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Contingency Planning for Product Prioritization and Selecting Appropriate Mitigation Approach

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Abstract

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Product contingency planning is a part of the risk management strategy of the case company, and the purpose of this thesis was to develop a standardized process for product prioritization and selecting appropriate mitigation approach in case of longer-term manufacturing unavailability. With the planning, the objective is to prevent potential medicine outages from retailers and end users.

In the thesis, the product importance was evaluated from different aspects. In addition to business significance aspect, other aspects that were considered were therapeutic importance and regulatory requirements, and more specifically, obligation storage. Not all the products must have the same level backup plan, so assessing product priority helps focusing on the most or moderately important products in more specific. In addition, from determining product importance, the predictability and demand of the products to help selecting appropriate mitigation approach was also considered. There was no “one-size-fits-all” solution, but the appropriate approach depends on the product’s type, importance, predictability and demand. The approaches variated between agile supply strategy and stockpiling.

This thesis is based on qualitative interviews, workshops applied research. The interviewees were from different stakeholder groups’ representatives who are closest to the context of this thesis. The developed process was contemplated in the workshop with different stakeholder groups’ representatives. Available knowledge and best practices were searched from the literature in the field and from article publications.

The outcome of this thesis was a standardized process chart whereby the company can assess, based on predefined aspects, the product priority and select an appropriate mitigation approach for different products. With prioritizing the products, the company can prioritize resources for most important products to advance their contingency planning.

Keywords: contingency planning, risk management, pharmaceutical, agile supply chain management

Tiivistelmä

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Tuotteiden jatkuvuussuunnittelu on osa yrityksen riskienhallintastrategiaa. Tämän insinöörityön tarkoituksena oli kehittää standardoitu prosessi tuotteiden priorisoimiseksi ja sopivan mitigaatiovaihtoehdon valitsemiseksi pidemmän tuotantokatkoksen sattuessa. Suunnittelulla pyritään estämään lääkkeiden mahdolliset toimituskatkokset jälleenmyyjiltä ja loppukäyttäjiltä.

Työssä arvioitiin tuotteen merkitystä eri näkökulmista. Liiketoiminnallisen merkityksen lisäksi muita huomioitavia näkökohtia olivat terapeuttinen tärkeys ja viranomaisvaatimukset, tarkemmin kuvailtuna velvoitevarastointi. Kaikilla tuotteilla ei tarvitse olla samantasoista jatkuvuussuunnitelmaa, joten tuotepriorisointi auttaa keskittymään kaikkein tärkeimpiin tai kohtalaisen arvotuskertoimen tuotteisiin. Lisäksi tuotteen tärkeyttä määritettäessä otettiin huomioon myös tuotteiden ennustettavuus ja kysyntä, joiden avulla valittiin tuotteelle sopiva mitigaatiovaihtoehto. Tuotteille ei ollut vain yhtä oikeaa sopivaa mitigaatiovaihtoehtoa, vaan sopiva vaihtoehto riippui tuotteen tyypistä, tärkeydestä, ennustettavuudesta ja kysynnästä. Lähestymistavat vaihtelivat ketterän toimitusstrategian ja varastoinnin välillä.

Tässä opinnäytetyössä toteutetut tutkimusmenetelmät olivat kvalitatiivisia haastatteluja sekä työpajoja. Tutkimusmetelmissä käytettiin ”applied research” -tyyliä. Haastatellut henkilöt olivat eri sidosryhmien edustajia, jotka olivat lähimpänä tämän opinnäytetyön kontekstia. Kehitettyä prosessia suunniteltiin eri työpajoissa eri sidosryhmän edustajien kanssa. Haastatteluiden lisäksi tietoa kerättiin alan kirjallisuudesta sekä artikkelijulkaisuista.

Työn tuloksena syntyi standardoitu prosessikaavio, jonka avulla yritys voi ennalta määritettyjen näkökulmien perusteella arvioida tuotteen tärkeyttä ja valita sopiva mitigaatiovaihtoehto tuotteelle. Tuotteita priorisoimalla yritys voisi kohdentaa resursseja jatkuvuussuunnittelua tärkeimpiin tuotteisiin.

Avainsanat:	jatkuvuussunnittelu, riskienhallinta, lääketeollisuus, ketterä toimitusketjun johtaminen

Contents

List of Abbreviations

API	Active pharmaceutical ingredient. An Ingredient of the medicine that relieves the symptoms of the patient.
BCP	Business continuity plan. A plan where is predefined procedures in case of manufacturing unavailability (e.g., plant fire).
CMO	Contract manufacturing organization. Manufacturing strategy where processes are outsourced to partner or subcontractor.
CSA	Current state analysis. Analysis where is viewed the current operation models of the company.
ESO	External supply operations. Manufacturing strategy, where the finalized product is bought from external operator and is sold under the subscriber company brand. In this strategy, the subscriber takes full responsibility for the safety of the product.
G-OPS	Global Operations. Unit as a part of the whole supply chain of the company.
MTI	Made to inventory. Manufacturing strategy where the products are made based on demand forecasts and they are stored before sending them forward.
MTO	Made to order. Manufacturing strategy where products are made based on the orders. Unlike in “made to inventory” strategy, the finalized product does not have to keep stored rather it can be sent to the customer right away.

OPP	Own propriety products. The company’s product that is an outcome of their own research and development processes. The finalized product is patent protected so other manufacturers in the industry does not have an availability to manufacture similar products.

1 Introduction

This thesis deals with a company which operates in the pharmaceutical industry, and the company's business units are divided into four different categories: in their Own Proprietary Products, in Speciality Products (which includes generic prescription drugs and self-care products), in Animal Health and lastly, in their own active pharmaceutical ingredient (API) production and contract manufacturing. The main market in which the company is operating is domestic, but it has businesses also in other parts of Europe, Scandinavia, North America and Asia. Some of these business operations is managed via the company's business partners.

The company has some key products from different business units whereby the company is keen to increase the revenue growth and strengthen the market position. In 2021, some of the main drivers increased significantly in sales, and the company has also other long-term objectives for building growth.

To accomplish the set objectives, the company must consider risks that can have an impact on business' revenue. The company can face a sudden event that can change the circumstances partly or fully. A sudden change can have an impact on for example, manufacturing, acquisitions or negotiations about new partnerships with other manufacturers in the industry. COVID-19 is a good example of the rapidly changed environment, where the demand of the specific medicines experienced a big peak in demand and vaccinations began to be developed.

Still, evaluating risks alone is not enough, and the company must consider the procedures that must be made to keep the medicine supply continuous to avoid drug shortages. According to a representative of the company (2022), the company can face a contractual penalty if it is not able to deliver the predefined amount of products and the subscriber needs to rely on other alternatives if they are available. For example, the manufacturing plant can experience major destruction, such as plant fire, that will disrupt the manufacturing process. It

might be hard to prepare for cases like this, but it is good to assess, how the company can keep supplying products when this kind of event occurs, and the products might have to be prioritized. In addition to prioritization, it is good to consider appropriate mitigation alternatives to avoid supply disruptions. In this thesis there is considered, what are the factors that the prioritization is based on, and what are the key drivers when a specific mitigation approach is selected.

At the moment the company does have some valuation procedures for products when it comes to potential gross profit losses and contractual penalties. It would be also good to determine what other aspects could have an impact on product prioritizing in potential manufacturing unavailability and assess what would be the most appropriate mitigation alternative.

Now the procedures can vary depending on the department and processes. Some partners require a concrete plan in case of interruption. The objective of this thesis is to develop, for use in Global Operations (G-OPS), a standardized process for product prioritization in case of manufacturing unavailability and in addition, present different alternatives for mitigation. The outcome of this thesis is a standardized process for product prioritization in case of manufacturing unavailability that also considers different mitigation alternatives.

This thesis is based on qualitative interviews, workshops, and the use of an applied research approach. The representatives of different stakeholder groups who are most relevant to the context of this thesis were chosen as the interviewees.

The thesis is divided into three main sections: research methods (chapter 2), literature section (chapter 4), and case study (chapter 3, 5 & 6), which analyzes the existing situation and builds a proposal. The proposal is then prototyped. The execution of this thesis is detailed in more specific in chapter 2.

2 Method and Material

In this chapter the execution of this thesis is introduced. The execution includes presenting how the research was approached, what the design of the research is and how the data was collected.

2.1 Research Approach

In this thesis the approach of the research is based on the applied research. Qualitative methods are used for collecting data for the thesis, rather than qualitative due to nature of the subject. To improve the knowledge of this particular business problem, the information and data is collected via different interview sessions, both in group workshops and in individual interviews.

People who have participated on the interview sessions were picked from different stakeholder groups and from different organization levels, but who are also closest to the problem, to get more diversity and depth for the subject.

To get deeper knowledge of the subject in general, the information was also gathered through different journal articles, online publications and books. Some of the articles were obtained from materials used in school courses. For searching online material, the keywords used were “agile supply chain”, ”contingency plan” “scenario planning” “ABC-matrix” “ABC-XYZ analysis” and “velvoitevarastointi” (obligation storage).

2.2 Research Design (Project Process Chart)

Figure 1 in below shows the project chart of the research. It also shows gathered data and the outcome in each phase of the research.

