



**CHALMERS**

# **The Feasibility of Dual Sourcing in the Medical Device Industry**

Bachelor thesis in the Bachelor of Science program Industrial Management and Production Engineering

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CHALMERS UNIVERSITY OF TECHNOLOGY  
Gothenburg, Sweden 2021  
[www.chalmers.se](http://www.chalmers.se)  
Thesis nr: E2021:081

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A case study of a Swedish MedTech company

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# **PREFACE**

This bachelor thesis was written at the end of three years studying Industrial Management and Production Engineering at Chalmers University of Technology in Gothenburg, Sweden. The thesis has a scope of 15 higher education credits. The company involved cannot be named due to confidentiality. Suffice to say, they are a smaller medical device company based out of Sweden and are referred to in the thesis as MTC. Sadly, we cannot name our contact at the company for the same reason, but he has our eternal thanks for all the time and effort he has put in helping us write this thesis. We would also like to thank all other employees of MTC who have gone above and beyond in answering all our questions and inquiries. Special thanks need to be directed to our supervisor at Chalmers, Riikka Kaipia, who has shown immense patience and dedication in helping us finalizing this thesis. Finally, we must thank Märtha Tilk, without whom this thesis would never have been written as, without her, we would never have gotten in contact with MTC.

## **ABSTRACT**

Companies today tend to spend more than half of their turnover on purchasing components and services. Therefore, it is of interest to look at purchasing strategies. This study was carried out at a Swedish medical device company, referred to as MTC, and aims to identify the possibilities and issues of implementing dual sourcing for small to medium-sized companies within the highly regulated medical device market. The study is focused on the European market and commercial products, meaning it does not investigate differences between global markets or medical products undergoing clinical trials. General models regarding purchasing strategies, namely the Kraljic- and Dutch Windmill models, have been applied to determine what purchasing strategies should be used for different products. An understanding of the market and how regulations affect the companies within it has been gathered through interviews with staff from the company which is involved in this study. The general finding is that resources should be allocated towards supply market research where both current suppliers and potential suppliers should be analysed. This ensures a careful supplier selection since switching suppliers is heavily resource and time-demanding due to the regulations within the market. The result presented in this study is in general that dual sourcing as a purchasing strategy is more suitable for products where the suppliers' contingencies are underdeveloped. The same result was found for products where the dependency of the supplier is exceedingly high, resulting in the possibility of the company being exploited by its supplier and incurring substantial price increases.

Key words: sourcing, strategy, contingency, supply risk, medical device, MDD, MDR

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# DESIGNATIONS

**Alpha** – alias for one of the products studied.

**API** – stands for “active product ingredient” and refers to a critical raw material.

**Bravo** – alias for one of the products studied.

**Contingency** – in this study interpreted as a company’s plans for preventing supply disruption as well as plans for what to do should a disruption occur.

**Contract manufacturer** – manufacturer of outsourced production.

**Gamma** – alias for one of the products studied.

**GPM** – Global Product Manager

**Jupiter** – alias for one of the suppliers studied.

**Lead-time** – the time from the start of a process until its completion.

**LSM** – Logistics and Supply Manager

**MDD** – stands for “Medical Device Directive” and is the regulation concerning medical devices in the **European** Union up until May 25<sup>th</sup>, 2021.

**MDR** – stands for “Medical Device Regulation” and is the new regulation concerning medical devices in the **European** Union coming into effect May 25<sup>th</sup>, 2021.

**Medical device** – any device intended for medical purposes.

**Multiple sourcing** – supply strategy where two or more suppliers are used.

**OME** – Operations Manager for Europe and rest of world

**Omega** – alias for one of the products studied.

**OMN** – Operations Manager for North America

**Patricia** – alias for one of the suppliers studied.

**Purchasing portfolio** – a technique for selecting purchasing strategies for different products.

**Safety stock** – inventory intended for use when the regular inventory cannot be used.

**Saga** – alias for one of the suppliers studied.

**Single sourcing** – supply strategy where only one supplier is used.

**Svea** – alias for one of the suppliers studied.

**TPM** – Technical Product Manager

# 1 INTRODUCTION

This chapter includes a background of the phenomenon of sourcing strategies, the company as well as the market in which they operate. It will then go on to specify the purpose of the study, the delimitations, and, finally, present questions which must be answered to fulfill the purpose.

## 1.1 Background

Companies today tend to spend more than half of their turnover on purchasing components and services (Van Weele, 2018). The author goes on to describe that choosing the right sourcing strategy is of importance for any company hoping to show short-term results and long-term competitiveness. Developing a sourcing strategy includes choosing the number of suppliers for each component, the geographical location of the suppliers and taking into account the potential for long-term relationships with suppliers. Doing this requires considering several factors which differ depending on the market and environment of the company in question.

This study looks at a Swedish company within the MedTech industry, here referred to as MTC (MedTech Company). They supply products to be used in transplantations of organs to clinics all over the world. The MedTech industry is highly regulated and the products relating to transplantation complex. This leads to issues finding and qualifying suppliers for companies developing products within the field. Firstly, there might be few available suppliers as components often require rare and complex processes. Secondly, due to the regulations, qualifying suppliers is a costly and time-consuming task. As a result, single sourcing is a prominent sourcing strategy used by MTC.

The issue with single sourcing is the risk of supply interruption. If a single supplier fails to deliver, the production seizes, and the clinics can no longer perform transplantations leading to increased risk for loss of patient life. As this would have catastrophic consequences for MTC's image and goes against their vision, there is a need of minimizing the risk.

MTC's vision is that no one should have to die waiting for an organ. In Sweden, 30 to 50 people die each year waiting for a donor organ (Socialstyrelsen, 2020). In the United States, that number is 17 people per day (Department of Health and Human Services, Health Resources and Services Administration's Healthcare Systems Bureau [HSB], 2020). It stands clear that ensuring a steady supply of vital components is of importance in saving lives.

## **1.2 Purpose**

The purpose of this study is to understand the factors which affect the number of suppliers for a single product within the medical device industry. It also investigates if there is a feasible solution to have two or more suppliers for specific components for a small to medium-sized company in the medical device industry.

## **1.3 Delimitations**

This study will only look at a small-sized company in the medical device industry, thereby excluding the perspective of larger corporations. Furthermore, the study will not look at products undergoing clinical trials but only focus on commercial products already on the market. Additionally, the study will revolve around the European medical device industry market and thereby not go into detail about the differences between different markets.

## **1.4 Clarification of issue**

The issue of determining the feasibility of multiple suppliers for a single product within the medical device industry is complex and it requires that the following questions be answered:

- Is having more than one supplier for a single product preferable for a small to medium-sized manufacturer in the medical device industry?
- What regulatory aspects affect the suitable number of suppliers?
- What factors determine the feasibility of implementing and maintaining a second source for a single product?

## **2 THEORETICAL FRAMEWORK**

This chapter includes general theories regarding the area of supply strategies and purchasing. Theories relating to purchasing strategies specifically in the medical device industry are very scarce. Van Weele (2018) mentions that lower end-use markets such as the medical device industry often produce highly specified and unique products, therefore innovation and supply are dealt with before cost and price aspects. Apart from that, most theory relating to the medical device market or the pharmaceutical market revolves around supply chain management in general and internal processes and is therefore of little relevance to this study. For that reason, the theoretical framework will revolve around general purchasing theories which will then be applied to the medical device market.

### **2.1 Purchasing management process**

The purchasing agenda has changed significantly in the later time. Earlier the main priority for purchasing managers was cost reduction. Nowadays, two other aspects are considered of the same importance. These are value improvement and risk management. Furthermore, the agenda of the purchasing manager has now evolved to become a task where you need to balance cost and risk factors against value aspects (Van Weele, 2018).

### **2.2 Supply strategies**

The risk management aspect of purchasing involves many elements including the sourcing strategy, quality assurance, and relationship with the supplier. This chapter will look at specifically sourcing strategies and explain the basic concepts of single- and multiple sourcing and the differences between them.

#### **2.2.1 Single & Multiple Sourcing**

Single sourcing is a strategy where all the purchasing requirements are established with one supplier (Van Weele, 2018). This strategy is broadly used for components and products with relatively low order volume and quantity as multiple suppliers generate higher administrative ordering costs (Jonsson & Mattsson, 2016). It is also common that single sourcing is chosen to lower the materials costs as it is often possible to negotiate preferable terms when dealing with only one supplier (Van Weele, 2018). Other factors that might result in the choice of single sourcing are the geographical location of a potential supplier and the number of potential suppliers that can provide the service that exists (Jonsson & Mattsson, 2016). Additionally, single sourcing is often used as a strategy to develop a great relationship with the supplier. This since it takes more resources to develop a great relationship when there is

more than one supplier for a specific object. The downside of single sourcing is that it increases the dependency on a specific supplier and the supply risk (Van Weele, 2018).

Multiple sourcing is a supply strategy where two or more suppliers are used parallelly for the same product. One of the principal causes for the utilization of multiple sourcing is that it generates a better position to negotiate prices and conditions since the suppliers are pitted against each other (Jonsson & Mattsson, 2016). The authors do, however, highlight that this is mainly true for commodities traded on a well-developed market. The usage of multiple suppliers is also an effective way of minimizing risk as, if one supplier fails to deliver, the capacity of the other can be increased (Jonsson & Mattsson, 2016). The authors indicate that multiple sourcing is more applicable if the costs of switching suppliers are low.

A variant of multiple sourcing is dual sourcing where two suppliers are used. It could be constructed in a way that splits the delivery share equally between the two. In other cases, one of the suppliers is chosen as the primary supplier with a higher delivery share while the other stands for the remaining volume (Jonsson & Mattsson, 2016). The authors describe that this strategy maintains the pros of single sourcing while still mitigating risk and maintaining competitive pressure on the primary supplier.

### **2.2.2 Risk analysis with outsourcing**

Outsourcing has become very popular as a business strategy in later years. This due to financial advantages and that it allows companies to focus on other areas such as research and development, (Van Weele, 2018). The cost-saving aspects often have to do with it being cheaper to locate the production elsewhere. However, outsourcing has its drawbacks. Van Weele (2018) states that outsourcing leads to increased dependence on suppliers and the risk of leakage of confidential information.

## **2.3 Category sourcing planning – Choosing a sourcing strategy**

Choosing a sourcing strategy is not about picking one and using it for all situations. A company may choose a combination of sourcing strategies to manage risks (Huang & Xe, 2015). This can be done by category sourcing.

Category sourcing is a concept where products are divided into groups depending on which category they belong to. Category sourcing consists of three stages: planning, sourcing, and implementation of the category (Van Weele, 2018).

Van Weele (2018) defines a category as:

*... a group of products or services which are purchased from the supply market and which are used as an element of the value proposition that our company offers to its customers or which are to be used in the internal company's operations. (Van Weele, 2018, p.216)*

From this categorization, plans are constructed on how to deal with the supplier markets to secure the supply of products and services included in the specific category. These plans are referred to as category sourcing plans (Van Weele, 2018).

Van Weele (2018) continues by stating that the category sourcing plan needs to be related to the company's goals and strategies as well as consider customer markets and key stakeholders. It should also define, in the broadest sense, future product and service requirements. These include delivery and quality specifications, future volumes, safety, legal and environmental conditions. Based on the requirements, targets and goals are set which often relate to elements such as supply risk, logistics, and financial issues. After targets are set, a discussion needs to be had regarding what number of suppliers are wanted for the future and what relationships are wanted to be pursued with those suppliers (Van Weele, 2018).

## **2.4 Purchasing portfolio analysis**

This chapter will look at purchasing portfolios, starting with the most famous model which is the basis for most studies; the Kraljic model (Caniëls & Gelderman, 2005). Thereafter, the Dutch Windmill, which stems from the Kraljic model, will be introduced.

### **2.4.1 The Kraljic Model**

Kraljic (1983) considered that suppliers are of different importance to a company and, therefore, differentiated supply strategies depending on the supply markets should be adopted (Van Weele, 2018). Kraljic (1983) introduced his model as a matrix with four quadrants, each representing a stage in purchasing: (1) purchasing management; (2) materials management; (3) sourcing management; and (4) supply management.

The Kraljic model highlights the issue of balancing the influence of power between a company and its suppliers. Preferably, the balance of power should always be in favour of the buyer, if not, something should be done to prevent or minimize the dependency of the supplier (Van Weele, 2018). Van Weele (2018) presents a few questions, based on the Kraljic approach, to simplify the analysis. These questions could be useful when constructing an effective supplier strategy, some of these are presented below.

