

A Framework to Enhance Supply Chain Resilience The Case of Malaysian Pharmaceutical Industry

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Abstract

Purpose: The purpose of this paper is to investigate the vulnerabilities and the capabilities of the Malaysian Pharmaceutical manufacturing supply chain. This is the first phase of a research to develop a framework for enhancing pharmaceutical supply chain resilience

Design/methodology/approach: The grounded theory method was applied from the managerial perspective. Semi-structured interviews were conducted with key supply chain personnel of seven Pharmaceutical companies with large manufacturing capacities in Malaysia

Findings: The findings of the survey revealed 4 dimensions of supply chain vulnerabilities (Turbulence, external pressures, sensitivity and connectivity) and 6 dimensions of supply chain capabilities (flexibility, visibility, adaptability, collaboration, reserve capacity and supplier dispersity. The survey also revealed that adapting the Halal-*Toyyiban* Assurance into the Pharmaceutical logistics had a mitigating effect on the supply chain vulnerabilities as well as an enhancing effect on the supply chain capabilities

Research implications: Since supply chain resilience can be determined from the constructs of supply chain vulnerabilities and supply chain capabilities, the next phase of this research would explore the dimensions of Halal-*Toyyiban* Assurance that impact on Pharmaceutical supply chain resilience. The last phase would evaluate the effect of Halal-*Toyyiban* Assurance in Pharmaceutical logistics, towards the relationship of resilience predictor variables (capabilities and vulnerabilities) and supply chain resilience.

Originality/value: This research provides a new understanding in the management of the Pharmaceutical supply chain as well as create critical insights for decision makers through policy formulations and guiding principles that would improve the long term global competitiveness of the pharmaceutical industry

Keywords: Supply chain, Logistics, Capabilities, Vulnerabilities, Halal, Resilience, Pharmaceutical industry

Paper Type: Conceptual Paper

Introduction

Interdependence and international integration due to global sourcing and distribution has made manufacturing more complex, dynamic and increasingly uncertain. The result of these has led to increase in the length and complexity of Pharmaceutical supply chains thereby making networks for the supply of Pharmaceutical products less predictable, more vulnerable and hence riskier. This reality has brought about a stiffer and competitive business climate which has led pharmaceutical companies to search for operational status that impart capabilities into their operations.

According to Swinehart & Green (1995), "an enterprise gains sustained competitive advantage over their competitors by applying innovation and quality in targeted areas". One of such targeted areas is the supply chain. Example of contemporary factors that impact on the global supply chain include globalization, market volatility, outsourcing, single point sourcing and variations in supply and demand. These factors increase the length of the supply chain and the complexity of the networks thereby making them more susceptible to risks (Christophe & Peck, 2004). Risks make the supply chain more vulnerable and hence more susceptible to disruptions. The management of supply chain risks therefore is critical to achieving supply chain fitness.

The conventional risk management techniques only have the ability to identify, categorize and interpret known and quantifiable risk events in the supply chain. However, they are deficient when it comes to risks that are unquantifiable, unforeseen, and unexpected. Therefore, they cannot be employed as an effective tool for unknown/unforeseen catastrophe and uncertainties (Kunreuther, 2006; Pickett, 2006; Starr, Newfrock, & Delurey, 2003), as even the most carefully designed supply chain is susceptible to unforeseen factors (Pettit, 2008).

According to Deborah Wince-Smith, Council on Competitiveness (2007) as cited in Petit, (2008) “managing this rapidly changing risk landscape is an emerging competitiveness challenge - a challenge that demands resilience” (Council on Competitiveness, 2007). Furthermore, the competitive position of an enterprise and the responsiveness of its supply chain are two vital elements that determine its resilience (Sheffi & James, 2005).

After surveying the literature, it is worthy of note that there have been a number of valuable studies on supply chain resilience (Pettit, 2008; Haohua, 2007; Haimes, 2006; Sheffi, 2005; Christopher & Peck, 2004; Peck, 2003; Rice & Caniato, 2003). Noorfa & Andrew (2009), argued that barriers exist to the widespread application of these knowledge. Cheng & Zhu, (2010), proposed more researches on supply chain emergency disruptions in academic and industrial fields to probe the effective response tactic to enhance supply chain resilience.

