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Optimizing the inventory system of a pharmaceutical company to improve efficiency - A Case Study

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Abstract

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Inventory is a major cost driver in the healthcare sector since inventory levels are often kept high to satisfy demand without any delay due to the criticality of pharmaceutical products for patients. The question "how to optimize the inventory system of a pharmaceutical company?" is answered in this study. A global pharmaceutical company's inventory in Finland is used as a case study. After introducing different inventory management strategies and analyzing the challenges in the pharmaceutical supply chain, the two-criteria version of the ABC analysis (ABC-XYZ) was done on selected 321 stock-keeping units (SKUs). Nine different categories with different safety stock levels were created and the inventory level of the case company was decreased by 4,35% with the new ABC-XYZ-based inventory management strategy. Additionally, three SKUs were suggested for "discontinuation" after analyzing products in the obsolete stock. A key employee in the case company was interviewed to aid in understanding the real-life implications of the challenges identified in the theory part of the study. It is also recommended that the case company improves its communication channels between internal and external stakeholders to increase the visibility of upcoming issues that can cause shortages or expiry.

Keywords: Pharmaceutical Supply Chain, Inventory management, ABC-XYZ Analysis

Contents

Glossary

3PL	Third-party logistics provider
API	Active pharmaceutical ingredient
CSL	Customer Service Level
DC	Distribution Centre
EMA	European Medicine Agency
EOQ	Economic Order Quantity
FC	Forecast
FGI	Finished Goods Inventory
FIMEA	The Finnish Medicines Agency
FTL	Full Truck Load
JIT	Just-in-time
LM	Lean Manufacturing
LTL	Less than Truck Load
MOQ	Minimum Order Quantity
NPD	New Product Development
OOS	Out of Stock

OTC	Over-the-counter products
PSC	Pharmaceutical Supply Chain
ROP	Re-order Point
RX	Prescription medicines
SKU	Stock Keeping Unit
SME	Small- and Medium-sized Enterprise
TPS	Toyota Production System
WIP	Work in Process

1 Introduction

Effective inventory management can benefit organizations in the areas of finance, supply chain, and marketing. However, no definitive inventory management solution has been developed to answer the needs of every organization, hence, the inventory system can be significantly distinctive for different industries and companies. Basic concepts and important inventory management strategies for finished goods are explored in this study. One industry that has such distinctive supply chain operations is the pharmaceutical industry, which is due to strong regulations and quality restraints surrounding the entire process from the development of new medicine to delivering medicines to patients.

The pharmaceutical industry is one of the biggest industries that created a total revenue of 1.42 trillion U.S. dollars in 2021 (Mikulic, 2022). According to the data published by Efbia (2022), the European market is responsible for 23,4% of the total pharmaceutical sales in 2021. The accessibility and affordability of medicines are the main goals for both authorities and individuals of the EU since, with the aging population in Europe, the expense and the need for medicines are expected to increase. Increasing the efficiency of the Pharmaceutical Supply Chain (PSC) means easier and faster access to treatments for patients, a more cost-efficient operation for companies, and eventually, optimized supply chain operations could lead to less financial burden for governments. Thus, a more efficient PSC will not only benefit companies but also patients and authorities.

The following authors have major contributions to the literature regarding the issues in PSC. Shah (2004) is one of the first authors to comprehensively identify the issues in PSC. Narayana et al. (2014b) provide a holistic review of the managerial research on the PCS; Argiyantari et al. (2020) conduct a literature review of the implementation of the lean principles in the PSC, while Singh et al. (2016) tackle the strategic issues in PSC. Following the previous studies listed here, challenges in the PSC have been identified with a holistic approach in this study also, the issues are categorized as R&D, primary manufacturing, distribution, and logistics. In addition, the current situation of pharmaceutical

expenditures in the EU and the plans of the EU commission for the pharmaceutical industry are discussed.

The focus area of the study is the inventory management part of the PSC. The following authors conducted insightful research on pharmaceutical inventory management which inspired this study: Kumar and Chakravarty (2015) conducted a study using ABC-VED classification for a hospital inventory, and Gizaw and Jemal (2021) optimized a pharmaceutical inventory using a more complicated method (ABC-VED-FNS). Moreover, Priyan and Uthayakumar (2013, 2014) developed an inventory management strategy for a hospital and pharmaceutical company. In this study, an optimized inventory management strategy for the case company using the ABC-XYZ classification is proposed (AbcSupplyChain, 2022). The suggested inventory strategy decreased the case company's inventory level by 4,35%.

2   Methodology

The paper consists of two parts: the theoretical background and the case study. Since the pharmaceutical industry is inherently global and inventory management covers a wide variety of topics and theories, the study will focus only on topics that are relevant to the case study. The scope of the research for the theoretical background is basic concepts and important practices used in inventory management, the characteristics and challenges of the pharmaceutical supply chain, and the pharmaceutical industry in Europe. The objective of the theoretical background is to provide the reader with the necessary understanding of inventory management and the pharmaceutical industry.

A global pharmaceutical company is chosen as a case study and since the company has different operational practices in different countries, the study will focus on the company's operation in Finland. The objective is to optimize the inventory of the case company by applying the ABC categorization that is introduced in the theory part.

The main question that this paper will answer is "How to optimize the inventory system of a pharmaceutical company to improve efficiency?" Additionally, supplementary questions will be investigated.

The theory-focused part of the study will answer the following questions:

- What are the main inventory management strategies?
- What are the characteristics of the pharmaceutical supply chain?
- How the pharmaceutical industry in Europe will change in the future?
- What kinds of challenges affect the efficiency of the pharmaceutical supply chain?

The methodology approach for this part will be exploratory research. The study will explore the relevant concept in inventory management and identify the challenges that the pharmaceutical supply chain faces, the secondary data will be the source, and the literature review will be used for data collection.

The second part will focus on the company case and will answer the following questions:

- What challenges does the company face in its supply chain process?
- How to lower the company's inventory level and expiry stock with the application of ABC-XYZ categorization?

The methodology approach for the case study will be empirical and problem-solving by using both quantitative and qualitative data collection methods. The primary data will be the source for this part and the data is gathered directly from the case company. To collect in-depth, detailed information a semi-structured interview will be held with a key employee of the case company. To collect the numerical data the data collection sheets will be used.

3 Inventory Management

Inventory is simply defined by Sanders (2011: ch.9) as quantities of goods in stock. These goods can be raw materials, work-in-process (WIP) goods, finished goods, supplies used in operations, etc. Effective management of the inventory is critical for a company commercially, financially, and logistically. Ziukov (2015, 26), emphasizes the fact that although inventory control is a problem for every company, there is no standard solution that would meet the unique conditions, features, and limitations of each company.

Ginting and Julita (2015: 22) state that inventory represents approximately 50% of the total investment of a company. The amount and location of the inventory are crucial decisions for companies because it has a direct effect on meeting customer service requirements and on-time deliveries (Rushton et al., 2017: 237). Companies cannot just keep the maximum inventory level to meet 100% customer service level due to high inventory holding costs, on the other hand, it is often not advised to minimize the inventory level due to uncertainties surrounding the market situation and customer demand along with uncertainties related to the sourcing and supply lead times. Furthermore, a minimum inventory level means a maximum number of orders placed in a given period which increases the order and transportation costs.

Companies are required to have strong inventory management strategies to compete on a global scale with the changing business environment of the 21st century (Schwartz and Rivera, 2010: 111). Along with globalization, many international organizations transferred their manufacturing operations to overseas locations and started sourcing materials and services from overseas suppliers. These radical changes in supply chain and logistics led to the need of adapting more complex inventory management strategies for companies. However, at its core inventory management should answer three basic questions: "What to order, when to order, and how much to order?"

3.1 Reasons for Holding Inventory

The most important reason for holding inventory according to Rushton et al. (2017: 238) is to provide a buffer stock between supply and demand. Holding stock can provide many different benefits. Grant et al. (2006: 128) list five purposes of holding stock within the firm;

- Supports the firm in achieving economies of scale
- Creates a balance between supply and demand
- Enables utilization of the manufacturing plants
- Protects the firm from the uncertainty in demand and order cycle
- Acts as a buffer in the distribution channel and critical interfaces

By purchasing raw materials or semi-finished materials in higher quantities companies can often benefit from economies of scale in manufacturing, purchasing, and transportation. Moreover, it is much cheaper to stock finished goods in the inventory rather than manufacturing them in small quantities due to costs related plant utilization and changeovers (Grant et al., 2006: 129).

Balancing supply and demand is especially important for seasonal products due to capacity constraints in production (Sanders, 2011: ch.9). In figure 1, the changes in demand for a seasonal product can be seen. Therefore, it is important to secure the stock level before the high peak season starts for a specific item.
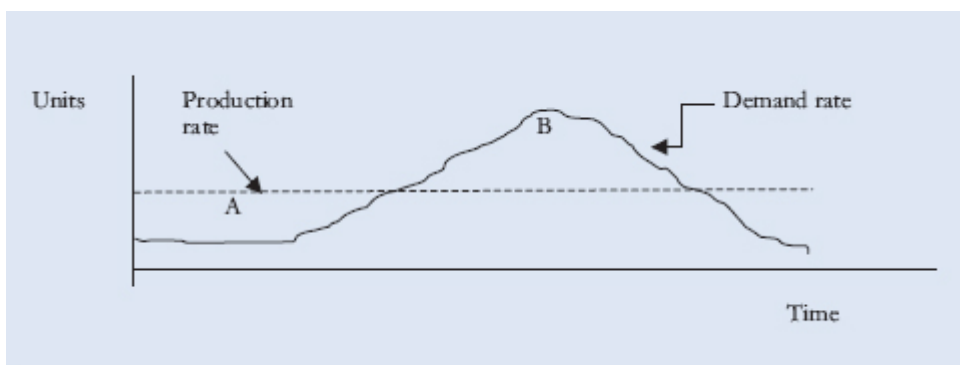
Figure 1 Difference in production and demand rate (Sanders, 2011: ch.9)

Raw materials and WIP inventories are often held to maintain manufacturing operations to avoid shutdowns in case of shortages in raw materials or technical problems in a critical machine. Finished goods are held in stock to provide maximum customer service since if a customer places an order and the item is not in stock, the waiting time can be long possibly causing the cancellation of the order and loss of future sales (Grant et al., 2006: 129). However, holding too much inventory can lead to obsolete stock which is a direct waste and loss of capital for the company. It is especially important to balance inventory for perishable, technological, or fashion goods.

3.2 Types of Inventory

Inventory is often categorized depending on the purpose of the inventory, the status of the product in the production line, and the nature of the product. According to Rushton et al. (2017: 239), the main categories are:

- *Raw materials, components, and packing stocks*: Used to feed into a production or manufacturing process.
- *WIP stock*: Part-finished stocks that are built up between different manufacturing processes.
- *Finished products:* Stocks that are held at the end of the production line usually in Finished Goods Inventory (FGI).
- *Pipeline stocks*: Held in the distribution chain for transfer to the final customer.
- *Spare Parts*: A special category that provides back-up to a manufacturer's machinery or plant. Also held by service and maintenance companies.

Grant et al. (2006: 131-135) categorize the inventories based on the reasons they are held:

- *Cycle stock:* The inventory is for replenishing the stock that is used or sold. This stock is used to meet demand under certain conditions when the firm can predict the demand and lead times which is often not the case.
- *In-transit inventories:* The inventory that is simple in transportation. An important note in this kind of stock is that if the information in ERP systems

is not synchronized or there is poor communication among parties included in the supply chain, it can lead to misinformation regarding the stock level in the warehouse or DC.

- *Safety or Buffer Stock:* This stock is held due to uncertainties in demand and lead times. The companies should manage the variability in demand and delays in transportation and production.
- *Seasonal Stock:* The accumulation of inventory before a seasonal period begins.
- *Speculative Stock:* Inventory held for reasons other than satisfying current demand. Sometimes companies can order higher quantities than current demand to benefit from price reductions or economies of scale in production.
- *Dead Stock:* This is the stock that no demand has been registered for a certain period. It might be overlooked but it can have a significant effect on the overall inventory costs.

3.3 Inventory Costs

Inventory costs have become one of the major contributors to the inefficiency of a company's supply chain, therefore it should be managed effectively and efficiently to minimize the total cost (Ginting and Julita, 2015: 22). Inventory costs are categorized by Sanders (2011: ch.9) as follows: "Holding (carrying) cost, ordering cost, set-up cost, and shortage cost." Most authors categorize inventory costs under these four categories. Waller and Esper (2014: ch.2) categorize ordering costs further into variable and fixed ordering costs.

Set-up costs might be incurred by the manufacturing plant if the goods are produced specifically for the company. This is usually not the case for most companies in day-to-day business (Sanders, 2011: ch.9).

Shortage costs occur when a company cannot fulfill the customer's order due to an out-of-stock (OOS) situation (Sanders, 2011: ch.9). The total cost of a shortage is usually hard to calculate because it is not only the cost of lost sales during the OOS period. In addition, it may cause a loss of customers, future sales,

and reputation if the company cannot provide a sufficient customer service level (CSL).