- Does the current purchasing strategy correlate with the long-term requirements for the company?
- How is the balance of influence between the company and their suppliers?
- Are the most critical products sourced from the best supplier?
- What risk of supply disruption could be expected from a specific supplier, and how would this affect the company's financial objectives?

Kraljic (1983) suggests using a four-phase framework for developing supply strategies for single products or product groups.

### 2.4.1.1 Phase 1 – Classification

The first phase is *Classification* where products are categorized based on their profit impact and supply risk. The classification and name of each category are shown in figure 2.1.

		Supply risk	
Profit impact	High	Leverage products	Strategic products
	Low	Noncritical products	Bottleneck products
		Low	High

Figure 2.1: Product categories based on profit impact and supply risk as described by Kraljic (1983). Source: created by the authors.

According to Kraljic (1983), the profit impact can be defined as the purchased volume, percentage of purchase cost, impact on product quality, or impact on financial growth. The supply risk also has multiple definitions, these include availability, number of suppliers, competitive demand, storage risks, and the possibility of substitution.

To further elaborate on the different classifications, their definitions as described by Van Weele (2018) are helpful:

- *Strategic products* – These are often products delivered to customer specifications and are of a high-tech and high-volume nature. They are single-sourced and changing suppliers cannot be done in the short-term without incurring substantial costs. The relationship between company and supplier is often complex and the balance of power between the two varies depending on the situation. In a buyer-dominated climate, the supplier is dependent upon the customer and therefore must follow the requirements set



by the customer. In a supplier-dominated climate, the roles are reversed, and the company is reliant upon its supplier. The company is often locked in a relationship with little to no possibility of changing suppliers. The final situation is the balanced relationship where neither company nor supplier is in a dominant position. This often leads to a partnership relationship. The main objective regarding strategic products is to create mutual commitment to generate a long-term relationship. Activities that are suggested to manage this are to produce an accurate forecast of future requirements where a cost analysis should be included. Another important activity is to perform a supply risk analysis together with a carefully executed supplier selection. The main objective regarding strategic products is to create mutual commitment to generate a long-term relationship. Activities that are suggested to manage this are to produce an accurate forecast of future requirements where a cost analysis should be included. Another important activity is to perform a supply risk analysis together with a carefully executed supplier selection.

- *Leverage products* – These products are often of standardized quality and can be obtained from various sources. They usually represent a big percentage of the end product's cost, and the product itself is often bought in big volume. Therefore, a small price change on the leverage products can have a big effect on the end product's cost price. In general, the strategy of most importance to manage is to obtain the best deal possible for short-term success. While this is managed, activities to gain market knowledge should be executed to be able to search for alternative suppliers or substitute products.
- *Routine products (in the Kraljic model referred to as Non-critical products)* - These products are often cheap and could be obtained from many alternative sources. Most so-called inventory items fall into this category. Usually, these products are more expensive to handle and store than to purchase. The main objective of non-critical products is to reduce the logistic complexity that they generate. Activities that are suggested to manage this are to standardize product assortment and to design effective internal processes regarding delivery and invoicing procedures. Another suggestion is to delegate order handling to the internal user.
- *Bottleneck products* – These products are recognized by large entry barriers and are often just one or a small number of suppliers which can deliver the service or product. This contributes to vulnerability regarding supply. The objective of most importance regarding these products is to secure supply. In general, this means securing short- and

long-term supply while reducing supply risk. To successfully execute this, activities such as developing accurate forecasts and supply risk analysis are suggested. Additionally, a ranking in suppliers' client risk should be performed in combination with a search for alternative suppliers.

### 2.4.1.2 Phase 2 – Market analysis

The second phase introduced by Kraljic (1983) is *Market analysis*. In this stage, the company determines the bargaining power of its suppliers as well as its strength as a customer. The supply market must be analysed to determine the strength of existing suppliers and the availability of strategic components and materials. Also, the company's own supply lines must be assessed to gain insight into the possibility of getting favourable supply terms. Kraljic (1983) proposes using several criteria to determine the strength of a company and its suppliers, these are presented in table 2.1. However, these criteria are of different importance depending on which industry a company operates in. Therefore, each company must make modifications to the criteria presented.

Table 2.1: The purchasing portfolio evaluation criteria. Source: Kraljic, P. (1983). "Purchasing Must Become Supply Management". *Harvard Business Review*.

Purchasing Portfolio Evaluation Criteria		
	Supplier strength	Company strength
1	Market size versus supplier capacity	Purchasing volume versus capacity of main units
2	Market growth versus capacity growth	Demand growth versus capacity growth
3	Capacity utilization or bottleneck risk	Capacity utilization of main units
4	Competitive structure	Market share vis-à-vis main competition
5	ROI and/or ROC	Profitability of main end products
6	Cost and price structure	Cost and price structure
7	Break-even stability	Cost of nondelivery
8	The uniqueness of product and technological stability	Own production capability or integration depth
9	Entry barrier (capital and know-how requirements)	Entry cost for new sources versus cost for own production
10	Logistics situation	Logistic

Kraljic (1983) further explains six of the criteria as he considers them harder to understand. The only one of relevance for this study among these is the following:

- *The uniqueness of suppliers' product* - if there are facility investment or other resource-demanding entry barriers in play, the probability of alternative sources or suppliers existing may be low which can result in supplier competition not contributing to cost reduction.

### 2.4.1.3 Phase 3 – Strategic positioning

The third phase is *Strategic positioning* where a company assesses risks and opportunities for products determined as strategic in phase 1 (Kraljic, 1983). This is done by placing the product into what Kraljic (1983) calls *the purchasing portfolio matrix*. The matrix plots the company's strength against the strength of the supply market in order to formulate a supply strategy for the product. The purchasing portfolio matrix can be seen in figure 2.2.

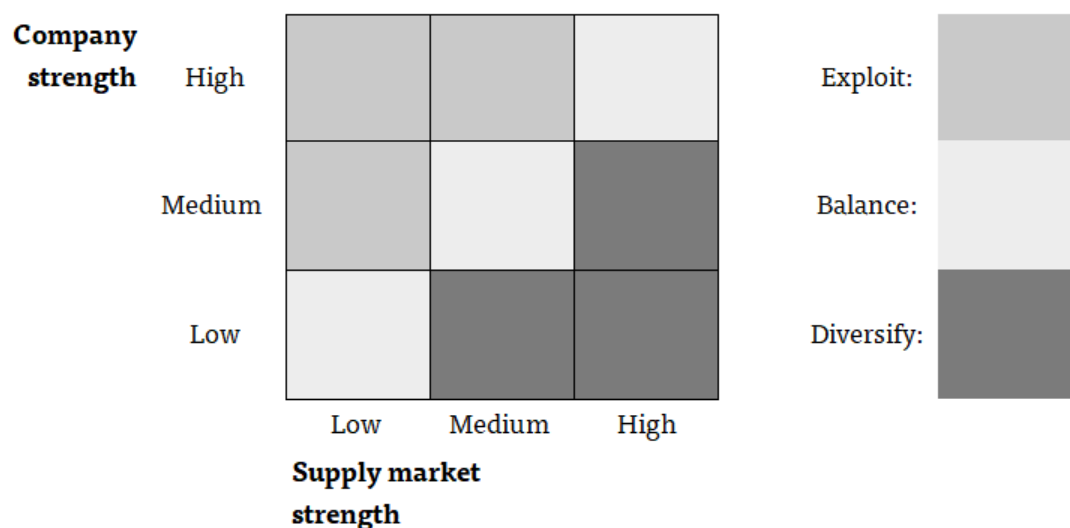


Figure 2.2: The purchasing portfolio matrix. Source: Kraljic, P. (1983). "Purchasing Must Become Supply Management". Harvard Business Review.

If the company's role in the market is favourable against the supply market regarding a specific product, which contributes to a low risk of supply disruption, an aggressive approach should be used (Kraljic, 1983). This contributes to better pricing and contract agreements. However, if the supplier's position is strong and the company's role is considered secondary, a more defensive approach should be taken. This involves searching for new suppliers which may result in more resources needed on market research and supplier relations. This to investigate the company's supply options. If no major risks or benefits could be identified in the company's status versus that of the supply market, a more balanced strategy should be adopted.

#### **2.4.1.4 Phase 4 – Action plans**

The fourth and final phase described by Kraljic (1983) is *Action plans*. In this stage, the company should look at different supply scenarios focusing on exploiting short-term opportunities and securing long-term supply. Costs, risks, returns, and strategic implications must be understood, and a clear plan should be laid out explaining goals, steps, responsibilities, and contingencies. Contingencies refer to plans a supplier has in place to prevent supply disruption as well as plans for what to do if and when a disruption occurs. The plan is then approved for implementation by top management.

#### **2.4.2 The Dutch Windmill**

The Kraljic approach has gotten critique since it mainly considers the buyers' perspective (Van Weele, 2018). To take the supplier's portfolio and dependence into account, the Dutch windmill has been introduced in many companies as an extension to their purchasing portfolio analysis. Van Weele (2018) describes that considering both parties' approach leads to a more realistic view on expectations and plans which are developed when collaborations between buyer and seller are constructed. What this means is that to design an effective purchasing strategy, both parties' perspectives need to be recognized.

How to interpret the Dutch Windmill (see figure 2.3) should be explained. Firstly, the products are categorized according to the Kraljic model meaning it is based on profit impact and supply risk. Then, the relationship with the supplier is categorized based on the supplier's competitive position and the company's attractiveness as a customer to that supplier. This introduces four new supply segments, which generate 16 different possibilities of buyer-seller relationships, where only one is suitable for the development of a long-term relationship. The four segments are:

- *Core segment* – The relationships within this segment are of great importance from both the supplier's and the customer's perspectives. Furthermore, this results in the possibility of constructing a long-term relationship between the two parties. This since it is of interest from both sides to invest time and resources into building and developing a relationship. The consequence of this is that aspects such as supply efficiency and continuous improvement could develop in a positive way (Van Weele, 2018), this since the supplier considers the customer as important and vice versa.
- *Development segment* – This supply segment demonstrates when the supplier is in a weak position in comparison to the buyer. The weakened position is often a

consequence of there being a large number of suppliers which are competing for the same share of the buyer's wallet. This results in that the aim from the supplier's perspective is to obtain more business from the buyer, leading to the supplier being more willing to invest in a relationship with the buyer (Van Weele, 2018).

- *Exploitation segment* – This segment represents the scenario when the supplier's position is in favour in comparison to the buyer. This due to that few alternative sources are available which contributes to a high degree of dependency and reliance on the supplier. This leaves little room for the buyer to manoeuvre (Van Weele, 2018). In conclusion, this often results in that the supplier seeks optimal benefit from its strong position which usually leads to higher prices.
- *Nuisance segment* – This segment represents a mismatch between the importance of the relationship between the buyer and seller. There is a significant amount of possible suppliers for the buyer to choose from which generates a lower switching cost between suppliers. This creates a low interest in developing a long-term relationship since the aim is to obtain the lowest price possible (Van Weele, 2018), which may contribute to switching suppliers when this opportunity presents itself. In combination with this, the importance and magnitude of the relationship from the seller's perspective are in general low since the buyer only represents a small commercial interest. The consequence of this is also that suppliers do not find a long-term relationship of big interest.

In the model below (figure 2.3) the 16 different relationships are visualized with standardized approaches that are modelled to obtain the best possible purchasing strategy.

