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Examining Perceptions of Supply Chain Vulnerability in the Indian Pharmaceutical Industry: With Special Reference to Regulatory and Financial Risks

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ABSTRACT

We investigate the perception on the severity and probability of key regulatory and financial risks within India's pharmaceutical supply chain, drawing insights from quantitative data and stakeholder perceptions. We assess the perception on eight major supply chain risks – changing domestic regulations, changing international regulations, compliance costs, import tariff changes, export tariff changes, tax payable changes, interest rate changes, exchange rate changes.

We have conducted a survey of 151 respondents involved in the supply chain function of Indian Pharma Companies. The results indicate that exchange rate changes emerged as the most critical risk in terms of severity. Import tariff changes emerged as the most probable risk in terms of probability. ANOVA analysis revealed that severity perceptions varied for changing international regulations and export tariff changes; probability perceptions varied for changing international regulations, compliance costs, export tariff changes and tax payable change.

Our findings implicate the need for differentiated risk mitigation strategies. By identifying and analysing these vulnerabilities, our study offers actionable insights for pharmaceutical managers aiming to enhance supply chain resilience, safeguard product quality, and ensure timely delivery in a complex and evolving market landscape.

Keywords: Pharmaceutical supply chain, regulatory and financial risks, export tariff changes

INTRODUCTION

India's pharmaceutical industry is a cornerstone of domestic and global healthcare supply chains. As of 2025, the market is valued at USD 66.66 billion and is projected to reach USD 88.86 billion by 2030, growing at a compound annual growth rate (CAGR) of 5.92% (Mordorintelligence, 2025). A dual engine of domestic consumption and export demand drives the sector. India supplies over 50% of global vaccine requirements and 40% of generic drugs consumed in the United States. According to the India Brand Equity Foundation (IBEF), the domestic pharmaceutical market is expected to reach USD 57 billion by FY2025. At the same time, the total industry, including exports, is projected to hit USD 130 billion by 2030 (IBEF, 2025). The government's Production Linked Incentive (PLI) scheme, with an outlay of INR 15,000 crore (USD 2.04 billion), is designed to boost manufacturing capacity and reduce dependence on imported Active Pharmaceutical Ingredients (APIs), particularly from China. In H1 FY2025 alone, INR 604 crore (USD 69.76 million) was disbursed under this scheme to support bulk drug production and infrastructure upgrades (IBEF, 2025). Therapeutically, anti-infectives dominate with a 19.6% market share, while oncology drugs are the fastest-growing segment, projected to expand at a CAGR of 7.10% through 2030. Statista reports that oncology alone is expected to generate USD 2.06 billion in revenue in 2025, underscoring the rising burden of chronic diseases and the shift toward speciality therapies

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(Statista, 2025). Distribution remains anchored in retail pharmacies, which account for 75% of the market, though online channels are multiplying at a CAGR of 7.3%, driven by digital adoption and urban demand. The oral route of administration holds 62% of the market, but injectables are gaining ground due to the rise of biologics and sterile manufacturing, with a projected CAGR of 6.5% . Regionally, North India leads with 33% of market share, while Northeast India is the fastest-growing zone at 6.4% CAGR.

Foreign direct investment (FDI) in the pharmaceutical sector reached INR 2,00,166 crore (USD 23.41 billion) between April 2000 and March 2025, reflecting investor confidence in India's long-term potential. These figures collectively highlight the sector 's robust growth trajectory, strategic importance, and the urgent need for resilient supply chains and logistics frameworks to sustain its momentum.

India's pharmaceutical industry is globally recognised for its scale, affordability, and export capacity. As the world's largest provider of generic medicines and a major supplier of vaccines, India plays a pivotal role in global healthcare. However, a complex and increasingly fragile supply chain ecosystem lies beneath this success. The COVID-19 pandemic exposed critical vulnerabilities in sourcing, manufacturing, and distribution, particularly due to India's heavy dependence on imported Active Pharmaceutical Ingredients (APIs), primarily from China.

