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Supply Chain Risk and Resolution in Pharmaceutical Sector

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ABSTRACT

Pharmaceutical companies today face a numerous array of risks. Though the industry is one of the world's most thriving sectors, it is not immune to the multitude of risks that threaten its ability to compete. The pharmaceutical industry is characterized by a highly risky and lengthy R&D process, intense competition for intellectual property, stringent government regulation and powerful purchaser pressure. On one hand, Pharma companies face similar risks like those faced by other industries- fire, explosion, machinery breakdown, natural disasters, business interruption, liability, etc. On the other hand, the huge exposure to inventory risks, widespread counterfeiting of prescription drugs, regulatory delays for marketing and patent expirations.

INTRODUCTION

The pharmaceutical industry has grown by leaps and bounds the risk affecting it has also increased proportionately. Furthermore, this thesis addresses the issues of risk mitigation in the pharmaceutical supply chain by providing quantified empirical results. Based on the review of literature four major risks affecting the pharmaceutical supply chain are identified as regulatory risk, inventory risk, counterfeit risk and financial risk.[1-4] Ranking and management strategies of these are based on the Analytical Hierarchy Process model. Also, solutions to these risks are provided based on the results of the survey questionnaires and literature study which would be best suited for the industry to flourish and survive in today's competitive global marketplace. The landscape of risks facing the pharmaceutical sector is evolving rapidly with increased globalization where alliances and outsourcing are becoming increasingly common and moving beyond borders. The changing business model driven by new technology, new products, and new markets- is creating strategic and operational risks for many pharmaceutical companies. This poses a perplexing new challenge for the management and regulation of risk. Though the pharmaceutical companies have a strong control culture and being a highly regulated industry, risks today goes beyond regulatory compliance to other aspects of the business such as reputation. Hence risk assessment, risk management, and risk mitigation plays a major role in the overall development of the company's growth.[5-7] The four major risks affecting the pharmaceutical supply chain were identified using available literature. The pharmaceutical supply chain was found to be affected mainly by the following four risks:

Regulatory Risk: [8-10]

Regulatory risks emerge when there is an error that can lead to regulatory disapproval, long lead time, satisfying the regulatory compliance for marketing, maintaining proprietary confidentiality, patent expiry. The growth of the international counterfeit drug market and mounting concerns about consumer safety has also led the government for increased regulatory scrutiny. The political and economic stability of the country also leads to higher regulatory risks due to delayed approval.

As per the interviewees, regulatory risks are ranked first in comparison to other risks affecting the pharmaceutical supply chain (**Table 1**).

EMPIRICAL RESULTS

The pair-wise comparison of the major criteria shown in **Table 1** as well as in **Figure 1** below indicates that the regulatory risk is the most important risk to manage with a priority of 0.383 followed by financial right risk (0.342), inventory risk (0.168) and counterfeit risk (0.107).

As per the opinion of the interviewees, regulatory risks can be best managed by transferring (**Table 1.3**), which is by outsourcing the regulatory activities to external agencies. The Pharma companies can improve cost efficiencies by fewer hiring of expertise personnel, training costs, facility requirement and refocusing employees on other essential activities.

Though regulatory outsourcing seems to be the better option in the management of regulatory risk it has its share of issues and hurdles which include data security, increased compliance risk, loss of control, sharing of internal responsibilities and trust.

Counterfeit Risk

According to WHO, counterfeit drugs refers to "a drug that has deliberately and fraudulently altered concerning the identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients with insufficient active ingredients or with fake packaging.

As per the questionnaire, counterfeiting is ranked fourth in the list of risks affecting the pharmaceutical supply chain (**Table 1.1**). The pharmaceutical drug supply chain from the manufacturer to the pharmacy usually includes several intermediaries such as wholesalers and distributors. This opens the supply chain to the risk of counterfeit drugs and encourages parallel trade, leading to lost sales for the manufacturer. The problem is more prevalent in developing countries like India and China with weak regulatory regimes. [11-15] It is estimated that counterfeit drugs accounted for about 10 percent of the global pharmaceutical market in 2007.