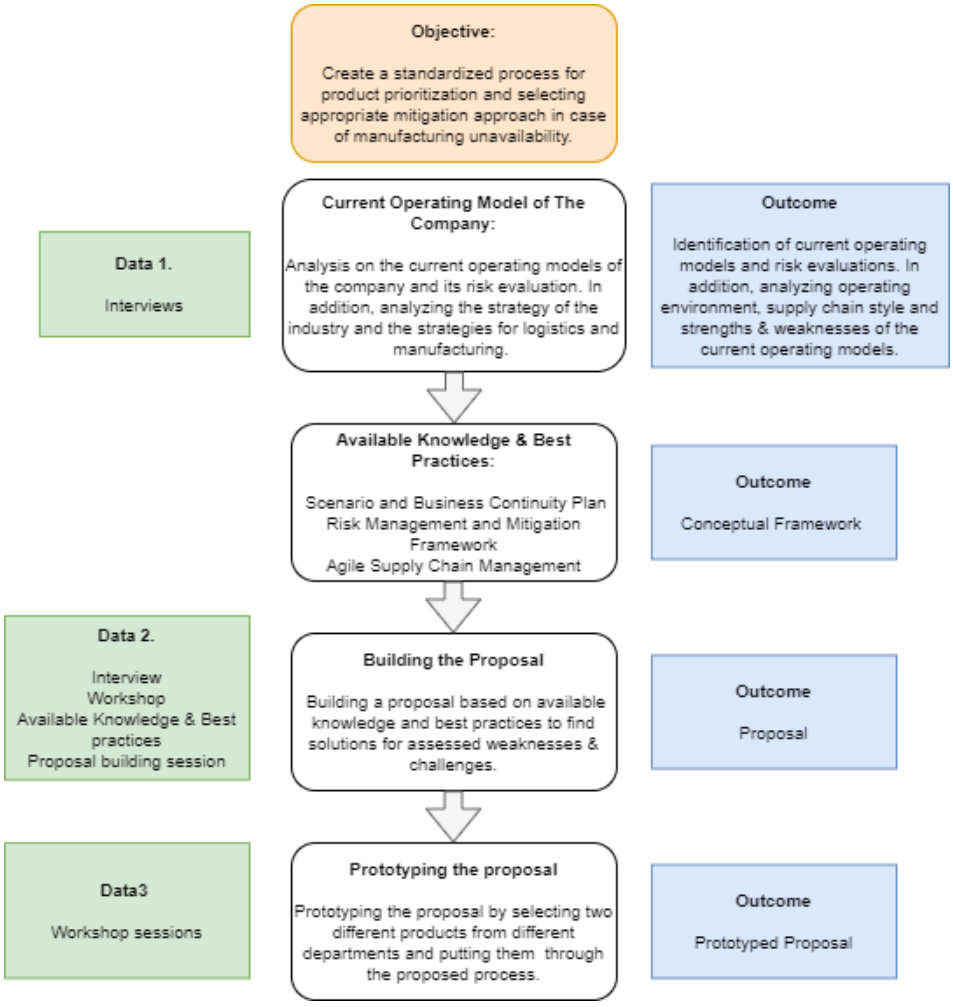

Figure 1. Research design chart.

The first phase of the research was to analyze the current operating models of the company related to their risks and, in addition, evaluate their business environment, styles and strategies related to supplying, logistics and manufacturing. The information and data were captured through interviews both, in group and individually, and the outcome was the identification of the current models and analyzed environment, strategies and styles. Based on the analysis, the strengths and weaknesses of the current situation were able to be determined.

The next phase of the research was to search knowledge that was available and best practices related to the subject. The phase provides a conceptual framework for this thesis where aspects from business continuity planning, risk management and agile subjects are presented in more detail. The knowledge was gathered through different journal articles, books, and online publications.

After creating the conceptual framework, the next phase was to start building the proposal. Key findings from the current state analysis and available knowledge and best practices created a base for building a proposal.

In addition, an individual online workshop and online interview was held to add more depth to the proposal. The outcome of this phase was the proposal for the predefined business problem.

The next phase after proposal building was to prototype the proposal. The prototyping was executed by two different workshop sessions with different departments. The objective was to have different types of products that were taken through the proposed process. With this concept, the proposal could be tested, and different valuations of the products created different outcomes and provided more depth to the proposal.

2.3 Data Collection and Analysis (Data Plan)

The data for different phases of the thesis was gathered via different types of interviews and workshops. The interviewees were selected based on their position in the organization for appropriate data collection. Table 1 on the next page presents the data collection in more detail.

Table 1. Data collection and analysis

	Participants/role	Data type	Topic, description	Date, Length	Documented as
		Data 1, for the current state analysis			
1.	**Group interview:** Director, Production; Head of Operations, Production Manager	Online interview	Workshop on current contingency processes. Get acquainted with the material sent by the partners	18, March, 30 min	Field notes
2.	**One-to-one interview:** Head of operations (tablet manufacturing)	Online interview	Reviewing the company's risk management in general. Get a big-picture overview for the risk management processes that the company uses	10, June, 30 min	Field notes
3	**One-to-one interview:** Vice president, operations (API department, subsidiary)	Online interview	Get acquainted with the contingency plan made by subsidiary for their operations. Recognize the key points from the plan.	13, June, 1h	Field notes
		Data 2, for building the proposal			
4.	**Group workshop:** Head of Operations, Production Manager, Development Manager	Online workshop	Workshop on presenting the proposal in progress. Going through the framework and brainstorm in group the vision of the proposal.	3, June, 30min	Field notes
5.	**Group interview with representatives of the hospital organization:** corresponding pharmacist & corresponding pharmacist for Hospital pharmacy	Online interview	Reviewing the product importance in patient treatment from hospital point of view.	14, June, 30min	Field notes
		Data 3, Prototyping the proposal			
6.	**Group workshop (inhalation):** Production Manager SC Planning Manager	Online workshop	Workshop on prototyping the proposal. Selecting products with different valuation and putting them through the process.	1, July, 45 min	Field notes
7.	**Group workshop (injection):** Production Manager, SC Planning Manager	Online workshop	Workshop on prototyping the proposal. Selecting products with different valuation and putting them through the process.	4, July, 45 min	Field notes

The data that was collected for this thesis has been divided in different data sections. In the first data section, the information was gathered for analyzing the company's current operating models. The interviews were held both in group and individually. The objective was to get familiar with the material which the company's partners sent to them. In addition, the objective was to review the company's risk management in general to get a big-picture view on the operations. Also, the interview was held with a representative of the subsidiary to get acquainted with the continuity planning made for their operations. The objective was to recognize the key points from the plan and use them as benchmarks when creating the proposal for G-OPS's use.

In the second data section, the data was gathered for building the proposal. The interview and workshop were held both in groups. The first interview session dealt with the proposal which was in progress. The objective was to go through the framework and brainstorm the vision of the proposal. To get more diversity for the proposal, people outside the company organization were also interviewed. This way it provided information in more detail from the user point of view.

In the third data section, the proposal was prototyped with different types of products, which were picked from injection and inhalation product portfolios. The prototyping phase was conducted in the form of a workshop, with separated sessions between injection and inhalation department. The objective was to pick different products with different features for different kind of purposes, and put them through the process and lastly, select the appropriate mitigation approach.

3 Current Operating Models of The Company

In this chapter the current operating models of the company is viewed. In addition, operation profile for production and strategies considering industry, supplying and manufacturing are evaluated. In the end of the chapter, strength and weaknesses of the current operating models are summarised.

3.1 Product Operations Process and Risk Evaluation

The company has a wide range of products in its portfolio, with products in three different segments: Proprietary Product (PP), Speciality Products (GX) which includes generic prescription drug and self-care products, and animal health (AH). The company also has its own subsidiary which is subcontracting active pharmaceutical ingredients (APIs) and other contract manufacturing processes. In every product segment, the manufacturing process consists of its own production process (OPP) or alternatively, the operations are fully outsourced via contract manufacturing, called external supply operations (ESO). In contract manufacturing, the company is purchasing the finished product from its subcontractor, which can be another pharmaceutical company that is providing their own products to the subscriber company.

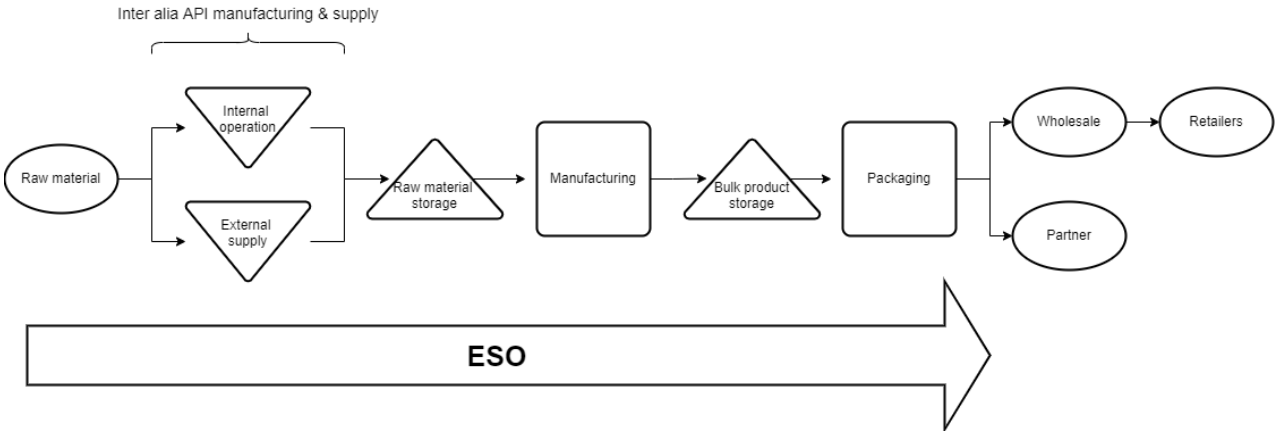

Figure 2. Supply chain for Own Product Process and External Supply Operations. The whole manufacturing and packing process can also be outsourced through ESO.

The clientele of the company includes different medical and healthcare professionals and services providers. These are for example doctors, pharmacies, hospitals, doctor's offices, laboratories and consumers with their pets. In some cases, the clients can be very dependent on the products that the company is providing. When the company is closely co-working with healthcare professionals, it often hears opinions and demand for drugs that are needed in patient treatment.

The products can have different features compared to each other which needs to be considered when assessing risks. According to the representative of a subsidiary (2022), the subsidiary's continuity planning is based on parent company's product demands: the most important raw materials for APIs have their own backup plans and sources.

