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Thriving Amidst Complexity: the Dynamics Within the Market of Parallel Imports of Pharmaceuticals in Sweden

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Oscar Privileggio Cederhed

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Supervisor: Bertil I Nilsson
Examiner: Ola Alexanderson

Lund University, Faculty of Engineering
Ole Römers väg 1, Box 118
SE-221 00 Lund, Sweden
Pm.lth.se

Preface

This thesis finalises five years of studies within Industrial Engineering and Management at the Faculty of Engineering (LTH), Lund University. Firstly, I would like to express my gratitude towards my supervisor Bertil Nilsson. Much like a steadfast lighthouse, he has allowed me to navigate and explore the subject matter while ensuring I remained on course. Secondly, I want to express my appreciation to my family, and especially Ebba, for their support during rainy autumn months, when performing this project has been the most challenging. Lastly, I want to thank my friends. Not only for their support and discussions related to this thesis, but also for the countless hours spent in the cellar in E-huset throughout the years.

Oscar Privileggio Cederhed, February 2024

Abstract

Theory on competition within free markets is well developed and creates a fundament on which operational and strategic decisions rest upon. Regulations, such as in the pharmaceutical industry, creates a dimension which highly affect the operations of all organisations within the industry - and thus also the competition.

The purpose of this thesis is to investigate the business environment and competitive forces within the highly regulated industry of parallel imports in Sweden.

An abductive research approach has been used to analyse qualitative data gathered through five interviews of industry personnel. The concepts from *Hills model* have been applied, interpreted and extended to the context of regulatory environment.

Order winners and qualifiers can be utilised to describe and explain how regulations affect the industry of parallel imports. This concept can be used to create alignment in operations strategy, but also to give insights to how regulations can be constructed to incentivise market operators to the desired behaviour. Through this process, the need for segmentation of products within the industry of parallel importation becomes clear. Finally, the market drivers are further investigated, where regulations on both EU and national level are identified as major drivers.

List of Abbreviations

3PL	Third-part logistics
ADR	Adverse drug reaction
CJEU	Court Justice of the European Union
CWH	Central warehouse
DTP model	Direct-to-Pharmacy model
DI	Direct import
EU	European Union
EMA	European Medicines Agency
EEA	European Economic Area
Fass	Farmaceutiska specialiteter i Sverige
OTC	Over the counter
MAH	Market authorisation holder
MPA	Medical Products Agency (Läkemedelsverket)
PI	Parallel import (product or concept), parallel importer
PRV	Patent- och registreringsverket
SC	Supply chain
SCM	Supply chain management
SFS	Svensk författningssamling (Swedish Code of Statutes)
TLV	Tandvårds- och läkemedelsförmånsverket

Definitions

Biologicals	A pharmaceutical product produced from biological material, such as blood or plasma from humans.
DI	A medicine that is imported or manufactured by the market authorisation holder.
Generic	A medicine developed with the same active ingredient as the original.
Operations	The performance of practical work or something involving practical application of principles or processes
Originals	The pharmaceutical product that was first patented with the active ingredient.
Parallels	A pharmaceutical product that is parallel distributed or parallel imported.
Retail	Sale of pharmaceutical drugs to; a consumer, public health authority, hospital or other health care institution, or to whom who is authorised to prescribe medication.
Value Chain	Set of procedures adding value for the final customer.
Wholesale	Operations that include purchasing, holding, export, delivery or sales of drugs that are not to be seen as retailing.

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1. Introduction

Chapter 1 covers an explanation of the context of the study, the problem statement, delimitations, and the research goal and purpose. Finally, the target audience and a summary of the thesis deposition is presented.

1.1 Background

1.1.1 Pharmaceutical Market

The pharmaceutical market in Sweden is part of a global network of trade with medicinal products and assures access to safe and effective medication nationally and internationally through exports. The market involves research, procurement, storage and distribution across the country - all regulated, monitored and controlled by the EU and national authorities. (Medicinal Products Agency [MPA], 2022)

The Swedish market for pharmaceutical products plays an important role in improving national welfare. Not only does it provide the Swedish people with essential medicines, but also economic and social improvements through taxes and job opportunities. The total turnover of pharmaceutical products sold to Swedish customers reached 54 billion Swedish kronor in 2021 (Macheridis, 2022) and employed around 15 000 workers (Lundmark, 2024). In 2022, national exports of pharmaceutical products and components reached 139 billion kronor (Statistiska Centralbyrån [SCB], 2023a), with imports totalling 66 billion kronor (SCB, 2023b).

Before a medicinal product reaches the market it has to go through a series of trials before being approved. This research process is expensive and after accounting for the cost of research where the results were not satisfactory, the investments needed to bring a new drug to market have been estimated to range between $0.9 and $1.5 billion for 95% of pharmaceuticals (Wouters et al., 2020). To protect new treatments and drugs, developing companies can obtain patents for 20 years with the possibility for an additional 5 years through one supplementary protection certificate (Garattini et al., 2022; Patent- och Registreringsverket, 2023). During this period the inventor can secure exclusive right to make, use or sell the patented substance (European Medicinal Agency [EMA], 2023a). When a patent expires, other companies can apply for a manufacturing licence for a drug with the same active substance and, but not necessarily, packaging, inactive substances and

name. Drugs that use the same active substance as the original product are called generic medicines. (EMA, 2023b; MPA, 2023b)

Even though a medicinal product is protected under patents filed, the free trade rules within the EU/EEA enable other companies to trade the products in parallel within the union. When the patent holder decides to distribute the product to a given market, a parallel importer or distributor can buy the product on that market and redistribute it to a market to which it has already been introduced. What enables this economically is the differences in national pricing structures, which can result in different prices on identical pharmaceuticals in different markets. Thus can the same product be priced differently in different member states which opens up a potential opportunity for buying the product in a country where the price is relatively low and redistributing it with a markup in a country where it can, even competitively, be sold at a higher price (MPA, 2023b; Siwiec & Bajer, 2023). This can be done legally without the permission of the patent holder, and this is called parallel imports. During the period 2018 – 2023, parallel trade accounted for between 7.8% and 10% of total sales of medicinal products in Sweden (De forskande läkemedelsföretagen [Lif], 2024).

1.1.2 Industry Trends and Market Dynamics

While parallel trade is allowed within the EU, it is still heavily restricted by regulations. Historic and new regulations will continue to shape the business environment within the sector. New or updated directives on both EU- and national-level control of the industry and rulings in the CJEU dictate how regulations should be interpreted in practice. The future regulatory environment can be expected to change following factors such as digital disruption, an evolving therapeutic landscape, a higher degree of centrality of the patient and a strive for global regulatory harmonisation (Chisholm & Critchley, 2023). Changes in the regulatory environment incentivise companies to continuously work with and stay up to date with regulatory affairs (Ali & Baboota, 2021).

Because of the competing effects a parallel importer has on a certain market, patent proprietors will try to disrupt importers if possible (Buitseva, 2013). This can be done by adjusting pricing policies (Sekip Altug & Sahin, 2018), market entry decisions (Sekip Altug & Sahin, 2018), delivery limiting actions (Krasniqi, 2013; Engberg, 2016) or legal actions, for example related to trademark infringements (Siwiec & Bajer, 2023). The highly regulated industry and multifaceted competition contribute to a business environment that is difficult to navigate.

Supply chain disruptions have become more common across all industries in recent years, and they can arise in all stages of the value chain. They can be caused by shortages in raw materials, packaging materials and/or critical components, or transportation disruptions (Shelley, 2022). To reduce the risk of disruptions in the pharma industry, a range of efforts are undertaken. This includes increased use of monitoring solutions, digital connectivity and advanced modelling capabilities to analyse real-time data with artificial intelligence (Shelley, 2022; Mukhlas et al., 2022).

1.2 Problem Statement

The highly regulated industry creates complex market dynamics which affect all companies acting on the market. This includes the regulations on the area, but also how the regulations relate to different market operators in a SC context from the importer's perspective. Connections between the nodes in the pharmaceutical SC, as well as incentives for the parties, will also have a great impact on the importer. The complexity of the business ecosystem explained will in itself create difficulties in managing strategic and tactical decisions, which makes operating appropriately more difficult. A parallel importer must strive to compete against other importers, but also to secure the industry's position and relevance in the pharmaceutical market. Accurate strategic and tactical decisions rely on a precise understanding of the market dynamics.

1.3 Delimitations

This thesis focuses on the market dynamics for the parallel import of prescribed pharmaceuticals for humans in Sweden. The research area has been further limited by also reducing it in terms of sales channels to the end consumer studied. In Sweden, prescribed pharmaceuticals can be sold to pharmacies, hospitals with permission and through authorised healthcare personnel (MPA, 2023a). The scope has been limited to medical products sold through pharmacies in Sweden. While the European suppliers of PI are covered briefly, the analysis of the business ecosystem mostly focuses on regulations, pharmacies and importers.

Details in the regulations presented should be seen as examples of how the industry is regulated, and not definitive or complete. Neither have all regulations been covered, even though the most important are. Interpretations of the regulations are difficult and will sometimes require specific expertise and years of experience. While regulations are studied through literature review, regulatory experts have also been involved in the empirics.

While parallel distribution shares many similarities with parallel importation and is treated identically by some market players, the focus of this thesis is on parallel importation.

Parallel importation of generic products is covered, as it will mainly differentiate from the original segment when it comes to the substitution systems at the pharmacy level.

1.4 Purpose of Study

The thesis has an ambition to fill the identified research gap, which is relevant for both the academy and industry. While different parts of the business ecosystem of parallel imports have been previously researched within the academy, the area has not been deeply analysed as a whole to the author's knowledge.

1.5 Objectives and Research Questions

Companies operating in the industry can be assumed to possess deep knowledge within the area. This thesis aims to concretise, summarise and compile industry insights regarding the dynamics within the business ecosystem. This could potentially lead to an extended basis for strategy decisions, enhanced efficiency and increased customer satisfaction for companies within the industry. Furthermore, the thesis can improve understanding of different perspectives within the industry, which could lead to better collaborations, partnerships or other types of win-win situations. Based on the presented objective, two research questions are formulated:

> ***RQ1****: Which dimensions are most important when describing the business environment?*
>
> ***RQ2:*** *How can insights from RQ1 be applied in practice?*

1.6 Target Audience

The target audience for this thesis is master students within Industrial engineering and management or students with similar educational backgrounds. Furthermore, the thesis also targets industry personnel who work with strategic and tactical decisions either at established companies operating on the Swedish market of parallel importation, or companies considering entering the Swedish market. Industry professionals within related areas such as regulations, supply, purchasing or warehousing are targeted through an ambition to portray different perspectives.

