

RISK ASSESSMENT FOR PHARMACEUTICAL INDUSTRY IN UNCERTAIN ENVIRONMENT: AN INTEGRATED MULTI-CRITERIA DECISION-MAKING APPROACH

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Received: 11 February 2023;

Accepted: 7 June 2023;

Available online: 4 July 2023.

Original scientific paper

Abstract: *The pharmaceutical industry is the backbone of the healthcare system for any country. However, this industry faces various risks, which hamper its efficient working in providing life-saving medicines/services to the people. In this context, the purpose of the study is to improve the resilience and performance of the pharmaceutical industry (PI) with identification, and assessment of supply chain (SC) risks. A case illustration has also been presented in the Indian context. The study utilizes an extensive literature survey and Delphi method for identifying, finalizing, and classifying the risks into seven categories. The Intuitionistic Fuzzy Analytic Hierarchy Process (IF-AHP) has been used to analyze and prioritize the risks to determine their criticality. The results show that the three most important risks are financial, supplier, and demand/customer/market. Within these risks, the three most critical sub-risks are found to be loss of customers, raw material (RM) issues, and bad reputation of the company, respectively. The study provides managers with an extensive list of PI risks for their consideration. The results also present the critical risks which need to be mitigated for enhanced performance and resilience of the industry. The study also emphasizes the importance of interconnection between various SC partners for better risk management.*

Key words: *Pharmaceutical industry, IF-AHP, Risk assessment, COVID-19, Delphi.*

1. Introduction

The global PI has been growing significantly, having a value of 1.25 trillion dollars (IQVIA, 2020), with an objective to provide an uninterrupted supply of the right quality and quantity of medicines at the right place and time in right condition (Kumar et al., 2019). The pharma products are very specialized products (Bartfai & Lees,

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2013), and their shortage affects not only the finances in SC but also precious human lives. For example, in the recent COVID-19 pandemic, various medicines like antibiotics, opioids, etc., were found to be in shortage, which threatened lives (British Medical Association, 2020). However, the complex SC environment, like the healthcare and pharmaceutical sector, are associated with risks associated with suppliers, operations, finances, etc. (Vishwakarma et al., 2016), which also affect all the important decisions like procurement, production, distribution, and hence the profitability (Handfield & McCormack, 2007). Though despite the risks, the pharmaceutical sector is still expected to grow by 160 percent worldwide between 2017 and 2030, with the most significant growth forecasted for India with 232 percent in the same period (Torreya Partners, 2017).

In India, this sector contributes a revenue of around US \$20 billion (IBEF, 2020). It is also the world's largest generic drug provider and accounts for 20 percent of global exports of generic drugs (IBEF, 2019). However, like the global industry, the Indian pharmaceutical industry (IPI) has also been facing risks and disruptions, which significantly affect its manufacturing performance. The influence of these risks can be observed on various manufacturing practices such as production schedules, inventory management (Truong & Hara, 2018), SC integration (Zhao et al., 2013), product quality, and ultimately the bottom line of the industry. Therefore, addressing these the pharmaceutical supply chain (PSC) risks for a manufacturer is of utmost importance as the manufacturer is a link in SC that adds the most value to the product by converting RMs into a finished product (medicines), and is responsible for producing high quality medicines for customers.

Thus, the above discussion arises a predominant need to identify and assess the PSC risks so that they can be addressed for more resilient PI. Hence, through this study, the following research questions have been examined:

RQ1: What are the risks faced by the PI in general, and are they relevant in Indian context?

RQ2: What are the most critical risks adversely affecting the performance of the IPI?

RQ3: What are the ramifications of these risks on the industry, and what are their managerial implications?

To address the above research questions, the risks are identified and categorized based on a thorough literature review. Next, using the Delphi method, their validation and augmentation have been done by industry experts. Also, the experts have determined the top five sub-risks from each category. These chosen sub-risks are then compared within their respective main category in a pairwise manner using IF-AHP. This helps determine the rank of sub-risks within and across the main risks to identify the critical sub-risks. The identification of critical sub-risks helps ascertain the sub-risks that need to be managed to improve the performance of the PI.

The rest of the paper is organized as follows: Section 2 describes the literature review related to the study, Section 3 discusses the methodology used in the paper, Section 4 includes the case illustration for the IPI, Section 5 provides the results which are further discussed in detail within Section 6, and Section 7 summarizes the study along with managerial implications, limitations and the future scope for further work.

2. Literature Review

This section presents a holistic view of SC risks identified in the PI based on an extensive literature review. The literature articles were primarily collected from

Elsevier's Scopus database, the largest peer-reviewed database for articles related to science and technology, medicine, social sciences, arts, and humanities (Fahimnia et al., 2015). The search was made using the word string ((“pharmaceutical” OR “medicine” OR “vaccine”) AND (“industry” OR “supply chain”) AND “risk”) in the title, abstract, or keywords parts of the database, and following observations were made with initial screening:

The major research areas found in the literature were “medicine”, “pharmacology, toxicology and pharmaceuticals” and “biochemistry, genetics and molecular biology” (Figure 1). The research articles related to decision sciences and management, which is the scope of the present work, are still limited, and hence, need to be researched exhaustively (n=325).

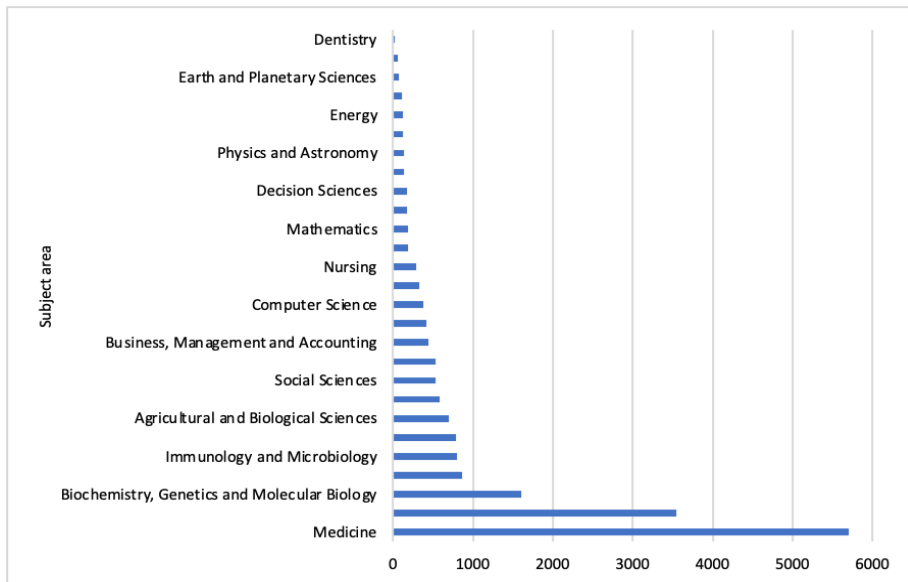


Figure 1. Subject-wise article distribution

As shown in Figure 2, the articles on the risks in pharmaceutical sector were almost similar every year; however, after 2016, there was an increase in published articles related to the topic. Also, the countries with maximum contribution to the publications are United States of America, United Kingdom, Germany, followed by India and China (Figure 3).

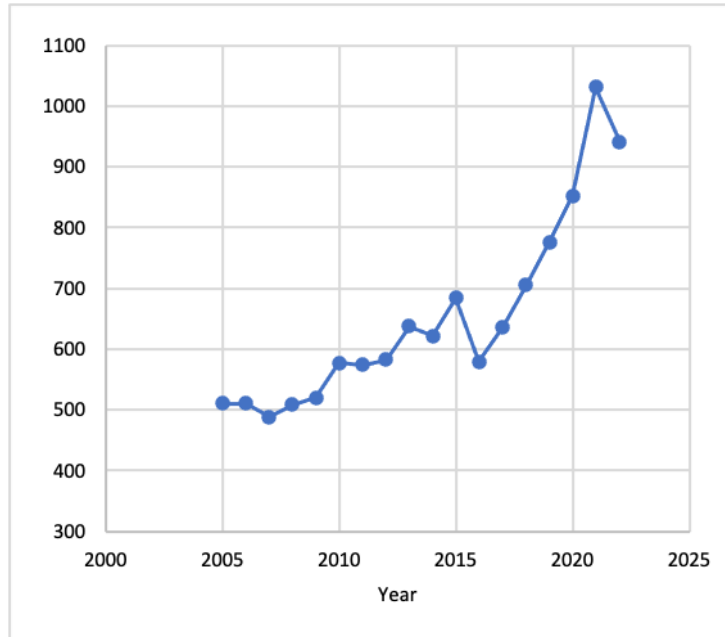


Figure 2. Year-wise article distribution.

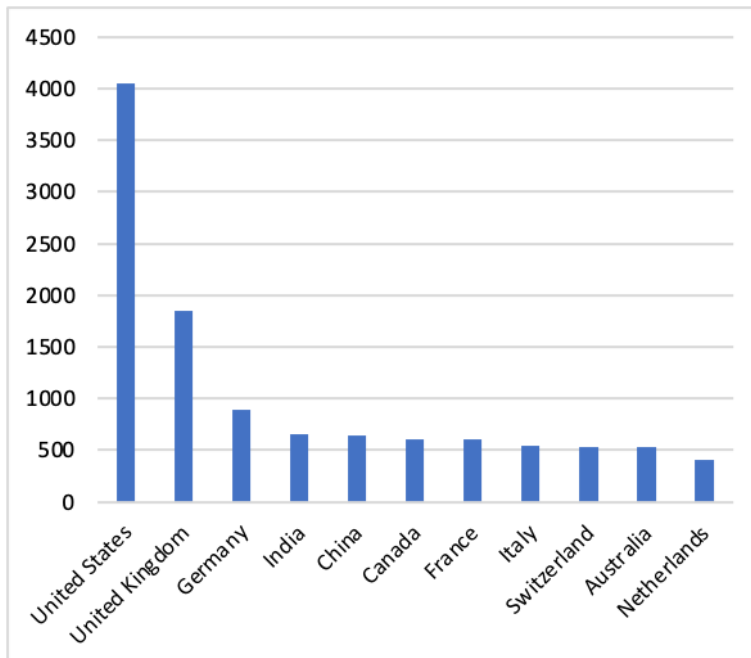


Figure 3. Country-wise article distribution

After initial articles search, the further screening was done including the “journal articles” within the subject area “Decision sciences” OR “Business management and

Risk assessment for pharmaceutical industry in uncertain environment: an integrated... Accounting”, published after “2005” in “English” language. The process of article selection has been shown in Figure 4.

