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Identifying the Key Determinators for Designing a Holistic Model for Improved Operating Conditions of the Indian Pharmaceutical Companies

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ABSTRACT
The study discusses the evaluation and growth of the Indian pharmaceutical industry and also presenting the historical background by explaining several drivers behind the growth and policies provided by the government. The article also provides the industry analysis and several strategies that are adopted by the Indian pharmaceutical companies to ensure their growth through generics, biosimilar, and other formulations. The study also discuss the future growth and challenges of Indian pharmaceutical company and also analyze the need to address by industry and government to achieve the Pharma vision 2020 effectively.

Keywords: Pharmaceutical companies, India, operating conditions, holistic model, quality, management, systems.

1. INTRODUCTION
India enjoys significant position in the global pharmaceuticals sector. As it is the largest provider of generic drugs globally. The country has a enormous pool of scientists, pharmaceutical professionals, and engineers with the potential to steer the industry ahead to greater heights. Given the increased scope of the pharmaceutical industry shortly, optimization of the operating conditions holds significant importance in the success of the industry.

Indian supplies over 50% of global demand for various vaccines, 40% of generic demand in the US, and 25% of all medicine in the UK. As per the survey conducted by the Indian Brand Equity Foundation (IBEF), it was noted that the market size of the industry was US$27.57 billion in the year 2016 which was expected to reach US$55 billion in the year 2020 by recording a compound annual growth rate of 15.92%. Indian Pharmaceutical industry is growing at a steady rate and is expected to reach US$100 billion. The total exports of the pharmaceutical industry were recorded to be US$

20.70 billion in the year 2020 which mainly included exporting products such as bulk drugs, intermediates, drug formulations, biologicals, Ayush and herbal products. On the other hand, the domestic Indian pharmaceutical industry market share increased to US$ 20.03 billion in the year 2019 from US$ 18.12 billion in 2018 by recording a growth percentage of 9.8% annually.

The study also examined the historical background of Indian pharmaceutical company and it wasfound that India's independence from the colonial rule of Britain in 1947, the multinational companies were allowed to import drugs in India at a low price, however some of the drugs are charged at high price. As a result, the Indian government felt increased pressure against the import of the finished product. Subsequently, the Government of India promoted several indigenous manufacturers for bulk drugs in 1970. After the implementation of the Indian Patent Act 1970, it provided the pharmaceutical industry with the rights of the patent not only the composition of the

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drug but also to patent the process of drug formulation for the period of five to seven years. Apart from this, the drug price control authority was also established during the same period to control the price and affordability of essential medicines.

The intellectual property protection Act known as India's Patent Law on 1st January 2005, was considered as a beginning of a significant change in the healthcare and pharmaceutical industry in India. Several Indian companies have adapted their systems and product development processes to the new environment. Subsequently, in 2009 India reached more than 120 US food and drug administration approved plants, 84 UK Medicine, and Healthcare product regulatory agency (MHRA) approved plants that provide the capability to produce the product with remarkable quality standard.

It was found that the growth of Indian pharmaceutical companiesalso depends on the several epidemiological factors that increased the profitability of the industry. It includes challenges such as high out of pocket (OoP) expenditure, pricing of patented drugs, spurious medicine, talent pool, inadequate health insurance schemes, public and government pressure that impact the pharmaceutical industry in India. Therefore, the government and regulatory authority focus on reducing taxes and import duty is incentive for setting up manufacturing unit by developing special economic zone to reduce the industry challenges. The study also focuses on the other facilities the government such as an incentive ,in house research,quality management systems and development also help in improving the quality of infrastructure in Healthcare sector.

2. AIMS AND OBJECTIVES

The study aims to identify the key determinators for designing a holistic model for improved operating conditions of the Indian pharmaceutical companies. The objectives are-

- To assess the status and the challenges faced by the pharmaceutical industries in India.
- To identify the importance of optimized operating conditions in the functioning of the pharmaceutical industries in India.
- To identify the key determinators for improved operating conditions of the Indian pharmaceutical companies.
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3. LITERATURE REVIEW

3.1 Pharmaceutical industry in India

According to **Fan, (2011)**pharmaceutical industry is an essential sector in India that significantly contributes to the economic growth of the country. **Festa, G., Rossi, M., Kolte, A., & Marinelli, L. (2020)** analyzed that the Indian pharmaceutical industry has expanded exponentially by developing a strong network of 3000 drug companies and more than 10500 manufacturing units. Amongst the several medical manufacturing units, about 1400 units are approved by the World Health Organization (WHO) and 1105 units acquiredcertification from Europe's certificate of suitability (CEPs). It was also recorded that more than 950 medical manufacturing units work as per the directive provided by Therapeutic Goods Administration (TGA) and 584 medical organizations acquired approvals from the US Food and Drug Administration (USFDA).Considering the bulk drugs segment of the Indian pharmaceutical industry, it forms the one-fifth segment of the industry and employs active pharmaceutical ingredients (APIs) for the creation of enhanced value-added products.