In the light of these, Ponomarov & Holcomb (2009), recommended further conceptualization of the resilience paradigm by applying different perspectives to the research on supply chain resilience. Andersson (2007), recommended the combination of quality management concepts as antecedents for supply chain resilience. This premise was supported by Mahmood & Shahab (2011), who stated that isolated improvements in particular aspects of businesses are no longer adequate and that a holistic strategy is needed to bring competitive advantage into the market place. This can only be achieved by the adaptation of techniques which are not just concerned with services, process development and customer delivery but also with the relationship with suppliers, customers, commercial and managerial processes.

Most studies on supply chain resilience have only been carried out in settings that lack industrial specificity. Therefore, the generalizability of the findings on supply chain resilience are rather problematic. Globally, no other industry is more dependent on public confidence than the pharmaceutical industry which in contemporary times exhibits more vulnerability to disruptive risks (Eyinda, 2009). These risks have defied different supply chain risk management techniques, and thus the industry is under intense pressure to safeguard supply chain security and integrity. Evidence from Nwabueze, (2012), in his paper on “process improvement in Pharmaceutical manufacturing companies” shows that each of these models is not a stand-alone operational tool and that the high failure rate of improvement programs can be overcome through using a combination of models that deploy the quality function.

The findings of Tieman, Jack & Ghazali (2012), show that halal control and assurance activities are put in place to reduce supply chain vulnerabilities. Yet to date, it remains a matter of concern that there is no research based framework designed for the evaluation of the strength and the zero-order causal relationship between halal logistics activities and supply chain resilience. This research attempts to fill this gap by incorporating the mediating role of Halal-*Toyyiban* Assurance in Pharmaceutical logistics to create a framework for improving Pharmaceutical supply chain resilience.

Furthermore, the findings of the Malaysian national innovation policy study as reported in Lai & Leong (2012), reported that the pharmaceutical and medical devices manufacturing industries, have not made the desired progress. This was attributed to the numerous vulnerabilities plaguing the supply chain of these industries. The problem herein lies as to discovering the vulnerabilities the pharmaceutical companies are susceptible to and the inherent capabilities they possess, which can contribute to mitigating, sidestepping and overcoming the disruptive risks in their supply chains.

Given the high level of complexity of the Pharmaceutical supply chain, and due to the critical short term and long term effects on the end users during periods of disruptions, the pharmaceutical industry is a necessary field of study. The subsequent section gives an overview of the Malaysian pharmaceutical manufacturing industry.

Malaysian Pharmaceutical Industry

The Malaysian pharmaceutical industry is comprised mainly of small and medium-sized companies engaged in the production of generic drugs, traditional medicines and herbal supplements. They also act as contract manufacturers for foreign multinational corporations. In the year 2011, the Malaysian pharmaceutical industry was estimated to be worth RM4.4 billion. The Government is the biggest purchaser of medicines in Malaysia. The total Government expenditure on medicines is expected to continue growing at a rate of 10% per annum (Gross, 2013). As part of the Malaysian Government’s Economic Transformation Programme, the pharmaceutical industry was

identified as one of the sectors within healthcare that has been targeted. This is in a bid to increase the nation's gross national income contribution by 22%, thereby delivering a total of RM16.6 billion by 2020 (Gross, 2013).

Due to safety concerns, and the knowledge that a mistake in product design or production can have severe consequences for patients, pharmaceutical companies in Malaysia are highly regulated. The National Pharmaceutical Control Board of the Ministry of Health, and The Drug Control Agency are the regulatory bodies. They ensure that the companies build their quality approach around Good manufacturing practices, Good laboratory practices, Good clinical practices and In-house standard operating procedure (National Pharmaceutical Control Bureau, 2014).

Currently, according to Ministry of Health statistics, there are 250 licensed manufacturers in Malaysia. Of these, 74 are licensed to produce synthetic pharmaceuticals such as analgesics and antibiotics, while the remaining 176 are licensed to produce traditional and herbal medicines (National Pharmaceutical Control Bureau, 2014)

The Malaysian pharmaceutical manufacturing companies globally source their active pharmaceutical ingredients (APIs), excipients and some finished products (Malaysia External Trade Development Corporation, 2014)

The increasingly complex supply chain for these items exposes the possibilities of regulatory oversight by the country of origin. This situation has raised the necessity of those in the supply chain functions to understand their role and work to implement and maintain a resilient and comprehensive quality system. Sourcing new materials and outsourcing manufacturing or other activities for the supply of product to the end-user requires careful evaluation.

