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Dissertation Supervisor: Ganiru Priscilla Ugwu

How Raw materials & API shortages are affecting Pharmaceutical Manufacturing in India

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DECLARATION

“I hereby declare that this dissertation entitled “How Raw materials & API shortages are affecting Pharmaceutical Manufacturing in India” submitted in the partial fulfilment the MSc in Pharmaceutical Business and Technology, is my own; based on my personal study and/research, and I acknowledged that all material and sources used for the study purpose. I also certify that I have not copied in part or whole or otherwise plagiarised the work of anyone else, including other students. “

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Arjun Premarajan Suraja

ABSTRACT

This study investigates how the shortage of raw materials and Active Pharmaceutical Ingredients (APIs), affects India's pharmaceutical industry. The report presents a thorough picture of the problem through interviews with industry specialists such as supply chain, production, procurement, and operations managers, as well as production operators, pharmacists, and diabetes patients.

According to the study, the lack of raw materials and APIs generates major challenges in the manufacturing of medications, resulting in delays and unfulfilled customer demands. These shortages also have an impact on the availability and cost of essential drugs, including those used to treat diabetes. As a result, people are finding it more difficult to obtain and purchase the medications they require. According to the research, these shortages are also limiting the expansion of India's pharmaceutical business and making it less competitive on the global market. Such shortages may push India to rely more on imports in the long run.

The report recommends a few techniques for dealing with these problems. These include obtaining raw materials and APIs from a wide variety of sources, increased communication among industry stakeholders, better planning, and the adoption of a 'Just-in-Case' inventory management system.

In brief, this study provides important information for the pharmaceutical professionals, governments, and future researchers. It highlights the importance of strategic planning in ensuring the robustness and worldwide competitiveness of India's pharmaceutical industry during issues like as raw material and API shortages.

Key words: Active Pharmaceutical Ingredients (APIs), Raw Material Shortages, Indian Pharmaceutical Industry, Manufacturing Disruptions, Medicine Availability, Medicine Affordability, Diabetic Medications, Global Competitiveness, Long-term Effects, Strategic Planning. 'Just-in-Case' System, Inventory Management, Supply Chain Diversification, Industry-wide Communication, Dependency on Imports.

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ABBREVIATIONS

6APA - 6-Aminopenicillanic acid

APIs - Active Pharmaceutical Ingredients

ASHP – American Society of Health System Pharmacists

CAGR - Compound annual growth rate

FDA – Food and Drug Administration

FIEO – Federation of Indian Export Organizations

ICMR – Indian Council of Medical Research

IPA – Indian Pharmaceutical Alliance

ISPE – International Society of Pharmaceutical Engineering

JIC – Just-in-Case

JIT – Just-in-Time

KSMs- Key Starting Materials

LMICs – Lower Middle-Income Countries

R&D – Research and Development

UUDIS – University of Utah Drug Information Service

CHAPTER 1

INTRODUCTION

1.0 INTRODUCTION

The Indian pharmaceutical industry is now worth \$42 billion and is generally considered to be the pharmacy of the world (Buddhavarapu, 2022). But the country's high dependency on China for API and other raw materials has led to China dominating the market. China meets about 70% of India's API needs, and for some antibiotics, that number grows to around 90%(Buddhavarapu, 2022). Still, the COVID-19 lockdown and the ongoing conflict between Russia and Ukraine have made it hard for China's manufacturing and supply chain systems to work. This has led to shortages of raw materials and APIs in India, which has caused prices to go up. This caused many problems in the manufacturing of pharmaceutical products in India.

Short-term supply chain interruptions, rising input costs, and logistical difficulties are affecting India's pharmaceutical importers, while trade restrictions are hurting exporters. However, there is optimism that Indian businesses, particularly those focused on exporting drugs, will overcome these obstacles given the continued strength of the drug market. The ability of India to increase domestic production of essential compounds and the improvement of Indo-China ties in the next months will determine the long-term success of the Indian pharmaceutical industry(Udayana, n.d.). It is anticipated that the institutional drug markets in low- and middle-income nations will be the ones most susceptible to the shock of this period of instability.

1.1 COVID-19 IMPACT ON AVAILABILITY AND AFFORDABILITY

The COVID-19 pandemic has had a significant negative impact on the Indian pharmaceutical sector, which is one of the biggest makers and suppliers of generic medications worldwide. The nation encountered many obstacles, including supply chain delays, a labour shortage, and logistical issues during the lockdowns(Udayana, n.d.). Throughout the lockdown, the Indian pharmaceutical companies have only been operating at roughly 50% of their total capacity, which has caused a shortage of crucial medications on both the domestic and global markets.

Smaller pharmaceutical companies have been more significantly impacted by the pandemic-related issues than larger companies with varied drug portfolios. The situation has gotten worse as a result of the lockdowns in China and India as well as border tensions between the two nations. The transportation of raw materials and completed goods to and from manufacturing centres has been obstructed by the national and regional lockdowns in India,

which were imposed in different phases between March and June 2020 (Udayana, n.d.). This has drastically reduced the availability of raw resources within the nation.

COVID-19 is responsible for a significant number of deaths across the globe. There are issues with the suggestions given for treatments because of contradictory results and incorrect information. This has resulted in increased costs as well as shortages of essential medications and safety equipment such as masks. These issues have caused a significant number of families in India to fall into poverty whenever a member of the family becomes ill. In India, community pharmacists play an essential role in the treatment and management of illness. Therefore, in order to assist in creating better planning for the future, it was crucial to look at the pricing of essential drugs as well as the availability of such medications during the early stages of the COVID-19 outbreak in India (Haque et al., 2021).

1.2 SHORTAGES IN RAW MATERIALS AND FINISHED PRODUCTS

Drug shortages are a big problem all over the world, and they affect countries without respecting their state of wealth. This problem is getting worse, and it has a big effect on many types of drugs, such as life-saving drugs, cardiovascular drugs, cancer treatments, antidiabetics, antimicrobials, parenteral products, painkillers, opioids, and radiopharmaceuticals. When compared to other dosage forms, the chance of a shortage is higher for sterile injectable products. These shortages are caused by a complicated mix of production, demand, and government rules (Shukar *et al.*, 2021). Factors that affect supply include problems with manufacturing, a lack of raw materials, logistics issues, and business problems. Factors that affect demand include just-in-time inventory practices, higher product demand, seasonal changes, and unpredictable needs. Problems with regulations, like the lack of a single term for drug shortages, make the situation even more complicated. Drug shortages affect everyone involved, including the economy, the health care system, and people's lives (Shukar *et al.*, 2021). The World Health Organization has set up a four-step plan to deal with these shortages around the world. The plan focuses on operational improvements, policy changes, short-term solutions, and educational programs for healthcare workers (Shukar et al., 2021).

1.3 PRICE HIKES

The rising cost of medicines is a problem in both rich and developing countries around the world. Healthcare costs are going up all over the world for a number of reasons, such as an aging population, higher patient demands, and the release of new, high-priced drugs that fill medical needs that aren't being met. Because of this, being able to buy and get to essential medicines is now a key part of the right to health. In the past, healthcare costs have often grown faster than the economy, and this is likely to continue in the coming years. This will put a lot of pressure on health systems that depend mostly on public funding. High prices for new medicines and price hikes for old drugs that don't make sense have caused a lot of worry because they can make it hard for patients to get care and stay on their medications. In low- and middle-income countries, the problem is made worse by low incomes, high out-of-pocket health costs, and health insurance systems that aren't very good. To deal with these problems and make medicines more affordable and easier to get, governments around the world have put in place a number of interventions and policies, such as price controls, rules for the supply chain, and the marketing of generic drugs (Kakkar, 2021).

1.4 DIABETES

India has the highest recorded number of diabetes patients worldwide. A study reveals that low-income people in urban areas spend approximately 27% of their annual income on diabetes treatment, whereas those in rural areas spend approximately 34% of their annual revenue on diabetes care, in this a large percentage going towards medicine (Bhargava and Kalantri, 2013). According to projections, the number of diabetics in India will surpass 80 million by 2030 (Bansode and Jungari, 2019), forcing immediate action to optimize the use of limited healthcare resources while under economic barriers. People from all different socioeconomic backgrounds are impacted by the costs of diabetes treatment. Recent studies indicate that the annual cost of diabetes care for patients in urban areas is approximately Rs. 10,000, while the annual cost for patients in rural areas is approximately Rs. 6,260 (Bansode and Jungari, 2019). There are significant costs associated with diabetes, both direct and indirect costs. Direct costs relate to the medical and non-medical expenses of individuals and their families, while indirect costs relate to the expenses incurred by society and the government because of lost productivity. Direct costs are higher than indirect costs. To reduce the financial burden of diabetes on the community, it is essential to implement a comprehensive diabetes prevention program (Bansode and Jungari, 2019).

1.5 RESEARCH PURPOSE

The purpose of this research is to analyse how raw materials & API shortages are affecting Pharmaceutical Manufacturing in India. Specifically, this study aims to assess the impact of shortages on manufacturing, drug availability and affordability, and competitiveness, as well as the long-term effects on the industry.

1.6 RESEARCH OBJECTIVES

1. To analyse the impact of raw material and API shortages on the manufacturing of pharmaceutical products in India.
2. To analyse the impact of raw material and API shortages on the availability and affordability of drugs in India.
3. To analyse the impact of raw material and API shortages on the growth and competitiveness of the Indian pharmaceutical industry.
4. To analyse the long-term effects of shortages of raw materials and API on the Indian pharmaceutical sector.

CHAPTER 2

LITERATURE REVIEW

2.0 LITERATURE REVIEW

2.1 INDIAN PHARMACEUTICAL INDUSTRY

India's pharmaceutical industry is growing quickly. It is made up of more than 11,000 manufacturing units and 3,000 companies (Festa *et al.*, 2021). Generic products make up 71% of the total market share and 20% of the volume of global exports. This makes India the largest supplier of generics in the world. Even though the industry is growing quickly, it is very spread out, with only one-third of the total revenue coming from the top ten firms, which include multinational companies (Festa *et al.*, 2021).

India's pharmaceutical industry has done very well, to the point where it is now known as the "Pharmacy of the Global South." India's pharmaceutical industry has third place in terms of most volume of medicines manufactured in the world. And 20% of all generic medicines exported around the world come from this country. India also provides more than half of the vaccines used around the world. But to make finished dosage formulations, the industry has become more and more dependent on imported raw materials.

The Indian API (Active Pharmaceutical Ingredients) industry is worth about 106 million USD and is expected to grow at a CAGR of 8.57 % to reach \$1,748 million USD by 2026 (James, n.d.). It is the third largest country right now, after China and the US. There are about 1,500 plants that make APIs. Dr. Reddy's Laboratories, Mylan, Aurobindo, Sun pharma, Divi's, Cipla, Cadilla Pharma, Pfizer, GSK, and IPCA are some of the larger companies that make APIs (James, n.d.). Many of these companies have more than one place where they make pharmaceutical products. In the API market, there are also more than 600 contract manufacturers. These companies make a wide range of products, from generic drugs to complex APIs. Some Indian companies make anti-cancer drugs, peptides, steroids, sex hormones, drugs that help people with diabetes, and anti-depressants.

India makes a lot of Active Pharmaceutical Ingredients (APIs), making up about 20% of the world's production by volume and 7% by value. However, it needs to import about 32% of what it needs. China is the main source of these raw materials, which include APIs, intermediates and Key Starting Materials (KSM). In 2018, the Minister of Chemicals and Fertilizers told Parliament that about 67.56% (by value) of the raw materials that Indian companies needed to make formulations came from China. In terms of volume, the Chinese import share is about 60% (Cherian *et al.*, 2021).

This reliance on imports is especially worrying for low-cost, high-volume, and off-patent essential drugs that are used by a lot of people in India. India also sells generic medicines, which are made in part with materials from China. The Indian Council of Medical Research (ICMR) saw the need to make India more self-sufficient in API production because of how important essential medicines are to public health. The ICMR's (Indian council of medical research)plan was to improve access to essential medicines in India by consulting with all the right people, with a focus on making the country more self-sufficient (Cherian et al., 2021).

2.2 INDIA'S DEPENDENCE ON CHINA FOR ESSENTIAL DRUGS

At the beginning of the 1990s, India made all of the APIs it needed on its own. But as China became a bigger producer of APIs, it took over the Indian market by making its products cheaper. This gave China high economies of scale. China's low-cost API manufacturing industry was driven by low capital costs, aggressive government funding models, and tax incentives, which made its operating costs much lower than India's. Due to lower profit margins and an unattractive industry, Indian pharmaceutical companies slowly stopped making APIs and started importing them instead. This led to higher profit margins on drugs. Because of this, India stopped making APIs for Vitamin C supplements, artificial sweeteners, and commonly used antibiotics, as well as materials used to make APIs, called intermediates, like anti-cholesterol drugs, anti-malarial drugs, anxiety drugs, and antibiotics(Chandna, 2020).

These days, India purchases a significant portion of its Active Pharmaceutical Ingredients from China (APIs). APIs are essential components of the manufacturing process for medicinal products. China is the source of about 90 percent of the raw materials that are used in the production of antibiotics in India, and a large number of Indian pharmaceutical companies source active medicinal ingredients from China. As a result of the COVID-19 epidemic in China, it has become more difficult to manufacture APIs, which has highlighted India's reliance on China. It caused the pricing of medications in India to go up quite a bit because there are fewer exports of medicines from China and fewer medicines in stock in India. Because of the interconnected nature of the pharmaceutical business around the world, a drop in API production in China could have implications for the manufacturing of medicines in other countries(KOPPIKAR-MOORTHY, n.d.).

India imports a significant portion of its raw materials for essential drugs like Losartan for heart disease, Metformin for diabetes, and basic antibiotics like Penicillin and Cephalosporins

from China. In fact, China is the only place making important drugs like Norfloxacin and Azithromycin which are used for bacterial infections. Also, India gets 75–77% of its Vitamin B12, B1, and B6 from China. The main reason for this dependence is the cost advantage (Akhter *et al.*, 2020). China have cost advantage in API and raw materials industry over other countries due to lower labour costs, easy access to raw materials, regulatory environment and good government support (Kong Deqiang, 2019).