The major Indian pharmaceutical companies are Sun Pharmaceutical Industries, Cipla, Lupin,Dr.

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Reddy's Laboratories, Aurobindo Pharma, Zydus Cadila, Piramal Enterprises, Glenmark Pharmaceuticals, and Torrent Pharmaceuticals, providing medical products to local and international markets. While focusing on the export trend of the Indian pharmaceutical industry, the sector has expanded its reach to more than 200 countries. The Indian generic medicine sector has lucrative aspects in the US markets as it provides increased growth in this segment to the Indian pharmaceutical companies. The Indian generic medical segment value has been recorded to be US$60 billion which compromises 25% of the total Indian medical shipmentdespite the strict regulatory measure laid down by the US medical organization. A significant growth was also noted in the segment of the patent by the Indian pharmaceutical industry during 2017-2019 and the patent amount was recorded to be US$ 55 billion during the same period.Apart form USA, the major countries to which India pharmaceutical industry exported their products were the United Kingdom, South Africa, Russia, and Nigeria with US$383.3 million, US$ 367.35 million, US$ 283.33 million, and US$ 255.89 million respectively.Therefore, it can be said that the Indian pharmaceutical industryis experiencing high growth and expansion in the domestic andglobal markets.

3.2 Challenges faced by the pharmaceutical industries in India

According to **Chataway, J., Tait, J., & Wield, D. (2007)** certain challenges such as high outof pocket (OoP) expenditure, pricing of patented drugs, spurious medicine, talent pool, inadequate health insurance schemes, public and government pressure are faced by the pharmaceutical industry in India. While focusing on high 'out-of-pocket (OoP) expenditure: it is the issue that is faced because of a lack of insurance section in the healthcare sector. The insurance sector in India does not focus on providing healthcare insurance to the outpatients which cause a discrepancy in the delivery of healthcare services. Considering the pricing of the patented drugs, the conduction of innovation practices in medical and patenting is not easy, because of which the cost of patented medicines is high in the market.

The challenge related to counterfeit medicine is also faced by the Indian pharmaceutical industry which adversely impacts the business performance of the company. Due to the high prevalence of fake medicines in the market, it negatively impacts the health conditions of the patients and degrades the repute of the company in the market. Additionally, issues related to lack of efficient manpower are also faced in the Indian healthcare sector especially in the segment of the pharmaceutical industry.

Astbury, J., & Gallagher, C. (2020) analyzed that public and private pharmaceutical companies feel pressured to provide quality medicinal products to consumers at a low cost. The pressure to produce more generic products is put down by both the governing agency and the civil society which makes it difficult for the pharmaceutical company to work accordingly and meet both the goals of organizational success and community welfare. Additional pressure is faced by the Indian pharmaceutical company because of the inadequate medical and healthcare insurance sector inIndia. Due to the absence of structured and organized healthcare insurance like in other countries such as South Africa, Sri Lanka, and Brazil, the dependency of the consumer on the pharmaceutical industry increases.

The issues related to poor research and current manufacturing practices Good Manufacturing Practices, (cGMP) are faced by the Indian pharmaceutical industry. The reason being the implementation of research and explorative activities requires huge investments and patience to acquire successful outcomes. However, the pharmaceutical companies in India majorly focus on increasing their profit aspects and allocate fewer funds towards research and development activities.

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As a result, innovations and inventions in the segment of medical research get restricted that hampersthe expansion of the pharmaceutical sector in India. Also the deficiencies and the warning letters issued by the foreign health authorities are indicative of weak quality management systems that leadsto rejections, recalls and withdrawal of the medicinal products from the market.

Duffull, S. B., Wright, D. F. B., Marra, C. A., & Anakin, M. G. (2018) examined that major hindrance in the growth and expansion of Indian pharmaceutical companies is related to the high dependency of the Indian pharmaceutical industry on China for the attainment of raw materials to manufacture generic medicines. Additionally, restrictive policies by the Indian government create issues in the advancement and expansion of the medical industry. The small scale medical company and incubators require raw material to manufacture products and perform research activities, however, the availability of the raw material and other research equipment is at a high cost to the incubators and small scale pharmaceutical company that reduces their ability to contribute towards the economic growth process. **Schiff, G. D., Seoane-Vazquez, E., & Wright, A. (2016**) examined theissues faced while carrying out the clinical testing of the samples as many times clinicians experience a lack of adequate infrastructure to test the sample or carry out the diagnostic activity.