The supply chain activities of a typical pharmaceutical manufacturing company in Malaysia and the disruption path are illustrated in Figure 1 and Figure 2 below:

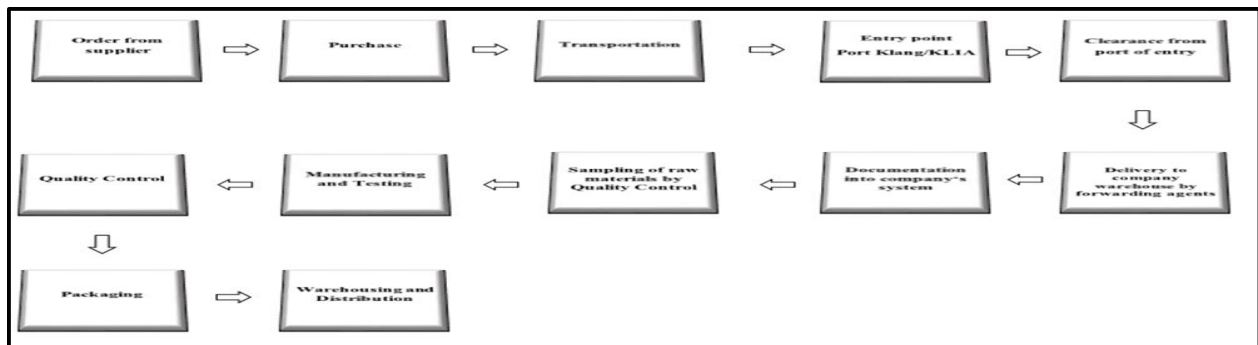


Figure 1: Supply Chain of a Typical Malaysian Pharmaceutical Manufacturing Company

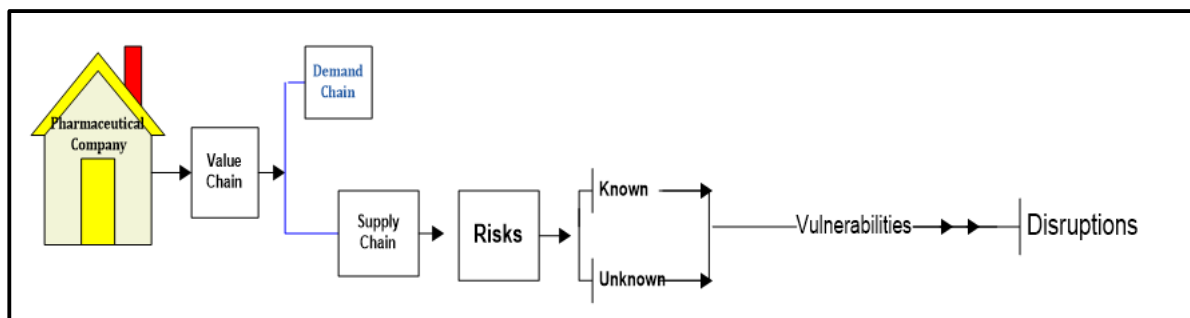


Figure 2: Value Chain Elaborating Supply Chain Disruption Path

All parties in the supply chain need to ensure that their activities support the health and well-being of patients who make up the end users of their products and also to maintain business continuity. This is especially important during times of economic downturn, since cost saving measures can increase risk.

In terms of the supply chain the following should be considered (The Chattered Quality Institute, 2010):

- Each supplier within the whole supply chain.
- What is supplied (material/product / service)

- The structure of the supply chain and interfaces between/within organisations, their suppliers and suppliers to the suppliers
- Security of the supply chain (potential for contamination or tampering)
- Internal processes used to manage the organisation's suppliers
- Internal production processes

Halal is an important and evolving area in the Malaysian pharmaceutical industry as Halal medicines are highly important to the Malaysian market, given that Islam is the country's official religion. Halal is an Arabic term meaning 'permissible'. With respect to pharmaceuticals, it excludes products derived from blood, animals slaughtered in the name of anyone but God, and swine (BMI, 2010). As such, many medicines – for example those compounded in capsules with the animal product gelatin – cannot be consumed by many observant Muslims. However, Halal is not just a purely religious issue; It is also important in the realm of business and trade (Mahdi Borzooei & Asgari, 2013). Pharmaceutical companies have been aware of this niche for some time, but it is only recently that pharmaceutical companies have explicitly targeted this growth area (BMI, 2010).

The use of Halal logo on the labels of pharmaceutical products is not allowed except for products that have been certified and approved as 'Halal' by the Department of Islamic Development Malaysia (JAKIM).