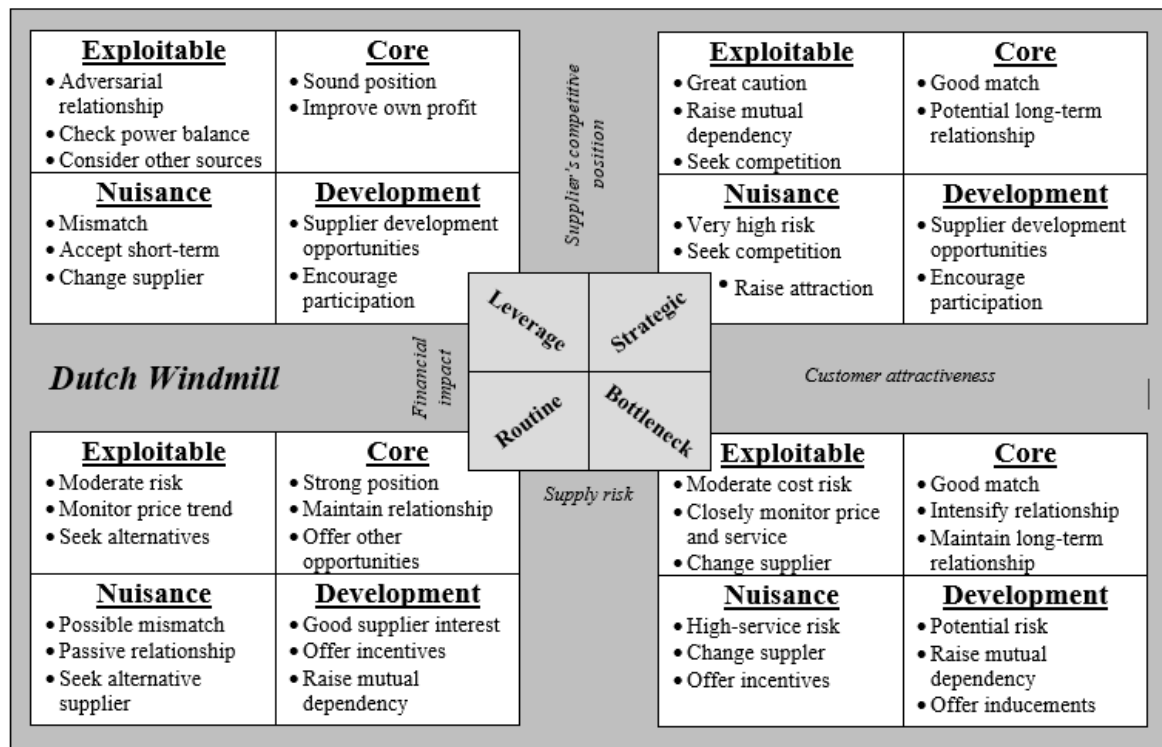


Figure 2.3: The Dutch Windmill. Source: Van Weele, A. (2018). "Purchasing and Supply Chain Management". Cengage Learning.

## 2.5 Supplier and buyer attractiveness

Aminoff & Tanskanen (2015) looks at what makes customer attractive to its suppliers and vice versa. They suggest that customer attractiveness could be categorised into four segments which are defined as foundations of the attractiveness of a supplier or customer. These are (1) economic-based attractiveness; (2) behaviour-based attractiveness; (3) resource-based attractiveness; and (4) bridging-based attractiveness.

- Economic-based attractiveness** – Aminoff & Tanskanen (2015) found that some of the drivers of economic attractiveness are short-term economic value, which often is connected to the customer's purchasing volume, price, and costs. Another important factor is the long-term economic value which is of strategic importance and is a driver that highly affects attractiveness. From the suppliers' point of view, customer success, new customer businesses, and the industry's future which the customer operate within were found to be important drivers of economic attractiveness. In the pharmaceutical industry sector, suppliers were found to evaluate the development of the industry as well as the strength of the buyer's position in that sector. Also, buyers who were investing in new business areas, attractive to the supplier, were found economically attractive.

- *Behaviour-based attractiveness* – Aminoff & Tanskanen (2015) found that communication, commitment, respect, and trust were the most important factors relating to the behaviour of suppliers and customers concerning their attractiveness. They also highlight that the history between the two parties plays a role, stating that “personal relations and a long common history were commonly seen as important antecedents of good communication, commitment, and trust.”
- *Resource-based attractiveness* – In their study, Aminoff & Tanskanen (2015), identified that resources contributing to attractiveness often were supply chain management, production process resources, and capabilities. This is true for both buyers and suppliers. The company size is also a factor of importance, but buyers and suppliers have differing views on it. Suppliers consider the size of their customers to be of economic value as a larger customer potentially leads to bigger sales. Buyers, on the other hand, want suppliers to be large enough to meet their demands but not so large that they do not influence them.
- *Bridging-based attractiveness* – In this case, Aminoff & Tanskanen (2015) refers to one party’s ability to act as a “conduit to a larger value network”. They identified three common aspects within this area contributing to the attractiveness of the buyer or supplier. Among these is geographical presence. For buyers, suppliers’ closeness to resources such as cheap labour was of importance while suppliers valued customers active within strategically important markets as important. Also, suppliers consider buyers which have a connection to other organisations important to them as more attractive.

### **3 METHOD**

This chapter will describe the methodology used throughout this case study. This includes a pilot study, a study of literature, data collection, and a reflection regarding the chosen methods.

#### **3.1 Pilot study and identification of problem**

The first activity performed in writing this paper was to get a wider understanding of the company and the industry they operate within. To attain the knowledge needed, less structured meetings with different employees took place. Employees to be interviewed were recommended by the Operations Manager for Europe and rest of world, based on their in-depth knowledge of areas such as operations, product development, production, marketing, quality, and regulations. The purpose is to get a broader understanding of the company and the industry but also to get the different employee's thoughts about the current single sourcing strategy.

#### **3.2 Study of literature**

The study of literature was performed with textbooks and scientific articles regarding scientific methodology, purchasing and supply chain management, and other topics which are affected by the sourcing strategy such as logistics. Some of the literature was given as suggestions from professors at Chalmers University of Technology who teaches in the topic of supply chain management while other literature, such as articles, was mainly found at the Chalmers database.

Literature describing sourcing and purchasing strategies within the medical device industry or highly regulated markets, in general, is limited. The theories presented in the study are therefore mainly focused on purchasing and sourcing strategies in general.

#### **3.3 Collection of Data**

This chapter describes the methods used for data collection which provided a basis for analysis. The primary source of data for the study was interviews with selected employees of MTC. Secondary sources of data come from electronic communication (see section 3.3.2). The data was used to give a fair description of the company's current situation (see chapter 4) regarding sourcing strategies which were then analysed using the theory presented in Chapter 2.



### 3.3.1 Interviews

Interviews can be carried out either quantitatively or qualitatively. Quantitative research requires that there are well-established theories regarding the subject (Lantz, 2013). As the research done within the area of sourcing strategies in the medical device industry is limited, a quantitative approach is not possible. For that reason, the interviews carried out in this study had a qualitative format.

Interviews based on qualitative research can be structured in different ways. Questions can be phrased either to have an open-ended or closed answer. In this study, a semi-structured approach was chosen where the interviewees were given the questions beforehand to prepare their answers. A semi-structured interview means the interviewees are asked questions of both open and closed nature and allows the interviewer to ask follow-up questions that may arise from the discussion (Kallio et al., 2016). This enables the interviewees to freely share their interpretation of the subject matter while also providing the interviewer with quantitative data (Lantz, 2013).

The interviewees in this study are presented in table 3.1 below. The specific interviewees were given as a recommendation by the Operations Manager for Europe and rest of world at MTC. Their titles are included as they speak to the expertise of each person. The interviewees will be referred to their respective alias when referenced in the report.

*Table 3.1: Information regarding interviews and interviewees. Source: created by the authors.*

Interview	Interview date	Interview duration	Interviewee (Title)	Alias
1	2021-03-03	34 min 55 sec	Technical Product Manager	TPM
2	2021-03-09	41 min 52 sec	Operations Manager for Europe and rest of world	OME
3	2021-03-09	30 min 17 sec	Global Product Manager	GPM
4	2021-03-11	23 min 15 sec	Logistics and Supply Manager	LSM
5	2021-03-11	35 min 42 sec	Operations Manager North America	OMN

Questions were created based on the literature as well as information gained from the initial meetings in the pilot study. The semi-structured format gave the possibility of individualizing questions, thereby giving the interviewees the ability to share their interpretation of sourcing strategies in the medical device industry from the perspective of their area of expertise.

Since the interviews were mainly performed virtually due to the SARS-CoV-2 pandemic, social interaction between interviewers and interviewees was limited. According to Lee et al (2021), this amplifies the importance of first impressions as it may increase implicit bias. The hope is that the initial informal meeting minimizes potential bias. However, there is little

research to be found on the matter and thereby it cannot be determined whether the initial meetings had an effect on bias or not.

### **3.3.2 Recordings and Transcriptions**

The interviews were recorded to ensure no data was lost. Each interviewee was aware that they were being recorded and gave permission before a recording was initiated. The recordings were solely used for transcribing and not shared with any third party.

The interviews got translated from Swedish to English and transcribed into text using the recordings. The use of recordings minimizes the risk of misrepresenting the interviewees and the information shared. To further make sure that no misrepresentation occurred, the transcription later got sent back to the interviewee for them to review. This enabled the person in question to make clarifications in areas where they felt their opinion had not been properly represented. After this had been verified, the recordings were deleted.

The choice of letting interviewees alter the content of the transcripts after they had been finished has both pros and cons. The pros being ensuring proper representation of the interviewee and making sure no information was inaccurate. The con is that it enables interviewees to modify the content based on what they consider sensitive information. This could lead to valuable information not being included and thereby harming the analysis of the study.

### **3.3.3 Other data sources**

Additional data used for analysis has been collected through video conferences and e-mails throughout creating this study. This includes power-points and documents presenting sales figures, purchasing data, sourcing strategies, supply network, and organizational goals.

### **3.3.4 Data analysis**

The data collected was used to make an accurate description of MTC's current position (see chapter 4). This included presenting the following: (1) the regulations relating to the medical device industry; (2) MTC's vision and current supply strategy; (3) the products relevant for this study and their suppliers; (4) MTC's risk classification of suppliers, (5) the supply strategy's logistics and financial effects; and (6) the staffs' view on implementing dual sourcing.

The data was then analysed through the usage of the Kraljic model. This included determining the profit impact and supply risk of the products studied. An important part of this step of the

analysis was determining each of the current supplier's contingencies as well as MTC's knowledge about them. This is important to be able to make accurate deductions regarding the supply risk of each supplier. The supply market was then analysed to ascertain the power balance between MTC and its current suppliers. Finally, the preferred supply strategy for products identified as strategic was determined.

The Dutch Windmill was then used to make an analysis where the suppliers' viewpoint was taken into account. This included ascertaining each supplier's competitive position as well as MTC's attractiveness as a customer to each of its current suppliers. The suppliers' competitive position was determined solely through the data gathered from the interviews while MTC's customer attractiveness was determined by applying the data gathered to Aminoff & Tanskanen's theories presented in chapter 2.

### **3.4 Reflection of Methodology**

Throughout this study, the work published by Van Weele (2018) has been heavily used to describe the theory presented in chapter 2, in combination with a few additional sources. More sources could have been used to dictate which theory would have been the most applicable for the study. However, the work by Van Weele references many other authors who have been covering and studying the topics presented in chapter 2. The usage of Van Weele's book was a suggestion given by a professor at Chalmers and his book is used as course literature for the master-program Supply Chain Management at Chalmers. Therefore, the fact of having one primary source for chapter 2 is not considered to damage the validity or reliability of the study.

Kraljic (1983) is another source that is used within chapter 2. This source, being 40 years old, could be viewed as outdated, and therefore not reliable. Kraljic's work which is presented in this study is however determined to still be of relevance since many authors' work refers to Kraljic and his model and has been used as a basis for their research.

The name of the company and its products were changed to be able to present information that would otherwise be damaging to MTC. The issue of sensitive information could have an impact on the validity of the usage of interviews as a primary source of data. Although interviewees were informed of the measures taken to ensure no such information was included, it is difficult to say whether the interviewees felt comfortable discussing the topics freely or not.

## 4 DESCRIPTION OF CURRENT SITUATION

This chapter will look at MTC's current position. Firstly, the current European regulations will be presented. An explanation of MTC and their current supply method will be included. The products studied as well as their suppliers will be presented. Finally, financial aspects and the staff's view on the current supply strategy and the prospect of dual sourcing will be explained.

### 4.1 Regulations – MDD and MDR

This chapter will look at the current regulations in the European Union, MDD (Medical Device Directive) as well as the new regulation, MDR (Medical Device Regulation), coming into effect in May 2021.

#### 4.1.1 The Medical Device Directive

As mentioned, the Medical Device Directive, or MDD, is the current legislation concerning medical device products. It applies a risk-based classification of medical device products which consists of five classes: I-nonsterile, I-sterile, IIa, IIb, and III (see table 4.1).