1.7 Thesis Disposition

Chapter 1 - Introduction: Explanation of the context of the study, the problem statement, delimitations, and the research goal and purpose. Finally, the target audience and a summary of the thesis deposition is presented.

Chapter 2 - Methodology: Theory on research methodology through the concepts of research objectives, research methods, scientific reasoning, techniques and research quality. Finally, the methodology used for this thesis is defined.

Chapter 3 - Theoretical background: The theoretical background needed for analysing the problem. SC theory and the pharmaceutical product life cycle is introduced. Lastly, the pharmaceutical SC is mapped and industry regulations reviewed.

Chapter 4 - Empirics: The empirics gathered in interviews during the research. Areas covered are the pharmaceutical SC, supplier- and customer interaction, regulations and the competitive effects seen on the market.

Chapter 5 - Analysis: An analysis of the gathered information, both from literature review and the empirics, in the context of competition theory. Lastly, speculations on the future are presented.

Chapter 6 - Conclusion: Summation the results from the analysis and present reasoning regarding the choice of methodology. Finally, the contribution to the academy and suggestions on further research is presented.

References: References to sources used in the project, sorted in alphabetical order according to the APA 7th edition reference system.

2. Methodology

Chapter 2 covers theory on research methodology through the concepts of research objectives, research methods, scientific reasoning, techniques and research quality. Finally, the methodology used for this thesis is defined.

2.1 Overview

The methodology is the fundamental research strategy that defines the principles and frames the research process. The choice of methodology is dependent upon the objective as well as the characteristics of the study (Höst et al., 2006).

2.2 Research Objective

The overarching objective of the research can be used to categorise the study. These are *Descriptive studies*, *Exploratory studies*, *Explanatory studies* and *Problem solving studies*. A study can use multiple purposes, both throughout and in different parts of the process or study. However, one will often predominate. (Robson, 2002) The research object defines what ambition level and thus which scope the study will have.

A descriptive study focuses on portraying an accurate description of the studied area, by discovering and describing how it works or is performed (Höst et al., 2006). This requires extensive knowledge of the study object so that the appropriate aspects can be focused on. Descriptive studies can have both qualitative and quantitative traits. (Robson, 2002)

An exploratory study aims to delve deeply into comprehending the mechanisms or execution of the studied area, as well as assess this phenomenon in a new light (Höst et al., 2006). The goal is to provide the reader with new insights, but can also be to ask questions. This type of purpose is often seen in qualitative studies. (Robson, 2002)

In an explanatory study, the focus lies in trying to explain the observed situation or problem, usually through casual relationships (Höst et al., 2006). The purpose of explanatory studies can be achieved both from qualitative and quantitative studies (Robson, 2002).

Problem solving studies revolve around an identified problem and a solution for that problem. It can either aim to identify a possible solution or implement a solution in a specific situation. (Höst et al., 2006).

2.3 Methods

2.3.1 Overview

The study method defines how the research will investigate the area to come up with a conclusion. Four main methods in applied sciences are commonly used in master theses (Höst et al., 2006):

1. A **survey study** is a study that compiles and describes the current state of the research object or phenomena.
2. A **case study** investigates one or multiple cases in depth where the studied objects are not affected by the research.
3. In an **experiment**, a comparative analysis of at least two alternatives is conducted where a few number of variables are isolated and adjusted individually to identify how the outcome is affected.
4. In **action research**, a highly monitored and documented study of an activity is conducted, where the aim is to solve an identified problem.

2.3.2 Survey

When the aim is to describe or map a phenomenon, a survey could be appropriate. Research questions could be to identify the main problems that had to be addressed by pharmaceutical companies in their market entry phase, or what kind of pharmaceutical products that are most profitable and why. (Höst et al., 2006)

The research question and how the results from the survey are intended to be used play a central role in preparing for a successful survey study. The population has to be identified and specified, as well as how the sample should be chosen. This will affect what conclusions can be drawn from the data collected. (Lekvall & Wahlbin, 2001; Höst et al., 2006)

2.3.3 Case Study

A case study will be an appropriate methodology to use when the aim is to in depth describe a phenomenon or a research object. This could be to analyse market entry strategies for new entrants in the industry of parallel imports of pharma. Case studies focus on one or multiple cases and are often chosen specifically to draw general conclusions applicable to similar cases. Since only a few cases are studied and chosen actively, statistically significant results cannot be achieved in the same way as in survey studies. However, case studies can give interesting and deep insights in the particular cases studied. (Höst et al., 2006)

Insights given through studying the cases can also contribute in forming the research focus itself. This is possible because of the qualitative characteristics of the data being collected. Since qualitative data can be analysed in multiple ways, this shift in focus is made possible. To gather data, methods like interviews, observations and archive analysis can be used. (Höst et al., 2006)

2.3.4 Experiment

To identify causality or explain how and which aspects a phenomenon depends on, the methodology is required to be more strictly monitored. This structure can be achieved by applying an experimental methodology. By isolating the aspect of interest by holding other variables fixed, changes can be identified and analysed with respect to the studied variable. This method requires that the research is well planned since the experiment cannot be changed as soon as it has been initiated. When planning an experiment it is important to consider the aim of the study, how the hypothesis should be formulated, which variables that should be analysed and how the subjects studied are chosen. Data collected are more often of quantitative character, but under some circumstances, qualitative data can be used as well. (Höst et al., 2006)

2.3.5 Action Research

When the study aims to improve the studied object while studying it, the action research approach can be applied. Action research is initiated by observing a situation to identify and concretise the problem. This is followed by an iterative process where possible solutions are implemented and, importantly, evaluated. To decrease the risk of bias, criteria for evaluation could be defined early in the process. This could lead to the evaluation being more objective. (Höst et al., 2006)

2.4 Scientific Reasoning

2.4.1 Overview

Scientific reasoning describes how observations are analysed to come up with a conclusion, and which type of conclusions the observations can support. Research methodologies tend to be divided into mutually exclusive clamps, while the reality is more complex (Silverman, 1997).

2.4.2 Research Philosophies

Three main research philosophies describe how reality is seen: analytical-, system- and actor approach.

With an analytical approach, the reality is seen from the perspective that a system is summative and is equal to the sum of the individual parts. The parts can be assigned quantitative values and the system can thus be analysed with statistical methods. Based on objective and measurable observations the systemic reality can then be explained (Holme & Solvang, 1997). This approach emphasises the need for objectivity in research (Kovacs & Spens, 2007).

The system approach differentiates from the analytical approach by realising that the system might not always be summative. Structural elements affect the interference between the parts resulting in a system that is not only affected by the parts of the system but also the structure of the system in itself. This approach tries to explain the parts based on the characteristics of the system. (Holme & Solvang, 1997)

The actor's approach emphasises the dynamics within the system just as the system approach. However, rather than focusing on the system, this approach relies on describing the system based on the characteristics of the different parts. (Holme & Solvang, 1997)

2.4.3 Qualitative Analysis

One aspect that characterises qualitative research is the nature of the data collected. In qualitative research, the data analysed is in the form of words, sentences or paragraphs, rather than numbers. This type of data is then analysed and put into context by giving them meaning, translating them or making them understandable. (Neuman, 1997)

Qualitative research emphasises the importance of the context in which an action appears. This means that it is important to also understand the surroundings of the focus of study (Neuman, 1997). When conducting qualitative research, three attributes of the research are especially important: transparency, methodically and empirically.

Transparency assures that other people can review and evaluate the procedures used to support the findings and conclusions. In practice, this means that the writer must describe and document the procedures, as well as keep all data available for inspection. (Yin, 2016)

The research should be conducted methodically meaning that there should exist an orderly set of research procedures so that unexplained bias and deliberate distortion is avoided. This also includes aspiring for a sense of completeness in the research effort as well as cross-checking the findings as well as data and procedures. (Yin, 2016)

The final objective is to conduct empirical research meaning that the research findings should be built upon an explicit and rigid body of evidence. Depending on the research objective and type, different types of evidence will be collected and analysed. The study's conclusions must be drawn in reference to that. (Yin, 2016)

2.4.4 Quantitative Analysis

Quantitative research revolves around a research object that can be statistically analysed because of the numerical nature of the data. The goal of quantitative research can be generalised to produce a set of cumulative, theoretically defined generalisations that is based on insights from a sifting of data (Silverman, 1997).

2.4.5 Research Approaches

Depending on the research approach used, the contribution to theory building will be unique. To build a theory, a combination of all three research approaches is needed. This way the strengths of the approaches complement each other. Abductive research creates a creative environment which introduces radically new theories, while induction can be used to expand and develop these theories. Finally, deductive research can be used to test the theories. (Kovacs & Spens, 2007)

In deductive research, the process starts with an established theory and the researcher then tries to test whether or not the theory applies to the specific situation. Therefore the research can be said to go from a general law to a specific case. A deductive research approach can modify or refine existing theories, but has been criticised for not being able to initiate new theories. However, this approach contributes to theory building uniquely. Not only by verifying or falsifying theories, but also by extending existing theories which can be seen as a way of new theory building. (Kovacs & Spens, 2007)

In inductive research, the process begins in empirical observations that create a fundament for propositions and their generalisation in a theoretical model. This reasoning is often seen in qualitative research, but inductive research can also encompass quantitative methods. (Kovacs & Spens, 2007)

Abductive research can be initiated in two ways. Firstly, an observation is made that deviates from a theoretical framework. In this case, the abductive research approach revolves around trying to search for matching theories that can be used to explain the deviation. Secondly, a new theory or framework can be applied to an already existing observation. In this case, the abductive research approach comes from using and applying theories from different research disciplines in a new way. (Kovacs & Spens, 2007)

2.5 Techniques

2.5.1 Literature Review

Reviewing existing literature related to the research subject is important to ensure that the study conducted is based on previous findings and also displays the current body of knowledge which can play an important role in the thesis itself. (Höst et al., 2006; Saunders et al., 2007; Neuman, 1997)

The process of literature review includes defining parameters, generating keywords, searching and obtaining literature, evaluating gathered information and recording the findings (Saunders et al., 2007; Neuman, 1997). The process should be conducted iteratively meaning that, for example, keywords should be regenerated based on insights from previous information that have been found (Saunders et al., 2007).

