CHAPTER -1
INTRODUCTION TO INDIAN PHARMACEUTICAL INDUSTRY

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1.1 Introduction

The Indian pharmaceutical industry holds the top most position among all science based industry with a wide range of technicalities in the complex field of drug manufacturing and drug innovations. The Indian pharmaceutical industry stands fourth in terms of volume and attains the fourteen in terms of value. Export of Indian pharmaceutical industry works as a fuel for the growth of the industry. The Indian pharmaceutical industry is exporting in almost all developed countries and facing the severe competition and government price control regulations.

In the last two decades, Indian pharmaceutical industry has expanded significantly. It has more than 250 larger units that rules over the 70 % of the market and rest 30% of the market taken by top ten companies. The Indian pharmaceutical industry produces around 400 bulk drugs and out of this, 300 bulk drugs are produced domestically. It is a highly fragmented industry consisting of more than 20,000 registered units and around 8,000 small scale units; and forms the
overall pharmaceutical industry.\textsuperscript{1} Indian industry satisfies the entire demand of the country with low cost of production, low R&D costs and equipped with skilled manpower and excellent & world class national laboratories specialized in cost effective technologies. The Indian drug industry is producing generic drugs with efficient and cost effective methods, especially the drugs which are about to expire their patents in the coming few years. Now days, India has become an excellent centre for clinical trials because it is having a wide diversity in the population.

1.2 \textbf{Key Characteristics of the Indian Pharmaceutical Industry}

The Indian Pharmaceutical industry stands fourth in the world. This industry is considered as a technologically strong & totally self-reliant and has a low cost of production, low R&D costs, and skilled manpower. Indian industry is able to produce a simple headache pill to sophisticated antibiotics & complex cardiac compounds domestically. These silent features added an advantage in the Indian pharmaceutical sector. And these features are as follows:
1.2.1 Persuasive in Matching the Nation's Need

The Indian pharmaceutical sector has come into existence after so many decades. Indian pharmaceutical industry was not in existence in the year of 1970 but in present times, the Indian drug industry is leading in the healthcare sector and fulfils almost 95 percent of the country’s pharmaceutical needs. During the independence, Indian pharmaceutical market was dominated by western MNC’s that controlled the core market through the process of import. At that time, 99 percent of the products were patented and sold by foreign companies, whereas domestic drug price were highest among all countries of the world. During the 1970’s, Indian market were import dependent until the
government has taken initiatives by stressing policies for making the Indian self reliance by domestic production of drugs. At that time, the government of India funded 5 state owned pharmaceutical companies to facilitate the local production. But today, Indian pharmaceutical Industry is a leading pharmaceutical industry.

The Indian pharmaceutical industry is touching the heights of the sky using value chain of various drugs. Now domestic market is moving towards the research driven, export oriented scenario and providing a wide range of value added quality services and products, innovation; and broaden its market reach. Indian companies are putting their best efforts to trap the highly regulated generic market of developing countries. Still the market of the United States is one of the most fascinating destinations for Indian companies due to its market size and going to best selling drugs which are going off patent.

1.2.2 Sustainable Development of Drugs

The Indian pharmaceutical industry is playing a vital role in the sustainable development of essential drugs, also facilitating the quality production of drugs in India. Leading International companies are associating and assisting Indian pharmaceutical industry in this dynamic world and helping out to put India on the pharmaceutical map of the
world. India is emerging as the favourite destination for research and development, bioinformatics, contract research and manufacturing & clinical trial. It is growing by a compound annual growth rate of 15 % from last 15 years and having huge growth opportunities. Hence, India has become unique market and fascinating destination for international organisations.\(^4\)

1.2.3 Production of High Quality Drugs

India is leading the world in producing high quality generic medicines that are sold around the world. There are so many factors that added inputs to the growth of the Indian drug market like continuously growing population, improving healthcare infrastructure, increased incomes, increased health insurance, increased number of product patents.\(^5\) Along with the domestic factors, foreign countries also playing a vital role in the growth of Indian pharmaceutical industry like- aging population of the US, Europe and Japan, continuously increasing prices of drugs in the above mentioned countries. All these factors are becoming the centre of attraction of MNC’s for investment in the pharmaceutical sector. Already 15 out of 20 largest pharmaceutical companies exist in India.\(^6\) Since 2000 to 2014, pharmaceutical and drug sector has fetched one of the highest foreign direct investment (FDI)
inflows of approximately 13 million US $. Most of the Indian pharmaceutical organisations are maintaining the highest standards in context of purity, stability and international safety, health and environment (SHE) protection in terms of production and supply of bulk drugs. These facts itself speak the high quality standards of Indian Pharmaceutical companies across the world.

