International Journal of Advances in Engineering and Management (IJAEM)
Volume 3, Issue 3 Mar. 2021, pp: 1005-1011 www.ijaem.net ISSN: 2395-5252

Indian Pharmaceutical Industry- A new perspective.

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Submitted: 10-03-2021 Revised: 30-03-2021 Accepted: 01-04-2021

ABSTRACT: The Indian pharmaceuticals industry is the world's third largest drug producer by volume. It is recognized globally due it the cost effectiveness and quality of the pharma products. A variety of medicines and vaccines are manufactured by the well-established industries of India. Moreover, the country's market manufactures about 60% of vaccines globally. This constitutes 40-70% of supply to satisfy the World Health Organization's demand for diseases like Diphtheria, Tetanus, Pertussis and 90% of the global demand for the Measles vaccine.During unprecedented times of Covid-19, pharmaceutical companies had to face rapid challenges arising from disruption in supply chains. But they strived hard for manufacturing the drugs and vaccines during the pandemic. Not only multinational companies but also the domestic players took an initiative of manufacturing life-saving drugs. They are competing globally in the market for both original and generic products. India is responsible for almost 8% of world pharmaceutical production. Innovative technologies and advance research strategy have been in the key role for the increase in demand of the Indian pharmaceuticals. It has also played a significant role in socio-economic development of the country by providing business, job opportunities and social benefits to the country. This review inculcates the evolution of pharmaceutical industry of India and also reflects the importance of the industry globally.

KEY WORDS: pharmaceutical industry, drugs, vaccine, Covid-19

I. INTRODUCTION

Indian Pharmaceutical Industry is poised for high consistent growth over the next few years, driven by a multitude of factors. Top Indian Companies like Ranbaxy, DRL, CIPLA and Dabur have already established their presence. The upcoming decades will show the pharmaceutical industry several good changes, largely in accordance with government policies. Commencing with repackaging and preparation of formulations from imported bulk drugs, the Indian industry has moved on to become a net foreign exchange earner and has been able to underline its presence in the global pharmaceutical arena as one of the top 35 drug producers worldwide.

The Indian pharmaceutical market is highly competitive and these pharmaceuticals are domestically-produced generics. In value terms, India accounts for less than 2% of the world market and per capita expenditure on pharmaceuticals is relatively low. India has a longtime domestic pharmaceutical industry, responsible for around 8% of world pharmaceutical production. India has a longtime domestic pharmaceutical industry, liable for around 8% of world pharmaceutical production. The industry is export-oriented and the larger domestic companies are competing in the global market for both generics and original products. The highly skilled domestic workforce offers good opportunities for outsourcing both research and production. However, on the basis of organizational perspective the most prominent performance related issues are mention below:

- Very high attrition rate of the sales personnel
- The number and the quality of medical representatives
- Unknown value of revenue from each retailer in the territory
- Varying customer perception
- Absence of ideal mechanism of sales forecasting from field sales level, leading to huge deviations

The change in dynamics of the worldwide pharmaceuticals industry especially that of the regulated markets like the united states of America and Europe have presented a number of capitalizable opportunities for IPI (International Pharmaceutical Industries). Some of the major concern been faced by the global pharmaceutical industry are higher healthcare cost, patent expiries for the blockbuster drugs, increasing competition from generics and increasing R&D cost. The IPI value road attempts to determine a growth path for the Indian pharmaceutical companies by

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identifying six growth segments in and increasing order perceived value that can be generated by following strategies focused on a specific segment. The segment identified are bulk-drugs, domestic formulation, export to nonregulated markets, exports to regulated markets and NCE research. These companies are mapped according to their current and future focus segment on the worth road which are likely to shape their growth within the almost medium term. The growth of the Indian pharmaceutical industries within the domestic market gets restricted with the MNCs introducing newer patented drugs in the country. The value of the drugs is going off- patents within the regulated markets is estimated at US $70-80 billon during subsequent five years and this represents an enormous opportunity for the Indian pharmaceutical companies to establish their presence in these markets. Pricing pressure in the regulated markets, high litigation expenses and counter strategies followed by the innovator companies are factor that would dampen the growth of Indian pharmaceutical companies the generic opportunity

