

## **RISKS IN THE PHARMACEUTICAL SUPPLY CHAIN: A THOROUGH ANALYSIS**

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### **Abstract**

**Introduction:** A primary priority in every healthcare system is the provision of medication. A significant participant in the medication supply chain, pharmaceutical businesses face several hazards. In various ways, including quantity, quality, and timely delivery to the correct clients and locations, these risks interfere with the supply of medicines. Therefore, it is strongly advised that risks be identified in the pharmaceutical industry's supply chain and be mitigated.

**Objective:** This research aims to look at potential hazards in the pharmaceutical supply chain from the standpoint of the manufacturing businesses.

**Methods:** Six separate sets of keywords were used to search for research on pharmaceutical supply chain risk management in Scopus, PubMed, Web of Science bibliographic databases, and Google Scholar. In four phases and using a methodical approach, all articles that weren't relevant were removed from the results of the keyword search after they were examined.

**Results:** The systematic review contained nine papers, and it identified 50 key hazards based on the research result that was of relevance and divided them into seven categories. Most hazards that were highlighted had to do with supply and supplier problems. Financial, logistical, political, market, and regulatory challenges were of a higher priority than organization and strategy difficulties.

**Conclusion:** It was shown that the majority of risks in the pharmaceutical supply chain were internal risks brought on by improper management of processes, people, and functions. These risks might be controlled by using effective mitigating measures. Supply chain risks, pharmaceutical supply risks, risks associated with the supply of medicines, risk management

### **Introduction**

Healthcare systems aim to provide drugs as a human right. The pharmaceutical supply chain must provide pharmaceuticals in the right quantity, quality, location, timing, and price to achieve healthcare system objectives and benefit stockholders. Pharmaceutical supply chain problems squander money and endanger patients' lives [3]. Risk management is essential for the pharmaceutical supply chain, medicine prescription, and use [4,5]. Health systems must assess and manage pharmaceutical supply chain risks [6]. Medicine is strongly controlled by governmental regulatory authorities, making risk management more important. In developing countries with significant economic, social, and political volatility, drugs as strategic commodities are more unpredictable and vulnerable.

A supply chain is a network of people, organizations, processes, data, and resources that turns raw materials and components into finished products and services and delivers [12]. Customers, suppliers, middlemen, and other service providers [13]. It also includes logistics, production, marketing, sales, product design, finance, and IT.

Supply chain management (SCM) integrates important business processes throughout the supply chain to provide value for customers and stakeholders [15]. Supply chain management connects supply and demand within and across enterprises profitably [16,17]. The Council of Supply Chain Management Professionals defines supply chain management as planning and managing sourcing, procurement, conversion, and logistics operations [18]. Supply chain optimization involves removing bottlenecks, balancing lowest material cost and transportation [19], optimizing manufacturing flow, keeping the right mix and location of factories and warehouses, vehicle routing analysis, dynamic programming, and efficient use of capacities, inventories, and labor [20]. All shareholders must configure and be flexible to produce best practice and meet problems in a continually changing environment [21].

Supply chain management (SCRM) is essential to achieving these aims [22]. SCRM mitigates supply chain risk [23]. Thus, identifying, assessing, and prioritizing risks is essential to reduce and manage adverse events. It manages risks in dynamic, complicated supply and demand networks.

Industrial supply chain risks and risk management have been studied extensively. Some systematic assessments on supply chain risk management (SCRM) in various sectors concentrate on counterfeit supply chain logistics quality assurance and enterprise risk management. There are no manufacturer-focused pharmaceutical risk management assessments.

As a first step in pharmaceutical supply chain risk management, this study identifies all supply process vulnerabilities that threaten medicine availability.

### **Methods**

Google Scholar, Scopus, PubMed, and Web of Science were used to find English-language pharmaceutical supply chain risk management studies. Risk, supply chain management, risk assessment, and pharmaceutical were searched in databases. While searching, each database's characteristics and PubMed MeSH were considered. In September 2012, the databases were searched.

Four methods filtered all research and conference abstracts: Steps taken: 1. All results titles were reviewed, and non-relevant articles were eliminated based on the researcher's study objectives and outcome of interests; 2. Duplicate articles were eliminated because some were found in multiple databases and had the same content using different keyword groups; 3. The abstracts of the remaining publications were reviewed, and those that did not suit the study were discarded. 4. All remaining papers were read, and several were deleted owing to probable conflicts of interest.

