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Indian Pharma—Some Challenges and Acceptances

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Abstract

Business enterprises are an important organ of society. The impact of a business enterprise's motive will directly affect society, which includes environment, consumers, employees, suppliers, and other stakeholders. Big pharma companies face a huge drop in revenue from blockbuster drugs coming off patent. Without generating revenues through sales, these companies will struggle to fund the development of new life-saving drugs. Artificial intelligence (AI) can be a powerful tool in the pharmaceutical industry's research and development. So with the help of modern technologies, pharmaceutical companies should aim for quality but cheap products for common people and serve society better.

Keywords: Artificial intelligence, Challenges, Health care industry, Pharmaceutical company.

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INTRODUCTION

ealth is fundamental for a quality life and having good Lhealth is a right of all humans. India's health care industry is growing at a tremendous pace, and its coverage consists of hospitals, drugs, medical equipment and devices, health insurance, telemedicine, etc. The health care industry stands on various elements-hospitals, which are the inevitable factors of everyone's life, including services and staffing, pharmaceuticals, health insurance, and devices. Hospitals staffed with doctors, nurses, and various paramedics play the central location for patient care and intervention. Pharmaceuticals provide drugs that help in curing the illness. Health insurances, like "mediclaim," provide support to the patients and families in managing their costly treatment and surgeries expenses. It is essential for pharmaceutical companies to lookup the social environment for long-range planning. Big pharma companies are in the business of making money, so they will generally develop those drugs that offer the greatest profit potential.

REVIEW OF LITERATURE

Reddy and Rao (2017), in their article "Opportunities and challenges for Indian pharmaceutical companies in overseas markets and need of digital tools for sustainable success," pointed out that Indian pharmaceutical companies are experiencing difficulty to survive in global markets due to the competition, lack of market knowledge, complex regulatory pathway, and not embracing the latest digital technologies. The study's main objective is to find out the use of various digital tools available for different pharma industry domains to become successful in global markets. They find out that there is a clear need for domain-based digital tools for Indian pharma companies to compete and sustain in global markets.

Dhar and Joseph (2019), in their article, "The challenges, opportunities, and performance of the Indian pharmaceutical industry post-TRIPS," pointed out that India's generic pharmaceutical producers are facing numerous challenges after the country's patent law was amended to make it compatible with **Corresponding Author:** Sajna T., Research Scholar, University of Kerala, Kerala, India, e-mail: sajnat12@gmail.com

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the agreement on trade-related aspects of intellectual property rights (TRIPS). They find out that leading generic companies of the industry have mixed performance.

OBJECTIVE

- To find out the potential and challenges faced by the pharmaceutical industry.
- To come up with some proposals for the pharmaceutical industry.
- To find out the application of AI in the pharmaceutical industry.

POTENTIAL OF THE INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmacology sector has the capacity to grow. According to the Indian Pharmaceutical Alliance (IPA), one of the emerging organization of pharmacists in India, the Indian pharmaceutical industry is one of the largest in global markets. According to them, the Indian pharmaceutical industry has to intend advancement to realize its true potential. In the pharma industry, there are four key drivers of growth. They are (i) increasing economic growth in India, (ii) strong growth in the US market, (iii) to introduce new innovative products, and (iv) increased grip in markets, such as, Japan.

In India, about 2.7 million jobs have been created both directly and indirectly due to growth in this industry. The current compound annual growth rate (CAGR) is estimated to be between 7 and 8%, and this would result in being worth up to

© The Author(s). 2020 Open Access This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons. org/licenses/by/4.0/), which permits unrestricted use, distribution, and non-commercial reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated. \$90 billion by 2030. But in fact, the industry has the potential to rise at a CAGR of up to 11–12%, potentially reaching \$120–130 billion by 2030.

The IPA presents four goals as the outcome for their potential.

