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Perceptions of non-price criteria in pharmaceutical tenders

A case study on the Norwegian market for generic antibiotics

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Abstract

Described as one of the cornerstones of modern society, the availability of antibiotics is crucial. A worrying trend is a drastic decrease in suppliers and producers (Roland Berger, 2018), and the increased frequency of medicine shortages. These worrying trends are further amplified by the global threat of antimicrobial resistance (AMR), worsened when manufacturers release resistance-causing materials into the local environment, or through the usage of broad-spectrum antibiotics. The market is experiencing a withdrawal of suppliers due to the low prices and volume, strict policies, and complexity. These issues call for new procurement practices, intended for more sustainable outcomes. Norway has introduced environmental criteria in tenders as a response to the challenges. This study investigates the Norwegian market for generic antibiotics and the introduction of environmental criteria. The aim of the study is to reveal how the implementation of environmental criteria can affect the supplier's longevity, availability, and reliability to make the market more sustainable.

To answer our research questions, we conducted a case study on the Norwegian market for generic antibiotics. Additionally, Sweden was used as a comparison to investigate countries with similar policies, but different populations. The data consists of semi-structured interviews, quantitative data, reports, and databases. The study has been carried out using a mix-method research strategy, with an abductive research approach. Our study uses literature and quantitative data to reveal the current challenges and market characteristics, further analyzed with qualitative data to determine the current effect of environmental criteria, and how it can further impact the market situation.

Our findings stipulate high consensus from suppliers and practitioners that awarding fulfillment of environmental criteria can be used as an incentive to generate longevity, availability, and reliability of suppliers and antibiotics. Awarding environmental considerations through higher prices and the possibility to compete with other drivers than price, was seen as positive. A secondary benefit was that it may increase supply chain transparency, allowing procurers to understand where active ingredients and finished products are produced. This increased knowledge, unavailable today, can be used as a preventative measure to alleviate shortages.

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List of abbreviations

AIP- Apotekenes innkjøpspris

AMR- Antimicrobial resistance

AMRIA- AMR Industry Alliance

API - Active pharmaceutical ingredient

CSR - Corporate Social Responsibility

EEA - European Economic Area

GDPR - General Data Protection Regulation

GHG - Greenhouse gas

GMP - Good manufacturing practice

GPP - Green public procurement

MA- Market Authorization

MAH- Marketing Authorization Holder

MIA - Measures for Improved Availability of Medicines and Vaccines

NRBV - Natural resource-based view

NSD - Norwegian Centre for Research Data

PSC - Pharmaceutical supply chain

PSM - Purchasing and supply management

RBV - Resource Based View

RDT - Resource dependency theory

RFI - Request for Information

RFP - Request for Proposal

RHA - Regional Health Authorities

SCC - Supply chain collaboration

SI - Norwegian Hospital Procurement Trust, Sykehusinnkjøp HF

SLV - Statens Legemiddelverk

SPP - Sustainable public procurement

WHO- The World Health Organization

1.0 Introduction

1.1 Background and motivation

Antibiotics are described as one of the cornerstones of modern society. Since its discovery in 1910, it has extended the average human lifespan by 23 years (Hutchings et al., 2019). Due to the vital impact of antibiotics, the availability is crucial to public health. The pharmaceutical industry and its supply chains suffer from many issues such as shortages, lack of transparency, availability, and environmental concerns. These issues combined with the high dependency have left countries vulnerable to supply chain disruptions and challenges. Another critical aspect is that the use, and in some cases, excessive use of antibiotics has created a vast global issue of antimicrobial resistance (AMR). The more an antibiotic is used the more likely bacteria will develop resistance to it. Broad-spectrum antibiotics target many types of bacteria, while narrow-spectrum antibiotics target a smaller set of bacteria. When there are shortages of narrow-spectrum antibiotics or uncertainties about their effectiveness, physicians resort to broad-spectrum antibiotics (WHO, 2001; 2019). The use of broad-spectrum antibiotics increases the risk of creating antibiotic-resistant bacteria (Gerber et al., 2018).

The issues posed are often related to generic competition, which occurs when products become generic after the patent period is over. Generic manufacturers offer these medicines at a lower price as the market competition increases significantly, shifting the market power to procurers (Rana & Roy, 2015). Public procurement agencies of pharmaceutical products have aggregated and pooled procurement units to further strengthen their power position. The market power has mainly been used to drive prices down, reducing margins and economic incentives for producers and suppliers. This has led to a dramatic situation in the sourcing of antibiotics. Norway has actively been restrictive in its antibiotic policy and, consequently, is one of the countries where narrow-spectrum antibiotics are most frequently used (Helsedirektoratet, 2019; Johnsen & Johansen, 2017). This has increased their dependency on availability and reliability, as the market for narrow-spectrum antibiotics suffers from few suppliers and low demand. Another compounding factor is that there is insufficient antibiotic innovation due to low returns on investment, leading commercial actors of antibiotics to shift production

to more profitable markets (Cogan et al., 2018). Consequently, Norway has reported critically insufficient numbers of Market Authorization Holders (MAHs) for important generic antibiotics (Helsedirektoratet, 2019), emphasizing the urgent need for responsive efforts.

In addition to the focus on securing availability and reliability, sustainability in pharmaceutical supply chains (PSC) has gained increased interest in recent times. Despite the vital role medicine plays in the modern world, attention in their procurement has mainly been on ensuring reliable delivery at the lowest possible cost. However, this practice has led to controversial operations throughout the supply chains. The activities in the health sector, such as disposing and waste of commodities, and incineration practices that cause air and water pollution, largely contribute to environmental degradation and AMR. For instance, 25 percent of England´s greenhouse gas (GHG) emission comes from its national health service agencies (Zaidi et al., 2021). 59 percent of the emissions were due to the procurement of supplies and services, yet the largest component was pharmaceuticals (WHO, 2015).

Another essential aspect is related to production in low-cost countries outside Europe because of the price pressure in tendering. Recent studies have exposed how producers in low-cost countries suffer from polluting local soil and water, and poor labor treatment (Årdal et al., 2021; Larsson, 2010; Li et al., 2008). Moving production to low-cost countries, primarily based in India and China, brings many challenges, i.e., increased complexity. This contributes to difficulties related to transparency and visibility through the supply chain, collaboration, and environmental concerns. An effort made to respond to these challenges has been the formation of The AMR Industry Alliance (AMRIA). AMRIA is a global organization, tasked with minimizing the risk of AMR as a result of antibiotic manufacturing waste streams that might contain antibiotic residues entering the environment. Through common global frameworks for manufacturing, AMRIA seeks to develop standardized processes, aimed to ease governance across stakeholders in the market for antibiotics (AMRIA, 2022). These issues have increased the focus on how PSCs can deliver better results in terms of sustainability.

1.2 Problem statement

The Norwegian public sector has implemented sustainability as criteria in tendering for other industries in the last couple of decades. Contrary, the pharmaceutical industry has lagged behind, focusing solely on price. To reach the stated national goals on sustainability, the Norwegian health sector has attempted to implement methods to ensure more sustainable markets, processes, and products. As a response, The Norwegian Hospital Procurement Trust (SI), introduced environmental criteria in the 2019 tender to provide more sustainable outcomes. Although environmental criteria have been used in other countries, Norway is, to our knowledge, the first to award environmental concerns in their pharmaceutical tenders.

Due to the recent introduction of environmental criteria, the literature is scarce. To fulfill the highlighted unanswered topic in the literature, we conducted a case study on the implementation of environmental criteria in the tendering of generic antibiotics in the Norwegian market. The purpose of the study was to explore the potential of environmental criteria in the tendering of generic antibiotics to investigate how they can affect the market towards sustainable outcomes. Through literature, we related this extended view of procurement to the term value-based procurement. Value-based procurement concerns a view of procurement extending beyond only cost (Ulaga, 2003; Prada, 2016). The case study was conducted in collaboration with the Norwegian Hospital Procurement Trust, Sykehusinnkjøp HF (SI), responsible for procuring all pharmaceutical products across Norwegian hospitals and hospital pharmacies. We developed the following research question to establish a futuristic and holistic perspective on the effects and potential for the implementation of criteria:

- *How can value-based procurement with emphasis on environmental criteria affect the situation for generic antibiotics and shift the market to more sustainable outcomes?*

The recent Covid-19 pandemic further exposed challenges concerning the availability and reliability of deliveries for pharmaceuticals. The reliability and availability of suppliers and antibiotics were an essential part of our research as environmental criteria are used as a tool to incentivize improvements. Therefore,

one aspect addressed how value-based procurement can drive sustainable outcomes by implementing environmental criteria and consequently affect supplier availability, reliability, and decrease environmental degradation. The market for generic antibiotics provided an excellent example as it is a market with significant sustainability, availability, and reliability problems. We analyzed data from the supplier market of Norway and Sweden from 2016 to 2022 to assess the current market situation. These countries present comparable data due to their similarity in size, policy, and expenditure. Additionally, we collected data through interviews in the supplier market to identify what they deem as problems in the market and their view on the implementation and effects of environmental criteria.

Literature and reports on the subject have revealed several challenges within the market. An issue we discovered was that there was no information from the procurer and supplier side regarding the challenges in the industry. To address the benefits that could come with the introduction, we deemed it necessary to understand the underlying issues. We developed the following sub-question to be answered in our analysis, further contributing to the main research question:

- *What are the current characteristics and challenges of the Norwegian and Nordic markets for generic antibiotics?*

Further, the industry struggles with low transparency. Actors are reluctant to share proprietary information with supply chain partners and thus only share the bare minimum. The low transparency is one of the main root causes of shortage situations, making it an essential aspect of the availability of antibiotics (Årdal et al., 2021; Gardner et al., 2019). Therefore, an important aspect was to investigate how other drivers, where participants are required to share more information, could increase the transparency level. The following sub-question was developed to analyze the current situation and how value-based procurement as a driver could influence that:

- *How can value-based procurement be a driver for transparency in PSCs?*

1.3 Relevance

1.3.1 Practical relevance

Suppliers are shifting production and portfolios to more profitable markets due to the low prices and margins in the older generic antibiotics markets. The low number of MAHs is a growing societal problem as it highly affects the availability of essential antibiotics. This is concerning as treatable infections can become life-threatening (Helsedirektoratet, 2019). The market also presumably struggles with a low number of active pharmaceutical ingredient (API) producers. This, along with the few suppliers operating in the Norwegian and Nordic markets, is a concerning issue. Fortunately, this issue has gained attention from practitioners and politicians in recent years and has gained traction during the recent Covid-19 pandemic. This thesis has studied the problem from a holistic perspective to investigate the current market trends, challenges, and practitioners' views to understand how the implementation of environmental criteria in tenders can affect the Norwegian market. Our findings contribute to the current and widely unaddressed knowledge of PSCs, especially regarding environmental criteria, and can be used as a basis for practitioners to make evidence-based decisions to improve sustainability, a more stable market, and supplier longevity in the pharmaceutical industry.

1.3.2 Theoretical relevance

The subject of environmental criteria in PSCs is scarce due to its recent and limited implementation in the sector. Although green public procurement or sustainable procurement has been covered in the literature, it usually contains other industries and seldom specifically within tendering (see for example Chin et al., 2015). The limited previous research on environmental considerations in pharmaceutical tenders has primarily been studied in large high-income countries (see Miller et al., 2019; Prada, 2016; Vogler et al., 2017). However, these studies only explain why environmental concerns should be implemented, not how they have affected the market when used as award criteria. Other literature addressed research barriers to its implementation, but this field is limited (see Meehan et al., 2017). We argue that our research contributes to the literature as we recognize awarding environmental criteria as a knowledge gap in this context. Hence, we contribute by providing up-to-date knowledge from participants in a small high-income country on an increasingly important subject. Our research contributes to the literature by investigating perceptions on the effect of environmental criteria in a small high-

income country struggling with the availability of suppliers. We further provide an extended understanding of the barriers and enablers to its implementation and the effect on transparency.

1.4 Limiting the scope

The scope of our thesis was limited to one small, high-income country, i.e., Norway, since no other country, to our knowledge, has awarded environmental criteria in medicine procurement. The research was limited to the effect on the supplier market, particularly regarding perceptions, challenges, availability, and environment. For the selection of suppliers, we first directed our focus towards SI and the suppliers they interact with. Suppliers, in this sense, can be interpreted as actors supplying and/or producing antibiotics, meaning they are either buying the antibiotics from another company and distributing it or producing and distributing it themselves. The narrowness of the scope stems from the limited research done on the subject.

1.5 Thesis Structure

The following section presents an extensive literature review and functions as the theoretical background for what we deem essential in answering the research questions. We then present our methodology that elaborates on the research design aspects to best answer our research questions. Moreover, before we present the conclusions and provide suggestions for future research, case description, findings, and discussion of the essential results in coherence with the literature are presented.

2.0 Theoretical Background

The two departure points for our theoretical background were purchasing and supply management (PSM) and sustainability, further specified as value-based procurement, sustainable public procurement, transparency, and collaboration. The topics were analyzed generally before it was tied to the pharmaceutical industry. Our thesis focuses on pharmaceutical supply chains; however, due to limited literature on this subject, we also found it necessary to gather insights from the health sector in general. Both constitute high degrees of similarities from the procurement side and, therefore, are deemed comparable. However, the market structure and its characteristics can vary across the two. PSCs revolve around sourcing medicine and substances, while the health sector includes all aspects, e.g.,

medical devices. This section will provide a theoretical background covering the aforementioned topics to gain the necessary insights. A conceptual framework will be provided to illustrate the main findings, serving as an outline for our analysis and discussion.

2.1 Sustainability

The origin of sustainability in its modern sense sprung out in the 1970s as a response to an increasing growth in understanding that modern development was causing worldwide environmental and social crises (Dragos & Neamtu, 2014). The term rose to the agenda of people and organizations with "The Brundtland Report" in 1987 (Brundtland, 1987). The report defined sustainability as "*utilizing resources to meet the needs of the present without compromising future generations´ ability to meet their own needs"* (Brundtland, 1987, p. 41). Sustainability has branched out to different terms and definitions suited to business objectives during the past decades. One commonly used term which expands on sustainability is ESG, where the three letters refer to economic, social, and governance responsibilities (Ahi & Searcy, 2013; Martins & Pato, 2019). Researchers have referred to sustainability within business as "*the creation of resilient organizations through integrated economic, social and environmental systems*" (Bansal, 2010, as cited in Ahi & Searcy, 2013, p. 329). This term also includes the 3BL presented by Elkington (1994), which states that businesses should equally focus on delivering results in the three aspects: people, planet, and profit. Another commonly used term in literature and business is Corporate Social Responsibility (CSR). CSR refers to firms' accountability for taking care of society and the environment (Ioannou & Serafeim, 2019). Wittstruck & Teuteberg (2012) researched merging sustainability with supply chain management. They defined it as "*an extension to the traditional concept of Supply Chain Management by adding environmental and social/ethical aspects*" (p. 142). They argue that by merging the two, environmental and social aspects must be considered to avoid related problems and identify more sustainable products and processes (Seuring, 2008).

2.1.1 Sustainability in Pharmaceutical supply chains

Like all other industries, the pharmaceutical industry has faced difficulties reaching the desired levels of sustainability. This can be exemplified through England's greenhouse gas emissions, where 25% of the total emissions stem from health service agencies (Zaidi et al., 2021). Through literature, it is argued that

sustainability cannot be established without collaboration (Chin et al., 2015). A high level of sustainability performance achieved by one firm can be damaged by poor supplier performance. This issue is aggravated in industries where procurement costs account for a larger share of total expenditure (Zhu & Wang, 2018). This is highly relevant for the pharmaceutical industry, as it is characterized by several stakeholders and complex supply chains with low transparency, consisting of in-house and third-party manufacturers (Nsamzinshuti et al., 2017; Lonaeus, 2016).

The pharmaceutical industry is strongly linked to many environmental issues, such as carbon emissions (Zaidi et al., 2021) and wastewater discharge during the manufacture of drugs (Årdal et al., 2021). Production sites are commonly based in low-cost countries such as India and China, with low regulations in terms of environmental protection. Previous studies found that wastewater in China and India showed very high concentrations of pharmaceuticals (Li et al., 2008; Larsson, 2010). Another study showed that wastewater treatment plants in India discharged therapeutic substances at levels over 1 million times the levels released by their Swedish counterparts (Larsson et al., 2007). These studies identified that substances had spread to groundwater and drinking water, creating severe problems for local populations. This pollution further contributes to the occurrence of resistant bacteria and resistant genes also known as AMR, which constitutes a large worldwide problem in modern medicine. Through corporate social responsibility, public procurement functions are responsible for ensuring that the pharmaceuticals purchased secure sustainability throughout the supply chain. This addresses the importance of having sufficient purchasing and supply management practices in place.

2.2 Purchasing and supply management

PSM can be seen as the "*strategic approach to planning for and acquiring the organization's current and future needs through effectively managing the supply base*" (Spina et al., 2013, p.1202). Supply management involves several factors, including purchasing, to essentially reach mutual goals. It builds beyond the typical characteristics of purchasing where relationships are adversarial and instead promotes long-term relationships beneficial for both the buyer and supplier (Monczka et al., 2015). PSM has gained traction and relevance in both research

and practice mainly due to the pressing complexity of global markets (Spina et al., 2013). This complexity primarily stems from the outsourcing and offshoring of raw materials or manufacturing and the development of e-businesses (Monczka et al., 2015; Spina et al., 2013). Baily et al. (2008) argue that efficient supply flow could be gained through proper procurement by establishing collaborative relationships. Hence, establishing such relationships will most likely decrease the complexity.

2.2.1 Procurement in the pharmaceutical industry

Public and private organizations operate differently regarding conditions, regulations, and requirements for transparency in their procurement (Stentoft & Freytag, 2012). The tendering strategy has increasingly been adopted in public procurement and is frequently used in the pharmaceutical sector. In theory, tendering is referred to as a model of rational behavior towards profit maximization, where several suppliers simultaneously submit one closed bid (Runeson & Skitmore, 2010). Tendering should be used to gain the highest possible quality at the lowest price. However, there are several risks associated with the tendering process, and it is necessary to establish good practices to gain the required output. A lack of consistency, transparency, and monitoring are some of the potential risks (Maniadakis et al., 2018). Another essential condition is the selection of one or multiple suppliers. Using a single supplier increases the risk of default and raises the possibility of potential shortages. Using multiple suppliers to minimize such a risk is beneficial in many scenarios (Dranitsaris et al., 2017).

The World Health Organization (WHO) defines pharmaceutical tendering as "*any formal and competitive procurement procedure through which offers are requested, received and evaluated for the procurement of goods, works or services and as a consequence of which an award is made to the tenderer whose tender/offer is the most favorable*" (as cited in Jalagam & Sathyanarayana, 2021, p.21). WHO differentiates between two methods, *Open* and *Restricted tenders*. The main difference is that suppliers are invited for prequalification under a restricted tender. Within these two, the pharmaceutical tendering process can be seen in Table 1.

Table 1. Pharmaceutical tendering process adapted from (Dranitsaris et al., 2017; Jalagam & Sathyanarayana, 2021)

Step	Explanation	
1	Establishing the format and its scope	**Pre-tender**
2	Defining the requirements for the medication and quantities needed	
3	Selection of suppliers to participate in the bidding	
4	Preparing and sending the documents	
5	Receiving and opening bids	**Tender**
6	Gathering bids for adjudication	
7	Adjudicating the tender	
8	Issuing contracts to the winning bidder(s)	**Post-Tender**
9	Monitoring performance and product quality	
10	Enforcing contract terms when needed	

Pharmaceutical tendering usually refers to the bulk acquisition of medicines over a fixed period. It is expected to reduce costs with many competing actors due to the competition on price. This will further increase economies of scale and scope and decrease administrative expenditures compared to regular purchasing. Several studies have found that tendering results in significant price decreases, especially in generic medicines. Generic medicines can yield substantial savings with prices 10-80 percent or even up to 95 percent lower than their originator product (Dylst et al., 2011; Petrou, 2016; Wouters et al., 2019). For instance, in the Netherlands, tenders reduced prices by 76-93 percent. The introduction of tendering in the generic market has resulted in significant public budget savings in several countries (Dylst et al., 2011). Moreover, in addition to the tendering, several programs, policies, and agreements on pricing to control costs have been established within the pharmaceutical industry. One is an increased use of generics to achieve savings (Dranitsaris et al., 2017).

Although this has positive short-term effects for the procurer, a study from New Zealand highlighted some long-term consequences. Tenders with only one winner experienced difficulties, especially under shortages, where supply had to be procured at a higher price due to a lack of fulfillment from the tender winner. Increased delivery problems were also highlighted if a smaller company won the tender (Dylst et al., 2011). However, Vogler et al. (2017) did not find any substantial evidence in their study supporting availability issues related to tendering. The market struggles with a constant decrease in prices due to competition and regulations from authorities. Tenders tend to be granted at the

lowest price, and some findings indicate that the prices decrease by 10% for each new entrant or competitor competing in the tender.

There is high consensus in the literature on the long-term negative consequences, as it could threaten the long-term sustainability in terms of suppliers leaving the market (Barbier et al., 2021; Petrou, 2016). It could also hamper innovation due to the constant pressure to compete on a certain price level, leaving innovation infeasible for many competitors (Dranitsaris et al., 2017). This could further decrease the possibility of new entrants due to the financial risk of engaging, prohibiting representation and investment (Dylst et al., 2011; Petrou, 2016; Vogler et al., 2017). According to Shafiq et al. (2021), the low profitability accumulated from the reduction in prices is one of the leading causes of generic medicine shortages. Therefore, reliability of delivery is a significant concern in the market, especially emphasized by the recent Covid-19 pandemic. This highlights that the "winner-take-all" principle and the low prices would not just alone drive companies out of the market but also create monopolies and make the market unhealthy. The low prices are also argued to encourage suppliers to keep lower stocks. The literature states that choosing suppliers should not be solely based on price but rather on fulfilling several criteria. Tendering, in that sense, can be defined as "*the acquisition of pharmaceuticals based on a competitive bidding process where the contract is granted to the pharmaceutical supplier who offered the best bid following strict criteria*" (Maniadakis et al., 2018, p. 592). Following that definition, this emphasizes the need for a broader procurement practice to implement other drivers.

2.2.2 Value-based procurement

Traditional procurement and tendering have focused on achieving the lowest possible price. However, a conceptual shift has been seen in research and business. Corsten & Felde (2005) argue a shift from a narrow focus on prices to a broader perspective encompassing innovation achieved through collaborative relationships. One of the approaches that have been a driver for this is The Resource Based View (RBV). RBV is based on the argument that organizations possess resources that form the basis for their survival, growth, and overall effectiveness (Barney, 1991; Wernerfelt, 1984). The main objective of RBV is to exploit resources that create value and success to achieve competitive advantages. The success and advantage

are further sustained through the resources being valuable, rare, difficult to imitate, and organized to capture value; these types of resources are termed VRIO (Barney, 1991). RBV has increasingly gained popularity as a theoretical lens to study sustainable purchasing and supply management (Johnsen & Johansen, 2017).