Out of all costs tied to inventory, the most significant one is the holding cost. Inventory carrying costs can be divided into many further categories as seen in figure 2.
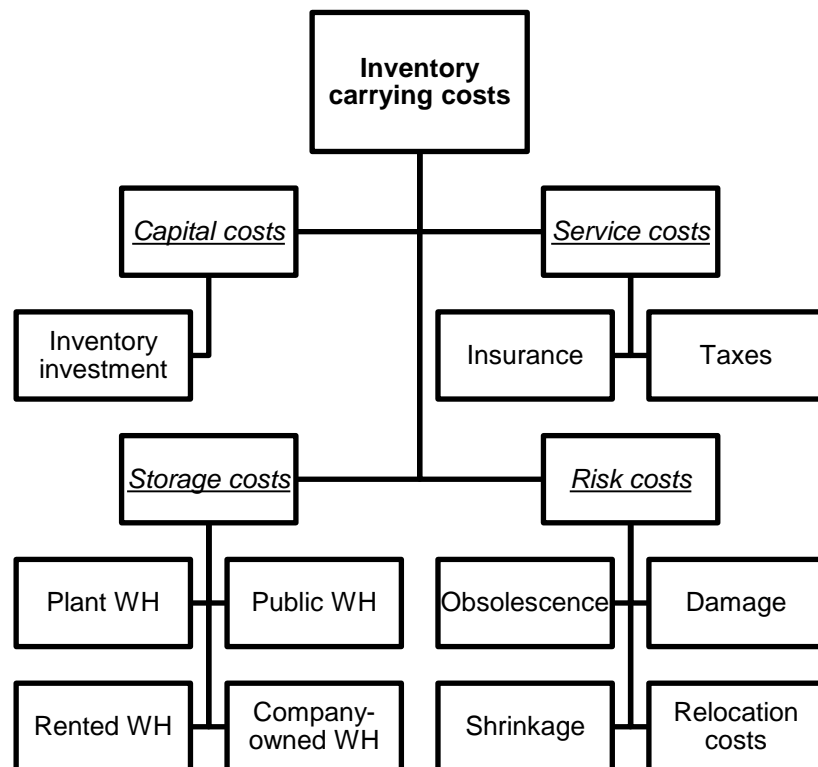
Figure 2 Normative Model of Inventory Carrying Cost Methodology (Grant et al., 2006: 143)

Grant et al. (2006: 142-143) emphasize the importance of calculating the precise inventory holding costs and add that most companies usually do not calculate these costs due to the difficulty of tracking them. "Inventory holding cost is generally underestimated and can roughly vary from 15% of the cost of goods per year to as much as 50% of the cost of goods" (Sanders, 2011: ch.9). The costs of obsolete (dead) stock will be explored further in this study with the company case.

3.4 Independent and Dependent Inventory

Based on the demand type the inventory can be separated as dependent or independent and each type has different inventory requirements. Independent demand occurs when the demand for one product is not influenced by the demand for another product (Rushton et al., 2017: 258-259). Independent demand requires forecasting to anticipate future demands and inventory requirements. Dependent demand occurs when the demand for a product is related to another product (Rushton et al., 2017: 258-259).

Muller (2011: 96) identifies the sectors that deal with independent and dependent demand: "In the worlds of distribution, retailing, and replacement parts, an organization deals with finished goods. In the manufacturing world, an organization deals with raw materials and subassemblies." Finished goods often have independent demand while raw materials and WIP items have dependent demand.

The scope of the study including the company case is limited to the inventory of the finished products located in Finland. Thus, inventory management strategies that apply to independent demand and finished product inventory will be discussed in the next chapter.

3.5 Inventory Management Strategies

Depending on the company's needs and products, different inventory management strategies can be implemented. Some of the most basic strategies are fixed-order and fixed-time period systems where either the order quantity or the order time is chosen as a constant. Economic order quantity, a more sophisticated version of the fixed-order system, is also briefly introduced. These models alone are not usually suitable for large organizations, and they are usually implemented together with different systems. Systems such as lean manufacturing, ABC categorizations, and multi-echelon are more comprehensive and complex.

3.5.1 Fixed-order Quantity System

In this system, the order quantity is constant and fixed, and it is referred to as "q". An order is placed when the inventory position drops to a predetermined level which is referred to as Reorder Point (ROP) (Sanders, 2011: ch.9). Under the assumption that demand and lead time are constant and known, ROP should be set to have enough inventory to cover demand during lead time. However, due to uncertainties, companies usually have a safety stock, in that case, the inventory level for ROP should be the demand for the length of the lead time plus the safety stock (Sanders, 2011: ch.9) (see figure 3).
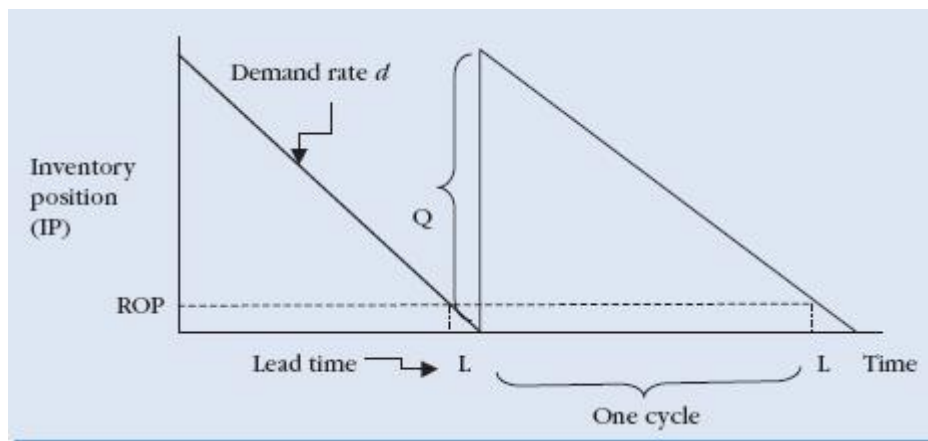
Figure 3 Fixed-order quantity system (Sanders, 2011: ch.9)

3.5.2 Economic Order Quantity (EOQ) and Continuous Review System

The most used deterministic model for inventory management, which is known as the EOQ model, was introduced by Ford W. Harris in 1913 (Teplická and Čulková, 2020: 9). The objective of EOQ is to pick an order quantity that minimizes the sum of both the holding and ordering costs, which is the minimum point on the total cost curve (Sanders, 2011: ch.9). The formula for calculating the EOQ is as follows (Grant et al., 2006: 137):

$$EOQ = \sqrt{\frac{2PD}{CV}}$$

"P = the ordering cost per year

D = annual demand or usage of the product (number of units)

C= annual inventory carrying cost (as a percentage of the product cost or value)

V = average cost or value of one unit of inventory"

Based on the formula above, figure 4 shows the total cost and EOQ model.
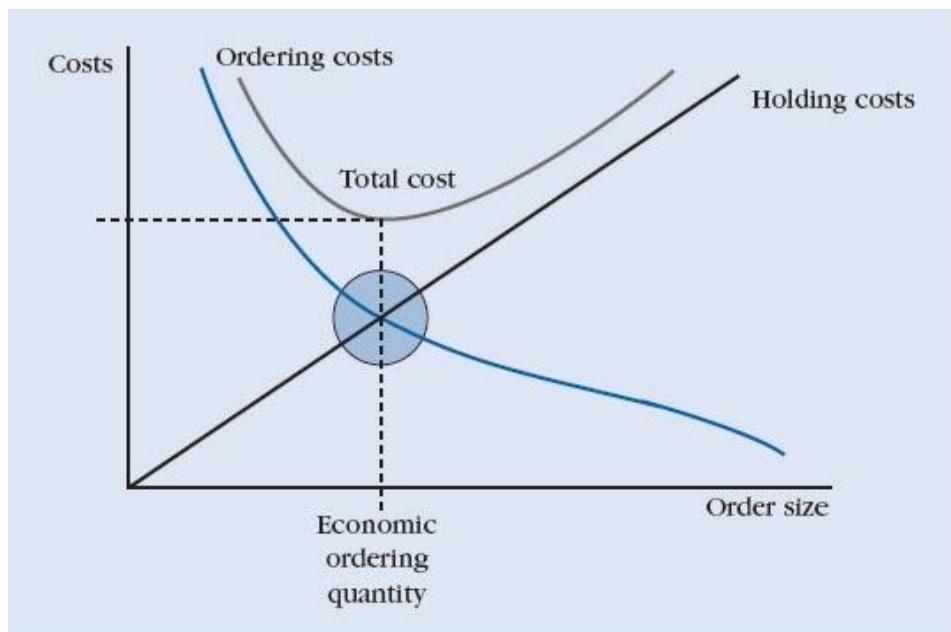
Figure 4 Total cost curve (Sanders, 2011: ch.9)

Although EOQ received significant attention and use in the industry, it does have major limitations since the simple EOQ model is based on the following assumptions (Grant et al., 2006: 138):

- A continuous, constant, and known demand rate
- Constant and known lead time
- Fixed purchase price independent of the order quantity and time
- Fixed transportation cost independent of the order quantity and time
- No stockouts are permitted
- No inventory in transit

- Only independent-demand items
- No limit on capital availability

In real life, the above assumptions are rarely plausible which makes the EOQ method quite difficult to apply to large organizations. Furthermore, EQO or any other model that is based on the fixed order quantity system requires the application of a continuous review system where inventory is continuously monitored. If a company does not have a highly optimized sophisticated ERP system, reviewing the inventory level constantly for each stock-keeping unit (SKU) would be highly costly and time-consuming. Additionally, ROP might be significantly different among SKUs which can trigger overly frequent order placement that raises the ordering cost significantly (Grant et al., 2006: 138).

Many researchers utilize EOQ for specific real-life situations. Weiss (1982), and Pentico and Drake (2009) have important research on the deterministic EOQ model. Additionally, Dobson et al. (2017) developed a deterministic EOQ model for perishable goods with age-dependent demand. Simple models such as EOQ could be utilized based on the needs of the organization.

3.5.3 Fixed-time Period and Periodic Review System

In this system, inventory levels are checked in fixed periods (T), and the quantity that is ordered varies. "The system sets a target inventory level (R), to be maintained. Sometimes, this system is called the periodic review system to indicate that the inventory level is checked periodically, rather than continuously" (Sanders, 2011: ch.9).
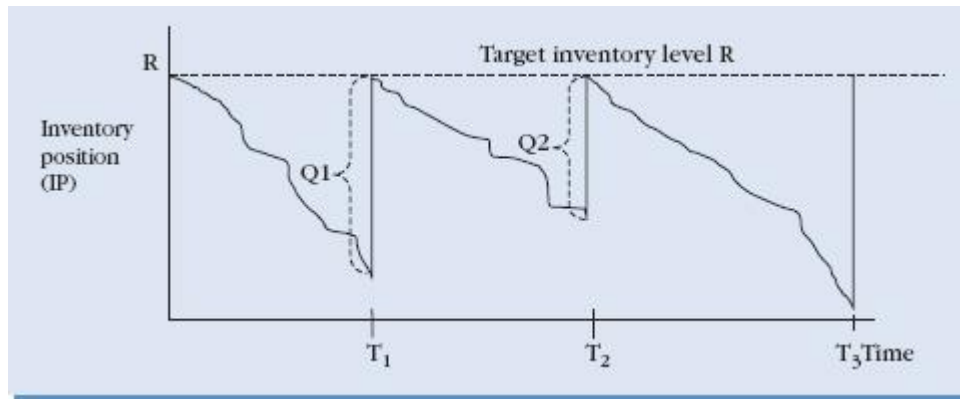
Figure 5 Fixed-time period system (Sander, 2011: ch.9)

Opposing the fixed order quantity system, "when to order" is constant and fixed while "how much to order" varies in each order. The fixed-time period system requires a higher safety stock level which means higher inventory holding costs although it is "order cost-efficient" compared to the fixed order quantity system. Sanders (2011: ch.9) summarizes both models' advantages and disadvantages as follows: In general, a fixed-order quantity system is more appropriate for high-value items as the average inventory carried is lower. Also, it is more appropriate when OOS situations are less desirable, as inventory is monitored continuously. However, this system is more costly to maintain as it requires the technology to record all transactions and compute the inventory position in real-time.

Both systems which were explored above are quite basic and often useful for a single SKU or could be optimized for companies that do not deal with many SKUs. The next two inventory management strategies are more suitable for more complex inventory systems.

3.5.4 Multi-Item Inventory Management

Multi-item inventory utilizes the continuous review policy that focuses on one SKU. In most cases, companies have hundreds of SKUs to deal with, therefore setting an ROP for each SKU and placing an order each time an item hits ROP would create high transportation costs since it is likely that most of the orders would have LTL (Less than truckload) that increases the transportation cost per a unit (Waller and Esper, 2014: ch.6). Another policy would be to wait until enough

SKU hits ROP and then place an order that would be FTL (Full truck load), however, that would create an uncertain lead time (Waller and Esper, 2014: ch.6).

Multi-item inventory management suggests a set-up of "reorder times", by strategically spacing out reorder times, each order would have enough SKU in ROP to fill at least one FTL (Waller and Esper, 2014: ch.6). The reorder times can be once a week, if that time set creates 2 truckloads then it can be set twice a week with one truckload each, which reduces the risk of stock-outs with the same ordering cost. The following constraints are required for this system (Waller and Esper, 2014: ch.6); Filling the transport unit, not exceeding the capacity of the facility, capital available for purchasing, and inventory investment.