*Table 4.1: Description of the different classes and their traits. Modified from: Daigle & Torsekar (2019). "The EU Medical Device Regulation and the U.S. Medical Device Industry". Journal of International Commerce and Economics*

Class	Risk level	Class Description	Examples	Relevance for MTC
I Non-sterile	Low	Non-sterile or is not used for measurements	Volumetric urine bags, tongue depressors	Low
I Sterile	Low - medium	Sterile and/or provides a measuring function	Bandage dressings, scalpels	Medium
IIa	Medium	Devices of an invasive nature intended for short-term use, the exception being devices used in mouth or ear (then class I)	Syringes, nebulizers	High
IIb	Medium - high	Devices of an invasive nature intended for long-term use, the exception being devices used in mouth or ear (then class IIa), or invasive devices intended for transient use with exceptions	Defibrillators, hemodialyzers, incubators, lung ventilators	Low
III	High	All devices utilizing a substance which on its own can be considered a medical product, blood derivatives, or incorporate animal tissues or derivatives. Also, any device controlling or monitoring blood circulation or the central nervous system.	Heart monitors, breast implants, catheters, stints, bioactive implantable devices, IUDs	High

Manufacturers also need to earn a *Conformité Européenne* (CE- or “European Conformity” mark) for their products through completing conformity assessments under the regulation (Daigle & Torsekar, 2019). Once achieved the company may sell devices in any member state of the EU or the European Free Trade Area.

For companies manufacturing and selling medium- and/or high-risk devices, the CE marks are provided by “notified bodies”. These are private organisations authorized to inspect and audit manufacturers to guarantee compliance with the directive (Daigle & Torsekar, 2019). Audits may be carried out at a manufacturer by a notified body periodically as soon as a device is placed on the market.

### 4.1.2 The Medical Device Regulation

The Medical Device Regulation, or MDR, is the regulation that should have replaced MDD in 2020 but its introduction was delayed until May 26<sup>th</sup>, 2021 due to the outbreak of Covid-19.

The major differences between MDR and MDD can be seen in table 4.2.

*Table 4.2: Major impacts of MDR. Modified from: Daigle & Torsekar (2019). "The EU Medical Device Regulation and the U.S. Medical Device Industry". Journal of International Commerce and Economics*

Major Regulatory Area	Transition from MDD to MDR	Relevance for MTC
Research and clinical trials	Tightened standards for research and clinical trials, setting a higher bar for certain research data in establishing safety and use of medical devices. Lower-risk products will now require clinical trials.	Low
Conformity assessment procedures	Medical devices will now require unique device identification (UDI) codes. Also, CE certifications will be needed for a variety of products previously not covered by MDD.	Low
Post-market surveillance	Under MDR, companies manufacturing advanced products that fall under classes II or III are now required to perform at least yearly assessments of their products' operation in the EU market. Also, yearly assessments must be made for any circumstances that may impact the health outcome or performance of their devices. These companies must also gather more data and increase their transparency.	High

As this study focuses on commercial products already on the market, research and clinical trials, as well as conformity assessment procedures, will not be explained in further detail. The area that is of interest is post-market surveillance.

For class III-devices, yearly assessments of the product’s operations within the EU market must be made by manufacturers (Daigle & Torsekar, 2019). Any development which could affect the effectiveness or health outcomes of the product must be reported, even if such a development has occurred outside the EU market. Comparing this to MDD, MDR will require more data to be collected and more transparency regarding high-risk devices.

### 4.1.3 The transition from MDD to MDR

The transition between the two regulations will likely increase costs for manufacturers and distributors operating in the medical device industry (Daigle & Torsekar, 2019). Furthermore, the number of notified bodies will likely be reduced as a consequence of MDR. About the

transition period, the Operations Manager for Europe and rest of world interviewed for this study says the following:

*...we cannot make any changes to our products or at our suppliers according to MDD, we have to go on the new regulations of MDR. However, the lead times at the notified bodies are very long right now meaning that, at the moment, the process of making changes is even longer. (OME, personal communication, March 9<sup>th</sup>, 2021)*

The interviewee also had concerns regarding the added risk stemming from the prolonged lead times at the notified bodies:

*If a supplier tells us that they are going to move their productions elsewhere or something of that magnitude, especially if it is connected to sterilization, we will not be able to handle it at the moment, we have to wait until we have been approved by MDR. (OME, personal communication, March 9<sup>th</sup>, 2021).*

## **4.2 MTC and its vision**

MTC is a Swedish medical device company specializing in products relating to organ transplantation. They have a dominant market position for one specific organ but have recently acquired another company to access markets relating to transplantations of other organs.

MTC delivers its products with the highest accuracy possible. However, there is still a big concern for MTC that their current supply strategy, which will be further discussed later in this chapter, generates a high dependency of suppliers and risk of disruption.

MTC's vision is to have a 100% delivery accuracy which means no deliveries should be delayed as the consequence could be the cancellation of transplantations.

*Our vision is that no one should die waiting for an organ that incurs the entire organisation. Therefore, we have very high demands regarding service level, and we do not accept backorders. Other companies I have worked for would set the service level at 97-98%, we aim for 100% (OME, personal communication, March 9<sup>th</sup>, 2021).*

MTC has a strong focus on research and development which is evident from them having no in-house production for their commercial products. The only production they do themselves relates to products currently under clinical trials.

### 4.3 Current supply strategy

MTC's current supply network consists of suppliers of raw materials and their outsourced production which is executed by contract manufacturers. Their strategic partners are mainly based in the EU, North America, and East Asia. The finished product is later delivered and stored in Sweden. A small portion of the company's production is located in-house in their facilities in Sweden.

MTC currently uses single sourcing for all raw materials and end products. The main reason for the usage of single sourcing is the significant gravity of resources that is needed to qualify and adapt to a new supplier. Another contribution to the use of the current sourcing strategy is that MTC's products are highly complex and unique which limits the availability of suppliers which can provide the sought services. This due to the aforementioned regulations set on their products and processes which need to be followed by both MTC and their supplier. The complexity and uniqueness of MTC's products do not just limit the availability of suppliers, it also contributes to the fact that a new production line needs to be established and set up at their contract manufacturer if they want an additional supplier.

The qualification of a new potential supplier is because of the reasons listed above done in extreme detail. The qualification is in short terms executed in four steps (TPM, personal communication, March 3<sup>rd</sup>, 2021).

1. *The screening phase* - intended to find potential candidates who meet the basic requirements set from both a regulatory point of view as well as MTC's requirements.
2. *Visiting the company* - if a potential candidate is found, the second step is to visit the company's facilities and meet the people involved. This to check and get a feel and understanding of the quality of the company and its personnel.
3. *Formal audit* - conducted to ensure that the regulatory requirements are met and validate the processes in the production. The audit also involves checking that the production line has the right purity and making sure that the personnel at the contract manufacturing company have had the right training and are qualified.
4. *Negotiation phase* - financial negotiation where a decision is made between the remaining candidates.

This process usually takes up to a year. Since this process require involvement from personnel such as quality assurance (QA), Technical Product Managers (TPMs), and many more from MTC, it is highly resource-demanding.

When all these steps are done and a validated and qualified candidate is selected as a supplier, the setup of a production starts. This is the biggest financial impact from the supplier selection and usually costs between three and twelve million SEK but rarely less than five million SEK depending on which product will be manufactured (OME, personal communication, March 9<sup>th</sup>, 2021; TPM, personal communication, March 3<sup>rd</sup>, 2021). The length from beginning the screening phase until the first supply from the contract manufacturer is delivered can roughly be assumed to take up to 18 months (OMN, personal communication, March 11<sup>th</sup>, 2021). Additionally, there are expenses related to the formal audit as a result of trips to the facilities and to get the new supplier regulatory validated for example. (TPM, personal communication, March 3<sup>rd</sup>, 2021)

As illustrated, the process of qualifying and implementing a new supplier is highly resource-demanding which contributes to the fact that the partnership established between MTC and the supplier is intended to be long-term. This applies more to contract manufacturers since the investment is of such high capacity regarding these kinds of suppliers. Despite this, MTC is highly aware of the downsides of single sourcing. The main area of concern regarding the current supply strategy is its impact on supplier dependency and the risk of supply disruption. Regarding this, the Operations Manager for Europe and rest of world says the following:

*The drawbacks are obvious; we are very dependent on the supplier and its performance. If they have short-term issues with their production, if they fail to obtain raw material or issues with machinery, for instance, it could lead to us not being able to supply our customers.*

*(OME, personal communication, March 9<sup>th</sup>, 2021)*

This is a view shared by all interviewees. A specific issue raised by many is the risk of factory fires and natural disasters. As stated by the Technical Product Manager:

*... a fire on one of the facilities would be one of the worst scenarios, or if a factory was burned down or bombed. The later example may not be of big risk, but how do our suppliers work with fire risk management for example? And is there a plan on what to do if the worst-case scenario happens, how fast can the production be up and running again? (TPM, March*

*3<sup>rd</sup>, 2021)*

The concern of supply disruption is of great interest due to the vision that MTC has which is that no one should die waiting for an organ. To cope with the uncertainties related to natural disasters, factory fire and smaller failures in the suppliers' production, MTC currently works with Business Continuity Plans, which involves looking over the supplier's production and



determine risks in terms of probability and consequences (OME, personal communication, March 9<sup>th</sup>, 2021). This action is used to minimize the potential of an unwanted occurrence to happen and to minimize the probability of failure in production which would result in no deliveries.

#### 4.4 MTC Product Portfolio and current suppliers

In this chapter, the MTC products which this study focuses on as well as their respective suppliers will be presented. As real names of products, raw materials, and suppliers cannot be included in this study, table 4.3 presents the aliases of the products, raw materials, and the specific suppliers of these.

*Table 4.3: Aliases for products, APIs, contract manufacturers, and suppliers of APIs. Source: created by the authors.*

Product	Included APIs	Contract manufacturer	Supplier of API
Alpha	Omega, Gamma	Jupiter	Saga, Patricia
Bravo	Omega	Svea	Saga

Alpha is a product used in organ preservation in connection to transplantations. It is produced by a single source contract manufacturer in Sweden. Alpha is a major source of income for MTC, and a long-term supply disruption would have substantial consequences. As it is a class III-device, finding, qualifying, and setting up a new contract manufacturer is difficult. The batch size is hard to change as it would require a regulatory process (OME, personal communication, March 9<sup>th</sup>, 2021). The volume of the containers of Alpha is very large making the number of suppliers which have the possibility of producing it limited (TPM, personal communication, March 3<sup>rd</sup>, 2021).

Bravo is, just like Alpha, used for organ preservation and is a class III medical device. It is also produced by a single source contract manufacturer, Svea, which is based in Germany. Bravo is, from a financial standpoint, MTC's most important product, taking up around 95% of the global market and generating a little over 50% of MTC's revenues (GPM, personal communication, February 2<sup>nd</sup>, 2021).

##### 4.4.1 The APIs – Omega and Gamma

The production of Alpha and Bravo requires two critical raw materials, or APIs (active product ingredients) referred to as Omega and Gamma. Omega is used in both products while Gamma is only used in Alpha. Both APIs are single-sourced due to there being few available suppliers and no substitutes (OME, personal communication, January 29<sup>th</sup>, 2021).

Furthermore, the process of changing suppliers for either API is time-consuming and costly, taking approximately two years and costing between five and seven million SEK.

In the case of Gamma, it is hard to find a contract manufacturer willing to introduce it into their production. This is due to Gamma comes from human blood which is a health issue for potential contract manufacturers (TPM, personal communication, March 3<sup>rd</sup>, 2021).

As it currently stands, if either contract manufacturer fails or if either supplier of the APIs fails, a major supply interruption could occur.

#### **4.4.2 Contract manufacturers – Jupiter and Svea**

Jupiter manufactures Alpha and is located in Sweden. Looking at MTC's annual purchasing costs, 2.5% is spent paying Jupiter for their services (OME, personal communication, January 29<sup>th</sup>, 2021). Looking at Jupiter's annual sales the business MTC provides corresponds to 0,1% of their revenue.

Jupiter's contingencies are, according to the Operations Manager for Europe and rest of world, questionable:

*We cannot force them to implement contingency plans. If they do not show a will to do so, however, that might be a reason we start looking for a second source. We do have one supplier which is problematic from this point of view... (OME, Personal communication, March 9<sup>th</sup>, 2021)*

This is a view shared by the Technical Product Manager:

*With Alpha, we do not have the same good partnership (as with Bravo) and they do not have the plans in place. (TPM, personal communication, March 3<sup>rd</sup>, 2021)*

The manufacturer of Bravo is Svea which is located in Germany. The percentage of MTC's annual purchasing spend paid to Svea is 8,5% which correlates to 0,007% of Svea's annual sales (OME, personal communication, January 29<sup>th</sup>, 2021).

