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Risk Perception of Outsourcing of Medicine in Indian Pharmaceutical Industry

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Abstract:
Pharmaceutical companies are increasingly outsourcing their supply chain activities due to significant pressure to cut R&D expenses. The ability to outsource parts of one's global supply chain can be seen as a strategic competitive weapon rather than a cost-cutting measure, as it can allow for more adaptability in production, greater satisfaction of the ever-changing needs of the ultimate consumers, lower fixed costs, and better leverage of market position. For this reason, outsourcing the global supply chain has become a need for pharmaceutical companies to remain competitive. It helps businesses to make far more use of their primary competencies and resources than is possible via other methods. When implemented properly, global supply chain outsourcing solutions may increase returns on capital, lower risk, increase flexibility, and help businesses be more responsive to the needs of their customers and shareholders. Despite widespread recognition of the appealing advantages of global outsourcing, many of the inherent hazards have been largely ignored. Regulatory risk, operational risk, technological risk, and corporate social responsibility risk are only some of the dangers associated with outsourcing the pharmaceutical supply chain. Avoidance, reduction (mitigation), transfer, and acceptance are all methods of supply chain risk management that may be used to lessen an organization's vulnerability to supply chain outsourcing risks.

1. Introduction

In today's fiercely competitive global economy, companies are increasingly concentrating on their core competencies and outsourcing non-essential services in which they lack in-house experience in order to keep costs down and boost profits. Due to a shortage of critical skills and knowledge experience bases, no single company can succeed in today's hypercompetitive global marketplace by going it alone in pursuit of market prospects in near real-time and cost-effective form. Pharmaceutical companies are intensifying their scrutiny of operations in an effort to increase shareholder value and profit margins in light of limited potential blockbuster pharmaceuticals in the pipeline and increased competition from generics companies. Outsourcing pharmaceutical production, in particular, has emerged as a practical strategic choice for companies seeking a competitive edge. The move from a fixed cost to a variable cost model, the availability of new technology and expertise, and the opportunity to obtain these things via the use of specialized external providers are all widely mentioned as causes for the rise in pharmaceutical outsourcing. Indeed, it is no longer necessary or significant to have one's own in-house pharmaceutical researchers in the modern day. Drug manufacturing expenses may be quite taxing on a business's resources.

There has been a dramatic decrease in the pharmaceutical industry's R&D productivity and the conventional development of novel

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chemically based small molecules. Contract research organizations (CROs) in India and China have become increasingly popular outsourcing destinations for multinational pharmaceutical corporations seeking to increase R&D productivity and efficiency and enter new markets. Information technology (IT) and IT support, human resources, research and development, purchasing, and logistics are all examples of the kind of tasks that might be outsourced. It has been argued that outsourcing supply chains is helping pharmaceutical companies boost their product pipelines and acquire a competitive edge. To reorganize their distribution networks, utilize resources, disperse risks, and concentrate on problems crucial to their continued existence, competitive advantage, and future development, pharmaceutical companies are increasingly turning to global outsourcing as a business strategy (Sink and Langley, 1997, Wang and Regan, 2003). Due to factors such as high R&D costs, regulatory pressure, patent expiration, and a dwindling blockbuster pipeline chain, pharmaceutical companies are increasingly outsourcing non-core supply chain activities to contract manufacturing organizations (CMOs) and/or contract research organizations (CROs).

As companies strive to improve their core offerings while keeping expenses down, they are increasingly turning to global outsourcing. There has been a significant increase in the number of global outsourcing contracts in recent years. It is one of the eight most important aspects expected to contribute to better supply chain performance in the future. A top-notch supply chain is one that helps a company maximize the profit it generates from its own operations, while also fostering the kind of fruitful alliances that may pave the way to profitable new ventures outside the company. According to Christopher (1999), only companies that effectively use the capabilities and expertise of their network partners would be able to respond quickly enough to the demands of the ever-evolving global market. There seems to be an increasing interest in outsourcing fixed assets and/or the whole manufacturing process, even though outsourcing originally included the transfer of non-core services usually handled in-house to CMOs (Markeset and Kumar, 2004). To wit, Calaf (1995) argues that many companies are choosing to outsource a substantial portion of their manufacturing operations to other companies that already possess a substantial manufacturing knowledge base. One good outcome of outsourcing to contract firms is enhanced supply chain agility, but there are also potential drawbacks to consider (Mason, et al, 2002). According to Lindholm and Suomala (2004), the purpose of outsourcing is to improve operational efficiency throughout the whole company and supply chain.