Due to the wide range of products, the company's operating models related to risk management and continuity planning can vary between different departments and they evaluate their own risks individually. According to a representative of the company (2022), different risks related to quality or to good manufacturing practise (GMP) compliance can lead to potential market ban set by the health authority. Also, if the risks are related to manufacturing equipment and their life cycle, continuous planning must be considered to that point of view, since product manufacturing is a multi-step process, and thus, it is linked through multiple different equipment. This can mean indirect purchases for the equipment, for example spare parts, consumables, detergents etc. The company must also consider the insurance aspect in their risk management policy, since fire safety and reliability are major components when it comes to infrastructure and its risks.

The company receives some polls from its partners regarding business continuity planning and risk assessment to ensure their own business continuity. For some partners it is enough that the company fulfils the poll's requirements but however, the questionnaires can vary between each other.

One of the company's core values is assuring patient safety and that is one aspect where the company is not flexible. With a wide range of product portfolio, there are individual illnesses where the company's product can be the only one suitable for the patient. Thus, the company plays a great role in public health treatment.

3.2 Operation Profile for Production

The company's operations can be reviewed with the 4V diagram as figure 3 shows below:

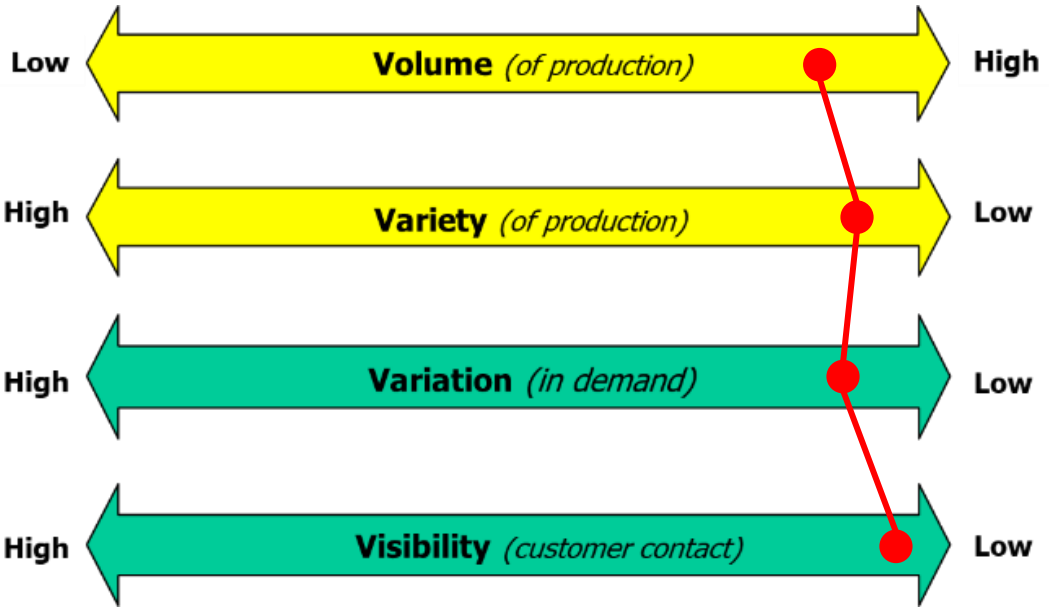

Figure 3. The 4V diagram of the operation variety.

Figure 3 describes the operation variations what comes to manufacturing processes. The variations are listed as four V's:

- **Volume** of production
- **Variety** of production
- **Variation** in demand

  and
- **Visibility** on customer contact.

The company’s production is repeatable, standardized, routinized and low cost (per unit). In terms of volume, the repeatable nature of the production and the high demand for many products means that the volume of production is high. The company’s portfolio includes only a very small number of low-volume products.

Due to the small number of low-volume products, the variety of production is also very low, as almost all products are in continuous demand. New products and spikes in demand may of course alter production, but however these spikes appear occasionally (pandemics etc.). Most of the variations in demand can be seasonal or when the company’s propriety product’s patent expires, and the rivals are expending into the market segment.

Due to the nature of manufacturing and the lack of direct B2C sales, the manufacturing transparency and the direct contact for the end consumer is low to none.

3.3 Industry Strategy

When viewing the pharmaceutical industry in general, the industry is not the most malleable and dynamic industry there is. It is, in fact, quite predictable and rigid industry where research and development practices are slow because of the extensive and exhaustive regulations. Figure 4 on the next page visualizes the position of the industry compared to other industries:

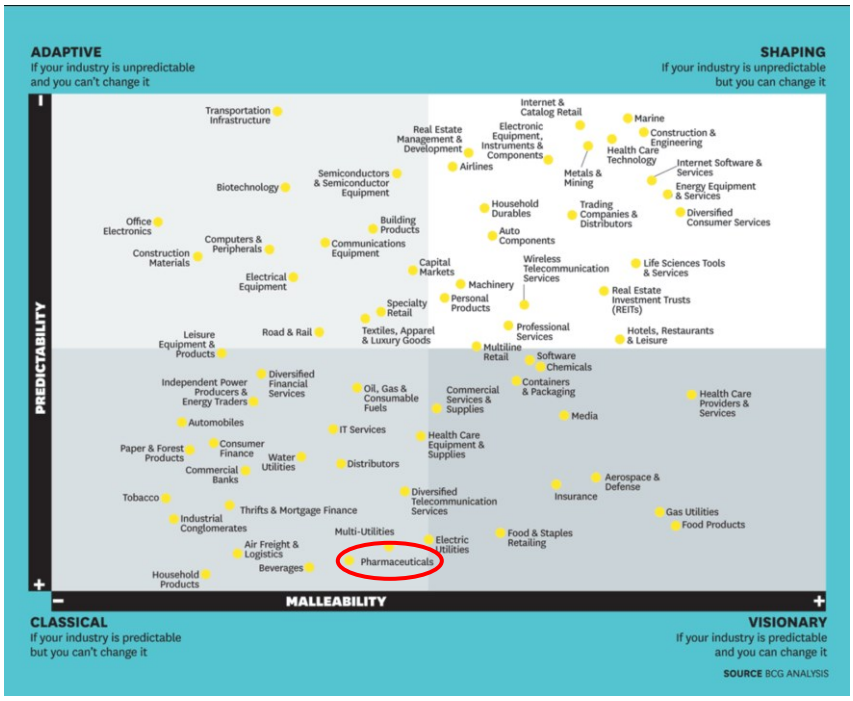

Figure 4. The pharmaceutical positioning in industry strategy matrix. (Love, Reeves & Tillmanns 2012.)

Figure 4 highlights, the position of the pharmaceutical industry in industry strategy matrix. As an actor in the pharmaceutical industry which isn't a fast acting, dynamic and constantly changing industry, strategic goals can be set further into the future, where the Classical style serves well. (Love, Reeves, Tillmanns 2012.)

Most of the company's business units utilize the classical style of strategy, as manufacturing is a very predictable and unmalleable business. The company and its partners have certain needs that need to be fulfilled when it comes to, for example, in API's.

3.4 Supplying & Manufacturing Strategy

In pharmaceutical industry, the supply chain is very complex (with the hundreds of suppliers around finished product), global and tightly regulated. Due to the nature of the industry and manufacturing processes, the products are made to inventory (MTI). Despite MTI manufacturing, some products can be made to

order (MTO). When viewing the supply chain logistics, their inventories are decentralized. The company's supply chain strategy can be placed in P/S matrix as figure 5 below shows:

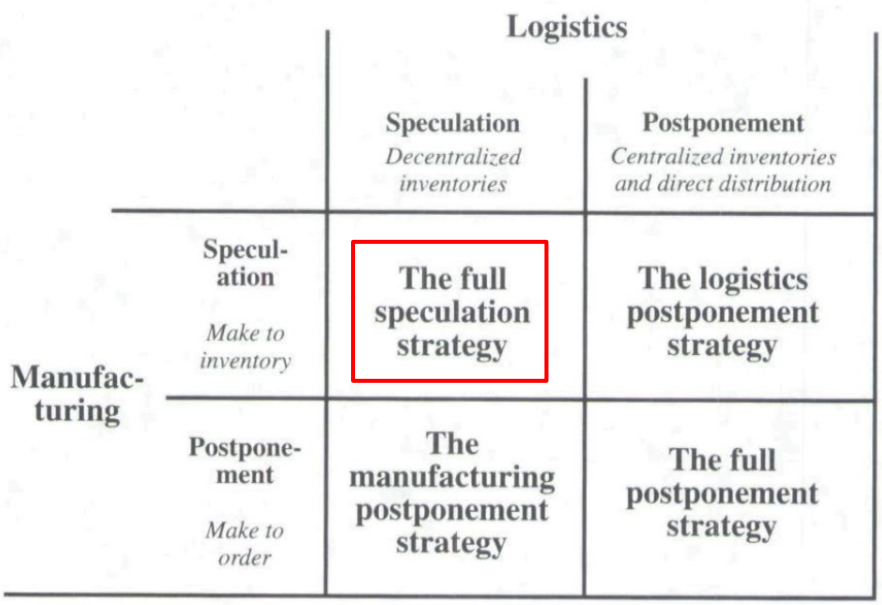

Figure 5. The P/S matrix and generic supply chain P/S strategies. (Cooper & Pagh, 1998.)

In the P/S matrix in figure 5, what supply chain strategy should be used due the nature of manufacturing and logistics is presented. The rows and the columns of the matrix show, whether speculation or postponement is employed in manufacturing and logistics.

The full speculation strategy is a strategy that companies traditionally use. In this strategy, all manufacturing and logistics are based on inventory forecasts. All the operations of manufacturing are made before the product is distributed to another location. The final products are distributed through decentralized distribution system all the way to the final warehouse that locates near the customer. (Cooper & Pagh, 1998.)

The figure 5 highlights the manufactural and logistical strategy that company utilizes. Despite the fact that some production is MTO manufacturing, the

strategy is still more speculation strategy due the nature of the manufacturing process.