The pharmaceutical supply chain in India is characterised by a multi-tiered structure involving raw material suppliers, formulation manufacturers, contract development and manufacturing organisations (CDMOs), distributors, and retailers. While this structure enables scalability and cost efficiency, it also introduces systemic risks ranging from geopolitical disruptions and regulatory bottlenecks to logistical inefficiencies and quality control lapses. For instance, over 70% of India's API requirements are met through imports, making the industry susceptible to external shocks such as trade restrictions or global price fluctuations (Corona Remedies, 2025). Moreover, the increasing complexity of pharmaceutical products, especially biologics and speciality drugs, demands more stringent cold chain logistics, advanced manufacturing capabilities, and regulatory compliance. These requirements amplify risk exposure across the supply chain, particularly for small and mid-sized enterprises that lack the infrastructure to adapt swiftly. The rise of e-pharmacies and digital health platforms has further transformed distribution dynamics, introducing new cyber security and data integrity risks.

In this context, supply chain resilience is no longer a peripheral concern but a strategic imperative. Risk management frameworks tailored to the pharmaceutical sector must account for operational and strategic risks, including supplier reliability, regulatory compliance, demand forecasting, and technological disruptions. The Indian government's Production Linked Incentive (PLI) scheme and initiatives like Ayushman Bharat aim to strengthen domestic manufacturing and healthcare access. However, their long-term impact on supply chain stability remains to be fully assessed.

The Indian pharmaceutical supply chain, despite its global prominence, faces a multitude of operational and strategic risks that threaten its reliability and efficiency. Among the most pressing concerns are transportation delays, which stem from overreliance on road networks plagued by poor infrastructure, traffic congestion, and limited connectivity in rural regions. These delays can disrupt the timely delivery of essential medicines, particularly in Tier-2 and Tier-3 cities (Mordorintelligence, 2025). Warehousing issues further compound these challenges, as many facilities lack adequate space, automation, and environmental controls, leading to inventory mismanagement and product degradation. Cold chain temperature excursions are especially critical for biologics and vaccines, where even minor deviations can compromise efficacy. According to ExpressPharma (2025), nearly 20% of temperature-sensitive pharmaceutical products in India are exposed to improper handling during transit or storage. Customs clearance delays also pose significant risks, particularly for imported Active Pharmaceutical Ingredients (APIs), which constitute over 70% of India's API consumption. Regulatory bottlenecks and inconsistent documentation requirements across ports can lead to prolonged clearance times and production halts (IBEF, 2025). Theft during transit and warehousing is another growing concern, especially for high-value or controlled substances. (KPMG, 2025) reports that pharmaceutical theft and diversion incidents have increased in recent years, often linked to gaps in third-party logistics oversight. Counterfeit drugs, facilitated by fragmented distribution channels and weak enforcement mechanisms, not only threaten patient safety but also erode brand trust and market share. The World Health Organisation estimates that up to 10% of medicines in low- and middle-income countries may be substandard or falsified. India is a key target due to its vast and decentralised supply network. Lastly, demand forecasting errors- driven by limited access to real-time data, seasonal variability, and

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unpredictable disease outbreaks - can result in stockouts or overproduction, straining financial and operational resources. These risks underscore the urgent need for integrated risk management frameworks, digital supply chain visibility, and regulatory harmonisation to enhance resilience and ensure uninterrupted access to quality medicines (Chopra & Meindl, 2012).

The COVID-19 pandemic subjected healthcare supply chains to unprecedented stress, exposing significant vulnerabilities in risk preparedness. With limited prior knowledge or established frameworks to address such large-scale disruptions, risk managers faced considerable uncertainty. The severe challenges of demand surges, stockouts, and bullwhip effects highlighted the vital role of resilience in ensuring continuity and reliability of healthcare product supply chains (Gupta & Kayande, 2023).

This paper seeks to critically examine the vulnerabilities embedded within the Indian pharmaceutical supply chain and propose a structured risk management approach to mitigate them. By integrating insights from industry reports, policy frameworks, and supply chain theory, the study aims to offer actionable recommendations for enhancing resilience and ensuring uninterrupted access to essential medicines (Emrouznejad et al., 2023).

