physician’s need. Similarly, Sushruta arranged 760 herbs in distinct sets based on some of their common properties. A large portion of the Indian population even today depends on the Indian System of Medicine – Ayurveda, ‘An ancient science of life’. The well known treatises in Ayurveda are Charak Samhitā and Sushruta Samhitā.

The History of Pharmacy and Pharmacology dates back to the medieval times with priests, both men and women, who ministered to the sick with religious rites as well. Many peoples of the world continue the close association of drugs, medicine, and religion or faith. Specialization first occurred early in the 9th century in the civilized world around Baghdad. It gradually spread to Europe as alchemy, eventually evolving into chemistry as physicians began to abandon beliefs that were not demonstrable in the physical world. Physicians often both prepared and prescribed medicines;
individual pharmacists not only compounded prescriptions but manufactured medicaments in bulk lots for general sale.

Combining different agents, or compounding, was considered an art form practiced by Priests and Doctors. The first known chemical processes were carried out by the artisans of Mesopotamia, Egypt, and China. Most of these craftspeople were employed in temples and palaces, making luxury goods for priests and nobles.

The first culture to consider these ideas scientifically was that of the Greeks. From the time of Thales, about 600 BC, Greek philosophers were making logical speculations about the physical world rather than relying on myth to explain phenomena. Thales himself assumed that all matter was derived from water, which could solidify to earth or evaporate to air. His successors expanded this theory into the idea that four elements composed the world: earth, water, air, and fire.

The Chinese system of medicine is still prevalent. This ancient system finds its references in the Yellow Emperor’s classic of Internal Medicine (Huang Di Nei Jing) which is believed to be prepared between 200 BC and 100 AD. This herbal is based on the idea that all life is subject to natural laws. The hypothesis includes two quite different systems, the Yin and Yang theory and the five elements (i.e. water, metal, earth, fire and wood). These two theories have been developed separately and differ in terms of diagnosis and treatment. The Yin and Yang theory says that everything in the universe consists of a dark (Yin) and light (Yang) side. These are complimentary opposites like wet and dry, up and down or day and night. The five elements theory proposes that each element leads to the next in a continuous fashion like fire to metal, to wood, to earth, to water and so on. The elements are the five phases indicating the process of continuous movement of life. The elements play a dynamic role in Chinese system of medicine like in making groups of herbal tastes and parts of body.

The traditional Chinese system of medicine spread to Japan and Korea in a form called Kampoh, called as the traditional system of Japanese medicine. Although, it has developed its own characters, giving due importance to the Japanese style of simplicity and naturalness, still the basic ideas like Yin and Yang have a crucial role in Kampoh medicine. As compared to Kampoh, Korean system is very much similar to Chinese system and includes most of the herbs in it.
Today modern pharmacists deal with complex pharmaceutical remedies far different from the elixirs, spirits, and powders described in the Pharmacopeia of London (1618) and the Pharmacopeia of Paris (1639).

The rapid change from hand methods to machine methods of production that characterized the Industrial Revolution found a ready application in pharmacy, especially under the impact of the scientific developments of the nineteenth century.

Industrialization had an impact on every aspect of the activity of the pharmacist. First, it led to the creation of new drugs, drugs that the individual pharmacist’s own resources could not produce. Second, many drugs that the individual pharmacist was able to produce could be manufactured more economically, and in superior quality, by industry. Third, industry assumed responsibility traditionally vested in the pharmacist for the quality of the medication.

The earliest drugstores date to the Middle Ages. The first known drugstore was opened by Arabian pharmacists in Baghdad in 754, and many more soon began operating throughout the medieval Islamic world and eventually medieval Europe. By the 19th century, many of the drugstores in Europe and North America had eventually developed into larger pharmaceutical companies.

The nineteenth century did not see the end of the art of compounding, but the art did give way, however grudgingly, to new technology. It has been estimated that a "broad knowledge of compounding" was still essential for 80 percent of the prescriptions dispensed in the 1920s.

Most of today's major pharmaceutical companies were founded in the late 19th and early 20th centuries. Key discoveries of the 1920s and 1930s, such as insulin and penicillin, became mass-manufactured and distributed. Switzerland, Germany and Italy had particularly strong industries, with the UK, US, Belgium and the Netherlands following suit.

Legislation was enacted to test and approve drugs and to require appropriate labelling. Prescription and non-prescription of drugs became legally distinguished from one another as the pharmaceutical industry matured. The industry got underway in earnest from the 1950s, due to the development of systematic scientific approaches,
understanding of human biology (including DNA) and sophisticated manufacturing techniques.

Numerous new drugs were developed during the 1950s and mass-produced and marketed through the 1960s. These included the first oral contraceptive, "The Pill", Cortisone, blood-pressure drugs and other heart medications. MAO Inhibitors, chlorpromazine (Thorazine), Haldol (Haloperidol) and the tranquilizers ushered in the age of psychiatric medication. Valium (diazepam), discovered in 1960, was marketed from 1963 and rapidly became the most prescribed drug in history, prior to controversy over dependency and habituation.

