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UNVEILING THE HIDDEN RISKS: EXPLORING VULNERABILITIES IN THE PHARMACEUTICAL SUPPLY CHAIN

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Abstract

The COVID-19 pandemic has highlighted the critical role of the pharmaceutical industry in global health and the economy. However, the industry faces various challenges, including financial difficulties and waste management issues. The cost of services and drug prices pose significant financial challenges that need to be addressed. Public health systems allocate specific budgets for pharmaceutical expenses to control costs. Additionally, issues such as intellectual property, sector fragmentation, and pricing control hinder progress in the industry, despite advancements in infrastructure and research and development capabilities. Developing countries particularly struggle with inadequate investment in research and development, emphasising the need for strengthening the pharmaceutical sector in these regions. Inventory management, new product development, process development, and lean manufacturing are major concerns within the pharmaceutical industry. It is crucial to improve supply chain efficiency, as pharmaceutical wholesalers heavily rely on drug manufacturers while facing fierce competition from retailers. By implementing effective health system workflows, better management of relationships with healthcare beneficiaries, quality monitoring, and information generation can be achieved. Trust and personal connections play significant roles in supplier-customer relations within the healthcare sector, alongside compliance with government regulations. This work also contributes by identifying and prioritising pharmaceutical supply chain risks. Industrial managers can implement proactive policies to minimise these risks, ensuring an efficient pharmaceutical supply chain. Recommendations are provided to assist managers in reducing the occurrence of risks and enhancing overall supply chain performance.

Keywords: Pharmaceutical supply chain, pharma industry, supply chain challenges, supply chain issues

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1. Introduction

The pharmaceutical industry, which includes both public and commercial institutions, is responsible for the discovery, development, and production of pharmaceuticals. After thousands of years of intuition and trial and error led people to believe that plants, animals, and minerals had therapeutic properties, the modern era of the pharmaceutical industry characterised by compound isolation and purification, chemical synthesis, and computer-aided drug design is generally regarded as having started in the 19th century. The knowledge of fundamental drug-discovery processes improved with the integration of research in the 20th century in domains like physiology and chemistry. The pharmaceutical industry is now faced with obstacles such as finding novel therapeutic targets, obtaining regulatory approval from government agencies, and improving drug research and development methods. The global control and eradication of illness depend critically on the pharmaceutical industry's ongoing development and improvement.

Nowadays, due to the COVID-19 epidemic, the pharmaceutical industries' importance to the world's economy and health is more apparent than ever. To introduce a medicine that needs a medical prescription, a pharmaceutical firm must first get authorization and negotiate the cost and payment system. This process is referred to as the "MA of new pharmaceuticals." MA stands for a strategic moment for the potential spread of the new oral medication. Pharmaceutical firms, patients, and the healthcare system all gain from it (availability of a new drug). Additionally, as MA suggests, a pharmaceutical company's profitability and long-term sustainability depend on negotiations with regulatory authorities over price and reimbursement. The medical science field mostly contributes to the academic debate. Through the MA process, the pharmaceutical industry interacts with a network of other parties. Non-business actors (NBAs), such as patient associations or citizens, play a significant role in addition to corporate actors. The whole effects that MA has on pharmaceutical firms and society make dealing with NBAs relevant. Pharmaceutical firms face difficulty in figuring out how to relate to NBAs (Syakirah et al., 2020).

Due to the COVID-19 epidemic operational risks as day-to-day hazards that range from mechanical breakdowns to variable demand and are primarily known to occur within the supply chain whereas disruption risks are external risks that emerge from social, political, or climate challenges (Sivan et al., 2023). The phrases supply chain risk and supply chain disruption, as well as risk management and supply chain resilience, are all subjects that receive constant attention from scholars. Over the recent year, more emphasis has been focused on disruption risks as both immediate and possibly long-term dangers to supply networks. Especially when such disruptions have the potential to alter the corporate environment in the future. Furthermore, despite the variations in risk categories (operational versus disruption) and in light of the coronavirus pandemic, researchers such as (Wooderson, 2022) contend that risk disruption management has received insufficient attention. Despite previous attempts and the immediate aftermath of the pandemic, COVID-19 presents fertile ground for more study in this area. For example, in comparison to supply chain disruption management and resilience, there have been significantly more articles based on risk assessment and mitigation relating only to operational hazards (Mkumbo et al., 2019; Selvaraju et al., 2019).