Moreover, standard regulatory measures are absent by the Indian government to exercise control over the working of the clinics and diagnostic centres which degrades the quality of clinical trials. As a result, many times the pharmaceutical company has to retrial the product in its diagnostic centre or laboratory to check the authenticity of the product. The conduction of the double trial process not only increases the cost of a clinical trial but also consumes a lot of time in carrying out the testing activity. **Tessman, L. (2020**) analyzed that patent issues also create a challenge for the pharmaceutical industry in India to expand its working in the medical innovation and invention segment.

It can be said that owing issues related to patent, clinical trial, restrictive government regulation, lack of manpower, and fake medicine adversely impact the working, growth, and expansion of pharmaceutical industries in India.

3.3 Optimized operating conditions

The Indian pharmaceutical industry has faced several changes in the production process, Good manufacturing practices, supply chain, management approach, product technological processes, and demand related to deliverance of supplies and services to the customer.It has become highly competitive so that it is difficult for the manufacturing organisation to find out and handle their competition and fulfil the expectation of the consumer and regulators.As a result, to meet the expectation of the customer it is essential for the organisation for effective working condition for the most of the equipment and achieve the deliveries effectively. There are several pharmaceutical companies who are realising that important reduction strategies related to the equipment maintenanceand reliability are highly effective competitive advantage of organisation. Under such conditions, itis essential for the organisation to streamline the maintenance processes so that there isreduction and elimination of wastes. Additionally, the implementation of total productive maintenance strategy is considered as the important improvement process as it is focused on equipment maintenance approach.It makes a positive impact on the several organisation by enhancing the responsiveness of organisation and defining the need of the expected customer the total productive maintenance also ensure the performance of a protective system. It is measured with core quantitative matrix and known as overall equipment effectiveness.It includes the rate of performance availability rate of quality that is measure of the losses of the equipment.Due to the

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implementation of overall equipment effectiveness strategy in manufacturing organisation, there is enhancement in the quality of product by reducing the equipment breakdown idle time accident rate and access the inventory as well as scrap and defect.

According to **Dong, Georgakis, Mustakis, Han & McMullen, (2020)** optimization of the operating conditions for the effective functioning of the pharmaceutical industries can be executedby adopting data-driven modeling tools such as Design of Dynamic Experiments (DoDE) andDynamic Response Surface Methodology (DRSM), , used to resolve the issues related to output data and improve time-based productivity. Considering the pharmaceutical industry, the DRSM model takes both times as well as factors of operating conditions into account. On the other hand, the DoDE based model helps in analyzing time-oriented inputs and factors related to design experiments. **Dong et al., (2019**) analyzed that both the model include using quantitative assessment tools and methodologies such as designing, experimenting, and process optimization to acquire data with several time instants.

Muchemu, (2008)analyzed that adoption of a quality management system helps in eliminating the issues that are faced by the pharmaceutical company concerning occupational and safety hazards. The adaptation of the quality management system helps in enhancing the workings ofthe operating system, change management, document management, program management, training management, and artwork management. All these activities support healthcare professionals to make informed decisions, assist clinical supplies, and strengthen enterprise collaboration. The quality management system also promotes the adoption of new technology within the workplace, and global product registration that help in the optimization of the operating conditions for the effective functioning of the pharmaceutical industries. Moreover, the conduction of the quality management process is also responsible for improving subsystems such as quality management, quality assurance, evaluation analysis, and quality risk management tools, preventive action, risk management, and continuous improvement that improve the working environment and reduces cost.

Grossmann, (2005) analyzed that when the subsystems of the quality management system are included in the optimization of the operating conditions, there is effective functioning of the pharmaceutical industries by enhancing the working of the production system, material system, and laboratory control system. It also brings improvements in the quality system, packaging system, facilities & equipment system, and labelling system. Additionally, the incorporation of a robust pharmaceutical quality system (PQS) also helps in eliminating the threats related associated with out of pocket (OoP) expenditure, pricing of patented drugs, spurious medicine, talent pool, inadequate health insurance schemes, public and government pressure. A PQS is based on implementing the guidelines related to the Food and Drug Administration (FDA) and builds the culture of inspection and scrutiny in the pharmaceutical industry.

