Chapter - 2

An Overview of Pharmaceutical Industry

2.1 Introduction
2.2 The Early History of Pharmaceuticals
2.3 Consolidation and Globalization in the Modern Era
2.4 The Modern Pharmaceutical Industry
2.5 Development of Pharmaceuticals Industry
2.6 Characteristics of the Pharmaceutical Industry
2.7 Characteristics of Pharmaceutical Product
2.8 Pharmaceutical Industry Structure
2.9 Pharmaceutical Company Business Strategies
2.10 Porter’s Competitive Forces
2.11 Demand Drivers for the Pharma Industry
2.12 SWOT Analysis of Indian Pharma
2.13 Scenario of Pharmaceutical Industry
2.14 Challenges to Pharmaceutical Industry
2.15 Economic Contribution of Pharmaceutical Industry
2.16 Factors Influencing Growth of the Industry
2.17 Major Risks to Indian Pharma Companies
2.1 Introduction

Today the heart of the debate regarding the globalization of the modern pharmaceutical industry lies in the question of generic drugs versus intellectual property rights. The debate is of particular importance in the disease-ridden third world nations. On one hand, generics that are cheap and widely available could combat diseases more effectively than expensive name brands. At the same time, name brand prices drive the market through their ability to cover the high costs of research and development. Generic drugs utilize the same active ingredients and dosages as equivalent name brand drugs but can be manufactured and sold for far less. Generics benefit third world countries and poor people in the West by making affordable drugs available for people of the world that are extremely poor and prone to large epidemics. At the same time, generic drugs undermine the property rights of the firms that do the research and ultimately test and invent these medicines. It is argued that the loss of these property rights weakens their ability to do the research necessary to invent life-saving drugs. With the widespread sale of cheap drugs, the large pharmaceutical companies thus lose money that is crucial to funding their research and development. The drug companies’ argument is that without large corporate research and development, new drugs are not created and the generic drug companies have nothing to imitate once the 20 year patent is up, ultimately hurting the medical conditions in the third world. While convenient, cheap and easily made generic drugs are not widely available throughout the world. In 1995, the World Trade Organization adopted the TRIPS agreement (Trade Related Aspects of Intellectual Property Rights) creating a world-wide regulation of intellectual property such as prescription patents and pharmaceutical formulas. TRIPS was sought to maintain the profitability and economics of the pharmaceutical industry in the developed world. Prior to this agreement, there was little regulation in the third world regarding generic drugs, allowing countries such as India, Brazil, and Thailand, to develop large amounts of generic drugs to sell to the developing nations at much lower prices than brand name drugs. For example, an AIDS cocktail developed in the West can cost between $10,000 and $15,000 per year, where in India, the identical cocktail ranges from around $350 per year. TRIPS eliminated this ability as 20 year patent protection laws were set in place to satisfy the leading Western
drug companies. Their argument is that the sale of generic drugs takes away their incentive to develop in two ways: First, the creativity of the pharmacists and researchers in major firms is compromised when a generic drug company imitates their drug formulas. Second, since the generic formulas of the leading drug companies’ medicines can be available for up to thousands of dollars less per dose, name brand drug companies cannot make the sales they need to fund, while also hurting manufacturing.

Prior to the 19th century, the pharmaceutical industry was confined to small scale apothecaries, simple laboratories in the back of local shops, and in the hands of self-proclaimed druggists. Medicinal shops date back to Greek and Roman times, with a more advanced drug industry found in the 6th and 7th centuries in the Middle East, before expanding into Europe. By the 18th century, countries such as Britain, Germany, Switzerland, and even the American Colonies had taken a keen interest in this small scale industry because of the growing interest in therapeutic remedies, as well as advances in the field of chemistry that had medicinal implications. Along with the Industrial Revolution, a large growth in the biological sciences and the growth of state-sponsored universal education, the pharmaceutical industry grew exponentially. With the ability to discover, study, and test new medicines, as well as the technological ease of manufacturing came the consolidation of all aspects of this process into large pharmaceutical companies. Scientists, pharmacists, manufacturers, researchers and everything in between now worked under one name for the common goal of high levels of production and innovation. With this production came the need to protect new medical formulas via patents and intellectual property rights. Patent laws motivated companies’ creativity and innovation and many gains were made in terms of disease fighting capabilities. In order to truly understand the complexity of this evolution, a closer look must be taken at the historical background of all of the various historical processes that evolved into the modern drug industry. After examining the history of the modern drug industry, this study will conclude by returning to the analysis of the debate about intellectual property rights and the need for cheaper generic drugs in the developing world.
The pharmaceutical industry develops produces and market drugs or pharmaceutical licensed for use as medications. Pharmaceutical companies are allowed to deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs.¹

2.2 The Early History of Pharmaceuticals

The historical roots of modern pharmacy lie within two fields of pseudoscience that date back to ancient civilization. To fully understand the evolution of modern the pharmaceutical industry, one must begin with the study of alchemists and apothecaries. These spiritualists, scientists, and healers sought everything from the transmutation of metals into riches, to the power of immortal life. As the science and technology grew, so too did the field of medicine, taking forms of early science from Asia all the way to Europe and molding them into something beneficial for the well being of society. One of the earliest traditions to impact the modern pharmaceutical industry is that of alchemy. Alchemy is a combination of primitive inorganic chemistry mixed with philosophy and a search for immortality and ultimate wisdom. Beginning in Egypt, various forms of alchemy spanned three continents between 5000 B.C.E., continuing to be practice in one form or another until the middle of the 17th century in Europe when it transformed into modern chemistry.

In the West, early practices of alchemy were performed by the Greeks and Egyptians. Their alchemical methods were central to their search for eternal life and philosophical wisdom, as well as their religious practices. The Egyptian King, Hermes Trismegistus was considered a founder of alchemy. Around 1900 B.C.E. he was the first to compile the works of Egyptian spiritualists dating back to the dawn of civilization. His ultimate desire was to unlock the knowledge required to understand the operation of nature (Cockren). Much like the work of the Egyptians, these ancient societies were able to make many scientific discoveries that were unimaginable even in the centuries to come, however much of their work was destroyed around 290 C.E. by the Roman Emperor Diocletian. Diocletian ordered that all alchemy texts be destroyed in order to prevent Egypt from
amassing riches through transmutation that could facilitate a successful revolt within the empire. One important book survived, known as the Emerald Tablet which became the main book of alchemy. The contents of this text deal with the transmutation of various metals into gold, as well as herbal compounding and other theories on the original elements. Egyptian and Greek alchemists had theorized that earth, wind, fire, and water, were the four elements that comprised and created everything in nature. While we now know this is far from scientific, the traditional classification of elements had become a stepping stone into modern chemistry that had a large impact on the pharmaceutical industry in return. At the same time as the discovery of the Emerald Tablet, the Chinese were practicing their own unique form of alchemy.

The 12th century also brought the first Arab medical schools and some of the first pharmaceutical scientists emerged based around alchemy and a motivation to create and test medicinal elixirs. Through conflict with the Holy Roman Empire, alchemy soon spread across Europe and became one of the pseudo-sciences in medieval times (Holmyard).

In the 13th century, one theory was asserted that would survive to transform the field of alchemy into chemistry in later centuries. In the middle of the 13th century, Albertus Magnus, a philosopher and scientist, claimed to have discovered what he believed was the “Philosopher’s Stone.” This was a tool which was said to be able to transmute substances into gold. He passed his work on to his pupil, Thomas Aquinas who continued to write about the stone. While the stone was not real, it sparked thought regarding the elements. In the 1500s, it was widely believed that the four elements--earth, wind, water, and fire--were various forms of one element. The medieval theory of the elements evolved from the belief that the Philosopher’s Stone could change substances into other substances resulting in three major theories of modern chemistry. These theories were that matter is not created or destroyed, the theories behind the periodic table of the elements, and the theory of compounding basic elements into more complex chemical bodies. Compounding elements and substances would of course become vital to the chemical industry’s ties to the pharmaceutical industry. Alchemists were still limited as they were often highly spiritual, monetarily motivated, and seeking power or scientific
enlightenment. The need for a more specialized industry had arisen from the development of medical compounds through alchemy. The stage had been set for the apothecary.\(^2\)

In the first part of a new series looking at the history of pharma, Robin Walsh takes a look back at the very origins of the industry itself. The roots of the pharmaceutical industry lie back with the apothecaries and pharmacies that offered traditional remedies as far back as the middle ages, but the industry as we understand it today really has its origins in the second half of the 19th century. Whilst the scientific revolution of the 17th century had spread ideas of rationalism and experimentation, and the industrial revolution had transformed the production of goods in the late 18th century, the marrying of the two concepts for the benefit of human health was a comparatively late development.

Merck in Germany was possibly the earliest company to move in this direction. Originating as a pharmacy founded in Darmstadt in 1668, it was in 1827 that Heinrich Emanuel Merck began the transition towards an industrial and scientific concern, by manufacturing and selling alkaloids. Similarly, whilst GlaxoSmithKline’s origins can be traced back as far as 1715, it was only in the middle of the 19th century that Beecham became involved in the industrial production of medicine, producing patented medicine from 1842, and the world’s first factory for producing only medicines in 1859.\(^3\)

Meanwhile, in the USA, Pfizer was founded in 1849, by two German immigrants, initially as a fine chemicals business. They expanded rapidly during the American civil war as demand for painkillers and antiseptics rocketed. Whilst Pfizer was providing the medicines needed for the Union war effort, a young cavalry commander named Colonel Eli Lilly was serving in their army. A trained pharmaceutical chemist, Lilly was an
archetype of the dynamic and multi-talented 19th century American industrialist, who after his military career, and trying his hand at farming, set up a pharmaceutical business in 1876. He was a pioneer of new methods in the industry, being one of the first to focus on R&D as well as manufacturing. Another military man in the drugs business was Edward Robinson Squibb, who as a naval doctor during the Mexican-American war of 1846–1848 threw the drugs he was supplied with overboard due to their low quality. He set up a laboratory in 1858, like Pfizer supplying Union armies in the civil war, and laying the basis for today’s BMS. "Whilst Pfizer was providing the medicines needed for the Union war effort, a young cavalry commander named Colonel Eli Lilly was serving in their army."

Switzerland also rapidly developed a home-grown pharmaceutical industry in the second half of the 19th century. Previously a centre of the trade in textiles and dyes, Swiss manufacturers gradually began to realise their dyestuffs had antiseptic and other properties and began to market them as pharmaceuticals, in contrast to the origin in pharmacies of other enterprises. Switzerland’s total lack of patent laws led to it being accused of being a “pirate state” in the German Reichstag. Sandoz, CIBA-Geigy, Roche and the Basel hub of the pharmaceutical industry all have their roots in this boom.