2.3 KEY RELIANCE IN TERMS OF % OF CHINESE IMPORTS

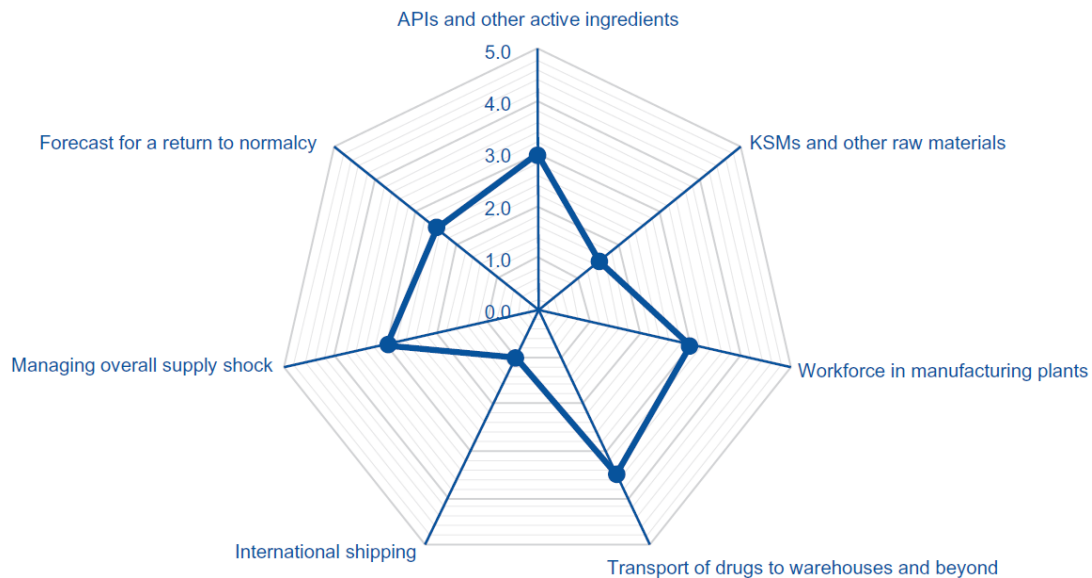
- Oxytetracycline (antibiotic): 100%
- Paracetamol: 100%
- Metformin: 100%
- Ampicillin: 100%
- Ciprofloxacin: 100%
- Tetracycline (antibiotic): 99.8%
- Azithromycin (antibiotic): 99.4%
- Norfloxacin (antibiotic): 98.5%
- Vitamin B12: 93.5%
- Amoxicillin: 90-95%
- Neomycin (antibiotic): 91.9%
- Ibuprofen: 80-95% 8
- Heparin: 86.3%
- Gentamicin (antibiotic): 85.4%
- Vitamin B6: 77.4%
- Vitamin B1: 73.6%
- Erythromycin and its derivatives: 63%
- Doxycycline (antibiotic): 57.5%

(Udayana, n.d.)

2.4 SOME OTHER CHALLENGES

The conflict in Ukraine and the uncertainty it has caused in the supply chain have made things worse. Also, US restrictions on the SWIFT payment system have made it hard for Indian pharmaceutical companies to make money, since they depend on exports to Russia and Ukraine. These exports make up less than 3% of all pharmaceutical exports, and they are now in danger because getting paid is difficult. This has led to \$400 million in unrealized receipts for exports that have already been sent, mostly to Russia. This is putting a strain on the

finances of Indian exporters. Banks have taken steps to stabilize payment systems, but the situation is still hard because the ruble currency is unstable(Chitsimran *et al.*, n.d.).



APIs: active pharmaceutical ingredients; KSMs: key starting materials.

Figure 1: Radar plot showing the relative magnitude of challenges (Bharat Bhushan Rewari *et al.*, 2020)

International shipping is one of the hardest challenges faced by pharmaceutical manufactures. This is causing difficulties of increased cost. In addition to that, they are also facing issues by factors like delays and increased lead time. Access to key starting materials (KSMs) and other raw materials needed for API synthesis was the next biggest problem. Concerns have been raised about how much India's manufacturers depend on China for APIs, but manufactures is saying this has become less of a problem in recent years. The most important factor to think about now is how dependent India on China and other overseas markets for KSMs and other raw materials needed to make API (Bharat Bhushan Rewari *et al.*, 2020).

The COVID-19 pandemic has had a substantial effect on the pharmaceutical production business in India. This is due to the fact that the pandemic began in India. The lack of available active ingredients, which also includes APIs, has resulted in a reduction in production capacity of between 20-30% (Basu and Chaudhuri, 2022) . Because of the new obstacles that the pharmaceutical businesses have been forced to overcome, such as the implementation of lockdown procedures and the modification of working standards, they are unable to function at their full capacity. The epidemic has also prompted a rise in the demand

for prescription pharmaceuticals, vaccinations, and medical gadgets, which has resulted in panic buying and anomalies in the supply chain. This has made it impossible for the pharmaceutical business to fulfil the basic mission of the sector, which is to make vital medicines available at prices that are affordable to the general public. The economic slowdowns brought on by the epidemic and the disruptions to international shipping have both contributed to an increase in the costs associated with the supply chain (Basu and Chaudhuri, 2022).

The formula shortage crisis, which was caused by Abbott Laboratories temporarily shutting down a plant because of fears of bacterial contamination and then recalling cans of infant formula, is a warning that supply chain problems could happen in other industries, including the pharmaceutical industry (BIOSPACE, n.d.).

The Indian government wants to increase API production because they think it's important for national security. But even if production barriers were removed, the industry might not be able to quickly increase production because Chinese imports are still cheaper. Companies need incentives and better infrastructure to get them to make APIs (Chatterjee, 2020).

2.5 IMPACT OF COVID-19 ON INDIAN PHARMACEUTICAL INDUSTRY

The COVID-19 pandemic has challenged the global healthcare system, including the pharmaceutical industry, with unusual difficulties. India, which provides approximately \$19 billion worth of pharmaceuticals to over 200 countries, is not exempt from this disruption (M. *et al.*, 2020a). The global medicines supply chain has been disrupted by the pandemic, and low- and middle-income countries (LMICs) are predicted to be more impacted.

China is a major supplier of active pharmaceutical ingredients (APIs) to the Indian pharmaceutical industry, which supplies 20% of the world's generic medicines. As a result of the impact of the COVID-19 epidemic on China's manufacturing and supply chain services, the Indian government has restricted the export of 26 essential pharmaceuticals and their formulations (M. *et al.*, 2020b). This has raised concerns regarding the global availability of generic medications, especially in lower middle-income countries (LMICs).

The Indian pharmaceutical industry is under risk as a result of factory shutdowns in China triggered by the COVID-19 epidemic. Around 70% of Indian companies' active pharmaceutical

ingredients (APIs) come from China, which is the world's largest manufacturer and supplier of APIs by volume. Concerns have been raised about the fragility of the Indian pharmaceutical supply chain as a result of the shutdown of Chinese plants. Prices for paracetamol, penicillin and vitamins have risen in India, and there are special concerns concerning the production of statins and various antibiotics. Despite this, the Indian Pharmaceutical Alliance has stated that there is no need for concern because the major pharmaceutical companies have enough API stocks for 2-3 months and are closely monitoring the situation in China(Chatterjee, 2020).

In addition, the COVID-19 outbreak has highlighted the significance of India's medical industry in ensuring the protection of millions of people worldwide. The ability of India to manufacture, produce, and sell pharmaceuticals will not only determine how LMICs respond to the epidemic, but will also have an effect on middle-income nations(M. *et al.*, 2020b). The condition of India's healthcare sector will also dictate its effect on the world's population.

To mitigate the consequences of the COVID-19 outbreak on the Indian pharmaceutical industry, extraordinary measures must be taken to enhance and preserve production facility operations. Governments and foreign organizations that rely on India for production should evaluate the Indian medical supply chain for their particular needs. There is a need for detailed plans to assure global access to APIs and medicines. To identify, treat, and prevent COVID-19 pathogens, regulatory agencies must approve testing devices, medications, and vaccinations(M. *et al.*, 2020a).

In response to the crisis, multiple high-level talks have taken place in recent weeks between the Indian Government and key stakeholders of India's pharmaceutical industry to increase API manufacturing capacity within India. These sessions resulted in suggestions such as expediting factory approvals, providing electricity concessions, and promoting pharmaceutical production clusters. As this relates to national security, the government is sincere about encouraging API manufacturers in India to increase their production capacity. However, the industry is unlikely to immediately increase production as long as APIs purchased from China stay in cheaper price (Chatterjee, 2020). According to the Public Health Foundation of India, fiscal and non-financial incentives, infrastructure development, and revitalization of public sector drug producers could be critical in convincing local drug manufacturers to create API.

In conclusion, the COVID-19 pandemic has had a big effect on the Indian pharmaceutical business. The government and other important parties must act quickly to make sure that the supply of medicines doesn't stop (M. *et al.*, 2020b). The role of Indian businesses in the transition to modernity after the outbreak will be crucial for the global economy and India's development.

2.6 IMPACT OF RUSSIA-UKRAINE WAR ON INDIAN PHARMACEUTICAL INDUSTRY

The Russia-Ukraine conflict has had significant effects on the global economy, with consequences that are witnessed in a variety of industries. The Indian pharmaceutical industry, which relies on imports for 90 % of its active pharmaceutical ingredient (API) requirements, has been especially affected. Due to the conflict, the volatility of API prices has increased, putting more strain on the margins and balance sheets of pharmaceutical companies (Sharna, 2022). In addition to affecting the prices of active pharmaceutical ingredients (API), the sanctions imposed on Russia have also impacted the payment mechanisms utilized by Indian pharmaceutical exporters. In 2020-21, Indian pharmaceutical exports to Russia and Ukraine totalled \$591 million and \$181 million, respectively (Sharna, 2022). The collapse of the ruble, which is a highly volatile currency, has worsened the problem of obtaining payments for shipments to Russia, resulting in a massive issue for Indian exporters (Sharna, 2022).

Offices of the pharmaceutical companies Sun Pharmaceuticals and Dr. Reddy's Laboratories are located in Ukraine, and the companies' production facilities are located in Russia. The pharmaceutical business already experienced difficulties due to the volatile prices of active pharmaceutical ingredients (API). The pharmaceutical industry in India relies on imports for 90 percent of its API requirements, and the sanctions imposed against Russia have caused major disruptions in the supply chain (Kaur, n.d.).

According to the Federation of Indian Export Organizations (FIEO), there have been approximately \$400 million in unrealized receipts for already-shipped exports, the majority of which originated in Russia (Sharna, 2022). Indian exporters will lose a lot of money because of these banks have taken strict steps to settle payment mechanisms. So, the Russia-Ukraine war's ongoing geopolitical tensions and foreign risks are likely to slow down global growth, which could hurt India's exports and capital spending significantly.

2.7 DRUG SHORTAGE

Drug shortage is a global problem affecting rich, middle, and low-income countries. The lack of a defined definition of drug shortage globally adds to the complexity of calculating and assessing medical shortages on a global scale. Some of the most widely used definitions of drug shortages are those provided by the University of Utah Drug Information Service (UUDIS), Health Canada, FDA, the International Society of Pharmaceutical Engineering (ISPE), the American Society of Health-System Pharmacists (ASHP), and the European Federation of Pharmaceutical Industries (Shukar *et al.*, 2021). However, these definitions differ in several dimensions, require various reporting standards, and do not provide an exact estimate of medicine shortages.

Manufacturing issues, business decisions, raw material shortages, problems with regulation, licensing of manufacturers/products, raw material shortage for a local manufacturer, smuggling of drugs, and lodging tax government policies are acting as major reasons for drug shortages (Shukar *et al.*, 2021). Drug shortages have a wide range of consequences for various stakeholders, particularly patients, including increased patient monitoring, transfer to other institutions, suboptimal treatment through the use of alternative drugs, delayed care, associated care cancellations, longer duration of hospitalization, readmission due to adverse events/treatment failure/relapse and even death (Shukar *et al.*, 2021). Drug shortages lead to serious health and economic crises, affecting almost all medical professionals.

Many institutions, associations, and governments have created various policies, programs, guidelines and research studies to address the medicine shortage, such as expanded reporting systems, policy modifications, drug shortage platforms, and faster drug approval. Some authorities assess drug shortages and provide instructions to health stakeholders directly, while others purchase extra inventory as a buffer stock to avoid shortages. Some regulatory bodies set up tools for tracking and reporting shortages, while others work to strengthen their food and drug institutions. Despite these efforts, medicine shortages continue to cause serious health and economic problems (Shukar *et al.*, 2021).

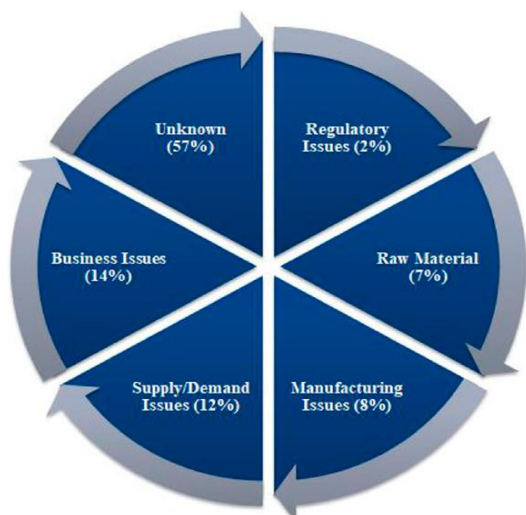


Figure 3: Reasons of drugs in shortages in 2012 reported by University of Utah Drug Information Service (UUDIS) (Shukar et al., 2021)

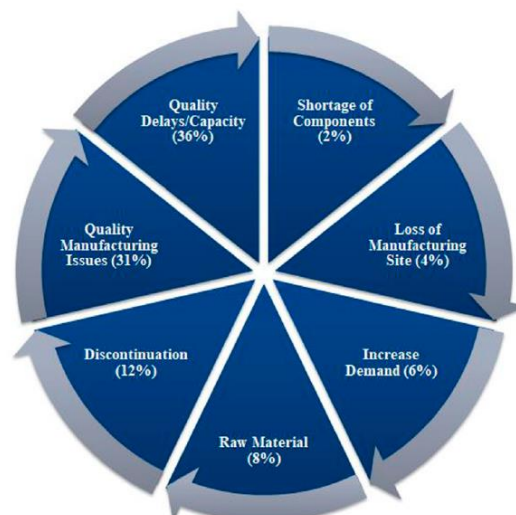


Figure 2: Reasons of drugs in shortages in 2020 reported by University of Utah Drug Information Services (UUDIS) (Shukar et al., 2021)

2.8 SHORTAGE IN ANTIBIOTIC APIs

The shortage of APIs and finished medicinal products is a worldwide problem. China and India are the main places where APIs, Key starting materials (KSMs), and finished pharmaceuticals come from. But because of the ongoing COVID-19 disease outbreak followed by slowdown in production process, there has been a shortage of important prescription drugs, especially antibiotics. This has caused their prices increase. Many APIs cannot be replaced or substituted. This is because these drugs may have specific mechanism of action or work against specific type of bacteria. The examples of these kind of essential APIs are amoxicillin, meropenem, vancomycin, potassium clavulanate, ceftriaxone potassium sterile, gentamicin, and ciprofloxacin, which are in short supply because of ongoing Covid-19 pandemic. To fix this problem, the Indian Pharmaceutical Alliance (IPA) has asked the Indian government to stop exporting all pharmaceutical products, active pharmaceutical ingredients (APIs), and formulations for use outside of India. But this does not solve this problem fully. The lack of APIs and high bulk prices in Indian markets have already started to hurt the industry. Prices have gone up by an average of 10-15%, and in some cases they could go up by as much as 50% (Ayati *et al.*, 2020).