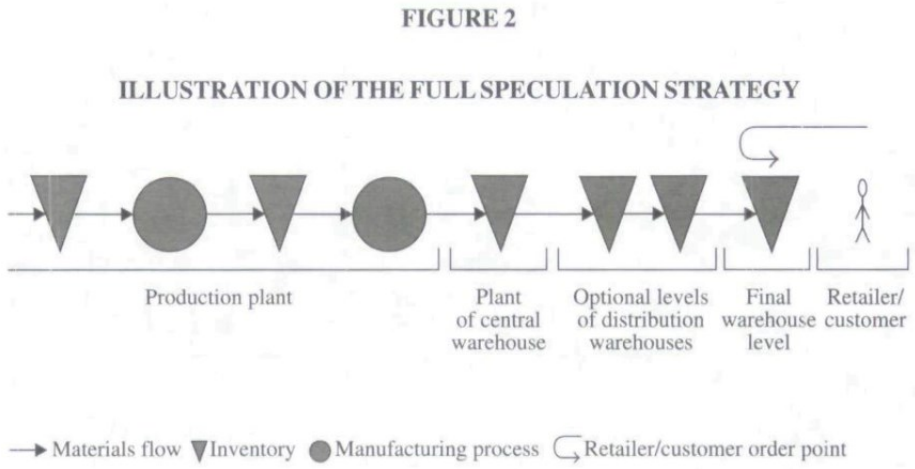

Figure 6. Illustration of the full speculation strategy. (Cooper & Pagh, 1998.)

When viewing the process, the production plant is not sending out semi-finished goods that are finalized near the customer (compared for example, paint manufacturing and distribution, where the correct paint is mixed near the end customer).

The company's manufacturing processes are standardized due to similar manufacturing styles and mostly predictable demand, so the lean principles are adapted in company's working styles. Even though the company's operation style is classical with minor malleability, it needs to have an ability to respond on quickly changed environment. To be capable to do so, the operations and supply chain needs to be also agile.

In general, the companies that are operating in the pharmaceutical industry, they have a lack of ability to adapt in changing environment, for example in unbalanced supply and demand, which is also called "bullwhip" or "Forrester Effect". The company in this thesis is a midfield player in the industry, so it has a better starting point to be more resilient and agile than its rivals.

3.5 Strengths & Weaknesses of CSA

Strengths

The company has a strong collaboration relationship with its partners in the markets and in product manufacturing. The company's operations rely on the use of global networks. These well-managed collaborations and partnerships give the company a competitive advantage. In addition, due to the size of the company, it can be more agile than larger companies with the outcome of gaining more advantage in competitive markets.

Weaknesses

The weakness of the current state is the lack of coherent way of risk management for the products. There is no one way to prioritize products due to possible manufacturing unavailability because of the different features of each product. When these features are taken into consideration, the outcome can be very different between the manufacturing departments.

Due to highly standardized manufacturing operations that are based on almost always predictable forecasting and with full speculation supply chain strategy, it can be difficult to react rapidly in changed circumstances.

In addition, due to regulations and ensuring the patient safety, there is no possibility for the company to suit their operations in order to gain maximum financial advantage from the market. This perspective individually restricts the company from being all agile in their operations and supply chain.

4 Available Knowledge and Best Practices of Contingency Planning

In this section the subjects that provides conceptual framework for this thesis is introduced. The subjects related to continuity planning, risk management and mitigation, and agile way of managing supply chain are presented in more detail.

4.1 Scenario and Business Continuity Plan

Ali and Luther (2020) write that scenario planning is a process that is originally developed by the U.S military. Scenario planning for the business enables identifying the range of potential outcomes and their estimated impact. With the planning, it is also possible to evaluate responses and manage both positive and negative possibilities

The authors also state that scenario planning can help leaders react swiftly and decisively, giving the company a competitive advantage. No one has to scramble during a crisis since a scenario has been thought out and actions are documented.

Scenario planning also provides the framework to the executives and boards of directors. Planning allows for more successful non-emergency decisions, such as offering insight into plans, budgets, and predictions. It also gives a clearer picture of the company's operations, as well as its significant growth drivers and the possible influence of future events. (Ali & Luther, 2020.)

Scenario Planning Compared to Business Continuity Planning

Scenario planning is not always equal to business continuity planning. Both processes are structured the way that the company can navigate the future, but the scenario planning takes the revenue into its account. Business continuity planning aims more how the company and business will react disaster, such as earthquakes or warehouse fire.

Business Continuity Planning

Where the scenario planning can focus a specific area or reviewing internal operations, Cardone (2019) states that business continuity planning (BCP) is a big-picture strategy for ensuring that business functions continue as usual in the case of disaster. The BCP should be created with the goal of identifying and mitigating risks, assign roles and ensure clear communication among key stakeholders. If the company does not have the BCP, the consequences of business disruptions may be as follows in figure 7 below:

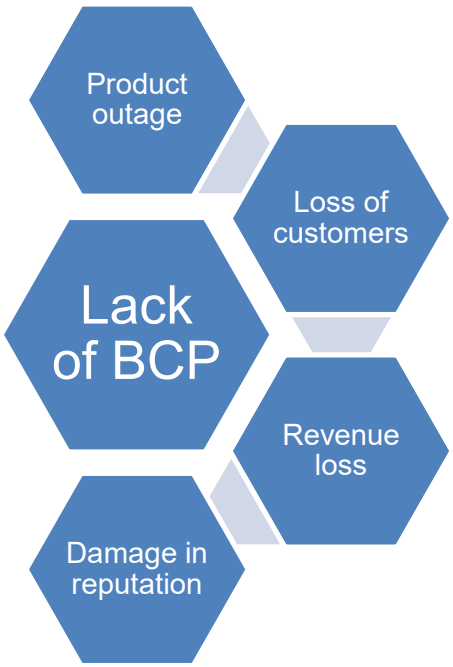

Figure 7. Lack of Business Continuity Planning.

Figure 7 lists the consequences of lacking the BCP. When the company is not prepared for unexpected disruption, the outcome can be product outages, and thus, losing customers to company's rivals. Due to loss of customers, the company is incurring revenue losses and these all in combined, they can and will damage the reputation of the company. Creating the BCP helps the company to maintain rational operation ways during emergency.

Creating the BCP contains several components, for example:

- Team identification
- Data understandment
- Ranking and evaluating risks
- Service and product priorization
- Pricing and solution building
- Developing policies and communication and
- Testing and refining the plan.

Each of these steps creates a clearer and bigger picture that helps to understand the threats and how the company is addressing them. (Cardone 2019.)

4.2 Risk Management and Mitigation Framework

When creating the framework for risk management and mitigation, the same components are utilized as in business continuity planning. Figure 8 in below shows the basic concept about the framework for managing and mitigating the risks:

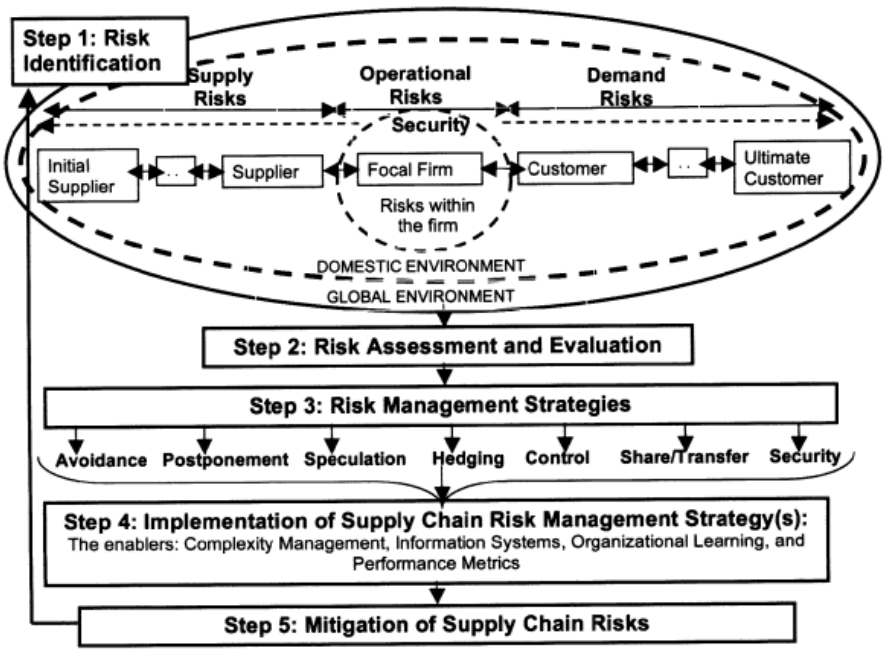

Figure 8. Risk management and mitigation framework for global supply chains. (Manuj & Mentzer, 2008.)

This thesis deals more with the risk management strategies as part of the risk management process, and therefore risk identification, determination and evaluation are considered in general level.

When managing and mitigating the risks, firstly it is important to identify and categorize the risks in the whole supply chain. The risks can occur both in the domestic and global environments. The risks can relate to supplying (supply risk), manufacturing (operational risk) or to end consumer behaviour (demand risk). The company can also have additional risk categories related to strategy, finance or compliance.

When risks are identified, the next step is to determine and evaluate the risks. As Manuj and Mentzer (2008) states that not all risks affect the supply chain in the same way. The supply chain may be prone to one risk while safe from another. According to the authors, the risks that the chain is more exposed to, should be considered more.

4.2.1 Selecting the Risk Management Strategy

After identifying and assessing risks, the following step is to choose an appropriate risk management strategy. The outcome of the strategy should reduce the probabilities of losses related to the risk event. The risk management strategy should correspond to the supply chain strategy of the company, which should correspond to the company's overall objectives. (Manuj & Mentzer, 2008.)

According to Lee (2002), based on the supply and demand uncertainties, risk management strategies can be divided into four types: efficient, responsive, risk-hedging and agile supply chains as figure 9 below shows:

		Demand Uncertainty	
		Low	**High**
Supply Uncertainty	**Low**	**Efficient Supply Chain** *Focus on Cost-efficiency* Postponement Single Sourcing	**Responsive Supply Chain** *Focus on Responsiveness and Flexibility* Postponement
	High	**Risk Hedging Supply Chain** *Focus on Pooling and Sharing Risks* Multiple Sourcing Transferring/Sharing Risk Hedging	**Agile Supply Chain** *Focus on Responsiveness and Hedging Risks* Hedging

Figure 9. Supply chain types and risk management strategies -matrix. (Manuj & Mentzer, 2008.)

