# Master's degree thesis

LOG950 Logistics

Supply Chain Risk Management at Pharco Pharmaceuticals, a pharmaceutical manufacturer in Egypt

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Molde, May 26, 2015



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# Preface

This Master's thesis is submitted in partial fulfillment of the requirements for the two-year Master of Science program in Logistics (Supply Chain Management specialization) at Molde University College, Norway.

The thesis represents an independent, extensive research work, which was carried out from December 2014 to May 2015 under the academic supervision of Professor Hajnalka Vaagen.

Hesham Mohamed

Molde, May 26, 2015

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# Abstract

The economic, social, and political events that recently occurred in Egypt have exposed the pharmaceutical supply chain to higher levels of uncertainties and vulnerabilities, which makes it extremely difficult to ignore the importance of supply chain risk management. The aim of this research is to address pharmaceutical supply chain risks from the perspective of an Egyptian manufacturer, Pharco Pharmaceuticals. The main purpose is to identify and rank the most significant supply chain risks confronting Pharco, describe the risk management strategies as applied by the company, and finally, to make recommendations that could improve the management of supply chain risks. The research design is mainly qualitative in nature, and draws upon both case study and normative approaches. The research has identified seven types of risks at Pharco's supply chain. It has also shown that external risks were perceived to be more significant than internal risks. The research has revealed that no clear strategy is deployed by the company to mitigate most of its supply chain risks. Several approaches—based on the concept of cooperation—are suggested for improving the management of supply chain risks. The empirical findings of this research are expected to enhance the company's understanding of its supply chain risks and their interconnectedness, which offer valuable insights for tailoring balanced and effective riskreduction strategies. The findings of this research serve as a basis for a further rigorous research project, incorporating the identification of supply chain risks within the pharmaceutical industry in Egypt.

*Keywords: Pharmaceutical Supply Chain, Supply Chain Risk Management, Pharmaceuticals Manufacturers, Egypt.* 

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# List of Abbreviations

API	Active Pharmaceutical Ingredient
BOM	Bill Of Material
CAPA	Central Administration of Pharmaceutical Affairs
CSCMP	Council of Supply Chain Management Professionals
EDA	Egyptian Drug Authority
EGP	Egyptian Pound
FDA	Food and Drug Administration
FMCG	Fast-Moving Consumer Goods
MENA	Middle East and North Africa region
NODCAR	National Organization for Drug Control and Research
OTC	Over-the-Counter
PSC	Pharmaceutical Supply Chain
R&D	Research and Development
RFID	Radio-Frequency Identification
RM	Risk Management
SC	Supply Chain
SCM	Supply Chain Management
SCRM	Supply Chain Risk Management

# **1. INTRODUCTION**

In this chapter, the background information to the present research will be provided. It will also introduce the research problem, purpose, and the associated research questions that this research seeks to address. Finally, the structure of the research will be outlined.

# 1.1 Background

Managing risks in supply chains has never been as challenging as it is nowadays. The challenges mainly arise from increased dynamics and uncertainties combined with globalization. Supply chain risks have expanded, resulting in a new set of uncertain and unfamiliar incidents that can create chaos and disruptions, posing a number of significant threats to business continuity (Paulson, Kouvelis, & Li, 2011, p. 3).

A great variety of risks exists, which can have significant effects on the short-term and long-term performances of supply chains. In addition to internal risks—which are controllable to some extent—the ever-increasing external risks continue to expose today's supply chains to completely new challenges. Examples include socio-political disruptions, security problems, terrorism, counterfeiting, etc. (Dani, 2009, p. 55).

The consequences of failure to manage supply chain risks have become more severe (Faisal, 2009, p. 42). This highlights the importance of Supply Chain Risk Management (SCRM). SCRM aims to identify and manage supply chain risks through a coordinated approach amongst supply chain members in order to reduce supply chain vulnerability as a whole (Jüttner, 2005, p. 124).

Pharmaceutical supply chains are subject to a wide range of risks that may disrupt the continuous supply of medicines. The disruptions are not only causing disturbance and increased costs, but can also aggravate the patients' health status by hindering access to medicines. Confronted with much greater economic, social and political instabilities, pharmaceutical supply chains in the developing countries are exposed to even higher levels of uncertainties and vulnerabilities.

Therefore, the identification of risks and the development of mitigation strategies in the pharmaceutical supply chain are highly recommended (Jaberidoost, Shekoufeh, Akbar, & Rassoul, 2013, pp. 1,6).

As a result, SCRM should be an essential part of the pharmaceutical companies' strategies. Pharmaceutical manufacturers are the most important players in the pharmaceutical supply chain because their performances affect the efficiency of the whole supply chain. Also, pharmaceutical manufacturers are the most at stake because of their large investments in R&D as well as their responsibility for the quality of the final product. Therefore, they are in the best position to take responsibility for identifying and managing their supply chain risks (Mollah, Long, & Baseman, 2013, p. 18).

In the light of the political, economic, and social events that have recently occurred in Egypt, as well as the associated negative effects on the business climate (OECD, 2014, p. 13), it is becoming difficult to ignore the importance of identifying and managing risks in the supply chains of Egyptian companies.

## **1.2 Research Problem**

A search of the literature was conducted through the following bibliographic databases and scientific search engines—ProQuest, PubMed, Science Direct, Google Scholar using the following keywords: *supply chain, risk management, supply chain risk management, pharmaceutical (medicine), Egypt, manufacturers,* in different combinations, to produce all the relevant results.

The search revealed that only one published study addressed the issue of supply chain risk from the perspective of Egyptian companies in the following sectors: FMCG manufacturing, retailing, transport and logistic services (Elzarka, 2013).

However, no prior empirical research was found that addresses supply chain risks in the Egyptian pharmaceutical sector.

#### **1.3 Research Purpose and Research Questions**

The purpose of this research is to: (1) identify the most important supply chain risks from the perspective of a pharmaceutical manufacturer in Egypt, Pharco Pharmaceuticals, (2) describe the current risk management strategies applied by the company, and (3) recommend potential strategies that can improve the management of risks.

The following set of research questions was developed to help fulfill the purpose of the research:

# RQ1: What are the most significant supply chain risks for Pharco?

Objectives:

- To identify the most important supply chain risks and understand their nature from the perspective of Pharco Egypt.
- To prioritize/rank the most important supply chain risks.

# RQ2: How does Pharco manage its supply chain risks?

Objective:

- To identify and describe the current risk management strategies, as applied by Pharco, to deal with its supply chain risks.

# RQ3: How can Pharco improve its management of supply chain risks?

Objective:

- To make recommendations which improve the current management of supply chain risks, by discussing the potential strategies that can be applied to mitigate such risks.

# 1.4 Research Outline

<u>The first chapter</u> provided background information for the research, and presented the research problem, research purpose and research questions.

<u>Chapter Two</u> presents the methodology applied for conducting this research. It describes the research design, case selection, and data collection instruments. It also discusses the research trustworthiness and limitations of the research methodology.

<u>Chapter Three</u> provides a theoretical framework for the research by reviewing the relevant body of literature on supply chain management, supply chain risks, and supply chain risk management.

<u>Chapter Four</u> starts by providing a brief overview of the pharmaceutical industry in Egypt and presents Pharco Pharmaceuticals, the case company. Finally, the risks identified in Pharco's supply chain are presented.

<u>Chapter Five</u> ranks and categorizes the identified risks, followed by a discussion on the risk management strategies applied by Pharco. Finally, recommendations are given to the company to improve the management of supply chain risks.

<u>Chapter Six</u> concludes with a summary of the research findings. Suggestions for further research are also considered at the end of the chapter.

# 2. METHODOLOGY

This chapter presents the methodology applied for conducting this research. It describes the research design, case selection, and data collection instruments. Finally, a brief discussion on the research trustworthiness, along with the limitations arising from the choice of the methodology, is given.

# 2.1 Research Design

This research primarily follows a qualitative approach. The first research question aims to identify and rank the most important supply chain risks at Pharco, as well as to provide a more in-depth understanding of their nature. The second research question aims to describe strategies applied by Pharco to manage its supply chain risks. <u>These</u> two research questions are addressed through a descriptive case study.

The third research question aims to make recommendations for the company, by using the theoretical literature based on SCM and SCRM. <u>This part of the research is normative in nature</u>. Unlike the descriptive approach, the main aim of the normative approach is not just to gather facts, but also to point out the respect(s) in which the object of study can be improved (Pentti, 2007).

The principal unit of analysis within this research is the supply chain risk facing Pharco.

# 2.2 Case Study Research Strategy

Yin (1994, p. 13) states that A case study is an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident.

Benbasat, Goldstein, and Mead (1987, p. 387) identify some of the characteristics of case study research as follows:

- The phenomenon is examined in a natural setting;
- Data is collected by multiple means;
- One or a few entities (persons, groups or organizations) are examined;
- The complexity of the unit is studied intensively;
- The focus is on contemporary events.

Among the aims of this research is to develop a more in-depth description and understanding of the most important supply chain risks at Pharco. The case study approach enabled the intensive study and examination of supply chain risks facing the company, which generated a deep and rich understanding of the situation.

In the case study approach, data is collected by multiple means. According to Yin (1994, p. 97), a major strength of case study data collection is the opportunity to utilize many different sources of evidence (data triangulation). This allows the development of *converging lines of inquiry*. In other words, the research finding or conclusion is likely to be more convincing, and accurate, if it is based on multiple sources of information. In this research, a combination of primary and secondary data sources was utilized.

#### 2.3 Case Selection and Data Collection

#### 2.3.1 Case Selection: Pharco Pharmaceuticals

Dul and Hak (2008, p. 250) suggest that when conducting a descriptive case study, case selection should be governed by convenience, feasibility, and likely effectiveness.

Pharco Pharmaceuticals is one of the largest private Egyptian pharmaceutical companies, operating in both local and international markets, with a complex global supply chain. These aspects make the company appropriate for studying the complexity of pharmaceutical supply chain risks.

Moreover, the openness of Pharco's employees and willingness to cooperate further encouraged the selection of the company for this research.

#### 2.3.2 Primary Data

*Primary data* is original research data in its raw form, without any interpretation or analysis, and thus original in character (Kothari, 2004, p. 95). In this research, <u>interviews</u> are the most valuable prime source of information, and semi-structured interviews were applied for data collection. In semi-structured interviews, a researcher asks predetermined, but flexibly worded questions. In addition, follow-up questions can also be asked to more deeply probe issues of interest to interviewees (Hancock & Algozzine, 2006, p. 40).

Despite the advantages of interviews as a data collection instrument (mainly allowing more in-depth, rich information to be obtained and providing greater flexibility), the interview method also has certain weaknesses. Among the important weaknesses are the following (Kothari, 2004, pp. 98,99):

- 1- The interview method is an expensive and comparatively more timeconsuming one;
- 2- There remains the possibility of interviewer and respondent bias; and
- 3- Participants may not be easily approachable.

For this research, a total of six semi-structured interviews were conducted face-to-face and by telephone in the period from January 2015 to March 2015.

The selection of interviewees directly influences the quality of information obtained (Hancock & Algozzine, 2006, p. 40). Accordingly, participants involved key experienced managers from various functional departments at Pharco, including: Quality Assurance Manager, Development Sector Head, Sales Manager, Import and Export Manager, as well as senior Returned Products Supervisor.

In most cases, the interview time spent with each participant ranged from 45 minutes to one hour. All the interviews were electronically recorded, and later transcribed, for closer scrutiny. Transcripts were analyzed in the light of the relevant body of literature, and compared with data obtained from other sources.

Having identified the important risks, a risk-ranking matrix was developed and then filled in by contacting the four managers to assign estimates for the impact and likelihood of each risk i.e. to prioritize/rank risks. In addition, follow-up telephone interviews were performed for further clarification. The interview protocol, which includes the questions asked, interviews details and risk-ranking matrix, is presented in **Appendix 1**.

#### 2.3.3 Secondary Data

*Secondary data* are those which have already been collected by someone else and which may have already been passed through a particular analysis (Kothari, 2004, p. 95).

In this research, various sources of secondary data have been used, including: textbooks, scientific journal articles, company documents, industry reports, internet

sources, newspaper articles, as well as documents and statistics obtained from the Egyptian Drug Authority.

# 2.4 Evaluating the Quality of the Research Methodology

Barnes (2001, p. 1078) states that any research method inevitably has both advantages and disadvantages, and there is unlikely to be one best way of approaching the task. In other words, methodologies cannot be true or false, only more or less useful, as Silverman (1993, p. 2) puts it.