Attempts were made to increase regulation and to limit financial links between companies and prescribing physicians, including by the relatively new U.S. Food and Drug Administration (FDA). Such calls increased in the 1960s after the thalidomide tragedy came to light, in which the use of a new anti-emetic in pregnant women caused severe birth defects. In 1964, the World Medical Association issued its Declaration of Helsinki, which set standards for clinical research and demanded that subjects give their informed consent before enrolling in an experiment. Pharmaceutical companies became required to prove efficacy in clinical trials before marketing drugs. Cancer drugs were a feature of the 1970s. From 1978, India took over as the primary center of pharmaceutical production without patent protection.

The industry remained relatively small scale until the 1970s when it began to expand to a greater rate. Legislation allowing for strong patents, to cover both the process of manufacture and the specific products, came into force in most countries. By the mid-1980s, small biotechnology firms were struggling for survival, which led to the formation of mutually beneficial partnerships with large pharmaceutical companies and a host of corporate buyouts of the smaller firms. Pharmaceutical manufacturing became concentrated, with a few large companies holding a dominant position throughout the world and with a few companies producing medicines within each country.

The pharmaceutical industry entered the 1980s pressured by economics and a host of new regulations, both safety and environmental, but also transformed by new DNA chemistries and new technologies for analysis and computation. Drugs for heart
disease and for AIDS were a feature of the 1980s, involving challenges to regulatory bodies and a faster approval process.

Managed care and Health Maintenance Organizations (HMOs) spread during the 1980s as part of an effort to contain rising medical costs, and the development of preventative and maintenance medications became more important. A new business atmosphere became institutionalized in the 1990s, characterized by mergers and takeovers, and by a dramatic increase in the use of contract research organizations for clinical development and even for basic R&D. The pharmaceutical industry confronted a new business climate and new regulations, born in part from dealing with world market forces and protests by activists in developing countries. Animal Rights activism was also a challenge.

Marketing changed dramatically in the 1990s. The Internet made possible the direct purchase of medicines by drug consumers and of raw materials by drug producers, transforming the nature of business. In the US, Direct-to-consumer advertising proliferated on radio and TV because of new FDA regulations in 1997 that liberalized requirements for the presentation of risks. The new antidepressants, the SSRIs, notably Fluoxetine (Prozac), rapidly became bestsellers and were marketed for additional disorders.

Drug development progressed from a hit-and-miss approach to rational drug discovery in both laboratory design and natural-product surveys. Demand for nutritional supplements and so-called alternative medicines created new opportunities and increased competition in the industry. Controversies emerged around adverse effects, notably regarding Vioxx in the US, and marketing tactics. Pharmaceutical companies became increasingly accused of disease mongering or over-medicalizing personal or social problems.

In a nutshell, Pharmacognosy is an important bridge between the pharmaceutical and basic sciences. Pharmacognosy is a vital link between Ayurvedic and Allopathic systems of medicines. It provides a system wherein the active principles of crude drugs derived from natural origin can be dispensed, formulated and manufactured in dosage forms acceptable to allopathic system of medicine.
1.4 History of Indian Pharmaceutical Industry

India is today one of the top emerging markets in the global pharmaceutical scene. The sector is highly knowledge-based and its steady growth is positively affecting the Indian economy. The organized nature of the Indian pharmaceutical industry is attracting several companies that are finding it viable to increase their operations in the country.

Modern Indian pharma industry has come a long way from the humble beginning of the last century to the advanced and largest in the developing countries.

The history of the Indian pharmaceutical and healthcare industry records the evolution and modularised growth of ‘bare-foot’ businesses servicing local needs into organised corporate houses taking on challenges in the international markets, mediated by the effective galvanisation of national policies in this sector and the development of human resources and infrastructure, especially related to science and technology. Today, the industry is at crossroads; the future direction will depend on its ability to light-footedly and strategically navigate the rugged landscape to gain new grounds and scale heights that have hitherto remained a pipe-dream. Business approaches will have to metamorphose, learning from the past while incorporating changes to service the needs of the evolving sector.

From the dawn of civilization developed an extensive folklore of remedies which are based partly on observations and partly on superstitions. Certain members in every community became specialists in the use of plant and animal products or treatment and cure of diseases. India’s work in science is very old. It was subsidiary interest of her priests.

Types of Drug Systems in India

Ancient civilization allowed India to develop various kinds of medical and pharmaceutical systems. In addition to the allopathic system, which is prevalent in the United States, Japan, and Europe, the following types of medical and pharmaceutical systems are used by the Indian people: Ayurvedic, Siddha, Unani, Homeopathy, and Yoga and naturopathy.
Ayurveda: Ayurveda translates as the “science of life.” It encompasses fundamentals and philosophies about the world and life, diseases, and medicines. The knowledge of ayurveda is compiled in Charak Samhita and Sushruta Samhita. The curative treatment lies in drugs, diet, and general mode of life.

Siddha: The siddha system is one of the oldest Indian systems of medicine. Siddha means “achievement.” Siddhas were saintly figures who achieved healing through the practice of yoga. The siddha system does not look merely at a disease but takes into account a patient’s age, sex, race, habits, environment, diet, physiological constitution, and so forth. Siddha medicines have been effective in curing some diseases, and further work is needed to truly understand why this system works.

Unani: The unani system originated in Greece and progressed to India during the medieval period. It involves promotion of positive health and prevention of disease. The system is based on the humoral theory, i.e., the presence of blood, phlegm, yellow bile, and black bile. A person’s temperament is accordingly expressed as sanguine, phlegmatic, choleric, or melancholic. Drugs derived from plant, metal, mineral, and animal origins are used in this system.