It wasn’t just Swiss companies had their roots in the dye trade. Bayer was founded in 1863 as a dye maker in Wuppertal, the hometown of Karl Marx’s collaborator Friedrich Engels. It later moved into medicines, commercializing aspirin around the turn of the 20th century, one of the most successful pharmaceuticals ever at that point.

The unregulated nature of the trade in medicines during this period ensured there was a far less strict delineation between “pharmaceutical” and “chemical” industries than we have nowadays. These companies focused as much on cod liver oil, toothpaste, citric acid for soft drinks, and hair gel as on prescription medicines, as well as selling products like heroin on the over-the-counter market.

The interwar years also marked two breakthroughs that presaged the arrival of the pharma industry as we know it today. The first was insulin, Frederick Banting and colleagues managed to isolate insulin that could treat diabetes, up until that point a fatal condition. But it was only in collaboration with the scientists at Eli Lilly that they were
able to sufficiently purify the extract and industrially produce and distribute it as an effective medicine.

The second was penicillin, a discovery of an impact possibly unparalleled by any other in medicine. After Alexander Fleming’s initial discovery of the penicillium mould’s antibiotic properties in 1928, and Howard Florey and Ernst Chain’s further experimentation, a government-supported international collaboration including Merck, Pfizer and Squibb worked on mass producing the drug during World War Two, saving thousands of soldiers’ lives. The immense scale and sophistication of the penicillin development effort marked a new era for the way the pharmaceutical industry developed drugs. The war had also encouraged research into everything from new analgesics to drugs against typhus, with a great deal of collaboration between the companies and government. "The Thalidomide scandal of 1961 prompted an increase in the regulation and testing of drugs before licensing"

After the war, the arrival of social healthcare systems such as the UK’s National Health Service (NHS) in Europe created a much more structured system, both for prescription of drugs and their reimbursement. In 1957, the NHS brought in what was essentially a price fixing scheme to allow reasonable return on investment for drug manufacturers, solidifying the incentive to invest in new medicines. This greater role for the state in healthcare was paralleled on both sides of the Atlantic in increasing government regulation of medicine production. The Thalidomide scandal of 1961 prompted an increase in the regulation and testing of drugs before licensing, with a new amendment to US Food and Drug Administration (FDA) rules demanding proof of efficacy and accurate disclosure of side-effects for new medications the Kefauver Harris Amendment being implemented in 1962. Likewise, the 1964 Declaration of Helsinki put greater ethical strictures on clinical research, clearly cementing the difference between production of scientific prescription medicines and other chemicals.

Fordian methods enabled more rational methods of mass production, and increasing understanding of biology and chemistry enabled drug candidates to be chosen systematically rather than discovered serendipitously. This ‘golden age’ of drug development took place in the broader landscape of the post-war boom, a general context
of massive improvements in standards of living and technological optimism that characterized the 40s to the early 70s, as well as the science-boosting competition of the cold war. As the barriers to entry in drug production were raised, a great deal of consolidation occurred in the industry. Likewise, the processes of internationalization begun before the war were continued – in 1951 alone Pfizer opened subsidiaries in nine new countries.\(^5\)

The list of novel drugs from the post-war era speaks for itself. The contraceptive pill, introduced in 1960, had an impact on society almost as massive as that of penicillin, enabling women to effectively control their fertility and enabling sexual equality for the first time. Valium (diazepam) was brought to the market by Roche in 1963, followed by the introduction of the monoamine oxidase inhibitor (MAOI) class of anti-depressants and antipsychotic haloperidol. These drugs ushered in a new era of psychiatric treatment, adding effective biological treatments to the psychoanalytic ones that had previously characterized psychiatry in this era. The 1970s provided a wave of cancer drugs, as part of the US government’s “war on cancer”, a recent report from Cancer Report UK showed that survival rates have doubled since the early 70s – due in large part to the massive innovation in oncology medicines that has occurred since then. ACE inhibitors arrived in 1975, improving cardiac health, and even drugs as ubiquitous as paracetamol and ibuprofen were developed in 1956 and 1969 respectively.

As the 1970s drew to an end, a shift began in the way the pharma industry focused its energies. In 1977, Tagamet, an ulcer medication, became the first ever “blockbuster” drug, earning its manufacturers more than $1 billion a year and its creators the Nobel Prize. This marked a new departure as companies competed to be the developer of the next big blockbuster, and many achieved great success. Eli Lilly released the first selective serotonin reuptake inhibitor (SSRI), Prozac, in 1987, once again revolutionizing mental health practice. The first statin was also approved in 1987, manufactured by Merck (MSD).\(^6\)

"But new technologies are what really promise a positive future for the industry in the 21st century."
But whilst there were some breakthroughs, the enormous expense and risks involved in R&D caused many to merely ape their competitors, trying to get a cut of market-share using “me too” formulations rather than innovating novel medications. For example, AstraZeneca’s popular proton pumps inhibitor Nexium (esomeprazole), released in 2001, is merely a purified single isomeric version of an older drug which happened to be losing patent protection. Patents, or the lack of them, became a problem for the industry. The Hatch-Waxman Act of 1984 regularised generic production in the US, and some developing countries made policy decisions to ignore medical patents. The industry’s focus increased on marketing to maintain market share, on lobbying politicians to protect commercial interests, and on lawyers to enforce legal claims on intellectual property rights. These activities have brought a greater suspicion of the industry in the public at large. However, this can be linked to a wider anti-science feeling and more pessimistic outlook on the possibilities of technology in society, as seen in panics over issues such as genetically-modified crops and suspicion towards nuclear power.

Companies have tried to overcome some of these problems by outsourcing various aspects of their processes, and through buying up smaller companies that perhaps retain more of the innovative entrepreneurialism of the pioneers of the 19th century. But new technologies are what really promise a positive future for the industry in the 21st century. Both computing and biotechnology have allowed great leaps forward in both development and production of new drugs. Automation of the drug discovery process through high-throughput screening, and the computerization of genomics have allowed breakthroughs at a much higher rate than previously. Starting with insulin in the 1970s, genetic modification has allowed production of human proteins by bacteria. And biological drugs such as the monoclonal antibodies, introduced around the turn of the millennium, hint at a whole new panorama of far more specific drugs that could impact on human health as much as the medicines of last century.\(^7\)

2.3 Consolidation and Globalization in the Modern Era

While the impact of colonialism brought countless monetary and scientific rewards to the pharmaceutical industry, some legal debates began for the first time. The modern issue of third world exploitation and generic or cheap, identical versions of name brand drugs saw
its beginnings in the American Colonies. For the first time, a newly discovered areas of land, with undeveloped infrastructure and a less militarily and scientifically advanced indigenous people became a subject of exploitation. Fortunes were made, and native civilizations were knocked down. The indigenous drugs from America and the pharmaceutical industry as a whole, however, benefited from the positives of advances in medicine and trade creating large scale growth in the industry. At this time, there was virtually no regulation on trade, patents, and monopolies in the medical field leading up to the 1900s. These issues that the world began to see during the emerging development of the Western Hemisphere would come back into play in the future with the modern arguments involving the development of generic drugs. As the scientific fields of chemistry and biology grew, they were quickly weaving themselves into a set of modern sciences that the pharmaceutical industry depended on. As the industrial revolution evolved, and technology grew, the pharmaceutical industry was becoming a self-sufficient machine such as we know today. 

A wealth of natural resources, emerging nations, advancing trade systems, and a rapidly advancing scientific field were allowing the pharmaceutical industry to evolve at a large rate. Educational requirements were found across Europe and America, and pharmacists were finding independence from physicians for their field of medicine. Local pharmacies were showing up everywhere, with the ability to mix and compound their own drugs and to prescribe and sell goods to their local areas. At the same time, advances in science and technology with particular emphasis on mass production were on the rise. Important discoveries with antibiotics, and two world wars would show the world the effectiveness of a pharmaceutical company that could supply their own raw materials, technology, scientists, medical experts, and everything in between. With the emergence of these companies came legal issues and ethical questions that would both plague and help flourish the modern pharmaceutical industry through the 20th century. In the late 1800s, the biology industry had made a number of advances in disease identification and diagnosis became far more accurate. Germ theory taught us to search for causes and utilize symptoms to decide how to treat specific ailments. At the turn of the 1900s and into the 1920s, the chemical industry expanded upon these theories and practices to treat diseases by synthesizing drugs based on need, but the pharmacy was still a far cry from
the pharmacy that sells a remedy for virtually everything that we know today. In the early 1900s, the majority of prescriptions were filled by local pharmacists. Pharmacists at this time were apothecaries with increased knowledge and resources, acting in the same traditional manner. They would mix powders and creams, and coat their own pills, attempting to create decent tasting and non-poisonous medicines to treat various diseases. While they were educated in medicine, and utilized documented ingredients, dosages and compounds were still a fairly inaccurate and inconsistent science.

With the arrival of the 1920s and the discovery of Bunting’s insulin boosting medicine to combat diabetes saw a push for an industrialized industry. There was enough biological and chemical knowledge regarding medicine to mass produce drugs in order to serve the population more effectively. Pharmacists could now purchase ready-made compounds from wholesale distributers for their local pharmacies. Companies began marketing drugs under brand names by gaining primitive medical patents and property rights for their products. Pharmaceutical companies such as these began drawing from the local druggist population to create a workforce made up of chemists, biologists, industrialists, and the local pharmacist that everyone was used to calling “Doc.” On the other hand, many remained in their local drug stores, however their jobs were changing with the involvement of chemists and creation of large pharmaceutical companies. Pharmacists were now responsible for far less knowledge, only needing to know which product treats which disease, and occasionally the reasoning behind the pharmaceutical cure. In 1932, it was required that all pharmacists in the United States hold a Bachelor’s degree. Many European nations followed suit shortly after. The difference between this new degree and the prior certification was that pharmacists were now studying a heavy dose of chemistry along with a broad range of the other physical sciences. There was less emphasis on compounding and the specifics of botany and disease identification due to the industrialization and consolidation of the pharmaceutical industry. Local pharmacists began selling products like foods, medical supplies, and other assorted items to maintain a source of income. Between the 1920s-40s, the local pharmacy was evolving into a medically oriented convenience store where prescriptions could be filled. At the same time the “apothecary” of old was falling victim to the consolidation of pharmacy and the
sciences into companies that could pool from all industries to be self subsistent (Holcomb).