## 2.4.1 Research Trustworthiness

In order to generate confidence in the research findings, this section will examine the quality of the research performed in light of the four elements of *trustworthiness*, as described by Guba (1981, pp. 79,80):

<u>Credibility:</u> refers to how one can establish confidence in the "truth" of the research findings. In this research, triangulation—by utilizing multiple data sources and multiple participants—allowed the cross-checking of data and interpretations. This provided the researcher with complementary aspects that increased the understanding of the researched object (supply chain risks).

<u>Transferability</u>: is the degree to which the findings of a particular research may have applicability in other contexts. This research addressed supply chain risks from the perspective of Pharco, with the aim to contribute to the knowledge of this particular company, rather than producing generalizable outcomes to the population. Accordingly, it could be argued that the transferability criterion is not satisfied for the research presented.

<u>Dependability</u>: refers to whether the findings of the research would be consistently repeated, if the research were replicated with the same subject and in the same context. In order to increase the dependability of this research, the interview protocol, which includes both questions asked and interviewees, was created (See **Appendix 1**). Therefore, it is believed that asking the same questions to the same interviewees would produce similar results.

<u>Conformability</u>: is the degree to which research findings are a function solely of subjects and conditions of the research, and not of the biases, motivations, interests, or

perspectives of the researcher. To reduce possible bias, interviews were recorded and transcribed, providing a permanent verbatim evidence, which can be recalled when needed. In addition, it is expected that data triangulation contributed toward lowering the potential bias induced by the researcher's subjectivity.

## 2.4.2 Limitations

Much of the data applied in this research was derived from analyzing and interpreting what the interviewees were saying. Thus, it is important to acknowledge that, despite the use of data triangulation, interviewees' bias as well as the researcher's assumptions and interpretations could have, to some extent, affected the outcome of the research.

In addition, since most of the data were obtained from one company, the applicability of research findings cannot go beyond this particular company. As a result, research findings are not expected to retain the same level of validity for other settings, making it less useful for other companies, without investigating new cases.

# **3. LITERATURE REVIEW**

This chapter presents the concepts and the theoretical framework used for this research by reviewing the relevant body of literature on supply chain management, supply chain risks, and supply chain risk management.

# 3.1 Supply Chain Management (SCM)

## 3.1.1 Definition and Objectives of Supply Chain Management

Over time, dozens of definitions have been developed to describe the relatively new terminology of *Supply Chain Management*. Because this discipline is still in its early stages, the lack of common agreement on a uniform definition is evident.

A number of studies has attempted to examine the existing definitions in the literature in order to develop a uniform definition of SCM (Bechtel & Jayaram 1997; Cooper, Douglas, & Janus, 1997; Mentzer, DeWitt, Keebler, Min, & et al., 2001; Stock & Boyer, 2009). The Council of Supply Chain Management Professionals (CSCMP) and industry experts have created the following official definition of SCM:

Supply chain management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In essence, supply chain management integrates supply and demand management within and across companies (CSCMP, 2014).

However, this definition does not highlight the ultimate objectives of SCM. Chopra and Meindl (2007, pp. 5,6) state that the ultimate objectives of every supply chain are to satisfy customer needs and to generate profits. Similarly, Christopher (2011, p. 3) views the main aim of SCM as delivering superior customer value at the lowest possible cost to the SC as a whole.

## 3.1.2 Pharmaceutical Supply Chain (PSC)

In order to describe a typical PSC, parties that form this supply chain should first be identified. According to Shah (2004, p. 931) and Pedroso and Nakano (2009, p. 378), a typical PSC includes, but is not limited to, the following parties: manufacturers,

intermediaries, healthcare providers, and customers. A typical PSC is illustrated in Figure 3.1.

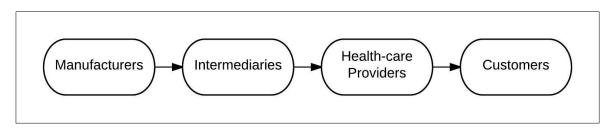


Figure 3.1 A typical pharmaceutical supply chain

**Manufacturers** include, among others, pharmaceutical and biotechnology manufacturers, medical suppliers, and medical device producers. **Intermediaries** include wholesalers, mail order distributors, and group purchasing organizations. **Healthcare Providers** include hospitals, physicians, and pharmacies. **Customers** include government, employers, and individuals.

Manufacturers can be categorized into primary and secondary manufacturers. Primary manufacturers produce the active pharmaceutical ingredients (APIs) of the medications. Secondary manufacturers are responsible for transforming the active ingredients into usable drugs (e.g. tablets, capsules). After that, finished products are distributed to the healthcare providers through intermediaries (e.g. wholesalers, distributors). Some manufacturers deliver their products directly to healthcare providers and bypass intermediaries (Kritchanchai, 2012, pp. 103,104).

A distinct feature of a PSC is that final consumers (patients) do not fully understand the medical practice; hence, they have control neither over drug choice nor over the amount to be consumed. As a result, healthcare providers play an important role in PSC. Because they write prescriptions for patients, demand for drugs is dependent on healthcare providers (e.g. physicians and hospitals). This feature highlights the importance of *technical information flow* for demand creation in PSC as opposed to other industries' supply chains (Pedroso & Nakano, 2009, pp. 378,379).

## 3.1.3 Recent Trends and Practices in Supply Chain Management

Changes in supply chain management are triggered by a number of drivers. Waters (2007, pp. 53–56) and Paulson et al. (2011, pp. 63,64) identified some of the most important drivers as follows:

- Increasing recognition that logistics management is an essential function and needs sound management;
- The importance of supply chain decisions and its subsequent strategic impact on organizations;
- New trends in supply chains in order to adopt operations such as just-intime, postponement, mass customization, lean operations, etc.;
- Increased level of globalization and international trade encouraged by continuous removal of trade barriers;
- Improved communication and information technology to ease the implementation of new solutions, such as tracking systems;
- Higher level of competition and access to global suppliers;
- Trends toward supply chain integration, mergers, strategic alliances and partnerships;
- Outsourcing non-core activities to third parties and focus only on core activities;
- Growing concerns about environmental changes, which have affected attitudes toward pollution, waste, etc.;
- The effects of changing regulatory environment and government policies on organizations.

The increased complexity of supply chains makes them more vulnerable to various types of internal and external risks. Organizations are trying to adapt to the above mentioned changes by altering the way they are doing business to improve their operational efficiency, which in turn increases their vulnerability to risks. For example, globalization enables organizations to find more efficient sources of supply by procuring from global suppliers, but also increases the risks associated with delays, loss of control, and reliance on foreign suppliers. If managers do not pay sufficient attention to these risks, the level of risks will expand and drift upward.

# 3.2 Risk in Supply Chain

# 3.2.1 Risk and Uncertainty

The term *risk* is still being debated among researchers. As various academic and professional disciplines are concerned with risk, it is difficult to find a definition that is

universally agreed upon. Also, the term *risk* is frequently used interchangeably with *uncertainty* (Ritchie & Brindley, 2009, p. 12).

Uncertainty refers to the *lack of predictability of outcomes* i.e. we do not know what will happen in the future. This implies that the outcome(s) can be <u>positive</u> (provide opportunities) or <u>negative</u> (cause harm) (Kahneman and Tversky, 1982). Uncertainty can be categorized into internal uncertainty and external uncertainty, according to Kahneman and Tversky (1982), as follows:

- *Internal uncertainty:* refers to the lack of knowledge and ignorance, which means that information is available, but the decision-maker does not know it.
- *External uncertainty:* refers to the situation where the decision-maker has no control over it.

This distinction is important in the sense that each type requires different responses from the decision-maker. For example, updating information can reduce internal uncertainty, while external uncertainty requires a more flexible approach to adapt unforeseen changes at the lowest possible cost.

The term "risk" is often reserved for the negative consequence, since the inference is the downside (negative) impact of the uncertain outcome (Spekman & Davis, 2004, pp. 416,417). Other authors share the same view of risk and define it as an event with the potential to have a significant negative impact on the organization (Agrawal, 2009, p. 2; Hopkin, 2013, p. 1; Mollah et al., 2013, p. 8).

Within the context of this research, the term risk will be used to indicate an event with potential negative consequences, whereas the term uncertainty will be used to refer to situations where both positive and negative consequences are considered.

## 3.2.2 Supply Chain Risk

In essence, risk in the supply chain context is viewed as disruptions of different flows (materials, information, and cash) that take place between supply chain parties. A key feature of supply chain risk is that it extends beyond the boundaries of a single organization (Jüttner, 2005, p. 122).

Jüttner, Peck, and Christopher (2003, pp. 200–206) highlighted the difference between supply chain *risk sources* and *risk consequences*.

Risk sources include environmental, organizational, and supply chain-related variables, which have an impact on supply chain outcomes, and cannot be predicted with certainty. Environmental risk sources include any uncertainties stemming from supply chain environment interactions (e.g. socio-political actions or acts of God). Organizational risk sources lie within the boundaries of SC parties (e.g. production uncertainties or strikes). Network-related risk sources arise from suboptimal interactions between parties within a SC.

Risk consequences are the focused SC outcome variables, such as cost, quality or demand. In other words, risk consequences are the different forms in which variance becomes manifest.

## 3.2.3 Categorization of Supply Chain Risks

Risks in the supply chain can be categorized into *internal risks* and *external risks*. Internal risks are those that are controllable—to some extent—by supply chain members.

According to Mieghem (2011, pp. 19,20), potential *internal risks* can be categorized on the basis of the stages in the value chain where the negative impact may take place. Based on this view, identified risks can be categorized into the following seven categories, as shown in Figure 3.2.

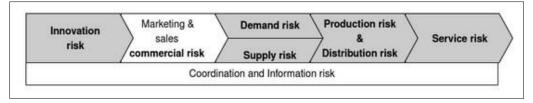


Figure 3.2 Internal risks within various stages of the value chain Source: (Mieghem, 2011, p. 19)

<u>Innovation risk:</u> This refers to the potential negative impact that originates during the research and development phase. In the pharmaceutical industry, a new drug may not meet the efficacy, potency, or safety standards necessary, so as to be approved by the relevant governmental authority.

<u>Commercial risk:</u> This refers to the associated negative impacts related to marketing and sales and, therefore, negatively affect revenues, such as lower than expected sales, which lead to reduced revenues.

<u>Demand and supply risks</u>: These refer to problems in the quantity demanded or supplied for a given product or service. Examples are decreased demand, which leads to overstocking of finished products at the retail level that must be sold at a discount, or problems in supplying the required inputs for production, such as a supplier's limited production capacity or quality issues.

<u>Production and distribution risks</u>: Production risk stems from internal processes, such as machine failure or capacity shortage. Distribution risk may occur as a result of logistics service provider failure, such as delays and damage to products during transportation.

<u>Coordination and information risks</u>: These refer to the failure in coordinating and communicating information with relevant parties in the supply chain, forecasting errors, and information system failure.

<u>Service risk:</u> This refers to problems that occur during after-sale service interactions, including inappropriate handling of customer inquiries and problems in product returns.

*External risks* can be categorized into natural, political, regulatory, competitive and strategic risks.

<u>Natural risk</u> refers to acts of God, such as earthquakes, fires, storms, and lightning strikes.

<u>Political and regulatory risks</u>: Unexpected changes in laws and regulations can lead to negative impact on organizations. War, strikes, and revolutions may lead to political unrest which can also negatively affect organizations.

<u>Competitive and strategic risks</u> refer to the potential negative impact of competitive pressure, such as changes in competitors' strategies.

Unlike internal risks, which are to some extent controllable by supply chain members, a key feature of external risks is that they are outside the control of the supply chain, as defined by Kahneman and Tversky (1982). In other words, managers cannot change an external risk, but they can deal with it by designing strategies that interact efficiently within a risky environment.

Waters (2007, p. 104) also differentiates between organization-specific and industrywide risks. Organization-specific risks may affect an individual organization and its supply chain (e.g. increased competition). On the other hand, industry-wide risks affect every organization within the same industry (e.g. new regulations), leaving them in the same boat.

The importance of this distinction is reflected in the type of response required because the scope of the risk determines the appropriate response. Unlike organization-specific risks, a single firm cannot deal with industry-wide risks alone; there must be cooperation between organizations, even with competitors, to enable them to work together to overcome risks for their mutual interests.

## 3.2.4 Risks in the Pharmaceutical Supply Chain

Manufacturers of medicines are the main players in the pharmaceutical supply chain. Through complex processing, chemical materials are converted into medications. These companies are subject to numerous types of supply chain risks.