However, there are limitations concerning the sustainability aspect where other theoretical developments have emerged. In this case, Hart´s (1995) natural resource-based view (NRBV) has been increasingly adopted. His perspective on competitive advantage is based on the three interconnected strategies: *pollution prevention, product stewardship, and sustainable development*. Moreover, an important aspect to understand with RBV is that its upbringing is based in the private sector and assumes open competition between organizations within the market. In contrast, public organizations operate in a tightly managed market or no market (Meehan et al., 2017). Despite this, RBV is increasingly being applied to public organizations' performance, as they rely on sources and capabilities to deliver value. For these public organizations, value refers to identifying and building strategic capacities to extract the greatest value for the public. Meehan et al. (2017) argue that value in the public context becomes a proxy for effective and efficient service delivery that is sustainable in the longer term, indicating that RBV is a valuable lens to understand how value, rather than how competitive advantage is created.

Another aspect of strategic procurement is the term value-based procurement. Similar to RBV, value-based procurement concerns a view of procurement extending beyond only cost. From a procurement perspective, organizations rely on the products and services they buy to improve the market offering and increase profitability (Ulaga, 2003). While we previously highlighted the conceptual shift from the traditional procurement focused on price to a broader scope, researchers have shown that the health sector is often immature and not strategically aligned (Nachtmann & Pohl, 2009; Miller et al., 2019). The policy pressure in the industry has led to an increase in pooled procurement strategies, managed by procurement organizations rather than individual healthcare delivery organizations or units (Miller et al., 2019). These developments have led to complaints where the processes have been criticized as overly technical, rigid, and price-focused. This has led to a failure in assessing other benefits or values such as innovation or

environmental and social (Miller et al., 2019). Pooling procurement is criticized for leading to "all or nothing purchasing" if utilized over more extended periods, creating challenges for supply reliability and cost over time. This can also create difficulties for small and medium-sized organizations bidding for public sector contracts (Miller et al., 2019).

Researchers have debated the core of value-based procurement, namely the value itself, for many years, and there has not been established a unanimous definition of the term (Meehan et al., 2017). Where value in RBV refers to identifying and building strategic capacities to extract the greatest value for the public, the term is different for value-based procurement. Anderson and Narus (1998) provide a general definition where value is seen as the utility received from the products in exchange for the price paid for the market offering. However, researchers highlight that the relationship between price and value is complex. Price changes do not necessarily affect the value but can change the incentive to purchase one market offering over another comparative offer. The literature on value-based procurement highlights the lack of a clear definition of public value due to the differences across public organizations and the many stakeholders involved. Therefore, it is difficult and crucial to understand what value it holds for different stakeholders and how this value can be achieved through public procurement practices (Malacina et al., 2022).

Prada (2016) investigated value-based procurement in Canadian healthcare, which constituted various definitions of value. The study highlighted the Ontario Health Innovation Council´s definition as a total of three factors. In those terms, value can be perceived as the sum of *social impact + health system benefits + economic impact*. These factors include improved health system outcomes, better patient access, investment incentives, job opportunities, and reduced costs. Therefore, the value is a sum of social and economic effects and benefits for the health system in decision making. These core elements constitute a change from the traditional short-term cost savings approach to long-term efficiency and effectiveness of decisions to better health system performance and patient outcomes (Rahmani et al., 2021). An essential dimension of value-based procurement becomes the need to assess the value from a longitudinal collaborative perspective, as the effects do not occur immediately and can be challenging to determine (Walker et al., 2008). Terpend et al. (2008) identified four core parameters of the value concept through

an extensive literature review; the four identified parameters were: *operational performance, integration orientation, capability factors, and financial performance*. Malacina et al. (2022) attempted to identify the main components of public procurement value. The literature review concluded that the value aspects differ between the actors involved, namely suppliers, public buyers, and consumers. The identified values can be seen in Table 2.

Table 2. Components of value (Malacina et al., 2022)

Supplier	Public buyer	Consumer
Improved supplier innovativeness	Innovation generation and promotion	Availability of product/service
New and improved market opportunities	Well-functioning supplier market	Quality of product/service
Better operative capabilities	Public procurement process effectiveness	Environmental and socal sustainability
Improved sustainable performance	Sustainable public procurement	

A consensus in the literature regarding the implementation of value-based procurement is the importance of competitive dialogue. Prada (2016) explains it as a procurement process that allows buyers to thoroughly discuss needs with suppliers before articulating them in *Request for Proposal* (RFP) tenders. The process is argued to lay the foundation for early collaboration, further identifying and defining value expectations and, subsequently, the best fitting value proposition. Utilizing the supplier's knowledge and experience to formulate challenges is proven to provide better results than a list of requirements based solely on their perspective (Prada, 2016; Rahmani et al., 2021).

Prada (2016) further highlighted vital lessons to help organizations transition toward more strategic and value-based procurement. These were:

- A longer-term view of success and broadened the definition of value, including, e.g., patient experience and longer-term efficiencies
- Foster collaboration and cooperation between public and private stakeholders
- Engage clinicians and other key opinion leaders in the procurement process to determine value and enable and accelerate adoption

- Ensure that value-based procurement is broadly adopted, aligned between all funders and buyers, and informed by relevant data.

2.2.2.1 Barriers to value-based procurement

Through research on the procurement practices for medical technologies in Canada, Miller et al. (2019) mapped the procurement approaches used in tenders. The types of tenders examined were price-only *tenders* and *RFP*. RFP refers to tenders where the price is not expected to be determinative, and factors such as product quality, service, and company reputation are considered. The study also contained contracts awarded without an open tendering process and request for information (RFI) that did not necessarily lead to a bid. The results showed that 40.7% of contracts were done with RFP, where quality was the most critical aspect, and only 5% of the tenders were done with price being the only dimension. Additionally, the study showed that most of the contracts were given with long lengths, and most buyers expected to award a single supplier. The study was primarily focused on the RFP tender type. As such, the representation of RFP over price is only higher than the actual representation of the tender kinds in the industry. However, an important takeaway is that where additional criteria than price are included, the main component is concerned with the product's quality, not other aspects.

The research on value-based procurement in the health industry is limited due to the field being somewhat immature. However, research has increased in recent years as the sector has increased its focus on the subject. An essential aspect of value-based procurement is the barriers connected to its implementation and reaping its benefits. Meehan et al. (2017) researched value-based procurement in the UK health sector and identified barriers to its implementation. The researchers identified two main categories of inter-related issues: *relational barriers and resource barriers*. Relational barriers refer to myths, mistrust, and perceptions of procurement, while resource barriers are capacity issues such as resource shortages and gaps in knowledge. Many of the perceptions stemmed from mistrust between the procurers and suppliers, where ambitious saving targets set for procurement suggested that suppliers are opportunistic. Suppliers viewed procurement as predominantly price-focused and the source of many problems. A common issue was the avoidance of involving buyers in negotiations to introduce value-based approaches. Resource-based barriers were identified as lacking capacity and

capability to provide standard procurement activities and proper contract management. The researchers further argue that since these barriers are interrelated, they are unlikely to be overcome by simply adding more resources to the area.

2.2.3 Sustainable procurement

Sustainable procurement should contain additional elements and avoid the lowest bid procedures in tendering, in line with the mentioned value-based procurement. Some countries have adopted this by including sustainability as criteria in their tendering to help reduce environmental degradation (Lonaeus, 2016; Montalban-Domingo et al., 2018). The bidders should be competing on other criteria such as environment, reliability, and social implication, as it would award the best-value option (Barbier et al., 2021). Closely related is the term sustainable PSM, which refers to how supply chains are affected when external resources are combined with sustainability criteria. Regarding the social and environmental impacts, these sustainable changes need to be internalized at the core of firms´ strategies. This can be explained as a set of "logics" that leads to values, attitudes, and behaviors towards sustainable outcomes (Silva & Nunes, 2021). Therefore, sustainable procurement refers to the procurement of products deemed more environmentally friendly (Erridge & Hennigan, 2012). In other words, sustainable procurement means ensuring that "*products and services an organization buys achieve value for money and generate benefits not only for the organization, but also for the environment, society, and the economy*" (ICLEI, n.d.).

Sustainable public procurement (SPP) is the term used for the public procurement processes of more social, environmental, economic, and innovative procedures. However, the more specific term only contemplating the environmental aspect is green public procurement (GPP). GPP is defined as "*a process whereby public authorities seek to procure goods, services and works with a reduced environmental impact throughout their life cycle when compared to goods, services and works with the same primary function that would otherwise be procured*" (European Commission, 2008, p. 4). Green requirements in tendering to award greener processes can be utilized through certifications such as ISO 14001 or transparent practices that demonstrate reduced emissions, CO2, and environmental degradation (van Berkel & Schotanus, 2021). The ISO 14000 accreditation would also improve the risks in terms of environmental procurement but is more of a voluntary standard

compared to ISO 14001 (Ding, 2018). Additionally, Roschanger et al. (2017) suggest a quantification of green suppliers to help with rewarding supplier performance in those terms.

Given the total value of public procurement and the extensive demand, public procurers can influence the market substantially. Incorporating environmental, social, and/or economic criteria in the tendering process can potentially affect the supplier selection process towards more sustainable outcomes. Traditionally, public procurement was solely based on economic objectives, which has changed with the concept of sustainable development (Dragos & Neamtu, 2014). Consequently, incorporating additional criteria that foster sustainable operations can encourage investments in green strategies and technologies (van Berkel & Schotanus, 2021). Although it might seem easy in theory, several barriers concerning sustainable procurement procedures were found by Sourani & Sohail (2011). One of them being the lack of funding and the restrictions on increasing expenditure. With that said, along with barriers such as lack of knowledge and insufficient practices, the public procurer and the corresponding authorities are seen as the most capable of removing these barriers (van Berkel & Schotanus, 2021).

Mélon (2020) states that companies lack the incentives to behave sustainably, especially if regulatory interventions are absent. It is further argued that public organizations should lead by example as they represent a tool for influencing private markets (Dragos & Neamtu, 2014; Mélon, 2020). Obtaining sustainable procurement practices could help companies avoid economic and reputational damage and secure sustainability (Hallikas et al., 2020). The readiness of procurers is stated by Stamm et al. (2019) as they found that it is deemed “easy” or “very easy” to include environmental criteria in procurement procedures. However, there are low considerations towards the competencies and resources suppliers can utilize to meet these criteria (Silva & Nunes, 2021).

Interestingly, the assumption of increased costs related to the acquisition of sustainable products could be wrong (Erridge & Hennigan, 2012). One interesting finding of Erridge & Hennigan's (2012) study was that introducing sustainable procurement issues in the supply chain could reduce costs. An issue is that the sustainability part is often handled separately and not embedded throughout the

tendering processes (Schulze & Bals, 2020). It is argued that they should be "built into" the selection criteria instead of being assessed separately (Erridge & Hennigan, 2012). Moreover, managing supply chains is comprehensive, and securing sustainability requires robust risk management skills (Hallikas et al., 2020). An extensive literature review from Miemczyk et al. (2012) highlights that the sustainability level of a company is no more than the suppliers from which it sources, meaning that in many scenarios sustainability problems often stem from indirect suppliers. This points to the importance of collaborating with supply chain partners in achieving sustainable outcomes.

2.2.4 Buyer- supplier collaboration

Traditionally, interactions through supply chains are mainly focused on achieving the lowest costs and reliable deliveries, with arms-length conditions to avoid dependence on individual suppliers. This approach also creates opportunities to switch among potential counterparts, preventing the buying firm from adverse lock-in effects (Gadde & Snehota, 2019). In recent decades, supply chains have increased in complexity due to the global involvement of numerous suppliers, logistic service providers, and customers (Christopher, 2016). This development has led to a shift from "buying well" toward "making the most of supplier relationships" (Gadde & Snehota, 2019). Firms must look outside of their internal organization for opportunities to collaborate with partners to ensure an efficient supply chain (Cao & Zhang, 2011). There is a plethora of research on supply chain collaboration (SCC), and with that comes numerous definitions. Our literature review shows that the terms SCC, coordination, and integration are sometimes used interchangeably. In contrast, other literature states that coordination and cooperation are two facets of collaboration (Gulati et al., 2012). Our study will not differ between them, as they refer to a tight coupling process between supply chain partners (Cao & Zhang, 2011). We have chosen to use the broad and highly cited definition of SCC from Simatupang & Sridharan (2005). They define SCC as "*two or more companies working together to create a competitive advantage and higher profits than can be achieved by acting alone*" (p. 258).

A common issue in traditional supply chains is that each actor makes decisions optimized for their operations, hindering optimal processes from a holistic view of the supply chain. This can further result in increased end-to-end pipeline inventory

or time lags to ensure products are available for production, which in supply chain literature is defined as the bullwhip effect (Cristopher, 2016). This could lead to increased lead times, costs, and low responsiveness. There is a divide between two main structures in the literature on SCC. The first structure is information which refers to how actors share, obtain, and communicate information. Secondly, the decision function refers to how actors decide what actions to take (Malone, 1987). Malone (1987) categorizes the decision function into centralized and decentralized decisions. Decentralized decisions imply that each function optimizes its operations and profit, while centralized decision aims to maximize overall supply chain profitability.

While the importance of collaboration in supply chains has risen on organizations' agendas, the benefits can be hard to identify in today's complex markets and supply chains. Cao and Zhang (2011) highlighted five primary supply chain-performance benefits through collaboration: *coordination, flexibility, increased synergies, quality, and innovation*. Additionally, through an extensive review of SCC, Hudnurkur et al. (2014) identified some key benefits: *cost saving, inventory reduction, increased visibility, and reduction in bullwhip effect*. Moreover, Gimenez & Sierra (2013) concludes from their study that environmental performance can be improved through supplier assessment and collaboration with suppliers. Consequently, evaluation of suppliers works as an enabler for collaborative efforts.

Johnsen & Johansen (2017) argues that the ability to form collaborative relationships with suppliers is valuable to improving sustainability. Vachon & Klassen (2006) proclaim that environmental collaboration increases when the supply base decreases. Another important aspect of collaboration is knowledge sharing. Knowledge sharing often occurs through close collaboration with upstream and downstream members and could further evolve into innovation. Porter (1985) stated that collaboration with upstream and downstream supply chain actors lowers costs for all participants. Fugate et al. (2006) state that collaboration can eliminate sub-optimization through aligning supply chain member incentives to be compatible with system-wide objectives. The literature shows that the benefits of collaboration are vast. It influences various parts of the supply chain and organization, from risk mitigation to innovation.

2.2.4.1 Factors affecting SCC

Duong and Chong (2020) present eleven factors influencing supply chain collaboration. These eleven were seen as particularly influencing factors on SCC. Understanding the most critical factors influencing collaboration is crucial to enabling successful SCC. Neglecting these factors will negatively affect the benefits of collaboration, while they will impact it positively by being present. The eleven factors can be found in Table 3.

Table 3. Influencing factors to SCC adapted from (Duong & Chong, 2020)

Influencing factors	Explanation
Information sharing and technology	Information sharing and technology is critical for collaboration and risk reduction to deal with disruptions. It enables learning from previous disruption events, facilitate risk assessment, and evaluate the value of relationships.
Trust	Trust refers to the belief of partners willingness and ability to accomplish their duties. A high level of trust leads to the better collaborative relationship and higher supply chain performance.
Culture	Refers to beliefs and shared values. Essentially, this means that collaborative culture tend to collaborate with other partners actively, whereas different cultures lead to collaborative failure between buyers and suppliers.
Stakeholders	Refer to support and commitments from partners for the collaboration. A strong relationship with stakeholders could cover all the basic needs during a disruption. The collaboration may also happen due to the pressure from stakeholders. Therefore, establishing with the right partner is the priority to secure response activities. Furthermore, the government is one of the key stakeholders, who could strive to collaborate and notice the lack of collaboration.
Divergent goals	Can be described as inconsistent and disconnected goals between partners as priorities may not align.
Flexibility	Can be described as the willingness to adapt and change for collaboration purposes.
Knowledge and experience	Lack of knowledge and experience is associated with behavioural barriers. Meaning that advisory and training are necessary for the success of collaboration.
Market factors	Supply and demand uncertainties results in lack of collaboration and influences the effective collaboration between public and private partners.
Measurement issues	The lack of measurement systems to provide timely and appropriate responses prevents organizational learning.
Resources	Superior financial capabilities, the availability of transportation, or human resources are vital for any collaboration activities.
Visibility	Complex supply chains increases the lack of visibility, which leads to information asymmetry.

Various researchers emphasize the importance of information sharing as an essential factor for collaboration to be successful along with one of the most important benefits (de Kok et al., 2005; Martinez-Olvera, 2008; Sahin & Robinson, 2005). An important enabler for collaboration is having technological solutions facilitating information sharing. The literature highlights that although technical solutions are vital, willingness to share information is the deciding factor (Cao et al., 2010; Cao & Zhang, 2011).

2.2.4.2 Collaboration in Pharmaceutical supply chains

The pharmaceutical industry is characterized by several stakeholders, where the delivery of medical products moves through various parts of the supply chain (Nsamzinshuti et al., 2017). As the actors in these supply chains are linked to providing healthcare to people, knowledge sharing and collaboration across the supply chain are essential but are currently neglected (Haque & Islam, 2018). Through a study on downstream pharmaceutical supply chains in Europe, Papalexi et al. (2020) found four root causes of operational inefficiencies. These were: financial, communicational, waste, and complexity issues. Furthermore, the findings showed a lack of effective communication and information sharing across the supply chain. The study's findings pointed to a further need for supply chain partners to invest in partnerships for efficient SCC. Additionally, Mandal (2017) found through research that hospital supply chain performance is dependent on supplier engagement and better relationships. A suggested measure to facilitate these partnerships is frequent meetings with suppliers. This can facilitate experience and knowledge sharing for involved parties. Coherently, regular supplier meetings can contribute to longer supplier relationships and positively build trust and commitment among partners (Du et al., 2012; Mandal, 2017).

2.2.4.3 Power and dependencies

An essential aspect of PSM is market power and dependency between supply chain actors. Dependence can positively and negatively affect the relationship between actors and further the overall collaboration in a supply chain (Mishra et al., 2016). In the literature, the subject is termed resource dependency theory (RDT), which is explained by how external resources affect an organization's decision (Cao & Zhang, 2011). According to RDT, no business is entirely dependent on its internal capabilities and resources. Hence it becomes dependent on other actors to acquire the needed resources (Hillman et al., 2009).

Markets can have high variations in market power; for example, markets characterized as supplier dominant have power in favor of suppliers. These markets are often characterized by having only a few or one supplier to source from. Markets having a buyer-dominated structure are described as a market of buyer dominance. Through literature, supplier dominant markets have been identified as having higher uncertainty, risks, and dependencies for the customer (Cannon & Perreault, 1999).

Mismatch in the power relationship often entails a lower incentive and willingness to collaborate for the actors with the greatest power (Cannon & Perreault, 1999). The literature on the subject states that to change this mismatch, it is essential to understand the current practice and the market situation (Benton & Maloni, 2005; Cannon & Perreault, 1999). A vital aspect of a buyer-seller relationship is information exchange (Cannon & Perreault, 1999). Information exchange is defined as the willingness and openness of two or more actors to share meaningful, even proprietary information. This can be directly connected to supply chain transparency which we will go further in-depth on below.

2.2.5 Supply chain transparency

Transparency can roughly be defined as the disclosure of information (Mol, 2010) or the ability to know internally and show externally that firms are exercising diligently (Brun et al., 2020). Similarly, supply chain transparency can be defined as sharing or disclosing detailed and accurate information about operations, products, and sustainability conditions (Egels-Zandén et al., 2015; Montecchi et al., 2021). This could be the origin of the product and its sourcing, who the suppliers are, how it is transported to the end-user, and the following environmental impact or costs. The existing literature on supply chain transparency also mentions closely linked concepts such as visibility, traceability, disclosure, and openness as near-synonyms (Montecchi et al., 2021). For instance, visibility ensures information flow to actors dependent on that information, both inside and outside the organization. Enabling them to monitor, control, and change supply chain strategy and operations if needed. Supply chain visibility is defined as the extent to which actors within the supply chain have access to or share mutually beneficial information (Kamble et al., 2020). We have seen that the terms have similarities in definition and are sometimes used interchangeably through our literature review. We will use the term transparency for consistency and not differ between them in this study.

The concept of transparency and its importance has gained exponential interest in recent years. This is mainly due to concerns regarding child labor, health and safety conditions, living wages, labor abuses, and the environment (Brun et al., 2020; New, 2015). The recent outbreak of the Covid-19 pandemic has further emphasized its necessity (Montecchi et al., 2021). The complexity of supply chains has

continued to increase in today's global environment, making questionable and unsustainable production practices more difficult to track (Gardner et al., 2019). Consequently, increasing the difficulty of having transparency of origin and manufacturing processes (Godar et al., 2016; Lafargue et al., 2021).

Transparency can be seen as both normative and substantive. Normative is usually seen concerning democracy, participation, and accountability. In contrast, substantive is seen as a set of criteria relevant to improving observation, monitoring, surveillance, disclosure, dissemination, reporting, marketing, complaints, and verification (Gardner et al., 2019). Mol (2010) argues that transparency has become more central in governance and politics, going from only "right-to-know" (normative) to more access and control over information. Moreover, transparency is related to power (Mol, 2010), and power is at the heart of all business relationships (Cox, 2001). Increasing transparency would therefore help empower the powerless. This argument appears to be supported by others as it represents a way to transfer power from the firm to its stakeholders (Egels-Zandén et al., 2015).

2.2.5.1 Transparency and the pharmaceutical supply chain

Quality, access, and reliability are critical aspects in the procurement of medicines. Pharmaceutical supply chains, like many others, struggle with low levels of transparency both before and during the delivery process (Papalexi et al., 2020). In addition, the market struggles with counterfeiting, shortages, production errors, distribution of temperature-sensitive products, and faulty drugs resulting in a severe threat to public health (Papert et al., 2016). For instance, the worldwide challenge of counterfeit medicines constitutes a dangerous problem as they often do not contain any or enough of the API, meaning they can be deadly. Besides the health risk, the following problem accumulated to a loss of 200 billion dollars in the US alone, which clarifies the need for supply chain transparency in pharmaceutical supply chains (Abbas et al., 2020). The willingness to share information with supply chain partners reflects the quality of the information communicated (Du et al., 2012). The pharmaceutical industry faces issues with participants usually sharing the bare minimum of information, especially upstream. Foremost due to the sharing of necessary information requiring a release of confidential and closely guarded financial or strategic information to partners that could be in direct competition, either now or in the future (Årdal et al., 2021; Du et al., 2012). Sodhi & Tang (2019)

also supports the risk of disclosing information as it could reveal suppliers' competitive edge and vulnerabilities. Finding the necessary and relevant information is also costly, complicated, and time-consuming. Although auditors make assurances on behalf of the manufacturers and suppliers, the information provided is insufficient and not up to date. Therefore, the real-time information utilizing real-time decisions to handle or prevent supply-demand interruptions is lacking (Handfield, 2016; Sodhi & Tang, 2019). Essentially, the willingness to share information is a trade-off between efficiency and the responsiveness of the information resources. In other words, gathering and sharing information that takes time and additional resources is likely to decrease efficiency (Du et al., 2012). It is also argued to increase supply chain efficiencies when used adequately and adopt suitable systems (Montecchi et al., 2021).