Atkins and Iyogun (1988: 791-792), compare this model to the continuous review "can-order" model and conclude that periodic-replenishment policies can outperform "can-order" policies for coordinated replenishment inventory systems, and such policies can do it with considerably simpler calculations. Can-order policy is a slightly optimized version of ROP, when an SKU hits ROP, other items under the "can-order" threshold are added to the order to reduce transportation costs.

3.5.5 Multi-Echelon Inventory Management

An echelon is the level of a supply chain and all the levels below it; multi-echelon inventory management is superior to a single-echelon supply chain although it is more complex to model (Waller and Esper, 2014: ch.6).

A multi-echelon inventory management model can be either centralized or decentralized. Retailers often use multi-echelon inventory management where stores receive their supply from regional or national distribution centers (DC) (Waller and Esper, 2014: ch.6). In a decentralized model, department managers would place an order from the DC based on the supply-demand and current inventory level. The responsibility of following the forecast and assessing the current situation would fall on local stores. This could be useful since the

employees in the stores have better knowledge and experience of the customers and might anticipate the demand better (Waller and Esper, 2014: ch.6).

In a centralized model, the orders would be created centrally based on the demand and inventory level of each store. If a certain store has a significantly low inventory for an item, the central team would be able to prioritize the replenishment of that store's inventory rather than other stores that have sufficient safety stock until the next replenishment. In the centralized model, there would be an automatic replenishment model that uses demand FC to create orders, however, local stores would not be able to alter this FC as easily as it is in the decentralized approach (Waller and Esper, 2014: ch.6).

Both systems have their advantages and disadvantages, and many variables go into the decision beyond simple demand and supply characteristics and the structure of the replenishment process. Therefore, corporations should choose the model that suits their company culture and needs the best (Waller and Esper, 2014: ch.6).

3.5.6 Push and Pull System

A push system is where inventory replenishment is based on the forecast and anticipated future demand. The goods are in stock before the customer places an order (build-to-stock). "The aim is to anticipate the extent and location of this demand and ensure that adequate stock is available in the right place at the right time" (Rushton et al., 2017: 259-260). The push system can be used for both dependent and independent demand and it is the more traditional approach to the inventory system. This system is especially useful in the presence of long lead times and uncertainties in the upstream side of the supply chain (sourcing, manufacturing, production).

"A pull system is where the actual demand for a product is used to pull the product through the system (build-to-order)" (Rushton et al., 2017: 259-260). The main benefit of the pull system is that it gives certain flexibility to the company to react the sudden changes in demand since it is a reactive approach. However, one

must note that to use the pull system effectively the manufacturing/supply and transportation lead times should be short enough to satisfy the customer's demand on time.

3.5.7 Lean Philosophy and Manufacturing

The roots of Lean philosophy date back to 1911 to the "scientific management" ideology of F.W. Taylor, and to Henry Ford when he developed a manufacturing system in 1913 in the Highland Park Manufacturing Plant. After World War 2, K. Toyoda and T. Ohno decided to adapt some of Ford's manufacturing strategies to Toyota's manufacturing process to become a competitive force in the automotive sector (Čiarnienė and Vienažindienė, 2012: 726). Taiichi Ohno and Shigeo Shingo developed the "Toyota Production System (TPS)". The key concepts and principles of TPS had evolved into "Lean Philosophy" over time, TPS is also the birthplace of the Just-In-Time (JIT) order system (Arnheiter and Maleyeff, 2005: 7).

After the advent of the recession at the beginning of the 21st century, many industries experienced structural changes in customer demand and new requirements were quickly born in the manufacturing and production world, these changes were natural consequences of recession and globalization (Bhamu and Singh Sangwan, 2014: 876). In contemporary economics, organizations are forced to reduce costs while maintaining a responsive and flexible supply chain. Lean Manufacturing (LM) has been widely perceived by the industry as an answer to these requirements because LM reduces waste without additional requirements of resources (Bhamu and Singh Sangwan, 2014: 876).

Lean Philosophy is based on two simple concepts: eliminate waste and create value (Čiarnienė and Vienažindienė, 2012: 727). According to Taiichi Ohno, seven wastes account for up to 95% of non-lean manufacturing environments (Kilpatrick, 2003: 1). Lean principle summarises three causes of waste as; Muda (activities and processes do not add value to the operations and customer), Mura (lack of consistency), and Muri (unnecessary and unreasonable requirements) (Slack et. al, 2016: 506-507). Those wastes are overproduction, waiting,

transportation, non-value-added processing, defects, excess inventory, and excess motion. Rawabdeh (2005: 802) categorizes those wastes as seen in figure 6.
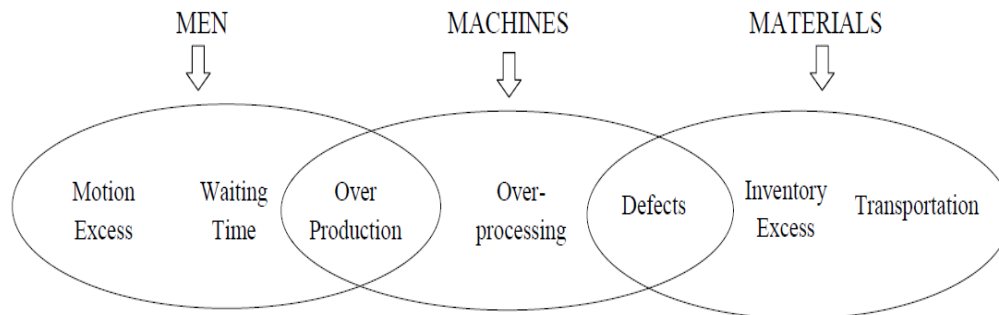
Figure 6 Three categories of waste (non-value-added activities) (Rawabdeh, 2005: 802)

LM emphasizes the pull system rather than push meaning that no product should be made until downstream customer demands. However, for many organizations switching from traditional SCM and the push system to LM and pull system can be an immense challenge. To implement LM successfully, companies need to overcome challenges such as poor logistics, supplier integration, and volatile demand (Bhamu and Singh Sangwan, 2014: 914). Not only the organization itself but all parties involved in the SC activities need to be synchronized and adjust their operations according to LM principles. Gulyani (2001: 1157) explains the importance of cooperation among SC parties as "Poor transportation creates external diseconomies by introducing inefficiencies and unreliability in the supply chain, making it seriously difficult for the manufacturers and assemblers to implement lean production."

In conclusion, implementing LM in an organization does not happen promptly, it involves an intensive analysis of the entire process from the primary production to the end customer, identifying and eliminating wastes, and training all internal and external stakeholders to create an organizational culture to make LM principles permanent. In addition to the changes within the organizations, external partners such as suppliers, distributors, and 3PL providers must be reliable to secure the products and avoid shortages.

3.5.8 ABC Analysis and Classification

Vilfredo Pareto (1848-1923) observed that 20% of the people controlled 80% of the wealth which later become the Pareto analysis/ABC analysis (80-20 rule (Rushton et al, 2017: 242). "The logic behind ABC analysis is that 20% of the firm's customers, or products account for 80% of the sales or profits" (Grant et al., 2006: 153). Thus, companies should identify the critical 20% and focus the majority of their resources on these products. In a typical ABC analysis, class A represents approx. 20% of the SKUs make up 80% of the sales, class B represents 30% of the SKUs that makes up 15% of the sales, and finally, class C represents 50% of the SKUs but only makes up 5% of the sales (Rushton et al., 2017: 242).

The usefulness of ABC analysis comes from the fact that even medium-sized companies might have to keep a large variety of products in their inventory. As stated by Cohen and Ernst (1988: 6), in many inventory systems, the number of SKUs is so large that it is not computationally feasible to set stock and service control guidelines for each item. In an article written by Soshko et al. (2010), the authors used ABC classification (by taking total revenue as criteria) for modeling a distribution company's inventory, as a conclusion of the authors' analysis, for group A; continuous review and high-level of safety stock, for group B; periodic review and average safety stock level and for group C; no safety stock and rare inventory control model was suggested.

However, Cohen and Ernst (1988: 6) stated that simple implementation of ABC analysis with the criteria of revenue or monetary value might conclude in unacceptable cost and service performance since it ignores important managerial variables related to production, distribution, and sourcing. Similarly, Yu (2011: 3420) stated that using annual dollar usage as the only criterion for ABC analysis might create problems and cause a significant financial loss since the other important aspects such as lead-time, commonality, obsolescence, criticality, durability, inventory cost, and order size are being ignored.

Due to issues mentioned about single criteria ABC classification, research on multi-criteria inventory classification has developed in the past 20 years (Ng, 2007: 345). For instance, Ng (2007) developed a simple model for multi-criteria inventory classification as an alternative to the weight linear optimization model. The author developed a model that converts all measuring criteria of an inventory item into a scalar score. Cakir and Canbolat (2008) purposed a system using a fuzzy approach and the AHP method to address uncertainties in inventory operations. Sarmah and Moharana (2015) developed a web-based approach for multi-criteria classification of spare parts inventories. To apply multi-criteria methods to the inventory of a company, a high amount of data should be available, most multi-criteria systems require complex mathematical calculations or usage of programming and algorithm. Therefore, developing a system that meets the needs of a specific inventory system requires time and investment.

Kumar and Chakravarty (2015) used ABC (always better control) – VED (vital, essential, desirable) analysis for a hospital inventory, the authors used two criteria: cost and criticality of the item which created 9 different categories. Gizaw and Jemal (2021) developed a more complex classification system for Ethiopian Pharmaceuticals Supply Agency Jimma hub by adding FNS (fast-, normal-, slow-moving) criteria to ABC-VED. The authors developed a matrix that has 27 sub-categories. Applying the criteria of VED is quite essential for pharmaceutical inventories since some medicines could be costly and slow-moving but critical for the patient, completely overwriting other variables.

3.6 Forecasting and Demand Planning

Forecasting is the action of predicting the future and it is rarely 100% accurate. However, a good prediction of future events will allow supply chain partners to be proactive rather than reactive. Forecasting and demand planning is directly connected to Inventory Planning Horizons. Sanders (2011: ch.8) defines forecasting as the process of predicting future events and planning as the process of selecting actions in anticipation of the forecast. Fundamentally, all other business decisions and planning will be based on the forecast. Rushton et al. (2017: 268) summarize the importance of forecasting by stating that "all mistakes

in forecasting end up as an inventory problem – whether too much or too little."
Forecasting accuracy has key importance for companies, and it is one of the most
challenging parts of inventory planning, notably when many external and internal
factors create uncertainty in the demand.

Many authors classify the Inventory and Manufacturing Planning Horizons as
follows (Rushton et al., 2017: 268; Grant et al., 2006: 180; Harrison et. al, 2019:
222):

- *Long-term:* Concerned with planning the capacity, new product
  development, and facilities. The time horizon is usually over 3 years and
  plans are made for strategic levels.
- *Medium-term:* Concerned with matching and balancing supply with
  demand. The time horizon is usually up to 3 years and the most important
  part of medium-term planning is accurate forecasting.
- *Short-term:* Concerned with day-to-day operations and demand changes.
  The time horizon is usually less than 3 months.

The main concern for inventory management is medium- and short-term
planning. The outcome of those plans will essentially determine the inventory
level and order quantities. Overestimating the demand will cause obsolete and
wasted stock which can be highly costly for the company, the underestimating
the demand will cause shortages, effectively decreasing the CSL, if the situation
occurs frequently it will cause a loss of customers and future sales which can ruin
the reputation of the company. Furthermore, in industries such as food, health
care, and pharmaceuticals, the consequences of the OOS situation could be
much more severe.

3.6.1 Forecasting Methods

Different forecasting methods can be applied to different types of data patterns
and historical data is an important prerequisite to having an accurate forecast
although, it is not possible to have available or useful historical data every time.

Sanders (2011: ch.8) and Harrison et. al (2019: 56) summarize the data pattern as follows:

- *Level (horizontal):* The simplest pattern, the data slightly fluctuates around a constant mean. It is easy to forecast the demand for this type of pattern.
- *Trend:* Data exhibits an increasing or decreasing pattern over time.
- *Seasonality:* Any pattern that regularly repeats itself has seasonality.
- *Cycles (Uncertainty):* Patterns created by economic fluctuations, cycles do not have a predictable or repeating length or magnitude. Therefore, this type of pattern is the hardest to predict.