PREVIOUS STUDIES

The pharmaceutical supply chain (PSC) has received increasing scholarly attention, particularly considering global disruptions such as the COVID-19 pandemic. Several studies have explored the nature, classification, and mitigation of risks within pharmaceutical logistics and operations, offering diverse methodological approaches and regional perspectives. (Azam et al., 2023) have conducted a systematic literature review to identify and prioritise critical success factors (CSFs) for resilient supply chains in SMEs. Using principal component analysis, they highlighted key CSFs including strategic partnerships, technology use, and capacity building to address uncertainty and enhance preparedness. Similarly, post COVID-19, Čerkauskienė & Meidute-Kavaliauskiene, (2023) have explored the key aspects of supply chain risk management in healthcare and identified the critical factors influencing supply chain performance and highlighted the need for improved risk assessment andresilience strategies in healthcare systems. An investigation of pharmaceutical supply chain resilience through focus groups with global stakeholders, conducted by Faggioni et al. (2023), reveals consensus on key resilience elements - adaptability, flexibility, agility, and collaboration (Shukla & Jharkharia, 2013).

In an examination of key resiliency strategies for pharmaceutical supply chains (Ganguly & Kumar, 2019) have used the Fuzzy Analytic Hierarchy Process to show that agility, visibility, and collaboration are top priorities for mitigating supply chain vulnerabilities, offering actionable insights for managers and policymakers in resilience planning.

The key drivers of resilient supply chains in India's pharmaceutical sector to enhance sustainable exports are manufacturing excellence, reverse logistics, and distribution as critical enablers, with sourcing and R&D supporting resilience through improved export performance and strategic socio-economic interventions (Gera& Singh, 2025).

Jaberidoost et al., (2015) have conducted a multi-phase risk assessment of Iran's pharmaceutical supply chain, identifying 86 risks across 11 categories. Financial and economic risks dominated, with financial management deemed most critical. Despite political challenges, half of the risks were internal and potentially manageable by pharmaceutical companies. (Pathy & Rahimian, 2023) present a two-stage optimisation framework to manage demand uncertainty in pharmaceutical supply chains. The first stage minimises prepositioning costs and risks at distribution centres, while the second reduces costs of recourse actions like reallocation and inventory management, enhancing overall supply chain efficiency (Lima & Yonamine, 2023).

An examination of supply chain resilience in the Indian manufacturing sector, particularly key antecedents like risk management culture, connectivity, visibility, collaboration, and agility, shows that ICT adoption and employee awareness can help enhance resilience and firm performance (Kumar & Anbanandam, 2020). Merkuryeva et al., (2019) have focused on using advanced demand forecasting methods in the pharmaceutical supply chain, presenting an integrated approach for product forecasting and purchase order generation. Through a case study, they evaluate SMA, multiple linear regression, and symbolic regression models, highlighting the practical implications in emerging markets. Some authors have proposed a blockchain-based infrastructure to enhance

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traceability and security in the pharmaceutical supply chain (Mishra et al., 2024) their model combats record forgery and counterfeit drugs using smart contracts and parallel search techniques. Theoretical and simulation analyses confirm its efficiency and practical viability.

Özdoğan & Mulgan, (2024) have examined healthcare logistics, emphasising its role in managing materials, services, and data to enhance care delivery. They highlight flexibility as a key component in overcoming disruptions like COVID-19, and stress the importance of coordinated supply chain strategies for improved healthcare system performance.