Transparency is strongly connected to accountability, legitimacy, and trust (Egels-Zandén et al., 2015). The active pharmaceutical ingredient (API) used in all medicines is presumably concentrated in a few countries with lower infrastructure and difficulties gathering suitable information, such as China and India, although due to a lack of transparency this is unknown (Årdal et al., 2021). The complexity of these supply chains is challenging due to many suppliers, sub-suppliers, and sub-sub-suppliers in different geographical locations. The high price pressure forces many suppliers to source manufacturing and raw materials to low-cost countries, which increases the difficulty of transparent operations (Sodhi & Tang, 2019). Since transparency efforts require strong organizational and supply chain capabilities such as collaboration, governance of these efforts, and leadership (Brun et al., 2020), accessing information in countries with poor infrastructure is associated with high costs in terms of collection procedures (Kamble et al., 2020; Marshall et al., 2015). Traceability has been incorporated in many sectors where stakeholders have been allowed to trace the product history; this is, however, relatively new in pharmaceutical supply chains (Sunny et al., 2020).

Researchers argue that increased transparency within complex PSCs could lead to an improved supply of medicines (Årdal et al., 2021) and enable participants to identify potential risks and minimize them accordingly (Gardner et al., 2019). Increased transparency will help the accuracy of forecasts, better adjustments to production plans, improve delivery performance, and reduce the possibility of

overstocking (Barrat & Oke, 2007; Somapa et al., 2018). Moreover, greater transparency enables more proactive processes to avoid shortages (Årdal et al., 2021). Several authors suggest that information sharing is critical to effective supply chain management and helps reduce the bullwhip effect significantly (Barrat & Oke, 2007). Transparency is seen as crucial in regulated industries. The pharmaceutical industry is one of the most regulated industries where participants are required to share a set standard of information with the public organizations (Klueber & O´Keefe, 2013). However, the public or governmental organizations cannot share that information with similar organizations in other countries due to its confidentiality (Årdal et al., 2021). This is also emphasized by Gardner et al. (2019), who state that information provided to public or governmental organizations often differs from what is given to private organizations. This leads to information dissymmetry (Fu et al., 2017), prohibiting participants from being aware of, interpreting, and using the information for resilience (Gardner et al., 2019).

Transparency has its shortcomings and limitations regarding access and the potential outcomes for its practitioners (Gardner et al., 2019). Private organizations are reluctant to share based on the possible insight that could reveal weaknesses or details. Transparency could also lead smaller organizations out of the market due to the financial robustness of bigger organizations (Årdal et al., 2021). The information provided could be used asymmetrical, meaning it could empower the powerful and increase inequalities (Mol, 2010). Transparency requires adopting several technological solutions and willingness and incentives (Papert et al., 2016). This is often a complex process due to all the different functions needing change, both internally and externally (Klueber & O´Keefe, 2013). It is also argued that technological solutions such as centralized traceability systems are frequently manipulated and addressed as monopolistic, asymmetric, and opaque information systems (Sunny et al., 2020). In addition, evidence on the effective use of collaborative systems is mixed. The main reasons for this are the lack of clarity regarding the conditions in which the use of collaborative systems is appropriate and disagreements between parties regarding the sharing of proprietary information (Grover & Saeed, 2007).

2.3 Conceptual framework

The conceptual framework illustrates our theory in relation to the literature review and can be viewed from the top (Figure 1). The framework aims to increase our understanding of the barriers and enablers of value-based procurement in PSCs toward sustainable outcomes.

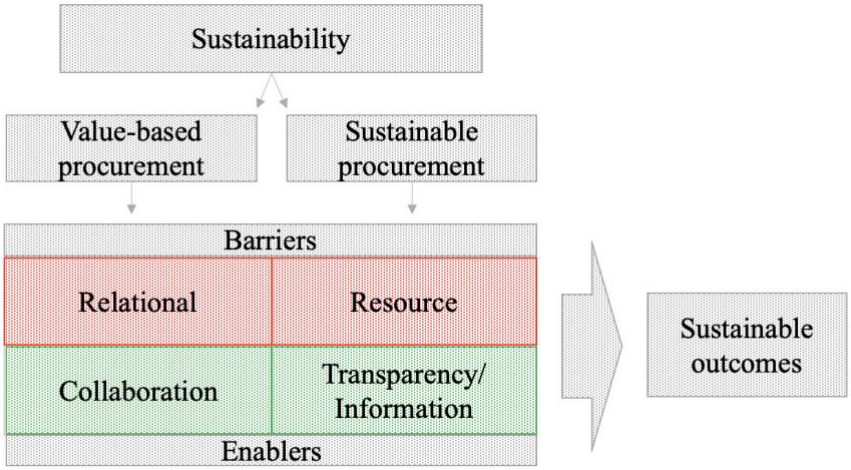

Figure 1. Conceptual framework (developed by authors)

Our research is directed towards how environmental considerations in the form of value-based procurement can result in better performance of the environment, supplier longevity, availability, and reliability. Value-based procurement strongly relies on collaboration and transparency in the supply chain to enable its desired outcome of bringing more value per dollar spent. However, relational and resource barriers make upbringing in the pharmaceutical industry difficult. Sharing of proprietary information, resource allocation towards better quality products, and willingness from supply chain actors are some of the barriers.

3.0 Research Methodology

This section provides the research methods used to answer our research questions. We first present the research strategy and design. Secondly, we introduce our method of data collection and analysis. Finally, we explain how we ensured the authenticity, quality, and limitations of our research and the ethical considerations taken.

3.1 Research Strategy

Research strategy refers to the overall approach to a project. A key distinction is the difference between qualitative and quantitative research. These terms reflect the type of research method used in the study. The qualitative method is mainly based on collecting data that comprise written or spoken words, while the quantitative method is based more on the collection of numerical data. There is also a method that combines both methods, namely the mixed method (Bell et al., 2019).

We applied a mixed-method strategy for our research, as it was deemed necessary to combine the two methods to answer the research questions posed. The strategy allowed us to collect qualitative and quantitative data and interpret it simultaneously. A common argument against mixed-method research is that quantitative and qualitative research are separate paradigms. However, we did not directly compare quantitative and qualitative data through our research. We used the quantitative data to facilitate the background of our qualitative research. The qualitative data were then further used for establishing insights and context to the quantitative data. Another critical aspect of choosing a mixed method is the desire to use the logic of triangulation. This is highly relevant as it enables cross-checking against the results from findings through both qualitative and quantitative methods (Deacon et al., 1998).

The quantitative data provided evidence about the current market of generic antibiotics in Norway and Sweden. The evidence gave us an understanding of the differences in the two markets and the trend in terms of the number of suppliers. This showcased the market challenges and provided the foundation for the qualitative data to explore further. The qualitative data gave us an overview of the actors involved in the market, their understanding of the challenges, perceptions on environmental criteria, collaboration, transparency, corresponding success factors, and improvement areas.

There are two primary approaches to research defined by Bell et al. (2019), inductive and deductive. The deductive approach is characterized as the theory testing practice, meaning hypotheses are driven based on earlier theoretical considerations. The inductive approach involves theory being “data-driven”. In recent times, a third approach has been developed, namely abductive. This approach

begins with observing a phenomenon and further seeks to explain it by studying iteratively between theory and data (Bell et al., 2019; Dubois & Gadde, 2014). For our research, an abductive approach was best applicable. Dubois & Gadde (2002) argue that an abductive approach is better for researchers to match theory and reality. This becomes important when the literature on the specific subject is scarce, such as in the case of our research. We began studying the literature on the topic before we gathered insights from practitioners. This gave us new directions in literature fields, meaning we had to go back and forth between practice and literature for further theory development. An illustration of our abductive approach can be seen in Figure 2.

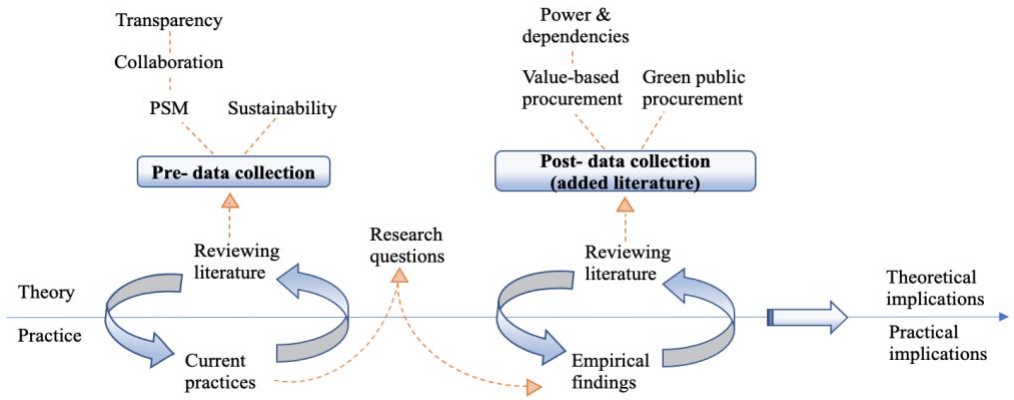

Figure 2. Abductive approach (developed by authors)

3.2 Research Design

A research design provides a framework for collecting and analyzing data to appropriately generate evidence. The design provides a detailed description of how a study will be conducted and affect both the results and quality of a study. Consequently, it becomes vital to choose an appropriate research design. The five prominent research designs are experimental/related, cross-sectional, longitudinal, case study, and comparative. To investigate our research question, we concluded that a case study design was the most suitable approach (Bell et al., 2019).

A case study is distinguished from other types of research design with "[...] *the focus on a bounded situation or system, an entity with a purpose and functioning parts'"* (Bell et al., 2019, p. 63). Yin (2014) argues that the more the research question seeks to explain in present circumstances, the more a case study will be

relevant. One of the critical aspects of choosing a case study design was that it offered unique flexibility and allowed us to dig deep into one case to assess the different elements of analysis within the same conditions (Bell et al., 2019; Ebneyamini & Moghadam, 2018). Furthermore, our research questions can be defined as exploratory. We aimed to gain unique insights into the complex market of generic antibiotics by gathering perceptions on the introduction of environmental criteria in the market. This was best answered by utilizing a case study design.

There are multiple types of case studies with different qualities and characteristics. Stake (1995) distinguishes between three case study types: intrinsic, instrumental, and multiple or collective case studies. Multiple or collective case studies are used for understanding a general phenomenon, connecting multiple studies. Intrinsic case studies are suitable for understanding the particularities of a situation rather than generic understanding (Stake, 1995). Instrumental case studies are found to be "[...] *those that focus on using the case as a means of understanding a broader issue or allowing generalizations to be challenged*" (Bell et al., 2019, p. 64). Through our study, we sought to understand the perceptions and possible effects on longevity, availability, and reliability of suppliers and antibiotics. Therefore, we perceived our study as an instrumental case study.

Due to case studies being set to bounded systems, an overview of the case study's boundaries is deemed necessary (Bell et al., 2019). Firstly, the case is bound by primarily gaining insights through Norwegian stakeholders in the market for generic antibiotics. Yet, data was also gathered from stakeholders in Sweden and Denmark, as suppliers operate across borders. The case study only sought data from tier-1 suppliers, given the time constraints and difficulties retrieving information further down the supply chain. A more thorough case description is provided in section 4.1.

It is important for researchers applying a case study to establish an overview of the level of analysis that the research will undertake (Bell et al., 2019). In other words, researchers need to question "what is the unit of measurement and analysis?". The level of analysis can focus on individuals, groups, organizations, and society. To gain insights into the Norwegian market of generic antibiotics, we used an organizational level of analysis. We argue for this level of analysis because even

though we interview individuals, they answer as a representative of their respective organizations. Furthermore, Bell et al. (2019) argues that a combination of two or more levels of analysis increases the complexity of the analysis.

3.2.1 Sampling

Sampling in research is defined as whom you would like to interview to obtain relevant information and data for the study. According to Bell et al. (2019), "*the goal of sampling in case studies is to understand the selected case or cases in-depth*" (p.11). The authors further argue that the best fit for qualitative research is purposive sampling (non-probability). This method does not gather participants randomly, but strategically samples the participants. The sampled participants should have various characteristics and viewpoints connected to the problem statement.

We wanted to identify relevant stakeholders in the Norwegian market of generic antibiotics in our research. An essential part of our research was to gain insights from suppliers, both existing and those who have left the market. This was seen as a necessity to get perceptions from participants who have deemed the market as unsustainable and therefore understand the challenges from a holistic view. Our collaboration with SI gave us historical data on active suppliers in the market of generic antibiotics from 2010 to 2021. This was our main departure point for sampling, where we reached out to the respective representatives. This sampling approach is characterized as a *maximum sampling approach*, defined as "*sampling to ensure as wide a variation as possible in terms of dimension of interest*" (Bell et al., 2019, p. 390). It was important for the holistic view to utilize the snowball effect to gather insights from other actors than suppliers. The snowball effect can be explained as when initial contact with a group of people relevant to the project is used to establish a connection with others (Bell et al., 2019). During the primary data collection, we asked participants for other relevant stakeholders that could be of interest to the project.

The desired interviewees were first contacted by email, containing a general introduction of the two interviewers, an introduction to the study, why the participant was requested to participate, and general information about what it entailed being part of the project (length, date, language, and platform). In the cases

where we did not receive a response, follow-ups were first made through email and later contacted by telephone.

3.3 Data collection and analysis

"*Data collection is the key point of any research project*" (Bell et al., 2019, p.11). Yin (2014) states there is no given data collection for qualitative research projects. However, qualitative research requires a qualitative data basis. The literature distinguishes between primary and secondary data. Primary data refers to when the researcher collects the data and conducts the analysis. Secondary data analysis refers to when the researcher performs an analysis based on existing data (Bell et al., 2019). Due to our chosen mixed-method design consisting of both quantitative and qualitative data, the collection and analysis were done in different ways to answer various aspects of our research questions.

To ensure the three pillars of reliability, replicability, and validity in our research, we applied the principles of triangulation. The qualitative part of our primary data was gathered through semi-structured interviews with important actors in the Norwegian market for generic antibiotics, ranging from the procurement side, previous and current suppliers, industry associations, and health organizations. The quantitative data collection was gathered from the national medicine agencies in Norway and Sweden. They provided excel sheets with data on yearly numbers of MAHs for generic antibiotics. After the primary data collection, several of the subjects were available for further clarifications or follow-up questions. This allowed us to triangulate and further investigate the findings after the data collection.

We gathered relevant literature by creating search strings in the three databases: Oria, Web of Science, and Google Scholar. By applying search strings, we narrowed the search while still ensuring that relevant literature was not excluded. These search strings consisted of different combinations of keywords pertinent to our problem statement (Appendix 1). Additionally, we identified important websites and databases through Google. To validate our sources, we used Web of Science and the Norwegian Centre for Research Data (NSD), where low cited sources were removed. Requirements were lowered for recently published articles of high relevance to our study.

3.3.1 Primary data

The primary data was gathered through semi-structured interviews with key stakeholders in the Norwegian pharmaceutical industry and quantitative data from national medicine agencies in Norway and Sweden. Quantitative data were used to assess the current situation of the supplier market, while semi-structured interviews gave us a holistic view of understanding different actors' perspectives across the supply chain. The interviewees were chosen based on their role in the supply and tendering of generic antibiotics in Norway, and our starting point was a list of current and former Norwegian MAHs. As the interviews carried on, other companies or organizations were suggested by the participants and were further contacted by us. Our objective was to gather insights into the market's current situation, the challenges concerning an increase in exits of MAHs, and valuable information concerning the implementation of environmental criteria in tenders. The next part addresses how the two types of primary data were gathered, cleansed, and prepared.

3.3.1.1 Qualitative

To ensure we complied with the General Data Protection Regulation (GDPR) requirements, our first step was to apply to NSD. Secondly, we had to determine whether we wanted a qualitative or quantitative interview method in our research. There are many differences between qualitative interviewing and interviewing in quantitative research. The main difference is that the approach tends to be less structured in qualitative research. While quantitative research's primary focus is to maximize the reliability and validity of measurements of key concepts, the qualitative approach is more interested in captivating the interviewee's point of view. Bell et al. (2019) differentiate between two main types of qualitative research interviews: unstructured and semi-structured interviews. An unstructured interview can derive from only a single question where the respondent is allowed to answer freely, and the interviewer responds to points that seem worth following up. Semi-structured interviews are conducted by having a list of questions on specific topics which need answering, referred to as an interview guide. This method allows for leeway for the researcher to follow up on interesting topics which may occur.

From our literature review, we established vital topics we wanted to gather insights on. Therefore, semi-structured interviews were chosen as our preferred method,

where we developed an interview guide based on the derived key concepts as seen in Appendix 4. These topics were: challenges in the market, sustainability, transparency, implementation of environmental criteria, collaboration, availability, and reliability. Previous research into relevant topics in the pharmaceutical industry had experienced reticent respondents argued by the fact that the topics were perceived as "business-sensitive information". For this reason, we decided to develop general questions in our interview guide. In some cases, the interviewees asked to be sent the interview guide beforehand, however, this was not done as a standard due to the questions being general, and we did not experience difficulties in the respondent's ability to answer the questions. As the interviews progressed, the semi-structured interview allowed us to ask follow-up questions and gather answers that could be perceived as confidential. The fear of sharing business-sensitive information that could be traced back to each firm or individual was seen as a concern for the most part. Therefore, we had to keep interviewees confidential based on the wishes of almost all participants.

Semi-structured interviews are argued to be suitable for individual and group interviews due to their flexibility (Kallio et al., 2016). Eleven of our interviews were conducted with two or three interviewers and one interviewee, while one of the interviews consisted of two interviewers and two interviewees. Utilizing semi-structured interviews gave us the ability to use the same interview strategy and structure throughout the process. The interviews lasted between 30-75 minutes and were carried out over Zoom or Microsoft Teams.

Table 4. Overview of participants

Interviewee/Identifier code		Date	Length
Supplier	P1	18.03.2022	60
Supplier	P2	22.03.2022	30
Supplier	P3	24.03.2022	45
Pharmaceutical organization	P4	05.04.2022	55
Supplier	P5	05.04.2022	50
Supplier	P6	18.03.2022	60
Supplier	P7	05.04.2022	30
Pharmaceutical organization	P8	15.03.2022	55
Norwegian Hospital Procurement Trust	P9, P10	24.11.2021	75
		21.04.2022	25
		21.05.2022	20
Pharmaceutical organization	P11	22.04.2022	50
Supplier	P12	26.04.2022	40
Pharmaceutical organization	P13	29.04.2022	60

The participants ranged from various stakeholders in the market (see Table 4). Interviewees were mainly divided into suppliers, public procurement agencies, and pharmaceutical organizations. Pharmaceutical organizations are in this case used as the general term for stakeholders not directly involved in supplying antibiotics, for ensuring anonymity The interviewee's position and background also varied, creating a challenge of standardization. As we were aware of this obstacle, we developed a set of standardized questions with modified questions for specific interviewees to overcome the challenge. Questions were general and open to not guide the respondents in any direction.

3.3.1.2 Quantitative

The quantitative data was collected by contacting the Norwegian Medicines Agency (In Norwegian known as Statens Legemiddelverk (SLV)) the national administration and regulatory body in medicines, both for humans and animals (SLV, 2020). SLV provided us with Microsoft Excel extracts of all MAHs for generic antibiotics every month from January 2016 to December 2021. To draw more generic results and conclusions from our research, we wanted to collect data from similar markets. We chose the Norwegian, Swedish, and Danish markets as they possess high levels of similarity in terms of high-income and smaller markets. These three also have the same policy for antibiotics, which is to reduce the usage to a minimum, and mainly use narrow-spectrum antibiotics to avoid resistance. We reached out to the Swedish Medical Products Agency (Läkemedelsverket) and the Danish public procurement agency for pharmaceutical products (Amgros). The Swedish Medical Products Agency gave us Microsoft Excel spreadsheets with a yearly overview of MAHs for generic antibiotics from 2016 to 2021. Despite numerous attempts, we could not receive the data requested from Amgros. Hence, the Danish market could not be analyzed in our research.

3.3.2 Limitations

We encountered a series of difficulties in the collection of data. First, we had issues concerning participants. Many suppliers declined our requests or did not want to participate in the study since they no longer served the market. This is a limitation of the study since it would be beneficial to understand the reasons for their

withdrawal and potential incentives for reentry. Additionally, some suppliers could not participate due to time constraints. Second, we also wanted to use Denmark as a comparison due to their similarities in the market and their lack of environmental considerations. This data was not provided as one authority lacked resources, and others did not answer our request. Finally, some participants could not provide extensive answers to all questions related to sustainability and transparency as they were tender managers, and the sustainability function was separate organs in some cases.

With the limitations in mind, we want to highlight that the participants willing to be interviewed answered the majority of our questions with valuable information about the problems stated. Their willingness to participate, however, was solely based on the anonymity provided. It was also emphasized that we have chosen to study a highly relevant problem.

3.3.3 Secondary data

Secondary data can be explained as existing data collected for another case. This is often used to validate your sample and analyze both quantitative and qualitative data (Bell et al., 2019; Adams et al., 2014). The collection process of own data can be very time-consuming and expensive, and in addition, needs approval in some cases. Due to the time-consuming process of several interviews and quantitative data gathering, secondary data becomes crucial to gain insight into topics not covered through our primary data. Through our process and collaboration with SI, we were also sent additional data, such as reports from both public Norwegian health agencies and EU reports relevant to our topic.

We began our initial data gathering by reviewing the existing literature. The topics were analyzed generally before it was tied to the pharmaceutical industry. This formed the basis of our theoretical framework and the guidance for our research moving forward. Due to our abductive approach, we had to go back and forth between research and observations throughout the process. Hence, literature was frequently added and removed. Contextual reports on the challenges in the market were also gathered. Reviewing the existing literature and reports gave us a solid background and understanding, allowing us to develop a well-designed interview guide to get the answers not yet discovered.

Due to the vast amount of secondary data collected and continuously refined due to the chosen abductive approach, a structured strategy was crucial. Our collection was done through a method called data-reduction meant to break down large amounts of data to simplify and construe it (Bell et al., 2019). The data reduction was done in Microsoft Excel, where different sheets were made for sorting various topics and themes.

3.4 Data analysis

Data analysis is primarily about data reduction, meaning breaking down large amounts of data to make it manageable and possible to interpret and analyze (Bell et al., 2019). We also collected different types of data requiring other techniques and methods of analysis. Due to the vast differences in methods of analyzing the data, the following sections will be divided between our quantitative and qualitative data analysis.

3.4.1 Qualitative data analysis

There is a multitude of potential methods for analyzing qualitative data. In our research, we found the thematic method of analysis to be most suited. A thematic method means examining data to find repetitions, categories, analogies, transitions, similarities and differences, linguistic connectors, missing data, and theory-related material (Bell et al., 2019, p. 519). As a tool for narrowing and interpreting the data, we transcribed the semi-structured interview recordings using Microsoft Word and NVivo. Most of our semi-structured interviews were done in Norwegian and had to be translated into English. However, we also had cases where we used English and even Norwegian/Swedish as a preference from the interview object. Furthermore, quality assurance is an integral part of the research. To ensure this, we compared the transcripts to the recordings multiple times. This was done to make sure that the data from the interviewees were not misquoted or taken out of context.