1.2.4 Experience and Expertise

Outside the USA, India is the only nation who has the maximum number of US-FDA approved plants and that is more than 100. Other than US-FDA plans, India has 793 WHO-GMP approved plants, 153 EDQM (European Directorate Quality Medicines) approved plants with modern technology. No other country in the world is having such kind of infrastructure. Indian drug industry is a mature industry with decades of experience in manufacturing the generic drugs and meeting the nation’s need. Indian drug companies are known for making high quality drugs with cost effective manner.

1.2.5 Low Cost of Manufacturing

India is capable to produce high number of generic alternatives due to various economic factors favouring the industry. These factors
consist with availability of low cost labour, low cost of resources like water, electricity, lower cost of manufacturing equipments & machinery.

### 1.2.6 Proficient Research and Development

Indian government is taking sincere efforts for strengthening the research and development in drug manufacturing sector by providing the fiscal incentives to R&D units and stimulating the procedures for clinical trials, development of new drugs and discovery of new molecules. A large scientific pool in India is devoted to research and development for manufacturing of drugs with non-infringing techniques.
• Indian pharmaceutical sector accounts for about 1.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms

• The country’s pharmaceutical industry is expected to expand at a CAGR of 23.9 per cent over in year 2020 to reach USD55 billion

• Manufacturing costs in India are approximately 35-40 per cent of those in the US due to low installation and manufacturing costs

• The generic market is expected to grow from USD11.3 billion in 2010 to USD31.1 billion by 2020; India’s generic market has immense potential for growth

• Attracted 5 per cent of the total FDIs into India from 2000 to Year 2014
• Cumulative FDI inflows worth USD11.6 billion from April 2000 to year 2014

• It is a prominent provider of the healthcare products and satisfy almost 95 percent of the country’s pharmaceutical needs

Figure No. 1.2: Overview of Indian Pharmaceutical Industry
1.3 Indian Pharmaceutical Sector: From Nascent Stage to Maturity

The evolution of the Indian Drug Industry could be divided into four different aeons. The first phase is from 1850 to 1945. The second aeon is from 1945 to late 1970s. The third epoch is from early 1980s to the early 1990s and the last phase is from the early 1990s to the present time. Broadly, the stages of pharmaceutical evolution can be divided into 2 phases, namely:

**Figure No. 1.3: Indian Pharmaceutical Sector: From Nascent Stage to Maturity**

Indian Patent Act
- passed in year 1970
- Several domestic companies start operations
- Development of production infrastructure
- Export initiatives increased

- Liberalised market
- Indian companies increasingly launch operations in foreign countries
- India become major destination for manufacturing generic drugs

- Approval of Patents (Amendment) Act 2005, which led to adoption of product patents in India
- Increased patent filings by pharma players
- Leading pharma companies have increased their R&D spending on new cost-effective generic products to strengthen their presence across global markets

Market was dominated by foreign companies, with very less domestic participation
1.3.1 Pre-Independence Scenario

During the British Rule, the indigenous forms of drugs were in use viz- Ayurvedic or Unani in India. British Government first introduced the allopathic form of drug in the country. At that time, there were no productions units in the country. Instead, MNC’s were used to export the raw material from India and again imported the finished product into the country. After putting sincere efforts by the indigenous entrepreneurs towards manufacturing of drugs, India became able to manufacture the drugs. Although the production of the country was very low and hardly satisfied the 13% need of the country. The drug industry, however, move forward during the Second World War due to the decreased supply of drugs from multinational companies and many more Indian companies like Unichem, Chemo Pharma, Zandu Pharmaceutical, Calcutta Chemicals, Standard Chemicals, Chemical Industrial and Pharmaceutical Laboratories (now known as Cipla), East India Pharmaceutical Works and others were established. With the establishment of new firms in the market, the production of medicines increased robustly and domestic firms were able to satisfy the country’s
need up to 70%. During this era, all the companies whether domestic or MNCs were involved in the manufacturing of drugs and the significance of R&D was unknown. New inventions were done only by individual efforts of scientists not by the firms.\(^9\)