The sub-optimal sales and operations planning exaggerates the critical risks - inventory planning, labour, storage, raw material availability, forecasting, and communication (Sangode, 2024). The global threat of counterfeit products in the growing medical device and pharmaceutical industries essentially requires a holistic approach involving robust healthcare systems, reliable data, international cooperation, and digital tracing technologies to mitigate risks and enhance supply chain integrity (Syed & Milburn, 2024). Based on the SWOT analysis of India's pharmaceutical supply chain, strategic interventions to enhance SCM performance, aiming to strengthen global competitiveness and operational resilience, have been proposed by (Wahab et al., 2024). A fuzzy AHP-based MCDM framework to identify and prioritise 24 risks in India's pharmaceutical supply chain has been proposed by Vishwakarma et al. (2016). Their analysis highlights supply and supplier risks as most critical, offering valuable insights for mitigating disruptions and enhancing healthcare system effectiveness through robust risk assessment. Recent academic studies have identified critical logistics and inventory management risks in the Indian pharmaceutical industry, including counterfeit drugs, demand fluctuations, and cold chain failures (Sharma et al., 2024). However, a significant research gap remains in developing integrated, technology-driven frameworks for real-time risk mitigation. Existing literature often focuses on isolated risk factors without addressing systemic vulnerabilities or the role of digital tools like blockchain and AI in enhancing supply chain resilience. Despite the growing importance of logistics and inventory management in the Indian pharmaceutical industry, academic research over the past decade reveals a limited focus on quantifying and mitigating supply chain risks. We find a gap in the context of an underdeveloped comprehensive framework for risk prioritisation (Skyes, 2018). Weak distribution networks and inadequate inventory systems continue to hinder operational efficiency in the Indian pharmaceutical industry (Feeney et al., 2024).

MATERIALS AND METHODS

Our study has employed a quantitative research design supported by primary and secondary data sources to assess regulatory and financial vulnerabilities in the Indian pharmaceutical supply chain. We adopt a quantitative research approach, grounded in primary data collection through a structured survey administered to employees working in pharmaceutical companies across India. We aim to obtain respondents' perceptions of supply chain risks, with particular attention to regulatory and financial vulnerabilities.

We initially conducted a pilot survey to identify the prominent risks in the regulatory and financial context in the supply chain in the Indian pharmaceutical industry for content validity. We have formulated a questionnaire comprising three sections based on the pilot survey results and industry experts. Section A seeks information on the organisation profile of the respondents – level of management in the supply chain, size of the organisation, drug segment, and type of market segment by disease type. Section B has explored the opinions on the perception of risk severity and probability for eight defined classes of regulatory and financial risks on a Likert scale. Section C explores the respondents' general perception of the evolving risks in the supply chain in the Indian pharmaceutical industry.

The key regulatory and financial risks have been classified into (a) changing domestic regulations, (b) changing international regulations, (c) compliance costs, (d) import tariff changes, (e) export tariff changes, (f) tax payable changes, (g) interest rate changes, and (h) exchange rate changes. We have used a purposive sampling method to target professionals with direct experience in logistics and inventory management. Out of the 180 individuals contacted, 151 valid responses have been received. The demographic profile of respondents reflects that the majority were mid-level managers with six to ten years of professional experience, predominantly working in large-scale pharmaceutical organisations. We use descriptive and inferential statistical methods to obtain the results. The reliability of the questionnaire has been tested using Cronbach's alpha (0.839). We have used one-

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way ANOVA to examine differences in severity and probability perception of regulatory and financial-related vulnerabilities across organisations' selected parameters. The qualitative results are supported with secondary data from policy documents, government reports, and prior academic studies to contextualise findings and enhance triangulation.

RESULTS AND DISCUSSION

Respondents are predominantly male, representing 95.4% of the total sample. Regarding organisational size, 60.7% of the respondents are employed in large enterprises, 26.1% in medium-sized firms, and 13.2% in small organisations. Our findings primarily represent large-scale pharmaceutical operations with more complex and expansive supply chains. Our sample is polarised towards mid-tier decision-makers, with limited representation from frontline staff and executive leadership, a limitation of the study. The sample is predominantly middle-aged, with 66.8% of participants in the 31–40-year bracket. Respondents aged 41–50 accounted for 17.9%, while those aged 21–30 represented 14.6%. Only 0.7% of the sample was above 50, suggesting limited input from senior professionals nearing retirement age.

Regarding market engagement, 75.4% of respondents reported involvement in branded and generic drug segments, while only 24.6% focused exclusively on branded products. Similarly, 96.7% of participants indicated engagement with general and specialised drug types, suggesting a broad therapeutic footprint across the sample. Tables 1 and 2 present the risk severity and probability results for the formulated risk categories.