Homeopathy: Homeopathy flourished in Germany in the seventeenth and eighteenth centuries. In India, it is one of the commonly used methods to treat diseases. Physicians in the time of Hippocrates (400 BC) first observed that some substances produce symptoms of conditions that they were then used to treat. On the basis of this finding, a homeopathic medicinal agent, which can produce artificial symptoms in healthy human beings, can cure a similar set of symptoms of natural diseases. It normally uses a single medicine, and the dosage is minimal—just enough to cure the disease.

Yoga and naturopathy: Yoga and naturopathy are ways of life. In naturopathy, one applies simple laws of nature. It advocates proper attention to eating and living habits. It also involves hydrotherapy, mud packs, baths, massage, and so forth. Yoga consists of eight components: restraint, observance of austerity, physical postures, breathing exercises, restraining of the sense organs, contemplation, meditation, and samadhi. The Department of Indian Systems of Medicines and Homeopathy was
established in 1995 as a separate department in the Ministry of Health and Family Welfare.

1.5 The Changing Scenario of Indian Pharmaceutical Industry

The first mention of a chemist’s shop that opened in India can be traced back to 1811, when a young Scotch named Mr. Bathgate, who came to India with East India Co. opened his shop in Calcutta (now renamed as Kolkata). This firm took up the manufacture of tinctures and spirits in 1910, one hundred years after it started its retail and dispensing business. The firm of Smith Stanistreet and Co. was started in 1821 as a small apothecary shop and commenced its manufacturing business only in 1918. They were the first to take up the manufacture of pure alkaloids like strychnine and brucine and they were at one time the biggest manufacturers in the world of these alkaloids. Even today the firm exports these alkaloids. At the beginning of the 19th century, Drug Industry was practically non-existent in India, and almost all the requirements of pharmaceuticals were imported from abroad mainly from the U.K., France and Germany.

The first stone in the foundation of the modern Indian pharma industry was laid down, when in 1901, a small factory known as the Bengal Chemical and Pharmaceutical Works with a capital of Rs.25000/- was started in Calcutta (now renamed as Kolkata) by Acharya Prafulla Chandra Roy.

In Bombay (now renamed as Mumbai), in 1903, Prof. T. K. Gajjar, opened a small factory at Parel. This factory led to the development in 1907 of another important pharmaceutical manufacturing concern, The Alembic Chemicals Works Ltd., for which Baroda was chosen as the site. Professor Gajjar was joined in his venture by his two friends, Shri A. S. Kotibhaskar and Raj Mitra B. D. Amin. Today, Bengal Chemical and Alembic Chemicals occupy a position of pride among the pioneer manufacturing concerns of India.

The demand for indigenous products also increased. The spirit of swadeshi gained ground, and consequently quite a few Indians and foreign firms sprang up for the manufacture of various types of pharmaceuticals at cheap rates, with a view to compete with the imported ones. Price and not the quality was the main consideration.
Hence, an unhealthy competition grew up, and the markets were flooded with both indigenous and imported drugs which were inferior, adulterated, misbranded and under standard.

In the matter of medicinal drugs, India was, until 1948, manufacturing mainly processed products, e.g., tablets, ampoules/capsules etc. besides vaccines and sera. It depended on foreign countries for supplies of medicines, raw materials and even packaging materials.

Before World War 2 most of the drugs used were derived from vegetables and inorganic sources. With the advent of modern technology and progress made in the field of organic chemistry and biochemistry, the trend has been to produce more and more antibiotics and synthetic drugs.

Till independence, the pharmaceutical industry was mostly confined to the area of local formulations of imported raw materials, controlled by foreign enterprises. The local industry, in general, attempting to make use of local inventories, faced several problems like competition from foreign producers, lack of support from government etc. and, therefore, could not make much headway. But a few private Indian firms like foreign firms, demonstrated a kind of capability, in producing medicines based on indigenous processes.

After independence, India started putting its energy to economic development in all the sectors and even the pharma industry was not left untouched.

The statutory policies framed soon after independence, keeping in view the status of domestic capabilities in terms of financial and technological resources, paved the entry of several multinational pharmaceutical firms to establish manufacturing facilities in the country, either as subsidiary firms or collaborators with Indian entrepreneurs. These firms developed a number of formulations (though some of them were least suited to Indian conditions), with the help of technology skills provided by their overseas partners.

At the time of independence, the country depended largely on the United Kingdom, France and Germany for its requirements of drugs and medicines. The Indian leaders focused their energies on the development of the country. The need of the time was to
develop and grow in all the sectors - industrial, agricultural, and economic, and, this included the pharmaceutical industry also.

In 1952 the Industries Development and Regulation Act was passed. The pharmaceutical industry along with others was brought under the purview of Directorate General of Technical Development (DGTD), which in turn constituted a Development Council in 1953 under the chairmanship of Major General S. L. Bhatia, to suggest various measures for fostering its growth.

