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Traceability in Legal Pharmaceutical Supply Chains

Ensuring Safety and Quality of Prescribed Medicinal Products

Master's thesis in the Master's Programme Supply Chain Management

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ABSTRACT

The legal pharmaceutical supply chains are today facing an increasing problem with counterfeit medicines worldwide. There are many documented cases where consumers have taken counterfeit medicines resulting in permanent injuries and even deaths. Supply chain traceability is fundamental to enable verification of authenticity for pharmaceutical products and to prevent counterfeit products to reach end consumers. The traceability is highly dependent on the supply chain actors' ability to share information. It is therefore of interest to study the information sharing in legal pharmaceutical supply chains to ensure safety and quality of medicinal products. The purpose of this master thesis is partly to present a framework to ensure safety of prescribed medicinal products in legal pharmaceutical supply chains. The aim is also to identify mandatory and voluntary information attributes that comply with legal and industrial safety requirements on information sharing.

To fulfill the aim a case study was conducted. Multiple sources of data was collected; a survey, semi-structured interviews and internal documents. Eight companies and the Medical Products Agency, MPA participated in the case study. It was found that there is today no standard for identifying products in the studied supply chain and a variety of technologies and standards are used for exchanging data. Another finding was that the companies in the Swedish pharmaceutical supply chain are in harmony with the legislation provided by the MPA. The empirical findings were analyzed together with theory to identify important areas of improvement for enhancing the traceability, and thereby also the safety of medical products, in the pharmaceutical supply chain. The identified components for enhanced traceability are *unique identification, standardized data carrier, standardized communication and guidelines for what information to share*. These are visualized in the framework TracePharma.

The theoretical contributions from this thesis are a comparison of published traceability frameworks within the food industry, and that the components identified in TracePharma can act as a starting point for further research. The practical implications are that the members of the pharmaceutical industry are provided with insight and understanding about how to improve the supply chain traceability and product safety. TracePharma can also be practically used for other supply chains, for example in other industries.

Keywords: traceability, pharmaceutical supply chain, interoperability, traceability framework

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Catharina Beckman and Emma Bernander

TERMINOLOGY

Bill of lading (BOL)	A document that accompanies the goods during transportation and contains information about the package such as weight, measurements and address of the recipient and consignor.
Contract manufacturer	A company manufacturing or processing products on behalf of another company.
Counterfeit medicine	"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging." (WHO, 2015)
Delivery order	A document that accompanies the goods stating the content of the package. The receiver of the package can use it to check if the content corresponds to what was agreed upon.
Directive	"A legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to decide how". (European Union, 2015)
Information attribute	A feature that describes the product in different aspects. Examples of information attributes are name, size, batch number, and date of delivery.
Medical Products Agency (MPA)	"The Swedish national authority responsible for regulation and surveillance of the development, manufacturing and marketing of drugs and other medical products." (Läkemedelsverket, 2015a)
Producer	A company holding a permission to manufacture and sell the drug. This company can either manufacture the drugs themselves or outsource the manufacturing of the drugs to a contract manufacturer.
Provision	A detailed regulation within certain areas. The parliament or the government can authorize the Medical Products Agency to translate directives into these regulations.

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1. INTRODUCTION

In this chapter the reader is introduced to the study. First a background to the thesis is provided followed by a problem description, where the reason for conducting the research is explained. The purpose of the thesis and the research questions are then presented. Lastly the limitations of the study and the outline of the report are described.

1.1 Background

The legal pharmaceutical supply chains are today facing an increasing problem with counterfeit medicines worldwide. In developing countries 10-30 % of the medicines sold are counterfeit, compared to 1 % in industrial countries (Bergström, 2013; Bagozzi, 2006). The problem has however increased also in the industrial countries the latest years. For instance, the amount of seized medicines at the EU border was tripled from 2006 to 2009 (European Commission, 2011a). The demand for medical products is high, resulting in high prices and price differentiation between identical products. This, together with low costs for manufacturing counterfeit medicines generate incentives for the counterfeiters to produce and distribute counterfeit medicines (WHO, 2015). A commonly used channel for distribution of the counterfeit medicines is e-commerce. 62 % of all medicines sold online are illegal or of inferior quality, and 96 % of the online pharmacies are illegal (Flodman Engblom, 2011).

Counterfeit medicines do not only decrease the revenue for serious actors in the industry, but a more severe problem is that it imposes a serious health threat to the end consumers. Some of the counterfeit products have no active substance, while others contain wrong or even forbidden substances (WHO, 2015; Flodman Engblom, 2011). There are several documented cases when end consumers have taken counterfeit medicines resulting in severe permanent injuries or deaths (WHO, 2010). In today's globalized world the distribution of goods is handled by a complex network of different actors. The high complexity in the distribution makes it difficult to control and ensure compliance with safety regulations (Leon, 2014).

On a global level the World Health Organization, WHO, is working to ensure of the safety of medicinal products (Bergström, 2013). To prevent the spreading of counterfeit medicines the European Union has also increased its efforts to counteract the problem and implemented a Falsified Medicines Directive to improve patient safety (European Union, 2011; Bergström, 2013; Jones, 2014). The European Federation of Pharmaceutical Industries and Associations, EFPIA, has initiated the European Stakeholder Model, ESM. The ESM is a system for verifying genuine pharmaceutical products in EU (EFPIA, 2014).

In Sweden, the Medical Products Agency, MPA is responsible for approving medicines before these are sold to end consumers. The international online sales however make it hard for the MPA to control what products reach the Swedish consumers (Läkemedelsverket, 2008). The problem with counterfeit medicines therefore has the potential to grow also within the Swedish borders, why it is of great importance to emphasize the problem and work proactively to ensure end consumer safety. A research project, Smedpack3, is currently conducted in Sweden to prevent this problem to grow. This thesis is conducted as a part of the Smedpack3 project.

1.2 Problem description

There are several potential ways where counterfeit medicine can enter legal pharmaceutical supply chains. Even if the pharmaceutical industry is characterized by tough regulations, the current systems are not enough to fully protect the consumers from the risk of counterfeit medicine (LIF, 2008). Furthermore, the globalization increases the complexity in pharmaceutical supply chains. Today, raw material is often manufactured in one country, while manufacturing of the medication is performed in another country and finally the products are sold in a third country. To ensure consumer safety in the pharmaceutical industry it is of great importance to be able to track and trace pharmaceutical products (Leon, 2014).

By having a well-functioning traceability system, supply chain actors can demonstrate compliance with safety regulations (Leon, 2014). A traceability system also makes it possible to retrieve detailed production, distribution and sales information. Moreover it enables rapid product recalls. Increased traceability can thus increase supply chain control and provide the consumer with proof of product authenticity (GS1, 2015a). The importance of traceability to be able to assure consumers health and safety has also been observed in the food industry, where much research has been conducted during the last decade to enhance the traceability (Salampasis et al., 2012; Storøy et al., 2013; Regattieri et al., 2007; Pizzuti et al., 2014). Folinas et al. (2006) states that the efficiency of a traceability system is dependent on the system's ability to record safety and quality related information. It is therefore of importance to identify what information attributes that is fundamental to collect to ensure efficient traceability (Folinas et al., 2006).

According to WHO, it is up to the nations themselves to create appropriate legislation for ensuring end consumer safety (WHO, 2015). Governments all over the world are currently reviewing their regulations, making traceability an obligation in pharmaceutical supply chains. Since the increasingly globalized industry does not have an international regulatory body, it is hard to obtain a consistency in the traceability regulations. Both the US and Europe are working to develop a comprehensive traceability framework for the pharmaceutical industry. Many countries like Belgium, France and Italy have already enforced traceability regulations (Leon, 2014).

Also in Sweden measures need to be taken to minimize the risk of counterfeit medicines entering legal supply chains. It is therefore of interest to study the current level of traceability in Swedish legal pharmaceutical supply chains and find means for how it can be improved to ensure product quality and end consumer safety.

1.3 Purpose

The purpose of the Master thesis is two-folded;

- a) to present a framework to ensure safety of prescribed medicinal products in legal pharmaceutical supply chains.
- b) to identify mandatory and voluntary information attributes that complies with legal and industrial safety requirements on information sharing related to the physical flow of goods in a legal pharmaceutical supply chain.

1.4 Research Questions

In order to fulfill the stated purpose three fields are of importance to study. Firstly, knowledge about how the different actors in the studied industry currently interact with each other needs to be obtained. This knowledge is crucial to be able to analyze the current degree of traceability and interoperability in this supply chain. Secondly, the current legal requirements on information sharing need to be compared with the information actually shared among the industry actors. To obtain an understanding of whether or not the industry actors and authorities have similar attitudes regarding what information attributes that are important to share is of importance to be able to identify mandatory and voluntary information attributes. It is also of interest to take the end consumers' preferences on product labeling into consideration when analyzing what information attributes is fundamental to share in the supply chain. Thirdly, existing frameworks to ensure safety of products in other industries will be examined. By transferring the body of knowledge from similar industries to the pharmaceutical industry, traceability and therefore also consumer safety can be increased.

The three areas of investigation has been formulated into the following research questions:

1. How are the companies involved in the research project interrelated regarding both information flow and physical flow?
2. What are the differences between legal requirements, industrial praxis and end consumer preferences regarding information attributes shared between actors in the Swedish legal pharmaceutical supply chain?
3. What traceability frameworks have been published in other industries, what differences and similarities do these industries have compared to the pharmaceutical industry and what framework components could be applicable also for the pharmaceutical industry?

1.5 Scope

The background to this study is the need to prevent counterfeit medicines from entering Swedish legal medical supply chains. Since prescribed medicines in general have a higher value compared to non-prescribed medicines it is assumed that it is more lucrative among counterfeiters to falsify prescribed medicines. A recent study conducted by the MPA show that 20 % of the people interviewed are willing to buy prescribed medicines on the Internet without a prescription from a doctor (Läkemedelsverket, 2015b). The interest among people to buy prescribed medicines online is increasing, despite the threat of counterfeit medicines flourishing in this channel (Lundin, 2015). Due to the higher value of prescribed medicines and the interest to buy these products without a prescription from a doctor, prescribed medicines are seen as a risk group among pharmaceutical products. To prevent counterfeiting in this products category this thesis is limited to focus on how to enhance traceability in the flows of prescribed medicines.

Since this thesis is conducted as part of the research project Smedpack3 only companies involved in this research project has contributed with empirical data to the study. All these companies are operating on the Swedish market, why the project is limited to only concern this market. Most of the empirical data requested from these companies were detailed and required

in-depth knowledge among the company representatives. Few people at each company had this specific knowledge why the data gathering was limited to only one or two people at each company.

To map the supply chain regarding its information flow and physical flow the companies in Smedpack3 project were contributing with data. Among the companies involved in Smedpack3, the following actors were represented; medicine producers, contract manufacturers, transporters, distributors, online pharmacies and pharmacies with physical stores. The study was therefore limited to these actors and did therefore for instance not include manufacturers of raw materials.

The thesis is furthermore limited to analyze only the external traceability, i.e. the traceability between the different supply chain actors. The pharmaceutical external traceability was regarded as interesting to investigate since Storøy et al. (2013) have identified external traceability as an obstacle for efficient traceability in the food industry.

The framework is developed to provide an overview of areas that are important to work with to enhance supply chain traceability, and does therefore not cover detailed guidelines for how to use information technology to improve these areas. The framework is therefore limited to not include the IT solutions behind each of the suggested framework components.

1.6 Outline of the report

This master's thesis consists of seven chapters. Below, a short description of each chapter is provided to guide the reader.

Chapter 1 - Introduction provides a background and a problem description to the research area. The purpose, the research questions and the scope are presented.

Chapter 2 - Frame of reference includes published research and relevant concepts to provide a foundation of the research. It describes the pharmaceutical industry, principles for tracking and tracing, legal requirements on information sharing and published traceability frameworks within the food industry.

Chapter 3 - Research methodology presents the chosen research approach, research strategy and the research process. The data collection is described and the method for mapping the supply chain is motivated. Lastly the quality of the research is discussed and the validity and reliability of the study is evaluated.

Chapter 4 - Empirical Findings presents the empirical findings from the interviews, surveys and internal documents. The actors in the supply chain are described and a process map including the physical flow and information flow is presented. The chapter ends with a presentation of the information attributes that are shared among the actors and the technology used for information sharing.

Chapter 5 - Results and Analysis analyzes the empirical findings with support from the frame of reference. The traceability and interoperability is analyzed and the information attributes shared in the supply chain are compared with the legal requirements. Lastly the framework to

ensure safety of prescribed medicinal products in legal pharmaceutical supply chains is presented.

Chapter 6 – Discussion of the validity and generalization of the research.

Chapter 7 – The conclusion presents the answers to the research questions. This is followed by an explanation of the theoretical contributions and practical implications. Lastly, future recommendations are suggested.

2. FRAME OF REFERENCE

In this chapter, published research and relevant concepts are presented to provide the reader with an understanding of the research area and trustworthiness to the study. The first section presents characteristics of the pharmaceutical industry followed by a description of different supply chain mapping techniques. The principles for tracking and tracing will be explained as well as the requirements on information sharing and documentation within the Swedish medical supply chain. Lastly, a section is dedicated to traceability within the food industry since there currently is more published research related to traceability within this industry compared to the pharmaceutical industry.

2.1 The pharmaceutical industry

This section will provide a brief introduction to the studied industry. By describing typical industry characteristics and information about some safety threats in this industry, the reader will obtain necessary background for the following chapters.

2.1.1 Industry characteristics

The pharmaceutical industry is characterized by complexity because of the variety of stakeholders and the many actors involved in the supply chain. In addition to this, the government is also highly involved and controls the industry through laws and regulations. The industry is driven by research and development and protection of intellectual property right is therefore required (ECORYS, 2009). Most products developed in this industry involve both primary active ingredient production and secondary formulation production. Both stages in the production take long time to complete mostly due to many quality control activities required. The supply chain cycle times are therefore often very long, hampering the responsiveness (Shah, 2004).

The barriers to enter the pharmaceutical sector is high, leading to less competition among the existing companies. The reasons for the high entry barriers are the existing companies' economies of scale and scope, the patents and the fact that the consumers are loyal to specific brands. Another characteristic worth mentioning is the complexity of the demand side, where the doctors, hospitals and patients are interlinked. The patient can choose another medicine than the one prescribed and is sometimes not the one paying for the product if there is an existing health system (ECORYS, 2009).

The main actors in the pharmaceutical supply chain are often identified as primary manufacturers, secondary manufacturers, wholesalers and retailers or hospitals (Shah, 2004). The medicine manufacturing industry is known to be dominated by a few large companies who stand for the majority of the annual turnover (in Europe). One of the reasons for this is the amount of money that can be earned when discovering a medicine that reaches the market. The large companies often have some of these "cash cows" to support the R&D for new medicines (ECORYS, 2009). The information flows among pharmaceutical supply chain actors are often fragmented. The data accompanying the physical flow of pharmaceutical products in these supply chains are captured repeatedly in non-integrated system, resulting in enhanced risk for errors and therefore also end consumer safety threats (Chircu et al., 2014).

2.1.2 Safety threats in the industry

The pharmaceutical industry is today facing many supply chain management challenges. These challenges are related to both medication quality and counterfeit products. Examples of problems affecting the medication quality are manufacturing issues, damaged containers or sensitive products that are shaken during transport. Such problems can have serious effects on product quality and also decrease end consumer safety (Chircu et al., 2014). The problem with counterfeit pharmaceutical products is increasing and is today a vast public health challenge. Counterfeit medicines can range from simple painkillers to anti-cancer medicines or antibiotics. The problem is today spread all over the world but counterfeiting is greatest in developing countries, where it is estimated that around 30 % of the medicines for sale are counterfeit (WHO, 2015; Grahnén et al., 2014). To be able to trace and track is therefore extra important in an industry like the pharmaceutical industry, where the products can be recalled at any point during the whole product life cycle. A good tracking and tracing system in a pharmaceutical industry can prevent fraud and thus increase industry security (Kelly, 2007). What techniques used for information sharing among supply chain members also impacts quality and safety of products. Today's techniques for product labeling, written texts or barcodes, are not enough to ensure consumer safety. Regulatory bodies all over the world emphasize the need for serialization, implying that each drug containers should be assigned with unique identification (Chircu et al., 2014).

2.2 Supply chain mapping techniques

Common reasons for supply chain mapping are to obtain a mutual overview, visualize distribution of information, improve communications and facilitate supply chain analysis. A map can point out certain areas characterized by inefficiencies that need further analysis and improvements. A well-documented supply chain map provides crucial material for improving the supply chain performance. There are a variety of different types of mapping techniques used for different purposes and in different environment, but it does not yet exist a universal set of mapping techniques specifically adapted for representing a supply chain (Gardner & Cooper, 2003). Different types of mapping techniques have been investigated to determine the most suitable approach for this project. In the following section the methods Process Mapping, Value-Stream Mapping and IDEF0 are described, followed by a table summarizing the characteristics of the different methods.

2.2.1 Process Mapping

The business processes are the activities performed to achieve the organizational objectives; to produce, promote and deliver products with the aim to receive payment. It also includes administrative activities performed to ensure that organizational, regulatory and legal requirements are satisfied (Graham, 2004). Business Process Mapping is a method for visualizing, documenting and achieving an overview of business processes and aspects related to those. Analysis of processes is important to ensure efficiency, effectiveness, customer service and profitability. By performing a holistic process analysis the degree of control can be increased, which minimize risks (Keller & Jacka, 2002). Process mapping is a general method for business development that can be applied in most industries and businesses. The process perspective emphasizes the importance of a comprehensive view. For instance, it needs to be

determined whether or not the analysis only should include the own organization or also customers and suppliers. If customers and suppliers are included it also needs to be decided whether or not to include customers' customers and suppliers' suppliers. The limits for what to include in the analysis need to be adapted from case to case (Ljungberg & Larsson, 2012).

According to Keller and Jacka (2002) the method for conducting process mapping consists of four main steps; "process identification", "information gathering", "interviewing and map generation" and finally "map analysis". After identification of the processes that are of interest to study it is important to get a deep understanding of each process. This understanding can for example be achieved by having a dialogue with people who are experts on individual processes. The second step, information gathering, implies that all relevant information relating to each process is gathered. Example of data gathered at this stage can for instance be statistical information. The data gathered at this stage increases the map's credibility. After creating a draft of the map, actors involved in each process need to review the draft and give feedback. When the third step is performed the full picture of the different processes and how they interact with each other is obtained, why the analysis with a focus on efficiency and effectiveness can start (Keller & Jacka, 2002).

Ljungberg and Larsson (2012) describe certain core components important to visualize a process. The different core components are "Object in", "Activity", "Resources", "Information in/out" and "Object out", see figure 1.

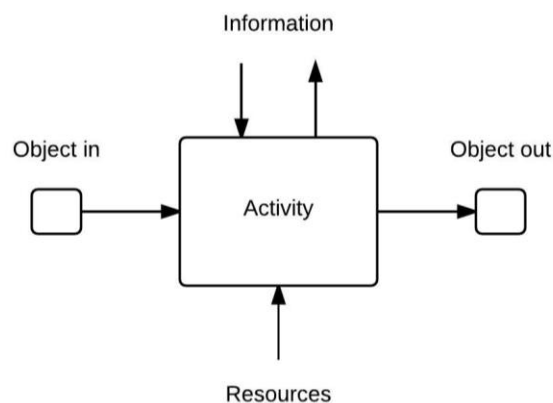


Figure 1. The core components of a process according to Ljungberg and Larsson (2012, pp. 210)

"Object in" is the objects necessary for starting the process. "Activity" is the business refining or converting the objects in. To start the activity certain "Resources" are needed. "Information" controls the process and goes both in and out from the activity. Objects refined or converted during the activity are leaving the activity as "object out". By using these core components of a process, a map can be drawn for visualizing most types of processes (Ljungberg & Larsson, 2012).

A variant of process mapping is the cross-functional process mapping where the people, function or role performing each activity are specified. Cross-functional process mapping thus enable visualization of the business value-creating chains. Each of the functions performing activities gets their own horizontal lane in the map.

Therefore, a cross-functional process map quickly can provide an overview of what activities are done and by whom (Damelio, 1996). The authors has created an example of a cross-functional process map, see figure 2, where A, B and C represents different functions or companies using different inputs to perform certain activities.

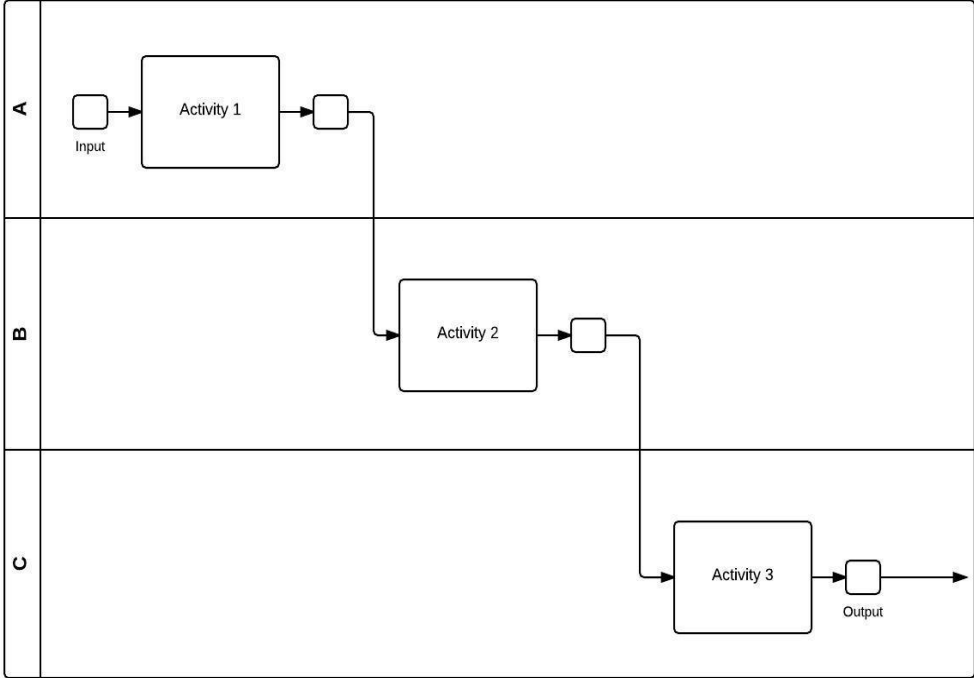


Figure 2. The authors own example showing the structure of a cross functional process map. A, B and C represents the functions or companies performing different activities. Adapted from Damelio (2011)

2.2.2 Value Stream Mapping

The method Value Stream mapping is the modeling, mapping and visualization of a supply chain with the purpose to detect waste (Lopes dos Santos et al., 2014). It is a tool for mapping all actions needed to create a product to the end consumer. The actions include both the value-adding actions and the wasteful actions. In this method two types of flows are mapped. The first flow, the demand flow, is the order flow from customers travelling upstream the supply chain. The second flow, the supply flow, is the physical flow of product travelling downstream the supply chain to the customer. Standardized symbols are always used when drawing the map (Jones & Womack, 2003). First a current state map should be drawn showing the system as it currently is. Then a future state map should be created, showing an improved system (Martin & Osterling, 2014). Value Stream mapping is about making the flow across the whole supply chain more efficient by reducing different types of waste according the lean principle. Examples of waste can be overproduction, unnecessary inventories or unnecessary transportation. By managing information flows and logistics in a better way such type of waste can be reduced. When drawing the current state map both the physical flow and the information flow needs to be included. The information flow is usually the hardest part since managers in general argue that the more information shared, the better. However, too much information is actually a type of waste (muda) according to the lean principle. Too much information shared between actors

can reduce the degree of control. Actors should therefore strive to limit the amount of information shared to what actually is needed for the other actors. When the current state is drawn, it is time to analyze it and find improvements to the future state map (Jones & Womack, 2003). Value stream mapping has many advantages. For instance it requires low investments, allows for mapping of whole supply chains and provides an operational perspective. Moreover the value stream mapping is fast and easy to carry out. Some method limitations are however that it only provides a simplification of the real system, it only maps one product family and furthermore the future scenarios are developed affected by feelings and common sense (Lopes dos Santos et al., 2014).

