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Investigating the Risks in the Pharmaceutical Supply Chain in Ghana

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Abstract

The study was to investigate the risks in the Pharmaceutical Supply Chain in Ghana. Questionnaire was the main instrument used for the data collection and the responses were analysed using SPSS. Sample size of Eighty (80) was used for the analysis. Data analysis was descriptive. The study revealed that Drug Shortages, Pilfering and Expiration of Drugs are the risks associated with the Pharmaceutical Supply Chain. The major reasons given for the occurrence of the risks include difficulty in obtaining raw materials, unethical attitude of pharmacists and chemical sellers, low income of consumers, poor inventory management and reverse logistics not being encouraged in the pharmaceutical industry in Ghana. The paper recommends the integration of Information and Communication Technology (ICT) tools in the management of inventory and also the strengthening of the Pharmaceutical Supply Chain. These measures would go a long way to reduce if not completely eliminated the exposure of the Pharmaceutical Supply Chain to risks.

Key Words: Risk, Supply Chain, Pharmaceutical Industry, Ghana

1. Introduction

In today's global marketplace, individual firms no longer compete as independent entities, but rather as an integral part of supply chain links. The ultimate success of a firm will depend on its managerial ability to integrate and co-ordinate the intricate network of business relationships among supply chain members (Lambert and Cooper, 2000). In this era of intense competition,

the key to sustainable competitive advantage lies in delivering high quality service that will in turn result in satisfied customers (Shemwell et al., 1998), which can be achieved through supply chain management.

Handfield and Nicholas (2002) refers to supply chain management as the integration and management of supply chain organizations and the activities through cooperative organizational relationships, effective business processes, and high levels of information sharing to create high performing value systems that provide member organizations sustainable competitive advantage. On this, Lee et al (2000) pointed out that supply chain management involves the flow of material, information, and finance in a network consisting of manufacturers, distributors, suppliers and customers. Coordination and integration of these flows and their correlated activities within and across companies through improved supply chain relationships to achieve a sustainable competitive edge is critical for effective supply chain management.

The objective of supply chain management therefore, according to Poole (1997), is to facilitate the processes whereby primary supply is ordered and transformed so as to satisfy consumer preferences efficiently. It is widely known that these processes have been marked by a continuing shift from the historical use of open markets to new business coordination mechanisms between vertically related market stages, such as those between producers and processors, and between processors and distribution systems. This is true above all for certain manufacturing industries such as vehicle production, but is increasingly evident in the agrifood and pharmaceutical industry (Boehlje and Schrader, 1996).

The key issues in supply chain management today are the formation of the supply chain and its efficient coordination with objectives of customer satisfaction and sustaining competency. This requires complex flow of information, materials, and across multiple functional areas both within and among companies. To achieve these, companies must identify, evaluate, rank, and manage its supply chain risks. The leaner and more integrated supply chains get the more likely uncertainties, dynamics and accidents in one link affect the other links in the chain. Companies' obsessed with speed and cost, also causes supply chains to break down particularly during the launch of new products (Lee and Whang, 2000). Furthermore, Narayanan and Raman (2004) asserted that coordinating actions across firms is extremely difficult because, organisations have different cultures and companies cannot count on shared beliefs or loyalty to motivate their partners.

Supply chain must be fully integrated to operate at maximum efficiency. Failing to understand the potential vulnerabilities can compromise the supply chain's ability to handle unexpected and sudden shocks. By understanding risk within and external to the supply chain, an organization can more clearly identify its options for optimizing the supply chain to ensure viability and strength. Optimized financial performance demands an ongoing analysis of the key risks spanning this increasingly complex supply network that connects suppliers, manufacturers,

distributors, retailers, and customers. Analyzing supply chains with the perspective of risk results in a better understanding of the potential sources and, most importantly, the potential costs of a disruption.

Although risk management is a topical issue in both practice and academic circles, no research to date has been investigated within the total Pharmaceutical supply chain as pertinent to national health care pharmacy, (Mahender, 2005). Such research is vital because pharmaceuticals are critical to healthcare (PhRMA, 2004). According to Savage et al (2006), practitioners believe that pharmaceuticals are different and cannot be treated like other commodities. This is because of the high cost and long duration of research and development and the repercussions of the product not being available, hence its criticality.