1.3.2 Post-Independence Scenario

The phase of the post - independence scenario can be divided into three different phases and these are:

1.3.2.1 Phase 1 (1945- Late 1970s)

In the early years after the independence of the Indian country, only MNC’s were allowed to export drugs in other countries worldwide, especially low-priced generics and few high priced medicines. After the pressure given by the Indian government against the import of medicines, MNCs started to establish their production units in India. In the early 1960s, the Indian government encouraged the indigenous manufacturers for the production of drugs. In the following decades, the Indian patent act has established for the prevention of food and healthcare products. Initially, only process patents were given to substances in the same sector from the five years of granting the patents and 7 years after filing the patent. In the same period drug price control order (DPCO) were introduced during the same period to prevent over
pricing of drugs. MNCs were forced by the government to reduce their holding up to 40% in India.

1.3.2.2 Phase 2 (Early 1980s-Early 1990s)

Up to 1970s, Indian pharmaceutical market was supplied by international organisations. Only bulk drugs were produced by domestic producers, these manufacturers were funded by state owned companies and World Health Organization (WHO). After that, Indian government has introduced some practices to reduce the import dependence for their pharmaceuticals. Domestic manufacturers started their productions by copying the drugs produced by the foreign producers. This approach became more effective way of development of drugs without investing a huge sum for research initiatives. 80% of the drugs were sold to the US and European market, which benefited the Indian companies due to the higher purchasing power of the population.\textsuperscript{10} On the contrary side, traditional sales markets like Russia, Southeast Asia was losing their importance in the pharmaceutical market. In 1980-1990s, Indian pharmaceutical industry has the boom phase and as a result, more than 75% MNC’s holding decreased up to 35% holdings in India.\textsuperscript{11}
1.3.2.3 Phase 3 (Late 1990s – Present)

India is having market of 9.4 billion US$ and growing at the rate of 14 % per year. It is one of the largest and most advanced countries, among the developing countries. Indian pharmaceutical has reached the market size of US $16.4 billion at the end of 2013\textsuperscript{12}. Growth of the Indian pharmaceutical industry has begun with the signing of general agreement on tariffs and trade in 2005. This action has come up with recognition of India in the global world of patent. In current times, India has become favourite destination and attracting global investors. Indian pharmaceutical sector, drug market, biotech sector witnessed the extraordinary growth in mergers and acquisitions (M&A) worth US $2000 million during the 1990’s. An enormous number of multinationals are entering into the pharmaceutical sector. Domestic companies establishing their production plant in foreign countries and with the help of these strategies, they are expanding their business all over the world. Now days, India is leading the world in context of producing and supplying generic drugs all over the world. One fifth of the global generic market is grabbed by Indian producers.
1.4 Dimensions of Pharmaceutical Industry

The pharmaceutical industry produces and supplies the drugs in the market for curing the diseases. Drug companies deal in the both generic and branded medicines. Drug companies deal in the both generic and branded medicines. The drug industry is having the several laws and regulations related to the patenting, testing & marketing of drugs. The aim of the pharmaceutical industry is to develop, research and distribution of drugs in order to create a healthy society. The pharmaceutical industry is very much dependent upon the developments and discoveries of molecules in order to search new medicines. Drug discoveries and drug innovations are the two aspects of the pharmaceutical industry.\(^\text{13}\)

1.4.1 Drug Discovery

Drug discovery is a process through which innovative potential molecules/drugs are discovered. Traditionally, the most of the drugs were invented by isolating the active component from the remedies which are traditional in nature or through another kind of discovery commonly known as serendipitous discovery.
1.4.2 Drug Development

Drug development is a process, which is taken forward after the drug discovery is done, and a thing is identified as a potential drug. Development takes place just after the component is turned into the medicine. It has a great importance in the drug industry.