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The pandemic of coronavirus illness (COVID-19) has developed as an unparalleled worldwide health concern. While health officials were trying to tackle the disease, the pandemic itself disrupted global supply lines. Health crises, such as epidemics, are often occurrences that overwhelm a health system and necessitate outside assistance. A pandemic affects the entire world at once, with unpredictable timing. As a result, referring to unaffected regions for assistance becomes difficult. This restricts the opportunities for resource sharing. COVID-19 is a global health emergency, affecting many layers of the supply chain at the same time. A risk management strategy is used to identify supply chain risks and disruptions, which include risks to product manufacturing, transportation, availability or supply, demand, and control. Supply chain interruptions during the COVID-19 pandemic proved that risk models that attempt to isolate and control only one part of a complex system always falls short, failing to handle behaviours caused by feedback loops, possible delays, and resulting in negative side effects (Shah, 2004; Sigala et al., 2022).

2. Issues in Pharmaceutical Industry

2.1. Instability of Management in The Pharmaceutical Industry Supply Chain

Qualitative data analysis has stated that there were factors that impacted the issues in the pharmaceutical industry. The data explained the issues that were affecting the instability of the management in the pharmaceutical industry supply chain:

Financial Issues - The first issues that the pharmaceutical industry has to deal with are financial issues the most important problem found was the high cost of the services that are produced. The clinical commissioning communities have to pay close attention to the drug costs. In an attempt to control their pharmaceutical expenditure, each of the public health systems has to assign a certain budget. (Shah, 2004). For example, the United Kingdom (UK) has stated that they oversee and dispense about 40 million pounds worth of medicines annually. Besides, Greece's budget also has been set aside for them and they have clarified that they were not allowed to spend more than 30 million euros. To forecast the demand, gratify their consumers, and at the same time to keep the costs manageable, the pharmacies have to be careful in managing the intricate pharmaceutical distribution system like this.

Waste Issues - In the community of pharmacists, they hold that the existing system itself is to blame for the high degree of wastage, along with the clinicians' prescribing practices and also the patients' attitudes (Shah, 2004). For example, community pharmacists in Greece stated that the consumer frequently failed to take their medication which is the cause that results in waste. Besides, according to the observation from Greek pharmacists', consumers request additional prescription medicines from various doctors until they have found the right treatment for them.

2.2. Lack of Medical Equipment

Did not have many valves for the patients that needed them - Some of the hospitals were immediately overwhelmed by the virus as they were not prepared to handle the significant number of patients that required intensive care. To help COVID-19 patients breathe more smoothly, hospitals are specifically using continuous positive airway pressure therapy (C-PAP), a method that requires a machine

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to increase the level of oxygen in the throat (Tani et al., 2022). For example, along with the neighbouring city of Bergamo, location Brescia was the first European city to be attacked by the COVID-19 virus in early March 2020. The C-PAP mask extension valve, which uses the Venturi principle to automatically control airflow, was requested by a nearby hospital (Ospedale Mellini in Chiari). After discovering the hospital administrators had tried but failed to clean and reuse these valves.

Delayed medicine delivery and a shortage of pharmaceuticals - During a pandemic, disruptions in the supply chain and logistics may result in delayed medicine delivery and a shortage of pharmaceuticals. This is due to an imbalance between demand and supply. The strategies used by pharmacists to control medicine distribution throughout the crisis have raised demand (Caban et al., 2016). For example, as part of medication supply schemes based on recommendations, a list of COVID-19 therapy medicines was produced. Patients now have easier access to medicines thanks to the availability of telephone and online drug buying.

Removal by standard and advanced drinking water treatment plants - Several articles have addressed the issue of the efficacy of various procedures in eliminating pharmaceutical residues from both ground and surface water that have been prepared for consumption. The areas of medicinal concentration drop and the likely locations of degradation product formation are also noted. In many circumstances, standard DWT delivers a significant but incomplete degradation of medicines.

The persistence of pharmacological residues as a result of conventional therapy has been demonstrated on several occasions. Similarly, numerous notable research groups have concluded that flocculation and sedimentation are unsuitable for removing dissolved organic pollutants such as polar medicines (Caban et al., 2016). For example, dual filtering and normal flocculation-coagulation stages, were ineffective in reducing carbamazepine, caffeine, cotinine, and atrazine concentrations, whereas ozonation reduced analyte concentrations by 66 to 100%.

The detection and identification of disinfection by-products and degradation products - While the percentage of medicines in finished drinking water is thought to be too low to pose a genuine health danger, there is currently concern regarding disinfection by-products (DBPs) that can be produced during drinking water treatment. For example, degradation products twenty-three diclofenac transformation products were found with the application of chlorine, ozone, chlorine dioxide, UV, and UV-Vis/H2O2 treatment, while twenty-seven sulfamethoxazole transformation products were generated utilising chlorine, ozone, and UV treatment. The development of chloro- and bromo-benzoquinones, as well as chlorinated amphetamine-type stimulant disinfection by-products, was also reported during drinking water disinfection (Caban et al., 2016).