Patients are the primary victims of the counterfeit trade because their health is at risk and even lives at times due to low-quality drugs. Legitimate manufacturers also are victims not only because of direct loss of revenue but because confidence in their products is

undermined, leading to loss of sales. The reputation of the company and the image of the products are both damaged. Healthcare professionals also stand to lose valuable trust and confidence in their service of the patients.

Counterfeiting varies from small “cottage industries” in some countries to large international consortia, including some elements of organized crime. Very often there is little consistent information on the source of counterfeits and also there is emerging evidence of links between pharmaceutical counterfeiting and international narcotics trade.

Counterfeiting risks are best managed by reducing the risk (**Table-1.4**) as per the interviewees. Different measures are adopted by the manufactures as well as regulatory agencies in combating the counterfeiting trade. Various anti-counterfeiting technologies are introduced by manufacturers. The various anti-counterfeiting techniques are as follows:

Holograms and Overt Visual Imaging techniques: To combat the problem of counterfeiting many of the world's leading pharmaceutical companies have directed efforts towards authenticating their packaging as part of the process of protecting their products. Diffractive optically variable devices- referred to generically as holograms—have become widely used. The success and near-ubiquitous use of holograms in anti-counterfeiting applications have inevitably led to attempts to copy or replicate them. The intrinsic features of holograms, however, are very difficult to cope with 100% accuracy which makes them a preferred detection feature for packaging.

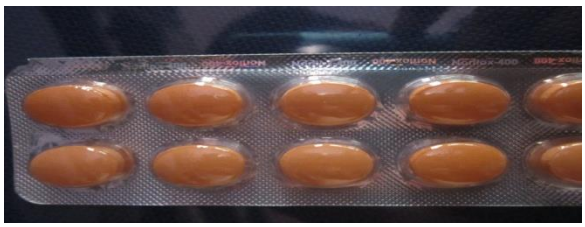

Figure No. 1: Norflox Strips containing Hologram

Mass Encoding Systems: For authentication of drugs a technique is used where all the products manufactured are issued with unique identification numbers which can be verified via SMS on mobile phones. The number when SMSed to the manufacturer’s database provides all the details regarding the product thus ensuring the consumer to cross-check with the product. Here below we can see the pack of Combiflam (Aventis) having an MES number.

Figure No. 2: Combiflam Cartons with MES codes

Barcodes: Barcodes are an optical machine-readable representation of data, which shows data about the object to which it attaches. Originally barcodes represented data by varying the widths and spacings of parallel lines and may be referred to as linear or one-dimensional (1D). Later they evolved into rectangles, dots, hexagons and other geometric patterns in two dimensions (2D). Although 2D systems use a variety of symbols, they are generally referred to as barcodes as well. Barcodes originally were scanned by special optical scanners called barcode readers and later, scanners and interpretive software became available which were connected to printers.

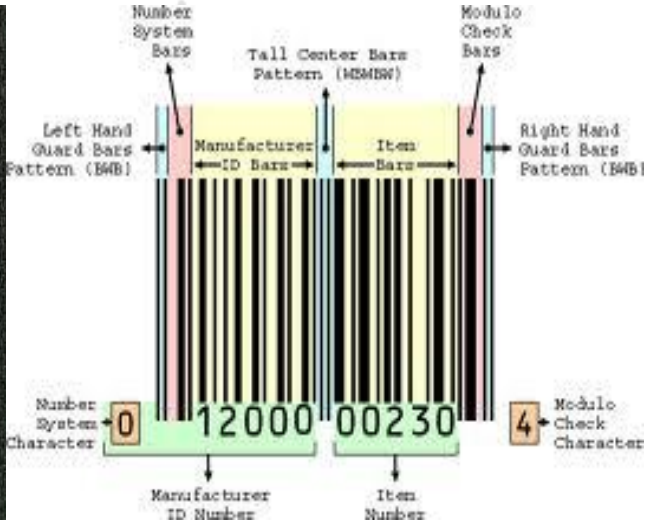

Figure No. 3: 2D barcode **Figure No. 4: 1D barcode**

Radio Frequency Identification Device: It secures the drug supply-chain, benefiting the manufacturers, distributors, pharmacies as well as the end consumers by checking the authenticity of the drug. In this technique, each drug package is tagged with an RFID tag with a unique ID which is unusable when peeled off from the package. The tags contain encrypted data like batch number, company, ID, date of manufacture, expiry date, etc which serves as identification of drug at various levels in the supply chain. RFID is a generic term for technologies that use radio waves to automatically identify individual items.