The Government of India encouraged both multinationals and Indian companies to establish and expand the pharmaceutical set-up in the country. Mumbai was the first choice for Americans, United Kingdom and European companies to have their establishment in India. In 1950, 1960 and 1970 many multinational companies came to India. Even Indian Manufacturers preferred Mumbai, because of easy import of bulk drugs and machinery from foreign countries. After 1980, more companies started pharmaceutical production of both bulk drugs and formulations.

With the production growth of allopathic drugs, Ayurvedic-Siddha-Unani medicines manufacturing was also on the rise. With the revolution and advancement in Pharmaceutical technology, it became possible to produce Indian System of Medicines in large quantity with better shelf-life.

The pharmaceutical industry in India is going through a major shift in its business model in the last few years in order to get ready for a product patent regime from 2005 onwards. This shift in the model has become necessary due to the earlier process patent regime put in place since 1972 by the Government of India. This was done deliberately to promote and encourage the domestic health care industry in producing cheap and affordable drugs. As prior to this the Indian pharmaceutical sector was completely dominated by multinational companies (MNCs). These firms imported most of the bulk drugs (the active pharmaceutical ingredients) from their parent companies abroad and sold the formulations (the end products in the form of tablets and capsules, syrups etc.) at prices unaffordable for a majority of the Indian population. This led to a revision of Government of India’s (GOI) policy towards this industry in 1972 allowing Indian firms to reverse engineer the patented drugs and produce them using a different process that was not under patent. The entry of MNC’s
was also discouraged by restricting foreign equity to 40%. The licensing policy was also biased towards indigenous firms and firms with lesser foreign equity. All these measures by GOI laid foundations to a strong manufacturing base for bulk drugs and formulations and accelerated the growth in the Indian Pharmaceutical Industry (IPI), which today consists of more than 20,000 players. As a result the Indian pharmaceutical industry today not only meets the domestic requirement but has started exporting bulk drugs as well as formulations to the international market. Currently the main activities of Indian pharmaceutical industry are broadly restricted to producing (i) bulk drugs and (ii) formulations with very few companies risking investing in primary research aimed at developing and patenting new drugs. The bulk drug business is essentially a commodity business, where as the formulation business is primarily a market driven and brand oriented business. Multinational companies which have entered the Indian market have mostly restricted themselves to formulation segment till date. The domestic pharmaceutical industry (MNC’s and Domestic) meets about 90% of the country’s bulk drug requirement and almost the entire demand for formulations. The economics of bulk drug business and that of formulation business are quite different. Since a majority of the Indian companies are producing both bulk as well as formulations, these are considered together for the purpose of the present study.

During the early 1990s, markets were opened by removing restrictions on imports and in 1994 licensing was abolished for producing bulk drugs and formulations. Other than this FDI restrictions into this sector had been modified to allow 74% foreign equity through the automatic route. More favorable conditions were to follow in future particularly for MNCs as soon as ‘Product Patents’ and ‘Exclusive Marketing Rights’ (EMRs) were permitted. In a situation like this, there was a lot of speculation that the indigenous companies that had been the mainstay of the Indian pharmaceutical industry over the past couple of decades finally becoming a formidable part of Indian economy and a major source of foreign income might be facing uncertain market conditions in the future. It might also come down to a state where most of the small scale companies would have to close down, with the multinational companies dominating and monopolizing the industry once again. There was a justified reason for this, and i.e., so far Indian companies had made use of the cheap labor and the reverse engineering skills under the favorable conditions of
process patent regime and developed generic replicas to drugs that were under patent in developed countries, which then were sold in the domestic markets and exported to other unregulated markets elsewhere in the world. This generic business enabled them to compete with multinational companies in India and abroad and resulted in good revenues. However, once the product patent regime got implemented from the year 2005, one was not allowed to reverse engineer drugs that were patented after 1995, and the revenues from that business would suffer. Whereas, the multinational companies in India, which had an impressive new product portfolio would get exclusive marketing rights to sell their products at higher prices and would be in a position to dictate the terms. Given the above, survival of Indian companies depended on producing generics of drugs whose patent had lapsed and export of the same to regulated markets. This was possible only if these firms were able to formulate these products at much lower prices allowing them to face competition from established players in the international markets. Other than this, avenues like contract research and manufacturing for multinational companies had become popular business models for many small scale and medium scale firms. Given this situation it was highly likely that individual firms adopted different strategies for growth. These strategies were dependent more on the management’s perception of the individual firm’s strength in terms of finance, manpower and material in relation with the other firms within the industry for a given environmental context. Some of these strategies might end in failure due to unexpected changes in the environment or bad judgment on the part of the management.

**Road Ahead**

The growth in Indian domestic market will be boosted by increasing consumer spending, rapid urbanization, increasing healthcare insurance and so on. The lifestyle segments such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers will continue to be lucrative and fast growing owing to increased urbanization and change in lifestyle patterns. Going forward, better growth in domestic sales will depend on the ability of companies to align their product portfolio towards these chronic therapies as these diseases are on the rise.
In various global markets, governments have been taking several cost-effective measures in order to bring down healthcare expenses. Thus, governments are focusing on speedy introduction of generic drugs into the market. This too will benefit Indian pharma companies.