Furthermore, there is no gainsaying that Pharmaceutical products are a key input into healthcare treatment, so it is imperative that risks attached to the sourcing, and passage of these products through to patients are identified and managed (Breen, 2008). There is considerable evidence that failure to manage supply chain risks effectively can have a significant negative impact on organisations (Mitchell, 1995) which pharmaceutical industry is not an exception.

In spite of the possible dangers or risks that an organisation may encounter for its inability to properly manage its supply chain, it appears that there is little or no impetus to properly address the internal company inefficiencies in the pharmaceutical industry let alone the inefficiencies associated with its external chains. The research therefore seeks to indentify the risks associated with the pharmaceutical industry supply chain in Ghana and also to determine the major reasons responsible for them.

2 Literature Review

2.1 Pharmaceutical Supply Chain

In spite of the similarities between supply chains in general, inherent differences that distinguish one industry supply chain from another also exist (Cooper et al., 1997). According to Mahender (2005) the supply chains of different industries are dissimilar as they address different needs. The pharmaceutical industry is unique in many ways and in a study made by Mahender (2005), it plays an extremely important role in preserving the health of people, and unlike other goods and services, access to health care services and products is often considered a personal right or universal entitlement. This is supported by Ghana National Drug Policy Statement (2004) which stated that, a national drug policy forms the basis of government's responsibility to ensure access of its citizens to good quality drugs at affordable prices, enacting drug regulations, developing professional standards, and promoting the rational use of drugs.

Without a doubt, products and services offered by the pharmaceutical industry are of a very different nature than those offered by most other industries. Consequently, the underlying dynamics of the industry are atypical, which in turn bring about strategic and operational

differences between the pharmaceutical industry supply chain and rest of the market supply chain (PhRMA, 2004).

Furthermore, Bradley and Weber (2004) postulated that the unique feature of the pharmaceutical industry is that it operates two very different types of supply chains at all times. One supply chain supports the drug development phase and the other one to sell a successful drug in the market. After a drug is launched, a completely different set of objectives, drivers, and constraints become dominant. Now, the focus shifts from agility to high availability. Consequently, there is a dramatic shift in the models and techniques employed to support this phase of drug life cycle. A typical pharmaceutical supply chain after a drug launch identified by Mahender (2005) is depicted in Figure 2.1 below.