- 1. As a global drug supplier, by establishing a market in the US generics and developing trade with other countries, Indian pharmaceutical industry could become the world's biggest drug supplier.
- 2. As an ideal manufacturer, by manufacturing high-quality medicines at an affordable price, low-priced drugs are needed to reduce patients' costs as part of the scheme to implement universal healthcare in the country.
- 3. As a contributor to the economy; at present, pharmaceutical companies contribute about \$11 billion, and they can bring more economy to India.
- As a world leader; Indian pharma has to set a goal of 3–5 molecular entities launched or in late clinical trial phases and about 10–12 innovations launches per year by 2030.

Some Challenges for the Indian Pharmaceutical Industry

In their report, the IPA says that there are still some problems in this industry. They are:

- A lack of a stable pricing and policy environment-The challenge created by unexpected and frequent domestic pricing policy changes in India. It has created a vague environment for investments and innovations. IPA suggests both the government and stakeholders work together to develop a plan to produce affordable Indian patients' drugs.
- Lack of capabilities in the innovation space-India is rich in its manpower and talent. The government needs to invest in research initiatives and talent to grow India's innovation. The government should support the clinical trials and subjectivity in certain regulatory decision-making removed.
- Generics market exporting-Due to price attrition, the success of generic exports to the United States has started to plateau. Due to increased buyer consolidation and higher competition, this market is starting to fade.
- Effect of external markets-Reports comments that India is heavily dependent on other countries for active pharmaceutical ingredients (API) and other intermediates. 80% of the APIs are imported from China. So India is, therefore, at the mercy of supply disruptions and unpredictable price fluctuations. Implementation of infrastructure improvement in the field of internal facilities is necessary to stabilize supply.
- Quality compliance inquiry-India has undergone the highest number of Food and Drug Administration (FDA) inspections since 2009; therefore, continuous investment for upgrading quality standards will distract the capital away from other areas of development and growth is reduced.

Some Proposals for Pharma Industry

To achieve the goals, Indian pharma companies have to take some bold strategic moves into uncharted territories. In a report, IPA suggests some actionable steps to encourage the growth of the pharma industry.

Good communication is needed for the development of any business. Similarly, improving communication between the industry stakeholders and Indian regulators would help build a stronger pharma platform. Policies should be framed to develop more faith around drug costs to a steady regulatory atmosphere. Establishing an independent body or a separate ministry would enable better coordination and faster decision-making. Another suggestion is to focus on API manufacturing so that they can less rely on imported APIs. This can be fulfilled in several ways, including constructing dedicated zones for the manufacture of APIs.

Several state governments in India have already undertaken positive steps to encourage industry growth. Provinces, such as, Andhra Pradesh and Uttar Pradesh announced their intention to build "pharma parks," which will provide the industry with a competitive edge. Regulatory authorities have to simplify the approval process because investment in emerging research and development (R & D) fields is much higher than generic ones. Working with other global regulatory bodies could help encourage pharmaceutical growth in India.

Application of Artificial Intelligence (AI) in Pharma Industry

Artificial intelligence and machine learning have revolutionized the industry and led to inventions, like virtual assistants, chatbots, robotic treatment, and much more. In this modern world, companies worldwide adopt big data and AI, where the pharmaceutical industry is no exception. AI can contribute a lot of opportunities for business transformation. Big data and AI powered analytics have brought a radical shift in the pharma industry's innovation paradigm. AI can significantly improve pharma companies' value by driving innovation and creating new business models. AI can be used in almost every pharmaceutical industry face starting from drug discovery, development, manufacturing, and marketing. AI can make all business operations efficient, cost-effective, and hassle-free. AI can be a powerful tool in the research and development of the pharmaceutical industry. We can look at some of the most worthy applications of AI in the pharmaceutical industry.