1.6 The Top Ten Pharmaceutical Companies in India

On the basis of sales revenue, following are the top ten pharmaceutical companies of India:

**Table 1.1: Top Ten Pharmaceutical Companies in India**

(₹ in crores)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name of the Company</th>
<th>Sales Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dr. Reddy’s Labs</td>
<td>8434.00</td>
</tr>
<tr>
<td>2</td>
<td>Cipla</td>
<td>8202.42</td>
</tr>
<tr>
<td>3</td>
<td>Lupin</td>
<td>7122.51</td>
</tr>
<tr>
<td>4</td>
<td>Aurobindo Pharma</td>
<td>5425.10</td>
</tr>
<tr>
<td>5</td>
<td>Cadila Healthcare</td>
<td>3675.70</td>
</tr>
<tr>
<td>6</td>
<td>Jubilant Life Sciences</td>
<td>3146.30</td>
</tr>
<tr>
<td>7</td>
<td>Ipca Labs</td>
<td>2778.42</td>
</tr>
<tr>
<td>8</td>
<td>Torrent Pharma</td>
<td>2766.23</td>
</tr>
<tr>
<td>9</td>
<td>GlaxoSmithKline</td>
<td>2546.15</td>
</tr>
<tr>
<td>10</td>
<td>Wockhardt</td>
<td>2471.18</td>
</tr>
</tbody>
</table>

1.7 Indian Pharmaceutical Market

India represents one of the fastest growing markets in global healthcare with a market size of USD 28 bn in 2010, which is expected to grow to USD 31 bn by 2015. The Indian Pharmaceutical Market (IPM) is ranked third largest in volume contributing to 10% of the global market. By value, it occupies the 14th position, accounting for 1.4% of the total global market. The share of the emerging market in the global pharmaceutical industry is expected to increase from 18% to 28% by 2015. India constitutes 8% of this segment currently (1.44% of the total market) and is projected to grow to 10% (2.8% of the total) by 2015.

1.8 Domestic Formulation Market

The domestic pharmaceutical formulation market has grown from USD 10.3 bn in 2010 to close to USD 14.7 bn in 2013 registering a growth of 10% and is expected to record a CAGR of 11.6% for the period 2013-2018, according to the IMS Prognosis Report 2014. Historically, the IPM has grown annually by twice the GDP growth percentage. It is now expected that IPM turnover will touch around USD 55 bn by 2020.

1.9 Revenue of Indian Pharmaceutical Industry

The Indian pharmaceuticals market is expected to expand at a CAGR of 23.9 per cent to reach US$ 55 billion by 2020.
1.10 Revenue Share of Indian Pharmaceutical Sub-segments

With 72 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector.

![Graph 1.2: Revenue Share of Indian Pharmaceutical Sub-segments](image)

1.11 Indian Pharmaceutical Market Segments by Value

Anti-infective drugs command the largest share (16 per cent) in the Indian pharma market.

![Graph 1.3: Indian Pharmaceutical Market Segments by Value](image)
1.12 Imports of Indian Pharmaceutical Industry

The country is almost self-sufficient in case of formulations. The imports are being made on quality and economic considerations and not necessarily due to non-availability from domestic sources. Manufacturers of Drugs and Pharmaceuticals are free to produce any drug approved by the Drug Control authorities.

Imports of Drugs and Pharmaceuticals are done as per Foreign Trade Policy. However, import of some drugs and drug intermediates is still restricted under current Foreign Trade Policy. Imports which are restricted are basically due to common HS codes for some narcotic substances or similarity to some Ozone Depleting Substances (ODS).

As per the Directorate General of Commercial Intelligence and Statistics (D.G.C.I.S.) Kolkata, value of imports of “Medicinal and Pharmaceuticals Products” for the period 2003-04 to 2012-13 is as under:

**Table 1.2: Imports of Indian Pharmaceutical Industry**

(₹ in crores)

<table>
<thead>
<tr>
<th>Year</th>
<th>Value of Import of “Medicinal and Pharmaceuticals Products”</th>
<th>Growth (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003-04</td>
<td>2956</td>
<td></td>
</tr>
<tr>
<td>2004-05</td>
<td>3139</td>
<td>6.19</td>
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<tr>
<td>2005-06</td>
<td>4515</td>
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<tr>
<td>2006-07</td>
<td>5866</td>
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<tr>
<td>2007-08</td>
<td>6734</td>
<td>14.79</td>
</tr>
<tr>
<td>2008-09</td>
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<tr>
<td>2009-10</td>
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<tr>
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<td>10937</td>
<td>9.82</td>
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<tr>
<td>2011-12</td>
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<td>30.64</td>
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<tr>
<td>2012-13</td>
<td>16965</td>
<td>18.74</td>
</tr>
</tbody>
</table>

1.13 Exports of Indian Pharmaceutical Industry

India exports to more than 200 countries; its share of exports is expected to grow manifold. The export of bulk drugs continue to grow to regulated markets and is supported by India’s existing foothold in semi-regulated market.