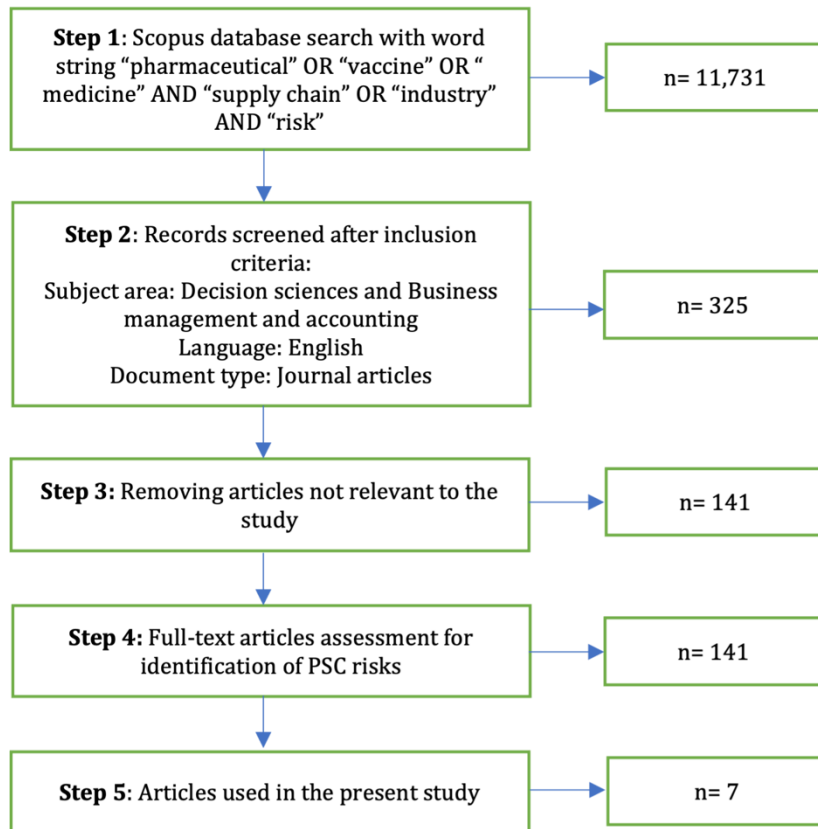


Figure 4. Articles selection process

After full-text assessment, only 7 articles were found to be relevant, which explicitly discussed the risks in the PSC or PI. Therefore, the snowball technique was used for tracking more documents of relevance cited within these finalized documents, which resulted in the addition of 22 more articles and 1 WHO report, making the final count 30, which were then used to identify the PSC risks.

2.1. Risks in pharmaceutical industry

Risks, which are associated with uncertain events and the potential occurrence of unfavorable outcomes, e.g., quality issues, loss of reputation, supply disruptions, etc. (Moktadir et al., 2018), can significantly hamper the working of PI. These risks not only affect the performance and profit margins but can also have detrimental effects on patients’ health due to issues like product discontinuity, drug shortage, fake drugs (Silva et al., 2020). Therefore, any risk affecting the PI needs to be mitigated effectively to reduce cost, improve its performance and satisfy the customers (Carlos et al., 2020; KT & Sarmah, 2021). As there are myriad of risks affecting the industry; hence, for better understanding and management, it is necessary to organize them in categories. In this context, many researchers have classified risks into various categories. For example, researchers have organized the risks based on various nodes of SC like

supply-related risks, operational, demand, etc. (Jaberidoost et al., 2013, 2015; Moktadir et al., 2018; Torasa & Mekhum, 2020; Vishwakarma et al., 2016). A study conducted in the Brazilian context organized the risks in fourteen dimensions like strategic, inertia, informational, capacity, etc. (Rangel et al., 2015; Silva et al., 2020) based on the literature review. Another paper categorized them into the upstream, internal, and downstream stages of SC (Ouabouch & Amri, 2013).

From the literature review, a total of sixty-seven PSC risks were identified, which are included in Appendix B. Also, as evident, there is a dearth of studies including all the major risks from PSC which affect the medicine manufacturers. Furthermore, there are very limited studies on the risk identification and assessment for developing countries like India, which is a major producer and exporter of medicines to the world. The literature review has been summarized in Table 1 for a better understanding of literature gaps.

Table 1. Summary of literature review for risks in pharmaceutical industry

Articles	Number of risks considered	MCDM technique	Country
(Breen, 2008)	35	-	UK
(Enyinda et al., 2010)	5	AHP	Ghana
(Láinez et al., 2012)	2	-	Global
(Mehralian et al., 2012)	37	Fuzzy TOPSIS	Iran
(Jaberidoost et al., 2013)	50	-	Global
(Ouabouch & Amri, 2013)	12	-	Morocco
(Elleuch et al., 2014)	11	AHP	Tunisia
(Mazer-Amirshahi et al., 2014)	1	-	USA
(Fox et al., 2014)	1	-	USA
(Jaberidoost et al., 2015)	32	AHP-SAW	Iran
(Huq et al., 2016)	20	-	Global
(El Mokrini, Kafa, et al., 2016)	18	Fuzzy AHP-PROMETHEE	France
(Vishwakarma et al., 2016)	24	Fuzzy AHP	India
(Bagozzi & Lindmeier, 2017)	1	-	Global
(Moktadir et al., 2018)	16	AHP	Bangladesh
(Forghani et al., 2018)	24	Z-TOPSIS	Iran
(Enyinda, 2018)	11	AHP	Global
(Merkuryeva et al., 2019)	1	-	Emerging market
(Bignami & Mattsson, 2019)	1	-	Global
(Silva et al., 2020)	43	Orders-of-magnitude AHP	Brazil
(Torasa & Mekhum, 2020)	15	-	Thailand
(EvaluatePharma, 2020)	1	-	Global
(Lawrence et al., 2020)	1	-	USA

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(Saxena et al., 2020)	1	-	Global
(Paul et al., 2020)	16	-	Bangladesh
(Ismael & Ahmed, 2020)	1	-	Iraq
(Hesarsorkh et al., 2021)	2	-	Global
(Nguyen et al., 2021)	14	-	Vietnam
(Sharma et al., 2022)	19	IF-DEMATEL	India
(Rajagopal et al., 2022)	1	-	India
This study	67	IF-AHP	India

2.2 Application of IF-AHP

The IF-AHP is an extension of traditional AHP technique to accommodate the uncertainty in the decision-making process. This technique has been implemented in many sectors with varied objectives. IF-AHP has been implemented in transportation sector for location hub selection (Gocer & Sener, 2022), staff satisfaction (Lotfi et al., 2021), service quality evaluation (Tumsekcali et al., 2021), corridor selection (Dogan et al., 2020), reverse logistics (Tavana et al., 2016), etc. Similarly, this technique has also been utilized in healthcare sector for disaster preparedness (Ortiz-Barrios, Gul, et al., 2022), medical procurement decisions (Yang et al., 2021), kidney allocation (Taherkhani et al., 2019) and performance evaluation (Otay et al., 2017). Furthermore, IF-AHP has been used in sustainable energy sector for technology selection (Onar et al., 2015) and location selection (Kutlu Gündoğdu & Kahraman, 2020). Some other major applications of this technique are in governance (Shayganmehr et al., 2022), risk assessment (Ilbahar et al., 2022; Liu et al., 2022), occupational health and safety (Ortiz-Barrios, Silvera-Natera, et al., 2022), supplier selection (Perçin, 2022; Afzali et al., 2022) and waste management (Büyüközkan et al., 2019).

As evident from the literature review, IF-AHP has found application in wide range of sectors; however, its application for risk assessment in PI is still very limited.

2.3 Research gap and contributions

As per the literature review summarized in Table 1, the number of risks discussed in the present study is far more than included in any other published work in the literature, making this study more inclusive as most studies focused on the individual node risks, and not including the risks from the entire PSC. Additionally, this study provides a description for each risk which is missing in most published works. Furthermore, the hesitancy (due to the limitation of knowledge or personal error) in experts' opinions has not been considered in the published literature. The present study accounts for this hesitancy in the decision-making process by using the Intuitionistic fuzzy set along with AHP technique, which is neglected in traditional AHP and fuzzy AHP (Chaira, 2019). Also, as per the authors' best knowledge, very few studies have been conducted on the risk assessment in the PI from manufacturers' perspective (Jaberidoost et al., 2013, 2015; Silva et al., 2020). Additionally, there are very few studies assessing the risks for the IPI, which is the major exporter of generic and other drugs to the world. Thus, this research work is being conducted from the manufacturer's perspective to identify and prioritize the PSC risks with a case illustration of the IPI, which would help in efficient risk management.

Main contributions:

-Identification of PSC risks affecting PI using an extensive literature survey. This list of all the potential risks, along with a brief description, is more inclusive than past

research works as it includes far more risks than any other study in this research area and provides a better understanding to the managers.

-Inclusion of hesitancy in the decision-making process with IF-AHP technique implementation. This technique includes the experts' limitation of knowledge or personal error in decision making.

-Elaborate discussion on the critical risk factors and managerial implications based on the obtained results. This helps managers in determining the risks which need to be managed for a more resilient and efficient PI.

3. Methodology

This work utilizes the integrated Delphi-IF-AHP approach in two-phased manner, which is presented in Figure 5 as a framework. In the first phase, an extensive literature survey was conducted for identifying the risks faced by the PI. The survey resulted into sixty-seven risks, which were then categorized in seven main categories as given in the literature. The study provides a case illustration for IPI; therefore, the obtained risks needed to be validated by experts for their relevance in the Indian context. Also, it is a tedious task for experts to analyze all the sixty-seven risks through comparison, so their judgement was required for determining the sub-risks in each category that are prominent and need to be compared in a pairwise manner for further analysis. For this, a panel of ten experts was formed, and Delphi, a qualitative consensus forming method, was utilized. Then, the finalized risks by the experts were used as input to the IF-AHP technique, which is the multi-criteria decision making (MCDM) method used in the present work.

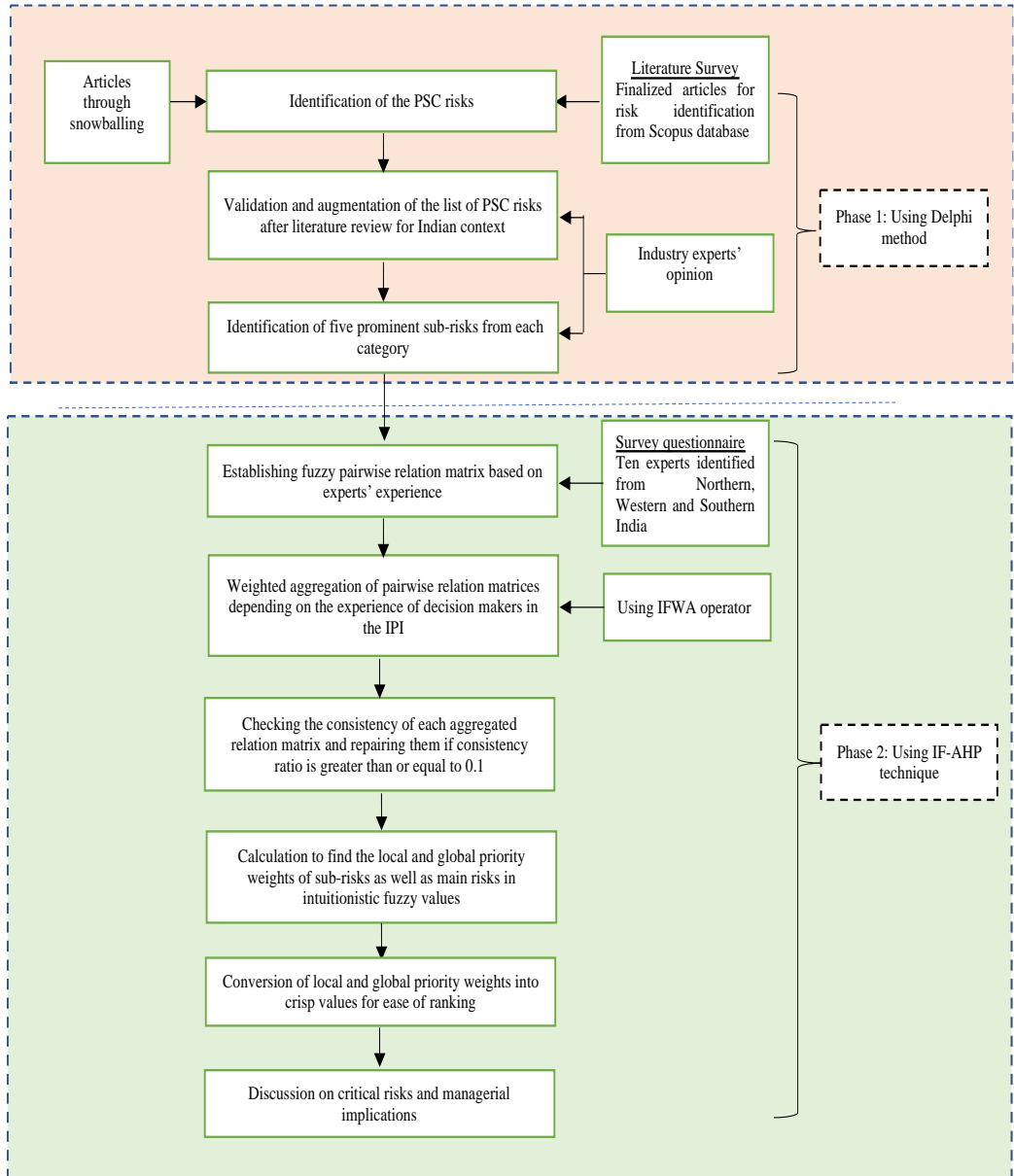


Figure 5. Two-phased research framework

3.1 Delphi Method

The Delphi method was developed in 1950s by The RAND Corporation to obtain the most reliable consensus of opinion of a group of experts over some central problem without their direct interaction with each other (Dalkey & Helmer, 1963). The key features of the Delphi method are anonymity, iteration, controlled feedback, and statistical aggregation of a group response (Rowe & Wright, 2001). The Delphi method has been used in various fields of research, e.g., public transport (Hirschhorn, 2019; Vesković et al., 2018), sustainable SC management (Tseng et al., 2015), participatory