Apart from the Jaberidoost et al. (2013) study, there is a general lack of research in the area of pharmaceutical supply chain risks. In their systematic literature review, Jaberidoost et al. (2013) concluded that PSCs face a total of 50 main risks classified into seven categories, as follows: supply risk, organization & strategy risk, financial risk, logistical risk, market risk, political risk, and regulatory risk. Jaberidoost et al. (2013, p. 1) emphasized the importance of identifying the potential risks in PSC, assessing their significance, and developing risk management strategies to handle them.

# 3.3 Risk Management and Supply Chain

#### 3.3.1 Supply Chain Risk Management (SCRM)

In supply chain literature, there are various definitions of SCRM. Jüttner (2005, p. 124) defines SCRM as a managerial activity that includes identification and management of supply chain risks, through a coordinated approach amongst SC members, to reduce SC vulnerability as a whole.

Rao and Goldsby (2009, p. 106) identified the key definitions of SCRM that exist in the literature. They highlighted that despite the minor variations among the definitions of different authors, it is obvious that they share a common central theme that SCRM extends beyond the ideology of a single-firm risk management.

SCRM lies on the border between supply chain management and risk management (Blos, Quaddus, Wee, & Watanabe, 2009, p. 248), as depicted in Figure 3.3.

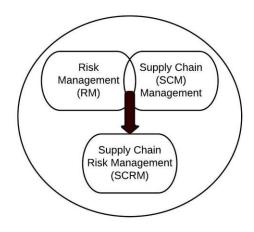


Figure 3.3 SCRM lies on the border between SCM and RM Source: (Blos et al., 2009, p. 248)

Generally, SCRM is similar to organizational risk management, but SCRM is much more complicated due to the need for cooperation and collaboration between organizations with different operations, aims, and views (Felea & Albastroiu, 2013, p. 63). The main focus of SCRM is to understand and try to avoid the ripple effects that risks can have on SC (Norrman & Jansson, 2004, p. 435).

Christopher (2002, pp. 38,39) suggests that the four main objectives of SCRM are to:

- Maintain the supply and continuous availability of products;
- Increase SC's ability to cope with disruptions;
- Avoid possible domino effects throughout the chain; and
- Make the SC more resilient to disruptions.

#### 3.3.2 Benefits of Supply Chain Risk Management

SCRM helps the organization and its supply chain achieve the following benefits:

- Risk-related issues are known in advance and become a part of normal operations;
- More balanced decisions are made, and operations that are financially unsound or too risky are avoided;
- The performance of management can be better measured;

- Early identification and analysis of potential risky events enable the proper design, planning, evaluation, prioritization, and allocation of resources to develop responses that mitigate risks, as it might be too late to adapt risk when it is observed far down in the supply chain;
- The absence of time constraints enables imaginative responses to be developed;
- Quick implementation of plans and contingencies after a risky event materializes;
- Better financial performance, customer service, corporate image, etc.;
- Development of historical risks record and analytical skills of people enable the improvement of future responses;
- Better communication, involvement, and understanding of relevant parties are ensured.

SCRM should not be viewed as an extra burden on the organization that adds more work and costs, but should be viewed as a way of improving customer service, reducing the overall costs and enhancing performance. This recognition should encourage managers to adopt formal SCRM methods to deal with the increased level of risks in their supply chains (Waters, 2007, pp. 87,88).

## 3.3.3 The Importance of the More Proactive Approaches in SCRM

SCRM approaches can be described as being reactive or proactive. The reactive approach is the default option when risk materializes (Dani, 2009, p. 58). A lack of preparations could result in significant problems. Organizations with no risk management follow a reactive approach in managing their risks. Managers react after the occurrence of a risky event, by analyzing the problems, and then design and implement their response, if any.

This approach is too slow, and may cause a considerable damage before a response starts to work. The result is a quick decision that has a high potential for error (Waters, 2007, pp. 75,76).

In contrast, a more proactive approach to managing risks is preferable. In this case, potential risks are identified, analyzed, and appropriate responses designed in advance, so as to better deal with the most important risks (Dani, 2009, p. 58).

#### 3.3.4 Supply Chain Risk Management Framework

Waters (2007, p. 90) suggests that SCRM has three core elements: identifying supply chain risks, analyzing them, and designing appropriate responses to the risks. These elements are general for all types of risk management, not only supply chain risks. Although these three elements are the core of SCRM, they do not capture the complete picture of the process. There are additional steps that take place beforehand to set the scene: these are the preparatory steps, as well as the monitoring and control steps, which take place afterward. The elements of SCRM are shown in Figure 3.4.

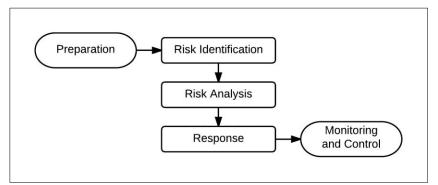


Figure 3.4 SCRM Framework Source: adapted from (Waters, 2007, p. 90)

In essence, the preparatory step starts with acknowledging the importance of supply chain risk management. Then, the organization's attitude toward risk and its risk strategy should be defined, followed by setting up an organizational structure responsible for the risk management, involving senior management.

Monitoring and control steps take place after the three core steps. Documentation and data collection are carried out throughout the supply chain to measure the effectiveness of the risk management process. This assist in the future identification and analysis of potential risks as well as allow the organization to learn and improve its risk management strategy (Paulson et al., 2011, pp. 3–7).

#### 3.3.4.1 Risk Identification

The identification of potential risks is a key activity in supply chain risk management. One way to identify risks is to ask people who have intimate knowledge of the organization and its supply chain, including the operations and the environment within which they operate. Another way is to ask consultants outside the organization as they can give valuable insights into risks; however, it is better to deal with internal people at the organization. Many tools are available to help identify the risks, such as:

- Process charts and process controls
- Interviews
- Group meetings
- Delphi methods
- Brainstorming
- Checklists
- Five whys
- Cause-and-effect diagrams
- Pareto analyses

Statistics over historical data is one of the most applied methods to identify uncertainty. As the higher the variance (e.g. demand, costs, prices, lead times, etc.), the higher the uncertainty.

#### > Challenges in risk identification

It is impossible to identify every conceivable risk to the supply chain. One reason is that every supply chain has its unique nature; therefore, there is no one size that fits all guidelines to identify all potential risks. As a result, managers should try to list the most significant (serious) risks and allocate their efforts toward these risks. Also, the decision related to the number of risks to be identified must remain a matter of management judgment, given the unique nature of the supply chain.

There are however generic ways to identify and handle uncertainty. E.g., identifying demand uncertainty it is mostly done by a combination of historical statistics and future market assessment.

Risk identification requires different sets of skills, and even people with intimate knowledge about the company's operations may fail to properly identify risks. One example is recognizing the most obvious risks rather than the most significant risks, which result in producing a list of trivial risks.

Additionally, managers may be reluctant to admit that risks exist within their organizations, because this implies some kind of failure or weakness. This is also a

result of the human bias of overconfidence. Acknowledgment that risks do exist is an important step (Waters, 2007, pp. 101–121).

## 3.3.4.2 Risk Analysis

The aim of risk analysis is to prioritize the identified risks, based on their significance. Having identified the most significant risks, managers should pay sufficient attention in order to control these in the step that follows. According to Waters (2007, p. 127), there are two approaches to risk analysis. The first approach is purely qualitative. This approach is useful to gain better understanding of risks, their effects and their consequences. Features of the identified risks are described qualitatively in terms of:

- The nature of each risk;
- Potential consequences/subsequent changes to operations;
- Likelihood;
- The scope and areas affected;
- Responsibility for risk control;
- Current management of risks and their efficacy;
- Suggestions and new policies for improving the current risk management.

According to Mieghem (2011, p. 22), a subjective risk map can be developed only on the basis of expert opinion, not on the basis of statistical analysis, as seen in Figure 3.5. Obviously, this risk map is company-specific, as the risk portfolio varies from one company to another.

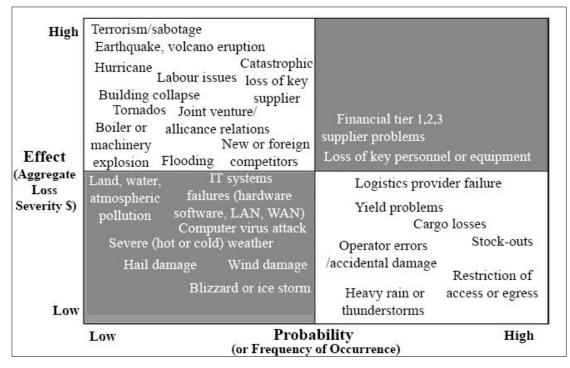


Figure 3.5 Example of a company-specific risk map

Source: (Mieghem, 2011, p. 22)

Different risks carry different weights, depending on the company's strategy and the industry within which it operates. The output of risk analysis is a ranked list of risks, based on the overall score of each risk, which is the combination of impact and probability, as seen in Figure 3.6 below. Risks with the highest scores occupy the upper right quadrant, whereas risks with lowest scores are located the lower left quadrant.

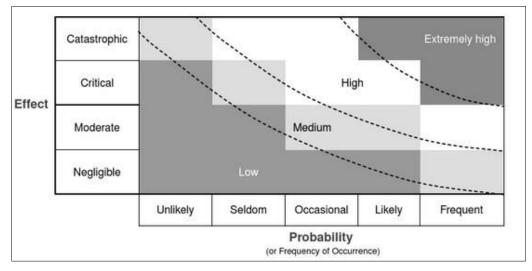


Figure 3.6 Qualitative risk assessment assigns an overall risk level to each identified risk

Source: (Mieghem, 2011, p. 23)

Compared to operational risks (in which it is relatively easier to quantitatively assess the probability/impact values), one should consider that some risks are more difficult to assess, such as political and natural risks (Mieghem, 2011, p. 24).

The second approach is based on quantitative measures, with the aim of providing precise and objective estimates of the likelihood of occurrence of each risk and its consequences (Waters, 2007, p. 128). Risks can be assessed quantitatively by estimating the financial impact and probability of each risk, based on historical data and expert knowledge. The expected impact can be quantified by multiplying the financial impact by the probability of occurrence (Mieghem, 2011, p. 24).

#### <u>Risk-Ranking Matrix</u>

A simple and most applied method for risk analysis is the risk-ranking matrix. The risk-ranking matrix is a table with several categories for likelihood and impact. Each row-column pair (cell) of likelihood and impact is associated with a recommended level of risk, urgency, or priority. Risk levels can be distinguished by red, yellow, and green colors to indicate the relative importance of each risk level as high, medium, and low respectively (Cox Jr, 2008, pp. 497–498).

In order to use this tool to perform a risk analysis, values of likelihood and impact are assigned to each identified risk, so as to give a two-dimensional view. For each identified risk, values of likelihood and impact are multiplied to give a risk score. Once scored, risks are then ranked on the basis of their relative importance. Ranges (weightings) for likelihood and impact can be modified to allow for different spread of risks (CQI, 2010, pp. 55–56).

In Table 3.1 and Table 3.2 below, a score of 1 for Low, 2 for Medium, and 3 for High is used to denote the likelihood and impact for each identified risk. Depending on the situation, more complex levels, with 5 or more, can be used to facilitate finer discrimination.

Potential Risks /	Risk Ar	<b>Risk Evaluation</b>		
hazards (from Risk Identification stage)	Probability	Severity	Score	
Event 1	Low (1)	High (3)	Med (3)	
Event 2	Med (2)	Low (1)	Low (2)	
Event 3	Med (2)	Med (2)	Med (4)	
Event 4	Med (2)	High (3)	High (6)	
Event 5	Low (1)	Low (1)	Low (1)	
Event 6	High (3)	High (3)	High (9)	
Event 7	Low (1)	Low (1)	Low (1)	

#### Table 3.1 Risk Ranking Score Source: (CQI, 2010, p. 56)

Table 3.2 Basic 3x3 Risk Matrix

Source: (CQI, 2010, p. 56)

Te lit	High	3	6	9
probab	Medium	2	4	6
ncreasing probability of an error or failure	Low	1	2	3
of a		Low	Medium	High
	Increasing severity of consequences as a result of an error or failure			

# > Challenges in risk analysis

Carrying out a risk analysis can be challenging for the following reasons:

- Lack of sufficient statistical data to derive the probability distribution of an event. Therefore, values are assigned on the basis of expert opinions, which are subject to the biases arising from individual interpretations.

- Common factors can contribute to more than one risk event and their occurrences can be correlated. Again, deriving such correlations is dependent upon subjective expert inputs.
- The consequences of a risky event are often multifaceted i.e. the impact on supply chain members can materialize in various forms. Hence, accurate assessment of the scope and magnitude of risk event consequences require cross-functional, inter-organizational communication. (Paulson et al., 2011, p. 6).