On Svea's contingencies, the Technical Product Manager states that Svea has a "really good plan in place" and that MTC is not worried about the prospect of a supply interruption (TPM, personal communication, March 3<sup>rd</sup>, 2021). Furthermore, the relationship with Svea is really good, as stated by the Technical Product Manager:

*Regarding Bravo, we have a really good relationship. And we know that there is a plan in place. It feels like we work in a partnership... (TPM, personal communication, March 3<sup>rd</sup>, 2021)*

#### **4.4.3 Suppliers of APIs – Saga and Patricia**

Saga which is the supplier of Omega is located in Japan and this specific API is involved in the production of both Alpha and Bravo. MTC annually spends 4,5% of total purchasing costs to secure Saga's services. This is about 0.11% of Saga's annual revenue.

MTC does not have a clear view of Saga's contingency plans. However, as Saga is not strictly a pharmaceutical or medical device company, the Operations Manager for Europe and rest of world believes that they may not have as strong plans in place as other suppliers (OME, personal communication, April 19<sup>th</sup>, 2021). This is of special concern as Saga is located in Japan which is prone to earthquakes. About this the Logistics and Supply Manager says:

*Cons are that we are more vulnerable if any kind of disaster like an earthquake were to happen. (LSM, personal communication, March 11<sup>th</sup>, 2021)*

Patricia is located in Germany and is the supplier of Gamma which is included in the production of Alpha. The annual amount paid to Patricia is 15% of the total purchasing cost which correlates to 0,03% of Patricia's annual revenue for 2020 (OME, personal communication, January 29<sup>th</sup>, 2021).

MTC does not have a clear picture of Patricia's contingency plans. However, as the supplier is a large pharmaceutical company supplying different healthcare systems, there are probably demands that ensure that sufficient plans are in place (OME, personal communication, April 20<sup>th</sup>, 2021).

#### **4.4.4 MTC's risk classification of suppliers**

MTC currently classifies suppliers on a scale from one to four where one represents the highest risk rating and four the lowest (OME, personal communication, March 9<sup>th</sup>, 2021). The classification is based on the importance of the supplier, how much of MTC's sales could be affected by a supply interruption, and what business continuity plans the supplier has in place. However, the classification is informal and no documents are stating what category each supplier is in.

## **4.5 The supply strategy's logistics and financial effects**

The lead times for MTC's products are obviously not the same for each one. The lead time for Alpha and Bravo is about two months from ordering until it is a finished product that is available for the market. The orders are however bounded to a forecast which is provided six to twelve months in advance (OME, personal communication, March 9<sup>th</sup>, 2021), these forecasts have some room for flexibility. These long lead times in combination with the use of single sourcing forces MTC to establish big levels of safety stock. This to cover if delivery was to be interrupted and to be able to still ensure delivery to customer with the highest accuracy.

## **4.6 The staff's current view on dual sourcing**

As previously stated, the personnel at MTC have a somewhat common perception of what disadvantages their current sourcing strategy has. The view on whether the implementation of dual sourcing would be an overall beneficial solution for the company is however more divided. Their views on the adaptability of dual sourcing are connected to a specific component or product and not a strategy that should be implemented across the entire company.

### **4.6.1 Views on dual sourcing on contract manufacturers**

Dual sourcing applied to contract manufacturers is complex since it involves a lot of resources to implement. Within the organisation, there are divided opinions regarding the feasibility of dual sourcing. The pros mentioned by the staff are the ones already mentioned, the fact that supply risk and dependency would be reduced. Another positive outcome that dual sourcing could result in is the commercial value of having two alternatives. The negotiation position would be much improved. However, having two contract manufacturers active for the same product does not necessarily generate a positive effect. Therefore, the possibility of just qualifying a supplier to be able to better the bargaining position is of more interest from the staffs' perspective. With this said the fact that the qualification of a supplier is resource-demanding and that a potential backup source could create a feeling of false security has also been brought up in this discussion.

*If looked upon closely, you can have a validated process, but it is required that this process is kept validated. It is not like you can validate a process and then let it be. It requires maintenance work otherwise it is not easy to get the production running quickly. I think that if a backup supplier would be implemented it has to be very well executed and be aware of the*

*consequences that follow. Otherwise, I think it contributes to a false sense of security. That is my personal view on it (TPM, personal communication, March 3<sup>rd</sup>, 2021).*

The TPM further explains that the adaptiveness of implementing dual sourcing is heavily dependent on how the current relationship is established between MTC and the supplier of interest. For those partnerships which are considered good, there is no particular interest in implementing dual sourcing since they have a well-developed view on the supplier's work regarding business contingency. For partnerships which are of the less developed kind, there is a bigger interest of changing supplier rather than qualifying an additional one (TPM, personal communication, March 3<sup>rd</sup>, 2021).

The Operations Manager for Europe and rest of world (March 9<sup>th</sup>, 2021) is in agreement with the Technical Product Manager in thinking that switching suppliers is a more suitable option than having two active contract manufacturers.

*If I weigh the value of having two suppliers against the work needed, I do not see many instances where dual sourcing would be the end goal. As I said, however, I definitely see a need of qualifying new suppliers, but I would rather switch suppliers entirely in that case.*

*(OME, personal communication, March 9<sup>th</sup>, 2021)*

He goes on to mention that their first approach to cope with the problems that single sourcing creates would be to work with the contingencies with their current suppliers.

*If the supplier works well for us, i.e., they deliver on time, the quality is high and so on, the first approach would be to minimize the risk with that supplier or maybe increase safety*

*stocks. (OME, personal communication, March 9<sup>th</sup>, 2021)*

However, the Operations Manager for Europe and rest of world does see a potential benefit to having dual sourcing for contract manufacturing stating that there is no stronger negotiating position than being able to tell a supplier that “we have an alternative supplier and they have given us this rate”. This could lower costs and COGS (cost of goods sold) would be greatly improved.

The Operations Manager for North America is not as negative towards the idea of having more than one active contract manufacturer for one product but agrees that it would be highly resource-demanding.

*Implementing dual sourcing requires resources, you cannot forget that. But I would rather categorize it as an investment if you want an additional supplier. There is an overhead connected to manage suppliers. (OMN, personal communication, March 11<sup>th</sup>, 2021)*

Another topic that has been brought up in the interviews is if an implementation of dual sourcing would influence the level of safety stock, which currently is restricting a significant amount of capital. The interviewees have a shared view regarding this topic, where they state that dual sourcing would make it possible to lower the current stock levels. However, they state that this is highly dependent on the supplier and what business contingency plans are in place to prevent disruption of supply. Thereby, the implementation of dual sourcing itself would not influence the level of safety stock. It would require the qualification and adaption of a supplier that is considered reliable to do so.

#### **4.6.2 Views on dual sourcing for the supply of raw material**

The use of dual sourcing for specific raw materials is something that the majority of the interviewees thought would be beneficial for the company.

*For some raw material, dual sourcing would be really beneficial. For a certain API for example I think it is really important due to different factors (TPM, personal communication, March 3<sup>rd</sup>, 2021)*

The API which is referred to in the quotation above is unique and only provided by two different companies globally. The TPM goes on to describe that it potentially would be of financial interest to put these suppliers up against each other in order to create a better bargaining position for MTC. This since this raw material is very expensive. However, the mentioned API requires a long regulatory process to ensure supply and therefore it is a complex process (TPM, personal communication, March 3<sup>rd</sup>, 2021).

## **5 THE KRALJIC METHOD APPLIED TO MTC**

This section will apply the Kraljic approach to MTC's products. Thereby it will include phases one through four of the Kraljic model for each of the four products.

### **5.1 Phase 1 – Classification**

Phase 1 of the Kraljic model is *Classification* which is executed to determine the correlation between a product's profit impact and its supply risk. Both profit impact and supply risk lack a clear definition, meaning that before any product can be categorized the factors on which it is based must be further explained.

In this study, the profit impact will be defined as the contribution the product makes to the revenue of MTC. The supply risk is defined as the probability of supply disruption which is determined through the data gathered in the interviews.

#### **5.1.1 Classification of Alpha**

From a financial standpoint, Alpha is contributing to 36% of MTC's revenue. Therefore, the profit impact of Alpha must be considered high.

To determine the supply risk of Alpha the contingency plans in place at the supplier, Jupiter must be considered. From the interviews, it is clear that Jupiter is underperforming in this area which leads to substantial supply risk. There are alternative sources that can perform the services that today are executed by Jupiter. However, there are multiple specific demands set by MTC on the production, such as specific batch size and specific volume, for Alpha which limits the numbers of suppliers available. Therefore, the supply risk of Alpha is considered high.

Alpha then, has a high profit impact and high supply risk, placing it as a strategic product within the Kraljic model.

#### **5.1.2 Classification of Bravo**

The sales of Bravo make up over 50% of MTC's total sales. Therefore, Bravo's profit impact is higher than that of any other product.

The supply risk of Bravo should be considered low. While there are few potential suppliers within the market the contingency plans of the current supplier, Svea, are very strong.

Therefore, the probability of supply interruption from Svea is to be considered low.

Furthermore, MTC's relationship with Svea is long-standing and their reliability is proven

over time. The fact that Bravo is single-sourced does increase supply risk but the contingencies in place are strong enough for the supply risk to be considered low.

Thereby, Bravo presents traits resulting in the conclusion that profit impact is high and supply risk is low, placing it as a leverage product using the Kraljic model.

### **5.1.3 Classification of Omega**

Omega is used in both Alpha and Bravo. As these two products make up approximately 90% of the annual sales, the profit impact of Omega is considered high.

Looking at the supply risk of Omega, the current supplier, Saga, has been reliable over time and is considered a valued partner by MTC. However, the contingency plans of Saga have not been researched by MTC, resulting in a high degree of uncertainty and potentially a substantial supply risk. This is further enhanced by the fact that Saga is not a pharmaceutical or medical device company which could mean that the regulatory demands, as well as the demands of Saga's customers, are low. As a result, the probability of the contingency plans not living up to expectations is high. Furthermore, Saga is located in Japan, which is prone to earthquakes which, if there are no adequate contingency plans in place, further enhances the supply risk. In short, the question of Omega's supply risk is surrounded by uncertainties. With all the above-mentioned factors in mind, the supply risk could range from moderate to high. The uncertainties themselves, however, should be considered to increase the risk resulting in the supply risk being set as high for this analysis.

Omega, thereby, has a high profit impact and a high supply risk, placing it as a strategic product using the Kraljic model.

### **5.1.4 Classification of Gamma**

The financial impact of Gamma is of high significance, Gamma is included in the product Alpha which contributes to 36% of MTC's annual sales.

The supply risk regarding Gamma is highly affected by the availability of the raw material. As described in the current situation, there are two global suppliers of Gamma. In combination with there being a long regulatory process to potentially implement a second supplier of Gamma, the supply risk is considered to be high. This since if any disruption of supply was to happen, MTC has very little room to manoeuvre. Furthermore, MTC has no detailed knowledge regarding the business contingency plans in place at Patricia. However,



Patricia is a big supplier to health care systems around the world, probably resulting in customers demanding that there are sufficient contingencies in place.

Thereby, the profit impact of Gamma is high and the supply risk moderate, placing it between being a leverage product and a strategic product. Of course, the distinction between the two product categories is of importance as they may result in different supply strategies. This will be further explored later in the analysis.

### 5.1.5 Summary of classifications

In the table below (table 5.1) the classifications of the products and raw materials are presented. Note that Gamma is placed both in leverage and strategic as it could be considered to be both.

*Table 5.1: Classification of Alpha, Bravo, Omega, and Gamma according to the Kraljic method. Source: created by the authors.*

Product classifications	
<u>Leverage products</u>	<u>Strategic products</u>
<ul style="list-style-type: none"><li>• Bravo</li><li>• (Gamma)</li></ul>	<ul style="list-style-type: none"><li>• Alpha</li><li>• Omega</li><li>• (Gamma)</li></ul>
<u>Routine products</u>	<u>Bottleneck products</u>
<ul style="list-style-type: none"><li>• No products in this category</li></ul>	<ul style="list-style-type: none"><li>• No products in this category</li></ul>

## 5.2 Phase 2 – Market analysis

The second phase of the Kraljic approach is to determine the bargaining power for the company, this is executed with a market analysis that takes the environment of the industry and the supplier's position in it into consideration.