2.2.3 IDEF0

IDEF0 is both a modeling language and a modeling technique that can be used to describe the relationships of a company's functions and activities (IEEE, 1998). IDEF0 models are mainly created by system engineers (Waissi et al., 2015). IDEF0 can facilitate the design and implementation of integrated systems, by clarifying different aspects. The method first investigates which functions are performed, who is performing these and how long each takes. It also reviews what information is needed to perform the functions and where this information comes from. Furthermore investigations should be done regarding what information is created during the function execution and where this information is sent. When used properly the method can give an improved understanding both of the daily operations in the system but also how the information apparatus in the system is functioning. The documentation made when conducting this method can later be used as material for future system analysis and changes for improving the system.

A benefit with IDEF0 is that it is not limited to a certain type of organization structure since it is focused on the processes and functions within the organization. A limitation with the method is however that it does not describe detailed process operations and it does not include quantities, such as inventory size (Jørgensen, 1995).

When modelling according to IDEF0 the function represents an activity, process or transformation. The function transforms inputs into outputs. This transformation is performed by using certain resources and is restricted by some constraints or rules (Waissi et al., 2015). When drawing the diagram there are certain principles that should be followed. Symbols used when mapping are simply boxes and arrows. Boxes are used to describe functions such as manufacturing of parts, control activities, product storage etc. Arrows usually describe information flows but sometimes also material flows. The method is however extra suitable for describing information flows (Jørgensen, 1995). Four types of information can be visualized by arrows: input, output, constraints and resource mechanisms which should be drawn on the left side, right side, from the top and the bottom respectively (Kawai et al., 2012; Jørgensen, 1995). See figure 3 on the next page.

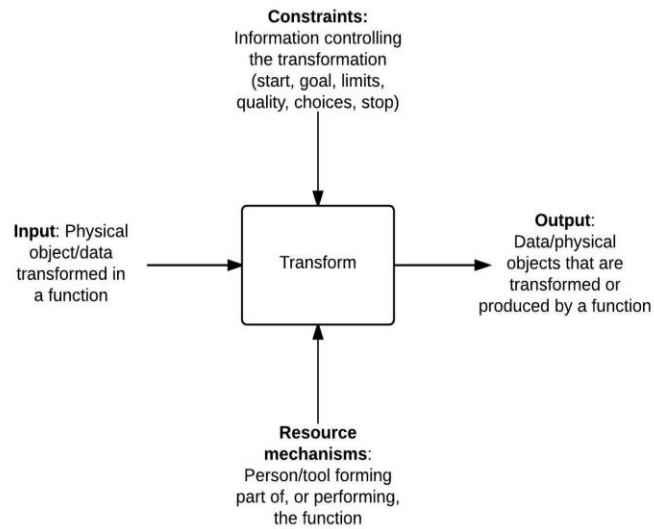


Figure 3. The main elements of an IDEF0 diagram are boxes, arrows and text. Adapted from Jørgensen (1995, pp. 345)

In table 1 below, the supply chain mapping techniques process mapping, value stream mapping and IDEF0 are summarized and compared related to their goal, area of investigation and main elements.

Table 1. A summary of the three described SC mapping techniques regarding three different characteristics; mapping goal, area of investigation and main elements mapped in each of the different methods.

Characteristics	Process Mapping	Value Stream Mapping	IDEF0
Goal	Increase visibility to ensure efficiency, effectiveness, customer service and profitability	Reduce waste according to the Lean principle	Facilitate design and implementation of integrated systems between different functions within a company
Area of investigation	Internal processes, but customers and suppliers are sometimes also included	Supply chains	Internal processes/ functions
Main elements mapped	Physical flow together with resources required and supporting information flows	Physical flow & Information flow	Internal functions and information flows

Sources: Dolcemascolo, 2006; Lopes dos Santos et al., 2014; Jones and Womack, 2003; Jørgensen, 1995; Keller and Jacka, 2002; Ljungberg and Larsson, 2012.

2.3 Principles for traceability and communication

Competition is today going from individual companies competing against each other to whole supply chains competing with other supply chains. This sets increasing requirements on the different actors within the supply chain to integrate their processes and operations. This in turn sets high requirements on effective information sharing in the supply chains (Ford et al., 2010). This section will focus on how effective information sharing between actors in a supply chain can be achieved by describing tracking and tracing, interoperability, data carriers, information sharing technologies and identification numbering systems.

2.3.1 Tracking and Tracing

Traceability is usually described by the terms tracking and tracing (Storøy et al., 2013). Tracking is according to Pizzuti et al. (2014) the process when a physical item is followed on its way upstream or downstream in the supply chain. Tracing is the process when an item's history is reconstructed based on information gathered about the item at each step in the supply chain (Pizzuti et al., 2014). Stefansson and Tilanus (2001) defines tracking as following an item on its way from consignor A to consignee B, while tracing is defined as finding the entity between consignor A and consignee B. Today's information technology can provide good support for tracking and tracing of items in a value chain (Jonsson & Mattson, 2011). Below, eight attributes for classifying a tracking and tracing system are described. This is followed by a section describing the difference between internal and external traceability.

Eight attributes for classifying a tracking and tracing system

According to Stefansson and Tilanus (2001) a tracking and tracing system, i.e. the interface between a physical transformation and an information system, can be classified by eight attributes and values related to these attributes. The eight attributes are described below.

Firstly, tracking and tracing systems can be classified by the technology used for identification of the products. Such technology could for instance be human-readable texts, manually scanned barcodes or automatically scanned radio frequency tags.

The tracking and tracing system could secondly be defined by the scope of the tracking and tracing system. The scope is in turn formed by the three dimensions of transformation; transportation (transformation of place), storage (transformation of time) or conversion processes during the value chain (transformation of form). All these transformations generate a need for recording new data in the tracking and tracing system. A well-functioning system should be able to gather information about all transformations an item is subject to during its way through the supply chain.

Thirdly the registration of an entity's time and place can be classifying the system. In most systems such registration is discrete.

Fourthly, the hierarchical level of packages can define the system. The registration of items in the supply chain could be done for different hierarchical packing levels. Registration could for instance be done for individual consumer unit, for boxes containing many consumer units, for pallets containing several boxes, for containers loaded with pallets etc. Depending on what

hierarchical level that is registered, different information attributes needs to be registered. The more hierarchical levels that is represented in a supply chain, the higher the demands on the traceability system becomes to be able to record more data.

The tracking and tracing system could furthermore be defined by the information attributes recorded in the system. A system could for instance record only three attributes; entity identity, current location and current time. A more advanced system might in addition also record shipment quantity and quality in different hierarchical levels.

The sixth attribute according to Stefansson and Tilanus (2001) is the organization of the information system storing the information about the products flowing in the supply chain. The system can be either centralized or shared by many different actors. A centralized information system can be operated by either a powerful actor in the supply chain or by a specialized third party. A decentralized system imply that each individual actor in the supply chain store information in its own information system.

The seventh attribute that can define the tracking and tracing system is the accessibility of the information system. The system could be non-automated, meaning that all queries must be made and answered manually for instance by telephone or email. It could also be automated, meaning that the queries can be made automatically for example by using EDI or Internet.

The eighth and final attribute is the activity level of the tracking and tracing system (Stefansson & Tilanus, 2001). Tracking and tracing systems can be either active or passive. In both systems an item’s status is registered and documented when the item enters or leave certain identification points along the material flow. In an active system the registered status is then compared to the planned status. If the registered status and the planned status differ, the deviation is reported to all stakeholders. In a passive system, on the contrary, no comparison between current and planned status is done. If a request of a specific item’s location comes to the passive system the product can however be traced to the latest identification point in the flow (Jonsson & Mattson, 2011).

Internal and external traceability

Full traceability across a supply chain, see figure 4, requires both internal and external traceability (Storøy et al., 2013; GS1, 2013).

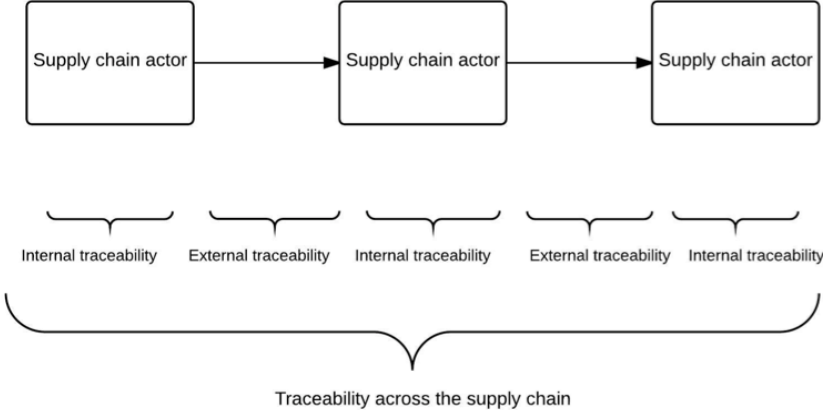


Figure 4. Internal and external traceability. Modified from GS1 traceability standard for healthcare (2013, pp. 19)

Internal traceability can be achieved by collecting data related to internal processes and product handling. Supply chain actors should record the data linking input into an internal transforming process with the output. The recording of such data will allow the supply chain actor to track and trace products through its internal processes (GS1, 2013). External traceability is the ability to exchange traceability data between trading partners (Gombas, 2010).

2.3.2 Interoperability

Ringsberg (2014) states that traceability can only be obtained if there is interoperability between the different information systems used in a supply chain. High interoperability allows for enhanced efficiency in product traceability. By increasing interoperability the visibility, agility and end consumer trust can also be increased (Bhatt & Zhang, 2013).

According to Ford et al. (2010) interoperability can broadly be defined as “the ability of two or more organizations to exchange and interpret all necessary information to collaborate” (Ford et al., 2010, p. 1). A more detailed definition of interoperability is “Being able to accomplish end-user applications using different types of computer systems, operating systems and application software, interconnected by different types of local and wide area networks” (Marakas & O’Brien, 2013, p. 692). Achieving supply chain interoperability is often a complex challenge since it both requires information sharing connectivity and willingness to cooperate among the organizations involved. However, as the trend in relationships between customers and suppliers goes from arm-lengths relations towards strategic alliances and partnership, interoperability between organizations is becoming increasingly important (Ford et al., 2010).

There are several articles published that explains interoperability but with slightly different approaches and focus. Hufnagel (2009) focuses on the technical aspects but both Kubicek et al. (2011) and Ringsberg (2015a) mentions the importance of taking other aspects into consideration as well. The framework of Ringsberg (2015a) is recommended by the European Commission and its focus is to secure safety through traceability of products. The starting point of the framework of Ringsberg (2015a) is the recommendations and guidelines of the European Interoperability Framework, EIF, developed to support Directive (EC) 98/34. The framework presents four categories of interoperability; technical, semantic, organizational and legal interoperability (Ringsberg, 2015a).

Technical interoperability concerns the use of standardized communication technology and information exchange protocols for integration of IT systems. This category emphasizes the importance of using the same technical specifications (such as interface specifications or data integration services) for companies when exchanging information (Ringsberg, 2015a).

Semantic interoperability refers to the importance of information structure principles when sharing information between companies. How the information structure is designed impacts the ability to trace products and information. Previous research shows for instance that different information layers should be used to facilitate traceability (Ringsberg, 2015a).

Organizational interoperability concerns the collaboration between different companies when setting and reaching mutual goals. The collaboration here refers to the integration of, and information sharing between, different business and logistics processes (Ringsberg, 2015a).

Legal interoperability is about companies' abilities to maintain legal validity when sharing information between companies in different countries with different legislations. It also concerns legislation regarding information protection (Ringsberg, 2015a), meaning that both the legal validity and protection legislation of such information must be respected in both the originating and receiving country (ISA, 2010).

Agreements should be made for each of the four interoperability categories. At the legal interoperability level agreements should be binding via legislation. Organizational interoperability agreements could for instance define expected service levels or contact details. At the semantic interoperability level agreements could concern reference taxonomies, data dictionaries etc. Technical interoperability agreements could concern interface specifications, communications protocols or data formats (ISA, 2010).

As stated above, interoperability is related to visibility (Bhatt & Zhang, 2013). Research shows that close cooperation between supply chain partners can increase the whole supply chain performance. By sharing information with partners these can adapt their operations to enhance the whole supply chain's efficiency and effectiveness (Lee et al., 2013). The degree of transparency between different actor's information systems determines what efforts that are required to obtain traceability. To achieve traceability in a supply chain at least some degree of visibility is required (Skilton & Robinson, 2009). Sharing internal information can however also imply strategic and operational risks, why many firms are hesitant to share information with supply chain partners. High visibility is therefore not good for supply chain actors in all aspects (Lee et al., 2014). Furthermore Skilton and Robinson (2009) claim that full supply chain visibility require that companies both are willing to share information and to make large investments in more effective information systems.

2.3.3 Data carriers

There are different methods to identify products or parts of products while being distributed through the supply chain. Different alternatives of data carriers will be presented in this section; one-dimensional barcodes, two-dimensional barcodes and RFID tags. Characteristics of the different data carriers are summarized at the end of the section.

One-dimensional barcodes

A one-dimensional, 1D, barcode is a linear code where the lines represent digits from 0-9. The combination of numbers can represent attributes such as the country of origin, the manufacturer and the product type. It is a cheap way of identifying products since the tag is printable and simple. When tracking pharmaceutical products 1D barcodes can be useful, since this is an effective method for storing the required information (Kelly, 2007). A drawback, however, according to McFarlane and Sheffi (2003), is that the system to number the barcodes have limitations, such as that they are limited to a manufacturer and that the barcode cannot contain a unique identification. The scanner also have to be physically close to the code to be able to scan it and if parts of the code is damaged the barcode is not possible to read. (McFarlane & Sheffi 2003; Kelly, 2007).

Two-dimensional barcodes

Characteristics of 2D codes are the capability, through geometric patterns, to store a relatively large amount of information about a product to which it is attached (Waters, 2012; Ringsberg, 2015b). This type of code can be classified into matrix codes and two-dimensional stacked codes. Examples of matrix codes used for traceability purposes are the quick response (QR) code and the Data Matrix code (Ringsberg, 2015b). During the time when writing this thesis, the possibility to use QR codes for medical products is considered both by pharmaceutical companies but also by the National Competent Authorities (NCAs). The technology could be used in a variety of ways. The technology could for example be used to give authorized people access to web pages with information about the medical product. It could also be used to provide the end user with information about the product's expiry date and batch number. Used in the medical industry Health Care Professionals or consumers could easily receive information about the product by scanning the QR code with a smartphone. (CMDh, 2014) Furthermore the technology could be used for production processes and inventory control, or to test whether a particular product is genuine or not (CMDh, 2014). Possible limitations for this technology are that it requires IT knowledge and ownership of a smartphone among the end users. It also requires the person scanning the code to be steady-handed (Ringsberg & Urciuoli, 2015).

Compared to a barcode, the matrix code can store more data (Waters, 2012). This is because for the matrix code, it is possible to store data not only vertically but also horizontally, which is not the case for barcodes. Another advantage that the QR code has is that it is more durable than a barcode since it can be read even if some part of the code is damaged (Lin et al., 2014).

Läkemedelsindustriföreningen, an association within the pharmaceutical industry promotes the introduction of 2D code since it will make traceability for medicines easier. Because of the unique identification the 2D code can provide it will be possible for pharmacies to verify if the code has been used before (LIF, 2015).

Radio Frequency Identification

The radio frequency identification (RFID) tags can store substantially more information than a barcode or QR code (Sweeney, 2005). The tag can either be active or passive, meaning that it can either actively send out signals or it can be registered when it passes a checkpoint. The benefits with RFID tags are many; several tags can be read at the same time as well as different hierarchical levels can be read simultaneously (McFarlane & Sheffi, 2003). For the active RFID tags, the location of the goods that the tag is attached to, can be provided. Furthermore, the tags do not have to be visible on contrary to barcodes. The drawback is mainly the cost when having a high volume of products that needs identification tags (Sari, 2010) and the low readability in environments that contain metallic products (McFarlane & Sheffi, 2003). Wyld (2008) argued that the use of RFID within the pharmaceutical industry will increase because of its benefits such as the reduction of theft, improved customer service and that it obstructs counterfeit medicines to reach end consumers.

Comparison of the different identification alternatives

The three alternatives all have their benefits and drawbacks related to traceability that are summarized in table 2.

Table 2. Comparison of 1D barcodes, 2D barcodes and RFID tags regarding cost, possibility of unique identification, speed of scanning and the amount of information possible to store.

Characteristics	1D-barcodes	2D-barcodes	RFID tags
Cost	Low	Low	High
Unique identification	No	Yes	Yes
Scanning speed	Slow, requires manual scanning, one tag at a time	Slow, requires manual scanning, one tag at a time	Fast, automatic and simultaneous scanning of tags
Amount of information	Low, One-dimensional	More than a 1D barcode, two dimensional	Substantial

Sources: McFarlane and Sheffi, 2003; Ringsberg, 2015b; Sweeney, 2005; Waters, 2012.

2.3.4 GS1's identification numbering systems for the pharmaceutical industry

GS1 is an international non-profitable organization that develops and administers standards for identifying, capturing and sharing information (GS1, 2015b). One of the industry sectors that GS1 provides standards for is the healthcare industry. GS1 has created a traceability standard, the Global Traceability Standard for Healthcare, GTSH (GS1, 2015c). Developing healthcare standards is of importance to improve supply chain efficiency, increase traceability of medication and assure patient safety (GS1, 2015d). The GTSH aims to provide an efficient communication regarding traceable items between supply chain actors. Depending on the logistical hierarchy level of the flow of goods this standard recommends different precision of identification. Trade items sold to the end consumer should according to the GTSH have a unique identification. Unique identification of individual products can be obtained by adding a Global Trade Item Number, GTIN, and a serial number to the product (GS1, 2013).

GTIN is a standard identification numbering system created by GS1. GTIN can comprise 8, 12, 13 or 14 digits. GTIN is used to give a product type a unique item number. By connecting trade items with GTIN a supply chain actor can efficiently send information about the product to their trade partners. Information about the trade item is connected to the GTIN and stored in a database. By scanning the GTIN the information can be retrieved. SGTIN, Serial Global Trade Item Number, is developed by GS1 to enable unique identification of individual products. The SGTIN consist of a GTIN and a serial number (GS1, 2015e). By implementing serial numbers in a healthcare track and trace system in Turkey, the number of counterfeit activities was decreased (Ebel et al., 2012). The serial number confirmed the authenticity of the medicine when disposed at the pharmacy since after the disposal the number was decommissioned. McKinsey (Ebel et. al., 2012) also concluded that using one global standard for medicine packages will decrease the cost compared to having two or more.

GS1 has developed a tool to improve the traceability in pharmaceutical supply chains, the GS1 Data Matrix. This makes it possible to describe information attributes such as a Global Trade Item Number (GTIN), batch number, best before date and unique identification serial number in a data matrix code in a standardized way (GS1, 2015f).

2.3.5 Information sharing technologies

There are several ways in which information can be exchanged between companies in the pharmaceutical supply chain. One common way is to use Electronic Data Interchange (EDI). The system was developed several decades ago and new ways of exchanging data over the internet has been introduced since then. This section shortly describes EDI, Extensible Markup Language and Web services because of their relevance for communicating information in the pharmaceutical industry.

Electronic Data Interchange (EDI)

Electronic Data Interchange (EDI) means that data in a predetermined and standardized format is transferred from one computer system to another in a way which enables the receiving system to interpret and process the information (Banerjee and Golhar, 1994; Anvari, 1992). There are various standards for EDI, such as EDIFACT which is an UN standard, Odette which is primarily used in the automotive industry and AnsiX.12, an American standard. EDIFACT includes 180 standardized messages used for different purposes such as purchasing orders, invoices and delivery plans (Anvari, 1992; Jonsson & Mattson, 2011).

For EDI, a file is generated in the system of the sending business system. EDI software then translates the content of the file to an Edifact-standard format and send it to the receiving system. It is then converted to the format that is used for that system. EDI is an offline communication meaning that the transferring of the information is separated from the processing of the information. This is happening either at certain points in time or after a certain event (Putte, 2003; Jonsson & Mattson, 2011).

EDI is mainly used for information sharing between companies who have a recurring exchange of structured information. It is useful when the exchange of information is frequent and of high volume since it lowers the transaction costs (Kaefer & Bendoly, 2000). The drawback is the complexity of the system, the need of IT-competency within the company and the heavy investment- and operation costs (Jonsson & Mattson, 2011). These are all reasons for why EDI mainly is used within large companies. To be able to interact with smaller customers a system combining EDI and the internet has been developed, so called web EDI (Putte, 2003). The companies without EDI systems can then access some of the functions through a browser. EDI can facilitate the automatic generation of files and transferring but does not necessarily automate the reception. For a company that can only receive the electronic message but have to register the information in the business system manually, the advantages of EDI is lost, which can be the case for a company using the web EDI (Jonsson & Mattson, 2011).

Extensible Markup Language (XML)

An alternative technique for transmission of files is Extensible Markup Language (XML). According to Jonsson and Mattson (2011) this technique will either complement or fully replace the use of EDI. Melton and Buxton (2006) also describes XML to become the standard for exchanging data on the internet. The standard is used to build web pages that are independent of hardware and platform and can be used to send structured information over the internet (Jonsson & Mattson, 2011; Hunter, 2007). This makes it a more flexible technique than EDI and it is possible to use the elements that are included in the Edifact-standard (Jonsson and

Mattson, 2011). It is therefore possible to replace the EDI or to use the two different techniques in parallel, for example to communicate with customers who does not have support for EDI in their business systems. In fact, the transition from traditional platforms of EDI to the Internet is likely to go faster because of new technologies such as XML (Angeles et al., 2001).

Web services

Web services can be defined as a computer based service provided by applications through internet based standards (Magnusson & Olsson, 2008). Web services enable new opportunities for a business system that both support the current operations and at the same time is flexible enough to support the future needs (Magnusson & Olsson, 2008). It enables building applications quicker since remote web services can be accessed to perform functions (Jorgensen, 2002). Web services are based on events and services rather than static objects and set structures. This architecture is sometimes named Service Oriented Architecture (SOA).

2.4 Requirements on information sharing and traceability within the Swedish legal medical supply chain

Regulations can either be mandatory and legally enforced or voluntary and informally enforced (Ringsberg, 2013). Examples of mandatory regulations are laws and voluntary regulations can be third-party certifications. There are different levels of the regulatory bodies which can be divided into levels of international regulations, national, subnational and private levels. This section deals with the first international EU-level and the national level. The role of the organizations on EU level is to produce directives and guidelines for the EU countries to adopt. On a national level there are national government agencies, which support the constitution of laws (Ringsberg, 2015c). The main part of the Swedish legislation under the control of the Medical Products Agency, MPA, is regulated on an EU level and is therefore fundamentally the same as in the member states of the EU (Läkemedelsverket, 2015c). On a national level, it is the Pharmaceutical Act (1992:859) and the drug regulation (2006:277) that regulates the medicines sold in Sweden. (Läkemedelsverket, 2014a)

The section is divided into three sub-sections. The first one concerns the requirements on supply chain actors regarding labeling of prescribed medicine, together with a description of the new directive of safety features on the packages. This is followed by the requirements of documentation on the different actors in the Swedish legal pharmaceutical supply chain. Lastly, the results from a study regarding consumer requirements are summarized.

2.4.1 Regulatory requirements on labeling of medicinal products

The regulations concerning what information attributes the medicinal products have to be labeled with, is of main interest to the producer of the products since it is this company who labels the medicine while the rest of the actors in the supply chain mainly forward the packages. An exception is the pharmacies who add a medicine dispensing label to the packages of prescribed medicine. When it comes to the labeling of prescribed medicine there are, at EU level, standards that are presented in Directive 2001/83/EC. On a Swedish level, this directive is transferred into MPA's provisions named LVFS 2005:11. There are a number of attributes that, according to this provision should be printed on the packaging and the medicament container (Läkemedelsverket, 2005). These are displayed in table 3.