2.3. Operational issues in the pharmaceutical supply chain

Capacity planning is the subject of capacity planning under uncertainty. They analysed the situation in which three. Products are beginning clinical studies, and plans for existing and future manufacturing capacities are being developed. The major trade-off in capacity planning is the time lag between deciding to invest in extra production capacity and that capacity coming on-stream. Deferring capacity planning choices until additional evidence from trials is available is a lower-risk method, but it extends the time to market. As previously said, this metric is crucial (Schmidt & Grossmann, 1996). For

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example, when Tagamet first entered the market in the 1970s, it was free of competition for at least 5 years, but now that time might be as short as 1-2 years.

Pipeline and development management - Schmidt and Grossmann investigated the problem of task sequencing in the presence of infinite resources. The essential aspect of the model that separates it from traditional project scheduling is that each work has a failure probability, which influences the demand for successor tasks. They addressed the problem by formulating it as a continuous-time MILP and maximising the total projected NPV. When several tests for a product are run concurrently, the testing activity becomes more expensive since the impact of failures on subsequent tests is not considered (Schmidt & Grossmann, 1996). For example, the testing activity is often resource-constrained, and some phases may be outsourced. Jain and Grossmann create a framework for sequencing and scheduling testing jobs with limited resources. Each product in this technique has a unique set of testing tasks. Each job has a length, cost, priority restrictions, resource needs, and success probability. Work may be outsourced for a greater cost; no internal resources are necessary in this situation. The income associated with a product is shown as a function of its market debut date (Jain & Grossmann, 1999).

3. Solutions for the Pharmaceutical Industry

According to qualitative data analysis, some elements had an impact on the problems in the pharmaceutical industry. These elements need to be solved and have cooperation from different parties.

Investment in the pharmaceutical industry = Financial difficulties - There is a wealth of research that shows how healthcare organisations are under pressure to save costs. The expense of the services that were produced was a crucial problem. Clinical commissioning groups have put a lot of emphasis on the cost of drugs, as mentioned in the United Kingdom. The United Kingdom indicated that they monitor and distribute about £40 million worth of medication annually as part of their effort to control pharmaceutical spending. The United Kingdom explained that particular funds are allotted to each healthcare organisation (Shah, 2004). In some nations, pharmacists presume that implementing any new or enhanced delivery procedures requires a specific expenditure that the healthcare organisation cannot sustain since there is no more cash for them. They appear to be hesitant to make any changes because they think doing so will be expensive and dangerous. Lean thinking and reverse logistics are two examples of efforts that may be implemented that require little to no financial input while yet being able to improve an organisation's performance. Businesses now pursue lean thinking if there is a need to increase value and reduce waste because it has value and waste reduction at its core. Lean thinking, value identification, value stream mapping, flow creation, pull creation, and pursuit of perfection are some of the lean principles that put the customer and their claim on a product front and centre. For a variety of enterprises, lean has been demonstrated to be a reliable method for enhancing overall operational performance (Ali et al., 2020; Papalexi et al., 2020). Community pharmacies must carefully manage the intricate pharmaceutical distribution system in a manner similar to this in order to anticipate demand, please their clients, and keep costs under control. The amount of money allocated for pharmaceuticals relies on the size of the company and consumer demand (Shah, 2004).

From the perspective of Research and Development in the Indian pharmaceutical industry, Indian pharmaceutical businesses invested about 9% of their 2018 revenue in Research and Development, while

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the country's pharmaceutical sector saw 46 deals for US$1.47 billion in 2016. To support economic growth, it is important to make prescription drugs more affordable and expand health insurance coverage, which will increase spending on both general health care and prescription drugs in particular. In rural India, in particular, over-the-counter medicines require special attention. Plus, the population in rural areas in India is very poor and the majority of them cannot afford to buy medicines. Because of this matter, Indians have a high percentage of diseases (Festa et al., 2022). As a solution, the government of India made an alternative to investing in the pharmaceutical industry. Given that the production costs of drugs in India are significantly lower than in the United States, India's capacity to create high-quality, affordable medicines represents a significant commercial opportunity for both the global and domestic sectors. This can help enterprises remain competitive and maintain profitable exports (Festa et al., 2022).