3.4 Key determinators for optimal operating conditions

According to **Jiménez-González, C., & Overcash, M. R. (2014)** the optimal operating conditions of the Indian pharmaceutical industry can be improved by bringing reforms in the resources, information systems, organization and process and culture aspect of the pharmaceutical company. The changes can be implemented by introducing technological advancements in the Indian healthcare sector and empowering it with industry 4.0 tools and techniques. It includes adopting different quality management systems by the pharmaceutical company so that the issue that is faced related to patent, clinical trial, and fake medicine is resolved. Some businesses additionally apply the concepts on risk-based strategy in conformity with determine strengths and weaknesses on the

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agency within the rule in imitation of tackle or sink the risk**.**There are several models adopted with the aid of the agencies according to described exorcism managementstructures for example-Process-based approach, Risk based approach chance-based approach, multiplication management provision approach yet a mixture of various tactics based on the administration philosophies.

Chittoor, R., Ray, S., Aulakh, P. S., & Sarkar, M. B. (2008)noted that that the pharma enterprise must support education of students. Industries should touch Indian tutorial establishments after be brought certified students anybody has the abilities or aptitude because of research yet improvement within pharma.**Kumar, A., Zavadskas, E. K., Mangla, S. K., Agrawal, V., Sharma, K., & Gupta, D. (2019)** examined that the Government of India unveiled 'Pharma Vision 2020' according to make India an international leader in end-to-end prescription manufacture. The approval period for new services has been reduced in conformity with raise investment. The government over India has presentedUS$ 942.8 million production associated incentives in 5–20% because of incremental income and plans in conformity with engaging up mega physic parks in conformity with drive sustainable value competitiveness.

4 RESEARCH GAP

As per the discussed facts, it can be said that the pharmaceutical industry in India is one ofthe major sectors that contributes towards the economic growth of the country. The facts related to the Indian pharmaceutical industry have been investigated by researchers before, but specific facts related to key determinates for designing a holistic model for improved operating conditions of the Indian pharmaceutical companies have been missing in the previous academic literature (**Tessman, 2020**). The study examined that there has been a discrepancy in the designing a holistic model by pharmaceutical as some companies apply principles of a risk-based approach to determine strengths and weakness of the organization, while other companies apply Process-based approach, risk-based approach, quality management system approach, and combination of various approaches based of themanagement philosophies to improve operating conditions. However, these facts related to the quality management systems and conditions of the Indian pharmaceutical industry were not discussed by scholars which created a gap between the previous and current academic literature. Therefore, the current research examined facts related to the status of the pharmaceutical industries in India, challenges faced by the industry, optimized operating conditions, and key determinates for optimal operating conditions to fill the gap adequately.

5. DISCUSSION

As per the above-discussed facts, it can be said that the pharmaceutical sector in India plays an important role in contributing towards the success of the country by increasing exports, generating revenues, providing employment opportunities, and improving the healthcare status of the individuals. Indianpharmaceutical sector has been of significant relevance since the historical times that are from the Colonial rule of Britain in 1947 to the present era where the pharmaceutical industry is well equipped with multinational companies. It was examined that India relishes a significantplace in the global pharmaceuticals sector. India also has a large pool of pharma professionals with the potential to steer the industry ahead to greater heights.It was also found that the insurance sector in India does not focus on providing healthcare insurance to the outpatients which causes a discrepancy in the delivery of healthcare services.. The study examined that several pharmaceutical companies who are realizing that important reduction strategies related to the equipment maintenance and reliability are highly effective competitive advantage of an organisation

so that the organization to streamed themaintenance process by reducing and eliminating wastes. Additionally, different approaches such as quality management and PQS can also be adopted by several pharmaceutical companies to the optimization of the operating conditions for the effective functioning of the pharmaceutical industries.

6. CONCLUSION

As per the discussed information, it can be concluded that the main aim of the study is to identify the key determinant for designing a holistic model for improve operating condition of Indian pharmaceutical company. Apart from this, the study also examined the background to the pharmaceutical industry in India and also examined the challenges faced by the pharmaceutical industry in India. The study analysed importance of optimised operating condition in the functioning of pharmaceutical industry in India and also identify the key determinators for improved operating condition of the Indian pharmaceutical company. The study also highlighted the importance of optimisation of the operating condition for effective functioning of the pharmaceutical industry and identify the factors that are crucial for designing a Holistic model and ensure improve operating condition for the pharmaceutical companies in India. Apart from this, the study also explains the Indian pharmaceutical industry which is subjected to multiple challenges so that the study elaborate on the different challenges effectively.

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