Table 3. Regulatory requirements on labeling for producers

Mandatory information	Explanation
The name of the medication	The name of the medication used on the market where it is sold
The active substances	The substance that is biologically active
The quantity recommended	A specified amount
The excipients	Inactive substance formulated with the active ingredient commonly used to bulk up formulations that contain potent active ingredients
The method of administration	E.g. “for injection”, “to be swallowed whole”, “for rectal insertion”
A storage warning	A warning that the medication should be stored out of sight and reach of children
A reference to that the leaflet should be read	A text referring to the importance for the patient to read the leaflet before taking the medication
Possible warning signs	Strong cautionary advice about possible dangers or contraindications in health-care-related activity or pharmacy
Best before date	Indicates the period during which it may be consumed if stored and consumed under appropriate conditions.
Storage directions	Directions of storage and transportation of the product
Name and address to the holder of permission to sell the drug	Contact details to the company approved by the MPA to sell the drug on the market
The number of the permission to sell the medicine	A number which the product receives when it is approved to be sold on the market
The producer’s batch number	The number of the quantity of goods produced in a single manufacturing run
The Nordic part number	A mandatory number for pharmaceutical products in Sweden to be labeled with. It is a six digit code with the purpose to identify the product at all stages in the supply chain

Sources: Läkemedelsverket, 2005; Läkemedelsverket, 2014b; The Free Dictionary (2015), The Business Dictionary (2015).

It is the owner of the permission to sell the drug that is responsible for that the packages contain the information above. (Läkemedelsverket, 2005).

For the distributors and the transporters, there are no additional legal requirements on adding information to the package of the medicine.

The pharmacies add five information attributes to the medicine dispensing label of the package when selling the medicine to the end consumer. This information is legally regulated according to the provision 2009:13 (Läkemedelsverket, 2009a) and is displayed in table 4.

Table 4. Regulatory requirements on labeling for pharmacies

Mandatory information	Explanation
The patient's name and birth date	The name of the patient according to the national registration and the date when he or she was born
Direction of how to use the medication	Directions of which dose to take and for what reason the medicine should be used
The name of the doctor	The name of the doctor who prescribed the medicine
The name of the pharmacy	The name of the pharmacy dispensing the medicine
Date of completion and number of dispensed packages of the medication	The date when the patient collects the medicine and the number of packages he or she collects

Source: Läkemedelsverket, 2009a.

In a quite recent directive that was approved in October 2012, it was decided on a common regulatory framework for medicinal products (Smedpack, 2014a). The Directive 2011/62/EU purpose is to stop counterfeit medicinal products from entering the legal market. A part of this directive says that packages for prescribed medicine should be able to be tracked all the way from the manufacturer to end-consumer through safety features. A security code should make it possible to identify and prove the authenticity of each and every one of the medicinal products at any point in the supply chain (Läkemedelsverket, 2013).

In addition to this, another safety feature should enable the verification of that the outer packaging has not been manipulated. (European Commission, 2011b) There are investments to be made before this system is planned to start operate in 2017, such as investments in software and computer equipment (Smedpack, 2014a). In table 5 on the next page, the legal requirements on labeling for the different actors are summarized.

Table 5. Legal requirements on labeling the product for the different actors

Attributes	Producer	Pharmacy
Name of the medication	x	
The active substances	x	
The quantity recommended	x	
The excipients	x	
The method of administration	x	
Warning text concerning children safety	x	
A reference to that the leaflet should be read	x	
Possible warning signs	x	
Best before date	x	
Storage directions	x	
Name and address to the holder of the permission to sell the drug	x	
The number of the permission to sell the medicine	x	
The producer's batch number	x	
The Nordic part number	x	
The patient's name and birth date		x
Direction of how to use the medication, which dose to take and for what reason the medicine should be used		x
The name of the doctor who prescribed the medicine		x
The name of the pharmacy		x
Date of completion and number of dispensed packages of the medication		x

Source: Läkemedelsverket, 2005; Läkemedelsverket, 2009a.

2.4.2 Regulatory requirement on documentation in the pharmaceutical supply chain

When the products are moving through the different actors in the supply chain, the actors are required to document some information attributes from each batch of products to enable tracking and tracing of the medical products. In this section, the different requirements of the different actors in the supply chain is described. The transporters are not included since there are no regulations regarding documentation of pharmaceutical products for this actor.

Requirements of documentation for producers

According to the provision LVFS 2004:6 the attributes presented in table 6 should be documented and available for inspection.

Table 6. Information required to be documented by producers

Mandatory information	Explanation
Specifications and test methods	A detailed description of the requirement with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.
Production methods	Processes and techniques that are used to manufacture a product
Instructions for manufacturing and packaging	A detailed description of the starting materials, equipment and computerized systems to be used and specification of all processing and packaging instructions
Protocol from the manufacturing process	Instructions for performance and recording of certain discreet operations

Source: Läkemedelsverket, 2004; The Free Dictionary, 2015; European Commission, 2010.

The documentation regarding manufacturing of pharmaceutical products should be archived at least a year after the best before date for the batch that it belongs to, or five years after the expert witness releases the batch (Läkemedelsverket, 2004).

Requirements of documentation for distributors

According to the provision LVFS 2014:8 (Läkemedelsverket, 2014c) a company that is operating as wholesale trader with medicinal products should document the handling of medicinal products in a way so that it can be tracked. The attributes in table 7 are the ones should be recorded in the documentation for distributors.

Table 7. Information required to be documented by distributors

Mandatory information	Explanation
Arrival- and delivery date	The date of when the products arrived to and was delivered from the distributor
Number of packages	The quantity of containers received
Batch number	The number of the quantity of goods produced in a single manufacturing run
The size of the package	The measurements of the container
The name of the medicine	The name of the medication used on the market where it is sold
Dosage form and strength or specific unambiguous product designation	Unit doses in the form in which they are marketed for use
The sellers, the buyers, and, when suitable, the agent's name and address	Contact details to the company approved by the MPA to sell and buy the drug on the market
Market approval	Information on if the medicine is approved to be sold on the market
A proof that the batch is released within the EEA	A certificate signed by the manufacturer's expert witness who has to verify that the batch is released within the EEA

Source: Läkemedelsverket, 2014c; The Free Dictionary (2015).

This documentation should be available for five years (Läkemedelsverket, 2014c).

Requirements of documentation for pharmacies

In order to secure the traceability of pharmaceutical products, they need to be documented also by the pharmacies. The attributes in table 8 needs to be documented by the pharmacies.

Table 8. Information required to be documented by pharmacies

Mandatory information	Explanation
Date of arrival	The date of when the pharmaceutical products arrived at the pharmacy
Number of packages	The quantity of containers received
Size of the packages	The measurements of the containers
Name of the product	The name of the medication used on the market where it is sold
Dosage form and strength	Unit doses in the form in which they are marketed for use
Name and address to the company selling the product to the pharmacy	Contact details to the company approved by the MPA to sell the medicine to the pharmacy
The actions taken when having deficiencies and withdrawals of products	Any action taken in connection with complaints and cancellations of products

Source: Läkemedelsverket (2009b); The Free Dictionary (2015).

This information have to be saved by the pharmacy for five years (Läkemedelsverket, 2009b)

Below, a summary of the legal requirements on documentation for the different actors is provided in table 9.

Table 9. Legal requirements on documentation for the different actors

Attributes	Producer	Distributor	Pharmacy
Specifications and test methods	x		
Production methods	x		
Instructions for manufacturing and packaging	x		
Protocol from the manufacturing process	x		
Date of arrival		x	x
Date of delivery		x	
Number of packages		x	x
Batch number		x	
The size of the packages		x	x
The name of the medicine		x	x
Preparation form and strength		x	x
The seller's name and address		x	x
The buyer's name and address		x	
Information on if the medicine is approved to be sold on the market		x	
A signed certificate to verify that the batch is released within the EEA		x	
Measures taken when having deficiencies and withdrawals or products			x

Source: Läkemedelsverket, 2004; Läkemedelsverket, 2014c; Läkemedelsverket, 2009b.

2.4.3 End consumer requirements

In a study conducted by Ringsberg and Urciuoli (2015) it was studied how consumers' preferences on visible information on packages differs between different consumer segments. Two different types of packages were studied, namely non-prescribed pharmaceutical packages and fresh fish packages. These products were of interest to their study due to various reasons, for example since traceability and handling requirements are of importance both for food and pharmaceutical products.

Ten attributes were identified as mandatory for product labeling for both non-prescribed pharmaceutical products and fresh fish products. It was investigated how important each of these ten attributes were for different consumer groups. Consumers were divided into different segments based on the consumer gender, age, source of income and income. The results from the study however showed that there were no correlation between the income and preferences. Instead the study shows that the younger the consumers are, the more they value and pay attention to the package's mandatory traceability information attributes. The study also showed that the information attributes storage conditions, geographical origin, and presence of allergenic substances were perceived as less important than other attributes among the consumers of pharmaceutical products. A hypothesis is that this result holds for non-prescribed pharmaceutical products since these have a lower value compared to prescribed pharmaceutical products. Therefore traceability of non-prescribed pharmaceutical products might not be as important for consumers. Moreover the study showed a lack of consumer interest in the scientific name and environmental labeling on pharmaceutical products. These attributes were however the ones that had the highest correlation relative the other information attributes (Ringsberg & Urciuoli, 2015).

2.5 Traceability within the food industry

The developments regarding traceability in the food industry are interesting to study since traceability has been central in this industry during the two latest decades (Salampasis et al., 2012). One of the reasons for this is the increasing consumer consciousness and requirements regarding safety and quality aspects of food products. Since safety of a food product require ability to track and trace a product along its supply chain, regulatory interventions has been enforced at an industry-wide level. As a result of this several types of frameworks for ensuring traceability in the food industry has emerged lately (Pizzuti et al., 2014). Traceability systems can be useful for many different ways; to improve quality controls, to enhance consumer confidence, to optimize production or when a food product needs to be recalled (Salampasis, 2012; Moe, 1998). An overall description of the food industry is provided followed by a description of three traceability frameworks and one ontology model developed for the food industry. At the end of the section different characteristics of the frameworks and models are summarized in a table.

2.5.1 Characteristics of the food industry

In general a food supply chain is a complex network of different actors sharing information on products and processes with each other to enable offering food products to the consumers. The actors register and share information on products and processes with each other. Products include both raw material and components. Processes are the activities performed by the actors

in order to create the food product (Pizzuti et al., 2014). The food market has high information asymmetries because the producers, processors and retailers have generally more information about the product quality compared to the consumers. Information about for instance the product animal welfare standards, organic production and food safety can often only be obtained by the consumer if the consumer is willing to pay big amount of money. To protect consumers against food hazards the regulation regarding food production has been intensified, especially in Europe (Heyder et al., 2012).

The majority of the information shared in food supply chains is heterogeneous and registered in different data collections. Information and knowledge is spread among the different supply chain actors in different formats. Standards for recording and exchanging of information in a consequent manner is therefore required in this industry (Pizzuti et al., 2014; Moe 1998; Folinas, 2006). Bechini et al. (2005) claims that diversity in systems among food supply chain actors obstructs integration. Furthermore, SMEs usually use same concepts but have different meanings, resulting in issues relating to semantic interoperability (Pizzuti et al., 2014). Folinas et al. (2006) suggest that traceability data can be classified into mandatory and optional data. It is important to identify the data to collect for ensuring traceability. The efficiency of the system is dependent on the system's capacity to document these information attributes related to traceability. It should be defined which data should be recorded at different stages in the supply chain. Mandatory data is attributes which should be documented and shared by all actors in the supply chain while optional data are useful but not fundamental to ensure an efficient traceability system (Folinas et al., 2006).

A food product can either be a fresh commodity (fresh vegetables for instance) or a manipulated or processed product. When raw ingredients or primary food commodities has been processed it can be referred to as processed food. The processed food can later on be used for further food processing. Processed food is usually made by many types of ingredients. Food product in general is characterized by perishability and a short shelf life. The shelf life can be affected by storage and handling conditions (Pizzuti et al., 2014). The value of a food product is in general low (Regattieri et al., 2007).

Examples of actors that can be involved in food supply chains are raw ingredient producer, manufacturers, transporters, wholesalers and final retailers (Pizzuti et al., 2014). 62 % of the food companies in Europe are small to medium sized enterprises, SMEs. The transporter play an important role in the food supply chain due to the great responsibility of handling the sensitive food products during transportation between all the involved actors. The wholesaler also plays a vital role by buying, warehousing and selling food products. During the warehousing at the wholesaler activities like mixing or packaging can be executed. It is of great importance that the wholesaler follow the product's storage conditions (Pizzuti et al., 2014).

A big problem in the food industry is the contaminated food products entering the food supply with possible severe consequences on the consumers' health (Bhatt & Zhang, 2013). According to Regattieri et al. (2007) seven million people is affected by food borne illness every year. Ringsberg (2014) gives several examples of food safety disruptions with severe consequences; the Escherichia coli salmonella outbreak in Germany 2011, the outbreak of the Creutzfeldt-

Jakob disease in the 1980s due to contaminated meat products and most recently the “horsemeat scandal” in 2013. Besides from affecting human health the mentioned cases resulted in severe brand damages and economic losses (Ringsberg, 2014). A perfect system should have the ability to both track for example the cow to the hamburger but also trace the hamburger to the cow in case it is found that the meat is infected with a disease (Stefansson & Tilanus, 2001). By implementing interoperability the food industry can increase visibility, agility and consumer trust (Bhatt & Zhang, 2013). Regattieri et al. (2007) furthermore states that effective tracing systems are required firstly to handle a product recall due to safety reasons and secondly to investigate the underlying reasons to what caused the problem.

2.5.2 Traceability frameworks for product traceability in the food industry

Three frameworks and one ontology model developed for improving the traceability in food supply chains are described in this section. In the end of the section a table is summarizing characteristics as well as similarities and differences between these frameworks/models.

TraceALL

To ensure safety, address the problem of fraud and increase end consumer confidence a framework to facilitate traceability in the food industry has been developed by Salampassis et al. (2012). The background for this development was the conviction that traceability is a complex integration and business problem requiring information sharing between different business processes along the food supply chain. The framework is based on the Semantic Web, SW, which is an extension of the World Wide Web. In the SW services and information semantics are defined. The framework provides a methodology for companies operating in the food industry to develop traceability applications. By using this framework all stakeholders can follow a product’s information trail along the supply chain which is in line with the product’s physical trail. The framework includes detailed descriptions of what ICT infrastructure to use when building the traceability application (Salampassis et al., 2012).

Since many stakeholders in the food industry are SMEs it was important to focus on cost-efficiency when developing the framework. Other aspects considered important when developing the framework was to make sure the traceability system should achieve full traceability, should have ability to maintain information about products during the whole life-cycle and should also have the ability to both track and trace products. Moreover it was important to ensure that the traceability system should easily be extensible, should have a high level of interoperability and that it should be easy to implement, apply and operate. The framework was developed with all these requirements in mind and consists of three basic components; (1) An ontology management component based on web ontology language, OWL, (2) An annotation component for “connecting” a traceable unit with traceability information using RDF and (3) Traceability core services and applications (Salampassis et al., 2012).

The first basic component relates to the vocabulary used when producing information in the traceability system. Knowledge management is done using ontologies in the framework. An ontology can be explained as a shared formal definition of the concepts and their relationships in a domain. OWL is a standard language for knowledge representation, declaring and describing ontologies. An ontology editor is required to create ontologies. The framework uses

the ontology editor ontologies-based enterprise application, ONAR. This editor creates a user interface, where the end-user for instance can create classes and relations (Salampasis et al., 2012).

The second basic component is a tool enabling to create information about a physical item, link the information to the physical item and store the information in a database. The traceable information is stored and retrieved servers using RDF/XML-formatted files. Each supply chain member could have its own server but the framework also allow the whole supply chain to have a central hub. The reason to why RDF has been chosen is first because this is the standard for metadata in the SW and second because this is a language for describing resources. By using this language the different supply chain members can retrieve traceability information, but this also facilitate for implementing traceability policies. Furthermore this enable food safety check and safety alerts (Salampasis et al., 2012).

The third component in the framework is a set of traceability services. These services enables for creation of traceability systems which can use the information stored in the databases. The services in this component can further be divided into three categories. The first service-type consists of the services that can identify a product by assigning a code to the product. The second service-type is a service that can assemble and provide information about a certain product route. Such information includes for instance production, movement and storage. The third service-type consists of services with ability to define an open set of checks and alerts based on rules (Salampasis et al., 2012).

The three components of the TraceALL framework are visualized in figure 5.

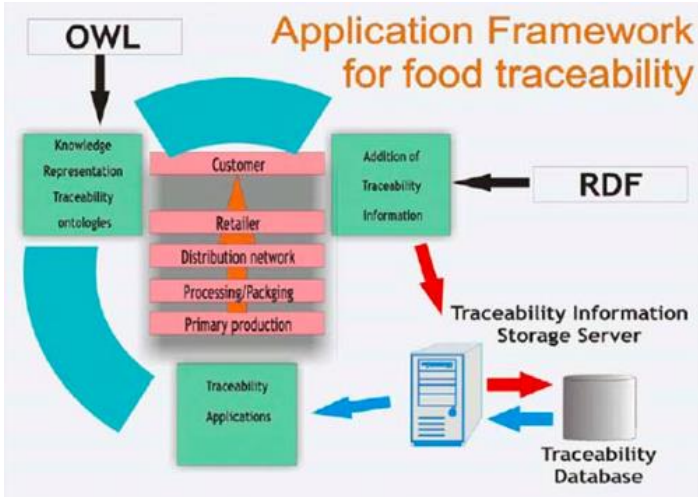


Figure 5. The three components of the TraceALL framework (Salampasis et al., 2012, pp. 308)

TraceFood

According to Storøy et al. (2013) systems for food supply chain traceability has gained increasing interest the latest due to demand for increased food safety and quality. Many companies in the food industry have currently well-developed traceability systems internally. The challenge is however the exchange of this information between different companies in this industry, since there are a diversity of different systems used by different companies. Also there is a proprietary nature of these internal systems. A lack of standardization can lead to a more costly and time consuming handling of data. By having manual means for data exchange such as telephone, fax and e-mails, errors are more likely to occur since the data needs to be recorded several times by different actors. The framework TraceFood has been developed to enable electronic interchange of data between companies in this industry. The framework aims to provide stakeholders with an international, non-proprietary standard. This standard defines how messages should be constructed, sent and received. It also defines how data elements should be identified, measured and interpreted. This framework is the result of collaboration between different EU-funded food traceability projects (Storøy et al., 2013).

The TraceFood framework is built on three important generic principles for achieving efficient traceability in the food industry. These are (1) Unique identification of traceable units, (2) Documentation of transformations, (3) Standardization of information exchange. The framework furthermore provides 6 guidelines for how to obtain electronic traceability, see figure 6. These are (1) Principle of unique identification, (2) Documentation of transformations of units, (3) Generic language for electronic information exchange, (4) Sector-specific language for electronic information exchange, (5) Generic guidelines for implementation of traceability and (6) sector-specific guidelines for implementation of traceability (Storøy et al., 2013).

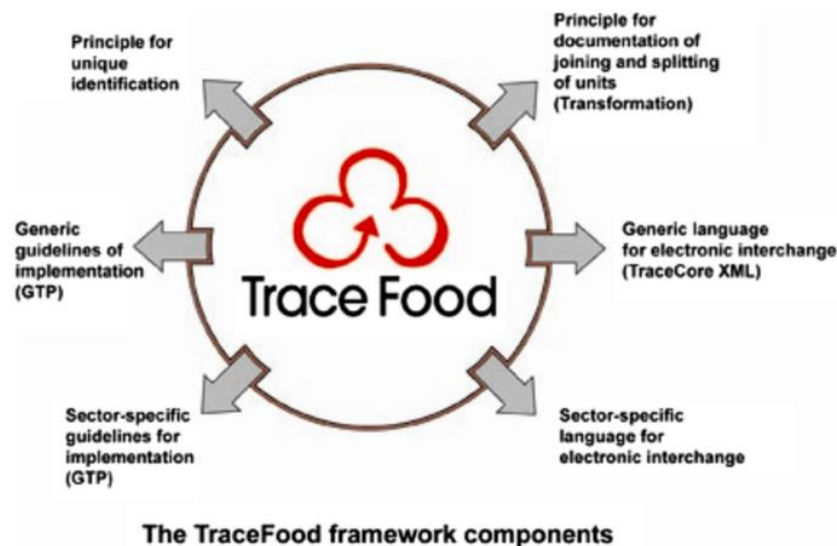


Figure 6. The six components of the TraceFood framework (Storøy et al., 2013, pp. 43)

The first principle of the framework requires that all traceable units should have a unique identification number containing a minimum of information about the product during its lifetime. This is important to assure integrity and traceability of products in the food industry.

The framework recommends usage of the GS1 system for unique identification of both traceable units (TU) and logistic units (LU). A technical explanation of how TUs and LUs respectively should be numbered according to the GS1 system is also covered by the framework.

The second principle of the framework requires that information about all the split and joins (transformations) a TU is subject to during its lifetime should be documented. This is crucial to later on be able to track and trace items along the value chain and analyze relationships between different TUs. Detailed guidelines for how this systematic documentation should be performed are also specified in the framework.

The third principle claims that a generic language should be used when exchanging information between different actors. The framework differs between two type information exchange; A data request regarding a specific product/product group or a response to a request comprising the requested data. A request-response scheme is provided for the user of the framework. The language to use for such electronic traceability data exchange proposed by the framework is TraceCore eXtensible Markup Language (TraceCore XML- TCX). TCX enables exchange of a minimum of information elements typically shared for food products. TraceCore XML is used for data exchange between different databases.

The fourth principle is included in the framework to ensure clear and unambiguous information exchange between actors. A sector-specific standard is required for all actors to interpret the exchanged information in exactly the same way. This standard should specify exactly what properties should be called and how these should be measured.

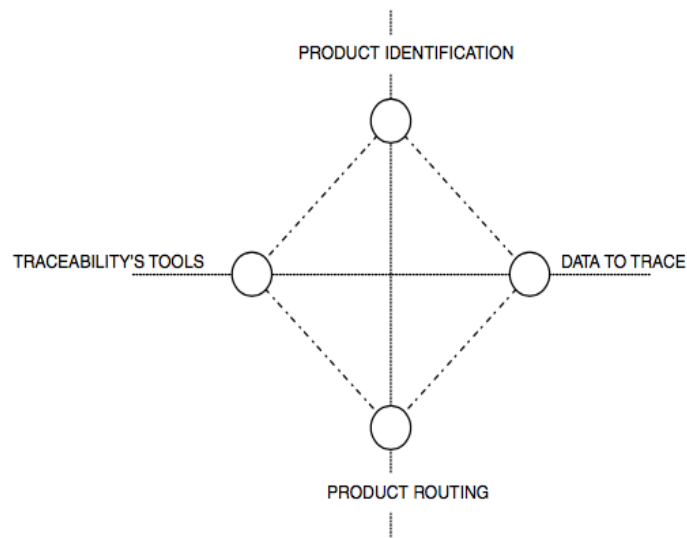
The fifth principle provides generic guidelines for implementation of traceability. Generic guidelines comprise a list of information elements that should be recorded for all kinds of food products. Examples of such information elements are producer ID or trade unit.

The sixth principle of the framework requires development of sector-specific guidelines that are product specific. Three rules for how these elements should be developed are provided. First a standardized list of information parameters for the product along the supply chain should be defined. Then data elements to be recorded at certain points in the value chain should be determined. Thirdly, a model for data management and information exchange needs to be created. This model should ensure traceability both internally and along the supply chain (Storøy et al., 2013).

The traceability system was tried during pilot studies. These studies showed that the benefits with the system did not exceed the costs for installing and operating the traceability system, why it was concluded that the food industry did not realize the true value of an electronic traceability system. It also appeared that all actors in the industry did not have the possibility to record and share information in a standardized way. Overall, there are organizational obstacles for implementation of a traceability system provided by TraceFood in the food industry since the actors lack motivation due to cost aspects and data security aspects (Storøy et al., 2013).