Whether the supply and demand uncertainties are high or low, the strategy should be implemented based on the sum of these two components as figure 9 shows. For example, if the supply chain uncertainty is high and the demand uncertainty is low, the supply chain should be more risk hedging and the strategies could be, for example, multiple sourcing, transferring/sharing risk or hedging. The same logic applies also for other alternatives.

Due to the nature of the business operations of the case company and its supply chain, the strategies that are gone through are hedging and transferring/sharing risks. The objective is that the risk can be reduced to desired level. This thesis also looks at what components and market environment the company should consider when it is choosing the right sourcing option from different sourcing alternatives.

4.2.2 The Hedging Strategy

Hedging is done in the supply chain with a portfolio that is geographically spread due to its suppliers, facilities and customers. In this approach, an individual occurrence such as a currency fluctuation or an emergency has no affect all of the chain's components neither at the same moment nor in the same volume.

Also, the company can use dual sourcing for its products to hedge against risks of quality, quantity or disruption. Furthermore, when dual sourcing is used, the underlying cost structures in plant and technology acquisitions, as well as operating costs, can be decreased, and risk can be mitigated by operating more versatile plants faster rather than more efficient plants dedicated. In addition, in current market environment, different suppliers can also help with risk management if, for example, another raw material supplier is unavailable to deliver the demanded amount of material.

If the company decides to use multiple contracting for the hedging strategy, it can reduce performance variability and also protect the company against a single-supplier opportunism. (Manuj & Mentzer 2008.)

4.2.3 Transferring/Sharing Risk Strategy

When the company's objective is to manage risks, it is not necessary for the company to do it alone as in the risks can be transferred or shared. The transfer and/or sharing the risk in the supply chain can be accomplished by outsourcing, offshoring, and contract manufacturing.

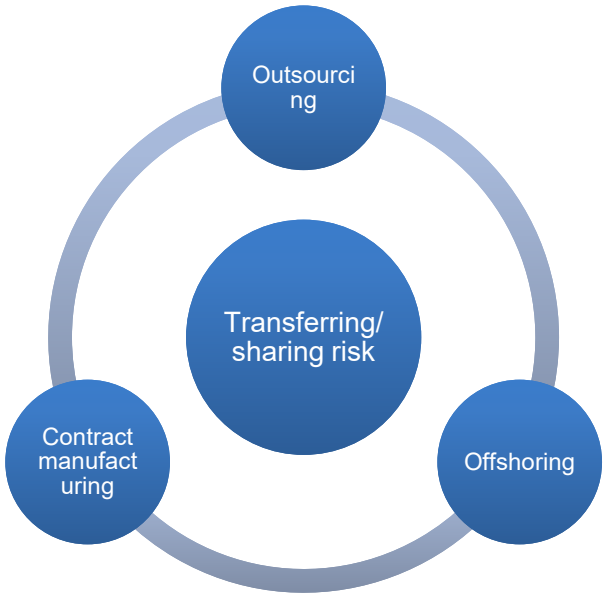

Figure 10. The components for transferring and or sharing the risk.

When viewing outsourcing in a global supply chain, domestic or foreign sourcing of services and products can be part of the chain's outsourcing. Also in the global chain, the phrase "offshoring" refers to sourcing that takes place beyond borders. When the company is using these two components, it is causing transferring the risks to suppliers. However, offshoring also has some collective risk, and it should be assessed against control. (Manuj & Mentzer 2008.)

The last component of risk sharing is contract manufacturing. It is the alternative where the whole manufacturing operation and processes are outsourced to subcontractor. The product can be a semi-finished or final product that is delivered to the subscriber company. This way the whole operation risks can be removed from the company to its subcontractors.

4.2.4 Power Regimes in the Supply Chain Sourcing

When the company is considering the sourcing options in buyers' role, it needs to take its leverage on the market into its account. That reflects the sourcing approaches that the company can utilize as seen in figure 11 below:

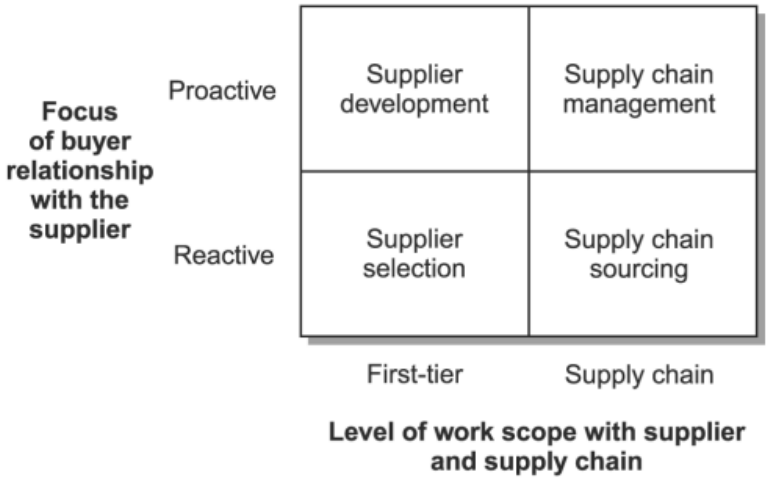

Figure 11. The sourcing options matrix. (Cox 2004.)

Figure 11 shows the alternatives that buyer has for sourcing based on the market leverage. For the company, there is no one way to manage business relationships to its suppliers due to different business circumstances and dependency ratios between the buyer and suppliers. The different ratios can be:

- The dominance of buyer **(>)** (few buyer/many supplier)
- The dominance of supplier **(<)** (many buyers/few suppliers)
- Interdependence **(=)** (few buyers/few suppliers)
  or
- Independence **(0)** (many buyers/many suppliers). (Cox 2004.)

For example, if the company (like in this thesis) is a midfield player to its own industry, it doesn't have an enormous leverage to its suppliers. But however, it has some leverage towards suppliers. If the company wants to impact to supply chain at "arms-length" in reactive way, the supply chain sourcing would be a good option. This way the company can have an impact in the whole chain and the resources for managing that could stay minor.

On the other hand, if the company wants to be more proactive, it can choose the supplier development to its option. Also, the supplier selections could be good alternative if the company wants to operate more at "arms-length". The whole supply chain management would not fit to company's options due to its size and power regime towards suppliers. Managing the whole supply chain also needs big resources due to its high costing functions.

4.3 Agile Supply Chain Management

When a company's objective is to keep the market share stable in a sudden and unexpected changed environment, it is important that the supply chain is responding quickly to changed circumstances. Lee (2004) states that because demand and supply in most industries can vary more widely and rapidly than they used to, being agile is essential.

Most supply chains operate by balancing speed and cost, while agile supply chains can respond rapidly while also being cost-effective. The author also states that the companies who are smart, they use agile supply chains to outperform their rivals.

The company can provide more agility to its supply chain in five heuristically way:

- Sharing data on supply and demand changes with its partners.
- Creating cooperative ties with customers and suppliers.
- Designing products the way that they share common parts and processes.
- Building dependable logistics system.

  and
- Putting together team that has a competence to create backup plans. (Lee 2004.)

When a company is providing continuous data about the changes of environment to its partners, it allows all of them to spot and adapt in demand or supply problems immediately. Today, sharing data at the same time to all the firms is relatively easy due to internet and cloud services. This ensures that there are no delays on information which is the first phase to create more agile supply chain. (Lee 2004.)

> The use of information technology to share data between buyers and suppliers is, in effect, creating a virtual supply chain. Virtual supply chains are information based rather than inventory based. (Christopher 2000.)

The author also states that collaboration with customers and suppliers is also important for creating more agile chain. In this way companies collaborate to design or redesign processes, components, and products, as well as preparing backup plans. When the company is designing a product, it should consider sharing common parts and processes so that in the first phases of manufacturing, parts and processes are standardized and at the very last end of manufacturing process, the products differ individually.

To be more agile in meeting client expectations, the organization should consider implementing a dependable logistics system that allows it to respond quickly to unexpected needs. There is no need for the company to invest in logistics themselves, but they can provide alliances with a third-party logistics provider. (Lee 2004.)

One and important aspect is that the manufacturing operations can face unexpected interruptions in manufacturing. Therefore, it is crucial that the company has prepared with contingency plans to tackle crises and mitigate consequences. For this, there should be gathered a team with a competence of creating backup plans. (Lee 2004.)

5 Proposal for Product Contingency Planning

In this chapter the proposal that has been built for product contingency planning is introduced. The phases start with introducing the steps that are executed when the proposal is built and key findings that provide guidelines for the proposal. After the steps and key findings for proposal building, the proposal is presented. Lastly, what benefits the proposal should provide for the company are analyzed.

5.1 Steps for Building the Proposal

Steps for building the proposal started with recognizing the key findings of chapters three and four. Based on the key findings, the proposal is starting to have a vision and the next phase is to create guidelines for the proposal.

When the proposal starts to have a rough outline, the next phase is to brainstorm in a group what aspects the proposal should include. The data collection is stated in chapter 2.3. The outcome of the proposal is a process chart for product prioritization and selecting appropriate mitigation option.

5.2 Key Findings for Building the Proposal

In this section the key findings from chapter three and four are listed. The proposal is built based on these findings.

5.2.1 Key Findings from Current Operating Model of the Company

When viewing the current operations of the company, the key findings from the operation process and supply chain emerged. In the operation process, the company has a wide range and dispersed product portfolio, that includes three different product segments in the market: Own patent product, generic products and animal health. In all these segments, the company does not only rely on its own production process but also implements external supply operations for its manufacturing allocation.