Through NVivo, we managed to break down the vast amount of data in the transcripts into different themes and topics. We systematically sorted relevant details from the vast number of transcribed notes; further systemized and color-coded in Microsoft Excel and NVivo. This enabled us to search for similarities and differences in how participants see and interpret the topics addressed. Due to the

critical part data analysis plays in research, we continuously worked together to discuss the different findings and how they should be sorted and presented.

3.4.2 Quantitative data analysis

The datasets retrieved from the Norwegian and Swedish Medicines Agency contained a vast amount of data, with some similarities and differences. The first order of attention concerned the period we wanted to analyze. The Norwegian data sets were provided monthly, while the Swedish were only given yearly. An important part became to standardize the datasets for the data analysis. We decided to extract the monthly data from January each year from the Norwegian data set and December for 2021, to allow for comparability with the Swedish data. This was possible as the monthly fluctuations in MAHs were close to non-existing, as entrants and exits lasted over longer periods.

The second stage of this process revolved around determining the substance-level we wanted to focus on. ATC codes are the international system for drug classification. The codes are divided into five levels: one anatomical, two therapeutic, and two chemical. The obtained datasets from Norway were given on both ATC level 4 and 5, while the Swedish were only given on ATC level 5. The data sets also contained information on the specific strengths and substance form. Due to a lack of knowledge into what levels the health agencies perceive as the issue, we decided to hold meetings with SI to establish this insight. From the meetings, we received recommendations to analyze the issue on ATC level 5.

After establishing the standardization of our dataset and the level of analysis, the next step concerned data cleaning and preparation. While the data acquired was reasonably well-organized, some level of cleaning was required. Firstly, MAHs were listed for each strength and form within an ATC code. Meaning, that for one antibiotic with different forms and strengths, a single MAH could be listed several times. Due to the limitations of the data, substance form had to be included when looking at registrations and de-registrations. For the categorization of MAH, we removed multiple entries for the same ATC to not count suppliers multiple times. Secondly, a minority of the MAHs were internal suppliers and not relevant, while some MAHs were listed multiple times with sub-organizations of the same company. The analysis could begin with the datasets finally prepared and the levels

specified. We merged the two datasets in Microsoft Excel and developed pivot tables with the different years, ATCs, and suppliers. From these pivot tables, we could further present the findings in different tables, graphs, and figures carefully chosen to present the data in an easily understood way.

3.5 Quality of the research

For assessing the quality of business research, emphasis is placed on three criteria. Reliability, replicability, and validity are the most prominent criteria for evaluating business and management research. It should be emphasized that replicability in business research is not very common. Therefore, we primarily focused on reliability and validity, as described by Bell et al. (2019).

3.5.1 Reliability

Reliability addresses the consistency of the measures, including inter-observer consistency and the stability of the actions (Bell et al., 2019). We have presented insights into the Norwegian market of generic antibiotics through our research process ranging from thorough literature searches, interviews with stakeholders, and quantitative data. The process ensured we gained a holistic perspective of the market, which increased the reliability of the study.

3.5.1.1 Internal Reliability

Internal reliability refers to whether members in the research project agree with the observations in the data collection (Bell et al., 2019). In this sense, we found it essential to ensure internal reliability through the concept of objectivity. Although objectivity is said to neutralize subjectivity and make the recipient a passive observer of information (Ratner, 2002), we found it necessary to use objectivity to not draw conclusions and direct interviewees and our quantitative data in a specific direction. Additionally, the researchers' objectivity was ensured by both participating in the interviews as well as discussions after the interviews to ensure an objective view of the data collected.

3.5.1.2 External Reliability

External reliability refers to what extent a study can be replicated. However, case studies can be difficult to replicate as social settings and circumstances differ (Bell et al., 2019). With it being a newly applied topic within the pharmaceutical industry,

replicability could be applicable to small high-income countries due to the participation of global actors. Although we encountered issues concerning secrecy and sensitivity, especially in terms of willingness to share proprietary information, we prioritized taking directions to ensure external reliability for the research. We argue that our study can be applied to other countries and generic medicines, and used as a reference to make evidence-based decisions for practitioners.

3.5.2 Validity

In terms of business research, validity is concerned with the integrity of the results generated from a research study. To assess our research's validity, we will examine internal and external validity in this section. Internal validity is related to causality, the relationship between cause and effect. External validity concerns whether the results of a study can be generalized beyond the research context (Bell et al., 2019). Bell et al. (2019) argue that validity is primarily relevant in quantitative research. As we utilized mixed-method research, we had to be aware of both quantitative and qualitative data validity. As the secondary data was not gathered through our research, the two measurements mentioned had to be assessed. We had to be critical of the validity to see if it was applicable in our study.

3.5.2.1 Internal Validity

One of the main difficulties with qualitative research is that it rapidly generates a large, complex dataset because it relies on unstructured language (Bell et al., 2019). Internal validity was secured by having interviews with a maximum of two interviewees from the same organization in our data collection. Although our interviews tended to only have one participant, we ensured a thorough process in finding the most competent option from each organization. This ensured that the interviewees were not restricted from sharing necessary information. The answers were cross-checked by both researchers, with audio recordings or additional documentation (e.g., documents and reports). Neither responses from interviewees nor information about who participated were shared with others during the research. We found it essential to not be overly captivated by the immense amounts of data presented, as it could make us unable to interpret the data´s broader significance. We had to make sure that the data was not manipulated into supporting the initial thoughts we had beforehand.

3.5.2.2 External Validity

Ensuring external validity can be challenging in qualitative research as they are often limited to smaller samples (Bell et al., 2019). A case description is provided in section 4.1 to help other researchers determine if the research can be used in different contexts. Although our qualitative data consist of a small sample containing twelve participating actors, the relevance of participants is high. We made sure to interview a mix of small and medium-sized enterprises and huge global organizations to get insights from all angles. The quantitative data also highlights the market trends in two small high-income countries where the market size in one is twice the size of the other. This emphasizes the growing concerns within PSCs, and the applicability of our findings is transferable to other countries as an incentive to create longevity and sustainable markets.

3.6 Ethical considerations

Ethics in research projects is essential for researchers to be aware of when conducting business research. Multiple ethical issues may arise, and it is crucial to handle them adequately. Four main ethical issues must be considered when designing and conducting research. These are *avoidance of harm, informed consent, privacy, and preventing deception* (Bell et al., 2019). Our research was conducted with all these ethical considerations in mind. The aim and purpose of the research were explained to all participants through an information letter (Appendix 3) and, if necessary, explained more in-depth before the interviews. Having confidentiality agreements and non-disclosure agreements before conducting the interviews addressed the ethical issues beforehand and was an important tool to utilize. With the 2018 regulations set by the European Union and the General Data Protection Regulation (GDPR), this has become a core concern in business research. As mentioned in the data section, following GDPR through our interviews was a must to use the data (Bell et al., 2019). Addressing this beforehand and following NSD's data handling plan provided a firm foundation for the issue (Norsk Senter for Forskningsdata, 2020).

The information letter contained a thorough description of the project. This explained how we would use the data and their rights in accordance with GDPR. Each participant had to consent by replying to the email or signing the information letter. Transcription of the interview was not sent to participants without explicitly

requesting it. Further, each participant was anonymized by giving them an "identifier code," and their names were stored on a password-protected server. Having complete anonymization enabled us to use the data by the agreement given in the consent, which essentially made the data rawer and freer from undesirable alterations. With that said, participants had the right to withdraw from the project without any further explanation.

4.0 Empirical findings and analysis

The following section presents the quantitative and qualitative findings and analysis. The objective of the thesis was to investigate and understand how the inclusion of environmental criteria influences the market and supply chains of generic antibiotics. This was done through a holistic view of the market, ranging from public procurement agencies, pharmaceutical organizations, and suppliers (MAHs) both past and present in the market. When referring to the supply chain, we refer to all actors involved, from API producers to the national procurement agencies.

We began our analysis by gathering quantitative data about the existing and deregistered MAHs in the market of generic antibiotics from Norway and Sweden. The findings created the context for further interviews and empirical data, assessed and connected in the coming section. The findings will be discussed and related to the literature, creating the foundation for the conclusions. The first section of this chapter will present the description of our case study, followed by a presentation of current challenges for generic antibiotics. Thirdly, we will introduce the first tender with environmental criteria, providing the foundation for our research angle. Fourthly, we will present our quantitative findings from the market of generic antibiotics in Norway and Sweden. Finally, we will present our empirical findings from the interviews.

4.1 Presentation of case study

The object of the case study was the Norwegian market for generic antibiotics. Norway is one of the leading countries in environmental considerations and is, to our knowledge, the first to award environmental criteria in pharmaceutical tenders. The objective of the study was to investigate the perceptions of how awarding environmental criteria has affected the market in terms of longevity, availability,

and reliability of suppliers and antibiotics. The organization responsible for the introduction of these criteria in Norway was SI.

The Norwegian healthcare sector is organized into three primary levels; national, regional health authorities (RHAs), and municipalities. As the research focuses on generic antibiotics, which fall under the specialized health service, the national and municipality levels will not be further explained. The specialized health services consist of the four regional health authorities who control the provision of 26 health trusts (Regjeringen, 2021). The specialized health service can in short be explained as all services in public hospitals, institutions, and pharmacies. Essentially, the four RHAs own the public hospitals and the Norwegian hospital procurement trust (SI). A simplified overview of the specialized health service is shown in Figure 3.

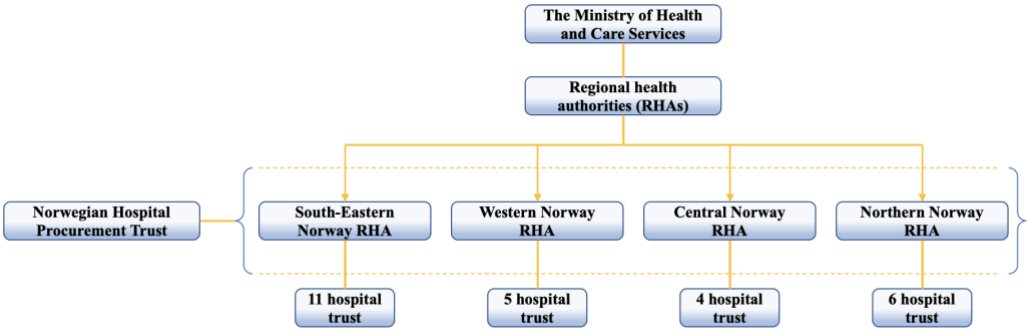

Figure 3. Simplified overview of the specialized health service adapted from (Regjeringen, 2021)

SI was formed from a merger of the Pharmaceutical Procurement Cooperation (LIS) and Procurement services for Health Enterprises Ltd (HINAS) in November 2016. SI contains six divisions, one of them entrusted with procuring pharmaceuticals for the specialized health service (Sykehusinnkjøp, 2022). The main objective is to give quick access to effective pharmaceuticals at the lowest possible price. SI prepares for tenders by forecasting the medical need per medicine. They coordinate the tender processes every year under strict application of the Public Procurement Law. Furthermore, each RHA estimates its needs per medicine based on the previous year's consumption, where SI negotiates the prices on their behalf. The starting price is usually based on the average of the three lowest prices in selected European countries and offers should contain a 5 percent discount on each item number in relation to the current maximum AIP (Apotekenes innkjøpspris). AIP is the maximum price set by SLV for the procurement of pharmaceuticals in the

Norwegian market (SLV, 2016). In essence, the provider with the best relationship between price and quality will enter into a framework agreement with SI. A framework agreement means that the buyer (SI) is not obligated to procure a specific volume during the agreement period of 24 months, whereas the provider is obligated to provide a specific volume to the buyer (Sykehusinnkjøp, 2021a).

In 2021, SI finalized 918 tenders with a total value of 20.5 BNOK, while the total value of their tender portfolio accumulated to 47.4 BNOK (Sykehusinnkjøp, 2021b). In contrast, yearly expenditure on antibiotics in Norway only total around 100 MNOK (P9, P10). While our case revolved around public procurement, the focus was not on the procurers' views but on gathering insights from all relevant stakeholders in the market, either directly or indirectly affected by tender policies. The research aimed to gain insights on the effects throughout the supply chain. However, data are only collected through tier-1 suppliers due to difficulties in identifying the companies further down the supply chains and willingness to participate. Furthermore, our case study begins with the first tender, including environmental criteria in 2019, further explained later.

Norwegian public tenders organized by SI are published on the website Mercell. Before the publication, SI specifies details regarding the contract such as length, specific details regarding demands and responsibilities for suppliers, and others. The detailed tender and contractual specifications are then published and open for possible suppliers. A requirement for participating in the tenders and supply to the Norwegian market is to have an active market authorization (MA). However, suppliers can participate without MA as long as they can document ongoing registration. A MAH is a company or legal entity that is authorized to market and distribute a pharmaceutical in one, several, or all European Union Member States (EudraGMDP, 2021). The MAH's responsibility is to ensure compliance with current regulations and on behalf of their partners (e.g., manufacturing sites). This includes requirements for distribution, pharmacovigilance, and good manufacturing practice (GMP) (EMA, 2021). Within the European Economic Area (EEA), the Member State's national competent authority (i.e., SLV in Norway) issues MAs. Figure 4 illustrates a simplified supply chain of generic antibiotics in the Norwegian specialized health service. The suppliers in the industry can either own and control the entire flow or only parts of it.

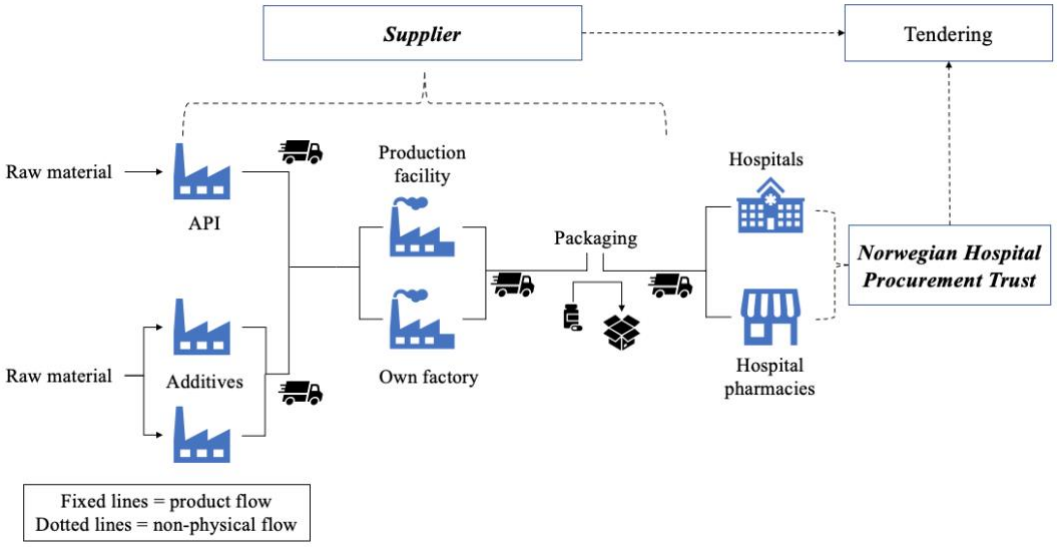

Figure 4. Simplified generic antibiotics supply chain in the Norwegian specialized health service adapted from (Lonaeus, 2016).

4.1.1 Challenges with generic antibiotics

Unreliable access to important antibiotics due to low prices are a significant concern, where Norway has reported a critically insufficient number of MAHs for important generic antibiotics (Helsedirektoratet, 2019). The problem is not new in literature and academia and has been highlighted in several conferences between key stakeholders (Cogan et al., 2018; WHO, 2019). In June 2021, the challenge was discussed at the G7 meeting, highlighting the importance of the subject (G7, 2021). The issue has also been prioritized in the EU, where reports on the problem and possible solutions have been presented (Roland Berger, 2018). Amgros (2019) and WHO (2019) illustrate an overview of the lifecycle of generic medicine, shown below in Figure 5, which explains the low price seen in the markets.

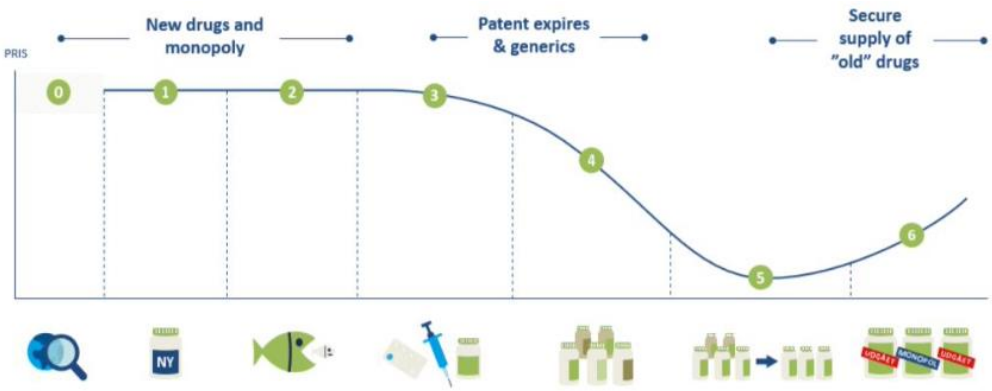

Figure 5. Generic medicine lifecycle (Amgros, 2019)

There have been low levels of antibiotic innovation in recent history, where some have been generic for many decades. When an antibiotic or other medicine loses its intellectual property protections (phase three), it becomes subject to generic competition by new entrants (Figure 5). Consequently, the competition drives the price down (phase four) until the market becomes *"too efficient"* or *"overpopulated"* and the number of actors is reduced as companies leave the market due to lack of profitability. Accordingly, this makes the product more vulnerable to disruptions and supply chain-related problems (phases five and six) (WHO, 2019). The market in phases five and six is subject to high market power for procurement organizations due to aggregated or pooled purchasing on a public level. The tenders have previously only focused on price, allowing for no other competitive comparison than price. These factors have led to intense pressure on prices for suppliers.

The price pressure in tendering is one of the leading causes of production in low-cost countries outside Europe. In a report from 2018, the issue was thoroughly described, illustrating the main drivers of the issue from local and global factors, as shown in Figure 6.

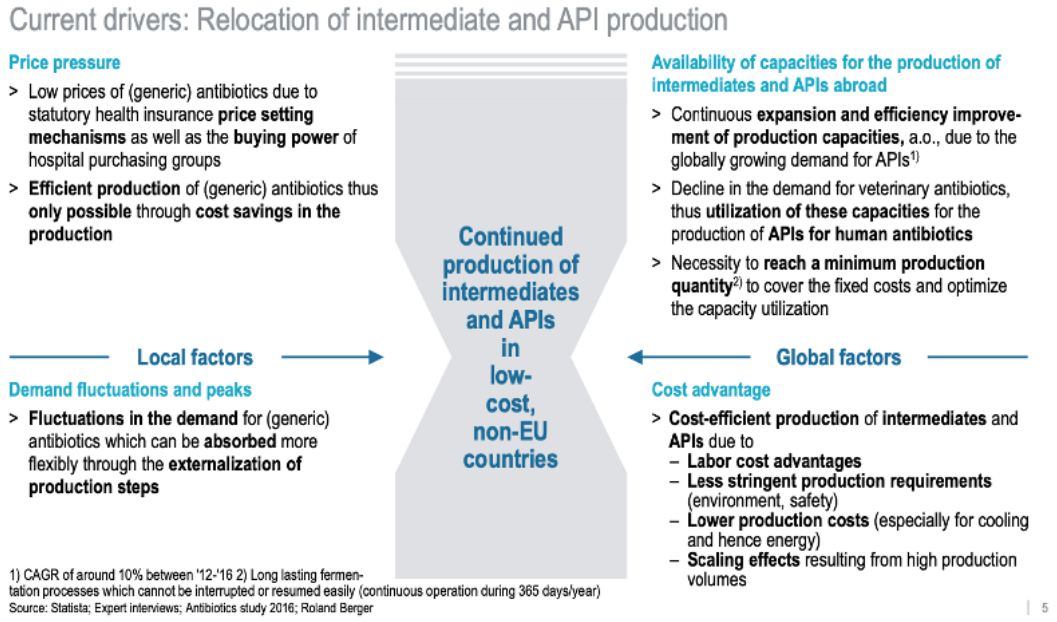

Figure 6. Main drivers (Roland Berger, 2018)

This issue has called for urgent action in the European Union, as the relocation of intermediate and API production comes with multiple challenges for countries and

procurers. One of the most imminent challenges is the increased supply chain complexity that comes with global sourcing and longer pipelines. This further leads to transparency, visibility, and collaboration difficulties. The dependency on importing from low-cost countries also contributes to an increased risk of supply shortages. Roland Berger (2017) points to multiple sources of these shortages. Firstly, the industry demands increased quality requirements that all manufacturers cannot fulfill. Secondly, the closing of other manufacturing plants in different countries and concentration in the low-cost countries removes alternative suppliers during shortages. Finally, the production facilities have static capacities of foreign intermediate and API producers, where local demand has prioritized coverage in the case of shortages.

4.1.2 Tender with environmental criteria

The pharmaceutical market is a constantly evolving competitive environment where the costs are increasingly weighing on the specialized health service budget. When looking at the global medicine expenditure, there has been a significant increase in the last decade and is reported to be nearly doubled when comparing the expenditure in 2010 to the forecast for 2024 (Statista, 2020). In Norway, expenditures on pharmaceuticals have continuously increased and were reported to be 8.7 BNOK in 2018 (Sykehusinnkjøp, 2021a). In contrast, the market for generic antibiotics struggles with low prices and profit margins for the suppliers, as most of the increased expenditure is related to patented antibiotics. Although the goal is to procure pharmaceuticals at the lowest possible price, SI has experienced that this approach in the generic antibiotics market is not sustainable and will not provide longevity of supply (P9, P10). Suppliers are withdrawing, leaving only one or two providers for critical antibiotics, threatening public health. With the desire to have cleaner production, less emission, better local conditions, and availability, SI incorporated environmental criteria in the antibiotic tender launched in 2019 to be used as an awarding and evaluation for the tender winner in 2020 (Sykehusinnkjøp, 2021a).

An important aspect of the awarding criteria was that it was based on the willingness and incentive placed on suppliers to achieve them, and not on stringent environmental surveillance. This becomes essential as the market for many

antibiotics is perceived as unattractive, and further penalization would increasingly reduce the incentive to enter or stay in the markets. This entails that a MAH could win the tender with a higher price than a competitor due to a higher score on the environmental aspect. In contrast, environmental criteria could also increase the risk of losing the tender when suppliers are not willing or able to adapt to environmental concerns in their supply chain.

Norway and Sweden have made significant strides to improve the environment, where the first requirements in Sweden were linked to the public procurement of medicines in 2003. The difference between Norway and Sweden is that Sweden has worked quite well with the criteria to be set but has not fully succeeded in weighing the answers to the requirements in tenders (P13). This was emphasized by P6, who states that "the difference between Norway and Sweden is where there are environmental requirements as an evaluation and award criterion in Norway, Sweden has contract terms. These are two very different things- there is almost no need to attach anything in Sweden". The Swedish contract terms leave limited needs to attach and follow up on the criteria, whereas Norway has detailed requirements for information. Hence, it has not been considered when deciding who will win the tender in Sweden. In contrast, Norway awarded environmental requirements in the antibiotic tender, where they used lawyers and communicated with suppliers to look at the various criteria and whether they were feasible. They consider and award the answers, which differ from Sweden, the UK, Denmark, Finland, France, etc. They are the first public procurers in the pharmaceutical industry that forced through the weighting and analyzed the answers accordingly (P13).