Framework for product traceability

An efficient and effective traceability system can provide many benefits such as reduction of operating costs and increasing productivity. Such a system can also increase consumer safety since detailed information about a product’s geographical origin, ingoing components and processing history can easily be retrieved. Regattieri et al. (2007) found that there are no legal requirements for the development of traceability systems in food supply chains, why the authors developed a framework for finding mainstays and functionalities in an effective traceability system in general. The framework emphasizes all factors with an impact on traceability and is a starting structure for an effective traceability system. It is built upon four categories; product identification, data to trace, product routing and traceability tools (Regattieri et al., 2007), see figure 7 below



PRODUCT IDENTIFICATION	DATA TO TRACE	PRODUCT ROUTING	TRACEABILITY'S TOOLS
dimensions volume weight surface conditions shortness perishability packaging cost life cycle length bill of material structure	number typology degree of detail dynamism data storage requirements confidentiality & publicity checks & alarms	Production cycle activities lead times equipments manual operations automatic operations movement systems storage systems	compatibility vs product compatibility vs process N' of data readings N' of data writings degree of automation data accuracy data reliability company's knowledge cost of system

Figure 7. A general framework for food traceability emphasizing all aspects with an impact on the traceability system (Regattieri et al., 2007, pp. 350)

The first category “product identification” includes information attributes relating to the physical product, such as volume, weight, dimensions and packaging. This category also includes attributes like perishability, life cycle length and the structure of the bill of material, BOM. The BOM contain information about all ingoing parts the product is made from. The second category “data to trace” concerns the characteristics of information that the system needs to manage. Example of such characteristics is number, typology, degree of detail and data storage requirements. It is also important to determine what level of information confidentiality that should be supported by traceability design. The third category “Product routing” concerns the production process. The system needs to be able to record information about the product during its path along the supply chain. Data regarding production activities, transportation and storage activities needs to be documented. Example of this type of information affecting traceability is product lead times, equipment used for production, storage systems, manual and automatic operations etc. The fourth category is “traceability tools”. This category emphasizes important aspects to consider when choosing what technique or tool (e.g. bar code, RFID etc.) to use for the traceability system. This choice should for instance be based on the compatibility with the product and production process, general knowledge about the tool among supply chain actors and the cost of the technique (Regattieri et al., 2007).

Despite the fact that different products have different characteristics, a traceability system for all types of products can be derived from the general framework described above. Since food products require a very detailed traceability system the entire framework shown in figure 7 should be used for this type of product (Regattieri et al., 2007).

The Food Track & Trace Ontology Model

As part of the work with creating a Global Food Traceability Framework for supporting quality and safety control, Pizzuti et al. (2014) has developed an ontology model which will be used in the framework. By using ontologies heterogeneous databases can be integrated, resulting in interoperability between the information systems used. An ontology can be described as formal representation of terms in a studied domain (Kim et al., 1995), why an ontology model can be used to improve shared understanding of frequently used concepts. The demand of ontologies has been increasing recently to facilitate communication and knowledge expression between heterogeneous agents. The ontology model developed by Pizzuti et al. (2014) is called Food Track & Trace Ontology, FTTO. The main goal with FTTO is firstly to comprise concepts frequently used among food supply chain actors and therefore provide the ability to integrate and connect typical features of the food traceability domain. Secondly, the goal is to connect the ontology with a global traceability system developed by Pizzuti et al. (2014). FTTO uses OWL as reference representation language since this language provides good support for describing relations among classes, properties and individuals.

Some general activities when building an ontology are pointed out by Fernández et al. (1997). Before starting developing an ontology the work needs to be planned. A specification of the ontology purpose, requirements and scope should be done. Next, knowledge in the ontology domain needs to be acquired before the conceptualization can start. This implies identifying domain terms as concepts, instances, verbs relations or properties. Each of these should have an informal representation. By using definitions from other ontologies in the ontology, the

uniformity can be increased among ontologies. Next, the ontology needs to be implemented in a formal language such as OWL. Before making the ontology available to others the ontology needs to be evaluated, to ensure it does not include any errors. Finally, it is of importance to document the ontology both to enable others to use it but also to enable maintenance and modification of the ontology later on (Fernández et al., 1997; Pizzuti et al., 2014).

The FTTO has four modules; Agent, Food Product, Process and Service Product. These four modules will briefly be described below. The detailed information technology behind each of these four modules provided by Pizzuti et al. (2014) will however not be included in this summary of the ontology model since this is out of the thesis' scope.

The first module, agent, concerns companies or operating actors engaged in food production. This module should represent information about the main actors in the food supply chain. Each actor should be able to communicate with the rest of the supply chain by sending traceability information to an observatory actor. Example of information that should be provided is the actor's role in the supply chain, a list of operating actors in each company and the location of the actor.

The second module "Food Products" represents food ingredients or raw material for all food products available for users.

The third module "Process" includes information about business processes and agro-food processes. To find commonly used concepts and terms related to processes operated in this context a food supply chain was studied in depth. Examples of processes in the class business processes are distribution, labeling, purchasing, and storage. Example of processes in the class agro-food processes are crop cultivation processes or livestock production processes. Information about all these processes and its ongoing activities are needed to ensure traceability in these supply chains.

Finally the fourth module "Service product" concerns the products during food manipulation activities. This includes knowledge about for instance product packages, machineries or food additives. Information in this module is important to ensure that legal regulation related to handling of food products is followed. This module is also important to enable traceability of food packages (Pizzuti et al., 2014).

The FTTO enables actors in the supply chain to communicate with each other in a standardized manner. It also helps authorities, government agencies and companies to handle food crisis in a better way since shared data is available for analysis. This ontology can therefore both reduce the damage of a food crisis and facilitate in finding the root causes to a food crisis, regardless if it is related to agents, food ingredients, processes or service products. Ringsberg (2015b) furthermore states that the technical and semantic interoperability in food supply chains can be increased by developing an ontology and using international standards for exchanging information.

Characteristics of the three traceability frameworks and the ontology model described in this section are summarized in table 10 on the next page.

Table 10. Summary of characteristics in the above described traceability frameworks and ontology model for the food industry

Characteristics	TraceALL (Salampasis et al., 2012)	FoodTrace (Storøy et al., 2013)	General Framework for food Traceability (Regattieri et al., 2007)	Food Track & Trace Ontology, FTTO (Pizzuti et al., 2014)
Purpose	To provide an international, non-proprietary standard for facilitating electronic interchange of data	To provide the necessary infrastructure enabling the food industry to implement traceability applications	To present a starting structure for an effective traceability system	To include the most representative food concepts involved in a supply chain all together in a single ordered hierarchy, able to integrate and connect the main features of the food traceability domain
Components or modules	(1) An ontology management component based on web ontology language (OWL), (2) An annotation component for “connecting” a traceable unit with traceability information using RDF and (3) Traceability core services and applications	(1) Unique identification of traceable units, (2) Documentation of transformations, (3) Standardization of information exchange	(1) Product identification, (2) Data to trace, (3) Product routing and (4) Traceability tools	(1) Food modules, (2) Service products, (3) Processes and (4) Actors
Allow end consumers to access information	Yes	No	No	No
Additional comments	Proposes the use of XML	Proposes the use of XML		OWL is used as reference representation language

3. RESEARCH METHODOLOGY

In this chapter the research approach is presented and the chosen research strategy is scientifically motivated. This is followed by a description of the research process which was divided into three phases. The methods for data collection are presented. The supply chain mapping technique that was used is motivated and the data analysis explained. Lastly the quality of the research and the research methodology is discussed.

3.1 Research Approach

The purpose of the paper is to create a framework to ensure the safety of products in legal pharmaceutical supply chains and to identify the voluntary and mandatory information attributes that are shared related to the physical flow of medicinal products. Based on this purpose, the research judged to be most suitable for the paper is a single case study. The case study is suitable when examining contemporary events and includes two important sources of evidences compared with history method; direct observation of events and interviews with stakeholders involved (Yin, 2009). A qualitative research should according to Bryman and Bell (2011) be applied for a study which purpose is to contribute to research rather than confirming established research, which was the case for this study. As a complement to this data collection, a survey and a literature review was made.

3.2 A Systematic Combining Research Process

Dubois and Gadde (2002) argue that since the purpose of all research studies is to combine the empirical world with the theory, a systematic combining is an iterative process where the theory continuously is confronted with the empirical world. The process for the paper, divided into three phases, is visualized in figure 8. These phases are not to be considered separate from each other since the literature review and the gathering of empirical data was an iterative process. The phases are instead a simplification of the reality to provide the reader with an understanding of which methods were the main focus for the different phases.

Since the purpose of the study was already defined, the goal of the first phase was to become familiarized with the subject and to define the scope of the study. In order to do this, it was necessary to start with the literature review, both regarding the methodology to be used but also to read about Smedpack3 and other relevant theory areas for the study, see figure 8 on the next page. In the second phase, after the scope was defined, the data collection started. To understand the relationships between the different members in Smedpack3 the case study was initiated. Surveys were sent out and collected and interviews were held during this phase. This empirical data was then composed, compared with literature and analyzed in order to answer the research questions and ultimately the purpose of the study.

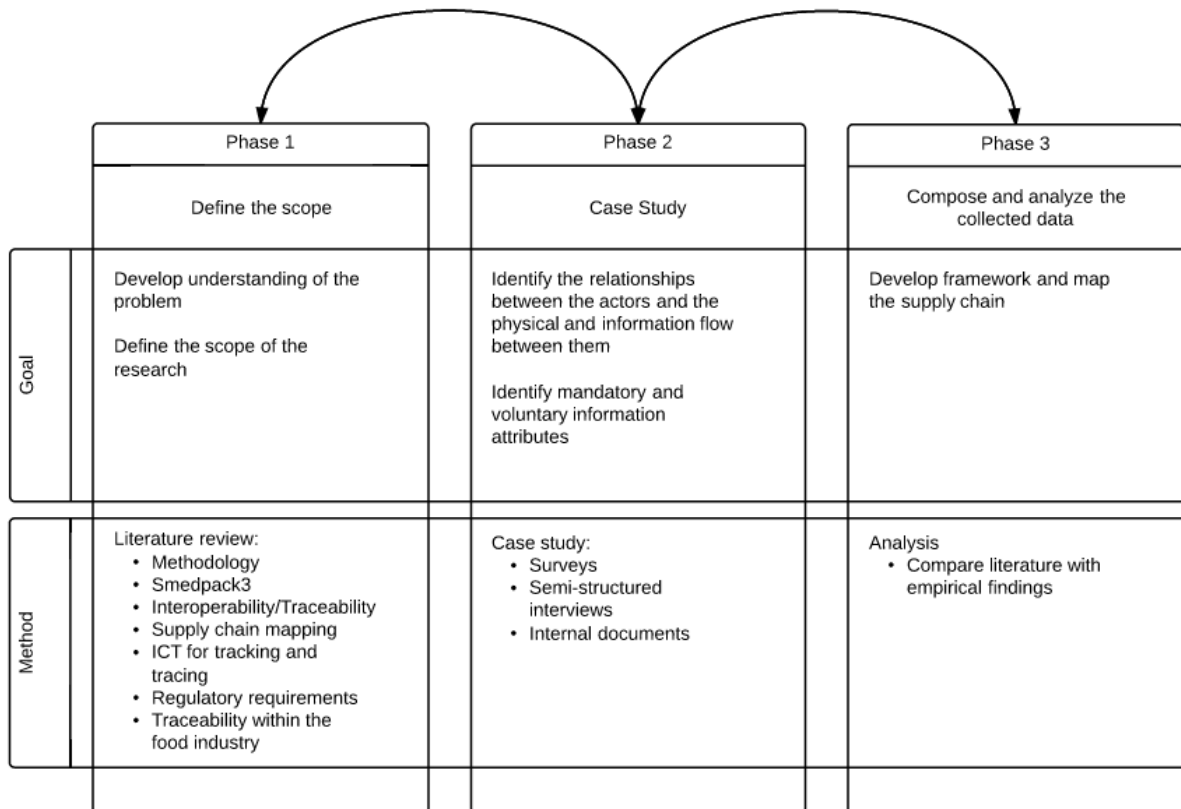


Figure 8. The research process of this study

3.3 Data collection

Multiple sources of data were collected as proposed by Yin (2009). The empirical data consisted of surveys, interviews and internal documents. A wide range of sources of evidence is likely to increase the quality of the thesis (Yin, 2009). The empirical data was collected from the actors of the studied supply chain. In addition to this, a literature review was carried out. In this section, the literature review and the three empirical data sources will be explained more in-depth. These sources were namely surveys, interviews and internal documents.

3.3.1 Literature review

The literature review was initiated by collecting relevant background information in order to understand the situation and in order to choose a suitable research method and approach. For the literature regarding methodology both books and articles were used. The most valuable sources of information in the frame of reference were printed materials, published scientific articles, reports and web sources. The majority of the scientific articles were collected using the online library of Chalmers University of Technology. The database Summon was reached through lib.chalmers.se, a database with access to scientific articles published in a variety of different journals. In addition to this, some articles were also found using the data base of Google Scholar.

To be able to answer the research questions, relevant literature for this paper was reviewed within the areas of mapping techniques, ICT for tracking and tracing, requirements of traceability and information sharing and traceability within other industries. Some of the keywords used in the search for relevant literature were “traceability” “interoperability”

“information sharing techniques”, “pharmaceutical supply chains”, “supply chain mapping technique”, “counterfeit medicine” and “identification techniques”.

3.3.2 Case Study

This section explains the research methods used for empirical data collection performed through the case study. The collected data, the surveys and the interviews, were mainly qualitative even if the survey had a couple of questions that could be considered as quantitative. The definition used for qualitative data is that the data is primarily written in text and that quantitative is presented in numerical data (Bryman & Bell, 2011). The data collected was primary data, which according to the definition of Bryman and Bell (2011) is collected by the researcher for the purpose of the specific study. No secondary data was collected, i.e. data that is collected by another person than the researcher (Bryman and Bell, 2011).

Survey

A web-based survey was chosen because of the time efficiency, i.e. the possibility to achieve many answers during a relatively short time period, and the limited time required from the responder to answer the questions. An advantage with web surveys is the possibility to automatically download the answers into a database which is time-saving and reduces the chances of making errors (Bryman and Bell, 2011). Since the purpose of the study partly was to collect information from the stakeholders in the supply chain that today is unknown, a qualitative survey was conducted. Trost (2012) states that a qualitative survey is recommended when the researcher wants to understand the reasons for peoples’ actions and to find patterns as opposed to when the purpose is to know how often or how many. The survey was conducted using Google Forms. The survey is shown in Appendix 1.

The respondents to the survey were selected companies involved in Smedpack3. The standardization of the survey was high since the questions were the same for the different actors (Trost, 2012). Semi-structured interview questions were used in the sense that there were both set answering alternatives and for some of the questions there were an answering alternative called “other” where the respondents could write their own answer if the options to choose from was not considered suitable. Before the survey was sent out, feedback on the survey draft was given from the supervisor and examiner to be able to increase the quality of the survey and to make sure that the questions should be clear and not subject for confusion.

According to Trost (2012) it is recommended to send an accompanying letter before or together with the survey. One of the purposes is to motivate the responder to answer the questions. In this case, an e-mail was sent out to the respondents a couple of weeks before the survey to introduce the master thesis that was going to be performed and to prepare the participants that they were to be contacted during the next weeks. Together with the link to the survey an accompanying e-mail was sent out to explain the purpose in order to motivate the responders to answer the survey.

Interviews

Interviews with company representatives constituted an important source of qualitative information in the project. Interviews can be a powerful method for accessing the interviewee’s understanding and experience of a given theme. By letting the interviewees use their own words

for describing activities, opinions and experiences related to the theme of the interview, a better understanding of the real situation can be perceived (Kvale, 2007). Therefore interviews were seen as a valuable complement to other information sources used. According to Kvale (2007) there are 7 stages of an interview inquiry. These are; thematizing, designing, interviewing, transcribing, analyzing, verifying and reporting. Thorough preparation for each of these steps was done to ensure the most appropriate layout of the interview inquiry.

Depending on how much “control” the interviewer has of the interview one can differ between three methods; unstructured, semi-structured and structured interviews. The different methods are appropriate in different environments (Harrell et al, 2009). The semi-structured interview was judged as the most appropriate method for this research, since this approach is suitable when the aim is to dig deep into the research theme and to obtain a thorough understanding of the interviewee’s answers. An interview guide was developed to ensure that the focus areas were covered as well as to ensure a structured approach. The semi-structured method is more time-efficient compared to the unstructured method, while also more flexible compared to the structured method (Harrell et al, 2009).

Before the interview, a summary of the interviewee’s response to the survey was sent to him or her. This was made in order to let them confirm that it was correct and to make it easier to refer to the survey during the interview. The interviews were held over the telephone since the authors and the interviewees did not have the opportunity to meet up for a face-to-face interview. Different interview guides were adapted for the different actors interviewed; manufacturing companies, transporters, distributors and pharmacies. Besides from the questions in the interview guide some questions regarding each interviewee’s survey answers were asked to clarify any uncertainties. The interview guides are published in appendix II. Small changes were however made if the previous interview led to that an additional question was judged to be suitable for the next interviewee. After permission from the interviewees, the interviews were recorded. After each interview, the notes from the interview were summarized and compared with the literature to see if there was any theory missing in the frame of reference. The data collected during the interviews was confidential why the interviewees are anonymous.

Internal documents

The third source of empirical data used is internal documents. Yin (2009) mentions several types of internal documents: personal documents, written reports of events, internal records and mass media such as newspapers. In this master thesis, the internal documents that were used, were personal documents such as e-mail correspondence and written reports from previous Smedpack3-meetings and projects as well as bill of ladings and delivery orders. Scott (1990) mentions four criteria to use when evaluating the quality of documents; the authenticity, the credibility, the representativeness and the meaning. These criteria were used by the authors to evaluate the internal documents used.

Overview of the companies and sources of data collected

In total, the survey was sent out to 24 people at 8 companies. The surveys were however sent out to people who did not have enough competence to fill out the survey why only 12 responses were collected. At least one person at each of the 8 companies responded. In total 8 interviews

were held, where 7 were held with company representatives and 1 was held with a representative from the Medical Products Agency. In table 11, a summary of the number of survey answers and interviews held as well as for which companies that internal documents were collected from is presented.

Table 11. Overview of number of survey responses and interviews with each company

Actors	Survey Responses	Interviews	Internal Documents
Producer 1	2	1	
Producer 2	2	1	X
Transporter 1	1	1	X
Transporter 2	1	1	X
Distributor	2	1	
Pharmacy 1	1		
Pharmacy 2	2	1	X
Pharmacy 3	1	1	
MPA		1	

3.4 Motivation of chosen supply chain mapping technique

The aim with mapping the supply chain is to provide a general overview of both the physical flow and the information flow between the different actors in the Swedish legal pharmaceutical supply chain. The overview provided by such a map is considered crucial to enable an analysis of the traceability and interoperability among these actors.

Three different mapping techniques have been described in section 2.2 *Supply chain mapping techniques*; Process mapping, Value stream mapping and IDEF0. The section is summarized in table 1, comparing certain characteristics of the different methods. As can be seen in this table these methods differ from each other in certain aspects why these can be more or less suitable to use depending on the mapping purpose.

The three different mapping techniques can be used for reaching different goals as can be seen in table 1. The method goal differs between the three techniques. Process mapping is generally used to increase visibility of processes to improve the current performance. The goal when using Value stream mapping is instead often to reduce waste in a supply chain according to the lean principle, while the goal with IDEF0 commonly is to facilitate design and implementation of integrated systems between different functions within a company. The mapping in this project does neither aim to reduce waste in the supply chain nor to investigate integration of systems between different functions. This project's mapping purpose is however similar to the goal of Process mapping, why this method was used.

Process mapping is most often used to investigate internal processes within an organization. It can however also be used for mapping processes on a supplier-customer level, why process mapping could be used to create an overview of how different companies involved in the Swedish pharmaceutical supply chain are interlinked both with respect to physical flow and information flow.

The main elements mapped in the method process mapping are the physical flow, resources required to perform activities and the supporting information flow. Since only the physical flow and information flow is of importance for this study the resource element will not be included in the map. The method for conducting process mapping according to Keller and Jacka (2002) was used, why each of the four main steps described in this method was performed. Cross-functional process mapping was used for better visualization of which actor that is responsible for which activity.

3.5 Data analysis

The analysis of the data was started in parallel with the collection of data in the case study. This type of iterative process is according to Bryman and Bell (2011) a common way of conducting the analysis of qualitative data. The first step was to analyze the result of the surveys which was a foundation for the interview.

Notes were taken during the interviews which were summarized and analyzed after each interview. Since the interview was compared with the theory after each interview, important findings could be highlighted straight away and the theory chapter could be complemented. The interviews were also continuously compared with each other, both to make the analysis more efficient but also to be able to update the interview guide. After the empirical data from the interviews had been summarized, the text was sent to each company so that they could verify that there were no errors or misunderstandings.

3.6 Evaluation of the research quality

To evaluate the trustworthiness of a study, the validity and reliability are important criteria (Bryman and Bell, 2011). For qualitative studies, Bryman and Bell (2011) specifies four criteria; credibility, transferability, dependability and confirmability. In line with this, Yin (2009) mentions four tests (construct validity, internal validity, external validity and reliability) which are common to use for empirical social research and since case studies fall into that category the tests are applicable here.

Yin (2009) has consequently developed tactics used for each of these tests. Table 12 on the next page lists the tests, the case study tactic and the phase of research in which the tactics occur.

Table 12. Tactics for evaluating the four research design tests. (Adopted from Yin, 2009, pp.41)

Research design tests	Case study tactic	Phase of research in which tactic occurs
Construct validity	<ul style="list-style-type: none"> - Use multiple sources of evidence - Establish chain of evidence - Have key informants review draft case study report 	<ul style="list-style-type: none"> - Data collection - Data collection - Composition
Internal validity	<ul style="list-style-type: none"> - Do pattern matching - Do explanation building - Address rival explanations - Use logic models 	<ul style="list-style-type: none"> - Data analysis - Data analysis - Data analysis - Data analysis
External validity	<ul style="list-style-type: none"> - Use theory in single-case studies - Use replication logic in multiple-case studies 	<ul style="list-style-type: none"> - Research design - Research design
Reliability	<ul style="list-style-type: none"> - Use case study protocol - Develop case study database 	<ul style="list-style-type: none"> - Data collection - Data collection

3.6.1 Construct validity

Construct validity is about finding valid operational measures for the studied topic (Yin, 2009). According to Yin there are three tactics to secure construct validity; using multiple sources of evidence, establishing chain of evidence and have key informants review draft case study report. The evidences that were used were interviews, surveys, internal document from the research project, internal documents from the companies and literature. This included the collection of data from different people at different times. An example is that for the majority of the surveys, more than one person at each company participated. One of these, or another one was then interviewed at a later time.

The data was collected between April 2015 and July 2015 mainly using surveys and interviews. The interviews were held after one another and complimentary e-mails and phone calls were made. Summaries of the interviews and conclusions were sent to everyone that contributed with empirical data through the interviews, so that they could confirm the interpreted situation.

3.6.2 Internal validity

Internal validity was increased by recording the telephone interviews so that the authors could go back and listen multiple times to make sure that the data was interpreted correctly. Another way to ensure internal validity is triangulation which means using several sources of data for

studying the same concept or phenomena (Bryman & Bell, 2011). Before drawing conclusions it was made sure that several sources of data pointed in the same direction, for example by confirming that findings in the empirical data could be supported by the theory.

3.6.3 External validity

External validity refers to the degree to which the conclusions of study is generalizable, i.e. to be applicable in other contexts. (Yin, 2009; Bryman and Bell, 2011). For this master's thesis the results were translated into a traceability framework. The framework could be used for studying a similar pharmaceutical supply chain, perhaps in another country. Even if the external validity could have been increased through having more interviews, an important aspect that increases the external validity is that the full supply chain was represented.

3.6.4 Reliability

Reliability deals with minimizing the errors and biases in a study and a reliable study is one that if a researcher were to do the same study again, it would result in the same conclusion (Yin, 2009). To be able to succeed with this, all parts of the process have to be saved such as how the participants of the study was selected, the data analysis decisions and notes taken during interviews (Bryman and Bell, 2011). These recommendations are in line with the tactics by Yin (2009) who states that case study protocols should be used as well as a case study database. This has been done through the whole process to ensure reliability of the study.