- Research and development (R & D)-Machine learning algorithms and AI-based tools contribute very much to streamlining the drug discovery process. These intelligent tools are designed to identify the complicated patterns in large data-sets. This capability results in drastic measures for studying various disease patterns and recognizing which drug compositions would suit treating specific traits of a particular disease. Pharma companies can invest in such R & D of drugs, which has the highest chance of success.
- Drug development-AI has the potential to improve the R % D process from designing and identifying target-based drug validation. According to an MIT study, only 13.8% of drugs are successful in passing clinical trials. A pharma company has to pay about the US \$161 million to US\$ 2 billion for



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a drug to get through the complete clinical trial process and get FDA approval. That is why pharma companies rely more on AI to improve the success rates of new drugs in more affordable drugs by reducing operational costs.

- Diagnosis-Maintaining electronic medical record (EMR) is a very important application of AI. EMR can store sensitive patient data securely in the cloud or any centralized storage system. Doctors can use advanced machine learning systems to collect, process, and analyze wide volumes of patients' healthcare data. Machine Learning (ML) and AI-based tools can process and analyze big data very quickly. It can boost up the diagnosis process, thus, helps to save millions of lives.
- Disease prevention-Generally, pharmaceutical companies, do not spend their time and resources to find treatment for rare diseases. According to Global Genes, nearly 95% of rare diseases do not have FDA approved treatment or cures. Pharma companies can use AI to develop cures for these rare diseases.
- Epidemic prediction-Many pharma companies and health care providers are already using AI and ML to monitor and forecast epidemic outbreaks across the globe. These technologies gather data from all possible sources on the web, analyze various geological, environmental, and biological factors on the health of the population of different geographical locations and connect all the factors and previous epidemic outbreaks. A very big example in recent times was the prediction of the novel coronavirus. This infection began in China, but a Canadian AI startup based in Toronto had marked this infection first. "Blue Dot" is another AI-based infectious disease surveillance system that searches the world 24 × 7 for large scale disease spread. These AI-based platforms got an indication of the possible pandemic around December 30, 2019. The company alerted their clients about this "unusual pneumonia." Nine days after this, the WHO issued their alert about the emergence of SARS-CoV-2. Such AI models become especially useful for underdeveloped economies that lack the medical infrastructure and financial framework to deal with an epidemic outbreak.
- Remote monitoring-It is a breakthrough in the pharma and healthcare sectors. Many companies have already developed wearable powered by AI algorithms that can remotely monitor their patients suffering from a life-threatening illness. For example, if a person with diabetes, the AI tool will monitor insulin sensitivity, duration of action, blood sugar levels, physical activity, etc. If the condition worsens or demands a treatment upgrade, the AI will alert the physician and arrange a checkup. Remote setups like these help eliminate the need to travel back and forth to the doctor's clinic by saving patients the bother to travel and wait.

- Manufacturing-AI can replace conventional time-consuming manufacturing techniques. So the pharma companies can launch drugs in the market much faster and at cheaper rates. By limiting human intervention in the manufacturing process, AI would also eliminate any human error scope. Companies can work with higher productivity, improved efficiency, and faster production of life-saving drugs. AI can improve all aspects of the manufacturing process, including quality control, predictive maintenance, waste reduction, process automation, and design optimization.
- Marketing-Though the pharmaceutical industry is a salesdriven sector, with the help of AI, pharma companies can explore and develop unique marketing strategies that can assure high revenues. AI can help to study the taste of customers, thereby allowing companies to frame a marketing technique. The same way pharma companies can aim at needy marketing strategies that can lead to most conversions and increase revenues. AI can analyze various marketing campaigns and can compare the results to identify the most profitable campaign. Moreover, AI tools can predict the success or failure rate of marketing campaigns.

CONCLUSION

There is still room for the industry to grow. Improving communication between stakeholders and Indian regulators would help to build a stronger platform for the Indian Pharmaceutical Industry. Big pharmaceutical companies are no longer providing the service they once did. India has joined "Global Partnership on Artificial Intelligence" (GPAI) as a founder member, which is a positive attitude by the government to support responsible and human-centric development and AI use. Being a developing country, India has to focus on similar mind situations in the future too. So the government should create an environment to start healthcare startup firms so the patients and companies can co-exist without being a burden on each other.

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