According to the National Pharmaceutical Control Board of the Malaysia Ministry of Health, the Malaysian Standard MS 2424: 2012 (P) describes the general guidelines in the manufacturing and handling of halal pharmaceuticals. It serves as a basic requirement for Halal pharmaceuticals in Malaysia. Other related guidelines that support Halal pharmaceutical logistics according to the Malaysia Institute of Transport, (2012) are:

- MS 2400-1:2010 (P): Halalan-*Toyyiban* Assurance Management System Requirements for Transportation of Goods and/or Cargo Chain Services
- MS 2400-2:2010 (P): Management System Requirements for Warehousing and Related Activities
- MS 2400-3:2010 (P): Management System Requirements for Retailing
- The implementations of these standards are consistent with the principles of the following standards:
- MS 2300: Value-based management systems - Requirements from an Islamic perspective: It consists of certifiable requirements which prescribe the framework for an organisation to establish a management system based on Islamic values.
- MS 1900: Quality management systems - Requirements from Islamic perspectives: It defines the quality management system requirements from the Islamic perspectives, whereby the standard can be used by organisations to inculcate Shariah requirements into their quality management practice with the emphasis on value-based management.
- MS 1500: Halal food - Production, preparation, handling and storage - General guidelines: It provides practical guidance for the food industry in the preparation and handling of halal food (including nutrient supplements) and to serve as a basic requirement for halal food product and food trade or business in Malaysia. Compliance to this standard ensures that products produced are halal, clean, safe and hygienic.

Methodology

The first phase of this research entails the investigation of the vulnerabilities and capabilities that affect the Malaysian pharmaceutical manufacturing supply chain. The Grounded theory method (Glaser, 1998; Glaser & Strauss, 1967) was applied from the managerial perspective. Antithetical to the traditional social science research, the grounded theory methodology first begins with data collection, and then allow the desired model to emerge from the data collected after systematic analysis (Glaser & Strauss, 1967).

Ponomarov and Holcomb (2009), recommends this approach in the research on supply chain resilience. It is proven to be useful in generating depth of understanding when not much is known about a phenomenon of interest. It is also recommended when it concerns complex social processes such as managerial decision-making under uncertainty.

In order to extract underlying vulnerabilities and capabilities, semi-structured interviews were conducted at separate times. The interviewee's comprised key supply chain executives of seven randomly selected Pharmaceutical companies in Malaysia (see table 1 below), three of which are among the top ten in the industry in terms of size, customer base and number of products. Individual interviews although more costly, but they tend to produce larger number of responses (Goldman, 1962).

From the data collected, the key points were marked with a series of codes, which were extracted from the interview.

Table 1: Characteristics of Interviewees

Company	Description of Company	Position of Interviewee	Experience in present position
A	Local producer of antibiotics, analgesics, parenterals and a wide range of OTCs. Also engaged in contract manufacturing for foreign brands	Purchasing/Supply Chain Manager	10 years
B	Manufacturer of generic drugs with over 300 products across a wide therapeutic group. Also Halal certified	Supply Chain Manager	12 years
C	Engaged in the manufacture of infusions, eye products as well as a wide range of health supplements and other OTCs	Senior Assistant Purchasing/Supply Chain Executive	6 years
D	Solely committed to the manufacture of generic pharmaceuticals. Have a wide array of product portfolio in their name	Purchasing Manager	7 years
E	Manufacturer of a wide range of generic drugs and some OTCs	Purchasing Manager	2 years
F	Engaged in the manufacture of a wide product range which includes injectables and antibiotics	Production/Supply Chain Manager	8 months
G	Specialized in the manufacture of a wide range of OTCs, veterinary, aquatic and some generic pharmaceutical products	Supply Chain Manager	2 years

Analysis and Finding

From the data collected, the key points were marked with a series of codes which were extracted from the interview. The data transcribed from the interview were subjected to the following process (Figure 3).