3.7 Discussion of the research methodology

The case study was made through surveys and interviews and thereby qualitative data. This was considered the most appropriate method to collect empirical data. There are however some risks related to the chosen methods. For instance when interviewing a person, there is always a risk that he or she will give their personal view and not the view that is representative for the whole company. He or she also might be reluctant to share problems in their organization. In addition, it would have increased the construct validity to use an extra source of evidence such as direct observations. But due to several reasons such as that the authors and the interviewees are located in different parts of the country, confidentiality issues and that the data collection phase was partly made during vacation times, this was not feasible.

The survey was quite detailed when it came to the technical aspects of information sharing which made it difficult for some respondents to answer. This resulted in a loss of planned responses although it was better that people who did not have the requested knowledge did not answer. This could have resulted in unreliable data. To be able to establish the findings, more data could be collected.

For the literature study, web sources were to some extent used, in particular for the chapter of laws regarding information sharing among actors in the Swedish medical supply chain. Web sources generally need more caution than printed material (Bryman & Bell, 2011) and the web sources were therefore thoroughly controlled to verify its reliability. The majority of the web sources were as mentioned used for laws and were taken from the Swedish Medical Product Agency's website. These laws were taken from its original document and were not interpreted or changed.

To not fatigue the respondents of the survey and to minimize the risk of respondents to terminate the survey not all of the mandatory attributes were added as options to choose from in the survey. It was noticed that the companies did not add the rest of the mandatory attributes why it can be suspected that they did not add any voluntary attributes as well, which could have affected the result of the study. It is possible that another method for finding out what information attributes shared among the companies could have been used however the results still gives an indication and is useful for the intended purpose.

As for many studies, the more empirical data, the better, if relevant for the study. In this case, more companies could have been interviewed and more representatives from each company could have participated in the study. Because of the limitation in time and scope, a couple of companies from each group of actors as in producers, distributors and pharmacies were considered enough to get an overview of the situation in order to answer the purpose.

4. EMPIRICAL FINDINGS

The empirical data presented in this chapter has been collected from anonymous interviews, surveys and internal document from companies and the research project Smedpack3. The actors included in the studied supply chain are presented and a process map including the physical and information flow is provided. Some different ways that counterfeit medicine can enter the legal supply chain are explained together with the actors' attitudes towards these scenarios. The interoperability in the current supply chain is described. The information attributes that are shared among the actors and the technology used for information sharing are presented. Lastly, the most important empirical findings are summarized.

4.1 Interrelations between the companies in the pharmaceutical supply chain

The first research question concerned the interrelations among the companies involved in the research project Smedpack3. The purpose with this question was to provide an overview of legal pharmaceutical supply chains, both regarding the physical flow and the information flow. This research question is answered in the following sections.

4.1.1 Overview of actors in the pharmaceutical supply chain

The pharmaceutical industry comprises a complex network of actors collaborating to offer pharmaceutical products to end consumers. Among the companies in the industry six categories of actors were identified as main actors during the case study phase. These are shown in figure 9 and described below. Representatives from all categories except from end consumers have contributed with empirical data to the study.

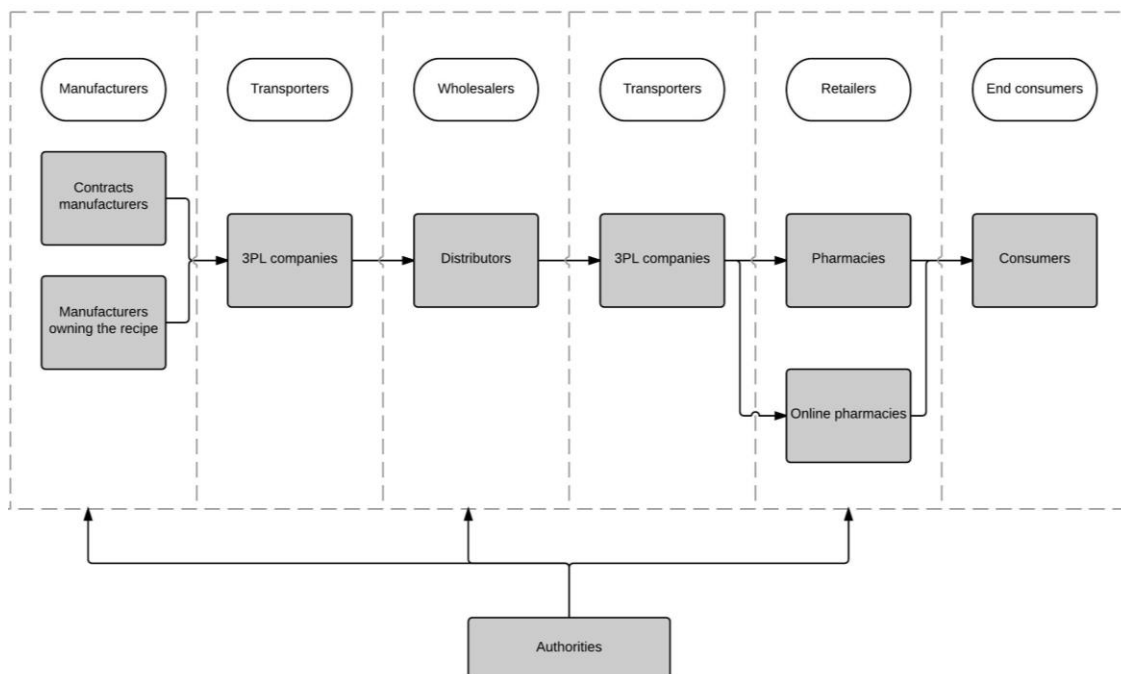


Figure 9. Actors in a general pharmaceutical supply chain in Sweden.

Two types of medical manufacturing companies were chosen for the case study; contracts manufacturers and producers. Contracts manufacturer in this context refers to companies manufacturing pharmaceutical products on behalf of another company. Producers refer in this context to companies holding the permission to manufacture and sell a drug. The producers can either manufacture the medicine themselves or outsource the manufacturing of the medicine to a contract manufacturer.

Transportation between the different stages in the supply chain is usually handled by third-party logistics providers, 3PL. There are many instances of product movements in the pharmaceutical supply chain; between the manufacturing companies and distributors, between distributors and pharmacies and between online pharmacies and end consumers. The transportation companies need to fulfil the government regulation for medical product movements (Smedpack, 2014b). It is up to the buyer of the transportation to make sure that the hired transportation company's haulier follows the legal requirements for transportation of pharmaceutical products.

The interviews showed that most manufacturing companies have agreements with distributors. Shipments of goods arrive to the distributor who is responsible for services like product storage, managing inventory marketplaces and handling the distribution of products to retailers (Smedpack, 2014b). According to interviews distributors mainly distribute to the retail stage but occasionally also to other distributors.

The retail stage is the last step before the pharmaceutical products reaches the end consumers. The distribution and sales of pharmaceutical products has changed significantly in Sweden the last years due to the deregulation of the market in 2009. The deregulation resolved the pharmacy monopoly and enabled a larger number of pharmacy chains to enter the market (Smedpack, 2014b). At this stage two types of retailers have been investigated in the case study; pharmacies and online pharmacies. Pharmacies refer to drugstores where consumers can buy pharmaceutical products in the store, while online pharmacies refer to the companies offering the pharmaceutical products online. According to interviews both types of pharmacies are responsible for storing and dispensing products to consumers. Moreover the pharmacies are responsible for informing the consumers regarding safety aspects and dosage instructions of prescribed medicine.

An authority who has impact on the pharmaceutical supply chain in Sweden is the Medical Product Agency, MPA. During the case study, one person from the MPA was interviewed. The government transposes EC directives into acts and ordinances and the MPA transposes them into provisions. The MPA is also responsible for surveillance of manufacturing companies as well as providing permissions to manufacture, distribute and sell pharmaceutical products. In figure 9 the arrows between authorities and manufacturing companies, distributors and retailers represents the legal requirements on these three actor groups regarding product labeling and documentation. Transporters however do not have any legal requirements on product labeling and documentation related to pharmaceutical products, why no arrows between authorities and transporters are present in figure 9.

4.1.2 Process map of the Swedish legal pharmaceutical supply chain

Interviews have been conducted with representatives from the actors described in section 4.1.1 *Overview of actors in the pharmaceutical supply chain*. The empirical data collected during the interviews has enabled drawing the process map shown in figure 10 below. The map visualizes how the different actors are interlinked concerning both the physical flow and the information flow.

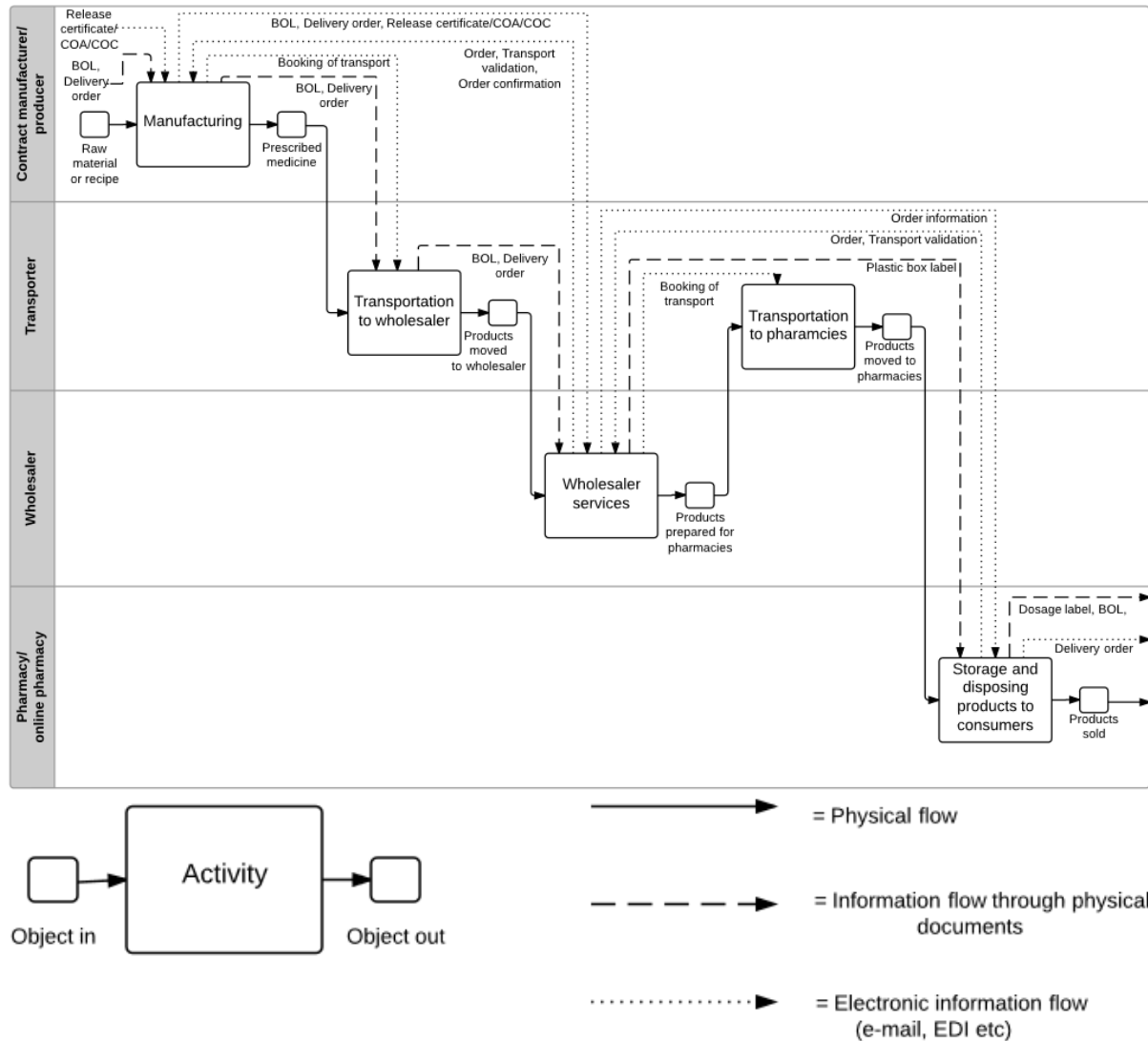


Figure 10. Process map showing the physical flow and information flow in a Swedish legal pharmaceutical supply chain

Manufacturing companies

According to an interview with a Swedish contract manufacturer the manufacturing process is initiated by a customer request for manufacturing a certain prescribed medicine. Most types of prescribed medicines can be manufactured by the contract manufacturer interviewed. The contract manufacturer is responsible for purchasing the raw material required for manufacturing the particular medicine. Raw material is purchased from suppliers who are approved both by the customers and the contract manufacturer themselves. When the raw material arrives to the contract manufacturer's site the freight is labeled with as little amount of information as

possible due to security reasons. The transporters do therefore usually not know what type of pharmaceutical product they are transporting. The freight is however usually accompanied with a physical bill of lading (BOL) and a delivery order. The bill of lading is a document created for the transporter with information about the where the goods is sent from, where the goods should be delivered, the quantity included in the consignment, the weight of the consignment and who is paying for the transportation. The delivery order is a document created for the receiver specifying the content of the consignment.

Moreover, a release certificate (certificate of compliance/COC) or a certificate of analysis (COA), should be sent from the supplier of raw material to the manufacturing company. It is a legal requirement that all incoming batches need to be accompanied with a certificate that specifies that the product batch has been manufactured according to the European legislation, that the batch is released by an authorized person and that it is released for the specific market. The certificate is created for each batch and is unique for that particular batch. The COC/COAs are usually sent to from the suppliers to the contract manufacturer by e-mail and these documents are saved both in archives but also in databases. After the manufacturing process is completed, the prescribed medicines are transported either to the customer who is the holder of permission to sell the drug, or to a distributor. Depending on the customers preferences the customer could arrange the transportation themselves or let the contract manufacturer arrange the transportation. The medicine packages sent from the contract manufacturer is always labeled with the prescribed medicine's batch number, created to facilitate traceability. The outgoing goods are also accompanied by a bill of lading and a delivery order. Batch number, bill of lading and delivery order is usually sent both as physical documents and electronically by e-mail.

A Swedish producer of pharmaceutical products was also interviewed. This producer has an agreement with a distributor implying that the distributor is responsible for the distribution of products to pharmacies and ensures that pharmacies receive the ordered goods no later than 24 hours after the order is placed. Orders from the distributor to the producer are placed through EDI. When a pharmacy is placing an order the distributor in turn places an order to the producer since the distributor is responsible for the replenishment of goods from the producer to their warehouse. The producer however own the products during the whole distribution process until the goods are delivered to the pharmacies. When the manufacturing of the prescribed medicines is finished and the products are packed the load carrier is labeled with a package number, address label and a delivery order. A bill of lading is also created to the transporter. The delivery order and the bill of lading are usually physical documents. A COC/COA is also generated for each batch and uploaded on the web, from which the distributor can download it. Transports from the interviewed producer to the distributor are arranged daily according to a set timetable and the size of the transports is dimensioned based on the pharmacy demand. In this particular case the distributor is responsible for the transportation between the producer and the distributor. When the goods are received at the distributor's site no signal is sent to the producer. The producer can however manually log on to an IT system to see how their own stock levels at the distributor's site have changed.

Transporters

An interview with a representative from a transportation company operating in the pharmaceutical supply chain showed that 3PLs mainly transport pharmaceutical products between producers' sites to distributors and from distributors' sites to pharmacies. The transportation companies interviewed have the ability to transport all kinds of prescribed pharmaceutical products; tablets, vaccine, narcotic compounds etc. Depending on the product there can be different requirements on the transport conditions. For instance some products require certain temperature during the transportation.

The flow from the producers or distributors is initiated by a booking from one of these actors. The interviewee gave an example of when the booking is sent from the producing company to the transportation company. Usually the booking is received by e-mail or by a web-based booking system. The transporting company then accepts the booking and a haulier is hired to perform the transport. Once the haulier reaches the consignor he or she controls that the information on the bill of lading corresponds to the consignment. If so, the goods is sealed, loaded on the truck and transported to the receiving company.

If the consignment does not match the specification on the bill of lading the driver note this on the bill of lading with a pen before performing the transport. At the receiving company's site the goods are unloaded, unsealed and validated. Validation implies that it is checked whether the transport has been conducted according to the booking specification or not. For instance it is common to control whether the transport has had the correct temperature during the transport. The documentation of the validation is usually sent by e-mail to the sending company. No booking of transports is done for the flow between distributors and pharmacies at the interviewed company. Instead the 3PLs are transporting goods between distributors and pharmacies daily, according to predetermined schedules.

Another transportation company interviewed describes their physical and information flow a bit differently. When the sending company is placing a transport order different methods can be used. Larger companies usually uses EDI, while smaller companies without integrated EDI systems instead call the transport company when booking the transport or place a transport order on the web page. The booking is then accepted and a confirmation is sent to the company ordering the transport. A haulier is informed, who then drives to the sending company, scans and picks up the consignment. The goods are then transported to the closest terminal where they are packed, labeled and loaded on the truck.

The consignments can include many different types of products, not only pharmaceutical products. When a truck is loaded with goods it is driven to a terminal close to the different receivers of all the different products in the consignment. At this terminal the goods are sorted on postal code, a route plan is automatically generated in a computer system and finally the goods are transported to each receiving company. A bill of lading is created for each transport and is usually electronic. The interviewed transport company strives to eliminate physical documents in their information flow since this increases the risk of quality problems.

Distributors

During an interview with a representative from a Swedish distributor the physical flow and information flow related to this distributor was described respectively. When it comes to the physical flow of prescribed medicines, there are different business models for the distribution of these products within Europe. In Sweden the most common business model for prescribed medicinal products is called DTP (Direct To Pharmacy). In the DTP model the manufacturing companies choose one distributor for the warehousing and distribution of their products. A written agreement specifies the details and responsibilities between the parties regarding all activities in connection to warehousing and distribution. In some cases the distributor is responsible for arranging the replenishment between the producer and the distributor and in some cases the producer is responsible for this. The consignment delivered to the distributor is labeled with storage conditions. Detailed information about the shipment is usually sent electronically from the producer to the distributor, using integrated EDI systems. According to the interviewee, integration of EDI systems between them and their suppliers are becoming more and more common. Today they have integrated EDI systems with most of their suppliers but not all. The distributor was not worried that the use of different systems was a security threat but the same person stated that it would be more efficient if everyone in the supply chain used the same technique for sharing information. The interviewee also said that it is not easy for companies to change systems overnight, since EDI is widely used in the pharmaceutical industry and new systems are sometimes dependent on information from these EDI systems.

The bill of lading is handed over from the transporter to the recipient at the delivery and this is signed both by the driver and the recipient. The incoming goods are accompanied by a physical delivery order with more detailed information about goods. Moreover, a release certificate/COA should be sent from the producer to the receiving distributor. When the goods arrive at the distributor it is controlled that the actual consignment corresponds to the order specification. This control is performed by employees who check the consignment manually. The goods are controlled for damages and other possible deviations. During this control it is for example investigated that the right products have arrived from the right supplier in the right quantity. After the control is done an order confirmation is usually sent electronically to the manufacturing company through EDI. The distributor interviewed can handle distribution of all types of prescribed medicines. The distributor delivers these products to all pharmacies in Sweden, both ordinary pharmacies and online pharmacies. The distributor can also deliver products to other distributors. Prior to delivery to pharmacies, the prescribed medicine are picked and packed in the distributor's own plastic boxes. Usually the medicine packages have barcodes but the ones that do not have a code are matched with a barcode on a storage location. The plastic boxes are labeled with the name and address of the distributor, the sending warehouse and the receiving company. Each plastic box is unique and is labeled with a unique number referring to each specific delivery. The unique information on the box corresponds to the content in each box. This detailed information is sent electronically to the receiving pharmacy. The distributor is responsible for the transportation of goods to the pharmacies. The distributor interviewed has agreements with different transportation companies. The deliveries to pharmacies usually follow fixed time schedules for effective transportation within a timeframe created by the distributor and agreed by the pharmacies.

Pharmacies

To gain insight in the retail stage in the pharmaceutical supply chain a representative from a Swedish pharmacy with physical stores was interviewed. This pharmacy never places purchasing orders themselves. Instead an automatic ordering system is used. When products are sold in the pharmacy store the system automatically sends a purchasing order to the distributor. The distributor is responsible for the transportation of the ordered products to the pharmacy. There are daily transportations between the distributor and the pharmacy according to a fixed time schedule generated by the distributor. If changes are made in the timetable the distributor sends a fax or a physical letter to the pharmacy about the schedule changes. When the goods are delivered to the pharmacy the incoming goods are reviewed and approved by employees at the pharmacy. After the incoming goods have been approved the stock balance automatically is updated in the IT system. The pharmacy employees then manually check that each of the incoming products corresponds to the delivery order. If the delivery does not correspond to the delivery order the deviations are reported in the IT system. A fax is then sent to inform the distributor about the deviation. The pharmacy interviewed provides all types of prescribed medicines to the end consumers. The pharmacy's main customers are end consumers buying medical products in store but the pharmacy to some extent also sells to clinics and nursing homes. Before selling prescribed products the products are labeled with a medicine dispensing label. Provisions generated by the MPA regulate what information to include on the medicine dispensing label, see section *2.4.1 Regulatory requirements on labeling of medicinal products*. This pharmacy mentioned that there is a continuous dialogue between them and the MPA about the regulations, meaning that they have an opportunity to affect the regulations.

An interview was also conducted with a representative from an online pharmacy. This pharmacy sells all types of prescribed medicines; tablets, liquids, vaccines etc. The products are only purchased from distributors approved by the MPA. Products are stored in a central warehouse. EDI or an e-mail is used when the online pharmacy is placing purchase orders to the distributor. When the ordered products are received the goods' barcodes are scanned and information about the products is thus automatically stored in the pharmacy's internal IT system. In general, no delivery confirmation is sent to the distributor if there is no deviation between the order specification and the delivered goods. If there is deviation however, the distributor is usually contacted manually. The pharmacies do not verify that the products they receive are genuine but presuppose that all products coming from approved distributors are genuine. It was mentioned by the pharmacy that a more integrated system with their distributor could increase the efficiency since they would have more information about stock levels etc.

The online pharmacy solely sells pharmaceutical products to end consumers. When an end consumer places an order the products are most often transported to agents geographically close to the end consumers where the consumers can pick up the order themselves. Examples of agents are grocery stores or convenience stores. In some cases the products can also be delivered directly to the end consumer's mailbox. The transportation from the online pharmacy's central warehouse to the agents or the end consumers is performed by external transportation companies. There are daily transportations between the online pharmacy and the agents according to a fixed time schedule. The consignment transported is accompanied with a

physical bill of lading. Delivery order is however sent to the end consumer by e-mail. Before the products leave the pharmacy warehouse the prescribed products are controlled by authorized pharmacists. It is for instance controlled that the prescribing doctor is authorized. After the control the products are labeled with medicine dispensing labels. This label for instance includes information about the selling pharmacy, the pharmacist and the doctor prescribing the medicine.

The process map shown in figure 10 both provides an overview of the studied supply chain and visualizes the information flow related to the physical flow of goods. During the information gathering process some findings are extra important for further analysis. First, an interesting finding was that COC/COAs are only sent between the producers and the distributors, but not to the pharmacies. Secondly, it was found that the most common data carrier currently used in this industry is barcodes. However, not all products have a barcode. Furthermore, it can be concluded that many different techniques are currently used for sharing information in the studied supply chain. Techniques are ranging from web services and EDI to more manual methods like fax, telephone and physical letters. It was also noticed during the interviews that none of the company representatives mentioned that they have an active tracking and tracing system. These findings will be brought up in the analysis.

4.2 How counterfeit medicines can enter the SC and estimated likelihood of occurrence

Previous work in the Smedpack3 research project has been done to identify different ways that counterfeit medicine can enter the Swedish legal supply chain. Possible scenarios for how counterfeit medicine can enter the supply chain was presented to the companies who in the surveys were asked to estimate the likelihood of these scenarios to occur. Gaining insight in what the companies in the industry think are the greatest risk factors is one way to understand what to prioritize in the work with ensuring consumer safety.