If available, those patterns will help companies to select an appropriate forecasting method. Typically, the forecasting methods are separated into two main branches quantitative and qualitative methods. Figure 7 shows the hierarchy of the demand forecasting methods. Qualitative methods are based on the subjective opinions of individuals, many different departments within the organization can contribute to this type of forecasting such as commercial, supply chain, finance, and executive management. Quantitative methods on the other hand are based on mathematical modeling. Both methods can be useful in different situations, and it is rather hard to find a method that fits all organizations or product types.

```
                                    ┌──────────────┐
                          ┌─────────│ Judgemental  │
              ┌─────────┐ │         └──────────────┘
              │Qualitative│─┤
              └─────────┘ │         ┌──────────────┐
             /            └─────────│ Experimental │
┌──────────┐/                       └──────────────┘
│  Demand  │
│Forecasting│                       ┌──────────────┐
│ Methods  │            ┌───────────│    Casual    │
└──────────┘\           │           └──────────────┘
             \          │           ┌──────────────┐
              ┌──────────┐──────────│    Common    │
              │Quantitative│         │  Projective  │
              └──────────┘──────────└──────────────┘
                          │         ┌──────────────┐
                          │─────────│   Advanced   │
                          │         │  Projective  │
                          │         └──────────────┘
                          │         ┌──────────────┐
                          └─────────│  Life Cycle  │
                                    └──────────────┘
```
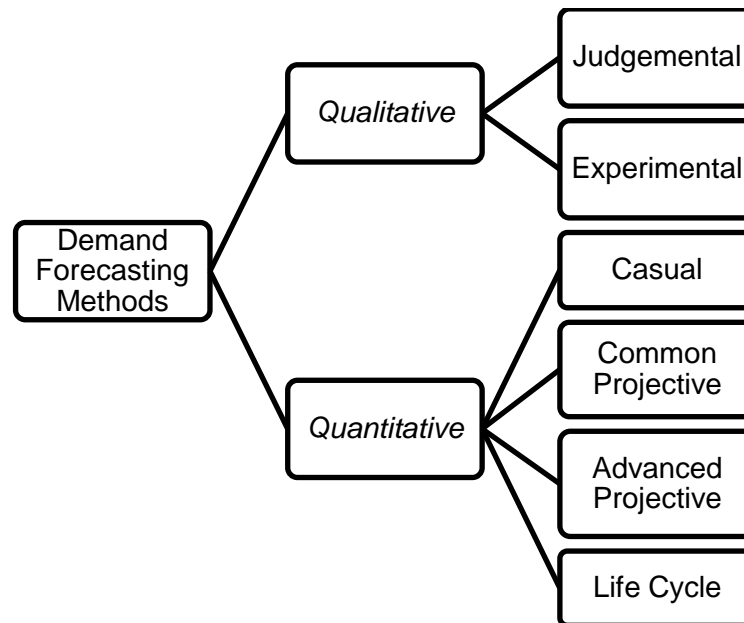
Figure 7 Different demand forecasting methods (Rushton et al., 2017: 269)

Both models have their advantages and disadvantages. In qualitative forecasting, the forecast can be adjusted based on the latest developments in the market such as pricing campaigns, and competitors being OOS which cannot be determined with mathematical calculation. However, the subjectivity of forecast planners can affect the accuracy, also it is much harder to use qualitative methods when there are many variables and a large amount of information affecting the demand. Quantitative methods can calculate complex demand profiles with many variables and a large amount of data and create an objective and consistent forecast. However, it could not have the market intelligence and not follow the latest trends as people could, in addition, the data and calculations used in those methods must be trustworthy and consistent. The details of each model mentioned in figure 7 will not be discussed since the forecasting methods are a quite broad subject and out of the scope of the case study.

3.6.2 Measuring Forecasting Accuracy

Measuring forecasting accuracy is critical and must be included in demand planning. It is important to have sufficient historical data to calculate the accuracy.

"Two of the most commonly used error measures are the mean absolute deviation (MAD) and the mean square error (MSE)" (Sanders, 2011: ch.8).

MAD is the average of the sum of the absolute errors:

$$MAD = \frac{\sum|Actual - Forecast|}{n}$$

MSE is the average of the squared error:

$$MSE = \frac{\sum(Actual - Forecast)^2}{n}$$

Both formulas provide critical information and are useful, MAD is based on absolute values and provides a total sum of the average error. MSE does magnify the error due to squaring in the formula (Sanders, 2011: ch.8). When comparing the performance of the forecast methods, the method that gives the lowest result in both formulas should be selected since that is the most accurate method.

Historical data must be available to use these formulas, thus, it might be hard to detect immediate issues in the forecast with them. Nevertheless, it can still help companies to prevent future errors and in the long-term great savings on inventory costs can be achieved.

4   Pharmaceutical Supply Chain

The pharmaceutical industry is defined by Shah (2004: 929) as "a complex of processes, operations, and organizations involved in the discovery, development, and manufacture of drugs and medications". Uthayakumar and Priyan (2013: 52) define the Pharmaceutical Supply Chain (PSC) as "the integration of all activities associated with the flow and transformation of drugs from raw materials to the end-user, as well as the associated information flows, through improved supply chain relationships to achieve sustainable competitive advantage."

Manufacturers, suppliers, wholesalers, distributors, 3PL (Third-party logistics) companies, governments, private/public health care providers, and pharmacies are the major players in PSC. The greatest challenge for the parties involved in PSC is to provide the right treatment/medication at the right time for the patients. Unlike other industries, shortages and unavailability of a product can escalate into life-threatening situations rapidly. For that reason alone, high CSL is always at the core of all operations in PSC, thus pharmaceutical companies are expected to have high inventory levels throughout the different levels of the supply chain.

Shah (2004: 931) identified the components of the PSC as follows;

- *Primary Manufacturing:* Responsible for the production of the active pharmaceutical ingredient (API). The manufacturing of APIs and intermediates are characterized by its complex and long processing time. The usage of contractors to produce some or all of the APIs is a common practice that adds up to its complexity. Therefore, primary manufacturing is one of the main reasons why PSC is not responsive or resilient.
- *Secondary Manufacturing*: Concerned with taking the API produced in the primary stage and inert the rest of the materials along with further processing and packing to produce the final product (in SKU form).
- *Market Warehouses/Distribution Centres (DC)*
- *Wholesalers*
- *Retailers/Hospitals*

4.1 Characteristics of the Pharmaceutical Industry

Laínez et al. (2012: 20) summarise pharmaceutical industry characteristics as shown below:

High cost and low success rate in product discovery, clinical developments, and extended time need for conducting clinical trials. This is one of the biggest reasons for companies to look for external partners and contractors and buy developed products from specialized smaller companies.

The heavy regulations and quality requirements with both national and regional variations.

Limited product shelf life due to the perishable nature of chemical and physical components.

The manufacturing lead time is quite long compared to other consumer goods. The manufacturing cycle can be up to nine months in many cases due to complicated processes related to production, quality controls, etc.

Most pharmaceutical companies have a global business structure with highly distributed and extended manufacturing and supply chain systems. Highly uncertain demands are often combined with a mismatch in timelines, the construction time necessary for added capacity, and time for product approval or actual assessment of initial market demand.

High competition for generic products at the end of product patent life.

Narayana et al. (2014a: 381) summarize the characteristics of the pharmaceutical industry as high R&D investment, high-quality constraints, long production lead times, high waste-to-product ratios, and shortened product cycles. One of the biggest cost drivers for pharmaceutical companies is research and development. Besides the high cost and low success rate of developing a new drug, pharmaceutical companies also invest greatly in marketing to physicians and other healthcare parties (Almarsdottir and Traulsen, 2005: 144).

Generic drugs tend to have high competition in the pharmaceutical industry since the components of the drugs from different companies are identical and sales numbers are purely driven by marketing activities. Many pharmaceutical companies earn the highest interest from patent products. However, as mentioned above producing a new patent product is a long and costly process. Shah (2004: 930) emphasizes the changing circumstances of the pharmaceutical industry; effective patent lives are shortening (around 1-5 years), and patents provide lower barriers to entry while the payers of healthcare such as

governments put strong price pressure on the industry (more information in chapter 4.2.1).

Priyan and Uthakakumar (2014: 177) summarise the effective management of pharmaceuticals as "ensuring the product availability at the right time, at the right cost, and in good condition to the right customer", which emphasizes the importance of reducing the supply chain cost without sacrificing the high customer service level. Nonetheless, certain attributes of the pharmaceutical industry and medicines create a challenge in maintaining a high CSL with a lower supply chain cost. Due to the chemical nature of medicines, the sensitive molecular entities in drugs can spoil and degrade during transportation and distribution (Laínez et al., 2012: 20). In addition to that, the pharmaceutical industry is mostly global with 80% of sales in North America, Europe, and Japan with rapid growth in the rest of the world (Laínez et al., 2012: 20). In conclusion, the products must be distributed around the world with a great risk of deviation which eventually adds to the cost of PSC.

4.2 Major Challenges in Pharmaceutical Supply Chain

The pharmaceutical industry has one of the most complex and challenging supply chain. "The pharmaceutical industry is inherently global, and its supply chain comprises a network of manufacturers (primary and secondary), which includes in-house or external contractors, packaging facilities, regional distribution centers (wholesalers), and final healthcare providers, such as hospital and pharmacies" (Sarkis et al., 2021: 6). In addition to the high amounts of partners and contractors being involved in the PSC, product portfolios becoming more complex while regulations are becoming more stringent which rises the costs of PSC.

The pharmaceutical industry has changed vastly and became much more challenging over the past 30 years. Influence and control of the regulatory authorities on the companies along with the market maturity and shortening patent life greatly increased the costs and time of developing new drugs, which led to a noticeable decrease in the productivity of research and development

(R&D) departments (Sousa et al., 2011: 2396). It can be predicted that those challenges will continue to grow due to the aging population, increasing demand for medicines, and strong pressure on prices and prescription policies (Shah, 2004: 930). Chapter 4.3 analyze the future of the pharmaceutical industry in Europe and more details about the aging population and price pressure can be found in those chapters.

In general, all global pharmaceutical organizations are facing challenges such as global quality standards, healthcare reform, patent expiries, and increased service requirements (Singh et al., 2016: 236). Shah (2004: 933) defines the key issues as "process development, capacity planning, network design, plant design, and pipeline and development management."

4.2.1 Challenges Related to R&D and Primary Manufacturing

The healthcare industry has the highest amount of R&D investment compared to other industries. According to Tollman et. al (2011), pharmaceutical companies invested 18% of their sales revenue in the R&D of a new drug in the USA in 2010. Based on the data shared by Efbia (2022), the health industry invested 12.5% of its net sales in R&D, the following industries are ICT services with 8,7%, and ICT products with 7,4% in 2021. The challenges related to R&D are summarised by Laínez et al., (2012: 21-23) and Narayana et al. (2012: 355) as "high cost, time-consuming clinical trials with low success rates in product discovery, generic competition at the end of product life, and high uncertainties in demand and capacity planning." According to a brochure published by Biopharmaceutical Research & Development (Phrma, 2015: 1), "it takes at least ten years for a new medicine to complete the journey from initial discovery to the marketplace, with clinical trials alone taking six to seven years on average. The average cost to research and develop each successful drug is estimated to be $2.6 billion and the overall probability of clinical success is estimated to be less than 12%." Despite the high costs and risk of new product development (NPD), the patent life is also diminishing therefore companies must have a capacity investment plan in advance to secure NPD in the future (Levis and Papageorgiou, 2004: 707). Due to mentioned challenges, pharmaceutical companies often use R&D joint

ventures, mergers & acquisitions, and outsourcing methods to develop new medicines (Simango, 2000: 32-33).

The primary manufacturing of APIs is the main bottleneck for the planning and scheduling of production in response to short-term demand fluctuation. The changeover, setup, and extensive cleaning tasks can be quite expensive and time-consuming in the primary manufacturing sites, this leads to long lead times, and high minimum order quantities (MOQ). "In the event of an API shortage, due to the lack of responsiveness of primary manufacturing, long campaigns emerge, which can then lead to drug product shortages and impact patients in need of the therapy" (Sarkis et al., 2021: 9).

Based on the review conducted by Jaberidoost et al. (2013: 1) most studies identified supply and supplier risks as the most important issues for PSC. The authors concluded that most risks related to PSC were internal and due to processes, people, and functions mismanagement in a firm which could be easily managed by suitable mitigation strategies. Sarkis et al. (2021: 3-4) summarize the challenges in PSC related to manufacturing as follows: identification of product portfolio, long approval times, batch-to-batch variability and shortages, long lead times for scale-up, capacity constraints, the uncertainty of long-term demand, adaptability to short-term demand fluctuations, quality assurance tasks lead times and lastly patient-specific products and process.

4.2.2 Challenges Related to Distribution and Logistics

The inherited challenges in primary manufacturing are affecting the whole PSC process until the patient. Due to uncertainty, lack of responsiveness, and transparency in upstream activities namely primary manufacturing, the companies are left with no option but to have high inventory levels since the high CSL and delivering the right medicine to the right patient at the right time is the primary goal of PSC which eventually increases the inventory costs. "Inventory costs in the healthcare sector are substantial and are estimated to be between 10 and 18 percent of net revenues" (de Vries, 2011: 60). Adding the demand

uncertainty in the long- and short-term to the uncertainty on the supply side result in a highly complex inventory problem for pharmaceutical companies.

The implementation of cloud-based IT platforms has become crucial in logistics activities for PSC since it will generate better visibility for tracking the products and manufacturing process between different facilities. Papathanasiou (2018: 498) highlights that cloud-based platforms would enhance communication and seamless connections between stakeholders and improve both agility and productivity in pharma sector operations. "Alongside cloud-based solutions, blockchain-based alternatives are being developed in recent years, the information stored in the blockchain is public, immutable, and tamper-proof, while the security of the sensitive data is assured by the utilization of strong state-of-the-art cryptographic algorithms" (Sarkis et al., 2021: 8). To utilize digital platforms, companies should give effective training to their value chain and ensure that every stakeholder (internal and external) uploads the most recent and relevant information to the platforms.