#### 3.3.4.3 Risk Response

In this step, prevention plans and countermeasures are developed to lower the probability and/or consequences of the highly ranked risk events. The categorization of risks based on their nature will help devise proper mitigation strategies, leading to realistic expectations of what such strategies can really achieve. Mollah et al. (2013, p. 20) states that a balance between benefits, risks, and resources must be achieved.

According to Kahneman and Tversky (1982), external risks are beyond the supply chain members' control; therefore, their proposed mitigation strategies should differ from those proposed to deal with internal risks. For instance, the likelihood that an earthquake will occur cannot be reduced; however, its consequences can be mitigated (e.g. by locating facilities away from risky areas or by strengthening the construction). In contrast, the likelihood of machine failures is largely determined by supply chain members. This reflects the importance of risk categorization in defining the right mitigation strategies (Paulson et al., 2011, pp. 5,6).

The following are the main types of responses that can be used to manage risks within a supply chain:

#### ➢ <u>Risk Acceptance</u>

Managers may choose to accept a given risk if it is insignificant. However, managers may also accept significant risks if these risks are not a major element of their planning problems. Trivial and small risks—with relatively low probability and insignificant consequences—may be ignored, especially if the cost of any remedial action is higher than the risk consequences. As a result, organizations knowingly accept the complete

consequence of the potential risk event. However, risk acceptance must be limited to trivial and very small risks (Waters, 2007, pp. 151,152).

#### Risk Avoidance

According to Jüttner et al. (2003, pp. 200–207), risk avoidance refers to a situation where a company drops a specific product, supplier or geographical market. In other words, the event that triggers the risk is eliminated. In extreme cases, where no other option is feasible, an organization may not be able to handle the severity of the risk, and exits the market.

#### ➢ <u>Risk Mitigation</u>

In this strategy, an organization may choose to mitigate the risk either by reducing the probability that a risk will occur or by reducing the consequences of the risk, because the risk significance is a factor of these two variables. Ideally, managers would reduce both the probability and the consequences of the risk (Waters, 2007, p. 157).

According to Mollah et al. (2013, p. 20), when an organization chooses to reduce risk, it should try to make changes inherent in the design, so that the risks are removed without introducing new risks. This can be achieved by including protective measures or controls. One of the major aspects of mitigations strategies, is creating flexibility to adapt sudden/unexpected events and changes, with least costs and without disturbing the remaining of the system.

#### ➢ <u>Risk Transfer</u>

Organizations may choose to transfer the risk to someone who is willing and able to handle it. The reason for risk transfer is that the cost of risk transfer outweighs the cost of internal management. However, when a risk is transferred, it is neither reduced nor eliminated. Surprisingly, the transferred risk may increase if it is transferred to an organization that is not able to handle it properly. The most common way of risk transfer is insurance (Waters, 2007, p. 157).

These four strategies are, in principle, general, which means that they need to be operationalized and translated into more detailed methods to achieve the desired result of SCRM. To do so, all the possible responses to the risk in question should be listed; then, a reasonable shortlist of responses is considered, and the best response is selected. Generally, the chosen response should achieve the following, as a minimum:

- Allow supply chain flows to continue normally with minimum disruptions.
- Allow efficient allocation of resources.
- Be effective in dealing with risks.
- Comply with rules, laws and regulations.

# 3.3.5 Issues in Supply Chain Risk Management

Despite the benefits of SCRM, little real progress has been made by organizations in this area. Waters (2007, p. 190) suggests that five levels of SCRM exist:

- 1- No risk management.
- 2- Risk management by individual organization working in isolation.
- 3- Joint risk management with immediate partners.
- 4- Integrated risk management along with more of the supply chain.
- 5- Full integration along the whole chain.

Most organizations fall within the first two levels, while Levels 4 and 5 remain a theoretical concept, rather than a practical proposition. Waters (2007, pp. 187–190) identifies the practical problems that represent barriers to more integrated SCRM as follows:

- Lack of training and knowledge of this relatively new concept.
- Unclear responsibilities.
- No satisfactory incentives.
- Unequal benefits to supply chain members.
- Lack of trust and commercial sensitivity.
- The need for considerable resources.
- Limited communication and information sharing.
- Differences in terminologies, working conditions and skills.
- Complexity of decisions.

Clearly, some problems are closely related and linked to each other. For example, the lack of trust and commercial sensitivity may lead to limited information sharing. This reason is often understandable. Spekman and Davis (2004, pp. 423–425) argue that one reason for lack of trust and information sharing is that partners within a supply chain

may take advantage of this trust and start to behave opportunistically. This view inevitably limits the transparency of supply chains, leaving other possible risks unidentified.

# 4. CASE STUDY FINDINGS

This chapter starts by providing a brief overview of the pharmaceutical industry in Egypt. Then, it presents the case company Pharco Pharmaceuticals, along with a description of its supply chain. Finally, the risks identified in Pharco's supply chain will be described.

## 4.1 Overview of Egyptian Pharmaceutical Industry

Egypt has the largest drug manufacturing base in the Middle East and North Africa (MENA) region, with over 120 pharmaceutical companies. In terms of volume, most of the demand for pharmaceuticals is met by the domestic production.

Companies operating within the pharmaceutical industry in Egypt come under three categories: public sector companies, private sector Egyptian companies, and multinational companies.

Pharmaceutical sales consist of generic drugs, over-the-counter (OTC) medicines, and patented drugs. In 2013, pharmaceutical sales totaled EGP 16.55 billion (USD 2.41 billion); it increased to EGP 17.66 billion (USD 2.49 billion) in 2014, which represents +6.7% in local currency terms and +3.4% in US dollar terms (BMI, 2014, p. 8).

The pharmaceuticals market is divided into private sales that are made to local pharmacies (driven by physicians' prescriptions), and sales by public tenders to the Egyptian Ministry of Health (MoH) for supplying government hospitals (Watkins, 2012, p. 52).

#### Key features of the Egyptian pharmaceutical industry include (BMI, 2014, p. 73):

- Egypt is the largest drug producer and consumer in the Middle East and Africa region in terms of volume.
- Over three-quarters of the local market are controlled by the private sector.
- One-third of the pharmaceutical market is controlled by the five largest companies.
- Low labor costs and a large pool of highly trained pharmacists, engineers, and skilled technicians.
- Local production of finished pharmaceuticals represents some 90% of domestic consumption.

- Imports are limited to APIs—raw materials, as well as patented and difficult-to-produce pharmaceuticals.

## 4.2 Company Presentation: Pharco Pharmaceuticals

Pharco is a family-owned corporation that consists of a group of nine healthcare companies operating in the pharmaceutical field in Egypt. Pharco develops, manufactures, markets, distributes and exports a wide array of branded and generic drugs, as well as a number of licensed pharmaceutical products.

Pharco Corporation has over 5,700 employees, and boasts over 345 million units in sales. The corporation is ranked number one in the Egyptian market, with a market share of 13.2 percent in 2011.

<u>Pharco Pharmaceuticals</u> is the founder of Pharco Corporation. The company is the second private Egyptian shareholding pharmaceutical company. It was established in 1984 and started production in 1987. The company formulates, produces and markets around 237 brands, generics, branded generics, and licensed products. Through the years, Pharco Pharmaceuticals has created several brands that have become market leaders in both local and international markets.

Pharco Pharmaceuticals products are exported to some 57 countries around the globe. The company aims at providing highly effective, safe pharmaceutical products to patients at affordable prices. Pharco Pharmaceutical's headquarter is located in Alexandria, Egypt (Pharco, 2014).

## 4.3 Pharco's Supply Chain

The main players in the supply chain include local suppliers, API global suppliers, the manufacturer- Pharco-, authorized drug distributors, pharmacies, hospitals, clinics and patients, as shown in Figure 4.1.

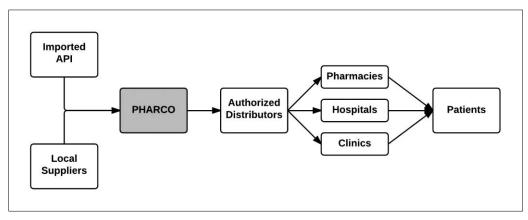


Figure 4.1 Pharco supply chain

#### This supply chain has the following characteristics:

- Many intermediaries: Pharco sells around 237 brands, generics, branded generics and licensed products to over a dozen large authorized distributors as well as many smaller distributors.
- Distributors have large distribution networks that cover the whole country, which in turn sell and distribute drugs to retail pharmacies, clinics and hospitals.
- High level of fragmentation: members of the supply chain operate independently from each other, which reduces the potential for coordinated efforts.
- Loss of drug information as products move downstream, because members of the supply chain use different coding systems, making it impossible for Pharco to track its products to the point of sale. Hence, the full tractability of the process cannot be maintained along the whole supply chain. Moreover, some pharmacies and warehouses still depend on paperwork to record inventory information.
- Products are pushed down the supply chain, and incentives are given to sales force (of manufacturer and distributors) based on their annual sales target. These contribute to an increased stock levels and a higher probability of expiration at the retail level. Additionally, upstream members are reluctant to accept all returns of expired drugs, resulting in expired products remaining at the retail level.

## 4.4 Identification of Supply Chain Risks

Based on the interviews conducted with key senior employees at Pharco, the following seven supply chain risks were identified: risks related to foreign currency and interest rate of loans, regulatory risk, supplier risk, political instability risk, strikes, counterfeit risk, and risk related to a lack of transparency in supply chains.

#### 4.4.1 Risks related to Foreign Currency and Interest Rate of Loans

Pharco's production inputs consist of active pharmaceutical ingredients and inactive ingredients (excipients). Almost all these chemical inputs are imported from global suppliers; therefore, their prices are tied to the exchange rate of foreign currencies and the cost of borrowing through letters of credit.

According to the development sector head at Pharco, there is a significant increase in the prices of imported raw materials as a result of the increased exchange rate of the U.S. dollar against the Egyptian pound in the past two years, as illustrated in Figure 4.2. Therefore, the company's total cost of production is susceptible to currency fluctuations.

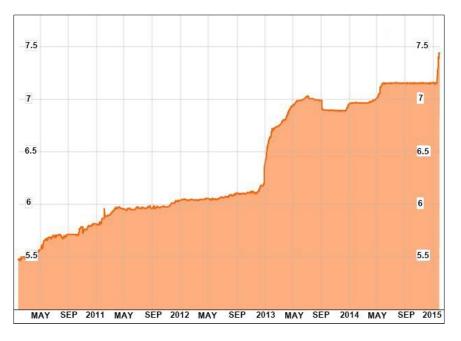


Figure 4.2 Price of 1 USD in EGP Source: (Bloomberg, 2015)

The continuous deterioration in the Egyptian Pound against foreign currencies is affecting the overall cost of production, and subsequently reducing the profit margin of the company.

In 2013, Egypt's credit rating has been downgraded by major credit rating agencies (e.g. Moody's and Standard & Poor's) due to the political unrest. Such movements in credit rating had an impact on interest rate of loans and the exchange rates of foreign currencies.

Global suppliers of API no longer accept credit payments (the norm was a credit period of three to six months). Currently, they are demanding advance payments before shipping, which has resulted in an increased pressure on Pharco because of the difficulties in obtaining sufficient foreign currency (Head of Development Sector, personal communication, February 2, 2015).

The purchasing department at Pharco divides the raw material planning order into scheduled purchase orders of partial shipments. The decision of the quantity purchased depends on a trade-off between current prices of raw materials, currency fluctuations, transportation and inventory costs. Timing is a crucial factor: if the current price is low, the purchase committee will go in for an annual contract with the supplier at a fixed price (Import and Export Manager, personal communication, January 26, 2015).

#### 4.4.2 Regulatory Risk

The pharmaceuticals industry in Egypt is heavily regulated and this tight regulatory environment presents a challenge for Pharco. Strict price controls and drug registration and approval are the most important hurdles.

#### 4.4.2.1 Drug Pricing Regime

Drug pricing regime is one of the biggest threats to Pharco. The Egyptian Ministry of Health is trying to keep drug prices affordable for patients. Previously, this objective was achieved by implementing a "cost-plus" pricing system, under which prices of drugs were determined by the Central Administration of Pharmaceutical Affairs (CAPA)<sup>(1)</sup> based on the costs of raw materials, packaging, distribution, production, tariffs, taxes, and fixed percentages of profit margins for manufacturers, distributors, and pharmacies.

Under this controlled pricing system, retail prices of many drugs remain fixed for over 10 years. In addition, the cost of production (including raw materials and labour costs)

<sup>&</sup>lt;sup>(1)</sup> CAPA is an affiliate of the Egyptian Drug Authority, and it is the final drug pricing decision-maker.

is variable. The increasing variable costs of the cheap drugs, and the continuous devaluation of the Egyptian pound against foreign currencies resulted in considerable losses to the company and shortages in essential drugs. This is mainly due to the relatively low, fixed retail prices which resulted in some drugs cost more than their sale prices.