Exclusion was based on authors' consensus. Piloted forms extract study risks.

### **Results**

#### **Outcomes of interest**

A table included the articles' qualities, major topic, and kind. The abstracts divided the papers' main topics into the following categories: supply chain with consumer safety approach, counterfeit, logistic risks, global supply chain, product development risks, environmental risk management, supply chain management with health policy approach, supply chain with company perspective, and third parties risk management.

After removing duplicate papers and evaluating abstracts, 28 Google Scholar, 10 Web of Science, 44 Scopus, and 12 PubMed articles remained for full text analysis. 85 of 94

complete texts were rejected due to insufficient findings. Nine publications were reviewed (Figure 1).

Production business pharmaceutical supply chain risk management was of interest. Publications addressing consumer safety, environmental risk management, health policy, and outside parties were rejected. After analyzing the full texts of 94 papers, 85 were rejected owing to result of interest, design, and method, leaving nine for the review study.

Based on expert evaluation, 50 dangers from all selected articles were classified into 7 categories: supply and suppliers, organization and strategy, financial, logistic, political, market, and regulatory. Articles identified most supply and supplier risks. 20 of the 50 threats were supply and supplier-related. There were 14 company structure and strategy risks, 7 financial risks, 3 market risks, 3 political risks, 2 logistical risks, and 1 regulatory risk.

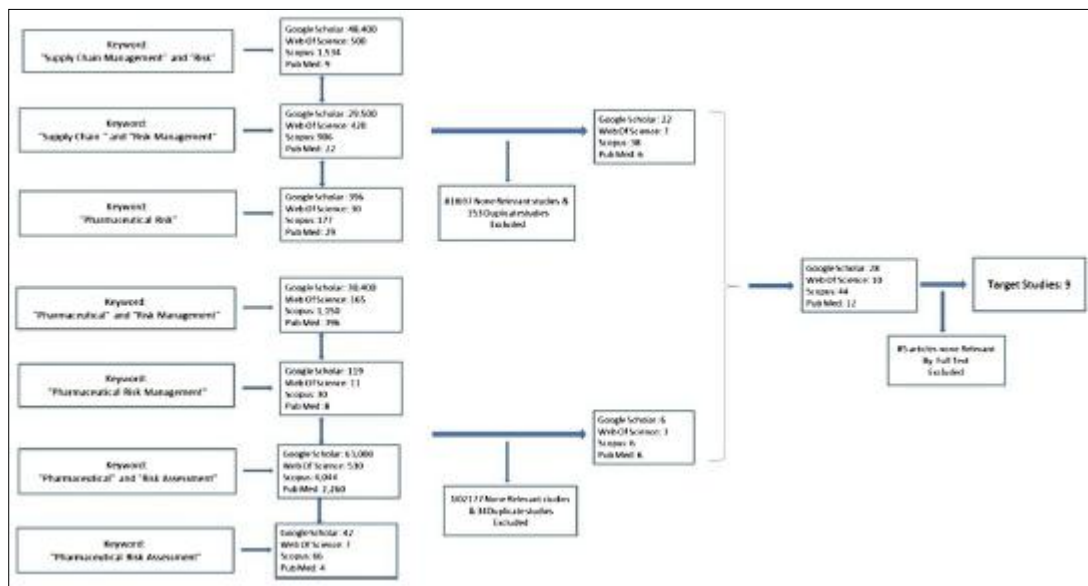


Figure 1 The steps of selecting the articles.

### Supply and suppliers risks

The supply and suppliers issue was highlighted in six out of the nine articles [8,16,22,36-38]. The risk of working with suppliers was noted by three distinct sources [36,37,39]. Ordering cycle time, raw material quality, and supplier adaptability were identified in 2 [36,37]. Supply chain risks are discussed in 2 [22,36] as being connected to contracts and agreements, supplier customization, and the supplier's GMP certificate. Breen recognized fragmentation as a risk in the pharmaceutical supply chain [22]. As supply dangers, Mehralian et al. mentioned delivery dependability, environmental assessment, technical level, information systems, good will, technology development, flexibility in delivery, flexible amounts, supplier quality management system, and prompt delivery.

