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# Indian Pharmaceutical Companies' Approach to API Sourcing and Procurement Risk Management

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## ABSTRACT

Management of Active Pharmaceutical Ingredients (APIs) sourcing and procurement risks in the Indian pharmaceutical industry. Research techniques from both descriptive and exploratory approaches make up the study's mixed-method methodology. Professionals in the fields of procurement, supply chain management, and regulatory affairs fill out a self-administered quantitative survey and participate in semi-structured qualitative interviews. Utilizing stratified random sampling, the data is compiled. Tactical, purposeful sampling was employed with the target population; thus, participants were not restricted. Question types included semi-structured and fully-structured interviews for open-ended inquiries, as well as dichotomous and attitude questions using Likert, ordinal, and nominal scales for quantitative data collection. Various sources of primary and secondary data were consulted. By utilizing data analytic methodologies, the study's conclusions were expanded upon. The statistical software SPSS, Microsoft Excel, or a comparable program was used to evaluate quantitative data. Descriptive statistics, mathematical means and standard deviations, bivariate correlations, and regression analysis were all part of the quantitative analysis.

***Key Words:*** *Indian Pharmaceutical Companies, API Sourcing, Procurement Risk Management.*

## 1. INTRODUCTION

The pharmaceutical sector in India is recognized as a major source of cost-effective and high-quality generic medications on a global scale. India hosts more than 3,000 pharmaceutical companies and 10,500 production facilities, accounting for nearly 20% of the total supply volume and serving as the largest source of generic medications worldwide (IBEF, 2024). The rigorous regulatory frameworks, commitment to international standards, and a significant skilled workforce have established this country as a reliable supplier to both emerging and developed markets. Indian companies are addressing the worldwide demand for crucial medications, particularly for conditions such as HIV/AIDS, tuberculosis, and malaria. Although the nation has achieved considerable progress in creating formulations for production, it is crucial to recognize that it continues to rely on foreign countries for its Active Pharmaceutical Ingredients (APIs), which are the vital chemical elements of the drugs. The advancement of the industry should depend on its formulation capabilities and a strong, self-sustaining API supply chain that can adeptly manage economic, political, and logistical obstacles.

### 1.1 The Importance and Function of APIs in Pharmaceutical Manufacturing

The physiologically active ingredients in any pharmaceutical product are called APIs. When APIs are not present, the drug has no therapeutic effect. The APIs are produced by intricate chemical procedures, and in order to guarantee safety and effectiveness, the final products must meet strict quality standards. From antibiotics to cancer therapies, active pharmaceutical ingredients (APIs) are used in a wide range of

pharmaceutical products in India. They are important for both local and international export markets. India may have highly advanced formulation facilities, but because of earlier regulations that gave priority to low-level bulk drug manufacture, a sizable amount of active pharmaceutical ingredients (APIs) are still imported, primarily from China. Consequently, changes in the global supply chain make even top Indian pharmaceutical companies susceptible to production-related shortages of essential chemicals, which forces them to depend on imports.

### 1.2 Challenges in the Organization of API Procurement

Most API sourcing mistakes are made by pharmaceutical firms, even though risks from outside the company are well known. Strategic buying gone wrong is the worst thing that can happen, especially for mid-sized and formulation-focused businesses. The process for making buying decisions doesn't look at long-term stability along with short-term cost-benefits. This leads to bad evaluations of vendors and too much focus on price-sensitive contracts. Operating myopia keeps businesses from putting money into better suppliers, safety systems, or planning for when employees will leave. Another problem with the company is that the procurement, regulatory, and quality assurance divisions don't talk to each other well. Because most companies have teams that work on separate tasks, they don't follow compliance rules during the buying process. It's against the rules for quality assurance teams to do supplier audits and for procurement departments to put a high priority on traceability and regulatory permit acquisition documents. This internal mismatch makes it harder for the company to quickly fix problems or make improvements. Instead of using automated buying solutions, some companies still use old spreadsheets and manual processes that are slow and prone to mistakes. To keep track of suppliers' success and plan ahead for stock shortages, businesses need digital dashboards or real-time supply insight. Another problem is vendor diversification, which happens when companies don't look at other providers because of costs or risks. All of these internal inefficiencies make it harder for the company to deal with buying threats, which is why it needs to align its strategy and make digital changes faster.