Despite the introduction of a new international drug referencing system for pricing, the re-evaluation process for drugs that were priced under the old cost-plus system is challenging. Moreover, the Pricing Committee <sup>(2)</sup> evaluates drug prices every three years, and may announce reductions in the prices of the existing drugs, which affect the profitability of the company. In 2012, the prices of five products were reduced by the pricing committee, as shown in Table 4.1.

Product Name	Price before Reduction (EGP)	New Price (EGP)	Change %
Atelol 100mg Tabs	10	8	-20%
Farcodarone50mg/ml Ampoule	20	18	-10%
Eurocox 100mg Tablet	18	16	-11%
Citro-K 1.102g/5ml Syrup	8	7	-12%
V-Gone 50mg Tablet	3	2	-33%

Table 4.1 Price reductions for five products produced by Pharco in 2012 Source: (CAPA, 2015)

The main reason is that the Ministry of Health is reluctant to consider any increase in prices so as to maintain affordability of drugs for patients, which, in turn, affects the company negatively. As a result, issues of pricing policies and the associated regulatory environment are unresolved, which represents a risk for Pharco (Head of Development Sector, personal communication, February 2, 2015).

#### 4.4.2.2 Complex Registration and Drug Approval Processes

The registration process of a new drug is complex and bureaucratic, which makes it difficult for Pharco to register new drugs. The Egyptian Drug Authority—the pharmaceutical regulatory body of the Egyptian MoH for drug registration and approval—has a complex structure, which includes various sub-organizations and

<sup>&</sup>lt;sup>(2)</sup> The Pricing Committee is a part of the Drug Registration Department at CAPA.

committees responsible for drug registration and approval. Head of Development Sector at Pharco indicated that the registration procedures lack transparency and need to be streamlined.

Samples of new proposed drugs have to be submitted by Pharco to the EDA for approval. The drug approval process is lengthy because samples have to be approved not only by the EDA, but also by other drug authorities in mature markets (e.g. U.S. Food and Drug Administration (FDA) (Head of Development Sector, personal communication, February 2, 2015).

#### 4.4.3 Supplier Risk

Pharco produces around 237 finished products, and the company's supplier base consists of over 800 local and global suppliers. For each product, the Bill of Material (BOM) includes some 20 raw materials (active pharmaceutical ingredients and inactive ingredients). The company is much more dependent on its global suppliers than on its local suppliers, because they supply the most important input for production, the active pharmaceutical ingredients.

Within Pharco's supply chain, global suppliers of active pharmaceutical ingredients add most of the value to the entire chain because pharmaceutical products are chosen primarily for their active ingredients.

One problem of global suppliers is the delay in the shipments of active pharmaceutical ingredients. However, quality issues of the raw materials, such as non-conformity problem, pose a greater risk to the company. Samples of the imported raw materials must be subject to laboratory inspections by the Egyptian Ministry of Health before they can be released to the company.

In case of non-conformity, strict procedures are applied to every successive shipment. Sampling and inspection of 100% of shipments is compulsory, until the issuance of five conformity decisions from the National Organization for Drug Control & Research (NODCAR). This process increases the time required to obtain the raw materials and results in delays in production and planning (See **Appendix 2**).

The purchasing department at Pharco considers alternative suppliers when receiving quotations for sourcing active pharmaceutical ingredients. Also, the purchase committee at the company continuously reviews suppliers' past experience to help future purchase decisions (Import and Export Manager, personal communication, January 26, 2015).

#### 4.4.4 Strikes

In 2011, after the January 25 revolution, employees at Pharco demanded an increase in their salaries, incentives and shares of annual profits. Also, members of the temporary staff wanted to be converted into permanent employees. The company's management failed to come to an agreement, which resulted in more than 3,000 workers going on a strike that lasted for over two weeks before the dispute was settled.

In 2013, employees went on a five-week partial strike, which then evolved into an openended strike, after the announcement of a new decision by the Chairman of Board of Directors limiting their share of annual profits. The company was shut and production stopped for over two weeks.

In both 2011 and 2013, strikes led to a halt in sales and production, resulting in a considerable influence on profitability and financial status.

#### 4.4.5 Political Instability

After the January 25 revolution, demonstrations, terror attacks, and government opposition have elevated the political and security instability during the last four years. Since 2011, Egypt has witnessed six different governments with different challenges, ideologies and visions.

The Egyptian Ministry of Health was led by eight ministers during the last four years, which resulted in the issuance of various—and sometimes conflicting—ministerial decrees affecting different aspects of the pharmaceutical companies, particularly those related to pricing. Subsequently, it has affected the company (Quality Assurance Manager, personal communication, February 5, 2015).

#### 4.4.6 Counterfeit Risk

#### 4.4.6.1 Types and nature of counterfeiting activities that face Pharco

Drug counterfeiting is a serious problem that affects Pharco and its supply chain members. Participants highlighted the nature and types of drug counterfeiting activities facing Pharco. They pointed out that counterfeiters deceive customers by passing off their fake products as genuine drugs.

The most common practice of counterfeiting is to imitate packaging, label, name, logo and colors of the genuine drug. In addition, counterfeiters extend their activities to precisely imitate the shape, size and color of the finished pharmaceutical product—e.g. tablets, capsules, vials, etc.—in order to <u>deliberately deceive customers into believing</u> that they are buying a genuine drug. One example is shown in Figure 4.3.



Figure 4.3 Samples of counterfeits along with samples of genuine products Source: (CAPA, 2014c)

Counterfeiters may also re-date an already expired drug or a genuine drug very close to expiration to prolong the approved shelf life and sell it again. Two reasons facilitate such kinds of counterfeiting activity. First, the low cost of obtaining expired and drugs with close-to-expiry dates, and second, it is relatively easy to illegally obtain a large number of genuine, used (empty) packages and packaging equipment at a low cost. The main reason for this problem is the lax control and monitoring of the disposal process, as pointed out by the participants.

Samples of seized counterfeit drugs imitating Pharco's products were chemically analyzed by the NODCAR. The results showed that they contained no active ingredients. Instead, counterfeiters choose to use impure or inactive chemicals, artificial colors, ammonia, and limestone to substitute the more costly active ingredients, which represent a fatal threat to health. One instance of a counterfeit hair treatment drug was replaced by alcohol, which can cause significant harm to patients (Quality Assurance Manager, personal communication, January 12, 2015).

Statistics of the CAPA show that the total number of reported counterfeit cases followed an increasing trend in the last three years. Pharco experienced three incidents of counterfeiting in 2013, and two incidents in 2014, as shown in Table 4.2.

Year	<b>Total Cases Reported</b>	Pharco
2010	18	0
2011 <sup>(3)</sup>	-	-
2012	18	0
2013	22	3
2014	34	2
Total	92	<b>5</b> (5.4%)

Table 4.2 Statistics of counterfeit pharmaceuticals in Egypt

Source (CAPA, 2014a)

The reported cases are: imprecise copies imitating package, label, leaflet, logo, colors, and identifier (barcode, batch number <sup>(4)</sup>, expiry/production date and registration number) of Pharco's genuine drugs. The average price of Pharco's genuine drugs that are copied is EGP 24.

#### 4.4.6.2 How do counterfeits enter Pharco's legitimate supply chain?

Within Pharco's legitimate supply chain, drugs are sold to major authorized distributors who, in turn, sell drugs to pharmacies and hospitals. As mentioned earlier, almost all the raw materials used by Pharco are imported, and counterfeit raw materials cannot enter the legitimate supply chain. Imported materials have to be approved by NODCAR before they can be released to Pharco. Also, further inspections are carried out by the Quality Control department at Pharco to ensure the safety, quality and efficacy of the imported materials before they are processed.

Counterfeit drugs can enter the legitimate supply chain in the form of finished products through unauthorized channels at distribution and retail levels. This occurs when the current measures of controlling counterfeit drugs fail to detect them. The current

<sup>&</sup>lt;sup>(3)</sup> No data is available for 2011.

<sup>&</sup>lt;sup>(4)</sup> The batch number helps to track or identify the production specifications of a medication with respect to its strength, dosage form, and expiration date.

controls are checking products' identifier and random inspections on distributors and pharmacies conducted by CAPA.

Counterfeiting activities take place in clandestine places and are distributed by unauthorized distributors, as illustrated in Figure 4.4. These counterfeit drugs are then sold to pharmacies, which are attracted by discounts, bonuses and the higher profit margins offered by the unauthorized distributors. This practice is illegal as drugs are sold without invoices. Unfortunately, some pharmacists and sub-distributors engage in this criminal activity, which increases the vulnerability of the supply chain.

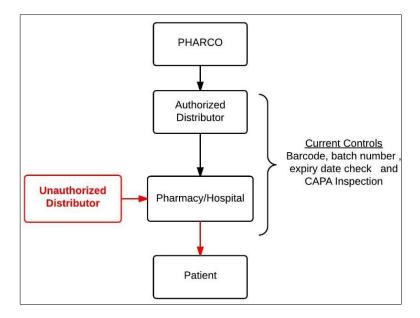


Figure 4.4 Potential infiltrations of counterfeits into Pharco's downstream supply chain

Another way of infiltrating the legitimate supply chain occurs when products are returned from downstream members. Counterfeits can enter the legitimate supply chain if distributors fail to identify whether the returned drugs are genuine or not, as illustrated in Figure 4.5 (Sales Manager, personal communication, January 5, 2015).

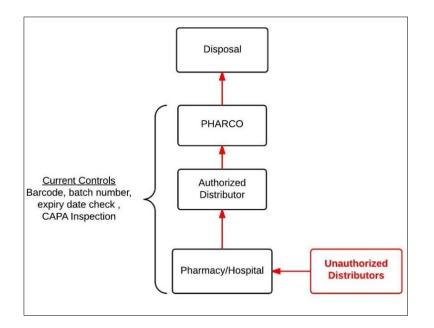


Figure 4.5 Potential infiltrations of counterfeits into Pharco's upstream supply chain

#### 4.4.7 Lack of Supply Chain Transparency

Pharco operates in a lengthy, complex supply chain. Products are sold to over 33,000 pharmacies, apart from hospitals and clinics (BMI, 2014, p. 83). In addition, Pharco's information system is not linked to those of its supply chain members.

Pharco's supply chain is highly fragmented. Each member within the supply chain uses different, incompatible information systems, and some do not utilize any information system at all. At Pharco, one aspect of the lack of supply chain transparency is the distorted picture of the location of inventories in the network. This limits the stock visibility, and makes it impossible to accurately recall or trace products as they reach their final destinations.

In addition, problems related to the expired products are magnified due to the loss of product information as it goes through the network (Sales Manager, personal communication, January 5, 2015).

The identified risks are summarized in the cause-effect diagram (fishbone diagram), as shown in Figure 4.6.

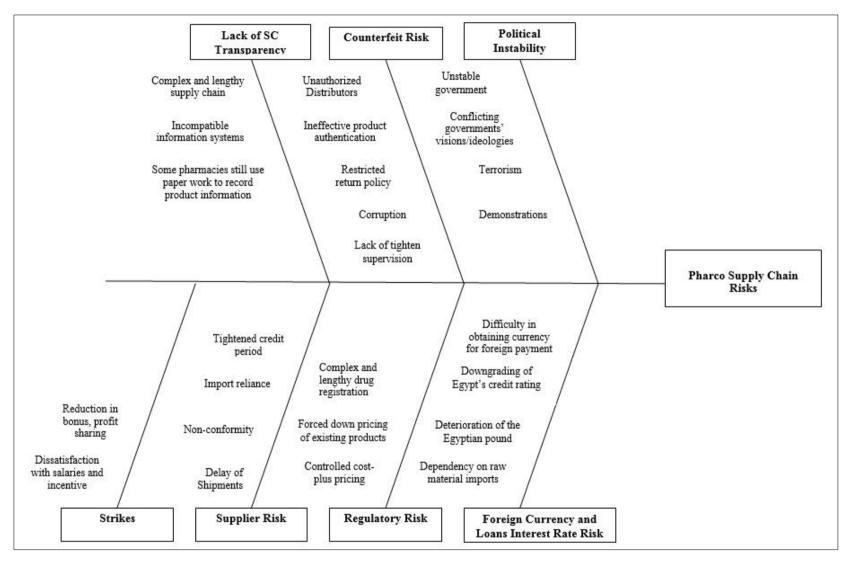


Figure 4.6 Cause-effect diagram of supply chain risks at Pharco

# 5. ANALYSIS, DISCUSSION AND RECOMMENDATIONS

This chapter begins by ranking and categorizing the identified supply chain risks. The risk management strategies utilized by Pharco will then be discussed in the light of the relevant body of literature. Finally, recommendations to improve the management of supply chain risks will be provided.