research (Kezar & Maxey, 2016), guidance in emergency nursing (Varndell et al., 2020), etc.

A brief stepwise procedure for Delphi method is as follows (Dalkey & Helmer, 1963):

(i) The first step deals with preparing the document to be submitted to the experts for consideration.

(ii) The next step is a follow-up questionnaire that contains closed-ended questions for experts. The experts are asked to answer the questions independently. In the next iteration, each expert is given the responses submitted in the previous iteration along with the statistical analysis of responses given by other anonymous experts with an option to change their opinion.

(iii) In the last step, the opinion of experts is converged to form a consensus on the answers to closed-ended questions in step (ii).

3.2 Intuitionistic Fuzzy Analytic Hierarchy Process

MCDM is a popular way to choose the most preferred alternative from multiple options based on decision-makers' perspectives according to established criteria (Sanaei et al., 2018). AHP (Saaty, 1988) is one such MCDM technique, which is used to evaluate the relative importance of elements using pairwise comparison (Stanković et al., 2019). It is the most popular decision-making technique for researchers; however, it has been criticized for not incorporating uncertainty and vagueness in the decision-makers' perception. Perceptions are usually vague and, cannot be represented by crisp data used in AHP. Hence, AHP was extended to include this vagueness by using the Fuzzy set theory (Zadeh, 1965) to become fuzzy AHP which was further extended to IF-AHP (Mou et al., 2017). IF-AHP utilizes an Intuitionistic fuzzy set (Atanassov, 1986), which is more powerful than a fuzzy set for hesitancy, vagueness, and uncertainty description and hence, gives a better explanation and cognition of decision-making processes (Chen et al., 2022; Z. Xu et al., 2014). IF-AHP has been utilized in various fields for analysis, e.g., outsourcing reverse logistics (Tavana et al., 2016), strategy analysis in aviation industry (Büyükožkan et al., 2020), municipal wastewater treatment (Ouyang & Guo, 2018), green supplier selection (Demir & Koca, 2021), SC resilience assessment (Ayyildiz, 2021), railway transportation (Yanginlar & Gül, 2022). The brief description of the IF-AHP process is as follows:

(i) The first step is to collect pairwise comparison data from experts (decision-makers) in the industry for preparing intuitionistic preference relation matrices, using linguistic rating given in Table 2. The decision-maker, as per their experience, gives the intuitionistic preference for each pair of alternatives, e.g., if one element (risk) is slightly more important than the other element with respect to its probability of occurrence and impact, then the expert chooses '4' rating for such comparison. This helps in constructing intuitionistic preference relation (R), as shown below:

$$R^k = (\rho_{ij}^k)_{m \times m} \text{ and } p_{ij} = (\rho_{ij}^k, \sigma_{ij}^k, \tau_{ij}^k)$$

where $i, j=1, 2, \dots, m$; k denotes the decision maker ($= 1, 2, \dots, q$)

Here, ρ_{ij} is the membership function, σ_{ij} is the non-membership function and τ_{ij} is the hesitancy degree of intuitionistic fuzzy set (Atanassov, 1986; Xu, 2007a; Xu et al., 2014) with following properties:

$$0 \leq \rho_{ij} + \sigma_{ij} \leq 1;$$

$$\tau_{ij} = 1 - \rho_{ij} - \sigma_{ij}$$

Table 2. Linguistic rating for experts

S No.	Linguistic rating	Intuitionistic Fuzzy Number
1.	Significantly less important	(0.10,0.80,0.10)
2.	Slightly less important	(0.25,0.60,0.15)
3.	Equally important	(0.50,0.40,0.10)
4.	Slightly more important	(0.75,0.20,0.05)
5.	Significantly more important	(0.90,0.05,0.05)

(ii) Next, for aggregation of decision-makers' opinion, first the weightage of each decision-maker (W_k) based on their experience in the field is calculated using Eq. (1) (Büyüközkan & Güteryüz, 2016). The importance criteria for decision makers' is given in Table 3 (Boran et al., 2009; Büyüközkan & Güteryüz, 2016), e.g., if the expert has more than 20 years of experience then such an expert is 'Very important' for the decision-making process and is given higher weightage, calculated using Eq. (1).

$$\text{Weight } (W_k) = \frac{\rho_k + \tau_k \left(\frac{\rho_k}{\rho_k + \sigma_k} \right)}{\sum_{k=1}^q (\rho_k + \tau_k \left(\frac{\rho_k}{\rho_k + \sigma_k} \right))}; \quad (1)$$

$$\sum_{k=1}^q W_k = 1$$

where k is the decision maker and $k=1, 2, \dots, q$.

Here, ρ_k, σ_k and τ_k denote the membership, non-membership, and hesitancy function for k th decision-maker.

Table 3. Linguistic rating for expert weights

Experience	Linguistic terms	TFIN
More than 20 years	Very important	0.90,0.05,0.05
16-20 years	Important	0.75,0.20,0.05
11-15 years	Medium	0.50,0.40,0.10
5-10 years	Unimportant	0.25,0.60,0.15
Less than 5 years	Very unimportant	0.10,0.80,0.10

The aggregated preference relation matrices are obtained by weighted aggregation of the responses using intuitionistic fuzzy weighted averaging operator (Xu, 2007b; Yu & Xu, 2020) given as follows:

Let $R = (p_{ij}^k)_{m \times m}$ be the aggregated preference relation matrix, then

$$\begin{aligned} p_{ij} &= \text{IFWA} (p_{ij}^1, p_{ij}^2, \dots, p_{ij}^q) \\ &= W_1 p_{ij}^1 \oplus W_2 p_{ij}^2 \oplus \dots \oplus W_q p_{ij}^q \\ &= (1 - \prod_{k=1}^q (1 - \rho_{ij}^k)^{W_k}, \prod_{k=1}^q ((\sigma_{ij}^k)^{W_k}), \prod_{k=1}^q (1 - \rho_{ij}^k)^{W_k} - \prod_{k=1}^q ((\sigma_{ij}^k)^{W_k})) \end{aligned} \quad (2)$$

(iii) Next, R obtained from previous step needs to be checked for consistency (Xu et al., 2014). The intuitionistic preference relation is considered consistent if distance (Eq. 3) between R and R' is less than the consistent threshold, where R' is perfect multiplicative consistent intuitionistic preference relation.

$$\text{Distance } (R', R) = \frac{1}{2(m-1)(m-2)} \sum_{i=1}^m \sum_{j=1}^m (|\rho'_{ij} - \rho_{ij}| + |\sigma'_{ij} - \sigma_{ij}| + |\tau'_{ij} - \tau_{ij}|) \quad (3)$$

R' can be calculated as follows:

a) For $j > i + 1$, let $p'_{ij} = (\rho'_{ij}, \sigma'_{ij})$

$$\rho'_{ij} = \frac{\sqrt[j-i-1]{\prod_{l=i+1}^{j-1} \rho_{il} \rho_{lj}}}{\sqrt[j-i-1]{\prod_{l=i+1}^{j-1} \rho_{il} \rho_{lj}} + \sqrt[j-i-1]{\prod_{l=i+1}^{j-1} (1-\rho_{il})(1-\rho_{lj})}}$$

$$\sigma'_{ij} = \frac{\sqrt[j-i-1]{\prod_{l=i+1}^{j-1} \sigma_{il} \sigma_{lj}}}{\sqrt[j-i-1]{\prod_{l=i+1}^{j-1} \sigma_{il} \sigma_{lj}} + \sqrt[j-i-1]{\prod_{l=i+1}^{j-1} (1-\sigma_{il})(1-\sigma_{lj})}}$$

b) For $j = i + 1$, $p'_{ij} = p_{ij}$

c) For $j < i$, $p'_{ij} = (\sigma'_{ji}, \rho'_{ji})$

If this distance is more than consistency threshold (which is taken to be 0.1 (Xu et al., 2014)), then there is a need to repair R. The inconsistent R can be repaired to form a fused intuitionistic preference relation (R^f) using following Eqs.:

$$R^f = (p_{ij}^f)_{m \times m} \quad \text{where } p_{ij}^f = (\rho_{ij}^f, \sigma_{ij}^f, \tau_{ij}^f),$$

$$\rho_{ij}^f = \frac{(\rho_{ij})^{1-\theta} (\rho'_{ij})^\theta}{(\rho_{ij})^{1-\theta} (\rho'_{ij})^\theta + (1-\rho_{ij})^{1-\theta} (1-\rho'_{ij})^\theta}, \quad i, j = 1, 2, \dots, m \quad (4)$$

$$\sigma_{ij}^f = \frac{(\sigma_{ij})^{1-\theta} (\sigma'_{ij})^\theta}{(\sigma_{ij})^{1-\theta} (\sigma'_{ij})^\theta + (1-\sigma_{ij})^{1-\theta} (1-\sigma'_{ij})^\theta}, \quad i, j = 1, 2, \dots, m \quad (5)$$

$$\text{and } \tau_{ij}^f = 1 - \rho_{ij}^f - \sigma_{ij}^f$$

In the above equation, θ is the controlling parameter and is determined by the decision maker. The fused intuitionistic preference relation again needs to be checked for consistency.

(iv) The third step is to determine the priority weights of criteria for each preference relation. Let $\omega = (\omega_1, \omega_2, \dots, \omega_m)$ be the priority vector for R with each weight ω_i as an intuitionistic fuzzy value and is calculated as given below:

$$\omega_i = \left(\frac{\sum_{j=1}^m \rho_{ij}}{\sum_{i=1}^m \sum_{j=1}^m (1-\sigma_{ij})}, 1 - \frac{\sum_{j=1}^m (1-\sigma_{ij})}{\sum_{i=1}^m \sum_{j=1}^m \rho_{ij}} \right) \quad \text{where } i=1, 2, \dots, m \quad (6)$$

(v) The next step is to determine the local and global priorities of the criteria by converting the intuitionistic weight values (ω_i) into crisp values (W_i) using Eq. (5):

$$W_i = \frac{\rho_i + \tau_i \left(\frac{\rho_i}{\rho_i + \sigma_i} \right)}{\sum_{i=1}^m (\rho_i + \tau_i \left(\frac{\rho_i}{\rho_i + \sigma_i} \right))} \quad \text{where } \tau_i = 1 - \rho_i - \sigma_i \quad (7)$$

(vi) The last step is to determine the global and local ranks of criteria and alternatives based on crisp weight values determined in the previous step. This would give the most important alternative based on the given criteria.