4.2.1 Identified ways for counterfeit pharmaceutical products to enter the supply chain

According to internal documents from the Smedpack3 project there are several ways for counterfeit medicine to enter legal medical supply chains. Risks have been identified at the production site, either that counterfeit substances enter the production or that the employees produce more than ordered and sell illegally. Risks have also been identified during transportation. Hijacking on the road could occur, for example when the driver stops to rest. Theft could also occur at transporter's terminals. At the distributor stage risks have also been identified. If distributors do not specify that they require some type of secure labeling on the packages it can lower the security. In addition, if the products are not labeled with for example barcode or RFID, it will hinder the possibility to trace the products. Another possible risk can occur during parallel imports. The medicinal products usually need to be re-packed and re-labeled and employees could seize the opportunity to swap real medicine for counterfeit products. The amount of transfers between actors involved in parallel import is larger compared to domestic distribution of medicines. Pharmacies are another place where counterfeit medicine possibly could enter the supply chain. The reason is according to Smedpack3 primarily theft (Smedpack, 2014b). It could be a safety risk for an end-consumer to buy products illegally since the medicine might not have been stored correctly and he or she will not be noticed if the product is recalled from the market. Stolen packages could also be used again and filled with

counterfeit medicine. It has been found that the more stakeholders that are involved in handling the medicinal products in a supply chain, the risk gets higher that counterfeit medicine can enter the legal supply chain (Smedpack, 2014b).

4.2.2 Ratings of the likelihood of possible scenarios to happen

The companies were in the survey asked to estimate the likelihood of occurrence for some possible scenarios for how counterfeit medicine can enter the Swedish pharmaceutical market. The rating scale ranged between 1-4 where 1 represented "most unlikely" and 4 "most likely". The options and the average of the answers are summarized in table 13.

Table 13. Average of the answers regarding the risk of counterfeit medicine entering the Swedish pharmaceutical supply chain

Risk	Average
Insufficient security during transportation	2.6
Lack of knowledge of the consumer (e.g. When purchasing products online)	3.8
False advertising (e.g. An online based company claims that counterfeit medicine is genuine)	3.5
Insufficient labeling of products (hard to verify that the product is genuine)	2.7
The employee lacks knowledge of the risk of counterfeit products	2.1
The employee swaps genuine medicine for counterfeit medicine for economic reasons	1.6
The employee swaps genuine medicine for counterfeit medicine because of threats	1.3
Deficiencies in the information sharing between the actors in the supply chain	2.3

As can be seen in table 13, the companies in the case study believe that the greatest risk is the consumers' lack of knowledge about the risks with counterfeit medicine. The companies also thought that false advertising could be a likely reason for consumers to buy counterfeit medicine. The results also showed that the companies believed that the employees were not likely to be involved in the introduction of counterfeit medicines in the Swedish supply chain. Insufficient security during transportation and insufficient labeling of products are not the risks that were judged to be the most likely but they are still judged as a risk by the companies in the study.

4.3 Hierarchical packaging levels in the pharmaceutical supply chain

In the survey the company representatives were asked what hierarchical level of units that were used during transports of goods from their company. Some alternatives were given to the respondents but it was also possible to add other transport units. The units used among producers, transporters, distributors and pharmacies according to the survey results are shown in table 14.

Table 14. Different hierarchical packaging levels used by different actors in the pharmaceutical supply chain

Packaging levels	Producers	Transporters	Distributors	Pharmacies
Containers for flight and sea transport	X			
Pallets	X	X	X	X
Big boxes	X			
Boxes	X	X	X	X
Barrels	X			
Own returnable plastic boxes			X	
Parcels		X		X
Consumer units	X	X		X

As can be seen in table 14, the companies reported that eight different transport units are used for transportation in the pharmaceutical supply chain. All different actors use pallets and boxes as transport units. A distributor also reported during an interview that they had developed a returnable system of plastic boxes that was frequently used for transporting pharmaceutical products to pharmacies.

4.4 Interoperability in the studied supply chain

Overall, the companies in the case study agreed that the cooperation in the industry is working well. A finding from the case study however is that 83 % of the respondents thought that if a closer cooperation between the actors in the Swedish medical supply chain could be achieved, it would have a positive economic effect because of more efficient administration with standardized procedures and cooperation.

The result of the survey showed that for the technical level of interoperability, information sharing and presentation between the different actors occurs both through EDI, XML and web-services and only three companies marked the alternative that they use international standards when doing so. The interviews confirmed the diversity in different technologies used for information sharing. A majority of the companies also mentioned that regular e-mails, letters, fax and telephone were common means of communication, especially for communication with customers and suppliers who did not use the same IT-systems.

To analyze the semantic level of interoperability in the studied supply chain, the companies were asked if they used the same IT system when storing incoming data or if they store it on a different system than the one it was received through. Out of the companies that answered this question, about 80 % said that that they have separate systems. Regarding the organizational level of interoperability, the companies were asked about the integration of the information sharing. Here, many of the respondents said that the information sharing is automatic through integrated information systems although the results show that the majority of the companies also share information manually. Lastly, for the legal level of interoperability, the companies were asked about the agreements and policies concerning information sharing. All companies in the case studied reported that they have legal agreements and guidelines regarding information sharing.

4.5 Information sharing in the pharmaceutical supply chain

In the case study the companies were asked about what information attributes they shared with the other members in the supply chain and what information attributes they documented in their systems. In the survey they were asked to report these attributes and in the follow-up interview the subject was brought up again. The survey also dealt with the methods for information sharing. The result from the survey and interviews regarding the information attributes and the methods for sharing them are presented in this section.

4.5.1 Attributes shared between Smedpack3 members

Based on the survey, the interviews and internal documents, a number of attributes has been identified to be shared between the members in the supply chain, see table 15.

Table 15. Attributes shared between members in the pharmaceutical supply chain

Attributes	Information shared by producers	Information shared by transporters	Information shared by distributors	Information shared by pharmacies
Batch-number (non-standardized)	X		X	
Batch-number (standardized)	X		X	
Product number (non-standardized)	X		X	
Product number (standardized)	X		X	X
Name of the product	X		X	X
Scientific name of the product	X			
Best- before date	X		X	
Quantity	X	X	X	X
Geographical origin	X			
Net weight	X	X		
Name of the seller	X			
Storage directions	X		X	
Delivery address	X	X	X	
Time of delivery	X		X	
Consignor's address	X	X	X	X
Address of the warehouse that the product is delivered from	X	X	X	
Release certificate/COC	X			
Dangerous goods warning	X			

What can be seen from the survey results and interviews but not in this table is that all people representing the same company group (i.e. manufacturing companies, distributors, transporters or pharmacies) did not mention the same information attributes. As can be seen in table 15, producers are the ones who share the most information attributes, which the other actors did not seem to forward. For instance only the producers share information about geographical origin of the product. When it comes to the batch number, the result from the survey reveals that both standardized and non-standardized batch-numbers are used in the supply chain. According to the interviews the batch-number was considered the most important attribute for tracing products when needed.

The transporters said that they only handle four information attributes; number of load carriers, the address of the consignor, address of delivery and weight. This is the only information they need. They are according to the companies in the case study not supposed to know anything about the content of the pallets, for security reasons.

It is only the producer that shares the release certificate/COC, which the distributor uses to verify that the products are authentic. The pharmacy does not verify that the product is genuine but instead presupposes that all medicines which are received from a distributor approved by the MPA are genuine.

In addition to the attributes in table 15 above, there are a number of other attributes on the bill of lading and packing slips that are not included above such as price, shelf from which the product is picked from and order number. These are all attributes that are not required by the MPA to share but are necessary for practical reasons for the companies involved.

4.5.2 Attributes documented by the Smedpack3 members

During the interview with one of the producers, the documentation of information was brought up. It was not possible for the interviewee to mention a certain amount of information that they record but the interviewee could confirm that they follow the guidelines of the MPA, see 2.4.2 *Regulatory requirement on documentation in the pharmaceutical supply chain*. The person interviewed also mentioned that they have a high level of trust in the MPA and does not think that any of the attributes that they have to share and document are unnecessary. They are confident that MPA's recommendations are what is best for the industry.

According to one of the transporters in the study, there are generally no requirements to document traceability data. Despite this they save data on colli level for 2 years but the data that the customer transfers to them such as weight and number of colli, is only available in their system for three months.

One of the distributors in the supply chain reported that the information they register in their system is the arrival- and delivery date, the supplier's customer number, article number (which includes name, preparation form, strength, size and measurements of packages), number of packages, batch number and expiry date. It was also mentioned that there is today no requirement of machine readability for the packages so there is no standard.

Even though the distributors forward several information attributes, one of the pharmacies stated that the only information they really need to register in their IT-system for incoming medicine are the information from the barcode, the product number, the batch number and the best-before date.

When the companies were asked which the most important attribute to record for the purpose of traceability were, the batch number was brought up by the majority of the companies. It was observed in the case study that each company documents the information only in their own IT systems and no common database for sharing information among the companies exists.

4.5.3 Methods for information sharing between the companies

When it comes to the methods for sharing information, 75 % of the companies say that they still use physical paper documents when sharing information. For most of these companies this is complemented by both internet based web services and digital documents. The information is registered to the largest part manually or with the help from bar codes. 87 % of the respondents specify that they register the information manually, sometimes complemented with the use of barcodes and EDI. This number should however be carefully considered since an explanation of “manually” was not given to the respondents and the question could have been interpreted differently among different persons. Another common way of registering information in the supply chain is through an EDI system. When looking at physical bills of lading and delivery orders one can see that parts of the information are written by hand. Data matrix codes and RFID codes do not seem to be used at all, based on the survey results.

4.6 Summary of empirical findings

In the case study, a few findings were of special interest for further analysis. This summary aims to highlight these areas. When mapping the supply chain it was found that the companies send documents both physically and electronically. There are also a variety of methods and standards used for exchanging information. The methods ranged from e-mails, telephone, EDI, web services and fax. Many of the companies also reported that they have separate IT systems for information registration.

The most important verification tool to ensure that only genuine pharmaceutical products reach the Swedish market is the COA/COC. These documents are however not forwarded from the distributor to the pharmacy. The pharmacies instead rely on that all products coming from authorized distributors are genuine. According to the companies in the case study, the batch number is the most important attribute to ensure traceability. There is no standard data carrier that all actors in the supply chain use for all products. One dimensional bar codes are however the most common one. The bar codes do however not include the batch number or unique identification.

The companies in the case study think that the consumers’ lack of awareness is one of the most likely reasons for counterfeit medicine to enter the Swedish pharmaceutical market. They also believe that illegal websites with false advertising is a possible reason.

Lastly, an important finding was that no companies expressed negative opinions of the MPA. In contrast, some companies expressed high trust in the MPA.

5. RESULTS AND ANALYSIS

To be able to fulfil the purpose of the thesis, to present a framework to ensure safety of pharmaceutical products in legal medical supply chains and to identify voluntary and mandatory information attributes, an analysis of the empirical data compared with the frame of reference has been conducted. The traceability and interoperability is in this chapter evaluated and the legal requirements on information sharing and documentation are compared with industrial praxis. The pharmaceutical industry and the food industry are compared, to analyze if features in previously published food traceability frameworks could be applicable also in the pharmaceutical industry. Lastly, a framework to ensure safety of prescribed medicinal products in legal pharmaceutical supply chains is presented.

5.1 Evaluation of traceability and interoperability in the studied supply chain

The map of the supply chain was made to be able understand the physical flow of products and the flow of information between manufacturing companies, transporters, distributors and pharmacies. Even if the visualization of these flows was a goal in itself, a few findings during the case study can be used to analyze the external traceability and the interoperability in the studied supply chain.

5.1.1 External traceability

The tracking and tracing in the studied supply chain can be analyzed by discussing the eight attributes which can classify traceability systems according to Stefansson and Tilanus (2001). The first attribute is the technology used for identification. In the studied supply chain, it has been seen that the main identification system used today are barcodes even if not all products have this technology of identification. With the current system it is not possible to track and trace each individual package. During the time writing this thesis much work is however conducted to enable traceability of individual pharmaceutical consumer units since the EU directive 2011/62/EU is planned to be introduced in 2017. The ability to uniquely identify products on a consumer item level, compared to on a batch level, would increase the chances of discovering counterfeit medicine in Europe since this enables verification of unique products' authenticity before products reach end consumers.

The second attribute that can classify a tracking and tracing system according to Stefansson and Tilanus (2001) is the scope of the tracking and tracing system. The scope is in turn determined by the three dimensions of transformation; transportation, storage and conversion processes through the supply chain. Depending on if it is the internal or the external traceability that is investigated, the analysis will focus on different transformations. Internal traceability requires in-depth analysis of internal processes. Since this thesis only examines the external traceability, only the transformations during the physical flow between the supply chain actors are analyzed. Therefore, it is only the transformation of place that is analyzed. Literature has shown that the complexity in pharmaceutical supply chains is high, why there are many linkages between different actors in the supply network that require transportation of goods. Each of the transportations is a transformation of place that generates new information that needs to be recorded in the tracking and tracing system. It can therefore be stated that the many

transportations in the pharmaceutical supply network set high demands on data recording on the tracking and tracing system to enable efficient traceability.

The third attribute is the registration timing and placing of the packages during its way between the supply chain actors. There is not a common system for registering the products but it is instead up to each company to register the products in their system and document the information attributes mentioned in section 2.4.2. *Regulatory requirement on documentation in the pharmaceutical supply chain*. Information is thus captured repeatedly in non-integrated systems, which according to Chircu et al. (2014) enhances the risk of errors and therefore reduces the consumer safety.

The fourth attribute concerns the hierarchical level of packages registered in the supply chain. The case study showed that there are many different types of hierarchical levels of packages used when shipping goods in the supply chain; containers, pallets, boxes, big boxes, barrels, plastic boxes and consumer units, see section 4.3. *Hierarchical packaging levels in the pharmaceutical supply chain*. When one hierarchical level is broken down to a new hierarchical level a transformation occurs. Each transformation generates data that needs to be recorded to assure traceability. Therefore, the more hierarchical packaging transformations in the supply chain, the more data needs to be registered in the systems.

The fifth attribute described by Stefansson and Tilanus (2001) concerns the attributes recorded in the tracking and tracing system. In the Swedish pharmaceutical supply chain there is not a standardized system with predetermined information attributes that should be recorded for each supply chain actor. There are however some attributes that according to the MPA's regulation should be documented in each actor's system, see section 2.4.2 *Regulatory requirement on documentation in the pharmaceutical supply chain*. Several attributes are in the current pharmaceutical supply chain recorded. The more attributes that needs to be documented, the more advanced the system needs to be. Therefore, it is of importance to make sure that the tracking and tracing system enables all the mandatory attributes can be recorded.

The sixth attribute is the organization of information system. Since many actors in the pharmaceutical supply chain today document information in their respective internal information systems, it can be stated that the information records today are spread in a decentralized system. Neither actors in the supply chain nor external stakeholder has the complete picture of the information related to the products currently flowing in the supply chain. The fact that the information is stored in separate systems makes the traceability less efficient, since the information visibility is low. When tracking and tracing in the current system it is required to ask each actor for the information wanted. By having a centralized system the visibility is increased why the process of tracking and tracing could be made more efficiently. But since high visibility usually requires sharing sensitive data, the attributes being shared should be carefully reviewed so that all companies feel comfortable with the system.

The seventh attribute that can define the tracking and tracing system is the accessibility of the information system. The case study showed that both manual and electronic methods are used for sharing information among the actors. During interviews it however appeared that if there were deviations between ordered and delivered goods at the pharmacies, these deviations were

reported manually to the distributor. This shows that the accessibility of information is non-automated. An exception from this is that some producers that deliver products to the distributors can log in through a web application and retrieve information about their stock levels at the distributor's site. This example shows that parts of the system allow for automatic accessibility of information.

The final and eighth attribute is the activity level of the tracking and tracing system. The case study showed that the current tracking and tracing system in the Swedish pharmaceutical supply chain is passive, since there is no systematic comparison between the current and the planned status of the products. During the interviews none of the company representatives mentioned that they had an active tracking and tracing system.

To conclude, efficient tracking and tracing sets high demands on the traceability system. The evaluation above, using Stefansson and Tilanus (2001) eight attributes, shows that the current system has the potential to be more efficient. This could be done for example by giving the product a unique identification and by increasing the information visibility with a centralized database.

5.1.2 Interoperability

The framework of Ringsberg (2015a) can be used to analyze the interoperability in a supply chain. This framework is recommended by the European Commission and highlights four levels that determine the interoperability.

The first level is technical interoperability. From the survey results it was seen that the companies in the studied pharmaceutical supply chain are using different means of technology for communicating with each other such as EDI, web services, fax, e-mail and telephone. The diversity in the different technologies used obstructs having same technical specifications when sharing information, which therefore also obstructs the technical interoperability. If same technical specifications for sharing information could be obtained, the interoperability could be enhanced. It can therefore be concluded that there are potential for improvements regarding the technical level of interoperability among the studied companies.

Semantic interoperability is the second level. According to literature the semantic interoperability refers to the importance of information structure principles when sharing information between companies. In the survey the companies were asked whether they use the same IT system when storing incoming information or if they store it on a different system than the one it was received through. The results showed that majority of the companies that answered this question in the survey have separate IT systems for storing incoming data. The information structure impacts the ability to trace products and information. The fact that most companies store incoming data on separate IT systems impedes the semantic interoperability. It can therefore be concluded that there are potential for improving the interoperability also for this level.

The third level, the organizational interoperability, refers to the collaboration between different companies regarding integration of, and information sharing between, different business processes. The results from the case study showed that integrated systems did occur in the

pharmaceutical supply chain, but half of the respondents said that they also share information manually in compliance with agreements. It is not stated which and how much information that is shared manually compared to automatically.

The last level, the legal interoperability, concerns among other things the legislation regarding information protection. To analyze this level, all companies were in the case study asked if they had agreements and policies concerning information sharing. All companies reported that they have legal agreements and guidelines for information sharing, why the interoperability for this level is judged to be high. It could be of interest to examine how these agreements and guidelines are constructed at the different companies in order to confirm the level of legal interoperability.

Based on questions asked about all four levels, it seems as if the interoperability has the potential to be improved. It can be questioned what degree of interoperability that is desirable. Higher interoperability requires increased visibility but there is usually resistance among companies to share sensitive information. An interesting finding from the case study however is the positive attitude among the respondents. In total 83 % thought that better cooperation between the companies would be positive for the economy because of more standardized procedures and cooperation, which could indicate that the companies are willing to increase the current interoperability. Ford et al. (2010) also argues that high interoperability is becoming more important as relationships in supply chains goes from arm's length to partnerships.

5.2 Comparison between legal, industrial and end consumer requirements on information sharing

In this section research question two concerning information attributes is answered. First, the legal requirements on information sharing and documentation is compared with the information attributes currently shared in the industry. This is followed by an analysis concerning end consumers' preferences on what attributes pharmaceutical products should be labeled with.

5.2.1 Comparison between legal requirements and industrial praxis regarding information sharing

In the survey the company representatives were asked which information attributes that they share. The information attributes which are legally required to label are here compared with the ones that the companies in the industry report that they are sharing. The mandatory information attributes has been defined as the legally required attributes to label and are marked with bold text in table 16 on the next page.

Table 16. Attributes shared by the actors according to the survey. The attributes that are legally required to label are marked in bold

Attributes	Information shared by producers	Information shared by transporters	Information shared by distributors	Information shared by pharmacies
Batch-number (non-standardized)	X		X	
Batch-number (standardized)	X		X	
Product number (non-standardized)	X		X	
Product number (standardized)	X		X	X
Name of the product	X		X	X
Scientific name of the product	X			
Best- before date	X		X	
Quantity	X	X	X	X
Geographical origin	X			
Net weight	X	X		
Name of the seller	X			
Storage directions	X		X	
Delivery address	X	X	X	
Time of delivery	X		X	
Consignor's address	X	X	X	X
Address of the warehouse that the product is delivered from	X	X	X	
Release certificate/ COC	X			

Most of the mandatory attributes are labeled by the producer and forwarded physically through the supply chain. In addition, the pharmacies add mandatory information on the medicine dispensing label. The attributes shared that are not legally required, and therefore voluntary, are mainly related to the transportation, such as addresses for pick-up and delivery, delivery time etc.

The survey showed that the producer was the actor that shared the most information and as stated in the empirical findings, they share information that the following actors in their turn do not forward. An example of that is the geographical origin which is a voluntary attribute.

Attributes like these should either be considered mandatory and be forwarded all the way to the customer, or it should be excluded since too much information decreases the level of control. The release certificate was mentioned in the empirical findings and the fact that it is only shared between the producer and the distributor. The release certificate is an important part of making sure that the products are made according to the legal requirements. The fact that the pharmacies trust that all the products coming from the approved distributors are genuine can however be considered as a risk in this context, since they cannot verify the genuineness of the products. The transportation is mentioned in the Smedpack final report (Smedpack, 2014a) as a potential risk for counterfeiters to bring fake medicine into the supply chain. The survey also showed that the companies rate the risk of insufficient security during transportation to be of importance. This could imply that an approved medicine could on its way from the distributor to the pharmacy be swapped for a counterfeit medicine and the pharmacy might not notice since they have no function in place to verify the genuineness of the products. The transporter is in the pharmaceutical supply chain a blind actor since they, for security reasons, should not know what are in the load carriers that they transport. The only attributes that they need, to be able to transport their customer's goods, are voluntary attributes related to transportation. Even though these are not regarded mandatory for ensuring traceability for pharmaceutical products they are still needed in the supply chain. When reviewing the attributes found on the delivery orders and bills of lading more attributes than the ones reported to be shared by the companies were found. One example of such an attribute is the storage place from which the products are picked. These can also be regarded as voluntary.

None of the companies expressed negative attitudes towards the provisions provided by the MPA. Some companies instead emphasized their trust in MPA and do not think that any of the legally required information attributes that are mentioned in section 2.4 *Requirements on information sharing and traceability within the Swedish legal medical supply chain* are unnecessary. On the other hand, the literature review revealed that managers often argue that more information shared the better. Too much information can however reduce the degree of control. The information shared in the supply chain should therefore be limited to the amount of information that is absolutely necessary. One of the pharmacies also mentioned that there is a continuous dialogue between the supply chain actors and the authorities, which indicates that supply chain actors to some extent can influence decisions made by the MPA. It can be concluded that the pharmaceutical industry and the authorities in Sweden are quite harmonized.

5.2.2 Comparison between legal requirements and industrial praxis regarding documentation

For documentation of information, it was seen that the information that is registered for incoming goods for distributors and pharmacies are almost the same as the legal requirement, see table 17. The legally required attributes to document are considered mandatory to ensure safety of medical products.

Table 17. Attributes documented by the actors. The attributes that are legally required to document are marked in bold

Attributes	Information shared by producers	Information shared by distributors	Information shared by pharmacies
Specifications and test methods	X		
Production methods	X		
Instructions for manufacturing and packaging	X		
Protocol from the manufacturing process	X		
Date of arrival		X	X
Date of delivery		X	
Supplier's customer number		x	
Article number		x	
Number of packages		X	X
Batch number		X	x
The size of the packages		X	X
The name of the medicine		X	X
Preparation form and strength		X	X
Best before date		x	x
The seller's name and address		X	X
The buyer's name and address		X	
Information on if the medicine is approved to be sold on the market		X	
A signed certificate to verify that the batch is released within the EES		X	
Measures taken when having deficiencies and withdrawals or products			X

The producers interviewed did not specifically mention the attributes that they document but they said that they follow the regulations by the MPA and support them. Therefore the mandatory attributes to document are marked with bold with no additional voluntary attributes.

Regarding the distributor, they document all the mandatory attributes but also three voluntary attributes; the supplier's customer number, the article number and the best before date. The pharmacies also follow the legal requirements and add two voluntary attributes, the batch number and the best before date.

The transporter is not represented in the table since this actor has no legal requirements on documentation of pharmaceutical products. They do not document the content of the load carriers since they are a blind actor in the pharmaceutical supply chain. This is considered good since if they did, it could be a risk for employees selling their inside information. The lack of documentation can however be a hinder for the purpose of tracking and tracing purpose.