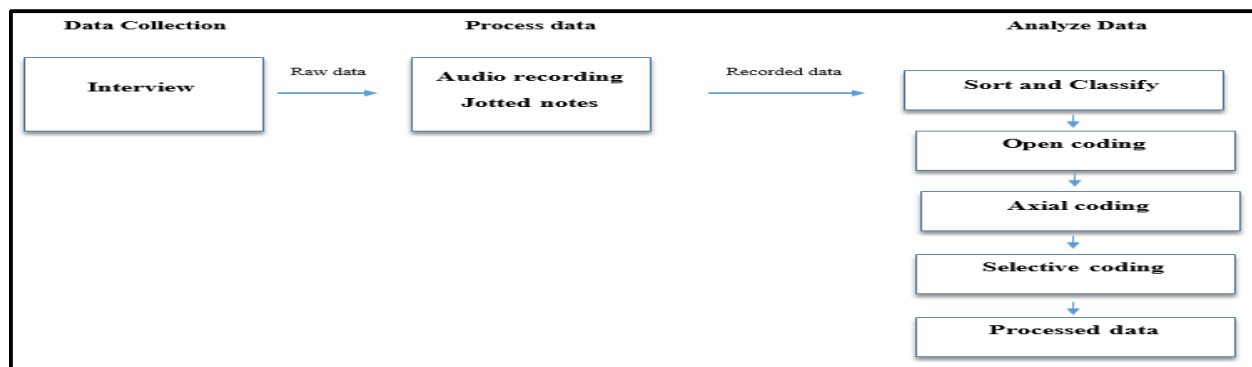


Figure 3: Sequence of Qualitative Data Analysis

The codes were grouped into similar concepts in order to make them more workable and can support theoretical propositions. From these concepts, categories were formed, and then grouped according to the constructs of vulnerabilities and capabilities.

The findings revealed 4 vulnerability factors (Turbulence, External pressures, Sensitivity and Connectivity) and 6 capability factors (flexibility, reserve capacity, visibility, adaptability, collaboration and supplier dispersity)

Furthermore, the findings also revealed adaptation of the Halal-*Toyyiban* Assurance principles into the pharmaceutical logistics played a significant role in imparting resilience into the supply chain. Hence this paper proposes the following conceptual framework (Figure 4) below.

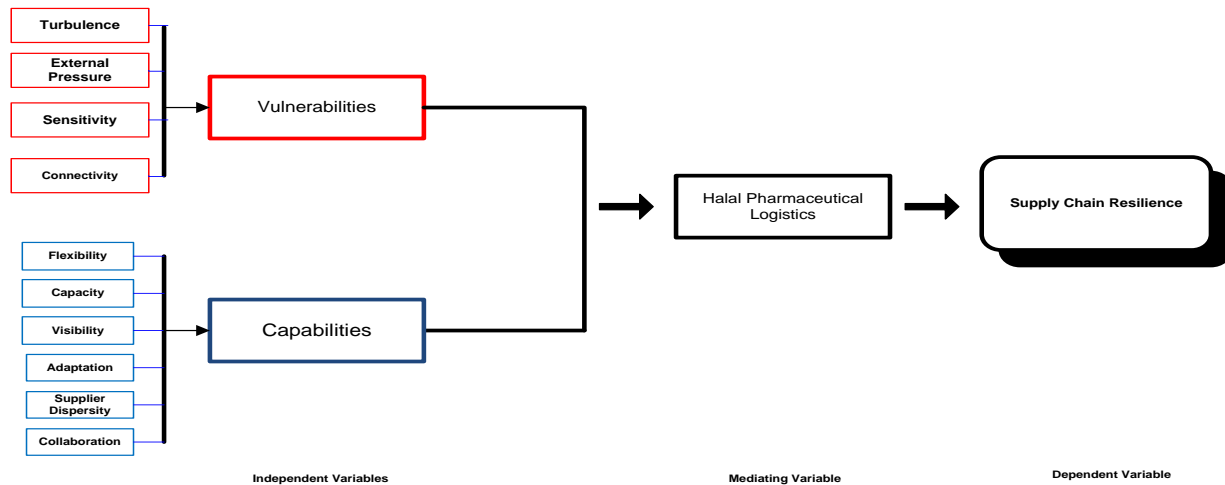


Figure 4: Conceptual Framework

Resilience can be analyzed from of two constructs; Vulnerabilities and Capabilities (Amir, M.F., La'ya, Kamran & Maghsoud, 2013; Pettit, Fiksel & Croxton, 2008). The visual display (Fig 4) is a representation of the conceptual framework, comprising of two independent variables - Vulnerabilities and Capabilities (with 4 and 6 dimensions respectively) which are antecedents of supply chain resilience (the dependent variable) and Halal Pharmaceutical Logistics (mediating variable).