4. Case illustration: Indian Pharmaceutical Industry

A case illustration has been presented to identify and prioritize the risks in the PI by integrating Delphi and IF-AHP techniques. An expert panel was approached for their viewpoint.

The present work first identified the risks posed to the PI through an extensive systematic literature review (F. Xu et al., 2022), and then based on the categorizations

Risk assessment for pharmaceutical industry in uncertain environment: an integrated... given in the literature, this research work has organized the risks into seven main headings, The number of categories was chosen to be seven, which is also the information processing capacity for humans (Cowan, 2015). Each main heading consists of various sub-risks, which are presented in Appendix B with a brief description and their sources from literature.

4.1: Phase 1: Identification and finalization of risks and sub-risks

In the present study, different risks posed to PI were identified and categorized into seven main categories, i.e., supplier, operational, financial, demand/customer/market, logistics, political, and technology, as per the literature. The experts' opinions were required to validate the list and add any more risks, and for this, a panel of ten experts from three major pharmaceutical manufacturing areas of India, i.e., Northern, Western and Southern parts (IBEF, 2021), was formed (Table 4), with their industry experience ranging from 5 to 26 years. As per the literature, ten experts are sufficient for implementing IF-AHP technique (Liu et al., 2022; Perçin, 2022).

Table 4. Basic profile of field experts

Job profile	Number of experts	Education
Senior manager	2	Master's
Quality control manager	3	Master's
Product manager	2	Master's
Project engineer	3	Bachelor's

A brainstorming session was conducted with following questions in focus:

B1: Can the risks identified through literature review be augmented?

B2: Are these risks relevant in Indian context?

B3: What are the prominent risks which need to be assessed for improved PI?

B1 and B2 helped in augmenting and validating the potential PSC risks for the PI. As it would be tedious to pairwise compare sixty-seven risks identified from the literature review, so, for answering B3, the potential risks were presented to experts for them to identify the top five prominent sub-risks from each main category as per their experience. The top five sub-risks from each main risk chosen by experts' consensus were then utilized in this study as an input to the second phase of the analysis using IF-AHP. The finalized risks after the brainstorming session with experts are presented in Figure 6.

4.2: Phase 2: Prioritization of risks and sub-risk

The five sub-risks from each main category chosen by experts are shown in Figure 6 in the form of a hierarchy model with three levels: Goal of study, risk category, and sub-risks. The experts were interviewed for pairwise comparison of finalized sub-risks in a categorical way. For the comparison, probability of risk occurrence and its impact on the industry, two most commonly used parameters, were used as decision criteria (Adabre et al., 2022; Dani, 2009; Komazec et al., 2018; Wu et al., 2021). Table 2 shows the linguistic rating scale used by experts to compare the risks (Boran et al., 2009; Büyüközkan & Güleriyüz, 2016).

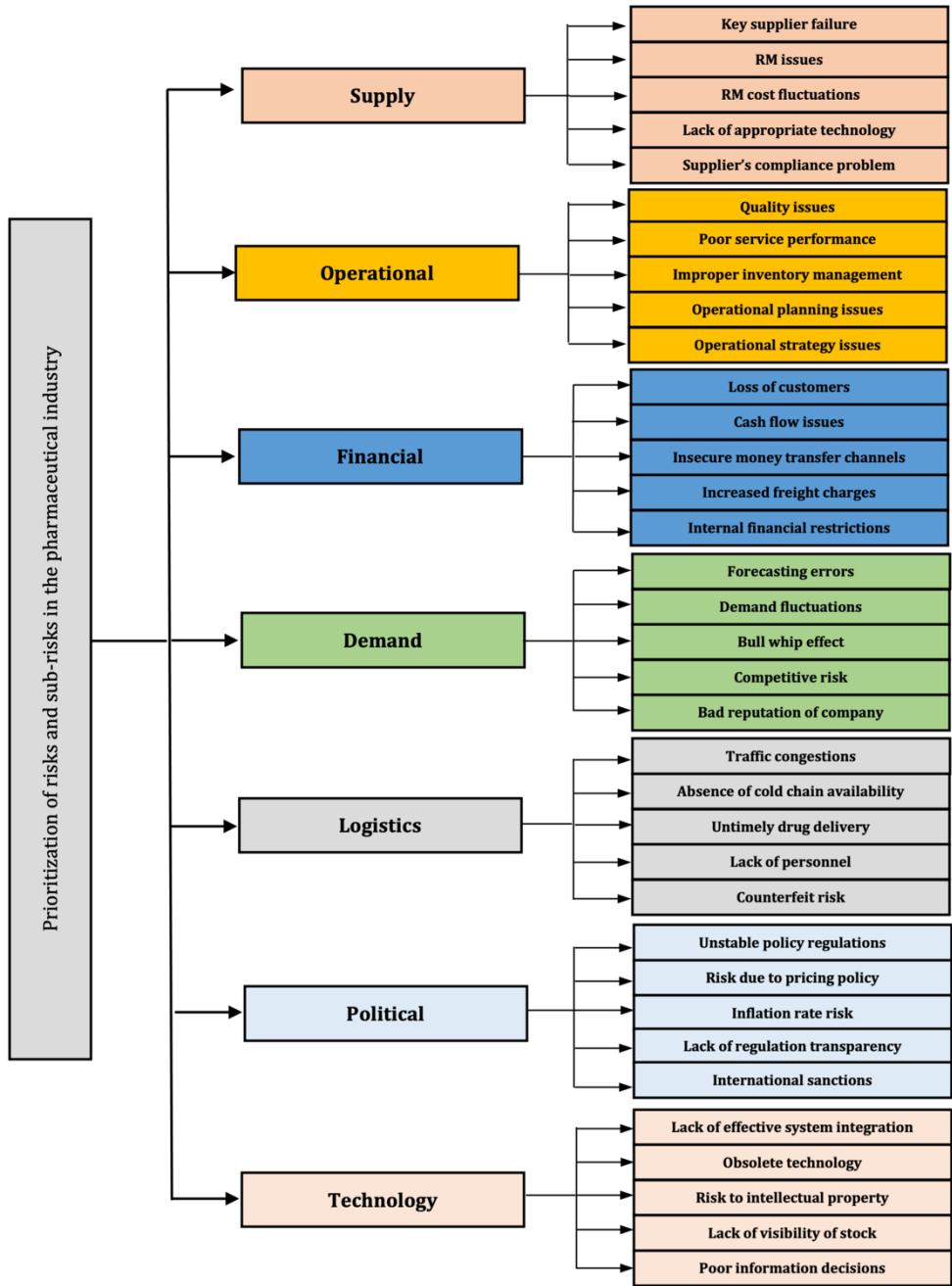


Figure 6: Finalized risks and sub-risks by pharmaceutical industry experts

Based on the weightage of the experts (Eq. 1), the preference relation matrices were obtained by weighted aggregation of their responses using intuitionistic fuzzy weighted averaging operator (Eq. 2) (Xu, 2007b). One of the aggregated preference relation matrices is shown in Table 5 and similarly, the aggregated matrices for rest of the main risks were prepared.

Table 5. Aggregated matrix for supplier side sub-risks

Supplier sub-risk	Key supplier failure	RM issues	Material cost fluctuation	Lack of appropriate technology	Suppliers' compliance problem
Key supplier failure	0.5000, 0.5000	0.3398, 0.5341	0.7277, 0.1836	0.4580, 0.4505	0.6282, 0.2871
RM issues	0.5341, 0.3398	0.5000, 0.5000	0.6699, 0.2502	0.5786, 0.3237	0.4652, 0.4279
Material cost fluctuation	0.1836, 0.7277	0.2502, 0.6699	0.5000, 0.5000	0.5830, 0.3274	0.6209, 0.3032
Lack of appropriate technology	0.4505, 0.4580	0.3237, 0.5786	0.3274, 0.5830	0.5000, 0.5000	0.5600, 0.3352
Suppliers' compliance problem	0.2871, 0.6282	0.4279, 0.4652	0.3032, 0.6209	0.3352, 0.5600	0.5000, 0.5000

Next, the preference matrices obtained from previous calculations has to be checked for consistency using steps given in section 3.2 (Eq. 3) and in case of inconsistency, the fused intuitionistic preference relation matrix has to be calculated using Eqs. (4) and (5), taking value of theta to be 0.8 (Z. Xu et al., 2014), in order to obtain consistent fused intuitionistic preference matrices.

Now using Eqs. (6) and (7), intuitionistic and crisp priority weights for main risks and sub-risks have been calculated and shown in Table 6 and Table 7 respectively. Also, the global priority weights have been calculated by multiplying the weights of respective main risk (Table 6) with local weight of sub-risks (Table 7).

Table 6. Intuitionistic and crisp priority weights for main risks

Main risks	Intuitionistic priority weight	Crisp priority weight	Rank
Supplier	0.1324,0.7819,0.0857	0.1736	2
Operational	0.1021,0.8214,0.0765	0.1326	5
Financial	0.1366,0.7820,0.0814	0.1783	1
Demand/customer/market	0.1212,0.8004,0.0784	0.1576	3
Logistics	0.0873,0.8465,0.0662	0.1121	6
Political	0.1041,0.8214,0.0745	0.1349	4
Technology	0.0864,0.8480,0.0656	0.1109	7

Table 7. Intuitionistic and crisp priority weights for sub-risks

Main risk	Sub-risks	Intuitionistic priority weight	Crisp priority weight (Local)	Crisp priority weight (Global)	Local rank	Global Rank
1. Supplier	1.1: Key supplier failure	0.1849, 0.7116, 0.1035 0.2223,	0.2331	0.0405	2	5
	1.2: RM issues	0.6824, 0.0953 0.1608,	0.2776	0.0482	1	2
	1.3: RM cost fluctuations	0.7554, 0.0838	0.1983	0.0345	3	9
	1.4: Lack of appropriate technology	0.1295, 0.7953, 0.0752	0.1582	0.0275	4	17
	1.5: Suppliers' compliance problem	0.1085, 0.8149, 0.0766	0.1328	0.0231	5	25
2. Operational	2.1: Quality issues	0.1733, 0.7312, 0.0955	0.2172	0.0289	2	15
	2.2: Poor service performance	0.1962, 0.7127, 0.0911	0.2446	0.0325	1	11
	2.3: Improper inventory management	0.1459, 0.7741, 0.0800	0.1798	0.0239	4	24
	2.4: Operational planning issues	0.1523, 0.7644, 0.0833	0.1883	0.0250	3	22
	2.5: Operational strategy issues	0.1367, 0.7745, 0.0888	0.1701	0.0226	5	26
3. Financial	3.1: Loss of customers due to poor service performance of partner(s)	0.2648, 0.6805, 0.0547	0.2988	0.0532	1	1
	3.2: Cash flow issues	0.1831, 0.7696, 0.0473	0.2050	0.0366	3	7
	3.3: Insecure money transfer	0.2103, 0.7358, 0.0539	0.2371	0.0423	2	4
	3.4: Increased freight charges	0.1369, 0.8246, 0.0385	0.1520	0.0271	4	18