It is of great importance that the reviewed literature is trustworthy, which will have to be evaluated by the researcher. The reliability of a source can be evaluated by investigating if the material has been reviewed, who guarantees the credibility, what method has been used and if the results are produced in a context which is applicable in this situation. If the source has been cited by other reliable sources, the likelihood of it being trustworthy increases. (Höst et al., 2006; Saunders et al., 2007)

When searching for relevant literature to review it is important to do this methodically. One way to begin the search process is to search broadly with a wide variety of keywords and different search engines for scientific material. Based on a quick overview of the broad range of collected sources, the most relevant resources could be studied in detail. This could be followed by deeper analysis in the most important topics, and repeated in multiple iterations. In this way, new keywords and sources will be received from previous sources. (Höst et al., 2006; Saunders et al., 2007)

2.5.2 Interviews

When conducting interviews, it is important to note that verbal formulations from subjects are not an appropriate substitute for the observation of actual behaviour. This statement is based on observations of the gap between what people say, believe and actually do. (Silverman, 1997)

There are three main interview styles: *Unstructured*, *Semi-strucured* and *Structured*. The styles differ to what extent the questions are prepared beforehand. In an unstructured interview, the questions are formulated broader and the direction of the interview is guided by the answers and insights that evolve during the interview. A semi-structured interview may contain main themes and questions, but still allows for improvisation and adjusting the focus slightly. Finally, a structured interview revolves around a defined set of questions asked to all interviewees. (Robson, 2002)

2.6 Research Quality

2.6.1 Overview

The research quality can be described through three main dimensions. These dimensions will have to be considered so that the research can reach conclusions with the potential to be used and aligned with the desired purpose. These dimensions are validity, reliability and transferability.

2.6.2 Validity

Validity describes to what extent the researcher is calling what is measured by the right name, or that the interpretation of observation is correct (Peräkylä, 1997). Depending on the specific research method used, validity can be assured appropriately in different ways (Peräkylä, 1997). Two techniques to validate findings are triangulation and member validation. Triangulation means that a result can be judged valid if different and contrasting methods of data yield identical findings. This limits the risk of results being affected by particular measurement biases (Bloor, 1997). In member validation, the research is validated by assuring alignment between the findings and understandings of the members of the collectivity. (Bloor, 1997).

2.6.3 Reliability

Reliability can be defined as the degree to which the findings are independent of accidental circumstances of the research. A high reliability would mean that the researcher could expect the same results if the research

would be reproduced (Peräkylä, 1997; Neuman, 1997). Four concepts can be utilised to increase research reliability. Firstly, constructs should be conceptualised by specifying and isolating them to reduce noise. Secondly, the level of measurement should be increased as this enables more specific information to be collected. Thirdly, by using multiple indicators of one variable, the risk of faulty indicators will be decreased. Lastly, pretests can be utilised to test a measure before applying it to the final situation. (Neuman, 1997)

2.6.4 Transferability

Transferability refers to the extent to which the results of the study can be generalised and applied also to other situations (Shenton, 2004). It is important that the researcher is cautious to how the methodology affects the transferability of the study, and provides the reader with a sufficient contextual setting from which the findings possibly can be transferred (Shenton, 2004).

2.7 Tailoring a Thesis Methodology

2.7.1 General Thought Process

When tailoring the methodology for this master thesis, the general thought process has been centralised around the writer's intended purpose of the study. This has created a methodology that is adapted to the uniqueness of the research, assuring that the purpose is met.

2.7.2 Research Objective

The procedure of mapping and describing the requirements of companies in the studied target market can sufficiently be acquired by applying an exploratory study. By doing this, the exploratory study can contribute results that will shine a light on the problem area in a new way and conclude results that will contribute to deeply comprehending the market dynamics. This defines the ambition of the study, and in what direction the results should be focused towards and is aligned with the writer's purpose of the study.

2.7.3 Methods

The case study method will sufficiently support the research with empirical data that can be analysed to reach conclusions in line with the research objective. By studying specific cases through industry personnel and how they interpret the dynamics within the industry, insights can be summarised to build a general understanding of the industry-specific challenges.

2.7.4 Analytical Reasoning

When studying the industry dynamics, a system approach will be effective concerning the ability to also explain how the different entities interact and together create the complex system that makes up the market dynamics. This approach will direct the research towards understanding not only the entities but also the structure's effect on a company. Furthermore, for this master thesis, a focus on mainly qualitative data can result in more interesting insights. This choice eventuates in importance to also understand the surroundings, since the interpretation of the quantitative data will be affected by the context in which an action appears. Finally, an abductive research approach is well suited, where a model for describing the market dynamics is created based on observations from the industry.

2.7.5 Techniques

Literature review is essential to gather insights from previous research and review written sources of for example regulations. Because of the important role of regulations in the industry, covering the most important regulations will be important. These are defined as regulations that have an impact on the PI operations in such way it directly affects how the importer will be able to operate. It can also be regulations that are important for the pharmaceutical industry in general. To assure sufficient coverage, extensive research will be conducted, which is later controlled with experienced industry personnel.

Potential interviewees will be identified with the ambition of covering different areas of interactions related to PI through their specific expertise. The structure of the interviews will be semi-structured, where the topics are defined as well as predetermined questions to direct the focus within the topics. The semi-structured approach allows for flexibility to dig deeper if the interviewee provides interesting insights into any specific area.

2.7.6 Research Quality

To ensure the research quality, an evaluation will be continuously applied. This will mean that aspects such as validity, reliability and transferability will be considered on an ongoing basis during the writing of the thesis. For example, the transferability will be affected by the choice of questions asked during interviews, as well as how the gathered data is interpreted. Finally, considering the transferability in the part where conclusions are drawn will ensure that the writer does not claim too striking or too generalisable results without constraining the transferability to a reasonable level.

3. Theoretical Background

Chapter 3 covers the theoretical background needed for analysing the problem. SC theory and the pharmaceutical product life cycle is introduced. Lastly, the pharmaceutical SC is mapped and industry regulations reviewed.

3.1 Supply Chain Theory

3.1.1 Context of Supply Chain Management

There are multiple ways to define a supply chain. Lambert, Stock and Ellram uses the definition that a supply chain is the alignment of firms that brings products or services to market (Lambert et al., 1998). Another definition that has been used is that a supply chain is a set of three or more organisations involved directly in upstream- and downstream flows of products, services, finances, and/or information from a source to a customer. This exact definition is used by Mentzer et al. (2001).

There are also multiple different ways to define supply chain management, which can generally be divided into three categories: a management philosophy, implementation of a management philosophy or a set of management processes (Mentzer et al., 2001).

3.1.2 Supply Chain Mapping

A supply chain map is a representation of the supply chain environment that simplifies relationships between different actors, while still capturing and communicating the essence in the supply chain characteristics (Gardner & Cooper, 2003). When creating this representation of the most important supply chain features, understanding the purpose of the mapping must be considered.

Key characteristics of the mapping include decisions related to the geometry, perspective and implementation issues. The geometry is defined by how many business units are represented as performing transactions, how broad the representation is within each transaction and if the map is geographically representative. The perspective includes the decision on firm-centric vs. industry-centric view and the scope of the perspective concerning product breadth, key processes beyond logistics, process view depth and cycle view. Implementation issues concern the information

density, the connections to the supply chain database and how the map is made available to the user. (Gardner & Cooper, 2003)

3.1.3 Operations Strategy

Operations strategy can be described as the common direction to which different operations in the company are coordinated towards. It will be important that the designing of the operations strategy is anchored in the market. Understanding the markets will therefore be essential for operating a business in a market-driven way. Markets are usually described from a marketing perspective, with geographical and/or sector segments. This clustering of a market would imply that the customer requirements are similar in that cluster, while it might not be in reality. It is important to describe the market in specific terms so that it can provide valuable insights and implications on an operational level - in terms that are not ambiguous. With this in mind, there are four main steps for securing insights on a market (Hill & Hill, 2009):

1. Avoid general words and phrases
2. Avoid a long list of how the company competes
3. Separate order winners and qualifiers
4. Weight order winners and qualifiers

Hill's model provides a structure for how to link corporate objectives with operations and marketing strategy development (Hill & Hill, 2009). The model includes five steps. When evaluating the business in practice, these steps should be evaluated and re-evaluated, as they affect each other. The first step is to define the corporate objectives at the business unit. It provides a first direction in which the strategy should be striving for. The second step is to assess future markets, both related to known and potential customers, products and competitors. Through this, the marketing strategy can be formed. The third step is to explore the target market requirements. Market requirements from the customer perspective can be divided into two main categories: *order winners* (OW) and *qualifiers* (Q). Qualifiers are competitive criterias that enable companies access to a market, but do not win orders. Order winners are criterias that customers value and make them prioritise the product. The strategic task of the operations will therefore be to meet the Q and perform better than competitors in the OW. The operations strategy will be formed through the process choice and supporting infrastructure. The process choice will affect the ability to provide the required OW and Q. The infrastructure describes non-process features such as systems, controls and compensation systems. Hill's model is visualised in *Figure 1*. (Hill & Hill, 2009)

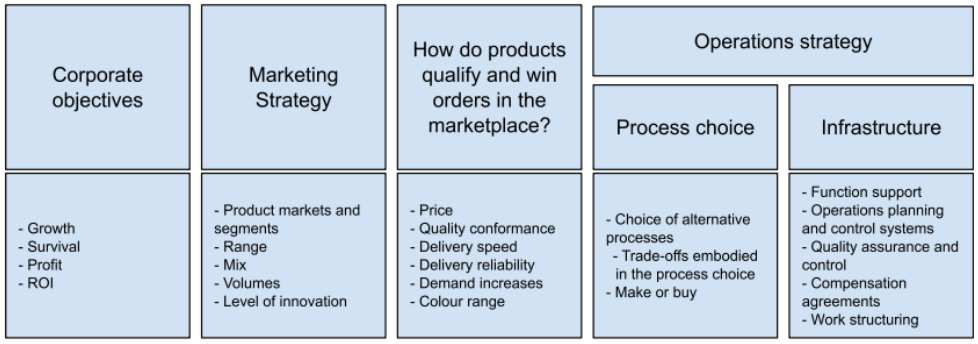

Figure 1: Hill's model (Hill & Hill, 2009)

3.1.4 Marketing Mix

The details of the marketing mix describes everything the company can do to influence the demand for its products. These can be clustered into four areas: *Product*, *Price*, *Place* and *Promotion*. Product involves the pharmaceutical product, inner/outer packaging, the packaging leaflet and any additional information associated with the product. Price is the amount of money that the customer has to pay to acquire the product. Place includes what makes the product physically available to the target customer. Promotion refers to the activities that communicate the benefits of the product. (Armstrong et al., 2009)

These factors generally describe the aspects that are especially important in the value proposition, and therefore describe what brings value to the customer. How these aspects are mixed, ranked and prioritised depend upon the market driving dynamics within the industry. (Armstrong et al., 2009)

3.2 Medical Product Life Cycle

3.2.1 Overview

Before a medicinal product reaches the market it has to go through a series of trials before being approved. This research process is expensive and after accounting for the costs of failed trials, the investments needed in research to bring a new drug to market (95% confidence interval) have been estimated to range between around $0.9 and $1.4 billion (Wouters et al., 2020). The process of developing a drug on the European market of pharmaceuticals can be described as four phases. Clinical development is estimated to account for between 50 to 58% of the total development costs (Simoens & Huys, 2021). An overview of the pharmaceutical development phases is illustrated in *Figure 2*.

