UNIVERSIDADE FEDERAL DE SÃO CARLOS

CENTRO DE CIÊNCIAS EXATAS E TECNOLOGIA DEPARTAMENTO DE ENGENHARIA DE PRODUÇÃO PROGRAMA DE PÓS-GRADUAÇÃO EM ENGENHARIA DE PRODUÇÃO

RESILIENCE ELEMENTS TO COMBAT COUNTERFEIT MEDICINES IN SUPPLY CHAIN

FLÁVIA RENATA PINHO DE LIMA

SÃO CARLOS - SP

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FLÁVIA RENATA PINHO DE LIMA

Dissertação apresentada ao Programa de Pós-Graduação em Engenharia de Produção da Universidade Federal de São Carlos, como parte dos requisitos para a obtenção do título de Mestre em Engenharia de Produção.

Orientadora: Prof^a. Dr^a. Andrea Lago da Silva

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Dedico este projeto a todos aqueles que acreditam na importância de um modelo de gestão capaz de equilibrar eficiência, qualidade e mitigação de riscos para a sustentabilidade e perpetuidade dos negócios.

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ABSTRACT

Supply chains are becoming more complex and vulnerable to specific disturbances scenarios, critical to business continuity. Counterfeiting is one of them, especially in markets where counterfeit products affect directly consumers' health, such as food, beverage and medicines. However, few authors have investigated how to analyze this disturbance from a managerial perspective. This study claims that supply chain resilience is a dynamic solution applicable to combat a disturbance in constant growth and innovation: counterfeiting. To bridge this gap, namely the lack of understanding in how to increase resilience to counterfeits, the purpose of this study is to understand how resilience elements influence the combat of counterfeit medicines. To do so, we developed systematic literature review, using the QDA Miner software to support the content analysis. After a careful screening, we selected 84 articles between 2002 and Oct/2016. The systematic review reveals 13 resilience elements and 16 counterfeit antimeasures. Furthermore, reengineering, collaboration, visibility, innovation, SCR culture and trust appeared as six key-elements to combat counterfeit. After a literature review, we conducted an empirical research – case study, to pursue our exploratory purpose. The case study encompasses two medicines supply chains, with two pharmaceuticals (focal companies) and members downstream, and agencies and associations that work across the medicines supply chain to combat counterfeits. The empirical analysis enabled a deeper investigation of the resilience elements and counterfeit anti-measures applied. Our findings show that, in accordance with literature, collaboration, trust and visibility, are crucial elements to strengthen resilience against counterfeiters. Furthermore, different from literature review, information sharing and sensing appeared as elements highly associated in counterfeit combat, leveraged by the existence of a huge amount of data and the possibility of improving the decision-making process. Thus, this study contributes to the field by (i) proposing a framework for increasing resilience to counterfeit in medicines supply chain, which characterizes the dynamics among resilience elements and counterfeit anti-measures and discusses the role of collaboration and information sharing such as barriers to increase resilience. (ii) By suggesting new avenues of research, such as exploring tradeoffs between resilience and anti-counterfeit literature, investigating the effectiveness of implementing each resilience element in counterfeit combat, and analyzing different sectors highly targeted by counterfeiters, such as fashion and food.

Keywords: supply chain, resilience elements, counterfeit anti-measures and medicines supply chain.

RESUMO

Cadeias de suprimentos estão se tornando cada vez mais complexas e vulneráveis a cenários específicos de perturbações, críticos para a continuidade do negócio. Contrafação é um destes cenários, especialmente em mercados onde produtos contrafeitos afetam diretamente a saúde do consumidor, como comida, bebida e medicamentos. Porém, poucos autores têm investigado como analisar esta perturbação por uma perspectiva de gestão. Este estudo sugere que a resiliência na cadeia de suprimentos é uma solução dinâmica aplicável a combater perturbações em constante crescimento e inovação, como a contrafação. Para suprir esta lacuna que é a falta de entendimento em como aumentar a resiliência à contrafação, o estudo visa entender como os elementos de resiliência influenciam o combate aos medicamentos contrafeitos. Para isso, uma revisão sistemática de literatura foi desenvolvida, com auxílio do software ODA Miner para a análise de conteúdo. Após um cuidadoso processo de análise, 84 artigos entre 2002 e out/2016 foram selecionados. A revisão sistemática revelou 13 elementos de resiliência e 16 medidas anti-contrafação. Além disso, reengenharia, colaboração, visibilidade, inovação, cultura de resiliência na cadeia de suprimentos e confiança apareceram como os seis elementos mais relevantes para o combate à contrafação. Após a revisão de literatura, foi conduzida uma pesquisa empírica – estudo de caso, para suportar o objetivo exploratório da pesquisa. O estudo de caso contou com duas cadeias de medicamentos, sendo duas farmacêuticas (empresas focais) e elos à jusante, e agências e associações que atuam em toda a cadeia para combater a contrafação. A pesquisa empírica possibilitou uma investigação mais profunda dos elementos de resiliência e anti-medidas aplicadas. Os resultados mostram que, em linha com a literatura, colaboração, confiança e visibilidade são elementos cruciais para fortalecer a resiliência à contrafação. Além disso, diferente do que foi observado na revisão da literatura, compartilhamento de informações e antecipação (sensing) apareceram como elementos muito associados às anti-medidas, impulsionados pela existência de uma enorme quantidade de dados e a possibilidade de melhorar o processo de tomada de decisão das empresas. Dessa forma, este estudo contribui para o tema ao: (i) propor um framework para aumentar a resiliência à contrafação na cadeia de medicamentos, o qual caracteriza a dinâmica entre os elementos de resiliência e as anti-medidas e discute o papel de colaboração e compartilhamento de informações como barreiras; (ii) sugerir novas linhas de pesquisa, como a exploração dos tradeoffs entre as literaturas de resiliência e contrafação, a investigação da efetividade da implantação de cada elemento de resiliência no combate à contrafação, e a análise de outros setores altamente suscetíveis à contrafação, como de vestuário e alimentos.

Palavras-chave: cadeia de suprimentos, elementos de resiliência, medidas anticontrafação e cadeia de medicamentos.

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DEFINITION AND STANDARDIZATION OF TERMS

Supply chain resilience practices and resources are referred to in literature as capabilities, principles, dimensions, enablers, elements, antecedents, competencies or activities (see discussions raised by Hohenstein et al., 2015, Kilubi and Haasis, 2015 and Ali, Mahfouz and Arisha, 2017). Taking into account Ali, Mahfouz and Arisha (2017) suggestion, aimed at bringing consistency to the terminology, this study remains neutral and uses the term "elements" or "resilience elements".

LIST OF ABBREVIATIONS

A IPren1	- Association'	s Representative	of CROSSASS1
AILICHI	- Association	S ixepresemanive	OI CIVOSSASSI

AIPrep2 - Association's Representative of CROSSASS2

ANVISA - Agência Nacional de Vigilância Sanitária

ANVrep - Representative of products controlling of ANVISA

B2C - Business to Consumer

CROSSASS1 - Association Focused on IP Rights and Counterfeit Combat

CROSSASS2 - Association Focused on IP Rights and Counterfeit Combat

CROSSORG1 - Organization Focused on Traceability and Standard Definition

CROSSORG2 - Organization Focused on Traceability and Standard Definition

DISTRIBUTOR 1 - Distributor from CASE 1

DISTRIBUTOR 2 - Distributor from CASE 2

DMgen2 - General Manager of DISTRIBUTOR2

DMlog1 - Logistics Manager of DISTRIBUTOR1

EDI - Electronic Data Interchange

GPS - Global Positioning System

HMpurlog12 - Logistics Manager of HOSPITAL1/2

HOSPITAL1/2 - Hospital from CASE 1 and 2

IP - Intellectual Property

MCNS - Medicines Control National System

OPL 1 - Logistics Provider from CASE 1

Orep1 - Organization's Representative of CROSSORG1

OTRACrep1 - Traceability Representative of CROSSORG1

\(\sigma\) \(\text{Crep2}\) - Traceability Representative of CROSSORG2

ol - Association's Representative of PHARMAASS1

LIST OF ABBREVIATIONS (cont.)

PArep2 - Association's Representative of PHARMAASS2

PHARMA 1 - focal Company of CASE 1

PHARMA 2 - focal Company of CASE 2

PHARMAASS1 -Pharmaceutical Association

PHARMAASS2 -Pharmaceutical Association

PMgenlatam1 - General Manager of Latin America of PHARMA1

PMlog2 - Logistics Manager of PHARMA2

PMqualsec2 - Quality and Security Manager of PHARMA2

PMrisk2 - Risk Manager of PHARMA2

PMtec1 - Technology Manager of PHARMA1

PSI - Pharmaceutical Security Institute

PSlog1 - Logistics Specialist of PHARMA1

R&D - Research and Development

RFID - Radio-frequency identification

SCR - Supply Chain Resilience

SCRM - Supply Chain Risk Management

SETRM - Technology Seminar for Medicines Traceability

SLR - Systematic Literature Review

TMS - Transportation Management System

TMsec1 - Security Manager of OPL1

TMsec2 - Security Manager of OPL1

TOcoord - Coordinator of TECORG1

TOcoordtec - Technical Coordinator of TECORG1

TODoper - Director of Operations of TECORG2

LIST OF ABBREVIATIONS (cont.)

TODred - Director of R&D of TECORG2

TOres1 - Researcher of TECORG1

USA - United States of America

USPTO - United States Patent and Trademark Office

WMS - Warehousing Management System

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1 INTRODUCTION

This section introduces concepts, justifications and objectives of this research. Firstly, item 1.1 presents the theme, followed by the research problem and questions raised (item 1.2). Then, item 1.3 specifies the main objectives and expected contributions, and item 1.4 justifies the relevance of this study.

1.1 Theme Presentation

Intellectual property (IP) is an intangible and valuable asset used by organizations to leverage competitivity and, therefore, has become a key-factor in organization evaluation (GREEN; SMITH, 2002; STAAKE; THIESSE; FLEISCH, 2009). One of the threats to IP are counterfeits, which means trade products that bear reference to a brand or organization without authorization and could be confused with an original one (STAAKE; THIESSE; FLEISCH, 2009). The number of counterfeit incidents reported has grown, especially in markets focused on research, development and innovation (STEVESTON; BUSBY, 2015). This may be explained by: (i) Asian market growth, where control of intangible assets, such as trademark and IP, is complex; (ii) global trend to eliminate borders and promote international trade; (iii) global organizations interaction (STAAKE; THIESSE; FLEISCH, 2009); (iv) use of more complex channels and methods by counterfeiters (WHO, 2006); and (v) growth of Business to Consumer (B2C) market and consequently internet shopping popularization (LYBECKER, 2008; WHO, 2010). Moreover, it may be especially critical in environments with strong concerns about consumer safety (RINGSBERG, 2014), such as food, electronics and medicines.

To combat counterfeit threat, fragmented literature on the topic explores a range of anti-measures. They might be about: (i) authentication practices – e.g.:

Almuzaini, Choonara and Sammons (2013) presented a Systematic Literature Review (SLR) about counterfeit medicines focused on assessing the quality of studies about drug analysis; (ii) **technologies** – e.g.: Kwok et al. (2010); Coustasse, Arvidson and Rutsohn (2010); Li (2013); Taylor (2014) and Dimase et al. (2016) provided technological solutions to address the issue; (iii) **consumers role** – e.g. Cesareo and Stöttinger (2015) developed a survey in luxury industry to propose anti-measures directed at consumers. Most articles on this subject do not focus on managerial perspectives of supply chains. Hoecht and Trott (2014) presented a broad review of such anti-measures, e.g. co-opt offenders, educating stakeholders at the source, aggressive advertising and internal and external guanxi (China), but focusing on Chinese scenarios. Focusing on the pharmaceutical industry, Chaudhry and Stumpf (2013) delineate the problem by presenting incidents and possible triggers to counterfeits. Cohn et al. (2012) describes an event of falsified medicines in Kenya and makes recommendations.

Despite the advances in counterfeit literature, more studies are needed to develop strategies to reduce vulnerabilities to counterfeits (COCKBURN et al., 2005; LYBECKER, 2008) and prepare organizations to deal with such a dynamic issue. Nowadays, as soon as new strategies are developed, counterfeiters start looking for new ways to mimic products without being detected (EVERTS, 2010; DIMASE et al., 2016).

This study suggests that Supply Chain Resilience (SCR) may be an effective way to prevent and combat counterfeits. It represents the supply chain's adaptative capability to prepare and adapt to respond positively to changes and disturbances in operations (PONOMAROV; HOLCOMB, 2009; KAMALAHMADI; PARAST, 2016; BRUSSET; TELLER, 2017), seek competitive advantage (HOHENSTEIN et al., 2015), learn from facts and evolve to a new operating state

(CHRISTOPHER; PECK, 2004; FIKSEL et al., 2015; ALI; MAHFOUZ; ARISHA, 2017).

In recent years, academics have been developing a vast body of literature involving SCR. Essentially, they are related to (a) generic mechanisms or frameworks to increase organizational or supply chain resilience (e.g. theoretical: Ehrenhuber et al., 2015; Hohenstein et al., 2015; Kilubi and Haasis, 2015; Tukamuhabwa et al., 2015; and Kamalahmadi and Parast, 2016; and empirical: Sheffi, 2005; Blackhurst, Dunn and Craighead, 2011; and Pettit; Croxton; Fiksel, 2013); (b) specific elements (e.g. theoretical: Christopher and Lee, 2004; Sheffi and Rice, 2005; Kache and Seuring, 2014; Chang, Ellinger and Blackhurst, 2015; and empirical: Christopher and Lee, 2004; Kache and Seuring, 2014; and Scholten and Schilder, 2015); (c) organizational functions or processes to increase organizational or supply chain resilience e.g. theoretical: Khan, Christopher and Creazza, 2012; Pereira, Christopher and Silva, 2014, and Wang, Jie and Abareshi, 2015); and (d) analysis of specific disturbance scenarios and how resilience could contribute (e.g. empirical: Rashid, Loke and Ooi, 2014; Scholten, Scott and Fynes, 2014; and Stevenson and Busby, 2015).

Thus, studies about SCR related to (d) - analysis of specific disturbance scenarios and how resilience could contribute - suggest the necessity of developing management controls and strategies to help organizations to reduce vulnerabilities (BLACKHURST; WU, 2009; PUNNIYAMOORTHY; THAMARAISELVAN; MANIKANDAN, 2013). It affects its performance and influences the companies capacity to fulfill consumer demand (BLACKHURST; WU, 2009). As illustrated in Figure 1.

Forces of change

Vulnerabilities

RESILIENCE

Management controls

Elements

Figure 1: Supply chain resilience framework

Source: adapted from Pettit, Fiksel and Croxton (2010, p.8)

Figure 1, developed by Pettit, Fiksel and Croxton (2010), represents that forces of change cause vulnerabilities, responsible for reducing resilience. Exposure to geopolitical disruptions, terrorism, piracy, theft, and disintegration of supply chain are examples of vulnerabilities to be addressed (CHOWDHURY; QUADDUS, 2015).

On the other hand, creating management controls help to develop resilience elements that increase SCR.

1.2 Research Problem and Questions

The complexity of supply chains and increased interconnection among organizations have raised supply chains' vulnerabilities. Therefore, organizations have become more interested in learning how to deal with specific disturbances (BLACKHURST; WU, 2009; PUNNIYAMOORTHY; THAMARAISELVAN; MANIKANDAN, 2013). Understanding supply chain risk sources and the severity of their impact is the first step in the design of efficient and resilient supply chain networks (PUNNIYAMOORTHY; THAMARAISELVAN; MANIKANDAN, 2013). Risk sources are classified as "the environmental, organizational or supply chain-related variables that cannot be predicted with certainty and that impact on the supply chain outcome variables" (JÜTTNER; PECK; CHRISTOPHER, 2003, p.200). Several authors, e.g. Tang and Tomlin (2008); Wagner and Bode (2008); and Punniyamoorthy, Thamaraiselvan and

Manikandan (2013), have identified and classified the main risk sources (see Lavastre, Gunasekaran and Spalanzani, 2012 for further discussion).

Tang and Tomlin (2008) present six types of supply chain risks: supply, process, demand, behavioral, political/social, and IP. Speier et al. (2011) state that supply chain disruptions may result from unintentional and intentional sources. While the first relates to accidents or natural disasters, the second refers to theft, contamination/sabotage, or terrorist attack. Moreover, the World Economic Forum (2017) released a report about Global Risk presenting the main global risks and its interconnections, as observed in figure 2.

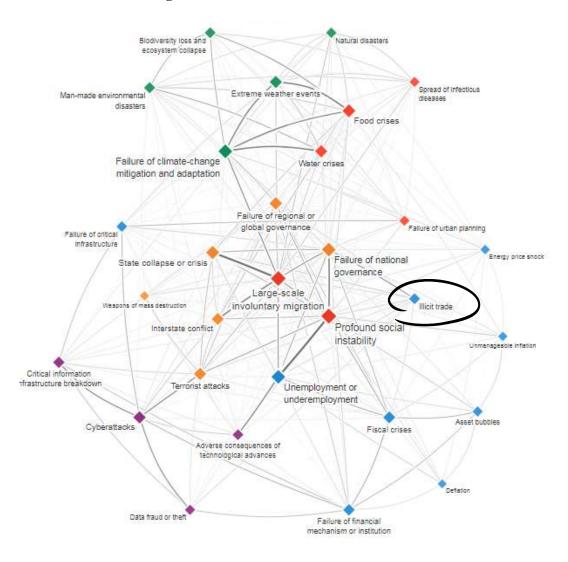


Figure 2: Global risks and interconnections

Source: Global Risks, 2017, Published by the World Economic Forum

Figure 2, therefore, represents how interconnected the risks are nowadays that supply chains are exposed to. Survey respondents were asked to identify between global risks they believe to be most interconnected. The bigger rhombus highlights the number and strength of interconnections. Blue rhombus represents economic risks, green environmental risks, orange geopolitical risks, red societal risks and purple technological risks. As highlighted, illicit trade appears as one of the global risks, and very interconnected among other global risks, which means it is likely to cause great impacts along globalized networks. More specifically, Donadoni et al. (2016) and Tukamuhabwa, Stevenson and Busby, (2017) presented counterfeit as one of the main types of supply chain disturbances.

Authors claim that the more resilient the supply chain, the greater the trend of better response to disturbances (SHEFFI, 2005; BRUSSET; TELLER, 2017). Thus, one opportunity to mitigate counterfeit risk is the development of resilience into organizations. Organization resilience, for the purpose of this study, is defined as

"the adaptative capability of an enterprise, which is highly dependent on its individuals, groups, and subsystems, to face immediate and unexpected changes in the environment with proactive attitude and thought and adapt and respond to these changes by developing flexible and innovative solutions" (KAMALAHMADI; PARAST, 2016, p.121).

A few authors have dedicated to study specific disturbance scenarios, (e.g. Rashid, Loke and Ooi, 2014 and Scholten, Scott and Fynes, 2014). However, despite the recent acknowledgment of counterfeit as a supply chain risk source, the SLR conducted in this research identified a single study - Stevenson and Busby (2015) - that explicitly links SCR elements and counterfeit anti-measures. They identified four sets of strategies used by counterfeiters to introduce illegitimate products and proposed anti-measures to

increase resilience. Hence, the study analyzed the theme from the counterfeiter perspective.

More studies are needed within this context to understand the role of resilience elements to combat counterfeit in supply chain. Stevenson and Busby (2015) demonstrated the importance of including counterfeit risk perspective during supplier selection process. Although criteria such as trust and risk of future competition with the supplier by market are found in literature, little is reported on the risk of the supplier using the organization's trademark improperly.

There is a gap in the literature, once few authors present managerial tools and practices to deal with counterfeit disruptions. Although some counterfeit antimeasures are similar in different industries (MACHADO; PAIVA; SILVA, 2018), it is clear that a counterfeit anti-measure found to be useful to one product may not work for another (QIAN, 2014). Anti-measures might need to be tailored to specific products (CHO; FANG; TAYUR, 2015). This study focuses on counterfeit of medicines, because its supply chain is one of the most threatened, due to the amount of existing counterfeited medicines, the direct impact on consumer health, and the difficulty to identify counterfeit products (COCKBURN et al., 2005; BERGER; BLIND; CUNTZ, 2012; STEVENSON; BUSBY, 2015). Hence, this study aims at answering the following question:

How do resilience elements influence the combat of counterfeit medicines in the supply chain?

1.3 Objective and Expected Contributions

The general objective is to understand how resilience elements influence the combat of counterfeit medicines.

In order to achieve this goal, we propose the following specific objectives:

• understand the counterfeit anti-measures:

- identify and characterize SCR elements;
- evaluate the resilience elements most and less often associated with counterfeit anti-measures;
- empirically explore how organizations in medicines supply chain might increase resilience to counterfeits.

This study provides managerial and academic contribution by (i) characterizing resilience elements to support counterfeit combat into medicines supply chain, by comparing the data obtained from the theoretical and empirical research; and (ii) proposing a set of actions to support medicines supply chain managers to strengthen organizations' resilience to counterfeit and, thus, be more prepared to deal with disturbances triggered by counterfeit incidents.

1.4 Justification

The capacity to recover and evolve to a new state of operation after a disturbance in product and/or information flow has proven to be a significant competitive advantage for organizations (FIKSEL et al., 2015). Bhatia, Lane and Wain (2016) corroborate with this statement, as they verified that more than 80% of organizations are worried on how to increase resilience. Deeper studies are being conducted to support organizations on how to develop resilience elements (FIKSEL et al., 2015; KAMALAHMADI; PARAST, 2016).

One of the main types of supply chain disturbance is counterfeit (DONADONI et al., 2016; TUKAMUHABWA; STEVENSON; BUSBY, 2017), and more studies are necessary to understand how to increase resilience to counterfeit (STEVENSON; BUSBY, 2015). A survey conducted by Berger, Blind and Cuntz (2012) showed the theme relevance in industries such as chemical, consumer goods and pharmaceutical. OECD (2008) also presented the result of its study and claim that there

has been an expansion of counterfeited goods from luxury items to health and safety products, such as pharmaceutical, food and drinks, medical equipment, personal care items, toys, tobacco and automotive parts.

Counterfeit affects more severely developing countries (COCKBURN et al., 2005; LYBECKER, 2008). However, the product flow might be found anywhere and therefore represents global issues (COUSTASSE; ARVIDSON; RUTSOHN, 2010; WHO, 2010), as illustrated in the incidents:

- epidemics linked to the consumption of contaminated diethylene glycol. First epidemic known took place in the USA (1937) and resulted in 105 deaths; the problem re-emerged in eight other situations, killing hundreds of people in developing countries like Haiti and Panama (WHO, 2008);
- in 2004, investigators discovered counterfeited versions of popular medicines being distributed to patients in the United Kingdom (COUSTASSE; ARVIDSON; RUTSOHN, 2010);
- investigators in the United Kingdom discovered counterfeit versions of the popular drugs Lipitor R (for cholesterol reduction); Cialis R (for erectile dysfunction); and Reducil R (for treatment of obesity) being distributed to patients (WYLD, 2008);
- in 2008, 150 people went to Singapore Hospital after taking counterfeited erectile dysfunction medicines – 4 of them died and 7 suffered brain damage (OSSOLA, 2015);
- From 2007 to 2010, federal criminal investigators discovered 610 counterfeited drugs after laboratory and visual analyses. The numbers show a trend of increase of counterfeit identification and the seizures were conducted in several locations,

- such as São Paulo, Paraná, Santa Catarina, Rio Grande do Norte, Distrito Federal, Rio Grande do Sul and Amazonas (AMES; SOUZA, 2012);
- in 2011, USA patients reported to FDA (*Food and Drug Administration*) that they required emergency treatment after taking medicines such as Ambien, Xanax and Lexapro bought online (OSSOLA, 2015);
- in 2012, a falsified tuberculosis medicine killed approximately 100 patients in a local Pakistan hospital (OSSOLA, 2015);
- more than 8.000 patients died in a hospital located in a remote region from the Himalayas after taking counterfeit antibiotics for surgery infection prevention (OSSOLA, 2015).

Moreover, counterfeit medicines might harm or be inefficient to patient's health and diminish brand image (COCKBURN et al., 2005; EVERTS, 2010). Hence, we selected the medicines supply chain for this study because of its criticality, global scope and potential negative effects.

The medicine supply chain encompasses the integration of key-process from end users to original suppliers to provide products and information at the right quality, place, and time, adding value to the client and other stakeholders (LAMBERT; GARCIA-DASTUGUE; CROXTON, 2005; ENYINDA; TOLLIVER, 2009). Many intermediates may exist, and multiple transactions may go back and forth before reaching the dispensing point (ENYINDA; TOLLIVER, 2009). Thus, it is a complex supply chain, once doctors prescribe medicines they have never seen; pharmacists who deliver the product usually use multiple distributors and wholesalers; the insurance company pays, in some cases, the medicines; and the patient consumes it (LYBECKER, 2008). The Brazilian medicines supply chain is not an exception.

Because of the general stimulus in 1960 to the establishment of foreign factories in Brazil, most medicines are produced in Brazil with imported raw materials, (PALMEIRA FILHO; PAN, 2003). According to a survey from IMS Health, ordered from Associação Brasileira das Indústrias de Medicamentos Genéricos (PróGenéricos), from January to September/2015, the sector handled R\$ 55.89 billion in Brazil, which means 2.53 billion medicine packages (MELO, 2015). The increasing flow of medicines in Brazil resulted in a complex network composed of more than 400 manufacturers, 300 wholesalers, 50.000 pharmacies, and 5.000 hospitals, besides other players (PWC, 2016). Moreover, specific regulators and supervisory agents work to monitor different aspects of the supply chain. Figure 3 illustrates a simplified scheme.

ANVISA

Ministry
of Health
Office

Representative
Doctor
Pharmacology
Pharmacoutical
Wholesaler

Representative
Doctor
Pharmacology
Pharmacoutical
Wholesaler

Sanitary
Surveillance

Figure 3: Scheme of medicines supply chain

Source: created by the author

This high complexity degree, added to the large contribution that actions may represent to the population, increase the relevancy of project development in healthcare (FERREIRA; MATOS; LEAL, 2015; AGARWAL et al., 2016).

Summing up, it is worth mentioning factors that motivated the author's interest are:

- criticality of threats in healthcare: consumption of falsified medicines may
 potentially cause death by absorption of illegal substances or by not consuming
 what the patient really needs (COCKBURN et al., 2005);
- counterfeiters broad operation: Cockburn et al. (2005) identified counterfeit
 incidents in almost all continents and different countries around the world –
 Southeast Asia, China, North America, Haiti, Nigeria, Bangladesh, India,
 Argentina, Niger and Central Africa;
- increased amount of incidents in healthcare: although there is no trustable database with all counterfeit incidents, Stevenson and Busby (2015) reported that 37% of incidents in CBI (International Chamber of Commerce division), FBI (US Federal Bureau of Investigation), and Nexis database were related to the pharmaceutical industry.

Moreover, another fact that called attention to the Brazilian medicines supply chain is that Brazil approved the Legislation 11.903/2009, modified in 2016 by 13.410/2016, which introduced the Medicines Control National System (MCNS). It aims at controlling medicines by means of a unique identification system and employment of available technologies to capture, storage and electronic data transmission (PAES, 2009; NOGUEIRA; VECINA NETO, 2011). MCNS is an example of Brazilian Government efforts to ensure greater safety to the medicine consumer. Mechanisms to combat sales and consumption of counterfeit medicines have been discussed and implemented all over the world (COCKBURN et al., 2005; LIMA et al., 2016).

For these reasons, the present study is going to focus on (i) a specific disturbance scenario, to explore how SCR may influence counterfeit combat and (ii) a specific supply chain – medicines, to explore and contribute to the available knowledge in SCR and counterfeit areas.

1.5 Dissertation Structure

Figure 4 presents the sections of the final dissertation and the scope designed.

Figure 4: Dissertation structure



Source: created by the author

2 SCOPE REVIEW

This section aims at presenting initial concepts that allowed deeper exploration of resilience and counterfeit themes in supply chain management, focused on medicines. The results from SLR are detailed in section 4.

2.1 Illegal Products in Supply Chain

Trafficking uncontrolled substances, stolen and smuggled goods, and trade products without IP rights are examples of illicit trade within the supply chain (STAAKE; THIESSE; FLEISCH, 2009). The growing emergence of such issues in the supply chain may be explained by increased globalization, dispersed value chains, distribution of goods in the international market (BERGER; BLIND; CUNTZ, 2012), challenging economic conditions and popularity of the Internet combined with privacy legislation (WILCOCK; BOYS, 2014).

Pharmaceutical Security Institute (PSI) defines three types of crimes related to illicit trade in the supply chain: illegal diversion, thefts, and counterfeit trade. Illegal diversion happens when a produced and approved genuine product is intercepted and sold in a different region. Thefts are products illegally obtained at any point of the supply chain, either by burglary, robbery, or at an embezzlement of goods. It is common to read about such incidents in magazines and newspapers of products with different value, from snacks (G1, 2016) to pumps (R7, 2016). Finally, counterfeit trade is the

[...] trade in goods that, be it due to their design, trademark, logo, or company name, bear without authorization a reference to a brand, a manufacturer, or any organization that warrants for the quality or standard conformity of the goods in such a way that the counterfeit merchandise could, potentially, be confused with goods that rightfully use this reference. (STAAKE; THIESSE; FLEISCH, 2009, p.322)

For each type of illicit trade, there are different actors, capabilities and mitigation mechanism to be evaluated (STAAKE; THIESSE; FLEISCH, 2009). To delimitate our research, we decided to focus on counterfeit trade.