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	3.5: Internal financial restriction	0.0970, 0.8684, 0.0346	0.1071	0.0192	5	31
	4.1: Forecasting error	0.1789, 0.7158, 0.1053	0.2277	0.0359	2	8
	4.2: Demand fluctuations	0.1340, 0.7818, 0.0842	0.1667	0.0263	4	19
4. Demand/ Customer/ Market	4.3: Bull whip effect	0.1424, 0.7702, 0.0874	0.1777	0.0281	3	16
	4.4: Competitive risk	0.1085, 0.8165, 0.0750	0.1336	0.0211	5	27
	4.5: Bad reputation of company	0.2265, 0.6504, 0.1231	0.2943	0.0464	1	3
	5.1: Traffic congestion	0.1054, 0.7962, 0.0984	0.1340	0.0151	4	34
	5.2: Absence of cold chain availability	0.2288, 0.6623, 0.1089	0.2944	0.0331	1	10
5. Logistics	5.3: Untimely delivery of product	0.1428, 0.7636, 0.0936	0.1806	0.0203	3	29
	5.4: Lack of personnel	0.1017, 0.8241, 0.0742	0.1260	0.0142	5	35
	5.5: Counterfeit risk	0.2025, 0.6737, 0.1238	0.2650	0.0298	2	12
	6.1: Unstable policy regulation	0.2223, 0.6728, 0.1049	0.2826	0.0382	1	6
	6.2: Risk due to pricing policy	0.1517, 0.7608, 0.0875	0.1892	0.0256	3	21
6. Political	6.3: Inflation rate risk	0.1216, 0.8024, 0.0760	0.1498	0.0202	5	30
	6.4: Lack of regulation transparency	0.1473, 0.7622, 0.0905	0.1843	0.0249	4	23
	6.5: International sanctions	0.1534, 0.7457, 0.1009	0.1941	0.0262	2	20
7. Technology	7.1: Lack of effective	0.1452, 0.7527, 0.1021	0.1832	0.0204	3	28

system
integration

7.2: Obsolete technology	0.2134, 0.6908, 0.0958	0.2675	0.0297	1	13
7.3: Risk to intellectual property	0.2107, 0.6937, 0.0956	0.2641	0.0293	2	14
7.4: Lack of visibility of stock	0.1151, 0.8127, 0.0722	0.1407	0.0156	5	33
7.5: Poor information decision	0.1173, 0.8029, 0.0798	0.1445	0.0161	4	32

5. Results

As per the results for main risks (Table 6), financial risk (0.178) is the most critical in the Indian context, followed by supplier (0.174) and demand/customer/market (0.158). The rest of the risks, i.e., political (0.135), operational (0.133), logistics (0.112), and technology (0.111), have fourth, fifth, sixth, and seventh rank, respectively. For better understanding, these results have been summarized in Figure 7.

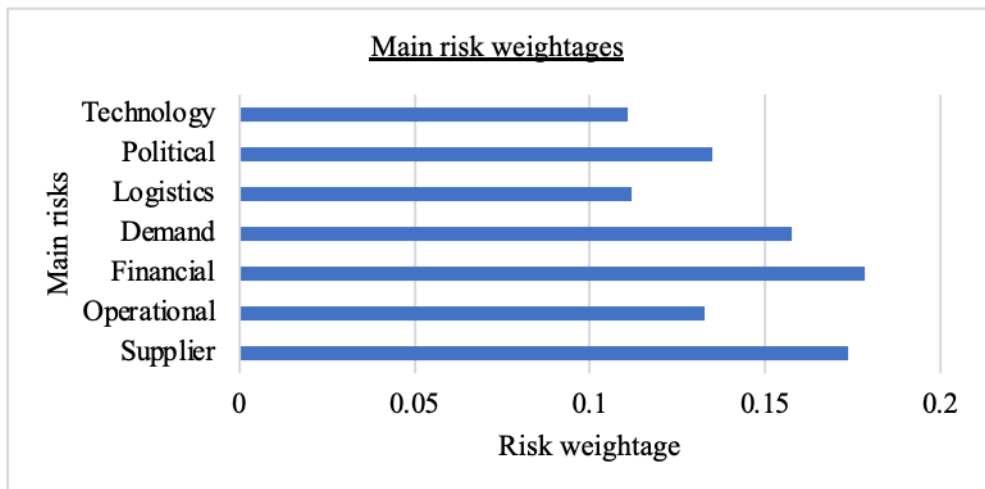


Figure 7. Main risk weightages

Similarly, in Table 7, the sub-risks are ranked based on their local priority weights, which indicates the criticality of each sub-risk within the main risk. For example, in the supplier risk category, RM issues should be the top priority for mitigation as it is ranked first in criticality, followed by key supplier failure, material cost fluctuations, lack of appropriate technology, and lastly, suppliers' compliance problem. In the same way, poor service performance in the operational risk category; loss of customers due to poor service performance of partner(s) in financial risk; bad reputation of company in demand/customer/ market risks; absence of cold chain availability in logistics risk;

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 unstable policy regulation in political and obsolete technology in technology related category, should have top priorities for mitigation efforts. The results for sub-risks have been summarized in Figure 8.

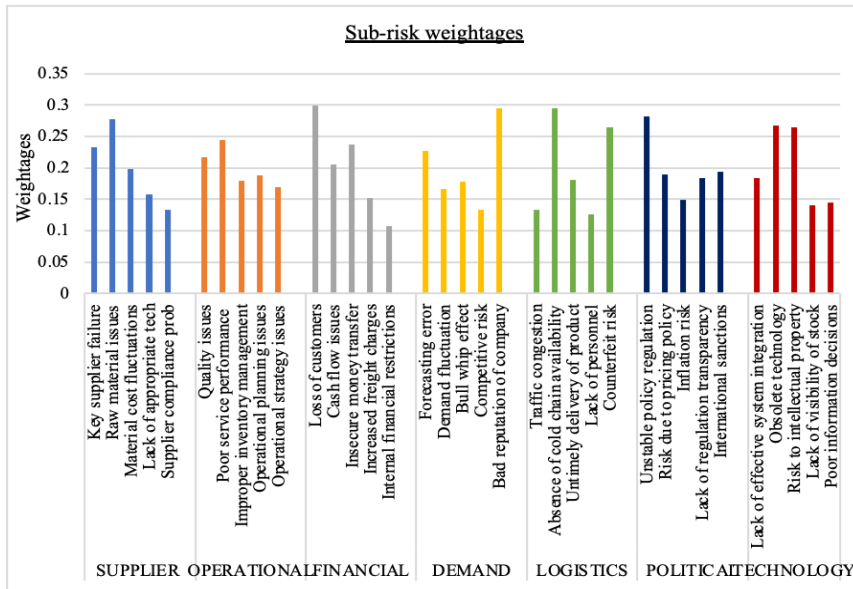


Figure 8. Sub-risk weightages within each risk category

Also, the sub-risks are ranked as per the global priority weights, indicating the criticality of each sub-risk across the different categories. As per the global ranking, loss of customer due to poor service performance of partner(s) (0.053) has the highest criticality for the IPI due to the highest risk weightage of financial risk, followed by RM issues (0.048) and bad reputation of the company (0.046). The rest of the sub-risks with their weights and ranks are also given in Table 7.

5.1: Comparison with traditional and fuzzy AHP

The results obtained using IF-AHP have been compared with traditional and fuzzy AHP techniques and the rank comparison is shown in Figure 9 and 10 for sub-risks and main risks, respectively. As per the comparison, there are cases where the ranks remain the same irrespective of the technique used; for example, financial sub-risks have same ranks for all the three techniques. Similarly, in main risks (Figure 10), three ranks remain the same across the techniques. However, there are cases with varied ranks due to incorporation of hesitancy degree in IF-AHP which is ignored in traditional and fuzzy AHP.

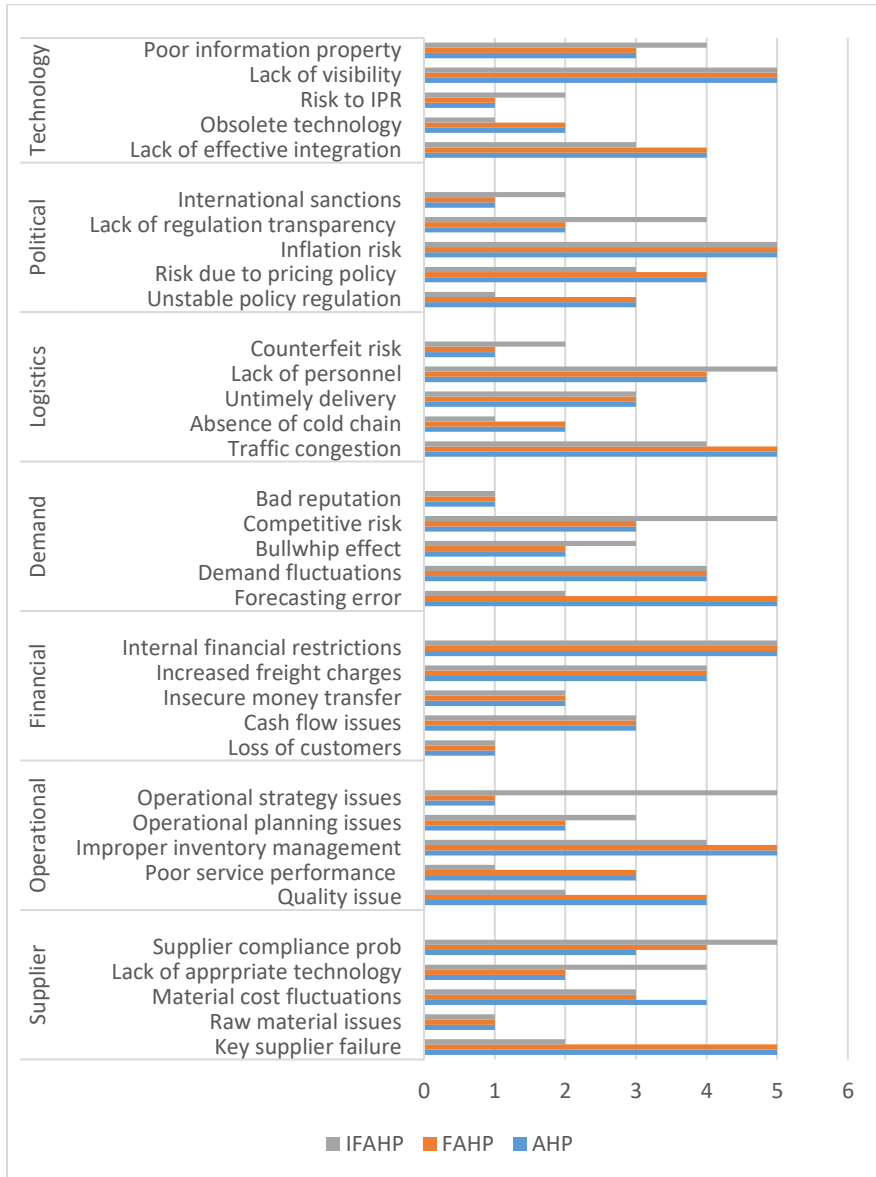


Figure 9. Sub-risk rank comparison of AHP, Fuzzy AHP and IF-AHP

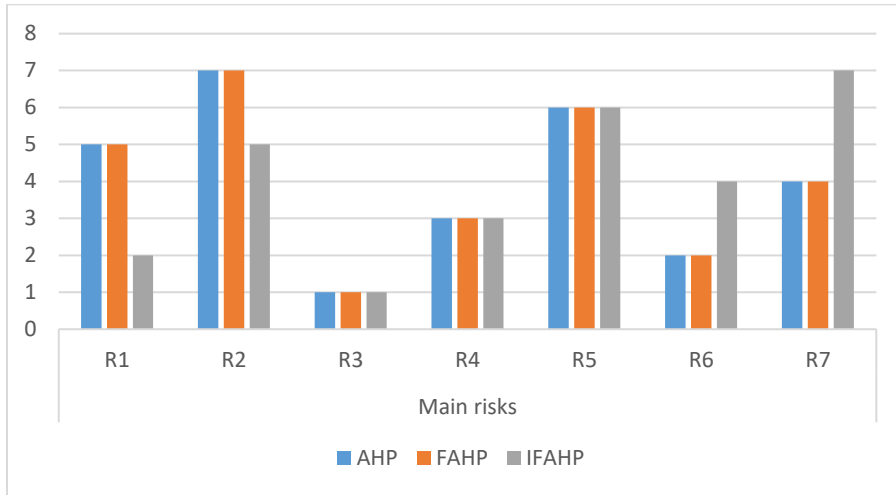


Figure 10. Main risk rank comparison of AHP, Fuzzy AHP and IF-AHP

5.2: Sensitivity analysis

Sensitivity analysis is an important step in MCDM techniques for validating the obtained results, as inputs are subjective and can be sometimes imprecise. Therefore, to examine the robustness and reliability of results, changes in the dependent output variables with small change in independent input are assessed. This helps the industry managers to make informed decisions for an improved performance. In this work, Spearman’s rank correlation coefficient (S’) is used for sensitivity analysis, which is expressed as Eq. (8).