### 1.3 Geopolitical and Economic Factors Influencing Supply Risk

The dependence of global pharmaceutical supply chains on geopolitical and macroeconomic processes is increasing. The heavy dependence of Indian pharmaceutical companies on China for crucial APIs has rendered their procurement processes vulnerable to additional risks that extend beyond traditional business challenges. Incidents between India and China, like those witnessed in Galwan in 2020, have arisen from geopolitical challenges that have resulted in strained trade relations and heightened concerns regarding potential disruptions in the supply chain. While this friction may be short-lived, it casts a significant shadow over other strategic sectors, like pharmaceuticals, where even a brief disruption in the supply of APIs can jeopardize drug production across all Indian facilities. The complexities of this issue have been exacerbated by economic factors. The relaxation of stringent environmental regulations in China, along with rising manufacturing costs, has led to the closure of many pollutant chemical plants. This has consequently restricted access to active pharmaceutical ingredients (API) and driven up their prices. Indian buyers are unable to influence these changes, yet they have a substantial impact on the procurement cycle. Furthermore, the disruptions in global supply chains, particularly during the COVID-19 pandemic, have led to significant delays in shipping, container availability, and port operations. This situation has heightened the risks associated with procurement in industries that are both time-sensitive and compliance-oriented, such as pharmaceuticals.

## 2. REVIEW OF LITERATURE

**Happer (2025).** The procurement tactics utilized by Indian pharmaceutical businesses are significantly variable due to factors such as company size, export risk, and differing regulatory constraints. In contrast to large corporations like Sun Pharma or Dr. Reddy, small and medium-sized enterprises (SMEs) often employ cost-based procurement tactics, neglecting long-term risk management considerations. This contrasts with the operational methods of huge corporations.

**Sang Ode (2024).** Some digital solutions are being applied, especially for enterprises that depend significantly on exports. Among these, you may find AI-driven risk engines, supplier dashboards, and enterprise resource planning (ERP) procurement engines. However, a study conducted in 2023 found that over 60% of SMEs in the Indian pharmaceutical industry still use manual or basic procurement tools, which leaves them vulnerable to data exploitation and makes them more likely to make impulsive decisions.

**Zhang & Liu (2023)**. China surpassed all other countries in the production of APIs because to its policy-driven export orientation, large-scale industrial parks, and enormous government subsidies. More than 35% of the world's API output is projected to come from China by 2023, according to. This ensures that antibiotics, antivirals, and cardiovascular medications will still rely heavily on Chinese manufacture. While this has increased productivity, it has also raised new systemic issues including over-concentration, quality uncertainty, and geopolitical exposure.

**Kumar & Deshmukh (2022)**. The transformation of India's API sourcing is marked by the country's remarkable dependence on imports in the 2010s and the future, as well as its development of self-sufficiency in the 1990s. Under the auspices of government ventures such as Hindustan antibiotics and Indian medicines and pharmaceuticals ltd., Indian API manufacturing businesses produced a wide variety of APIs within the nation prior to the deregulation of the chemical industry. The domestic production of active pharmaceutical ingredients (APIs) has been overlooked ever since India joined the World Trade Organization (WTO) and adopted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005. This has resulted in a tendency towards formulation-based exports.

**Jadhav, N. V., Singh, N., Targhotra, M., & Chauhan, M. K. (2021)** This new coronavirus (COVID-19) has produced unique challenges that countries and industry are still grappling with. The uncertainty surrounding the effects of the COVID-19 epidemic on pharmaceutical supply chains in India and throughout the world is a source of worry. The significance of establishing a risk management system that considers future hazards that arise when nations experience disruptions in their supply networks was highlighted by the COVID-19 issue. Examining the responses of the Indian pharmaceutical industry to the epidemic is the primary objective of this research. This analysis takes a look at the ripple effects that COVID-19 has on the Indian economy and the implications that this has for the future. Possible means: In addition, the COVID-19 pandemic has presented an opportunity for Indian pharmaceutical businesses to establish themselves as a supported trade center for the acquisition of pharmaceuticals and chemicals. The findings confirm that India's massive pharmaceutical industry has always provided decent social services, and this trend is only going to continue. Finally, COVID-19's measures should shift public perception of Indian pharmaceutical organizations and wean private associations off of suppliers like China.