Table 1: Risk Severity – Regulatory and Financial Risks

Risk Category	Very less severe (%)	Somewhat severe (%)	Severe (%)	Very severe (%)	Extremely severe (%)
Changing Domestic Regulations Risk Severity	2.0	2.6	11.9	39.1	44.4
Changing International Regulations Risk Severity	2.6	2.6	17.2	31.1	46.4
Compliance Costs Risk Severity	3.3	2.6	8.6	33.8	51.7
Import Tariff Changes Risk Severity	0.0	2.6	12.6	31.8	53.0
Export Tariff Changes Risk Severity	0.7	1.3	7.9	39.1	51.0
Tax Payable Changes Risk Severity	0.0	3.3	14.6	39.1	43.0
Interest Rate Changes Risk Severity	0.0	2.6	11.3	36.4	49.7
Exchange Rate Changes Risk Severity	0.7	1.3	11.3	29.1	57.6

Source: Author's Computation

Table 1 highlights the perceived severity of various financial and regulatory risks. Across categories, the majority of respondents perceive risks as **very severe or extremely severe**, with percentages often exceeding 40–50%. Exchange rate changes (57.6% extremely severe) and import tariff changes (53.0% extremely severe) emerge as the most critical concerns. Compliance costs and export tariff changes also show high severity, indicating significant financial strain. Domestic and international regulation changes are moderately severe but still pose

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substantial challenges. Overall, the data suggests businesses face heightened vulnerability to external economic shifts, particularly tariffs and currency fluctuations, demanding robust risk management strategies.

Table 2: Risk Probability – Regulatory and Financial Risks

Risk Category	Very less probable (%)	Somewhat probable (%)	Probable (%)	Very probable (%)	Extremely probable (%)
Changing Domestic Regulations Risk Probability	2.0	7.3	17.2	29.8	43.7
Changing International Regulations Risk Probability	4.0	4.0	23.2	22.5	46.4
Compliance Costs Risk Probability	3.3	3.3	21.9	23.8	47.7
Import Tariff Changes Risk Probability	4.0	2.0	15.9	35.8	42.4
Export Tariff Changes Risk Probability	4.0	4.6	14.6	33.1	43.7
Tax Payable Changes Risk Probability	2.6	6.0	13.9	36.4	41.1
Interest Rate Changes Risk Probability	3.3	3.3	19.2	34.4	39.7
Exchange Rate Changes Risk Probability	2.0	4.6	20.5	29.8	43.0

Source: Author's Computation

Table 2 highlights the perceived probability of various financial and regulatory risks. Most categories show high likelihood, with **very probable and extremely probable** responses dominating. Compliance costs (47.7% extremely probable) and international regulation changes (46.4% extremely probable) stand out as the most expected risks. Domestic regulation changes, export tariffs, and exchange rate fluctuations also show strong probabilities above 40%. Import tariffs and tax payable changes are slightly lower but still significant, with over 40% in the highest probability ranges. Overall, businesses anticipate frequent disruptions from regulatory shifts, tariffs, and financial variables, underscoring the need for proactive risk planning.

Table 3: Risk Severity and Risk Probability – Mean Comparison

Regulatory and Financial Risks	*Risks Severity*		*Risks Probability*	
	Mean	SD	Mean	SD
Changing Domestic Regulations	4.212	0.899	4.06	1.041
Changing International Regulations	4.159	0.980	4.033	1.104
Compliance Costs	4.278	0.967	4.093	1.061
Import Tarriff Changes	4.351	0.802	4.106	1.008
Export Tarriff Changes	4.384	0.747	4.08	1.062
Tax Payable Changes	4.218	0.816	4.073	1.014
Interest Rate Changes	4.331	0.781	4.04	1.012
Exchange Rate Changes	4.417	0.795	4.073	1.001

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Source: Author's Computation

Table 3 highlights the perceived severity and probability of various regulatory and financial risks. Overall, all risks score above 4 on both severity and probability, indicating they are considered highly significant and likely. Exchange rate changes emerge as the most severe risk (mean severity 4.417), closely followed by export tariff changes (4.384) and import tariff changes (4.351). These results suggest that external trade and currency fluctuations are viewed as particularly impactful. Compliance costs also rank high in severity (4.278), reflecting the burden of adhering to evolving regulations. On the probability side, import tariff changes (4.106) and compliance costs (4.093) are slightly more likely than others, though differences are marginal. Standard deviations around 0.8–1.1 show moderate variability in perceptions, suggesting consensus but with some divergence among respondents. In essence, the data underscores that regulatory shifts and financial volatility are both pressing and probable challenges for organizations.