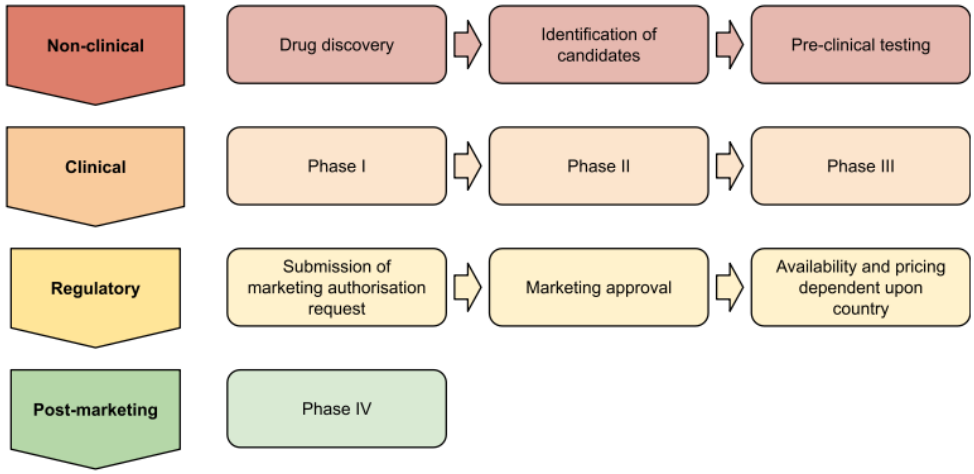

Figure 2: Pharmaceutical development in Europe (Bere, 2005)

3.2.2 Research Phase

The initial stage in the research phase includes the identification of a target molecule that is believed to contribute to, or to aggravate, a disease state. This molecule is then tested against hundreds of chemical or biological compounds that have the potential to limit its impact as a disease. The most promising compounds are then further tested in experimental models that are similar to conditions in the human body, to ensure that the compounds are safe for proceeding to a clinical development process. If so, a *Clinical Trial Application* can be filed and assessed. If the application is accepted, the researchers can proceed to clinical development. (BioStock, 2023)

The clinical development consists of three phases. *Phase I* is similar to the pre-clinical stage, but this time the compound is tested in a small population of healthy volunteers to ensure that the components still behave as expected when used on humans. In this phase the safe dosage is determined, as well as further analysis on how the drug is being absorbed, moved through, and how it leaves the body (BioStock, 2023). This is also known as the pharmacokinetics (Le, 2022). In *Phase II*, the candidate is tested on patients with the disease or condition that is the target of the treatment. Minimum and maximum dosages are also explored. During *Phase III,* a larger number of patients are tested to further ensure that the drug is safe and contributes to the treatment as intended. Side effects are also identified in this phase. (BioStock, 2023)

3.2.3 Market Approval

3.2.3.1 Registration Process

Given that the compound passed all phases in the clinical development, a market registration process will be initiated (BioStock, 2023). There are four main procedures for this; the *Centralised procedure*, the *Decentralised procedure*, the *Mutual recognition procedure* and the *National procedure* (Bere, 2015).

In the *Centralised procedure*, a *Marketing Authorisation Application* (MAA) will be submitted to EMA, which summarises all available data gathered during the research phase (BioStock, 2023). If approved, the authorisation is valid throughout the EU, Iceland, Norway and Liechtenstein (EMA, 2023f). The EMA has no authority to permit authorisation for marketing in EU member states, but its role is to recommend a decision to the European Commission, which makes the final decision and possesses the required authority (EMA, 2019). The centralised procedure is mandatory for certain medicines such as those treating rare diseases, HIV, cancer and neurodegenerative disorders, only to name a few (Bere, 2015). As of 2023, the current basic fee for a marketing-authorisation application (single strength, one pharmaceutical form and one presentation) starts at €345 800 (EMA, 2023g). This fee is heavily reduced for micro-, small- and medium-sized enterprises (EMA, 2022).

In the *Decentralised procedure*, an application is filed for authorisation in one or multiple EU member states, where one state acts as the reference member state. This state performs the initial evaluation of the medicine and creates a draft assessment report. If accepted, the other states then agree on the reference member state and issue authorisation in their respective country. (Heads of Medicines Agencies [HMA], 2023)

If a medicine is authorised in at least one EU member state, an application for marketing authorisation is filed through the *Mutual recognition procedure*. The authorisation could be issued for one or multiple other member states. If accepted, marketing authorisations are granted by the member states in their respective country. (HMA, 2023)

The *National procedure* route is chosen if the company wants to authorise the medicine for one country only. This route is common for generic- and non-prescription medicines. It is the national competent authority that processes this authorization application, which is MPA in Sweden. (EMA, 2023h)

3.2.3.2 Pricing

As a part of the procedure when the product is being prepared for the market, the medicine will be subject to price negotiations with the potential buyers (BioStock, 2023). In Sweden, the pricing of medicines is based on the principle that it should be in line with the value it offers to patients - *Value-based pricing*. (Tandvårds- och Läkemedelsförmånsverket [TLV], 2022a)

Value-based pricing stems from the principle that the cost of medicine covered in the high-cost reimbursement scheme shall be reasonable in relation to its benefits. New medicines that substitute older because of better effect will therefore often have a higher price than its precursor, as TLV because of the value-based pricing can accept the higher price (TLV, 2022a). In many other European countries, a system of international reference pricing is instead used. This means that the price of a pharmaceutical in one or multiple other countries is taken into consideration during the pricing of the pharmaceutical on a national level (TLV, 2022b).

In Sweden, the high-cost reimbursement scheme sets an upper bound to the yearly expenses an individual will need to cover for prescribed drugs, some non-prescription medicines and some consumables related to the control or injection of the medicine. TLV decides which medicines and products should be included in the scheme, and to which price. Companies can apply to TLV for their product to be included, and must then be able to show that the product is cost-efficient (FASS, 2019). eHälsomyndigheten is responsible for tracking each individual's expenses so that the correct discounts are given at the particular level. The maximum cost a patient can be required to cover is 2600kr per year (eHälsomyndigheten, 2022). The high-cost reimbursement scheme results in a market where most of the cost is covered through the scheme, and only 18% by the patient in 2021 (TLV, 2022a).

3.2.4 Product on the Market

3.2.4.1 Patent Protected Phase

To protect new treatments and drugs, developing companies can obtain patents for 20 years with the possibility for an additional 5 years through one supplementary protection certificate (Garattini et al., 2022; Patent- och Registreringsverket, 2023). During this period the inventor is secured exclusive right to make, use or sell the patented substance (EMA, 2023a). This gives financial incentives that stimulate innovation and investments in

research, as a monopolistic market with no producing competitors can be assured during the initial time the pharmaceutical is on the market (Törnvall, 2013).

From a lifecycle perspective, the price of a drug is generally the highest when it has been on the market for 5 to 15 years. During this time, the drug is well established on the market leading to high usage but is still protected under patents eliminating the generic competition. In Sweden, however, it is common for medicine to keep its original price throughout the period, in comparison to many other European countries where the price is rather decreasing during the patent-protected phase. (TLV, 2022a)

3.2.4.2 Post-Patent Phase

When a patent expires, other companies can apply for a manufacturing licence for a drug with the same active substance and, but not necessarily, packaging, inactive substances and name. Drugs that use the same active substance as the original product are called generic medicines. (EMA, 2023b; MPA, 2023b)

When generic competition has been active within a substitution group for four consecutive months, TLV will start to evaluate if the criteria for setting a price ceiling are fulfilled. This happens when the price within the substitution group has decreased to at least 30% of the highest price noted when generic competition was first introduced, called the initial price ceiling. Furthermore, this product must stand for at least 10% of the sold volume within the group. The new price ceiling is then set at 35% of the initial price ceiling. A price ceiling is then set for all groups with the same formulation and active ingredient, restricting higher prices for pharmaceuticals within these substitution groups. (TLV, 2023)

Even when there is no or only little generic competition, a price reduction is planned for medicines after 15 years on the Swedish market, which is called the 15 years-rule. The rule states that the price for medicines that are older than 15 years from the time of market authorisation, should be decreased by 7,5%. (TLV, 2022a)

3.2.4.3 Distribution

The distribution model widely used in Sweden is Direct-to-Pharmacy-model (DTP-model), which is known for its cost-effectiveness, reliability and that cost reductions to a large extent is beneficial for the general public rather than leading to increased profits for companies (Johnson & Gabrielson, 2023). A DTP-model differentiates from traditional wholesale distribution

in that the manufacturer keeps the ownership of the products to the pharmacies, and rather uses 3PL providers for distribution (Deloitte, 2016).

3.2.4.4 Post-marketing Surveillance

For some medicines, post-marketing studies are required to be conducted after the market approval. This could be done for treatment of complex or unusual medical conditions, or of pregnant women that usually are not included in the clinical development process. This phase aims to evaluate how the medical product interacts with other substances and further confirm the safety and intended effect of the substance (BioStock, 2023). A pharmacovigilance process is used to notice adverse drug reactions (ADR). The information flow in the pharmacovigilance process is shown in *Figure 3* (Bere, 2015).