Outsourcing logistics activities to 3PL providers is a common practice in the pharmaceutical industry, companies can focus on their core activities by outsourcing their logistics activities to specialized 3PL providers. This is especially beneficial in the pharmaceutical industry since regulations, laws, and policies regarding medicines could vary in each country. Therefore, many global pharmaceutical wholesalers choose to outsource the distribution activities in local markets to already specialized local 3PLs. Deavers (1997: 504) emphasizes that the changes in the competitive market environment will increase outsourcing activities, these changes are "rapid technological change, increased risk and search for flexibility, greater emphasis on core competencies and globalization." Deavers (1997: 508) has additionally identified the following reasons for outsourcing: improving company focus, accessing world-class capabilities, acceleration of benefits from reengineering, sharing of risk, and freeing resources for other purposes.

However, outsourcing usually causes communication and information-sharing issues with external partners and it gives little control to the company over its operations. This issue usually results in the delay of the administrative tasks in supply chain processes which could have been avoided by better communication and information sharing. Additionally, excessive outsourcing might negatively affect the implementation of cloud-based solutions since the usefulness of these platforms depends on how effectively people use them and on the quality and relevancy of the information on the platform.

Other challenges in PSC are related to applying the emerging trends in SCM such as lean manufacturing, reverse logistics, and green SCM. Although authors Xie and Breen (2012: 44) suggested that reverse logistics can be implemented by creating a channel through which expired medicines can be sent back to the manufacturers, in most cases expired medicines cannot be reused, utilizing the components of expired products would be quite expensive and challenging. As Biehl et al. (2007: 445) have observed, unlike forwarding supply chains, "reverse supply chain operations are more complex and prone to a high degree of uncertainty, affecting collection rates, the availability of recycled production inputs, and capacities in the reverse channel." Considering that PSC is already highly complex and heavily regulated, it is unlikely that reverse logistics will become a common practice in the pharmaceutical industry in near future.

Most companies in the pharmaceutical industry still use the traditional push-based system in their inventory management until the wholesale level which creates high inventory levels downstream (Shah, 2004: 932). Therefore, inventory management systems such as "JIT and stockless inventory philosophies have been criticized in the literature for not being pragmatic, given the critical nature of medicine availability" (Narayana et al., 2014a: 381). "It is observed that the pharmaceutical industry is still in the nascent stage of implementing Lean manufacturing initiatives" (Singh et al., 2016: 243). bin Wan Ibrahim et al., (2017: 2) stated that lean initiatives were not adopted by the industry due to a greater focus on quality that is strictly controlled by regulatory compliance. Thus, regulatory compliance could be regarded as a challenge, a

source of conflict, and a barrier to the implementation of lean practices in the field (Sieckmann et al., 2018: 819). It is important to note that while the lean approach focuses on waste elimination and simplified processes, regulatory policies concentrate on the quality and safety of the drugs which naturally restrains the implementation of lean philosophy in the pharmaceutical industry. However, Knut (2017) argues that implementing lean principles does not necessarily acquire major capital investments, and a pharmaceutical company that implements lean principles successfully could benefit from significant cost savings and competitive advantage. Argiyantari et al. (2020: 475) found that the most attention on implementing lean principles in the industry was focused on manufacturing sites while upstream suppliers and downstream activities have received less attention. In conclusion, due to recognized challenges related to MOQ, long lead times, and supply, and demand uncertainties, the implementation of the lean approach in a pharmaceutical company would be a challenging and costly process that would require intense administrative work.

Singh et al. (2016) reviewed 136 research papers on PSC and stated that "because of many uncertainties and unpredictability, capacity planning and inventory management are major challenges for the pharmaceutical sector" and most pharmaceutical firms are lacking in terms of Lean and green operations. Other major issues emerging in PSC are "product and process development, plant, and network design, E-business and IT applications, outsourcing, and reverse logistics" (Singh et al. 2016: 248).

4.3 Pharmaceutical Industry in Europe

The pharmaceutical industry is in constant change and improvement, R&D is constantly working on alternative treatments to the current ones or treating conditions that are previously considered incurable. However, as explained in chapter 4.1, the costs of developing new pharmaceutical drugs can be significantly high (Laínez et al., 2012: 20), putting great pressure on the healthcare budgets of the member states of the EU.

According to OECD/European Union's report (2020: 170) in 2018 "retail pharmaceuticals (prescription medicines and over-the-counter products) alone accounted for one-sixth of all health care expenditure and were the 3rd largest spending component in EU countries after inpatient and outpatient care." In total, the EU retail pharmaceutical bill was around EUR 190 billion alone in 2018. However, the statistic excluded the pharmaceuticals used during hospital treatment (usually referred to as inpatient or day-case spending), and available data suggest that including those spendings would be an additional 20%.

OECD Health Statistics 2020 (Eurostat Database) provides a detailed breakdown of those spending which provides a concrete base for readers to understand pharmaceutical expenditures.

"Spending for retail pharmaceuticals averaged EUR 381 per person across EU member states in 2018 (adjusted for differences in purchasing power). Around four out of every five euros spent on retail pharmaceuticals goes on prescription medicines, with most of the rest on OTC". Spending in Finland is slightly lower than the average of the EU with EUR 374 per person (see figure 8).
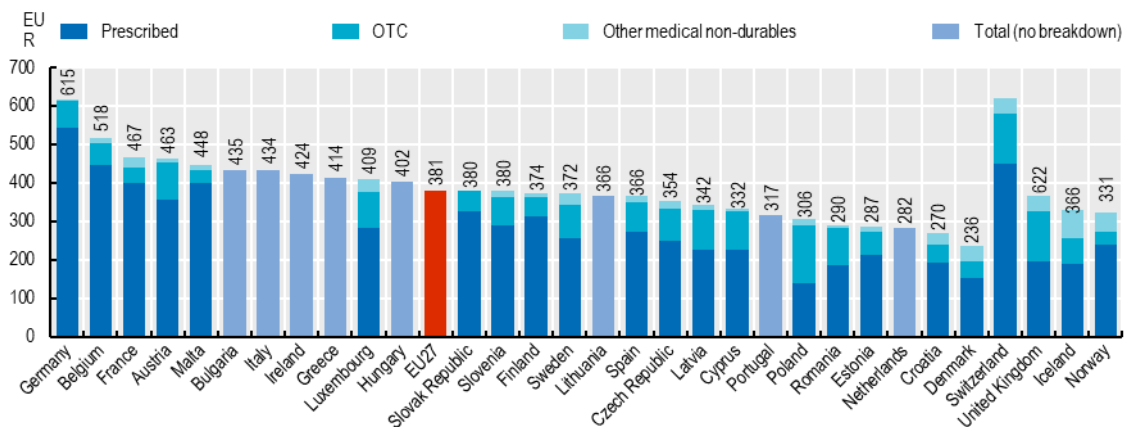

Figure 8 Expenditure on retail pharmaceuticals per capita, 2018 (Source: OECD Health Statistics 2020: 171; Eurostat Database)

"In most countries, the costs of pharmaceuticals are predominantly covered by government or compulsory insurance schemes. Public coverage is most generous in Germany and France, where government and compulsory insurance

schemes pay for more than 80% of all pharmaceutical costs." In Finland and on average EU member states' governments and compulsory insurance schemes pay 56% of all retail pharmaceutical costs (see figure 9).
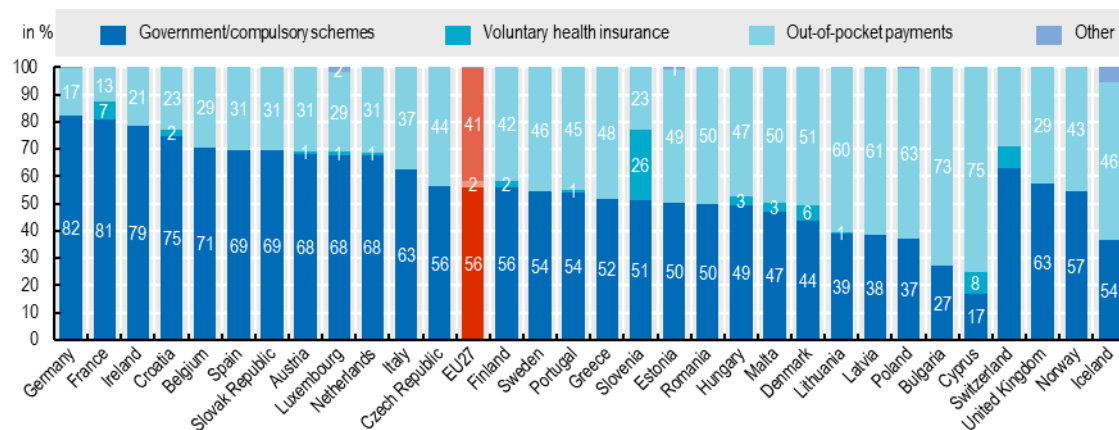
Figure 9 Expenditure on retail pharmaceuticals by type of financing, 2018 (Source: OECD Health Statistics 2020: 171; Eurostat Database)

The OECD/EU (2020: 170) publication also emphasizes the rapidly increasing number of cancer medicines, such treatments are known to be quite expensive and costly. The value and sales of oncology medicines have more than doubled in Europe in the past decade according to the report. The data above proves that pharmaceutical expenses are a serious issue for EU states and their citizens, along with that, it can be assumed that the expenses will only grow in the future with the aging population (see figure 10).
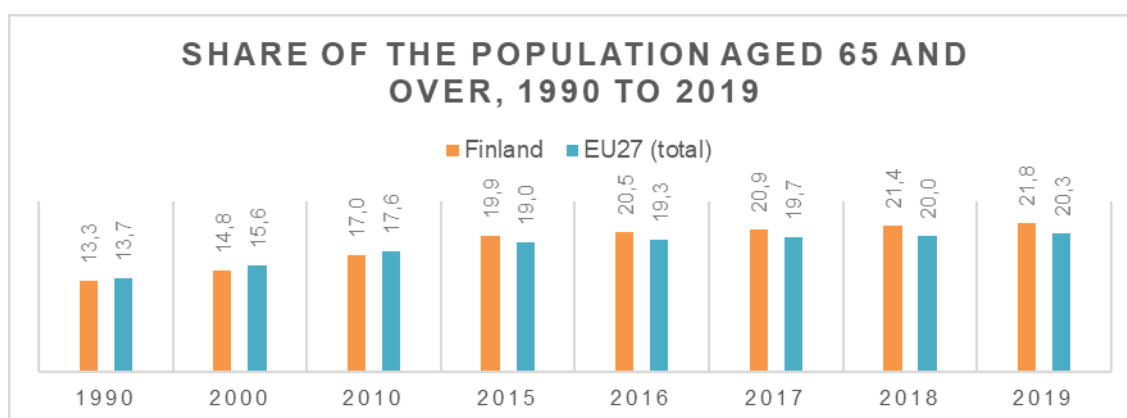
Figure 10 Share of the population aged 65 and over (Source: OECD Health Statistics 2020: 231; Eurostat Database; data extracted in September 2020)

The pricing policies and high competition among pharmaceutical companies for generics and biosimilar medicines help on controlling pharmaceutical expenditures in many countries. According to the paper published by Belloni et al. (2016: 34), pharmaceutical spending is still expected to grow in some countries, but growth is expected to be slower. However, the number of high-cost drugs and their prices will continue to grow. "New high-cost specialty drugs are coming to the market and are expected to account for 50 to 100% of pharmaceutical spending growth in the near future" (Belloni et al., 2016: 40). The increasing availability of expensive specialty medicines in oncology, hepatitis C, pulmonary hypertension, and rare diseases will account for most of the pharmaceutical spending in the future according to Belloni et al., (2016: 40). It is important to provide those specialty drugs to patients with rare or life-threatening diseases. Additionally, financial incentives are needed to encourage pharmaceutical companies to invest in the costly development of new products.

4.3.1 Pharmaceutical Strategy for Europe

The EU developed a strategic plan to tackle the problem with the pharmaceutical industry to decrease the costs of health care and make it more accessible for its citizens. European Commission published its plan in detail under the name "Pharmaceutical Strategy for Europe" in 2020. In this chapter, several strategies mentioned in the plan and what they mean for the pharmaceutical industry in the EU will be discussed.

Although rapid progress and innovations were achieved in the healthcare industry, many patients were unable to afford those treatments therefore, the main goal of the EU's Pharmaceutical Strategy is to provide safe, effective, and affordable medicines and treatments for all of its citizens by ensuring that the industry is strong, competitive and green (EUROPEAN COMMISSION, 2020: 5). It is mentioned by the commission that the Covid-19 pandemic validated the vulnerabilities related to data availability, supply of medicines, and manufacturing capacity limits.

The plan emphasizes the collaboration among important parties such as The Commission, the European Medicines Agency (EMA), and the medicines regulatory authorities in the member states to ensure that patients have access to high-quality, effective, and safe medicines (EUROPEAN COMMISSION, 2020: 6)

Promoting investment in R&D is an essential part of the plan since innovative medicines and treatments are the only way for making progress in preventing and treating diseases. "There are over 7 000 known rare diseases, including rare cancers, of which 95% still have no treatment option" (EUROPEAN COMMISSION, 2020: 9). As mentioned in chapter 4.1, with high costs and low success rate in product discovery, pharma companies have a less commercial interest in R&D than they did a few decades back when the patent life after discovering a new medicine was much longer. Therefore, it is indicated that the EU may try to encourage investment in R&D since the current interest of the companies is not enough.