The company's clientele is also wide: including healthcare professionals, retailers and even the end consumer via retailers. The company has to serve all its clientele needs and that is why the company is collaborating with different stakeholders, for example, with healthcare professional in the market. This way the company receives primary information from the field regarding what is the demand for different products. Different products and their dosage can have different value for patient treatment.

The company's operation processes can also be evaluated in general with the four V's that are introduced in chapter 3.2. Each V describes a different aspect about the company's operations. The four V's are: **volume** of production, **variety** of production, **variation** in demand and **visibility** in customer contact.

Due to the nature of the industry and its market, the volume of production is high because products have a great demand in general. However, the demand of an individual product can vary, for example due to an expired patent, when the rivals can begin to manufacture the same product and the supply increases. When viewing the variety of the product, it can be stated that the product variety

is low. The same product can be in different dosage forms or in different sizes, but the end customer does not have the possibility to influence for example, what is the colour of the drug tablets when they are manufactured.

When viewing demand variation in general, it also can be stated that the variation is low. The pharmaceutical company has almost always its own clientele and especially when the company is considering today's megatrends in healthcare sector as a part of the company's strategic implementations. The variation in demand has the opposite effect on the production volume: When the variation is low the volume is high and vice versa. In addition, the same way as in production volume, the expired patent of the product can provide variation in the demand of the product from a specific manufacturer.

The visibility of the operation processes in customer contact are also considered low. Due to manufacturing style on supply chain (full speculation), the whole manufacturing is centralized inside the plant and only the final product is shown to the end consumer.

As stated in chapter 3.3, the company's operation processes are standardized due to a similar manufacturing style and mostly predictable demand, the lean principles are adapted in the company's working style. Even though the processes are highly standardized, it is good to have the capability to adapt to sudden changes in environment, for example, in prolonged downtime.

Supply Chain

The supply chain for the pharmaceutical industry can be very complex with strict regulations by authoritative. Around the final product, there can be tens or hundreds of different suppliers. The supply cain represents the classical style due to its minor malleability and mostly predictable forecasting. The chain's operations are based on full speculation strategy, where manufacturing and logistics are both based on inventory forecast with decentralized inventories. The production is mostly made to stock-manufacturing even though the same batches are made to order for example, some products that are delivered to the

United States. All the operations of manufacturing are done before the final product is distributed to another location.

Strength and Weaknesses

When viewing the pharmaceutical industry in general and comparing the company of this thesis to its major rivals, it can be said that the company is more adaptable and agile than its rivals whereby it is gaining a competitive advantage from the market. The company also collaborates with different partners and stakeholders, including healthcare professionals. This way the company gains primary information from the field which can be adapted to the company's business strategies.

Since production is a highly standardized process, the operations can be hard to adapt to sudden changes. The company is using lean in their operations and in that sense, it would be good to consider being also agile. And if the production is experiencing a sudden long-term outage, there should be a framework whereby to products can be prioritized and allocated.

5.2.2 Key Findings from Available Knowledge & Best Practices

Chapter 4 offers the conceptual framework for the objective of this thesis. The importance of business continuity planning as a part of business operation's risk management is told. It is important to be aware that not only assessing risks are important, but also what the procedures are when the risk is realized. The consequences of lacking BCP can be, for example: production outages and due to it loss of customers, revenue losses and in the worst case, it can damage the reputation of the company.

As Hustead (2021) states, it is important to recognize that the BCP is not only a single time event rather it should be adjusted and re-evaluated periodically. The key components for the BCP at the point of view of this thesis are shown in figure 12:

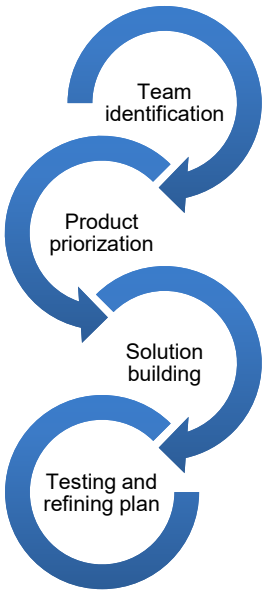

Figure 12. Key components for BCP.

When BCP is a part of the operation's risk management, it is also important to assess what the proper risk management style is for different supply chain types. In chapter 4.2.1, the matrix for selecting appropriate risk management strategies for different supply chain strategies is presented. The appropriate supply chain type and risk management strategy is based on the uncertainties of supply and demand. There are different risk management strategy alternatives in the chain type column. The **hedging** and **transferring/sharing** risk strategies fit the best in the company's supply chain type, so they are presented in the text in more detail.

In the hedging strategy, the supply chain's operations are globally dispersed and this way the chain is shielded for individual occurrence, such as monetary instabilities or natural disaster. In the transferring/sharing risk strategy, the point is that the company does not have to carry all the risks only by themselves, but the risks can be divided to different operators of the chain. This could mean procedures, such as outsourcing, offshoring or contract manufacturing.

As stated in chapter 4.3, in most industries today, the variation of supply and demand can be more volatile than they used to be, which is why being agile is

essential to meet the changed needs of the environment. Thus, the company can keep its market share stable or outperform its rivals. When the supply chain is agile, it can respond to changes rapidly, while also being cost effective.

In the same chapter, ways are introduced whereby the company can increase their capability to be more agile. The means can be, for example: sharing a supply and demand data to its partners, creating cooperative ties with customer and supplier or building a dependable logistic system.

5.3 Proposal

To prevent drug shortages during manufacturing unavailability, there is some primary components that should be considered: product prioritizing, what aspects to consider in order to supply, approaches for mitigation and lastly, testing and refiring the plan. These activities should be done in the order where the product priority is assessed first. When the prioritization is done, the outcome is that the products are ranked from top tier products to the low priority products which have less impact on the company's business or end consumers. Due to variation of impact, it is not necessary to develop same level mitigation options for every product.

5.3.1 Assessing the Product Priority

When assessing the product priority for pharmaceutical products, Hustead (2021) states that there should be a balance between the company's business and critical patient needs and therefore, the products are critical to evaluate from different kind of aspects.

For this purpose, a cross-tabulation would be a good alternative. The cross-tabulation helps visualize the influence of different fundamental combinations. ABC-analysis can be one example of this type of tool as figure 13 shows:

ABC-Analysis

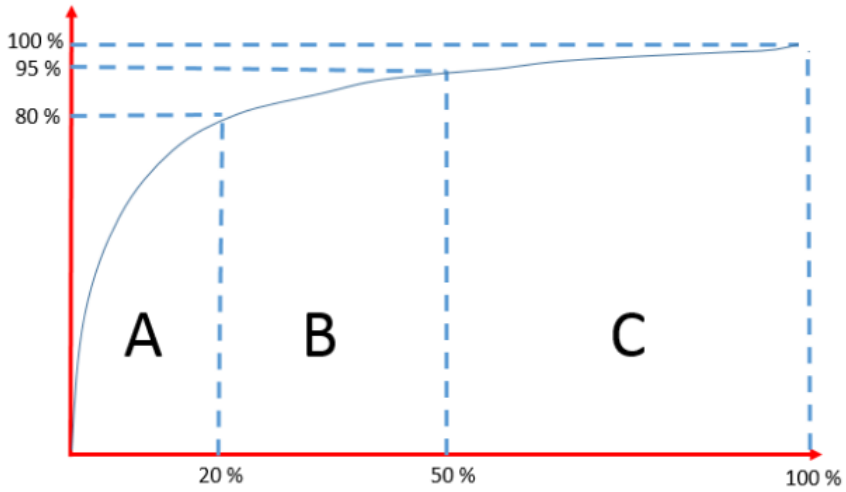

Figure 13. Observational image of the ABC analysis. In the y-axis is described sales and in the x-axis the percentages of the total amount of products in the warehouse. (Logistiikanmaailma n.d.)

The ABC analysis is a method that is traditionally used in warehouse management and with the analysis, the products are sorted and stored in the warehouse due to their significance. Martinsuo et al. (2018) states that the products are categorized so that in the A items represent 20 percent of the total amount of products that provides the largest cash flow for the business. The mid 30 percent provides 15% cashflow and in the C items 50 percent of products provide the least cashflow.

As a rule of thumb, it can be assumed that A items create 80 percent of the warehouse's value, B items 15 percent and C items 5 percent of the warehouse's value.

Adding XYZ Components to the Analysis

Often ABC-analysis alone is not enough, and companies can often use different variations of the analysis. The ABC-analysis can be fulfilled by adding XYZ components to the analysis, which turns the cross tabulation into a matrix. This way products can be reviewed and ranked in more depth. The perspectives for

additional components can be, for example, the variations in predictability and demand as table 2 below shows:

Table 2. ABC-XYZ matrix. (Stojanović & Regodić 2017.)

	A	B	C
X	High importance High predictability Continuous demand	Moderate importance High predictability Continuous demand	Minor importance High predictability Continuous demand
Y	High importance Moderate predictability Variating demand	Moderate importance Moderate predictability Variating demand	Minor importance Moderate predictability Variating demand
Z	High importance Minor predictability Intermittent demand	Moderate importance Minor predictability Intermittent demand	Minor importance Minor predictability Intermittent demand

In the table 2, a matrix is presented where is listed different fundamentals that have an impact on valuation. Different importance levels are listed in columns A to C from high importance (A column) to minor importance (C column). In the same logic for rows, different predictability and demand levels from X to Z are listed. With the matrix, it is possible to rank products in different priority levels so that the products that are in AX segment is in top tier in prioritization and products in CZ segments are the lowest in prioritization and thus, it might not be necessary to develop a contingency plan for the products in this segment.

Determining the Importance of Product

As stated before, the importance of the product should be assessed so that it keeps the balance between the company's incoming cashflow, and patient treatment and regulatory obligations. Hustead (2021) states that because of the multiple viewpoints that must be considered when determining product priority within these three categories, the evaluation of priority is best to conduct as a cross-functional process, with experts from the different business areas.

Therapeutic Importance

One of the important aspects when evaluating product importance, is to have knowledge on what additional value the product is providing to the patient. The product can be for example life supporting or lifesaving that have an impact on the patient's life quality. According to the representatives of a hospital organization (2022), in some cases for example HIV, the medication must be continuous to sustain the patient life quality.