In summary, the actors in the Swedish pharmaceutical industry are quite aligned with the regulations provided by the MPA. The case study showed that there are not many voluntary attributes added by the actors when it comes to documentation which is good from a traceability perspective since too many attributes can decrease the level of control.

5.2.3 Consumer preferences

The second research question did not only concern the legal requirements on information sharing and the industrial praxis, the consumer preferences were also mentioned to be of importance. In the frame of reference, the consumer preferences regarding the information attributes for the medicinal packaging to be labeled with was brought up. A study made by Ringsberg and Urciuoli (2015) showed that there were no information attributes considered significantly important for the consumers. It should be remembered however that the research was made for studying non-prescribed medicine and the result could be different for prescribed medicine where the consumers might be more interested in for example the scientific name and the geographical origin. Since no such research has been made, this perspective has not been taken into consideration when developing the framework for ensuring safety of medicinal products in the Swedish legal pharmaceutical supply chains.

The case study showed that the companies in Smedpack3 believe that the most likely reasons for counterfeit medicine to enter the Swedish supply chain is the lack of knowledge among the consumers when purchasing products online, see table 13 in the empirical findings. Another risk that was rated high among the companies was the false advertising among online-based companies. These results highlight the importance of increasing consumer awareness about risks with purchasing pharmaceuticals since they can be counterfeited. This is supported by the fact that 62 % of all medicines sold online are illegal or of inferior quality and 96 % of all online pharmacies are illegal (Flodman Engblom, 2011). In addition, a recent study conducted by the MPA show that one out of five consumers are willing to buy prescribed medicines on the internet without a prescription of a doctor (Läkemedelsverket, 2015b).

5.3 A framework for ensuring safety and quality of medical products

The purpose of this thesis is to develop a framework for ensuring safety of products in Swedish legal pharmaceutical supply chains. Ensuring safety of products is of importance not only in the pharmaceutical industry but also in many other industries. No frameworks regarding traceability for prescribed pharmaceutical products have been found in published material. However, research regarding safety and quality of products has for example been conducted in the food industry (Storøy et al., 2013; Salampasis et al., 2012; Pizzuti et al., 2014; Regattieri et al., 2007). Such research claims that safety and quality of food products can be enhanced by increasing traceability in food supply chains. To obtain the desired level of traceability different types of food traceability frameworks has been developed. Examples of such frameworks were presented in 2.5.2 *Traceability frameworks for product traceability in the food industry*. As stated in section 5.1 *Evaluation of traceability and interoperability in the studied supply chain*, the current traceability among the studied companies in the pharmaceutical supply chain has potential to be improved. By improving the traceability in the pharmaceutical supply chain the safety of products in the industry can be enhanced. A traceability framework adapted for pharmaceutical supply chains is therefore required.

A comparison of the food industry and the pharmaceutical industry is provided in the next section. By evaluating similarities and differences between the two industries it can be seen that the research related to traceability conducted in the food industry can be applicable also to the pharmaceutical industry. The comparison is followed by a discussion of what components from the food traceability frameworks that are judged to be relevant also for the pharmaceutical supply chain in order to increase the traceability.

5.3.1 Comparison between the food industry and the pharmaceutical industry

In table 18, the food industry and the pharmaceutical industry is compared. Table 18 describes general characteristics of the two compared industries, why it is of importance to emphasize that the information is not applicable for all products and supply chains in these industries.

Table 18. Comparison between the food industry and the pharmaceutical industry

Characteristics	Food industry	Pharmaceutical industry
Supply chain actors	Raw ingredient producer, manufacturers, transporters, wholesalers and final retailers	Raw material producer, manufacturers, transporters, wholesalers and final retailers/hospitals
Market regulation	High	High
Safety threat	Contaminated food products entering supply chains	Counterfeit pharmaceutical products entering legal supply chains
Information sharing among supply chain actors	Information and knowledge is spread in different formats	Information and knowledge is spread in different formats

Source: Pizzuti et al., 2014; ECORYS, 2009; Heyder et al., 2012; Bhatt and Zhang, 2013; WHO, 2015; Shah, 2004.

As can be seen in table 18 on the previous page, the main actors in the food supply chain and the pharmaceutical supply chain are almost identical. It can be concluded that there are many types of actors with different responsibilities involved in the product distribution in both industries. The two studied industries both struggles with enormous safety threats which are important reasons for the high regulations. In the food industry a great safety problem is contaminated food products entering legal food supply chains. A big safety problem in the pharmaceutical industry is the counterfeit medicines. Both contaminated food products and counterfeit medicines could have devastating effects if reaching out to the end consumers, why the work with ensuring safety and quality of products has a high priority in both industries. Both industries also need to be prepared for reducing the negative effects if counterfeit/contaminated products enter legal supply chains, by having the ability to recall products at any point during the product life cycle. Traceability is therefore a central issue in both industries. The fact that the information shared between the different supply chain actors in both industries are spread in different formats however obstructs the traceability. Much research has been conducted on how to enhance traceability in the food industry, which has led to that several frameworks have been developed for increasing food product traceability. By proving that the industries have similar characteristics it can be concluded that certain research made within the food supply chain traceability can be applicable also to the pharmaceutical supply chain.

5.3.2 Components from the previously published frameworks identified to be relevant for the studied supply chain

Based on published frameworks for traceability within the food industry and the empirical data gathered about the pharmaceutical industry during the case study, the following concepts have been identified as relevant areas for development in the pharmaceutical industry; (1) unique identification, (2) standardized data carriers, (3) standardized communication and (4) guidelines regarding what attributes to share. These will be the core components of the framework TracePharma, developed by the authors for increasing pharmaceutical product traceability. Motivation and recommendation to each of the four components are found in the following sections.

1. Unique Identification

The case study showed that each batch of pharmaceutical products today are labeled with a unique batch number. To verify genuineness and quality of products COC/COA are issued by the manufacturing company for each batch. The COC/COA documents are always sent to the distributor as a quality verification. The case study however showed that the COC/COA were not sent to the pharmacies. Pharmacies instead relied on the verification made at the distributor stage in the supply chain. Therefore no verification of genuineness is performed from the point in the supply chain where the products leave the distributor. As can be read in section 4.2.1 *Identified ways for counterfeit pharmaceutical products to enter the supply chain* counterfeit medicines could enter legal supply chains at different stages in the supply chain. If counterfeit products enter the legal supply chain after products leave the distributor no specific efforts to prove genuineness are performed, which imply a safety deficiency in pharmaceutical supply chains.

As mentioned in the frame of reference the work with developing a unique identification system according to the Directive 2011/62/EU has already started. By implementing a unique identification of each product distributed and sold in Europe it would be possible to verify the genuineness of a unique product before dispensing the product to end consumers, thus eliminating the identified safety issue explained above. By enabling verification checks at any point in the supply chain, including the pharmacies, the risk of counterfeiting products reaching out to end consumers could be reduced.

The empirical data showed what risks company representatives regarded as most likely to occur and result in counterfeit products reaching out to end consumer. As can be seen in table 13, company representatives judged insufficient security during transportation to be a likely reason (2.6 on a scale between 1-4) for counterfeit medicines to enter legal pharmaceutical supply chains. Transporters are a blind actor in the supply chain since as little information as possible is shared with them. Due to safety reasons the transporter should not know the content of the transport. Still the results indicate that supply chain actors believe that the security during transportation is too low. Unique identification of individual products would however enable for safety verification of products after the transport is performed. This implies that the risk for counterfeit medicines entering due to insufficient security during transport could be reduced.

Table 13 also shows that the company representatives ranked insufficient labeling of products as a likely reason (2.7 on a scale between 1-4) for enabling counterfeit medicines to reach out to end consumers. This result can be interpreted as supply chain actors believing that the current labeling system is insufficient to ensure end consumer safety, which further motivates introduction of unique product identification.

Unique identification of individual products can for example be achieved by labeling each product with the numbering system SGTIN developed by GS1. SGTIN consists of a global trade item number and a serial number.

Research for enhancing traceability in food supply chains also emphasizes the importance of unique identification to enhance traceability. Salamphasis et al. (2012) and Regattieri et al. (2007) include unique identification of traceable resource units in their frameworks for food traceability. Storøy et al. (2013) also includes unique identification in their traceability framework FoodTrace. The unique identification number should enable retrieving information about a particular product during its life cycle which would facilitate traceability. Since many authors have pointed out unique identification of products as fundamental for an efficient traceability system in the food industry this is regarded as important also for the pharmaceutical industry since these two industries have many similarities.

2. Standardized data carrier

In section 2.5.2 *Traceability frameworks for product traceability in the food industry*, the importance of a commonly agreed, standardized way of sharing information is highlighted. Storøy (2013) states that lack of standardization in product identification is one of the greatest obstacles when implementing a traceability system in food supply chains. This concept is therefore considered relevant in the pharmaceutical industry as well because of the similarities regarding for instance safety threats and actors involved, see comparison in 5.3.1 *Comparison*

between the food industry and the pharmaceutical industry. According to the empirical data, there is no common technology for identifying the pharmaceutical products, why this is an area for improvement.

The identification system has been discussed at EU level and the identification technology currently recommended by different organization is a 2D code. The benefits with using a 2D code are that it can store more information than a barcode, it can be read even if parts of the code is damaged and it is cheaper than using an RFID system. It also gives the opportunity for the product to be labeled with a unique identification which, as mentioned in the previous section, is also recommended for products in a pharmaceutical supply chain.

RFID systems also have many benefits. It can, compared to barcodes, store large amount of data and several product tags can be read simultaneously. Despite such appealing opportunities, implementation is expensive. Due to the cost perspective, RFID does not seem to be a realistic option in the Swedish pharmaceutical industry today. Wyld (2008) however believe that RFID is the future data carrier in the pharmaceutical industry.

No matter which data carrier is used, it needs to be standardized to increase the security and efficiency in the supply chain. According to Ebel et al. (2012) a globally accepted standard can decrease the risk of counterfeit drugs reaching the end consumer since serial numbers can be used to discover duplicative and fake serial numbers. Having one global standard will also decrease the cost compared to having two or more. The GS1 Data Matrix is a good alternative for a data carrier since it is developed for the pharmaceutical industry and contains mainly four attributes: the product code of the producer (GTIN), the expiry date, the batch number and the unique serial number. It was confirmed in the case study that the batch number is an important attribute to ensure traceability however both standardized and non-standardized batch numbers are currently used. By introducing a standardized data carrier with a standardized way to represent batch numbers, the traceability can be improved, since all members in the supply chain are using the same system.

3. Standardized communication

In section 4.1.2 *Process map of the Swedish legal pharmaceutical supply chain* the information flow between the interviewed actors in the Swedish pharmaceutical supply chain is shown. In this map it is shown that information flows today comprise both physical paper documents but also electronic messages. One interviewee claimed that EDI system integration between them and their suppliers is becoming more and more common. Another interviewee explained that their company strived to eliminate all physical documents in their information flow since electronic information flows reduced the amount of quality problems. Currently information sharing methods range from web service and EDI to telephone, fax and e-mails. This is verified by the results from the survey where it could be seen that various methods are used for information sharing. This is also confirmed in the frame of reference by Chircu (2014) who states that information flows in the pharmaceutical supply chain is often fragmented.

The exchange of information is according to Storøy et al. (2013) a big challenge in the implementation of supply chain traceability. If there is a lack of standardization, the handling of data is both costly and time consuming. This problem was also mentioned by the participants

in the case study. One of the interviewees was not worried that the use of different systems was a security threat but the same person stated that it would be more efficient if everyone in the supply chain used the same technique for sharing information. At the same time the interviewee said that it is not easy for them to change systems overnight, since EDI is widely used in the pharmaceutical industry and new systems are sometimes dependent on information from these EDI systems. Storøy et al. (2013) claim, that the use of manual means for data exchange such as e-mail and fax are inefficient and the fact that the data needs to be recorded several times at different actors in the supply chain, errors are more likely to occur. Bechini et al. (2005) found the same problem in food supply chains and claims that diversity in systems among food supply chain actors obstructs integration. To enable efficient information sharing and thus increased traceability, Salampasis et al. (2012) state that data and the way they are organized must be standardized. Furthermore, the data meaning and carrying semantics need to be agreed on. The fact that manual means for communication is common in the pharmaceutical industry and the fragmented use of different techniques, shows that the information sharing could be improved by using a standardized way of communicating.

Since previous research shows that it is more efficient if the actors in the food supply chain have a standardized way of exchanging files (Storøy et al., 2013; Salampasis et al., 2012) this is likely to be the case for the pharmaceutical industry as well. The case study also showed that the majority of the respondents in the survey thought that if a closer cooperation between the actors in the Swedish medical supply chain could be achieved it would have a positive economic effect because of more efficient administration with standardized procedures and cooperation. In addition, one of the representatives of a pharmacy mentioned that a more integrated system with their distributor could increase the efficiency since they would have more information about stock levels etc.

Based on the research that shows the potential of increasing the efficiency by having a standardized way of exchanging files and the positivism among the companies, two things should be highlighted. Firstly, setting up a standardized way of communicating in the supply chain requires large investments however the above reasoning shows the potential to get a return on the investments. The second thing is that when implementing TraceFood there were organizational obstacles such as lack of motivation and cost aspects that made the implementation fail. These obstacles seems, when looking at the result from the survey, be less present in the Swedish pharmaceutical supply chain. The positive attitude among the pharmaceutical supply chain companies increases the potential for a successful implementation of TracePharma.

The case study also showed that many of the companies use EDI when placing orders but the system is not always used for confirming orders and to receive confirmations that the goods have been transported according to the plans. This is either not done or it is done using a different IT system. Supported by the fact that manual handling of orders are likely to increase errors, a standardized way of exchanging data in the supply chain should be introduced to avoid such errors. In this way, the traceability can be improved. Since EDI is complex, requires IT competency and involves large investments the use of XML as a way of describing the exchanged data is recommended. By using XML based web services to a larger extent, the

companies that are currently using EDI can continue to do so because of the flexibility of XML (Jonsson & Mattson, 2011). This flexibility can enable a common standard for information exchange since XML is a standard that is independent of hardware and platform.

Salampasis et al. (2012) developed an ontology-based application framework to support knowledge representation and information modelling in food traceability frameworks. The importance of using an ontology in the food industry has also been emphasized by Pizzuti et al. (2014) who argues that information and the way it is organized should be standardized and conceptualized to enable to trace the cause to a foodborne outbreak disease. Therefore Pizzuti et al. (2014) developed an ontology adapted to the food industry. Ontologies can also facilitate integration of heterogeneous databases resulting in increased interoperability between the information systems used. An ontology is regarded as important for creating a universal understanding of data concepts and increasing interoperability also in the pharmaceutical industry. Ensuring that all actors in the supply chain interpret data in the same way is fundamental for efficient collaboration. The concepts defined by the ontology can then efficiently be connected to traceable products for documenting relevant information about the product life cycle. When developing the pharmaceutical ontology Fernández et al. (1997) general steps could be used. Both Pizzuti et al. (2014) and Salampasis et al. (2012) recommends the use of standard language in the semantic web OWL, web ontology language, when describing ontologies. This language could be considered also for describing the ontology for the pharmaceutical supply chain.

4. Guidelines regarding what attributes to share

According to Folinas et al. (2006) there should be rules in a traceability system defining which data should be recorded at different parts of the supply chain. The efficiency of a traceability system is dependent on the ability for the system to document safety and quality related information. Folinas et al. (2006) further emphasizes the importance of identifying the information attributes to collect for ensuring traceability. Two of the components of the food traceability framework of Storøy et al. (2013) is related to this. The authors recommend a list of information attributes to be recorded for all the food products and in addition to this a standardized list for each individual product. This information should be identified and recorded at each stage in the supply chain.

Folinas et al. (2006) differs between mandatory and optional traceability data where mandatory data is to be documented and communicated by all members of the supply chain. The optional data is still necessary since it is useful for the actors but it is not fundamental in the establishment of an efficient traceability system.

The case study conducted in the Swedish pharmaceutical industry included reviewing which information attributes that the Swedish law demands the different supply chain actors to label the products with and document in their databases. These attributes were defined as mandatory for the purpose of traceability. These attributes were compared with the attributes that the actors in the Swedish pharmaceutical industry are sharing and documenting in practice. It was seen that the industry are following the directives of the authorities and are not dissatisfied with the current regulation. It turned out that the voluntary attributes that they share are mainly related

to transportation. These attributes are important to enable transportation in the supply chain but are not necessary to ensure efficient traceability.

TracePharma recommends a similar suggestion as Storøy et al. (2013). For each actor in the supply chain there should be a predetermined amount of mandatory attributes. These should be documented in a standardized way so that it is easy to trace products if they for example need to be withdrawn from the market. The voluntary attributes are also important from a practical perspective, for example for performing transportations, but not from a tracking and tracing perspective. It is important to limit the list to the necessary attributes since too much information decreases the level of control. In addition, it is mentioned in the frame of reference that the data from the information attributes to be recorded in a system increases with more hierarchical levels. Since it has been observed in the case study that the pharmaceutical supply chain uses several hierarchical levels this is another reason to limit the amount of attributes in the standardized predetermined list to limit excessive data.

It is of importance to emphasize that the mandatory and voluntary information attributes can be changed over time for example due to changes in regulation. The system for documentation therefore has to be flexible to be able to adjust to these changes.

5.3.3 The TracePharma Framework

By reviewing three traceability frameworks and one ontology model developed for the food industry, four components were identified to be relevant also for the pharmaceutical industry, see section 5.3.2 *Components from the previously published frameworks identified to be relevant for the studied supply chain*. These are presented in the traceability framework TracePharma, see figure 11.

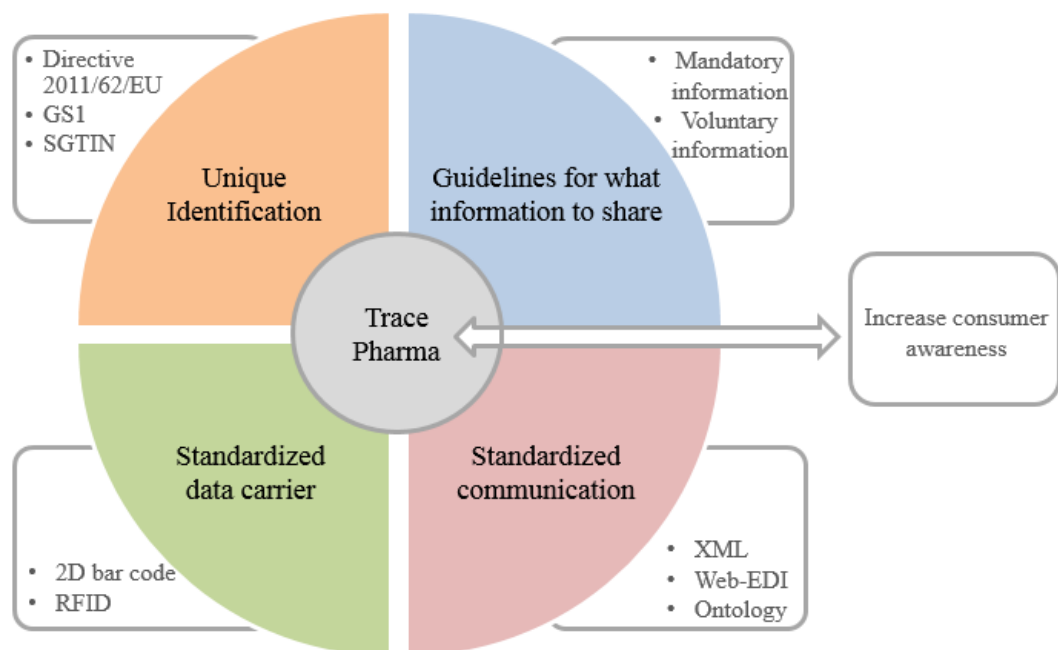


Figure 11. TracePharma visualizes important areas of improvement for enhancing safety of pharmaceutical products

The unique identification should be a mandatory attribute since it is considered one of the most important attributes to ensure traceability. The predetermined mandatory attributes should as stated in the previous section be the ones currently regulated by the MPA for pharmaceutical products to be labeled with and documented. The reason for this is that they are relevant for traceability purpose and are currently also the attributes being shared by the companies, with the exception of voluntary attributes related to transportation which are also shared in practice. The mandatory attributes could for example be stored in a central database to easier recall products suspected to be counterfeit. Before implementing such a system with predetermined attributes, the list of attributes should be carefully reviewed since some attributes stated as mandatory are more important for ensuring traceability than others. For the purpose of traceability, the batch number is for example more important than the quantity recommended. To ensure efficient and correct data exchange the data carriers used in the supply chain should be standardized. RFID is the most advanced alternative although it is currently not realistic from a cost perspective. The 2D barcode is a good alternative since it can store much information and is also cheaper compared to RFID. GS1 has developed a 2D barcode for the healthcare industry, which could be considered by the Swedish pharmaceutical industry. Furthermore, it is recommended to have a standardized way of communicating between the companies why a common ontology for the pharmaceutical supply chain should be developed. There should also be a standardized way of exchanging this data where web services and XML are flexible options.

If all actors in the pharmaceutical supply chain works with each of these components a higher level of traceability can be obtained. The traceability will also be more efficient than today why it will be easier and faster to withdraw products from the market. A unique identification will also make it more difficult for counterfeiters to reach out with counterfeit products to consumers.

It should be remembered however that the most common way for counterfeit medicine to enter the Swedish legal pharmaceutical supply chain today is consumers purchasing counterfeit medicine from illegal web pages. No matter how good the traceability system becomes, there will always be a risk of counterfeit medicines reaching out to end consumers if not the consumer awareness about the problem is increased. In parallel with increasing product traceability, work should also be conducted to inform consumers about the risk with buying counterfeit pharmaceutical products online. Consumer awareness could be enhanced by using different channels such as campaigns, advertisements or alerts in newspapers and TV. The efforts for controlling and closing down illegal web pages could be further increased. Furthermore, by labeling each product with a unique identification that can be scanned by end consumers' smartphones, the consumers can verify the genuineness of the product themselves before taking the medicine.

TracePharma provides an overview of important areas to develop for enhancing the traceability in the pharmaceutical supply chain. Each of these areas currently has the potential to be improved according to findings from the case study conducted in the Swedish pharmaceutical supply chain. Each framework component are also supported by previous research for increasing traceability in similar industries such as the food industry. TracePharma

has been developed to ensure safety and quality of products. Increased traceability in legal supply chains is important for this purpose, but unfortunately not enough due to the increasing sales of counterfeit medicine through e-commerce. TracePharma therefore also highlights the importance of increasing consumer awareness about the risk of purchasing pharmaceutical products online in order to increase end consumer safety. TracePharma should be seen as a starting structure for the enhancing traceability and end consumer safety, and might require adaptations depending on future changes in the Swedish pharmaceutical industry.

6. DISCUSSION

The aim of the study was partly to present a framework to ensure safety of prescribed medicinal products in legal pharmaceutical supply chains. The focus of this chapter is the framework, TracePharma, developed by the authors and presented in chapter 5. Results and Analysis. Both the validity of the results and the generalization of the study are discussed.

6.1 Validity of the results

TracePharma has been developed for the Swedish pharmaceutical industry. A case study has been conducted to gather necessary information about the studied industry. The companies that have been chosen to participate in the case study are the companies involved in the research project Smedpack3. Not all companies involved in this research project however were able to participate in the case study. In total, 11 companies contributed with information why the empirical data should be seen as an indication of the industry reality. To secure the results from the case study, the amount of companies contributing to the study could have been increased. In addition, companies not engaged in Smedpack3 could have been chosen to further strengthen the results from the case study. However representatives for all actors, from manufacturing stage to retail stage, in the pharmaceutical supply chain has been contributing with information to the study which increases the validity since the full picture is captured.

Since there is limited research related to traceability frameworks conducted in the pharmaceutical industry, research about traceability frameworks developed in the food industry has been used when developing TracePharma. Even if other sources of data also have been used, the framework is to the greatest extent based on literature within the food area. The validity of TracePharma therefore relies on the validity of the literature used. Many of the different frameworks reviewed however highlighted similar concepts to be of importance for high traceability. This increases the validity of the literature used, which in turn increases the validity of TracePharma.