## 5.1 Analysis and Evaluation of Supply Chain Risks

Having identified the risks, the next step is to evaluate each risk by assigning estimates for the impact of each risk and for the likelihood of its occurrence. For this purpose, a risk-ranking matrix was utilized. The identified risks were assessed by the four managers at Pharco, who were previously interviewed. The risk analysis was based on the scoring key shown below in Table 5.1 for impact and likelihood of occurrence. Then, the risks were ranked on the basis of the overall score of each risk, which is the multiplication of impact and likelihood of occurrence, as shown in Table 5.2.

]	mpact		Likelihood of Occurrence					
			Low (1) Medium (2) High (3)					
Insig	nificant (1)		1 2 3					3
M	linor (2)		2 4 6					
Мо	derate (3)		3 6 9					
N	lajor (4)		4 8 12					
Cata	strophic (5)		5 10 15					5
Low	Medium	Hi	gh					
1–3	4–6	7–	15					

Table 5.1	Risk	rating	matrix	scoring	key
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Table 5.2 Supply chain risks at Pharco, rank-wise

Identified Potential Risks	R	isk Analysis	Risk Factor	
Identified I otential KISKS	Impact	Likelihood	Score	
Foreign Currency and Loans'	4	3	12	
Interest Rate Risks				
Regulatory Risk	3	3	9	
Political Instability Risk	3	3	9	
Counterfeit Risk	3	2	6	
Lack of SC Transparency Risk	2	3	6	
Supplier Risk	2	2	4	
Strikes	4	1	4	

## 5.2 Categorizing the Identified Risks

Waters (2007, p. 104) highlights the importance of the risk categorization because it reflects the appropriate type of response required. According to Kahneman & Tversky (1982), lack of knowledge and ignorance may cause *internal risks*. This means that particular information needed is available somewhere, but the decision-maker does not know it. Internal risks can be reduced or even eliminated by updating knowledge and information.

On the other hand, *external risks* are those over which the decision-maker has no control. These risks cannot be eliminated, but the consequences can be reduced by, for example, creating flexibility in the supply chain to quickly adapt unforeseen events.

The risks identified in Pharco supply chain are categorized into internal and external risks, as seen in Figure 5.1.

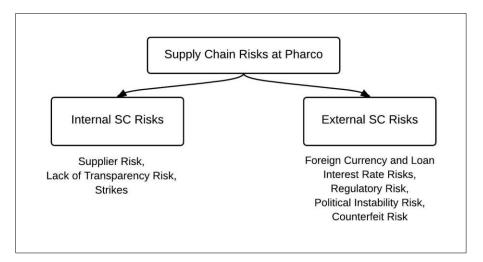


Figure 5.1 Categorization of supply chain risks at Pharco

Risks related to foreign currency and the interest rate of loans, political instability and regulatory risks are the highest ranked risks at Pharco. All these highly ranked risks come within the category of external risks, which means that Pharco's supply chain cannot eliminate them. The next section discusses how Pharco deals with the identified risks.

## 5.3 Managing External Risks at Pharco Supply Chain

#### 5.3.1 Risks related to Foreign Currency and Interest Rate of Loans

The purchasing department at Pharco follows a flexible approach to mitigate these risks, by utilizing two buying strategies to <u>reduce the consequences</u> of price changes in the active

pharmaceutical ingredients as a result of foreign currency fluctuations and changes in interest rate of loans.

The first is a *hand-to-mouth* buying strategy, which enables Pharco to reduce the risk of price change -through the purchase of many smaller shipments- in case of high price uncertainty. In this strategy, decisions are updated after the purchase of each small shipment. Then, the next decision is made when more information becomes available for the company, and when market conditions make it feasible to do so.

Moreover, this strategy helps Pharco economize on the required foreign currency to purchase the active pharmaceutical ingredients in case of difficulties in obtaining enough foreign cash. As mentioned in Section 4.4.1, API suppliers currently demand immediate payments, which result in pressure on the required foreign cash flow; thus, hand-to-mouth strategy helps the company alleviate this problem.

The second strategy is *forward buying*, which enables Pharco to take advantage of the situation and save money by going in for longer contracts when prices are relatively low and, hence, reduce the risk of exchange rates moving unfavorably.

According to Handfield (2008, p. 3), in today's turbulent business environment, up or down price changes in raw materials (e.g. due to foreign exchange rate fluctuations) are rapid and can have significant effects on business. Defining the most appropriate purchase strategy is critical for organizations who face this challenge.

Handfield (2008, p. 3) suggests that if the prices are expected to go up, organizations may utilize one of the common strategies (e.g. *forward buying* and *hedging*) to stockpile raw materials in order to reduce cost (buy in larger-than-normal quantities and store these for future use).

Contrariwise, when prices are expected to fall down, organizations may choose to utilize a hand-to-mouth buying strategy. In this strategy, frequent purchases of smaller quantities help organizations save money and reduce risk. Organizations may also adopt a hand-to-mouth strategy to secure its foreign cash flow in case of cash flow constraints (Sollish & Semanik, 2005, p. 309).

#### 5.3.2 Regulatory Risk

The drug registration process in the Egyptian Ministry of Health is *convoluted* and *overly bureaucratic*. Until recently, it could take up to three to five years to register a new drug in Egypt. Moreover, the pharmaceutical sector in Egypt is one of the few sectors that operate under strict price controls. The risk of possible downward pricing spiral is evident as CAPA -the final drug pricing decision-maker- continues to announce decreases in the price of many drugs (including Pharco's products), which directly affect the profitability of the pharmaceutical companies (BMI, 2014, pp. 66–69).

Pharco <u>accepts the risk</u> of downward pricing of its drugs for two reasons. First, the company continues to produce drugs which were down priced as long as their losses are offset by those drugs which make higher profits. Second, Pharco's social responsibility towards patients contributes to the acceptance of this risk, even though it might not be economically feasible for some drugs, as indicated by the interviewees.

A number of studies have indicated that regulatory risk (e.g. problems caused by new or existing regulations) is one of the major risks affecting the pharmaceutical supply chain (Enyinda, Mba, Manu, & Adase, 2009, p. 538; Kamath, Kamath, Azaruddin, & Subrahmanyam, 2012, p. 284). In 2009, a global survey of executives in the pharmaceutical industry was conducted, and results showed that pharmaceutical companies perceive the regulatory risk to be one of the biggest threats to their business (KPMG, 2009, p. 4).

#### 5.3.3 Political Instability Risk

Instabilities of political, security and economic situations are critical to supply chains (Handfield, 2008, p. 15). The current and potential political instability in Egypt expose supply chains to an increasing political risk (Banham, 2014, p. 24). According to BMI (2014, p. 9), the political upheaval in Egypt is affecting businesses and increasing risks in the short and long terms.

A country risk report produced by AMB (2014) (See **Appendix 3**) indicates that Egypt's political risk is considered a very high risk, compared to the world average, as seen from the radar chart in Figure 5.2. In this report, political risk is assessed on the basis of the scores for nine different aspects scored on a scale of one to five, with one being the least amount of risk and five being the highest amount of risk.

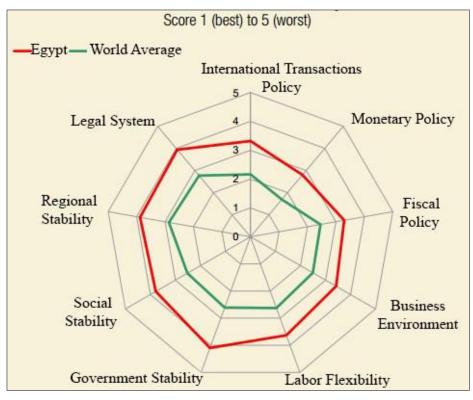


Figure 5.2 Egypt's political risk summary Source: (AMB, 2014, p. 3)

One aspect of the political risk is government stability, which measures the extent to which a government is stable (AMB, 2014, p. 4). This aspect has the highest risk score of 4 out of 5, compared to the world average of a slightly more than 2.5. This score indicates a high level of government instability.

Since 2011, the Egyptian Ministry of Health has been led by eight ministers with various ideologies and visions. This has resulted in various amendments related to the pricing regime. More importantly, these changes in the pricing system are negatively affecting local drug manufacturers, such as Pharco (BMI, 2014, p. 71).

Interestingly, initial interpretations of the highly ranked risks at Pharco suggest that there may be links between them. In other words, these risks appear to be interrelated and may have effects on each other, as seen in Figure 5.3. A possible explanation for this is given in the section that follows.

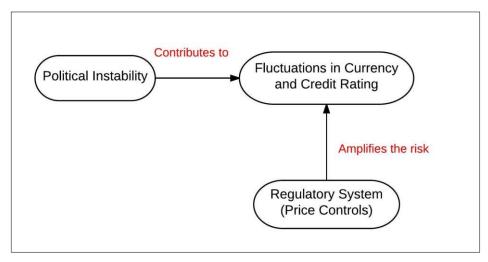


Figure 5.3 Potential interactions between supply chain risks at Pharco

Since Egypt's economic situation is intrinsically linked to its political one, the political unrest will have an effect on the country's economic situation, and therefore, may cause fluctuations in the local currency and the country's credit rating. As a result, the prices of imported active pharmaceutical ingredients would be directly affected.

Regulatory risk—through strict price controls—interacts with the currency fluctuation risk and acts as an amplifier for it. When the prices of active pharmaceutical ingredients increase due to currency fluctuations, Pharco takes the whole risk, and faces higher costs because of the fixed retail prices and the increased variable cost.

In other words, the cost increase due to changes in the price of active pharmaceutical ingredients cannot be passed to, or shared with, other members in Pharco's supply chain. As a result, the company bears the whole risk of the cost increase. The reason is that profit margins of both distributors and pharmacies are determined by law, as fixed percentages <sup>(5)</sup> of the retail price. Moreover, retail prices are fixed, and cannot be changed without negotiations with the relevant governmental body, which are complex and bureaucratic.

Faisal (2009, pp. 42,43) highlighted the importance of understanding interactions between risks. The reason is that examining risk factors in isolation may lead an organization to either overestimate or underestimate its risk exposure. Also, Chopra and Sodhi (2004, p. 53) state that by understanding the interconnectedness of supply chain risks, managers will

<sup>&</sup>lt;sup>(5)</sup> For detailed information about pricing, the reader is referred to *Pricing Ministerial Decree No.* 499/2012, <u>http://www.eda.mohealth.gov.eg/Articles.aspx?id=26</u> (Last accessed April 25, 2015)

be able to ensure balanced and effective risk-reduction strategies that are tailor-made for their companies.

#### 5.3.4 Counterfeit Risk

The continued presence of counterfeit medicines is considered to be one of the significant challenges that confront pharmaceutical companies operating in the Egyptian market (BMI, 2014, p. 68).

Based on CAPA statistics related to counterfeits and the interviews conducted at Pharco, the counterfeiting activities facing Pharco are completely fraudulent products which contain entirely different contents and with packaging that look somewhat similar to the genuine drugs.

These imprecise copies of Pharco's genuine medicine can be detected when entering the legitimate supply chain by checking the product identifier (barcode, batch number, expiry/production date and registration number). However, the company does not apply specific controls dedicated toward mitigating the risk of counterfeit medicines, as all the counterfeit cases were detected and seized through random inspections conducted by CAPA.

Surprisingly, Pharco has <u>no clearly defined strategy</u> to manage counterfeit, regulatory, and political risks. This implies that the company follows <u>a risk acceptance strategy</u> with respect to these three risks. This contradicts Waters' (2007, pp. 151,152) suggestion that the risk acceptance strategy must be limited to only trivial and very small risks. A possible explanation might be that these risks are perceived to be outside the control of decision-makers, and so are neglected.

## 5.4 Managing Internal Risks at Pharco Supply Chain

#### 5.4.1 Lack of Supply Chain Transparency

The lack of supply chain transparency is evident at Pharco. The company's lengthy and complex supply chain limits the accessibility to high-quality information. The absence of a uniform information system and the use of paperwork to record product information at the retail level are the main reasons for such a lack of supply chain transparency. No strategy was applied to mitigate this risk at Pharco's supply chain.

Lack of supply chain transparency and hesitancy in sharing accurate and timely information with supply chain partners contribute to the supply chain's inability to perform as intended (Spekman & Davis, 2004, p. 420).