Figure No. 1.4: Dimensions of Drug Industry

1.5 Key Drivers of Pharmaceutical Industry

1.5.1 Research & Development

The Indian drug industry is a highly fragmented market, which is constituted with 250 large and around 20,000 mid-sized and small sized companies. It is a successful and high tech industry that is witness of consistent growth over that past few decades. Research and development is the key to success of the pharmaceutical industry. In no
other industry, R&D is as critical as in the pharmaceutical industry. In the field of research and development (R&D) India ranks eighth position globally with expenditure of 30 billion US $. United States top the list of maximum R&D expenditure on drugs whereas, the India is also have the leading position for the same against so many countries like China, Japan, Germany and South Korea. Investments in biotechnology, clinical trials and contract research activities are playing the vital role in the growth of the Indian drug industry. The R&D expenditure of top 30 companies, with R&D spending above Rs 30 cores in the year 2013, increased the amount of Rs. 5000 crore as compared to last year. The Indian companies also have set up their subsidiaries in the developed nations like US, Europe and Japan that boost up the production as well as the turnover.

1.5.2 Domestic Demand

More than 90 per cent of the formulations produced and sold in the domestic market. India is a largely self-sufficient country, in case of formulations. Some life saving drugs, new generation under-patent formulations continue to be imported, especially by MNCs which are marketed in India. The size of the domestic formulation market is around Rs160 billion and it is growing at 10 per cent per annum.$^{14}$
1.5.3 Increasing Incomes & Health Care Spending

The total expenditure on healthcare products and services in India has reached the level of CAGR of 14% since 2000 due to the continually increasing income levels, shifting diseases and health care reforms. It is expected to increase the per capita income from US$ 463 in 2005 to US $ 765 in 2015. Hence, the pharmaceutical sector will witness the highest growth rate in health care spending in the year 2015.

1.5.4 Expiring Patents as an Opportunity for Domestic Generic Companies

A massive number of patents will expire in the US and Europe over the year of 2011-2020, including the top selling brands. This fact will decrease the sale more than US$ 80 billion in the patented market solely and on the other side of the coin, it will provoke the growth of the generic drug market. This disadvantage of the developed countries will become the opportunity for the other countries like India. It is estimated that Indian companies would make the new market with the worth of 18 billion US $.

1.5.5 Emerging Markets

The Pharma sector considered as an emerging markets in developing countries, including the BRIC countries, South Africa, Mexico, Turkey, Poland, Indonesia and Romania. IMS (Market research firm) shows that “Pharrmerging” market has been increasing its share by
16% (2009) to 25 % (2015). The Indian generic market is replicating its success in different countries of the world like Russia, Brazil and Mexico which are branded in nature.

1.5.6 M & A: Potential Catalyst

With higher growth prospects in emerging markets, many multinational branded drug companies are trying to expand their presence in generic pharmaceuticals. This action has increased their interest in generic companies with an established product portfolio and sales/distribution network in emerging countries including India. In India, this sector is 100 percent open for FDI since the year 2001, encountered various numbers of series of takeovers between 2005- 2015 viz. Ranbaxy by Dai-Ichi, Shanta Biotech’s by Sanofi Aventis, Piramal Healthcare by Abbott Laboratories, merger of Sun Pharma and Ranbaxy. In the coming time, India will have the largest number of mergers and acquisitions (M&A’s) in the pharma and healthcare sector. The foreign acquisitions of Indian drug companies will enable domestic companies to gain a grip on the western regulated markets, to diversify their portfolio, to acquire recognized brands and strengthen the R&D capabilities. Apart from the acquisitions, they have also been targeting the growth opportunities through in-licensing deals with domestic generic players, both for domestic as well other emerging market competitors.
1.6 Mechanism of Pharmaceutical Sector

Figure No. 1.5: Mechanism of Pharmaceutical Sector
Pharmaceutical Industry is research driven industry with the major concern for drug discovery and production of innovative drugs. Research, Labour and Chemicals are the basic inputs for the production of drugs. The pharmaceutical industry is producing Active Pharmaceutical Ingredients (APIs) and Formulations through Research and Manufacturing services. Finally the finished product is manufactured and distributed by the government & private health care institutions among end users.

1.7 Classification of Pharmaceuticals

The three main drug categories are patented medicines, generic medicines, and OTC medicines.