With advances over the previous two decades, and the effects of World War II in terms of casualties and need for medicine, the 1940s became known for advances in antibiotics. Large numbers of infected soldiers resulted in the need to discover antibiotics and develop advanced penicillin-based compounds. Penicillin, discovered in 1928, is regarded as one of the greatest medical discoveries in the modern era, leading to the development of many antibiotics and disease and infection cures as a result. Scientists were now able to develop compounds that could cure specific diseases. Antibiotics were being prescribed by doctors at a large rate. Pharmaceutical companies were receiving a large amount of monetary aid in order to research and mass produce antibiotics to treat the wounded soldiers. Two European discoveries from the 1930s joined penicillin in the WWII mass production boom. They were Sulfonamide, which was used for pneumonia and resulted in many sulfur based antibiotic compounds, and Prontosil which was able to control bacterial infections at a high rate. Sulfa was issued to each soldier during WWII and was often the first item put onto an open wound, resulting in far more effective treatment and greatly increasing the survival rate. Pfizer, an early pharmaceutical company, was able to perfect a process to mass produce penicillin at a safe and effective rate. As a result of the casualties of war, the United States government authorized and funded 19 companies to use Pfizer’s process to mass produce antibiotics. Once again, European nations followed suit (Steinert, 2000). Other medical compounds such as the aforementioned sulfa and plasma a protein-salt liquid that accounted for a large portion of blood content were mass produced and government funded as well. With cures such as these, came many patients that were kept alive but still in pain. A market for large scale production of pain and fever reducers was created as a result. Squibb created a way for an opium based morphine compound to be administered on the frontline by medics. This was called a Syrette, and was similar to the modern syringe (Steinert, 2000).

The Pacific theater in particular saw a need to fight malaria. Quinine based drugs were also mass produced from existing formulas to save the lives of many soldiers in the East. Lessons learned and advances made during WWII would change the industry for good.
The apothecary as it had been for the previous decades faced extinction, and the mass production of safe and effective drugs was seen on a large scale (Steinert, 2000). With the end of the 1940s, the post war society saw a need to regulate the hasty dosages issued during the war. The FDA, for the first time in history, regulated mass produced drugs in 1951. Over-the-counter, and prescription strength drugs had been divided for the first time, creating a broader market for the latter half of the 20th century.\(^9\)

### 2.4 The Modern Pharmaceutical Industry

The new millennium marked the start of a great debate regarding the pharmaceutical industry over the past two decades. Countries like the United States, Germany, and Britain had made large advances in this field as a result of mergers, regulations, and scientific breakthroughs. Plans like that of America’s Health Management Organizations (HMO) also emerged during the 1980s to contain the rising costs of medicine. Intellectual property laws emerged to also protect the rights of pharmaceutical companies worldwide. 20 year patents were enforced by the World Trade Organization’s TRIPS agreement in the 1990s. In countries like America, prescription drugs are largely regulated by the government and pharmaceutical companies are given a virtual monopoly by the restriction of the importation of global pharmaceutical products. According to the drug industry, companies must charge prices beyond their costs of production in order to cover their large research and development budgets. Arguments for international regulation say that generics, or drugs manufactured with the same active ingredient as the name brand, as well as drugs made in leading pharmaceutical nations such as India, may not be properly tested or safe for the U.S. population. On the other hand, the medical industry will still argue that health is jeopardized when medicine is unaffordable to many citizens (Paul).

While that is just one small example of the global debate within the pharmaceutical industry, the major issue is the role that should be played by the free market. A free market would lower trade barriers allowing market price to dictate what citizens pay, while patent laws would still exist. With most of the drugs coming from the Western world, availability would become more open to 3rd world nations that were in dire need
of cheaper drugs. Along with the issue of free market competition for drugs, comes the debate on whether generic drugs do not do damage to the research and development initiatives of pharmaceutical companies. One example of the ability of a generic drug became evident in 2001 as an AIDS cocktail developed in India could be imported by developing nations at a rate of $350-600 per year. The exact same cocktail costs between $10,000-15,000 when manufactured in the United States. The Indian firm, Cipla, challenged that the pharmaceutical industries ability to decide which company manufactures what drug, and the World Trade Organization’s patent laws restricting the production and sale of generics is severely hindering the potential health benefits for third world nations. In 2003, the WTO amended its patent laws in order to allow African nations to import low costs generics due to their inability to manufacture necessary medicines at home. This proved to be successful in many ways by allowing drugs to become available for lower prices at distances closer to the drug patients. This was however, only developed on a small scale. The ultimate challenge that the modern industry is facing deals with the fact that developing nations record the largest number of diseases, yet the drugs necessary to combat and control these diseases are hardly affordable in the United States, let alone the third world. At the same time, diseases that are highly curable in developed nations are often deadly in the 3rd world. Much of this is attributed to regulation and the lack of availability of cheap, patented, western medicines (Holland 1-3).

On the other hand, a market allowing any sort of generics can allow for the international stealing of patented formulas. Unregulated generic drug development can also lead to potentially harmful products furthering the health problems of the third world. Generics manufactured in places like India and Brazil are subject to less regulation, less sanitary conditions, and are more susceptible to formulation issues that can lead to incorrect dosages and even death. Finally, the unregulated availability of generic drugs can put the industry leaders of pharmaceutical development in a financial bind due to the unfair competition by companies that violate their patents. Inventers, developers, and generic drug critics will argue that the sale of cheap drugs will ultimately inhibit their ability to produce effective medicinal formulas by taking away the necessary funding for research and development. While the leading pharmaceutical firms have much of their funding
tied up in research and development, the generic drug companies are able to focus all of their money on manufacturing alone and can sell their products for prices that the leading companies cannot compete with. That is why the major pharmaceutical firms argue that there is a need for patents and that their high prices are the only thing truly driving the success of the industry.\textsuperscript{10}

2.5 Development of Pharmaceuticals Industry

The Indian pharmaceutical industry has come a long way since the time of independence when multinational corporations dominated the industry. Over the years, under a favorable policy regime, the industry has grown phenomenally and has established itself as a major supplier of not only generic products but also new formulations. The industry, in addition to meeting domestic demand, is in a position to export significant volume of pharmaceutical products to various destinations, including the developed markets of USA, EU and Japan. Evolution of Indian pharmaceutical industry can be classified into the following four periods:

(A) Pre-1970s:

The first Indian pharmaceutical company, Bengal Chemicals and Pharmaceutical Works, which still exists today as one of 5 government-owned drug manufacturers, appeared in Calcutta in 1930. For the next 60 years, most of the drugs in India were imported by multinationals either in fully-formulated or bulk form. The government started to encourage the growth of drug manufacturing by Indian companies in the early 1960s, and with the Patents Act in 1970, enabled the industry to become what it is today. This patent act removed composition patents from food and drugs, and though it kept process patents, these were shortened to a period of five to seven years. The lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market, and while they streamed out, Indian companies started to take their places. They carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model until the present.
During this period, the size of Indian pharmaceutical industry was small, both in terms of number of firms and volume of production. MNCs dominated the market, both in terms of volume of production and patent holdings, in India. The patent regime, based on Indian Patents and Designs Act, 1911, recognized both product and process patents. Due to monopoly status enjoyed by the MNCs, drug prices remained high during this period.

(B) 1970 – 1995:

Up until the 1970s, India's pharmaceuticals market was mainly supplied by large international corporations. Only cheap bulk drugs were produced domestically by state-owned companies founded in the 1950s and 60s with the help of the World Health Organization (WHO). These state-run firms provided the foundation for the sector's growth since the 1970s. Back then, India's government aimed to reduce the country's strong dependence on pharmaceutical imports by flexible patent legislation and to create a self-reliant sector. In addition, it introduced high tariffs and limits on imported medicines and demanded that foreign pharmaceutical companies reduce their shares in their Indian subsidiaries to two fifths. This made India a less attractive location for international companies, many of which left the country as a consequence. Especially India Drugs and Pharmaceutical Ltd. (IDPL) are credited with speeding up the development of a national pharmaceutical industry. Several IDPL staff has successfully founded their own firms, which now belong to the top group among India's pharmaceutical companies. In the 1980s, however, the decline of state-run companies began – among other things because of increasing central government bureaucracy and insufficient corporate governance.

Government of India introduced a new Patent Act, which came into effect in 1972, recognizing only process patent and not product patent. The Act enabled Indian firms to use "reverse engineering process", to manufacture drugs, without paying royalty to the original patent holder. The Act, along with Drug Price Control Order, provided little incentive for 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. Production of bulk drugs increased
from Rs. 18 crores in 1965-66 to Rs. 1518 crores in 1995, while that of formulations increased from Rs. 150 crores to Rs. 7935 crores during this period. The increase in production was more pronounced in case of formulations due to large-scale production of generics by domestic firms. Low cost and high volume production has helped the Indian pharmaceutical industry in opening export channels to explore many developed and developing countries. Share of exports as a Percentage of total production has shown significant increase from 3.22% in 1980-81 to 24% in 1994-95.

(C) 1995-2005:

As there was no efficient patent protection between 1970 and 2005, many Indian drug producers copied expensive original preparations by foreign firms and produced these generics by means of alternative production procedures. This proved more cost-efficient than the expensive development of original preparations as no funds were required for research, which contained the financial risks. This spending block may come to as much as EUR 600 mn for only one drug. This kind of money could previously only be raised by large corporations in the industrial countries. The competitiveness of generics producers is based on cost-efficient production. In this field, Indian companies are currently in top position. At one-fifth, India’s share in the global market for generic drugs is considerably higher than its share in the overall pharmaceuticals market (approximately 2%). At the same time, India’s pharmaceutical companies gained know-how in the manufacture of generic drugs. Hence, the name pharmacy of the poor is frequently applied to India. This is of significance not least for the domestic market as disposable income is as little as EUR 1,900 per year for roughly 140 million of the total of 192 million Indian households Just et al 2006 which means the majority of Indians cannot afford expensive western preparations.

India’s pharmaceutical industry has been in transition for several years now. This is the result mainly of the changes to drug patent legislation in 2005. Prior to the Patent Amendment Bill, not the substance itself but merely the manufacturing process was protected for a period of seven years. India’s patent legislation had frequently been the reason for legal disputes with large western drug firms, especially from the US. In line
with international standards, the sector is now subject to product and process patents valid for a period of 20 years. Indian companies seeking to copy drugs before the patent expires are forced to pay high licence fees. This became necessary following the signing by India's government of the TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights. So Indian drug firms could no longer simply copy medicines with foreign patents by using alternative manufacturing processes and offer them on the domestic market. As a consequence of these major changes to India’s drug patent legislation, the country’s pharmaceutical industry is undergoing a process of re-orientation. Its new focus is increasingly on self-developed drugs and contract research and/or production for western drug companies.