2. Literature Review

Majd Mohammad Omoush (2020),The purpose of this research was to examine the connection between supply chain management (SCM) actions and operational performance by putting the mediating element of strategic agility through its paces in sixteen pharmaceutical businesses trading on the Amman stock market in Jordan. Which is one of the most important industrial sectors, where the work and problems encountered in supply chain performance were identified as the causes of delays in logistical orders of raw materials they needed from suppliers, and where it was discovered that there is a missing link between partners and is the proportion of obtaining the information needed to complete operations. Modified to facilitate simple manufacturing. When it comes to determining what aspects of supply chain management are crucial to the success of SCM best practices in pharmaceutical organizations, it is vital to first determine which activities comprise supply chain management (i.e., Alliances with suppliers, Customer Relation Management, Logistic, flow Information and knowledge sharing). A questionnaire was used to conduct a field survey among a simple random sample of pharmaceutical companies; 150 were distributed and 139 were collected from the study population of pharmaceutical company executives and directors of departments, sections, and employees specializing in supply chain management. In addition, several statistical methods have been utilized for data analysis, including the statistical analysis package for the social sciences (SPSS) and AMOS, which is

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reliant on the Structure Equation Modelling method due to the presence of a single variable and the purpose of assessing the significance of the underlying track. The statistical research indicated that supply chain management has an effect on operational performance; however, Path Analysis revealed that the link is only partial in terms of the strategic agility variable serving as the intermediary variable.

Ward R., Hargaden V. (2019),Due to the growing frequency of drug shortages, it is important to evaluate the robustness of pharmaceutical supply chains in order to identify any potential weak spots. At first, exploratory study of pharmaceutical supply chain resilience in the downstream is described in this chapter. Several pharmaceutical industry supply chain managers were surveyed using a tried-and-true methodology (the Supply Chain Risk Assessment Method—SCRAMTM). Flexibility in sourcing, flexibility in order fulfilment, visibility, and cooperation are all highlighted as areas where supply chain skills should be strengthened to create more resilient supply chains.

Wong WP., Soh KL. (2019),All industries, including the pharmaceutical industry, rely on logistics to streamline their supply chains and increase their competitiveness. This article's purpose is to examine the current state of pharmaceutical maritime logistics as well as four research articles by Malaysian 3PLs focusing on service quality, cost and service differentiation, integration and information system of freight-forwarding and container freight. The purpose of this literature evaluation is to anticipate medication shortages and identify logistics supply chain difficulties by determining whether third-party logistics are possibly capable of supporting maritime pharma non-cold chain freight. According to the findings, SCI influences operational and environmental performance, low prices and service differentiation influence enterprises' sustainable financial competitiveness, integration of depot and hauliers improves national logistics performance, and so on. Freight-forwarding businesses, their clients, container depots, and trucking companies were all studied as LSPs throughout the supply chain. According to the standards set out in the reviewed professional logistics publications, the reviewed logistics service quality may be enough to satisfy the needs of typical ocean-going non-cold chain pharma container freight. Given their adaptability and resilience in the face of economic difficulties, it is very improbable that freight forwarders be responsible for a scarcity of essential medicines. The enterprises' internal and external environments can be managed with ease because to their nimbleness. To avoid delays, the study also offers solutions to the SCI problems that plague the standard ocean container freight supply chain at the depot-haulier interface. Malaysia, located in the centre of Southeast Asia, is the focus of this article's evaluations of related study studies of 3PL.

Prabal Chakraborty (2020),The medicines business in India has rapidly gained international attention in recent years. It is now one of the fastest-growing sectors worldwide, accounting for 2.4% of global GDP in terms of value and 10% in terms of volume. Twenty percent of the world's generic drug exports come from just one country—India. The Indian pharmaceutical business generated $16.89 billion in exports in 2016, and that number is projected to grow to $40 billion by 2020. Foreign direct investment (FDI) of USD14.53 billion entered into the generics industry between April 2000 and December 2016, demonstrating the enormous potential for FDI inflows in the current generics sector. We have seen Indian pharmaceutical firms engage in strategic alliances and co-marketing, contract research and manufacturing services, export, acquisitions and mergers, expansion into non-U.S. and European markets, the purchase of overseas production facilities, and the raising of equity stakes in other firms. The pharmaceutical industry in India is also gaining popularity as a place to put money. This article aims to examine the Indian pharmaceutical business, including its opportunities and dangers, as well as the strategies of Indian enterprises, with a focus on the trade-related elements of intellectual property rights.