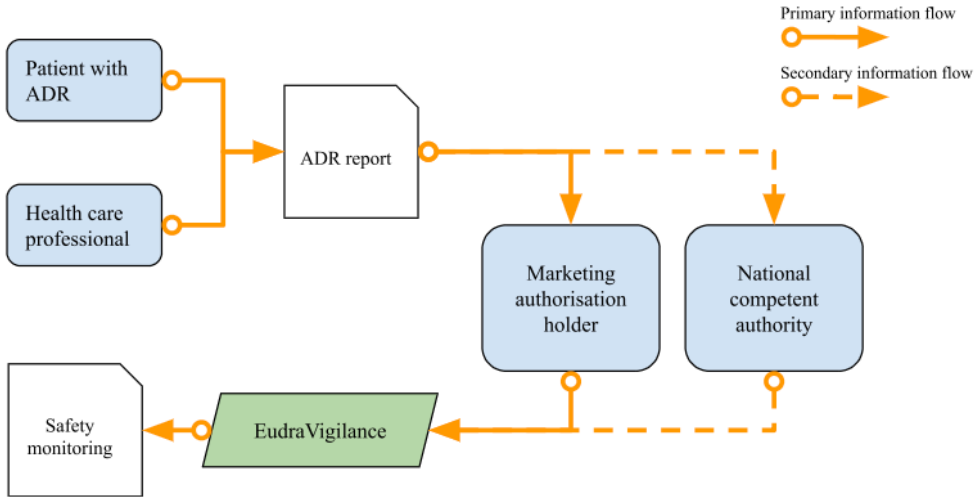

Figure 3: Pharmacovigilance and Risk Management; Data collection and management (Bere, 2015)

3.3 Market of Parallel Imports

3.3.1 The Concept of Parallel Imports

Parallel imports of medicinal products within the EU are the result of two distinctive features of the market. Firstly, the variable price regulations of pharmaceuticals and secondly the manufacturers' weak vertical control over the SC. (Kanavos et al., 2005)

As a result of the reimbursement practices within different countries, health insurance organisations will in most cases regulate or negotiate prices

creating an upper limit to the price level for reimbursed drugs. This creates price variability for identical products within the EU market, enabling opportunistic parallel importers to buy the medicine in a country where the price is low and redistribute it to a country with a higher price. This activity is protected by the principle of free movement of goods within the inner market of the EU. (Kanavos et al., 2005)

The vertical control is limited by the regulatory environment which prohibits manufacturers from selling directly to customers. Instead, manufacturers supply wholesalers, who in turn supply pharmacies. Prescription-holding patients will access the medicinal products at the pharmacy (Kanavos et al., 2005).

3.3.2 Stakeholder Effects

Pharmacies are reimbursed for trade in pharmaceutical products through trade margins. It is these margins that create the financial incentives for the pharmacies, in combination with any discounts provided by wholesalers or parallel importers (Kanavos et al., 2005). This means that the parallel importer can have a positive impact on the pharmacies' trade margins and thus contribute to the pharmacies' position on the market.

Patients could benefit from parallel trade through lower prices and increased access to pharmaceuticals (Läkemedelshandlarna, 2023). But, because of the co-insurance system existing on the Swedish market, the patient financial benefits from parallel trade can only be marginally positive (Kanavos et al., 2005). Patients who reach the price ceiling in the high-cost reimbursement scheme will not experience any cost savings. In those cases, the direct savings are instead located at the healthcare system level. This direct effect is equal to the intra-price spread between the locally sourced and parallel imported product for the imported volume (Kanavos et al., 2005).

The patent holder will experience a loss in profitability equal to the difference in price between the low-price country from which the product is exported, to the high-price country to which it is imported, times the volume. This assumes that the organisational structure for the patent holder measures sales on a European level. Differentiating the organisation into market divisions on regional or national levels will result in a relocation of sales into another market filial, which in this case would be considered external.

The prevalence of parallel importers can affect the product launch decision for a patent holder who considers entering a new market from where parallel

importation might be feasible. There are three main strategies that patent holders consider in this situation (Sekip Altug & Sahin, 2018):

1. Launch the product and accept parallel import
2. Launch the product and deter parallel import through pricing
3. To not launch the product

Patent holders are less likely to enter a new market if the price is determined through negotiations with the government. Whether or not the threat of parallel import has an affect on the product launch decision is also affected by the level of insurance coverage, market sizes and quality perception of the imported medicinal product. (Sekip Altug & Sahin, 2018)

3.3.3 Suppliers of Parallel Imports

Pharmaceutical parallel imports reach Sweden through a few different sourcing alternatives at the European market. In order to make a profit from the imports, the price in the export country must of course be lower than the import country. This does not necessarily mean that the prices in general are lower in the export country - many large importers are also large exporters. Instead, the sourcing possibility arises from identifying opportunities of specific products with a relatively low price. Around 60% of the PI to Sweden stem from countries with a high gross domestic product per capita. For other countries within the EU, the percentage of imports from these types of countries are commonly around 50%. The largest source for importation to Sweden is Germany, followed by France and the UK. (Aguiar & Ernest, 2021)

There are a few different actors that can be involved in supplying the importer with pharmaceuticals, such as wholesalers, brokers, pharmacy chains, other PI companies or the producers themselves. (EMA, 2023d)

In order to pursue wholesale trade with pharmaceuticals, a wholesale licence is required. This includes purchasing, storing and distributing pharmaceutical goods on the internal market of the EU, if you do not manufacture it yourself. The four biggest wholesale companies in the EU are Phoenix Pharma SE, McKesson Europe AG, Alliance Healthcare Distribution Ltd and Noweda Apothekergenossenschaft eG. (IBIS World, 2022)

A broker is involved in the sale or purchase of medicinal products without selling or purchasing the products themself, and without owning or distributing the physical products. The brokers provide value to the SC by connecting potential buyers and sellers on the market. In order to be

involved in this, the company must be registered as a broker and hold the required permits (Bundesinstitut für Arzneimittel und Medizinprodukte [BfArM], 2024a). For reference, there are 71 brokers active only on the German market (BfArM, 2024b).

3.3.4 Customers of Parallel Imports

3.3.4.1 Introduction to Customers

Under the scope of this thesis, the direct customers from the importers' perspective are the pharmacy chains that purchase and sell the prescribed pharmaceuticals to patients, under the high-cost reimbursement scheme. Five nationwide pharmacy chains are operating in Sweden as of 2022 (Sveriges Apoteksförening, 2022).

Within the reimbursement scheme, regulations affect how pharmacies can substitute different alternatives within each substitution group through substitution systems. These systems affect the interaction between the parallel importer and the pharmacy chain, as they frame the negotiation room and possibility for prioritisation from the pharmacies and are generally divided into two categories: *PV-substitution* and *Parallel substitution*. The substitution rules should be construed under the pharmacy's availability obligations and describes how and when different products are allowed to substitute each other. (TLV, 2014)

3.3.4.2 PV-System

In Sweden, generic substitutions of medicinal products within the reimbursement scheme are controlled through the Periodens Vara-system (*Product of the Month)*, which is administered by TLV. Ever since the formalisation of the pharmacies in 2009, out-patient pharmacies have been forced to primarily offer the substitution that is determined to be the product of the month by TLV (Aho & Rönnholm, 2016). The generic substitution system also includes the substitution of PI when it is imported with reference to a generic (TLV, 2014). Approximately 50% of all packages sold at outpatient pharmacies are part of the PV-system. The system simulates generic competition on the market, and a well-functioning competition decreases prices which can explain why Sweden is one of the countries with the lowest price on pharmaceuticals in Europe (Aho & Rönnholm, 2016). The prices for medicines in the PV-system were almost 50% lower than the average in 19 other European countries (TLV, 2022a).

A substitution group contains medicinal products that have the same active substance, formulation and strength and are considered possible to substitute. MPA is responsible for the placing of a product in a specific substitution group, which is done on article level (Aho & Rönnholm, 2016). Within the PV-system, the substitution groups consist of at least two different drugs. A group could, for example, consist of (TLV, 2014):

- Generic + original (+ any parallels)
- Generic + generic (+ any parallels)
- Generic + originals parallel
- Original + generic parallel

For pharmaceuticals within the reimbursement scheme, a product of the month is elected within each substitution group - *Periodens vara*. This is done monthly and based on the price per unit offered to the pharmacies. However, the pharmaceutical company which imports or manufactures the product must also ensure that they can sufficiently supply the expected demand throughout the market and during the upcoming period, and actively report this in the system. Because all companies cannot assure availability for all products during all periods, the selected PV is not always the cheapest on the market (Aho & Rönnholm, 2016). During 2015, the number of groups where PV was not the cheapest alternative was around 20% (Aho & Rönnholm, 2016). If conditions change and the company can no longer supply the whole market, a new PV is elected (Aho & Rönnholm, 2016). Stockout or any other disruption will generally be associated with a penalty fee from TLV.