The EU is dedicated to keeping the pharmaceutical industry competitive to achieve more efficient and affordable medicines for patients, a certain way to achieve affordable treatment is through generic and biosimilar medicines. The commission also emphasizes monitoring the mergers and acquisitions between companies since that can affect the competition hence prices of medicines (EUROPEAN COMMISSION, 2020: 12).

"The pharmaceutical strategy will create a stable and flexible regulatory environment that offers legal certainty for investment and accommodates technological trends" (EUROPEAN COMMISSION, 2020: 16). This indicates that the EU will support and protect the innovative actions of the companies regardless of their size, creating an opportunity for SMEs to compete with large pharmaceutical companies. It is a common practice to outsource certain functions of the business to focus on investing in therapeutic areas in the pharmaceutical industry, this trend allows new players to enter the industry such as technology companies. The commission aims to have an EU-wide data access infrastructure

that will improve cross-border analysis of health data in the EU, support innovation, and better health care delivery while providing a guide for policymaking and regulation. It is also mentioned that digital technology and artificial intelligence will enable more efficient and flexible regulatory processes and legislation.

Securing the supply of medicines and avoiding shortages is another concern mentioned by the Commission which was increased during the Covid-19 pandemic. The reasons for the shortages are listed in the report as follows: "marketing strategies, parallel trade, scarce API, intermediates and raw materials, weak public service obligations, supply quotas, or issues linked to pricing reimbursement." Some legislative measures mentioned by the Commission to address shortage issues: "stronger obligations on industry to ensure the supply of medicines, earlier notification of shortages and withdrawals, enhanced transparency of stocks across the supply chain, and a stronger coordinating role for EMA in monitoring and managing shortages." (EUROPEAN COMMISSION, 2020: 24).

The Covid-19 pandemic revealed many issues related to the PSC and manufacturing, most notably the issues related to the resilience of the PSC, the Commission was called by the EU to address this issue. Above all, the supply issues related to raw materials, and APIs can cause shortages in critical products. The Commission's solution is to start communication with the actors in the pharmaceuticals manufacturing value chain, public authorities, and research facilities, identifying different potential vulnerabilities in the global supply chain and formulating policy options and possible measures to address those issues. Although it is not clear what kind of measures and solutions would take place, one thing is certain; transparency and effective communication among all partners across the supply chain will play an important role in achieving a resilient PSC.

The actors involved in PSC must understand all issues mentioned in this section are a roadmap towards a more resilient, sustainable, and efficient

Pharmaceutical Industry and the companies should expect the changes mentioned in this chapter will take place in the near future since the plan published by the European Commission.

Pharmaceutical expenses are a major concern for the EU and as indicated in this chapter, the Commission highly emphasizes price reduction by increasing the competition, the pressure on the pharmaceutical companies will push them to be much more cost-effective since they cannot simply increase the prices to cover their costs. Along with that, CSL must be kept at a maximum to ensure that patients can receive the medicine/treatment without delays. In conclusion, pharmaceutical companies will have to focus on their supply chain processes to be more efficient. Inventory is a major cost driver within the supply chain, and it is only natural that inventory management will be the main focus area for decreasing costs.

5   Case Study

The main purpose of the case study is to discover the real-life implications of the theory that is discussed and suggest a new inventory strategy based on ABC-XYZ analysis (AbcSupplyChain, 2022) to decrease the inventory level. In addition to numerical data, a key employee of the case company has been interviewed. The purpose of the interview is to acquire non-published information and insights about the pharmaceutical industry and the case company to gain a professional point of view on the reality of the challenges and trends in PSC that have been discussed earlier (chapter 4). The quantitative data and ABC-XYZ analysis will provide objective and numerical information about the inventory of the company while the qualitative data gained through the interview will provide a deep understanding of the issues in the industry that is not quantifiable.

5.1   Background of the Case Company

The case company is a global pharmaceutical company. In this paper, the focus will be only on the Finnish cluster, and only selected 321 SKUs will be included

in the ABC-XYZ analysis. Figure 11 shows briefly the supply planning process in the case company. The supply chain model for the Finnish cluster is decentralized multi-echelon inventory management and the production is heavily based on the push system. The local teams including finance, commercial, and supply collaborate through monthly demand review meetings to create the most accurate demand plan and upload it to a cloud-based IT system, the demand forecast usually covers the demand for the targeted market for the next 24 months and it is updated by the demand planners beginning of each month. Based on these forecast reports, supply planners in the global team assess inventory levels, evaluate supply shortages and create aggregate supply planning. For the Finnish cluster, the inventory is stocked in two locations: in a distribution center (DC) in Europe and the warehouse of the 3PL provider in Finland. The aimed safety stock level in the 3PL provider's warehouse is 90 days and the aimed safety stock level in central DH in Europe is another 90 days for all SKUs. It is the supply planners' responsibility to ensure the stock is available in the Europe DC for Finland to order. Demand planners on the other hand should provide an accurate forecast.

Demand Planning
- Demand Forecast
- 0-24 months

Supply Planning
- Finalize and publish constrained Supply Plan
- 0-24 months

Capacity Planning
- Create and maintain constraints
- 0-6 months

Production Planning
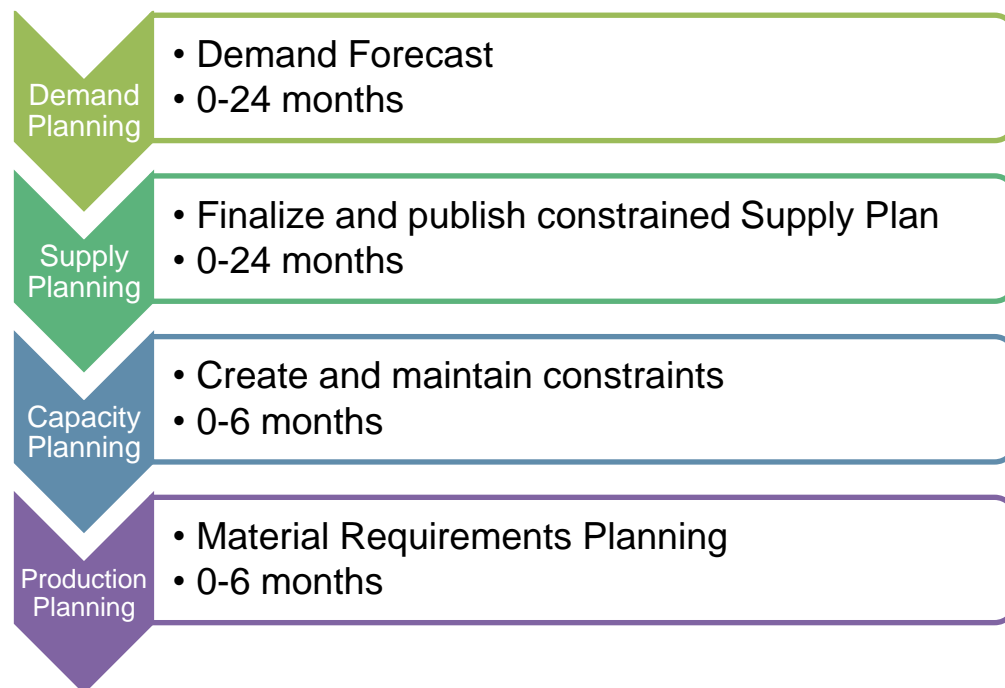- Material Requirements Planning
- 0-6 months

Figure 11 Supply planning the case company

The lead times in the production site and the limitation with the capacity usually are the main causes of the shortages within the company. The lead times for the production of a batch are typically between 4-6 months. The transportation time from the manufacturing to the central DC is hard to determine due to various, unpredictable variations affecting the overall time. The transportation time from the DC to Finland is mostly changing between 14-21 days, in an urgent situation, express shipment can be placed which decreases the time to 7-10 days.

5.2 Supply Chain Challenges for the Case Company

To identify the challenges for the case company an interview was held with a highly experienced employee of the case company, the interviewer is the author of this study. Only the key parts of the interview will be discussed in this chapter to avoid repetition and details of questions and answers can be found in appendix 1.

The key challenges not only for the case company but for the industry are the availability issues and dysfunctionality of the supply chain according to the interviewee (2022). Adding to the issues with the scarcity of APIs; issues related to outsourcing, capacity constraints, and communication among the external and internal partners were highly emphasized by the interviewee (2022). All these issues usually escalate to extremely long lead times (usually 4-6 months).

Pharmaceutical companies rely on outsourcing for cost savings and quality requirements. However, this creates highly complex, dispersed supply chain processes for the companies. For instance, a product might have to be transferred between many different contractor sites and plants before it becomes the final product ready for the market and each site might face capacity constraints regarding APIs, raw materials, packing materials, artworks, quality controls, etc. Thus, a small issue and delay in the supply chain can quickly escalate to a shortage. Additionally, this kind of system is extremely vulnerable to volatility in demand since these issues will add to the initial lead times mentioned above. Effective communication with external partners and

simultaneous information sharing are crucial to have a proactive approach to upcoming issues.

Recent studies by Papathanasiou (2018) emphasized the benefits of cloud-based seamless information sharing and Sarkis et al. (2021) note the development of blockchain-based alternatives for reliable, public information (see chapter 4.2.2). These kinds of solutions can be greatly beneficial for the case company by allowing the downstream supply chain to have visibility on the upcoming supply issues in advance. Furthermore, the company can keep track of the repeating issues that are causing shortages and address them more effectively.

5.3 Application of ABC-XYZ Method for Inventory Optimization

The case company has a 90 days-on-hand (DOH) safety stock rule for all items in its inventory and a periodic review system is used for order management. The orders are placed monthly, and order quantities are different each month because they are determined by the difference between the current stock level in the local inventory and the 90 DOH safety stock level. The products are categorized based on their pharmaceutical features such as Generics, OTC, RX, etc. This categorization is important to have since each group will have different regulatory/quality requirements, marketing approaches, etc. However, when it comes to inventory strategies, these categories are not enough to answer the needs of the company.

Although the 90 DAYS policy provides enough safety stock for most products, it is still rare to have a policy that suits all products. Therefore, ABC-XYZ analysis will be applied to the case company's inventory, and according to the outcome of those analyses, different inventory strategies will be suggested. ABC will divide the products into 3 categories based on the yearly sales (A = 50% of the total sales, B=30% of the total sales, C=20% of the total sales) and XYZ will divide the products into 3 categories based on their demand fluctuations (X=demand is the least volatile, Y=demand is average volatile, Z=demand is the most volatile). In the end, each product will have two letters presenting the group they belong in

the ABC-XYZ matrix. In total 9 different categories were created. In addition to that, the criticality of the products for the patients was considered and the products were separated into 3 categories: vital, essential, and desirable. Vital is the most critical category, in absence of it, patients might be in a life-threatening situation, essential products are not as critical as vital ones but still important for patients to have access to it while desirable products not being critical at all. Based on this categorization, a different approach to inventory strategies for vital and essential products will be suggested.

In total 321 SKUs were considered and the data from October 2021 to September 2022 (the last 12 months) was used for conducting the analysis. Due to data unavailability, some SKUs were kept out of the calculations. The numerical data collected includes the following: sales values both as quantity and as monetary on monthly basis, the scrapped stocks due to expiry and their monetary value, and the current inventory level.

5.3.1 The outcome of the ABC Analysis

For ABC, the monetary value of the last 12 month's sales was considered on the SKU level. Based on the calculations made, 18 products appeared to be responsible for 49% of the sales, 54 products were responsible for 31% of the sales and 249 products were responsible only for 20% of the total sales in the last 12 months (see table 1).

Table 1 Distribution of the SKUs in ABC classification

Group	Number of SKUs	Percentage
A	18	49,04 %
B	54	30,80 %
C	249	20,16 %
SUM	321	100,00 %

The majority of the products have less than 1% of contributions to total sales therefore, grouping the products responsible for 80% of the total sales did not meet the need of the case company since the main purpose is to identify the most important items that would need extra attention if the number of items in A group

is too large, it would be difficult show the same attention for each item and would ultimately increase the inventory level. Below figure 12 and 13 demonstrate the significance of products in A group for the case company.