![Classification of Pharmaceuticals](image)

**Figure No. 1.6: Classification of Pharmaceuticals**
(Source: Mckinsey Report)
1.7.1 Patented Medicines

Patent give the monopoly rights to the manufacturer. These rights affect the prices of the drug, but these powers cannot be eliminated, as these interfere with the price regulations made by the states, nations and other regulating authorities. For example, government forming a monopsony to purchase drugs on behalf of all residents, issuing a compulsory license to another producer or using policy instruments like restrictions on pharmaceutical company profits.

The market also limits the monopolist’s price structure. The potential profits from a monopolist’s attract the competitors to produce the similar drugs of same therapeutic results because the patents are granted for the chemical composition not for the drug. The entry of competitive products restricts the price-setting power of the monopolist. In the United States, competing drugs are estimated to enter into the market between one to six years after the original medicine introduced in the market.\(^{16}\) When a large number of competitive products enter into a specific segment, it satisfies the clinical needs and it creates genuine price competition; and drugs come into the “Me too Competition”. Although a degree of competition is desirable, the development and aggressive marketing of patented me-too drugs consumes
pharmaceutical budget and divert the resources as well. Whereas, from the societal point of view, it is questionable that the incremental benefits from the me-too drugs are that worthy?

1.7.2 Generic Medicines

When the patent expires, generic medicines are allowed to enter into the market. Absence of patent protection of drugs, motivate the companies to enter into the generic market because generic companies do not bear the high cost of research and development. Reduced R&D cost attracts the firms that ultimately increase the competition. However, expiration of patent doesn’t mean that it has removed all the entry barriers of the manufacturer. An originator company develops a significant marketing leverage while protected by the patent, which must be overcome by new generic drugs. Consumers are not always aware with all generic drugs, they are persuaded by promotional advertisement to purchase the specific brand, or sometimes consumers consider as inferior or of poor quality. Absence of patent protection encourages the entry of generic medicines but strict regulation of drugs has been associated with a lower penetration of generic medicines into the market, because reduced profitability keeps generic firms protected from covering the costs of market entry.
1.7.3 Over the Counter Medicines (OTC)

Those drugs which are safe and effective for use by the general public without a prescription are defined as Over the Counter (OTC) drugs. These drugs can be sold directly to the consumers, unlike the prescription drugs which compulsorily required a prescription from a doctor. These OTC drugs have various attributes like:

- There is a low chance for misuse and abuse
- The benefits of these drugs outweigh the risks
- A Consumer could use them for self diagnosed health conditions
- These are appropriately labeled
- There is no additional need of health professionals for the safe and effective use of the product

1.8 Therapeutic Categorization of Drugs

![Figure No. 1.7: Classification of Drugs by Therapeutic Category](Source IMS, Cygnus research)
Drugs are classified into different groups according to their chemical characteristics, structure and how the drug treats the specific disease. There are numerous therapeutic categories of drugs. The major categories are as follows:

1.8.1 Anti-infective

Anti-infectives are those drugs which either kill anti-infectious agents or prohibit from spreading. Anti-infective include antibacterial, antifungal, antiviral and antiprotozoans. Anti-infectives have scored the highest place in the classification that is 17 per cent.

1.8.2 Gastro-Intestinal

Gastrointestinal issues include nausea, diarrhea, or ulcer. Gastrointestinal category further divided into few categories that are Anticholinergics, Antidiarrheals, Antiemetics, Antiulcer Medications. This category got the success to have the 11 per cent in the classification.

1.8.3 Antibiotics

Antibiotics are used to treat an ample variety of bacterial infections. Antibiotics inhibit the growth of bacteria by interfering with the production of certain biochemical, which is compulsory for
sustaining the bacteria’s life. This course of action supports the body to defend from bacterial growth and take very less time in eliminating the infection. This category has the largest share among the rest ones.

1.8.4 Analgesics

The analgesic category also called as ‘Pain Killer’ category. All members of this category are used to achieve analgesia- relief from the pain. The word ‘Analgesic’ is a Greek word which means without pain. Analgesic drugs act in various ways on the peripheral or central nervous systems. Analgesics include paracetamol, the non-steroid, anti-inflammatory drugs. Analgesic category attains the fourth position in the same classification. This category is one of the common classes.