As described in chapter 2, the market analysis is done to get an insight into which relationships generate good bargaining positions and thereby favourable contract terms. This by evaluating if the company or the supplier has a favourable position for negotiation. To determine this, the first step in the market analysis is to analyse the purchasing evaluation portfolio where supplier strengths are put up against company strengths.

It should be noted that representatives of suppliers' have not been interviewed for this study. As a result, the market analysis will only be based on the opinions of employees at MTC and public financial documents. The supplier strength, therefore, is hard to objectively define.

Thereby, all the purchasing portfolio evaluation criteria presented in table 2.2 will not be included due to a lack of data.

Due to the issues mentioned above, a limited number of criteria will be evaluated. These are chosen due to their importance for the study as well as the amount of data collected. As stated in chapter 2 some criteria are more or less relevant depending on the industry a company operates in which, of course, has also affected the choice of criteria analysed in this study. The criteria that will be evaluated can be seen in table 5.2.

*Table 5.2: Purchasing portfolio evaluation criteria relevant for this study. Modified from: Kraljic, P. 1983. "Purchasing Must Become Supply Management". Harvard Business Review. Modified by the authors.*

<b>Purchasing Portfolio Evaluation Criteria</b>	
<b>Supplier strength</b>	<b>Company strength</b>
Competitive structure	Market share vis-à-vis main competition
The uniqueness of product and technological stability	Own production capability or integration depth
Entry barrier (capital and know-how requirements)	Entry cost for new sources versus cost for own production

### 5.2.1 Market analysis for Alpha and Bravo

For Alpha and Bravo, there are few available suppliers. The processes required for manufacturing are rare and complex. The current suppliers thereby have a favourable competitive structure giving them an advantageous negotiating position. It should be noted, however, that this advantage is higher for Jupiter than for Svea since the manufacturing process of Alpha requires Gamma which few suppliers want to introduce in their production.

From MTC's perspective, it becomes apparent that the fact that Alpha and Bravo hold a significant share of the market is a strength. Although there is no exact data for the market share of Alpha it can be considered large based on the interviews (see chapter 4). For Bravo the market share is between 90% and 95%, meaning there are almost no competitors.

Chapter 4.3 mentions that MTC's products are unique which is the case for both Alpha and Bravo. The fact that the qualification, validation, and adaption of a new supplier is highly resource-demanding results in high entry costs giving MTC a disadvantageous negotiating position. A scenario could for example be if a contract manufacturer was to raise their prices for their services or change the capacity of their production. If any of these scenarios were to

occur, without any other supplier qualified for the specific service, it leaves MTC with little room to take any sort of action.

The uniqueness of the products directly results in necessary facility investments in the form of production set-up, reducing the number of available suppliers. This contributes to the consequence that if an additional supplier was to be implemented, the supplier competition between the two suppliers does not need to contribute to cost reduction. This further better the current supplier's negotiating position.

Since MTC mainly has their production outsourced, their production capacity is limited. The only in-house production MTC has is for products currently in medical trials. This means that for Alpha and Bravo, MTC has no production capacity at all. This can only be seen as a weakness.

The entry barriers for new potential suppliers in the market are high. The processes that are involved in manufacturing Alpha and Bravo are complex and require a high degree of knowledge as well as allocating plenty of resources. This, of course, gives the current suppliers an advantage. If MTC was to switch supplier for Alpha and Bravo, multiple aspects need to be inspected and validated by MTC's staff as well as authorities for both these products before any kind of production can start. In addition to this, the set-up of the production after an agreement has been reached is also a resource-demanding process. MTC thereby has a considerable disadvantage as the entry cost for new sources is substantial.

### **5.2.2 Market analysis for Omega**

The competitive structure in the supply market of Omega is more open than for the other products and thereby there are a higher number of available suppliers. However, it is still a complex raw material and there are no substitutes. Therefore, the competitive structure does not represent a significant strength, nor a significant weakness. The uniqueness of the product, however, does give an advantage. The entry barriers for new entrants in the supply market are unclear and more data would be required for a definitive view. However, the entry barriers are probably still high. With this said, the competitive structure is neither a strength nor a weakness from the supplier's perspective while the uniqueness of the product and the entry barriers into the market is recognized as strengths.

Looking from MTC's point of view, the market share is extremely low as MTC's purchasing makes up 0.11% of Saga's annual sales. Furthermore, MTC has no in-house production which

further worsens their negotiating position. These factors are therefore viewed as weaknesses for MTC.

For Omega, it can be said that the regulatory entry barriers are lower than for MTC's other products. However, when switching suppliers, all documentation must be updated and as Omega is used in multiple products this would require a lot of resources. Therefore, the entry costs for a new source of Omega are high and represent a weakness for MTC.

### **5.2.3 Market analysis for Gamma**

The competitive structure of the supply market for Gamma strongly favours the current supplier. There are only two global alternatives making the market share for those suppliers close to 50%, assuming they have an equal share. Furthermore, Gamma is a unique and complex raw material that requires a high degree of knowledge, making new entrants in the market unlikely. The competitive structure, uniqueness of products, and the entry barriers thereby represent strengths for the supplier.

Patricia is as mentioned one of two global suppliers of Gamma. Since the annual revenue which MTC contributes to for Patricia is only 0.03%, the market share held by MTC is minimal which damages MTC's bargaining position. Furthermore, MTC has no production of their own and the entry cost for switching suppliers is high as it is a long regulatory process. It should be noted, however, that introducing the second global supplier as a second source might result in better terms, resulting in lower prices making the entry costs a sound investment. Nevertheless, the entry costs are high, which should be regarded as a weakness.

### **5.2.4 Summary of market analysis**

The table below (table 5.3) summarizes the strength and weaknesses of the suppliers and MTC as they relate to each other. Note that there are in some cases no strengths or weaknesses identified. This is a consequence of the criteria studied, the nature of the market, and possibly a lack of data.

Table 5.3: Summary of strengths and weaknesses of MTC and suppliers as they relate to each other. Source: created by the authors.

	Strengths	Weaknesses
<b>Suppliers Jupiter and Svea</b>	<ul style="list-style-type: none"> <li>• The complexity of manufacturing leads to few competitors</li> <li>• The uniqueness of the product leads to few competitors and the ability to pressure customers.</li> <li>• High entry barriers lead to fewer competitors and more dependent customers.</li> </ul>	<ul style="list-style-type: none"> <li>• No weaknesses were found within the criteria studied.</li> </ul>
<b>MTC</b>	<ul style="list-style-type: none"> <li>• Market share for Alpha and Bravo leads to no competition.</li> </ul>	<ul style="list-style-type: none"> <li>• No in-house production capacity increases dependency on current suppliers.</li> <li>• High entry costs for new sources make switching suppliers resource-demanding and increases dependency on the current supplier.</li> </ul>
<b>Supplier Patricia</b>	<ul style="list-style-type: none"> <li>• The uniqueness of the product leads to few competitors and the ability to pressure customers.</li> <li>• There might be high entry barriers resulting in fewer competitors which increases customer dependency.</li> </ul>	<ul style="list-style-type: none"> <li>• The competitive structure could represent a weakness. However, more data is required to definitively say so.</li> </ul>
<b>MTC</b>	<ul style="list-style-type: none"> <li>• No strengths were found within the criteria studied.</li> </ul>	<ul style="list-style-type: none"> <li>• Low market share leads to suppliers viewing the business as unimportant.</li> <li>• No in-house production capacity increases dependency on current suppliers.</li> <li>• High entry costs for new sources make switching suppliers resource-demanding and increases dependency on the current supplier.</li> </ul>
<b>Supplier Saga</b>	<ul style="list-style-type: none"> <li>• Competitor structure favours suppliers as there is only one competitor and new entrants are unlikely.</li> <li>• The uniqueness of the product leads to few competitors and the ability to pressure customers.</li> <li>• High entry barriers lead to fewer competitors and more dependent customers.</li> </ul>	<ul style="list-style-type: none"> <li>• No weaknesses were found within the criteria studied.</li> </ul>
<b>MTC</b>	<ul style="list-style-type: none"> <li>• No strengths were found within the criteria studied.</li> </ul>	<ul style="list-style-type: none"> <li>• Low market share leads suppliers to view the business as unimportant.</li> <li>• No in-house production capacity increases dependency on current suppliers.</li> <li>• High entry costs for new sources make switching suppliers resource-demanding and increases dependency on the current supplier.</li> </ul>

### 5.3 Phase 3 – Strategic positioning

In this chapter, an analysis will be done to determine which approach is the most suitable for each specific product. Since the strategic positioning only takes those products which have

been categorised as strategic into account, Bravo will be excluded. It should also be noted that Gamma is here considered to be strategic. A deeper look into the repercussions of Gamma being seen as a leverage product will be included in chapter 6.

As the supply market strength has been determined to be high and the company strength low, the strategic positioning will result in the same strategy for Alpha, Omega, and Gamma – diversify. This is visualized in figure 5.2.

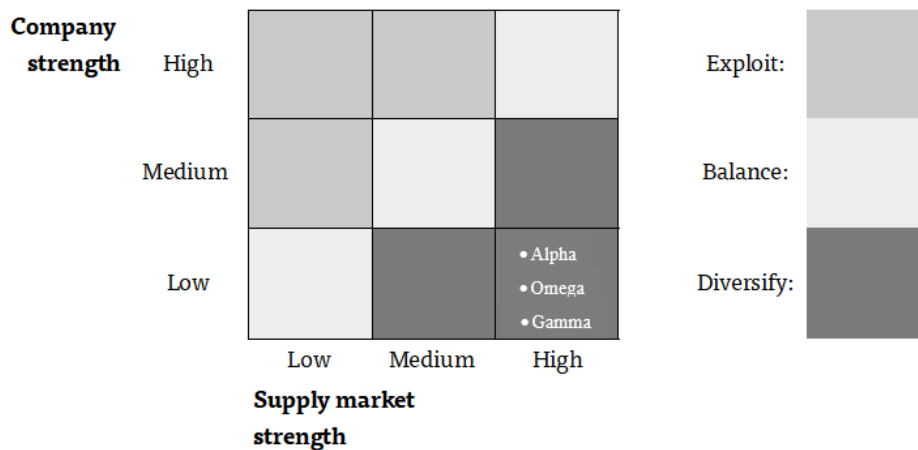


Figure 5.1: The purchasing portfolio matrix with strategic positions of Alpha, Omega, and Gamma. Source: Kraljic, P. (1983). "Purchasing Must Become Supply Management". Harvard Business Review.

The diversified approach is described in the theory as a position where the company does not pressure the current supplier. The focus should rather be on investigating the availability of other suppliers within the market. Because of this more resources need to be delegated towards market research and improving supplier relationships. Another alternative is to focus on major investments in their production capacity. The latter suggestion would in MTC's case be difficult since no in-house production is established within the company.

## 6 THE DUTCH WINDMILL APPLIED TO MTC

Since the Kraljic model has gotten critique due to its lack of considering the suppliers' approach, the Dutch Windmill model will be applied to the products to get a more realistic view on which expectations and plans could be developed in the future. The Dutch Windmill takes the attractiveness of the customer into account as well as the supplier's competitive position. Furthermore, the Dutch Windmill takes all the different product categories into account, which enables conclusions regarding Bravo to be made. Also, recommendations regarding Gamma can be made if it is considered a leverage product.

The knowledge regarding current supply relationships and the suppliers' current contingencies has earlier been described as limited, however, this knowledge is considered to be of too high importance to exclude from the study. For this study, the competitive position of the suppliers has been to be determined to be strong based on annual reports and the views of the MTC employees interviewed. Note that further research should be done, and interviews carried out with representatives of the suppliers to fully establish that that is the case.