Moreover, in most cases, organizations are not able to recognize the actual sources of risks without transparency because it is assumed that the majority of risks is invisible to them (Kersten, Boger, Hohrath, & Spath, 2006, p. 11).

#### 5.4.2 Supplier Risk

Within Pharco's supply chain, global suppliers of active pharmaceutical ingredients add most of the value to the entire chain, because drugs are chosen primarily for their active ingredients. APIs are the most important input for production at Pharco, because they are the main component of the drugs, and they represent a large share of the cost price.

Pharco utilizes two strategies to <u>reduce the risk</u> that arises from its APIs global suppliers. The first strategy is a *multiple sourcing* strategy, when receiving quotations for sourcing active pharmaceutical ingredients. This enables the company to secure the supply of inputs in cases of delay or non-conformity. In other words, Pharco utilizes this strategy to <u>reduce</u> the consequences of supplier risk through the increased flexibility, by having alternative sources.

The second strategy is *vendor (supplier) rating*. Pharco continuously reviews its API suppliers' past experiences to help in future purchase decisions. This is important for Pharco to identify the critical factors in suppliers' performance as well as their relative importance and, subsequently, avoid potential risks arising from suppliers. Thus, this strategy reduces the likelihood of supplier risk.

For most organizations, suppliers represent a major source of risk (Waters, 2007, p. 163). According to Silbermayr and Minner (2014, p. 37) and Tang (2006, p. 35), sourcing from multiple suppliers is the most common approach to deal with and reduce supplier risk. Costantino and Pellegrino (2010, pp. 27,28) also summarized the advantages of adopting a multiple sourcing strategy in a risky environment. Typical advantages include: securing alternative sources in case of delivery problems, reduced probability of bottlenecks due to insufficient production capacity to meet peak demand, and more flexibility to deal with unexpected events that could endanger supplier's capacity.

According to Waters (2007, p. 163), one way to reduce supplier risk is to utilize vendor rating. Vendor (supplier) rating is a general term for seeing how well a supplier matches the requirements of its customer. Vendor rating helps organizations evaluate potential suppliers and choose the one that gives the least level of risk.

#### 5.5 Recommendations for Pharco

#### 5.5.1 Potential Approaches to Improve the Management of Industry-wide Risks

Like Pharco, other local drug manufacturers in Egypt are operating within the same regulatory environment, which is mainly characterized by a strict pricing regime. Also, they import around 85 percent of their main raw materials—APIs—because of their limited capacity to produce these (BMI, 2014, pp. 29,33). Therefore, some of the risks identified at Pharco appear to be industry-wide risks—in particular, those related to the regulatory environment and changes in the prices of imported APIs. Industry-wide risks affect organizations within the same industry, leaving them in the same boat (though the degree of their exposure to risks may vary). As a result, there should be cooperation between organizations, even between competitors, enabling them to work together to overcome risks in their mutual interests. Accordingly, with respect to industry-wide risks, recommendations for Pharco will be partly based on this cooperative approach.

#### 5.5.1.1 Consortium Purchasing

Regarding the risk of price increases in the imported APIs, *consortium purchasing* could be advantageous to Pharco in mitigating this risk. Consortium purchasing<sup>(6)</sup> can be defined as *the cooperation between two or more organizations in a purchasing group in one or more steps of the purchasing process in order to achieve various benefits* (Schotanus & Telgen, 2007, p. 53; Tella & Virolainen, 2005, p. 162).

Nollet and Beaulieu (2003, p. 9) state that consortium purchasing should expand tremendously in circumstances where the marketplace forces organizations, which are normally competitors, to put together some of their purchasing activities.

<sup>&</sup>lt;sup>(6)</sup> In the literature, various terms are used to refer to this concept, such as: horizontal cooperative purchasing, group purchasing, pooled purchasing, alliance purchasing, collaborative purchasing, collective purchasing, joint purchasing, shared purchasing, bundled purchasing, etc.

In addition to other advantages, typical advantages of consortium purchasing include reduction in supply risks, lower purchasing prices, lower transaction costs, and reduction in logistics costs. Chae and Heidhues (2004, pp. 1,2) also explained how an organization can gain advantages by engaging in consortium purchasing. They pointed out that members of a consortium purchasing would be risking only part of their business. Stated differently, consortium purchasing facilitates *risk sharing* between its members.

The implementation of this strategy would entail a high level of cooperation and collaboration between Pharco and its potential partners (other local manufacturers) to better understand factors that play important roles in the success or failure of consortium purchasing. In addition, careful assessment of the associated costs, risks and benefits—as well as the choice of a suitable organizational form—is crucial if Pharco is willing to consider this strategy.

#### 5.5.1.2 Joint Pressure Group

According to Waters (2007, p. 157), instead of accepting risks that are outside the supply chain members' control—such as regulatory risk—an organization, usually through *joint pressure group*, may try to oppose a change by resisting it and try to prevent it from happening. Pressure groups seeks to influence people who have power to make decisions, e.g. policy makers or legislators. This can be achieved by campaigns or lobbying, as managers may utilize these to influence political or regulatory climate affecting their organizations.

This could be a possible strategy for Pharco and other local manufacturers by working together to reduce the regulatory risk posed by the strict pricing regime and forced reductions of drug prices.

Currently, the Egyptian Ministry of Health is proposing further amendments to the current pricing regime with the main goal of "keeping prices affordable for patients," and has subsequently increased uncertainties for drug manufacturers with respect to the potential new pricing regime (Faten, 2015).

It is important for Pharco to carefully assess the chance of success of engaging in such oppositions (if a pressure group decided to do so), as it depends on many factors, including their relative power and other socio-economic aspects. If the probability of success is low, then Pharco should better save its time and resources by spending them in adjustment to the new situation.

#### 5.5.2 Taking a More Proactive Approach toward Managing Risks

Christopher (2003, p. 18) states that socio-political disruptions—such as regulatory changes, protests or strikes—rarely occur without warning. He also suggests that routine scanning of the business environment should enable the identification of threats of this kind.

Lee (2004, p. 6) highlights the importance of developing a team that knows how to invoke backup plans so as to tackle crises with contingency plans. A contingency plan serves as a blueprint for a timely and complete response to a specific risk(s). Organizations which are linked via complex supply chain networks should develop contingency plans in order to minimize the potential negative impacts of disruption on their supply chain performance levels (Skipper, Hanna, & Cegielski, 2009, pp. 40,42).

According to ManMohan S. Sodhi and Tang (2009, p. 36), the advance development of contingency plans for different types of disruptions would certainly reduce the consequences of risks by identifying and implementing actions/strategies beforehand.

Craighead, Blackhurst, Rungtusanatham, and Handfield (2007, pp. 146,147) suggest that one possible capability for mitigating supply chain risks is the *Warning Capability*. It refers to interactions and coordination of supply chain resources to detect pending or realized risk(s), and subsequently, disseminate relevant information to supply chain members. The quicker a supply chain risk is detected, and the quicker pertinent information about it is disseminated, the more time a supply chain would have to prepare itself for dealing with the negative effects of the risk, and the less severe it would likely be.

Socio-political disruptions have become frequent during the past four years in Egypt, which increases the potential negative impact on companies. A recent study by Elzarka (2013) concluded that Egyptian companies from various business sectors have a low degree of preparedness to deal with supply chain risks. This was demonstrated by their reactive actions to recover from the recent socio-political disruptions, since they did not have previous plans to mitigate risks. The study also recommends that Egyptian companies should follow a more proactive approach in managing their supply chain risks.

Therefore, Pharco—in cooperation with its key supply chain members—should <u>draw up</u> <u>contingency plans and develop a crisis management team</u> to deal with such events. This team should continuously *identify*, *measure*, and *evaluate* disturbances within the operating environment. Gathering and analyzing the relevant data, for example, about the socio-political situation in Egypt will facilitate the discovery of relationship and patterns that would help identify potential disruptions in advance.

Regarding the political disruptions, it is also recommended that Pharco should <u>consult</u> <u>experts from the field of political science</u>, and more preferably, involve them in the process of identifying and analyzing such kind of events. Elzarka (2013, p. 489) suggests that experts from political science field would provide valuable insights for Egyptian companies into the local and international political situation, which are not possessed by business experts.

On the basis of that, it would be possible be project probable future scenarios and develop proper plans for different situations, enabling the company and its supply chain members to be well prepared to deal with the potential risks.

Doing so will only be possible if Pharco has some degree of flexibility in its processes to deal with different threats. Also, having well trained managers and employees with the appropriate set of tools and techniques, which enable them to develop the right contingency plans, is crucial for this strategy. In addition, roles and responsibilities of supply chain members must be agreed upon, implying higher levels of coordination and collaboration. Contingency plans are not free, and all their associated costs need to be justified by the decision-maker.

#### 5.5.3 The Need for Improved Supply Chain Transparency

Internal risks arise because relevant information about the supply chain cannot be obtained. While every single member has better information about itself, risks arise due to a lack of relevant information about other members in the supply chain. In order to reduce risks, supply chain members should obtain more information from other key members (Yu, Hong, & Cheng, 2001, p. 115).

Supply chain transparency means that important information is captured, analyzed and readily available to help supply chain partners in making decisions, <u>mitigating risk</u>, and

improving processes. Consequently, supply chain transparency brings benefits to risk management (Caridi, Moretto, Perego, & Tumino, 2014, pp. 1–3).

Lack of transparency weakens supply chain partners, by letting them make decisions without having detailed knowledge of what is happening in the rest of the supply chain, and subsequently it represents a risk for the supply chain (Jain & Benyoucef, 2008, p. 471).

As indicated by the interviewees, Pharco currently has a rather low level of transparency with respect to its supply chain. The achievement of a high level of supply chain transparency at Pharco depends on the close collaboration with its key partners, upstream and downstream. This necessitates, as a prerequisite, <u>greater communication and information sharing</u> between Pharco's key supply chain partners.

One aspect of supply chain transparency is to have a clear picture of the locations of inventories in the network. This will enable a timely and effective response when a disruption does occur, because information provides higher levels of visibility and greater flexibility in planning. As a result, a company would know which materials to reroute, which production resources to redeploy, how to adjust capacities, and how to revise production plans (Chad, Autry & Sanders, 2011, p. 316).

<u>On the upstream side</u>, Pharco can reduce supplier risk through improved transparency by increasing the level of communication and information sharing with its key global suppliers to enable signaling alerts of potential disruptions (e.g. delays in the raw material flow).

In case of deviations in the supplies of raw materials (particularly of active pharmaceutical ingredients), Pharco has to be informed by its suppliers or other relevant parties (e.g. 3PL). Depending on the type of deviation, Pharco should collaboratively make responsive corrective actions through a pre-defined contingency plan. One example that shows how information sharing can help mitigate risks form suppliers is given below.

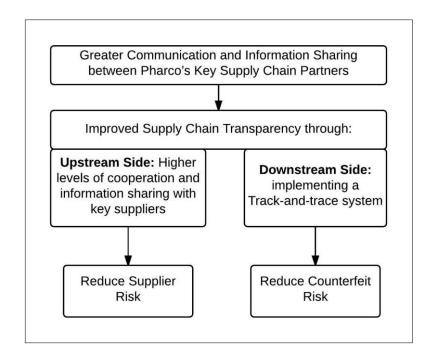
A major pharmaceutical company has deployed an information system for transportation. This system tracks the departure and arrival times of shipments through high-risk distribution channels. In case the average "*planned*" time is exceeded by a certain parameter, a "*trigger*" is sent to the company. Such a trigger alerts the management to take action to mitigate the impact of the disruption as quickly as possible (Handfield, Blackhurst, Elkins, & Craighead, 2008, p. 43).

<u>On the downstream side</u>, implementing a track-and-trace system will allow Pharco to know where the products are at a timely manner, and follow them forward through the distribution chain. Other supply chain members (e.g. distributors and pharmacies) will be able to trace and verify past locations of products. This improved transparency will help reduce the risk of counterfeit drugs.

Track-and-trace technologies are considered an important component for reducing the risk of counterfeits (OECD, 2008, p. 367). Track-and-trace systems use serialization to assign a unique identifier to products. As a result, unauthorized products cannot be accounted for throughout the supply chain, and will be treated and removed from the market.

A number of technologies can be used to store the unique identifier of the product, such as barcodes, electronic product code, Radio Frequency Identification (RFID), or long-digit serial number (Gostin & Buckley, 2013, p. 183).

Given the numerous technologies, each with different characteristics and advantages, the adoption of any given technology is complex. This decision involves issues, amongst others, of cost, compatibility, feasibility, and reliability (OECD, 2008, p. 367). Gostin and Buckley (2013, pp. 183–189) provide a detailed examination of different track-and-trace systems used in the pharmaceutical industry.