Since then, several tenders with the inclusion of environmental criteria have been completed in Norway. The growing expectations of safeguarding corporate social responsibility have stipulated that: "The Health Trust shall be a driving force for ethical trade and environmentally-friendly procurements" (Sykehusinnkjøp, 2021a). This has resulted in modifying the tender award criteria from solely price to the criteria and corresponding weight found in Table 5.

Table 5. Awarding criteria (LIS 2201a, 2020)

Criteria/ sub-criteria	Weight	Weight by category
Price (P)	*25%*	*25%*
Ease of use, packaging, and product range (PP)	*30%*	*30%*
Delivery security: Sales in several countries (LP1)	*4%*	*15%*
Delivery security: Joint Nordic packaging (LP2)	*1%*	
Delivery security: Stock (LP3)	*10%*	
Environment at supplier level: Strategy (ML1)	*7.5%*	*30%*
Environment at supplier level: Risk management and Environmental audits (ML2)	*7.5%*	
Environment at supplier level: Procedures for Environmental audits (ML3)	*7.5%*	
Environment at supplier level: Production and emission (ML4)	*7.5%*	

The emphasis on criteria can differentiate between tenders, but these are obtained from one of the newest tenders with environmental criteria (LIS 2201a, 2020). A detailed overview of the environmental criteria in LIS 2201a can be found in Appendix 2. Current practices of SI do not award contracts solely based on criteria related to environment and transparency, but rather incentivize and enable other drivers to compete on. Contract awarding criteria is divided between so-called "musts" and "shoulds". "Musts" refers to requirements that the suppliers must meet, while "shoulds" refer to additional criteria which could award contracts besides price. Appendix 2 shows this distinction where criteria marked with S are "musts" and B are "shoulds". This is an essential distinction as it implies that markets with only one actor can still win tenders without considering the additional criteria.

4.2 The Norwegian and Swedish Market for generic antibiotics

A crucial part of our study was to establish an understanding of the current challenges and characteristics of our chosen markets. While the issue has been highlighted on governmental levels, a full analysis has not been done to assess the current situation.

The analysis began by examining all MAHs in the Norwegian and Swedish markets in the period from January 2016 to December 2021. The data gathered contained information about whether the MA was still active or the date of deregistration. This data consisted of MAHs at substance levels, meaning that the MA differs between form and strength. Figure 7 illustrates the number of MAHs for all generic antibiotics from 2016 to 2021, with new registrations and de-registrations from the number of active MAHs at the start of 2016.

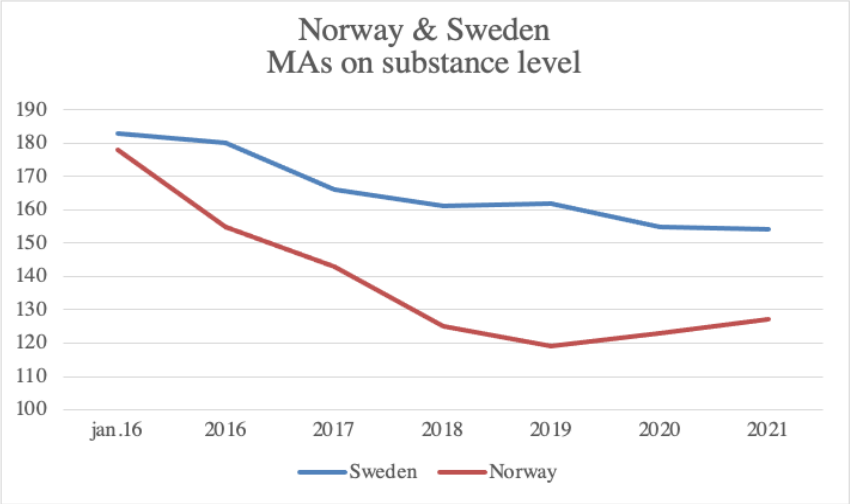

Figure 7. MAs on substance level for Norway and Sweden

From the above figure, we can identify that both markets have experienced rapid declines in the number of MAHs for antibiotics since 2016. The Norwegian market has seen a 29% decrease in the number of MAHs in the period, while Sweden has seen a 16% decrease. A more thorough analysis can be seen in Figure 8. The graphs illustrate both new registrations and deregistered MAs, which form the basis for Figure 7.

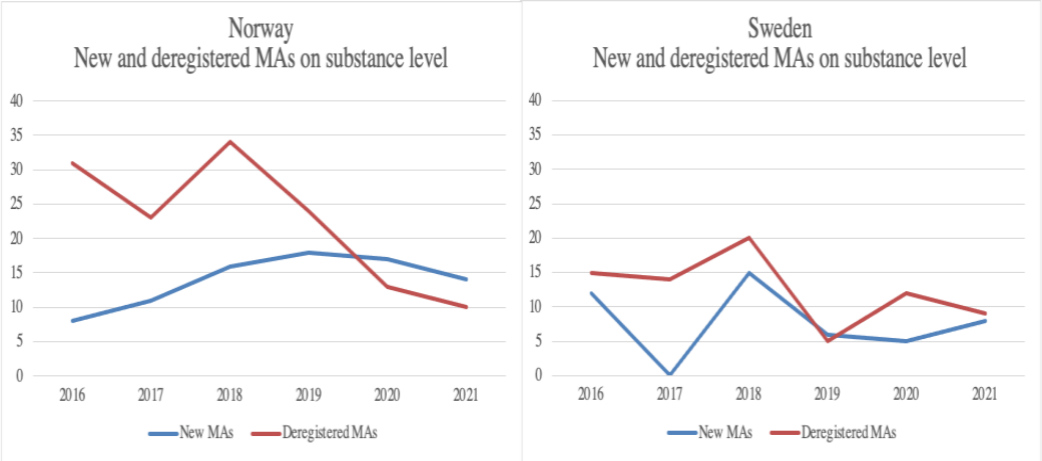

Figure 8. New and deregistered MAs on substance level

While the previous figures provide an understanding of the pressing issue seen in the market for generic antibiotics, they do not tell the whole picture. As the representatives stated in one of our interviews, the total number of MAHs is not that relevant because it cannot explain where the critical areas are (P9, P10). De-

registrations do not represent public health concerns if there are still a sufficient number of MAHs to serve the market. Yet, it is challenging to know what this number is.

To gain further insight into the current market situation, we utilized the quantitative data collected for categorizing the number of MAHs per ATC. Due to limitations in the datasets provided and the time constraints in our research, a decision was made to analyze and categorize MAHs on ATC level five through discussions with the representatives from SI. An essential aspect of the categorization was to understand how the public actors perceive the different levels of MAHs for antibiotics. We held a meeting with SI to gather this insight to discuss the specific subject. Their answer was given in the following quote:

> "*We perceive ATCs with three or more MAHs as healthy, ATCs with two as concerning, while ATCs with only one MAH are perceived as critical situations*" (P9, P10).

The data were then analyzed and categorized based on the given answer, where the results can be seen in Figures 9 and 10.

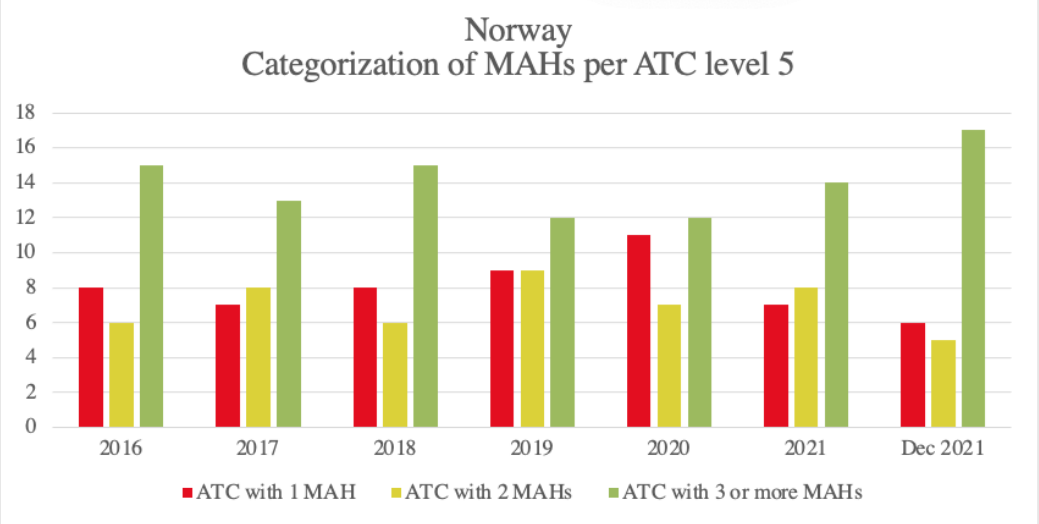

Figure 9. Categorization of MAHs in Norway

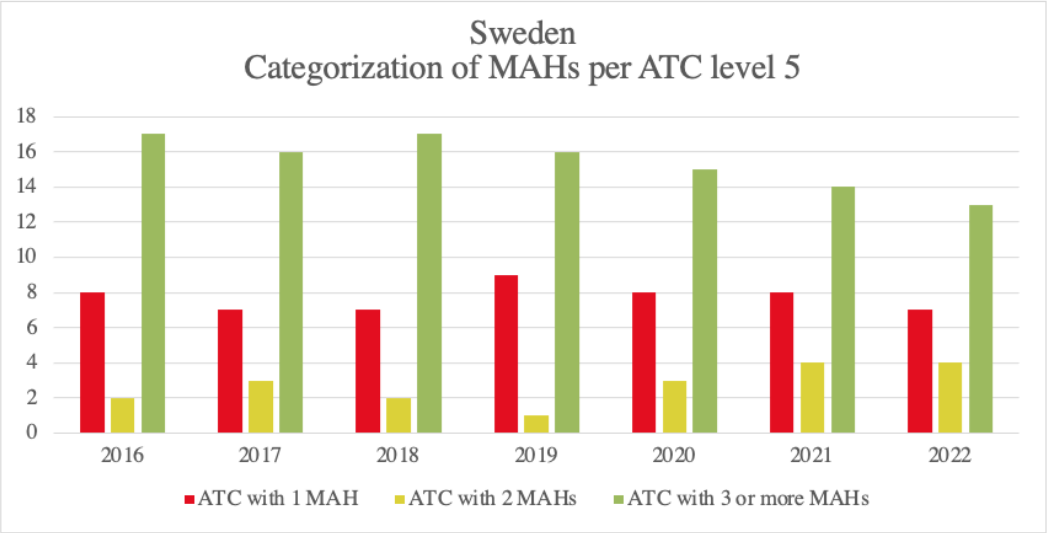

Figure 10. Categorization of MAHs in Sweden

The most important finding from the analysis is that a high degree of ATCs only has one active MAH for both the Norwegian and Swedish markets, which was categorized as critical by SI. For several years, Norway has almost as many ATCs characterized as critical as there are healthy. If any of the MAHs of these ATCs decide to leave the market, the countries will have to resort to non-standard measures to secure the related antibiotics, which may result in shortages. Following the introduction, if the country is unable to source narrow-spectrum antibiotics, broad-spectrum antibiotics must be used, which hastens the development of AMR. While the Swedish market appears to have more stable levels of critical and healthy markets, the Norwegian market seems to have higher fluctuations of MAHs. Furthermore, Sweden appears to have a higher distribution of healthy markets than Norway. The data shows that Norway experienced an increase in critical markets and subsequently yearly de-registrations until 2019/2020 when the first tender with environmental criteria was introduced. The market illustrates a trend toward more healthy market situations since the introduction. However, the data is limited and cannot be perceived as a significant finding. Further research could provide more robust findings when data on more tenders are available.

To cope with abnormal situations, shortages, and supply chain risks, the Norwegian government developed a list of prioritized medicines to have in national storage. The list is called the B180 and has been developed through a collaboration of a specialist group consisting of doctors, pharmacists from regional health care, SLV,

SI, and Mangelsenteret. The group utilizes multiple criteria in the selection, such as the risk for patient groups, cost of society in the face of shortages, risk of shortages, and the cost of the medicine (Sjukehusapoteka Vest, 2021). We decided to extract the generic antibiotics from the list and likewise categorize the number of MAHs per ATC for further analysis (Figures 11 & 12). While Sweden does not utilize the same list for prioritization, we applied the same extract in our analysis to see if there were any differences or similarities.

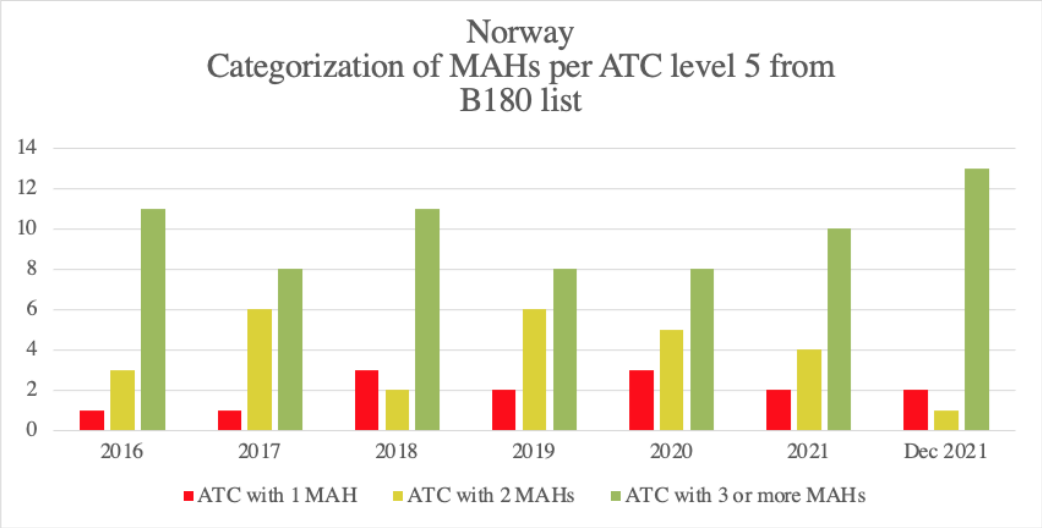

Figure 11. B180 list: Categorization of MAHs in Norway

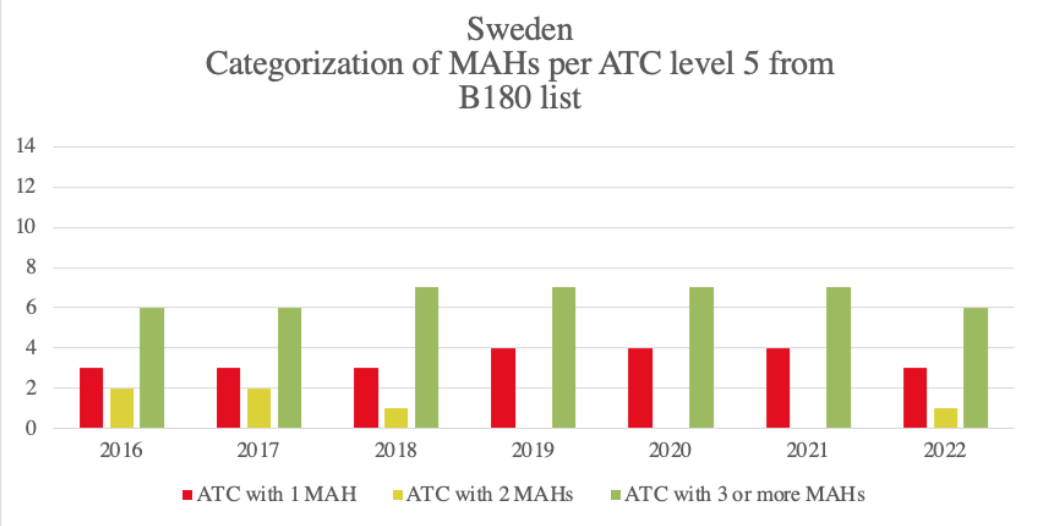

Figure 12. B180 list: Categorization of MAHs in Sweden

One of the most interesting findings from the B180 figure is that almost all ATCs on the B180 list are considered healthy market situations, especially in Norway. Compared to the graph of all generic antibiotics, the percentage of healthy markets

is significantly higher for the B180 list. Furthermore, Sweden has more ATCs defined as critical markets, in contrast with the graph of all generic antibiotics compared to the Norwegian market. This poses interesting questions regarding the differences perceived in the two markets, both for the complete list and the B180 extract. Why are there more healthy markets in the B180 list than the complete list of generic antibiotics, and why does Norway have less critical ATC markets than Sweden for the same list? To obtain context regarding these findings, we scheduled an interview with SI, who holds insights into the pharmaceuticals and the list. One of the main arguments was that the antibiotics included in the list were primarily narrow-spectrum, and of those with the highest volume used in Norway (P9, P10). This could argue that volume and reliability of demand are a vital part of the decision making for suppliers in the market.

4.3 Perceived challenges in the market

The previous section established an overview of the current market situation in both Sweden and Norway. The findings presented critical situations for many generic antibiotics. To understand the reason behind this data, an integral part of the research was to gain insights into the current challenges in the market, as perceived by the actors involved.

4.3.1 Policies, market size, and volume

Compared to other markets with several suppliers, the generic antibiotics market has become a market with few suppliers and less freedom (P1). The market is also highly diversified in terms of company size. A recent trend is that smaller companies get a higher market share because bigger companies are withdrawing from the market or have become more selective toward antibiotics with higher margins (P1). Moreover, one of the main issues in the Norwegian and Nordic markets for generic antibiotics is that the authorities have policies regarding the usage of antibiotics. They want to use the least amount of antibiotics, and if you are to use something, it should be the narrow-spectrum, older antibiotics, particularly those launched in the 1960s. This means that suppliers must update the file to be approved in the 2022 standard, which has relatively high costs. P4 summarizes the challenges in the market as:

> "First, *the authorities do not want to use antibiotics. Second, the market is declining. Third, the prices are extremely low. Finally, very low earnings and low volumes*" (P4).

Hence, the accumulated production is not a high priority for the suppliers simply because of the small markets (P4). The Nordic policies result in very little resistance but make the markets extremely vulnerable (P8). To exemplify this issue, P1 further emphasized that *"[..] We will soon be alone on one of the substances we have, almost throughout the Nordic region. It is now being deregistered in another country in the Nordic region, which is very vulnerable for the market but good for us".*

The policies mentioned contribute to the low volume demand in the Nordic countries. The data provided showed that some antibiotics only use a substantially low number of packages each year, making it highly unprofitable to produce in such low quantities. The low volumes are therefore deemed challenging as there is 1) uncertainty around the needed volume, i.e., how much to deliver during the tender period, and 2) the low volume per antibiotic. This is exemplified by P1, who states that "*there is a reason why antibiotics are a niche industry; it is not where the large volumes lie*" (P1). These challenges do not apply to all markets as emphasized by the B180 list as seen in section 4.4. These antibiotics were characterized by more stable demand and predictability, showcasing a higher number of suppliers.

4.3.2 Price

As public tenders aim to secure the lowest possible price, the Norwegian market for generic antibiotics has been exposed to constant pricing pressure. This has become a concerning challenge in PSCs as it has driven prices and profit margins to a precarious and potentially unsustainable level. Our findings further emphasize this issue as all participants addressed their struggles with price and profit margins. P7 states that "*great price competition and pressured prices are the biggest challenges for us as suppliers*". The locked prices are also seen as an issue where tenders are over a long period, thus prohibiting increases in unforeseen times. Hence,

> "[..] *The price challenges and bad price agreements that apply for a long time are difficult and can lead to "shortcuts" (without me saying that it is done), but it is quite difficult to be tough in pricing*" (P5).

This could result in suppliers providing a lower price than what is needed and are quickly locked into an unprofitable agreement. Therefore, the unit price of low-volume products should be significantly higher (P4). It becomes essential that suppliers have profitable products, as they cannot sell at a two percent margin (P6). For suppliers, price per unit is only one of the concerns as they must also consider the volume for total contract value. The previous segment explained that forecasted demand is only an estimate and not a guaranteed order volume. The total contract value is therefore subject to significant uncertainty, and in combination with the low price per unit, creates a difficult market to operate in. In terms of delivery prioritization for substitutes during normal or abnormal situations, the volume can become a problem as suppliers failing to win the tender have allocated their supplies to other markets. This is emphasized by P2:

> "*When you lose a tender and are out for two years, that volume is allocated to other markets. If the price is so low that one hardly goes in plus, it goes without saying that in the long run, you will have a situation where you may have only one or two generic suppliers left*" (P2).

Some generic antibiotics have higher costs than the prices set by the authorities (P1). In this case, more requirements could become problematic. Especially if suppliers must spend extra money on developing a product to meet the criteria, "[..] *then you must get paid for it*" (P7). P1 further emphasizes that there are no possibility of entering new (old) markets when they look at the price levels and that the AIP must be regulated in the Norwegian market (P1). P2 pointed out that:

> "*If you want to maintain more players to stay in the market in the long run to get generic competition, the authorities cannot just look at the price. It is not sustainable. In this sense, a price guarantee will help. This is an area where prices are terribly low*" (P2).

The market has seen a shift in recent decades towards moving production to low-cost countries like China and India, however, this is difficult to verify due to the opaqueness of supply information. This indicates that if the price is the only thing that counts, suppliers must buy from factories in low-cost countries to achieve profit (P2). There is also a decreasing shift in the number of API producers who operate in the market, making the suppliers and consumers more vulnerable to disruptions and securing supply, especially when everyone uses the same source (P5).

A frequent suggestion and current hot topic amongst researchers and practitioners are to move production to Europe. P4 states that "*the market is experiencing a shift from suppliers in many of them moving their production facilities to Europe*". Two suppliers expressed that having production in Europe should be an advantage in tenders and be awarded accordingly (P2, P12). One participant claimed that having production closer would also generate better safety and security in relation to delivery (P4). Another suggested solution would be to have a third party solely focusing on approving API facilities, which essentially would generate much more control of the supply chain (P6). Approval in this sense would prolong the regular GMP and focus on other aspects not currently available. It has also been discussed to move production even closer geographically to Norway. However, P11 argues that "[..] *the incentives to start in-house production for a small market are absent*". This is further supported by P4, who argues that:

> "*If you think of pure generic production, the cost level in Norway is too high, but if you see products that may have an annual cost per patient of NOK 300,000-30,000,000, there are opportunities*" (P4).

4.3.3 Tender form and complexity

A consensus amongst the interviewees was issues regarding unbalanced contracts. The current lack of index regulation and balanced contracts, creating difficulties to commit and participate in future tenders for some suppliers, was emphasized by P5:

> "*The form of the tenders can be a challenge in the future. I know that the big companies and everything they experience now with costs, are*

wondering if there is a justifiable way to get out of a contract - because the obligations become so severe" (P5).