II. DISCUSSION

India is the most successful country compared to other countries in pharmaceutical manufacturing sector. There are a number of aspects including government policies and incentives on import and exports of pharmaceuticals, that help to understand the expansion of the Indian pharmaceutical sector. India has a very large population which is around 1.35 billion, including a large segment of individuals living on low incomes. The factors which will be relevant to establishing a successful pharmaceutical sector a really " during a country with a very large population and a developing market could also be different from the factors relevant to a smaller country/underdeveloped country and/or one experiencing different economic circumstances. In 1969, Indian pharmaceuticals had a 5 percent share within the domestic market and global pharma had a 95 percent share. By the end of 2020, Indian pharma has almost 85 percent share. The Ministry of Health & Family Welfare under the Dr. Harsh Vardhan regulates the industry in our country.

R&D Infrastructure: As per the information Indian pharma companies spends between 2-10% of its revenue on Research and Development department. Authentic research and development activities helps the industry to move ahead in combating any unexpected circumstances or any crisis.

U.S. FDA Compliance: A prominent growth driver is that we have one of the highest number of FDA compliant plants outside of the U.S. This speaks volumes about our medical infrastructure.

Health Insurance: Most of the medical expenses in India are paid out of the pocket. This means that most of it is paid by the Indian citizens and very minimal is covered by health insurance. Health insurance is critical to the growth of this industry and thus it is aspiring opportunity for industry.

Medical Technology: Growing medical technology also provides us with a great opportunity. Research was conducted by the government 3 years ago valued the medical devices industry $520 crores in 2017. Robust medical technology is one of the main pillars as it plays an important role in the delivery of healthcare services.

Types of pharmaceuticals

Mainline: These are the larger drug companies that have many different drugs to their name. Moreover, these established companies, like Pfizer, AstraZenecahave thousands of researchers working for them, and a number of other manufacturing plants.

- Mainline Industry sells and services a broad range of flow wrapping, packing machine and product-handling equipment, labeling and specializing in the food industry. Our company is dedicated to helping customers succeed in their business

Research and Development: These are smaller research organizations and pharma businesses that focus on R&D. Additionally, while their ongoing research and unavailability of drugs in the market, they assist bigger firms with clinical test observation as subcontractors on larger projects.

- The term R&D is widely attached to upheaval both within the corporate and government world or the general public and personal sectors. Research & Development allows a corporation to remain before its competition. Without an R&D program, a corporation might not survive on its own and should need to believe in other ways to innovate like engaging in (M&A) mergers and acquisitions. Through R&D, companies can design new products and improve their existing offerings.
- Types of Research & Development (R&D)- One R&D model is a department of employee which is controlled primarily by engineers who develop new products a task that typically

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involves extensive or productive research. There is no specific goal or application in mind with this model. Instead, the research is completed for the sake of research. Once it is done then after it will be done on large scale. The second model involves a department composed of commercial scientist all of who are tasked with applied research in technical,scientificor industrial fields. This model promotes the event of future products or the development of current product. Also, M&Aspartnerships of R&D as companies join forces to take advantage of other companies' institutional knowledge and talent.

Generic: Since the expiry of drug patents help in lowering the value of manufacture, drug companies help mass-produce drugs. Moreover, these pharmaceutical companies do not work much on R&D but help bring patent-expired medicines to the market at lower costs.

A drug works precisely sort of a brand-name drug but usually costs too much less. Generic drugs hit the market as soon as a pharmaceutical patent expires. Furthermore, generic medicine costs less because the companies which are producing them do not have to spend on R&D. Hence, such drugs help make life-saving medicines more accessible and affordable to the overall public. Furthermore, generic drugs share an equivalent safety, effectiveness, performance, and quality characteristics as a brand-name drug. Similarly, these similarities help a generic medicine work the way a brand-name one does.