Between 1996 and 2006, nominal sales of pharmaceuticals on the Indian subcontinent were up 9% per annum and thus expanded much faster than the global pharmaceutical market as a whole (+7% p.a.). Indian companies strongly expanded their capacities, making the country by and large self-sufficient. Nonetheless, with total sector sales of roughly EUR 10 bn, India commands a less than 2% share in the world’s pharmaceutical market (1966: 1.5%). This puts the country in twelfth place internationally, even behind Korea, Spain and Ireland and before Brazil, Belgium and Mexico. Among the Asian countries, India’s pharmaceuticals industry ranks fourth at 8%, but has lost market share to China, as sales growth there was nearly twice as high and sales volumes nearly four times higher than in India.

The year 1995 recorded another milestone for the Indian pharmaceutical industry. One of the Agreements under the World Trade Organization was complying with the Trade Related Intellectual Property Rights (TRIPS) provisions. The TRIPS Agreement reintroduced product patent in India. Further, during this period, tariff and non-tariff measures have come down. Such developments have worked in favour of 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 process and low manufacturing cost.
India's new product patent regime is the result of the WTO's Doha Round of negotiations in 2001. Final agreement was reached on TRIPs ground rules for patent protection among WTO member countries, stating that both processes and products should be protected. Subsequently, on March 22, 2005, India's parliament approved the Patents (Amendment) Act 2005, bringing in a system of product patents backdated to January 1, 2005. The new regime protects only products arriving on the market after January 1, 1995, abolishing the previous process patent system established by the 1970 Patent Act. Since the introduction of product patents the MNCs have largely returned, the most recent being Merck & Co, which inaugurated its wholly owned subsidiary MSD India Pvt Ltd in July 2005 after being absent for approximately 20 years. Assoc ham believes the new patent regime will enable the development of innovative new drugs, which will increase profitability for MNCs. It will also force domestic players to focus on R&D, which, for those who can afford to do so, will have long-term beneficial effects.  

2.6 Characteristics of the Pharmaceutical Industry

Several characteristics distinguish the pharmaceutical industry from other industries. A newly released pharmaceutical agent is usually available only by physician prescription. Patients in effect transfer decision-making authority on the appropriateness of medications for their ailments to the gate-keeping physicians or pharmacists and nurses in some countries. Generally, a prescription may become available OTC i.e., without physician prescription for a non-chronic condition that is relatively easy to self-diagnose and has low potential for harm from self-medication under conditions of widespread availability.

i. Industry Growth

The Centers for Disease Control (CDC) estimated that in 2005 more than 130 million Americans got prescriptions monthly. Physicians acting as the decision maker for patients and health insurance coverage of prescriptions create a market with fairly “inelastic product demand.” An inelastic product demand means that buyers’ percentage change in
quantity purchase decisions are relatively insensitive to a given percentage price change that brought it about. Pharmaceutical product demand elasticity estimates vary depending on many factors, including the setting (e.g., inpatient versus outpatient or military versus no institutional population), brands versus generics, stringency of regulatory and provider reimbursements, and the strength of the consumption habits of consumers.

Some experts predict that the rise in insurance coverage is a major culprit in the undisciplined rising consumption of prescribed drugs. Other experts contend that the growth in prescription drug use is partly a function of greater marketing efforts of the drug firms. The pharmaceutical industry in 2003 spent $3.3 billion on direct-to-consumer advertising and marketing expenditures totaled $25.3 billion. Doctors’ prescribing habits are directly influenced by the probability of patient noncompliance, and advertising targeted at doctors and patients. Direct-to-consumer advertising reportedly slowed noncompliance rates. The U.S. drug firms spend a similar percentage of their sales revenue on advertising as on research and development.

The pharmaceutical industry manufactures innovative products with government-granted patent rights that may be extended after application approval from the FDA. Patents give researchers and inventors exclusive rights to market an invention for twenty years before others may duplicate and sell it. Therefore, producers of new drugs are free to limit the supply and set prices that reflect profit-maximizing mark-ups with exclusive marketing rights. Most pharmaceutical manufacturers in the United States are multinational enterprises operating globally across countries. In 2004 the Pharmaceutical Research and Manufacturers of America Pharma recorded drug sales of $159 billion within the United States and $79 billion abroad. The industry boasts investment rate of return that is four times the magnitude of the typical Fortune 500 firm. Technological progress in this industry and in the broader health care sector has led experts to project the global pharmaceutical market sales to be $842 billion in 2010.

There were more than 700 companies operating in the “pharmaceutical preparations” industry in 2006. The leading ten firms accounted for more than 40 percent of total industry sales. Other factors in this industry include retail pharmacies, health care
provider institutions, and wholesalers. According to a 2000 report, the pharmaceutical industry earned 80 percent of the drug sales directly from wholesalers, 12 percent from retailers, and 4 percent from hospitals. Consumers typically buy drugs from retail pharmacies but there has recently been a rising trend in purchased drug activities via the Internet and from mail-order services within and outside the United States. Prescription drug buyers consider nontraditional purchasing outlets more convenient and private relative to traveling to a retail drugstore. Physicians may suggest Internet pharmacies to some homebound patients in order to improve compliance.¹²

ii. Research and Development (R&D)

In the United States new drugs must be approved by the FDA. In order to satisfy safety and benefit considerations of the FDA, pharmaceutical companies conduct on average ten to fifteen years of research on a new medication. Approval of a new drug is a rigorous process and for every 5,000 to 10,000 compounds tested, only one receives FDA approval and become a new or improved treatment. The entire U.S. pharmaceutical industry spent an estimated $51.3 billion on research and development in 2005. Nearly 80 percent of global R&D spending takes place in the United States and the major portion of the remaining 20 percent occurs in Europe.

The drug discovery process begins with the screening of thousands of compounds and modifying them to raise disease-fighting activity and/or minimize undesirable side effects for patients. Both laboratory and animal studies may be used to evaluate a drug’s safety and efficacy during preclinical testing. Investigational new drugs go through a rigorous review by the FDA before moving to the clinical trials stage. Clinical trials of new medicines occur in three testing phases. Phase I includes drug tests in a small group of about 20 to 100 healthy volunteers to determine safety. During Phase II, 100 to 500 volunteer patients participate in controlled trials to determine whether the medicine effectively treats the disease. Phase III includes 1,000 to 5,000 patients taking the new drug and being monitored to confirm effectiveness and identify any side effects with comparison to patients in the placebo inactive substance group.
Drug development responds to the urgency and intensity of consumer demand, and economic harm, measured by disease-specific mortality, in the United States largely motivates the global distribution of drug development. The FDA approved 28 new drugs in 2005 and more than 350 medications became available for treating patients in the last decade. New medicines in development in 2006 included 682 to treat cancer, 531 to treat neurological disorders, 341 to treat infections, and 303 to treat cardiovascular disorders. One study in 2005 reported that new drugs generated 40 percent of the two-year gain in life expectancy achieved in 52 countries from 1986 to 2000.

When a company’s patent rights expire, other companies can imitate the drug and produce generic brands of the medication. According to Pharma, the generics’ share of the U.S. prescription drug market was 57 percent in 2005. This share is expected to rise within the next decade as the rate of brand patent expirations increases.

iii. Economic Features

The discovery and manufacture of new drugs is a risky business without guaranteed profitability. The cost of developing one new medicine is estimated to be about $800 million higher if genetically engineered and on average, only three of every ten prescription medications available to treat Americans generate revenues that meet or exceed average R&D costs.

In the absence of patent protection, imitators could copy the new medication and manufacturers would lack practical incentives to invest millions of dollars on R&D of new drugs. Although patents nominally last for 20 years, the average effective patent life of prescribed medicines is only about 11.5 years due to time lost during the development and distribution of the new medicine to the market. Patent protection gives pharmaceutical manufacturers a monopoly status although generic drug makers can start preparing copies of drugs for FDA approval before patent expiration. A monopoly provides the patent owner with the sole right to manufacture the drug and determine the quantity to supply hence the market price according to its projected profit margin. The Treaty of Marrakech, signed in 2004 during the international trade negotiations, provided
full patent protection for pharmaceutical products across industrialized nations as well as in the less-developed nations.

The pharmaceutical sector is controlled or strictly regulated by the government acting as a single buyer (payer) or a monophony in countries with nationalized health systems e.g., Canada, the United Kingdom. There are many end-users but they buy at government-regulated prices. Governments can regulate drug prices in a variety of ways. The most common methods of price regulation are reference pricing, formula pricing, capping or budgetary control, profit regulations and item-by-item negotiation. Reference pricing is a reimbursement rule where the government sets the maximum reimbursement for one drug by reference to the price of a comparable drug in the same market. Under formula pricing, governments use a wide criteria set, such as therapeutic novelty, to set drug prices. Capping or budgetary control would involve limiting reimbursement to the providers at a certain captivated level.

Other regulatory instruments generally target the profit margins of pharmaceutical companies and quality of manufacturing practices. For example, a 1990 law in the United States required drug manufacturers to apply on retail Medicaid prescriptions the largest discount they give any purchaser the Medicaid drug rebate program. The U.K. government has used a rate of return regulation in which each firm negotiates with the government an allowed before-tax rate of return on its assets. Germany has used aggregate budget constraints and rollbacks. In this application, the government sets a tight overall budget and any amount above this budget would be deducted from payments to a third party e.g., from the incomes of physicians, from the reimbursements to the drug manufacturers. These are all examples of government regulations to control drug prices and regulate excess profitability in the pharmaceutical industry.

The future pharmaceutical industry faces multi-faceted challenges that include setting and enforcing manufacturing standards; rapid patent expiration of widely used brand drugs; unregulated parallel trades re-importation in the European context that ignores intellectual property rights; highly fluid and unregulated Internet sales; shortage of pharmaceutical scientists; biotechnology drugs and genetically engineered products As of 2006 the FDA had no generics approval process in place for patented biotechnology
drugs whose patents are about to expire. Ineffective post-marketing surveillance; foreign manufacturing, regulatory, and pricing challenges of drugs for major diseases afflicting developing countries e.g., AIDS and malaria and counterfeit products.

Intellectual property abuse and counterfeiting, the fastest growing economic crime, is a $200 to $400 billion global industry. In 2006, the National Association of Boards of Pharmacy (NABP) reported that the prevalence of counterfeit medicines can range to over 10 percent of the drug supply globally. A dramatic growth of global counterfeit and piracy activities would seriously threaten the economic well-being of international pharmaceutical companies.\textsuperscript{14}

2.7 Pharmaceutical Product Characterization

The pharmaceutical industry manufactures bulk substance pharmaceutical intermediates and active ingredients which are further processed into finished products.

I. Medicinal and Botanicals (SIC 2833)

Companies in the Medicinal and Botanicals industry category are primarily engaged in 1) manufacturing bulk organic and inorganic medicinal chemicals and their derivatives and 2) processing grading, grinding, and milling bulk botanical drugs and herbs. The industry is made up of establishments or facilities that manufacture products of natural origin, hormonal products, and basic vitamins, as well as those that isolate active medicinal principals such as alkaloids from botanical drugs and herbs (OMB, 1987). These substances are used as active ingredients for the Pharmaceutical Preparations industry category. Companies often produce both Medicinal and Botanicals and Pharmaceutical Preparations at the same facility.