**Greeff (2020).** In the 40 years since its inception, the API sourcing landscape has changed dramatically throughout the world. The active pharmaceutical ingredient (API) industry was quite decentralized from the 1980s through the 1990s, with key production centers in the United States, Europe, and Japan.

However, Western governments choose to outsource API production to countries with cheaper production prices, such as China and India, due to rising environmental and labor expenses and stringent compliance norms.

## 3. RESEARCH METHODOLOGY

A research methodology explains the methods and techniques used in the selection and evaluation of information related to a certain study topic. By employing the research tools they have chosen, researchers plan their study to help them accomplish their goals.

### 3.1 Definitions of Organizations Terms

- **Risks in Procurement**

The term "procurement risks" refers to the potential dangers and unknowns that may develop during the process of sourcing and acquiring Active Pharmaceutical Ingredients (APIs) by pharmaceutical companies. During the course of this investigation, the term "procurement risks" was defined as disruptions in the supply chain, changes in price, variations in quality, and delays in procurement that were brought about by logistical issues, non-compliance from suppliers, or geopolitical conflicts. For the purpose of quantifying risks in surveys, indicators such as the frequency and severity of incidents of this kind, as reported by procurement managers or supply chain specialists, are utilized.

- **Government Policy and Regulation**

"Policy mix" means both the Indian government's and regulators' reaction to establishing directions on API sourcing and the directive to encourage domestic manufacturing. The Production Linked Incentive (PLI) system, export and import restrictions, quality standards, and comparable measures can all be part of a policy. The researchers hope to learn a few things from this study, including if the participants are familiar with this policy mix and how it influences their choices about risk management strategies and procurement.

- **Risk Management Strategies**

"Risk management strategies" refer to the actions taken by pharmaceutical corporations to detect, evaluate, and control potential threats during the acquisition of active pharmaceutical ingredients (APIs). Inventory buffers, digital supply chain tracking, supplier audits, multi-sourcing, and long-term contracts are all examples of risk management tactics. Structured questionnaire items will be created for use by procurement experts and heads of supply chain to assess the availability and perceived efficacy of these approaches.

### 3.2 Objectives of The Study

1. To assess the impact of procurement risks on operational efficiency of Indian Pharma Companies.
2. To examine the effect of procurement risks on regulatory compliance of Indian Pharma Companies.
3. To explore the role of government policies and regulatory frameworks in influencing API sourcing decisions in Indian Pharma Companies.
4. To investigate the role of government policies and regulatory frameworks in influencing risk management strategies in Indian Pharma Companies.

### 3.3 Research Design

This study examines how Indian pharmaceutical companies handle API sourcing and procurement risk management via a descriptive and exploratory research approach. The purpose of the design's descriptive part is to gather data on the industry's present practices, potential risks, operational efficiencies, and compliance outcomes. This part will also look at the relationships and variations among important dependent variables like regulatory compliance, procurement risks, and the government's impact on procurement risks. The goal of the study design's exploratory phase is to unearth tactics, decision-making procedures, and hidden factors that are difficult for quantitative measures to detect. Interviews with professionals in the field as well as other policymakers in the area can yield qualitative insights that help with this kind of finding. Thus, this research influences policy and action on sustainable procurement and supply chain management by combining descriptive and exploratory components in a single research design. It effectively combines understanding of the current state with discovering potential new concepts and trends for future decisions and action.

### 3.4 Study Area

The pharmaceutical industry in India is the subject of research, with a particular emphasis on the sourcing and procurement of active pharmaceutical ingredients (APIs) by Indian businesses that are active in this sector. Due to the fact that India is a significant player in the pharmaceutical sector on a global scale, the purpose of this research is to engage with important industrial locations that are responsible for a significant portion of the sourcing and purchasing that occurs with the pharmaceutical market. The well-established pharmaceutical hubs and industrial sites that are home to API sourcing or manufacturing companies, contract research organizations (CROs), and formulation firms are the potential venues for research or study. Because of this geographical reservice, research on the procurement risk management techniques that Indian pharmaceutical companies employ when acquiring API within the context of both domestic and global supply chains can now focus on local supply chains, regulatory frameworks, and market considerations. This is all attributable to the fact that this reservice has been implemented. As a consequence of this, the research has the ability to quickly shed light on the possibilities and risks those Indian pharmaceutical enterprises face in this area, as well as the logistics and distribution elements of API procurement.