The framework agreements present in today's tenders constitute that the suppliers are obliged to deliver, but there is no duty to buy for the procurer. This means that suppliers need to have stock available at any moment, indicating that a lot is being thrown away if the requested tender quantity from the buyer is not utilized (P6). P7 further explained that if the procurer chooses not to sell or use the forecasted amount, the supplier is left with an extensive number of products. On the other hand, if it turns out that they sell more than what is estimated, there will be a shortage, and the supplier gets a penalty. This can further be exemplified as P12 quotes:

"*When we submit a tender, we do not know what volume we will receive; it can also be changed during the agreement period. It can be a challenge when there is also a low unit price. We have already removed some of these products from our portfolio. We do not spend much time with the cheap and old antibiotics because there were no profits due to the low prices*" (P12).

Moreover, we asked the participants about their perception of the tender length present today. These views varied, as one believed that the current practice used to be preferred but expressed concerns due to the vulnerability of global supply chains as exemplified by abnormal situations, e.g., Covid-19 and the Ukraine war (P5). In contrast, more frequent tenders could work against the desired outcome, as it could weaken the interest and predictability of a supplier that the earnings and volume distributed would not make the hassle worth it (P11). Current operations involve long lead times for production and minimum requirements for production units. More frequent tenders with lower volumes could therefore create challenges for suppliers. P12 also supports this argument as they prefer that it is biennial, especially in markets where prices are driven down from year to year. "[..] *Tenders becoming too frequent will push prices down even faster, so it is better to have longer periods*" (P12).

Building on the frequency of tenders, another expressed concern was the complexity of these tenders, especially when criteria are formulated or

communicated poorly. Several findings from our interviews suggest that the information provided in tenders are challenging and that it must not become too administrative (P1).

> "*There is so much to deal with, many documents. It is not always easy to understand what is needed at the various points in the tender process. There is a lot of information*" (P2).

Product specifications and contents can become a disadvantage in the tender when the requirements are too extensive and not relevant. P1 argues that "[..] *It is negative if things are just done without no meaning. Requirements are being put in place where one wonders why this requirement is here*". Additionally, requirements in being part of different organizations are also seen as a potential issue when adding new requirements in tenders. P1 states that:

> "*We must be a member of all sorts of things. Not only do the countries and the authorities set requirements, but we must also be a member of different organizations and everything else that comes*" (P1).

However, these are concerns that SI is aware of as they state that they "*must make sure that suppliers do not fall out of the process as a result of criteria becoming too extensive*" (P9, P10).

Table 6 depicts an overview of the identified challenges in the market from our findings. The challenges are categorized between external and internal. External refers to challenges where SI cannot directly influence it, and internal challenges are impacted by SI's tenders.

Table 6. Identified challenges

External	Market	Policies
		Market size
		Low volume (demand)
	Price	Price per unit • Low profitability
		Contract value
Internal	Tender form	Unbalanced contracts
		Tender period
		Single winner
		Complexity

4.4 Perceptions of the introduction of environmental criteria

Gathering insights on the implementation of environmental criteria was pivotal for providing a basis for further research and for stakeholders' decision-making. Participants expressed their views on its implementation, where the majority found it to be necessary criteria to spur better practices.

Several of the suppliers interviewed were subsidiaries of large international organizations. The general perceptions from the head offices were positive as they have a strong focus on good environmental stewardship (P1, P2, P5, P12). This view also reasoned with other suppliers, as emphasized by P6:

> "[...] *I see nothing but benefits. We end up with higher prices. We can probably go further with the environmental criteria*".

The focus on having more drivers in tenders is deemed necessary to provide a more sustainable market. Several participants shared this view and would like it to be implemented in other tenders (P2, P6, P12).

4.4.1 Formulation and complexity of requirements

Despite the positive views, several concerns were raised by the participants. For instance, P13 constitutes one main challenge for the procurer and one main challenge for the supplier/recipient. For the procurer, the challenge becomes the formulation of the criteria and how they should be asked. The procurer must be able to assess and weigh the answers' worth, especially if they are to acquire a more expensive product. For the supplier, the challenge is how these questions should be answered and what data is needed. Few MAHs in Norway have personnel who work specifically with sustainability and the environment, these questions often end up with the tender manager who may not fully understand the technicalities. This becomes a challenge, as it is difficult to gather suitable data from the parent company when they do not know what to ask for.

Furthermore, P5 was concerned with getting the requirements as soon as possible, as information must be obtained, and there is a big difference between tenders within and outside Norway. This is supported by P2 who states that:

> "*What may be a challenge is the little time given. It is not always that the environmental criteria are translated into English, so you must do it yourself. It can also be a stressful time, as we need to be in dialogue with the head office to provide answers. Having a little more predictability and having the required information available in English will help us*" (P2).

Others raise concerns about the feasibility of criteria (P1) as "*they cannot be set to look good on paper and be practically impossible*" (P6). P6 further emphasizes that some pharmaceutical companies might find it challenging that Norway has stricter criteria than other Nordic countries, especially if they are not represented in Norway.

4.4.2 Resource allocation

Cost and additional resources allocated towards becoming greener were frequently addressed. P1 says that "*[..] the environmental part must be done properly so that we are not left with spending a lot of money and resources, which makes the margins even worse. Satisfying everyone with different requirements will be a very*

challenging task that takes a lot of time and resources". It will cost more, and if you look at the second most used antibiotic, doxycycline, which is used worldwide, there is no manufacturer in Europe. Including environmental requirements without adjusting prices in markets when there is no production in Europe could become a problem (P8). The incentives to make this standard practice must therefore become more significant for participants operating in countries with different regulations and views on environmental degradation. Furthermore, it is also argued that environmental criteria can award European production and give more control and incentive to maintain European production (P11). P4 further emphasizes this argument:

> "*If you have European production, it will be more sustainable and provide greater reliability. It costs more to produce in Europe than it does in India even if you add transport costs. If the surrounding authorities are willing to take a higher price, then the industry does not mind that more should be produced in Europe*" (P4).

4.4.3 Managing the supply chain

The necessity of having control of the supply base in terms of audits and willingness from raw material suppliers and production facilities to prohibit wrongdoings and sustainable operations were also emphasized (P1, P5). There are some selection processes for subcontractors in place to avoid situations where subcontractors withdraw or have difficulty complying with the requirements (P2). Yet, this could become a pointless process when there is a lack of substitutes. Enforcing these requirements downstream can be challenging as the supply base might be reluctant towards change, sharing proprietary information, and complying with rules from a reasonably small market outside their own country´s regulations. P6 states that:

> "[..]*Where we have MA, we can enforce environmental requirements. Where we are only a distributor, we have less influence. In these cases, we must instead do audits on the environment. Some are feasible while others are not*" (P6).

Having control over subcontractors becomes essential, and that suppliers are willing to state where the raw materials are produced. Especially when production takes place in India and China, where not all factories have sufficient routines or treatment plants (P2). API suppliers' willingness to take on additional costs when they have licenses and approved inspections in their respective countries could therefore be challenging as:

> "[..] *They simply do not have the time if all countries are to have many different requirements"* (P1).

This issue is frequently addressed as suppliers face different criteria in the Nordic countries. Although the market size, narrow-spectrum policy, and culture are quite similar, the similarity in requirements is still different, making the market very vulnerable (P6).

> "*We have requirements from different countries, which is today's big challenge. There is no consensus in Europe on how to operate. Each country sets its requirements for the environment. [..] We cannot have ten requirements in Sweden, something completely different in Finland, Denmark, and something completely new in Norway. For us, it requires an incredible amount of work and costs*" (P1).

Each country has its own national rules within the Nordic countries and outside these countries. This means that the environmental criteria set in Norway must, in many scenarios, override national criteria set in other countries. It becomes a challenging and complex task to do environmental work and satisfy everyone when there are different requirements that use a lot of time and resources (P1). For instance, "*Denmark buys these products without sacrificing anything, and in Norway, we make demands*" (P9, P10). Although Norway and Denmark collaborated in the recently introduced Nordic tender, Norway and Sweden may be more similar when it comes to environmental criteria. While these two countries have included environmental concerns, P6 exemplifies the difference between Norway and Sweden:

> "*The difference between Norway and Sweden is where there are environmental requirements as an evaluation and award criterion in Norway, Sweden has contract terms. These are two very different things - there is almost no need to attach anything in Sweden*" (P6).

This problem is amplified by looking at countries outside the Nordic and European regions. It is difficult for SI to enforce requirements on API producers in low-cost countries where they comply with the regulations given in their respective countries. This difference might be explained as cultural, that there is a variation concerning the importance of things (P1). Consequently, P6 emphasized that "[..] *this could result in producers finding it easier to say that they will not produce for you*" (P6). These difficulties illustrate a concerning point for the cruciality of common requirements for suppliers (P11). Especially when "*Norway has tougher requirements than those with 20 million people*" (P6).

4.4.4 Possibility of withdrawal

Participants were asked whether the introduction of environmental criteria constituted a reason to leave the market and thus make it less attractive for suppliers to operate. The consensus was that no one would leave the market. P4 states that:

> "*I do not think anyone will withdraw due to environmental criteria because it will close the door for further operation. Environmental criteria have come to stay and will only be strengthened in the time to come, which makes sense*" (P4).

P2 argued that although Norway is a small market, it will gradually be adopted globally where one sees a consecutive shift in Europe (P2). P6 further emphasized that "*once you have taken the step to become environmentally certified, it is very strange to get out of it*" (P6). However, some contradictory interpretations were also established. P11 believes that some will withdraw as their willingness to meet the expenses associated with quality increase is lacking, "*it costs more than it rewards*" (P11). P7 further highlights that "*based on the current situation, there is a risk that strict environmental criteria may cause us to choose not to participate*" (P7).

Table 7. Key factors for succeeding

Key factors for succeeding with the implementation of environmental criteria	
• Enough time	• Information sharing
• Formulation of criteria	• Standardization
• Weighting of criteria	• Collaboration
• Feasibility of criteria	• Willingness to change

To summarize, participants' perceptions can be viewed as generally positive as they would compete with other drivers. An overview of the identified key factors is summarized in Table 7. Yet, there are still concerns, especially in terms of complexity, resource allocation or costs, and information sharing. The following section presents findings regarding transparency and information sharing, as it constitutes a vital part of environmental criteria feasibility.

4.5 Transparency

An important aspect of SIs new tender policy is to increase transparency through the supply chain and gather data for better procurement practices moving forward. To improve our understanding of the current level of transparency and its challenges, we included questions regarding transparency and willingness to share information. Our initial interview with SI introduced us to the current practice of transparency:

> "*Transparency in the pharmaceutical industry is often regarded as business sensitive, as suppliers do not want to share information about the supply chain. The place of production is regularly a trade secret. Additionally, some of the companies that deliver in Norway do not own the entire chain themselves and thus do not have full insight into it. The further away you are from the production, the less transparent it becomes. Often, several sub-suppliers supply different companies in the same market for pharmaceuticals. With such few producers supplying the same market combined with the low levels of transparency, we become very vulnerable in shortage situations and long-term supplier reliability*" (P9, P10).

Another characteristic of the market was the change from few and large organizations to smaller niche organizations. While large pharmaceutical

organizations usually represented the majority of suppliers, these have mostly sold their portfolios to smaller specialized generic companies. Furthermore, these niche companies are characterized by frequent exits and new entrants (P9, P10). This was further emphasized by one of the suppliers interviewed:

> "*Compared to other markets with several suppliers, the generic antibiotics market has become a market with few suppliers and less freedom. The market is also highly diversified in terms of company size. A recent trend is that smaller companies get a higher market share because bigger companies are withdrawing from the market or have become more selective towards antibiotics with higher margins. However, the market is still fragmented in terms of size*" (P1).

An interesting question that arises from this finding is how the market shift affects transparency. The respondents in our study varied greatly from large pharma organizations to smaller specialized companies. This enabled us to gain insights into the consequences of this change. One interviewee gave us this answer when asked about the topic:

> "*In terms of competition, a larger company usually has better processes and audit programs in place, making it easier to obtain data and have data. Additionally, larger companies also have greater resources to work on finding the right data*" (P13).

One of the original suppliers who control the entire supply chain highlighted:

> "*It is very transparent what happens with us. It is also very advantageous for us to do the production ourselves because then you have control over it*"
> "[…] *We can go to the API producers to check that things are being done. They also say they are open to doing so. They probably have an agreement with their suppliers as well*" (P5).

Further, suppliers that do not control the entire supply chain also present good availability of information through the supply chain, as described by the following quote:

> "*We get reports on what we need from our manufacturers - some are API producers, some supply raw materials, some assemble finished products, and someone who distributes the product. But everyone shares information and does not have a problem with that*" (P6).

These findings point to the high availability of information in the supply chain to the vertically integrated private companies, but this information is not in the public domain. On the contrary, other interviewees from pharmaceutical organizations not directly involved in the supply of generic antibiotics pointed to the opposite:

> "*The supply chain from raw material to API production to finished product is characterized by secrecy. That one does not know who supplies what. When it comes to setting a climate certification, it is challenging to have an overview because there are so many confidential links in the supply chain*" (P11).

The answers given by the respondents in terms of availability of information and transparency in the supply chain are seen as conflicting. While suppliers argue that they have extensive access to information, other stakeholders argue otherwise. An interesting point that arises is i) whether there is an actual lack of information, ii) whether the procurement side lacks the tools to extract this information, or iii) whether the suppliers lack incentives or willingness to share that information. Several of the interviewees also pointed to the need for several licenses and information provided to different governmental organizations to supply in the market. An argument that arose was that the information was sufficient and available for public organizations, as P1 describes:

> "*The authorities approve the production units; they get licenses issued - then they have inspections. These production units constantly have audits from authorities from different countries. These are inspected all the time. We also inspect the raw material suppliers and ensure they have the right certificates. If it does not match and you get serious findings, you close the factory. It happens occasionally, but not as often in Europe, but perhaps more in other parts of the world*" (P1).

The argument was further emphasized by P5, as all medicines coming from outside Europe will not be put on the market without being analyzed. This entails that the product has the required quality and licenses, but there is still little understanding of the manufacturer`s impact on the environment. These production units are constantly audited by authorities in their respective countries and constitute one of the main arguments from the participants that transparency is present in PSCs.

4.5.1 Willingness to share information

The new tender policy presented by SI is primarily focused on suppliers' willingness to share information about their supply chain and sourcing. An essential aspect of our research was to uncover the party's willingness to provide this information. We encountered a large variety of responses regarding the subject. For example, one of the interviewees presented an apparent openness to information sharing:

> "*There are many companies that say they do not want to state who their API manufacturer is. But is it that dangerous? Why is it so dangerous? Is there really something to hide*? […] *I find it surprising that people find it difficult to provide information about, for example, API manufacturers, etc. I am open to openness*" (P6).

Not all participants shared the same view as this respondent. One of the main arguments mentioned by several interviewees was that the supply chain is competition sensitive. Finding suitable suppliers in the chain is a competitive advantage, and from a business perspective, it is not wise to be open about all information (P11). The subject of information sharing was further contextualized by one interviewee who stated that the data is competition related, further argued by saying that authorities need to respect the fact that there is some secrecy in how the value chain operates in various companies (P4).

An interesting obstacle to information sharing that arose through our interviews was related to trust. Due to the research being primarily done in Norway, perceived as a country with high trust, we did not expect to see this issue. P11 expressed concerns that the authorities could destroy the market dynamics by publishing information.

Other interviewees reported similar concerns, pressing the matter further by expressing the possibility of not participating in future tenders because of it:

> "*It is not certain that things will be confidential, and that is what we suppliers are afraid of. That information is leaking. We also work with other suppliers. We are not the only ones who decide whether we can share this information. Based on the current situation, there is a risk that strict environmental criteria may cause us to choose not to participate*" (P7).

These findings are a cause of concern for SIs new tender policy. The goal is inherently to provide better markets with more suppliers for critical markets. Pressing requirements for information sharing could therefore damage the wanted outcome. Despite the previous concerns from actors, we also gained insights into a current shift in the market. One interviewee underlined this recent trend:

> "*I experience that it has gotten better and better over the years. There has been a shift where more and more people support more openness. There is a greater focus on it, and one cannot sit and think that everything is sensitive information*" (P12).

The change was further elaborated by another respondent, contributing some of the change to the new tender and strategy of SI:

> "*It's business-sensitive, absolutely. As companies understand that there is a business opportunity to be rewarded for sharing information, there is somewhat more willingness to share information about the production processes. Even though Sweden has worked with this and included it for so many years, there was a tendency for those with the lowest price to win anyway. The companies felt that it did not matter that they shared information, the lowest price won anyway. I have experienced a tendency for less openness in Sweden than in the examples I have seen from Norway. There are clear examples from the Norwegian tenders where a product with a somewhat higher price was awarded the contract because of better environmental performance. Then the company is stimulated by its openness. It is not the case that you measure sustainable performance to*

build the companies' name, but you see that when this type of information is shared with SI, you get something back" (P13).

The findings derived from interviews reveal that pharmaceutical companies have started to transition towards more transparent supply chains. Although there is still some discrepancy, the industry is moving towards more openness and needs to do so in meeting environmental requirements set by authorities.

4.6 Solutions and further incentives

Several participants suggested solutions to the issues posed. Procurement in Norway that takes place outside hospitals has, in principle, no environmental criteria. These markets are often supplied by the same suppliers as in the specialized health service. Standardization within the pharmaceutical industry would therefore help significantly. Moreover, the need for European collaboration to influence the market was also emphasized (P8). All participants also mentioned the need for increased prices and profit margins, and that environmental criteria could be "[..] *weighted a little higher than what is done today at the expense of price"* (P2). Other payment solutions and alternatives must also be investigated as argued by P6:

> "[..] *You must look at payment solutions and alternatives. It is a bit bad that there are no balanced contracts. The current standard of framework agreements means that the buyer has no purchase obligation, it is only an estimate*" (P6). P13 further says that "*we really should start looking at new payment models to ensure the availability of these antibiotics in the future*" (P13).

More coordination within the Nordics would also help with tenders, as it would decrease the complexity of information, different requirements, and ease of distribution across borders (P4). This view is also shared by P1, who thinks that "*Nordic authorities should cooperate on the environmental aspect to have a common understanding on what to ask''*. While there may be some discrepancies, the bulk of criteria should be at a Nordic level. Time for gathering information was also mentioned several times as this is a long process, especially when the English translation is needed. It was also emphasized that SI must keep talking with suppliers and ask what is possible, and "[..] *realize that there is a big difference*

between suppliers" (P3). These concerns are emphasized by P1 and supported by P12, who states that:

> "*The most important thing for us is that things do not become too administrative. It must be easy to understand the environmental part. They must work with the supplier when setting these requirements and have good collaboration so that the supplier is always "up-front" because this must be entered further into the system. We must be involved and have time*" (P1).

Participants in our interviews frequently addressed these issues. The concerns about the complexity of environmental criteria and the differences between countries and their utilization. The empirical findings portray strong arguments for the lack of unity and consensus between buyers in the Nordic countries. This is concerning as suppliers have several countries and contracts to deal with. P3 argues that the best solution would be to:

> "*Negotiate this on a European level and make the same criteria for all markets. I do not think it makes sense that each country has a different set of rules and is doing this individually*" (P3).

Another solution would be as several interviewees have suggested and in particular, P12, who states that:

> "*Everything should be in English and digital, where there are English in the packages other languages can be stored digitally. I understand that it must be possible to pick up Norwegian, but then the pharmacies can provide for those who do not understand English*" (P12).

Another solution that has recently been tried to manage this situation was the introduction of a Nordic tender. One occurring challenge is the lack of Nordic packaging and that there are three countries with different currencies further increasing complexity.

> "*The criteria state that the price must be stated in Euro, but neither Norway, Denmark, nor Iceland are Euro countries"* (P6).

Additionally, there are also problems with the requirement of having an MA in all three countries to participate in the tender. P12 suggests that "*one MA would absolutely make the process simpler*" (P12).

Continuing on the improvement areas, increasing profitability significantly, and giving more flexibility in the locked price are also highlighted (P5, P8). This means that when difficult and unforeseen events happen, the price should be flexible and possible to increase in contracts. Multiple winners in tenders are also emphasized, as it would create more predictability for several suppliers. P4 states that "*it is ideal to have three winners so that you divide the market into three parts"*. P2 also supports this as an advantage due to the long period out of a given market, which could be challenging to come back from and thus *"make it more attractive for more suppliers to stay in the market*" (P2). The predictability aspect was mentioned several times by participants, where for instance, P11 states that:

> "*[..] tenders must provide predictability by ensuring that you get a large enough volume or a good enough price while not becoming too vulnerable. One must get a guarantee for a certain volume. It is very vulnerable if you have only one provider*" (P11).

Moreover, working closer together, communication, and better planning are mentioned several times. The main emphasis was better buyer-supplier communication, especially in the formulation and feasibility of environmental criteria. P6 states that:

> "*There is far too little communication today, it comes at the last minute*" (P6)

Extensively pointed out is the lack of collaboration between supply chain partners. Although collaboration within tenders might be uncommon, it is seen as a necessity within the generic antibiotics market and has been frequently addressed throughout this study. Today, there are some mixed feelings about the collaborative efforts within the supply chain. For instance, two interviewees believe there is too little dialog and collaboration between buyers and suppliers (P11, P12), whereas P3 feels

involved in the framework for upcoming tenders. P3 states that "*SI has to keep talking with suppliers and ask what is possible and realize that there is a big difference between suppliers"*. P6 also highlights that there is "*far too little communication today. It comes at the last minute, and they say you must have stock, etc."* (P6). Increased Nordic collaboration between buyers in setting requirements was also emphasized as it would provide more reliable deliveries (P1). P1 also elaborates on the necessity of collaboration between buyers and suppliers:

> "[..] *Must work with the supplier when setting these requirements. You must have a good collaboration with the suppliers so that the supplier is always "up-front" because this must be entered further into the system*" (P1).

Working closer together where there are few MAHs and more start to disappear, it could be a "*solution to set a price, and then you compete on other things*" (P12). The increased focus on preparedness is also seen as essential and has helped in terms of the availability and reliability of delivery. Once again, the necessity of having joint European or Nordic packaging is emphasized, as it would make things easier. In shortage situations, the procurer could obtain delivery from packages with (what used to have different packaging) across borders instead of buying from a different supplier at retail price. This was emphasized by P11, who stated that:

> "*[…] you must do something with the packaging attachments so that the flow of goods can go between the Nordic countries in a much better way than is done today. This will make the market bigger for the suppliers. It will also secure more suppliers at the Nordic level*" (P11).

Hence, suppliers must be allocated a certain volume and awarded for environmental considerations (P2, P3, P8), which constitutes one of our most important findings. The proposed solutions are summarized in Table 8.

Table 8. Summarization of proposed solutions

Proposed solutions	
• Higher prices and profit margins	• New payment solutions
• Increased predictability of demand/volume	• Balanced contracts
• Multiple winners	• Increased buyer-suppler communication

• Standardization
  ○ European and Nordic
  ○ Private and public
  ○ Package attachments
	• Higher weighting of other drivers at the expense of price

5.0 Discussion

The following section presents the discussion of our empirical findings in relation to the existing literature established in the theoretical background. The discussion will answer the following two sub-questions: 1) *what are the current characteristics and challenges of the Norwegian and Nordic markets for generic antibiotics?* and 2) *how can value-based procurement be a driver for transparency in PSCs?* The sub-questions will lay the foundation to answer our main research question: *how can value-based procurement with emphasis on environmental criteria affect the situation and shift the market to more sustainable outcomes?* The section will be summarized through a revised conceptual framework, linking our findings to the existing literature.