II. Pharmaceutical Preparations (SIC 2834)

The Pharmaceutical Preparations industry category is made up of companies that manufacture, fabricate, and process raw materials into pharmaceutical preparations for human and veterinary uses. Finished products are sold in various dosage forms including,
for example, tablets, capsules, ointments, solutions, suspensions, and powders. These are 1) preparations aimed for use mainly by dental, medical, or veterinary professionals, and 2) those aimed for use by patients and the general public (OMB, 1987). A more in depth discussion of these finished products is provided in Section III.A.3. Pharmaceutical products also are often classified in terms of their availability to the general public.

Both prescription and over-the-counter (OTC) drugs are available to the public. Prescription drugs can be purchased only with a prescription from a licensed health care professional authorized to prescribe, while OTC drugs may be purchased without a prescription. The FDA will consider approving the switch of a drug from prescription to OTC when the manufacturer presents evidence that consumers can self-diagnose the condition for which the drug is approved, i.e., cold or seasonal allergy, and directions for use can be written for the consumer Pharma, 1997.

III. In Vivo and In Vitro Diagnostic Substances (SIC 2835) and Biological Products (SIC 2836)

The In Vivo and In Vitro Diagnostic Substances industry category (SIC 2835) includes facilities that manufacture in vivo (tested inside a living organism) and in vitro (tested outside of a living organism) diagnostic substances. They produce chemical, biological, and radioactive substances used in diagnosing and monitoring health. The Biological Products industry category (SIC 2836) produces bacterial and virus vaccines, toxoids, serums, plasmas, and other blood derivatives for human and veterinary use, other than in vitro and in vivo diagnostic substances OMB, 1987.15

2.8 Pharmaceutical Industry Structure

Despite a series of acquisitions in the past years, the number of companies in the industry is growing as increased partnering and outsourcing also enable new companies to partake in the development and manufacturing of pharmaceutical drugs (Hunt et al., 2011). Some of the principle organizations in the industry and their interrelations are illustrated in
Figure 1.1. The principal stages of pharmaceutical production are also illustrated. In the following, these organizations and processes are briefly described.

I. Pharmaceutical corporations

At the center of the industry are the large pharmaceutical corporations, who develop and manufacture pharmaceutical drugs. Developing a new drug is a long, expensive and uncertain process. Most drugs fail to ever reach the market as they do not perform as expected or show unfortunate side-effects. For preserving commercial continuity and to diversify the risk of the R&D projects, companies always have several different products in the pipeline in different stages of maturity. Managing these pipelines is an important strategic issue for the companies and pipeline planning has been developed to support companies in how to invest in different R&D projects.

Diagram 2.1 Overview over the pharmaceutical industry

The production of pharmaceutical drugs, as described in Bennett and Cole (2003), can be divided into two stages; primary and secondary production. Between the stages, inventories are found. Primary production refers to the production of the active pharmaceutical ingredient (API). Raw material is put through a series of chemical processes where liquids are pumped between different reactors, transforming the liquids
into the desired compounds. Secondary production consists of turning the API into a consumable drug in e.g. vial or pill form. Sometimes more complex drug delivery systems are used such as special syringes, inhalers or other devices. After this step the drug is packaged and labeled for the specific market where it is intended to be sold.

Production is subject to many strict requirements described in a series of guidelines called Good Manufacturing Practices (GMP) issued by the Food and Drug Administration (FDA), U.S. Food and Drug Administration, 2010. These requirements safeguard patients by putting high demands on quality and cleaning to avoid cross contamination in production. This can however also lead to setups in the order of weeks. To reduce the number of setups, long campaigns are used in which several batches of each product are produced in succession in primary production. It is not uncommon for an entire year’s demand to be produced in one campaign Grunow et al., 2003. With many different processing steps integrated in large networks, that produce many different products, production planning is very difficult and plans are not easy to change.

Secondary production has a shorter lead time than primary production. API production is usually managed independently of secondary production due to the high complexity. API inventory is used to buffer for any demand variations and act as a natural decoupling point. Secondary production is demand driven, whereas primary production is strictly make-to-stock.

II. Regulatory authorities

Governmental bodies regulate the industry within one or more countries and hence govern all companies as seen in Figure 1.1. The most influential regulatory body is the FDA in the US, but also the European Medicines Agency (EMA) is gaining more influence due to the centralization of regulatory tasks in the European Union. These authorities put up guidelines and regulations for how pharmaceutical companies should behave. Most noteworthy are the prescribed clinical trials, which re-quire companies to test their drugs on a sizable population in a controlled manner such that the efficacy of the drug can be proven and any possible side effects discovered.
To protect the public, the authorities also issue the GMP guidelines that govern how production should be handled in a clean, safe and controlled manner. To gain access to a market, the local authorities have to validate production before a drug can be sold in that market. Afterwards they will regularly perform inspections of production sites to ensure the guidelines are still followed. For every market, a possibly different authority gives the final market authorization after reimbursement levels, maximum price etc. have been negotiated.

III. Generic manufacturers

When the patent on a drug expires, generic manufacturers are quickly ready with cheap copies, which drive the price down. Hereafter the drug can be considered a commodity. Drugs that go off-patent are often transferred to the big pharmaceutical companies’ own generic divisions, so the pharmaceutical division can focus on new drugs. Generic manufacturers launch a high number of drugs every year, and much of the methodology that we develop here is also applicable for them.

IV. Pharmaceutical SMEs

Referring to small and medium sized enterprises [SME], this group of companies are normally only capable of either performing services for the large multi-national pharmaceutical companies such as offering e.g. pilot plant capacity for prototype batches or perform the first steps of drug development. The price of running the clinical trials are often so high that these companies have to partner up, when they have a drug ready for later stages of the clinical trials. Generally, different levels of partnering, outsourcing, mergers and acquisitions are found in the industry as all companies constantly try to balance their R&D pipeline of new potential drugs.

V. Contract manufacturers

This group of companies run production sites and sells their capacity to the pharmaceutical companies for a premium. This option of outsourcing some volumes or even entire processes, gives the pharmaceutical companies the flexibility they otherwise
lack in their rigid production systems. A comprehensive treatment of the interactions between these companies and coordination of their operations is presented in Boulaksil (2010). 16

2.9 Pharmaceutical Company Business Strategies

What’s the secret behind these successes? For one, the company operates in niche formulations (chronic) segments such as psychiatry, cardiovascular, gastroenterology and neurology. While most of the top Indian companies have focused on antibiotics and anti-infectives (acute), Sun Pharma focused on therapeutic areas such as depression, hypertension and cancer. The company has introduced the entire range of products and has gained leadership position in each of these areas. Being a specialty company insulates Sun Pharma from the industry growth. The first quarter results for FY02 explain this to some extent. While the industry was affected to a large extent by a slowdown in the domestic formulations market, Sun Pharma logged a growth of 26% in revenues. Over the years Sun has also used the strategy of acquisitions and mergers to grow quickly. It acquired Knoll Pharma’s bulk drug facility, Gujarat Lyka Organics, 51.5% in M. J. Pharma, merged Tamil Nadu Dadha Pharma & Milmet Labs and acquired Natco’s brands. Post Merger with Tamil Nadu Dadha Pharma the company gained presence in gynecology and oncology segments.

One of the constants of pharmaceutical company strategy over the past decade has been increasing scale. Only by growing larger are companies able to afford the considerable costs of drug development and distribution. Within this broad approach at least two business models are discernable:

(i) **Super Core Model** involving the search for, and distribution of a small number of drugs from Chronic Therapy Area that achieve substantial global sales. The success of this model depends on achieving large returns from a small number of drugs in order to pay for the high cost of the drug discovery and development process for a large number of patients. Total revenues are highly dependent on sales from a small number of drugs.
(ii) **Core Model** in which a larger number of drugs from Acute Therapy Area are marketed to big diversified markets. The advantage of this model is that its success is not dependant on sales of a small number of drugs.

(i) **Marketing approaches of Super Core Model**

In pharmaceutical market there has been a significant shift from Acute towards Chronic Therapy area. Chronic segments are driving the growth of the market as leading prescribers in these segments are specialists as opposed to general practitioners. This is evident from high growth rates achieved by firms like Sun Pharma, Dr. Reddy laboratories and Dabur Pharma Ltd. Who have focused on these segments during last five years pharma companies have started identifying the hidden potential of ontological market. A number of drugs have been launched into the ontological market by pharmaceutical companies, including new biological drugs and drugs that can be used as a support for patients undergoing cytotoxic chemotherapy. As a matter of fact, pharmaceutical companies are merging, and, through the merging process, the portfolio of the new companies changes.

Medical representatives are rearranged throughout the new companies. Some of the sales representatives are now afraid of losing their job, due to the changing scenario and the possible layoffs. On the other hand, the new, bigger, pharmaceutical companies are competing more and more with one another, and, in order to stress their products, might adopt a more aggressive sales strategy. For example, sometimes in the same geographical area there are five representatives for just one company, or different representatives for the same drug in different settings. As a result of the new, aggressive strategy, the aggressiveness of representatives has also been increasing, since the larger stress exerted by their companies might affect their stay in the company. Therefore, they tend to have more frequent visits to encourage doctors to prescribe drugs and thus increase sales.

In this model medical representatives are the key actors for example in a small oncology unit almost 40 sales representatives interacting with doctors, and most of them are coming for a visit on a regular once-a-month basis as this is the restriction put by doctors of meeting only once in a month that to on a fix time only, in order to stress the
usefulness of their products and push clinicians towards the use of their drugs. This means that, basically, there are at least two representatives every day in busy clinic asking for a ‘short’ meeting to support their product.