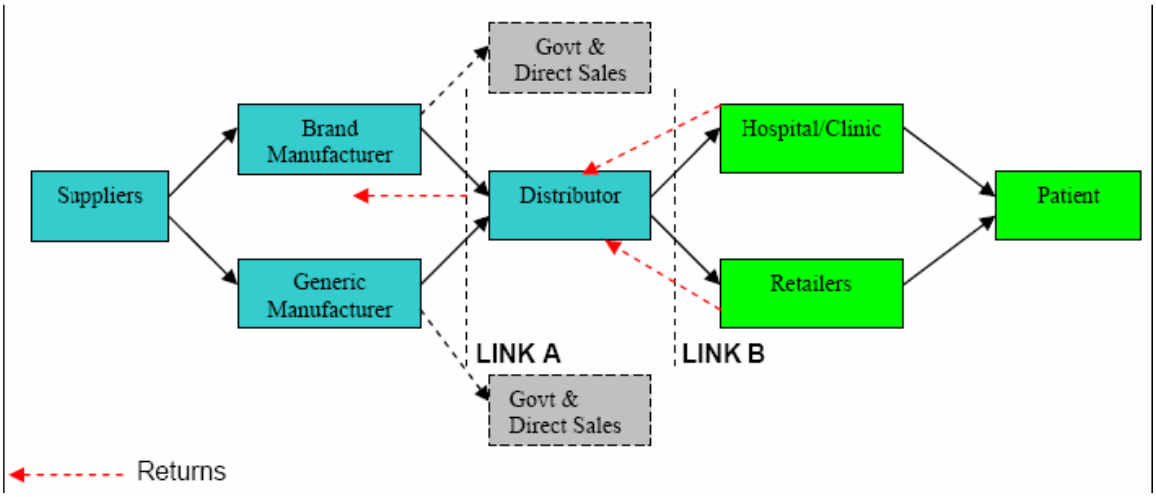

Figure 2.1 Pharmaceutical Supply Chain

In this phase, the complexity of the pharmaceutical supply chain results from the involvement of multiple large independent organizations of very diverse nature. The key stakeholders in this supply chain include multiple government agencies, hospitals, clinics, drug manufacturers, drug distributors, pharmacy chains, retailers and research organizations. To compound matters further, the same supply chain is responsible for the distribution of prescription drugs, over-the-counter (OTC) medicines, generics, as well as biologics having different handling needs and operational objectives. Furthermore, due to the regulatory nature of the industry and numerous mergers and acquisitions to acquire more research and development (R&D) expertise, many pharmaceutical supply networks have grown in an uncontrolled fashion rather than being planned for optimal performance. On this Bradley and Weber (2004) pointed out that a simple inspection will, however, reveal that, in general, the pharmaceutical industry lays little emphasis on its supply chain operational efficiency.

Obviously, the objectives and constraints active in these two phases are very different requiring very different types of supply chain capabilities. While one supply chain is focused on facilitating a quick completion of the clinical trials to obtain a quick approval, the aim of the

other supply chain is to meet sales targets. As a result the drivers motivating the supply chain design are speed and high availability respectively. Important considerations in both cases include safe custody and special handling requirements.

2.2 Pharmaceutical Supply Chain Risk

Mahender (2005) proposed that pharmaceutical supply chain risk include supply shortages, reverse logistics, counterfeiting and raw material quality and availability. He added that along with security, the problem of shortages is also becoming critically important to the pharmaceutical industry. The main reasons for shortages include regulatory issues, product discontinuation, raw materials issues, manufacturing problems, supply and demand problems (Tyler and Mark, 2002).

In Johnston (2004) view, the problems of shortages arising due to poor forecasts are central to the efficient operation of any supply chain. In general, product shortages occur when unexpected demand for a product exceeds production capability. In the pharmaceutical industry, poor forecast accuracy may result from, new indication for an existing product, unusual disease outbreak , new product sales dramatically exceeding expectations, inaccurate demand forecasting techniques, Just-in-time (JIT) inventory levels unable to meet demand spikes, off label usage by prescriber, domino effect from shortage of a related product, hoarding that exaggerates a potential shortage, contract awards that produce large demand shifts in a short period of time (Tyler and Mark, 2002).

Furthermore, Mahender (2005) asserted that inventory management also poses risk in pharmaceutical supply chain. He said that, in the meantime, the industry also had a realization that throwing more inventories at the supply chain does not always guarantee that product availability targets are met. But, due to the highly segmented nature of the market, inventory management in the pharmaceutical industry is inherently difficult. The complexity of inventory management problem results from multiple inventory policies, volume variability, seasonality, and local attributes or events. It is further compounded by the pressure to respond quickly.

A key requirement with ethical and financial implications prompting over cautious approach for extreme over-buffering on inventory levels leading to unnecessary economic waste. Again, due to numerous products, market combinations, regulatory restrictions, and safety concerns present a tough challenge (Bradley and Weber, 2004). Additionally, lack of data integrity makes it extremely hard for planners to forecast and decide with confidence how much inventory of each item should be kept at any point in the chain at any time.

Another risk which is prevalent in pharmaceutical supply chain is reverse logistics. Johnston (2004) commented that, managing product returns in the pharmaceutical industry is much more than a simple logistics challenge. Due to the sensitive nature of drugs and their potential health and financial implications, management of returned goods is a serious business with legal ramifications. Adding to this Mahender (2005) pointed out that drug recall and drug

expiration makes reverse logistics to manage. In explaining he said, drugs can be recalled either due to a temporary problem with the product or a permanent removal of the drug from the market due to drug safety related issues. In either case, drug recall is a major event that creates numerous problems, not the least of which is the tarnished reputation of the company.

Mahender further argued that from operations standpoint too, drug recall poses a significant challenge in terms of orchestrating the removal of every unsold item from every point in the supply chain. As a result, there are sudden shifts in the volume of recalled drug in the network leading to capacity issues a shortage resulting from a temporary recall or an excess due to a permanent recall - requiring immediate attention.