## 4. DATA ANALYSIS AND INTERPRETATION

This study employs statistical methods like analysis of variance, correlation analysis, and regression analysis to test the hypotheses and show how the independent variables (government policies and procurement risks) relate to the dependent variables (operational efficiency, regulatory compliance, and sourcing decisions). Various scenarios also include analyzing and exploring relationships that serve as mediators or moderators in order to acquire a better understanding of the underlying reasons involved in pharmaceutical corporations' decision-making processes. Ensuring that every discovery directly helps to addressing the basic concerns being studied in this study requires meticulous matching of statistical output interpretations with research objectives and theoretical framework.

### Profile of the Respondents' Demographics

**Table 1: Gender of the Respondents**

| Gender | | | | | |
|---|---|---|---|---|---|
| | | Frequency | Percent | Valid Percent | Cumulative Percent |
| Valid | Female | 159 | 53.0 | 53.0 | 53.0 |
| | Male | 141 | 47.0 | 47.0 | 100.0 |
| | Total | 300 | 100.0 | 100.0 | |

The participants' gender distribution is shown in Table 1. Of the 300 people who took part, 159 (or 53.0%) are women and 141 (or 47.0%) are men. This indicates a fairly balanced gender representation, with slightly more female respondents. According to the valid and cumulative percentages, all of the responses were genuine, and the majority of those respondents were female. When the total proportion of males reaches 100%, we may say that gender categorization is complete. The study will adequately reflect perspectives from both genders thanks to this fair representation.

**Table 2: Age Group of The Respondents**

| Age Group | | | | | |
|---|---|---|---|---|---|
| | | Frequency | Percent | Valid Percent | Cumulative Percent |
| Valid | 25–34 years | 52 | 17.3 | 17.3 | 17.3 |
| | 35–44 years | 68 | 22.7 | 22.7 | 40.0 |
| | 45–54 years | 68 | 22.7 | 22.7 | 62.7 |
| | 55 years and above | 52 | 17.3 | 17.3 | 80.0 |
| | Below 25 years | 60 | 20.0 | 20.0 | 100.0 |
| | Total | 300 | 100.0 | 100.0 | |

Table 2 shows the breakdown of the 300 participants' ages. There is a sizable presence of professionals in the middle of their careers in the research, with the 35-44 and 45-54 age groups making up 22.7% of the sample (68 respondents apiece). Consequently, 20.0% of respondents are under the age of 25, while 17.3% are between the ages of 25 and 34 and 55 and over, with 52 respondents apiece. With the youngest age group added on, the cumulative percentage reaches 100%, indicating a progressive buildup. Research on pharmaceutical procurement procedures is enhanced by the distribution, which shows a diverse workforce ranging from early-career specialists to late-career experts.

**Table 3: Educational Qualification of The Respondents**

| Educational Qualification | | | | | |
|---|---|---|---|---|---|
| | | Frequency | Percent | Valid Percent | Cumulative Percent |
| Valid | Bachelor’s Degree | 59 | 19.7 | 19.7 | 19.7 |
| | Diploma | 54 | 18.0 | 18.0 | 37.7 |
| | Doctorate (Ph.D.) | 66 | 22.0 | 22.0 | 59.7 |
| | Master’s Degree | 71 | 23.7 | 23.7 | 83.3 |
| | Other | 50 | 16.7 | 16.7 | 100.0 |
| | Total | 300 | 100.0 | 100.0 | |

Table 3 shows the educational qualities of the respondents. The majority own a Master’s Degree (23.7%), closely followed by individuals with a Doctorate (Ph.D.) at 22.0% and those holding a Bachelor’s Degree at 19.7%, suggesting that a considerable segment of the sample has advanced academic qualifications. Furthermore, 18.0% of the participants possess a Diploma, whilst 16.7% are classified as "Other," perhaps encompassing certificates or non-conventional educational qualifications. The cumulative percentages demonstrate a consistent increase across educational levels, culminating in 100% with the incorporation of all categories. This varied educational background indicates that the respondents provide a broad spectrum of intellectual proficiency to their positions in pharmaceutical procurement.