The PV-system effectively decreases the prices of products within the system. On average, the price of sold pharmaceuticals drops by 50% after 8 months of competition, as seen in *Figure 4* (TLV, 2022a)

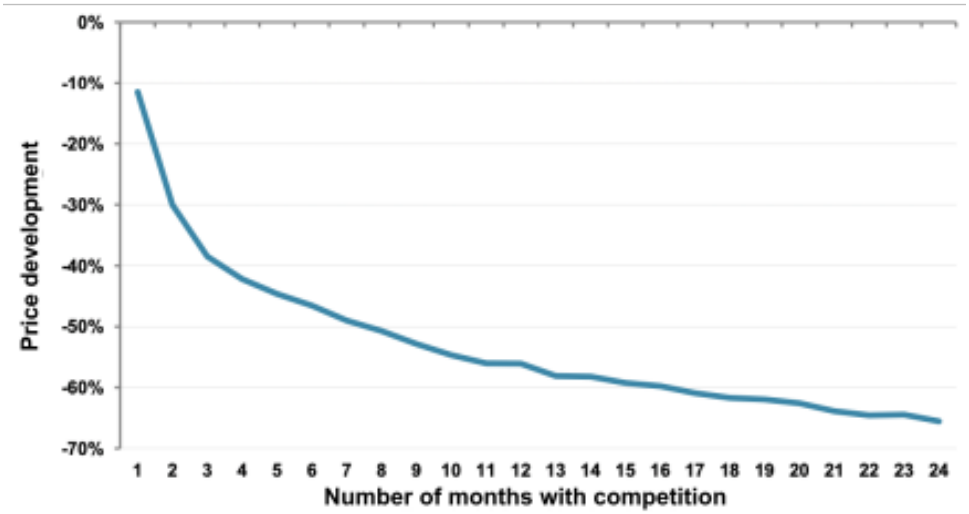

Figure 4: Price as function of time under competition (TLV, 2022a)

The price development has also been evaluated when separating the substitution groups based on the number of competitors within the group, which is seen in *Figure 5.* The number of competitors within a group seems to have a clear effect on the price development. (TLV 2022a)

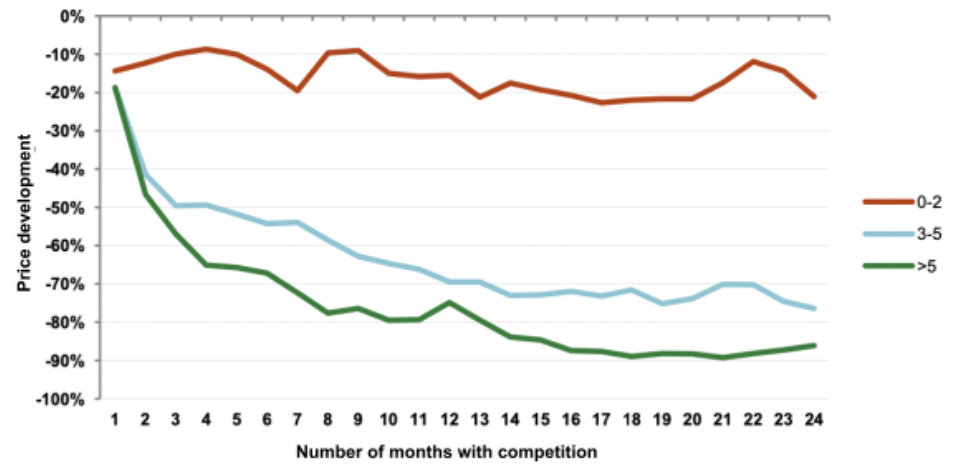

Figure 5: Price as function of time under competition, separated by number of competitors (TLV 2022a)

3.3.4.3 Parallel Substitution

Parallel substitution refers to the substitution of pharmaceuticals through parallel imports or parallel distribution. While the PV-system is regulating the reimbursed pharmaceuticals with generic competition in the whole market, parallel substitution rather gives options for substitution at a specific pharmacy. (TLV, 2014)

Within the parallel substitution, the substitution groups should only consist of the same drugs. This requires that the drugs have the same market authorisation holder. A substitution group could consist of, for example (TLV, 2014):

- Original + original parallel
- Two parallels of the same drug
- Generic + the generics parallel

A pharmacy is required to offer a substitution to a product within the same substitution group if it has a lower price and is available on the specific pharmacy. The pharmacies are also required to order the prescribed product if the customer does not accept the substitution to the cheaper alternative that is available in the specific pharmacy. Furthermore, the pharmacies must inform the customer what the substitution means. However, they are not required to order any other substitutable drug other than the prescribed one, which means that the pharmacy can decide if they want to stock a parallel. These obligations are illustrated in *Figure 6*. Additional costs are not covered by the pharmaceutical benefits scheme. (TLV, 2014)

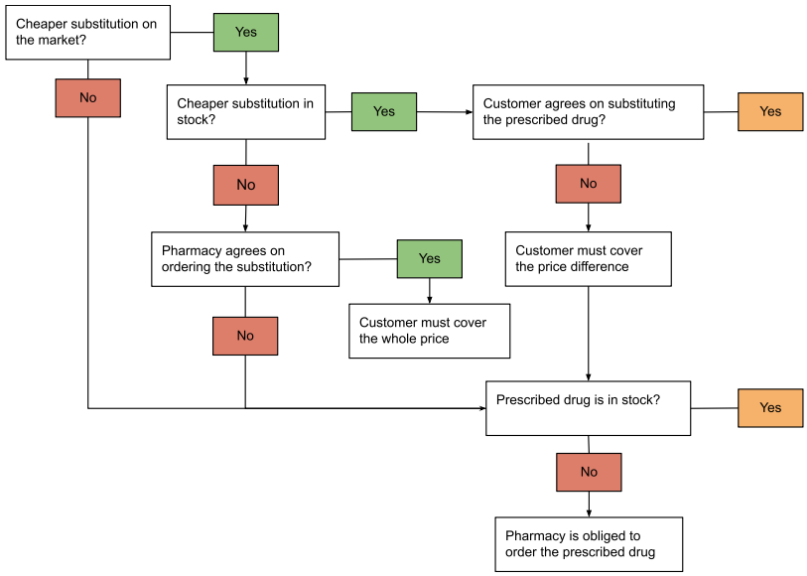

Figure 6: Obligations for pharmacies in parallel substitution

3.4 Regulatory Environment

3.4.1 Regulatory Overview

The pharmaceutical industry is one of the most regulated industries in the world (Arthur D. Little, 2023). As Sweden is a member of the European Union, organisations are entitled to also follow EU regulations. The regulations consist of laws, rulings, directives and decrees related to pharmaceuticals and the related industry.

3.4.2 EU Legislation on Pharmaceuticals

3.4.2.1 European Union Bodies

The CJEU is an institution that assures that EU law is interpreted and applied the same way throughout the union (Court of Justice of the European Union [CJEU], n.d.). The EMA protects human health by facilitating development and access to medicines, evaluating MAA's, monitoring the safety of medicines across their life cycle and providing information on medicines in any language (EMA, 2020). The European Parliament is the law-making body within the EU, and negotiates and adopts EU laws together with the Council of the EU (European Union [EU], 2023a, 2023b).

3.4.2.2 Community Code Relating to Medicinal Products

The directive on the Community code relating to medicinal products is a directive issued by the European Parliament and the Council in 2001 regarding medicinal products in general. This directive relates mainly to the countries within the EU, and is thus required to be implemented into the national regulations in each member state. Because of this, the specific details of the directive is not necessary to know when working in the industry. However, it does give insights into what similarities can be expected to be seen in national regulations within the EU. (Directive 2001/83/EC)

3.4.2.3 Good Distribution Practice of Medicinal Products for Human Use

The Good distribution practice guidelines are issued by the European Commission and encompass various areas related to the distribution of medicinal products. These are quality management, personnel, premises and equipment, documentation, operations, counterfeits and returns, outsourced activities, self-inspections, transportation, special provisions for brokers and

final provisions. (EMA, 2013) The content under these themes are summarised shortly in *Appendix 2*.

The purpose for the GDP is to ensure that the products that flow on the market are authorised in accordance with EU legislation, correctly stored and transported throughout the supply chain and that contamination is avoided. Furthermore, GDP will also ensure enough turnover of stored medicines and adequate order delivery times (EMA, 2023c).

3.4.2.4 Commission Regulation on Safety Features on Packages

The commission's delegated regulation on Safety features on packages provides specific guidelines on what information must be present on the packages on medicinal products. This includes technical specifications for the unique identifier used to identify individual packs, modalities for verification of the safety features and repositories system where the information should be contained. Furthermore, which prescription medicines it does not apply to and which non-prescription medicines it does apply to are specified. (Regulation 2016/161)

3.4.2.5 CJEU Rulings

BMS Conditions

In 1996, CJEU defined five conditions that must be fulfilled for an importer to repackage a product without consent from the trademark holder, through the rulings in the Bristol-Myers Squibb case (Siwiec & Bajer, 2023). These conditions are fulfilled if the importer can demonstrate that (CJEU, 1996):

1. The opposition of repackaging of the products creates an artificial separation between markets in member states
2. The repackaging will not affect the condition of the repackaged product
3. The new package clearly indicates who produced and who repackaged the product
4. The quality and presentation of the repackaged product is proper and thus cannot damage the reputation of the trademark
5. The trademark proprietor is informed prior to the placement of the product on the market and provided with a specimen of the repackaged product if requested.

Case C-379/97 Pharmacia & Upjohn SA v Paranova A/S

Upjohn held and used different trademarks for the same medicine on different markets within the EU. Paranova purchased products manufactured by Upjohn in Greece and France, and when distributing it to Denmark,

remarked the products to the trademark used by Upjohn in Denmark. The court rules that it is acceptable to do so if it is objectively necessary to change the trademark to the one used in the market of import, in order for the PI to market the product on that market. (CJEU, 1999)

Joined cases C-253/20 and C-254/20 Impexeco NV and PI Pharma NV v Novartis AG and Novartis Pharma NV
Novartis has two different market divisions, one for production of originals and one for production of generics. Within the Novartis group, both an original and a generic product is manufactured and sold in Belgium and Netherlands. The generic and original are in fact identical. The importer imported generic pharmaceuticals from the Netherlands, which thus were under the generic trademark, to Belgium, but relabeled with the name of the original. The court rules that the trademark proprietor may oppose the marking unless the products are in all aspects identical, and the BMS-conditions are fulfilled. (CJEU, 2022a)

Case C-147/20 Novartis Pharma GmbH v Abacus Medicine A/S
Novartis produces a product that comes with an anti-tampering device on the package. Abacus wanted to break the tampering, and repackage the product with a new anti-tampering device with the intention of importing the product to the German market, which Novartis opposed. The court judged that the trademark proprietor cannot oppose repackaging if the breakage of the original outer package would result in an obstacle to effective marketing. (CJEU, 2022b)

3.4.3 Swedish Legislation on Pharmaceuticals

3.4.3.1 Swedish Regulatory Bodies

The Swedish market for pharmaceuticals is regulated by multiple authorities. Swedish Medical Products Agency (MPA) is responsible for approval, control and supervision of humanitarian- and animal pharmaceuticals (Regeringskansliet, 2023). The Swedish Dental and Pharmaceutical Benefits Agency (TLV) is responsible for pricing and subsidy decisions on medicinal products covered by benefits schemes (TLV, 2021). The government issues statutes and ordinances which are published in the Swedish code of statutes (Regeringskansliet, 2018). These are all examples of national legislation which regulates the business environment for companies within the pharmaceutical market.