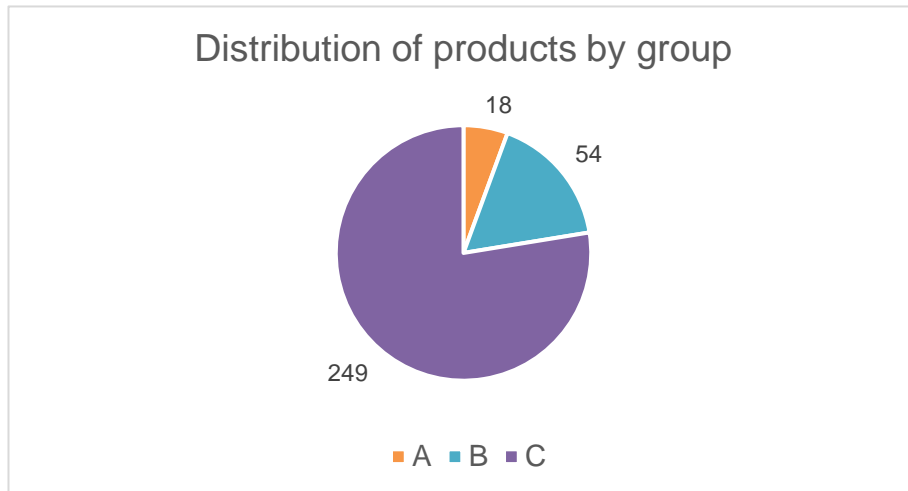Figure 12 Pie chart for the distribution of products by group

Group A includes only 6% of total products, while group B includes 17% and group C includes 78% of the total products. Only one product from the A group is fallen under the vital category in terms of patient criticality and 3 items were considered essential.
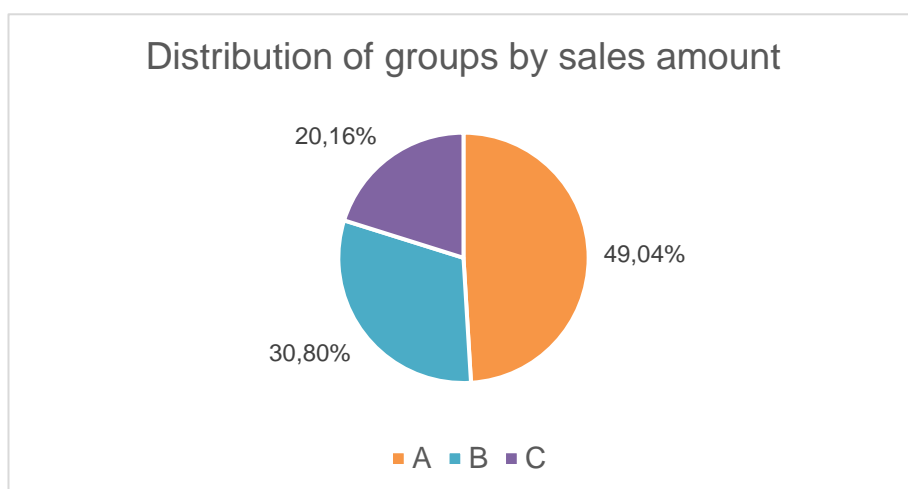

Figure 13 Pie Chart showing the distribution of products by sales amount

5.3.2 The outcome of the XYZ Analysis

For calculating the demand pattern for the products, the monthly sales of the last 12 months were used as data. Firstly, the standard deviation of each SKU was calculated to see how dispersed the data compare to the mean however by itself, the standard deviation is not enough to categorize the products since the calculation will give a value based on the quantity which is irrelevant for comparing different products. What is needed is a percentage value of the standard deviation therefore, the coefficient of variation was also calculated by dividing the standard deviation value by average/mean which gave the relative standard deviation value for each item. The smaller the coefficient of variation, the flatter the demand pattern, the higher the coefficient of variation, the more volatile the demand.

The SKUs with less than a 10% coefficient of variation were classified as group X, the SKUs between 10-40% were classified as group Y and 40% and above were classified as group Z. The below table 2 shows the distribution of the products.

Table 2 Distribution of the SKUs in XYZ classification

Group	Number of Products	Percentage of Products
X	37	11,53 %
Y	138	42,99 %
Z	146	45,48 %
SUM	**321**	**100,00 %**

Figure 14 shows the distribution of the products in a pie chart. The number of products in groups Y and Z is almost even, showing that the differences in demand patterns are not as sharp as the sales amounts which are expected.
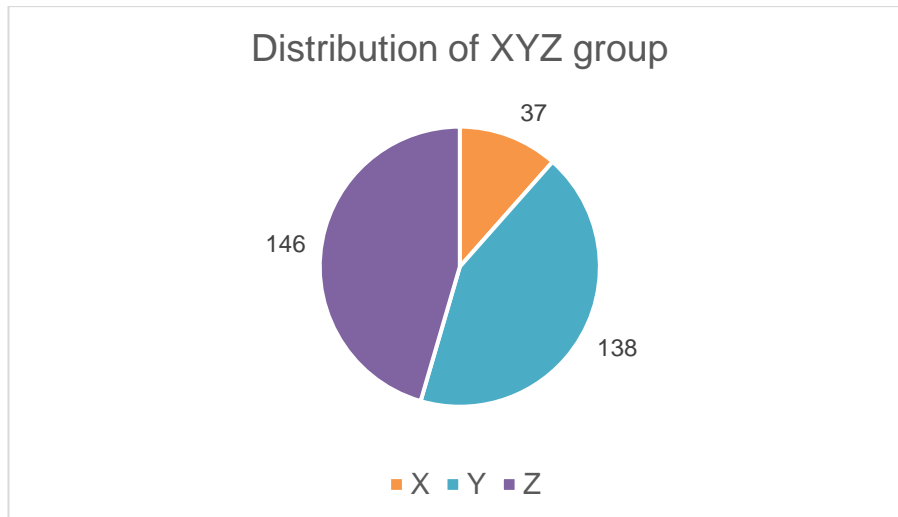
Figure 14 Pie Chart showing the distribution of products in XYZ group

The differences between demand patterns from each category are demonstrated in figure 15. Product 73 is from group X with a 4,2% coefficient of variation, product 211 is from group Y with a 39,20% coefficient of variation and lastly, product 242 is from group Z with a 46,16% coefficient of variation.
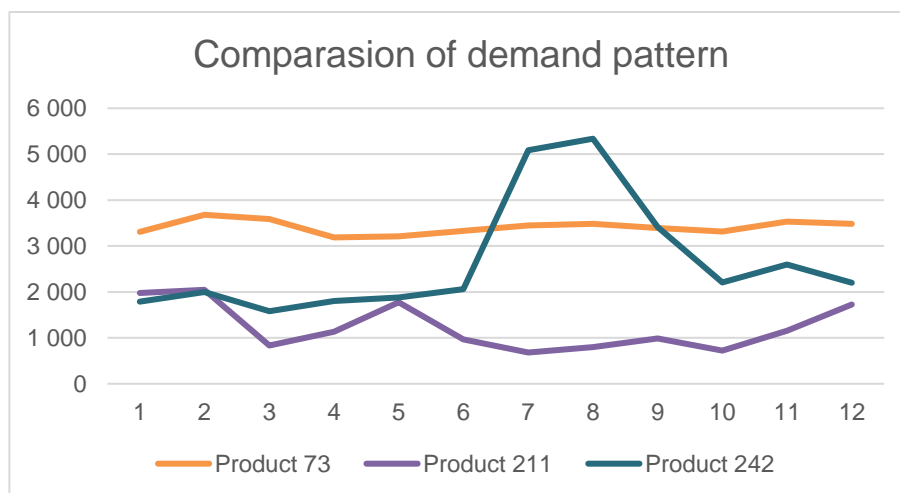
Figure 15 Comparison of demand pattern of 3 items from each group

The weakness of this calculation is that it ignores the seasonality which in most cases are predictable fluctuations. For instance, some medicines that are used for treating cold or flu will sell more in winter while the medicines for allergies will peak during the spring.

5.3.3 The outcome of ABC-XYZ Matrix Analysis

The inventory strategy must take into account both categorizations, therefore, a matrix was created to group the items under 9 categories based on the ABC-XYZ analysis. The following groups were created: AX, AY, AZ, BX, BY, BZ, CX, CY, and CZ. The number of items in each group can be seen in table 3.

Table 3 Number of items in each category

| Matrix	A	B	C	SUM
X	7	9	21	37
Y	7	26	105	138
Z	4	19	123	146
SUM	18	54	249	321

As seen in table 3, group CZ has the highest amount of items (38% of the total). The items in the category CZ have high demand uncertainty causing a challenge to the company. However, in terms of financial gain and revenue, the company must pay special attention to the group AX, AY and AZ. Since there are only 18 items in those categories, the resources should focus on securing the stock of those items. Below in figure 16, the distribution of the items in each category is visualized.
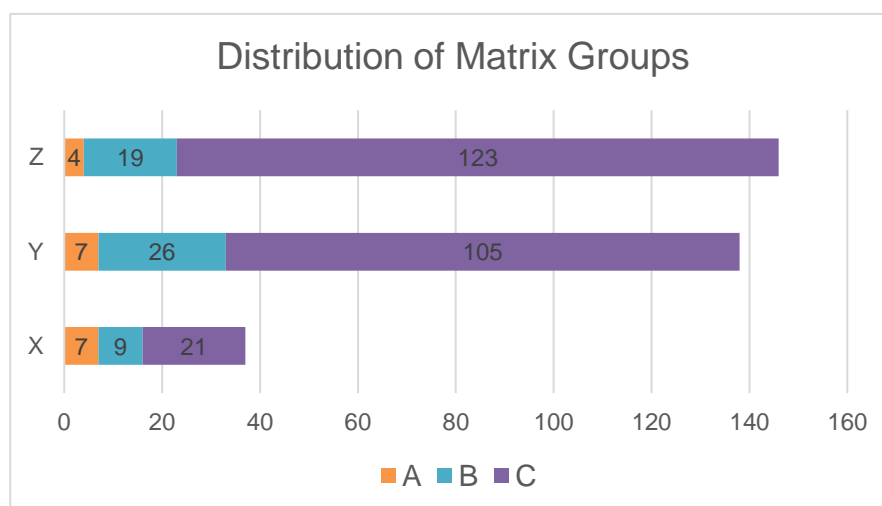

Figure 16 Distribution of the SKUs in the ABC-XYZ matrix

Patient critical medicines, regardless of their financial aspects in the company, must be available for the patients at all times for humanitarian reasons. Therefore, recommendations on inventory strategy will consider the criticality of the medicines in addition to ABC-XYZ. Below table 4 shows the distribution of the critical SKUs among the 9 determined groups. Only 12 items were recognized as vital and 7 of them are in category C, not carrying any financial significance for the company. Regardless, it is important to have a high stock level for those 12 items as mentioned already. A similar result can be seen for Essential items, 19 of them are under the category of C.

Table 4 Distribution of criticality of medicines in ABC-XYZ groups

	AX	AY	AZ	BX	BY	BZ	CX	CY	CZ	Sum
Vital	0	0	1	0	0	4	1	0	6	12
Essential	1	1	1	1	7	2	2	9	8	32
Desirable	6	6	2	8	19	13	18	96	109	277

Although the items could be divided into 27 categories as shown in table 4 and different inventory management approaches could be recommended for each category. However, many categories would have only a few items and some none, thus, for the simplicity and manageability of the orders and inventory, 9 categories based on ABC-XYZ are selected as the final categorization.

5.4 Recommendations for Inventory Strategy Based on the ABC-XYZ Analysis

The criteria chosen for ABC analysis can change based on the needs of the company but the purpose of it is to categorize the goods based on their value so the companies can give the most attention to the most important products. In the previous chapter, 321 items were divided into 9 categories. In this chapter, different inventory management approaches will be suggested for each group.

The first adjustment must be done at the safety stock level, for each category different safety stock levels will be suggested. For items in group A, a higher stock level must be maintained to avoid any shortages since these products are solely responsible for half of the sales and any loss of sales must be avoided. For the

items in B and C, the safety stock level will be decreased. In addition to that, the safety stock level will be higher for category Z compared to X and Y due to demand volatility. The suggested stock level can be seen in table 5.

Table 5 Safety Stock Level (in days) based on each category

Matrix	A	B	C	
X	90	80	70	DAYS
Y	100	80	70	DAYS
Z	120	90	80	DAYS

Since there only 4 products are in category AZ, the higher stock level will be compromised by the lower stock level of categories BX, BY, CX, CY, and CZ since the number of items in those categories are significantly higher. In addition to that Vital products will have 120 DAYS and Essential products will have 90 DAYS regardless of their placement in ABC-XYZ categorization. Although it can be financially unbeneficial for the company, these products are critical for the life of patients, therefore the shortages must be avoided at all costs.

After the consideration of the medicine criticality, the overall desired stock level and number of items can be seen in table 6. The majority of the items are piled up in 80 and 70 days.

Table 6 Stock levels (in days) and number of items

Stock level (in days)	Number of Items
120	15
100	7
90	48
80	137
70	114

The products that are in category AX, AY, AZ, and Vital must have a multi-item inventory management system which is a more utilized version of the continuous

review system. The stock level items in the 3PL inventory and the central DC will be checked and the supply plan and scheduled shipments to the central DC will be monitored weekly. The scheduled shipments are usually visible in ERP systems but the information in those systems might not be the most reliable source, therefore the situation of the shipments must be always confirmed with supply planners. Implementing such a system for all items requires a high amount of resources and administrative work and is simply not realistic. However, this system is suggested for only 15 SKUs.

The rest of the categories must be reviewed periodically, and the orders ideally should be placed monthly to avoid high order, transportation, and transaction costs. Please notice that the suggested safety stock levels are only for the local inventory in Finland, the central DC in Europe should have the pre-determined 90 days safety stock at all times against long lead times and unpredictable production sites.

Based on the reported sales in the last 12 months, a safety stock level calculation was made to determine the difference between the current 90 DAYS inventory strategy and the suggested ABC-XYZ categorization inventory strategy. The total quantity sold in the last 12 months for 321 SKUs is 3 220 234 units. Based on this number the daily sales of each SKU are calculated and then multiplied by 90 to find desired safety stock level with the current system. After that, the daily sales quantities are multiplied by the indicated safety stock quantity by the ABC-XYZ analysis. The difference between the two safety stock levels can be seen in below table 7.