Changes in the industry, for instance related to regulations, could have an impact on the validity of the framework. It is therefore important to review the framework's components and adapt them depending on changes in the industry or market.

TracePharma is developed to highlight important areas of development to enhance traceability in the pharmaceutical industry. It is out of this thesis's scope to define the information technology behind each of the framework components. The feasibility of the technical implementation of the recommendations in TracePharma has therefore not been examined. It is therefore possible that certain information technology challenges will be encountered when converting the framework into practice. The framework however represents a starting point in the work with enhancing traceability in the Swedish pharmaceutical supply chain. Future research needs to investigate the IT required to fulfil the recommendations in the framework.

To achieve higher traceability by using TracePharma, it is important that all companies are committed to go through the changes. The chain is no stronger than its weakest link which is why the validity of the findings can be questioned if companies decide not to participate in for example implement a standardized data carrier. The case study however showed that the

companies are positive to increased interoperability and have trust in the MPA so there seems to be potential in implementing standardization in the studied supply chain.

The legally required attributes shared in the supply chain was defined as the attributes that according to the MPA is required to label the products with. The reason for this is that there is no law controlling what information should be included in the bill of lading, delivery order or other documents. For laws defining what information to be documented this was easier since regulations regarding documentation exist. Depending on how “information sharing” is defined, the result could have been different.

6.2 Generalization

As mentioned, no previously published frameworks for ensuring traceability for prescribed pharmaceutical products have been found by the authors. It is therefore believed that the results from this study can contribute to the research within pharmaceutical supply chains.

Despite this, it has to be taken into consideration that pharmaceutical supply chains is a broad concept. Hence, the result might not be applicable to all pharmaceutical supply chains depending on for example the amount of actors, the conditions and the regulations of the supply chain. With that being stated, even if the framework is developed for the Swedish legal pharmaceutical supply chain, there might be other supply chains with similar products and characteristics that can use the findings of this study.

For the results to be generalized and applicable in other pharmaceutical supply chains and in other countries it is of the authors' belief that the framework components should be adjusted to each supply chain's individual environment. For example, if the results are to be used in a different country than Sweden, the largest risks and safety threats concerning counterfeit medicine needs to be identified. In Sweden, end consumers purchasing pharmaceuticals products online through illegal webpages is regarded as one of the most common ways of counterfeit medicine entering the legal supply chain. In other countries however, the largest problem might be lack of sufficient regulation. Another example is that in Sweden the companies in the pharmaceutical supply chain are harmonized with the MPA why the guidelines on what attribute to be regarded as mandatory would be almost the same as the ones that are currently shared. In a country where the companies and the authorities are not agreed upon what information attributes that should be legally enforced to label and document, this component should have more focus. In such situation a more thorough review of what attributes to be regarded as mandatory and voluntary needs to be made.

7. CONCLUSION

This chapter summarizes the answers to the three research questions. Furthermore the theoretical contribution, practical implications and recommendations of further research are presented.

7.1 Answers to the research questions and contributions

The purpose of the study was two-folded. Firstly, the purpose was to present a framework to ensure safety of prescribed medicinal products in legal pharmaceutical supply chains. The second purpose was to identify mandatory and voluntary information attributes that complies with legal and industrial safety requirements on information sharing related to the physical flow of goods in a legal pharmaceutical supply chain. The stated purpose was fulfilled through answering three research questions.

RQ1. How are the companies involved in the research project interrelated regarding both information flow and physical flow?

A map of the Swedish legal supply chain was made using a process mapping technique. The process map both presents the physical flow and information flow between the studied supply chain actors. The map is shown in figure 10. This map was made to provide an overview of the supply chain interrelations. This overview enables a common understanding for the companies involved in the supply chain. Some important findings useful for the analysis were also discovered during the working process when creating the map. An example of such a finding was that many different techniques are today used for sharing information in the supply chain. With the process map as a basis, the interoperability in the studied supply chain was discussed. It can be concluded that the interoperability in the Swedish pharmaceutical supply chain has potential to be increased. The tracking and tracing system in the studied supply chain was also investigated and evaluated using the model developed by Stefansson and Tilanus (2001). It could be concluded that to support the current data exchange in the studied supply chain the tracking and tracing system needs to be efficient, and that the efficiency in the current system has potential to be improved.

RQ2. What are the differences between legal requirements, industrial praxis and end consumer preferences regarding information attributes shared between actors in the Swedish legal pharmaceutical supply chain?

To answer this question the companies involved in the case study were asked what information attributes they shared with each other. The regulations regarding product labeling and documentation were also reviewed and summarized to enable a comparison. This comparison revealed that most of the attributes shared by the companies are the attributes required to share according to the regulations.

According to Folinas et al. (2006) the efficiency of a traceability system depends on its ability to record necessary information. It is therefore of importance to identify mandatory and voluntary attributes. The mandatory attributes should be recorded at each stage in the supply chain. It was concluded that the mandatory attributes should be the ones required by the MPA for product labeling and documentation, since the industry is harmonized with these regulations

and they are relevant from a tracking and tracing point of view. There could however be some exceptions why these attributes should be reviewed by the industry.

Regarding the end consumer preferences, no previous studies have been conducted to investigate consumers' preferences regarding information on product labeling for prescribed medicines. A study has however been conducted by Ringsberg and Urciuoli (2015) where consumer preferences regarding information on product labeling for non-prescribed medicines were investigated. This study showed that the end consumers do not have any certain preferences as to what attributes they regard important. To involve consumers' preference on medicinal product labeling more studies need to be conducted for prescribed medicines.

RQ3. What traceability frameworks have been published in other industries, what differences and similarities do these industries have compared to the pharmaceutical industry and what framework components could be applicable also for the pharmaceutical industry?

In the frame of reference, three traceability frameworks and one ontology model, all within the food industry, were reviewed. It could be concluded that the food industry and pharmaceutical supply chain have similar characteristics which motivated that certain characteristics of the frameworks made within the food industry also could be applicable for the pharmaceutical supply chain. The empirical findings highlighted that there are deficiencies in the verification of product genuineness, that there is no standard for identifying the medicinal products, that many different standards for data exchange occur and that the attributes shared between the companies are similar to the provisions by the MPA. These findings were the basis when defining what components to include in the framework TracePharma. The traceability framework includes four components. Three of these components are mainly based on theory and the fourth one is in addition to theory also based on empirical data.

The first component is unique identification since this is important to ensure traceability. If each package of medicine is provided with a serial number it is possible to increase the safety for the end consumer who can ensure the authenticity when purchasing the product at the pharmacy. The second component is to introduce a standardized data carrier since this is likely to decrease the time and cost of handling and it can include the unique identifier. Thirdly, a more standardized way of communicating is recommended. This is supported by the fact that the majority of the companies in the supply chain believe that a better cooperation in the pharmaceutical supply chain will lead to an improved economical result due to more efficient administration with more standardization. Also, the literature study showed that less manual handling of data exchange is likely to decrease the risk of error. Many companies are today using EDI for exchanging data but it is recommended to increase the usage of web services and XML based protocols. The fourth component is based on previous research that there should be a predetermined list of attributes with a specification on where and by whom they should be recorded. Folinas et al. (2006) recommend identifying which mandatory and voluntary attributes to record. This has been done by answering research question two.

The answers to the research question and hence the fulfilment of the purpose of the thesis has generated some contributions, both theoretically but also practically. The thesis contributes theoretically to the research field of traceability for pharmaceutical products and practically for

practitioners in the pharmaceutical industry, such as supply chain members and authorities. Table 19 visualizes the thesis' theoretical contributions and practical implications.

Table 19. Overview of what the answer to each research question contributes with, theoretically and practically

Research Question	Theoretical contributions	Practical implications
RQ1 Interrelations of actors in the supply chain		The Smedpack3-members are provided with a greater insight and understanding.
RQ2 Information attributes		Useful for practitioners
RQ3 Traceability frameworks	Comparison of traceability frameworks within the food industry. The components identified in the TracePharma can act as a starting point for further research in the field.	TracePharma can practically be used for other supply chains, for example in other countries The companies involved in the Swedish pharmaceutical supply chain can understand what to be prioritized to increase traceability in the industry.

7.1.1 Theoretical contributions

The thesis has contributed to the research field with a comparison of different previously developed frameworks and ontology models for the food supply chain. Certain components in these frameworks and models have also been analyzed in the context of a pharmaceutical supply chain.

Moreover, TracePharma in itself is a theoretical contribution since this is, according to the authors' knowledge and research review, one of the first starting structures of a traceability framework developed specifically for prescribed medicine in the pharmaceutical industry. In general few publications related to traceability in the pharmaceutical industry has been found.

7.1.2 Practical Implications

The first practical implication, related to the first research question, is that the companies involved in the Swedish legal pharmaceutical supply chain can increase the understanding for the complete supply chain. They can also gain knowledge about the requirements that other actors in the supply chain have. The information flow has never before in the Smedpack project been mapped why this also is a practical contribution for the companies involved.

The second research question was related to finding the mandatory and voluntary attributes by comparing the legal requirements on information sharing and documentation with the industrial praxis. This was later connected to the fourth component in TracePharma. It was shown that the companies in Sweden follow the laws provided by the MPA. Many of these attributes has also been judged as important for the purpose of traceability, why the legally required attributes to share and document are recommended to be mandatory. A predetermined standardized list of attributes to be recorded at each stage in the supply chain can be practically used in a traceability system. The recording of the attributes can be facilitated for example by having a shared database. A common database could also generate more efficient handling if a product needs to be taken off the market.

The third research question resulted in the development of TracePharma. This framework could be used to increase the traceability in other supply chains with physical flows of prescribed pharmaceutical products. A similar study could be made using this framework and comparing the results. The framework can also be useful for companies in the Swedish pharmaceutical industry since TracePharma provides an understanding of what areas that needs to be the focus for increasing traceability for prescribed medicine.

7.2 Future research

The research within the area of traceability for prescribed pharmaceutical products is limited why it is recommended that more research is done to further increase the safety and quality of pharmaceutical products. The results of this study, the TracePharma framework can serve as a starting point for future research within the field of traceability for prescribed medicine. There are a number of areas where research needs to be done before TracePharma could be implemented.

The first one is that it needs to be studied what can be done to increase the awareness among consumers regarding the existence of counterfeit medicines outside of the legal system. In addition, the consumer preferences regarding prescribed medicine should also be researched to find out which attributes that the end consumer thinks are important for them to know.

Secondly, an ontology needs to be developed for the pharmaceutical industry for several reasons. By using ontologies heterogeneous databases can be integrated, why the interoperability between the information systems used in the pharmaceutical supply chain can be increased. Furthermore, an ontology model can also facilitate shared understanding of frequently used concepts among stakeholders in a supply chain. By developing an ontology the communication and knowledge expression between heterogeneous agents in the supply chain can be facilitated. By better communication in the supply chain the traceability can also be enhanced.

Thirdly, this study was limited to external traceability but the internal traceability is also important to ensure full traceability across the supply chain. For this reason it is recommended that further studies are made also for ensuring internal traceability of prescribed medicines.

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APPENDIX I - Survey

Informationsdelning och kommunikation i svenska medicinska värdekedjor

Denna enkätundersökning är ett första steg i datainsamlingen för vårt exjobb som är en del av Smedpack3-initiativet som Ert företag är med i. Syftet med vårt exjobb är dels att ta fram ett ramverk för att öka säkerheten för receptbelagda medicinska produkter i svenska värdekedjor. Syftet är också identifiera vilken typ av information som delas i svenska värdekedjor som är obligatorisk respektive frivillig. Enkätundersökningens syfte är att kartlägga informationsdelningen samt identifiera graden av interoperabilitet mellan företag engagerade i Smedpack3. Era svar kommer att behandlas anonymt. Stort tack för att du är med och bidrar till vår datainsamling samt stärker underlaget som vi gärna delar med er när vi är klara!

* Required

Ditt namn:

Du är helt anonym i undersökningen. Namnet kommer endast att användas för att eventuellt kontakta dig för att få förklaringar till specifika svar.

Vilket företag representerar du?

Inom vilket eller vilka områden arbetar du?

- Inköp
- Kvalitet
- Säkerhet
- Logistik

Hur många anställda har ditt företag? *

Vad är omsättningen på ditt företag? *

1. Vilken/vilka typer av transportenheter används vid transport av receptbelagda läkemedel från ditt företag? *

- Pallar
- Lådor
- Big-boxes
- Tunnor
- Konsumentförpackningar
- Other:

2. Med vilken/vilka av nedanstående aktörer inom Sverige delar Ert företag/koncern/organisation information med i samband med fysiskt flöde av receptbelagda produkter? *

- Primär producent
- Grossist Import
- Grossist Export
- Företag inom process-/förädlingsindustri
- Apotek
- Web-apotek
- Myndighet
- Transportföretag
- Vi delar ingen information med aktörer inom Sverige

3. Med vilken/vilka av nedanstående aktörer inom EU delar Ert företag/koncern/organisation information i samband med fysiskt flöde av receptbelagda produkter? *

- Primär producent
- Grossist Import
- Grossist Export
- Företag inom process-/förädlingsindustri
- Apotek
- Web-apotek
- Myndighet
- Transportföretag
- Vi delar ingen information med aktörer inom EU

4. Med vilken/vilka av nedanstående aktörer utanför EU delar Ert företag/koncern/organisation information i samband med fysiskt flöde av receptbelagda produkter? *

- Primär producent
- Grossist Import
- Grossist Export
- Företag inom process-/förädlingsindustri
- Apotek
- Web-apotek
- Myndighet
- Transportföretag
- Vi delar ingen information med aktörer utanför EU

5. Vilka metoder använder Ert företag/koncern/organisation för delning av information? *

- Pappersdokument som ej lagras digitalt
- Internetbaserade web-tjänster (exempelvis http eller ftp)
- Digitala dokument; mail, XML/ EDI filer

6. Hur registreras information om inkommande produkter på ditt företag? *

- Manuellt
- Streckkoder
- QR-kod
- RFID
- Other:

7. När inkommande produkter registrerats - skickas någon information till andra aktörer i värdekedjan? *

- Ja, vi skickar information till kunder
- Ja, vi skickar information till leverantörer
- Ja, vi skickar information till både kunder och leverantörer
- Nej, vi skickar ingen information till andra aktörer
- Vi skickar ingen information aktivt, men delar gärna information med andra aktörer om de frågar efter den
- Vi har helt integrerade IT system för delning av information

8. Vilken av följande information följer med inkommande produkter? (Exempelvis via packsedel/medföljande dokument) *

- Batchnummer (Egna icke-standardiserade batchnummer från leverantör)
- Produktnummer (Egna icke-standardiserade produktnummer från leverantör)
- Batchnummer (Standardiserat GS1/EAN från leverantör)
- Produktnummer (Standardiserat GS1/EAN från leverantör)
- Produktens namn
- Produktens vetenskapliga namn
- Bäst före-datum
- Produktionsmetod
- Kvantitet (Antal pallar/lådor)
- Geografiskt ursprung för produktion
- Nettovikt (gram, kg, ton)
- Återförsäljarens namn (namnet på företaget som placerar produkten på marknaden)
- Speciella krav på förvaringsmiljö vid lagring och transport
- Allergiframkallande substanser
- Miljö/hållbarhetsmärkning (certifierade märkningssystem för mat- och konsumentprodukter)
- Säkerhetskod
- Leveransställe
- Leveranstid
- Avsändarföretag
- Avsändande lager
- Other:

9. Vilken av följande information följer med utgående produkter? (Exempelvis via pappersedel/medföljande dokument) *

- Batchnummer (Egna icke-standardiserade batchnummer från leverantör)
- Produktnummer (Egna icke-standardiserade produktnummer från leverantör)
- Batchnummer (Standardiserat GS1/EAN från leverantör)
- Produktnummer (Standardiserat GS1/EAN från leverantör)
- Produktens namn
- Produktens vetenskapliga namn
- Bäst före-datum
- Produktionsmetod
- Kvantitet (Antal pallar/lådor)
- Geografiskt ursprung för produktion
- Nettovikt (gram, kg, ton)
- Återförsäljarens namn (namnet på företaget som placerar produkten på marknaden)
- Speciella krav på förvaringsmiljö vid lagring och transport
- Allergiframkallande substanser
- Miljö/hållbarhetsmärkning (certifierade märkningssystem för mat- och konsumentprodukter)
- Säkerhetskod
- Leveransställe
- Leveranstid
- Avsändarföretag
- Avsändande lager
- Other:

10. Vad tror du sannolikheten är att förfalskade läkemedel tar sig in på den svenska marknaden pga följande orsaker? *

(1= högst osannolikt, 2= mindre troligt, 3= troligt, 4= högst sannolikt)

	1	2	3	4
Bristande säkerhet under transport	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bristande kunskap hos konsument (t.ex. vid köp på internet)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Falsk marknadsföring (t.ex. internetbaserat företag lurar kund att falsk medicin är äkta)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bristande märkning av produkter (svårt att verifiera att medicinen är äkta)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bristande medvetenhet hos anställda om risken för förfalskade produkter	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anställd byter ut legala läkemedel pga. ekonomiska motiv	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anställd tvingas på grund av hot att föra in förfalskade läkemedel i värdekedjan	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Brister i informationsdelning mellan aktörer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. Hur tror du att ett närmre samarbete mellan aktörerna i den medicinska värdekedjan i Sverige skulle påverka Er verksamhet ekonomiskt? *

- Negativt (i huvudsak på grund av investeringar i t.ex. IT-system och utbildningar)
- Positivt (i huvudsak på grund av ökade intäkter då säkerheten i läkemedelskedjorna kommer leda till ökad försäljning av legala läkemedel)
- Positivt (i huvudsak på grund av mer effektiv hantering med standardiserade procedurer och samarbete)
- Other:

12. Frågor om interoperabilitet

För att underlätta utbyte och presentation av information är det viktigt att beakta interoperabilitet på följande nivåer:

- Teknisk nivå (användning av tekniska specifikationer för informationsutbyte)
- Semantisk nivå (till vilken grad sändaren och mottagaren tolkar information på samma sätt)
- Organisatorisk nivå (samarbete vid delning av information)
- Legal nivå (lagar och regler för informationsdelning samt skydd av information)

Ange vilket av nedanstående alternativ som bäst passar in på er organisation avseende interoperabilitet (ett eller flera alternativ kan väljas)

Teknisk nivå

Delning = information som delas men som inte aktivt presenteras/synliggörs för mottagaren, Presentation = information som aktivt presenteras för mottagaren

- Internationell standard (t.ex. DS1 standards) används för märkning av gods
- Standardiserade protokoll/ språk (t ex XML, EDI) används vid delning av information
- Delning av information sker genom utbyte av standardiserade datafiler
- Presentation av information sker genom utbyte av standardiserade datafiler
- Delning och presentation av information sker via standardiserade web-tjänster
- Endast delning av information sker genom standardiserade web-tjänster
- Endast presentation av information sker genom standardiserade web-tjänster

Semantisk nivå

- Inkommande information lagras på separata IT system/ nivåer
- Lagring av inkommande information sker i samma IT system/ nivåer

Organisatorisk nivå *

- Informationsdelning sker per automatik genom sammankopplade informationssystem
- Informationsdelning sker manuellt i enlighet med överenskommelser och avtal
- Informationsdelning sker manuellt vid förfrågningar från affärspartners
- Informationsdelning sker manuellt för att uppfylla legala krav

Legal nivå *

- Informationsdelning sker enbart baserat på juridiskt bindande avtal
- Riktlinjer finns för informationsdelning med svenska affärspartners
- Riktlinjer finns för informationsdelning med utländska affärspartners
- Avtal samt och riktlinjer saknas för delning av information

APPENDIX II - Semi-structured interview guides

Interview guide for manufacturing companies

1. What kind of prescribed medicines do you manufacture?
2. Are the prescribed medicines distributed through different channels? If yes, how does these channels look like?
3. When the raw materials used for medicine manufacturing are delivered to you, what information must the goods be labeled with?
4. With what information do you label the finished goods (prescribed medicines) with before these are shipped from your site?
- 5 a) Before sending the prescribed medicines do you send any information to any other supply chain actor?
 - b) If yes, is this information send automatically or only if the actor ask for the information?
 - c) What technique is used when sending this information?
6. Question number 9 in the survey dealt with what information attribute that accompanied outgoing goods.
 - a) You reported in the survey that you are labeling your products with X attributes. In general, do you only label your products with these X attributes or are there sometimes more?
 - b) If yes, can you give examples of such attributes?
 - c) Are there any difference when prescribed medicines are labeled compared with when non-prescribed medicines are labeled?
 - d) Are there any regulations regarding what information you need to label prescribed medicines with?
 - e) Are there any information beyond the information attributes legally required to label with, that you generally label your prescribed products with? If yes, in what purpose do you add this information to the product?
- 7 a) How do you work with product traceability?
 - b) What information do you add to the product specifically to improve the product traceability?
 - c) What technique is used for product traceability?
- 8 a) What information about prescribed medicines do you document?
 - b) How is this information registered in your system?

c) How long do you store this information?

9 a) Do you have your own trucks or do you use external transporters for shipment of products from your site?

b) If external transporters are used, what information is given to the transporter?

c) What technique is used for sending this information?

10. Do you notice that there is an illegal market for counterfeit pharmaceutical products? How does this affect you?

Interview guide for transporters

1. What kind of prescribed medicines do you transport?

2 a) Do you have any experience of counterfeit medicines entering the Swedish legal supply chain?

b) Do you work to counteract this problem? If yes, how?

c) Are there any way for you to verify that the goods you are transporting are genuine?

3. Do you transport prescribed medicines for different actors like manufacturing companies, distributors, online pharmacies etc? Is any of these actors a bigger customer for you?

4 a) Can you explain what happens when you receive a booking of transportation?

b) When you receive a transport booking for prescribed medicines, what information about the goods do you need to be able to transport the goods?

5 a) Do you send any information to any supply chain actor before performing the transportation?

b) If yes, what technique is used for sending this information?

6 a) After the goods have been transported, do you label the transported goods with any information?

b) Are there any legal requirements on information you need to label the prescribed products with?

c) Are there any other information, beyond the legal requirements, that you label the product with to enhance safety?

Interview guide for distributors

1. What kind of prescribed medicine do you distribute?

2 a) Do you buy these products directly from the manufacturing company or from intermediaries?

3. Do the manufacturing companies usually use several different distributors to reach out with their products to end consumers?
4. Do you distribute the prescribed medicines directly from your warehouses to pharmacies or does intermediaries occur?
- 5 a) When you receive a delivery of goods what information do you need about the prescribed medicines to be able to handle and store the products?
- b) Do you send any confirmation about the delivery to any supply chain actor? If yes, what technique is used for sending this information?
- 6 a) Do you label the products before delivery to the pharmacies? If yes, what information do you label the products with?
- b) Are there any legal requirements on information you need to label prescribed products with?
- c) Are there any other information, beyond the legal requirements, that you label the products with?
7. How do you track and trace products in your distribution system?
8. Do you have your own trucks or do you use external transporters for shipment of products to and from your site?
9. Do you have any method for verifying that incoming products are genuine?

Interview guide for pharmacies

1. What type of prescribed medicine do you handle?
2. Do you have many warehouses geographically spread, or a central warehouse?
3. Do you purchase the prescribed medicines direct from the manufacturing companies or from intermediaries?
4. What customers do you have?
5. When you receive a delivery of goods, what information do you need about the prescribed medicines to be able to handle the products?
- 6 a) Do you label the products before selling them? If yes, what information do you label the products with?
- b) Are there any legal requirements on information you need to label prescribed products with?
- c) Are there any other information, beyond the legal requirements, that you label the products with?
- 7 a) Do you document any information about prescribed products in you IT system?

- b) If yes, how is this information registered in the system?
 - c) How long is this information saved in the systems?
 - d) Are there any legal requirements on documentation of information regarding prescribed medicines?
8. How do you track and trace products?
9. Do you have any method for verifying that incoming products are genuine?

Additional question for online pharmacies:

- 10 a) How are the prescribed medicines delivered to customers?
- b) Do you have your own trucks or do you use external transporters for shipment of products to the consumers?
 - c) Do the transporter know the content of the transport?