2.2 Counterfeit

IP is an intangible and valuable asset used by organizations to leverage business and, therefore, has become a key-factor in organization evaluation (GREEN; SMITH, 2002; STAAKE; THIESSE; FLEISCH, 2009; LAU; KONG; BAARK, 2012). To protect IP, organizations apply formal methods, such as patents and trademarks, and informal ones, such as confidentiality agreements (LAU; KONG; BAARK, 2012). However, despite the efforts, the number of counterfeit incidents reported has grown, especially in markets focused on research and development and innovation, such as pharmaceutical, automotive, electronic, and aviation (STEVENSON; BUSBY, 2015), driven by increased globalization, and complex and fragmented supply chains (EVERTS, 2010). Unfortunately, there is no reason to believe that this reality is going to change soon (CESAREO; STÖTTINGER, 2015), and organizations have to prepare to deal with this threat.

Counterfeiting may jeopardize organizations and consumers. From an organization perspective, it may lead to revenue losses, because customers may associate these products with poor quality, and costs increase, due to actions to be taken when a disruption occurs, necessity of recall, potential legal liabilities, and loss of brand value (STAAKE; THIESSE; FLEISCH, 2009; STEVENSON; BUSBY, 2015). Consumers may also be harmed for purchasing counterfeit products. There are two types of market scenarios when customers buy such products (GROSSMAN; SHAPIRO, 1988a, 1988b). Grossman and Shapiro (1988a, 1988b) present these scenarios as deceptive and nondeceptive counterfeit market. Deceptive counterfeiting consumers are unaware that they are not purchasing original products and cannot detect them by inspection or inference from place of purchase. Thus, imperfectly informed clients characterize it and they will purchase counterfeit products only when deceived into believing that counterfeit

products are authentic (WILCOCK; BOYS, 2014). Deceptive counterfeits are potentially harmful to health and safety and represent losses in government operations (due to taxes not collected) and brand loss of sales and/or equity (GREEN; SMITH, 2002). These products tend to receive more enthusiastic responses from local authorities for requests for IP protection (GREEN; SMITH, 2002).

On the other hand, nondeceptive counterfeiting consumers know or strongly suspect when they purchase not original products. They distinguish fakes from legitimates and deliberately chose to buy counterfeits. Although in practice markets for counterfeit may not be entirely deceptive or nondeceptive, distinguishing them may help studies on the subject (GROSSMAN; SHAPIRO, 1988a). Nondeceptive counterfeits usually encompass designer brands, audio and video products, and software (GREEN; SMITH, 2002). Regardless of the type of market, the purchase of counterfeiting may cause severe damages to the consumer. In medicines supply chain, for example, counterfeit products may include the incorrect quantity of ingredients, be composed by the wrong formula, or contain non-active or even toxic additives (OECD, 2008). Thus, they may be toxic, resulting in treatment failure or death, and contribute to a growing resistance to medicines (e.g. antimalarial drugs) (COUSTASSE; ARVIDSON; RUTSOHN, 2010).

2.3 Counterfeit Medicines

As stated, counterfeit medicines represent a safety risk and a global health problem. The issue has drawn attention from supranational organizations, national governments, supply chains and organizations (GREEN; SMITH, 2002). They have tried to present a consensual definition, as presented in table 1.

Table 1: Definition of counterfeit medicine

One which is deliberately and fraudulently mislabeled with respect to identify
and/or source. Counterfeiting can apply to both branded and generic products
and counterfeit products may include products with the correct ingredients or
he wrong ingredients, without active ingredients, with insufficient active
ngredients or with fake packaging.
Manufactured using incorrect or harmful ingredients. These medicines are then
packaged and labeled to look like real brand-name and generic drugs.
Counterfeit medicines are unsafe because they may not be effective or may even
narm you.
Those sold under a product name without proper authorization. Counterfeiting
can apply to both brand name and generic products, where the identity of the
source is mislabeled in a way that suggests that it is the authentic approved
product. Counterfeit products may include products without the active
ngredient, with an insufficient or excessive quantity of the active ingredient,
with the wrong active ingredient, or with fake packaging

Source: created by the author

However, its definition in the medicine supply chain is reason for ongoing debate and influences country's perspective in its fight. Kenya, for example, has more inclusive counterfeit law definition, which may imply in generic medicines being considered as counterfeits (CHATTERJEE, 2010; MACKEY; LIANG, 2011).

Despite its conceptual definition, steering groups within national governments have formed several inter-agency task forces and auditing groups, such as Operation Pangea from Interpol, aimed at fighting illegal trade of medicines on the Internet. This operation happens every year since 2008 and brings together more than 100 countries. In June 2015 (Pangea VIII), the operation seized 20.7 million of medicines, estimated in US\$ 81 million, arrested 156 people, launched another 429 operations, and removed from the internet 550 advertisements and 2.410 websites (INTERPOL, 2016). Besides Pangea, just Interpol guides five other operations focused on counterfeit medical products and pharmaceutical crimes in Southeast Asia, East Africa, West Africa, Southeast Africa and West Africa (INTERPOL, 2016). In another operation performed in Europe, within just 2 months more than 34 million counterfeit pills were seized (WHO, 2010).

Medicines are high-value products, easy to transport, in high demand, and with large margins, which makes it a susceptible industry for counterfeiters (LYBECKER, 2008). Furthermore, counterfeiting is facilitated in weak regulatory control and enforcement, unregulated market, and where there is a scarce and/or erratic supply (LYBECKER, 2008; WHO, 2010). Therefore, despite the risks associated with intensification of risk awareness to counterfeiting, such as negative publicity and loss of brand equity (COCKBURN et al., 2005), organizations and governments are increasingly acknowledging counterfeit medicines as an actual threat and discussing elements to support its combat (LYBECKER, 2008).

However, literature on the theme rely on managerial findings that date back to 1980, - Grossman and Shapiro (1988a, 1988b) - despite the dynamism and advances of counterfeiters techniques, and focus on specific countermeasures such as awareness campaigns (STAAKE; THIESSE; FLEISCH, 2012) and traceability (BENDAVID; BOECK; PHILIPPE, 2012). To reduce vulnerability of medicines supply chain and make them more prepared to respond and react to disturbance in a dynamic environment, studying the role of resilience elements in combating counterfeits in medicines supply chain should be an interesting avenue of research.

2.4 Resilience

This section presents the main differences between Supply Chain Risk Management (SCRM) and Supply Chain Resilience (SCR) and discusses how different authors characterize SCR.

2.4.1 Introduction to Supply Chain Risk Management (SCRM)

The level of globalization, interdependency, and complexity have increased in modern supply chains (JÜTTNER; PECK; CHRISTOPHER, 2003), that are searching ceaselessly for cost reduction through management practices, such as Just in

Time and Lean Manufacturing (FIKSEL et al., 2015). While enhancing efficiency in stable environments, they make organizations more vulnerable to risks and disturbances (JÜTTNER; PECK; CHRISTOPHER, 2003; PETTIT; CROXTON; FIKSEL, 2013; FIKSEL et al., 2015; KAMALAHMADI; PARAST, 2016). As a result, managing risks of supply chain has been on the agenda of many researchers and executives.

Supply chain risk management (SCRM) is the identification and management of several risks in the supply chain, through a coordinated action among all chain members to reduce its vulnerabilities (JÜTTNER; PECK; CHRISTOPHER, 2003). Hence, the traditional risk management methods are based on the notion of stability as a "normal" state (FIKSEL et al., 2015). Fiksel et al. (2015) suggest that despite the effort to develop an integrated risk management approach, such as (i) enterprise risk management, which brings details and insights associated with business activities; and (ii) business continuity management, which incorporates crisis management practices to disasters recovery, they have relevant deficiencies. Both approaches focus heavily on risk identification. However, many risks are unpredictable or dependent of information that may not exist, not be available, or not be trustable (FIKSEL et al., 2015). Thus, applying them in every case and every link of the global supply chain may be too costly (PETTIT; FIKSEL; CROXTON, 2010). Moreover, these approaches are not seen as strategic initiatives directed to all employees, but local practices developed by security professionals (SHEFFI; RICE, 2005).

Therefore, authors have looked for a new approach able to support the complex and dynamic nature of modern supply chains, by providing solutions to ensure constant and systematic surveillance to vulnerabilities, and to enable agile and flexible responses in any type of disruption, not just to return to "normal" stage, but also to learn

and evolve. (JÜTTNER; PECK; CHRISTOPHER, 2003; JÜTTNER; MAKLAN, 2011; FIKSEL et al., 2015).

This approach is known as resilience. It goes beyond risk mitigation by supporting the achievement of competitive advantage and migration to a new state of equilibrium (FIKSEL et al., 2015).

2.4.2 Supply Chain Resilience (SCR)

As discussed above, organizations are being challenged to develop more resilient supply chains, by creating elements that enables management and mitigation of vulnerabilities (CHRISTOPHER; PECK, 2004). These vulnerabilities are boosted by trends such as supply chain globalization (NORRMAN; JANSSON, 2004; AMBULKAR; BLACKHURST; GRAWE, 2015), outsourcing, and reduction of supplier's base, buffers and life cycle (NORRMAN; JANSSON, 2004).

There is no unique definition accepted in academia, as observed in Table 2. However, it is possible to observe a convergence towards similar constructs, related to the ability of response to disruption and recovery, returning to the original state or surpassing it.

Table 2: Definition of SCR

Author(s)	Definition		
Fiksel (2006)	The ability to survive, adapt and grow in the face of turbulent change		
Ponomarov and Holcomb (2009)			
Ponis and Koronis (2012)	The ability to proactively plan and design the Supply Chain network for anticipating unexpected disruptive (negative) events, respond adaptively to disruptions while maintaining control over structure and function and transcending to a post-event robust state of operations, if possible, more favorable than the one prior to the event, thus gaining competitive advantage.		
Chowdhury and Quaddus (2015)	The capability of a supply chain to reduce the impact of vulnerabilities (due to disruptions) through developing required level of readiness, quick response and recovery ability.		
Hohenstein et al. (2015)	SCR is the supply chain's ability to be prepared for unexpected risk events, responding and recovering quickly to potential disruptions to return to its original situation or grow by moving to a new, more desirable state in order to increase customer service, market share and financial performance.		
Tukamuhabwa et al. (2015) The adaptive capability of a supply chain to prepare for and/or responsible disruptions, to make a timely and cost-effective recovery, and therefore progress to a post-disruption state of operations – ideally, a better state prior to the disruption.			
Kamalahmadi and Parast (2016)	The adaptive capability of a supply chain to reduce the probability of facing sudden disturbances, resist the spread of disturbances by maintaining control over structures and functions, and recover and respond by immediate and effective reactive plans to transcend the disturbance and restore the supply chain to a robust state of operations".		

Thus, for the purpose of this study, resilience supply chain presents adaptative capability to prepare and adapt to positively answer changes and disturbances in its operations (PONOMAROV; HOLCOMB, 2009; KAMALAHMADI; PARAST, 2016), seek competitive advantage (HOHENSTEIN et al., 2015), learn with facts and evolve to a new operating state (CHRISTOPHER; PECK, 2004; FIKSEL et al., 2015).

This comprehensive definition may help future practitioners and academics to guide their research. First, it summarizes the main points mentioned by other authors. Second, it considers disturbances predictable and unpredictable events. Third, it highlights the importance of resilience elements, developed to compensate supply chain vulnerabilities (FIKSEL et. al, 2015) and ensure better responses in case of disruption

(CHRISTOPHER; PECK, 2004; PEREIRA, 2014; SCAVARDA et al., 2015). Hence, elements are attributes to support anticipation and overcoming of disturbances (PETTIT; FIKSEL; CROXTON, 2010; ALI; MAHFOUZ; ARISHA, 2017). Fourth, it underscores the importance of all resilience phases comprised in SCR definition.

Presented by Hohenstein et al. (2015) and Tukamuhabwa et al. (2015), it represents an evolution of resilience concept and framework phases presented by other authors, such as Sheffi and Rice (2005) and Scholten, Scott and Fynes (2014). They establish 4 phases, namely (i) readiness, preparation before an event occurs, (ii) response, which is the immediate response after an event, (iii) recovery from the event; and (iv) growth to a new state and gain of competitive advantage. Different elements may better respond to different phases of resilience.

3 RESEARCH METHODOLOGY

This section discusses the choices made involving research method and research protocol planning, to ensure external and internal validity, respectively. As illustrated in figure 5, the study focuses on characterizing the resilience elements, which contribute to medicines supply chain counterfeit combat.

Resilience elements

Counterfeit antimeasures

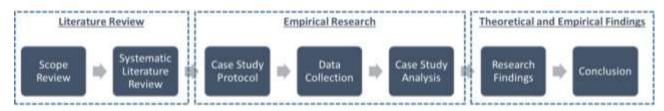
Figure 5: Research focus

Source: created by the author

3.1 Approach and Research Method

Authors often indicate qualitative studies to reflect a different form of knowledge, focused on individual perspectives. It helps to emphasize subjective interpretations, the process, and organizational culture and promotes more proximity with the phenomenon studied (BRYMAN, 1989; CROOM, 2009), requires characteristics to enrich the research outputs. Thus, aiming to investigate how resilience elements influence to combat counterfeit medicines in supply chain, this research involves a theoretical and an empirical part, and a combined analysis of relevant findings of theoretical and empirical studies, as illustrated in Figure 6.

Figure 6: Research design



The following sections detail each step overcome during research conduction and the deliverables defined for each phase. This practice helps to ensure the expected rigor required for a scientific research (VOSS, 2009).

3.2 Literature Review

Literature review enables the identification and organization of relevant concepts (ROWLY; SLACK, 2004), and the understanding of the explored theme, and relevant and emergent key-problems not solved (BADGER et al., 2000; FAWCETT et al., 2014). Thus, this study initiated with research scope and objective definition. Jesson, Matheson and Lacey (2011) claim that scope review is a fundamental step to SLR. The main deliverables of this step were the research scope established, and the SLR research questions formulated.

The large amount of information available in recent years resulting from dissemination on the internet and new journals and conferences constantly emerging, as well as the importance of literature reviews as the basis for good scientific work have increased the need for more systematic approaches to understand existing knowledge in more depth (BADGER et al., 2000; FAWCETT et al., 2014). Taking this into account, SLR was chosen to ensure that no relevant research was overlooked and also to improve the validity of the findings, rigor in research and minimize biases (TRANFIELD; DENYER; SMART, 2003; DENYER; TRANFIELD, 2009; TUKAMUHABWA et al., 2015) and complement the Scope Review Phase.

The SLR started with two questions from a broader perspective: (Q1) "What are the counterfeit anti-measures in the supply chain?" and (Q2) "What are the resilience elements associated with these anti-measures?" Question 1 provided a wider overview of anti-measures applied by different sectors and supply chains to mitigate counterfeit risks. Literature from specific sectors, such as shoes (QIAN; XIE, 2014), fashion (MERAVIGLIA, 2015), construction (NADERPAJOUH et al., 2015) and electronics (DIMASE et al., 2016) were selected, as the ones presenting generic antimeasures (MACKEY; LIANG, 2011; LI, 2013; QIAN, 2014; and CHO; FANG; TAYUR, 2015). Question 2 also enabled the analysis of both theoretical (KAMALAHMADI; PARAST, 2016) and empirical (SPEIER et al., 2011) articles, focused on several supply chains. It supported the map and characterization of resilience elements and the understanding of how these elements may be associated with the counterfeit antimeasures raised in Question 1. After investigating the first two questions in depth, the SLR focused on articles that deal specifically with the medicine supply chain by addressing question 3: (Q3) "How do resilience elements influence to combat counterfeit medicines in the supply chain?" Question 3 enabled us to analyze peculiarities of the medicine supply chain and suggest new avenues of research.

We divided the SLR in three phases, as observed in figure 7.



Figure 7: Phases of SLR

Source: Adapted from Tranfield, Denyer and Smart (2003) and Pereira, Christopher and Silva (2014)

The rigorous performance of these phases allowed the following outputs: (i) definition of gap analysis through clarification of objectives (DENYER; TRANFIELD, 2009; COSTA, 2016) and delimitation of study area (TRANFIELD; DENYER; SMART, 2003); (ii) establishment of criteria and materials to be studied (WEBSTER; WATSON, 2002; GUARDIA et al., 2013; TRANFIELD; DENYER; SMART, 2003); e (iii) development of research protocol, with rules, steps to be overcome (GUARDIA et al., 2013), recommendations (TRANFIELD; DENYER; SMART, 2003) and description of acquired knowledge (WEBSTER; WATSON, 2002).

Phase 1 develops the SLR Protocol, as Table 3 shows, aimed at protecting research objectivity by providing an explicit description of activities to be performed (TRANFIELD; DENYER; SMART, 2003 The SLR Protocol provides an explicit description of activities to be performed (DENYER; TRANFIELD, 2009; COLICCHIA; STROZZI, 2012). Its development enables the assurance of SLR transparency, validation of review method, and guidance of research (DENYER; TRANFIELD, 2009).

Table 3: SLR Protocol

Step	Deliverable	Data	Detail	
1- Plan SLR Identify study strategy		 constructs key words research strings database period 	- Table 4: constructs, key words and research strings (items 1, 2 and 3) - Database: Proquest, Web of Science, Scopus and Scielo - period: last 15 years (2002 – Oct/2016)	
2 - Conduct	Select studies	Filter 1: title, abstracts and key-words assessment Filter 2: introduction and conclusion assessment Analysis of inclusion and exclusion criteria	- Table 5 shows Filter 2 detail	
SLR	Collect data	 Full reading Data coding → support of QDA Miner software Article critical analysis 	- codebook in Appendix V	
3 – Report and disseminate results	Analyze data Synthesize data	- answer SLR questions - raise relevant information and literature gaps	- Content analysis by cross-checking data of several concepts, discussions and authors with support of QDA Miner software	

Source: created by the author

The SLR Protocol details the method applied in each of the three phases from Figure 7. Plan SLR encompasses constructs, key words, and string definition through information collected during Scope Review. First, for each question, the constructs were established. Second, we raise the most common words found in articles related to the constructs in Scope Review, with support of the website http://www.wordclouds.com. English dictionaries such as Cambridge Dictionary and Thesaurus were consulted for synonyms identification. Table 4 details the constructs, key words and strings used.

Table 4: SLR constructs, key words and strings

Construct	Key words	Strings
- Counterfeit	- Counterfeit; - Counterfeit organization; - Counterfeiting supply chains.	((("supply chain") OR ("organization*") OR ("organisation*") OR ("compan*") OR ("firm*")) AND ("counterfeit*"))
- Supply chain resilience (SCR)	 Supply chain resilience; Resilient Supply Chain; Resilience; Supply resilience; Vulnerability; Supply chain vulnerability. 	(("supply chain*") w/3 (resilien* OR risk* OR vulnerabilit*))
- Supply chain resilience (SCR) - Counterfeit - Medicines	 Counterfeit; Counterfeit organization; Counterfeiting supply chains. Supply chain resilience; Resilient Supply Chain; Resilience; Supply resilience; Vulnerability; Supply chain vulnerability. Medicines; Pharmaceuticals; Pills. 	((("counterfeit*") AND (("pharmaceutic*") OR ("medicine*") OR ("pill*") OR ("drug*")) AND ((("supply chain") OR ("organization*") OR ("organisation*") OR ("firm*")) near/4 (resilien* OR risk* OR vulnerability* OR disruption*))))

Source: created by the author

Our approach was to minimize bias and cover a wide range of sources and information. We chose the databases Web of Science, from Thomson Reuters Institute of Scientific Information, and Scopus, from Elsevier, because they are regularly updated databases, with a wide breadth of coverage in most scientific subjects (JACSÓ, 2005; CHADEGANI et al., 2013). These bases also offer power features for conducting and refining results (JACSÓ, 2005; BOYLE; SHERMAN, 2008). Although they are powerful

tools, researchers advocate that combining them may provide better research results (CHADEGANI et al., 2013). Furthermore, ProQuest ABI/INFORM databases were considered because of their coverage of publications in the management field (RÜLING, 2005). In addition, Scielo was considered for Brazilian studies, which discusses Brazil's reality and sometimes are not published in worldwide peer-reviewed journals.

The study considered articles published in last 15 years, from 2002 to Oct/2016, because counterfeit and resilience themes have significantly grown in recent years (LYBECKER, 2008; PEREIRA; CHRISTOPHER; SILVA, 2014; KAMALAHMADI; PARAST, 2016; LINNENLUECKE, 2017), especially in the medicine supply chain (LYBECKER, 2008). Furthermore, anti-measures to combat counterfeiters are changing with technology advances, more access to medicines, and new counterfeit techniques (LYBECKER, 2008; STAAKE; THIESSE; FLEISCH, 2012).

Then, a two-step screening process was followed to assess the relevance of the remaining papers according to pre-stipulated inclusion and exclusion criteria, as observed in Table 5.

Table 5: Inclusion and exclusion criteria

Criteria	Inclusion	Exclusion	
Journal Quality	Scientific periodic peer-reviewed	Business magazines, conference, books, and notes	
Access	Full content written in English or Portuguese	Full content not written in English or Portuguese	
Objective Alignment	Resilience and/or counterfeit concept within the scope of Operations Management	Resilience and/or counterfeit concept within the scope of other research areas such as materials engineering, pharmacology and medicine	
SLR Unit of Analysis Organizations or supply chains		Communities	
Focus	Deal directly with resilience elements in organizations or supply chains or with counterfeit anti-measures	Not deal directly with resilience elements or with counterfeit anti-measures under organizations or supply chains perspective	
Clarity Clearly define resilience elements or counterfeit anti-measures		Not define clearly resilience elements or counterfeit anti-measures	

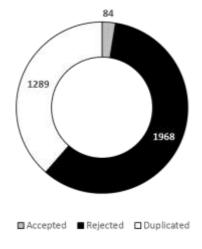
Source: created by the author

Step 1 (Plan SLR) was crucial to this research, once the materials quality and relevancy to study and theory synthesis orient all findings interpretation and

determine the relevance of articles' inferences (CONFORTO; AMARAL; SILVA, 2011; TRANFIELD et al., 2004). Phases 2 refer to execution of SLR, by selecting the articles raised important to answer the research questions Q1, Q2 e Q3.

Based on the key words, 3.341 articles were returned and 1.289 were duplicated. Then, a two-step screening process was followed to assess the relevance of the remaining articles according to pre-stipulated inclusion and exclusion criteria, such as objective alignment, focus, unit of analysis and clarity (Table 5). The aim was to ensure that the focus was on resilience elements and/or counterfeit anti-measures in the context of organizations or supply chains. Articles which meet all inclusion criteria and, consequently, violate all exclusion criteria were considered in the SLR to ensure quality of the selected materials (TRANFIELD; DENYER; SMART, 2003). The review was limited to articles published in peer-reviewed journal articles in order to ensure the high quality of this project (DENYER; TRANFIELD, 2009). It resulted in 84 articles for further analysis, as illustrated in Figure 8.

Figure 8: Status of articles' assessment



Source: created by the author

Phase 3 represents the analysis, synthesis and communication of results from the three proposed questions. This study applies the content analysis methodology, following Bringer (2006), Johnston (2006) and Krippendorff (2013). It is recommended

for facilitating the rigorous exploration of complex issues in the management field (Duriau et al., 2007). Thus, after reading the full texts, the chosen articles were uploaded in QDA Miner for more in-depth investigation (QDA, 2017). First, the study categorized the available data following the basic requirements proposed by Krippendorff (2013), which are mutually exclusive and exhaustive categories. Categorization is crucial to support the identification of relationships and establishment of connections among the different authors studied that write about the same constructs (Gibbs, 2009).

QDA Miner enabled us to better understand the frequency and potential clusters and relationships of both resilience enablers and counterfeit anti-measures. Results are presented in a proximity plot graph (Figure 3) as it can be observed better which key enablers are most often associated with counterfeit anti-measures (QDA, 2017). The coefficient of co-occurrence is calculated based on Jaccard's coefficient, which gives equal weight to cases where co-occurrence is identified (a) and cases where one item is found but not the other (b and c). Thus, it is calculated from a fourfold table as a/(a+b+c) (QDA, 2009). Finally, the conclusion summarizes the results and sheds light on recommendations of future research, as well as policies and practices (Denyer and Tranfield, 2009).

3.3 Empirical Research

To ensure the applicability of the proposed solution to real problems, this study empirically validated the contribution in exploring the role of resilience elements to combat counterfeits (TRANFIELD et al., 2004). The SLR identified that few authors have tried to empirically validate counterfeit anti-measures (e.g. Green and Smith, 2002; Cesareo and Stöttinger, 2015), and just one studied the counterfeit anti-measures through resilience lens (Stevenson; Busby, 2015). Moreover, to the best of our knowledge, no

study has specifically focused on the medicines supply chain, despite the increased focus on combating counterfeit medicines.

The empirical research method chosen was case study, often used in Operations Management (VOSS; TSIKIRKTSI; FROHLICH, 2002) to pursue an explanatory purpose (YIN, 2001) and deal with questions that the researcher has little or no control (YIN, 2015). In addition, the method enables the phenomenon study in its real context, the deep understanding of phenomenon complexity and nature, the investigation of cause and effect relationships, and expansion of research horizons (PEDROSA; NÄSLUND; JASMAND, 2012; FAWCETT et al., 2014). Therefore, the empirical study investigates how resilience elements influence the combat of counterfeit medicines.

The first step to conduct a case study is to determine the unit of analysis. The research question should address it, which is generally a bounded entity – e.g. organization, person, behavioral condition (YIN, 2015). Therefore, to determine the unit, one has to understand what the study is going to investigate (BAXTER; JACK, 2008). Thus, the unit of analysis addressed in this study is the set of resilience elements that combat counterfeit within the pharmaceutical focal company and key supply chain links from the downstream product flow. These supply chain links are specific agents of medicines supply chain that obtain possession of the unit before final consumer: wholesalers, distribution centers (logistics operator), pharmacies and hospitals.

To define the pharmaceutical focal company and its downstream key supply chain links, specific criteria for focal organizations' selection were established:

- medium or large organizations, where practices of risk management and counterfeit mitigation should be more well-developed than in small organizations;
- organizations involved in traceability discussion forums, where risks of practices to increase patients' security is likely to be more developed;

- organizations located in Brazil, not just because of researcher location, but also due to lack of studies in Brazilian medicines supply chain;
- logistic providers, pharmacists and/or hospitals responsible for the custody of the
 medicine from focal organization, with the objective of analyze the downstream
 flow and practices established among the organizations to mitigate counterfeit
 risks.

We made contacts by e-mail, telephone and with the help of the research group with which the author interacts, where the study objective and methods of data gathering were presented. In addition, a formal letter (Appendix II) was attached to the e-mail providing all research and confidentiality details. However, due to the criticality and secrecy of the theme exposed, many organizations did not accept participating in this scientific research. Other researchers expose the same problem.

Medicine piracy is directly related to the institutional image of the company and involves the national and international investigation area, which makes discussions on the subject even more secretive and restricted in regard to obtaining information, which hinders scientific research. (MACHADO, 2011)

We overcame this limitation with the identification of two relevant pharmaceutical focal companies and four members from downstream flow in the supply chain that accepted to participate in this empirical study. Although authors such as Eisenhardt (1989) suggests the necessity of a sample of four to ten units of analysis, other current studies (e.g. Blackhurst, Dunn and Craighead, 2011 and Scholten, Scott and Fynes, 2014) have been successful in using up to three cases. Moreover, the objective of this study is not to build theory but deduce testable hypothesis in general theory (KETOKIVI; CHOI, 2014).

Thus, we believe that the selection of two relevant medicine supply chain cases are plentiful to meet the research objective: investigate how resilience elements influence to combat counterfeit medicines in the supply chain. We claim that these two

cases are relevant because: (a) the two pharmaceutical companies are engaged in discussions about traceability and its implementation, which demonstrates the interest in reducing counterfeit risks; (b) one pharmaceutical (PHARMA1) is a multinational, working in most of the countries around the world, while the other pharmaceutical (PHARMA2) is a big national organization – this factor impacts on how they deal with counterfeit incidents, locally or globally; (c) both pharmaceutical companies influence its supply chain links downstream to increase security; and (d) although both cases are engaged in mitigating counterfeit medicines, the approaches adopted by the organizations are different in several ways.

To deeply understand the phenomenon complexity and nature, during this research (approximately 18 months), nine other entities and associations that work through all medicines supply chain were interviewed to increase validity of the data and understand how they affect the fight against counterfeiters. In medicines supply chain, a big part of the counterfeit threat is addressed to Anvisa - the Brazilian health regulatory agency (similar to Food and Drug Administration - FDA - in the United States) and other associations, such as industry or class entities, responsible for representing the interest of the supply chain members and support the government in identification of counterfeit vulnerabilities. Therefore, including them on the study was crucial to enrich the analysis performed. Table 6 and 7 present main information about the organizations/entities studied.