Table i : Generic drug with price

Name of the generic drug	Price	Indication	Milligram
Amoxicillin	875	Bacterial infection	500
Cefixime	700	Bacterial infection	200
Paracetamol	10	Fever	500
Ofloxacin	27	diarrhoea	200

AI Manufacturers: These corporations produce bulk compounds, biomolecules and other AIs for drug manufacturers. Further, they also help to create vaccines, serums, and other products.

Artificial intelligence (AI) can be applied to nearly every different aspect of the pharmaceutical and healthcare industry, to build up all data processing. Accepting the technology will reveal the astonishing potential of the healthcare and pharmaceutical sector, successfully rates flying above ever before – especially within the research and development of crucial, life-changing drugs.

- **Drug design and trialing**

Artificial intelligence can optimize the pharmaceutical industry through its ability to upgrade R&D, from discoveries and identifying new molecules to target-based drug corroborates and designing.Notonly itcan reduce the amount of time it takes for a trial to be conducted, but also to get approval, meaning a drug can be set down on the market quickly. This can end in cost savings, more treatment options and cheaper therapies for those that need access to the drugs.

Drug discovery

In medicine, biotechnology and pharmacology, drug discovery is that the process by which drugs are discovered and/or designed.In the past most drugs are discovered either by identifying the active ingredient from traditional remedies or by serendipitous discovery.A new approach has been to know how disease and infection are controlled at the molecular and physiological level and to focus on specific entities supported this data.The process of drug discovery involves the identification of candidates, synthesis, characterization, screening, and assays for therapeutic efficacy.Once a compound has shown its value in these tests, it'll begin the method of drug development before clinical trials

Effect of new technology on drug discovery

During the main portion of the twentieth century drug research was formed and improved by a few new advancements, all of which left their engraving on medication revelation and on treatment. In 1938, E. Chain, Howard Florey, and their partners chosen penicillin, a metabolite from a Penicillium shape that could lyse staphylococci, for additional investigation. Penicillin had been found in 1929 by Alexander Fleming, and countless anti-microbial substances had been portrayed in the logical writing somewhere in the range of 1877 and 1939. Chain and Florey's decision ended up being blessed. On account of its viability and absence of harmfulness, penicillin made the most convincing case for anti-microbials as a rule. It made the way for another time in the treatment of bacterial diseases. After the revelation of penicillin and along these lines, of different anti-microbials, many medication organizations set up divisions of

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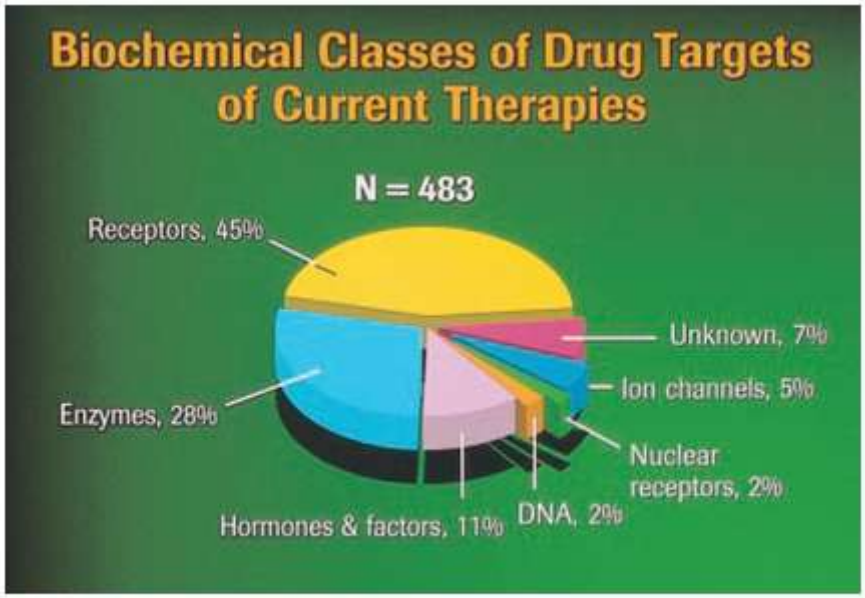
microbiology and maturation units, which added to their innovative degree. There were a couple of huge organizations that didn't partake in the quest for new anti-toxins.