2.9 DRUG SHORTAGE DUE TO UNAVAILABILITY OF RAW MATERIALS

Drug shortages are a usual issue that can arise as a result of a lack of raw materials. Political unrest, military conflicts, economic disputes, and environmental circumstances, as well as degradation during transport or low plant yield, can all contribute to these shortages (Shukar *et al.*, 2021). Many countries rely on India and China for active pharmaceutical ingredients (API), and shortages in these countries might have a worldwide impact. The COVID-19 pandemic brought up the issue of medicine shortages, with supply chain interruptions contributing to global shortages of APIs, excipients, and medications. The pandemic has also created delays in delivery, customer clearance, and restricted API and medicine import-export. If there is a problem, shortages can happen if a product has a single source of raw materials. To solve the issue of medicine shortages, it is preferable to have at least three raw material sources. Raw material shortages have been highlighted as a major cause of medicine shortages in nations like Saudi Arabia, Pakistan and Canada (Shukar *et al.*, 2021). Because of the global nature of the pharmaceutical industry, addressing the issue of drug shortages requires international cooperation and a priority on enhancing the reliability of the raw material supply chain.

According to the findings of a recent study, the most common cause of medication shortages is a lack of raw materials. The issue of a lack of raw materials was regarded to be a global problem because there are a limited number of enterprises that are actively operating as a direct result of lengthy or complicated production chains. When a particular raw material manufacturer is relied upon by subcontractors, and that raw material manufacturer experiences quality concerns in its manufacturing, the raw material is withheld from being sent to the subcontractors, which results in a shortage. However, lengthy or complicated production chains that included several subcontractors have also contributed to the shortage of medicines (Heiskanen *et al.*, 2017). In summary, these production chains, increased the risk of quality issues and cost of manufacturing.

2.10 PRICE HIKES OF RAW MATERIALS

From 2020 January to March, China was still under lockdown because to the COVID-19 pandemic, which had an impact on the flow of raw materials to the pharmaceutical industry. After the lockdown, raw material supplies resumed, but input costs for many chemicals rose sharply, with average Chinese API and KSM costs rising by 20–30% and prices for

fermentation-based KSMs and APIs by about 30% (Udayana, n.d.). Costlier freight contributed to this price hike in part. Due to labour shortages and low supply from traffic restrictions during the lockdown, raw materials became scarce, which eventually led to price increases for Chinese businesses. Due to the paucity of raw materials, some Chinese manufacturers are now charging their Indian customers twice as much as they were before the outbreak.

2.11 PRICE HIKES OF SPECIFIC APIs

- The cost of Isopropyl alcohol (IPA) rose by 100% - Antiseptic
- Prices for Nimesulide rose by 189% - Used for Pain
- Prices for Azithromycin nearly increased as a result of supply issues - Antibiotic
- Costs for Hydroxychloroquine nearly tripled.- Malaria, Rheumatoid Arthritis
- Prices for Paracetamol rose by 62%. – Fever, Pain
- The cost of Oseltamivir rose by 70%. - Antiviral
- Prices for Tramadol (Pain), Gentamicin, Norfloxacin, and Tetracycline rose by 12–20% - Antibiotics
- Prices for Vitamins and Antibiotics rose by 40–50%.
- Prices for 6APA rose by more than 360%. - Antibiotic
- Prices for Penicillin G increased by more than 50%. – Antibiotic

(Udayana, n.d.)

2.12 CHALLENGES IN ACCESSING MEDICATIONS

Many people in India are unable to obtain the necessary medications for their conditions. This is a significant issue because many people must pay for healthcare themselves. In fact, individuals pay four times more on healthcare than the government. When someone is ill, they are responsible for covering all costs of care, including medication. This can be quite costly, particularly for those with little financial resources. Over 650 million Indians, according to the World Health Organization, frequently lack access to the medications they require. Free generic medications are being offered in public health institutions as part of the government's effort to improve conditions. Yet, there are a few issues that make it challenging for people to get the medication they require. For instance, some individuals are unaware of the distinction between branded and generic medications. Also, because of poor government regulation, the cost of medicines is frequently exceedingly high. Also, some drugs on the market are unsafe for people to use or don't function very well (Bhargava and Kalantri, 2013).

In addition, the lack of APIs and raw materials caused by the COVID-19 pandemic and the Russia-Ukraine war also affects availability of medicines in India. These shortages have disrupted the global pharmaceutical supply chain, impacting India's pharmaceutical industry, which is highly dependent on imports of APIs and raw ingredients. As a result, India has experienced difficulty in producing and exporting pharmaceuticals, resulting in shortages and price increases. This has compounded the already existing problem of population access to medicines, particularly for those who rely on inexpensive generic medications (Basu and Chaudhuri, 2022).

2.13 CHALLENGES IN ACCESSING ANTIDIABETIC MEDICATION

Metformin is the drug that people with diabetes use the most, no matter how long they have had it. (Singla *et al.*, 2019). In India, the management of diabetes faces many challenges, because of lack of enough anti-diabetic drugs and active pharmaceutical ingredients (APIs). In addition, the prices keep increasing, and people have trouble taking their medicine because it's so expensive. The National List of Essential Medicines says that glibenclamide, metformin, and insulin are essential anti-diabetic drugs. However, their availability in public health settings differs from state to state, with only 3.8% of them being available in West Bengal. This shortage of anti-diabetic drugs is worsened by the lack of price regulation in the private sector, which makes it hard for patients to afford the necessary medication. Consequently, compliance with medication and other diabetes management recommendations is low, especially in lower socioeconomic groups, with only 30% of patients reporting medication compliance in one facility-based study (Venkataraman *et al.*, 2009). The situation may be worsened by India's reliance on Chinese imports for antidiabetic APIs such as metformin and glibenclamide, which are now in short supply.

In India, diabetes adds a significant economic cost and has multiple negative impacts on the population. Lower-income groups spend a greater proportion of their income on diabetes care, while urban populations spend more overall. The cost of diabetes has a significant impact on total expenses, especially for economically vulnerable households, who will be the most adversely affected. A recent study found that patients in urban areas spent an average of Rs. 10,000 annually on diabetes care, while those in rural areas spent an average of Rs. 6360 (Bansode and Jungari, 2019).

Therefore, comprehensive, accessible, and affordable healthcare facilities must be constructed for diabetics. To maximize the use of funds for the treatment and prevention of diabetes, careful planning based on health economic assessment is necessary. As the incidence of cardiovascular diseases and diabetes continues to rise in India, more households will experience financial strain. Sadly, economically vulnerable households will be the hardest hit. To reduce the disease's burden on the population and the economy, governments must prioritize effective measures to prevent diabetes and improve diabetes care (Bansode and Jungari, 2019).

2.14 GROWTH & COMPETITIVE ADVANTAGE IN API INDUSTRY

The Indian pharmaceutical sector is a world leader in medicine production and technology, capable of producing a diverse range of medications of excellent quality that have been accepted by several regulatory organizations. The sector was expected to increase at a compound annual growth rate of 11.3% in the next years. India's pharmaceutical turnover was predicted to hit USD 55 billion by 2020, with exports exceeding USD 20 billion. 40% of the generic drug demand in the United States and 25% of the total UK drug demand are satisfied by the industry, which also supplies 20% of the generic drug market globally and 50% of the vaccine market globally (Kolte *et al.*, 2022). But the home market isn't growing at the same rate because of things like the high number of branded generics, the fact that local players have the advantage, and low prices.

To overcome these problems, Indian pharmaceutical businesses are transitioning from big generic medication makers to researchers. Organizational, technological, and economic ambidexterity may be critical in this change, with the goal of capitalizing on India's worldwide dominance in generics while investigating the potential benefits of India's emerging R&D capacity. However, the per capita income in India might not make room for the commercialization of innovative products, necessitating the need for exporting (Kolte *et al.*, 2022). Indian pharmaceutical businesses would confront many hurdles in order to better address this ambidextrous effort, and it presents scientific and management implications for potential strategic and operational actions that the industry may take.

The quality of APIs has a serious influence on the pharmaceutical industry's competitiveness. A sponsor can gain a competitive advantage from high-quality APIs by bringing products to market faster, securing licensing agreements, or obtaining higher bids for their products.

Compromised or poorly manufactured APIs, on the other hand, can result in costly delays, legal actions, and reputational harm to the sponsor. APIs have become a focal point for mergers and acquisitions, innovation investments, and the development of new chemistry platforms in today's dynamic pharmaceutical industry. In 2022, the global API market was valued at \$195.29 billion, and by 2026, it is anticipated to reach nearly \$250.66 billion. Delays in API production can result in missed market opportunities and interfere the industry's growth and competitiveness(America, 2016). So, ensuring API quality is essential for the growth and competitiveness of the pharmaceutical sector. To assess the Indian pharmaceutical industry's competitiveness, raw material and API shortages should be analysed on API quality and availability.

India is now the nation with the fastest growing production of generic active pharmaceutical ingredients (APIs) for the commercial market. With a Compound Annual Growth Rate (CAGR) of 19.5%, the industry grew from USD 2.27 billion in 2008 to USD 6.62 billion in 2014, capturing 26% of the global API supplies. India's industry is now second only to China's and nearly twice as large as Italy's. On each of the world's major markets, Indian API companies hold a dominant position. Even though there are nearly 620 API manufacturers in India, only 70 Indian API firms with experience supply regulated markets. China, on the other hand, has 1300–1500 registered API manufacturing firms, of which only 55 supply regulated markets. But India has superior experience and proficiency in regulatory compliance. In terms of their knowledge of chemical synthesis and engineering, as well as the large number of skilled scientists with Western education, Indian API suppliers have a competitive advantage over Chinese API suppliers. In addition, since 2015, Indian API players have accounted for 45% of all new USDMF (United States Drug Master File) filings, while Chinese API players have accounted for 15%. In the coming years, this trend is likely to boost the market share of Indian API players(Shreyan, 2020).

The lack of studies on the impacts of shortages of raw materials and APIs on the availability and affordability of medicines for different population groups is a **key gap** in the literature. This population group include most vulnerable people such as low household income people and people with chronic diseases like diabetes. So more research in this area could tell us a lot about how these shortages affect people's lives and the economy. There are possible ways to overcome this shortage. To that companies should aim to create more efficient

relationships with partners and other firms in order to reduce the costs of their products. They should accomplish this by reducing internal lead times and work in process inventories, increasing forecast accuracy and repeatability, and adopting just-in-time delivery strategies for their expensive raw materials (Moosivand *et al.*, 2019). In addition, the recommendations of the Boston Consulting Group, Confederation of Indian Industry, and Drug Manufacturers' Association are centered on lowering the sector's reliance on imported APIs, strengthening overall self-sufficiency, and promoting exports. To maintain an adequate supply of pharmaceutical raw materials, the government can redirect revenue from import duties toward long-term risk diversification options, such as domestic manufacturing, to assure an adequate supply of pharmaceutical raw materials. In addition, India might pursue innovative methods, such as technology transfer and supporting other Asian or non-Asian nations in developing API capacity, to diversify the geographic distribution of API suppliers. In order to determine future policy, particularly for medicines on the list of Essential Medicines, and to develop new technologies for the cost-effective and non-polluting manufacture of these medications, it is necessary to closely monitor the trend in API import dependency. Lastly, the collection of accurate information related to public sector production plants and the feasibility of recovering them can increase national self-sufficiency in critical and essential pharmaceuticals (Cherian *et al.*, 2021). As a result of these activities, indirect costs will significantly decrease, which will create opportunities for improvement and potential solutions to the shortage of APIs and raw materials in the Indian pharmaceutical industry. By focusing on cost reduction and improving supply chain management, pharmaceutical companies in India can potentially mitigate the impact of raw material shortages and improve the availability and affordability of medications for patients.

2.15 LONG-TERM EFFECTS OF SHORTAGES OF RAW MATERIALS AND APIs

The COVID-19 pandemic has the potential to have long-term consequences for the pharmaceutical business, including delays in product approval for non-COVID-related medicines, a slowing of industry growth, and changes in consumer trends. Furthermore, the lack of raw materials and active pharmaceutical ingredients (APIs) from nations such as India and China have caused several nations to think about supply chain self-sufficiency (Ayati *et al.*, 2020). As a result, some governments have implemented restrictions to prevent shortages during similar emergencies. However, the pandemic may result in

increased import restrictions and additional regulatory incentives for local production. These alterations may result in long-term shifts in patterns of consumption, with one potential impact being shifting habits associated to consuming and renewing prescriptions, particularly in chronic disease treatment areas. The pandemic's prolonged duration may also result in ongoing behavioural changes in the general population, such as a greater focus on personal hygiene care (Ayati *et al.*, 2020). While both the short- and long-term impacts of the global crisis on the pharmaceutical sector are still being determined, it is clear that the industry will face significant challenges in the coming years.

CHAPTER 3
RESEARCH
METHODOLOGY

3.0 RESEARCH METHODOLOGY

For this study, the researcher used a mixed-methods strategy because it would be the most productive in examining the effects of raw material and API shortages on the Indian pharmaceutical manufacturing industry. Instead of simply drawing generalizations from factual data, this method enables the researcher to dive into the subjective experiences and opinions of numerous stakeholders, including industry experts, pharmacists, and diabetic patients. The researcher can acquire important insights into how people's lives are impacted by shortages and their ideas on possible solutions by using a mixed-methods approach.

The researcher will be able to accurately capture the participants' subjective experiences and opinions by using both qualitative and quantitative methods for data collecting, such as interviews and survey with a mix of both open-ended and closed questions. This study methodology's main objective is to gain a deeper understanding of the topic at hand and to make more insightful and useful recommendations for resolving the issue of raw material and API shortages in the Indian pharmaceutical industry.

3.1 RESEARCH PHILOSOPHY

The researcher has chosen pragmatism as the research philosophy for this study because it fits well with the mixed-methods strategy, which combines qualitative and quantitative methodologies. Pragmatism is a flexible and practical research philosophy that allows for the incorporation of multiple approaches, strategies, and perspectives to answer the research issue (Allemang *et al.*, 2022). This theory is based on the idea that no single technique can provide a thorough understanding of a complicated subject, such as the impact of raw material and API shortages on India's pharmaceutical manufacturing sector. Pragmatism focuses on the need of approaching the study subject from various viewpoints and examining the findings' real-world implications. The researcher can focus on the subjective experiences and opinions of industry experts, community pharmacists, and diabetic patients while also analysing objective data from multiple-choice survey questions and yes or no questions by employing pragmatism. This research philosophy allows the researcher to investigate the problem's character and generate realistic, actionable solutions to address the issue.