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Valentin Steinwandter, Christoph Herwig (2019),Economically motivated manufacturing enterprises in the pharmaceutical sector are subject to regulation and oversight by regulatory bodies. Production facilities for medicines need to generate mountains of analytical and process data to prove their wares are safe for consumers. Since regulatory agency decisions are dependent on this information, manufacturers must demonstrate that the data they provide is secure against technological intrusions and manipulation. Technical solutions to ensure data integrity are available, however they are insufficient at present. Numerous papers have been issued by regulatory bodies drawing attention to the present data integrity challenges. In this article, we demonstrate how blockchain, the underlying technology for Bitcoin and other cryptocurrencies, may be used to strengthen industrial data and data science analytical processes. This is why we have integrated a smart contract built on Ethereum's blockchain with the tools that are commonly used by programmers today. The provided process exemplifies a means through which data integrity may be ensured on a technical level without the intervention of reliable outside parties.

3. Research Methodology

Multi-criteria decision making (MCDM) refers to a decision-making process in which many criteria or goals must be considered (Hwang and Yoon, 1981). The evaluation and management of qualitative and quantitative criteria in the context of outsourcing risk in the pharmaceutical supply chain is a classic MCDM challenge. Saaty's Analytic Hierarchy Process (AHP) is an example of the MCDM used to represent risk management in the outsourcing of pharmaceutical supply chains (1980). It is preferred because its hierarchical structure depicts the interrelationships among the problem's overarching aim, criteria, sub-criteria, and options. Positive aspects of AHP have been discussed at length in the published works, but there have also been a few critical voices questioning the theory behind it. Belton and Gear (1986) and Dyer and Wendel (1985) are only two authors that claim that AHP is not supported by theory. According to Watson and Freeling (1982), AHP asks decision-makers meaningless questions like "which of these two criteria is more essential for the aim and how much more," in order to elicit the weights of the criterion using a ratio scale. On the other hand, Harker and Vargas (1987) and Perez (1995) provided theoretical support for a defense of Satya's AHP, showing that the critiques leveled at the AHP approach were unfounded. They maintained that AHP had a solid theoretical foundation. This has led to widespread acceptance of its usefulness across a variety of disciplines. Supplier selection (Lee et al., 2001); project selection and management (Liberatore, 1987; Al-Harbi, 2001); international business management; operations and logistics/supply chain management; marketing (Dyer and Forman, 1992); and pharmaceutical marketing and management (Dyer and Forman, 1992) are all examples of fields where AHP has been used.

Empirical Results:

Table 1 illustrate pairwise comparisons of the most critical factors, where regulatory risk ranks highest with a priority of 0.383, followed by IP risk (0.342), tech risk (0.168), and commercial risk (0.173). (0.107).

Table 1 Pair-wise Comparison Matrix for Risk objectives w. r. t the Goal

Goal		Priority	Rank
Regulatory Risk		0.383	1
Business Risk		0.107	4
Technical Risk		0.168	3
Intellectual Property Risk		0.342	2
Inconsistency = 0.02			
Priorities with respect to:			
Goal: Manage Pharma SC Outsourcing Risk			

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Regulatory Risk	.383		
Intellectual Property Risk	.342		
Technical Risk	.168		
Business Risk	.107		
Inconsistency = 0.02			
with 0 missing judgments.			

Risk Management Strategies:

Regulatory risk, commercial risk, technical risk, and intellectual property risk are the four primary decision factors, and tables 2-5 detail the risk management solutions for each. Risk transfer mechanisms like insurance are the greatest tactic for dealing with regulatory and corporate risks. However, it is preferable to minimize exposure to technological and intellectual property risks.

Table 2. Pair-wise Comparison Matrix for Policy Option w. r. t Regulatory Risk

Regulatory Risk	Reduce Risk	Accept Risk	Avoid Risk	Transfer Risk	Priority	Rank
Reduce Risk	1	2	2	2	0.261	2
Accept Risk	1/2	1	2	3	0.169	3
Avoid Risk	1/2	½	1	3	0.119	4
Transfer Risk	1/2	1/3	1	1	0.451	1

Inconsistency = 0.03

Table 3. Pair-wise Comparison Matrix for Policy Option w. r. t Business Risk (BR)

Business Risk	Reduce Risk	Accept Risk	Avoid Risk	Transfer Risk	Priority	Rank
Reduce Risk	1	5	1	3	0.226	2
Accept Risk	1/5	1	3	5	0.068	4
Avoid Risk	1	1/3	1	3	0.193	3
Transfer Risk	1/3	1/5	1/3	1	0.513	1