Science, pharmacology, microbiology and natural chemistry helped to shape the course of medication disclosure and carry it to a level where new medications are not, at this point produced exclusively by the creative minds however the outcome from a discourse between researcher furthermore, scientific experts. This exchange focused on biochemical systems of activity originate from the comprehension of the organic design and capacity and offers ascend to the making of novel substance structures. Atomic science has applied a significant effect on medication disclosure, permitting the idea of hereditary data to be managed in extremely concrete biochemical and synthetic terms. From the start, nonetheless, the impact of sub-atomic science seemed, by all accounts, to be confined to cloning and communicating qualities that encode remedially valuable proteins. Sub-atomic focuses of medication treatment.

Classification concurring to biochemical rules:

In view of a cutting-edge standard work of pharmacology, the atomic targets of all known medications that have been described as protected and successful have been gathered what's more, recorded by their biochemical nature.



Graph 1 : Biochemical Classes of Drug targets

Drug approval processes

A pharmaceutical company seeking FDA approval to sell a new prescription drug must complete a five-step process:

- Discovery/concept
- Preclinical research
- Clinical research
- FDA review
- FDA post-market safety monitoring.

Drug approval processes are designed to allow safe and effective drugs to be marketed. Drug regulatory agencies in various countries conceive to accept premarketing scientific studies of the consequences of medicine in animals and humans so as to work out if new drugs have a favourable risk-to-benefit ratio. Although most countries require similar types of premarketing studies to be completed, differences in specific regulations and guidelines exist. Thus, if pharmaceutical firms wish to plug their new drugs in many countries, they will face challenges created by the differing regulations and guidelines for premarketing studies. In order to simplify the approval process for multinational marketing of drugs, the WHO and lots of drug regulatory agencies have attempted to provide harmonization among regulations in various parts of the world. Harmonization, which aims to create regulations and guidelines more uniform, theoretically can decrease the value of latest drugs by decreasing the value of development and

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regulatory approval. Because every new drug is somewhat different from pre-existing ones, unforeseen safety or efficacy issues may arise during the regulatory review. Some of these issues may prompt a private regulatory authority to need additional safety or efficacy studies. Thus, agreements on harmonization of regulations and guidelines are often more complicated and difficult to attain than could seem to be the case.

Patent:

A patent may be a sort of property that gives the owner with a sole right to create, use and sell an invention for a stipulated period. In exchange for this statutory right, the inventor must publish details regarding the planning. Around the world, patents help provide companies with a competitive advantage, because it enables them to regulate who uses or sells their invention. Pharma companies patent their drugs to protect their interests and have a monopoly selling the drug for a stipulated period

Patent Types in India

1. PTC International patent: -Applications filed with India as the Receiving office as per the guidelines of the patent co-operation treaty making it valid in over 150 countries
2. Ordinary patent: - Ordinary patent do not claim any priority or contain any reference to earlier application and applications for the same go to the patent office.
3. PTC National patent:- When the application is from India, the applicant must file a national claim within 31 months of submitting the international request.
4. Provisional patent:- This patent type is useful when the invention is still in the experimentation stage as it is valid for a year. A provisional patent is simpler to file mor cost-effective and requires less documentation.

Patent Rights and Laws in India

The first legal right or law in India was through the Indian Patents and styles Act, 1911, which later gave way to the Patents Act, 1970. After coming into force in 1972, another round of amending occurred through the Patents (Amendment) Act, with effect from 2005. This amendment includes the supply to file for product patents. After coming into the force, the amendment led to the repealing of the Exclusive Marketing Rights provisions.

Patents give applicants exclusive property rights to use, market, and sell their invention. Once such an application has been done, it may be legally implemented, assuring that the applicant enjoys sole rights to their invention. Moreover, the legal system is efficacious to the Pharmaceutical Industry, because it helps companies protect their investments. Additionally, around the world, biopharmaceutical manufacturers spend millions on research and development. Moreover, the patent system acts as security for their investment in several ways. Here's a look at the relationship between patents and the global biopharmaceutical industry.