Table 6: Characteristics of CASE 1 and CASE 2

Case	Pharmaceutical company	Third-party logistics company	Medicines distributor	Hospital	Interviewees and Roles
CASE1	PHARMA1 is a multinational organization with approximately 100 thousand employees working in more than 150 countries.	OPL1 is the single-medicine logistics provider of PHARMA 1. The organization is a large American company with operations in most of countries around the globe.	DISTRIBUTOR1 is one of the main clients of PHARMA 1. The organization is one of the biggest Brazilian distributors focused on pharmaceutical sector.	HOSPITAL1/2 has a history of purchases from DISTRIBUTOR 1 and DISTRIBUTOR 2. The organization is a famous public hospital in São Paulo State.	- PHARMA1: PMgenlatam1 (General Manager of Latin America), PSlog1 (Logistics Specialist) and PMtec1 (Technology Manager) - OPL1: TMsec1 (Security Manager) and TMsec2 (Security Manager) - DISTRIBUTOR 1: DMlog1 (Logistics Manager) - HOSPITAL 1/2: HMpurlog12 (Logistics Manager)
CASE 2	PHARMA2 is a well-known national pharmaceutical company with more than 2.000 employees and a large medicines portfolio	-	DISTRIBUTOR 2 is one of the organizations responsible for distributing the products of PHARMA 2. The organization is highly respected in healthcare sector and operates throughout the national territory.		- PHARMA 2: PMlog2 (Logistics Manager), PMqualsec2 (Quality and Security Manager) and PMrisk2 (Risk Manager) - DISTRIBUTOR 2: DMgen2 (General Manager) - HOSPITAL 1/2: HMpurlog12 (Logistics Manager)

Table 7: Characteristics of studied entities that affect both cases

Entity Objective Regarding Counterfeit/ Resilience	Main characteristics	Interviewees and Roles
Association Focused on IP Rights	CROSSASS1 aims at developing the economy and strength business. One of its goals is improve enforcement of IP rights in Brazil	AIPrep1 (Association's Representative)
and Counterfeit Combat	CROSSASS2 is an association of companies that aims at fighting illegal activities that harms Brazilian business	AIPrep2 (Association's Representative)
Organization Focused on	CROSSORG1 focus on developing and disseminating best practices to improve Logistics	Orep1 (Organization's Representative) and OTRACrep1 (Traceability Representative)
Traceability and Standard Definition	CROSSORG2 is responsible for developing and disseminating best practices involving medicines	OTRACrep2 (Traceability Representative)
Dhamaantial Association	PHARMAASS1 is an association of pharmaceutical companies in São Paulo State	PArep1 (Association's Representative)
Pharmaceutical Association	PHARMAASS2 is an association of national and international pharmaceutical companies	PArep2 (Association's Representative)
Health and Regulatory Authorities	ANVISA is a federal health regulatory body of the Brazilian government	ANVrep (Representative of products controlling)
Technology Organizations	TECORG1 is a group of researchers that works in the areas of research and development of automation and process redesign TECORG2 is an automation engineering company, responsible for studying innovative	TOcoord (Coordinator), TOcoordtec (Technical Coordinator) and TOres1 (Researcher) TODoper (Director of Operations) and TODred
	solutions to integrate and promote communication between traceability systems	(Director of R&D)

Semi-structured interviews were conducted with individuals of the organizations involved in CASE 1 and CASE 2. The interviewees were selected after a conversation with one of the knowledgeable managers or specialists from the organization involved in traceability implementation discussion (see appendix III), because of the person's background on the subject and to mitigate problems with different structure names. Thus, all the interviewees are involved in mitigating counterfeiting risks in different areas, according to their functions (Logistics, Technology, Quality, Purchase and Security). Regarding downstream organizations, this study prioritized individuals that have direct contact with the previous supply chain link, to understand the antimeasures applied. Unstructured interviews were also conducted with individuals from entities, governmental or not, involved in combating counterfeit threat.

Due to the criticality of the theme, as previously discussed, most of the time the person involved in traceability implementation discussion was the most qualified to be interviewed. We detail the semi-structured questionnaire used with the interviewees in appendix IV. A pilot-test conducted with a manager and researcher in the field validated the research protocol (appendix I) (VOSS, 2009; YIN, 2015). Although face-to-face interviews might encourage a better connection with the interviewee, studies have to consider time, financial and logistical constrains (DEAKIN; WAKEFIELD, 2013). This study remained flexible by proposing face-to-face interviews or online interviews (e.g. Skype tool), according to the interviewee's preference. In total, we interviewed, between June and September of 2017, 11 individuals from focal companies and downstream organizations. We conducted 7 face-to-face interviews and 4 Skype interviews, they lasted around 60 minutes each. The interviews aimed at understanding the role of the interviewer in the organization and in the counterfeit fight and the strategies adopted by the organization to combat the counterfeit threat. After some open questions

about the anti-measures adopted, the researcher asked about the relevance to the company of each counterfeit anti-measures and resilience elements raised from SLR. Moreover, during the two years of this study, we conducted several discussions with 13 individuals from other entities that work cross supply chain. A follow up with e-mails and telephone calls helped to understand questions originated during the analysis and increased data gather reliability (VOSS, 2009).

Besides interviews, the case study analysis involved data triangulation by combining varied data collection sources, which increases research validity (VOSS; TSIKIRKTSI; FROHLICH, 2002; VOSS, 2009). The other sources of data collection were:

- participation in seminars, congresses and other events related to counterfeit antimeasures and risk management practices. For example, the author attended national and international seminars focused on medicines traceability SETRM (Technology Seminar for Medicines Traceability) and security in pharmaceutical supply chain Pharma Supply Chain & Health Brazil International Forum of Security in Pharmaceutical Logistics;
- group discussions about traceability implementation and data sharing challenges
 with managers on the field;
- analysis of primary and secondary data, with the objective of analyzing reports
 containing counterfeit incidents description, risk management information, and
 tender decisions. Further information about the organization's history and other
 general data were collected from it or through other websites;
- observation of organization and its processes related to counterfeit combat.

Figure 9 summarizes the organizations involved in case study.

ENTITIES Traceability and Standard IP Rights and Anti-Health and Technology Regulatory CASE 1 Ο. DISTRIBUTOR PHARMA OPL 1 CASE 2 O., Θ. 0. PHARMACY &

Figure 9: Medicines supply chain links and case studies selected

The data collected, was transcript and documented to support the content analysis. The method enables the evaluation and inference of the implicit and explicit content collected (BARRATT; CHOI; LI, 2011; PEDROSA; NÄSLUND; JASMAND, 2012). As in SLR, we performed the qualitative data analysis with support of QDA *Miner* software, following the approach proposed by Bringer (2006), Johnston (2006) and Krippendorff (2013): categorization based on dimensions and categories identified in advance and revised during the codification process. The analysis started from the codes identified in SLR and added new ones by means of inductive analysis (BARDIN, 2008).

This study analyzed data in two ways: within-cases and, subsequently, cross-case analysis. Within-case analysis ensures greater familiarity with each of the cases studied and identification of patterns. Thus, supports the necessary deepness to the next step. Then, in cross-case analysis, matrices represented the relation among the categories. The categories were refined in order to corroborate or refute the conclusions obtained in the cross-case analysis (VOSS, 2009).

3.4 Research Findings and Conclusions

The last and most complex step of this study encompasses analyze, synthetize and communicate results. A clear and concise process is necessary to support relevant data presentation of the extensive material collected in the previous stage (TRANFIELD; DENYER; SMART, 2003). Finally, the conclusion summarizes the empirical and theoretical findings and sheds light on recommendations of future researches and policies and practices (DENYER; TRANFIELD, 2009). This study applies content analysis, following Bringer (2006), Johnston (2006) and Krippendorff (2013) methodology. It is recommended for facilitating the rigorous exploration of complex issues in the management field (DURIAU; REGER; PFARRER, 2007; BARRATT; CHOI; LI, 2011; PEDROSA; NÄSLUND; JASMAND, 2012).

For both theoretical and empirical parts, the relevant documents were uploaded in QDA Miner for deeper investigation. QDA Miner is a qualitative data analysis tool, which provides accessibility and flexibility to analyze texts and relate its content to structured information (QDA, 2017). First, the study categorized the available data following the basic requirements proposed by Krippendorff (2013), mutually exclusive and exhaustive categories. Categorization is crucial to support the identification of relationships and establishment of connections among different authors studied that write about the same constructs (GIBBS, 2009). Thus, the approach enabled a co-occurrence analysis, applied to explore the potential association among the categories (QDA, 2017). It allowed a better understanding of which key elements are most often associated with counterfeit anti-measures and, therefore, might better prepare the medicine supply chain to increase resilience to counterfeit.

Moreover, Krippendorff (2013) suggests further analysis in the information provided by content analysis indices are required. He argues that analysts

have to distinguish between quantifications that lead to the testing of a statistical hypothesis and quantifications that indicate something other than what is measured. In light of this suggestion, the research approach adopts two bases defined by Ketokivi and Choi (2014). First, a quantitative portion to examine concepts in terms of frequency; second, a qualitative portion in terms of their meaning and interpretation in specific contexts of inquiry. Thus, this study concludes with a critical analysis of all data investigated and present findings and new avenues of research.

4 SYSTEMATIC LITERATURE REVIEW (SLR)

The SLR enabled synthesizing the highly fragmented literature involving how to combat counterfeit and provided a better understanding of current literature gaps about elements most and less often associated with counterfeit anti-measures. Moreover, it evidenced that only limited research has been conducted into choosing and implementing practices for improving resilience to counterfeit.

Anti-counterfeit literature explores a range of anti-measures. However, it is highly fragmented. Almuzaini, Choonara and Sammons (2013) present a SLR in counterfeit medicines focused on assessing the quality of studies about drug analysis Coustasse, Arvidson and Rutsohn (2010), Li (2013), Taylor (2014), and Dimase et al. (2016) provide technological solutions to address the issue. Most articles on the theme do not focus on managerial perspective of supply chains. Hoecht and Trott (2014) present a broad review of such anti-measures but focused on Chinese scenario. Lybecker (2008) presents managerial mechanisms specific to pharmaceutical industry.

An alternative path to study measures to combat counterfeit is to see it as a disruption in the supply chain. Therefore, SCR may be an effective way to prevent and combat counterfeiting. In recent years, academics have been developing a vast literature involving SCR. Essentially, they are related to (a) generic mechanisms or frameworks to increase organizational or SCR (e.g. theoretical: Ehrenhuber et al., 2015; Hohenstein et al., 2015; Kilubi and Haasis, 2015; Tukamuhabwa et al., 2015; Kamalahmadi and Parast, 2016 and Ali, Mahfouz and Arisha, 2017; and empirical: Sheffi, 2005; Blackhurst, Dunn and Craighead, 2011; Pettit; Croxton; Fiksel, 2013 and Brusset and Teller, 2017); (b) specific elements(e.g. theoretical: Christopher and Lee, 2004; Sheffi and Rice, 2005; Kache and Seuring, 2014; Chang, Ellinger and Blackhurst, 2015; and empirical: Christopher and Lee, 2004; Kache and Seuring, 2014; Scholten and Schilder, 2015, and

Liu et al., 2017); (c) organizational functions or processes to increase organizational or SCR(e.g. theoretical: Khan, Christopher and Creazza, 2012; and empirical: Khan, Christopher and Creazza, 2012; Pereira, Christopher and Silva (2014), and Wang, Jie and Abareshi, 2015); and (d) analysis of specific disturbances scenarios and how resilience could contribute (e.g. empirical: Rashid, Loke and Ooi, 2014; Scholten, Scott and Fynes, 2014; and Stevenson and Busby, 2015).

Literature considering SCR elements as tools to combat counterfeit is still in its infancy stage (STEVENSON; BUSBY, 2015). Stevenson and Busby (2015) were the first to link resilience elements and counterfeit construct. They identified four sets of strategies used by counterfeiters to introduce illegitimate products and propose countermeasures to increase resilience based on signaling theory and the resource-based view. More studies are necessary within this context, as SCR may play an important role in the fight against counterfeit medicines.

4.1 Descriptive Analysis

After a careful selection (detailed in section 3), this study contributes with an overview of 84 peer-reviewed journal articles from 2002 to Oct/2016. Figure 10 presents the results.

Search in electronic databases

1st filter

398

2nd filter

84

Figure 10: Results of SLR

Source: created by the author

When evaluating the formal characteristics of the collected material, the authors can (1) provide a consistent analysis of the articles and (2) use them to support the content analysis (Seuring and Gold, 2012). The SLR considered 84 papers, from which 57% (48 articles) discuss mainly resilience enablers and 42% (35 articles)

counterfeit anti-measures. As stated, only one article presents resilience as a solution to mitigate counterfeit disruptions. Moreover, only 18 articles (21%) address the anti-counterfeit measures and/or resilience enablers from a medical perspective. It corroborates with the claim that few articles are concerned with these topics. The articles selected mainly (48%, or 40 papers) address the issues from a general perspective, 6 papers (7%) discussed the food and beverage sector, 5 papers (6%) the fashion sector and 15 papers (18%) other industries.

Most of the articles (70%) were published from 2011-2016 which shows the increased attention to topics on resilience and counterfeiting, despite the decrease in articles in 2016. Table 8 presents the articles distribution according to the correspondent Journal. Table 8 considers just journals with more than 1 occurrence.

Table 8: Articles distribution per Journal (> 1occurrence)

Journal	Occurrences
Supply Chain Management: An International Journal	6
Business Horizons	6
International Journal of Physical Distribution and Logistics Management	5
International Journal of Production Economics	3
Journal of Operations Management	2
The International Journal of Logistics Management	2
Journal of Transportation Security	2
International Journal of Production Research	2
Computers and Industrial Engineering	2
Journal of Fashion Marketing and Management	2
Journal of Business Logistics	2

Source: created by the author

Moreover, figure 11 the articles distributed per year.

Figure 11: Articles distribution per year

Moreover, this paper analyzes the origin of the authors of the 84 papers and which countries or regions the articles focus on. Table 9 presents an overview of the main findings.

Table 9: Studied regions and origin of authors

Region	Regions researched	Origin of authors
General	44	-
Africa	2	1
Asia	15	18
Europe	11	39
North America	8	46
Central America	1	1
South America	2	1
Oceania	1	5

Source: created by the author

As observed, most of the research (52%) does not focus on any area, but analyzes the problem from a global perspective. Moreover, although 77% of the authors come from Europe and North America, Asia is the scenario which has been more studied among the selected papers. The articles were probably influenced by the increasing economic rates in the area and their susceptibility to counterfeiting. Less attention has been paid to Africa, Central and South America and Oceania.

The next items in section 4 aim at reporting the findings by answering the SLR questions. (Q1) What are the counterfeit anti-measures in the supply chain? (Q2)

What are the resilience elements in the supply chain associated with counterfeit antimeasures? (Q3) How do resilience elements influence counterfeit combat in medicines supply chain?

4.2 Counterfeit Anti-measures in Supply Chain

This review identified and characterized 16 anti-measures, detailed in Table 10, which sheds light on a diverse set directed to both counterfeit markets. Moreover, authors (GREEN; SMITH, 2002; HOECHT; TROTT, 2014; NADERPAJOUH et al., 2015) claim that sometimes the best strategy to be taken is simply do nothing or withdraw from the market. Although these measures initially cause a certain discomfort, they may be an intelligent solution when: (i) the costs involved overlap the likely benefits (HOECHT; TROTT, 2014); (ii) in non-deceptive markets where the organization faces many difficulties in terms of authority cooperation (GREEN; SMITH, 2002); or, (iii) when the risks are too high (SHARMA; BHAT, 2014; CESAREO; STÖTTINGER, 2015).

Table 10: Definition of counterfeit anti-measures identified in the present literature review

Group	Counterfeit anti- measures	Definition	Authors
es and	Strict government requirements	Develop laws, regulations and requirements to help countries to monitor and control counterfeiting and to penalize counterfeiters appropriately.	Chaudhry et al. (2009); Urciuoli (2010); Chaudhry; Stumpf (2013); Hoecht; Trott (2014)
l process s	Enforcement of IP rights	Ensure the application of enforcement actions (public and private policies) enabling right-owners from copyrights and related rights, trademarks, and designs or patents to impose their rights and facilitate the grant of rights to others to be resisted.	Chaudhry et al. (2009); Urciuoli (2010); Fernandes (2013); Hoecht; Trott (2014); Qian (2014)
Inter-organizational processes and policies	Enhance national and international cooperation	Develop practices to enable collaboration among national and international entities (e.g. NGOs, WHO, QBPC), government, regulatory authorities, police, judiciaries and companies.	Lybecker (2008); Jameson et al. (2009); Coustasse; Arvidson; Rutsohn (2010); Almuzaini; Choonara; Sammons (2013); Qian (2014)
Inter-org	Monitor supply chain members	Establish a system of surveillance, supervision, control and auditing of other supply chain members to protect the network, as well as detect and expose counterfeiters.	Kumar; Dieveney; Dieveney (2009); Urciuoli (2010); Hoecht; Trott (2014); Cho; Fang; Tayur (2015); Dimase et al. (2016)
and	R&D strategies	Develop R&D strategies regarding products, processes and infrastructure to mitigate counterfeit risks	Green; Smith (2002); Berger; Blind; Cuntz (2012); Hoecht; Trott (2014); Qian (2014); Stevenson; Busby (2015)
	Price strategies	Use strategies to increase or decrease prices of products to combat counterfeiters.	Stumpf; Chaudhry (2010); Li (2013); Qian (2014); Cesareo; Stöttinger (2015); Cho; Fang; Tayur (2015)
ational pr policies	Create an internal structure	Develop a structure within the organization responsible for mitigating and/or combating counterfeit risks.	Green; Smith (2002); Lybecker (2008); Chaudhry et al. (2009); Meraviglia (2015); Wilson; Grammich; Chan (2016)
Intra-organizational processes policies	Improve quality	Offer customers better quality products to enhance the brand's value perception by adding features, improving product's testability, making it more durable and offering complementary services.	Urciuoli (2010); Qian (2014); Cesareo; Stöttinger (2015); Cho; Fang; Tayur (2015); Meraviglia (2015); Stevenson; Busby (2015)
Intr	Supply/partner strategies	Review relationship strategies with suppliers and other partners by analyzing potential long-term damage to IP and counterfeiting risks and creating partnerships to combat it.	Hoecht; Trott (2014); Qian (2014); Meraviglia (2015); Stevenson; Busby (2015); Wilson; Grammich; Chan (2016)

Table 10: Definition of counterfeit anti-measures identified in the present literature review (cont.)

	Enhance risk awareness	Raise general awareness of risk involving counterfeit activities and seriousness of the problem, from customers, organizations, supply chains and government perspectives.	Chaudhry et al. (2009); Chaudhry; Stumpf (2013); Cesareo; Stöttinger (2015); Cho; Fang; Tayur (2015); Stevenson; Busby (2015); Wilson; Grammich; Chan (2016)
Behavioral	Enhance brand reputation	Develop mechanisms to strengthen the brand's image and reputation to diminish the counterfeiter's urge to imitate and emphasize positive experiences from buying legitimate products (e.g. quality, ethics, and status).	Green; Smith (2002); Berger; Blind; Cuntz (2012); Cesareo; Stöttinger (2015); Stevenson; Busby (2015)
Beh	Standardize and train practices and processes	Define practices and processes and train supply chain personnel to handle counterfeit issues.	Chaudhry et al. (2009); Jameson et al. (2009); Berger; Blind; Cuntz (2012); Naderpajouh et al. (2015); Dimase et al. (2016); Wilson; Grammich; Chan (2016)
	Train members to identify fakes	Communicate about how to differentiate between counterfeit and genuine products.	Chaudhry; Stumpf (2013); Hoecht; Trott (2014); Cesareo; Stöttinger (2015)
Technology	Traceability	Track and trace history, apply or locate which is under consideration across supply chain to show the chain of custody, ensure pedigree to manufacturers and certify product authenticity.	Wyld (2008); Jameson et al. (2009); Coustasse; Arvidson; Rutsohn (2010); Kwok et al. (2010); Dimase et al. (2016)
	Authentication technologies	Overt and covert technologies, developed to facilitate original product verification and counterfeit recognition by providing solutions difficult to duplicate without being easily detected by counterfeiters.	Green; Smith (2002); Lybecker (2008); Kwok et al. (2010); Li (2013); Taylor (2014); Wilson; Grammich; Chan (2016)
	Big data & analytics	Application of sophisticated mathematical and statistical models to manage, process and analyze big data ("5Vs") to support decision-making in counterfeit issues.	Kwok et al. (2010); Urciuoli (2010); Meraviglia (2015); Papadopoulos et al. (2016)

The SLR raised a set of anti-measures and this study proposes dividing them into four groups to make it easier to understand: (1) inter-organizational processes and policies, that are anti-measures and require coordination among supply chain links; (2) intra-organizational processes and policies, which are anti-measures applied only inside the organizations; (3) behavioral, which are anti-measures that influence the behavior of supply chain stakeholders; and (4) technology, which includes cientific and technical knowledge and application of technological tools to avoid counterfeiters.

4.2.1 Inter-organizational processes and policies

Aline Plançon, an Interpol police officer, states that "counterfeiters can make more money than hard-drug traffickers, and they have less chances of going to prison [...]. The attractive revenues don't come with heavy enough consequences" (EVERTS, 2010, p.27). Thus, stricter government laws/regulations are essential tools to make it difficult for counterfeiters to enter and fight against them. For this purpose, a legal framework to specifically address falsification is needed (COHN et al., 2012). Although the literature normally criticizes "soft" laws (mild, less severe) in regions such as Asia and developing countries, developed countries such as France and Norway also do not have severe regulations (NAYYAR; BREMAN; HERRINGTON, 2015). Stricter legislations are also necessary concerning legitimate supplies. For example, although some pharmaceutical companies in the United States were willingly implementing traceability systems, this massive implementation just initiated when its regulatory agency pushed them (KUMAR; DIEVENEY; DIEVENEY, 2009; COUSTASSE; ARVIDSON; RUTSOHN, 2010).

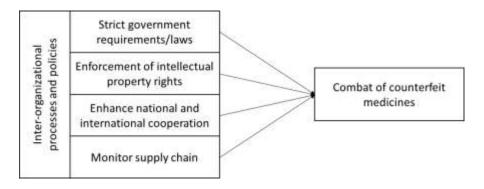
Severe regulations to punish counterfeiters and assure supply chain security are necessary. However, they are pointless without the appropriate enforcement (HOECHT; TROTT, 2014). In many cases, encouraging the government to enforce

existing laws is more effective than lobbying for new ones (CHAUDHRY et al., 2009). The most mentioned enforcement tools are raids, which result in seizures and confiscations of counterfeited products (e.g. Chaudhry et al., 2009; Everts, 2010; Fernandes, 2013), and arresting counterfeiters (e.g. Wyld, 2008; Chaudhry et al., 2009). In addition, increased border inspection is used to prevent importation of counterfeited products (FERNANDES, 2013). Licenses or certifications are also mentioned, which are provided by local governments, independent organizations or the company itself (to its partners or suppliers), and to obtain it the organization has to comply with a set of anti-counterfeit criteria (URCIUOLI, 2010).

Organizations can also help by making efforts to register, establish a renovation process, monitor trademarks and patents (CHAUDHRY et al., 2009) and promote self-enforcement (QIAN, 2014). These efforts facilitate public-private partnerships developed to detect and seize counterfeit products (MACKEY; LIANG, 2011). A more comprehensive outcome of these initiatives is achieved when there is cooperation among national and international entities involved in counterfeit combat. International organizations may contribute by promoting joint initiatives, such as Interpol and World Customs Organization, who have been working, together with national police forces, to combat illicit trade of medicines (ALMUZAINI; CHOONARA; SAMMONS, 2013). Governments need to be willing to develop strategies to reduce criminal activities by promoting collaboration between regulatory authorities, the police, customs services and judiciaries (COUSTASSE; ARVIDSON; RUTSOHN, 2010). Within supply chains, alliances between wholesalers, distributors, manufacturers and retailers are important to diminish its vulnerability (LYBECKER, 2008) because if one link is susceptible to counterfeiters, the whole chain is exposed (DIMASE et al., 2016).

Another anti-measure to reduce supply chain vulnerability can be achieved through constant monitoring. Blackhurst, Dunn and Craighead (2011) discovered through an empirical study that organizations consider it important to have a system to monitor supply chains in real time to help make strategic decisions to avoid disruption and to predict them. More specifically, Cho, Fang and Tayur (2015) state that monitoring systems should focus on identifying members who are selling counterfeits, facilitating seizure and punishing counterfeiters and their intermediates. Inside organizations, monitoring controls may include closed circuit television systems, perimeter alarms, physical barriers and high value storage areas (URCIUOLI, 2010). Figure 12 presents the main counterfeit anti-measures discussed.

Figure 12: Summary of inter-organizational processes and policies counterfeit antimeasures



Source: created by the author

4.2.2 Intra-organizational processes and policies

Reviewing the literature concerning counterfeit anti-measures, the two practices of quality and price are widely discussed and controversial when associated with counterfeits. Cho, Fang and Tayur (2015) developed a theoretical model and evaluated the effectiveness of quality and price, marketing, enforcement and technology strategies against deceptive and non-deceptive markets. Qian (2014) presents a framework to find the equilibrium level of prices, quality and purchase decisions. In this context, quality strategies involve upgrading the quality of the product, making it more durable, adding

features, improving the product's testability or offering complementary services to distinguish the legitimate product from counterfeits. By increasing the brand's value to the consumer, they become less tempted to purchase illegal products (FERNANDES, 2013; CHO; FANG; TAYUR, 2015) and the widened quality gap hampers the counterfeiters' ability to fool consumers (QIAN, 2014). Wilcock and Boys (2014) studied the integration of anti-counterfeits and standard quality management plans and state that they should at least be aligned to proactively prepare organizations for counterfeit issue. However, the authors claim that quality strategies are not always effective, because high quality products may increase counterfeit interest (e.g. Green and Smith, 2002); and time is needed for changes to take place, therefore they might not be applied when the counterfeit problem is urgent and requires immediate actions. In this case, organizations might opt for price adjustment responses (CHO; FANG; TAYUR, 2015; MERAVIGLIA, 2015).

Setting low prices, entry-level products make originals more accessible to consumers, by lessening the savings associated with buying a counterfeit, without alienating more the affluent who can afford pricier product lines (STUMPF; CHAUDHRY, 2010; CESAREO; STÖTTINGER, 2015). It increases the perceived importance of the original product (FERNANDES, 2013), improves access, increases sales volume (LI, 2013), drives counterfeiters out of the market (LYBECKER, 2008; LI, 2013) and helps to connect customers to the original manufacturer, who apparently understands their needs (CESAREO; STÖTTINGER, 2015). On the other hand, authors such as Qian (2014) and Cho, Fang and Tayur (2015) also discuss raising price strategy to discourage the licit distributor from taking the risk of selling counterfeits (and lose their current large margin) and distinguish the brand from counterfeiters.

Creating a moving target is constantly mentioned as a counterfeit antimeasure, which is linked to R&D capacity of developing new characteristics difficult to copy (GREEN; SMITH, 2002). Thus, R&D strategies, such as creating effective labelling and featured packaging (CESAREO; STÖTTINGER, 2015), redesigning products and increasing product's complexity (CHO; FANG; TAYUR, 2015) discourage illegal imitator from copying. A survey conducted by Berger, Blind and Cuntz (2012) shows the negative relationship of R&D intensity and patent infringement. In addition, the intelligence gained from efforts to detect counterfeit incidents should be reverted to the product design so that improvements can be planned and ensure that the manufacturer is a step ahead.

Furthermore, strict contractual agreements to penalize and reward other supply chain members should be developed. This includes detailing penalties for non-conformance, rights to audits and quality assurance (WILSON; GRAMMICH; CHAN, 2016), and incentives to risk arise activities (CHAUDHRY et al., 2009; HOECHT; TROTT, 2014). To apply the contractual agreement, monitor supply chain, and enhance brand-protection, companies may proactively create internal teams (CHAUDHRY et al., 2009; WILSON; GRAMMICH; CHAN, 2016) to analyze counterfeiter activities and perform initial investigations (GREEN; SMITH, 2002; LYBECKER, 2008; MERAVIGLIA, 2015). Figure 13 summarizes the counterfeit anti-measures discussed in this item.

Price strategies

Quality strategies

R&D strategies

Combat of counterfeit medicines

Supply/partner strategies

Create an internal structure

Figure 13: Summary of intra-organizational processes and policies counterfeit antimeasures

4.2.3 Behavioral

In complex environments, if knowledge is limited and good governance practices do not exist, the potential for counterfeits will be high (ENYINDA; TOLLIVER, 2009). Thus, counterfeit anti-measures should focus on modifying stakeholders' behavior to make them more active counterfeit fighters. The most mentioned anti-measure in the behavioral group is also one of the most challenging for organizations (MERAVIGLIA, 2015), raising general awareness of risk involving counterfeiting and the seriousness of the problem.

From a customer perspective, organizations should tailor solutions to stem the demand for counterfeit products (CESAREO; STÖTTINGER, 2015). This means (i) fighting the perception that counterfeiters are as good as the genuine product; (ii) combating anti-big business sentiments; (iii) enhancing awareness concerning legal impacts of consuming counterfeits (CHAUDHRY et al., 2009; FERNANDES, 2013; MERAVIGLIA, 2015); (iv) reinforcing the potential use of illegal/child labor (WILCOCK; BOYS, 2014; CESAREO; STÖTTINGER, 2015; MERAVIGLIA, 2015); (v) challenging the view that purchasing counterfeits is a victimless crime (MERAVIGLIA, 2015); (vi) explaining disadvantages for countries and society

(CESAREO; STÖTTINGER, 2015); (vii) emphasizing positive experiences from buying legitimate rather than counterfeits and reinforcing the value of the genuine product (WILCOCK; BOYS, 2014). Programs should be tailored addressing specific beliefs and ethical norms within regions/countries (WILCOCK; BOYS, 2014) and looking for incentives to strengthen the bond with consumers (CESAREO; STÖTTINGER, 2015; WILCOCK; BOYS, 2014).

Furthermore, enhancing counterfeit risk awareness makes customers more attentive to the likelihood of receiving such products. The Chinese customers surveyed by Cho, Fang and Tayur (2015) were substantially more proactive regarding counterfeits than customers in the United States, where counterfeit activities are less frequent. Companies, governments and policymakers should also inform and educate their own employees about risks associated with counterfeits in supply chains (JAMESON et al., 2009; STUMPF; CHAUDHRY, 2010) and enhance risk awareness. Sources (see Wilson, Grammich and Chan, 2016) have emphasized the need for aligning brand-protection values with performance objectives to help the understanding of risk culture and increase counterfeiting risk awareness.

Its operationalization may be achieved through inter and intra-organization communication programs, guidelines and training (NADERPAJOUH et al., 2015), attending conferences and seminars and benchmarking other players (WILSON; GRAMMICH; CHAN, 2016). Having the participation of all members of the organizations throughout the supply chain, it can more readily identify anomalies and better prepare to respond to disasters (GOULD; MACHARIS; HAASIS, 2010). The organization's level of risk awareness usually reflects on its practices and processes. Naderpajouh et al. (2015) conducted a survey in the construction industry and reported that a lack of awareness implied a lack of assessment and mitigation strategies.