As Per DGCIS, Kolkata Exports of “Drugs and Pharmaceuticals and Fine Chemicals” for the period 2003-04 to 2012-13 are below:-

Table 1.3: Exports of Indian Pharmaceutical Industry

(₹ in crores)

<table>
<thead>
<tr>
<th>Year</th>
<th>Value of Exports of “Drugs and Pharmaceuticals and Fine Chemicals”</th>
<th>Growth (%)</th>
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<tbody>
<tr>
<td>2002-03</td>
<td>12826</td>
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<tr>
<td>2003-04</td>
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<td>25666</td>
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<tr>
<td>2012-13</td>
<td>55693</td>
<td>8.37</td>
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1.14 A Brief Profile of the Selected Pharmaceutical Companies

1. Alembic Pharmaceuticals Ltd (Alembic)

Alembic Ltd is one of India's most experienced manufacturers of bulk drugs and pharmaceuticals formulation in human and animal healthcare. It is the first pharmaceutical company in India to cross 100 years of operation. The company is in the business of improving the quality of life and healthcare in over 75 countries around the world. It is an ISO-9002 and ISO-14001 certified company with manufacturing practices and facilities that conform to WHO-GMP guidelines. Alembic Ltd was incorporated in the year 1907 with the name Alembic Chemical Works Co. Ltd in Vadodara to manufacture tinctures and alcohol.

The company has its manufacturing facilities at Vadodara in Gujarat and Solan in Himachal Pradesh. It manufactures pharmaceuticals and chemicals, bulk drugs (penicillin and other antibiotics) and formulations. The company started to manufacture cough syrup, vitamins, tonics and sulphur drugs in the year 1940. In the year 1961, the Pencillin Plant was inaugurated. Then in 1971, Erythromycin was manufactured using expertise from Eli Lilly, USA and in the following year, Althrocinc was launched. In 2001, it started to manufacture Cephalosporin C and in 2005, the company launched ZERO, a new generation, no calories, Sucralose Based Sugar Substitute which gave entry for the company into the high-growth lifestyle OTC product segment. During the year 2005-06, the company also acquired API Plant at Karakhadi in Vadodara. In the year 2007, the company acquired the Non-Oncology Business of Dabur Pharma Ltd. Also in the same year, it entered into a licensing agreement for its Novel Drug Delivery Platform for Keppra XR with UCB Belgium. During the year 2007-08, the company acquired the API manufacturing facility of Nirayu Pvt Ltd at Panelav near Vododara.

2. Cadila Healthcare Ltd (Cadila)

Cadila Healthcare Ltd is a well known research-oriented, technology-driven pharmaceutical company focused on the research areas of biotechnology, formulations and Active Pharmaceutical Ingredients. It is an Indian based pharmaceutical company having its presence around the world.
Cadila Healthcare Ltd. is one of the largest privately held pharmaceutical companies in India, with headquarters at Ahmedabad, in the state of Gujarat. Over the last five decades, it has been developing and manufacturing pharmaceutical products and selling and distributing these in over 50 countries around the world. The company has its manufacturing facilities at Ahmedabad, Ankleshwar and Vadodara in Gujarat, Ponda in Goa, Raigad in Maharashtra and Solan in Himachal Pradesh.

Cadila Healthcare Ltd, the flagship of Zydus Cadila Group was incorporated in May 1995 and it became a public limited company in July 1996. The company's operation includes pharmaceuticals, which includes human formulations, veterinary formulations and bulk drugs, diagnostics, herbal products, skin care products and OTC products.

An integrated healthcare solutions provider with pharmaceutical product basket, it caters to over 45 therapeutic areas that include cardiovascular, gastrointestinal, analgesics, haematinics, anti-infectives and antibiotics, respiratory agents, antidiabetics and immunologicals. Cadila Pharmaceuticals has a multicultural, multilingual and multinational workforce of more than four thousand employees including over two hundred people outside India in forty-nine countries of Africa, CIS, Japan and USA.

3. Dishman Pharmaceuticals and Chemicals Ltd (Dishman)

Dishman Pharmaceuticals and Chemical Limited (Dishman) was incorporated as a Pvt. Ltd. Co. and as a research-oriented organization in 1983. It became a deemed Public Limited Company with effect from 1st April 1996. After obtaining necessary approval the status was converted into a Public Limited Company with effect from 1st January 1999.

Dishman is engaged in manufacturing and marketing of chemicals such as Quaternary Compounds (Quats) including Phase Transfer Catalyst (PTC), Bulk Drug and Intermediates and Fine and Specialty Chemicals. The Company is a recognized export house and holding ISO 9002 certificate issued by BVQI, Switzerland.
The first facility of the Dishman Group was built in 1987 in Naroda; in 1996 the company initiated its expansion at Bavla where it is currently headquartered. Through several acquisitions, the Dishman Group became a global company with multiple manufacturing facilities in India, Europe and China serving pharmaceutical and biopharmaceutical companies.

Dishman Pharmaceuticals and Chemicals Ltd is a recognized supplier of cost-effective, high quality chemical services and products to the global pharmaceutical and chemical industry. The company is involved in the manufacture of active pharmaceutical ingredients (API), API intermediates, quaternary ammonium compounds and fine chemicals. The company is in the process of setting up Pharmaceutical and Chemical SEZ near Bavla. For this, the company has acquired 390 acres of land. The company is also in the process of building Asia's largest facility to manufacture cancer drugs and other high potency drugs at their Balva plant.

4. Glenmark Pharmaceuticals Ltd (Glenmark)

Glenmark Pharmaceuticals Ltd is a research-driven, global, integrated pharmaceutical company. The company is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity) with five molecules in various stages of clinical development. The company has a significant presence in branded generics markets across emerging economies including India.