The company can also have some patent protected products in their portfolio, so there is only one supplier for that specific product on which the patient may be highly dependent. And vice versa, there can also be generic alternatives for the company's products so that the patient does not have to rely on only one supplier. This can have an impact on product valuation.

In hospital care, intravenous drugs are critical products due to their usefulness. For example, if the patient is not capable of swallowing tablets due to unconscious state, the requisite dosage can be given despite the state of the patient. Drugs that are used in intensive care or child or cancer treatment, are also seen as critical products. During COVID-19 pandemic, sedatives which were used in intensive care, experienced a high peak in demand. Hospitals had to manually calculate the adequacy of the drugs. In addition, the demand of certain products can vary seasonally, and on good example is children's RS virus, which usually occurs in wintertime.

Business Importance

The revenue significance for prioritizing products should be considered from different kind of aspects. The aspects could be, for example:

- What is the amount of revenue the product is generating to the company?
- What is the product's market share?

  or

- Is there interdependence with other product or company?

When reviewing products from the revenue point of view, it is important to assess the essentiality of the product for the company. Hustead (2021) states that there may not be a chance for even a one-day unavailability for the products if they are considered as highly essential for the company's revenue. On the other hand, it is important to be aware that a product might have a low manufacturing volume due to fluctuate or minor demand, but the product can still be quite significant for patients who may rely on it. This type of product can be defined as high value as well, but with varying or intermittent demand.

The company can also analyse the product's share in the market. This should include some kind of analysis what the market leverage for individual product is compared to other suppliers with their possible substitutes. For example, if in the market there are a few replacement products from rivals and the market share is quite even between these suppliers, it may not have a substantial influence for the market in general if one company is incurring disruptions in their manufacturing. However, if the market leverage is notable with one supplier, the disruption can drive a shortage that affects the whole industry and other suppliers may have not a capability for increased manufacturing in order to close the supply deficit. Additionally, Hustead (2021) states that if supply issues will affect numerous suppliers (e.g., all companies use the same raw material supplier), a product could be prioritized higher.

When assessing business importance for product, one aspect that should be considered is the product's possible interdependence with other products. These can be within the own product portfolio or connections with the partner company. The interdependence could consider, for example:

- marketing
- regulatory quality
- manufacturing supply requirements
- or
- strategies. (Hustead 2021.)

Depending on connection type, a product that would normally be of lower priority may become more important as a result of a disruption in its supply that might have an impact on the company's other products or partnerships with other companies. (Hustead 2021.)

In addition, changes in a rival’s product portfolio for example, manufacturing of a specific product is discounted, might have an impact on the company’s individual product. This may be difficult to detect in advance.

Regulatory Obligations (obligation storage)

In legislation, there is predefined specific medicine types that need to be stored in the national stockpile. This procedure is called obligation storage and it is part of the national security of supply. The purpose of storing is to secure the availability and useability of the medicines in the situations where the availability has become more difficult or blocked due to shortages, crisis or other reasons. (Fimea n.d.)

The obligation storage applies both on OPP and ESO products. Storing the correct number of medicines is critical. For example according to a representative of the company (2022), the pharmacy stores always need to have a two-week demand of medicine stored for providing the availability of the products. Another good example is the COVID-19 pandemic, when the demand of the certain medicines spiked up and their supply needed to be secured. In addition, the European Medicine Agency (EMA) should provide the list till the end of 2022, where is listed the most critical products that the companies should provide.

In the obligation storage, the number of stored products is based on external domestic sales of products between the beginning of March till the end of August the preceding year. Balances are reported at regular intervals to the authoritative, and predefined balances are not allowed to undercut without a special permission. It is also defined that the obligation storages must be located inside domestic boards. In the OPP, if the product is not stored

physically, the company must be secure that the bill of material is available for manufacturing demanded amount. (Finlex 2008, A representative of the company 2022.)

5.3.2 Aspects to Consider in Supplying

Once the product prioritization is done, it is good to consider the risks and features that could affect in supplying. Table 3 shows what features and risks should be taken into account when assessing solution building.

Table 3. Aspects to consider in supplying (Hustead 2021.)

Area	Aspects to consider
Product	• Technical complexity (e.g., non-sterile, sterile, cold storage, etc.) • Product's shelf life • The volume of production: 1 batch/week or 1 batch/0,5year?
Supply	• Internal manufacturing plants or third-party manufacturing firms? • Suppliers who are secondary or tertiary • Details about the manufacturing facility (e.g., locations and capacity)
Logistics	• The complexity of supply chain • Distribution channel vulnerabilities • Reserve inventory
Patients	• Will patients be able to swap products? • Are there generic options available? • Uniqueness for patient

In table 3 different aspects are listed that should consider when assessing supplying risk to products. The products can have a different feature and the manufacturing ways can vary due to their technical complexity. For example, some products may not need to be sterilized in autoclave, some products must be stored in cold etc. When building the solution to avoid drug shortage, the

manufacturing volume and product's shelf life is critical aspect to consider since they may have an impact when selecting appropriate mitigation option.

On the supply and logistics point of view, it is good to evaluate the manufacturing type of the product: is it in-house manufacturing or more from external supply operations? In addition to the primary supplier, the products may also have secondary or tertiary suppliers for example, for raw materials or API's. In case of manufacturing unavailability, it may be a good choice to have multiple sources in product components which can be agreed to be delivered for example, in contract manufacturing plant. It is also good to consider the complexity of the supply chain and evaluate the possible vulnerabilities of the chain. The products can also have a reserve inventory already, so it is the addition aspect that should be considered when selecting mitigation option.

As stated in the product priority chapter, the therapeutic importance is one critical aspect in evaluating product's importance and the same is true with risks. On patient point of view is good to evaluate for example, will the patient be able to swap product to different or is there generic options available? The product can also be unique for the patient so that the patient's treatment or general well-being can rely on that specific product.

5.3.3 Approaches for Mitigation

When determining the possible mitigation approaches, there is no "one size fits all" approach for the products. The appropriate approach is highly dependent on the importance of the product and its market predictability and demand. The appropriate approach is also highly dependent on the features of the product, of which some of them are listed in table 3 above. The appropriate approaches are dependent on the product profile and can vary between agile supply chain strategy or stockpiling as figure 14 shows.

Figure 14. Selecting the appropriate mitigation approach. The products fall in somewhere between the agile supply strategy and stockpiling.

Agile Supply Strategy

If the product is assessed with high importance with high predictability and continuous demand, it is important that the manufacturing of the product continues without interruptions. If the own manufacturing plant is not capable of manufacturing, the processes should be forwarded to another operator, for example in the form of contract manufacturing. This approach gives an ability to pivot the operations rapidly to another manufacturer to avoid product shortage. The strategy can be more cost effective compared to stockpiling, since the overhead costs in enlarged inventory are not increasing.

When using the agile supply strategy there are multiple components that must be considered when evaluating the backup manufacturer. For example, if the CMO is in another region where the primary company is operating, the regulatory requirements or other qualifications of the product and manufacturing may deviate from original. This strategy needs a strong business relationship and transparency between the company and CMO so that the CMO have an ability to adapt at changed circumstances and quickly start manufacturing the demanded products. According to Hustead (2021), Companies may wish to form alliances with competitors so that they can work together amid major supply interruptions to give patients a temporary alternative source of supply.

Stockpiling

If the product is assessed high but the predictability and demand is variable or minor, it might not be necessary to implement agile strategy for these profiles and the stockpiling strategy might be more appropriate alternative. The company has already storage obligations for some products set by authoritative to avoid drug shortages. For example, in case of an emergency, the company has a reserve inventory to supply for increased demand. This means that the stockpiling strategy is already executed in some level.

Compared to the agile supply strategy, stockpiling is more clearly specified, and it is generating the intended outcomes. It is also more expensive due the enlarge inventory and overhead costs. In the stockpiling approach, it is good to evaluate the batch volume and the shelf-life of the product: How long and what temperature (e.g., cold storage products) the products can be stored before they must be consumed and when the newer batch is replacing the older one.

Process Chart for Product Prioritization and Selecting Appropriate Mitigation Approach

Based on the aspects that are presented in subsections 5.3.1-5.3.4, a process chart can be derived to help to visualize the steps for product prioritization and picking the appropriate mitigation approach. The flowchart is presented in Appendix 1.

The process chart shows that depending on the product importance combined with predictability and demand variations, there can be different outcomes for selecting appropriate mitigation approach. The outcome can be either agile supply strategy or stockpiling or combination of both (as shown in figure 14), which is also known as hybrid outcome. In the hybrid outcome, the ratio between agile strategy and stockpiling can be defined based on the current circumstances of demand legislation (for example, obligation stored product) and the type of product profile.

As stated earlier, not all products have the same importance so it might not be necessary to create a most robust backup plan for the least importance valued product or product with moderate value and minor predictability and intermittent demand.

5.4 Expected Benefits of the Proposal

The expected benefits of this proposal are that it provides a concrete process chart that clarifies the decision making. When evaluating products, the process gives clear frames to process the metadata that will have an impact on the valuation process. The valuation individually is often not enough, so different mitigation alternatives are also considered in the process chart. In the chart, what components should be considered, are also assessed when selecting appropriate mitigation approach.

As has been stated before, depending on the product valuation, predictability and demand, there is no need to create a same kind of robust continuity plan to all products, but the planning can rather be more lightweight or not necessary. Different importance categories help to divide the products based on their metadata, whereby the heaviest planning is done solely for high importance products and, for the products in moderate category, the planning does not have to be as heavy as for high importance products. This helps to sort out the least important products for planning and focus on more important products and at same time, the overall workload is reduced.