The researcher has chosen this category for the research purpose through convenience sampling. Reason of selecting this category is that one could easily get the large number of patients of this category. Another reason for selecting the same category is that the drugs of analgesic category are easily available at almost each and every drug store.
This study used four most common and popular drugs of analgesic category for the research purpose on the basis of the Musician Study (2012).\textsuperscript{19} The names of the drugs are as follows:

**Figure No. 1.8: List of Selected Drugs for the Research Purpose**

### 1.9 Major Players in the Pharmaceuticals Industry

Competition is mainly from the domestic manufacturers and imports from China because of the low manufacturing cost. With the entrance of patent regulations, industry faces a major structural shift towards foreign pharmaceutical manufacturers. There are five government-owned central companies the Indian public sector.
1.9.1 Major Pharmaceutical Public Sector Undertakings

- Indian Drugs & Pharmaceuticals Limited (IDPL)
- Hindustan Antibiotics Limited (HAL)
- Bengal Chemicals & Pharmaceuticals Limited (BCPL)
- Rajasthan Drugs and Pharmaceuticals Limited (RDPL)
- Karnataka Antibiotics & Pharmaceuticals Limited (KAPL)

This study is based on two public sector undertakings. These companies were selected through convenience sampling while considering the fact that these two companies are consistently profit making and also deals in analgesic category. Companies are namely:

- Bengal Chemicals & Pharmaceuticals Limited (BCPL)
- Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)
1.9.2 Top 10 Private Sector Companies (On the basis of Net Sales) in India

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name of The Company</th>
<th>Net Sales (Rs Crore)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Dr Reddys Laboratories</td>
<td>9,728.00</td>
</tr>
<tr>
<td>2.</td>
<td>Cipla</td>
<td>9,380.29</td>
</tr>
<tr>
<td>3.</td>
<td>Lupin</td>
<td>8,939.38</td>
</tr>
<tr>
<td>4.</td>
<td>Aurobindo Pharma</td>
<td>7,110.71</td>
</tr>
<tr>
<td>5.</td>
<td>Cadila Health Care</td>
<td>4,042.10</td>
</tr>
<tr>
<td>6.</td>
<td>Ranbaxy</td>
<td>3,672.79</td>
</tr>
<tr>
<td>7.</td>
<td>Torrent Pharma</td>
<td>3,364.87</td>
</tr>
<tr>
<td>8.</td>
<td>IPCA</td>
<td>3,234.82</td>
</tr>
<tr>
<td>9.</td>
<td>Sun Pharma</td>
<td>2,828.79</td>
</tr>
<tr>
<td>10.</td>
<td>GlaxoSmithKline</td>
<td>2,546.15</td>
</tr>
</tbody>
</table>

Table No. 1.1: Top 10 Private Sector Companies-On the Basis of Net Sales (Source: BSE India)

The researcher has chosen these top ten private companies as the sample of private sector units.

1.10 Regulatory Framework of Indian Pharmaceutical Industry

Under the current Indian legal and regulatory regime, production, sale, import, export and clinical research on drugs and is governed by the following laws:

1. The Drug and Cosmetics Act, 1940
2. The Pharmacy Act, 1948
3. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

4. The Narcotic Drugs and Psychotropic Substances Act, 1985

5. The Medical and Toilet Preparations (Excise duties) Act, 1956

6. The Drugs (price control) Order 1995 (under the Essential Commodities) Act²⁰

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![Diagram](image.png)

**Figure No. 1.10: Regulatory Framework of Indian Drug Industry**
1.10.1 The laws and Regulations which affect the Pricing Practices of Drugs are as follows:

1.10.1.1 The Drugs Price Control Order (DPCO), 1995

This is an order issued by central government to regulate the prices of essential drugs under the Essential Commodities Act, 1995. The order provides the prices of essential drugs and also provides the procedure for fixation of prices of drugs. For implementing the provisions of DPCO, central government has given the authority to the National Pharmaceutical Pricing Authority (NPPA).

1.10.1.2 Essential Commodities Act, 1955

The essential commodities act is an act of parliament of India, which was enacted for ensuring the delivery of certain commodities or products, the supply of these products are misused due to black-marketing or hoarding practices. The essential commodities include:

- Food Stuff
- Drugs
- Fuel (Petroleum Products)

This is an act for controlling production, supply and distribution of essential commodities in the interest of the general public. For preventing the black-marketing and maintenance of supply, Essential
Commodities Act, 1980 is being enacted by the state governments. This enactment of the act empowers the state governments and central governments to detain any person who is involved in these activities. The central government and the state governments have the power to revoke the detention orders.