Furthermore, recovery and knowledge-sharing plans need to be formulated and distributed (GOULD; MACHARIS; HAASIS, 2010). Absence of standardized practices and processes and/or its training generates a knowledge gap and may harm a firm's capability to respond to a counterfeit incident. Therefore, a multi-pronged action plan directed at employees and supply chain members is necessary (CHAUDHRY et al., 2009).

To be effective, behavioral anti-measures should be associated with training consumers to identify illegitimate products. This can be achieved through constant communication aimed at customers, distributors and other supply chain members, about how to validate a real product (e.g. package, label, and appearance) (CHAUDHRY; STUMPF, 2013; HOECHT; TROTT, 2014) and about the authorized retailers (CESAREO; STÖTTINGER, 2015). Notwithstanding, advertising on how to identify counterfeits may be difficult to implement (LYBECKER, 2008) and have only a limited effect (GREEN; SMITH, 2002). The disparities on the success of implementation might explain the significant variation in perspectives of executives from different countries on the benefits of its implementation in the survey conducted by Stumpf and Chaudhry (2010). Figure 14 sum up the relevant concepts discussed in this item.

Enhance risk awareness

Enhance brand reputation

Standardize and train practices and processes

Train customers to identify fakes

Figure 14: Summary of behavioral counterfeit anti-measures

Source: created by the author

4.2.4 Technologies

The literature on the subject of technologies is vast (NADERPAJOUH et al., 2015). From the articles reviewed that focus on specific counterfeit anti-measures, most of them are related to technologies (E.g. Coustasse; Arvidson; Rutsohn, 2010; Everts, 2010; Kwok et al., 2010; Li, 2013; Taylor, 2014; Nayyar; Breman; Herrington, 2015; Dimase et al., 2016). Anti-counterfeit technologies are developed to ensure products' authentication and security. Thus, they should be difficult to imitate, easy to identify, hard to reuse and easy to notice when tampered with (LI, 2013).

Authentication technologies aim at facilitating original products' verification and counterfeit recognition by providing solutions that are difficult to duplicate without being easily detected by counterfeiters. In a survey conducted across five countries by Stumpf and Chaudhry (2010) to understand executives' opinions of counterfeit problems, special packaging/labeling (e.g. hologram) appears as the most valuable counter measure overall. Authentication technologies may be divided into two categories. The first category is named overt technologies, which are visible to the naked eye and authenticated by human inspection, such as holograms, color-shifting ink and watermarks. They tend to be easy to identify and not so expensive. On the other hand, they may require training and be easier to falsify (KWOK et al., 2010; LI, 2013; WILSON; GRAMMICH; CHAN, 2016). The second category is covert technologies, which require special reading devices for authentication, including security inks, digital watermarks, chemical fingerprints and invisible printing (CHAUDHRY et al., 2009; KWOK et al., 2010; LI, 2013; WILSON; GRAMMICH; CHAN, 2016). In this case, experts usually conduct authentication analysis from basic physical exams to sophisticated statistical algorithms (EVERTS, 2010). They tend to be harder to copy and regulatory approval is usually not necessary. However, compromise risk should be monitored if the supplier is delegated to administer the device, and it is harder for users to identify fakes because special devices are needed (KWOK et al., 2010; LI, 2013).

Certification of product authenticity may also be achieved by traceability system implementation (COUSTASSE; ARVIDSON; RUTSOHN, 2010), which enables track and trace products across the supply chain, ensuring pedigree to manufacturers and guaranteeing the product flow to the consumer (DIMASE et al., 2016). It includes different technologies, such as bar codes and RFID (EVERTS, 2010) and the definition requires a cost-benefit analysis. Many authors present traceability as a solution to address counterfeit prevention and claim that they are essential to ensure supply chain safety (see Kwok et al., 2010). This is because it permits rapid identification and reports of suspected products and it also enables greater warehouse and inventory efficiency and control (COUSTASSE; ARVIDSON; RUTSOHN, 2010), providing real time information (ENYINDA; TOLLIVER, 2009), speed-up inspection operations (URCIUOLI, 2010) and increasing control in reverse logistics due to expired, recalled or dispensed drugs (KUMAR; DIEVENEY; DIEVENEY, 2009). The widely known solution is applied in different industries such as handbag manufacturing (LI, 2013), medicines (MACKEY; LIANG, 2011; LI, 2013) and electronics (DIMASE et al., 2016).

Another possible benefit of traceability is support risk-informed decision making (DIMASE et al., 2016). However, organizations are still struggling in terms of how to analyze all the information gathered and how to use it as a tool to counterfeiting detection (KWOK et al., 2010). For this purpose, regarding information collected from traceability system or other sources, they need to develop big data analytics solutions, intelligent systems created to analyze the enormous amount of information gathered. In this context, Kwok et al. (2010) designed a system architecture to enable automatic acquisition and effective sharing of information in supply chains. Big data analytics may

help, for example, to detect changes in sales and supply chain flow patterns, which indicate counterfeit evidence. Furthermore, it can look into disaster management and analyze how people respond to disasters in order to act appropriately measures and devise policies (PAPADOPOULOS et al., 2016).

In fact, big data & analytics may support the development of social and natural capital during the preparedness phase, alleviate and help recover from disturbances and cope with the future (PAPADOPOULOS et al., 2016). Finally, figure 15 summarizes the discussed strategies.

Traceability

Authentication technologies

Big data & analytics

Traceability

Combat of counterfeit medicines

Figure 15: Summary of technologies counterfeit anti-measures

Source: created by the author

4.3 Resilience Elements in Supply Chain

SCR elements is an ongoing debate. Christopher and Peck (2004) present four main principles in SCR: reengineering, agility, collaboration and SCRM culture. Faisal, Banwet and Shankar (2006) state that trust, collaboration, information sharing, and SCRM culture play a key role to counter risks in a supply chain. Kilubi and Haasis (2015) propose visibility, flexibility, multiple sourcing, redundancy and coordination for effective SCRM. Hohenstein et al. (2015) revealed that the largest number of studies deal with flexibility, redundancy, collaboration and visibility, agility, and multiple sourcing as core elements of SCR.

Resilience elements are rather interlinked, once one enabler for risk mitigation can have a direct positive influence over the other (RAJESH; RAVI, 2015). Several studies corroborate the statement. For example, Scholten and Schilder (2015)

empirical findings highlight how information sharing increases visibility, flexibility, and agility. Hohenstein et al. (2015) state that ones can enhance agility through higher visibility from information sharing and, by doing so, improve the reengineering process. As a result, they have been used interchangeably (KAMALAHMADI; PARAST, 2016) and various concepts frequently overlap (EHRENHUBER et al., 2015).

From the most studies, this literature review mapped and conceptualized the 13 elements, presented in Table 11.

Table 11: Definition of resilience elements identified in the present literature review

Elements	Definition	Authors
Flexibility	The ability of a firm and supply chain to sense threats, react, and adapt to changing requirements with minimum time, effort, cost and performance drop.	Rashid; Loke; Ooi (2014); Soni; Jain; Salmador (2015); Tukamuhabwa et al. (2015); Wang; Jie; Abareshi (2015)
Redundancy	Replication/Addition of capacity and/or resources that can be invoked during a disturbance to replace the loss of capacity and/or resources during a disturbance.	Sheffi; Rice (2005); Chang; Ellinger; Blackhurst (2015); Kilubi; Haasis (2015); Tukamuhabwa et al. (2015); Soni; Jain; Salmador (2015)
Collaboration	The ability to join efforts and work effectively within an organization or with other supply chain entities for mutual benefit. In the context of resilience, it reinforces the importance of internal and external communication.	Scholten; Scott; Fynes (2014); Ehrenhuber et al. (2015); Scholten; Schilder (2015); Soni; Jain; Salmador (2015); Tukamuhabwa et al. (2015); Zhang et al. (2016)
Trust	Relationship of trust among supply chain members, a critical component in building successful long-term relationships: goodwill trust (expectation that partners will not act in an opportunistic way) and/or competence trust (belief of the ability to perform as expected).	Dekker; Sakaguchi; Kawai (2013); Kamalahmadi; Parast (2016); Papadopoulos et al. (2016)
Information sharing	Share important and possibly proprietary information among supply chain members and inside organizations.	Dekker; Sakaguchi; Kawai (2013); Papadopoulos et al. (2016); Riley et al. (2016)
Information security	Secure information communicated inside the firm with supply chain partners and other stakeholders against deliberate intrusion or attacks.	Rajesh; Ravi (2015)
Agility	The ability to react and adapt quickly to changes and potential or actual unpredictable events.	Christopher; Peck (2004); Scholten; Scott; Fynes (2014); Tukamuhabwa et al. (2015)
Visibility	The ability to transparently see through all supply chain links to reduce the information asymmetry, quickly identify needs and disruptions and be able to implement changes in an effectively.	Christopher; Peck (2004); Glickman; White (2006); Tukamuhabwa et al. (2015); Ehrenhuber et al. (2015)
Sensing	The ability of discerning processes ahead of time and anticipating potential future events or situations.	Pettit; Croxton; Fiksel (2013); Ehrenhuber et al. (2015)
SCR culture	Infusing a culture of resilience and risk awareness to make it the concern of everyone.	Christopher; Peck (2004)
Leadership	Commitment and support of top managers to implement and maintain SCR.	Wilcock; Boys (2014); Kamalahmadi; Parast (2016)
Innovation	Reach beyond the organization's boundaries and strive to continuously transform knowledge and ideas into new products, processes and systems for the benefit of the supply chain.	Golgeci; Ponomarov (2013); Ehrenhuber et al. (2015); Wang; Jie; Abareshi (2015)
Reengineering	Redesigning the supply chain considering certain characteristics to build resilience, reduce risk exposure and overcome disruptions.	Christopher; Peck (2004); Scholten; Scott; Fynes (2014)

Source: created by the author

The increased level of risk exposure in supply chain indicates the necessity of adjusting the conventional optimization goal for the process design to focus not just on cost and customer service, but also risk performance. This means reengineering the supply chain to build resilience in advance of disturbances and incorporate readiness to enable an efficient and effective response (CHRISTOPHER; PECK, 2004; SPEIER et al., 2011; CARVALHO et al., 2012; SCHOLTEN; SCOTT; FYNES, 2014). By doing so, organizations map bottlenecks and critical paths, which helps to identify supply chain vulnerabilities (CHRISTOPHER; PECK, 2004; SCHOLTEN; SCOTT; FYNES, 2014) and to develop a holistic perspective of tradeoffs to make decisions such as location and number of facilities, capacity, inventory level, outsourcing, and centralization (BLACKHURST; DUNN; CRAIGHEAD, 2011; CARVALHO et al., 2012; LAVASTRE; GUNASEKARAN; SPALANZANI, 2012; HOECHT; TROTT, 2014; SCHOLTEN; SCOTT; FYNES, 2014).

Reengineering is achieved through incorporation of redundancy and/or flexibility into the supply chain (KAMALAHMADI; PARAST, 2016). Therefore, many authors (see Kamalahmadi and Parast, 2016 and Chang, Ellinger and Blackhurst, 2015) have discussed these two elements and tradeoffs. Carvalho et al. (2012), for example, developed a simulation model and empirically demonstrated in automotive industries in Portugal that redundancy and flexibility are powerful tools to deal with flow interruption. Chang, Ellinger and Blackhurst (2015) draw upon contingency theory to present a conceptual framework that matches flexibility and redundancy. Although some authors have considered them as mutually exclusive, recent literature have argued that building redundant resources increases flexibility, and vice versa (SHARMA; BHAT, 2014; TUKAMUHABWA et al., 2015), and that they depend on specific risk contexts (CHANG; ELLINGER; BLACKHURST, 2015). Redundancy may be helpful in

vulnerable supply chain points (CHRISTOPHER; PECK, 2004). It is usually achieved through safety stocks, strategic reserves, surplus inventory, multiple suppliers, strategic stock, backup energy source, backup of critical components, alternative and reserve capacity, and deliberately low capacity utilization (SHEFFI; RICE, 2005; STECKE; KUMAR, 2009; CHANG; ELLINGER; BLACKHURST, 2015; CHOWDHURY; QUADDUS, 2015; KILUBI; HAASIS, 2015; TUKAMUHABWA et al., 2015). While it is commonly part of the resiliency strategy, unless it is needed due to a disruption, it represents sheer cost with limited benefit (SHEFFI; RICE, 2005). On the other hand, flexibility makes the supply chain more resilient by providing a lower total cost and a better lead time ratio (CARVALHO et al., 2012) and can create a competitive advantage in day-to-day operations (SHEFFI; RICE, 2005; KILUBI; HAASIS, 2015). Examples of mechanisms to enhance flexibility may be modularity and postponement, multi-skilled labor force, multi-purpose machines, flexible contractual arrangements (e.g. partial order and payment, partial shipment), multiple suppliers, alternative suppliers, flexible manufacturing process, well-responsive pricing, flexible transportation mode, standardize processes, empowerment, cross training, and having multiple locations with built-in interoperability (SHEFFI; RICE, 2005; TANG; TOMLIN, 2008; STECKE; KUMAR, 2009; RASHID; LOKE; OOI, 2014; CHOWDHURY; QUADDUS, 2015). Scavarda et al. (2015) present empirical examples of vulnerability caused by the lack of these mechanisms.

To perform a quick supply chain redesign, agility is important (HOHENSTEIN et al., 2015). In fact, "resilience implies agility" (CHRISTOPHER; PECK, 2004, p.7) and many organizations are at risk because their response times to demand changes or supply disruptions are too long (CHRISTOPHER; PECK, 2004; HOHENSTEIN et al., 2015). Although some authors mention agility and flexibility as

interchangeable terms (see Braunscheidel and Suresh, 2009) resilience literature usually present them as two separated elements. Supply chain agility is a key to inventory reduction, more efficiently adaptation of market variations, quicker responses to consumer demand, and more effectively integration with suppliers (FAISAL; BANWET; SHANKAR, 2006). It may be achieved through information flow support, collaborative relationships, inventory buffer, reliable logistics system, development of contingency plans, locally produced parts (RASHID; LOKE; OOI, 2014). In recent literature, its relation to other elements have been explored. Scholten, Scott and Fynes (2014) capture visibility, velocity, and flexibility as important building blocks and antecedents of agility. Kamalahmadi and Parast (2016) present visibility and velocity as drivers for agility. Rashid, Loke and Ooi (2014) suggest that organizations should proactively seek for innovative risk mitigation strategies and tools to support quick recovery. Cohn et al. (2012) present rapid involvement of responsible bodies, velocity in falsified medications removal, fast identification of potential suppliers and quick communications with stakeholders as crucial activities during a disruption. Hohenstein et al. (2015) propose that "the faster the recovery time of the supply chain, the higher the level of growth of the firm's performance after a supply chain disruption (p. 110). Thus, agility may help the organization to evolve to a new state of operation, one of SCR goals. Agility may be enhanced through higher supply chain visibility and information sharing in real time among supply chain partners (HOHENSTEIN et al., 2015).

In a SLR conducted by Kilubi and Haasis (2015), visibility was observed in the largest number of studies. The great interest of practitioners and academics in this resilience enabler may be explained by the tendencies of globalization and fragmentation of supply chain, which decrease transparency and increase difficulties to monitor supply chain flows. Thus, visibility is necessary to develop transparent structures and processes

to identify needs and disruptions quickly and to be able to implement changes in an effective manner (COHN et al., 2012; EHRENHUBER et al., 2015). It implies in a clear view of upstream and downstream inventories, demand and supply conditions, production and purchasing schedules, and risks (CHRISTOPHER; PECK, 2004), and in the evaluation of how disruptions propagate throughout the supply chain (BLACKHURST; DUNN; CRAIGHEAD, 2011). Visibility is also internal, with clear and open lines of communications within organization (CHRISTOPHER; PECK, 2004; COHN et al., 2012).

The lack of visibility is usually related to limit exchange of information between supply chain members (CHRISTOPHER; PECK, 2004). Thus, visibility and information sharing are requirements to reduce vulnerability (GOULD; MACHARIS; HAASIS, 2010). According to Lavastre, Gunasekaran and Spalanzani (2012) survey, they are also the best ways to manage risks. Information sharing is an important enabler within organization and supply chain (CHOWDHURY; QUADDUS, 2015). Indeed, it is a key element in supply chain management (LI et al., 2015), which involves the willingness to exchange relevant information to improve coordination (LI et al., 2015), reduce asymmetric information, and support collaborative efforts (CHRISTOPHER; PECK, 2004; DEKKER; SAKAGUCHI; KAWAI, 2013). The major benefits are the creation of a risk informed decision-making process (DIMASE et al., 2016) and the development of a detection risk event system (STECKE; KUMAR, 2009; HOHENSTEIN et al., 2015). Moreover, it supports better tracking and communication, and helps to reduce redundancy (KUMAR; DIEVENEY; DIEVENEY, 2009). As a result, information sharing is mentioned as a solution in most disruption case studies identified (e.g. Cohn et al., 2012), and Scholten, Scott and Fynes, 2014). However, it is important to highlight that the information shared with supply chain member is among the most critical of an organization's assets (FAISAL; BANWET; SHANKAR, 2006; CHOWDHURY; QUADDUS, 2015). Thus, the increase of visibility and collaboration leads organizations to invest in information security to protect data and mitigate the risk of losses caused by cyber-attacks, computer virus, unauthorized access (STECKE; KUMAR, 2009), system misuse, tampering or fraud (FAISAL; BANWET; SHANKAR, 2006).

The exchange of information requires real-time, accessible to relevant actors (GOULD; MACHARIS; HAASIS, 2010), high quality (RASHID; LOKE; OOI, 2014), and secure data (RAJESH; RAVI, 2015). Christopher and Lee (2004) and Faisal, Banwet and Shankar (2006) present it as a pre-requisite for trust. Trust is necessary to increase resiliency within the organization (BERGER; BLIND; CUNTZ, 2012) and across the supply chain (FAISAL; BANWET; SHANKAR, 2006; RASHID; LOKE; OOI, 2014). Moreover, encompasses the expectation that partners will not act in an opportunistic manner, and the belief of the ability to perform as expected (DEKKER; SAKAGUCHI; KAWAI, 2013). Christopher and Lee (2004) argue that lack of trust can increase risk exposure. It happens when there is no confidence in order cycle times, supply, or demand, from inside the organization or partners and organization decide to maintain excessive inventories and capacity levels. Thus, trust is necessary to increase SCR. It is deployed through effective communication, consistent acts over an extended period (FAISAL; BANWET; SHANKAR, 2006), and commitment (FAISAL; BANWET; SHANKAR, 2006). To achieve this level of relationship, authors (e.g. Rashid, Loke and Ooi, 2014) suggest focusing on key suppliers to develop more honest relationships with a non-adversarial and collaborative nature, and more open communication. It should also be an antecedent to longer supply chain engagements especially when it involves IP risks (HOECHT; TROTT, 2014). Thus, information

sharing and trust are necessary to supply chain collaboration (KAMALAHMADI; PARAST, 2016).

There is consent in the literature that collaboration is an essential enabler in SCR (SCHOLTEN; SCOTT; FYNES, 2014) and a key to overall supply chain performance (LAVASTRE; GUNASEKARAN; SPALANZANI, 2012; KACHE; SEURING, 2014; RASHID; LOKE; OOI, 2014). This can be explained by supply chain nature, which extends across different organizations and demands a high level of collaboration if risk is to be identified and managed (CHRISTOPHER; PECK, 2004). Collaboration may reduce uncertainty (CHRISTOPHER; PECK, 2004; KILUBI; HAASIS, 2015) by setting up and managing mechanisms such as contractual contingency planning, coordination of tasks across firm boundaries, exchange of know-how with departments and supply chain partners, collaborative problem resolution, collaborative planning, development and support (e.g. product development, and marketing initiatives), collaborative communication SAKAGUCHI; (DEKKER; KAWAI, 2013; CHOWDHURY; QUADDUS, 2015; SCHOLTEN; SCHILDER, 2015). Operations management literature have also discussed collaborative efforts to mitigate bullwhip effect risk, such as Vendor Management Inventory, (GOULD; MACHARIS; HAASIS, 2010); Collaborative Planning, Forecasting and Replenishment (LI, 2013); and joint proactive assessment and strategies (CHRISTOPHER; PECK, 2004; RASHID; LOKE; OOI, 2014). Machado (2011) discovered that Brazilian pharmaceutical organizations develop coordinated actions to dialogue with local government.

Authors (e.g. Urciuoli, 2010; Scholten, Scott and Fynes, 2014; Soni, Jain and Salmador, 2015; Tukamuhabwa et al., 2015) argue that collaboration is equally important before, throughout, and after a disruptive event to enhance SCR. Hohenstein et al. (2015) present collaboration to share knowledge and establish joint effort as a major

enabler for readiness phase. In addition, it may help to identify potential vulnerabilities (KAMALAHMADI; PARAST, 2016). In post-disruption phases, Hohenstein et al. (2015) highlight the importance of collaboration to a shorter response time. Furthermore, Rashid, Loke and Ooi (2014) state that cooperation with the needed knowledge experts facilitates effective response alternatives. Zhang et al. (2016) specifically studied the role of inter-organizational collaboration in emergency response. In recovery phase, Scholten, Scott and Fynes (2014) state that collaboration enables the use of resources and complementary skills in the most effective and efficient way. Finally, Soni, Jain and Salmador (2015) argue that it is likely to have a positive impact on the supply chain's ability to deal with future disruptions, hence, to learn and grow.

Especially in readiness and response phases, collaboration may be connected with sensing, a resilience enabler that represents the ability of discerning processes ahead of time and anticipating potential future events or situations (PETTIT; CROXTON; FIKSEL, 2013; EHRENHUBER et al.,2015). To our knowledge Pettit, Croxton and Fiksel (2013) were the first authors to raise sensing enabler (named as anticipation) in SCR literature. Before that, Blackhurst, Dunn and Craighead (2011) had empirically observed the importance of anticipating a disruption to help reduce response time. Moreover, Ehrenhuber et al. (2015) highlight its importance in anticipating disruptions.

A major driver to implement initiatives to mitigate risk is mindfulness. Mindful managers have implemented a broader range of them (SPEIER et al., 2011). Thus, the deployment of resilience elements depends on the creation of risk management culture in the supply chain (CHRISTOPHER; PECK, 2004; SCHOLTEN; SCOTT; FYNES, 2014; DIMASE et al., 2016). Employees from all levels need to understand that risks for business continuity may come from the wider supply chain rather than from

within the organization (CHRISTOPHER; PECK, 2004) and embrace SCRM (TUKAMUHABWA et al., 2015). Pettit, Croxton and Fiksel (2013) argue that by educating and providing measurement tools to managers to guide the resilience improvement process, supply chains will better survive, adapt and grow in face of disruptions. For that, organizations are applying governance models across entire supply chains through contractual requirements, rewards, education, training, handbooks, enforcement, certifications, and auditing (FAISAL; BANWET; SHANKAR, 2006; CHAUDHRY et al., 2009; HOHENSTEIN et al., 2015; NADERPAJOUH et al., 2015). Risk management strategies should be implemented company-wide (RASHID; LOKE; OOI, 2014) and be a formal part of the decision-making process at every supply chain level (e.g. R&D and supplier selection) (CHRISTOPHER; PECK, 2004). However, because it is not always possible to prescribe well defined disruption processes, employees must be prepared to take risk-driven initiatives (SHEFFI; RICE, 2005).

As observed, leadership plays an important role in dissemination of risk management culture. Lavastre, Gunasekaran and Spalanzani (2012) empirically evaluated that manager attitude toward risk is critical for SCRM. Thomas et al. (2014) underscore the initiatives target at senior managers before starting the implementation of a proposed resilience model. Leaders must be committed and dedicated to implement risk management initiatives (SPEIER et al., 2011; WILCOCK; BOYS, 2014), influence employee behavior, ensure the expected culture, and assume direct responsibility for coordinating initiatives and outcomes (WILCOCK; BOYS, 2014). Leadership and SCRM culture may be used to increase resilience by encouraging innovation and focus on continuous improvement opportunities (SPEIER et al., 2011). It implies receptivity to change and willingness to face new challenges (GOLGECI; PONOMAROV, 2013) and involves the organization's ability to successively transform knowledge and ideas into

processes, products and systems (WANG; JIE; ABARESHI, 2015). Kamalahmadi and Parast (2016) conclude from literature review that culture of innovation and innovative individuals enable effective and immediate response to a disruption. More than that, organizations can practice continuous innovation to achieve resilience (EHRENHUBER et al., 2015).

Resilience elements are powerful tools for organizations to prepare and adapt to respond positively to disturbances on operation (KAMALAHMADI; PARAST, 2016). One of these risk sources is related to IP, more specifically, to counterfeits (DONADONI et al., 2016; TUKAMUHABWA; STEVENSON; BUSBY, 2017). The medicines supply chain is one of the most affected by counterfeits, because counterfeit medicines might harm or be inefficient to the patient's health and brand image is a crucial issue (COCKBURN et al., 2005; EVERTS, 2010). The next item explores how resilience elements might influence this combat.

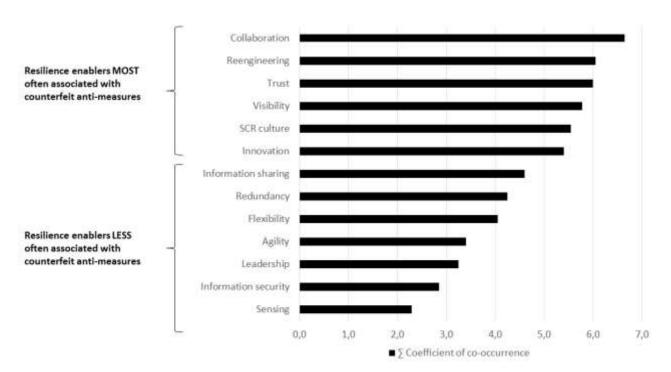
4.4 The Role of Resilience Elements in Combating Counterfeits in the Medicine Supply Chain

To combat counterfeit medicines in the supply chain, organizations have to develop strategies which reduce vulnerabilities to this disturbance (COCKBURN et al., 2005; LYBECKER, 2008), and prepare them to deal with disruptive events. Thus, based on what has been discussed so far about resilience elements and counterfeit antimeasures, this study proposes that strengthening resilience elements helps to combat counterfeiting in the medicine supply chain.

We conducted a codification process. The codebook is presented in appendix V. After this process, a co-occurrence analysis with QDA Miner was conducted. The aim of this analysis is to understand the potential association among the counterfeit anti-measures and resilience elements. The true proximity of codes to each other is more

accurately represented by a proximity plot graphic, because it visually shows which resilience enabler is most often associated with counterfeit anti-measures (QDA, 2017) (Figure 16). The coefficients of co-occurrence (axis X) of all anti-measures are summed up, as observed in the stacked bar graph for each resilience enabler (axis Y). Thus, the resilience elements that are most often associated with counterfeit anti-measures present higher coefficients of co-occurrence.

Figure 16: Proximity plot - resilience elements most often associated with counterfeit anti-measures



Source: created by the author

It can be observed in the proximity plot (figure 16) that there are 6 resilience elements most often associated with counterfeit anti-measures in the 84 articles studied in this literature review, considered as the ones with more than 5 points of coefficient of co-occurrence: **collaboration, reengineering, trust, visibility, SCR culture** and **innovation**. For these 6 resilience elements, item 4.4.1 discusses what their roles are to increase resilience to counterfeiting by adapting the existing literature and

investigating the literature gaps that could be further analyzed considering counterfeit vulnerabilities.

Moreover, Krippendorff (2013) suggests that further analysis concerning the information provided by content analysis indices is required. He argues that analysts have to distinguish between quantifications that lead to testing a statistical hypothesis and quantifications that indicate something other than what is measured. In light of this suggestion, the research approach adopts two bases defined by Ketokivi and Choi (2014). First, a quantitative portion to examine concepts in terms of frequency and second, a qualitative portion in terms of their meaning and interpretation in specific contexts of inquiry. Thus, the frequency of co-occurrence represents the strength of associations between resilience elements and counterfeit anti-measures in the selected texts. Furthermore, its absence (or weaker association) does not necessarily mean that they do not have an important role to increase resilience to counterfeiting, but that further studies are required to evaluate their role. Thus, item 4.4.2 sheds light on resilience elements less associated with anti-measures and proposes new avenues of research.

4.4.1 Resilience elements most often associated with counterfeit anti-measures Collaboration

Collaboration across supply chains may significantly help mitigate risks (CHRISTOPHER; PECK, 2004). Despite the existence of many studies to understand its relevance to SCR (SCHOLTEN; SCOTT; FYNES, 2014) and performance (KACHE; SEURING, 2014; RASHID; LOKE; OOI, 2014), little has been researched about the role of collaboration to increase resilience to counterfeiting. Most studies about collaborative relationships aim to establish incentive alignment and joint coordination (see Dekker, Sakaguchi and Kawai, 2013). The challenge raised by Christopher and Peck (2004) of

developing a set of practices in which collaborative working is possible still shows a gap in the current literature (DEKKER; SAKAGUCHI; KAWAI, 2013).

From SLR, we were able to identify the degree of association established between collaboration and each counterfeit anti-measure, as observed in figure 17. The bigger the rhombus, the higher the coefficient of co-occurrence, and therefore higher the association between collaboration and each counterfeit anti-measure.