### Organization and strategies risks

Inventory management was regarded as the biggest risk in four out of nine papers [16,22,37,40]. research on worker skill, R&D, and business strategies were covered in three [16,22,37], two [16,41], and two [37,41] research, respectively. Information flow and stock visibility were the subject of one study [22]. Two articles [16, 37] mentioned organization and process as hazards to the pharmaceutical supply chain. The correlation between waste management and production costs was shown by Mehralian et al. [36]. While Blos et al.

cautioned about a disruption in time to market and customer service, one study [41] noted mergers and acquisitions.

**Financial risks**

The usage of money and the pace of change were depicted in three of the nine articles [8,36,38]. Financial difficulties were noted in two out of nine publications [36, 40]. Changes in tax paid, expenditures associated with the delivery of goods and services, interest rates, and tariff laws were all included in one section [36]. Cash flow was cited as a financial concern in another piece [22].

**Logistic risks**

Four out of nine studies [8, 22, 38, 40] considered counterfeiting to be a logistic risk. Three publications mentioned the danger of transportation in the pharmaceutical supply chain.

**Market issues**

Market concerns were included as supply chain hazards in 2 studies [22,41]. In 2 out of the 9 articles, consumer preference and demand were both referenced. All dangers mentioned in the chosen research are included in Table 1.

**Table 1 Reported risks with source of studies**

Category	Risks	A	B	C	D	E	F	G	H	I	Total
Supply and supplier issue		✓		✓	✓	✓		✓	✓		6
Partnership with supplier		✓	✓	✓							3
Raw material quality		✓		✓							2
Ordering cycle time		✓		✓							2
Contract & agreements				✓	✓						2
Customization of supplier				✓	✓						2
Certificate of GMP				✓	✓						2
Flexibility of supplier		✓		✓							2
Fragmentation					✓						1
Delivery reliability				✓							1
Supply & suppliers issues				✓							1
Environmental assessment											1
Technology level				✓							1
Information systems				✓							1
Good will				✓							1
Technology development				✓							1
Flexibility in delivering				✓							1
Flexible quantities				✓							1
Flexibility in product variety				✓							1
Timely delivery				✓							1
Quality management system				✓							1
Customer services disruption		✓									1
Inventory management		✓			✓			✓		✓	4

Operation issues	✓			✓			✓			3
R & D						✓	✓			2
Skill of workers			✓	✓						2
Strategy	✓					✓				2
Planning issues	✓			✓			✓			3
Organization & strategies issues				✓						1
Information flow				✓						1
Visibility on stock				✓						1
Organization & process	✓						✓			2
Mergers and acquisition						✓				1
Time to market	✓									1
waste management			✓							1
Production cost			✓							1
Tax payable change			✓							1
Currency rate			✓		✓			✓		3
Financial risks			✓						✓	2
Financial Tariff policies changes			✓							1
Costs related to supply			✓							1
Cash flow				✓						1
Interest rate			✓							1
Counterfeit				✓	✓			✓	✓	4
Logistic Transportation	✓		✓	✓						3
Market Market				✓		✓				2

**Table 1 Reported risks with source of studies (Continued)**

	Consumers taste	✓	✓	2			
	Demand	✓	✓	2			
Political	Natural disasters & terrorism	✓	✓	✓	3		
	Political issues	1					
	Sanction	1					
Regulatory	Regulation	✓	✓	✓	✓	✓	✓
			6				

**Discussion**

Supply and supplier risks were the most important themes in the paper analysis. These studies found 40% of risks in this group. The bulk of articles cited regulatory issues, which tend to play a big influence in pharmaceutical companies' supply chain management, although this study did not explore them. Organizational and strategic risks, with 28% of expressed worries, are next in importance.

This is the first systematic review of pharmaceutical supply chain risk management from the



perspective of production companies. Previous pharmaceutical industry systematic reviews have covered logistics, drug safety, counterfeiting, quality risk management, and other topics. To eliminate diversity and focus on the study's aim, expert comments restricted terms. Thus, it limits research.

No substantial research was found using the keywords. Thus, none of the articles in this study were able to cover all of the outcomes of interest; instead, they each used and explored distinct aspects of pharmaceutical supply chain hazards. All authors agreed to omit studies, however selection bias may still occur.