Finally, pragmatism is the best research philosophy for this study because it enables the researcher to effectively combine qualitative and quantitative techniques, resulting in a more comprehensive understanding of the impact of raw material and API shortages on the Indian

pharmaceutical industry. By considering the unique viewpoints and experiences of the numerous stakeholders participating in the research, this philosophy supports the development of more meaningful and successful solutions.

3.2 RESEARCH APPROACH

In this study, the researcher used a deductive research technique, which is compatible with the pragmatist research philosophy and the use of both qualitative and quantitative methods. Deductive research begins with a broad theory or hypothesis, which is then tested against empirical evidence to get precise findings. In this study, the researcher used news reports and literature reviews to develop hypotheses about the impact of raw material and API shortages on the Indian pharmaceutical business.

The deductive technique enables the researcher to build on existing knowledge and theories in the subject while also producing new insights by testing these hypotheses against the facts obtained (Hyde, 2000). This method ensures that the study is based on the broader literature and adds to the ongoing research debate on this topic. The researcher used a logical technique to uncover patterns and links between variables in quantitative data, as well as qualitative methods to study the subjective experiences and viewpoints of the participants. This combination allows for a thorough comprehension of the research problem as well as significant insights into the findings' real-world consequences.

In conclusion, the deductive research technique is well-suited to this study because it allows the researcher to compare hypotheses developed from existing literature and news reports against empirical evidence acquired using a mixed-methods approach. This approach contributes to the pragmatism philosophy by giving a rich and comprehensive understanding of the complicated issue of raw material and API shortages in the Indian pharmaceutical industry, and finally by suggesting practical solutions to the problem.

3.3 DATA COLLECTION

3.3.1 PRIMARY SOURCES

The data for this study was gathered by three sets of questionnaires customized to three separate participant groups: industry experts, pharmacists, and diabetes patients. These questions are aimed to gather quantitative and qualitative data, as well as open-ended and

closed questions, in order to acquire a thorough knowledge of the impact of raw material and API shortages on the Indian pharmaceutical industry.

A total of 13 questions were designed for industry professionals to investigate their perspectives on the difficulties and implications of shortages in this sector. These questions cover a wide range of topics, including the frequency and length of shortages, the categories of raw materials and APIs most affected, and the steps taken to manage risks. The use of open-ended and closed questions enables a thorough assessment of industry experts' opinions, capturing both precise data points and their subjective experiences.

A series of 10 questions were meant for pharmacists to investigate their personal experiences of delivering drugs during instances of raw material and API shortages. The questions address issues such as the effect of medicine shortages on drug availability, price, and client demand. Pharmacists can share their thoughts and comments while also providing structured data on the scope of the problem using a mix of open-ended and closed questions.

Finally, 14 questions were developed for diabetic patients to better identify the effects of raw material and API shortages on drug access and affordability. The first 12 questions aim to gather background information on the participants, while the latter two open-ended questions explore their subjective experiences and perspectives during times of shortage. The research gets a comprehensive understanding of the patient's issues and concerns by including both open-ended and closed questions.

The research includes a total of 37 questions across three participant groups, ensuring a thorough and robust data collection approach. The research technique aims to present a comprehensive picture of the impact of raw material and API shortages on the Indian pharmaceutical sector by incorporating the unique viewpoints and experiences of industry professionals, pharmacists, and diabetic patients. The combination of open-ended and closed questions will not only yield an extensive amount of qualitative and quantitative data, but will also allow the researcher to find patterns, trends, and viable solutions to the current difficulties.

3.3.2 SECONDARY SOURCES

Secondary sources are important in giving essential context and background information for this research. Academic journals, books, industry reports, news stories, and government publications are among the sources that provide a complete overview of the Indian pharmaceutical sector, raw material and API shortages, and the potential consequences on medicine supply and affordability. The researcher receives insights into the historical context, current trends, and future estimates for the industry by evaluating these secondary sources. Furthermore, secondary sources aid in the identification of knowledge gaps in existing literature, allowing the researcher to develop research questions and objectives that address these unexplored areas. Furthermore, secondary data is used to compare and validate primary data collected from industry experts, pharmacists, and diabetic patients. In conclusion, secondary sources play an important role in enhancing research by providing a larger context and assisting with the analysis and interpretation of main data.

3.4 QUANTITATIVE AND QUALITATIVE QUESTIONNAIRE

To collect thorough data from participants, the study methodology adopts a mixed-methods approach, integrating both quantitative and qualitative questionnaires. The study can effectively capture the range and depth of the participants' experiences and viewpoints on the impact of raw material and API shortages on the Indian pharmaceutical sector by combining these two types of questionnaires.

Closed-ended questions, such as multiple-choice or yes/no questions, are used in quantitative questionnaires to provide numerical data that can be statistically examined. This sort of questionnaire allows the researcher to detect patterns, trends, and correlations between variables, giving the researcher a more objective perspective of the research issue. Quantitative questions aid in the collection of demographic information, the measurement of the frequency of raw material and API shortages, and the assessment of the impact on production timelines and drug supply in this study.

Open-ended questions in qualitative questionnaires, on the other hand, generate elaborate, narrative responses from participants. This sort of questionnaire enables the researcher to dive into the participants' subjective experiences, opinions, and insights, resulting in a more in-depth understanding of the study problem. In this study, qualitative questions are utilized

to capture industry experts', pharmacists', and diabetes patients' personal experiences, as well as their recommendations for addressing the issue of raw material and API shortages.

The research benefits from the strengths of both methodologies by combining quantitative and qualitative questionnaires, offering a more thorough and sophisticated knowledge of the impact of raw material and API shortages on the Indian pharmaceutical industry. This mixed-method approach not only improves the findings' reliability and validity, but also provides a solid framework for producing relevant and practical suggestions to address the identified difficulties.

3.5 ANALYSIS OF DATA

The data analysis in this research includes analysing both quantitative and qualitative data from the questionnaires. The study attempts to give a full knowledge of the impact of raw material and API shortages on the Indian pharmaceutical sector by evaluating the data using appropriate approaches for each category of data.

Thematic analysis will be used to analyse the qualitative data. Thematic analysis is concerned with discovering reoccurring themes, patterns, or ideas in data to comprehend the underlying meaning or message given by participants. These qualitative methodologies allow for the exploration of the participant's subjective experiences, opinions, and ideas surrounding the study problem (Willig and Rogers, 2017).

Descriptive statistics, on the other hand, offer a data summary with a clear picture of trends, attitudes, and opinions. This is a quantitative method. This study uses frequency distribution to count and categorize replies, which aids in visualizing the prevalence of various points of view. And central tendency measures are employed to identify an average response, whilst cross-tabulation is used to evaluate potential relationships between different variables (Fisher and Marshall, 2009).

3.6 ETHICAL CONSIDERATIONS

Ethical issues were critical in ensuring that the research was carried out with integrity and respect for the participants' rights, dignity, and well-being. Several ethical considerations were taken into consideration in this study:

- All individuals provided informed consent prior to participation in the study. They were given enough information regarding the research's objective, procedures,

possible risks and benefits. Participants were also advised that they could withdraw from the study at any moment without penalty.

- Confidentiality and anonymity: Throughout the research procedure, the participants' privacy was respected and maintained. Personal information was kept private, and any data gathered was anonymized so that no direct identifiers could be attributed to the participants. When presenting the research findings, pseudonyms or codes were used to maintain anonymity.
- Data Storage and Security: The researcher made certain that all data obtained during the study was securely maintained and safeguarded against unwanted access. Electronic files were password-protected. Furthermore, data were only kept for as long as was necessary, in accordance with applicable data protection regulations.

By carefully evaluating and addressing these ethical issues, the researcher ensured that the study was carried out in a responsible and respectful manner, which added to the legitimacy and trustworthiness of the research findings.

3.7 INCLUSION AND EXCLUSION CRITERIA

3.7.1 INCLUSION CRITERIA

- Industry Experts: Participants needed pharmaceutical manufacturing, supply chain management, or API and raw material procurement experience.
- Pharmacists: Participants had to be licensed pharmacists with expertise in dispensing anti-diabetic drugs and understanding their availability and price during raw material and API shortages.
- Diabetic Patients: Participants had to be diagnosed with diabetes, use anti-diabetic drugs, and live in Malappuram or Kozhikode, Kerala, India.

3.7.2 EXCLUSION CRITERIA

- Individual who has no experience in pharmaceutical field.
- Pharmacists: Unlicensed pharmacists, those without expertise dispensing anti-diabetic drugs, or those who were unaware of their availability and pricing in shortages were disqualified.

- Diabetic Patients: Non-diabetics, non-users of anti-diabetic drugs, and non-residents of Kerala's Malappuram and Kozhikode districts were excluded from the study.

CHAPTER 4

FINDINGS & ANALYSIS

4.0 FINDINGS AND ANALYSIS

4.1 INTRODUCTION

To analyze and interpret the data acquired from surveys and interviews, two basic methods of analysis were used in this study. Thematic analysis was used on the open-ended questions, which is a qualitative technique which enables for the identification and evaluation of repeating patterns, or 'themes,' throughout the data. This strategy was useful in analyzing the participants' complex experiences and perspectives.

Descriptive statistics, on the other hand, provide a data summary, providing a clear overview of trends, attitudes, and opinions. This is a quantitative technique. This study counts and categorizes responses using frequency distribution, which helps to visualize the prevalence of distinct perspectives. And central tendency measures are used to establish an average response, while cross-tabulation is used to investigate potential correlations between different variables.

4.2 THEMATIC ANALYSIS FROM INTERVIEWS

4.2.1 CHALLENGES FACED BY PHARMACEUTICAL FIRMS

In the last four years, all six industry experts (100% participants) have noted both raw material shortages and price increases for APIs. Nobody reported only experiencing shortages or price hikes. This shows that the pharmaceutical sector has had considerable difficulty, in procuring raw ingredients and APIs, which could have an impact on medicine supply and pricing.

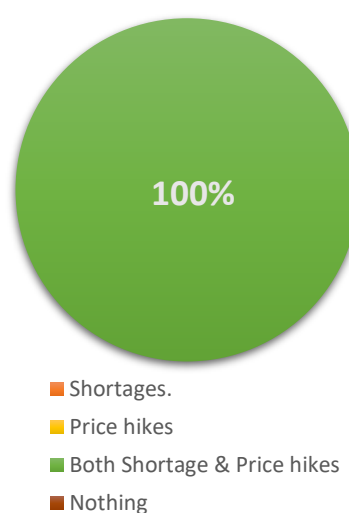


Figure 4. Pie Chart of Challenges Faced By Pharmaceutical Firms

4.2.2 MOST AFFECTED CATEGORIES OF RAW MATERIALS

Raw materials in Shortage	No. of Participants Reporting
APIs	6
Excipients	5
Packaging Materials	2
Other	0

Table 1. Most Affected Categories of Raw Materials

Six of the six industry experts said APIs were in short supply, five said excipients were, and two said packaging materials were. No other categories were reported by the experts as in shortage. According to these statistics, APIs were the most impacted category of raw materials or APIs during the last four years, followed by excipients and packaging materials. To ensure continuous manufacture and supply of essential pharmaceuticals, the pharmaceutical industry must monitor the availability and pricing of these critical raw materials.

4.2.3 FREQUENCY OF API OR RAW MATERIAL SHORTAGES

In the last four years, all six industry experts (100% participants) said that their organizations suffered raw material or API shortages occasionally. This shows that shortages are not uncommon in the business and can have an influence on pharmaceutical manufacturing and availability. Because of the frequency of these shortages, the industry needs to discover alternate sources for raw materials and APIs, as well as improve communication and coordination among suppliers and manufacturers, to reduce the impact of shortages.

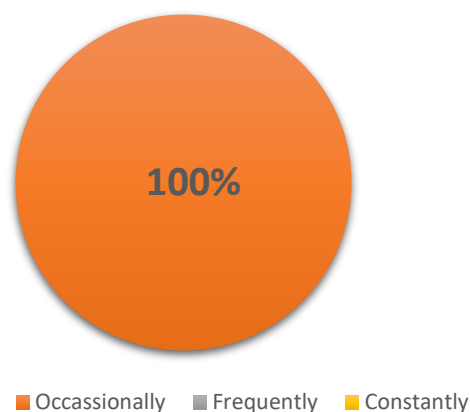


Figure 5. Pie Chart of Frequency of API or Raw Material Shortages

4.2.4 LENGTH OF SHORTAGES

According to the comments of six industry experts, the majority of shortages lasted one to three months. Only one person claimed that shortages lasted less than a month, and none reported shortages lasting three to six months or more. The length of a shortage can have a serious effect on medicine manufacturing and availability, as lengthier shortages can lead to a lack of supply of certain medications and potentially affect patient care.

Length of Shortage	No. of Participants Reporting
Less than a month	1
1-3 months	5
3-6 months	0
More than 6 months	0

Table 2. Length of Shortages

4.2.5 HOW SHORTAGES AFFECTED BUSINESS OPERATION

Over the last four years, all of the participants have faced acute raw material and API shortages in their companies. Medicine production was frequently impacted by these shortages, resulting in major revenue losses and disruptions to operations. Manufacturing shutdowns caused by regulatory concerns resulted in unfulfilled customer demand and delayed supplies. Some participants identified certain APIs and crucial raw materials that were in short supply, posing a threat to the manufacturing of top-selling medications. This caused problems in resources and the need to seek alternate suppliers, generally at a higher cost. Overall, the shortages seriously interrupted production plans and harmed the companies' ability to meet customer expectations. This finding aligns with the first research objective, that is to analyse the impact of raw material and API shortages on the manufacturing of pharmaceutical products in India.

4.2.6 CAUSES FOR API & RAW MATERIAL SHORTAGE

All participants highlighted many significant causes for raw material and API shortages in the Indian pharmaceutical sector. Supply chain disruptions caused by covid-19 pandemic, trade conflicts and natural disasters, as well as an overreliance on imports from certain nations such as China, were among them. Further obstacles were identified because of a weak domestic raw material manufacturing ecosystem and complex, time-consuming regulatory processes that resulted in delays. Participants also mentioned an inability to respond rapidly to sudden changes in global market conditions. A lack of advanced technology, restricted access to skilled personnel, and insufficient investment in research and development were further problems. In summary, a combination of external and internal factors has contributed to the sector's raw material and API shortages.

4.2.7 IMPACT OF RAW MATERIAL SHORTAGES

Raw material and API shortages have had a substantial influence on the organizations of the participants, notably in terms of manufacturing capacity, product quality, and ability to meet customer demands. Many companies were unable to provide the expected output, with some even ceasing production due to shortages. Product quality suffered because of enterprises being forced to use alternate, often inferior, raw materials from other suppliers. As a result, the end product's quality decreased. Finally, the capacity to meet customer demands suffered significantly when delivery deadlines were disrupted due to production delays. This resulted in bad client relationships and reputational damage for the organizations.