**Table 4: Job Role/Designation of The Respondents**

| Job Role/Designation | | | | | |
|---|---|---|---|---|---|
| | | Frequency | Percent | Valid Percent | Cumulative Percent |
| Valid | Operations/Production Manager | 42 | 14.0 | 14.0 | 14.0 |
| | Procurement Executive/Manager | 45 | 15.0 | 15.0 | 29.0 |
| | Quality Assurance/Compliance Officer | 46 | 15.3 | 15.3 | 44.3 |
| | Regulatory Affairs Professional | 62 | 20.7 | 20.7 | 65.0 |
| | Senior Management | 58 | 19.3 | 19.3 | 84.3 |
| | Supply Chain Manager | 47 | 15.7 | 15.7 | 100.0 |
| | Total | 300 | 100.0 | 100.0 | |

Table 4 shows how the 300 respondents were classified or what their job duties were. Twenty.7% of the sample is Senior Management, followed closely by Regulatory Affairs Professionals at 19.3%. People involved in regulatory planning and senior decision-making are strongly represented here. The distribution of key functional areas within the pharmaceutical business is fairly represented, with Supply Chain Managers (15.7%), Quality Assurance/Compliance Officers (15.3%), Procurement Executives/Managers (15.0%), and Operations/Production Managers (14.0%) occupying major positions. Confirming the diversity of roles, the cumulative percentage progress provides data from a range of strategic and operational perspectives. Procurement strategies and organizational dynamics are better covered in the study thanks to the varied roles represented.

**Table 5: Years of Experience in Pharma Industry of The Respondents**

| Years of Experience in Pharma Industry | | | | | |
|---|---|---|---|---|---|
| | | Frequency | Percent | Valid Percent | Cumulative Percent |
| Valid | 11–15 years | 52 | 17.3 | 17.3 | 17.3 |
| | 2–5 years | 73 | 24.3 | 24.3 | 41.7 |
| | 6–10 years | 50 | 16.7 | 16.7 | 58.3 |
| | Less than 2 years | 62 | 20.7 | 20.7 | 79.0 |
| | More than 15 years | 63 | 21.0 | 21.0 | 100.0 |
| | Total | 300 | 100.0 | 100.0 | |

Table 5 shows the duration of respondents' employment in the pharmaceutical sector. A significant proportion of early to mid-career professionals is evident, with the largest segment of respondents (24.3%) possessing 2-5 years of experience. Individuals with over 15 years of experience constitute 21.0% of the group, and individuals with less than 2 years of experience account for 20.7%. This encompasses both seasoned professionals and young graduates in the discipline. Approximately 17.3% of respondents possess 11–15 years of experience, whilst 16.7% have 6–10 years of experience. The distribution reflects a balanced array of experience levels, enhancing the diversity of perspectives from individuals at various stages of their pharmaceutical careers and so enriching the study.

## 5. CONCLUSION

The current study's research problem is a complicated interaction among procurement-related risks, operational efficiency, and regulatory compliance in India's pharmaceutical industry, with a focus on the mediating role of governments and regulatory frameworks. When it comes to the pharmaceutical industry,

and particularly the manufacture and export of generic medications, India is well-known across the globe as a major participant. The country's dependence on APIs from other countries, particularly China, has made the supply chain more susceptible to disruptions. The COVID-19 pandemic exposed the limitations of these patterns by disrupting supply networks, which in turn hampered production timelines and quality assurance systems that were crucial for meeting international compliance standards. In this case, the provided research will aid in increasing our understanding of the procurement risks in this sector, how those risks impact the firm's performance metrics, and how official rules impact organizational ways to tackling this difficulty.

The study used a mixed-methods approach, combining quantitative and qualitative techniques, to achieve these aims. Three hundred individuals with first-hand experience in the Indian pharmaceutical industry's supply-chain, operations, procurement, and regulatory departments were surveyed using standardized questionnaires to gather quantitative data. The purpose of the sampling was to ensure that the results could be applied to a wide range of organizations, regardless of their size, ownership structure, or function. Researchers used semi-structured interviews with policy experts and seasoned professionals in the field to glean qualitative insights about data trends gleaned from their own notes and experiences. The resource-based view and risk management theory provided the conceptual framework for this study. Companies that openly discuss the risks of procurement and align their business strategies with regulations have a competitive advantage. Like any other significant external variable, government policy might have both enabling and disabling effects.

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