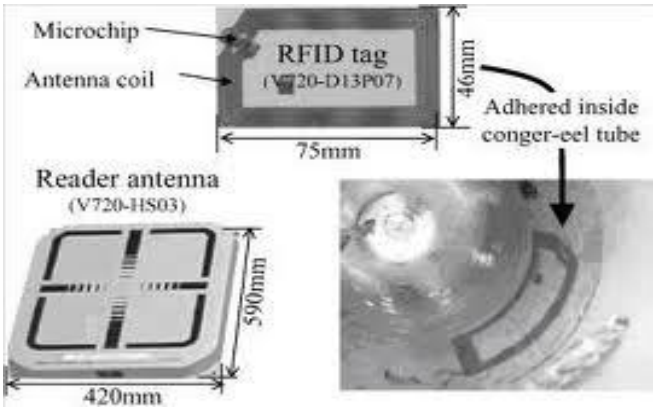

Figure No. 5: RFID tags

There are several methods of identifying objects using RFID, but the most common is to store a serial number that identifies a product and perhaps other information, on a microchip that is attached to an antenna (the chip and the antenna together are called an RFID transponder or an RFID tag). The antenna enables the chip to transmit the identification information to a reader. The reader converts the radio waves returned from the RFID tag into a form that can be passed on to computers that can make use of it. The Auto-ID Centres have chosen to focus on "passive" RFID tags, i.e., tags that are not powered by internal batteries but by the electromagnetic energy that comes from the reader. This type of tag is very simple to produce and its cost is low.

This technology has presently not been introduced in India, even though it has been in the USA for the past couple of years. Pfizer's Viagra containers are fixed with these types of tags because of its very high rate of duplication and internet sales.

There is a need for greater international awareness and acknowledgment of the hazards to the health of counterfeit medicines. Political will is needed to mobilize resources for the implementation of effective countermeasures. Without political will and effective regulation, counterfeiting will continue to thrive. Implementation of appropriate legislation that identifies the import, transit, and export of goods is necessary.

Inventory Risk

Risks arising due to lack of inventory planning and forecasting can be termed as Inventory risk. Inventory control is challenging in business. Managing inventory can directly affect the business performance of a company. Having too much inventory, on one hand, means high

holding cost, and having too little leads to decreased service level. Even though inventory is considered to hurt the business since a large proportion of the total expenses are generated here, but having inventory is still a must for many kinds of business. Inventory risk is ranked third in the list of risks as per the questionnaire (**Table 1.2**).

Inventory risks may also arise due to logistics disruption and poor vendor management.

Inventory Management

Inventory management is challenging in business. Managing inventory control can directly affect business performance. The reason for having inventories or stocks is to buffer against demand and supply. Managing and controlling inventory are compulsory practices for firms that seek for profitability. The goals for controlling inventory are minimizing the total cost and maximizing service level by balancing demand and supply. There are several approaches involved in managing inventory. Businesses are characterized by two distinguished systems, Just In Time (JIT) system and EOQ (Economic Order Quantity) system.

JIT system is the concept of inventory management which is based on holding no inventories. The production or manufacturing is started only based on the demand and once the order is confirmed. In the EOQ system buffer stock is always maintained. It is based on the forecast of demand for direct feedback from the customers.

In a business environment, fluctuation in demand is a common situation. Especially in the healthcare industry where demand cannot be accurately forecasted since it depends on several external factors. (**Figure 2.6.**) below illustrates the factors affecting the fluctuation in the demand of pharmaceuticals. All of these factors can influence fluctuation in drug consumption.