Table ii : Top 10 leading pharmaceuticals in India

Sun pharmaceutical industries limited	INR 273.28 billion
Aurobindo pharma limited	INR 164.99 billion
Lupin limited	INR 159.55 billion
Cipla limited	INR 155.77 billion
Dr Reddy's Laboratories	INR 144.36 billion
Cadila healthcare limited	INR 120.50 billion
Intas pharmaceuticals limited	INR 108.86 billion
Glenmark pharma limited	INR 91.86 billion
Torrent pharmaceuticals limited	INR 63.01 billion
Mankind pharma limited	INR 52.00 billion

1. Sun Pharmaceutical Industries Limited

Sun pharmaceutical industries limited is a MNC and was established by Mr. Dilip Shanghvi in 1983 offering products to treat psychiatry ailments. Today the company works in cardiology, psychiatry, neurology, gastroenterology and diabetology medication.

2. Aurobindo Pharma Limited

Aurobindo pharma limited was established in 1986 and it's key business segments are active pharmaceutical ingredient, Formulations and Packaging. About 35% sales are generated through APIs, and About 65% of the company's revenue is generated from formulations business, of which 63% of formulation sales comes from us .

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3. Lupin Limited

Lupin was established in 1968 and it's key business segments are APIs and Formulations, and the company manufactures and sells pharmaceutical products in all major markets all over the world. Lupin has a presence in key growth therapies such as Cardiology, Gynecology , Anti-Infective, Gastro-Intestinal and Oncology, centre nervous system, respiratory, cadiology, diabetology.

4. Cipla Limited

Cipla limited , was incorporated in 1935. Cipla Limited was founded by Dr. K.A. Hamied. Cipla is a therapy leader in India for anti-malarial drug.

5. Dr. Reddy's Laboratories

Dr. Reddy's Laboratories is headquartered in Hyderabad and was founded in 1984. The company manufactures and markets a good range of pharmaceuticals in India and overseas. The company has over 190 medications, diagnostic kits, 60 active pharmaceutical ingredients (APIs) for drug manufacture, biotechnology and significant care products.

6. Cadila Healthcare Limited

Cadila Healthcare Limited was founded in 1952. Zydus Cadila provides total healthcare solutions ranging from formulations, API's and animal healthcare products to wellness products.

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7. Intas Pharmaceuticals Limited

Intas was founded in 1984. Intas has 13 commercialized biosimilars including Docetaxel & Paclitaxel. As on date, Intas continues its R&D efforts in chronic disease areas such as rheumatology, oncology and auto-immune, ophthalmology, nephrology, and plasma-derived product based therapies.

8. Glenmark Pharma Limited

Glenmark Pharma Limited was founded in 1977. Glenmark is a research-driven organization which is developing high-quality generics for people all around the globe. The company's drug discovery strive continue to play a vital role in the therapeutic areas of dermatology, respiratory and oncology.

9. Torrent Pharmaceuticals Limited

Torrent Pharmaceuticals Limited was founded in 1959. The company is engaged in manufacturing and marketing of branded and unbranded generic formulations. Currently, the company consumes most of the APIs manufactured in its facility.

10. ManKind Pharma Limited

ManKind Pharma Limited was founded in 1995. The company is engaged in manufacturing of a wide range of products – Antifungal, Antibiotic, NSAIDs(Nonsteroidal anti-inflammatory drugs), Gastrointestinal, cardiovascular, Erectile dysfunction, Anthelmintic, Dermal and several other categories.