Strict government Price strategies requirements/laws Enforcement of Quality strategies intellectual property rights Enhance national and R&D strategies international cooperation Supply/partner Monitor supply chain strategies Create an internal Collaboration structure Enhance risk awareness Enhance brand reputation Traceability Standardize and train Authentication technologies practices and processes Train customers to identify Big data & analytics fakes

Figure 17: Association of collaboration and counterfeit anti-measures

Source: created by the author

From the viewpoint of combating counterfeits, the most evident practice (but not the most correlated) involves improving national and international cooperation. In an empirical study, Scholten, Scott and Fynes (2014) present problems related to the lack of collaboration to meet clients' urgent needs and make efforts in the necessary regions. Jameson et al. (2009) state that governments and organizations such as USPTO (United States Patent and Trademark Office) provide training and technical assistance activities to foster respect for IP and encourage best practices in the enforcement of rights. In order to work, governments need to be willing to promote cooperation among agents (Figure 18) to effectively establish adequate medicine regulations, control the legitimate

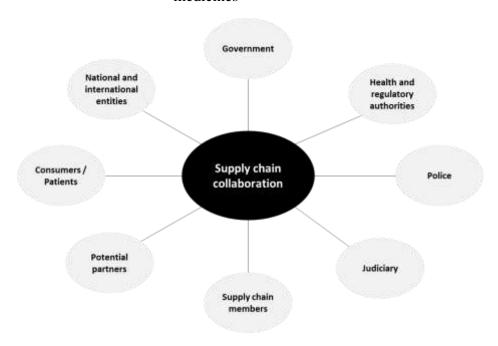
market, and reduce counterfeiting (COUSTASSE; ARVIDSON; RUTSOHN, 2010). Organizations might help the government to identify and seize counterfeits by developing internal teams to provide information and report incidents (GREEN; SMITH, 2002). Johnsohn & Johnsohn and Pfizer have added this anti-measure to its structure (LYBECKER, 2008).

Collaboration can also be considered as a way to increase supply chain costs for counterfeiters (LYBECKER, 2008), by establishing licenses or certifications to their distributors, so that local pharmacists would not collaborate with counterfeiters (LYBECKER, 2008); and/or increase the monitoring of supply chain partners (MACKEY; LIANG, 2011), which includes active and real time surveillance of licit and illicit medicine supply chain actors, using enhanced labeling, packaging security measures, and supply chain security systems (MACKEY; LIANG, 2011). Because counterfeit medicine can enter the supply chain at any one of its links because of the large number of intermediaries, Lybecker (2008) states that organizations should collaborate with other medicine supply chain links to overcome these challenges. Developing relationships is essential for sharing information (KACHE; SEURING, 2014).

Moreover, organizations might share information with consumers and encourage them to collaborate with the combat against counterfeiters in the medicine supply chain (CESAREO; STÖTTINGER, 2015). Resilience literature advocates that organizations can treat disruption as an opportunity to have more in-depth relationships with customers (SHEFFI; RICE, 2005). Thus, organizations may use two-way communication channels to engage consumers more actively by reporting suspected products, inquiring about the products' authenticity or asking about purchases from authorized sellers (CESAREO; STÖTTINGER, 2015). By doing so, they tend to increase risk awareness and enhance brand reputation. Thus, collaboration requires network

thinking, which is achieved through alignment and engineering among supply chain agents (shown in Figure 18) (CHRISTOPHER; PECK, 2004).

Figure 18: Agents involved in increasing resilience collaboration to counterfeit medicines



Source: created by the author

Reengineering

There are certain features that may be engineered into a supply chain to improve its resilience (CHRISTOPHER; PECK, 2004; KAMALAHMADI; PARAST, 2016). They may also be used to enhance SCR to counterfeiting, as observed in figure 19, that illustrates how reengineering is associated to counterfeit anti-measures in SLR. The bigger the rhombus, higher the coefficient of co-occurrence, and therefore higher the association between reengineering and each counterfeit anti-measure.

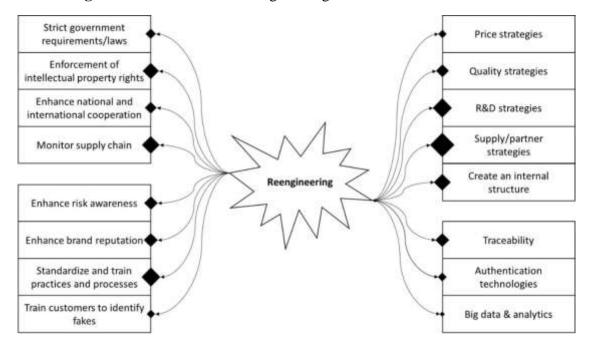


Figure 19: Association of reengineering and counterfeit anti-measures

Source: created by the author

Christopher and Peck (2004) show the importance of supply chain understanding, design principles for engineering resilience and supply base strategy. The first step is map the critical path and main vulnerabilities. In this context, Chaudhry et al. (2009) state that it is important to analyze IP environments (regulations and enforcement) before deciding on new investments. Organizations must be aware about law requirements and the possible punishments for counterfeiters and evaluate the risk and probability of counterfeit incidents. Moreover, important reengineering decisions are related to facilities and partners locations, as well as make-or-buy tradeoffs. Kamalahmadi and Parast (2016) state that the likelihood of disruption in supply chains increases when operating in risk-prone areas. In the literature on counterfeiting, this means moving critical functions to ensure overall effectiveness against pro-copying (BERGER; BLIND; CUNTZ, 2012; HOECHT; TROTT, 2014) and minimizing global sourcing vulnerability (RASHID; LOKE; OOI, 2014).

Meraviglia (2015) observed that offshoring has made it easier for other manufacturers to imitate production processes and/or processes. Stecke and Kumar

(2009) mention the difficulties of a United States pharmaceutical company during a port strike in India. Wilson, Grammich and Chan (2016) argue that vertical integration of supply chain processes provides the most direct control, surveillance and communication for minimizing counterfeiting risks. Therefore, literature on counterfeiting advocates that organizations should analyze potential long-term damage when taking decisions related to outsourcing (HOECHT; TROTT, 2014). On the other hand, authors state that a rapid response involves using standard processes and having multiple locations with built-in interoperability (SHEFFI; RICE, 2005).

Studies on the importance of considering the risk of counterfeits when deciding the R&D process are needed, such as decisions concerning location of investments (BERGER; BLIND; CUNTZ, 2012) and integration of suppliers in product development (STEVENSON; BUSBY, 2015). Regarding the suppliers' selection, Enyinda and Tolliver (2009) argue that a high number of intermediates increase counterfeiting vulnerability in the medicines supply chain. Moreover, in Green and Smith's (2002) case study, the authors state that maintaining exclusive importers and distributors is an effective strategy to reduce counterfeiters and mitigate counterfeit risks. On the other hand, Cohn et al. (2012) examine a real medicine disruption and reinforce the importance of having back up or substituting suppliers in such events.

Trust

Organizations should develop a relationship of trust with their customers. Customers tend to trust products of reputable brands and offer loyalty in return (GREEN; SMITH, 2002). Figure 20 shows the association of trust and counterfeit anti-measures identified in SLR. The bigger the rhombus, higher the coefficient of co-occurrence, and therefore higher the association between trust and each counterfeit anti-measure.

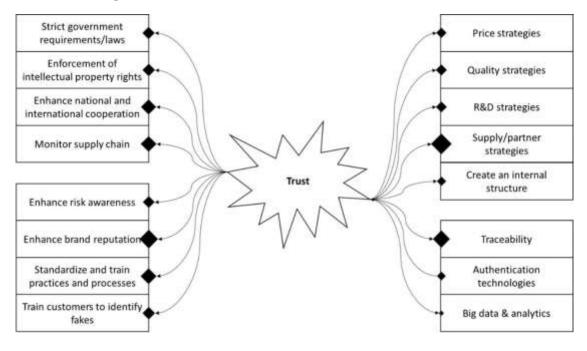


Figure 20: Association of trust and counterfeit anti-measures

Source: created by the author

If consumers recognize that counterfeiting is less likely, they will have more confidence in the product (LYBECKER, 2008; CESAREO; STÖTTINGER, 2015). Thus, organizations are paying more attention to communicating with their customers about the different ways to identify counterfeit products (CESAREO; STÖTTINGER, 2015). At the same time, the opposite is also true: when consumers are aware of potential counterfeits in a supply chain, their trust in the brand may erode (GREEN; SMITH, 2002).

Willing to protect the supply chain, organizations are avoiding suspicious wholesalers and eliminating redundant tiers (LYBECKER, 2008; SPEIER et al., 2011), increasing surveillance (LYBECKER, 2008), and investing in long-term relationships (RASHID; LOKE; OOI, 2014). Eckerd, Johnson & Johnson, and Abbott Laboratories are making efforts to increase trust among members of the medicine supply chain (LYBECKER, 2008). Speier et al. (2011) observed that the pharmaceuticals organizations surveyed were concerned about having trusting relationships with suppliers. Trust in the supply chain is affected when its members do not think the processes are reliable. This lack of trust may lead to individual actions that collectively

Visibility

increase risk exposure (CHRISTOPHER; LEE, 2004). On the other hand, when positively applied, trust works as an antecedent of collaboration (DEKKER; SAKAGUCHI; KAWAI, 2013; KAMALAHMADI; PARAST, 2016) by, for example, encouraging consumers to report incidents and illegal activities related to counterfeiting (CHAUDHRY et al., 2009).

Papadopoulos et al. (2016), state that relationships built on trust should be supported by exchanging reliable information. Thus, organizations have invested in integrated systems with a number of anti-counterfeit technologies, such as traceability (ENYINDA; TOLLIVER, 2009; LI, 2013; DIMASE et al., 2016) authentication (LI, 2013) and quickly analyzing the data collected. Despite the advances in technology, it is hard to assure quality and performance when products leave the authorized supply chain. Therefore, trusted sources have to monitor and control supply chain material flow in order to ensure visibility of the supply chain and product authenticity (DIMASE et al., 2016).

Visibility is one of the most important elements for SCR, as observed in theoretical and empirical studies conducted by Kilubi and Haasis (2015) and Blackhurst, Dunn and Craighead (2011). Managing a supply chain with limited visibility is challenging (BLACKHURST; DUNN; CRAIGHEAD, 2011) because managers rely on good information systems and connectivity throughout the supply chain for decision-making (GLICKMAN; WHITE, 2006). However, in the literature on counterfeiting this is a sensitive subject, because organizations are afraid of negative impacts on brand perception (CHAUDHRY et al., 2009; CESAREO; STÖTTINGER, 2015) and competitors use counterfeit incidents to gain competitive advantage. Nonetheless, the recent increase in the number of counterfeit medicine and their criticality in patients' lives has led pharmaceutical companies to find new anti-counterfeit strategies (LYBECKER,

2008) by adopting innovative ways to detect anomalies and provide real-time information to take decisions (GOULD; MACHARIS; HAASIS, 2010). Thus, SLR identified a high degree of association among visibility and counterfeit anti-measures, as illustrated in figure 21. The bigger the rhombus, higher the coefficient of co-occurrence, and therefore higher the association between visibility and each counterfeit anti-measure.

Strict government Price strategies requirements/laws Enforcement of Quality strategies intellectual property rights Enhance national and **R&D** strategies international cooperation Supply/partner Monitor supply chain strategies Create an internal Visibility structure Enhance risk awareness Enhance brand reputation Traceability Standardize and train Authentication practices and processes technologies Train customers to identify Big data & analytics fakes

Figure 21: Association of visibility and counterfeit anti-measures

Source: created by the author

End-to-end medicine supply chain visibility helps organizations to increase the level of control over partners and other supply chain members (ENYINDA; TOLLIVER, 2009) and also monitor critical paths to improve threat awareness and better prepare for disturbances (RASHID; LOKE; OOI, 2014; TUKAMUHABWA et al., 2015). In a case study carried out by Wilson, Grammich and Chan (2016), they identified that all surveyed firms use physical and virtual market monitoring against counterfeiters.

Another opportunity is the development of traceability systems (SPEIER et al., 2011), as it helps to protect consumers, prevent and respond adverse disruptions (ENYINDA; TOLLIVER, 2009; COUSTASSE; ARVIDSON; RUTSOHN, 2010; TAYLOR, 2014). Traceability in healthcare has been used in emergency rooms, for

surgeries and hospital supply management (COUSTASSE; ARVIDSON; RUTSOHN, 2010; TAYLOR, 2014) and has been broadly discussed in the medicine supply chain (e.g. Wyld, 2008, and Kwok et al., 2010). Ideally, traceability should be applied as early as possible in the supply chain to increase transparency and enable data collection even before medicine production.

The increase in transparency, accountability and responsibility enabled by visibility, inhibits illegal behavior because it is easier to link it back to the organization. Furthermore, visibility can promote collaboration by sharing sensitive information among supply chain agents (CHRISTOPHER; LEE, 2004; SONI; JAIN; SALMADOR, 2015). Thus, more than having available information, organizations need to develop decision structures (GOULD; MACHARIS; HAASIS, 2010) and eliminate functional decisions that do not consider "the big picture" (CHRISTOPHER; PECK, 2004), which means developing well-defined communication protocols (BLOS et al., 2009; BLACKHURST; DUNN; CRAIGHEAD, 2011), as well as big data & analytics solutions. Complementary to these measures, Cohn et al. (2012) highlight the importance of communicating with civil society. To do this, Wilcock and Boys (2014) suggest (i) co-ordination among chain members' databases, sharing IP information and counterfeit incidents, and (ii) actively disseminating information about counterfeiters and their products.

SCR Culture

Many authors have discussed the importance of introducing SCR culture (see Christopher and Peck, 2004; Kamalahmadi and Parast, 2016). They argue that implementing a culture of resilience may help to mitigate specific vulnerabilities. Counterfeiting threat is one of them. Developing anti-measures to influence behavior is crucial to diminish counterfeits, as observed by the high association with counterfeit anti-measures, as represented in figure 22. The bigger the rhombus, higher the coefficient of

co-occurrence, and therefore higher the association between SCR culture and each counterfeit anti-measure.

Strict government Price strategies requirements/laws Enforcement of Quality strategies intellectual property rights Enhance national and R&D strategies international cooperation Supply/partner Monitor supply chain strategies Create an internal SCR Culture structure Enhance risk awareness Traceability Enhance brand reputation Standardize and train Authentication practices and processes technologies Train customers to identify Big data & analytics fakes

Figure 22: Association of SCR culture and counterfeit anti-measures

Source: created by the author

A SCR culture supports the development of all resilience elements (CHRISTOPHER; PECK, 2004; SCHOLTEN; SCOTT; FYNES, 2014; DIMASE et al., 2016) at all levels (CHRISTOPHER; PECK, 2004). Moreover, plans should be developed, aimed at employees, partners, local law enforcement and other relevant organizations focusing on preserving IP and disseminating SCR culture (CHAUDHRY et al., 2009). Naderpajouh et al. (2015), in their empirical study on the construction industry, highlight the negative impact of a lack of awareness in counterfeit practices. Moreover, Cohn et al. (2012) report the increase of counterfeit risk awareness and visibility of problems as the most important anti-measures after a big incident of falsified medicines.

Pettit, Croxton and Fiksel (2013) and Hoecht; Trott (2014) highlight the importance of educating decision makers to act before, during and after a disruption. Thus, it seems important for researchers to explore SCR culture elements and develop

empirical studies to evaluate barriers and best practices to implement governance of counterfeit risks within the supply chain. Complementarily, Christopher and Peck (2004) encourage including risk awareness as a selection criterion. Rashid, Loke and Ooi (2014) suggest rewarding excellent performer suppliers and demand a countermeasure plan for poor performer level suppliers. Their performance may be linked to avoiding counterfeits (WILSON; GRAMMICH; CHAN, 2016).

From the consumer's perspective, SCR culture supports the increase of general awareness of counterfeit risks (CESAREO; STÖTTINGER, 2015), as direct communication with customers may reduce the counterfeit market (HOECHT; TROTT, 2014) and help them to learn more about counterfeits, and even monitoring and reporting suspicious events (CHO; FANG; TAYUR, 2015).

Innovation

Innovation helps organizations to provide agile responses to disruptions, withstand impacts and support organizational restructuring (GOLGECI; PONOMAROV, 2013). Few have discussed its role in increasing SCR (e.g. Golgeci and Ponomarov, 2013; and Wang, Jie and Abareshi, 2015) and no empirical study has been found which discusses their role in increasing resilience to counterfeiting. However, the SLR demonstrate the high coefficient of association between innovation and counterfeit antimeasures, as represented in figure 23. The bigger the rhombus, higher the coefficient of co-occurrence, and therefore higher the association between innovation and each counterfeit anti-measure.

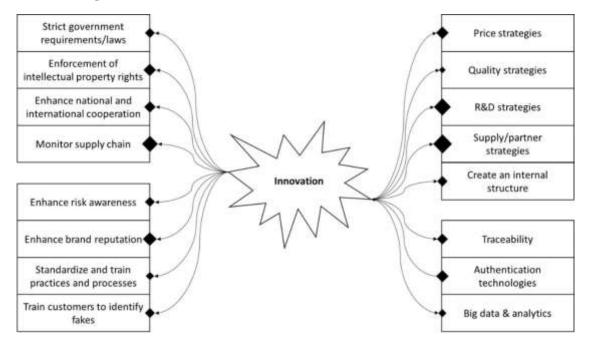


Figure 23: Association of innovation and counterfeit anti-measures

Source: created by the author

In counterfeiting literature, Qian (2014) suggests through empirical analysis that organizations that did not innovate were more susceptible to counterfeiters. Furthermore, Lybecker (2008) argue that pharmaceutical companies that invest a large amount on innovation have more expertise to combat counterfeiters.

Innovation may help to enhance the quality of products (MERAVIGLIA, 2015) and support different price strategies by introducing new materials, processes and ideas into the supply chain. Although it may be applied to any supply chain process and link, it is of the utmost importance in R&D. It directly affects R&D intensity, mitigates the likelihood of imitation and creates barriers for counterfeiters (BERGER; BLIND; CUNTZ, 2012). R&D teams should also analyze and address supply chain vulnerabilities (CHRISTOPHER; PECK, 2004). One option used by organizations is to look for suppliers and national or international organizations to help develop solutions to combat and mitigate the risks (LI, 2013), and to induce them into collaboration (HOECHT; TROTT, 2014).

The medicine supply chain has been looking for suppliers to develop authentication technologies (EVERTS, 2010; CHAUDHRY; STUMPF, 2013). Although these technologies are important, counterfeiters reproduce mimics a few months after a new feature development (DIMASE et al., 2016). Therefore, it must be associated with agility and innovation, so that the organization is always one-step ahead of counterfeiters. Pfizer maintains a queue of new technologies to replace the ones that have already been copied (EVERTS, 2010). Furthermore, the fact of suppliers to deploy serialization and traceability systems is often discussed in the literature as a counterfeit anti-measure (COUSTASSE; ARVIDSON; RUTSOHN, 2010). This can enable real-time surveillance and monitoring of the whole supply chain from consumption by the patient, to traceability of the chain of custody (COUSTASSE; ARVIDSON; RUTSOHN, 2010).

4.4.2 Resilience elements less often associated with counterfeit anti-measures

Redundancy, agility, flexibility, information sharing, leadership, information security and sensing are the resilience elements identified in SLR with weaker coefficient of co-occurrence (see Figure 16). Although at first glance, it may seem that they are not all relevant to increase resilience to counterfeiting in the medicine supply chain, this study suggests that deeper analysis is required to understand its role to increase SCR, and then include counterfeit perspectives.

Sensing, for example, is an enabler still little explored in the literature on resilience. Despite its popularity, little is known about its application in supply chains (PAPADOPOULOS et al., 2016). Sensing represents the ability of discerning processes ahead of time and anticipating potential future events or situations (PETTIT; CROXTON; FIKSEL, 2013; EHRENHUBER et al., 2015), thus a hypothesis that sensing influences resilience to counterfeiting could be put forward. Ehrenhuber et al. (2015) highlight its importance in anticipating disruptions. This ability may be achieved through specific

functional structures within organizations (BLOS et al., 2009), the development and dissemination of standardizing processes (BLACKHURST; DUNN; CRAIGHEAD, 2011) and investments in information sharing and monitoring performance (KAMALAHMADI; PARAST, 2016). Furthermore, in counterfeiting context, it could be highly associated with big data & analytics opportunities and should not be underestimated. Increasing sensing organizations could, for example, enhance the ability of analyzing information generated overall by their customers, identify problems and define actions.

Moreover, little is known about the relevance of information security to increase SCR, or specifically resilience to counterfeiting in the medicines supply chain. SLR identified five authors that mention it as a resilience enabler. However, the information that an organization communicates with its supply chain partners is among the most critical of its assets (FAISAL; BANWET; SHANKAR, 2006), and may help to prevent intentional man-made incidents (STECKE; KUMAR, 2009), such as counterfeiting. In the medicine supply chain, assuring information security is a prerequisite for information sharing and visibility, once it involves sensible data about patients' lives.

4.5 Conclusion of SLR

SLR proposes that disruptions and disturbances caused by counterfeit medicines could be mitigated by more resilient supply chains. SCR has become one of the major ways to support practitioners to prepare for, respond to, recover and grow successfully from disruptions (SCHOLTEN; SCOTT; FYNES, 2014; EHRENHUBER et al., 2015; HOHENSTEIN et al., 2015). Thus, by increasing collaboration and trust among supply chain links, organizations might achieve higher levels of IP enforcement and support local governments to combat counterfeit threats. Moreover, raising awareness

about resilience might help organizations to monitor supply chains by transforming their customers into "auditors". To do so, customers might be supported by innovative solutions, which help them to connect fast with their brands.

The SLR is unique as it provides an in-depth analysis of the literature on SCR elements and anti-counterfeit measures. The findings show that there is potential for future research in this emerging topic with relevant impacts on different agents of the medicine supply chain. Figure 24 represents the association between the resilience enablers and each counterfeit anti-measure. The bigger the bubble, the higher the coefficient of co-occurrence (the coefficient is extracted based on from the QDA Miner software through the same co-occurrence analysis used in the proximity plot analysis).

Figure 24: Framework of resilience elements influence on counterfeit anti-measure in medicines supply chain

		c.	Napagia,	endineein o	True	Agolid &	J.R. dillura	inton	nater stains	Soun deutory	Flestolité	Adille .	e de de de la constante de la	al for associated
Inter- organizational processes and	Strict government requirements		•	•	•	•	•	•	•	•	•			•
	Enforcement of intellectual property rights	•		•	•	•	•	•	•	•	•			
	Enhance national and international cooperation		•	•	•	•	•	•	•	•	•	•	•	
	Monitor supply chain		•	•	•	•		•			•	•	•	•
Intra-organiz ational processes and policies	Improve quality	•	•	•	•	•	•	•	•	•	•	•		•
	Price strategies	•	•		•	•	•	•	•	•	•			
	R&D strategies	•		•	•	•	•	•	•	•	•		•	•
	Supply/partner strategies			•				•				•		•
	Create an internal structure	•	•	•	•	•	•	•	•	•	•	•		•
	Enhance risk awareness		•	•	•	•		•		•	•	•	•	•
Behavioral	Enhance brand reputation	•	•			•	•	•	•	•		•	•	
ahav	Train members to identify fakes	•	•		•	•	•	•			•	•		•
ä	Standardize and train practices and processes		•		•			•				•		•
Technolog y	Authentication technologies	•	•		•	•	•	•	•			•		
	Big data & analytics	•		•	•	•	•	•	•	•	•			•
	Traceability		•	•			•	•	•		•	•	•	•
	∑Coefficient of co-occurrence SLR	6,7	6,1	6.0	5,8	5,6	5,4	4,6	4,3	4,1	3,4	3,3	2,9	2,3

Source: created by the author

As illustrated, the SLR provided insights on how SCR elements influence anti-counterfeit measures and, thus, can be used as a tool to strengthen resilience to

counterfeit the medicine supply chain. Collaboration, reengineering, trust, visibility, SCR culture and innovation were the resilience elements most often associated with counterfeit anti-measures.

5 RESULTS AND DATA ANALYSIS OF CASE STUDY

This section aims to describe the case study and present the general results of the within-case analysis and the cross-case analysis. The case studies under analysis deal with the counterfeit anti-measures of medicine supply chain and the resilience elements that influence them. As discussed in item 3.3 and represented by figure 9, we conducted two case studies composed by two pharmaceutical organizations (focal companies) and chosen supply chain links downstream. Figure 25 illustrates the structure of case study analysis.

RESULTS AND DATA ANALYSIS OF MULTIPLE CASE STUDY DATA COLLECTION FROM PHARMAL DATA ANALYSIS AND GENERAL OPL 1, DISTRIBUTOR1 **RESULTS FROM CASE 1** AND HOSPITAL 12 DATA COLLECTION GENERAL RESULTS FROM FROM CROSS-**CROSS-CASE** ANALYSIS **ENTITIES** DATA COLLECTION FROM PHARMAZ, DATA ANALYSIS AND GENERAL **DISTRIBUTOR2 AND** RESULTS FROM CASE 2 HOSPITAL 12

Figure 25: Structure of multiple case study data analysis

Source: created by the author

As previously explained, we collected data from different sources in 6 organizations: CASE1 consists of PHARMA1, OPL1, DISTRIBUTOR1 and HOSPITAL12. CASE 2 consists of PHARMA2, DISTRIBUTOR2 and the same HOSPITAL12 emcompasses CASE 2. Moreover, to enrich the analysis, both cases consider data collected from 9 cross-entities. The results are presented in three sections. Item 5.1 and 5.2 detail the within analysis of each case, and item 5.3 presents the cross-case analysis.

5.1 Data Analysis and General Results from CASE 1

This section aims at providing an overview of CASE 1, discussing how its organizations combat counterfeit threat and present highlights on how SCR elements may help organizations to increase resilience to counterfeiting in medicines supply chain.

5.1.1 CASE 1 presentation

The focal company of CASE 1, denominated as **PHARMA1**, is a multinational organization with approximately 100 thousand employees working in more than 150 countries. One of the most famous products of PHARMA1 is an erectile dysfunction medicine, sold in most of the countries where the company operates. Erectile dysfunction medicines are known to be highly targeted by counterfeiters (MACHADO, 2011), because of its high aggregated value and the demand for these types of medicines without prescription (MACHADO, 2011). Implementing an anti-counterfeit culture among the company seems to be on the agenda of most managers and specialists that work for the company and goes beyond the erectile dysfunction medicine.

To avoid the trade of medicines labeled with PHARMA 1's logo without its authorization, i.e. counterfeiting, PHARMA1 pushed its organizations downstream to implement practices aimed at avoiding falsifications, thefts and misappropriations. Thus, the organization has been working close to its logistics providers and distributors to increase security of the supply chain. PHARMA1 works with a unique third-party logistics operator, **OPL1**, responsible for all its logistics functions. OPL1 is highly focused on increasing security of its operations and is known as one of the safest logistics providers in the world. It distributes products from PHARMA1 to **DISTRIBUTOR1**, one of the largest Brazilian distributors focused on the pharmaceutical sector. DISTRIBUTOR1 focus on delivering medicines with quality and safety to hospitals around the whole country.

One of the hospitals that DISTRIBUTOR1 delivers products branded from PHARMA1 is **HOSPITAL12**. HOSPITAL12 is a famous public health entity in São Paulo State. The purchase decision from PHARMA1 depends on a rigorous tender process focused on ensuring needed quality at the lowest price available. These tender processes are usually electronic. Specialists define the characteristics of the medicine and companies registered according to the government's procedures are allowed to participate.

Moreover, many associations and entities are engaged in the counterfeit combat and work together with the government and organizations from the medicine supply chain with that goal from different perspectives. CROSSASS1 and CROSSASS2 are associations focused on IP rights and counterfeit fight from a business perspective. They do not focus on any specific market. CROSSORG1 and CROSSORG2 are organizations responsible for developing traceability systems and defining standard protocols. While CROSSORG1 works for the whole industry, CROSSORG2 works specifically for healthcare and medicines sectors. To represent the pharmaceutical companies, they associate to associations such as PHARMAASS1 and PHARMAASS2, responsible for consolidating and fighting for needs common to all pharmaceuticals. These associations work close to Anvisa, Brazilian health regulatory agency. Finally, to implement the MCNS, technology organizations are working in solutions for the challenges involved in its implementation in terms of processes and technologies. Two of these technology organizations are TECORG1 and TECORG2.

5.1.2 Counterfeit anti-measures identified in CASE 1

Table 12 presents which anti-measures applied by which organization from CASE 1. The highlighted anti-measures (underline and bold) were not identified in SLR or the meaning was expanded.

Table 12: Counterfeit anti-measures identified in CASE 1

Groups Counterfeit anti-measures		PHARMA1	OPL1	DISTRIBU TOR1	HOSPITAL 12
al d	Strict government requirements	~			
ar- ationa es an ies	Enforcement of IP rights	~		~	~
Inter- organizational processes and policies	Enhance national and international cooperation	~	•		~
10 d	Monitor supply chain members	•	•	•	•
Se	R&D strategies	•			
cess	Price strategies	~			
al pro	Create an internal structure	~			
anizational p	Improve quality	~		~	
Intra-organizational processes and policies	Supply/partner strategies	~		~	~
a-org	Hot line to help patients	~			
Intr	Investment in security equipment and systems	~	•	•	
	Enhance risk awareness	•	•		
oral	Enhance brand reputation			~	
Behavioral	Standardize and train practices and processes	~	~	•	~
	Empower customers to combat counterfeits	~			
gg	Traceability	•	~	•	~
Technology	Authentication technologies	~	~	~	~
Tec	Big data & analytics	~	~	•	~

Source: created by the author

Table 12 shows that all counterfeit anti-measures raised in the literature review were identified in at least one of the organizations from CASE 1. Based on the ratio of quantity of anti-measures identified in the companies studied in CASE 1 divided by the total of possibilities, the two anti-measures groups most used by organizations from CASE 1 to mitigate counterfeit risks are technology and inter-organizational processes and policies.

Technology

Organizations in CASE 1 apply, in different levels, all the technology antimeasures identified in the literature review. Thus, they are investing in technologies to mitigate counterfeit risks. Authentication technologies are an example, which are in constant evolution, trying to be one-step ahead of counterfeiters. PHARMA1 is the main responsible for introducing them, once the company is responsible for manufacturing the medicines. The solutions developed may have two goals. The first one is help employees from PHARMA1 to identify counterfeited products.