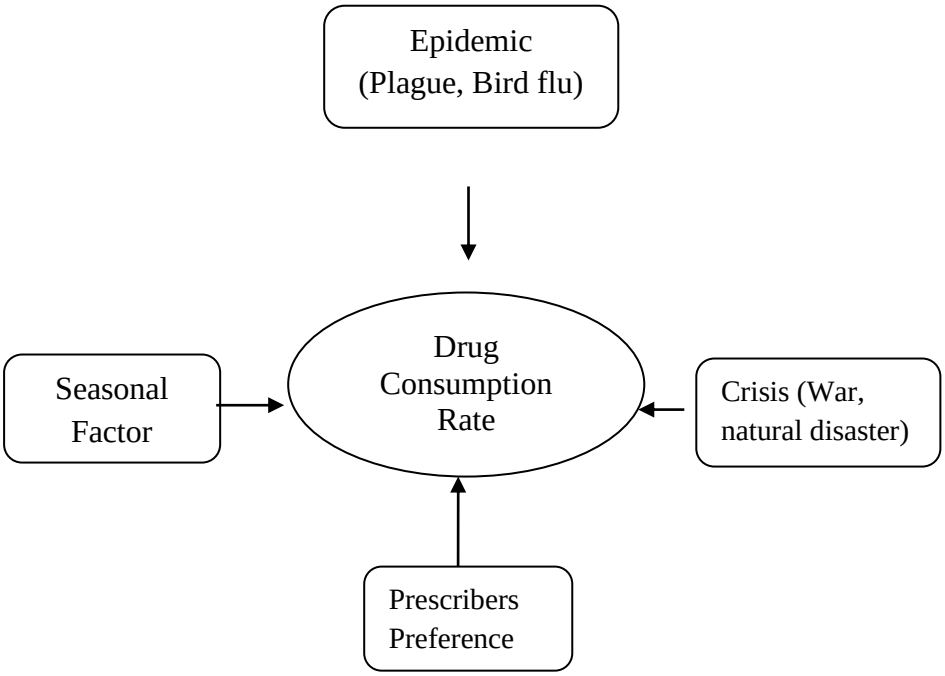

Figure No. 6: Factors affecting drug consumption rate

Logistics Management

Logistics is regarded as a crucial part of the pharmaceutical industry since the activities are highly time-sensitive. Besides, pharmaceutical products need temperature-controlled storage and distribution. Logistics in the Pharma industry is very critical for providing the right medicine to the right patient at the right time, place and dosage and most importantly at the right price. Since business is highly competitive today, success largely depends upon the efficiency of the supply chain.

The supply chain is very critical as it maintains the complex network relationship between the organizations (drug manufacturers), trading partners to source raw materials, delivery products, retailers and hospitals. With the growing competition among major pharmaceutical players in the industry, inventory control plays a significant role in the pharma value chain as lots of inventory exists in the supply chain. For instance, out of stock situation in the existing business environment is unacceptable.

Financial Risk

Financial risk ranks in at two in the list of risks as per the results of the questionnaire in **Table 1.2.** The pharmaceutical industry currently represents a highly competitive environment where companies compete with each other over all the segments of the market. Almost all of them are active in R&D and production of drugs.

Secondly, the companies experience significant profit- losses due to completion from generic drug manufacturers. Where the research-oriented companies invest significantly in the R&D, the generics manufacturers spend the minimum in R&D and start manufacturing already developed formulations after the expiry of patents thus causing a dramatic loss in the revenues of the R&D oriented companies.

Price control regimes in some countries too significantly limit the profit margins of pharmaceutical companies which have invested heavily in the research of new drug molecules. Drug portfolio management is also one of the most important determinants where major pharmaceutical companies invest in citing long-term prosperity. Since new drug molecules take an extremely long time to develop and a very small portion of them reach the final marketing stage. Financial risks facing the Pharma industry are quite too many.

Financial Risk Management

Financial risk management is best managed by transferring the risk in the form of certain transformational changes presently taking place in the Pharma industry. The majority of "Big Pharma" companies generate high returns, thus providing them with excess cash for further rapid growth through mergers and acquisitions. Although the size of the company on its own does not guarantee success, it gives a significant advantage, especially in the pharmaceutical industry.

Besides economies of scale in manufacturing, clinical trials, and marketing, bigger companies can allow investments in more research and development (R&D) projects that diversify their future drug portfolio and make them much more stable in the long term. As a result, top-companies in the industry were active participants of mergers and acquisitions (M&A), new joint ventures and spin-offs of non-core businesses.