4.2.8 MEASURES TAKEN TO MINIMIZE THE RISK OF SHORTAGE

The participating companies have created a variety of techniques to manage the risks posed by raw material and API shortages. The diversification of their supply chains has been central to these, with some seeking various suppliers for the same raw materials and others aiming to localize their supply chains to lessen reliance on foreign suppliers. Regardless of the increased storage costs, another typical solution has been to retain higher inventory levels to protect against future shortages. To better identify and handle shortages, businesses have also invested in advanced forecasting tools and implemented more comprehensive supply chain management techniques. Finally, some participants pointed out the value of strong supplier connections and improved collaboration, with some even suggesting backward integration to obtain more control over their supply chains. These initiatives show the

proactive actions that businesses are taking to ensure business continuity in times of supplier uncertainty.

4.2.9 IMPACT OF RAW MATERIAL & API SHORTAGE IN COMPETITIVENESS

Raw material and API shortages have had a substantial influence on the competitiveness of Indian and global pharmaceutical enterprises. Production delays caused by these shortages have limited the capacity to meet delivery deadlines, resulting in customer dissatisfaction as well as market share loss. Profit margins have been reduced because of the additional costs associated with storing more inventories and buying from many local suppliers. Furthermore, a business claimed negative impact on their reputation because of quality difficulties caused by the use of substitute or inferior materials. These forces have combined to diminish their competitive advantage, both domestically and worldwide. This finding aligns with the third research objective, that is to analyse the impact of raw material and API shortage on growth and competitiveness of the Indian pharmaceutical industry.

4.2.10 IMPACT OF RAW MATERIAL SHORTAGE IN GROWTH AND EXPANSION

Raw material and API shortages or price increases have significantly impacted the growth and expansion plans of the companies interviewed. Specific examples include delayed or postponed expansion projects, decreased profitability because of increasing expenses, and missed growth opportunities. Due to lack of crucial raw materials, some companies were forced to postpone the launch of new products or discontinue manufacturing of specific products. Others were forced to lower manufacturing volumes, which impacted market growth. Increased raw material and API costs also impacted profit margins, which had a direct impact on enterprises' expansion investment capacity. Overall, these circumstances have impacted their growth plans and forced a vital rethinking of their expansion strategy. This finding aligns with the third research objective, that is to analyse the impact of raw material and API shortage on growth and competitiveness of the Indian pharmaceutical industry.

4.2.11 PARTNERSHIPS AND COLLABORATIONS TO MITIGATE ISSUE OF RAW MATERIAL SHORTAGE

Participants reported successful collaborations and partnerships to address raw material and API supply chain concerns. These have included strategic connections with local suppliers,

vendor diversification, and long-term ties with important suppliers. Some companies also stated collaborating on forecasting and planning with their partners to guarantee supply continuity. A few corporations have gone over standard suppliers and ties to collaborate with academic institutions on alternative material research and development. These collaborations have been critical in decreasing reliance on single sources, assuring timely material delivery, and, ultimately, limiting disruptions to their company operations.

4.2.12 HOW INDIA CAN ACHIEVE SELF SUFFICIENCY IN API & RAW MATERIALS

The participants proposed a variety of solutions for increasing raw material and API production to achieve self-sufficiency in the Indian pharmaceutical industry. There was a universal recognition on the necessity for government assistance, notably in the form of favourable laws and financial incentives, to boost domestic production. Increased R&D expenditure has been recommended, with a focus on novel manufacturing technologies and supply chain management. Several responders highlighted the significance of strategic cooperation to exchange knowledge and resources, both domestically and internationally. The importance of improving the quality of domestically created APIs to meet international standards was pointed out with participants suggesting the use of modern technology and quality control procedures. Training and skill development were also viewed as critical in order to generate a workforce capable of competing on a global scale. Finally, the need for raw material source diversification was advised to reduce the risk of shortages and improve supply chain stability. To boost self-sufficiency, a combination of strategies including governmental support, R&D, collaborations, quality upgrading, talent development, and diversification was recommended.

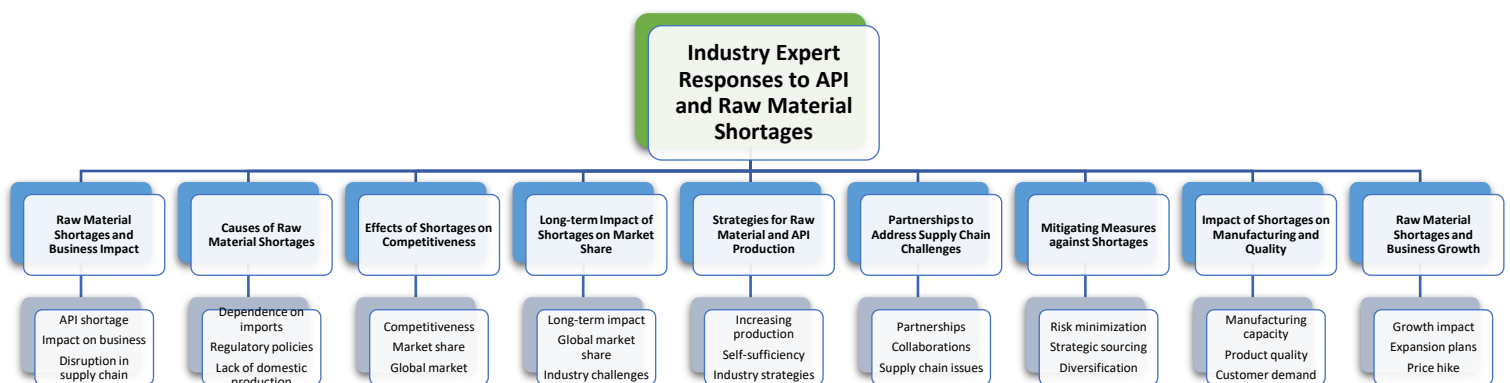


Figure 6. Thematic Map of Industry Expert Responses to API and Raw Material Shortages

4.2.13 LONG TERM EFFECTS OF RAW MATERIAL AND API SHORTAGE

The participants agreed that the continuous shortage of raw materials and APIs could compromise the Indian pharmaceutical industry's long-term share of the global market. They predicted that diminished competitiveness, reduced production capacity, and impaired product quality would weaken the industry's global status. Participants also raised the possibility of missing out on opportunities for growth and expansion because of price hikes and uncertainties in supply chain. The general view was that these concerns would increase India's dependency on imports, damaging the industry's self-sufficiency and potentially limiting India's footprint in the global pharmaceutical market. This finding aligns with the fourth research objective, that is to analyse the long-term effects of shortages of raw materials and API on the Indian pharmaceutical sector.

4.2.14 ISSUES RELATED TO DIABETES MEDICATIONS

After reviewing the responses of 13 pharmacists, it was discovered that the majority (10 out of 13) faced both diabetic medication shortages and price hikes in the previous four years. A smaller proportion of responders (3 out of 13) reported only price increases. Notably, none of the participants claimed to have observed no problems or merely shortages. While shortages were reported, most respondents indicated that they were not severe. However, the price increases were universally recognized. This implies that in the Indian pharmaceutical business, cost inflation is a more pressing concern than supply shortages in the field of diabetic drugs.

Issues in Diabetes Medications	No. of Participants Reported
Shortages	0
Price hikes	3
Both shortage and price hikes	10
None of the above	0

Table 3. Issues Related to Diabetes Medications

4.2.15 REASONS FOR SHORTAGE OF ANTI-DIABETIC DRUGS

When the comments of the 13 participants were examined, a mixed picture of the key causes of diabetes medication shortages or price increases were identified. Active Pharmaceutical Ingredient (API) shortages were identified as a key cause to these concerns by over half of the participants (6 out of 13). Raw material shortages and changes in market demand were also mentioned as primary reasons by almost one-third of the participants (5 out of 13). Only one

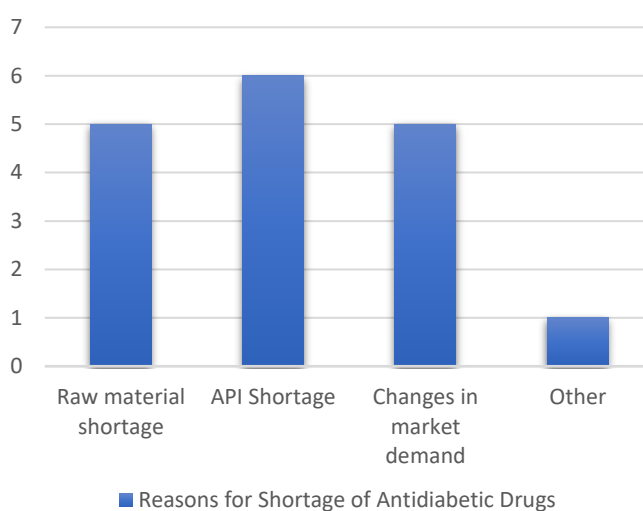


Figure 7. Bar Graph Showing Reasons for Shortage of Anti-Diabetic Drugs

participant elaborated on other reasons, including a lack of new formulation inventions in India, the presence of patented diabetic medicines, the introduction of different drug formulations such as sustained-release and extended-release versions, and high competition among Indian pharmaceutical industries. The participant underlined that market complexity, rather than a simple supply-demand imbalance, were essentially driving price increases.

4.2.16 PHARMACY EXPERIENCES DURING ANTI-DIABETIC DRUG SHORTAGES

During raw material and API shortages, pharmacists reported diverse experiences in dispensing anti-diabetic medications. Many people admitted overcoming these obstacles by sourcing alternate suppliers and drugs, demonstrating an efficient supply chain strategy. Some expressed more strain and stress as a result of having to explain the situation to patients and address their worries. A pharmacist said, their pharmacy is currently facing shortage of insulin. Due to the shortages, pharmacists were forced to limit the number of anti-diabetic medications sold each consumer. Several pharmacists reported a decrease in

patient adherence to treatment regimens, with patients either purchasing less medication or delaying purchases. On the other hand, some pharmacists said, they don't even faced any shortages.

4.2.17 IMPACT OF RAW MATERIAL AND API SHORTAGES ON ANTI-DIABETIC DRUG AVAILABILITY

Raw material and API shortages have significantly impacted the supply of anti-diabetic medications in pharmacies. Because of these shortages, the a few pharmacists said they were unable to dispense certain anti-diabetic drugs. As a result, substitutes with alternative drugs or brands were required, which were not always preferred or as effective. Some participants stated that the scarcity of medications occasionally forced patients to skip them or change their dosages, thus compromising their diabetic management. It is visible that raw material and API shortages have not only affected the supply chain, but also caused substantial obstacles to sustaining effective patient care in pharmacies. However, not all participants reported experiencing such effects. A small percentage (5 out of 13) reported that the shortages had little impact on the availability of anti-diabetic drugs in their pharmacies since they were able to successfully manage the issue by diversifying the suppliers or maintaining solid inventory management.

4.2.18 IMPACT OF RAW MATERIAL AND API SHORTAGE ON AFFORDABILITY OF ANTI-DIABETIC DRUG

There are differing opinions about how anti-diabetic drug shortages affect consumer affordability. The majority of respondents agreed that these shortages did certainly result in higher drug prices, affecting the affordability of their clients. A notable example is the drug metformin hydrochloride, which is widely used to treat diabetes. According to participants, the cost of metformin has risen significantly in recent years. Insulin price is also increased. And some other price increased medicines are Glycomet and Glyciphage. Customers purchased lower quantities of medications in some cases, probably due to increasing prices. However, a few participants expressed a different viewpoint, stating that the pricing of certain medicines, including some anti-diabetic medications, had actually fallen due to patent expirations. They believed that the price cut helped to alleviate some of the affordability concerns, demonstrating that not all customers were adversely affected by the shortages. A

minority of participants, on the other hand, reported that there was no major impact on medicine affordability, implying that their consumers could still buy their drugs despite the apparent shortages. The wide range of responses demonstrates the complicated dynamics of drug pricing and customer affordability in the face of supply shortages.

4.2.19 IMPACTS OF DRUG SHORTAGE AND PRICE HIKES ON PATIENTS

Pharmacists presented various concrete examples of how the reduced availability or increased cost of anti-diabetic medications due to raw material and API shortages impacted their clients. Many pharmacists reported cases when clients had to delay or discontinue medicine due to high expenses or a lack of availability. Some patients' health has suffered because of this. However, according to a few pharmacists, some clients were able to adjust by switching to alternative but less expensive prescriptions. Surprisingly, a minority of pharmacists reported little to no impact, implying that the consequences of shortages and price increases may differ across locations or demographics. The complexities of patient experiences highlight the importance of comprehensive solutions to secure the availability and cost of important medicines.

4.2.20 HOW PATIENTS DEAL WITH THE SHORTAGES AND PRICE HIKES

It was observed that patients typically handled the shortages and price hikes associated with antidiabetic medications in a variety of ways. When their regular medications were unavailable, a significant number of them switched to alternative medications or brands. Some patients chose to purchase smaller quantities due to price hikes. A few patients have discontinued their medications entirely due to unavailability or high costs. Nevertheless, it is important to keep in mind that some participants reported no changes in their patient behaviour, indicating that not all patients were affected by these factors. Despite the variations in response, it was clear that the shortage and price increases affected diabetes patients' treatment continuity and health outcomes.

4.2.21 MEASURES TAKEN BY PHARMACISTS TO MITIGATE THE ISSUE OF RAW MATERIAL AND API SHORTAGES

The pharmacists adopted a variety of solutions to address the challenges caused by raw material and API shortages. Many began broadening their supplier base in order to assure a

consistent supply of diabetes medications. When specific prescriptions were unavailable, pharmacists frequently replaced them with alternate drugs from other manufacturers or dispensed generic medicines. To prepare for possible shortages, some pharmacies increased their inventory levels. Communication with patients was also an important technique. Here pharmacists played a role on counselling patients on the situation and advising potential alternatives. A few pharmacists stated that they did not need to take any special precautions, indicating that their supply was mostly unaffected. Overall, proactive planning and flexibility in sourcing were the key approaches taken by pharmacists to mitigate this problem.

4.2.22 RECOMMENDATIONS FROM PHARMACISTS TO RESOLVE ISSUE OF RAW MATERIAL AND API SHORTAGE

Pharmacists made a variety of suggestions to address the problem of API and raw material shortages in the production of anti-diabetic medications. A considerable percentage of respondents advocated for India to become self-sufficient in API production, eliminating reliance on imports. They advocated strengthening indigenous manufacturing capabilities and investing in R&D to develop local raw material sources. Another typical add was to diversify suppliers to ensure a consistent supply even if one source is experiencing shortages. Pharmacists also recommended creating an efficient supply chain management system to reduce disruptions. They called for buffer stocks to manage unexpected shortages and better forecasting to predict market demand and supply fluctuations. A few others suggested that the government, manufacturers, and pharmacists work together more closely to come up with comprehensive solutions.