Reduce waste, reduce cost - The cost of purchasing and distributing pharmaceutical items can be substantial, but there is also a large cost associated with wasting resources on superfluous or low-quality medications, incorrect use of medications, and shortages of vital medications. Community pharmacists think that the present system itself is to blame for the high degree of waste. It has to do with how doctors treat their patients and how they behave (Shah, 2004). Other than that, Inappropriate medicine donations waste resources and create complications for the pharmaceutical supply chain. The critical complications include increased competition and hindered coordination. A study highlights that donors rarely fund the overseas transport cost. Pharmaceutical waste at the disaster site can instigate new cases of infectious disease and pose a threat to the environment (Patil et al., 2022). According to a local Greek pharmacist, individuals frequently do not take their medications as prescribed, which results in waste. According to the pharmacists, people in Greece frequently request more medications by switching doctors until they find a treatment plan that they believe would work for them. On the other hand, various physicians frequently prescribe different medications. anyone they think will treat their patients most effectively. Community pharmacists in the United Kingdom share this belief that the waste is produced by the system. People typically buy their prescription, fill it till they feel better, and then store it in their medicine cabinet for later use, which results in them keeping a lot of expired medications on hand (Chua et al., 2022; Shah, 2004). Hospital pharmacists agree with community pharmacists that the greatest source of waste is a lack of coordination and communication between the pharmacy and the wards.

The United Kingdom specifically stated that the wards produce the majority of the waste. Every day, patients leave the hospital without taking their medication with them, or the treatment has changed, leading to drug returns to the pharmacy. According to research from the UK, this drug causes waste because it must be destroyed after being used or ordered for a specific patient. Another sort of waste results from some lines/types of medications that, following General Pharmaceutical Council recommendations, must be stored in the pharmacy (Shah, 2004). The United Kingdom clarified that we should always have some medications on hand, such as toxic antidotes, just in case. But because we don't use them very often, they frequently become outdated. However, according to the United Kingdom, separating the medicines that can be reused from those that must be destroyed is a time-consuming process. We must ensure that these medicines can be reused because some of them may not be labelled and we cannot re-use them until we have correctly identified them, according to the General Pharmaceutical Council's guidance (Shah, 2004).

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Rent or run a personal warehouse to keep inventory - The delivery system's perceived complexity difficulties are the final theme to emerge from the investigation. According to a group of academics, the pharmaceutical supply chain is more complicated than supply chains in other industries. The variety of services provided is sufficient to convey the degree of complexity of this system. Usually, the pharmaceutical industry has to deal with both pricey and sensitive products. It is widely acknowledged that medicines can be altered to produce harmful or useless goods for users. There are various distribution channels within the pharmaceutical supply chain. They cannot handle each of the products they oversee in the same manner. Depending on how frequently a product is used, several ways of storage are used. They naturally place fewer orders more frequently when they can easily obtain those that are consumed right away (Shah, 2004). There are several parties involved in the pharmaceutical supply chain who are in charge of the distribution of medications. The United Kingdom emphasised this, stating that the system requires a great relationship with our suppliers as well as a high level of trust. Hospital pharmacies have agreements in place with a few significant suppliers that allow them to negotiate prices and obtain better deals. Community pharmacies, on the other hand, are not in a position where they can negotiate contracts with their suppliers, thus they typically work together instead or run their own wholesale business to supply their stores. Community pharmacies in the UK are frequently large corporations with numerous locations throughout the nation. They manage their warehouse, which enables them to negotiate favourable prices with pharmaceutical firms. They can cut costs by renting a private warehouse to keep supplies and they can easily operate with their warehouse (Shah, 2004).

Lack of medical equipment - The ability to switch and layer between many models of governance is necessary for effective network governance, producing two hybrid forms of governance (Camargo, 2021; Rajagopal et al., 2016). Government should be supportive when times are good and aggressive when things are bad. Rotating responsibilities, a participatory decision-making process, and legitimacy based on experience are how supportive governance is accomplished (Peters et al., 2023). This would prevent layering because it depends on the network's connections of trust and cooperation, which promote inclusiveness and stability. Because it is impossible to participate in the network when organisations are inactive, this also implicates the participatory decision-making structure, rotating duties, and experience-based legitimacy that characterise the supportive governance mode. Switching calls for shared knowledge and agreement on the objectives and available resources because it is a decision-based process. The management of the network must be the responsibility of one or more organisations. Once more, this does not imply centralising the procedure but rather legitimate operational management of the network. It is important to consider trust and expertise alongside the issue of the basis of command (Peters et al., 2023; York et al., 2021). The formal command structures were undermined by the lack of knowledge and experience, which also caused a lack of confidence. Without trust, knowledge, and experience which are defined as legitimacy based on experience, a clear basis of command cannot be achieved. Lack of trust and knowledge undermine assertive governance, which depends on formal control by one or more organisations, as well as the foundation of command. However, this formal control cannot be formed without the network's cooperation, knowledge, and experience. The network's dearth of consulting organisations appears to be impeding the growth of legitimacy based on experience (Peters et al., 2023).