3.4.3.2 The Medicinal Products Act

The Medicinal Products Act (SFS 2015:315) contains 18 chapters covering areas related to medicinal products in general. The first three chapters concern how to use and interpret the act itself. Chapter 4-8 covers areas relevant for patent holders, trade approvals or manufacturing permits for medicinal products. Chapter 9 covers import of products and active substances from outside EEA and imports for personal usage. Chapter 10 describes that anyone who manufacture, import, trade, transport, store or in any other way handle medicinal products professionally must take precautionary actions to assure no harm is caused and the quality is maintained. Chapter 12 states that marketing campaigns of prescribed medicinal products are not allowed, with exception for campaigns for vaccination against infectious diseases. Chapter 13 concerns professionals authorised to prescribe medicines and pharmacies. Chapter 11 and 14-18 concerns obligations and authorisations of the MPA and other national authorities. (SFS 2015:315)

3.4.3.3 Medicinal Products Ordinance

The Medicinal Product Ordinance (SFS 2015:458) complements the Medicinal Product Act (SFS 2015:315) and is divided into 9 chapters. Chapter 1 describes the scope of the ordinance, and chapter 2-5 does not apply directly to an importer within the scope of this thesis. Chapter 6 explains that an importer who intends to import a centrally approved medicine to Sweden, but does not hold the trade permission, must inform the trade permission holder and EMA of the intentions. Chapter 7 describes obligations for MPA, such as time thresholds for responding to applications. Chapter 8 relates to special cases, and chapter 9 to authorisation of MPA in regulating practical application of other regulations, such as the Medicinal products act. (SFS 2015:458)

3.4.3.4 Act on Pharmaceutical Benefits

Act on pharmaceutical benefits (SFS 2002:160) concerns regulations on the pharmaceutical benefits scheme, price regulations of pharmaceuticals, substitution of pharmaceuticals and related questions. The pharmaceutical benefits scheme is explained through the magnitude of subsidies provided at determined thresholds. It is described that TLV establishes purchase prices and selling prices for the pharmaceuticals within the benefits scheme. An outpatient pharmacy is allowed to both purchase a pharmaceutical or parallel import that has a lower purchase price than the one established by TLV. The market authorisation holder has the right to withdraw the pharmaceutical from the benefits scheme. Conditions on substitution within

the parallel substitution groups are established, and substitution of products outside of the benefits scheme. The organisation with the lowest price with available products must supply outpatient pharmacies. TLV is authorised to penalise pharmacies that fail to substitute products correctly, and to pharmaceutical companies that fail to supply the outpatient pharmacies despite reporting availability. (SFS 2002:160)

3.4.3.5 Decree on Pharmaceutical Benefits

The decree relates to the Pharmaceutical benefits act. Regulations on prescription- and expediting procedures related to the benefits scheme are described. TLV is delegated authorisation to regulate how purchase- and sale prices are to be determined, how they can be adjusted and who is allowed to apply for a pharmaceutical to be included in the benefits scheme. TLV are also authorised to issue regulations on the substitution systems and practical application of the Pharmaceutical benefits act. Time frames for TLV to announce decisions related to pricings are presented. Finally, regulations related to outpatient pharmacies are presented, such as how and when they are reimbursed within the pharmaceutical benefits system. (SFS 2002:687)

3.4.3.6 Act on Trade in Medicinal Products

The Act on trade in medicinal products (SFS 2009:366) further specifies regulations regarding different areas of trading with pharmaceuticals in Sweden. Chapter 1 concerns the content of the act and how it should be interpreted. Chapter 2 revolves around retail trade, which is not the scope of this study. However, it is interesting to note that while approval for retail trade will not be given to applicants who hold a trade permit, permits for parallel importation is an exception from this. (SFS 2009:366)

Chapter 3 states the requirements for acquiring a wholesale permit. These are:

1. Suitable premises shall be used for all operations
2. Required documentation for statistical purposes shall be shared to the Swedish eHealth Agency
3. Document the handling so that traceability is achieved
4. Disposal of a responsible person assuring safety and quality
5. Self-inspections shall be conducted controlling the wholesale and handling in general
6. Deliveries to outpatient- and hospital pharmacies shall be as soon as possible
7. Distribute only approved medicinal products
8. Source only from approved suppliers
9. Source only according to regulations
10. Distribute only to holders of wholesale- or retail permits
11. Immediately notify MPA and, where applicable, the holder of the trade approval, if an offering or order is received that may be falsified.
12. Accept returns from outpatient pharmacies
13. Meet the requirements for security details according to Commission Delegated Regulation (EU) 2016/161
14. Follow GDP

Furthermore, the government or designated authority may issue regulations on definition of suitable premises, required documentation to be shared to Swedish eHealth Agency, requirements on the responsible person, self-inspections, delivery times and the security details. (SFS 2009:366)

A wholesaler must accept returns of prescribed medical products provided directly to consumers, from outpatient pharmacies. However, this does not apply to products that are to be destroyed according to a decision on recall or revocation of marketing authorisation. Neither does it apply to products that ought to be stored refrigerated or in frozen conditions. Finally, approved reasons, timeframes, limits of value and compensations for recalls are further specified. (SFS 2009:366)

3.4.3.7 Decree on Trade in Medicinal Products

The Decree on Trade in Medicinal Products connects to the SFS 2009:366 and further specifies application fees, required product availability, transaction information and authorisations of the MPA. (SFS 2009:659)

In order to apply for a wholesale permit a fee of 45 000 SEK shall be paid to MPA. A yearly fee of 45 000 SEK is required to keep the permit. Orders placed by outpatient pharmacies (for an individual customer) before 16:00 on a weekday must be delivered to the pharmacy by the wholesaler no later than the next weekday at 16:00. This does not apply to medicinal products which the wholesaler usually does not keep in stock. (SFS 2009:659)

Each month, transaction information must be submitted electronically to the Swedish eHealth Agency. It should contain information on the product's name, pharmaceutical form, strength, package sizes, quantities, date, price and recipient. Information on returns should also be submitted. (SFS 2009:659)

MPA is authorised to issue regulations on the Act on Trade in Medicinal Products (SFS 2009:366). More specifically, regarding the design of premises, self-inspections, documentation required, competence and experience required for the responsible person, appliance of the notification obligation and GDP. Furthermore, MPA is also authorised to issue regulations on this decree and define when a product can be considered to not usually be in stock. (SFS 2009:659)

3.4.3.8 MPA Regulations on Wholesale Trade in Medicinal Products

This code relates to specific regulations on the wholesale of pharmaceuticals. Firstly, the information required in an application for permit of wholesale trade with medical products to MPA is presented. To summarise, it is information that assures that the company has an appropriate organisation structure, premises, systems, personnel and in general will be able to follow GDP and other regulations. (HSLF-FS 2021:95)

The code also regulates what qualifications are required for the responsible person. The responsible person must possess at least one year of experience from the specific industry, be familiar with the current regulations and appropriate for the role. The guidelines regarding the responsible person found in the commission's guidelines on GDP do also apply in Sweden. (HSLF-FS 2021:95)

Furthermore, chapter 2 provides information on specific parts in regulations that concerns GDP, self-inspections, control and deactivation of safety details, documentation, premises and equipment, deliveries and product withdrawals. (HSLF-FS 2021:95)

3.4.3.9 MPA Regulations on Parallel Imported Pharmaceuticals

Firstly, this code does not apply to centrally approved pharmaceuticals. The requirements for an approval of importing a specific PI are explained (LVFS 2012:19):

1. The DI is approved for trade in Sweden upon arrival of the application
2. The PI is approved for trade in the export country
3. The export country is a member of the EEA
4. The PI is similar enough to the DI

What information is needed in the application is also presented here. Further information required specifically for biologicals are also presented. The market authorisation holder shall be informed of the intention of imports, and for a list of specific export countries, this needs to be done at least 30 days before the application. Fees are established through regulation 2010:1167 on fees for the governmental control of pharmaceuticals. Regulations on packaging, labelling, package leaflet, product name, expiration and storage are established as supplement to other regulations issued by MPA and the Ministry of Social Affairs. These are (LVFS 2012:19):

1. MPA regulations (LVFS 2006:11) on approval of pharmaceuticals for trade etc.
2. MPA regulations (HSLF-FS 2021:96) on labelling and package leaflets for pharmaceuticals for humans
3. MPA regulations (HSLF-FS 2021:102) on permission for manufacturing and imports of pharmaceuticals

4. Empirics

Chapter 4 covers the empirics gathered in interviews during the research. Areas covered are the pharmaceutical SC, supplier- and customer interaction, regulations and the competitive effects seen on the market.

4.1 Overview

The empirical material has been gathered through five interviews conducted during December 2023. An overview of the interviewees is summarised in *Table 1*. The general thought process when selecting the interviewees followed the methodology presented in chapter 2.7.5. Because of how all interview guides were tailored specifically for the interviewee, and adjusted based on previously gathered information, one interview guide has been selected to be presented as an example. This can be found in *Appendix 1*.

Table 1: Interviewees and their experience in PI

Alias	**Experience**	**Date**
PersonA	Overall insights from decades in the pharma industry	7/12
PersonB	Insights in purchasing at a Swedish pharmacy chain	8/12
PersonC	Insights in purchasing at a Swedish pharmacy chain	11/12
PersonD	Insights in approval procedures and regulations, MPA	13/12
PersonE	Insights in monitoring of GDP, MPA	13/12

4.2 Pharmaceutical Supply Chain

4.2.1 Overview of Pharmaceutical Supply Chain Setup

The pharmaceutical supply chain setup can be described through the main stakeholders involved in the flow of information, goods and finances. The key stakeholders and what differentiates them, how these relate to each other, and a Swedish context of PI in the SC is presented in this chapter.

4.2.2 Key Supply Chain Stakeholders

In the complex pharmaceutical supply chain there are multiple different key stakeholders with different roles and connections. These include raw

material suppliers, manufacturers, regulatory agencies, wholesale distributors, pharmacies, healthcare providers and patients (Kaylor, 2023). Other actors that affect the SC are traders, brokers, parallel importers, market divisions, pharmacy chain's CW and 3PL-providers, which has been touched upon during the interviews.

Raw-material suppliers supply the manufacturer with raw materials or components that are needed for the production of pharmaceuticals. The patent holder manufactures the original and exports it to its other market divisions within the EU, where it becomes a DI. When the patent expires, generic producers are allowed to enter the market and produce identical or similar pharmaceuticals. When generic alternatives are transferred between different market divisions, they can sometimes be PI instead of DI.