$$S' = 1 - \frac{6 \sum_{x=1}^X D^2}{X(X^2-1)} \tag{8}$$

where X is the total number of risks/sub-risks, x is the number of risks/sub-risks, and D is the difference between ranks (original and revised). S' can vary between -1 to 1 where 1 denotes perfect correlation and -1 denotes perfect negative correlation. S' = 0 denotes no association (Govindan et al., 2015).

To check the sensitivity, the original weight (0%) for the most experienced expert has been varied by ±5%, ±10%, ±15%, and ± 20%. The results of the analysis are provided in Table 8.

Table 8. Sensitivity analysis with variation in DM weight

Risks/sub-risks	0%	5%	10%	15%	20%	5%	-10%	-15%	-20%
1. Supplier	2	2	2	2	2	2	2	2	2
1.1: Key supplier failure	2	2	2	2	2	2	2	2	2
1.2: RM issues	1	1	1	1	1	1	1	1	1
1.3: RM cost fluctuations	3	3	3	3	3	3	3	3	3

Risks/sub-risks	0%	5%	10%	15%	20%	-5%	-10%	-15%	-20%
1.4: Lack of appropriate technology	4	4	4	4	4	4	4	4	4
1.5: Suppliers' compliance problem	5	5	5	5	5	5	5	5	5
2. Operational	5	5	5	5	5	5	5	5	4
2.1: Quality issues	2	2	2	2	2	2	2	2	2
2.2: Poor service performance	1	1	1	1	1	1	1	1	1
2.3: Improper inventory management	4	4	4	4	5	4	4	4	4
2.4: Operational planning issues	3	3	3	3	3	3	3	3	3
2.5: Operational strategy issues	5	5	5	5	4	5	5	5	5
3. Financial	1	1	1	1	1	1	1	1	1
3.1: Loss of customers due to poor service performance of partner(s)	1	1	1	1	1	1	1	1	1
3.2: Cash flow issues	3	3	3	3	3	3	3	3	3
3.3: Insecure money transfer	2	2	2	2	2	2	2	2	2
3.4: Increased freight charges	4	4	4	4	4	4	4	4	4
3.5: Internal financial restriction	5	5	5	5	5	5	5	5	5
4. Demand	3	3	3	3	3	3	3	3	3
4.1: Forecasting error	2	2	2	2	2	2	2	2	2
4.2: Demand fluctuations	4	4	4	4	4	4	4	4	4

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Risks/sub-risks	0%	5%	10%	15%	20%	-5%	-10%	-15%	-20%
4.3: Bull whip effect	3	3	3	3	3	3	3	3	3
4.4: Competitive risk	5	5	5	5	5	5	5	5	5
4.5: Bad reputation of company	1	1	1	1	1	1	1	1	1
5. Logistics	6	6	6	6	6	6	6	6	6
5.1: Traffic congestion	4	4	4	4	4	4	4	4	4
5.2: Absence of cold chain availability	1	1	1	1	1	1	1	1	1
5.3: Untimely delivery of product	3	3	3	3	3	3	3	3	3
5.4: Lack of personnel	5	5	5	5	5	5	5	5	5
5.5: Counterfeit risk	2	2	2	2	2	2	2	2	2
6. Political	4	4	4	4	4	4	4	4	5
6.1: Unstable policy regulation	1	1	1	1	1	1	1	1	1
6.2: Risk due to pricing policy	3	3	3	3	3	3	3	3	3
6.3: Inflation rate risk	5	5	5	5	5	5	5	5	5
6.4: Lack of regulation transparency	4	4	4	4	4	4	4	4	4
6.5: International sanctions	2	2	2	2	2	2	2	2	2
7. Technology	7	7	7	7	7	7	7	7	7
7.1: Lack of effective system integration	3	3	3	3	3	3	3	3	3
7.2: Obsolete technology	1	1	1	1	1	1	1	1	1

Risks/sub-risks	0%	5%	10%	15%	20%	5%	-10%	-15%	-20%
7.3: Risk to intellectual property	2	2	2	2	2	2	2	2	2
7.4: Lack of visibility of stock	5	5	5	5	5	5	5	5	5
7.5: Poor information decision	4	4	4	4	4	4	4	4	4
S'		1	1	1	0.999	1	1	1	0.999

The value of S' is equal to or very close to 1 which shows that the obtained results are valid and robust with certain variation of DM's weight.

The detailed discussion of the above results is suitably presented in the next section.

6. Discussion

The results obtained from the above section have been discussed in the following section under two sub-headings, i.e., Global ranking across risks and Local ranking for sub-risks in different categories.

6.1 Global ranking across risks

The top ten ranks have been observed for analyzing the criticality of main risks. It has been observed that two main risks, i.e., financial and supplier, each had three sub-risks in the top ten global ranks. Demand/customer/market had two sub-risks in the top ten ranks, and political, and logistics risk each had one sub-risks. Two main risks, i.e., operational and technology, had no sub-risks in top ten global ranks. Similarly, based on priority weights (Table 6), financial, supplier, and demand/customer/market risks are most important, with weights 0.1783, 0.1736, and 0.1576, respectively. This shows that the main categories which are more important than the other are financial (Jaberidoost et al., 2015), supplier (Jaberidoost et al., 2015; Vishwakarma et al., 2016) and demand/customer/market. The financial risks are important as finances are required to initiate any process in a system, e.g., RM procurement, distribution, etc. Therefore, these risks will hamper the rest of the processes as well. The supplier risk is another category that is critical as risks posed to the supply side would affect the availability and quality of RM procured for further operations to produce medicines for patients. Also, this risk can result in a shortage of good quality affordable medicines in the market; hence, affecting the healthcare system of a country. Similarly, demand/customer/market risk is also crucial as the market provides the initial input for production planning in the industry, and issues like forecasting error, demand variation, etc., lead to poor managerial decisions and, ultimately, revenue loss to the company. Furthermore, to get a deeper insight into these risks, local ranks of sub-risks in each main category have been further considered.

6.2 Local ranking for sub-risks in different categories

The top three sub-risks of each main category of risks have been elaborately discussed in this section as per their priority weights shown in Table 7.

6.2.1: Financial sub-risk

In financial risk category, the most critical sub-risk is found to be the loss of customers due to poor service performance of partner(s). The lost customers due to poor service of the company's partners like wholesalers, retailers, etc., will lead to loss of profit margins and shift of customers to the competitor for their pharmaceutical demand. While insecure money transfer is the second most important sub-risk. As the transfer of money through digital modes has increased in recent times due to initiatives like the Digital India programme (Cashless India, 2021) and COVID-19 (PwC, 2020), the instances of fraudulent transactions, identity theft, etc., through hacking also increased, causing loss of money and mistrust among the PSC partners. Therefore, it is one of the critical financial risks in the PI. Further, the third important sub-risk is cash flow issues. The cash flow issues can be caused due to longer billing cycles, low profits, over-investment in the capacity, etc., which can tie up the cash leading to financial as well as non-financial problems (e.g., poor relationship among partners, restricted growth, low employee morale, etc.).

6.2.2: Supplier sub-risks

RM issues are ranked as the most critical sub-risk within supplier risk. The products in the PI are important to the well-being of its customers; therefore, issues caused due to poor quality of RM (like Active Pharmaceutical Ingredients) result in substandard products, posing health issues. Another important sub-risk, i.e., key supplier failure (Moktadir et al., 2018; Ouabouch & Amri, 2013), is posed by supplier failure to deliver RM due to some unforeseen events like fire, strikes, etc., hampering all the subsequent processes in production and can lead to late delivery of medicines and lost margins for the company. The third sub-risk is material cost fluctuations. In recent times, due to COVID-19, there have been a lot of fluctuations in the cost of pharmaceutical RM (Cherian et al., 2021). These cost fluctuations affect the profit margins of the industry, and the prices of the products for the customer would vary, leading to their dissatisfaction.

6.2.3: Demand sub-risks

The third most important risk, i.e., the demand category, has the bad reputation of the company as the most critical sub-risk, which can cause sales loss, lack of customer loyalty, employee retention issues, etc. Hence, this sub-risk is most critical as it results in both external (e.g., customer loss) and internal (e.g., employee retention crisis) issues. The second sub-risk is forecasting error. Demand forecasting is the basis for other managerial decisions like procurement, logistics, etc., and forecasting accuracy has been a challenge (Johnston et al., 2020; Merkuruyeva et al., 2019) which can result in poor operational planning leading to shortage or excess inventory. Another important sub-risk is the bullwhip effect, which is caused due to distorted information transfer upstream in a SC. Due to this, the PI can have excess inventory that must be sold before its expiry date. Therefore, this sub-risk is quite important as it results in cash tied up in the form of excess inventory and other ill-informed decisions.

6.2.4: Political sub-risks

Next, in the political risk category, the first ranked sub-risk is unstable policy regulation, which affects the functioning of the industry as in an environment with recurring changes, it is challenging to perform long-term planning (Vishwakarma et al., 2016) and investment in the industry also becomes unattractive. The next important sub-risk is international sanctions, which can affect the import/export of drugs or RM, resulting in an inefficient healthcare system. For example, international sanctions faced by Iran affected their import of pharmaceutical RM and finished goods (Cheraghali, 2013; Far, 2019). The third sub-risk is the risk due to pricing policy. In some countries like India, the prices of medicines and medical products are monitored by a central government authority, which fixes the prices of essential drugs, leading to less profit margins for the manufacturer and sometimes forcing companies to go out of production (Sahay & Jaikumar, 2016).

6.2.5: Operational sub-risks

In operational category, which is ranked fifth, poor service performance is ranked as the most critical sub-risk. This sub-risk, which is posed due to issues like unacceptable responsiveness, time to market, etc., results in dissatisfied customers. In the recent pandemic, to fulfil the unprecedented demand for critical drugs and to make sure that they reach the customer within an acceptable timeframe, the PI needs to be highly responsive and flexible. The second important sub-risk is quality issue, which can be a result of bad manufacturing practices, lack of quality regulations, poor infrastructure, etc. The poor quality of products can lead to detrimental effects on the health of its customers; hence, there is a need to ensure optimum product quality (Dengler et al., 2021). Another important sub-risk is the operational planning issue. Poor operational planning results in low effectiveness of the production process (Mateljak & Mihanović, 2016) since business functions like sourcing, procurement, distribution, etc., are affected by it, therefore, making this sub-risk a critical concern.