Table 7 Safety Stock level (in units)

Quantity Sold (last 12 m)	3 220 234
Safety Stock (ABC-XYZ)	759 519
Safety Stock (90 DAYS)	794 030
Difference	**-34 511**

Please note that, in reality, the process is not as smooth and perfect as in the calculations, the exact numbers seen here will never be reached since many

variables and uncertainties upstream and downstream will affect the stock level. Supply uncertainties, delays in primary and secondary manufacturing, marketing activities, price actions, and financial considerations are only a few variables that affect the stock level. The calculation in table 7 does indicate that the inventory level would be ultimately decreased by 4,35% with the suggested inventory strategy. Additionally, the availability of critical products can be monitored, and a proactive approach can be achieved in risky situations.

Please note that the values shown in table 7 and page 48 are altered to protect the data privacy of the case company, however, the ratio relation between numbers is real and relevant.

5.4.1 An Analysis of the Expired Items

The obsolete stock in inventory is nothing but a financial loss for a company in addition to the costs of products and service costs by the 3PL provider, there is also the cost of scrapping. In short, if an inventory is not managed properly, the obsolete stock can create an unexpectedly high cost for the company, this is especially important for perishable products with an expiry date.

As mentioned in chapter 4.2.2, returning expired products to manufacturers in hopes of decreasing the overall cost with reverse logistics is not yet a common practice in the pharmaceutical industry. The strict regulations and concerns on product safety simply make such practices highly expensive and challenging. To avoid waste and become more sustainable, pharmaceutical companies must show exclusive consideration to the expiring stock. Hence, the scrapped items due to expiration in the last 12 months will be analyzed in this chapter. In addition to the costs directly tied to the sales value, the cost of holding the stock inventory and the costs of scrapping the goods should be considered.

Although there are more scrapped batches than shown here, the majority of the lines are responsible for less than 1% of the total cost, thus, only the products that are responsible for 80% of the total cost will be analyzed. To protect the case company's data privacy, quantities and sales values of the products are not

shown but the ratio values and classifications of the products can be seen in table 8.

In total, there are 15 lines (15 different batches) responsible for 80% of the total cost. Please note that products 138, 196, and 259 written twice indicates the different batches of the same product. Only one of the items is considered vital and is also solely responsible for 27% of the total cost.

Table 8 Expired stocks table (80% of total) - Last 12 months

Index	Percentage	Cumulative	Matrix	VED	Cost-Sales Ratio
Product 138	24,97 %	24,97 %	BZ	Vital	86,32 %
Product 74	8,45 %	33,41 %	CY	Desirable	256,19 %
Product 169	6,59 %	40,00 %	CZ	Desirable	132,58 %
Product 196	4,21 %	44,22 %	CZ	Essential	119,77 %
Product 77	3,67 %	47,89 %	CY	Desirable	86,19 %
Product 252	3,61 %	51,50 %	BZ	Desirable	24,44 %
Product 259	3,00 %	57,82 %	BY	Desirable	25,47 %
Product 259	2,94 %	60,76 %	BY	Desirable	24,97 %
Product 232	2,46 %	68,59 %	CZ	Desirable	108,05 %
Product 110	2,14 %	70,72 %	CZ	Essential	34,71 %
Product 138	1,83 %	72,56 %	BZ	Vital	6,34 %
Product 196	1,74 %	74,30 %	CZ	Essential	49,47 %
Product 104	1,65 %	75,95 %	CZ	Essential	92,07 %
Product 137	1,48 %	77,42 %	CY	Desirable	20,52 %
Product 292	1,43 %	78,86 %	CZ	Desirable	2267,31 %

All products listed in table 8 are either scaled in Y or Z in XYZ classifications and B and C in ABC classifications, indicating that demand volatility is an important factor in expiry issues. The products in group B and C does not have high sales numbers compared to group A, meaning the high revenue created by the group A items are mostly due to the high number of units sold, therefore they can be considered as fast-moving while the products in group C are recognized as slow-moving.

As discussed previously in chapter 4, primary manufacturing in the pharmaceutical industry is known for long lead times and turnover periods and relatively high MOQ which cannot respond to the changes in demand in the short term (Shah, 2004). Therefore, a slow-moving product with high demand volatility has a high risk of expiry or shortage. Companies often must assess the situation for these kinds of items and decide whether to discontinue or not. For example, for product 292, the case company has decided to discontinue. However, for items such as products 138 and 104 such a decision cannot be taken lightly since those products are critical for the patients.

The cost-sales ratio in table 8 is found by the following formula:

$$\frac{Cost\ of\ scrapped\ product\ (last\ 12\ months)}{Total\ sales\ value\ of\ the\ product\ (last\ 12\ months)}$$

The formula will compare the revenue generated by an item with the cost of expiry of the same item, the higher the percentage is, the more costly the product. The products with over 100% ratio in the above formula mean that more units were scrapped than sold to the customer. Based on this calculation, the case company should consider the following items for discontinuation: Products 74, 169, 232.

In an ideal world, where forecasts are 100% accurate, all variables (external and internal) that affect the sales are known, and there would be no scrapping due to expiry. However, in reality, the environment and the market situation can change rapidly, and the demand is too dynamic to accurately forecast. There is a certain pressure on pharmaceutical companies due to competition to maintain a wide product portfolio. Below are the main reasons detected for the expired stocks in the past 12 months: Environmental changes such as Covid-19, high MOQ, high stock levels due to mandatory reserve supplies, declining sales due to availability issues, high competition over generic drugs, and forecast accuracy.

"The Act on Mandatory Reserve Supplies (979/2008) applies to the pharmaceutical companies importers, health care units, and the National Institute for Health and Welfare." (Fimea, 2022). The mandatory reserve is an act to

ensure the availability of certain medicines in cases of crisis and emergencies (Fimea, 2022). The mandatory reserve is calculated based on the previous year's sales amount and is different for each product, although the batches kept in mandatory reserve can be changed with a newer batch, it still does not prevent scrapping due to expiry since the stock level of that product must be much higher than normal. The Finnish Medicines Agency and The National Emergency Supply Agency pay compensation to the companies for the cost of maintaining reserve supplies (Fimea, 2022). Nevertheless, discontinuation of a slow-moving, low-sales product is much harder if the product is on the list of medicines for the mandatory reserve.

Most of the issues mentioned above cannot be resolved easily since controlling external factors such as mandatory reserve, competition, Covid-19 can be challenging. However, issues related to forecast accuracy must be addressed, the chapter 3.6.2 provides formulas to calculate forecast accuracy. Due to data availability issues, the forecast accuracy of the products was not calculated in this study.

6 Conclusion and Recommendations

The cost of pharmaceuticals accounted for 3rd largest spending of the EU in 2018 (OECD/European Union, 2020: 170) and the cost is expected to increase due to the aging population in Europe and the development of personalized medicines (Belloni et al., 2016: 40). The plan published by the European Commission (2020) confirms that the authorities will keep price pressures and motivate the competition to cope with the expenditures. Pharmaceutical companies must move towards more efficient supply chain processes to decrease their costs and have a competitive advantage.

Besides all developments and digital transformations towards more responsive, agile, and flexible supply chain processes, most pharmaceutical companies still adopt a traditional, push-based supply chain due to strict regulations, quality concerns, and inherited issues in manufacturing. Pharmaceutical companies are

expected to have high customer service levels and availability which reflects in high inventory levels and wide product portfolios.

According to the interviewed employee of the case company (Anonymous, 2022), competitive advantage can be gained with cost efficiency and proactively managed product portfolios. Product portfolio management is heavily related to marketing and commercial activities and is not a concern for this study. Cost efficiency on the other hand could be achieved with an efficient supply chain process. One of the biggest cost drivers in the supply chain is the inventory (Ginting and Julita, 2015: 22) and by optimizing the stock level across the supply chain, companies can decrease their costs substantially.

The case study showed that the total stock level can be decreased without creating the risk of an OOS situation by applying the ABX-XYZ classification method to the inventory system. Additionally, for 15 critical products, a continuous review system was suggested, and close monitoring of the upstream supply chain is also required for these products. The number of expired products could be decreased by calculating the forecast accuracy in the future when more data is available.

The issues related to availability are far more complex to be resolved by the Finnish cluster alone. The case company must closely monitor the entire supply chain process for the products that have frequent availability issues and identify the major reasons causing them. Additionally, the case company must consider the implementation of a cloud-based (Papathanasiou, 2018: 498) and/or blockchain communication channel (Sarkis et al., 2021: 8) to enhance the real-time information sharing between external, internal, upstream, and downstream stakeholders for a proactive approach to the incoming supply issues and uncertainties in the demand. Implementing such a platform will require an extensive analysis of the current supply chain process, training of the people involved in the entire process including the outside contractors and partners, and building a new company vision and culture that emphasizes information sharing, visibility, and transparency.

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Appendices

Interview Questions and Answers

Q. What is the role of quality and regulatory in a Pharmaceutical Company?

A. The regulatory and the quality can mean different things depending on the company, in the case company's organizational structure the regulatory is responsible for the management of the marketing authorization while the quality is responsible for quality control and assurance. Quality control happens during or immediately after the production process such as lab tests, processes control, etc. Quality assurance is typically making sure that the documentations and other authorization processes are in line with quality-related laws and regulations. The quality must ensure that the product is suitable for sale, safe for patients, and manufactured according to the marketing authorization.

Q. What are the key challenges for the case company and the industry from the quality perspective?

A. The key challenge for both the case company and the industry is the availability and functionality of the supply chain. In cases of product recalls and defects due to problems in production, the availability of a product can be postponed until the production and quality control of the next batches which can be challenging to determine the lead time.

In the last 20 years, the manufacturing of APIs are shifted from the many diversified manufacturers in Europe to the control of a few companies in Asia, and the global pharmaceutical industry is dependent on these few companies for sourcing the API meaning that an issue with one manufacturing plant can cause global supply issues. In addition to that, increasing outsourcing is causing further delays and dysfunctionality in the supply chain. The main motivation for pharma companies to outsource manufacturing sites is cost savings and quality

requirements. For instance, a pharma company might want to keep a small product in its portfolio but manufacturing it the house can be extensively costly due to quality requirements, capability issues, and so on. Therefore, it is much easier and cheaper to outsource it to a small manufacturer who specialized in the product. However, this brings one more external party to the overall supply chain.

Q. The EU commission indicates changes in regulations towards a more responsive and flexible process, do you believe this is something achievable?

A. Over the decades, many regulations are built up on top of each other to ensure the safety and quality of the products. Therefore, mangling that regulatory package would require heavy risk management and collaboration of many different parties within the pharma industry. In the end, the main question is what is sufficient and what is the safest option for the patient.

Q. The EU commission indicated many times that they will implement competition in the pharmaceutical industry to keep the prices low. How will the case company keep its competitive advantage in such a competitive industry?

A. The key to competitive advantage is cost efficiency. A lot of considerations regarding the launches of new products must be done since launching every product in every country might not be ideal due to country-specific regulations and laws affecting the prices. In addition to that, the portfolio of the company is an important asset therefore, the portfolio must be maintained proactively and kept fresh with relevant and interesting products by following the market trends, and changes in the environment, anticipating the needs well in advance. In terms of generics competition, heavy branding is a key factor in keeping a competitive advantage.

Q. For many industries, lean manufacturing and responsive supply chain practices can be the answer to competitive advantage. Do you think LM practices can be truly implemented in a pharmaceutical company?

A. Some pharma companies were able to implement lean manufacturing practices in their production and supply chain successfully. However, there is limited discussion about the lean approach in the case company and even though there are considerations, it is not visible to the internal stakeholders yet. Optimization of the lean approach is the main issue because often lean practices can be implemented in the company that can work so well within but because external stakeholders are left out from the implementation that the lean approach cannot be optimized throughout the whole supply chain.

Regardless of the difficulties, it is possible to successfully implement lean practices in pharma by carefully recognizing the value-adding processes related to regulations, safety, and quality and applying the lean approach to other processes that would not necessarily affect the safety and quality of medicines. It is important to note here that recognizing the processes that are not easily achievable, dedicated planning of every step, a thorough analysis of each process, and complete collaboration of the whole company is a must-have. Because a poor implementation of the lean approach can have serious consequences for the company's financials and reputation.

In conclusion, a pharma company can be lean, but it requires intensive administrative work, and the company must be invested in that as well as the suppliers and contractors. Collaboration and communication between the company and the external stakeholder is the key to implementing the lean approach.

Q. Data sharing and collaboration among all actors in the pharma industry was a highly emphasized topic for the EU commission. Do you believe this kind of

communication is plausible considering the highly competitive environment of the pharma industry?

A. If authorities make data sharing mandatory, the companies have no choice but obey. In an ideal world, collaboration and transparency in data sharing would bring many benefits to patients. However, sensitive information and competitive edge is a big issue that needs to be addressed. The authorities hardly ever think from the commercial perspective which means that initiatives and ideas may have been quite idealistic. In the end, the companies are also concerned about their commercial advantage in that they might not want to reveal information that would hurt their operations. In Finland, Fimea does require information about upcoming availability issues from the companies and although they encourage communication among competitor companies to address these issues, there is hardly a transparent conversation. Instead, the common practice is that Fimea assumes the role of middleman and approaches the companies to arrange a substitution for availability risk by keeping the other company's identity safe.