The company engaged in discovery of new molecules both new chemical entities (NCEs) and new biological entities (NBEs). The company operates in five geographical areas: India, United States, Latin America, Europe and the rest of the World. They operate in three segments: specialty, generics and out-licensing.

Glenmark Pharmaceuticals Ltd was incorporated in the year 1977. In the year 1979, the company entered the dermatology market with the launch of 'Candid Cream'. In 1980, they started exporting their products. In the year 1983, the company commissioned their first manufacturing facility at Nasik in Maharashtra. The R&D department was established in 1984 at Nasik Plant.
It operates in the formulation business in over 95 countries that includes India. The company has a significant presence in branded generics markets across emerging economies including India. The company was chosen as the ‘Best Company Across Emerging Markets’ 2011, and recognized for the 'Best Overall Pipeline' 2011 by SCRIP, the largest selling and most respected pharmaceutical magazine in the world.

5. Intas Pharmaceuticals Ltd (Intas)

Intas Pharmaceuticals Ltd is an Indian company headquartered in Ahmedabad, India. The Biologics BU is located in Moraiya, Ahmedabad and is one of the leading biosimilar product manufacturers in Asia. The Biologics BU of Intas Pharmaceuticals has biopharmaceutical operations with R&D facility and an EU-GMP certified bio-pharmaceutical manufacturing facility.

In the domestic market, Intas is the 5th largest corporate in Indian Chronic Pharma Market with a market share of 5.06%. It also has presence in cardiovascular system (CVS), diabetology, gynecology, infertility, respiratory care, gastroenterology, pain management as well as other therapeutic segments.

Besides rapidly growing domestic prominence, Intas is also present in more than 70 countries worldwide with robust sales, marketing and distribution infrastructure in markets like North America, Europe, Central and Latin America, Africa, Australia, New Zealand, Asia - Pacific as well as CIS and MENA countries. Intas' global strategy includes alliances with leading Global Pharma Companies for development and distribution of products as well as direct product distribution.

Intas has made a substantial commitment to its Biologics Business Unit in terms of creating R&D, manufacturing and marketing capabilities for its biotech portfolio. As on date, Intas commercialized 11 biologic products and continues its R&D efforts in chronic disease areas such as Oncology (Cancer), Rheumatology, Auto-Immune, Nephrology, Ophthalmology and Plasma derived product based therapies.

Intas has made strategic investments in ten manufacturing facilities, globally. Between them, these facilities have received approvals from various prominent international regulatory bodies, including U.S. Food and Drug Administration (FDA). Pioneering efforts in providing medications for both chronic and acute medical
conditions, has truly led Intas live up to its corporate line "Expressions for a HealthyLife".

6. J B Chemicals and Pharmaceuticals Ltd (J B Chemicals)

The Company was incorporated in December 1976. J.B. Chemicals and Pharmaceuticals Ltd. is the flagship of the 'Unique' group of companies. The Company's manufacturing facilities are situated at Thane, Belapur, Ankleshwar, Panoli and Daman.

Products like metrogyl, rantac (a ranitidine-based formulation), and nicardia (a cardiac care medicine) form a significant part of the company's sales. JBC had a tie-up with Justesa Imagen, Spain, to manufacture and market radio diagnostics under the Trazograf brand name. JBC has also diversified into high-growth agro-based products by acquiring McDa Agro (MAL). The products manufactured by MAL complement fertilisers and increase crop productivity. It has entered into an MoU with GNFC to distribute these products locally. The pharmaceutical divisions of Ifiunik Pharmaceuticals and Unique Pharmaceutical Laboratories has been merged into the company with effect from Apr.'00.

In Feb. 2002 the company achieved another breakthrough in its major R & D Activity- Invention biologically active molecules - New Chemical Entity. In 2001-02 the company introduced 3 products Reducin XX and two in the Cholesterol reducing segment i.e. Ifistatin and Vasolip. The company launched five new products during the year 2003-04 in the global markets to widen its product portfolio. During 2004-05, the company launched new products Cephalosporins, Moviz and its expansion Movi 3D and a nueropsychiatry product through Zephyr for the first time.

During 2004-05, the company set up a new facility conforming to international standards in Panoli (Gujarat) to manufacture contrast media products by June 2006. During 2005, the company entered into two agreements, one with Pharma-a-Care Pharmaceuticals Pvt. Ltd in Australia to develop its niche products in Australian market and another with Ranbaxy Laboratories to enter in the Romanian market.
7. Lupin Ltd. (Lupin)

Lupin was founded in 1968 with the vision to develop new drugs to combat and eradicate life-threatening diseases; to manufacture drugs of the highest social priority so as to nurture, protect and enrich our society. Embedded in Lupin was a formula for growth. Forty-four years on, what has stayed with us is that same entrepreneurial spirit, culture of creativity and innovation and pride in belonging to an industry that makes a difference in the lives of people.

Today the company is a fully integrated pharmaceutical company with an unrivaled position in the US, India and Japan. This position is built on a backbone of cutting-edge research, world-class manufacturing facilities and a truly global supply chain. With the building blocks in place, the future looks brighter than it has ever been.