Impact of covid-19 on Indian pharmaceuticals

If we talk about the volume of pharmaceutical production, we are ranked 3rd globally, supplying drugs to over 200 countries and fulfilling 50% of the global vaccine demands. Generic drugs have traditionally been India's stronghold and have contributed over 70 % to the overall market revenue in 2018.We produce and supply economical, quality-controlled generic drugs all over the world, both in highly regulated markets like the USA, Japan & Europe, and other parts of the world like Africa, Latin America & ASEAN countries.During these unprecedented times, pharmaceutical companies are responding to the rapid challenges arising from a disruption in supply chains and the need to change business processes. If the current COVID-19 pandemic lasts for a long span of time, it may impactthe supply of active material and ingredients (mainly from China), as well as the import and export of pharmaceuticals.There is also the potential for negative impacts of both a medium- and longer-term nature on Research & Development and manufacturing activities, as well as delay on projects not related to the core supply chain/data management operations. While the full impact of the global pandemic is still unknown, pharma companies need to respond, recover and thrive

The impact of the SARS-CoV-2 coronavirus outbreak has exposed the dependency of the Indian pharma sector on China for its Active Pharmaceutical Ingredient procurement. Supply chain disruptions and product exportation restrictions from India resulted from manpower shortages in China's manufacturing plants. This was caused by the quarantine policies adopted by different provincial governments in China in response to the coronavirus. Supplies were further impacted by the perturbation of logistic and transportation systems, restricting access and movement of products to and from ports.India's pharmaceutical industry has not always been so dependent on the material which is imported from China. In 1991, Chinese ingredients made up only

0·3% of India's bulk drug (API) imports. But as India's drug makers moved onto formulations, they started to acquire APIs from China, where the production cost is lower.

The common objective of the industry, society, as well as the government, was to assure consistency in the supply of critical, life-saving medicines that are mandatory for minimizing health problems during the pandemic.The Indian pharmaceutical industry has a complex network of domestic and global suppliers, regulatory authorities and consumers, manufacturers, logistic service providers, and distribution.For companies, bring back the supply chain to ensure the supply of goods and services, required them to understand and effectively navigate this complex system and seek the necessary support from a number of stakeholders.Short-term impacts of the COVID-19 pandemic include change of demand, regulation revisions, R&D process changes and the shift towards tele-communication and tele-medicine. In addition, industry growth becomes slow, approval delays, moving towards self-sufficiency in pharm-production supply chain and trend changes in consumption of health-related products along with moral dilemma could be anticipated as long-term impacts of COVID-19 pandemic on the pharmaceutical sector in both global and local levels.

III. CONCLUSION

The Indian pharmaceutical industry keeps growing at 7- 8% annually, with experts predicting an 11% growth in the year 2020. Additionally, Better access to medication, the higher onset of chronic illnesses, and an increase in health spending are helping the industry grow at such an unusual pace. Moreover, their report states that Indian households spend 1% of their total income on pharmaceuticals, with it expected to hit 2400 rupees every year by 2020. Additionally, the biopharmaceutical industry in India brings in 2700 crores every year and employs over 27 lakh. Therefore, a careful Indian pharmaceutical industry analysis by McKinsey shows it has become India's fourth-largest export industry

Since pharmaceuticals affect millions of people, every country has set up a governing body that regulates the testing and approval of drugs. Therefore, these bodies examine chemical and drug patents to ensure the effectiveness, safety, and quality of drugs. Rules and guidelines also help regulate the patent application, advertising, marketing, generic competition, and pharmaceutical production. Moreover, the various sub-industries related to it include marketing companies, pharmaceutical manufacturing, Generic drug companies, and R&D groups.

Judging by the total levels of Research and development investment, there are signs that the R&D intensity of the Indian pharmaceutical industry is increasing. The presence of low-cost production facilities and a large science base in India will help drive this trend over time. Although innovative Research and Development remain a long-term ambition, in the near term, there is likely to be enhanced generic activity from Indian companies. This is because a number of high-profile drugs have come off patent and this has opened up an opportunity for various Indian companies to develop generic versions for sale in the US and European markets. For example, the share of Dr. Reddy's total revenue generated by exports rose from 36% during 1998 to 46% by 2001. The trend for Aurobindo was more impressive with the export share increasing from 32% during 1998 to 55% by 2001. The work in the generics field has positive implications for Indian companies.

Indian pharmaceutical industry has been characterized by acore ability to compete in generics' manufacturing and relatively immaturecapabilities in research and development. This outlook has evolved substantially since the 1990s andIndian companies have been making investments to expand drugdiscovery and development capabilities.

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