Unfortunately, most conference abstracts on pharmaceutical supply chain risk management in pharmaceutical companies were not available.

Some papers listed hazards by name but didn't elaborate [22,36]. Some had dangerous weights.

Several papers discussed mitigation methods, but none addressed how supply and supplier risks affect corporate operations or other duties.

Risk impacts and mitigation strategies for each function affected by hazards may be beneficial.

Mehralian et al. examined the pharmaceutical industry's supplier selection factors. Their study involves literature reviews, expert comments, statistical analysis, and MADM models. They covered 37 topics in 9 main groups. This research only considers 33 of the listed hazards. This research found that suppliers and risks should prioritize delivery. Price and quality rank next. Fuzzy TOPSIS was used for risk weighting and risk minimization. This article discusses pharmaceutical supply chain dangers, most of which involve supplier selection and supply.

Enyinda et al. examined pharmaceutical global supply chain outsourcing risk control using the analytic hierarchy process model. The research focused on regulatory risk and supplier relationships, two of the global supply chain outsourcing risks. Transfer risk is a common regulatory risk reduction strategy.

Blos et al. assessed external supply chain risk and provided a risk reduction and business continuity strategy. They found 12 supply chain risk hazards. This article discusses hazards that may apply to the pharmaceutical supply chain and aid risk management. One of the article's most intriguing topics is pharmaceutical supply chain risk management in business units using the six stages of the business continuity planning process life cycle (risk mitigation management, business impact analysis, supply continuity strategy development, supply continuity plan development, testing, and maintenance).

"A Preliminary Examination of Risk in the Pharmaceutical Supply Chain (PSC) in the National Health Service (NHS) in the UK" by Breen examined the nature and prevalence of risk in the pharmaceutical supply chain using a workshop discussion. The study's approach differed from ours, but the article's findings demonstrated that the dangers identified are similar to those seen in industrial chains across several categories. The key vulnerabilities were supply chain fragmentation, lack of stock placement and availability information, inaccurate customer estimates, and inability to satisfy demand. Due to competing interests, Breen recorded and rated 35 major hazards, but this study only considered 18.

"An Empirical Analysis of Risk Mitigation in the Pharmaceutical Industry Supply Chain: A Developing-Country" by Enyinda et al. assessed supply chain hazards and prioritized

mitigation strategies using AHP. The study's top dangers were the FDA, supplier failure, counterfeit cash, and exchange rate instability. This analysis included currency and exchange rate variations, which Enyinda considered independent dangers [8].

In a 2010 conference paper, Reschke examined how organizational decision-making and strategy formulation may affect knowledge growth to identify biopharmaceutical business risks. The research examined markets, law, strategy, R&D, and mergers and acquisitions.

Shah also studied pharmaceutical supply chain operational issues. This article discusses pharmaceutical pipeline uncertainty, process development, capacity planning, network design, and plant design.

"Quantification of Risk Mitigation in Ghanaian Pharmaceutical Industry Supply Chain" by Enyinda et al. assessed and rated hazards that risk portfolio decision-makers should consider. The AHP Model graded mitigation alternatives in the article. The Food and Drugs Board cited supplier failure, counterfeit products, currency volatility, and exchange rate changes as pharmaceutical supply chain risks. This study confirmed a prior study by the same group.

Kamath et al. say regulatory, financial, inventory, and counterfeit risks are the biggest issues in the Indian pharmaceutical supply chain. This study employed AHP on manufacturers, intermediaries, and dispensing pharmacists. This article rates mitigating options.

### **Conclusion**

The effectiveness of supply chain management is significantly impacted by the performance of pharmaceutical businesses as key participants in the pharmaceutical supply chain. Pharmaceutical businesses may optimize processes, increase productivity, and reduce business risk by identifying and reducing risks. This will also assist health systems achieve the Accessibility, Quality, and Affordability objectives of supply chain management. Numerous dangers mentioned in this research are internal risks brought on by improper management of processes, people, and functions in a company. These risks might be readily controlled by effective mitigation techniques. Even if there aren't many external hazards, their effects on business interruption haven't been well researched. Future studies should also explore evaluating the risk consequences of hazards on business processes and functions and researching mitigation measures to manage them.

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