Commenting on drug expiration, Johnston (2004) accepted that, it is normal to expect a small percentage of drugs to remain unsold for a long time and eventually expire he accepted that, it is normal to expect a small percentage of drugs to remain unsold for a long time and eventually expire. An occurrence that is exacerbated by the industry wide practice of carrying high levels of finished goods inventory. In general, the expired drugs are removed from the customer locations and destroyed by licensed companies. In many cases, the manufacturer will accept the expired drug and refund a certain percentage of the price back to the buyer too. It is extremely important for the drug manufacturers to carefully monitor the quantity and pattern of drug expiration. An analysis of this data can be used to evaluate and tune existing inventory policies and forecasts.

The issue of counterfeits is a disturbing risk facing the pharmaceutical industry globally (Mahender, 2005). A recent report indicated that, the Pharmaceutical Security Institute stated that counterfeiting, theft, and diversion of prescription drugs rose by 16% worldwide in 2004 (PhRMA, 2004). Additionally, according to the USA Today report, the United States reported the highest number of incidents for the second year in a row. Of the 553 incidents reported worldwide last year (up from 477 in 2003,) 76 took place in the United States, while 60 occurred in Columbia, and 59 were in China. For counterfeit events alone, the United States ranked fifth (Mahender 2005). Furthermore according to Mahender (2005), raw material quality and availability have a huge impact on the ability of a pharmaceutical company to manufacture drugs for the market. The pharmaceutical companies, however, are uniquely limited in their ability to control these factors. In most cases, there are only a handful of suppliers of critical raw materials and manufacturers are at the mercy of their capability to maintain supply. An act of nature or a regulatory concern at a single plant can cripple the supply of the raw material to the whole world for a long duration. The pharmaceutical companies respond to this situation by maintaining large stocks of such raw materials at all times. Since the cost of raw material is negligible compared to the opportunity cost of a lost sales, it is advisable for the pharmaceutical companies to retain this policy.

3. Methods

The research seeks to investigate the various risks associated with the Pharmaceutical supply chain in Ghana and the major reasons responsible for them. It was therefore a descriptive research. The target population for the study were the manufacturers (12), importers (17), wholesalers (31), as well as retailers (25) of pharmaceutical products in Ghana. A total of eighty-five subjects were chosen for the study. These comprised one Managing Director or Pharmacist for each of the twelve Pharmaceutical manufacturing companies under review, one Manager or one Pharmacist for the Thirty-one pharmaceutical wholesale companies, seventeen Managers for importers of pharmaceutical products and twenty-five retail companies in the research area. Moreover, only pharmaceutical manufacturing companies, importers, wholesale companies and retail companies in the Kumasi and Accra Metropolises were conveniently selected for the study because of the high concentration of the major pharmaceutical companies in these places. The major instrument for data collection was the questionnaire. At the end of the exercise, it was found out that with the exception of two manufacturing companies, two importing companies and one wholesale company, the rest of the target group responded to the questionnaires distributed. This made available a usable sample of 80 out of 85 initially earmarked for the study. This represents a returned rate of 94.1%. A four-point Likert type rating scale of strongly agree (SA), agree (A), disagree (D) and strongly disagree (SA) was offered as possible responses to the respondents (Best and Khan, 1989). For the section that deals with the investigation of the pharmaceutical supply chain risk, the responses were pooled into agreed and disagreed categories. No weights were attached to the responses given by respondents. However the section that deals with the major reasons for the supply chain risks has weights attached to the responses as : (1=Strongly Agree, 2= Agree, 3= Strongly Disagree, 4= Disagree). The responses were analysed using Statistical Package for Social Sciences (SPSS).

4. Results

Table 4: Perception and Identification of Business Risk.

Responses	Frequency	Percentages (%)
Yes	78	98
No	2	2
Total	80	100

The results in Table 4 show that 78 representing 98% of the respondents agreed that they are able to identify the risks confronting them whenever they occur. This shows that pharmaceutical companies in Ghana are on the right path to manage risks confronting them.

This confirms Norrman et al (2004) as he postulated that the first stage in risk management is the identification and analysis of risk.