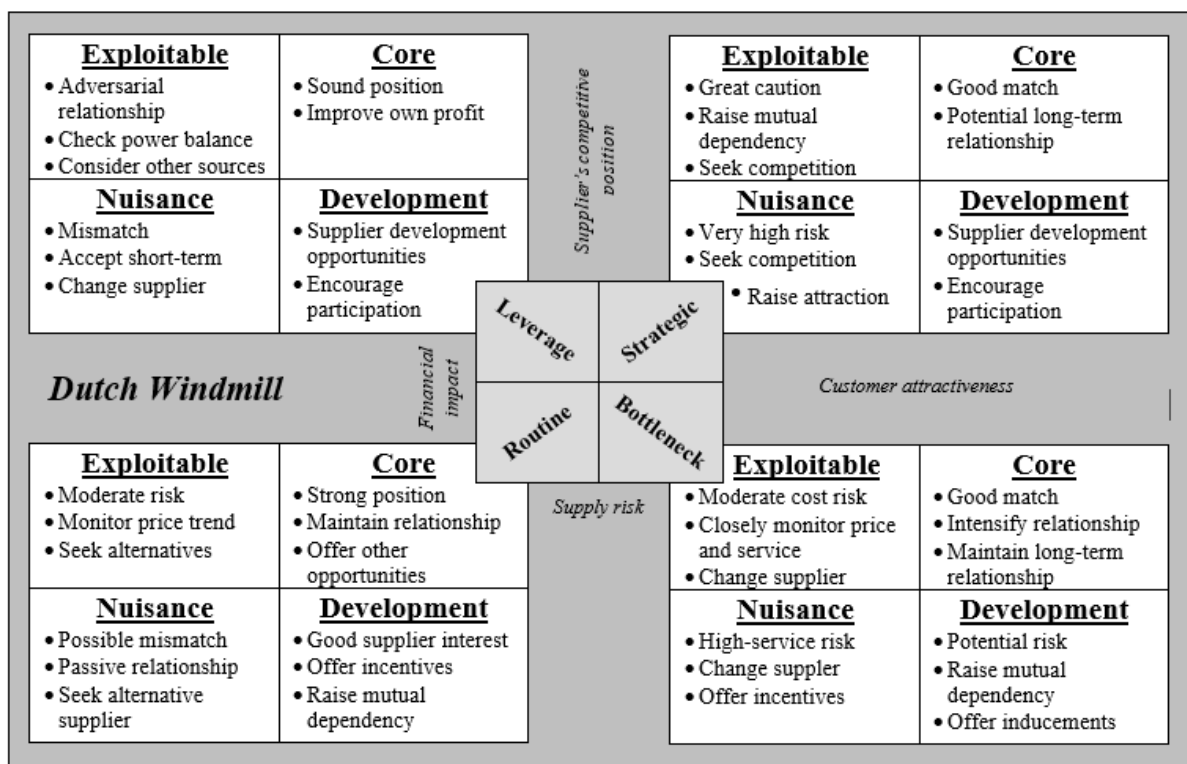


Figure 6.1: The Dutch Windmill. Source: Van Weele, A. (2018). "Purchasing and Supply Chain Management". Cengage Learning.

## 6.1 The Dutch Windmill applied to Alpha

Earlier work presented in the Kraljic model shows that the supplier, Jupiter, has a favourable position in comparison to MTC. Due to this, the supplier's competitive position is regarded as strong. To determine the attractiveness of MTC from Jupiter's perspective, their annual revenue is reviewed. As MTC only is responsible for 0,1% of Jupiter's annual sales, it could be viewed as a negative impact on MTC's economic as well as resource-based attractiveness. However, MTC holds a big share of the market that they are operating in and since the industry is developing and growing this could have a positive impact on MTC's attractiveness. At the same time, MTC is investing in other business fields in the market could have a positive impact on the attractiveness from an economic perspective.

An aspect that points to low attractiveness is the fact that Jupiter has shown little interest to develop contingency plans. In general, MTC has found that the commitment and the communication from Jupiter have been below wanted standards which suggest that MTC is not considered an attractive customer from a behaviour-based perspective. The lack of commitment cannot be ignored, and it overshadows the possible economic attractiveness of MTC. MTC's attractiveness as a customer of Jupiter is therefore determined to be weak in general.

The consequence of this is that product Alpha is categorized as *Exploitable* in the strategic segment in the Dutch Windmill.

## 6.2 The Dutch Windmill applied to Omega

The Kraljic model applied to Omega shows that Saga has a relatively strong position. This is determined by the standards presented at the beginning of this chapter. The attractiveness MTC has as customers of Saga is considered to be low, this both from an economic- and resource-based perspective. This is shown by the fact that MTC only contributes to around 0,11% of Sagas annual sales.

It should be mentioned that the staff of MTC considers the relationship with Saga as strong and they have been given a very competitive rate. This would suggest that there is good communication and commitment from both parties, increasing the behaviour-based attractiveness. However, MTC has not been given any information from Saga regarding contingencies relating to minimizing supply risk. This should be considered of high importance as Saga's geographical location substantially increases the risk of supply



interruption. This lack of communication could speak to a lack of commitment and thereby decreasing the behaviour-based attractiveness.

There is also something to be said about the bridging-based attractiveness of MTC.

Saga's main focus is not the medical device market and thereby MTC could be considered a bridge to a new market. This, however, is reliant upon Saga considering the medical device market as important for their future growth.

All factors considered result in that Omega is categorized as *Exploitable* in the strategic segment.

### **6.3 The Dutch Windmill applied on Gamma**

As MTC only contributes to a fraction of Patricia's annual sales, MTC's attractiveness as a supplier is, from a financial standpoint, weak. This is further enhanced by the fact that MTC most likely purchases a small volume of specifically Gamma from Patricia. This is due to Patricia being one of two global suppliers, meaning that they are likely to sell large quantities which render MTC's orders insignificant. Thereby the economic- and resource-based attractiveness of MTC is low.

There is no indication from the data suggesting that MTC is attractive from a behaviour-based perspective. Furthermore, MTC does not grant Patricia any new market opportunities meaning that there is no bridging-based attractiveness to mention.

The low attractiveness combined with Patricia's competitive position being set as strong results in the relationship being categorized as *exploitable* within the strategic products segment in the Dutch Windmill.

As described in chapter 5, Gamma could also be considered a leverage product. This would place the relationship as exploitable in the leverage segment of the Dutch Windmill instead. The difference between them will be summarized under heading 6.5.

### **6.4 The Dutch Windmill applied on Bravo**

Bravo was earlier in the study placed as a leverage product. This places Bravo in a different section than the other products within the Dutch windmill. To fully determine the supply strategy, the relationship between MTC and the supplier, Svea, must be evaluated.

MTC from a financial point of view is indeed a small customer of Svea which could result in MTC being viewed as unattractive from an economic- and resource-based perspective.

However, based on the data collected for this study, the relationship with Svea is exceptional. The supplier has been reliable over time and has obliged in explaining their contingencies as well as sent over documents showing they have a structure in place minimizing the risk of supply interruption. The dedication from Svea's side to MTC seems to show an interest in maintaining a strong relationship bordering on a partnership. This speaks to behaviour-based attractiveness, introduced in chapter 2, where personal relationships and long common history are considered to increase the attractiveness of buyers from a supplier's perspective.

It should also be mentioned that Bravo dominates the market segment in which it is sold. This speaks to MTC being a strong player within that market segment which could increase MTC's economic-based attractiveness given that Svea considers that market segment as important. With all factors considered, MTC's attractiveness as a customer is considered high.

As Svea's competitive position has been set as strong and MTC has been determined to be an attractive customer, the relationship between MTC and Svea is categorized as *Core* in the leverage product segment in the Dutch Windmill. This results in the current situation being seen as sound.

## 6.5 Implications of the Dutch Windmill

- *Strategic products identified as exploitable* – The approach that is suggested by the Dutch Windmill for products that have been categorized as strategic and exploitable is to develop a caution strategy and try to shift the dependency to be mutual. This should be executed parallel with seeking other alternative sources which can execute the service required. The search should be done with a high focus on supply risk analysis to be able to perform a careful supplier selection. This forces more resources to be redistributed towards market research and other areas which are involved in the search and selection of suppliers.
- *Leverage products identified as exploitable* – Within this categorization, the recommendation from the Dutch Windmill is to monitor the power balance between company and supplier as well as considering other sources.
- *Leverage products identified as core* – No action is required for the relationships identified as core. The company should seek to lower prices to boost its profits.

## 7 RESULTS AND DISCUSSION

Firstly, this chapter presents the pros and cons identified through the usage of the Kraljic model and the Dutch Windmill. Secondly, it presents which supply strategy has been identified to be the most suitable for the different products according to theory. Thirdly, a discussion relating to the results as well as the suitability of the models will be presented. Finally, our final recommendations to MTC as well as suggestions for further research are included.

### 7.1 Potential supply scenarios

To be able to present the most suitable supply strategy for MTC, different supply scenarios will be examined. Firstly, the pros and cons of keeping the current single source strategy will be presented. Thereafter, the same will be done for implementing a second source.

#### 7.1.1 Keep the current single source supply strategy

It might be worth looking at the possibility of keeping the current strategy for all or some of the products in question. The pros and cons of doing so for each product are presented in the table below (see table 7.1).

*Table 7.1: Identified pros and cons with keeping the current single source supply strategy for each product. Source: created by the authors*

Product	Pros	Cons
Alpha	<ul style="list-style-type: none"><li>• No investment needed</li></ul>	<ul style="list-style-type: none"><li>• Supplier's contingencies are still below wanted standard – supply risk remains the same.</li><li>• No alternative source in case of serious supply disruption – goes against company vision.</li></ul>
Bravo	<ul style="list-style-type: none"><li>• Develop an already sound relationship into a partnership.</li></ul>	<ul style="list-style-type: none"><li>• No real threat.</li></ul>
Omega	<ul style="list-style-type: none"><li>• The price at the current supplier is very low.</li><li>• The current relationship could be further developed.</li></ul>	<ul style="list-style-type: none"><li>• MTC would have to accept a price increase due to dependency.</li><li>• Supply risk would remain high due to geographical location.</li><li>• Supply risk would remain high due to uncertainties regarding supplier's contingencies.</li></ul>
Gamma	<ul style="list-style-type: none"><li>• Develop relationship.</li></ul>	<ul style="list-style-type: none"><li>• MTC would have to accept a price increase due to dependency.</li><li>• The negotiating position would remain unfavourable.</li><li>• Supply risk unchanged.</li></ul>

### 7.1.2 Implement dual sourcing

This supply scenario will investigate if qualifying and implementing a second source would generate more possibilities and meet MTC's goals and vision in a more accurate way than the current strategy. The pros and cons are listed below in table 7.2.

*Table 7.2: Identified pros and cons with implementing dual sourcing for each product. Source: created by the authors.*

Product	Pros	Cons
Alpha	<ul style="list-style-type: none"><li>• Pressure current suppliers to implement contingencies.</li><li>• Substantially lowered supply risk.</li><li>• Possibly lower prices due to a better negotiating position.</li></ul>	<ul style="list-style-type: none"><li>• Very high initial investment.</li><li>• Added costs due to increases in documentation and administration.</li></ul>
Bravo	<ul style="list-style-type: none"><li>• Possibly lower prices due to a better negotiating position.</li><li>• Even lower supply risk.</li></ul>	<ul style="list-style-type: none"><li>• Very high initial investment.</li><li>• Added costs due to increases in documentation and administration.</li><li>• Lower order quantities might damage the relationship with the current supplier.</li></ul>
Omega	<ul style="list-style-type: none"><li>• Substantially lower supply risk securing supply of resource used in products making up 90% of annual sales.</li><li>• A new supplier is hopefully not placed in an area prone to earthquakes.</li></ul>	<ul style="list-style-type: none"><li>• Possible price increase at current supplier due to lower volumes.</li><li>• Higher price at the new supplier as current purchasing price is very low.</li><li>• Resource-demanding administrative process to implement new supplier.</li></ul>
Gamma	<ul style="list-style-type: none"><li>• Possibly lower prices due to substantially improved negotiating position.</li><li>• Lower supply risk.</li></ul>	<ul style="list-style-type: none"><li>• Investments could be unnecessary if prices remain the same.</li></ul>

## 7.2 Discussion regarding results

From the result, it is quite clear that for all products apart from Bravo dual sourcing would be preferable over the current sourcing strategy. The question, of course, is whether it is feasible to implement or not.

Looking at Alpha, the most urgent matter to address is the fact that the current supplier, Jupiter, does not have sufficient contingencies in place. This leads to the immediate conclusion that a new source must be found to secure continuous supply at an acceptable risk level, especially since Alpha generates significant profit for MTC. This, however, gives rise to another question: how should the two suppliers be set up if dual sourcing was implemented?