Another form of structural change in the industry was the establishment of new strategic alliances and joint ventures. So far as the research and development process for each drug takes many years and requires significant investments, and the outcome of these investments of time and financial resources remains unclear until the final approval of the drug, "Big Pharma" companies are constantly looking for synergies that they can get from cooperation with their competitors.

Finally, "Big Pharma" companies to maintain strong sales growth and meet profitability expectations of their shareholders were actively selling low-profitability or non-core businesses and concentrating on the core business of manufacturing and sales of pharmaceuticals.

Quality Assurance in Pharmaceutical Supply Chain and Stability Testing

Quality and stability management remains an important concern in the pharmaceutical supply chain. Stability is the capacity of a drug substance or drug product to remain within established specifications to maintain its identity, strength, quality, and purity throughout the retest or expiration dating periods. Physical, chemical, and microbiological data are generated as a function of time and storage conditions (e.g., temperature and relative humidity [RH]). Stability testing provides evidence that the quality of a drug substance or drug product under the influence of various environmental factors changes with time.

Although the storage conditions are relatively constant, the distribution environment can vary greatly, especially when a drug product is shipped between various climatic zones. Seasonal changes, mode of transportation, and the number of drop-off points are also variables that should be considered within the pharmaceutical supply chain. Drug products requiring controlled-temperature storage conditions must be distributed in a manner that ensures that the product quality will not be adversely affected. Except for short transit times within the same climatic zone, it is virtually impossible to validate a shipping method against all environmental conditions.

Pharmaceutical products should be shipped in a manner that ensures products will not be adversely affected by environmental conditions based on product stability, product history, packaging information, and the transport system used. The effect of temperature excursions, outside of labeled storage conditions, can be evaluated based on the stability analysis for that drug.

Stability data from the stability tests are used to provide the information necessary to develop product-specific shipping criteria use which is used to design a shipping document (i.e., shipping and distribution control strategy document) that complements the overall robustness of a distribution program.

Table No. 1: Pair-wise Comparison Matrix for the Four Criteria:

Criteria	Regulatory Risk	Counterfeit Risk	Inventory Risk	Financial Risk
Regulatory Risk	1	3	3	1
Counterfeit Risk	1/3	1	2	3
Inventory Risk	1	2	1	2
Financial Risk	1	1/3	2	1

EMPIRICAL RESULTS:

The pair-wise comparison of the major criteria shown in **Table 1.1** as well as in **Figure 1.1** below indicates that the regulatory risk is the most important risk to manage with a priority of 0.383 followed by financial right risk (0.342), inventory risk (0.168) and counterfeit risk (0.107).

Table No. 2: Pair-wise Comparison Matrix for Risk objectives concerning the Goal

Goal	Priority	Rank
Regulatory Risk	0.383	1
Counterfeit Risk	0.107	4
Inventory Risk	0.168	3
Financial Risk	0.342	2