4.2.23 INSIGHTS FROM RAW MATERIAL AND API SHORTAGES TO MANAGE FUTURE PHARMACEUTICAL INDUSTRY CHALLENGES

The pharmacists' experiences gave important insights for future API and raw material shortage management. A major lesson learned was the significance of diversifying sources to reduce reliance on a single source. This technique may contribute to consistent drug availability, even during times of scarcity. Another important lesson was the importance of good communication and collaboration among various stakeholders, such as manufacturers, suppliers, and pharmacies. Some pharmacists highlighted the importance of advanced preparation and better forecasting to predict and eliminate any shortages. Some others

suggested having a buffer stock to deal with sudden market changes. Overall, major lessons included diversifying suppliers, enhanced communication, and strategic planning.

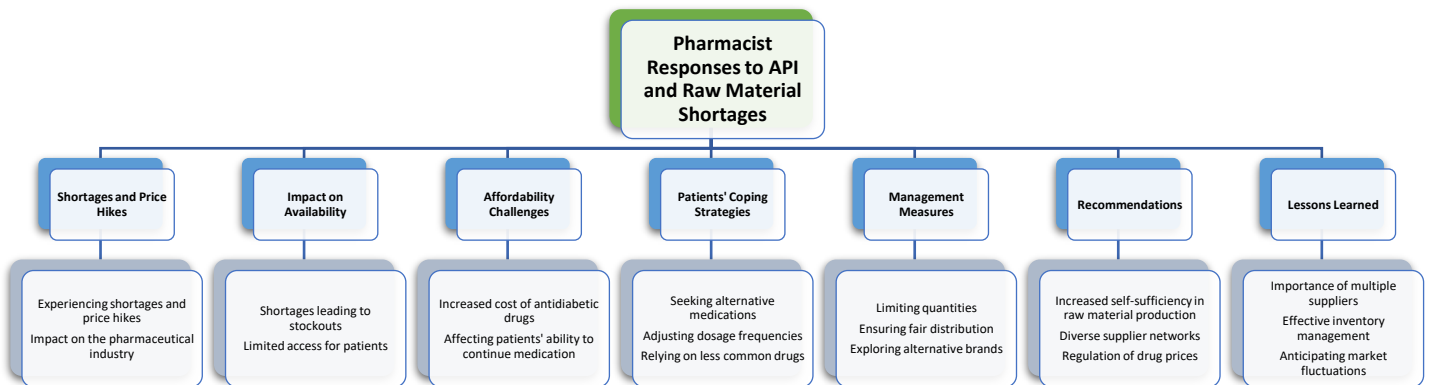


Figure 8. Thematic Map Showing Pharmacist Responses to API and Raw Material Shortages

4.3 QUANTITATIVE ANALYSIS FROM SURVEY

4.3.1 LOCATION OF PARTICIPATING DIABETIC PATIENTS

The survey was carried out among residents of two neighbouring districts in Kerala, India: Kozhikode and Malappuram. More than half of those counted (52.8%) came from Kozhikode, whereas Malappuram had somewhat fewer (47.2%). This suggests that the survey provides a good representation of opinions from people who live in both of these places. The findings should help us understand the availability and affordability of anti-diabetic drugs in these two districts.

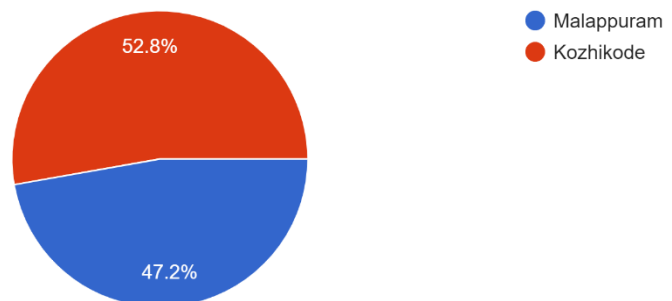


Figure 9. Pie Chart Showing Location of Participating Diabetic Patients

4.3.2 IDENTIFYING DIABETIC STATUS

The majority of the participants were diabetics, with 88.9% (32 persons) responding "Yes" to the question. As a result, their responses are critical for understanding how the shortage of raw materials and APIs may affect the availability and cost of diabetes drugs. On the other side, 11.1% (4 persons) of the participants were not diabetes patients.

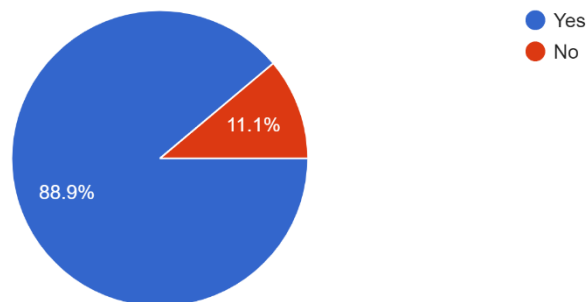


Figure 10. Pie Chart Showing Diabetic Status of Participants

4.3.3 DURATION OF DIABETES DIAGNOSIS

When asked how long they had been diagnosed with diabetes, individuals gave a variety of answers. The majority of participants, 36.1% (13 persons), had been diagnosed with diabetes less than a year. The next largest

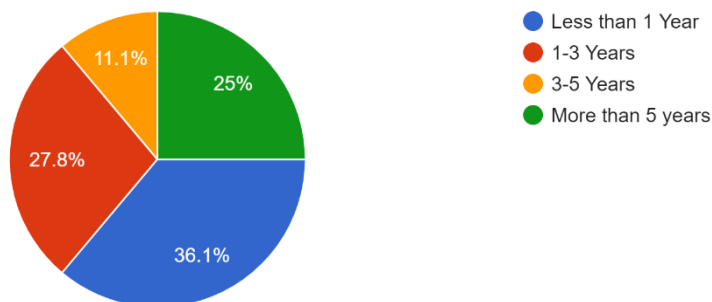


Figure 11. Pie Chart Showing Duration of Diabetes Diagnosis

group, 27.8% (10 persons), was diagnosed between one and three years ago. A smaller proportion of respondents, 11.1% (4 persons), had diabetes for 3 to 5 years. Finally, 25% of the participants (9 persons) had been diagnosed with diabetes for more than 5 years. The participants having diabetes durations of more than 3 years may see a high chance for price fluctuation.

4.3.4 STATUS OF ANTI-DIABETIC MEDICATION USE

The majority of survey respondents, 77.8% (28 persons), acknowledged that they are currently using diabetes drugs. This implies that any changes in the availability or cost of these medications because of raw material and API

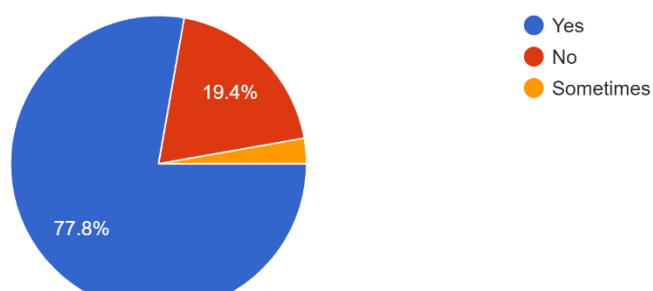


Figure 12. Pie Chart Showing Status of Anti-Diabetic Medication Use

shortages would have a direct impact on the vast majority of participants. However, 19.4% (7 persons) of the participants are not currently taking any anti-diabetic drugs. Finally, 2.8% (1 person) of participants reported taking anti-diabetic drugs just sometimes.

4.3.5 EXPERIENCES WITH DIFFICULTY IN PURCHASING ANTI-DIABETIC MEDICATION

According to the survey, more than half of the participants, 55.6% (20 persons), have had difficulties purchasing their prescribed diabetes medicine. This highlights the difficulties that many patients face in obtaining the medication they require. However, a close 44% (16 persons) of the

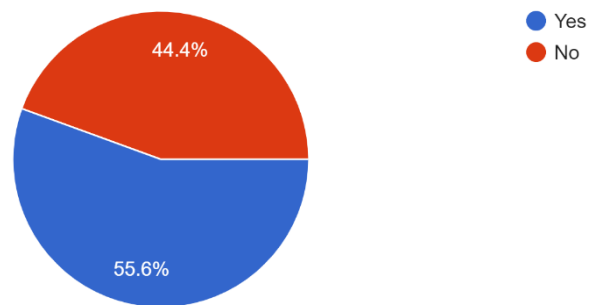


Figure 13. Pie Chart Showing Experiences With Difficulty In Purchasing Anti-Diabetic Medication

participants claimed that they had no problems acquiring their diabetes medicine. This data shows that a considerable proportion of diabetes patients have had difficulty obtaining their medication, which might be caused by raw material and API shortages.

4.3.6 OBSERVATIONS ON PRICE CHANGES OF ANTI-DIABETIC DRUGS

The vast majority of survey respondents, 80.6% (29 individuals), had seen an increase in the cost of their diabetes medication during the last four years. It also indicates that most diabetic patients are facing higher medicine costs, which may be influenced by raw material and API shortages. Meanwhile, 19.4% (7 persons) of participants have not

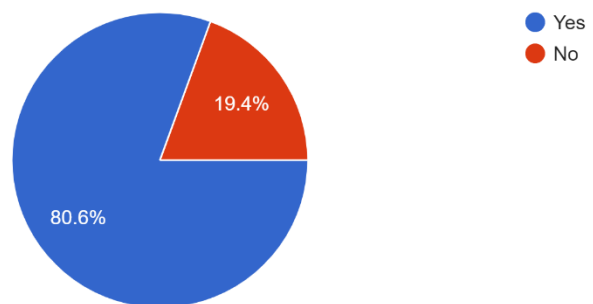


Figure 14. Pie Chart Showing Observations on Price Changes of Anti-Diabetic Drugs

seen any price increases in their diabetes medication throughout the same time period. This may be because of the price control of such medications.

4.3.7 ASSESSING THE IMPACT OF PRICE HIKE ON CONSISTANT MEDICATION PURCHASE

Among those who participated in the survey, 61.1% (22 people) said that the price increase in their diabetes medication has impacted their ability to purchase their medication on a consistent basis. This shows that increasing drug prices have become a barrier to keeping a consistent supply of their medication for a significant percentage

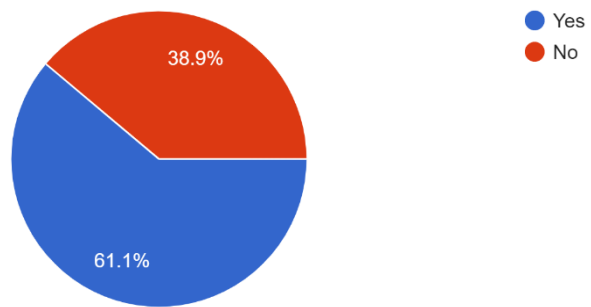


Figure 15. Pie Chart Showing Impact of Price Hike on Medication Purchase on Consistent Purchase

of diabetes patients. However, 38.9% (14 persons) said that the price rise had no effect on their ability to get their prescriptions on a consistent basis. This may be because they have better financial backgrounds compared to others.

4.3.8 ALTERNATIVE MEDICINE: BECAUSE LACK OF AVAILABILITY AND AFFORDABILITY ISSUES

More than half of survey respondents, 58.3% (21 individuals), said they had to switch to a different anti-diabetic medication due to a lack of availability or affordability. This shows that a considerable number of diabetes patients have been directly impacted by raw material and API shortages, resulting in adjustments to their treatment plan. However, a sizable proportion of participants, 41.7% (15 persons), have not had to make such a change, showing that they

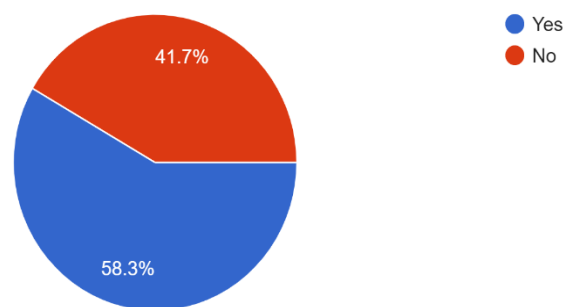


Figure 16. Pie Chart Showing Patients Used Alternative Medicine Because of Lack of Availability And Affordability Issues

have been able to continue taking their regular prescription regardless of the challenges in the pharmaceutical industry.

4.3.9 FREQUENCY OF DIFFICULTY IN OBTAINING ANTI-DIABETIC DRUGS

According to the survey, participants had different frequencies of difficulties obtaining their diabetes drugs. The largest group, 27.8% (10 persons), stated that they faced difficulty "Sometimes." This means that people occasionally have problems obtaining their medication. A similar proportion,

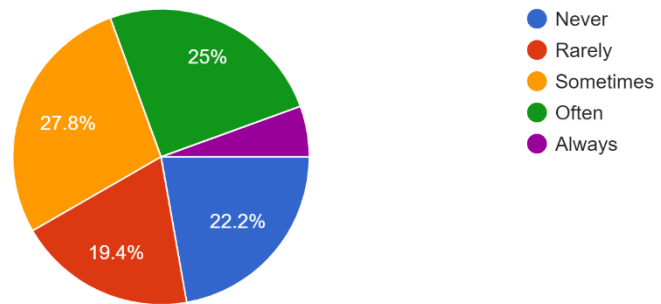


Figure 17. Pie Chart Showing Frequency of Difficulty in Obtaining Anti-Diabetic Drugs

25% (9 persons), reported issues "often," implying a more frequent difficulty in acquiring their medication. A smaller group, 5.6% (2 people), reported "Always" having trouble, indicating an ongoing struggle. On the opposite end of the scale, 22.2% (8 people) say they "never" have trouble receiving their diabetic medicine, while 19.4% (7 people) say they "rarely" do. These findings illustrate the varied experiences of diabetic patients in acquiring their prescription, with a large number reporting some level of difficulty, which could be caused by raw material and API shortages in the pharmaceutical sector.