The most obvious answer would be to have two suppliers with a 50% share of the order volume. However, doing this might lead to a substantial price increase for purchases from Jupiter as well as less preferable terms at the new supplier. Perhaps it would be better to find a new supplier which has contingencies that meet MTC's standards and switch suppliers altogether. While this would decrease supply risk, the long-term validity would be reliant on being able to build a strong relationship bordering on a partnership where a sense of mutual dependency exists. This to ensure that no extreme price increases occur. The final option would be to find and qualify a new supplier and move a majority of the manufacturing from Jupiter making the new supplier the primary contract manufacturer of Alpha. This would most likely result in higher prices for the manufacturing still being done at Jupiter's factory as the volume would be drastically decreased. However, the terms at the new supplier would probably be better than if they were to have only 50% of the order quantity. Furthermore, should a major supply disruption occur at the primary supplier, there would be a qualified supplier in place, where MTC already holds a share of the capacity. While it is not certain that the secondary supplier can scale up the volumes immediately, it would greatly decrease the lead time.

Looking at Bravo, there are more benefits to keeping the current supplier than for the other products. The cost of implementing a second source is, just like for Alpha, highly resource-demanding and costly. The difference between Jupiter and Svea is that Svea does have sufficient contingency plans. Furthermore, the relationship between MTC and Svea has worked well for several years, rendering Svea reliable over time. The supply risk of Bravo does not lie at the contract manufacturer but with the supplier of Omega.

The supply risk of Omega is very high as the consequence of supply disruption would be that production of Alpha and Bravo stopped. This risk factor puts 90% of MTC's annual sales at stake. Due to this, high levels of safety stocks are required to cover for long-lead times if

deliveries of Omega were to be interrupted. The fact that this supplier is located in a geographical area that is prone to natural disasters adds to the risk of supply disruption.

Finally, the supply of Gamma must be discussed. The current situation where a large company that holds a significant market share of Gamma is the sole supplier leads to far too high dependency. This allows Patricia to pressure MTC and could potentially lead to substantial price increases. The answer to this would be to implement the second global supplier of Gamma as a second source. While this would lead to lower supply risk, that would not be the primary goal. Patricia, being a global supplier to many health care systems around the world, is very unlikely not to have sufficient contingencies in place. Therefore, the reason for implementing a second source would be to ensure favourable contract terms. This would not only ensure no price increases occur but also give the opportunity to pressure Patricia and a lower rate than they have today.

A factor of significant importance if MTC were to implement a second source for any product is costs. To implement dual sourcing for a contract manufacturer MTC must perform screening and market research, conduct audits, make trips to the facilities, and set up a new production line. In addition, there are regulatory costs connected to the get the contract manufacturer approved to produce the product by a notified body. This all adds up to it being very costly to implement a second source. Therefore, it is necessary to discuss whether the costs are warranted as a means to manage supply risk.

Firstly, it should be mentioned that the costs are mostly prevalent in the short term. It is not nearly as expensive to maintain a second source once everything is up and running. Secondly, MTC would potentially be able to reduce safety stocks and thereby freeing up capital through the implementation of a second source. Thirdly, an additional source creates a better bargaining position, potentially reducing costs in the future. These benefits, however, are small and it would take a long time before they covered the high short-term cost of implementing a second source.

This all goes to say that it is hard to determine whether the investment of implementing a second contract manufacturer is warranted and, in the end, it would be up to management to decide if it is worth it.

The costs for implementing a second source for the APIs must also be mentioned. The costs pertaining to screening, market research, and trips to facilities are similar to that of implementing a second contract manufacturer for Alpha or Bravo. Notably, a new production

line does not need to be set up and the regulatory approval is usually less costly than for contract manufacturers. Thereby, it would be financially less demanding to implement a second source for the APIs. However, it is still a long process, taking roughly 24 months, and it is by no means cheap.

The financial benefits of implementing a second source for the APIs are, just like in the case of the contract manufacturers, potentially lowering safety stocks and getting a better bargaining position leading to better contract terms. From the interviews, it is clear that the benefits stemming from the improved bargaining position are greater for the APIs than for Alpha and Bravo. This is especially true for Gamma, where the interviewees were in agreement that having both global suppliers as active sources would decrease prices.

It then stands to reason to say that it is, from a financial standpoint, more suitable to implement a second source for an API than for Alpha or Bravo.

### **7.3 Discussion regarding the suitability of the models**

As stated in chapter 5, the Kraljic model only takes products that have been categorized as strategic into consideration while it to an extent excludes the supplier relationships from the evaluation. These issues have been countered with the implementation of the Dutch Windmill which has both of these aspects covered. However, the evaluation of whether a product is categorized as a strategic or bottleneck product, for example, is determined by its contribution to financial impact. The definition of financial impact is vague and could be interpreted in multiple ways. In this study, the financial impact has been defined as the specific product's contribution to the annual profit for MTC. This has resulted that raw materials, Omega and Gamma, has been categorized as strategic since they are involved in the production of Alpha and Bravo which contributes to around 90% of MTC's annual sales. If the financial impact would have been interpreted as exclusively the purchasing cost of the material, Omega would have been categorized as a bottleneck product since it is relatively cheap from this perspective. With this said, dependent on how the different factors are interpreted, the categorisation could generate a result unlike the one presented.

The definition of supply risk has similar issues. It can be based on the numbers of suppliers available, available substitutes, and geographic distance for example. In this study, the supply risk has mainly been determined by MTC's description of the partnership and the suppliers' current contingencies and to some extent the geographical location of the supplier. This was mainly a result due to limitation of market knowledge and time constraints. MTC's

knowledge about its suppliers' contingencies is in some cases underdeveloped or unidentified. For the creation of a more accurate description of the supply risk, more time would be needed to research the market and the suppliers involved in the supply chain of MTC's products. This since it now is mainly based upon the opinions and views of the MTC staff.

Another factor that to an extent influences the supply risk is the possible consequence of supply disruption. In this case, the disruption could potentially put human life at risk. Therefore, it is hard to determine if the descriptions of the contingencies have been influenced by this since it is difficult to exclude from the picture.

Another aspect that needs to be highlighted is the fact that while the used models are implementable for most cases due to their simplicity, it is hard to determine its accuracy regarding outsourced production and its adequacy on highly regulated markets. Since own production capability is one measure in the product portfolio evaluation which determines company strength, it will for companies within MedTech mainly result in weakness. If this is a weakness or not is debatable.

As a result of the high regulatory nature of the medical device industry, it might be unavoidable that suppliers are in a dominant position. The regulations put immense demands on the manufacturers resulting in high costs relating to the qualification and maintenance of suppliers which puts them at an immediate disadvantage. This results in the Kraljic model always resulting in a weak bargaining position for small to medium-sized companies in the medical device industry. Therefore, it is relevant to ask whether the Kraljic approach is the best way to analyse the market. Does the Kraljic model hold up when one factor automatically gives one side a substantial advantage?

Furthermore, the Kraljic model does not take moral aspects and consequences into consideration when evaluating financial impact against supply risk. Since the supply risk for a company in the medical device industry is not primarily determined by the economical result if delivery is to be interrupted. In the case of MTC, a supply disruption could potentially put human life at stake. So, from a certain perspective, the model in this study pits profit impact against human life which results in human ethics and morals to influence the choice of supply strategy.

If the suppliers are aware of this, they are potentially less likely to exploit a situation where they are in a dominant position as there are moral values involved. Looking at the Dutch



windmill, similar arguments can be made. When determining the attractiveness of MTC as a customer of its suppliers, quantitative data such as how large a customer they are is preferable when using the model. However, the fact that MTC's products are used in transplantations might increase their attractiveness as their products are viewed by the supplier as too important not to consider MTC a preferred customer.

To summarise, the models used in this study are suited to analyse products for most markets. Even though it to some degree considers unique and customer-specified products, it is difficult to determine how applicable these models are for products within the medical device industry. Firstly, the regulatory nature of the industry is a huge factor that immediately puts medical device companies at a disadvantage as switching costs become very high. Secondly, there are moral aspects relating to the bargaining position between company and supplier which the models cannot consider. The strength of medical device manufacturers as a customer, therefore, becomes difficult to determine as they have moral arguments which play in their favours which cannot be quantitatively measured. Even though MTC may not contribute to the most revenue for the supplier, since the medical device industry is a supplier dominant market, other factors such as the saving of human lives could contribute to a high attractiveness. Therefore, the recommendations stemming from the exploitation segment in the Dutch Windmill might be of lesser importance in the Medical Device industry than in strictly business-driven markets.

## **7.4 Final recommendations**

Here, recommendations will be presented on how to proceed regarding sourcing for the products studied. Firstly, general recommendations not specific for any one product will be presented. Secondly, recommendations for each specific product will be given. It should be noted that the specific recommendations are based on the current knowledge of supplier's contingencies and might be invalid if those contingencies are found to be better than anticipated.

### **7.4.1 General recommendations**

A first approach to minimize supply risk for any product would in general not be to implement a second source since the resources and time needed to execute this is of such magnitude. Instead, a suggested approach would be to further develop the knowledge regarding existing suppliers and their contingencies as well as to research the market for potential suppliers of each product where issues have been identified.

- *Develop an understanding of the current suppliers' contingencies and work to minimize supply disruption.*
- *Allocate more resources towards market research to find potential suppliers. This to execute a careful supplier selection if a second supplier was to be implemented.*
- *Formalize a risk analysis regarding each supplier that is of high importance.*

#### **7.4.2 Recommendations for Alpha**

Regarding Alpha, a second source should be found. However, whether to switch suppliers completely or to keep Jupiter as a backup must be further investigated.

- *Search the supply market to identify potential contract manufacturers for Alpha. Thereafter, either move all production to the new supplier or a majority of it.*

#### **7.4.3 Recommendations for Bravo**

When it comes to Bravo, not much needs to be done. The contingencies at Svea are good and the relationship between them and MTC is great. We do not see any need to implement a second source for Bravo. Instead, the current relationship should be maintained.

- *Maintain the current relationship and work to improve contract terms.*

#### **7.4.4 Recommendations for Omega**

Based on the data gathered for this study, a second source is needed for Omega. The current supplier's geographical location and the uncertainties regarding their contingencies generate far too high supply risk. It should be noted that Saga's contingencies should be understood before making a final decision.

- *Identify and implement a second source to mitigate supply risk.*

#### **7.4.5 Recommendations for Gamma**

Regarding Gamma, the final recommendation is to implement dual sourcing and thereby implement the second global source for Gamma. This decreases dependency as well as gaining bargaining power to obtain better contract terms.

- *Implement the second global source of Gamma.*

## 8 CONCLUSIONS

This case study was carried out to determine what factors affect the appropriate number of suppliers for a specific component or product for a small to medium-sized company within the medical device industry. Also, it was carried out to determine the suitability of implementing a second source for a specific component in the industry. To answer this, a case study was carried out where two contract manufactured products sold by the case company and two critical raw materials used in the case company's outsourced production were studied. All items studied are currently single sourced and the feasibility of implementing a second source was determined through applying the Kraljic- and Dutch Windmill model. The study thereby provides the case company with an in-depth understanding and guidelines on how to source the studied products. The models used in this study has been found to be generally applicable on companies within the medical device market. Furthermore, the factors identified to influence the number of appropriate suppliers is not specific to the case company. Thereby, the study gives insight into the specific conditions affecting sourcing choices within the medical device industry in general. The factors identified are the product's uniqueness, the regulatory nature of the market, and the power balance between company and supplier. Dual sourcing has been determined to be an effective way off mitigating risk within the medical device market. However, the high regulatory demands make introducing a new supplier extremely resource demanding. Thereby, careful risk analysis must be carried out continuously for each specific product to determine whether the cost of implementing and maintaining a second source is warranted. In this case study it has been concluded that of the four products studied, a second source is likely to be desirable for all but one. Furthermore, the study shows that implementing a second source is likely more desirable for the supply of the critical raw materials than for the contract manufactured products.

### 8.1 Further research

The models used in this study might give a skewed perspective as ethical aspects and arguments of the medical device market are not considered. The high regulatory nature of the market supposedly gives suppliers a great advantage. However, the fact that human lives are at stake might give manufacturers arguments enhancing their negotiating position. Thereby the models might not represent the true balance of power. Answering this, however, lies outside the scope of this study. Therefore, we recommend further research to centre around the possibility of creating a model which considers the ethical aspects of the market.

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