5.1 Challenges and characteristics of the market

The theoretical background combined with the analysis provided a firm foundation to discuss the aspects surrounding our first sub-question:

> *What are the current characteristics and challenges of the Norwegian and Nordic markets for generic antibiotics?*

The literature underlined that tendering within the pharmaceutical industry is primarily used to reduce costs. These costs are further reduced for generic medicines as it yields substantial savings compared to the original patented product (Dylst et al., 2011; Petrou, 2016; Wouters et al., 2019). Although this creates

positive short-term effects for the procurer, the literature emphasizes the adverse long-term effects in the market. Our findings confirmed this as all participants viewed the current price level as the most substantial challenge. Moreover, having only one winner resulted in difficulties regarding deliveries under shortages and higher prices for the procurer (Dylst et al., 2019. In shortage situations, procurers would have to buy substitutes at a higher cost, which could become a problem when the API comes from a handful of sources and, in some cases, only one. The utilization of only one supplier is argued to increase the risk of default and potential shortages (Dranitsaris et al., 2017), emphasizing the possible solution of having more winners to minimize the risks. Furthermore, our analysis highlighted the concerns of losing a tender, as being out of the market over a long period makes it difficult to reenter with the low price levels. This stipulates the solution of having more winners allocated a percentage of the tender contract.

The literature also underlined that low prices characterize the market due to the competition and regulations from authorities. Our findings suggest that this issue is prevalent in the Norwegian and Nordic markets, as the strict policies towards antibiotic usage make it a niche industry characterized by, at one stage, many competitors and low prices, and at a later stage, very few suppliers but with the same low prices as a result of the previous stage. According to Shafiq et al. (2021), the low profitability accumulated from low prices is the leading cause of generic medicine shortages. Therefore, delivery reliability is a significant concern in the market, especially emphasized by the recent Covid-19 pandemic. This poses a significant threat to long-term sustainability, especially concerning suppliers leaving the market (Barbier et al., 2021; Petrou, 2016). These characteristics strongly apply to the Norwegian and Nordic markets as well. These markets for generic antibiotics can also be described as lacking innovation, as the constant price pressure makes it infeasible due to the low profits generated (Dranitsaris et al., 2017). Consequently, the market becomes unattractive for new entrants, and previously participating actors lack incentives to reenter (Dylst et al., 2011; Petrou, 2016; Vogler et al., 2017). Our analysis confirms that the market suffers from few suppliers and low flexibility. The challenges of price and unbalanced contracts make it difficult for suppliers in terms of low margins and to endure the tender period as there is no room for adjustments during unforeseen events. The presented

challenges are consistent with the literature, which underlines their presence and significance.

Our analysis confirms that generic antibiotics have experienced rapid declines in the number of MAHs since 2016. The data for new-and de-registrations provides no correlation to show that new entrants pick up the market space for those who exit. This supports the damaging long-term threat of suppliers leaving the market found in the literature due to the price pressure in tenders (Barbier et al., 2021; Petrou, 2016). The generic medicine lifecycle illustrates the challenge of markets becoming "too efficient" when the number of actors is reduced when companies leave the market due to a lack of profitability (Figure 3). These markets are vulnerable to disruptions and supply chain-related problems (WHO, 2019). Our analysis stipulated these issues as we uncovered that a large share of generic antibiotics only has one active MAH (Figure 7 & 8). This threatens long-term availability, where shortages could leave Norway unable to source specific antibiotics. This inability to source narrow-spectrum antibiotics further increases the risk of AMR (Gerber et al., 2018; WHO, 2001; 2019). Another consequence is the aspect of shortages, as markets with only one supplier remove the possibility of dual sourcing better situated when faced with shortages. The findings also provide information regarding the current power situation in the market. Most of the ATCs can be characterized as supplier-dominant. These structures are further connected to higher uncertainty, risks, and dependencies for the customer. A mismatch in the power relationship is further related to a lower incentive and willingness to collaborate for the actors with the greatest power (Cannon & Perreault, 1999).

The findings concerning the B180 list, characterized by higher and more stable demand, illustrate that these antibiotics attract more suppliers and contain more healthy markets (Figures 11 & 12). This underlines that higher and more stable demand increases supplier attractiveness. This was confirmed in our analysis, where participants argued for improved practices in the aspect of demand. The literature stated that current procurement practices have been criticized as overly technical, rigid, and price-focused. This is further argued by a failure to assess other benefits or values such as innovation or environmental and social (Miller et al., 2019). This was consistent with our analysis where suppliers displayed a positive attitude towards extended criteria. While our quantitative data contains a limited

period and number of tenders, we can identify a positive trend with an increased number of MAHs from the first introduction in 2019 and onwards in 2020. Due to the limited data available, these findings cannot be interpreted as significant but provide an interesting tendency and aspect for further research.

Table 7 shows our extended findings on current challenges in the market not prevalent in the literature and the subsequent effect on the market situation.

Table 9. Summarization of challenges

		Analysis	Literature
External	Market	Policies	Policies
		Market size	
		Low volume (demand)	
	Price	Price per unit • Low profitability	Low profitability
		Contract value	
Internal	Tender form	Unbalanced contracts	Single winner
		Tender period	
		Single winner	Complexity
		Complexity	
		Suppliers leaving the market	
		Unattractive for new entrants	
		Increased risk of shortages	

5.2 Value-based procurement- a driver for transparency

Transparency is seen as crucial in regulated industries, where the pharmaceutical industry is one of the most regulated industries, as participants are required to share a set standard of information with the public organizations (Klueber & O´Keefe, 2013). The literature revealed strong evidence of a lack of transparency in the industry (Papalexi et al., 2020). Prior research on the subject argued that increased transparency within complex PSCs could lead to an improved supply of medicines (Årdal et al., 2021) and enable participants to identify potential risks and minimize them accordingly (Gardner et al., 2019). Another important aspect of increased transparency in PSCs is that it could enable more proactive processes when faced

with shortages (Årdal et al., 2021). Information sharing is also crucial in reducing the bullwhip effect (Barrat & Oke, 2007). The literature highlights several critical implications increased transparency could have on the industry. Therefore, one of the most critical findings from our analysis was connected to our second research question:

How can value-based procurement be a driver for transparency in PSCs?

One of the most important aspects of transparency is actors' willingness to share information. The theoretical background established that the pharmaceutical industry faces issues with participants usually sharing the bare minimum of information, especially upstream. The main concern regarding the willingness to share information was a fear of releasing confidential and closely guarded financial or strategic information to partners that could be in direct competition, either now or in the future (Du et al., 2012; Årdal et al., 2021). This concern and skepticism were confirmed through our analysis as actors argued their unease of competitors possibly acquiring knowledge into their supply chain. Some of the interviewees also declared issues related to trust in the governmental organizations, strengthening their apprehension of sharing information. This argument was supported by prior leaks from public organizations and the increased rate of cyber-attacks related to gathering information.

While we encountered the same challenges related to information sharing as identified in the literature, our research uncovered a changing stance in the market. Our analysis revealed that many of the actors in the market show a clear positive stance towards information sharing. For example, some of the interviewees supported fully open tenders, including prices and characteristics of the sourcing. Several of the study's participants underlined this change of heart to the new tender policy, where openness now was something that impacted the bottom line. This finding and its reasoning were further strengthened by one of the participants, who asserted an observed difference in suppliers' views between Norway and Sweden. While Sweden has attempted to include environmental criteria and gather information, suppliers struggled to perceive any benefits from sharing information. In the extension of this insight, the importance of adequately weighing and further awarding the contracts appears to be a crucial part of increasing supply chain

transparency. A vital finding not apparent in the literature is how suppliers' and actors' perspective has changed to the positive from the introduction of environmental criteria. To further enhance this finding, our interviewees collaborated with head offices to provide the required information in many cases. Their feedback was that the top management viewed the new policy and tender mechanic as positive and were willing to provide the necessary information.

Although several participants exhibited a positive approach toward transparency, participants were divided, with some stating the concerns displayed previously. The literature on transparency argued that providing necessary information requires strong organizational and supply chain capabilities, and is associated with high costs (Brun et al., 2020; Du et al., 2012; Kamble et al., 2020; Marshall et al., 2015). This coincides with the identified barriers to value-based procurement where resource-based barriers were seen as a key challenge (Meehan et al., 2017). Our analysis provided further insights into the potential negative consequences following pressure on transparency. The respondents emphasized difficulties in both acquiring and sharing information. Some stated that a high focus on transparency in the awarding of contracts could push them out of the market. This issue becomes pressing when put in context with the analysis of the Norwegian and Swedish markets. Several of the markets are deemed as critical, with only one current MAH, where stringent criteria in these markets can expose the public procurers to shortage situations without active suppliers. Some of the interviewees stated concerns about how an extensive list of “musts" could pose risks to the supply of antibiotics through the exit of MAHs from critical markets.

The foundation of transparency primarily stems from the two aspects of willingness to share information and the availability of information. The literature stated that finding the necessary and relevant information was perceived as costly, complicated, and time-consuming (Sodhi & Tang, 2019). While much of the information is provided through both internal and external auditors on behalf of the manufacturers and suppliers, the information provided is not sufficient and up to date. This is also stated to decrease efficiency (Du et al., 2012). It is further argued that real-time information utilizing real-time decisions to handle or prevent supply-demand interruptions is lacking (Handfield, 2016; Sodhi & Tang, 2019). Additionally, the process of gathering and sharing information is time-consuming

and demands additional resources, which was argued to decrease efficiency (Du et al., 2012). Our analysis provided similar findings to the existing literature. Respondents stated that acquiring the requested information was time-consuming and resource-demanding. Most of the information had to be obtained from head-office departments located outside of the Nordic countries for original suppliers. This process was tedious and required resources to establish what exactly was requested. These requirements had to be translated to English or the preferred language with the needed specifications. These issues point to a need for standardization to reduce the complexity of the gathering of information.

The original suppliers stated great availability of information throughout their supply chain, predominantly to the level of producers. Smaller actors also stated high availability of information. The perceived difference between the two groups was that the smaller companies argued that auditors should have the necessary information, and additional resources to extract information were redundant. This stipulates that suppliers who control the whole supply chain have greater availability and the possibility to extract the needed information. In contrast, smaller companies, to a greater extent, had to rely on external auditors. Resources can also be argued to favor larger companies as they, to a larger extent, have departments and strategies concerning sustainability and environmental performance in their supply chain. However, the departments responsible for the information were mainly located at head offices where time was an essential factor in gathering the data.

Our findings have identified challenges in coherence with the literature related to transparency. These issues mainly concern resources and the fear of disclosing business-sensitive information. However, the most important finding is that we have gathered strong evidence displaying how the newly implemented environmental criteria have changed actors' perspectives and thus can be a strong driver for increased transparency in PSCs. The findings are illustrated in Figure 13.

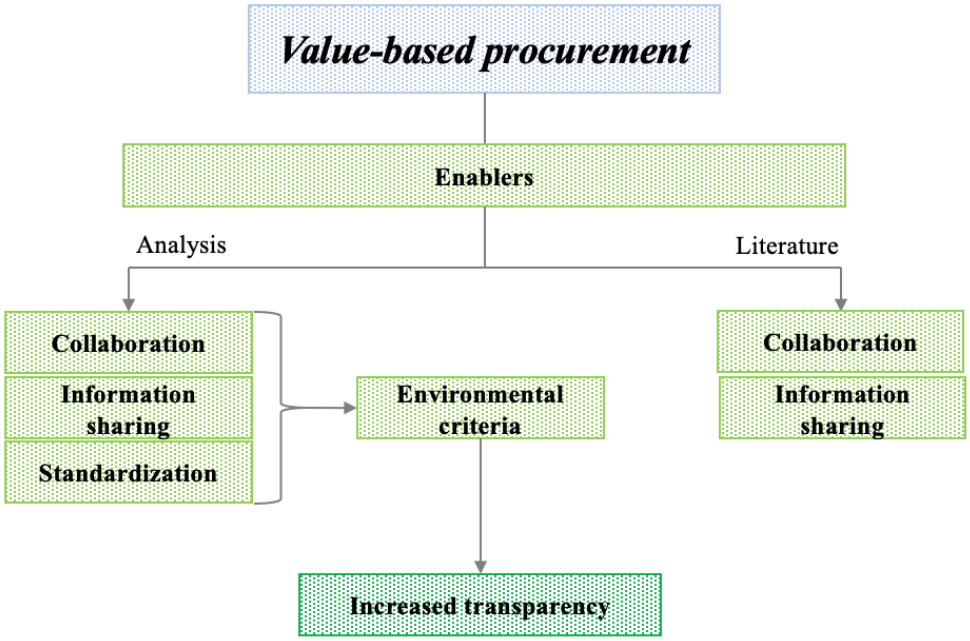

Figure 13. Value-based procurement as a driver for transparency (developed by authors)

5.3 Value-based procurement towards sustainable outcomes

Following sections 5.1 and 5.2, the two sub-questions built the foundation for answering the main research question:

> *How can value-based procurement with emphasis on environmental criteria affect the situation for generic antibiotics and shift the market to more sustainable outcomes?*

We have identified the pressing challenges seen from existing literature in context with the findings through our analysis. The following section will further elaborate on these challenges through the lens of value-based procurement for a futuristic view of how it can benefit the industry as a whole. The perspectives will be discussed in relation to established theory.

Value-based procurement

The literature shows a conceptual shift from the traditional focus on price, whereas the health sector is often deemed immature and not strategically aligned (Nachtmann & Pohl, 2009; Miller et al., 2019). The present pooled procurement strategies have led to complaints where the processes have been criticized as overly technical, rigid, and price-focused. This has led to a failure in assessing other values

such as innovation, environment, and social (Miller et al., 2019). Our analysis stipulated a strong consensus on these views, as the market is deemed unprofitable and tenders too complex. Environmental criteria were argued to increase the complexity even more, as there are challenges in information gathering and the understanding of the given requirements, which poses a risk of participants withdrawing from the market. Consequently, decreasing the desired outcome by solving challenges related to low margins but further complicating the process. In that respect, some participants raised concerns, argued by the immense pressure on resources needed to become greener and provide the necessary information.

Although RBV and value-based procurement has gained popularity as a theoretical lens to study sustainable PSM (Johnsen & Johansen, 2017), the literature revealed that researchers had debated the core of value itself (Meehan et al., 2017). Value can be challenging to determine as its perception can vary and hence lack standardization across countries. Our findings emphasize that the term value fluctuates and cannot be interpreted as "one size fits all", especially in relation to generic antibiotics. As there is high differentiation of competing actors, the price can still be weighted differently depending on the antibiotic. In terms of securing availability, the importance of using other drivers in low competition markets is more vital than in markets with several competitors. The analysis further showed a strong consensus that Norway has succeeded in determining the value of other drivers in choosing the tender winner. In contrast, Sweden mainly chooses winners based on price, as the environmental value is not weighted and awarded accordingly. This is emphasized by the perceived differences in information sharing in Norway and Sweden since the former is awarded and the latter is not. Our findings suggested strong evidence for the approval of environmental criteria in tenders. SI seeks value through requirements in a better environment, availability of essential medicines, and reliability in deliveries at a reasonable price. This can be linked to the Ontario Health Innovation Council´s definition mentioned in Prada (2016), where the value in healthcare can be perceived as the total social impact + health system benefits + economic impact. These core elements are further argued to constitute a change from the traditional short-term cost savings approach to long-term efficiency and effectiveness of decisions to better health system performance and patient outcomes (Rahmani et al., 2021).

Collaboration and information sharing

Collaboration plays a vital role in the success or failure of value-based procurement. Through literature, it is argued that sustainability cannot be established without collaboration (Chin et al., 2015). A high level of sustainability performance achieved by one firm can be damaged by poor supplier performance. Collaboration is also integral in the integration of transparency. Through our literature review, we identified important factors for achieving collaboration. Duong and Chong (2020) presented eleven factors that influence SCC. These eleven factors were: *Information sharing and technology, trust, culture, stakeholders, divergent goals, flexibility, knowledge and experience, market factors, measurement issues, resources, and visibility* (Table 3). Various researchers also emphasized the importance of information sharing as an important factor for collaboration to be successful and one of the most important benefits from it (de Kok et al., 2005; Martinez-Olvera, 2008; Sahin & Robinson, 2005). The two are shown to be interconnected, hence it is needed to develop both processes to achieve the best outcome of value-based procurement.

Our analysis emphasized the cruciality of collaboration and information sharing in value-based procurement. Barriers to value-based procurement were mainly categorized as relational and resources (Prada, 2016), whereas collaboration was seen as one of the enablers in the literature and in our analysis. Suppliers argued that providing the demanded information was intense on resources, stating that early information sharing and dialogue on the specifications of criteria were crucial. Literature on value-based procurement argues the importance of the term competitive dialogue to succeed (Prada, 2016; Rahmani et al., 2021). The process is claimed to lay the foundation for early collaboration, further aiding in identifying and defining value expectations and, subsequently the best fitting value proposition. Utilizing the supplier's knowledge and experience to formulate challenges is proven to provide better results than a list of requirements based solely on their perspective. SI has actively utilized this practice in the development of the new tenders. A consensus among our interviewees was the great appreciation for competitive dialogue. This aided in developing achievable criteria, which is crucial for capturing value. It was also critical for suppliers to clear misunderstandings or uncertainty related to the criteria specifications. Another challenge found in our analysis was the tender forms. Collaboration with suppliers to reveal and discuss

the identified issues could be of great importance in improving tender forms and the current market situation. Dialogue was also found to be important in building trust and reducing misconceptions. Thus, our findings highlight the importance of collaboration and information sharing in value-based procurement, giving further evidence to existing literature.

Collaboration plays an important part not only in buyer-supplier relationships in PSCs but also between the buyer and other governmental stakeholders. As identified in Table 4, some of the challenges in the market are characterized as external, meaning SI cannot directly influence them. The maximum price set for procurers (AIP) is decided by SLV, as well as policies and approval of new strategies. Collaboration between procurers and the different stakeholders is therefore essential for developing value-based procurement. The current situation emphasizes the pressing issues, as only the necessary information is shared between stakeholders, prohibiting efficiency and effectiveness in PSCs. Collaboration and information sharing between stakeholders would enable SI to harvest value by influencing the external factors i.e., policies, demand, price, and contract value.

Moreover, in section 5.2, we discussed how value-based procurement could be a vital driver for increased transparency in the market for antibiotics. An interesting aspect that arises is to further extend the view on how it could influence the procurement and supply of antibiotics. We found that applying environmental incentives in tenders for medicine procurement serendipitously increased supply chain transparency. Environmental criteria can benefit procurers by gathering relevant data such as where the API and products are produced and supplied. This could aid procurers in the process of risk management, especially in mapping suppliers. Procurers can utilize the increased knowledge, previously unattainable, to incentivize processes reducing the risk of shortages (Årdal et al., 2021). To exemplify, criteria could weigh European or other geographical locations to diversify manufacturers and alleviate shortages. This could create a more flexible supply chain, with increased resilience when faced with shortages.

Sustainability

The literature pointed to many environmental problems in the pharmaceutical industry, such as carbon emissions and wastewater discharge (Årdal et al., 2021; Zaidi et al., 2021). Production in low-cost countries showed fewer regulations in terms of sustainability and, consequently, high concentrations of pharmaceuticals in wastewater (Li et al., 2008; Larsson, 2010). The literature further highlighted the spread of substances in groundwater and drinking water, creating severe resistant bacteria and resistant genes for local populations, constituting a growing problem in modern medicine. Our findings underlined the struggles to regulate these practices as the manufacturers of APIs in these countries comply with their national regulations, which mainly stems from the historical primary consideration of gaining the lowest price. This addresses the pressing need for more sustainable procurement initiatives and stricter regulations. In situations where the procurers lack the power to influence local regulations, joint global initiatives such as AMIRA become integral. These initiatives could reduce the environmental degradation, risk of AMR, and increase transparency through standardization. However, the stated benefits cannot be harvested without the crucial component of collaboration between stakeholders. Having common platforms for information sharing throughout the supply chains with up-to-date information can greatly benefit sustainable procurement practices, by reducing the resource-based barriers addressed by Meehan et al. (2017) for suppliers.

Scholars argue that sustainability within public procurement is significantly underdeveloped and overlooked (Olsson & Öjehag-Pettersson, 2020). The literature has a strong consensus that public procurers should set the standard for sustainable values and be the frontrunner in the sustainable shift (van Berkel & Schotanus, 2021), thus having the power to change the behavior of their supply chain members. This constitutes a problem for Norway as their total expenditure on antibiotics is only a fraction of the allocated national budget and global market expenditure, reducing the potential influence on sustainable development. This addresses the difficulties of a small high-income country incorporating environmental criteria in the procurement of generic antibiotics. Sourani & Sohail (2011) found several barriers concerning sustainable procurement procedures, one of them being the lack of funding and restrictions on increasing expenditure. Our findings emphasize these

barriers as Norway still has the policy of acquiring pharmaceuticals at the lowest price, giving little room for developing more value per dollar spent.

Our analysis stipulated several solutions to the proposed obstacles in gaining sustainability. European production would i) shorten the pipeline, ii) secure delivery reliability, iii) give more control, and iv) make it easier to enforce criteria through the supply chain. The extension of criteria could as argued, incentivize European production where possible, harvesting the stated benefits. Although this is argued by suppliers, there is little evidence to support the arguments. Concentrating all production in Europe would create new geographic vulnerabilities. However, the current concentration of production in low-cost countries and local demand prioritization in case of shortages (Roland Berger, 2017) points to the necessity of strategic geographical locations. This could be incentivized by awarding European production in Norwegian and Nordic tenders to mitigate against the posed challenges. Having closer production would also highly contribute to the environment, as policies in Europe are deemed more stringent. This would in turn also decrease transport emissions due to shorter distances, and one could argue that more stringent policies would also decrease the possibility of faulty and counterfeited drugs.

The complexity of different package attachments across Nordic countries was also demanding. Enabling attachments at a Nordic or European level would ease the discrepancy and make it easier for suppliers to distribute antibiotics across countries, increasing availability in normal and abnormal situations. The lack of standardization therefore prevents effective distribution of the preferred narrow-spectrum antibiotics during shortages, contributing to the pressing issue of AMR (Gerber et al., 2018; WHO, 2001; 2019). Furthermore, the deemed challenges with the differences in countries specify the necessity to have more coordination and collaboration between countries, especially in setting requirements. The lack of unity between Nordic and European countries poses a significant challenge when suppliers compete on different criteria in seemingly similar countries.

Our findings further argue that environmental criteria can shift the market towards more sustainable outcomes. There is strong consensus from our participants that competing on other drivers would make the market more attractive, which further implies increased availability and longevity. Hence, suppliers get higher prices and

margins, other drivers to compete on, and more predictability. However, the willingness to reenter markets with low margins is deemed unpresent, as the current situation with environmental criteria is not a strong enough incentive. The price is still the main concern for suppliers and, thus, necessary to regulate. In contrast, the incentive is deemed significant enough for participating actors and even preferred to be implemented in other tenders. Consequently, this will provide procurers with increased quality, supply chain information, and supplier longevity and availability, while the industry receives better transparency and collaboration, healthier markets, and decreased environmental degradation.