Table 5: Pharmaceuticals Companies Share Important Information

Responses	Frequency	Percentages (%)
SA	10	13
A	40	50
D	25	31
SD	5	6
Total	80	100

The results from Table 5 indicate that pharmaceutical companies share important information with their suppliers and customers, 50 representing 63% of the total respondents agreed that they share important information with their major customers and suppliers. In a quest to become more agile and lean, in Christopher's (2005) view organisations are becoming more dependent on outside support which also adds to the overall risk vulnerability. He said that although it is impossible to completely eliminate risks from a supply chain but rather, organisations can better prepare themselves to neutralize them and this can be done if there is a shared information and understanding among supply chain partners of the variables that could impact the risks and the mitigation strategies.

The findings again confirm Chopra and Sodhi (2004) assertion that some of the variables that enable risk mitigation are information sharing, aligning incentives, risk sharing and corporate social responsibility. Information is therefore very crucial in deal with risk management as postulated by Handfield and Nicholas (2002) that a high level of information sharing is necessary in supply chain to create high performing value systems that provide member organizations sustainable competitive advantage.

Table 6: Maintaining Minimal Number of Suppliers

Responses	Frequency	Percentages (%)
SA	12	15
A	44	55
D	10	12
SD	14	18
Total	80	100

A look at the findings from table 6 gives an interesting revelation where 56(70%) of the total respondents agreed that they always try to maintain a minimal number of suppliers to reduce vulnerability.

This finding confirms Mentzer (2001) comment that a key component for supply chain management is sharing both risks and rewards between the members of the supply chain, hence the more the members of a supply chain the more may be the risks to share among the members. Furthermore, Treleven and Schweikhart (1988) argue that single sourcing exposes companies to less risk and facilitates effective communication by reducing the number of suppliers a customer has to deal with.

In contrast, Zsidisin et al. (2000) argued that single sourcing can lead to over-dependence on one source of supply, with the risk that the supplier could exploit their position and take advantage of the customer. Adding to this, they further advocate the use of multiple sources of supply as a risk reduction strategy in some cases.

Table 7: Risk of Drug Shortages

Responses	Frequency	Percentages (%)
SA	35	44
A	30	38
D	10	12
SD	5	6
Total	80	100

From Table 7 above, majority of the respondents generally agreed that their companies face the problem of Drug Shortages. Out of the 80 respondents, 65 respondents representing 82%

agreed that Drug Shortages is a risk to their companies. However 18% disagreed that Drug Shortages is a risk to their companies.

Table 8: Risk of Pilfering

Responses	Frequency	Percentages (%)
SA	30	38
A	21	26
D	20	25
SD	9	11
Total	80	100.00

Pilfering is a serious risk that has led many giant companies to go bankrupt. It is a financial leakage which if not managed well and on time will reduce the profitability of the company. The results from Table 8 indicate that 51of the respondents forming 63.8% agreed that Pilfering is one of the major risks facing their companies (Pharmaceutical Companies). However 36% disagreed that Pilfering is one of the major risks facing their companies.

Table 9: Risk of Counterfeit and Fake Drugs

Responses	Frequency	Percentages (%)
SA	10	13
A	22	28
D	30	37
SD	18	22
Total	80	100

Even though 48 of the respondents representing 59% disagreed that Pharmaceutical companies face the risk of fake or counterfeit drugs in their business. The finding goes contrary to the assertion made by the USEPA (2004) that the issue of counterfeits is a disturbing risk facing the pharmaceutical industry globally. However 41% agreed that their companies face the risk of fake or counterfeit drugs. The 41% is still a significant figure considering the fact that Counterfeit Drugs can easily claim the lives of people. Estimate of 192,000 patients were killed by fake drugs in China in 2001 (Cockburn et al., 2005)

Table 10: Risk of Expiration of Drugs

Responses	Frequency	Percentages (%)
SA	10	13
A	42	52
D	12	15
SD	16	20
Total	80	100

From Table 10 above, the responses of the respondents show that 52 of the respondents representing 65% of the total respondents admitted that they face the risk of drugs expiration. Commenting on drug expiration, Johnston (2004) accepted that, it is normal to expect a small percentage of drugs to remain unsold for a long time and eventually expire. Adding to this, Mahender (2005) asserted that in United States of America, the expired drugs are removed from the customer locations and destroyed by licensed companies. In many cases, the manufacturer will accept the expired drug and refund a certain percentage of the price back to the buyer too. It is extremely important for the drug manufacturers to carefully monitor the quantity and pattern of drug expiration.