The pharmaceutical distribution channel is indirect with usually three channel members i.e. depot/C&F, stockiest and chemist. Pharmaceutical companies appoint one company depot or C&F agent usually in each state and authorized stockiest in each district across the country. Company depot/C&F sends stocks to authorize stockiest as per the requirement. Retail chemists buy medicines on daily or weekly basis from authorized stockiest as per demand. Patients visit chemists for buying medicines either prescribed by a doctor or advertised in the media. Here patient is end customer and doctor is direct customer for any pharmaceutical company. But for doctor customer is more important so he wants an effective supply chain management from prescribed company. And for pharmaceutical companies their customer that is doctor is more important that’s why they emphasize more on supply chain management. Moreover field force should have good product knowledge and USP of their products over other so as to convince doctors and PULL the demand for their products i.e. from Doctor to Retailer to Stockiest to CFA to company.¹⁷

Diagram no. 2.2 Pull Systems Working In Chronic Therapy Segment
In this system, doctors are the core customers and the major thrust is given to build and retain these customers because they are pulling the demand for products hence companies also give main emphasis in building and retaining these customers. For retaining and developing customers, the companies normally provide gifts like sponsorship for various conferences like RSSDI, FOGSI, APICON, UPCON etc. For example Dabur having PASS (Professional Academic and Scientific Services) activities for promoting its chronic therapy range. Also it is interesting to note that since this is a pull system demand is being pulled in to the market so generally representatives place product orders from their stockiest on the basis of following formula:

\[ \text{CLOSING STOCK} \times 2 - \text{OPENING STOCK} = \text{ORDER} \]

Normally there are absolutely no chances of dumping of goods at stockist and retailer level is yet reported also payment recovery of companies is also very good.

(ii) Marketing approaches of Core Model

In present scenario companies are focusing more and more on the availability of products so as to enjoy good image in their customer’s (doctors) chamber. Many companies such as Glaxo, Pfizer, Dabur, FDC, Aventies, Cipla etc. are known for their availability of products. For marketing of these types of products companies require more and more field force to remind their products on daily basis to their direct customer (doctor). Moreover field force should have good knowledge of product schemes and offers. Also field force is required to have a good rapport with retailers. Field force also required to ensure good availability of their products to convince doctors and PUSH their products i.e. from to Stockiest to Retailer to Doctor.

It has been observed that sometimes there are more than fifteen or sixteen representatives in a day are meeting with their customer and requesting for same type of products. Although field force visits are important for an update on drugs and their use. The doctors are, in general, sneaking away, trying to hide from sales representatives, since there are too many and they are too pushy and there is too little time, and the representatives
probably have noticed that the reluctant doctors have always less time for short meetings and less interest and tend to reduce the time of the visit.

The relationship between clinicians and representatives has always been good and pharmaceutical companies have provided, and still provide, the major economical support for customers' continuous medical education. Something needs to be done to find a solution to this problem that takes into account the needs of both pharmaceutical companies and their representatives on one side and physicians on the other, for a better professional interaction.

Diagram no. 2.3 Push Systems Working In Acute Therapy Segment

In this system, doctors and retailers are the core customers and the major thrust is given to build and retain these customers. Here retailers are also core customer as most of the times they are substituting the products based on their own discretion. For retaining and developing customers, the companies normally provide gifts like sponsorship for various conferences like small gifts & sponsorship to remind the products on daily basis. Also it is interesting to note that since this is a push system products are being pushed in to the
market so generally representatives place product orders from their stockiest on the basis of SKUs sold and schemes.

Normally the chances of dumping of goods at stockiest and retailer level are reported also payment recovery of companies is also not very good. Supply Chain Managers can provide considerable value to their companies by understanding the customers' delivery requirements. A very powerful tool for understanding these requirements is account segmentation. A company can use account segmentation to identify market segments such as Acute & Chronic therapy market. Which is well positioned to serve and then organize its product range and even SKU’s and service in a superior way.

Delivery and delivery chain-delivery can be defined as "how well the product or service is delivered to the consumer". Delivery is the final link in the chain of the total Logistics function; that is, it is the point where the logistic function finally meets the customer. The focus is on efficiency and effectiveness and it includes fleet routing, deciding on timing and locations of delivery, scheduling and vehicle planning, etc. 

2.10 Porter’s Competitive Forces

Porter's five forces analysis is a framework for the industry analysis and business strategy development developed by Michael E Porter of Harvard Business School in 1979. It uses concepts developed in Industrial Organization (IO) economics to derive five forces which determine the competitive intensity and therefore attractiveness of a market. Attractiveness in this context refers to the overall industry profitability.

Porter referred to these forces as the micro environment, to contrast it with the more general term macro environment. They consist of those forces close to a company that affect its ability to serve its customers and make a profit. A change in any of the forces normally requires a company to re-assess the marketplace. The overall industry attractiveness does not imply that every firm in the industry will return the same profitability. Firms are able to apply their core competences, business model or network to achieve a profit above the industry average. By applying unique business models have been able to make a return in excess of the industry average.
Diagram no.2.4: Porters Five Force analysis on Pharmaceutical Industry


i. Industry competition

Pharma industry is one of the most competitive industries in the country with as many as 10,000 different players fighting for the same pie. The rivalry in the industry can be gauged from the fact that the top player in the country has only 6% market share, and the top five players together have about 18% market share. Thus, the concentration ratio for this industry is very low. High growth prospects make it attractive for new players to enter in the industry. Another major factor that adds to the industry rivalry is the fact that the entry barriers to pharma industry are very low. The fixed cost requirement is low but the need for working capital is high. The fixed asset turnover, which is one of the gauges of fixed cost requirements, tells us that in bigger companies this ratio is in the range of 3.5 to 4 times. For smaller companies, it would be even higher. Many smaller players
that are focused on a particular region have a better hang of the distribution channel, making it easier to succeed, albeit in a limited way. An important fact is that pharma is a stable market and its growth rate generally tracks the economic growth of the country with some multiple. Though volume growth has been consistent over a period of time, value growth has not followed in tandem.

The product differentiation is one key factor, which gives competitive advantage to the firms in any industry. However, in pharma industry product differentiation is not possible since India has followed process patents, with laws favoring imitators. Consequently, product differentiation is not the driver, cost competitiveness is. However, companies like Pfizer and Glaxo Smith Kline Beecham have created big brands in over the years, which act as product differentiation tools. This will enhance over the long term, as product patents come into play from 2005.

**ii. Bargaining power of buyers**

The unique feature of pharma industry is that the end user of the product is different from the influencer read doctor. The consumer has no choice but to buy what the doctor says. However, when we look at the buyer's power, we look at the influence they have on the prices of the product. In pharma industry, the buyers are scattered and they as such do not wield much power in the pricing of the products. However, government with its policies plays an important role in regulating pricing through the NPPA (National Pharmaceutical Pricing Authority).

**iii. Bargaining power of suppliers**

The pharma industry depends upon several organic chemicals. The chemical industry is again very competitive and fragmented. The chemicals used in the pharma industry are largely a commodity. The suppliers have very low bargaining power and the companies in the pharma industry can switch from their suppliers without incurring a very high cost. However, what can happen is that the supplier can go for forward integration to become a pharma company. Companies like Orchid Chemicals and Sashun Chemicals were basically chemical companies, who turned themselves into pharmaceutical companies.
iv. Barriers to entry

Pharma industry is one of the most easily accessible industries for an entrepreneur in India. The capital requirement for the industry is very low; creating a regional distribution network is easy, since the point of sales is restricted in this industry in India. However, creating brand awareness and franchisee amongst doctors is the key for long-term survival. Also, quality regulations by the government may put some hindrance for establishing new manufacturing operations. Going forward, the impending new patent regime will raise the barriers to entry. But it is unlikely to discourage new entrants, as market for generics will be as huge.

v. Threat of substitutes

This is one of the great advantages of the pharma industry. Whatever happens, demand for pharma products continues and the industry thrives. One of the key reasons for high competitiveness in the industry is that as an ongoing concern, pharma industry seems to have an infinite future. However, in recent times, the advances made in the field of Biotechnology, can prove to be a threat to the synthetic pharma industry.20

2.11 Demand Drivers for the Pharma Industry

i. Accessibility

- Over US$200 billion to be spent on medical infrastructure in the next decade.
- New business models expected to penetrate tier 2 and 3 cities.
- Over 160,000 hospital beds expected to be added each year.

ii. Acceptability

- Rising levels of education to increase the acceptability of pharmaceuticals.
- Patients to show greater propensity to self medicate, boosting the OTC market.
- Acceptance of biologics and preventive medicines to rise.
- Vaccine market could grow 20% per year in the next decade.
iii. Affordability

- Rising income could usher 73 million households into the “middleclass segment” over the next ten years
- Over 650 million people expected to be covered by health insurance by 2020
- Government-sponsored programs expected to provide health benefits to over 380 million economically challenged people

iv. Epidemiological Factors

- Patient pool expected to increase over 20% in the next ten years mainly due to a rise in the population
- Newer diseases and changes in lifestyles to boost demand

2.12 Swot Analysis of Indian Pharma

i. Strengths

- Cost Competitiveness
- Low-cost, highly skilled set of English speaking labour force
- Growing treatment naïve patient population
- Diverse ecosystem
- Low cost of innovation, manufacturing and operations
- Low cost of skilled manpower and proven track record in design of high technology manufacturing devices.
- Good marketing and distribution system

ii. Weaknesses

- Stringent price controls
- Lack of data protection
- Poor all-round infrastructure is a major challenge
- Low investment in R&D
- Lack of coordination between the industry and academia
Stringent pricing regulations affecting the profitability of pharma companies. Presence of more unorganized players versus the organized ones, resulting in an increasingly competitive environment, characterized by stiff price competition.

### iii. Opportunities

- Global demand for generics rising
- Increased penetration in non-metro markets
- Significant investments from MNCs
- Prescription Drugs
- Online Drug Retailing
- Opening of the health insurance sector and increase in per capita income - the growth drivers for the pharmaceutical industry
- India, a potentially preferred global outsourcing hub for pharmaceutical products due to low cost of skilled labour.

### Iv. Threats

- Labor Shortage
- Spurious Drugs
- Wage inflation
- Competition from other emerging economies
- Product patent regime is a major threat to the domestic industry
- Other low-cost countries such as China and Israel affecting outsourcing demand for Indian pharmaceutical products
- Entry of foreign players (well equipped technology-based products) into the Indian market.\(^\text{21}\)

### 2.13 Scenario of Pharmaceutical Industry

The annual turnover of the Indian pharmaceutical industry is over 11 billion USD. Globally it ranks 4th in terms of volume with a share of 8% in the world pharmaceutical market. In terms of value, it ranks 14th. Key therapeutic segments of Indian
pharmaceutical industry include anti-infective, gastrointestinal and cardio-vascular. Acute therapies make up 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 also showing good performance in terms of exports. It is one of the top export items from India accounting for more than 4% of India’s total exports in 2006-07. Exports, which constitute around 50% of the industry’s total production, have grown at a CAGR of 14% in the last decade. Major export markets include highly regulated markets such as USA, Germany, UK and Canada. Europe is the biggest export destination for Indian pharmaceuticals accounting for more than 30% of the total exports, followed by the Americas 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), Indian Patents (Amendment) Act (2005), have played a major role in the growth of Indian pharmaceutical Industry. The Government has also formulated a Draft National Pharmaceutical Policy (2006), which will be finalized after consultation with the stakeholders. Besides, the Government has also facilitated the growth of the Indian pharmaceutical industry through institutional framework and encouraging investments in R&D.