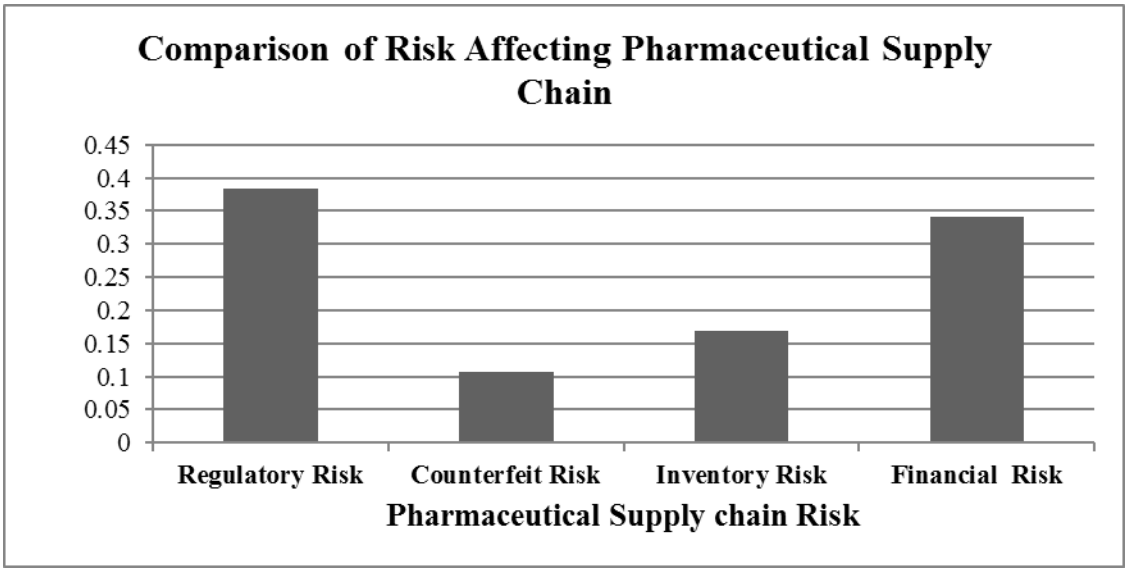

Figure No. 7: Comparison of risk affecting the pharmaceutical supply chain.

RISK MANAGEMENT STRATEGIES

The tables given below report the risk management strategies for the four major decision criteria, including regulatory risk, counterfeit risk, inventory risk, and financial risk. For both regulatory and financial risk, the best strategy is risk transfer such as insurance. However, for both counterfeit risk and inventory risk, the preference is to reduce risk.

Table No. 3: Pair-wise Comparison Matrix for Policy Option concerning 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	2	1	2	3	0.169	3
Avoid Risk	2	2	1	3	0.119	4
Transfer Risk	2	1/3	1	1	0.451	1

Table No. 4: Pair-wise Comparison Matrix for Policy Option concerning Counterfeit Risk

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

Table No. 5: Pair-wise Comparison Matrix for Policy Option concerning Inventory Risk

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

Table No. 6: Pair-wise Comparison Matrix for Policy Option concerning Financial Risk

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

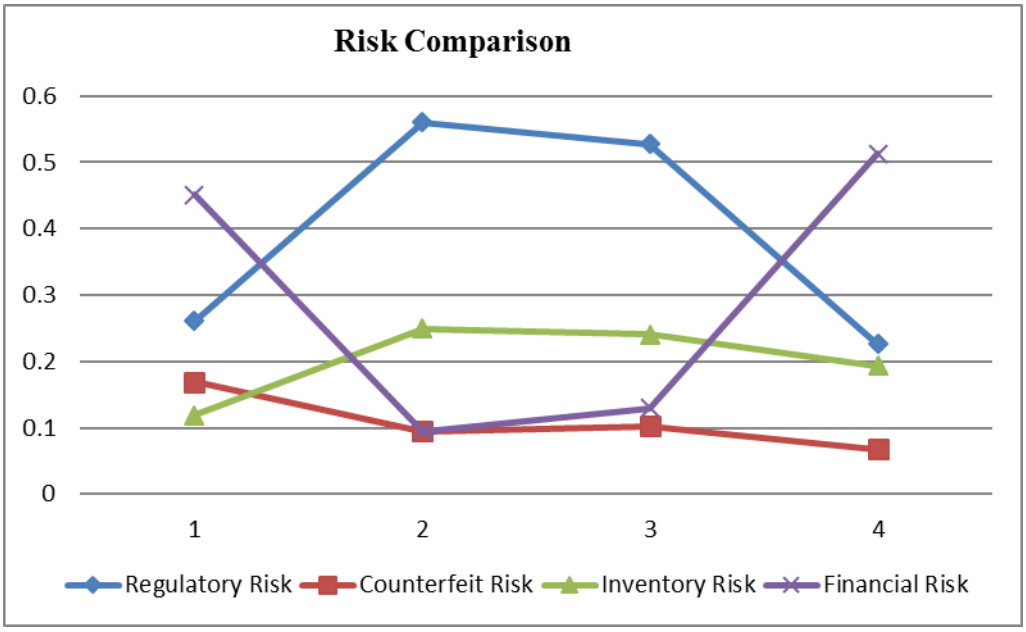

Figure No. 8: Comparison Chart of Policy Options for Pharmaceutical Supply Chain Risks

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