6.2.6: Logistics sub-risks

In logistics risk, the absence of cold chain availability is the most critical sub-risk. Some medical products require a specific environment, e.g., temperature, humidity, etc., for their storage to retain therapeutic properties and other qualities (Faghih-Roohi et al., 2020; Lau et al., 2021; Yadav & Kumar, 2022), and hence, specialized containers are required for transporting such products. Therefore, the absence of cold chain can result in poor quality of medicines leading to adverse effects on patients. The second important sub-risk in this category is counterfeit risk. Counterfeit drugs have been prevalent in markets which can result in injurious effects on patient health (Sample, 2019) and loss to the industry. This sub-risk is one of the main challenges faced by PSC and has been threatening the healthcare systems worldwide (Mackey & Nayyar, 2017; PSI, 2020; Uddin, 2021). The third sub-risk is found to be the untimely delivery of product. The pharmaceutical products are critical to the patients' health; therefore, timely delivery of such products is also important for efficient healthcare services.

6.2.7: Technology sub-risks

In the last ranked risk category, i.e., technology risk, obsolete technology is found to be the most important sub-risk. The technology is the driver which integrates the different units in a production system as well as across PSC and helps in fulfilling the

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demand with quality medicines. The recent pandemic has also highlighted the importance of the latest technology for surviving in the market. Therefore, obsolete technology is a major sub-risk in this category. The second important sub-risk is the risk to intellectual property. IPR provides the rights to companies to exclusively produce and distribute the drugs and, therefore, prevents other companies from doing the same. Hence, the risk to IPR (Huq et al., 2016) is a major issue that can tarnish the brand name of the company and lead to financial losses. The third sub-risk is the lack of effective system integration. There is a requirement for seamless information flow between different partners in PSC for an efficient production system which can be achieved by effective system integration across SC. However, lack of such integration results in information discrepancies and slows down the decision-making process, leading to redundancies in the system.

7. Conclusion

The PI plays a vital role in manufacturing and delivering drugs to various healthcare systems and improving the quality of life for its customers. Through this study, various PSC risks faced by this industry globally, e.g., poor service performance, forecasting error, key supplier failure, etc., have been identified. These identified risks have been categorized into seven prominent categories and prioritized using IF-AHP technique for obtaining the critical risks that are posed to the PI affecting its overall working, which is one of the major contributions of the work. Another contribution is the incorporation of the hesitancy and vagueness in the decision makers' opinion, which makes the findings more inclusive and robust. The results of the study help in improving the resilience, efficiency, and responsiveness of the PI. They can also support in achieving the Sustainable Development Goals related to responsible production and consumption and building resilient infrastructure. With mitigation of identified critical risks, the society will also be impacted in a positive way with right quality and quantity of medicines delivered on time to the right patient. The resilient and efficient PI would assist the health organizations in eradicating various diseases, and hence, further improving the lives of the people.

Following observations have been made based on the results:

-The three most important risk categories for the IPI are financial (0.178), supplier (0.174), and demand/customer/ market (0.158).

-Within these risk categories, the most critical sub-risks are found to be loss of customers due to poor performance of partner(s), RM issues, and bad reputation of the company, respectively.

-These sub-risks affect the performance of the industry and result in customer dissatisfaction, ultimately affecting the bottom line.

-The loss of customers and bad reputation can be improved through good customer relationship management. Similarly, RM issues, one of the supplier side sub-risks, can be dealt with effective and regular communication between the supplier and the manufacturer and utilizing various appropriate technologies for a better supplier experience. The rest of the risks and sub-risks have been discussed in the previous section.

As far as managerial implications are concerned, this study helps the industry managers in more efficient risk management by identifying and analyzing the critical risks that need to be mitigated for better overall performance and working of the PI. The study shows that the PI is affected by risks found within it as well as by those prevalent in SC. COVID-19 has proved this point as the disruptions in one part of the

world have affected the entire PSC across the world. In this context, the managers can provide proper training to the personnel as per the risk criticality for implementation and monitoring of mitigation plans. There is a need to understand the importance of better interconnection of risk management plans across SC so that risks can be managed effectively, and the risk assessment presented in the paper would aid the managers to prepare a comprehensive risk management plan for the entire PSC. This will also help in identifying areas where regulations and compliances are lacking within the industry which can be corrected for improved quality and standards. Some control measures, e.g., changes to production process, testing or packing process, can be implemented for risk mitigation. Since the risk assessment is a continuous process, managers can monitor the risks constantly and identify any new emerging risk for an updated and improved plan. The managers should also cultivate a risk management work culture, which should include the dissemination of risk information and its importance for long-term reputation and success of the PI.

7.1. Limitation and Future Scope

This work has some limitations as well. The study is based on a survey, and even with the best efforts of the authors in conducting unbiased research, the results are dependent on the experience and understanding of the experts. In the future, this study can be extended to include more experts from all the major pharmaceutical production regions. A comparison-based study among countries can also be conducted from a global perspective. The present study categorizes the risks into seven prominent groups, which can be extended to include more categories. The inter-relationship between the identified critical risks and sub-risks can be established with the help of techniques like ISM, DEMATEL, etc., in future work. Apart from IF, other latest fuzzy environments like linear Diophantine, spherical, decomposed, fermatean, neuro-fuzzy, etc., can be implemented in the future for MCDM process.

Author Contributions: Conceptualization, A.S.; methodology, A.S.; validation, A.S., formal analysis, A.S.; investigation, A.S.; data curation, A.S.; writing—original draft preparation, A.S.; writing—review and editing, A.S.; supervision, D.K. and N.A. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Acknowledgments: We are grateful to all the field experts for their insightful opinion.

Conflicts of Interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A

Preliminaries: Intuitionistic fuzzy set

The Intuitionistic fuzzy set (IFS) was first defined by Atanassov in 1986 to extend the traditional fuzzy set for addressing its inability to include the uncertainty in real-world problems. IFS has better performance as compared to fuzzy set for incorporating vagueness and uncertainty in decision-making process, which is done using three degrees, i.e., membership, non-membership and hesitancy degree.

Let M be the finite set, then N which is an IFS, is defined as:

$$N = \{ \langle m, \rho_N(m), \sigma_N(m) \rangle \mid m \in M \}$$

where $\rho_N: N \rightarrow [0,1]$ and $\sigma_N: N \rightarrow [0,1]$ are the membership and non-membership function of intuitionistic fuzzy set N, respectively.

$$0 \leq \rho_N(m) + \sigma_N(m) \leq 1$$

The values for $\rho_N(m), \sigma_N(m) \in [0,1]$, are the membership and non-membership degrees of $m \in M$ in N.

The hesitancy degree, $\tau_N(m) \in [0,1]$, denotes the uncertainty/vagueness or lack of knowledge in decision-making whether m is a member of intuitionistic fuzzy set N. The value of $\tau_N(m)$ becomes small when the certainty about m is more and vice-versa. The relation between hesitancy degree, membership and non-membership function is given by following expression:

$$\tau_N(m) = 1 - \rho_N(m) - \sigma_N(m)$$

The IFS allows flexible and robust decision-making process, especially in uncertain cases or situations where decision-makers have limited information/knowledge.

Appendix B

Categorization of sub-risks with brief description

Sno.	Sub risk	Description	Source
		Category 1. Supplier Sub-risks	
1.1	Absence of Environmental Assessment Framework	absence of environmental assessment affecting social status of pharmaceutical company leading to loss of reputation, order cancellation, etc.	(Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012)
1.2	Contracting/ Agreement Issues	contracts and partnerships between RM (API, excipients, etc.) suppliers and manufacturer, e.g., rights to	(Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012); (Breen, 2008)

1.3	Fragmentation of PSC	seek alternative supplier, etc. resulting in decreased profit. lack of communication among multiple channels leading to medicine stockout, mismanaged inventory, etc. and therefore, affecting the demand fulfilment.	(Jaberidoost et al., 2013, 2015); (Breen, 2008)
1.4	Key Supplier Failure	failure of supplier caused by unforeseen events, e.g. fire, worker strikes, etc. to deliver the RM such as API for manufacturing, leading to disrupted production process and unfulfilled demand.	(Sharma et al., 2022); (Forghani et al., 2018); (Moktadir et al., 2018); (Ouabouch & Amri, 2013); (Jaberidoost et al., 2013); (Mehralian et al., 2012); (Enyinda et al., 2010)
1.5	Lack of Appropriate Technology Level	lack of proper information sharing from suppliers to manufacturers leading to glitches in pharmaceutical production process.	(Nguyen et al., 2021); (Sharma et al., 2022); (Moktadir et al., 2018); (Mehralian et al., 2012)
1.6	RM Cost Fluctuations	changes in RM (like API, excipients) prices caused by changing tariffs, freight charge fluctuations, etc. affecting profit margins.	(Forghani et al., 2018); (Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Ouabouch & Amri, 2013); (Mehralian et al., 2012)
1.7	Personnel Incapabilities	unskilled personnel such as managers, workers leading to decision making issues in turn affecting the quality of drugs.	(Forghani et al., 2018)
1.8	RM Issues	poor quality of RM leading to substandard quality of drugs or non-availability of RM resulting in drug shortage.	(Nguyen et al., 2021); (Forghani et al., 2018); (Moktadir et al., 2018); (Jaberidoost et al., 2015); (Elleuch et al., 2014); (Ouabouch &

			Amri, 2013);(Jaberidoost et al., 2013); (Mehralian et al., 2012); (Breen, 2008)
1.9	Risk due to Customization of Supplier	manufacturer specific demands regarding quantity, product variety, delivery time, etc., which leads to delay in production, unfulfilled demand, etc.	(Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012)
1.10	Suppliers' Compliance Problem	supplier failure in complying with its customer requirements e.g., time in making delivery, delay in import arrivals, etc., leading to production delays and mistrust among partners.	(Forghani et al., 2018); (Moktadir et al., 2018); (Vishwakarma et al., 2016); (Jaberidoost et al., 2015); (Elleuch et al., 2014); (Jaberidoost et al., 2013)
1.11	Suppliers Conditions	working conditions prevailing at suppliers e.g., poor work culture affecting manufacturer's brand name.	(Jaberidoost et al., 2015)
1.12	Unpredictable Trade Barriers	unpredictable barriers like tariff, non-tariff constraints, foreign government changing the standards for accepting the imported drugs, etc.	(Huq et al., 2016); (Ouabouch & Amri, 2013)
1.13	Transportation Failure	transportation failure from suppliers to manufacturer leading to delayed production, loss of business goodwill, etc.	(Ouabouch & Amri, 2013)
2.1	Accidents	Category 2. Operational Sub-risks accidents such as occupational hazards which disrupt the pharmaceutical production leading to loss of lives, absenteeism, etc.	(Huq et al., 2016); (Ouabouch & Amri, 2013)