We have different authentication processes depending on the incident. For instance, imagine that the consumer complains about an unexpected reaction. The pharmacovigilance team investigates the issue. If they identify a problem, they coordinate a complete investigation, that involves the quality team to analyze the product inside the lab...we have many tools for that, you know? We have a sample of each medicine batch that may be requested if needed. (PMtec1)

Thus, organizations develop specific processes and devices to improve the investigation and authentication of medicines. This process may be very complex, once counterfeited medicines may be hard to identify. The second goal is help consumers and other members in the supply chain to identify suspicious products. For that, pharmaceuticals usually introduce overt – visible (see Kwok et al., 2010; Li, 2013; Wilson, Grammich and Chan, 2016), and covert – not visible (see Chaudhry et al., 2009; Kwok et al., 2010; Li, 2013; Wilson, Grammich and Chan, 2016) technologies. These features may be introduced by internal requirements, e.g. details on the package and/or the company's hologram, or because of regulations established by Anvisa.

There are devices named overt technologies, you know? An example in Brazil is the reactive ink in the cartridge, i.e., one rub a metal and can see the company's logo inside a square. That's law. Nowadays it has a reduced effectiveness, but when it was implemented, it was a good anti-measure. (PMtec1)

As pointed out by PMtec1, authentication technologies have limited effectiveness, once counterfeiters are dynamic and learn fast how to copy the solutions implemented. Because of that, organizations in CASE 1 rely on traceability systems to optimize the reach of authentication solutions.

Recently, we have been fighting for the serializations. Unitize each medicine sold to enable the appropriate traceability. Then, the consumer will be able to recognize the authentic medicine in the drugstore. (PMtec1)

Although not so technological, DISTRIBUTOR1 has been investing for a few years in traceability, by introducing a tag in its medicine packages to help its consumers, as HOSPITAL12, to visualize the origin of the medicine. DISTRIBUTOR1 combines information about the product's batch, invoice and internal ID to increase its products' safety.

Besides medicines, DISTRIBUTOR1 and OPL1 invest in traceability for its vehicles, as explained by TMsec2: "we have installed geo-fencing, which includes tracking of the vehicle through a GPS system. So, even if the vehicle is stolen, we know the location". Traceability solutions, in this case, are usually associated with intelligent systems to help the decision-making process, as explained in the excerpt below.

We have traceable trucks, you know They all have geolocation. We monitor route and the driver has to follow it, he knows even where to stop. If they change the route, an alarm is triggered. An intervention team analyzes what is going on. (DMlog1)

When the data to be associated increases in terms of volume, velocity, variety, veracity and value, big data & analytics solutions may be implemented. Although organizations in CASE 1 have been studying several applications, its full implementation still demand many improvements to truly boast the benefits of both traceability and big data & analytics systems, once the application in the companies is in the early stages of maturity.

Inter-organizational processes and policies

As observed, regulatory agencies are the main responsible for directing the technology anti-measure to be implemented and then evolved by organizations in the medicines supply chain. The scenario is not different when developing inter-organizational processes and policies anti-measures. Thus, Anvisa and other entities took on the proactive role of combating the counterfeit threat. For that, Anvisa analyzes best practices among the world that are worth being implemented in Brazil.

Certainly, the Latin America governments are all observing what the others are doing; looking for best practices to improve the life of our population. (PMgenlatam1)

To establish such regulations, legislative and Anvisa usually involves entities, such as PHARMAASS1 and PHARMAASS2, to contribute providing specific knowledge about peculiarities in the medicines supply chain. Thus, cooperation is crucial. PMtec1 details the importance of creating Anvisa and strengthening Brazils' regulations.

In the end of the 90's, beginning of 2000, we experienced many changes in the health sector. First, legislative changed the regulation and the punishment for falsification has become much more severe. People were dying in Brazil because of fake medicines. TV was talking a lot about that. Moreover, Anvisa was created to ensure enforcement and propose new regulations. The sector become more regulated.

Thus, as observed in the excerpt, more than proposing regulations, Anvisa is responsible for enforcing the existing ones. To do so, the agency relies on its local employees, distributed around the country to audit organizations.

Anvisa's definitions are mandatory. Anvisa has a crucial role through audits. These audits are usually not programmed; it is a "surprise", because that's how they see if the supply chain member is following the rules. (PSlog1)

Besides audits conducted by Anvisa, the organizations themselves contribute to the enforcement of these regulations by demanding that their suppliers and clients follow the established rules.

We demand all the required licenses, whether fiscal or sanitary. For example, if I will sell to a distributor, the distributor has to acquire all the necessary licenses from Anvisa, etc. for that. However, no pharmaceutical audits a pharmacy network or a hospital...not that I know about. (PMtec1)

We have been demanding in our tenders a norm of pharmaceutical laboratory's best practices. Anvisa defined it. This document is usually from the manufacturer. Therefore, the distributor has to ask it for the pharmaceutical company. (HMpurlog12)

The process of monitoring the supply chain tends to be more rigorous when organizations refer to their logistics providers, once the custody of the product still belongs to the logistics provider's client.

Behavioral

As observed, Anvisa defines, or even conduct, most of the anti-measures that exceed the internal boundaries of the company, due to the necessity of having a holistic view of the situation, considering several counterfeiters that work in different cities and countries. Nonetheless, organizations tend to have a more proactive approach on the extent to which clients become more worried about counterfeiters and it represents a competitive advantage. For instance, DMlog1 (DISTRIBUTOR1) mentioned the notion that mitigates counterfeit risk is an opportunity to enhance brand reputation.

It is important to mention that we have the concern of having a Benchmark certification. It is not a legal requirement for distributors, right? [...] Nevertheless, we do have. When the pharmaceutical company comes to see how we are working, it is important for them. They can see how much we care. (DMlog1)

Thus, DISTRIBUTOR1 implements practices and processes, e.g. not mandatory licenses to ensure quality standards, because they believe that it increases their reputation and, consequently, pharmaceuticals companies, such as PHARMA1, feel safer to sell their products to them. As observed, in this case this anti-measure is directed at its suppliers and not consumers, which is a different approach than the ones explored in literature (e.g. Green and Smith, 2002, Lybecker 2008, Wilcock and Boys, 2014 and Cesareo and Stöttinger, 2015). PHARMA1 is the unique organization in CASE 1 to directly address anti-measures directed at consumers. PHARMA1 website, for example, encourages consumers to recognize their medication and be familiar with its features. Thus, the company trains consumers to identify falsified products.

Intra-organizational processes and policies

Counterfeit anti-measures within the organization's boundaries are implemented mostly by PHARMA1. This is explained because the pharmaceutical company is responsible for manufacturing the product (and the other members just for its logistics and manipulations), and for communicating with patients about medicines.

Therefore, to protect the brand, PHARMA1 highlighted the necessity of having a <u>hotline</u> to help patients, where they may call whenever they have doubts about the products purchased or feel there is something wrong with it. This counterfeit anti-measure was not previously identified in SLR.PHARMA1 created specialized teams to analyze the complaints, as the pharmacovigilance team mentioned above by PMtec1. When they identify a problem, it triggers a security team analysis, responsible for investigating the origin of the medicine. "This team looks like police officers, you know? They do not have a profile of logistics or pharmaceuticals and they work globally". These security teams often define specific protocols to be followed by all employees. These protocols are usually combined with equipment and systems to control its application.

Inside our warehouses, the risk is low. We have several controls, e.g. biometry, access control, we introduce several tools to increase safety and avoid counterfeit. (DMlog1)

Thus, another anti-measure not previously identified in SLR is <u>investing</u> in security equipment and systems to detect risks associated to counterfeiting. The interviewer PMgenlatam1 stated that it becomes even more important when dealing with more sophisticated products, with high aggregated value. Examples of this anti-measure are investments on warehousing management system (WMS), transportation management system (TMS), routing system and high technology equipment to transport, store and track products.

Finally, in the controversial discussion raised in literature review concerning setting low or high prices strategies, PHARMA1 follows the suggestions proposed by Qian (2014) and Cho, Fang and Tayur (2015), who argues that elevated prices help consumers to distinguish the brand from counterfeiters. Its brochures state that "the price of the product X is high, be wary if you find prices too appealing". However, it is important to highlight that Anvisa regulates the price of most medicines. Therefore,

we did not identify any evidences that PHARMA1 control the prices charged by other supply chain members downstream.

5.1.3 Resilience elements in CASE 1

Information security

Leadership

Redundancy

All resilience elements were identified in at least one organization studied in CASE 1. Figure 26 presents, on the left, how many interviewees (from the total of seven) mentioned each resilience element - quantity - and, on the right, how many times each resilience element was mentioned - frequency.

■ Quantity in CASE 1 III Frequency in CASE 1 Visibility: Information sharing Collaboration Agility Information sharing 17 Innovation. Reengineering Collaboration Innovation SCR culture Trust Flexibility | Agility 5 Reengineering SCR culture Flexibility 3

Figure 26: Number of interviewees who mentioned each resilience enabler and its frequency in CASE 1

Source: created by the author

Redundancy 2

Leadership 1

Information security 1

Six of seven interviewees mentioned visibility and information sharing as important elements applied in their organizations. They are also mentioned often. The combination of these two parameters enable a better understanding of the most relevant elements, once the reader may evaluate if the elabler was cited many times but from a single interviewer, for example.

Visibility is necessary to develop transparent processes along the supply chain (COHN et al., 2012; EHRENHUBER et al., 2015). In medicines supply chain this benefit becomes even more relevant, once it is not easy to visually identify if the product is original or not.

Knowing exactly where each medicine unit is from would be great! [...] For the society, it would become easier to withdraw counterfeit medicines from the market, the police would be able to identify who is selling these products. [...] Moreover, recall today has a limited coverage, it is hard to achieve the last supply chain link, we have little pharmacies really dispersed and many movements are made without invoice (PMtec1)

The combination of visibility and information sharing is necessary to reduce vulnerabilities (GOULD; MACHARIS; HAASIS, 2010). As raised in the literature review (STECKE; KUMAR, 2009; HOHENSTEIN et al., 2015; DIMASE et al., 2016), the exchange of information enables the detection of risky events – in this case, suspicious products – and making well-informed decisions. The excerpt bellow presents an example directed at sharing information with consumers.

It is important to share information with consumers and be available for eventual doubts or suspicious incidents reports. Many times, they have simple doubts that may help them to avoid buying from illegal suppliers. (PMgenlatam1)

Thus, by sharing information organizations promote the collaboration of consumers in the fight against supply chain. Moreover, collaboration may work as an antecedent of trust, as detailed below.

Well...we have a team of experts for different stages of shipment. We analyze infrastructure regulatory regulations, and other characteristics in different countries. Than we provide our clients with a set of good practices to improve their security (TMsec1)

The example shows how by increasing collaboration organizations may enhance the safety of the supply chain. When clients and suppliers are more confident about the processes and products involved, the trust in the supply chain tends to grow. Knowing in which supply chain link to trust or not is an effective way to avoid

counterfeiters. Therefore, as observed in Figure 26, most of the interviews mentioned trust and collaboration, and frequently.

On the other hand, 4 interviewees cited agility, innovation and sensing as relevant enablers. However, they did not bring it up so often. Although they all recognize the relevance of agility, organizations did not apply this element in many different cases. Agility is usually associated with the ability to perform recalls.

In fact, I think the hospital plays a more important role once the problem is detected. Let's assume that we receive a recall from Anvisa. The more resilient that the hospital is, the quicker we do the recall. Because we have to be quick and go back to regular operation. Actually, more than that, because we have to remove all the medicine and replace it with another batch. (HMpurlog12)

Another association for agility is innovation. As counterfeiting becomes a dynamic process, organizations cannot have long innovation processes, or they will be always behind the counterfeiters. Thus, agility works as an antecedent for innovation. PHARMA1, for instance, is always looking for new technologies to implement in its products to beat counterfeiters.

PHARMA1 has a team of experts who constantly assess new and existing technologies, right? They are responsible for identifying technologies that will make it more difficult for counterfeiters to make convincing copies and for patients and healthcare providers to identify counterfeiting medicines (PMgenlatam1)

Moreover, organizations may look for proactive solutions to combat counterfeits. Anticipate problems is an example. For that, organizations may focus on the development of new technologies, which will be further explored in the next sections, or define procedures based on constant improvement. OPL1 has an interesting process to illustrate this second approach.

The most important preventive KPI that we have is the following: the risk management company once a month randomly select 4 cases that we had no security problem and evaluates if there was any operational failure. We noticed that we had been experiencing many route deviations or drivers' indiscipline and despite the system's warning, our partners weren't doing anything. (TMsec2)

Finally, information security, leadership and redundancy are the resilience elements that less brought up and less frequently. Few interviewees mention these elements as relevant to combat counterfeit threat, as they believe other solutions are more effective in enhancing resilience to counterfeit. These findings support the conclusions raised in the literature review.

5.1.4 Role of resilience elements in combating counterfeit medicines in CASE 1

Interviewees from CASE 1 believe that counterfeits take advantage of the complex network of distributors to insert illegal products into legal medicines supply chain. This complex network is leveraged by the characteristics of the Brazilian medicines supply chain, once distributors tend to sell medicines to other distributors and not just the hospital and/or pharmacy. Few distributors, like DISTRIBUTOR1, sell just directly to pharmacies and/or hospitals. PMtec1 states, "We calculate that the medicines change custody six times before consumption". This characteristic increases the difficulty of controlling supply chain and ensuring the authenticity of medicines traded. Moreover, PHARMA1 focus on promoting counterfeit anti-measures directed at patients. However, the interviewees state that it has to be a careful process once is forbidden for pharmaceuticals to advertise their medicines in Brazil.

From the data gathered and the content analysis performed, this research was able to analyze how CASE 1 uses the resilience elements to increase its resilience to counterfeiting. Figure 27 illustrate the association between each resilience element and each counterfeit anti-measure (extracted from QDA Miner, as the proximity plot graph). The bigger the bubble, the higher the coefficient of co-occurrence, thus, higher the association between them. From figure 27 we observe that resilience elements may have more or less influence in each counterfeit anti-measure.

Figure 27: Resilience elements and counterfeit anti-measures association in CASE 1

		Collab	oration	Reeng	ineering	ng Trest		Visibility		SCR culture		Innovation		Information sharing		Redundancy		Flexibility		Agility		Leadership		Information security		Sensing	
		SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1	SLR	Case 1
E :: 8	Strict government requirements		•	•		•	•		•	•	•	•						•	•	•							
zati.	Enforcement of IP rights			•		•			•	•	•	•	•	•		•	•	•	•	•			•				
	Enhance national and international cooperation			•	•	•	•			•	•	•	•	•				•		•		•	•		•		
8 4 8	Monitor supply chain members			•	•	•	•		•	•	•		•	•			•	•	•	•		•	•			•	
	R&D strategies	•				•	•		•	•	•		•	•				•	•	•						•	
e er	Price strategies	•	•	•		•	•		•	•		•		•		•		•						•		•	
ig ig	Create an internal structure	•		•	•	•	•		•		•	•		•		•		•		•					•	•	
Intra-organizational rocesses and policies	Improve quality	•	•	•	•	•			•	•	•	•		•		•	•	•	•	•		•		•	•	•	
5 E	Supply/partner strategies	•	•		•	•	•	•	•	•			•	•						•		•	•	•		•	
esse	Hot line to help patients		•	•		•	•		•	•		•		•		•		•		•		•					
H ood	Investment in security equipments and systems	•	•	•	•	•	•			•	•	•	•	•		•	•	•		•		•	•	•		•	
	Reverse logistics capabilities	•		•		•				•				•		0		•								•	
-	Enhance risk awareness			•	•	•	•		•	•	•	•		•		•		•	•	•		•		•		•	
ioral	Enhance brand reputation	•	•	•			•			•	•		•	•		•		•				•		•		•	
Behav	Standardize policies, practices and processes		•	•	•	•		•	•	•	•	•							•	•		•	•	•	•	•	
ñ	Empower customers to combat counterfeits	•	•	•	•	•	•		•	•	•	•	•	•		•		•		•		•			•	•	
70 .	Traceability		•	•	•	•		•		•	•	•	•	•		•	•	•	•	•			•	•	•	•	
Technol	Authentication technologies	•	•	•	•	•			•	•	•	•		•	0				•	•	0	•			•		0
Te	Big data & analytics	•	•	•	•	•	•	0	•		•	•	•	•		•			•						•	•	
	∑Coefficient of co-occurrence	7,9	6,6	7.6	5.6	6,9	7.2	6,8	7.1	7.0	5.4	6,4	4.8	5,7	6,6	5,3	2.4	4.7	3.7	4,2	4,5	4.4	2.3	3,6	3,1	3,1	6,1

Source: created by the author

5.1.4.1 Associations from CASE 1 often observed in SLR

As observed in Figure 27, visibility, trust and collaboration continue to appear in the top of our list, now as the resilience elements most often associated with counterfeit anti-measures. These findings confirm SLR results, as these elements are three of four most associated according to the literature. These three resilience elements are particularly important in the medicine supply chain because of its complexity of having many intermediates and pharmacies all over the country. This structure increases the difficulty of reducing information asymmetry and unreliability, and quickly identifying counterfeiting vulnerabilities and incidents (LYBECKER, 2008). "I think there are too many intermediates in our supply chain. Not just ours, but the whole industry, you know? We have to somehow control it better" (PSlog1)

As the most cited anti-measure groups are inter-organizational processes and policies and technology (see Table 12), the necessity of coordination with visibility, trust and collaboration is clear. **Inter-organizational processes and policies** anti-measures ensure the holistic approach of the problem. Chaudhry et al. (2009) and Wilson, Grammich and Chan (2016) state that it is crucial to increase the supply chain surveillance. Organizations from CASE 1 also pointed out **monitor and control** operations across all of the supply chain as one of the most important anti-measures to combat counterfeiters. Supply chain **visibility** helps organizations to identify counterfeiters' operations and supply chain **collaboration** influences the development of joint works, e.g. with the government, to conduct raids and prisons to interrupt the illegal work and, consequently, to **promote enforcement**. By doing so, organizations focus on identifying and punishing members who are helping counterfeiters (CHO; FANG; TAYUR, 2015) and, consequently, increasing **trust** in supply chain. However, to ensure

the applicability of these measures, governmental associations need enough resources to combat counterfeiters.

We believe that our clients are all trustworthy, that's a fact. But it would be good if...well...not everyone is our client, right? It would be good if regulatory and inspection organisms could be more effective. Unfortunately, we know that Government's inspection organisms don't have enough resources. Their staff are below their needs they are sometimes out of gas for their vehicles or small number of vehicles...it is complicated to inspect the whole supply chain, you know? Brazil is too big and the market too fragmented! (DMlog1)

Moreover, all organizations from CASE 1 invest in **collaboration** by developing alliances to diminish vulnerabilities, as mentioned by Lybecker (2008). To do so, they rely on trustable associations (such as CROSSASS1, CROSSASS2, PHARMAASS1 and PHARMAASS2) to (i) represent their needs from the government and ask for **more strict regulations** and **enforcement**; and (ii) share worldwide best practices, by **enhancing national and international cooperation**. However, as pointed out by the interviewees of these associations, the collaboration among them and governmental entities, such as Anvisa, is still incipient in Brazil.

The anti-measures group of inter-organizational processes and policies is interrelated with the <u>technology</u> group, once technologies may leverage the supply chain **visibility**. <u>Traceability</u> and <u>big data & analytics</u> capabilities to enable a more efficient and effective use of the data available. Besides increasing **visibility**, the anti-measures combined enhance **trust** in the supply chain, as organizations would be able to know and monitor about each package manufactured.

Furthermore, technology solutions may help the development of **behavioral** anti-measures. PHARMA 1 believes it is important to encourage consumers to **collaborate** and engage them on this fight. As in Cesareo and Stöttinger (2015)'s study, the pharmaceutical company invest in strategies to **empower consumers on counterfeit combat**. These strategies, as proposed by Chaudhry and Stumpf (2013) and Hoecht and Trott (2014), focus on constant communication with consumers about how to validate

real products. However, it is important to highlight that other organizations from CASE 1, except PHARMA1, are not actively engaged in empowering consumers.

Nonetheless, the association of this anti-measure with <u>intra-organizational processes and policies</u> group may leverage its success. For instance, the communication with consumers is more effective when organizations have a structured <u>hotline to inform consumers</u> and develop other ways of communicating, such as online games to help consumers to identify odd characteristics in their medicines. To help consumers to notice these odd characteristics, PHARMA1 share <u>standard procedures</u> of the medicines, i.e. how should their medicine look in terms of size, taste, color, appearance, package content, etc. As PHARMA1 states that consumers should distrust whenever one of these standard characteristics seems different, the solution proposed by Green and Smith (2002) of creating a moving target, which is linked to <u>R&D capacity</u> of developing new characteristics difficult to copy, does not fit this proposal.

Moreover, CASE 1 shows that enhancing **visibility** of supply chain promote **reengineering**, once organizations may identify vulnerabilities and be proactive, preventing counterfeit incidents from happening. For instance, by evaluating its suppliers organizations may make decisions based on their security performance. "Well...for example...last year we suspended a third-party logistics provider because we experienced 2 thefts in a row!" (PSlog1). As stated by Blackhurst, Dunn and Craighead (2011), monitoring systems should help real time decision-making. Interviewees state that **reengineering** to mitigate counterfeit risk crucial. Christopher and Peck (2004) and Kamalahmadi and Parast (2016) demonstrate that introducing certain features into the supply chain increase its resilience. To do so, PHARMA1, for instance, considered the counterfeit threat was a pre-requisite when deciding about PHARMA1's new **supplier strategy** of logistics providers. The organization also developed **functional structures**

<u>of experts</u> to mitigate counterfeit risks. For instance, PHARMA1 has a global multi-task outsourced team, due to the international nature of counterfeiters' operation, to investigate criminal organizations of counterfeiters. "They are not logistics or pharmaceutical experts, right? They are more like police people" (PMtec1).

These teams are international, once they work for all units of PHARMA1, and need the collaboration of local units to direct their efforts to the right targets. On the other hand, OPL1, DISTRIBUTOR1 and HOSPITAL12 have internal security teams responsible for mapping and mitigating counterfeit vulnerabilities in their operations. However, they do not investigate counterfeiters, but report the problem, and leave it to Anvisa to investigate and decide on appropriate action. Moreover, as suggested by Kamalahmadi and Parast (2016), organizations in CASE 1 map their counterfeit vulnerabilities and delimitate the risky regions where they **do not operate** and **define standard policies** in risk-prone areas.

However, all organizations interviewed from the chain in CASE 1 recognize that improvements need to be made in this direction, as more variables related to counterfeiting should be considered while redesigning the supply chain. For instance, no evidence was found that the organizations analyze overall effectiveness against procopying (BERGER; BLIND; CUNTZ, 2012; HOECHT; TROTT, 2014) and global sourcing vulnerability (RASHID; LOKE; OOI, 2014) when deciding about suppliers or facilities location.

5.1.4.2 Associations from CASE 1 not often observed in SLR

CASE 1's organizations rely on **information sharing** and **sensing** to increase resilience to counterfeit. Differently from what has emerged from SLR (as observed in figure 27), these elements were mentioned in most interviews and present a high association with counterfeit anti-measures. These enablers are achieved mainly by

investing in **technologies** anti-measures. Data collected from CASE 1 shows that organizations are investing in **traceability systems** and **big data & analytics** capabilities to enable a more efficient and effective use of the data available. In line with Pettit, Croxton and Fiksel (2013) and Ehrenhuber et al. (2015) findings, by effectively and efficiently sharing and analyzing the data available, organizations may anticipate possible failures even though no disruption occurred, strengthening **sensing** enabler. To do so, TMsec1 highlight the necessity of associate data from different sources.

To anticipate counterfeit incidents and arrest counterfeiters and thefts, it is important to use advanced management systems capable of correlating data from different sources. That is security 4.0! One example is "Detecta" a system built for São Paulo State's police, which correlates information about license plate, driver background, etc... that's the future! (TMsec1).

TMsec2 state that OPL1 began to develop solutions in this direction. They consolidate information shared from different sources, such as <u>security equipment and systems</u> (e.g. biometry systems, access control, WMS, TMS, EDI information, GPS, etc.), and define a sequence of commands that is automatically triggered when the system identifies a problem through data analysis. It is important to highlight that **sensing** depends on access and profound analysis of information. Thus, interviewees state that information sharing is a barrier to more accurate and relevant outputs to mitigate counterfeit medicines, because of the criticality of the theme.

5.2 Data Analysis and General Results from CASE 2

This section aims at providing an overview of CASE 2 and how its organizations combat the counterfeit threat. Moreover, it presents highlights on how SCR elements may help organizations to increase resilience to counterfeiting in medicines supply chain.

5.2.1 CASE 2 presentation

The focal company from CASE 2 is a well-known national pharmaceutical company, with more than 2.000 employees, denominated as (1) **PHARMA2**. The organization's portfolio is focused on medicines with high aggregated value, which increases the interest of counterfeiters. To combat this threat, the organization focus on increasing security among pharmaceuticals, distributors, hospitals, pharmacies and the government; and on strengthening its internal security by investing in innovative solutions. The company is, for example, one of the leaders in projects regarding medicines traceability. By doing so, the organization enhance the brand's reputation to consumers, employees and supply chain, as argued by one of the interviewees.

We are worried about counterfeits because they affect the patient's health, we work so hard to maintain the quality of our products! [...] When an incident happens, the patient always associates it with the brand. (PSqualsec2)

One of its distributors is **DISTRIBUTOR2**. The organization operates in the whole country with the health sector, serving the public and private market. The two strategic pillars of DISTRIBUTOR2 is security and quality, and the company focus on developing different solutions for warehousing and transportation of health products, such as specific cold chambers depending on the customer's needs. One of its clients is **HOSPITAL12**, a public hospital that offers from simple to highly complex medical procedures and attend approximately 3 million patients per year.

The associations, organizations and Anvisa, which the main responsibilities were explained above, also play important roles in CASE 2. In fact, organizations from CASE 2 have been working closer to Anvisa and the technology company TECORG1 to implement the MCSN.

5.2.2 Counterfeit anti-measures identified in CASE 2

Table 13 presents which anti-measure is applied by which organization from CASE 2. The highlighted anti-measures (underline and bold) were not identified in SLR or the meaning was expanded.

Table 13: Counterfeit anti-measures identified in CASE 2

Groups	Counterfeit anti-measures	PHARMA2	DISTRIBUTOR2	HOSPITAL12
al id	Strict government requirements	•	~	
Inter- organizational processes and policies	Enforcement of IP rights	~	~	>
Inter- ganizatio ocesses policies	Enhance national and international cooperation	~	*	>
or	Monitor supply chain members	✓	,	>
þ	R&D strategies	✓		
es an	Price strategies			
ocess	Create an internal structure	✓		
ial pr	Improve quality			
zational p policies	Supply/partner strategies	~		<
ganiz	Hotline to help patients	~		
Intra-organizational processes and policies	Investment in security equipment and systems	~		
TI II	Reverse logistics capabilities	~		
	Enhance risk awareness		·	
Behavioral	Enhance brand reputation	~	·	
3ehav	Standardize policies, practices and processes	~	~	~
	Empower customers to combat counterfeits	✓	·	>
ogy	Traceability	✓	·	>
Technology	Authentication technologies	✓	·	~
Тес	Big data & analytics	✓	•	>

Source: created by the author

Table 13 shows that, based on the ratio of quantity of anti-measures identified in the companies studied in CASE 2 divided by the total of possibilities, as in CASE 1, most of anti-measures implemented belong to the groups of technology and inter-organizational processes and policies. Moreover, PHARMA2 is the unique organization in CASE2 to implement almost all intra-organizational processes and policies anti-measures.

Technology

The organizations involved in CASE 2 implement in different levels all technology anti-measures. First, PHARMA2 and HOSPITAL12 are involved in the

project to implement the traceability system in Brazil. The employees interviewed believe a lot in the system. PMlog2, for instance, has already experienced the potential benefits of this system. "In [retail company], I participate in this project. The QR code is an ID for the product, its role is to provide visibility about where in the supply chain the product is and, most important, reduces piracy". In medicines supply chain, organizations believe that it is important to track each package and combine information with other data to monitor the supply chain.

Traceability? Should be package by package. When someone steals your load, you will tell Anvisa that the IDs 1-10 were stolen. Then, when Anvisa find the ID 9 with a hospital or pharmacy, they will investigate the place and may find out that this place buys counterfeited products. (PMlog2)

As stated, by tracing each package not just the batch, the supply chain increases the visibility of its products and regulatory agencies have more information to work with. However, when we refer to hospitals, the challenge is even bigger, as explained in the excerpt bellow.

For us traceability is different, and it's really expensive. Just the biggest private hospitals have it fully implemented nowadays, and they don't communicate with other supply chain links, it's for their own control. Why is it more complicated? Well, for us the ID should be in the last unit, the pill for instance, because we manipulate products. (PMlog2)

Thus, when fully implemented, the traceability system will enable the collection of a huge amount of data. To enable an agile decision-making process, this amount of information gathered may need the application of big data & analytics solutions. PMlog2 exemplifies these new necessities in his area: "You have to be analytical, analyze the process every day. If you do that just when the problem occurs, you won't make the best decision. Every day we have more and new data for that". Therefore, traceability and big data & analytics systems are being constantly studied to improve the organization's capabilities. As explained in CASE 1, an opportunity is to combine these solutions to work as an authentication tool, together with other technologies that PHARMA2 develops to facilitate the identification of original products.

"The visible technologies help consumers to understand that there is something wrong with their product. When a consumer sees something different in his products, he will ask himself if it is right and may even call us" (PSqualsec2). However, as PSqualsec2 explained during the interview, these security items are not released to the public. First, not to call attention of unwary counterfeiters.