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Network capabilities underpinning operational solutions - Analysis from the perspective of high-reliability theory emphasises how strategies and activities are interconnected and the importance of a comprehensive strategy in redesigning supply chain resilience design. Contrary to recent research findings and policy developments in the literature on supply chain resilience, which encourage supply networks to develop supply chain management capabilities and implement mitigating measures like supply base management, stockpiling, and domestic manufacturing capacity, these complements and contrast those developments. Of course, these actions are crucial and pertinent for future readiness. Although necessary, they are insufficient. Regardless of whether the operational answer entails instituting national crisis protocols or centralising the purchase of medical supplies, all solutions are certain to be ineffective without network knowledge. The latest body of supply resilience literature benefits from the addition of the high-reliability theory (Peters et al., 2023; Singh et al., 2016).

Operation management in the pharmaceutical supply chain - In 2010, the U.S. Drug Enforcement Agency promoted a take-back initiative to support the proper disposal of unwanted medicine. In the classificatory review, they proposed incorporating circular economy principles into the pharmaceutical supply chain. The present study builds on their suggestion by proposing and evaluating circular economy strategies. We assert that implementing circular economy principles within the pharmaceutical supply chain can substantially improve environmental and operational aspects. opportunity and challenges of reverse logistics and discovered pharmaceuticals to be the most (Patil et al., 2022; Tukamuhabwa et al., 2023). The findings of the present study highlight the link between supply chain management, total quality management and operational performance in the pharmaceutical industry. Understanding this link is useful for managers to ensure drug production efficacy and efficiency, but also ensures consumers are protected from harm by ensuring supply chain quality that delivers quality products and services. The implications are not limited to the domestic Indian pharmaceutical market, but they can be applied to foreign markets as well. Pharmaceutical companies should focus on maintaining quality in the entire supply chain, starting from third-tier suppliers to end consumers, the authors say. In terms of improving quality, organisations have applied quality management systems since the 1990s. Practices and operational performance measures. supply chain practices to improve operational performance. Inventory management is another area to target for improvement, and includes carrying costs, work-in-progress inventories, raw materials, and finished products (Jambulingam & Kathuria, 2020; Sharma & Modgil, 2019).

4. Recommendations for the Pharmaceutical Industry

These recommendations might assist hospital and community pharmacists in understanding the operational inefficiencies they must deal with and point them in the direction of appropriate, innovative solutions that enable them to increase effectiveness and efficiency (Caban et al., 2016). First, procedures used in drug distribution need to be improved. Specifically, it may assist pharmaceutical industries in addressing the problem of how to be more productive while utilising fewer resources, which is a crucial topic for academics and practitioners (Shah, 2004). Second, the role of drug regulatory authorities is crucial for enhancing the quality, safety, and efficiency of medications in a country. The regulatory mechanisms for pharmaceuticals in LMICs have been strengthened and improved because of extensive

efforts by WHO on this issue. One such instance is Malaysia, which has done an outstanding job of raising the quality, safety, and efficiency of medications. Enhancing the nation's drug regulating agency is achieved. The other LMICs must take a lesson from Malaysia's book. The issue of raising consumer knowledge of drug safety and fake medications is also a topic of discussion. Although raising public awareness of the dangers of fake drugs is important, when a nation's regulatory structure is ineffective, this hardly succeeds (Syakirah et al., 2020; Vatumalae et al., 2022, 2023).

5. Conclusion

In conclusion, while this article primarily focuses on PSC's downstream practices, understanding the pharmaceutical sector as a whole is important to comprehend the impact that other stakeholders' actions, such as those of pharmaceutical companies, have. An overview of the variables influencing pharmacy productivity, with a focus on the overall sector, can contribute more information and be based on more trustworthy research. For instance, determining the issues' priority based on their relative relevance can be done by utilising structural equation modelling to analyse the issues that occur. The emphasis on responsible component elements and the facilitation of the decision-making process will help healthcare organisations develop solutions (Selvaraju et al., 2017; Zulfakar et al., 2019). This study's theoretical perspective also opens up a new line of inquiry for subsequent investigation, one that will seek out novel strategies for boosting the pharmaceutical sector. Additionally, if future studies are undertaken in other industries, including industrial food, they can broaden the applicability of research findings. Given their quick expiration dates and social influence, food goods are seen to have traits with medications.

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