5.4 Summary of discussion

The findings and discussion can be summarized through the revised conceptual framework (Figure 13). The figure illustrates the findings from our empirical data with the aim of answering the research questions posed about value-based procurement´s introduction in PSCs. The revised conceptual framework contains theoretical and practical enablers and barriers, which are also intertwined. As relational and resource barriers subsequently concern mistrust, perceptions, and capacity issues (resource shortage and knowledge gaps), the practical barriers coherently align. Additionally, both practical and theoretical enablers intertwine as it is deemed necessary to increase collaboration and transparency between actors and within the supply chain. Therefore, the revised conceptual framework points to the associated benefits if sustainable outcomes are achieved through value-based procurement.

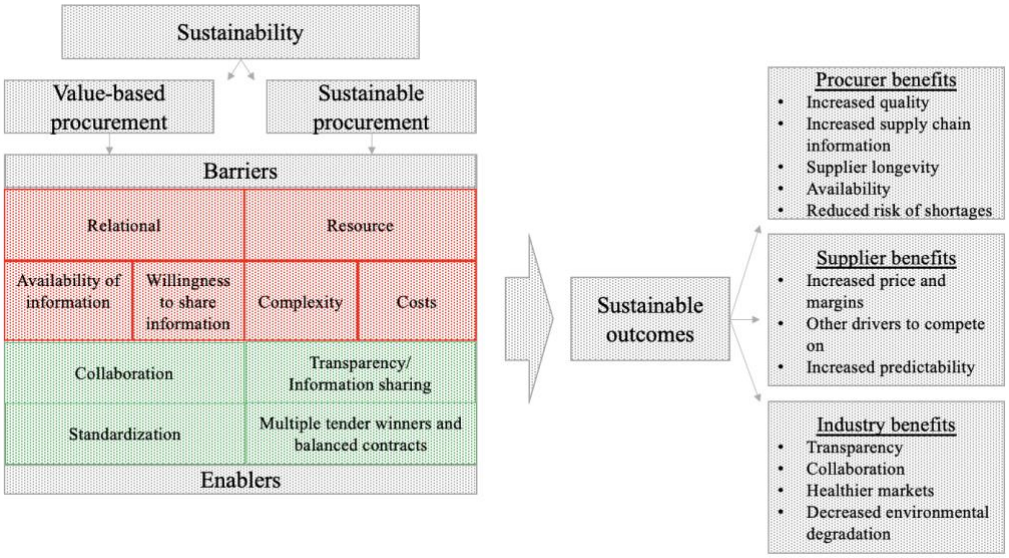

Figure 14. Revised conceptual framework (developed by authors)

The theoretical background pointed to the general relational and resource barriers. These barriers were also found in our analysis as the willingness to share information, the availability of information, complexity of tenders, and challenges with price and volume are strongly present in the market for generic antibiotics. The literature highlighted collaboration and information sharing as the two main enablers to overcoming these barriers and was also the most frequently addressed enabler in our findings. Standardization in countries' requirements, formulations, and tender forms was deemed critical for suppliers in adapting and changing toward sustainable outcomes. In addition, suppliers emphasized a demand for more balanced contracts and multiple winners. Furthermore, the long-term sustainability in the market for generic antibiotics constitutes a great concern for procurers, suppliers, and authorities. The struggles with price, antibiotic policies, complexity, collaboration, and transparency emphasize the need for participants to compete on more drivers such as environmental criteria to enable the perceived benefits. Therefore, incorporating value-based procurement in generic antibiotics tendering becomes essential in achieving procurer, supplier, and industry benefits.

6.0 Conclusion

This section provides the conclusion to our research containing theoretical and practical implications, followed by the limitations and recommendations for future research. The objective of this research has been to investigate the perceived benefits and challenges of introducing environmental criteria in the pharmaceutical industry to reach sustainable outcomes. This has been done through a case study on the Norwegian market for generic antibiotics, providing us with in-depth insights on the influence of environmental criteria in tenders. Semi-structured interviews and quantitative data on the current market state and perceptions were collected, analyzed, and discussed in relation to the theoretical foundation presented.

6.1 Theoretical implications

Value-based procurement is an established term in research and practice. However, literature on the topic of PSCs is limited. Our study clarifies challenges with the current Norwegian market for generic antibiotics, which may provide a general

representation of the generic antibiotic market in small high-income countries. While prior literature mainly attributed the challenges to low profitability, complexity, and single tender winners, our research extends these issues. We have identified external and internal challenges for the procurers, including market size, contract value, demand, unbalanced contracts, and tender periods. Our research further strengthens identified enablers and barriers in the literature and adds new contributions.

The lack of transparency and collaboration in PSCs has been widely acknowledged in the literature. While transparency was previously identified as an important enabler for value-based procurement, we uncovered how it could also be a driver for increased transparency. Through awarding environmental criteria, participants showed that they are willing to share required information regarding their operations and supply chain partners. This aspect has not previously been established and constitutes an important finding to the literature on transparency in PSCs. Furthermore, the literature highlighted the importance of power and collaboration in supply chain relationships. The Norwegian market of generic antibiotics can be characterized as supplier dominant. Although some of the markets can have multiple competitors, the struggles with market size, low volume and prices, and policies could argue that the power favors the supplier. Our findings can point to a shift in power as the buyer increases its specifications, requiring the supplier to follow. The change in power only comes into effect if it draws more suppliers to the market, thus increasing competition. Hence, in situations with only one or two MAHs, the power still lies with the supplier. These findings provide an understanding of how the value-based procurement literature can be connected to the change in power and dependencies.

The literature had previously identified that buyer-supplier collaboration in tendering was perceived as inadequate. Our research has emphasized this perception but has revealed that collaboration in the Norwegian market has seen a positive shift. While collaboration was still regarded as insufficient, procurers had actively been seeking to improve the collaboration. The use of competitive dialogue, as defined in the literature, had been extensively used with a positive response from both buyers and suppliers. These findings strengthen the existing literature on the importance of collaboration in tenders.

6.2 Practical implications

Due to the scarcity of prior research on value-based procurement in the pharmaceutical industry, our study provides important implications for practitioners in developing and implementing extended criteria in tenders. Our findings emphasize that the market for generic antibiotics is in dire need of changing from the traditional price-focused procurement practices. The illustration of the current antibiotic situation showed several ATCs with critical supplier situations. The trend demonstrated that the de-registrations exceeded the number of new entrants. The findings emphasize the pressing need for practitioners to broaden their view of procurement as attempted by SI. Suppliers exhibited a strong positive consensus toward the ability to compete on other criteria and not solely price, further highlighting the aforementioned point of maturity in the market.

An introduction and standardization of environmental criteria on a European or Nordic level could attract more suppliers and simultaneously reduce AMR risk. Increased availability of suppliers enables the procurer to source from more suppliers during shortages, as standardization of criteria and package attachments would enable effective distribution across borders. This could potentially remove the need for practitioners to use broad-spectrum antibiotics, further preventing the increase of AMR. The standardization would also help in antibiotics expenditure during shortages, as the availability for the procurer rises and decreases the need to acquire substitutes above AIP. The environmental requirements could further decrease the risk. However, a small-high income country such as Norway is dependent on standardization of requirements in the Nordics and Europe to gain the perceived benefits, as they constitute small market power on the global scale.

We have identified several weaknesses and challenges with the current generic antibiotics market. On the supplier side, the market struggles with extremely low prices and profit margins, policies on the usage of antibiotics and low demand, market size, unbalanced contracts, and complexity. On the buyer side, the market struggles with a low number of MAHs, low transparency, and difficulties enforcing environmental criteria through the supply chain. Furthermore, our findings posed several solutions to obtaining a healthier market and achieving sustainable outcomes. 1) Standardizing criteria across the public and private sectors are requested, as many suppliers operate in both. This reduces the incentive as suppliers

must invest extensive resources on becoming greener when it is only necessary for one sector, 2) collaboration in the Nordics and Europe in setting requirements and increased buyer-supplier collaboration, 3) increased prices and profit margins in addition to more balanced contracts, making it easier to raise prices during unforeseen events, 4) English and digital packages make it easier to distribute products across borders, which further reduces entry barriers, 5) more tender winners and increased volume predictability, 6) concerning the Nordic tender, joint MAs across participating countries to prevent suppliers not being able to participate.

Another key implication for practitioners is the perceived change in willingness to share information. While prior literature on the subject had depicted an unwillingness to share information, our findings suggest a positive change towards it. For practitioners, it is crucial to understand what information they value and how the data can improve their procurement practices. A correct assessment of the value is deemed necessary to award the suppliers willingness to share information appropriately. The move towards more information-driven procurement practices can also aid in developing strategies to improve reliability and reduce the risk of shortages. We connected this approach to the possibility of incentivizing different geographical production facilities. Our findings emphasize the difficulties in European production as the sourcing of APIs mainly stems from Asia, implying that the challenges during disruptions are not neutralized. However, we found high consensus among participants that back-shoring production would eliminate many of the current challenges. Thus, awarding European production and increasing prices would stimulate a high incentive.

The final implication for practitioners concerns the critical aspects to succeed in introducing value-based procurement with extended criteria. Collaboration and, more specifically, competitive dialogue were perceived as crucial for developing and implementing new criteria from our analysis. Furthermore, our findings highlighted the need for a dynamic approach to different antibiotics. Some suppliers expressed concerns about whether they could survive in the market if the pressure on transparency and environmental impact were too high. In contrast, other interviewees were very positive to highly weighted criteria besides price. This further enhances the need for collaboration to understand the underlying market situation to achieve the wanted outcomes.

6.3 Limitations and recommendations for future research

The most prominent limitation of our study was the willingness of suppliers and practitioners to participate in interviews. This obstacle was predominantly faced in attempts to interview participants withdrawn from the market. This prevents a more complete picture of suppliers' perceptions on introducing environmental criteria and how the market has been affected. Following the limitation, we were only able to interview tier-1 suppliers. Although we aimed at gathering insights throughout the supply chain, the information could not be verified through other tiers. Additionally, the secrecy in the industry prevented us from obtaining sufficient quantitative data to determine the effect of environmental criteria more concretely, as the participants' views only stem from a smaller proportion of the market. Despite the time and resource constraints of a master thesis, we believe that our findings provide interesting and relevant insights for practitioners to make evidence-based decisions, and further research angles.

Due to the scope and limitations of the study, several interesting opportunities for future research are present. As the literature on the subject is scarce and newly introduced, our findings can be characterized as explorative and general within the generic antibiotics market. The general findings of the thesis consequently lay the foundation for many interesting research areas and can be demonstrated through the revised conceptual framework. Further research could utilize the framework in other countries and pharmaceuticals to possibly strengthen and generalize our findings, and provide additional information regarding barriers, enablers, and outcomes. The framework can also be applied by practitioners as it illustrates the important barriers and enablers to consider in succeeding with harvesting value from environmental criteria.

Our findings illustrate that the decline of MAHs has flattened since the 2019-2020 introduction of environmental criteria. Although this cannot be perceived as a direct cause, a strengthened conclusion can be drawn with more data available on the topic as it is included in more tenders. Quantitative studies to investigate how other value considerations have affected the price levels in the generic antibiotics market should be researched. Similar studies could be applied to explore the tenders' environmental effects in terms of emissions, environmental degradation, and AMR. Finally, our study uncovered interesting findings concerning the change in actors'

view of transparency. An increased availability of information can also be connected to the literature on supply chain risk management. Research on how practitioners could best utilize it and the potential effects would serve a great purpose to the literature. This could further aid procurers in assessing the best practice and strategies connected to the information not previously available.

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8.0 Appendices

Appendix 1: Search strategy

Parameters	**Subject terms, synonyms**	**Search strings/restrictions**
Language	English and Norwegian	
Database and search engine	Web of Science Google Scholar Oria PubMed	
Keywords/subject	Collaboration Criteria Purchasing and supply management Purchasing Procurement Supply management Sustainability Supply chain collaboration Transparency Tender Tendering Value-based procurement	Antibiotics Drug supply chains Environment Generic Generic drugs Generic medicines Generic pharmaceuticals Generic antibiotics Health supply chains Health sector/industry Improvement strategies Medicine industry Off-patent Pharmaceuticals Pharmaceutical industry Public Public health sector
Geographical area	Global	

Appendix 2: Tender requirements (retrieved from LIS2201a, 2020)

4.1	Leverandøren forplikter seg til å opprette og forvalte 30 dager sikkerhetslager i Norden av tilbudte produkter. Sikkerhetslageret skal være avsatt til det norske markedet.	S	[redacted]	Kontraktskrav til forvaltning av sikkerhetslager fremgår av rammeavtalen punkt 7.6.2.
4.2	Leverandør skal ha 3 måneders lager som Sykehusinnkjøp skal kunne revidere senest en måned før avtalestart. Dette kravet gjelder kun ny anbudsvinner, da eksisterende avtaleleverandør allerede har varer hos grossist og apotek/HF.	S		30 dagers sikkerhetslager er inkludert.
4.3	Leverandøren bør ha en overordnet miljøstrategi som omfatter hele porteføljen. Angi eventuelt også hvilke deler av porteføljen man ikke har miljøstrategi for.	B	ML1	Leverandøren bes om å gi en oppsummerende og konkret beskrivelse. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.4	Leverandøren bør ha en overordnet miljøstrategi som omfatter hele verdikjeden fra råvare til ferdig produkt. Angi eventuelt også hvilke deler av verdikjeden man ikke har en miljøstrategi for.	B	ML1	Leverandøren bes om å gi en oppsummerende og konkret beskrivelse. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.5	Vil leverandøren være villig til å opplyse om hvilke / hviket land API- / råvareproduksjonen for tilbudte produkter skjer, dersom LIS anmoder om slike opplysninger?	B	ML2	Leverandøren bes svare ja/nei. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.6	Omfatter miljøstrategien fabrikk / fabrikkene som ferdigstiller de salgsklare pakningene?	B	ML2	Leverandøren bes svare ja/nei. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.7	Omfatter miljøstrategien API- / råvareprodusent(er)?	B	ML2	Leverandøren bes svare ja/nei. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.8	Omfatter miljøstrategien renseanlegg for API- / råvareprodusent(er)?	B	ML2	Leverandøren bes svare ja/nei. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.9	Omfatter strategien massebalanseberegninger og / eller overvåking av utslipp og tilsvarende miljørisikovurderinger?	B	ML2	Leverandøren bes svare ja/nei. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.10	Leverandøren bør foreta miljørevisjoner av anskaffelse, produksjon og avfallshåndtering av API- / råvarer, og bes om å beskrive omfanget av slike revisjoner, herunder eventuell frekvens for utførelse av miljørevisjoner.	B	ML3	Leverandøren bes om å gi en oppsummerende og konkret beskrivelse av omfang og frekvens. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.11	Leverandøren bør være villig til å dele resultater fra gjennomførte miljørevisjoner, herunder hvem som har foretatt miljørevisjoner, og bes om å beskrive i hvilket omfang slike resultater kan fremvises etter anmodning fra LIS.	B	ML3	Leverandøren bes om å gi en oppsummerende og konkret beskrivelse. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.12	Leverandøren bør gi en innholdsoversikt av sine miljøprosedyrer for avfallshåndtering av API, eller oversikt over prosedyre for revisjon av avfallshåndtering hos API-produsent i de tilfeller leverandør ikke har API-produksjonen.	B	ML4	Leverandøren bes om å oppgi en innholdsoversikt over miljøprosedyrer (tittel) for avfallshåndtering av API. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.13	Leverandøren bør ha miljøprosedyre som gjelder for både leverandørens fabrikk(er) og / eller API- / råvareprodusent(er). I de tilfeller leverandør ikke har egne fabrikker bør leverandør ha prosedyrer for miljørevisjon av fabrikker.	B	ML4	Leverandøren bes om å oppgi en innholdsoversikt over miljøprosedyrer eller prosedyrer for miljørevisjon (tittel) der det fremkommer hvilke som er for fabrikk(er) og/eller API/råvareprodusent (er). Leverandøren skal ikke vedlegge øvrige dokumenter.
4.14	Leverandøren bør gi tredjepartsprodusenter opplæring i leverandørens miljøprosedyrer.	B	ML4	Leverandøren bes om å gi en oppsummerende og konkret beskrivelse. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.15	Leverandøren bør, som ledd i leverandørens miljørisikovurdering, utføre prøvetaking av avløpsvann fra API- / råvareprodusent(er).	B	ML4	Leverandøren bes om å gi en oppsummerende og konkret beskrivelse. Leverandøren skal ikke vedlegge øvrige dokumenter.
4.16	Leverandøren bør, som ledd i leverandørens miljørisikovurdering, gjennomføre massebalansekalkulasjoner av avløpsvann fra API- / råvareprodusent(er).	B	ML4	Leverandøren bes om å gi en oppsummerende og konkret beskrivelse. Leverandøren skal ikke vedlegge øvrige dokumenter.

Appendix 3: Information letter

Are you interested in taking part in the research project-

"Master Thesis on environmental criteria in the tendering of generic antibiotics"?

This is an inquiry about participation in a research project where the main purpose is to investigate the effects of environmental criteria in the tendering of generic antibiotics. This letter will give you information about the project´s purpose and what your participation will involve.

Purpose of the project
We are two students currently in our last semester of a Master of Science (MSc) in Business degree, with specialization in Logistics, Operations and Supply Chain Management at BI Norwegian Business School. We are writing a master thesis and aim to collect and analyze data on the effect of environmental criteria in the tendering of generic antibiotics.

Our aim is to investigate the supply chains of generic antibiotics to get an insight and understanding of involved stakeholders, processes, and decisions in the supply chain. We will go in-debt on the current environmental criteria and how they have affected the market, seen historically. Meaning, how it affected supplier availability, reliability and longevity, and market competition. Further, we will investigate how these criteria can be further increased and try to understand how this will affect market sustainability if implemented.

Who is responsible for the research project?
BI Norwegian Business School is the institution responsible for the project.

The Master Thesis will be carried out as a part of the MIA (Measures for improved availability of medicines and vaccines) project at BI Norwegian Business School.

Why are you being asked to participate?
You have been asked to participate based on your knowledge/experience on the topic and/or the field, which could benefit this master thesis.

What does participation involve for you?
Participation in the project will entail an online/physical interview. It will be relevant to collect both qualitative and quantitative data, as a mixed-method approach with an embedded design will be used in this study. The questions will address environmental criteria, including challenges and opportunities, transparency, collaboration, and other criteria in the tenders. Participation in this project will entail that your answers will be stored and/or sound recorded. The length of the interview will vary depending on the situation as we conduct semi-structured interviews.

Participation is voluntary
Participation in the project is voluntary. If you choose to participate, you can withdraw your consent at any time without giving a reason. All information about you will then be deleted. There will be no negative consequences for you if you choose not to participate or later decide to withdraw.

Your personal privacy – how we will store and use your personal data

We will only use your personal data for the purpose(s) specified in this information letter. We will process your personal data confidentially and in accordance with data protection legislation (the General Data Protection Regulation and Personal Data Act).

The Master Thesis´ supervisor and the two students responsible for the project will have access to personal information (e.g., professional position, educational background, work background or name). The final Master Thesis will be published on BI Norwegian Business School´s online library service and can be accessed by everyone with authorization to BI Norwegian Business School´s online library service).

To ensure that non-authorized individuals get access to personal information, data will be stored on password-protected devices and files.

Others:

- Names of data processors that will collect, process and store data: Andreas Wangen and Mikal Pettersen
- The names of the participants will be anonymized in publications and other material.

What will happen to your personal data at the end of the research project?
The project is scheduled to end 1st of July 2022.

At the end of the project, all personal data will be anonymized. Additionally, all sound-recordings will be deleted at the project end. Further storage (professional position, educational background, work background or name) will purposely be kept as verification, for enabling future research and follow-up studies. All personal information will be stored on the author´s devices until 1st of October and will be handed to the examiner and/or supervisor on request.

Your rights
So long as you can be identified in the collected data, you have the right to:

- access the personal data that is being processed about you
- request that your personal data is deleted
- request that incorrect personal data about you is corrected/rectified
- receive a copy of your personal data (data portability), and
- send a complaint to the Data Protection Officer or The Norwegian Data Protection Authority regarding the processing of your personal data

What gives us the right to process your personal data?
We will process your personal data based on your consent.

Based on an agreement with BI Norwegian Business School, NSD – The Norwegian Centre for Research Data AS has assessed that the processing of personal data in this project is in accordance with data protection legislation.

Where can I find out more?
If you have questions about the project, or want to exercise your rights, contact:

- BI Norwegian Business School via Marianne Jahre (supervisor), by email [redacted] or by telephone: [redacted]
  [redacted] Master Thesis students: Mikal Pettersen, by email: [redacted] or by phone: [redacted]. Andreas Wangen, by mail: [redacted] or by phone: [redacted]
- Our Data Protection Officer: [redacted]

- NSD – The Norwegian Centre for Research Data AS, by email: (personverntjenester@nsd.no) or by telephone: +47 55 58 21 17.
- Sykehusinnkjøp via Eirik Sverrisson, email: [redacted]

Yours sincerely,

Andreas Wangen.
Student

Mikal Pettersen
Student

Consent form

I have received and understood information about the project ***Master Thesis on environmental criterions in the tendering of generic antibiotics*** and have been given the opportunity to ask questions. I give consent:

- ☐ To participate in an interview
- ☐ For information about me/myself to be published in a way that I cannot be recognized (e.g., professional position, educational background, and work background).

I give consent for my personal data to be processed until the end date of the project, approx. 01.07.2022.

(Signed by participant, date)

Appendix 4. Interview guide

Introduction:

- Consent reminder about interview being recorded for transcription/note taking purposes
- Introductions: 2 interviewees (Mikal and Andreas)
- About the Master thesis
- This interview focuses on the supplier's role in the Norwegian market for generic antibiotics.

Duration: 45-90 minutes

Questions:

1) Overall question about the organization and role in the organization etc.
2) General thoughts on the market, challenges etc
3) Uncovering the aspects of price/total cost
4) Thoughts/view/perspectives on availability, reliability
5) View on sustainability
6) Future sustainability considerations

1. Can you describe your role in the organisation?
    a. Your background, professional and educational, experience in the industry?
2. What is your organization's current and historical role in the Norwegian and possibly Nordic market for generic antibiotics?
3. Please describe what you deem the biggest challenges in the market for generic antibiotics?
4. Where does your organisation stand in terms of sustainability or environmental criterions?
    a. What do you perceive as the biggest challenges in terms of implementing and enforcing sustainability throughout the supply chain?
    b. Does the organisation expect to further its focus and investment in this direction?
    c. How do you think environmental criteria will affect your role in the market, pull out, more incentive to stay, etc?
5. What information do you have about the production processes and how is information shared?
    a. Are you able to provide full information about every step of each process throughout the supply chain?
    b. How far back in the supply chain are you able to enforce and “check” changes in terms of sustainability
6. Have you experienced any increase in lead times or other difficulties in regard to increased environmental considerations?
7. In terms of market prioritisation, how do you think such criteria will affect Norway's position?
8. What are the key areas for improvement when it comes to managing the supply chain in terms of ensuring availability and reliability (not limited to your sphere of influence)?
9. What incentives would you prefer to improve your sustainable operations and ensure reliability to the Norwegian market?
10. Do you have anything you would like to add before the end of the interview?

Do you have any recommendations in terms of who we can speak to?