The process chart is a tool that helps to make importance valuations now and in the future. The importance and appropriate mitigation approaches might have to be refined if an event occurs that have an impact on products and their demand. These kinds of events can be, for example changes in product portfolio; the patent of the product expires, and the company’s rivals start to appear in the market with their similar products. It is also possible that some newly developed product is considered to be a key market driver in the future and based on that it is considered on high importance as well. Another reason when valuation might

have to be refined is changes in official regulations. For example, the product can be dropped or set in in obligation storage or there might have been changes at the market authorization. These changed circumstances can also be tested by creating a “case study” where the company demonstrates what could happen in the business environment and how to adapt to it. With the chart, it is possible to make swift adaptions in the changed circumstances.

6 Prototyping The Proposal

In this section the process chart was prototyped using products that are sold in the domestic market. The products are selected from the injection and inhalation product portfolio. The objective is to pick different types of products with variable valuations, with different features in different kind of use and put them through the proposed process and lastly, select appropriate mitigation approach.

6.1 Inhalation

Product A

Product A is a short-acting asthma medicine that is used to open up bronchial tubes and the API used in the product is salbumatol. This product is valuated in category A due to its business significance and additionally, the product is categorized as an obligation stored product. The predictability is quite accurate, and the demand is continuous and high. The forecast is based on newly diagnosed patients who have been given prescriptions.

According to Apteekkariliitto (n.d.), at the moment there is no biosimilar product in the market that could replace Product A. In addition, according to representatives of the company (2022), there is no alternative manufacturer currently available that could start to manufacture the product in terms of contract manufacturing. Thus, stockpiling would be the appropriate mitigation approach.

It is worth noting that when storing the product after filling operation is ended, there is a holding time when picked samples from bulk products are sent to laboratories for further investigations. In addition, the bulk product must be stored in certain type of temperature and humidity. After an examination of the samples, the product can be released to the markets. The duration of the examination of the samples can be up to two months, and the package must be withdrawn from selling when an eligibility period is under four months.

Product B

Product B is a long-acting asthma medicine that is used to keep the bronchial tubes open and the prevent chronic obstructive pulmonary disease (COPD) from going worse. The product contains two APIs: salmeterol and fluticasone propionate. Salmeterol helps to open up the bronchial tubes and keep them open so that the airflow can move in and out more freely, and API's effective time is at least 12 hours. Fluticasone propionate is a corticosteroid that decreases the swelling and irritations of bronchial tubes.

The Product B is valuated in category B due to its business significance and it is not categorized as an obligation stored product. The product is a low-volume product since compared to product A, the sales of Product B were only less than a tenth of Product A's sales. When comparing Product B to Product A, Product B is more complex to manufacture due to its dual API function and in addition, raw materials used in manufacturing are considered valuable.

As for Product A, currently there is no contract manufacturing option available and when the product importance is considered moderate with minor demand, there might not be necessary to create continuity plan for this product. However, some light backup planning could also be executed since according to Apteekkariliitto (n.d.) there is no currently biosimilar alternative available in the market. If some light planning is decided to execute, the strategy should be in the format of stockpiling. As in Product A, same rules apply to Product B when it comes to storage and the eligibility period.

6.2 Injection

Product C

Product C is an aseptic injection fluid which API is perphenazine decanoate. Perphenazine is an anti-psychotic API that is generally used in the treatment of severe mental health disorders, such as schizophrenia and long-term psychosis.

The product is valuated in category A+, so it is a patient critical product, but however, it is not categorized as an obligation stored product. The predictability for product C is quite high, and the demand is also high and continuous. According to Apteekkariliitto (n.d.), there is no biosimilar alternative available in the market.

Based on the type of the product and data, the agile supply chain strategy would be appropriate option. However, based on the complexity in manufacturing, outsourcing can be difficult. For example, raw materials for the product come frozen and before manufacturing they need to be defrosted. In addition, the injection fluid is an oil-based liquid that makes it difficult to inspect the product visually, and no electric current can be used when doing final inspections for the product before packing it.

The product’s eligibility period is around two to three years, and the lead time of the product (including the examination of the samples) is good, and the storing requirements are quite normal (e.g., the product does not have to be stored in cold). In addition, it is plausible that the bulk product can be manufactured beforehand so that stockpiling can also be implemented in contingency planning. Thus, the hybrid strategy can also be an appropriate mitigation alternative for the product.

Product D

Product D is a veterinary medicine that is used for bovines and horses, and the medicine has calming and pain-relieving effect. The API that the product contains is a detomidine hydrochloride which is manufactured by subsidiary.

The product is valuated in category C due to its business significance for the company and it is not categorized as an obligation stored product. According to the representatives of the company (2022), it is however worth noting that the same Product C with different bottle size is defined in obligation storage by the amount of three months' average consumption. Compared to Product C, the sales of Product D were only a tenth of Product C' sales.

When comparing Product D to Product C, it can be stated that Product D is a low-volume product with the risk of a low gross profit loss, or contractual penalties which have a minor impact on company's businesses. Thus, there might not be necessary to create a backup plan for the product in category like this.

However, according to Apteekkariliitto (n.d.) there is no biosimilar alternative available in the market, so creating a light backup plan could be also an appropriate mitigation approach for the product. If light backup planning is executed, the strategy should be in the form of stockpiling. As for Product C, the same rules apply to Product D when it comes to storage and the eligibility period.

7 Summary and Conclusions

In this section an executive summary is presented, what could be done next with the proposal. The objective of the thesis is also evaluated compared to the results and lastly, final words about the thesis.

7.1 Executive Summary

This thesis dealt with planning contingency for products by prioritizing them and selecting appropriate mitigation approach for them. Speaking in general, companies are good at defining and evaluating potential risks, but it is also important to have some sort of procedure implemented if the risk is starting to realize. The operating environment can be changed quickly, and COVID-19 is a good example on that. Depending on the extent and impact of the risk, the circumstances can look much more different than it used to be for example, six months ago. That is why companies should have the ability to react and adapt in swiftly at changed circumstances.

Contingency planning is not a ready “all at once” process, but it needs to be tested and refined every once in a while. The objective of the planning is to reduce risks at the wanted level and the individual company does not have to carry all the risks individually but rather hedging them by transferring or sharing some risks with its partners.

The objective of this thesis was to create a standardized process for product prioritization and for selecting appropriate mitigation approach for them. The outcome is a process chart, whereby prioritization and the appropriate mitigation approach can be selected. Prioritization is based on ABC-XYZ analysis, which evaluates product importance and the levels of predictability and demand of the product. Since the products have variations in their importance, predictability and demand levels, the level of contingency planning does not have to be the same for all products.

In addition to the product's business significance, when assessing a product there must also be considered the therapeutic point of view. If the product is not a relatively big turnover maker for the company, the same product can have a great value for a patient. If the patient's quality of life is heavily relying on the use of the product and no biosimilar alternatives are available in the market, it can have an impact in product importance. In addition, the obligation storage, which is set by authority, can have an impact on the importance of the product and on selecting the appropriate mitigation approach, since a certain amount of products has already been stored.

Since the product can have different features (e.g., sterile, cold-stored product or certain amount of holding time after the filling operation has ended) and variations on their predictability and demand, there is "no one size fits all" type of mitigation approach. The appropriate mitigation approach can vary between agile supply strategy and stockpiling.

The objective of agile supply strategy is to keep the manufacturing processes continuous by using contract manufacturing in case of manufacturing unavailability for own production plant. This requires that the product importance is high, and the predictability and demand is continuous for the product. In stockpiling strategy, the objective is to keep a certain amount of products in store, usually a product's average consumption in between a predefined timeline.

In addition, the appropriate mitigation approach can be a hybrid version which connects both styles, agile supply strategy and stockpiling. This type of mitigation approach could be appropriate for example, if the product is in continuous demand and at the same time is categorized as an obligation stored product.

It is also worth noting that surveying the product importance and appropriate mitigation approach should be done regularly, for example once a year. The business environment is continuously under changes for example, some

competing business can cease the production of its own product, and the demand of the company's own product increases. In addition, it is possible that the authority sets new legislations that could have an impact on, for example, in the sales license for the product or in the obligation storage. That is why it is important to keep the prioritization of the products and their mitigation approaches up to date.

7.2 Next steps of the Proposal

The next steps of the Proposal are to assess potential partners for the agile supply strategy and define the wanted location and stock levels for the stockpiling strategy. In agile supply strategy, it is worth nothing when looking for potential contract manufacturers is that they have the necessary technical equipment (for example, devices for visual sorting) and requirements to be capable of manufacturing the products despite their technical complexity.

In addition, it can also be considered whether it is possible to build a secondary production line to another location that can be used for manufacturing in case of own manufacturing unavailability. The secondary production line would be in "hold mode" and it would take a predefined amount of time to get the line in the condition where substitute manufacturing can be started.

In the stockpiling strategy, the next step would be that the desired stock levels and locations should be assessed. It is also worth noting that the stocks do not have to be locked out from selling the products in the markets and prevent them from expiring but the stocks can be refilled when older product batches are sold first. The need for refilling can be measured with a predefined re-order point and the manufacturing pace for the refilling batches can be reviewed with inventory turnover metric.

The chart also helps to manage the departments' portfolios since with the chart it is convenient to provide a list which sorts the products that fall within the scope of continuity planning and products that are left outside the planning. This

list should be implemented in the company's regular risk management review which is done at least once a year. In the review the departments describe the current situation of their products or whether there have been some changes in valuations or not.

7.3 Thesis Evaluation: Objective vs. Results

When comparing the objective of this thesis to the results, it can be stated that they are aligned with each other. The objective was to develop a standardized process for product prioritization and selecting appropriate mitigation approach and the result is a process chart for the procedure. Thus, the objective of this thesis has been accomplished.

7.4 Final Words

I want to thank all the people that participated for this process and especially those people who have been involved since the beginning when the subject was introduced to me, and the scope was defined more precisely. The subject of this thesis was interesting and educational which strengthened my own understanding on managing supply chain in case of emergency. The persons interviewed were very helpful throughout the whole project and the guidance was always available. The outcome of this thesis provides concrete benefits for the company since they can use the result of the work for assisting their decision-making.

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Appendix 1: Process chart for product prioritization and selecting appropriate mitigation approach