4.3.10 PATIENTS APPROACH DURING SHORTAGES AND PRICE HIKES OF MEDICINES

During medication shortages or price hikes, survey participants reported a variety of diabetes management techniques. The most common strategy, reported by 38.9% (14 persons), was to seek medical advice, demonstrating that

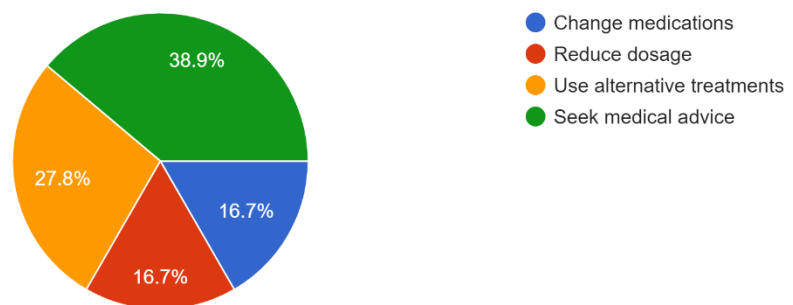


Figure 18. Pie Chart Showing Patients Approach During Shortages And Price Hikes Of Medicines

when presented with these issues, these participants choose to consult healthcare specialists. The next most common reaction, given by 27.8% (10 persons), was to try alternative treatments, implying that some patients seek non-prescribed means of diabetes management. Changing drugs and lowering dosage were both chosen by 16.7% (6 persons),

demonstrating that a fraction of patients adjusts their pharmaceutical regimen by switching to a different drug or changing their consumption pattern. These replies demonstrate the numerous techniques utilized by diabetic patients in response to drug shortages or price rises, which could be due to raw material and API shortages.

4.3.11 KNOWLEDGE OF COST AND AVAILABILITY OF ANTI-DIABETIC DRUGS

The study found that 72.2% (26 individuals) of participants believe they have a good awareness of the availability and cost of anti-diabetic medications in their area. It means that most diabetic patients are actively aware of their medication condition in their community.

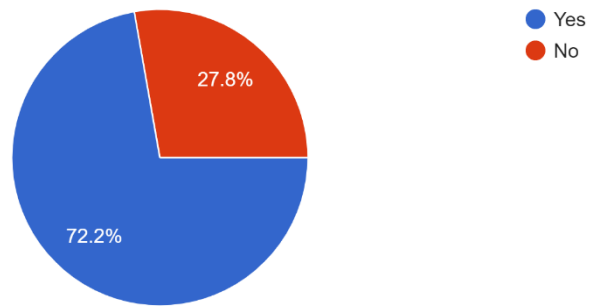


Figure 19. Pie Chart Showing Patients Knowledge on Cost And Availability of Anti- Diabetic Drugs

This information could help them in handling any issues associated with medicine shortages or price hikes. In contrast, 27.8% (10 participants) said that they do not understand the availability and cost of anti-diabetic medications in their location. Because of their lack of knowledge about the local drug landscape, this group might face extra challenges when there are bottlenecks in the pharmaceutical supply chain, such as raw material and API shortages.

4.3.12 EVALUATING SATISFACTION WITH CURRENT DIABETES MEDICATION AVAILABILITY AND COST

Participants in the study showed varying degrees of satisfaction with the current availability and pricing of their diabetes medication. The largest group of participants, 41.7% (15 persons), were "Neutral," indicating that they have neither serious complaints nor are

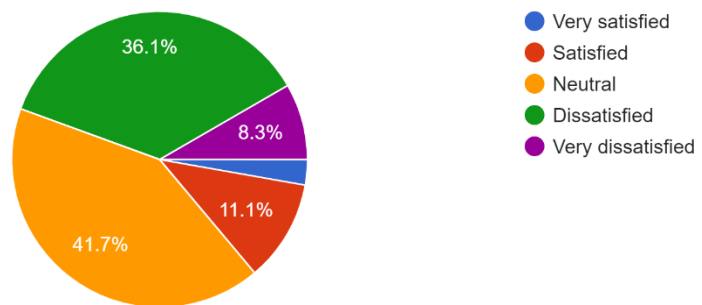


Figure 20. Pie Chart Showing Patient Satisfaction on Current Availability And Cost of Anti-Diabetic Medications

completely satisfied with the situation. A similar proportion, 36.1% (13 persons), were "Dissatisfied," suggesting dissatisfaction with the existing situation, possibly because of

medicine availability concerns or high prices. A lesser proportion of respondents, 11.1% (4 persons), reported being "satisfied," while a single participant (2.8%) reported being "very satisfied," indicating that they are satisfied with the current situation of their diabetes medication availability and pricing. These distinct responses highlight diabetic patients' diverse experiences and perceptions of managing their disease in the face of current or future pharmaceutical sector issues.

4.4 QUALITATIVE ANALYSIS FROM SURVEY

4.4.1 UNDERSTANDING PATIENTS EXPERIENCE: DIFFICULTY IN PROCURING ANTI-DIABETIC MEDICATIONS AND HEALTH IMPACTS

The survey replies provide a full insight of the participants' different experiences in getting anti-diabetic medicines. These experiences range from having no problems at all to having severe barriers to obtaining their essential medicines. From the responses, we can see the increase in drug shortages and high costs, which have a negative impact on the lives of many diabetic patients. Many respondents reported difficulty getting anti-diabetic drugs, because of shortages or price hikes. This sometimes resulted in patients skipping dosages or switching to alternate drugs, which were ineffective in managing their diabetes. As a result, these people had inadequate blood sugar regulation, which led to health issues like fatigue, exhaustion, and difficulties concentrating at work. This finding aligns with the study's second objective, which is to focus on the impact of raw material and API shortages on availability and affordability of drugs in India, as well as the health and well-being of diabetes patients.

In contrast, several respondents had no trouble obtaining their anti-diabetic drugs. They said that they were able to get these drugs because there were many medical shops in their area, which gave them options when their first choice wasn't available. Furthermore, when faced with the unavailability or unaffordability of their prescription anti-diabetic drugs, many patients are preferring generic medicines and a few patients turned to alternative treatments such as Ayurvedic medicine or lifestyle adjustments such as diet restriction and yoga.

The patient experiences highlight the complicated relationship between drug availability, affordability, and patient health outcomes. They show that there is a gap in the healthcare system, which could make patients' health problems worse if they can't get their medicines. Furthermore, the replies reflect socioeconomic gaps in access to healthcare, with those from

lower socioeconomic backgrounds being more negatively affected by increased anti-diabetic medicine prices and shortages. These people often go for less effective options or skip doses altogether, which compromises their health and well-being.

4.4.2 SUGGESTIONS FROM DIABETIC PATIENTS FOR IMPROVING AVAILABILITY AND AFFORDABILITY OF ANTI-DIABETIC DRUGS

How to make diabetes drugs readily available and less expensive in the community point out a few areas of concern and possible solutions. A common theme is the need for government to take initiative. Setting price controls, promoting domestic drug production, providing free diabetic treatment at public hospitals, and assuring increased availability of regular anti-diabetic medicines rather than generic equivalents are all examples of approaches. Several respondents also underline the importance of improving supply chain management. Some of the ideas are for local pharmacies to keep a steady stock of medications, for manufacturing companies to store more raw materials, and for businesses to improve their relationships with suppliers. Others advocate for individual initiatives such as adopting healthier habits and selecting lower-cost alternatives.

Surprisingly, a few respondents advocate for patient counselling and public education regarding medications and their costs. This instructional method has the potential to empower individuals to make informed health decisions. However, it is crucial to highlight that some respondents believe the issue is out of their hands and must be addressed by larger entities such as pharmaceutical firms. A few respondents are also pleased with the current state of affairs, claiming that they have no complaints about the cost or availability of their prescriptions. Overall, the comments underline the importance of a multimodal strategy to addressing the problem, including a combination of policy interventions, supply chain management improvements, and public education.

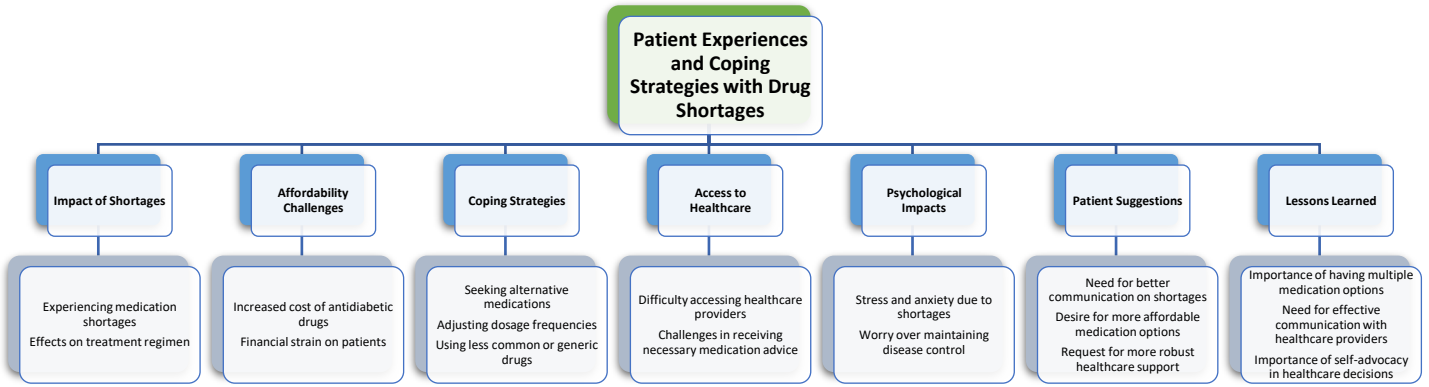


Figure 21. Thematic Map Showing Patient Experiences and Coping Strategies with Drug Shortages

CHAPTER 5

CONCLUSIONS &

RECOMMENDATIONS

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSION BY RESEARCH OBJECTIVES

5.1.1 TO ANALYSE THE IMPACT OF RAW MATERIAL AND API SHORTAGE ON MANUFACTURING OF PHARMACEUTICAL PRODUCTS IN INDIA

The study's findings give strong evidence of the negative impact of raw material and API shortages on pharmaceutical manufacturing in India. This conclusion complies with the patterns described in previous studies. Recent global crises, such as the COVID-19 pandemic and the Russia-Ukraine war, have caused major supply chain disruptions, led to raw material and API shortages. According to specialists in the field, these events, have made it more difficult for companies to continue operating and satisfy customer needs.

Manufacturing shutdowns due to regulatory concerns, as noted by participants, resulted in unsatisfied customer demand, and delayed deliveries. Similarly, low-quality raw materials used as alternatives to deal with shortages reduced the quality of finished products. This pattern matches up with previous studies, underlining the issues of ceasing production, quality control, and failure to meet customer demands.

Pharmacists validated the impact of these shortages on drug availability for patients, which is in line with previous research on the consequences of raw material and API shortages.

In conclusion, the research findings highlight the important issue of raw material and API shortages in the Indian pharmaceutical industry, which has been formed by global crises and disruptions. This causes a series of problems from manufacturing to patient care, underlining the need for intense efforts to address these difficulties and assure a stable supply of essential drugs.

5.1.2 TO ANALYSE THE IMPACT OF RAW MATERIAL AND API SHORTAGES ON THE AVAILABILITY AND AFFORDABILITY OF DRUGS IN INDIA

The shortage of raw materials and active pharmaceutical ingredients (APIs) has had a substantial impact on the availability and affordability of drugs in India, including diabetes medications. These shortages have caused supply chain interruptions, forcing pharmacists to seek other substitutes that may not always be as effective. Furthermore, these shortages have resulted in price increases, hurting the affordability of drugs for patients.

When the findings are compared to the literature review, it is clear that the impact of raw material and API shortages on medicine availability and affordability is a global concern. Political unrest, military conflicts, economic disputes, and environmental factors, according to (Shukar *et al.*, 2021), can all contribute to these shortages. And as per (Heiskanen *et al.*, 2017), complex production chains may worsen these shortages. The COVID-19 epidemic, as well as the Russia-Ukraine war, have stressed these supply chains even more, resulting in a global impact on drug availability and pricing.

The experiences described by Indian pharmacists, underlines the need of diversifying raw material and API suppliers to maintain continuous medicine supply. Increasing indigenous manufacturing capabilities, better forecasting to anticipate market demand and supply variations, and developing effective supply chain management systems are all part of this.

The analysis of literature also verifies the findings that price increases have occurred as a result of these shortages. Due to supply concerns, the price of isopropyl alcohol (antiseptic) increased by 100%, Nimesulide (NSAID) increased by 189%, and azithromycin (Antibiotic) nearly doubled. In the findings with respect to diabetic medications, we can see price hikes of medicines like Metformin, Glycomet, Glyciphage and Insulin. These price increases made medicines unaffordable for many people in India.

The findings and literature analysis both highlight the significant challenges that patients experience in obtaining required medications as a result of these shortages and price increases. Many patients in India have been forced to delay or discontinue treatment due to excessive costs or a lack of availability, putting their health at risk. These concerns are especially evident in the case of diabetes drugs, where shortages and price rises have impacted treatment continuity and health outcomes for a large number of patients.

Finally, the shortage of raw materials and APIs has a significant impact on medicine availability and affordability in India, mirroring global trends observed in the literature. To ensure the availability and affordability of essential medicines, comprehensive solutions such as diversification of raw material sources, improved supply chain management, and proactive planning are required.

5.1.3 TO ANALYSE THE IMPACT OF RAW MATERIAL AND API SHORTAGES ON THE GROWTH AND COMPETITIVENESS OF INDIAN PHARMACEUTICAL INDUSTRY

The shortage of raw materials and Active Pharmaceutical Ingredients (APIs) have a considerable impact on the Indian pharmaceutical industry's growth and competitiveness. Although being a global leader in drug manufacturing and technology, the Indian pharmaceutical sector is dealing with barriers like as raw material and API shortages, which limit domestic market growth and restrict the transition from generic drug manufacturing to research and development.

Our findings support the basic notion that these shortages have an impact on both competitiveness and growth. Companies reported production delays because of raw material and API shortages, resulting in diminished ability to meet delivery deadlines, customer dissatisfaction and market share loss. Profit margins have been impacted by increased costs associated with managing greater inventories and buying from various local vendors. Furthermore, the use of inferior or alternative materials has harmed the reputations of a company. Raw material and API shortages have resulted in delayed or postponed expansion plans, lost profitability due to price increases, and missed growth opportunities. Due to the lack of crucial raw materials, some companies have had to postpone new product launches or cancel specific product lines. Overall, these factors have forced a critical rethinking of growth strategies.

To mitigate these impacts, measures such as improving partner relationships, lowering lead times and inventories, and diversifying API sources are proposed. This holistic approach would assure the Indian pharmaceutical industry's continuing expansion and competitiveness in the global market.

5.1.4 TO ANALYSE THE LONG-TERM EFFECTS OF SHORTAGES OF RAW MATERIALS AND API ON THE INDIAN PHARMACEUTICAL SECTOR

The long-term effects of raw material and Active Pharmaceutical Ingredients (API) shortages on the Indian pharmaceutical industry are complex, and they may have an impact on the industry's worldwide status. The COVID-19 epidemic has increased these fears, revealing the industry's reliance on API and raw materials from certain nations like China and requiring a reconsideration of API and raw material self-sufficiency.