Inconsistency = 0.04

Table 4. Pair-wise Comparison Matrix for Policy Option w. r. t Technical Risk (TR)

Technical Risk	Reduce Risk	Accept Risk	Avoid Risk	Transfer Risk	Priority	Rank
Reduce Risk	1	5	3	5	0.560	1
Accept Risk	1/5	1	3	1	0.095	3
Avoid Risk	1/3	1/3	1	3	0.249	2
Transfer Risk	1/5	1	1/3	1	0.095	3

Inconsistency = 0.02

Table 5. Pair-wise Comparison Matrix for Policy Option w. r. t Intellect Property

Intellectual Property	Reduce Risk	Accept Risk	Avoid Risk	Transfer Risk	Priority	Rank
Reduce Risk	1	5	3	3	0.527	1
Accept Risk	1/5	1	3	1	0.102	4
Avoid Risk	1/3	1/3	1	2	0.241	2
Transfer Risk	1/3	1	½	1	0.129	3

Inconsistency = 0.03

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Figure 1 displays the results of a performance sensitivity analysis, which demonstrates the relative importance of various risk management techniques with regard to each of the five criteria and to the overall evaluation. A decision maker may examine the overall priority for each potential risk management technique along the right "y-axis" to help narrow down the options and choose the most effective one. Risk avoidance is 0.19, risk acceptance is 0.13, risk reduction is 0.39, and risk transfer is 0.30. The left y-axis represents the relative importance of each main criteria as determined by the decision maker's paired comparison. As a result, the performance sensitivity analysis suggests a value of 0.39, with a business risk of 0.11, a technical risk of 0.17, and a technical risk of 0.34.

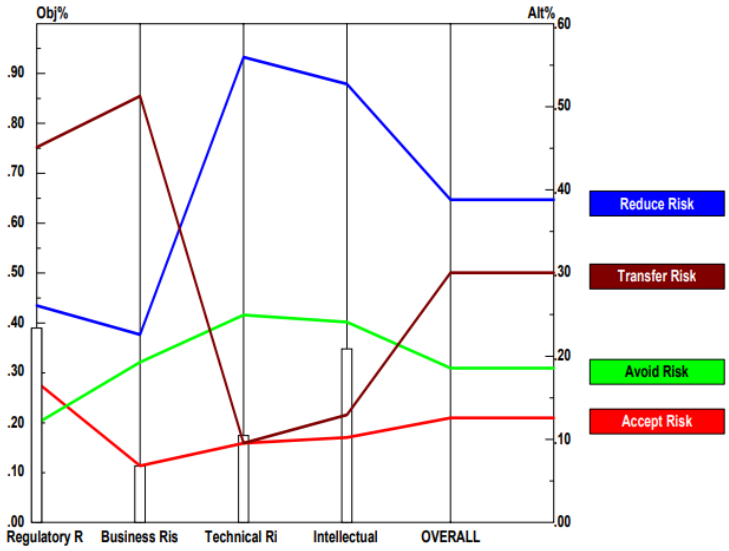

Figure 1. Performance Sensitivity Analysis

Risk transfer for the alternative risk management method is around 0.75, risk reduction for about 0.44, risk acceptance for about 0.26, and risk avoidance for about 0.20, with regard to regulatory risk and reading from the right y- axis. Risk transfer equals 0.85, risk reduction equals 0.39, risk avoidance equals 0.32, risk acceptance equals 0.10, and risk acceptance equals 0.15 in terms of business risk. Reducing technical risk is around 0.94, avoiding it is about 0.41, transferring it is about 0.15, and accepting it is about 0.14. Risk acceptance is around 0.16, risk transfer is about 0.19, risk avoidance is about 0.88, and risk reduction is about 0.88 when discussing intellectual property. Last but not least, it is advisable to reduce risks rather than transfer them, avoid them, or accept them.

4. Conclusions and Implications

Global pharmaceutical enterprises face growing obstacles to boost profit margins in today's environment of falling R&D productivity, rising price pressure, and shifting regulatory constraints. Companies in the pharmaceutical industry are consolidating via mergers and acquisitions and international outsourcing in order to meet these issues. Pharmaceutical companies may increase shareholder value by focusing on their core capabilities, gaining access to specialized knowledge, and maximizing cost savings via smart outsourcing arrangements with partners. Outsourcing research and development and production functions to other countries has been commonplace in the pharmaceutical business in recent years due to the increased importance of these activities in today's cutthroat market. When it comes to outsourcing, pharmaceutical

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companies have graduated from the lowest tier to the next higher one.

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