Asbjørnslett & Rausand (1999), defines vulnerability as “the properties of a production system that may weaken or limit its ability to endure threats and survive accidental events that originate both within and outside the system boundaries”. By addressing the vulnerability of the supply chain, the supply chain risks are mitigated (Blos, Quaddus, Wee, & Watanabe, 2009; Wagner & Bode, 2006; Svensson, 2002).

Siggelkow, & Rivinkin (2005) views turbulence risks which are frequent unpredictable changes in external factors beyond one's control. External pressures are influences, not specifically targeting the firm, that create business constraints or barriers (Pettit, Fiksel & Croxton, 2008). Sensitivity is “the importance of carefully controlled conditions for product and process integrity” (Pettit, Fiksel & Croxton, 2008). They also defined connectivity as “the degree of interdependence and reliance on outside entities”.

As defined by Pettit, Fiksel and Croxton (2008), capabilities are “attributes that enable an enterprise to anticipate and overcome disruptions”. A majority of the researches on creating a resilient supply chain have concentrated on the capabilities of the supply chain. Flexibility is the swift response to status change in the supply chain (Uman & Vipul, 2011). Reserve capacity involves storage of physical goods in order to make allowance for uncertainties in the production process (Stock & Lambert, 2001). Visibility as defined by Christopher, (2005) is the ability of a firm to keep track and monitor supply chain events and patterns as they happen – or even before they happen. According to Pettit, Fiksel & Croxton, (2008), Adaptability is the ability to modify operations in response to challenges or opportunities.

Supplier dispersity is a unique capability which we discovered in our research and we define it as “Wide distribution of suppliers over a considerable extent”.

Tieman, Jack & Ghazali (2012), in their research on “Principles in halal supply chain management” described Halal logistics as “procedures that ensure product quality in the procurement and supply chain management of commodities, according to Halal prescribed standards”.

A number of definitions as regards to resilience have been put forward in the literature. The term "resilience" was defined by (Revetria, Bruzzone, Mosca, & Rapallo (2000), as the ability to return to the desired state after a major disturbance. Gunderson (2000) defined resilience as attribute of a system that encompasses “quantity change endurance; ability to self-organize; thirdly, ability to adapt all in response to disruption.

Peck (2003) defined supply chain resilience as the ability of a global supply chain to reorganize and deliver its core function continually, despite the impact of external and or internal shocks to the system.

Christopher & Peck (2004) defined resilience as the ability of a system to return to its original state or move to a new and more desirable state after being disturbed. In summary, from the definitions discussed so far, resilience confers on the supply chain the ability to return to original or perhaps better supply chain performance under emergency risk environment.

Conclusion

This paper is one in a series of studies that culminates in a research which aims to create a framework for enhancing pharmaceutical supply chain resilience. Since supply chain resilience can be measured from the constructs of supply chain vulnerabilities and supply chain capabilities. The objectives of this paper were therefore to identify the vulnerabilities and the capabilities that exists in the Malaysian pharmaceutical manufacturing supply chain.

Via semi-structured interviews, four vulnerabilities (Turbulence; External pressure; Sensitivity; and Connectivity) and six capabilities (Flexibility; Reserve capacity; Visibility; Supplier Dispersity; and Collaboration) were identified. The identification of these factors is a first step in proactively building a resilient supply chain capable of side stepping supply chain risks and bouncing back from unavoidable supply chain disruptions. The goal of every company should be to mitigate as much as possible the vulnerabilities. This can be done by first identifying the capabilities that matches the particular vulnerabilities involved and then strengthening these capabilities.

Furthermore, it was also discovered that the Halal-*Toyyiban* standards imparted on the supply chain for those that adapted the standards into their supply chain procedures.

In this research we propose a framework that incorporates the mediating role of Halal pharmaceutical logistics into the framework for Supply chain resilience. The role of Halal in the Pharmaceutical logistics is made possible by the Hala-*Toyyiban* Assurance Pipeline which is a value supply chain management system of the of the Malaysian Department of standards that conforms to the standards of hygiene, safety, sanitation, cleanliness, nutrition, risk exposure, environmental, social and other related aspects in accordance with the Shariah requirements.

Contemporary research on Halal logistics have looked at the applications of Halal quality with a product perspective in mind, but the impact this has on the resilience of a supply chain has not been previously explored. Therefore, the findings of this research provide a framework for the application of Halal logistics techniques in enhancing supply chain resilience. The next phase of the research would determine the dimensions of Halal-*Toyyiban* Assurance in Pharmaceutical logistics that impart on supply chain resilience.

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