Inter-organizational processes and policies

Healthcare is severely regulated, not just about merchandising but the whole sector, including the medicines supply chain. The legislative and Anvisa define regulations to be implemented by the supply members and Anvisa has the role to enforce and audit them.

For instance, the regulatory ordinance 244 details how to handle chemical substances that may be used to produce drugs. Thus, we are inspected by the Army, Federal Police, Civil Police, etc. They evaluate how many medicines you bought and how many you sell. Thus, you have to manage your processes quite well, otherwise the company will pay fines for not following Anvisa's standards. (PMlog2)

When we identify a problem, there is a procedure established according to Anvisa's rules. We analyze the situation to ensure if the medicine is authentic or not. If it is not, we notify Anvisa and inform them about our investigation. (PSqualsec2)

As observed, the responsibility of defining and enforcing interorganizational processes and policies is associated to Anvisa and other governmental agencies, as in CASE 1. Anvisa has been developing specific regulations to promote cooperation and ownership of the counterfeit problem among supply chain links.

The sanitary legislation empowers all supply chain links to report any kind of counterfeit, theft, falsification and so on. The pharmacy normative, distributors, manufacturing practices for industry...they all have. Thus, all links have this sanitary guide and have to report when they identify a potential harmful medicine. (PSqualsec2)

Thus, to reduce counterfeit risks, PHARMA2, DISTRIBUTOR2 and HOSPITAL12 apply some practices to monitor its suppliers and partners and avoid the existence of counterfeited medicines. For instance, PHARMA2 and DISTRIBUTOR2 are investing in the relationship with its logistics providers, by defining contracts more

appropriate to its reality and ensuring that the security requisites are being applied in all deliveries, instead of just investigating when they have a problem. From another perspective, the company developed reports about online pharmacies that are selling PHARMA2's products. HOSPITAL12 establishes severe quality and security standards for companies that want to compete in the bid.

Intra-organizational processes and policies

As most of the anti-measures applied by organizations in CASE 2 depends on regulations established by the legislative and Anvisa (as presented above), and most of them are directed to the manufacturer, DISTRIBUTOR1 and HOSPITAL12 have few anti-measures related to the intra-organizational processes and policies group. We extracted similar findings from CASE 1.

PHARMA2 applies most of the inter-organizations anti-measures. Nevertheless, although widely discussed and controversial in literature concerning mitigation of counterfeit risks (see Green and Smith, 2002, Qian, 2014 and Cho, Fang and Tayur, 2015), we did not identify any evidence about the application of the counterfeit anti-measures improve quality and price strategies in CASE 2 (see Table 13). Interviewees state that Anvisa establishes quality and price standard in the medicines supply chain. Thus, they must follow the regulation and there is no margin for making changes.

Medicines are 100% controlled. Anvisa decides the price. Actually, the process is: we propose a price and Anvisa compares with other similar products and asks why ours is different. We explain and Anvisa decides whether she agrees with our price or not. (PMlog2)

Talking specifically about PHARMA2, the company is investing in new R&D solutions for its products. The study of biosimilar medicines is an example in that direction: the company is investing in more complex products that, among other benefits, reduce the risk of counterfeit, once it is harder to copy. The company also evaluates the

best features and formats to implement in its medicines to help consumers to identify fakes. To ensure that the employees are following these and other processes to increase security and quality, PHARMA2 has specific areas here denominated Security and Quality.

Our Quality area audits our suppliers and partners and analyze their processes in terms of quality. Moreover, the Security team evaluates in terms of safety...they may even forbid the sales to client if they understand that they may damage our product! (PMlog2)

Thus, as observed, the strategies directed to suppliers and partners may even involve PHARMA2's clients, i.e. distributors, once they work as intermediates and may influence the quality of the final product. Interviewee from HOSPITAL12 suggests an even more proactive approach. "As we buy mostly from distributors, it's hard to ensure the quality of the medicine. We would like if he certified his suppliers." (HMpurlog12)

In addition, PHARMA2 also cited the relevance of having <u>reverse</u> <u>logistics capabilities</u>. Medicines dispensed without correct procedures may became an "easy opportunity" for counterfeiters, because they can easily reuse the package or resell the pills, which may have expired, for example. Recall of medicines may also be necessary and is a major undertaking, requiring complex logistics. When the government decides to recall a product all the supply chain should be prepared to pick the product and record data. PHARMA2 and HOSPITAL12 have their own structure to dispense the medicines not consumed and the secondary package.

The pharmaceutical company pays for the destruction of the medicine, or the distributor, but we reimburse them. There are many compliance rules for that and rigorous safety control to ensure the correct dispensation and no deviation (PMlog2).

Behavioral

By monitoring the supply chain, organizations gather information about vulnerabilities and opportunities to change policies, processes and procedures. The implementation of these opportunities often depends on change management capabilities, once changing behavioral attitudes may be required. The easiest way to transform behavior is defining standard procedures to be followed.

We have a procedure when a theft happens, for example. We have 24h to warn Anvisa, which is done by our regulatory area. It cascades: the Logistics have a time frame to warn the regulatory area, and our logistics provider has a time frame to warn us. If they don't do it right, we punish them and eventually stop working with this partner. They have to understand how important this is to us. (PMlog2)

Thus, more than learning how to handle the incidents, standardized practices and processes may be applied with three other goals. (i) First, to avoid incidents from happening. For instance, PSqualsec2 stated that risk management practices and policies are established along with Insurance and Risk Manager Organizations. (ii) Second, to mitigate the losses during counterfeit incidents. DISTRIBUTOR2, for instance, limits the value that may be transported in the same vehicle to minimize losses in case of theft. (iii) Third, to help employees and clients to deeply know the characteristics of medicines and easily identify when something is not in place, for example, PHARMA2 provide trainings in universities and general public to explain about the main features to know an original product. Therefore, the meaning of **standardize and train practices and processes** was expanded to more accurately represent its content. The anti-measure is now denominated **standardize policies**, **practices and processes** and encompasses the definition, implementation, enforcement and training of standard policies, practices and processes addressed to mitigate risks associated to counterfeiting.

Different from CASE 1, organizations in CASE 2 do not apply antimeasures focused on communicating directly with its final consumers. However, they believe it is important to empower consumers and provide them tools to authenticate their medicines. The excerpt bellow details a project being developed with this goal.

Nowadays it is almost impossible for consumers to know if they are buying an original product. There are some falsification signs, but it is vague for the

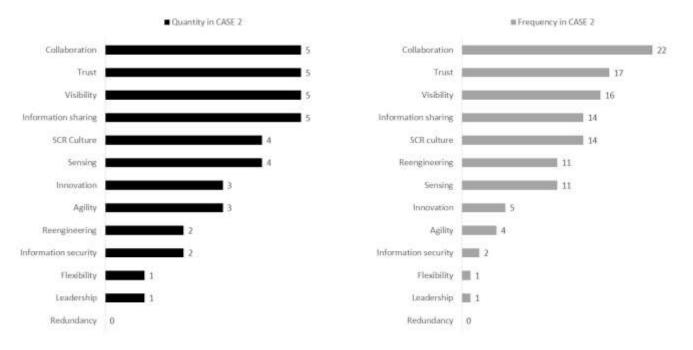
buyer, you know? This authentication process should be easier for the consumers. That's why we believe in implementing a QR code. The client would have an app and check in the pharmacy, before buying, if the product is original. (HMpurlog12)

Thus, the meaning of <u>train customers to identify fakes</u> becomes a subitem of a broader anti-measure, targeted at <u>empowering consumers to combat</u> <u>counterfeits.</u> That means transforming consumers into auditors of the medicines supply chain.

5.2.3 Resilience elements in CASE 2

By analyzing the data collected in CASE 2, this research aims at investigating the role of resilience elements in influencing the organizations' combat against counterfeits. Figure 28 demonstrates, on the left, how many interviewees (from the total of five) mentioned each resilience enabler in CASE 2 - quantity - and, on the right, how many times each resilience enabler was mentioned - frequency.

Figure 28: Number of interviewees who mentioned each resilience enabler and its frequency in CASE 2



Source: created by the author

As in the literature review, collaboration, trust, visibility, appear as relevant elements to increase resilience to counterfeit, as all interviewees affirm that the company applies them and cited them often. Supply chains encompass a set of organizations and, as the literature has largely explored, coordination is necessary to increase overall performance (RASHID; LOKE; OOI, 2014). It is not different with SCR, where the complexity and interconnection of risks enhances the necessity of collaboration (CHRISTOPHER; PECK, 2004). The risk of counterfeiting in medicines supply chain is affected by the complex network among its links, highly interconnected, which increases the vulnerability. Thus, organizations in CASE 2 claim that the supply chain has to join efforts and work together to avoid counterfeit risks. (i) First, collaboration may promote the exchange of best practices.

The ideal is to share best practices. We always learn something, someone says: "this thing that you are doing is not working, why don't you try like that…?" We have these open discussions with other pharmaceuticals, distributors, other associations, etc. Thus, we are always improving. (PSqualsec2)

PHARMA2 also disseminates best practices among its clients, as DISTRIBUTOR2. For that, interviewees state that it is important to know the reality of each client and understand its strengths and weaknesses. "We have a process to analyze the supply chain end-to-end and deeply understand our main clients. Then we evaluate solutions to improve their processes" (PMlog2). (ii) Second, collaboration may be a relevant tool to identify counterfeiters.

We receive calls of clients saying that they saw our medicines being sold with characteristics that we don't manufacturer. Then the client sends us a screen print of an online pharmacy, for example. We report that to teams responsible for investigating these incidents. (PMrisk2)

As observed, collaboration is maximized when the client trusts the pharmaceutical company enough to ask questions and share uncertainties. This is also true for other supply chain members, as having reliable partners make organizations more prone to collaborate with each other. Moreover, as organizations start to work in joint

investigations, the visibility of the supply chain increases. Thus, this study corroborates with the findings of Christopher and Peck (2004), that information sharing is an antecedent for visibility, and of Hohenstein et al. (2015), that sharing knowledge is crucial for readiness phase. Data gathered in CASE 2 shows that organizations believe that information sharing is a first step to increase resilience to counterfeit, as observed in the documents provided by PHARMA2: "The set of information will enable the complete monitoring of Brazilian medicines, avoiding illegal trade and counterfeiting".

However, just the collection of different sources of data is not enough to mitigate counterfeiting. Organizations in CASE 2, led by PHARMA2, believe that it is necessary to create processes and systems capable of using the information gathered to anticipate problems and help decision-making.

For instance, if it is a product with high probability of theft, my decision is based on processes to anticipate that. The ideal is not to make decisions when the problem occurs, but to rethink about that every day and create specific security routines and processes. (PMrisk2)

Thus, unlike what was raised during the literature review, sensing appears as a relevant element to increase resilience to counterfeit. Despite the advances in this direction, interviewees admit that increasing SCR culture is still a challenge.

To make an analogy, I could say that PHARMA2 is the goalkeeper and are trying to minimize that something wrong happens, the patient is at the other side, trying to take the pill and recover, and he is the striker. Then we have the midfield, they are equally important but you don't hear so often about them, right? Then what happens is that not everyone pays enough attention if they are doing a good job. We try to control and increase the risk awareness, but it is really hard. (PMrisk2)

On the other hand, flexibility and leadership were mentioned by just one interviewee and just once, and no data collected demonstrated the use of redundancy to increase resilience to counterfeit. These findings corroborate with what we identified in SLR, although we often raised flexibility and redundancy in the articles (mainly the ones related to resilience elements), the association among them and the counterfeit antimeasures was weak.

5.2.4 Role of resilience elements in combating counterfeit medicines in CASE 2

CASE 2's interviewees also mentioned the complexity of supply chain, leveraged by the quantity of times that the medicine changes custody between distributors, as one of the main challenges to combat counterfeit. HMpurlog12 highlighted the difficulty of assuring that the medicine purchased is legal when buying from a distributor, once it is not easy to associate through documents the medicine to its original pharmaceutical producer. Moreover, PHARMA2 has been struggling to monitor the sales of its products from online pharmacies. By hiring systems and specialized suppliers to monitor the World Wide Web. According to PMrisk2, the consumption of medicines from online sellers has been growing fast in recent years; however, the control of these distributors is complex because of the size of the World Wide Web and the difficulty to track the website owner.

From the data gathered and the content analysis performed, this research was able to analyze how CASE 2 uses the resilience elements to increase its resilience to counterfeit. Figure 29 illustrate the association between each resilience element and each counterfeit anti-measure (extracted from QDA Miner, as the proximity plot graph). The bigger the bubble, the higher the coefficient of co-occurrence, thus, higher the association between them. From figure 29, it can be observed that resilience elements may have different influences in each counterfeit anti-measure.

Figure 29: Resilience elements and counterfeit anti-measures association in CASE 2

		Collab	ollaboration Reengineering		Trest		Visibility		SCR culture		Innovation		Information sharing		Redundancy		Flexibility		Agility		Leadership		Information security		Sensing		
		SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2	SLR	Case 2
8 s 8	Strict government requirements		•	•	•	•	•		•	•	•	•	•	•		•		•							•		
nter- nization ocesses	Enforcement of IP rights			•	•	•	•			•	•	•		•		•		•	•	•		•	•		•		
organi alproc	Enhance national and international cooperation			•	•	•				•		•	•	•		•		•	•			•	•	•	•		
용별물	Monitor supply chain members			•	•	•					•		•	•				•	•	•		•	•	•	•	•	
	R&D strategies	•	•			•	•		•	•				•		•		•	•	•				•	•	•	
E S	Price strategies	•		•		•				•		•		•		•		•									
ig ig	Create an internal structure	•		•		•			•		•	•		•		•		•	•	•		•			•	•	
d pd	Improve quality	•		•		•				•		•		•		•		•		•		•		•		•	
organizational ses and policies	Supply/partner strategies		•				•		•	•				•						•		•		•	•	•	
F 8	Hot line to help patients		•	•	•	•	•		•	•	•	•		•		•		•		•		•			•		
E South	Investment in security equipments and systems	•	•	•		•			•	•		•	•	•	0	•		•		•		•		•		•	
	Reverse logistics capabilities	•				•	•		•	•			•	•	0			•				•		•		•	0
-	Enhance risk awareness	•		•		•	•		•	•	•	•	•	•		•		•		•		•		•		•	
iomi	Enhance brand reputation	•	•	•	•				•	•			•	•	0	•			•		0	•		•			
Behav	Standardize policies, practices and processes			•	•	•		•	•	•	•	•	•	•					•	•		•	•	•		•	
ĕ	Empower customers to combat counterfeits	•	•	•	•	•	•		•	•	•	•	•	•		•		•		•		•				•	
70	Traceability			0	•	•	•	•	•	•	•	•	•	•		•		•	•	•		•	•	•	•	•	
echnol ogy	Authentication technologies	•	•	•		•	•		•	•		•	•	•								•					0
He He	Big data & analytics	•			•	•	•		•	•	•	•	•	•		•		0	•	•					•	•	
	∑Coefficient of co-occurrence	7,9	8,2	7,6	6,4	6,9	7,0	6,8	7,5	7,0	6,1	6.4	7,2	5,7	7,5	5,3	0,0	4,7	5,4	4,2	6,3	4,4	0,9	3,6	4,1	3,1	8,4

Source: created by the author

5.2.4.1 Associations from CASE 2 often observed in SLR

CASE 2 presents **visibility**, **trust** and **collaboration** as resilience elements mentioned by all interviewers and most frequently, and with a high coefficiency of association with counterfeit anti-measures. As observed in figure 29, these findings match the ones identified in SLR and CASE 1, although in a different order.

PHARMA2 also works close to Anvisa and invests in **visibility** to **monitor the supply chain** to identify patent infringements and in **collaboration** to inform the sanitary agency looking for **enforcement of intellectual property rights**.

We strongly monitor patent request...it is important for us to analyze if our IP rights have not been violated. When we have a problem, we notify ANVISA and they analyze it. (PMrisk2)

To increase visibility, organizations believe that an effective solution is investing in the <u>technology</u> anti-measure group. However, <u>promoting the cooperation</u> <u>among supply chain</u> members has been a challenge for them. For instance, in the first pilot conducted by PHARMA2, only a few organizations have agreed to take part in it, invest money and share their data.

HOSPITAL12 is one of the organizations that took part in this project and thus, has a more active participation in mitigating counterfeit in CASE 2 than in CASE 1. PHARMA2 and HOSPITAL12 have been working for more than a year, in a collaborative effort, together with TECORG1 and Anvisa in trial projects to evaluate the challenges of implementing the MCNS, the Brazilian's traceability system.

We conducted a pilot project to better understand how we could use traceability to have more accurate information about the products purchased from PHARMA2. It helped us to understand our challenges in implementing it in all the country; we want to be ahead of it. We also shared the information with other companies that work close to us. (HMpurlog12)

Thus, in line with what has been discussed in literature (e.g. Wyld, 2008, Coustasse, Arvidson and Rutsohn, 2010, Kwok et al., 2010, and Taylor, 2014),

organizations from CASE2 have been focusing on <u>traceability</u> systems to mitigate counterfeit risks by increasing **visibility**.

When we implement traceability, we and our clients and consumers will have more confidence in our medicine. Moreover, the package will be tracked. Thus, when we identify a counterfeited medicine with a patient, Anvisa will have the necessary visibility to investigate who did it and when. (PMlog2)

Another benefit of <u>traceability</u> involves developing **innovative** solutions to influence the **behavioral** anti-measure group. For instance, CROSSORG2 and TECORG2 claim that the implementation of a traceability system should be developed together with serialization (i.e. unique code to identify the unit) and authentication (i.e. proof that the product is original, and the custody makes sense) systems. By doing so, organizations or the government could develop specific devices (apps, for example), that enable consumers to identify if the product is original or not, thus, <u>empowering them</u> to combat counterfeits. Communicating with civil society is crucial to combat counterfeiters (COHN et al., 2012).

PHARMA2 has also been developing other innovative solutions to address new trends in the medicines supply chain and anticipate counterfeiters. For instance, with the increase of online pharmacies, PHARMA2 has developed a robust system capable of **monitoring its products online** and identifying frauds, in line with the companies surveyed by Wilson, Grammich and Chan (2016).

From a strategic perspective, the pharmaceutical company is developing new **R&D strategies** by investing in bio similar medicines, which have structures that are more complex and, therefore, are harder to imitate. Although interviewees recognize that the main goal is to prevent from generic market, in clear expansion in Brazil, they state that the solution is also relevant to address counterfeit threat.

As CASE 2 organizations, influenced by PHARMA 2, look for collaborative solutions to combat counterfeit threat, most of the initiatives against

counterfeiters promoted seek to combine **visibility**, **trust** and **collaboration**, and depend on all of them to work.

Ideally, we have to start treating these issues together. We observe that the supply chain links are looking for isolated solutions, which increases cost and difficulty to implement. (DMgen2)

For instance, PHARMA2 <u>created two internal structures</u>, Quality Assurance and Corporate Security. Both structures are responsible for <u>monitoring</u> and visiting distributors and authorizing the commercialization of products in terms of products' quality and safety, respectively.

We developed an end-to-end perspective of our supply chain. Thus, we suggest solutions, counterfeit anti-measures and evaluate with the clients how to implement them. (PSqualsec2).

The excerpt from PSqualsec2 exemplifies the consultant approach developed by these two areas. Although they have the power to decide that PHARMA2 cannot sell products to a specific distributor anymore, they tend to have a collaborative approach, by working together with clients to share best practices and developing joint actions to implement improvements.

On the other hand, they apply a mandatory approach to define <u>suppliers</u> and <u>partners strategies</u>. In these cases, the <u>internal structures</u> of PHARMA2 conduct audits and may suspend partners when they do not adjust to the standards of quality and security defined by the company. The company also invested in <u>security equipment and systems</u>, such as GPS, trackers, circuit television systems, perimeter alarms among others, to avoid monitoring its partners. However, interviewees highlighted the difficulty of beating counterfeiters.

We had a case of a cargo with approximately 250 thousand oncological medicines that, when arrived at our client, was full of books!! We went in loco to check because we couldn't believe it. None of our security signals were activated." (DMgen2)

By investing in these internal anti-measures, the company collect inputs about its partners and suppliers that work as antecedents to **behavioral** anti-measures.

Interviewees from DISTRIBUTOR2 state that investing in security increases its **reputation** with PHARMA2, which is important to maintain the good relationship among them. Thus, the organization invests in **increasing risk awareness** of its employees.

5.2.4.2 Associations from CASE 2 not often observed in SLR

Unlike the SLR (as observed in figure 29), **sensing** and **information sharing** appears in CASE 2 as resilience elements most often associated with counterfeit anti-measures.

In a more traditional approach, organizations from CASE 2 are investing in <u>intra-organizational processes</u> and <u>processes</u> anti-measures. Organizations use historic information to define new <u>standardized policies</u>, <u>practices and processes</u> to avoid vulnerabilities and take actions to anticipate disruptions. For instance, PMlog2 state that different security measures during warehouse and transportation are applied depending on history of counterfeit incidents.

We introduce many security items to our products. Therefore, we have to do a product risk profile [...] through this risk profile you determine what should be applicable for each product to help identify if it is original and increase product's security. It is too much money that we have to spend. Therefore, we have to invest in our vulnerabilities. That's the concept of risk intelligence! (PMrisk2)

As observed, the definition of these risk protocols, for products, regions or processes, which affects the ability to promote sensing into the supply chain, depends on collecting, maintaining and sharing a large amount of information and using them to make right decisions. Thus, organizations have to look for global not local optimal decisions (CHRISTOPHER; PECK, 2004) and develop decision structures (GOULD; MACHARIS; HAASIS, 2010).

This difficulty also applies to the development of solutions related to **technology** anti-measures. For instance, Dimase et al. (2016) reinforces the necessity of using the large amount of data collected with **traceability** systems to support risk-

informed decision-making. One of the concerns of the traceability pilot being conducted is exactly to define the technologies and protocols needed to maximize the potential benefits of the data collected. As suggested by Papadopoulos et al. (2016), CASE 2 organizations have been discussing the use of **big data & analytics** to leverage data analysis and vulnerability identification. "Through big data & analytics tools we would be able to identify normality deviations and act, right? It should be part of the process" (HMpurlog12).

information about purchase and sales of medicines, they may map all the medicine custody, thus the vulnerable spots among the supply chain will be clear. From a logistics perspective, organizations may develop block chain solutions; which leverages the possibility of reducing costs and improving consumer experience. Due to existing amount of data, big data & analytics solutions are fundamental to enable this process with the necessary agility. However, the companies and entities studied admit that there is a long path to be covered in this direction and the healthcare sector has a lot to learn from other industries.

5.3 General Results from Cross-Case Analysis

CASE 1 and CASE 2 present many similarities. Although with different priority, they consider **visibility**, **trust**, **collaboration**, **sensing** and **information sharing** as resilience elements most often associated with counterfeit anti-measures. Figure 30 presents the coefficient of co-occurrence of CASE 1, CASE 2 and SLR. Green represents a high coefficient of co-occurrence, yellow a medium coefficient and red a low coefficient.

Figure 30: Resilience elements most often associated with counterfeit anti-measures according to the empirical research and comparison with SLR

			Visibility			Trust		Co	llaborat	ion		Sensing	,	Information sharing			
Resilien	Resilience enabler		Case 1	Case 2	SLR	Case 1	Case 2	SLR	Case 1	Case 2	SLR	Case 1	Case 2	SLR	Case 1	Case 2	
ion ses	Strict government requirements	0,3	0,3	0,3	0,4	0,3	0,3	0,4	0,1	0,3	0,1	0,4	0,5	0,1	0,3	0,3	
Inter- anization rocesses	Enforcement of IP rights	0,3	0,6	0,7	0,4	0,6	0,5	0,4	0,6	0,8	0,1	0,4	0,5	0,1	0,4	0,7	
- E E	Enhance national and international cooperation	0,5	0,5	0,9	0,4	0,3	0,6	0,6	0,9	1,0	0,0	0,4	0,7	0,3	0,5	0,9	
	Monitor supply chain members	0,5	0,8	0,9	0,5	0,5	0,6	0,6	0,6	0,7	0,2	0,4	0,7	0,5	0,7	0,9	
w	R&D strategies	0,3	0,4	0,3	0,3	0,3	0,3	0,3	0,4	0,3	0,2	0,6	0,4	0,2	0,4	0,3	
tional	Price strategies	0,2	0,1	0,0	0,3	0,1	0,0	0,2	0,1	0,0	0,1	0,0	0,0	0,1	0,1	0,0	
Intra-organizational ocesses and policie	Create an internal structure	0,2	0,3	0,6	0,3	0,2	0,6	0,3	0,5	0,7	0,3	0,5	1,0	0,2	0,2	0,6	
and	Improve quality	0,2	0,3	0,0	0,3	0,6	0,0	0,3	0,3	0,0	0,3	0,3	0,0	0,3	0,2	0,0	
60.8	Supply/partner strategies	0,6	0,5	0,3	0,6	0,8	0,3	0,6	0,5	0,3	0,2	0,6	0,5	0,6	0,6	0,3	
888	Hot line to help patients	0,4	0,1	0,3	0,3	0,3	0,3	0,4	0,1	0,3	0,1	0,0	0,5	0,4	0,1	0,3	
Intra-	Investment in security equipments and systems	0,2	0,5	0,1	0,3	0,2	0,1	0,3	0,2	0,2	0,3	0,3	0,3	0,3	0,4	0,1	
	Reverse logistics capabilities	0,3	0,0	0,1	0,3	0,0	0,1	0,3	0,0	0,2	0,2	0,0	0,3	0,2	0,0	0,1	
<u></u>	Enhance risk awareness	0,4	0,3	0,4	0,3	0,2	0,3	0,4	0,9	0,5	0,1	0,3	0,4	0,4	0,6	0,4	
ehavioral	Enhance brand reputation	0,2	0,1	0,2	0,5	0,1	0,6	0,3	0,3	0,3	0,1	0,0	0,3	0,1	0,0	0,2	
e p	Standardize policies, practices and processes	0,7	0,5	0,5	0,5	0,6	0,7	0,7	0,3	0,6	0,3	0,4	0,5	0,6	0,5	0,5	
œ.	Empower customers to combat counterfeits	0,2	0,3	0,3	0,3	0,5	0,4	0,3	0,3	0,3	0,3	0,3	0,4	0,2	0,4	0,3	
를 숨	Traceability	0,7	0,7	0,9	0,5	0,6	0,7	0,6	0,2	0,8	0,2	0,5	0,5	0,4	0,4	0,9	
Techn	Authentication technologies	0,2	0,3	0,1	0,3	0,6	0,1	0,3	0,2	0,2	0,1	0,2	0,3	0,2	0,3	0,1	
	Big data & analytics	0,2	0,5	0,7	0,1	0,4	0,5	0,2	0,2	0,8	0,2	0,5	0,8	0,3	0,6	0,7	
	∑Coefficient of co-occurrence	6,8	7,1	7,5	6,9	7,2	7,0	7,9	6,6	8,2	3,1	6,1	8,4	5,7	6,6	7,5	

Source: created by the author

In accordance with the SLR, visibility, trust and collaboration appeared as relevant resilience elements to combat counterfeit in the empirical research. Moreover, other elements raised from the case study: sensing and information sharing.

As observed, some anti-measures are more significant in composing the coefficient of co-occurrence. Data collected from both cases shows the importance of regulatory associations and other national and international entities to counterfeit combat. First, data gathered presents that organizations from CASE 1 and CASE 2 rely mainly on Anvisa's regulations to make decisions about investments to increase resilience to counterfeiting.

ANVISA has a crucial role in our sector...you know? First, it defines the regulations that we all have to follow. For example, if traceability was not a law and if it wasn't for the documents that ANVISA is creating to support this law, I can't imagine when the companies would decide to implement traceability systems. Moreover, the local surveillance teams are responsible for the enforcement and control of the supply chain. Finally, they investigate reported cases about falsification (DMlog1).

Regulatory and quality areas have a strong influence in logistics functions. They define what the logistic function will be. But not just logistics, their role is to ensure that what has been agreed with Anvisa is being accomplished by PHARMA2 in terms of quality, security, regulations, etc. (PMlog2)

Second, they join national and/or international associations to defend their needs and conduct investigations about counterfeiters. Most of the combat that cross the organization's borders are carried out by these associations and the government. AIPrep1 illustrates the difficulty involved in investigating counterfeiting incidents.

Medicine supply chain organizations fund associations such as PHARMAASS1 to help them to defend their interest. Imagine, a company cannot fight alone counterfeit; you have to remember that we are talking about organized crime, and they often act globally! (AIPrep1)

This strategy is similar to medicines supply chains in other countries such as the United States, as reported by Kumar, Dieveney and Dieveney (2009) and Coustasse, Arvidson and Rutsohn (2010). However, it increases the government's necessity of having enough resources, which is not always true in Brazil.

ANVrep reinforces the necessity of enhancing **supply chain visibility** to better prepare and deal with counterfeit incidents. Visibility enables Anvisa to support the development of **strict government requirements/laws** and its **enforcement**, and to **monitor the supply chain**. Moreover, Brazilian organizations also understand that a more comprehensive outcome of these initiatives is achieved when there is **cooperation among national and international entities** involved in counterfeit combat, as demonstrated by Coustasse, Arvidson and Rutsohn (2010) and Almuzaini, Choonara and Sammons (2013). For instance, ANVrep states that better results are achieved when **visibility** is associated with **collaboration**. "For example, nowadays thefts reported in our ports and boarders may trigger joint actions among Anvisa and Federal Policy, which help us to solve the crimes".

Thus, while literature advocates that visibility can promote collaboration (CHRISTOPHER; LEE, 2004; SONI; JAIN; SALMADOR, 2015), this study also identified that collaboration can promote visibility. However, when few organizations are truly willing to collaborate, this may inhibit visibility. For instance, despite advances in

medicines traceability and the current enforcement of its regulation worldwide, there is no standardized policy accepted overall to identify and code pharmaceutical products. Thus, many countries are developing their own serialization patterns, creating a complex and fragmented system, which further hinders the visibility of the supply chain. Brazil is not different, and this lack of standard may lead to rework and many investments. Thus, the lack of interest in collaboration may transform the resilience element into a barrier to increase visibility.