Our findings support this concern and confirm the initial hypothesis. Participants agreed that ongoing shortages might harm India's pharmaceutical industry's long-term competitiveness in the global market. Reduced manufacturing capacity, poor product quality, and decreased competitiveness have been identified as potential threats to the industry's global standing. Participants also mentioned that fluctuations in prices and supply chain uncertainty could limit growth and expansion plans of companies. Furthermore, the industry's rising reliance on imports was viewed as a potential threat to self-sufficiency, thereby limiting India's global pharmaceutical footprint. Participants, on the other hand, proposed numerous ideas for dealing with future issues, such as diversifying supplies, boosting communication and collaboration among stakeholders, and improving forecasting to mitigate shortages. In addition, the necessity for government support, higher R&D spending, strategic collaborations, quality upgrades, and workforce development were underlined for the Indian pharmaceutical industry to reach self-sufficiency. Diversification of raw material sources was also mentioned as a method for improving supply chain stability and decreasing the risk of shortages.

In conclusion, to minimize the long-term effects of raw material and API shortages on the Indian pharmaceutical industry, a mix of government support, better R&D, strategic collaborations, quality enhancements, workforce development, and diversification is required.

5.2 CONCLUDING THOUGHTS

5.2.1 CONTRIBUTIONS AND LIMITATIONS OF THE RESEARCH

This study contributes greatly to our understanding of the impact of raw material and API shortages on the Indian pharmaceutical industry, a topic that has grown relevant in regard to recent global crises. It provides practical insights and ideas for addressing these challenges, with the potential to affect policymaking and industry practice. The study, however, has limitations. The dependence on participant perceptions could have caused by bias. Despite efforts to assure a diverse sample, it may not accurately reflect the industry's perspectives. Other possible variables influencing the pharmaceutical business, such as government regulations or global market dynamics, are not considered in the study. Furthermore, it lacks precise data on individual medicine price fluctuations year by year, which might provide a

more complete assessment of the impact of shortages. These limitations indicate potential for future research to build on the findings of this study and go deeper into these topics.

5.2.2 RECOMMENDATIONS FOR PRACTICE

The Indian pharmaceutical business can benefit from the following suggestions, which can be made on the basis of the findings:

1. **Diversify Supply:** To avoid the risks associated with relying on a single source of raw materials and APIs, businesses should diversify their supply chains, taking into account suppliers from several areas.
2. **Improve Forecasting:** Create robust forecasting systems to predict changes in market demand and supply. This can aid in the planning and maintenance of buffer stocks to deal with unexpected market shifts.
3. **Improve Communication and Collaboration:** Improve communication and collaboration among various stakeholders, such as manufacturers, suppliers, and pharmacies, to enable smooth operations and fast reaction to any difficulties.
4. **Concentrate on R&D:** Increase investment in R&D, particularly in novel manufacturing technologies and supply chain management.
5. **Government Support:** Forming good government policies and financial incentives to boost domestic production and make the business more resilient.
6. **Improve Quality Control:** Prioritize quality control measures to guarantee that APIs manufactured domestically satisfy international standards.
7. **Workforce Development:** Invest in education and training to create a workforce that can compete on a global basis.
8. **Just in Case (JIC) Inventory System:** Based on the findings of this study and considering the barriers found in the Indian pharmaceutical business, the researcher suggests implementing a 'Just-in-Case' (JIC) inventory system. The JIC approach is more conservative than the 'Just-in-Time' (JIT) system, which relies on exact timing and efficiency to acquire materials when they are needed in the manufacturing process. It involves maintaining more stocks as a buffer against supply and demand fluctuations. Adopting a JIC approach could reduce the risks of raw material and API shortages by guaranteeing a sufficient reserve to maintain production during supply chain disruptions.

While this may result in greater inventory costs, the trade-off may result in improved supply reliability, lower risk of production outages, and improved capacity to meet patient needs for important medicines.

If effectively adopted, these ideas can assist the Indian pharmaceutical industry in managing raw material and API shortages, ensuring constant drug availability, and strengthening its worldwide competitiveness.

5.2.3 RECOMMENDATIONS FOR FUTURE RESEARCH

While this study provides important insights into the impact of raw material and API shortages on the Indian pharmaceutical sector, it also identifies areas that require additional research.

1. **More Detailed Analysis of Specific Drugs:** This study is general, and a more detailed analysis of specific drugs and how their prices change every year could give more complex insights of shortages of raw materials and APIs.
2. **Evaluating the 'Just-in-Case' Inventory System:** Because this study recommends the 'Just-in-Case' inventory system, future research should conduct a detailed comparative analysis of the 'Just-in-Time' and 'Just-in-Case' systems in the context of the Indian pharmaceutical industry.
3. **Impact on Other Stakeholders:** To acquire a more comprehensive perspective, future study might investigate the impact of raw material and API shortages on other stakeholders in the pharmaceutical supply chain, such as hospitals and clinics.
4. **Global Comparison:** A study of how different countries handle raw material and API shortages could provide more insights and best practices from which the Indian pharmaceutical sector could learn.

By addressing these areas, future studies can contribute to a more solid understanding of the dynamics underlying raw material and API shortages in the Indian pharmaceutical sector.

5.3 FINAL CONCLUSIONS

The report provides a thorough examination of the impact of raw material and API shortages on the Indian pharmaceutical industry, revealing good insightful findings. It indicates that these shortages have a negative impact on manufacturing processes, drug availability and affordability, industry growth and competitiveness, and may have long-term consequences for the sector's worldwide status.

The study highlights the importance of diversifying raw material and API sources, boosting communication among stakeholders, and strengthening forecasting tools to address these shortages. Furthermore, it makes a recommendation of implementing a 'Just-in-Case' inventory system, which might provide a robust protection to future problems.

However, the study acknowledges how complicated these problems are and how many different things can affect them. This opens a lot of possibilities for future research. Exploration in this field should continue to face the challenges and uncertainties that remain in the future, opening the way for a more robust and self-sufficient Indian pharmaceutical industry.

Finally, raw material and API shortages are critical challenges for the Indian pharmaceutical industry. However, with strategic planning, proactive actions, and effective stakeholder collaboration, these impacts can be mitigated, assuring the industry's long-term growth and competitiveness on a global scale.

REFERENCE

1. Akhter, Y. et al. (2020) Antimicrobial Resistance: Present Challenges and Opportunities, Health Care Associated Infections: A Global Threat, Different Testing Methods Used for Detection of COVID-19: Present Scenario.
2. Allemang, B., Sitter, K. and Dimitropoulos, G. (2022) 'Pragmatism as a Paradigm for Patient-oriented Research'. Health Expectations : An International Journal of Public Participation in Health Care and Health Policy, 25(1), pp. 38–47. DOI: 10.1111/hex.13384.
3. America, S.N. (2016) Quality APIs for Competitive Advantage - Seqens. Available at: <https://www.pcisynthesis.com/quality-apis-for-competitive-advantage/> (Accessed: 18 February 2023).
4. Ayati, N., Saiyarsarai, P. and Nikfar, S. (2020) 'Short and Long Term Impacts of COVID-19 on the Pharmaceutical Sector'. DARU Journal of Pharmaceutical Sciences, 28(2), pp. 799–805. DOI: 10.1007/s40199-020-00358-5.
5. Bansode, B. and Jungari, D.S. (2019) 'Economic Burden of Diabetic Patients in India: A Review'. Diabetes & Metabolic Syndrome, 13(4), pp. 2469–2472. DOI: 10.1016/j.dsx.2019.06.020.
6. Basu, S. and Chaudhuri, R. (2022) 'Effect of COVID 19 Pandemic on Pharmaceutical Industry in Terms of Inventory and Logistics Management'. Himalayan Research Papers Archive. Available at: https://digitalrepository.unm.edu/nsc_research/89.
7. Bharat Bhushan Rewari., Nabeel Mangadan-Konath. and Sharma, M. (2020) 'Impact of COVID-19 on the Global Supply Chain of Antiretroviral Drugs: A Rapid Survey of Indian Manufacturers'. WHO South-East Asia Journal of Public Health, 9(2), pp. 126–133.
8. Bhargava, A. and Kalantri, S.P. (2013) 'The Crisis in Access to Essential Medicines in India: Key Issues Which Call for Action'. Indian Journal of Medical Ethics, 10(2), pp. 86–95. DOI: 10.20529/IJME.2013.028.
9. BIOSPACE Formula Shortage Highlights Supply Chain Concerns Facing Pharma Industry – PharmaLive. Available at: <https://www.pharmalive.com/formula-shortage-highlights-supply-chain-concerns-facing-pharma-industry/> (Accessed: 30 January 2023).
10. Buddhavarapu, R. (2022) India Wants to Be the 'pharmacy of the World.' But First, It Must Wean Itself from China. CNBC. Available at: <https://www.cnbc.com/2022/05/27/india-needs-to-fill-china-gaps-to-become-the-pharmacy-of-the-world.html> (Accessed: 28 January 2023).
11. Chandna, H. (2020) What Are APIs and How They Threaten India's Status of a 'Pharmacy to the World'. ThePrint. Available at: <https://theprint.in/theprint-essential/what-are-apis-and-how-they-threaten-indias-status-of-a-pharmacy-to-the-world/370941/> (Accessed: 30 January 2023).
12. Chatterjee, P. (2020) 'Indian Pharma Threatened by COVID-19 Shutdowns in China'. The Lancet, 395(10225), p. 675. DOI: 10.1016/S0140-6736(20)30459-1.
13. Cherian, J.J. et al. (2021) (2) 'India's Road to Independence in Manufacturing Active Pharmaceutical Ingredients: Focus on Essential Medicines'. Economies, 9(2), p. 71. DOI: 10.3390/economies9020071.
14. Chitsimran, M. et al. CONTEMPORARY ISSUES IN BUSINESS AND ECONOMICS: VOLUME-1. RED'SHINE Publication. Pvt. Ltd.

15. Festa, G. et al. (2021) 'Envisioning the Challenges of the Pharmaceutical Sector in the Indian Health-Care Industry: A Scenario Analysis'. *Journal of Business & Industrial Marketing*, 37(8), pp. 1662–1674. DOI: 10.1108/JBIM-07-2020-0365.
16. Fisher, M.J. and Marshall, A.P. (2009) 'Understanding Descriptive Statistics'. *Australian Critical Care*, 22(2), pp. 93–97. DOI: 10.1016/j.aucc.2008.11.003.
17. Haque, M. et al. (2021) 'Utilisation, Availability and Price Changes of Medicines and Protection Equipment for COVID-19 Among Selected Regions in India: Findings and Implications'. *Frontiers in Pharmacology*, 11. Available at: <https://www.frontiersin.org/articles/10.3389/fphar.2020.582154> (Accessed: 18 April 2023).
18. Heiskanen, K. et al. (2017) 'The Reasons behind Medicine Shortages from the Perspective of Pharmaceutical Companies and Pharmaceutical Wholesalers in Finland'. *PLOS ONE*, 12(6), p. e0179479. DOI: 10.1371/journal.pone.0179479.
19. Hyde, K.F. (2000) 'Recognising Deductive Processes in Qualitative Research'. *Qualitative Market Research: An International Journal*, 3(2), pp. 82–90. DOI: 10.1108/13522750010322089.
20. James, T.C. 'Bulk Drug Industry in India: Challenges and Prospects'.
21. Kakkar, A.K. (2021) 'Pharmaceutical Price Regulation and Its Impact on Drug Innovation: Mitigating the Trade-Offs'. *Expert Opinion on Therapeutic Patents*, 31(3), pp. 189–192. DOI: 10.1080/13543776.2021.1876029.
22. Kaur, D.M. 'POSITIVE AND NEGATIVE IMPACT OF UKRAINE AND RUSSIA WAR ON INDIAN ECONOMY'. 13(11).
23. Kolte, A. et al. (2022) 'Ambidexterity's Influence on Export Strategy Development—The Case of the Indian Pharmaceutical Industry'. *Thunderbird International Business Review*, 64(5), pp. 465–476. DOI: 10.1002/tie.22278.
24. Kong Deqiang, D.L. (2019) 'Analysis of the Current Situation of Active Pharmaceutical Ingredient (API) Export in China'. *亚洲社会药学*, 14(3), pp. 126–134.
25. KOPPIKAR-MOORTHY, A. Understanding the Coming Challenges to India's Pharma Sector. ORF. Available at: <https://www.orfonline.org/expert-speak/understanding-the-coming-challenges-to-indias-pharma-sector-66556/> (Accessed: 29 January 2023).
26. M., S.K. et al. (2020a) 'Social Economic Impact of COVID-19 Outbreak in India'. *International Journal of Pervasive Computing and Communications*, 16(4), pp. 309–319. DOI: 10.1108/IJPCC-06-2020-0053.
27. M., S.K. et al. (2020b) 'Social Economic Impact of COVID-19 Outbreak in India'. *International Journal of Pervasive Computing and Communications*, 16(4), pp. 309–319. DOI: 10.1108/IJPCC-06-2020-0053.
28. Moosivand, A., Rajabzadeh Ghatari, A. and Rasekh, H.R. (2019) 'Supply Chain Challenges in Pharmaceutical Manufacturing Companies: Using Qualitative System Dynamics Methodology'. *Iranian Journal of Pharmaceutical Research : IJPR*, 18(2), pp. 1103–1116. DOI: 10.22037/ijpr.2019.2389.
29. Sharna, S. (2022) 'Impact of Household Chores Situation on Female University Teachers in the Context of Bangladesh'. In pp. 268–283. DOI: 10.25215/1387734229.24.
30. Shreyan, M. (2020) 'Indian API Industry Has the Tide Turned?' *Journal of Generic Medicines*, 16(1), pp. 27–38. DOI: 10.1177/1741134319887782.

31. Shukar, S. et al. (2021) 'Drug Shortage: Causes, Impact, and Mitigation Strategies'. *Frontiers in Pharmacology*, 12. Available at: <https://www.frontiersin.org/articles/10.3389/fphar.2021.693426> (Accessed: 18 April 2023).
32. Singla, R. et al. (2019) 'Drug Prescription Patterns and Cost Analysis of Diabetes Therapy in India: Audit of an Endocrine Practice'. *Indian Journal of Endocrinology and Metabolism*, 23(1), pp. 40–45. DOI: 10.4103/ijem.IJEM_646_18.
33. Udayana, R. 'Examining COVID-19 Impact on Indian Pharma Production'.
34. Venkataraman, K., Kannan, A.T. and Mohan, V. (2009) 'Challenges in Diabetes Management with Particular Reference to India'. *International Journal of Diabetes in Developing Countries*, 29(3), pp. 103–109. DOI: 10.4103/0973-3930.54286.
35. Willig, C. and Rogers, W.S. (2017) *The SAGE Handbook of Qualitative Research in Psychology*. SAGE.