Table 4: ANOVA – Size of Organization

Risk Type	**Risk Severity F Ratio (Sig.)**	**Risk Probability F Ratio (Sig.)**
Changing Domestic Regulations	0.211 (0.810)	2.609 (0.077)
Changing International Regulations	*3.787 (0.025)*	*5.732 (0.004)*
Compliance Costs	0.163 (0.850)	*3.220 (0.043)*
Import Tarriff Changes	0.148 (0.862)	2.262 (0.108)
Export Tarriff Changes	*4.891 (0.009)*	*4.182 (0.017)*
Tax Payable Changes	1.454 (0.237)	*5.887 (0.003)*
Interest Rate Changes	1.928 (0.149)	1.870 (0.158)
Exchange Rate Changes	0.635 (0.531)	1.531 (0.220)

Source: Author's Computation

Table 4 presents the results of ANOVA tests assessing differences in perceptions of regulatory and financial risks across two dimensions: severity and probability. For risk severity, most factors show non-significant variation, suggesting that respondents generally agree on the seriousness of these risks. For example, changing domestic regulations ($F = 0.211$, $p = .810$), compliance costs ($F = 0.163$, $p = .850$), and import tariff changes ($F = 0.148$, $p = .862$) all indicate consistent perceptions with little variation among groups. However, changing international regulations ($F = 3.787$, $p = .025$) and export tariff changes ($F = 4.891$, $p = .009$) are statistically significant, implying that respondents differ in how severely they view these risks. This highlights that international regulatory shifts and export tariffs are perceived with more variability, potentially reflecting differing exposure levels across industries.

In terms of risk probability, several factors demonstrate significant differences. Changing international regulations ($F = 5.732$, $p = .004$), compliance costs ($F = 3.220$, $p = .043$), export tariff changes ($F = 4.182$, $p = .017$), and tax payable changes ($F = 5.887$, $p = .003$) all show statistically significant variation, suggesting that respondents hold diverse views on the likelihood of these risks occurring. Conversely, risks such as interest rate changes ($F = 1.870$, $p = .158$) and exchange rate changes ($F = 1.531$, $p = .220$) do not exhibit significant differences, indicating more uniform perceptions of their probability. Overall, the findings emphasize that international regulations, taxation, and trade tariffs are areas where perceptions of both severity and probability vary most, underscoring their importance in strategic risk management.

Conclusion

The paper has looked at the views of regulatory and financial risks in the Indian pharmaceutical supply chain based on a survey conducted on 151 supply chain professionals. The results indicate that regulatory changes and financial fluctuations are seen as a major threat to stability of the supply chain. The most extreme risk was

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identified to be the exchange rate changes whereas the import tariff changes and compliance costs were the most likely risk that would influence operations. The findings indicate that global trade policies, financial volatility and regulatory frameworks have a significant impact on pharmaceutical supply chains. The ANOVA analysis also shows the differences in perception involving international regulations, export tariffs, compliance costs, and changes in taxation among organizations. In general, the research highlights the importance of active risk management techniques such as enhanced regulatory oversight, financial risk management planning, and enhanced coordination of supply chain partners. The reinforcement of these mechanisms will contribute to the fact that pharmaceutical companies will make the process of supply chain management more resilient, with no disruptions in the supply of medicines and contribute to the sustainable development of the industry.

AUTHOR DECLARATIONS

CRediT Author Statement / Author contributions

Syed Shaamikh Ahsan: Conceptualization; Methodology; Software; Validation; Formal Analysis; Investigation;
Pankaj Kumar Gupta: Data Curation; Writing – Original Draft; Visualization.
Conceptualization, Supervision; Project Administration; Writing – Review & Editing; Resources.

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