Moreover, as raised in SLR, interviewees from CASE 1 and CASE 2 state that **trust** is crucial to increase resilience to counterfeit. However, it is worth mentioning that although literature review has addressed trust in relation to consumers (LYBECKER, 2008; CESAREO; STÖTTINGER, 2015) and other supply chain members ((LYBECKER, 2008; SPEIER et al., 2011), few has been said about trusting in the government and regulatory agencies. For instance, Anvisa had a genuine intention in postponing the regulation about the implementation of traceability system in Brazil. The goal was to engage more supply chain members in this journey and develop guidelines and best practices to address the challenges. However, it made many companies feel that they invested lots of money to adequate their processes and were "betrayed". Thus, the lack of definitions, last minute changes and postponements lead to a lack of credibility of the supply chain in the regulatory system.

Although the strategies are similar, the study identified relevant differences regarding the approach of both cases. CASE 1 is largely influenced by PHARMA1 strategies, a multinational pharmaceutical company. Thus, most of the strategies are global and performed by **international teams created** to collaborate with governments overall.

Global teams are responsible for counterfeit medicines, because we have huge international mafias, thus keeping the problem in Brazil would not solve the root cause. These global teams work with security and IP experts. Usually

counterfeiters involve five or six countries in their process. Thus, one has to have a holistic view of the problem to fight it. (AIPrep1)

Therefore, CASE 1 seems to have more power and ability to combat the counterfeit threat from an external perspective, as counterfeiters also work globally and a holistic perspective is necessary to investigate them. On the other hand, organizations from CASE 2 have just local influence and, consequently, limited ability to investigate counterfeit incidents. Despite the challenges, the company also created internal teams responsible for increasing security and quality of its products and processes.

Moreover, PHARMA 1 has promoted anti-measures directed at consumers focusing on empowering consumers on counterfeit combat, mostly by encouraging them to buy from reputable sources and sharing information about how to identify fake products. Such anti-measures have not been identified in CASE 2. When asked, interviewees from PHARMA2 argue that PHARMA2's role is to help the government to develop innovative solutions to help consumers to authenticate their products. For instance, they state that consumers will have a better visibility of counterfeited medicines with implementation of traceability, because they will be able to consult if the package ID is trustable.

Despite these efforts and different approaches of anti-measures directed at consumers, it is worth mentioning that, although these initiatives empower consumers to identify suspicious products, they focus just on one of the two market scenarios proposed by Grossman and Shapiro (1988a, 1988b). As their goal is to help consumers to identify counterfeited products, they are directed at deceptive counterfeiting – i.e. when consumers are unaware that they are not purchasing original products and cannot detect them by inspection or inference from place of purchase. However, unlike common sense, the other type of trade also applies to the medicines supply chain: the nondeceptive counterfeiting, when consumers know or strongly suspect when they purchase not

original products. The excerpt from the Anvisa's representative (ANVrep) explains the scenario.

I believe the demand for suspicious medicines is higher for the ones that need a prescription. Due to the several problems to address our health systems, the consumers opt to purchase from illegal pharmacies where he may buy the controlled medicine without prescription. (ANVrep)

Thus, the demand for nondeceptive counterfeiting mainly exists for consumers to buy medicines without prescription or because of the high price of the medicines, which may be found cheaper on the internet, for instance. To combat this market scenario and to leverage the benefits of deceptive counterfeiting as well, organizations should focus on increasing SCR culture against counterfeiting. However, as stated by Cesareo and Stöttinger (2015), the use of consumer-direct anti-counterfeit measures depends on how open, transparent and proactive an organization is willing to be about this sensitive subject with its clients. During all interviews and data gathered, it could be noticed that talking about counterfeit medicines is still a taboo in the medicines supply chain. Due to the criticality of the theme, CASE 1's and CASE 2's organizations address for governmental and non-governmental associations the responsibility of improving SCR culture. Nonetheless, CROSSASS2 was the only association to openly address the problem and develop brochures and merchandising to explain the impact of counterfeited products.

6 CONCLUSIONS

Counterfeiting in the medicine supply chain has been growing, because of free trade agreements, lack of severe regulations, globalization, an increase in emerging markets, the increase of purchase on the internet, lack of protection in intellectual property and advances in counterfeiting technologies (CHAUDHRY; STUMPF, 2013).

In Brazil, besides these factors, the country experiences in the medicines supply chain (i) a complex network with many intermediates before consumption, which increases the vulnerability along the supply chain; (ii) a greater presence of Anvisa as a regulatory agency in recent decades, aimed at enforcing higher degrees of quality and security; (iii) the increase of generic medicines, which increases price competition and pressure companies to be lean and innovative; (iv) the increase of purchase and demand of medicines with more added value and greater degree of sophistication; and (v) the increase of government purchase of medicines, which leads to higher quantities of medicines at the lowest price available, and to the purchaser's necessity to promote risk-free tenders.

Despite the potential danger for society (WILCOCK; BOYS, 2014; QUADRI, 2017) and the escalating medicine counterfeit market (see Almuzaini, Choonara and Sammons, 2013), just in recent years academics, practitioners and governments have drawn their attention to the issue. Thus, little has been researched to address counterfeit threats from a business perspective (WILSON; GRAMMICH; CHAN, 2016). In this context, this study proposes that disturbances caused by counterfeit medicines could be mitigated by more resilient supply chains and points out some directions in terms of elements.

6.1 Results from Theoretical and Empirical Research

The theoretical and empirical research performed in this project present insights on how the medicine supply chain may strengthen its resilience elements to better deal with counterfeit disruptions. In both cases, Anvisa, followed by the pharmaceutical company are primarily responsible for defining the approach taken by the supply chain against counterfeiters. Besides the health problems to the patients, as the pharmaceutical possess the brand of the medicine, counterfeit incidents mainly damage the image of the

pharmaceutical company and its reputation, which explains their higher interest in mitigating this threat. Nonetheless, as the concern of the pharmaceuticals increase, organizations downstream have to adapt and enhance security to maintain its reputation and continue to have the permission to buy from the manufacturer. Moreover, all organizations rely on Anvisa and other national and international entities to fight for more strict regulations and ensure enforcement of existing laws. Figure 31 presents a framework of the findings of this research.

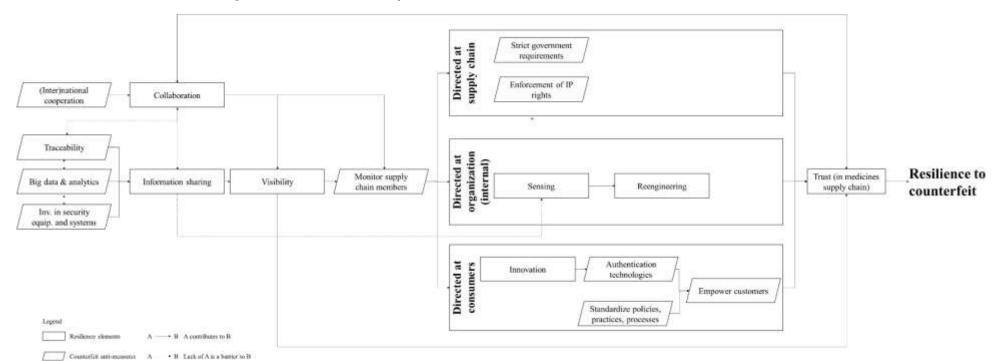


Figure 31: Framework of dynamics to increase resilience to counterfeit medicines

Source: created by the author

Two of the main resilience elements applied by the case studies and in accordance with the literature findings are visibility and collaboration. The data analysis frequently identified these elements as the most often cited and most associated with counterfeit anti-measures. Willing to create visibility, empirical research shows that the medicines supply chain have been investing for a long period in security equipment and systems and, more recently, in traceability systems to gather information from different sources about the product location and chain of custody. The large amount of data collected and new technologies available triggered the necessity of investing in big data & analytics solutions, enabling the combination of several data from several sources to help decision-making. From a government perspective, combining data from traceability systems and invoices may help the identification of counterfeiters that work through the legal supply chain. Pharmaceuticals may gather data from different websites that sell its products and identify counterfeit patterns. Logistics providers and distributors may associate data from the GPS, vehicle and TMS to evaluate suspicious activities.

Thus, although its potential is still in its infancy, both cases have been using big data & analytics solutions to improve the decision-making process before and after a counterfeit disruption. By **sharing information** analyzed with other supply chain members, organizations strengthen the **visibility** of the medicines supply chain. For instance, hospitals may better prepare its tenders or purchase processes based on information of other members of new techniques to prevent from counterfeiters. The strong influence of information sharing in combating counterfeit was not raised during the literature review.

<u>Cooperation among national and international members</u> promotes the exchange of the best practices and practices, which enhances **collaboration** through the supply chain. By combining visibility and collaboration, the supply chain may strengthen

its ability to **monitor the supply chain**. Its control influences anti-measures with three different focus: (i) supply chain, (ii) organization (internal) and (iii) consumers.

First, by monitoring the supply chain, Anvisa may strengthen its ability to apply its scarce resources at the right targets and promote **enforcement** of regulations. As stated by Everts (2010), heavy enough consequences are necessary for counterfeiters. Moreover, organizations and entities may help the government to identify potential vulnerabilities and develop **stricter regulations**, similar to the one existing in developed countries (NAYYAR; BREMAN; HERRINGTON, 2015). These anti-measures increase the **trust** in the medicines supply chain, of medicines supply chain members, potential new players studying the Brazilian market, and consumers.

Second, the information gathered, boosted by big data & analytics systems, enable organizations to monitor the supply chain and anticipate potential disruptions, strengthening its sensing capability. The vulnerabilities identified may be reengineered to mitigate counterfeit risks. Distributors and logistics providers may define risk-prone regions to be avoided or define automatic triggers when suspicious activities are identified. Hospitals may withdraw medicines batches based to anticipate recalls based on information provided by Anvisa or pharmaceutical's hotlines. Pharmaceuticals may make changes on its supplier's database based on counterfeit risks. These anti-measures help organizations to increase **trust** in its products and processes.

Third, medicines supply chain is investing in anti-measures against counterfeits directed at consumers and patients. On one hand, organizations (especially PHARMA2) are enhancing its **innovation** capabilities and investing in solutions to help consumers to **authenticate** medicines. The creation of apps that tell consumers if its medicine belongs to the formal supply chain is an example. On the other hand, organizations have focus in communicating with consumers and explaining the

standards of policies, practices and processes to help consumers to identify suspicious medicines. These anti-measures aim at empowering consumers to identify fakes and, consequently, enhance their trust in medicines supply chain. By developing these elements and anti-measures, the medicine supply chain increases its resilience to counterfeit.

Another relevant finding of this research is that the absence of collaboration and information sharing work as a barrier to increase resilience to counterfeiting. The lack of collaboration among the supply chain complicates the implementation of the medicine traceability system, responsible for increasing supply chain visibility. The lack of information sharing between organizations and other sources seriously reduces the capability of the big data & analytics systems, as their relevance is built on the ability of combining data from different sources and trigger actions to avoid or mitigate incidents. Therefore, the lack of collaboration and information sharing suppress the supply chain resilience to counterfeiting.

6.2 Managerial and Theoretical Implications

From a managerial perspective, our findings show the importance for practitioners to increase SCR to prepare for, respond to, recover and grow successfully (SCHOLTEN; SCOTT; FYNES, 2014; EHRENHUBER et al., 2015; HOHENSTEIN et al., 2015) from disruptions caused by counterfeiting. Our results also indicate the outcomes of strengthening resilience elements. From a theoretical perspective, this paper is unique as it provides an in-depth analysis in both fields: resilience elements and counterfeit anti-measures literature. By combining them, our findings present new insights and avenues of research to be further explored from different perspectives and in different fields about the relevance of resilience.

For instance, this study presents how the increase of collaboration and trust among supply chain links may (i) support government and organizations to share best practices and map vulnerabilities, and thus, promote more properly enforcement to combat counterfeit threats, and (ii) empower consumers and transform them into "auditors" of this complex supply chain. We also investigated new associations not often observed in literature. For example, how information sharing influences the fight against counterfeiters, and the role of big data & analytics to enhance sensing and, consequently, increase the ability of organizations to anticipate disruptions. Thus, our study shows that visibility, collaboration, trust, information sharing and sensing are the most relevant elements to increase resilience to counterfeiting. Moreover, agility, reengineering and **innovation** may leverage the expected outcomes. Figure 31 illustrates the dynamics between them and the counterfeit anti-measures. Moreover, this paper has also discussed the role of resilience elements as barriers, and not facilitators, to prepare and respond for disruptions. Other studies, as Costa et al. (2017) have already explored this outcome. These findings may influence how organizations should prioritize and focus its efforts to increase resilience to counterfeit.

This study also contributes to SCR and anti-counterfeiting literature, as the findings show that there is potential for future research in this emerging topic with relevant impacts on different agents of the medicine supply chain. Although this research promotes some advances on how resilience elements may mitigate counterfeit risks, more studies are needed. For instance, the role of collaboration, trust and reengineering needs further investigation. Stevenson and Busby (2015) illustrate this gap by stating that although the literature on resilience regarding supplier selection considers trust, flexibility and redundancy, little is known about the risk of passing-off products under the original trademark. In addition, understand the importance of elements less associated with

counterfeit anti-measures in literature in other scenarios represents a relevant contribution to a field in constant growth.

Moreover, authors may investigate trade-offs raised from theoretical and empirical discussion. For instance, while counterfeiting literature advocates that offshoring and outsourcing may have potential long-term damage (HOECHT; TROTT, 2014; MERAVIGLIA, 2015), resilience literature affirms that a rapid response involves using standard processes and having multiple locations with built-in interoperability (SHEFFI; RICE, 2005) and dual sourcing (LÜCKER; SEIFERT, 2017). Furthermore, while literature on resilience states that the complexity of products increases the risk of the supply chain, making it difficult to recover in the event of a disruption (BLACKHURST; DUNN; CRAIGHEAD, 2011; KHAN; CHRISTOPHER; CREAZZA, 2012), academics who study counterfeiting claim that companies should enhance technological complexity of their products and make it harder to imitate (CHO; FANG; TAYUR, 2015). PHARMA2, for example, is investing in biosimilars, medicines much harder to imitate. Finally, counterfeit literature states that R&D departments should invest in creating a moving target to complicate copy (GREEN; SMITH, 2002). However, having medicines with standard characteristics appears as a relevant anti-measure to help consumers to identify changes that may lead to counterfeit incidents. Thus, this paper reinforces that understanding these tradeoffs and proposing equilibrium is necessary.

The literature review also identified the need of understanding the effectiveness of such resilience practices. A few authors (e.g. Liu et al., 2017 and Mandal, 2017) have drawn conclusions in this sense by investigating the impact of SCR in performance, however more studies are needed. The efficiency and effectiveness of strengthening resilience elements to combat counterfeit is also not clear and was not addressed in this research. For instance, despite the increased academic anti-measures

aimed at consumers (FERNANDES, 2013), practitioners and academics doubt their effectiveness and efficiency (CHAUDHRY et al., 2009) and, to the best of our knowledge, no empirical studies have explored the effectiveness of implementing specific practices to mitigate counterfeit risks.

This study also suggests that new trends in the medicine supply chain, as the increase in online pharmacies and the constant increase of available data, require more studies on how to address these new exposures once if one link is susceptible to counterfeiters, the whole chain is. Big data & analytics systems may be an important tool to help the decision-making process and to optimize the existent resources, as they may help to identify more vulnerable processes. Moreover, this study encourages researchers to conduct empirical studies in vulnerable areas still little explored, such as Africa and South America, and focused on how to address these specific new trends in the medicines supply chain. This project is a first step to address this gap.

Finally, the counterfeit issue is also a threat in other supply chains, and many similarities may be observed. For instance, the criticality of counterfeit products for consumers' safety and health may also be identified in other sectors such as food, beverage and aviation parts. Moreover, complex and extensive networks are also not restricted to medicines. Cash, for example, presents innumerous opportunities for counterfeiters to introduce illegal banknotes. Luxury, fashion and cigars sectors are also constantly threatened by counterfeiters. Thus, this study urges researchers to investigate similarities and differences on how to increase resilience to counterfeiting in other industries.

6.3 Limitations

Even though efforts were made to maintain the rigor of the research, limitations associated with it need to be addressed for future implications. Our research

is not free from limitations. First, as aforementioned, counterfeiting is rapidly evolving and, therefore, anti-measures require constant monitoring and updating. Studies on the subject may shift dramatically over time. Second, although the search strings were carefully formulated, and relevant databases were carefully selected, potentially relevant articles that do not explicitly use any of these terms or that have not been published in one of the three databases searched may not have been identified. Moreover, this study does not address the literature concerning other relevant types of trade crimes. Third, although we carefully selected cases truly engaged in counterfeit combat and from different perspectives, one limitation regards the fact that we conduct two case studies of an emergent economy and, as expected from case studies, generalization of the results may not be possible. Forth, interviews were conducted with just 11 key executives and 13 representatives of cross-entities. However, given the key role that the interviewees played in each supply chain, we argue that the relatively low number of executives interviewed does not pose a major constraint on the validity of our findings, in particular because we were able to triangulate the findings. Fifth, we had no access during research to the pharmacy segment. Exploring them is also relevant to increase resilience to counterfeit in the medicines supply chain. Other supply chain links, such as doctor's representatives, may also represent new opportunities to be more deeply investigated. Our findings are exploratory rather than definitive but indicate some insights and areas of interest for practitioners and academics to explore in future studies.

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APPENDIX I: Case Study Protocol

1) Objetivo da Pesquisa

O objetivo deste trabalho é compreender o papel dos elementos de resiliência no combate à contrafação de medicamentos na cadeia de suprimentos.

2) Pergunta de Pesquisa

Como é que os elementos de resiliência contribuem no combate à contrafação de medicamentos na cadeia de suprimentos?

3) Foco da Pesquisa

Conforme apresentado na figura abaixo, o objetivo é entender a intersecção entre três constructos: cadeia de medicamentos, elementos de resiliência, e medidas anticontrafação.



4) Seleção dos estudos de caso

Empresa focal:

- médias ou grandes empresas;
- empresas envolvidas nos fóruns de discussão sobre rastreabilidade, pois há maior chance de terem desenvolvido práticas para aumentar a segurança do paciente e da cadeia de medicamentos;
- empresas com operação no Brasil.

Operadores Logísticos, Farmácias e/ou Hospitais:

 empresa responsável, em algum ponto da cadeia de suprimentos, pela custódia do medicamento da empresa focal.

5) Coleta de dados

- Entrevistas presenciais ou por Skype, permitindo maior flexibilidade ao entrevistado. O seguinte roteiro é seguido:
 - Roteiro de Abertura primeiro contato com a organização, entendimento geral de sua estrutura e identificação dos futuros entrevistados;
 - Questionário entrevistas com colaboradores responsáveis pelos processos de Produção, Logística e Pesquisa e Desenvolvimento da empresa focal, e colaboradores responsáveis pelos processos de Compras e Logística das empresas de Operação Logística, Farmácia e/ou Hospital. Pretende-se entrevistar pelo menos três pessoas de cada empresa, sendo um deles responsável pela gestão.

- Dados adicionais:

- documentos internos da empresa focal e empresas à jusante;
- outros relatórios (descrição de incidentes de contrafação, informações de gestão de riscos, decisões de licitação);
- informações de seus websites;
- dados de seminários, congressos e outros eventos relevantes relacionados a medidas anti-contrafação e práticas de gestão de riscos na cadeia de saúde.

- Procedimento:

- introduzir o objetivo da pesquisa e destacar a confidencialidade dos dados coletados;
- seguir o roteiro de entrevista com cada entrevistado;
- gravar as entrevistas e realizar anotações.

5) Análise dos Dados

- adicionar todas as notas, transcrições e documentos na base de dados dos casos
 (QDA Miner) –ver o livro de códigos (codebook- Appendix V);
- realizar análises intra e inter casos e avaliar os resultados e conclusões à luz da revisão de literatura.

APPENDIX II: Formal e-mail sent to Brazilian organizations

Prezado (a), boa tarde.

Sou Flávia Lima, orientanda de mestrado da Profa. Andrea Lago da Silva (em cópia) do Depto Engenharia de Produção da UFSCar e com atuação há mais de 4 anos em Consultoria de Gestão, como foco em projetos para revisão de modelo de governança e operação das organizações.

Estou realizando um projeto de mestrado que visa entender o papel dos elementos de resiliência* no combate à contrafação** na cadeia de medicamentos. Esse estudo busca identificar práticas de gestão para mitigar o risco de medicamentos falsificados, devido aos problemas que estes produtos podem causar ao paciente e à imagem da empresa.

Gostaríamos de incluir a empresa em que o Sr.(a) trabalha na pesquisa, devido a sua estrutura e posição no mercado. Durante a pesquisa, será necessária a realização de entrevista com gestores das áreas de Produção, Logística e Pesquisa e Desenvolvimento com duração média de 50 minutos. A entrevistadora, desde já, gostaria de destacar que o nome e os dados específicos da empresa e dos entrevistados serão protegidos por sigilo, sem nenhum tipo de identificação.

Após o término da pesquisa, compartilharemos um sumário executivo com as

principais ações a serem aplicadas para aumentar a resiliência à contrafação, ou seja,

mitigar o risco de medicamentos falsificados na sua cadeia e ações para tornar a sua

empresa mais preparada para lidar com possíveis incidentes.

Finalizando, colocamo-nos à disposição para mais informações e agradecemos

desde já a atenção.

Flávia R. P. de Lima

Andrea Lago da Silva

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* Resiliência é a capacidade dinâmica das organizações de se preparar e se adaptar para responder

positivamente a perturbações na operação.

** Um dos exemplos de perturbação é a contrafação, que representa o comércio ilegal de produtos que

carregam referência à uma marca ou empresa, sem a devida autorização.

APPENDIX III: Semi-structure Interview Protocol

ROTEIRO DE ABERTURA

Objetivo: Este questionário será aplicado durante o primeiro contato com a empresa,

preferencialmente com um funcionário de perfil mais estratégico e posto elevado

na hierarquia da empresa. A função principal desse questionário é auxiliar a seleção dos

entrevistados e conhecer melhor a estrutura da empresa.

Início: Informações gerais sobre o entrevistado.

- (a) Nome:
- (b) Função:
- (c) Tempo na empresa:
- (d) Tempo trabalhando em empresas do ramo de saúde:

Parte 1: Verificar o entendimento do entrevistado sobre contrafação.

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(1) Você já ouviu falar em contrafação de medicamentos?

a. Se sim, você já teve que lidar com um incidente de contrafação de medicamentos?

b. Se não, dar uma explicação e, em seguida, perguntar se ele já teve que lidar com

algum incidente relacionado a isso.

(2) Quais os ações sua empresa toma para evitar e solucionar esses incidentes?- Após

deixá-lo lembrar espontaneamente, dar exemplos encontrados na literatura.

Você poderia me dar indicação dos entrevistados seguintes? Procuramos

colaboradores com perfil de gestão, que atuem nas áreas responsáveis por aplicar os ações

acima mencionados (importante incluir pelo menos uma pessoa de Pesquisa e

Desenvolvimento, Compras, Logística e Produção, dependendo do escopo da empresa).

APPENDIX IV: Questionnaire

QUESTIONÁRIO

Objetivo: Este questionário é destinado a gerentes e coordenadores envolvidos em

atividades que demandem a aplicação de práticas de gestão para combater a contrafação

de medicamentos.

Questionário

(1) Primeiramente, poderia falar de forma geral suas responsabilidades na empresa?

(2) Tempo de empresa e na área, formação, idade

(3) Na sua visão, quais os principais riscos enfrentados pela sua empresa em relação aos

medicamentos?

(4) Você acredita que a cadeia de medicamentos está exposta ao risco de contrafação?

(5) Quais são as especificidades/diferenças relacionadas à contrafação que só ocorrem no

setor de medicamentos?

- (6) Sua empresa especificamente está exposta a vulnerabilidades relacionadas à contrafação de medicamento?
- (7) Você poderia descrever algumas das vulnerabilidades que ela enfrenta?
- (8) Como ela mitigou ou poderia ter mitigado isso? Dê exemplos.
- (9) No seu dia-a-dia, o risco de contrafação é considerado na sua tomada de decisões? Dê exemplos.
- (10) As medidas anti-contrafação listadas abaixo são importantes no combate aos contrafeitores de medicamentos? Em que sentido?

Medidas anti-contrafação	Breve explicação	Importância?
Leis governamentais mais	Desenvolver leis que suportem os países a	
severas	monitorar e penalizar os contrafeitores.	
Assegurar propriedade	Garantir a aplicação de ações que garantam a	
intelectual	propriedade intelectual a quem é de direito.	
Aumentar cooperação	Desenvolver práticas entre entidades nacionais	
nacional e internacional	e internacionais, policia, judiciário e	
	empresas.	
Monitorar membros da	Estabelecer um Sistema de vigilância e	
cadeia de medicamentos	controle sob os demais elos da cadeia.	
	Aumentar a consciência geral dos riscos	
Aumentar a consciência do	associados à contrafação e seriedade do	
risco	problema (consumidores, empresas e	
	governo).	
Aumentar reputação da marca	Melhorar a imagem e reputação da empresa.	
Padronizar e treinar práticas	Definir e treinar práticas e processos para lidar	
e processos	com contrafação.	
Treinar para identificação de	Comunicar a diferença entre produtos	
produtos falsos	verdadeiros e falsos.	
Estratégias de pesquisa e	Desenvolver estratégias sobre produtos,	
desenvolvimento	processos e infraestrutura.	
Estratégias de preços	Aplicar estratégias de aumento ou redução de	
	preços.	
	Desenvolver estruturas internas para mitigar	
Criar estruturas internas	ou responder à contrafação	
Melhorar qualidade	Oferecer produtos de maior qualidade e	
	aumentar o valor percebido da marca.	
Estratégias com fornecedores e parceiros	Rever estratégias de relacionamento	
	analisando potenciais riscos à propriedade	
	intelectual e contrafação.	
Rastreabilidade	Rastrear o medicamento para garantir sua	
	autenticidade.	
Tecnologias de autenticação	Desenvolver tecnologias para facilitar o	
	reconhecimento de produtos originais.	
	Aplicar modelos sofisticados matemáticos e	
Big data & analytics	estatísticos para suportar a tomada de decisões	
	relacionadas à contrafação.	

(11) Quais são os elos ou agentes da cadeia que teriam um papel importante para aumentar a resiliência nas empresas ou na cadeia produtiva como um todo à contrafação de medicamentos? Fale um pouco a respeito, por favor.

(12) Os elementos abaixo

Elementos	Breve explicação	Influencia +/- no combate à contrafação?		
Flexibilidade	Habilidade da empresa ou cadeia de suprimentos de prever ameaças e responder e se adaptar a mudanças com a mínima necessidade de tempo, esforço, custo e/ou queda de desempenho.			
Redundância	Replicação/adição de capacidade e/ou recursos que podem ser utilizados durante uma perturbação para repor perdas.			
Colaboração	Habilidade de unir esforços com outras empresas e/ou membros da cadeia de suprimentos para benefício mútuo.			
Confiança	Relação de confiança entre os membros da cadeia é crítico para criação de relacionamentos de longo prazo.			
Compartilham ento de informações	Compartilhamento de informações relevantes entre os membros da cadeia e dentro das organizações.			
Segurança da informação	Proteger as informações da empresa e/ou cadeia de suprimentos de ataques e intrusões deliberadas.			
Agilidade	Habilidade de reagir e se adaptar rapidamente a mudanças e eventos imprevisíveis.			
Visibilidade	Habilidade de ver de forma transparente a cadeia para reduzir divergências de informação e identificar de forma rápida necessidades e rupturas.			
Antecipação (sensing)	Habilidade de discernir processos antes de acontecerem rupturas, antecipando possíveis problemas.			
Cultura de resiliência	Disseminar uma cultura de resiliência e consciência de risco tornado os riscos preocupação de todos.			
Liderança	Comprometimento e apoio da alta gestão para implantar e manter a resiliência na cadeia de suprimentos.			
Inovação	Alcançar além das fronteiras da empresa e lutar para transformar continuamente o conhecimento e ideias em novos produtos, processo e sistemas que beneficiem a cadeia de suprimentos.			
Reengenharia	Redesenhar a cadeia de suprimentos considerando certas características para construir resiliência, reduzir exposição ao risco e superar rupturas.			

- (13) Na sua opinião, o que você mudaria para aumentar a resiliência nas empresas da sua cadeia de suprimentos (para frente e para trás) à contrafação?
- (14) Há algum outro ponto relevante que queira destacar?

APPENDIX V: Codebook

- Counterfeit antimeasures:
 - do nothing;
 - withdraw from market;
 - inter-organizational processes and policies:
 - o strict government requirements/laws;
 - o enforcement of intellectual property rights;
 - o enhance national and international cooperation;
 - o monitor supply chain;
 - o reverse logistics capabilities;
 - intra-organizational processes and policies:
 - o price strategies;
 - o quality strategies;
 - o R&D strategies;
 - supply/partner strategies;
 - o create an internal structure;
 - o investments in security equipment and systems;
 - hotline to help patients;
 - behavioral:
 - o enhance brand reputation;
 - train customers to identify fakes → empower consumers to combat counterfeits;
 - o enhance risk awareness;
 - standardize and train practices and processes → standardize policies,
 practices and processes;

• te	echno	ologies:
	0	traceability;
	0	authentication technologies;
	0	big data & analytics.

- Resilience elements

- reengineering;
- flexibility;
- redundancy;
- agility;
- visibility;
- information sharing;
- leadership;
- trust;
- collaboration;
- SCR culture;
- innovation;
- information security;
- sensing.