The potential benefits of improved transparency are illustrated in Figure 5.4.

Figure 5.4 Potential benefits of improved transparency in Pharco's supply chain

#### 5.5.4 Considerations for Adopting the Recommended Approaches

Obviously, the given recommendations are general approaches that could be beneficial to the company in managing risks. However, with so many strategies available to operationalize them, Pharco must determine how to adapt these general approaches to its particular circumstances. Generally, any decision to implement a particular strategy should be made in the light of the following considerations:

#### Costs versus benefits

Having defined the potential strategies (alternatives) to be considered, Pharco must conduct a *cost-benefit analysis* to help appraise the value of each strategy in improving the management of supply chain risks. The basic rationale of cost-benefit analysis lies in the idea that things are worth doing if the benefits that result from doing them outweigh their costs (Sen, 2000, p. 934). In addition, each of the choice of an alternative must be considered in relation to other potential alternatives, because one alternative might exclude others.

Essentially, each strategy must be evaluated on the basis of: (1) the <u>positive effects</u> (benefits) on a particular risk(s), and (2) the <u>negative effects</u> (expected total costs). For example, if Pharco considers a specific track-and-trace system to be implemented—to reduce the risk of counterfeit and improve transparency—the benefits of this system must outweigh its costs in order to justify the decision-maker's selection of this particular system.

Conceptually, the given recommendations would enhance the management of supply chain risks at Pharco, which would eventually lead to a better competitive position of the company and its supply chain, especially if competitors are exposed to the same set of supply chain risks. However, it is difficult to quantify the value of improved competitiveness, so the company needs to carefully assess the outcomes of each potential strategy.

In addition, all the recommended approaches require some resources in terms of investment and people because preparing for risks has always some early extra costs and potentially uncertain outcomes. Therefore, if a given risk never materializes, it becomes very difficult to justify the time and cost spent on developing and implementing the associated strategy (Zsidisin, Panelli, & Upton, 2000, p. 196). Thus, some approaches—

such as being more proactive by developing contingency plans—can be viewed as *"insurance premiums."* Because it is more difficult to evaluate their returns, if risks never materialize, especially when reliable data for probability that a risk would occur and its impact are lacking (ManMohan S Sodhi & Tang, 2012, p. 106).

It is worth noting that it is not always possible to obtain good estimates for the probability of occurrence of a given risk, and accurately measure its potential impact. As a result, it becomes difficult to evaluate the total costs of such events occurring against the benefits realized from having strategies in place to deal with them (Dani, 2009, p. 58). This is especially true with respect to risks, such as political instability and regulatory changes.

#### ➢ <u>Strategic fit</u>

The recommended approaches will not be very effective if they do not fit the company's overall business strategy. *Strategic fit* means that both supply chain strategies and company's business strategy have aligned (consistent) goals (Chopra & Meindl, 2007, p. 24). Thus, any potential strategy to manage supply chain risks must fit Pharco's business strategy to form a coordinated overall strategy. To clarify this, let us consider the simplified example in the section that follows.

Currently, Pharco maintains a large number of suppliers of APIs within its supply base to secure its supplies of APIs. Consider, for example, that the company decides to invest in a new joint information system with its global suppliers to improve transparency and mitigate the impact of disruptions in the supply of APIs. This requires Pharco to rationalize its supply base (i.e. reduce the number of suppliers of a particular type of APIs), since it is costly to develop a higher level of collaboration (strategic relationship) with many suppliers; otherwise, such strategy would seem to be an inconsistent strategy.

This example indicates the importance of a strategic fit when assessing potential strategies to manage supply chain risks. Lack of strategic fit results in conflicts arising within the firm or across the supply chain, leading to suboptimal supply chain performance. The main reason is that different functions within the company—and different members within the supply chain—may be targeting different, inconsistent goals (Chopra & Meindl, 2007, p. 25).

# 6. CONCLUSION AND FURTHER RESEARCH

This chapter concludes with answers to the research questions by summarizing the research findings. Thereafter, it provides suggestions for potential further research.

## 6.1 Conclusion

The recent economic, social, and political events that have occurred in Egypt have exposed the pharmaceutical supply chain to higher levels of uncertainties and vulnerabilities. These make it extremely difficult to ignore the importance of supply chain risk management.

Owing to the importance of the manufacturer's performance in the pharmaceutical supply chain, <u>this research sought to answer the following questions from the perspective of an Egyptian pharmaceutical manufacturer, Pharco:</u>

**Research Question 1**: What are the most significant supply chain risks to Pharco?

The research has identified seven types of risks, which were categorized into external and internal supply chain risks. Then, the identified risks were ranked using a risk-ranking matrix.

Risks related to foreign currency and interest rate of loans, regulatory risk, and political instability risk were ranked high risks. On the other hand, counterfeit risk, lack of SC transparency risk, supplier risk and strikes were ranked medium risks.

This finding indicates that external risks were perceived to be more significant than internal risks. The research has also provided an explanation of possible interactions between the identified risks, which enhances Pharco's understanding of the interconnectedness of its supply chain risks. The understanding of risk interactions is of key importance because it offers valuable insights for Pharco to devise tailor-made, balanced and effective risk-reduction strategies.

#### - Research Question 2: How does Pharco manage its supply chain risks?

The research has described the strategies applied by the company to deal with its supply chain risks. *Hand-to-mouth* and *forward buying* strategies are utilized to reduce the risk of currency fluctuations and interest rate of loans. *Multiple sourcing* and *vendor rating* are also used to deal with supplier-related risks.

However, these strategies do not reflect the importance of a joint risk management approach, since they are only used by the focal company in isolation of other supply chain members. An implication of this is the poor level of awareness with respect to the importance of SCRM at Pharco.

Another important finding to emerge from this research is that despite the significance of regulatory and political instability risks, no clear strategy was utilized by Pharco to deal with them.

These findings seem to be consistent with those of Elzarka (2013), who concluded that SCRM awareness is still poor among a sample of Egyptian companies from various business sectors. She also reported that the companies that were studied were not prepared to deal with socio-political disruptions, as evidenced by the lack of dedicated risk management strategies.

# - **Research Question 3**: How can Pharco improve its management of supply chain risks?

Based on the findings of the previous two research questions, recommendations were made to improve the management of supply chain risks at Pharco. The recommended approaches were mainly centered on the concept of cooperation, not only between supply chain members, but also between potential Egyptian pharmaceutical manufacturers, enabling them to work together to overcome risks in their mutual interests.

Costs-versus-benefits and strategic fit were highlighted as key considerations for operationalizing any of the recommended approaches. The research findings are briefly summarized in Table 6.1.

Identified SC Risks		Ranking/ EvaluationCurrentStrategies Utilized by Pharco		Recommended Approach to Improve the Management of SC Risks	
	Risk related to Foreign Currency and Loans' Interest Rate	High (12)	-Hand-to-mouth buying -Forward buying	-Utilize Consortium Purchasing	
	Regulatory Risk	High ( <b>9</b> )	-	-Create Power through Joint Pressure Group	
External SC Risks	Political Instability Risk	High ( <b>9</b> )	-	-Develop Contingency Plans and Crisis Management Team -Consult Experts from Political Science Field for Risk Analysis	
	Counterfeit Risk	Medium (6)	-	Invest in Track-and-Trace System	
Internal SC Risks	Lack of SC Transparency Risk	Medium (6)	-	Improve SC Transparency through Greater Communication and Information Sharing -New information technology system, that enable real-time information for each part in the SC	
	Supplier Risk	Medium (4)	- Multiple Sourcing - Vendor Rating	Develop Higher levels of Cooperation and Information Sharing with Key Suppliers of APIs	
	Strikes	Medium (4)	-	Develop Contingency Plans and Crises Management Team	

Table 6.1 Summary of research findings

## 6.2 Suggestions for Further Research

It is recommended that further research be undertaken in the following areas:

- Targeting a large sample of companies could usefully identify potential variations among the Egyptian pharmaceutical companies in terms of their exposure to and preparedness to deal with supply chain risks. Also, a typology of risks in the pharmaceutical supply chain can be developed, which further enhances the understanding of the prevailing risks and enable the development of appropriate risk mitigation strategies for supply chains.

- It would be also interesting to compare experiences of local pharmaceutical manufacturers with those of multinationals operating in Egypt. A close examination of risk management strategies is desirable to extend the knowledge of the Egyptian companies, enabling them to learn and improve their management approaches.

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# **Appendix 1—Interview Protocol**

## **INTERVIEW QUESTIONS**

- General information (name, department, experience, roles)
- Can you give a description of your company's supply chain?
- What are the supply chain problems that you face as a pharmaceutical company operating in Egypt?
- What are the potential threats/risks in your supply chain that may prevent your company from achieving its goals?
- How does the company deal with its supply chain risks?

Interview Date	Interviewee	Interview Type
January 5, 2015	Sales Manager	Personal Interview
January 5, 2015	Returned Products Supervisor	Personal Interview
January 12, 2015	Quality Assurance Manager	Personal Interview
January 26, 2015	Import & Export Manager	Telephone Interview
February 2, 2015	Development Sector Head	Telephone Interview
February 5, 2015	Quality Assurance Manager	Telephone Interview

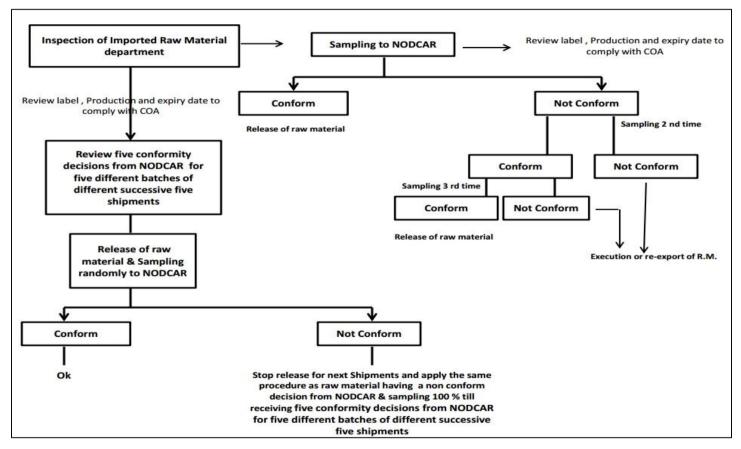
#### PARTICIPANTS AND DATE OF INTERVIEWS

#### **RISK RANKING/PRIORITIZING**

	Risk	<b>Risk Factor</b>	
Identified Risks	Impact (I)	Likelihood (L)	Score
	(score 1–5)	(Score 1–3)	I * L
Regulatory Risk			
Risk related to Foreign Currency and Loans'			
Interest Rate			
Supplier Risk			
Counterfeit Risk			
Lack of SC Transparency			
Strikes			
Political Instability			

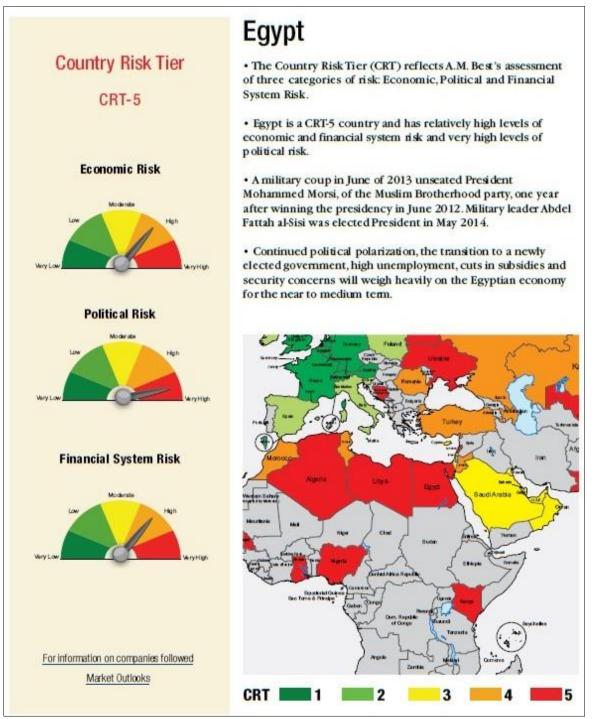
# **Appendix 2— Flow Chart on Inspection of Imported Raw Materials**

General Directorate of Pharmaceutical Inspection Department of Imported Raw Materials Inspection



Source: http://www.eda.mohp.gov.eg/Files/383 FlowChart Imported Row Materials.pdf (Last Accessed: February, 22 2015)

# **Appendix 3—Egypt's Country Political Risk**



Source: <u>http://www3.ambest.com/ratings/cr/reports/Egypt.pdf</u> (Last Accessed: April, 25, 2015)