Lupin Ltd was incorporated in the year 1983 with the name Lupin Chemicals Ltd. In the year 1987, the company commenced operations in Cephalexin Plant at Mandideep and 7 ADCA plant at Ankleshwar. In the year 1989, the company established a joint venture in Thailand, namely Lupin Chemicals (Thailand) Ltd. Then in 1991, it initiated production of Injectable cephalosporin (bulk and dosages) at Mandideep The company set up Fermentation Plant at Tarapur, Maharashtra in the year 1992. Also, a Sterile Plant for injectable Cephalosporins (bulk) was commissioned at Mandideep.

Lupin Ltd is an India-based pharmaceutical company. The company produces a range of generic and branded formulations and Active Pharmaceutical Ingredients (APIs). The company's product basket consists of formulations from Cephalosporins, CVS, CNS, Anti-Asthma, Anti-TB, Diabetology, Dermatology, GI, and other therapy segments. The company's drug delivery platforms include Bioadhesive/Gastroretentive Extended Release, Laser-Drilled Extended Release, Matrix/Coated Extended Release, Taste Masking Technologies and Improved Bioavailability through Solubilization and Nano-particle technology. Their APIs products include antibiotics, Antibiotics, ANTI-TB, Cardiovasculars, Central Nervous System, Analgesics and ANTI-GOUT.
In June 2011, the company's Generic Healthy Pvt. Ltd acquired worldwide rights for the Goanna Brand and the complete range of premium therapeutic oils, rubs and ointments marketed under the brand. In July 2011, the company entered into a research and development agreement with Medicis Pharmaceutical Corporation (Medicis) to apply Lupin technologies to multiple therapeutic compounds.

8. Sun Pharmaceuticals Industries Ltd (Sun Pharma)

The Company was incorporated as a partnership firm at Vapi, Gujarat to manufacture pharmaceutical formulation. It was converted into a Public Ltd. Company effective from 1st March 1983. The Company specializes in selected therapeutic segment to psychiatry, cardiology, neurology and gastroenterology. The company offers formulations in various therapeutic areas, such as cardiology, psychiatry, neurology, gastroenterology and diabetology. It also provides APIs such as warfarin, carbamazepine, etodolac and clorazpate, as well as anticancers, steroids, peptides, sex hormones and controlled substances.

Sun Pharmaceuticals was established in 1983 in Vapi with five products to treat psychiatry ailments. Cardiology products were introduced in 1987 followed by gastroenterology products in 1989. Today it is the largest chronic prescription company in India and a market leader in psychiatry, neurology, cardiology, orthopedics, ophthalmology, gastroenterology and nephrology. The 2014 acquisition of Ranbaxy will make the company the largest pharma company in India, the largest Indian pharma company in the US, and the 5th largest speciality generic company globally.

9. Themis Medicare Ltd (Themis)

Themis Medicare Ltd., formerly known as Themis Chemicals Limited (TCL) was incorporated in 1969 as a Limited Company in the form of a Joint Venture between M/s Chemosyn Private Limited and Medimpex Trading Company Ltd. (Medimpex). The joint venture had technical and financial participation by Medimpex, a Hungaria trading company for pharmaceuticals products.
Themis Chemicals Limited was incorporated with the aim of manufacturing and marketing life saving drugs and their formulations. At present the Company is engaged in manufacturing and selling of synthetic bulk drugs and formulations. TCL operates in the therapeutic segments of antituberculosis, cerebroactivators, bronchodilators, antiasthmatic, anesthetic and other segments.

The company has manufacturing facilities located at Vapi and Hyderabad. The plant at Vapi manufactures intermediaries and bulk drugs for the anti tuberculosis segment. Besides this, it manufactures various formulations in the tablet form, for anti tuberculosis and other therapeutic segments.

Anti-tuberculosis bulk drugs and formulations account for 60% of its turnover and the company is rated fourth in terms of turnover in this segment. TCL has also started manufacturing and exporting fumagillin, an anti-bacterial drug, for veterinary use for which it has a confirmed buy-back arrangement with Chinoin, Hungary.

The company with the help of M/s Pharmograd, Moscow a manufacturing unit, is planning to market its Anti-T.B. formulation products through the collaborators throughout the Russian Federation for trade, tenders and govt. supplies.

10. Torrent Pharmaceuticals Ltd (Torrent)

Torrent Pharmaceuticals Ltd is one of the leading pharmaceutical companies having presence in Indian and global markets. The company is a dominant player in the therapeutic areas of cardiovascular (CV) and central nervous system (CNS) and has achieved significant presence in gastro-intestinal, diabetology, anti-infective and pain management segments. The company has its presence in 50 countries and has nine wholly owned subsidiaries in markets of Europe, United States, Latin America and Asia Pacific.

Torrent Pharmaceuticals Ltd, the flagship company of the Torrent Group was incorporated in the year 1972. In the year 1980, it started its first manufacturing facility at Vatva and it received its first export order in the year 1983. In the year 1986, the second manufacturing plant was started at Chhatral. In 1995, Torrent Gujarat Biotech Ltd plant was commissioned.
Its manufacturing facilities are located at Indrad (Gujarat) and Baddi (Himachal Pradesh). These units have received various certifications for its quality management such as ISO 9001, ISO 14001 and OHSAS 18001 and ISO/IEC- 17025. The Company is a leader in the Cardiovascular segment with a number of brand leaders in its product portfolio like Dilzem, Cordarone, Listril, etc.
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