India’s pharmaceutical industry currently comprises about 20,000 licensed companies employing approximately 5,00,000 staff. Besides many very small firms these also include internationally well-known companies such as Ranbaxy, Cipla or Dr. Reddy’s. With sales of roughly EUR 1 bn, Ranbaxy is currently the world’s seventh largest generics manufacturer. Currently the most important segment on the domestic market is anti-infectives; they account for one-quarter of total turnover. Next in line, and accounting for one-tenth each, are cardio-vascular preparations, cold remedies and painkillers. By contrast, medicines against civilization diseases such as diabetes, asthma and obesity or so-called lifestyle drugs anti-depressants, drugs to help smokers to quit and anti-wrinkle formulations are of little significance at present. All in all, the Indian pharmaceutical industry produces about 70,000 different drugs, which is higher than the number produced in Germany 60,000 Uwe Perlitz 2008. India gained its foothold on the global scene with its innovatively-engineered generic drugs and active pharmaceutical
ingredients (API), and it is now seeking to become a major player in outsourced clinical research as well as contract manufacturing and research.\textsuperscript{22}

### 2.14 Challenges to Pharmaceutical Industry

All of these changes are ultimately good for the Indian pharmaceutical industry, which suffered in the past from inadequate regulation and large quantities of spurious drugs. They force the industry to reach a level necessary for global competitiveness. However, they have also exposed some of the inadequacies in the industry today. Its main weakness is an underdeveloped new molecule discovery program. Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy's Laboratories spent only 5-10\% of their revenues on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This disparity is too great to be explained by cost differentials, and it comes when advances in genomics have made research equipment more expensive than ever. The drug discovery process is further hindered by a dearth of qualified molecular biologists. Due to the disconnect between curriculum and industry, pharmas in India also lack the academic collaboration that is crucial to drug development in the West (Dyer et al 2004).

It is expected to witness drugs sales rise by an annual 8\% to nearly EUR 20 bn between 2006 and 2015. To be sure, this growth rate is higher than that seen for Germany (+5\% p.a.) and the entire world (+6\%). Nonetheless, India’s share in world pharmaceutical sales will rise only marginally to a good 2\%. Growth of India’s pharmaceutical industry and thus its share in 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 even lose market share in Asia. Mainly affected by this development are smaller Indian companies with sales of up to EUR 10 mn which focus on traditional Indian medicines. It is likely that many of these companies will merge or disappear from the market altogether. By contrast, large pharmaceutical companies with sales volumes of over EUR 50 m will be able to increase their sales as they will be better equipped to adjust their product ranges to the demands of 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-sized businesses will benefit from increasing contract production for western firms.

Overall the share of pharmaceuticals in the total chemicals industry in India will come to roughly 17% in 2015 (2006: 18%), 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 population’s demand for drugs cannot be met by the country’s own production in all segments. At EUR 1.5 bn, India’s total drugs 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 the five largest manufacturers, while India will join the group of the ten largest suppliers.

- Growth in the domestic formulations market is slowing down and the domestic bulk drugs industry is facing intense competition due to cheap imports.
- Price wars between regional and local pharma companies are driving down prices, exerting pressure on margins and creating a downward spiral (Airline industry syndromel).
- Till today there is exists tremendous confusion in the grant of EMR (Exclusive Marketing Rights) due to lack of transparency in the process and regulations are getting more stringent and in some areas it is obscure, as with regenerative medicine and bio-similar.
- Multinational pharma companies are getting more aggressive in protecting their patents and defending their market share, even after patent expiry and are taking the generics and local brands head-on.
- Attracting and retaining talent and the ability to leverage technology remain key challenges for the industry.
- The support and infrastructure around the pharma industry still continues to be poor and several billions of dollars of investment is required in the warehousing and cold-storage logistics networks for medicines.\(^{23}\)
2.15 Economic Contribution of Pharmaceutical Industry

The global pharmaceuticals market grew rapidly in the 1990s and in the early 2000s, spurred primarily by market demand in North America and Europe. However, with impending patent expiries, declining R&D productivity, increasing regulatory and pricing pressures, growth in these markets have been slowing down. As a result, pharma companies are looking for new avenues of driving growth and ways to improve operational efficiencies. In this context, emerging markets represent a potential growth driver for the industry – its contribution to the growth of the global pharma market increased from eight per cent in 2003 to 40 percent in 2010. Consequently, global pharma MNCs have adopted prudent strategies to further expand their footprint in emerging markets such as Brazil, Russia, India and China.

1. Burgeoning Indian pharma industry

India is among the most significant emerging markets for the global pharma industry, given that it will feature among the world’s top 10 sales markets by 2020. Currently, it is regarded as one of the fastest-growing pharma industries globally, primarily driven by a large population, evolving patient demographics, increasing health care expenditure, growing urbanization, rising life expectancy, and active private-sector participation.

Table no. 2.1 Contribution of emerging markets to overall sales of key pharma MNCs

<table>
<thead>
<tr>
<th>Contribution of emerging markets to overall sales of key pharma MNCs (current and future estimates)</th>
<th>25%</th>
<th>33%</th>
<th>20%</th>
<th>20%</th>
<th>25%</th>
<th>25%</th>
<th>25%</th>
<th>10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>13%</td>
<td>10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pfizer</td>
<td>10%</td>
<td>20%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>10%</td>
<td>20%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSD</td>
<td>10%</td>
<td>10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>10%</td>
<td>20%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novartis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2. Domestic companies are transforming their business model to play a larger role in global pharma market

The Indian pharma industry has been able to claim a share in the global market by leveraging its strengths and enhancing its regulatory and technical maturity. Formulations manufactured in India constitute 20 per cent of the global generics market by value, and the overall share of Indian manufactured formulations is as high as 46 per cent in the generics segment in the emerging markets. However, with the onset of the patent regime, the traditional reverse engineering capabilities of Indian pharma companies are no longer helpful, as they would not be able to replicate the patented product and launch it in the domestic market. Hence, going forward, India would be required to leverage its strengths in supply of low cost medicines across the world and invest in newer areas to drive growth. Opportunities exist ranging from the low-value added segment, comprising of NDDS ($134 billion opportunity by 2013), super generics ($135 billion worth of product expiring between 2010 and 2015) and biosimilars ($115 billion worth of biologics expiring by 2015), to the high value New Chemical Entity (NCE) New Biopharmaceutical Entity segment. Thus, domestic companies can look forward to pursue all these opportunities and build capabilities to conduct drug discovery and in house development.

Table no. 2.2 Indian pharmaceutical market by 2020 (US $ billions)
3. **Pharma MNCs to continue active participation in India**

After years of anemic growth in the Indian pharma market until the 1990s mainly due to a feeble intellectual property environment pharma MNCs have recorded steroid-led growth in the domestic market. They have increased investments in the domestic market over the past few years and are now comfortably placed to capture a substantial share of the domestic market. Evidently, pharma MNCs are projected to capture a 35 per cent market share of the market by 2017, compared with 28 per cent in 2009. Over the years, pharma MNCs have adopted India-focused strategies to tap the growing potential of the country’s pharma market.

4. **Increased patented drug launched in India:**

The advent of the product patent regime in 2005 instilled confidence in the country’s IP regime. With renewed confidence, large pharma MNCs are now looking to launch their patented drugs in India and such product launches are expected to increase further in future.

5. **Adopting inorganic route to enhance presence:**

Pharma MNCs have been considering acquisitions of domestic players to gain sizeable share in the domestic market. These acquisitions have also enabled pharma MNCs to access the infrastructure, distribution networks, and management capabilities of domestic players, thereby strengthening their business operations in the country. On the other hand, licensing agreements with Indian companies have helped pharma MNCs access a ready basket of generic products. Going forward, these deals are likely to accelerate the launch of products in various emerging markets while offering MNCs the advantage of cost-effective manufacturing. Furthermore, pharma MNCs consider India as a preferred strategic outsourcing partner with services ranging from Contract Research Manufacturing (CRO) and clinical research services to sales and marketing, information technology, finance and accounting, and customer-relationship management.
6. Differential pricing strategy to strengthen market reaches:

In a bid to compete with domestic generic players, pharma MNCs are launching patent-protected drugs in India at relatively low price points than those in developed markets. Simultaneously, a differential pricing strategy is helping these MNCs to enhance their market reach by addressing affordability issues. Drugs such as Diovan (Novartis), Januvia (Merck Sharp & Dohme), and Galvus (Novartis) are being sold at discounts of up to 80 percent on global prices.

7. Rural-centric initiatives to enhance market access:

Robust consumption in the rural economy is expected to be a key growth driver. Rural India accounts for more than 70 percent of all Indian households and close to 40 percent of the total consumption pie. Henceforth, a large number of companies are organising their efforts to derive a major portion of their overall sales from this untapped market. Additionally, pharma MNCs are looking to implement new and effective business models in India and improve the health of patients. Delivering patient health outcomes implies getting involved in the cycle of care, rather than just delivering drugs to a health care system.

8. Merck’s Sparsh:

In 2009, Merck’s Indian subsidiary, MSD Pharmaceuticals, launched Sparsh, a multilingual helpline for diabetics on its drugs Januvia and Janumet to provide diet, exercise, and adherence advice.

9. J&J’s Mobile Health for Mothers:

In September 2010, Johnson & Johnson (J&J) launched a mobile health initiative for expectant mothers in India. Mobile Health for Mothers provides free text messages on prenatal care, appointment reminders and calls from health coaches.
10. Pfizer-ITC:

In July 2011, Pfizer collaborated with FMCG major ITC to enhance its product sales in the rural markets. According to the agreement, Pfizer will sell its over-the-counter products through ITC channels in rural areas. Such noble initiatives can be expected to help pharma MNCs further augment their brand awareness in the domestic market and help tap the segment’s growth potential.

11. Favorable demographics and changing disease patterns characterise increasing demand

India has witnessed rapid epidemiological transition as a consequence of economic and social change. Historically, acute disease segments have dominated the market, with the anti-infective sub-segment contributing a major share. However, with growing urbanisation, the disease profile of the Indian population has become increasingly skewed toward lifestyle-related ailments such as obesity, heart disease, stroke, cancer, diabetes and respiratory diseases. The number of people suffering from chronic diseases such as cancer, diabetes, neuropsychiatric conditions and cardiovascular disease is set to double...
in India by 2020. Thus, change in patient demographics will fuel demand for quality and affordable products in the domestic market.

12. Adequate government support to further boost the domestic market

In the last 10 years, the Government of India (GoI) has aggressively adopted prudent strategies to boost the country’s healthcare industry. From granting 100 per cent Foreign Direct Investment (FDI) in the drugs and pharma sector to establishing various pharma SEZs across the country, a range of initiatives have further strengthened the Indian pharma industry. Moreover, the GoI is providing incentives to encourage investment in the pharma sector.