2.2	Difficulty in Order Processing	order error caused either by customer placing wrong order details or by company delivering wrong order leading to negative impact on customer satisfaction.	(Huq et al., 2016)
2.3	Improper Inventory Management	mismanaged inventory, e.g., inadequate buffer stock, expired drugs in storage, etc., leading to wastage of resources and delayed production schedules.	(Huq et al., 2016); (Jaberidoost et al., 2013, 2015); (Ouabouch & Amri, 2013); (Breen, 2008)
2.4	Lack of Flexibility in Operations	restrictions on production line e.g., drug variety leads to inability to meet unexpected demand fluctuations.	(Vishwakarma et al., 2016); (Mehralian et al., 2012)
2.5	Operational Cost Uncertainty	changes in operational costs, e.g., due to failure of equipment, improper maintenance, etc. affecting profit margins.	(Jaberidoost et al., 2015); (Mehralian et al., 2012)
2.6	Operational Planning Issues	poor long- and short-term planning including outsourcing functions leading to poor production and delivery schedules.	(Nguyen et al., 2021); (Sharma et al., 2022); (Huq et al., 2016); (Jaberidoost et al., 2013, 2015); (Breen, 2008)
2.7	Operational Strategy Issues	non-standard practices and other operational strategies (e.g., redundant suppliers) leading to quality issues and loss of profit.	(Nguyen et al., 2021); (Sharma et al., 2022); (Jaberidoost et al., 2013, 2015); (Breen, 2008)
2.8	Lack of Personnel Capabilities	insufficient managerial decision-making knowledge leading to planning issues and operational inaccuracies.	(Huq et al., 2016); (Jaberidoost et al., 2013, 2015); (Breen, 2008)
2.9	Poor Infrastructure and Handling Risk	the poor infrastructure and handling e.g., operations, machine failure etc., leading to	(Silva et al., 2020); (Torasa & Mekhum, 2020); (Moktadir et al.,

		delayed production process, unsatisfied demand, etc.	2018); (Ouabouch & Amri, 2013)
2.10	Poor Service Performance	poor service issues such as unacceptable degree of responsiveness, flexibility, time to market, customer service disruption, etc., leading to unfulfilled drug demands and unsatisfied customers.	(Vishwakarma et al., 2016); (Jaberidoost et al., 2013); (Breen, 2008)
2.11	Power Failure	absence of secondary power source affecting the operations in the pharmaceutical industry.	(Moktadir et al., 2018); (Huq et al., 2016)
2.12	Quality Issues	unacceptable quality standards of the pharmaceutical products affecting the health of the customers.	(Ismael & Ahmed, 2020);(Silva et al., 2020); (Moktadir et al., 2018); (O'Connor et al., 2017); (Huq et al., 2016); (Vishwakarma et al., 2016); (Mehralian et al., 2012)
2.13	Storage Contamination Risk	uncontrolled environment (e.g., temperature, humidity, etc.) and unwanted contaminants (e.g., pyrogenic substances) in the storage area leading to loss of profit due to discarded drugs.	(Moktadir et al., 2018); (Vishwakarma et al., 2016)
2.14	Theft Risk	theft of resources such as RM, drugs, etc., and its diversion from legal distribution channel leading to loss of resources, lost margins, etc.	(Silva et al., 2020); (Elleuch et al., 2014); (Breen, 2008)
2.15	Waste Generation Issues	waste production which leads to regulatory restriction e.g., license cancellation, environment pollution, etc.	(Jaberidoost et al., 2013, 2015)
3.1	Banking Regulations	Category 3. Financial Sub-risks changes in bank interest rate, leading to financial restrictions	(Moktadir et al., 2018); (Jaberidoost et al.,

		in the pharmaceutical activities.	2013, 2015); (Mehralian et al., 2012)
3.2	Cash Flow Issues	money collection problems ultimately hampering stability in production schedules and trust.	(Jaberidoost et al., 2013, 2015)
3.3	Currency Fluctuations/ Exchange Rates Fluctuations	uncertainty in the currency exchange rates which affect the import/export of RM or drugs to the international markets leading to profit margins.	(Nguyen et al., 2021); (Silva et al., 2020); (Moktadir et al., 2018); (Enyinda, 2018); (Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012); (Enyinda et al., 2010)
3.4	Dynamic Taxation Issues	changes in the tax payable, affecting the profit of the pharmaceutical industry.	(Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012)
3.5	Economic Stagnation	stagnant economy reflected by high unemployment rate and low purchasing power, ultimately leading to sluggish growth of pharmaceutical industry.	(Jaberidoost et al., 2015)
3.6	Increased Freight Charges	increased fuel cost, low availability of carriers, etc., which affect the profit margins.	(Sharma et al., 2022); (Moktadir et al., 2018); (Vishwakarma et al., 2016); (Mehralian et al., 2012)
3.7	Insecure Money Transfer Channel	safety issues in money transfer channels considering threat of cyber hacking.	(Sharma et al., 2022); (Jaberidoost et al., 2015)
3.8	Internal Financial Restrictions	insufficient funds in the company which imposes financial restrictions.	(Moktadir et al., 2018); (Breen, 2008)

3.9	Investment Risk	investment issues in R&D of new drugs as the clinical success rate is very low with long development cycle.	(Vishwakarma et al., 2016)
3.10	Loss of Customers due to Partners' Poor Service Performance	poor performance of partners like pharmacists, leading to disenchanted customer and bad reputation, causing revenue loss.	(Sharma et al., 2022); (El Mokrini, Dafaoui, et al., 2016)
Category 4. Demand/Customer/Market Sub-risks			
4.1	Bad Reputation of Company	bad reputation of pharmaceutical company due to litigations, negative press etc., adversely affecting the sales.	(Nguyen et al., 2021); (Rajagopal et al., 2022); (Sharma et al., 2022); (Enyinda, 2018); (Jaberidoost et al., 2013); (Mehralian et al., 2012); (Breen, 2008)
4.2	Bull Whip Effect	distorted information flow in PSC which does not reflect the actual demand of the drugs leading to excessive inventory investment, lost revenues due to discarded drugs, etc.	(Sharma et al., 2022); (Moktadir et al., 2018)
4.3	Competitive Risk	market competitors for acquiring maximum market share using marketing strategies, product positioning, etc.	(Enyinda, 2018); (Moktadir et al., 2018); (Vishwakarma et al., 2016); (Laínez et al., 2012)
4.4	Delivery Uncertainty	uncertainties in drug delivery, leading to customer dissatisfaction and economic loss.	(Nguyen et al., 2021); (Ouabouch & Amri, 2013); (Mehralian et al., 2012)
4.5	Demand Fluctuations	demand uncertainty caused by changes in consumer preferences, unpredictable events like COVID-19, leading to change in procurement, production plan, etc.	(Sharma et al., 2022); (Moktadir et al., 2018); (Vishwakarma et al., 2016); (Elleuch et al., 2014); (Ouabouch & Amri, 2013);

			(Jaberidoost et al., 2013); (Mehralian et al., 2012); (Breen, 2008)
4.6	Disparity in Cultures of Different Markets	cultural differences in the market in which the company operates leading to lost contracts, misunderstanding among partners, etc.	(Huq et al., 2016)
4.7	Drug Shortage	shortage of essential drugs in market, e.g., drugs for cancer treatment, etc.	(Fox et al., 2014); (Mazer-Amirshahi et al., 2014)
4.8	Forecasting Error	either lack or error in forecasting the demand, affecting all the other activities in the production process, e.g., inventory management, procurement, etc.	(Torasa & Mekhum, 2020); (Merkuryeva et al., 2019); (Moktadir et al., 2018); (Huq et al., 2016); (Breen, 2008)
4.9	Natural Disaster and Terrorism	natural disasters like earthquakes, tsunami, etc., and terrorism, leading to disrupted manufacturing process, drug shortages, etc.	(EvaluatePharma, 2020); (Huq et al., 2016); (Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012)
4.10	Time Limit of Drug in Medicine Cabinet	irregular checking of medicine cabinets, leading to drug expiry.	(Elleuch et al., 2014)
5.1	Absence of Cold Chain Availability	Category 5. Logistics Sub-risks unavailability of cold chain logistics required for transporting environment-sensitive drugs, leading to loss of drug efficacy.	(Sharma et al., 2022); (Breen, 2008)
5.2	Counterfeit Risk	fake drugs in market, leading loss of brand name, health problems to customers, etc.	(Sharma et al., 2022); (Saxena et al., 2020); (Bagozzi & Lindmeier,

			2017); (Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Enyinda et al., 2010); (Breen, 2008)
5.3	Lack of Personnel	unavailability of skilled personnel for logistic functions like loading, unloading, etc., leading to delayed delivery, exertion of few workers, etc.	(Sharma et al., 2022); (Paul et al., 2020); (Elleuch et al., 2014)
5.4	Traffic Congestion	freight delay due to traffic congestions leading to dissatisfied customers.	(Sharma et al., 2022); (Paul et al., 2020); (Breen, 2008)
5.5	Unavailability of Fuel	unavailability of fuel for transportation caused by import restrictions, leading to logistics failure, unfulfilled demand, etc.	(Paul et al., 2020); (Breen, 2008)
5.6	Untimely Drug Delivery	untimely delivery of drugs, leading to customer dissatisfaction.	(Nguyen et al., 2021); (Huq et al., 2016)
5.7	Weather Risk	unpredictable weather conditions, e.g., floods, landslide, etc., leading to disrupted PSC.	(Paul et al., 2020); (Lawrence et al., 2020); (Breen, 2008)
6.1	Inflation Rate Risk	Category 6. Political Sub-risks inflation in economy leading to financial crunch and ultimately resulting in planning disruption across SC.	(Jaberidoost et al., 2015)
6.2	International Sanctions	international sanctions caused by economic and political decisions for national security or to protect international laws, etc., leading to unavailability of RM and drugs, closed markets, etc.	(Sharma et al., 2022); (Jaberidoost et al., 2015, 2013); (Mehralian et al., 2012)

6.3	Lack of Regulation Transparency	absence of transparency in regulations, leading to ambiguous decisions resulting in uninformed investments, operational planning, etc. political instability, affecting internal and external affairs of a country, e.g., regulatory policies, tariffs, etc., undermining investors and providing unfavorable business conditions.	(Sharma et al., 2022); (Jaberidoost et al., 2015)
6.4	Political Instability	regulations and other changes in prices induced by government, e.g., ceiling price for essential drugs, which can impact the company's profit margins.	(Enyinda, 2018); (Vishwakarma et al., 2016)
6.5	Risk due to Pricing Policies	changes in the policy regulations, leading to economic loss to companies.	(Silva et al., 2020); (Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Enyinda, 2018); (Sharma et al., 2022); (Silva et al., 2020); (Huq et al., 2016); (Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012)
6.6	Unstable Policy Regulations	Category 7. Technology Sub-risks	
7.1	Lack of Effective System Integration	ineffective information system, resulting in information asymmetry between different trading partners, leading to inefficient and unresponsive SC.	(Sharma et al., 2022); (Huq et al., 2016); (Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Mehralian et al., 2012); (Breen, 2008)
7.2	Lack of Visibility of Stock	lack of inventory visibility considering availability and placement of stock, leading to wastage of resources, etc.	(Jaberidoost et al., 2013, 2015); (Breen, 2008)

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7.3	Obsolete Technology	obsolete information systems including all its components, leading to vulnerability to cyberattacks, data loss, etc.	(Sharma et al., 2022); (Huq et al., 2016); (Vishwakarma et al., 2016); (Jaberidoost et al., 2013, 2015); (Ouabouch & Amri, 2013); (Mehralian et al., 2012)
7.4	Poor Information Decisions	poor quality of gathered and shared information between the partners in SC leading to information scraps and misinformed decisions.	(Breen, 2008)
7.5	Risk to Intellectual Property	lack of protection and safety framework that threatens the confidentiality and lead to infringement of intellectual property rights (IPR).	(Nguyen et al., 2021); (Silva et al., 2020); (Huq et al., 2016)
7.6	Risk to R&D Capabilities	failure in development of a new drug, leading to economic loss.	(Hesarsorkh et al., 2021); (Silva et al., 2020); (Bignami & Mattsson, 2019); (C I Enyinda, 2018); (Jaberidoost et al., 2013, 2015); (Láinez et al., 2012)

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