Intellectual property is the creation of the mind. Hence it is a different kind of property that is intangible, so required a different kind of protection. Intellectual property is the body of law which protects the creative invention of the person who has disclosed the creative invention of the benefits for the mankind from those who can copy or imitate the idea.

Patent is a grant from the government for the limited span of time for manufacturing, selling and marketing the product, for which a patent is granted. Patent Act, 1970 and amendments act 2005 protects the product of the creative mind. This is a grant for 20 years. This act ensures that drug should be available at reasonable price to the consumers. There are also some provisions to meet the public health emergency. Revocation of patent for the public interest is also on the security side.
1.10.1.4 National pricing Policy, 2012

Cost-based pricing is complicated
- Market-based pricing is expected to create greater transparency in pricing
- Prices of NLEM drugs linked to WPI

Essentiality of drugs is determined by including the drug in National List of Essential Medicines (NLEM) (348 drugs at present)
- Promote rational use of medicines based on cost, safety and efficacy

Only finished medicines are to be considered essential which would prevent price control of APIs

Figure No. 1.11: National Pricing Policy, 2012

1.11 Challenges and Opportunities of the Indian Pharmaceutical Industry

1.11.1 Opportunities

A patent is granted to unique invention that is novel, not common and useful too. Indian pharmaceutical industry has an opportunity to become a part of the international patent community for having the patents. A patent is granted to new molecules, new medical invention, or existing molecule which is produced with the modification in the
existing process, this service encourages manufacturers to invent new drugs or medicines.

Low manufacturing costs and process skills are the strongest assets of the Indian pharmaceutical industry and India can do well by utilizing this important opportunity. The Indian industry is having a high quality infrastructure which motivates the industry to merge with international organizations. Mergers will enhance their effectiveness by the huge amount of fund, and efficient number of resources to manufacture and formulations of bulk drugs at a large scale; and would shrink the cost of manufacturing. This would help to make bulk drugs and formulations of these drugs with cost effective and competitive techniques in the world market. Focused R&D and the development of clinical trials centers in India would allow the Indian drug industry to discover new drugs for curing crucial diseases.

1.11.1.1 Benefits to India from Modernizing the Indian Pharmaceutical Industry

Indian pharmaceutical industry is in the marathon of new discoveries of drugs. With the modernizing of Indian Pharmaceutical Industry, it creates several benefits to the same and these are as follows.
1.11.1.2 Social

As the Indian drug industry is developing, it creates new job opportunities. The Indian drug industry is providing new drug formulations and efficient health care system to its patients.\textsuperscript{22} For the new discoveries companies are investing a huge amount in R&D, and patients are able to have the medicines & treatment of critical diseases at low cost.

1.11.1.3 Economical

The development of the pharmaceutical industry would help the Indian economy and producing more national wealth. Indian companies have the opportunity to merge with foreign companies which indirectly promotes the foreign investment in India. Growth of Indian pharmaceutical industry generates the job opportunities in India, and if citizens get the domestic job opportunity they would not feel the pressure of migrating United States. Expansion of Indian pharmaceutical industry is promoting the vast growth of Indian economy.

1.11.1.4 Political

Economic growth brings the stability in political environment too. It creates international credibility and makes a visionary regime rather than a reactionary political regime. The availability of medicines to the
poor people is not only the basic objective of the Indian Pharmaceutical system but also to provide a fair distribution of low-priced medicines among the public at large. India could achieve the growth at a macroeconomic level through education, infrastructure, sanitation, and with the help of a healthy society. These developments will promote the win-win situation for both the Indian citizen as well as for the politicians. Policies must be prepared after considering the demand of patients and as well as by understanding the continuously changing pattern of treatment of disease.23

1.11.2 Challenges

The Indian pharmaceutical industry is a rapidly growing industry and competing with different pharmaceuticals. Indian pharmaceutical market may face the threat of discarding the bulk drugs produced by the neighboring countries. Indian industry is compelled to compete with multinationals for their survival. There are so many Industrial and environmental factors that are must be considered, and if proper measures are not taken properly, they will hamper the business growth.24
References


adulthood: Results from a population-based cross-sectional study (the MUSICIAN study). Pain, 153(1), 27-32.