In August 2010, the GoI announced its plans to set up a $639.56-million venture capital (VC) fund to give impetus to drug discovery and strengthen the country’s pharma infrastructure. Both domestic and MNC pharma players are expected to leverage these initiatives to expand their operations in the country.

The Department of Pharmaceuticals has prepared “Pharma Vision 2020,” aimed at making India one of the leading destinations for end-to-end drug discovery and innovation. It envisages meeting this objective by building top-notch infrastructure for talent and research, encouraging public-private partnership (PPP) models, offering financial incentives to encourage and incubate innovation and shaping a favourable regulatory environment. The GoI also aims to position India among the top five pharma innovation hubs by 2020, with one out of every five to 10 drug discovered worldwide by 2020 originating from the country.

The GoI’s long-term vision is to provide quality and affordable health care services to all classes of Indian society. Consequently, the GoI plans to cover at least 50 percent of the country’s population under health insurance by 2020, compared with the current average of 15 percent.
13. Expanding health care infrastructure and changing demographics to supplement growth

The Indian healthcare sector is forecast to reach $280 billion by 2020, contributing expected GDP expenditure of eight per cent by 2012, compared with 4.2 percent in 2009, according to a report by an industry body. Over the past two decades, India’s thriving economy has driven the need for urbanisation, thereby creating an expanding middle class with increased disposable income to spend on healthcare. Other key growth drivers for this sector include a growing population, the opening of new hospitals, growing lifestyle related health issues, less expensive treatment costs, the growth of medical tourism, improving health insurance penetration, government initiatives and enhanced focus on PPP models.

The overall growth of the Indian healthcare sector is likely to create a sizeable demand for quality and affordable medicines, thereby providing significant growth opportunities for both domestic and pharma MNCs.

14. In the sum

India’s pharma market has evolved and shifted gears to set foot on an accelerated growth path. In conclusion, as emerging markets become increasingly important and India’s role among these becomes progressively significant, both domestic and pharma MNCs will need to adapt their business models, organizations and processes and create customised strategies. Overall, active participation from domestic and international pharma companies, increased investments and strategic initiatives will likely underpin future growth and enable the Indian pharma market to break into the global top tier in the present decade.²⁴

2.16 Factors Influencing Growth of the Industry

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 product 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. Some of the major factors that would drive growth in the industry are as follows:

a) Increase in domestic demand:

More than half of India’s population does not have access to advanced medical services, as they usually depend on traditional medicine practices. However, with increase in awareness levels, rising per capita income, change in lifestyle due to urbanization and increase in literacy levels, demand for advanced medical treatment is expected to rise. Moreover, growth in the middle class population would further influence demand for pharmaceutical products.

b) Rise in outsourcing activities:

Increase in the outsourcing business to India would also drive growth of the Indian pharmaceutical industry. Some of the factors that are likely to influence clinical data management and bio-statistics markets in India in the near future include:

1) Cost efficient research vis-à-vis other countries
2) highly-skilled labour base
3) Cheaper cost of skilled labour
4) Presence in end-to-end solutions across the drug-development spectrum and
5) Robust growth in the IT industry.

c) Growth in healthcare financing products:

Development in the Indian financial industry has eased healthcare financing with introduction of products such as health insurance policy, life insurance policy and cashless claims. This has resulted in increase in healthcare spending, which in turn, has benefitted the pharmaceutical industry.
d) **Demand in the generics market:**

During 2008-2015, prescription drugs worth about US$ 300 bn are expected to go off patent, mostly from the US. Prior experience of Indian pharmaceutical companies in generic drugs would provide an edge to them.

e) **Demand from emerging segments:**

Some of the emerging segments such as contract research and development, bio pharma, clinical trials, bio-generics, medical tourism and pharma packaging are also expected to drive growth of the Indian pharmaceutical industry.²⁵

f) **Research and Development:**

Pharmaceutical companies spend billions on R&D each year. R&D for new medicines and treatments for a variety of disorders has become more complex and specialized. According to the Pharmaceutical Manufacturers Association (Pharma), a consortium of leading pharmaceutical companies, the industry's expenditures on R&D into new therapies totaled $67.4 billion in 2010. Many of these new compounds were biopharmaceuticals, 300 of which were approved by the FDA between 2000 and 2010. The ability of these companies to recoup their investments and turn a profit depends on how many therapies make it through the approval process, which can take up to a decade. According to the Cato Institute, the cost of drug development has skyrocketed by more than 400 percent in less than 20 years. The Office of Technology Assessment estimates the cost of developing a new drug averages $394 million. Drug companies must conduct on average 60 clinical trials of each new drug for marketing approval and dozens more to extend that approval to new indications. Afterward, they have only a few years of patent protection before competitor companies are allowed to manufacturer their products at a fraction of the cost.

h) **Government Regulation:**

The degree of government regulation of the pharmaceutical industry also determines profitability. Each successive federal government administration regulates the
pharmaceutical industry to a different degree. Some countries, such as Canada and Germany, have price controls, or caps, on pharmaceuticals sold in their borders. Also, the U.S. government and the FDA exert a great deal of control over pharmaceutical advertising and the "claims" of what a particular drug can and cannot do. Complying with the strictures of these regulating bodies costs pharmaceutical companies millions of dollars per year. According to the Cato Institute, 85 percent of the cost of pharmaceutical development goes to complying with FDA regulations, which amount to a tax on investing in biomedical research.

i) Consumer Demand:

During the past several decades, consumer demand for pharmaceuticals as maintenance therapy, as well as "lifestyle" drugs that enhance one's health and well-being, have grown tremendously. This increase is a major driver of industry growth. "Blockbuster" drugs such as Claritin, Viagra and Lipitor, have been heavily advertised, fueling consumer demand. According to Medical Marketing & Media, direct-to-consumer advertising spending reached a high point of $5.2 billion in 2006. Educated patients have driven the prescription-writing explosion in the doctor's office, driving sales of these drugs to the hundreds of millions of dollars. Also, tailored therapy is becoming a larger portion of pharmaceutical market share as genetic testing allows for new, highly targeted therapies for many conditions. As blockbuster brand-name drugs go off-patent, consumer demand for less expensive, generic versions is increasing.

j) Insurers and Managed Care:

In the United States, prices are set by a free-market system, although individual health care organizations e.g., Medicare, managed care companies have formularies that include tiered selections of therapies at different prices. Consumers rarely pay full price for prescription drugs, which most often are paid for by third-party insurers. Third-party payers are able to negotiate lower prices for drugs, thus depressing prices and lowering profit margins for drug companies.⁰
2.17 Major Risks to Indian Pharma Companies

1. Price control of drugs

Currently, MNC Pharma companies have higher exposure to price controlled products Namely Glaxo Smith Kline Pharma (GSK), Merck and Pfizer. The high exposure to the price controlled products has a direct impact on their EBIDTA margin.

2. Increasing scrutiny by US FDA

Increased scrutiny and stringency in norms by US FDA can be a deterrent to the planned Growth for Pharma companies. Warning letters, import alerts and bans may seriously Damage growth plans and also sentiment for the sector leading to value deduction loss of momentum.

3. Fluctuations in currencies

Indian pharma companies derive a considerable portion of their revenues from the overseas market and hence have high exposure to foreign currencies. Hence, the companies have resorted to the hedging of currencies to minimize the risk but face stringent limits under laws don‘t want to get classified as currency arbitragers.

4. Elongated approval timings

Longer average approval timings for the ANDAs (Abbreviated New Drug Application).

5. Attrition is the biggest challenge

For the domestic Pharma industry attrition is a big challenge. The top talent of the Pharma industry is becoming more mobile moving between industries such as FMCG, Insurance, Banking and IT. Major attrition over 20% takes place among the Medical Representatives, who move for higher studies or to BPO/KPOs.

6. Risk from at-risk launches

At risk launches generally tend to bode well for companies and stock prices, but in two
instances in the past (Sun Pharma: Protonix and Glenmark‘s: Tarka) courts in the US have ruled against the Indian companies. Liabilities arising out of this can hurt cash flows as well as valuations

7. Policy reforms

Policy changes by the Government of India could curtail some of the existing incentives for the players in the industry like the DEPB scheme, SEZs, Mauritius tax treaty advantages etc.

8. Counterfeit drugs

Counterfeit drugs are likely to pose a big threat to the global Pharma companies. Counterfeit drugs do not have active ingredients placebos or have lower amounts of active ingredients resulting in longer treatments with no recovery.

Conclusion

As a conclusion Pharmaceutical industry contributes to the welfare of humanity and provides significant socio-economic benefits to the society through creation of jobs, supply chains and community development. The industry also plays an important role in technological innovation, which may reduce costs of economic activity elsewhere in the economy. IPI is one of the world’s largest and most developed, ranking fourth in terms of volume and thirteenth in terms of value. The country accounts for an estimated 10% of global production and 2% of world markets in pharmaceuticals. It has over the years made significant progress in infrastructure development, technical capability and hence produced a wide range of pharmaceutical products. The industry now produces bulk drugs under all major therapeutic groups. It has a sizable technically skilled manpower with prowess in process development and downstream processing. It has the capital investment of about US$4.1billion. It produced bulk drugs of value of US$3.5 billion and formulations worth US$15.4billion in 2008. Bulk drugs have grown at a rate of approximately 14%, and formulation by 24% in the nineties. There is an increasing interest and investment in R&D. It provides employments 29 million people. The contribution of pharmaceutical sector in India’s GDP is 2% and 12% of manufacturing
sector GDP. Presently, 70% of requirement of the country in bulk drugs and almost all the demands for formulations are met by the domestic industry. In addition to catering to the needs of the domestic demand it is also the leading supplier of bulk drugs and cheap formulations to the world and engaged in contract manufacturing contract research, clinical trials, contracts R&D. Huge population with a large growing middle class, low cost of production but high quality standard and existence of good infrastructure are the main strengths of Indian pharmaceutical. China is being touted as the biggest threat to the IPI, but large opportunities exist for Indian companies internationally as many Indian drug manufacturing facilities conform to international quality certificates like USFDA, UK MCA.
Reference

5. http://www.pfizer.com/about/history/history.jsp
8. See Today’s Online Textbook of Bacteriology.


19. Fabian Dalken, Are Porter’s Five Competitive Forces still Applicable? A Critical Examination concerning the Relevance for Today’s Business, University of Twente P.O. Box 217, 7500AE Enschede The Netherlands


21. GATT came into existence in 1948 with 23 countries as founding members. Later, more than 100 countries joined in. GATT was the only multilateral instrument governing international trade from 1948 until 1995, when the WTO was established.