Table 11: Responses on the major reasons responsible for the risks in the pharmaceutical supply chain

Total number of Respondents (N): 80

Scale: (1=Strongly Agree, 2= Agree, 3= Strongly Disagree, 4= Disagree)

Major Reasons	N	Mean	Std. Error	Std. Deviation
Poor supervision by the Regulatory Bodies	80	2.17	0.094	0.839
Poor Inventory Management	80	2.28	0.097	0.871
Reverse Logistics not encouraged	80	2.19	0.128	1.148
Low income of final consumers	80	2.30	0.114	1.024
Unethical attitude of Pharmacists and Chemical sellers	80	2.61	0.116	1.037
Poor security system	80	2.04	0.109	0.974
Ineffective communication flow throughout the entire supply chain	80	2.05	0.089	0.794
Difficulty in obtaining quality Raw Materials	80	2.86	0.119	1.064
Poor forecasting of demand and supply	80	2.15	0.104	0.929
Valid N (listwise)	80			

From table 11 above, it is observed that respondents agreed to almost all the reasons stated in the table as the major reasons responsible for the risks in the pharmaceutical supply chain. This is observed from the mean score values of above 2.00 and relatively low standard deviation values which to a high extent confirm consistency in agreement among the respondents. Again relatively low standard errors also support the fact that the respondents agreed to almost all the reasons indicated in the table as major reasons for the pharmaceutical supply chain.

5. Conclusion

Risk exists in virtually every supply chain activity whether it is recognised or not. As Supply chain professionals, we need to be cognisant of the risks that exist in-house and with our

suppliers. This study was to investigate the risks associated with Pharmaceutical Supply Chain in Ghana.

With respect to information sharing, the study revealed that pharmaceutical companies share important information with their suppliers and customers and this was indicated by 50 respondents representing 63% of the total respondents.

Again the study revealed that Pharmaceutical companies always try to maintain a minimal number of suppliers to reduce vulnerability. This was indicated by 70% of the respondents.

With respect to the risks associated with the Pharmaceutical Supply Chain, the study revealed that Drug Shortages, Pilfering and Expiration of Drugs are the risks associated with Pharmaceutical Supply Chain. They point to the fact that Pharmaceutical companies face the problem of Inventory Management. The inventory management problem confirms the assertion made by Mahender (2005) that inventory management also poses risk in pharmaceutical supply chain. However Counterfeit or Fake Drugs was not considered by the respondents as among the risks associated with pharmaceutical Products. Thus 59% disagreed that Pharmaceutical companies face the risk of fake or counterfeit drugs in their business.

The study revealed the major reasons the respondents attributed to the risks associated with the pharmaceutical supply chain and they include difficulty in obtaining raw materials, unethical attitude of pharmacists and chemical sellers, low income of consumers, poor inventory management and reverse logistics not being encouraged in the pharmaceutical industry in Ghana.

6. Recommendations

The following recommendations were made:

- An efficient inventory management must be adopted and practice. This can be done by the use inventory management software and stringent security measures to reduce expiration, shortages and pilfering of stocks. Employees who manage the accounting and inventory systems must be qualified and well trained on the use of these systems for efficient and effective performance.
- Pharmaceutical companies must be proactive in their approach to their product supply chain. Effective and efficient supply chain will minimise the difficulty of obtaining quality raw materials for production of drugs if not eliminated completely and again it will help to ensure proper inventory management within the pharmaceutical supply chain in Ghana.
- Even though 59% of the respondents disagreed that Counterfeit or Fake Drugs is a risk to Pharmaceutical companies the institutions such as Pharmacy Council of Ghana, Ghana Food and Drugs Authority and Ghana Customs must be well resourced to prevent

Counterfeit or Fake Drugs from entering our market. This will go a long way to do away with Counterfeit or Fake Drugs to ensure the health and safety of the people in the country.

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