3PL-providers are logistics service providers that are commonly used by PI in Sweden. While the PI owns the products, the 3PL-providers store and move the physical products. The ownership changes first when the pharmacy chain purchases the products.

Wholesalers, or traders, are organisations that source and resell pharmaceutical packages on the European market, as explained by PersonE. They hold a wholesale permit and often have a small warehouse to which they send the products in order to build up large enough batches for redistribution. They source from different actors on the open European market and sell it to other traders or parallel importers. The traders can be seen as a leakage point of DI which enables PI. Traders own the products in contrast to brokers, who only pair suppliers and customers together.

Within the scope of this thesis, the patient contact comes through the pharmacy chains. In Sweden, these are mainly structured without a central warehouse where the products are owned by the pharmacy chain.

The parallel importers are often active on multiple markets within the EU, both regarding sourcing and supply. It is common to trade with pharmaceuticals approved both through the centralised and decentralised procedure.

Regulations within the EU are issued through different organisations, such as the CJEU, EMA and the Parliament. The most important national regulatory authorities in Sweden are MPA, TLV and the government.

EVIS is a Swedish non-profit organisation that manages the safety features, and EMVO is the corresponding organisation on a EU level. The Swedish

eHealth Agency collects information on a monthly basis on trade in pharmaceuticals in Sweden.

4.2.3 Mapping Pharmaceutical Supply Chain

Figure 7 displays an overview of the pharmaceutical supply chain. The raw material suppliers supply the patent holder with the components needed for production. The producers often have local market divisions in the different markets. In some markets, wholesalers commonly own the products between the producer and pharmacy, while the DTP distribution system is more common in some markets, such as in Sweden. In Sweden, some pharmacy chains use a central warehouse while others supply directly to the out-patient pharmacies with the use of 3PL services. The SC is affected when crossing national borders within the EU, as well as in time, with a breaking point when the patent expires for the pharmaceutical. When patents expire, more producers are introduced which increases the number of sourcing alternatives. The brokes can be involved in trade between the regular SC and other actors, such as other PI companies or traders. While products flow from these to the PI, there is also a flow of products back. This is illustrated as a secondary product flow. The PI stores the products and repackages them upon decision to release a batch to a specific market. There are 3PL logistics service providers supporting this product flow, which ultimately can go to either the Swedish market or another European market.

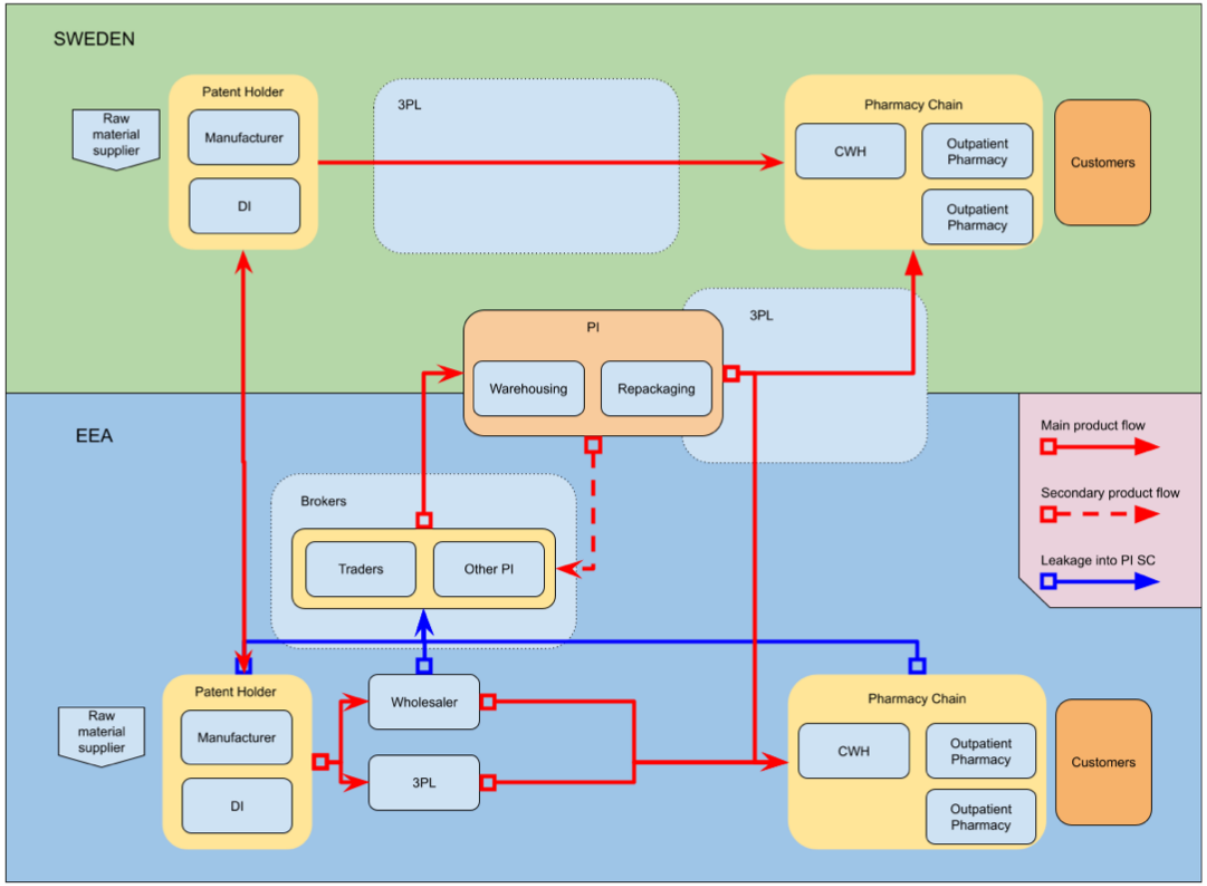

Figure 7: Mapping of the Pharmaceutical SC

4.2.4 Parallel Importation in Sweden

The market of parallel importation in Sweden is complex and difficult to navigate. The financial requirements on organisations competing on the market are high, because of how capital is tied-up in sourced products before being released to the market. Person 5 also describes how the measures the importer takes in order to follow the regulatory requirements, such as applications, developing regulatory expertise and performing monitoring actions, requires available capital to cover the costs. PersonE highlights that the regulatory requirements are truly enforced and monitored in detail by the regulatory authorities, meaning that the market really is highly regulated in comparison to many other markets. Because of this, the Swedish importers must have deep insights into the regulatory frameworks on both a national- and European level, which they also possess according to PersonB. Because of the importance for the trade margins for pharmacies, the declining trend of PI will have to change in order for the pharmacy market to thrive, according to PersonC.

PersonC explains that because of the alternative markets within the EU for releasing the products onto, the Swedish market of PI is highly affected by its financial potential in comparison to other markets. This in turn depended upon the value of the Swedish krona. As the different PI in Sweden often are involved in multiple European markets, both regarding sourcing and supplying, alternative markets might yield larger margins. As the supply is generally limited, a weakened currency position will thus decrease the flow of products to Sweden.

Various barriers to entry within the industry have been covered in the interviews, such as sourcing issues under a limited supply. Language barriers can sometimes occur, and of course the regulatory barriers.

The regulatory requirements are multifaceted. There are two main applications that must be approved for a PI by regulatory authorities in Sweden before any importation can be made. The organisation must have a wholesale permit, and must have a permit for importing the specific pharmaceutical. This is explained by PersonD and PersonE.

4.3 Supplier Interaction

4.3.1 Sourcing Process

PersonA explains how PI can be sourced on the European market from direct importers, wholesalers or pharmacy chains. These are all authorised to

trade with the products. PersonA describes how successful supplier interaction might be the most important factor when competing on the Swedish market of parallel imports. Being able to source products when there is a limited supply, at a competitive price point, is very important in order to be able to compete effectively. With good relations on the supplier side, the importer can secure supply at a competitive price point and develop the supply chain logistics. The importer can often find suppliers that can offer lower prices than the market price in the sourcing country, for example if the importer buys large quantities.

There is a high demand on the Swedish market for PI of newly approved pharmaceuticals. According to PersonC, the pharmaceutical chains could benefit if the PI could manage to source and include those in their portfolios more quickly. But PersonC also explains how this is probably a result of international PI-firms prioritising other European markets over Sweden. While the PI can continue to supply the pharmacies through the PV-system when the patents expire, the pharmacies do not gain anything from PI in the PV-system.

4.3.2 Sourcing Risks

PersonA highlights how sourcing from other countries induces a risk related to the trade in currencies. This risk comes not only from the weak Swedish krona, but also from its high volatility. Companies adjust for this by increasing the demanded trade margins, which in turn decrease the trading opportunities. This does also affect which price levels the importer is comfortable to present to TLV. The strength of the Swedish Krona in comparison to other currencies within the EU is a factor that PersonC also highlights as important for the industry.

PersonB describes that it is vital for the importer to ensure high quality of the products, through correct markings and packages to assure no alterations have been made previously in the SC.

4.3.3 Sourcing Opportunities

Large markets generally create greater opportunities for export to PI, according to PersonA. As an example, Germany is a significant supplier of PI to Sweden and is one of the largest markets in the EU. Larger markets could also sometimes supply at lower prices as the mere volume provides gains from the economies of scale. This will of course benefit the importer. The choice of market for sourcing can also be affected by the currency used on the specific market.

According to PersonB, the demand for the product on the Swedish market is important when the PI considers to source a product. This will have to be evaluated in relation to the expiration dates in the sourcing opportunity. High volume products and products that are expensive are prioritised, as this creates a better opportunity for the importer to cover the costs related to importation of the goods. For example, total repackaging costs are related to the number of packages rather than the value of the drug.

4.4 Customer Interaction

4.4.1 Purchasing Process

PersonC explains their purchasing process for patented pharmaceuticals in broad terms, and says it is most often initiated by a supply opportunity from the PI. This is then often followed by negotiations. According to PersonB, the negotiations often revolve around price, volumes and supply. PersonC describes that the level of negotiation varies depending on how the negotiation power is distributed between the importer and pharmacy chain for the product line in particular.

PersonC describes how every pharmacy chain has their own purchasing process and models they use. For example regarding how the contracts are made. Some prefer longer contacts while others use a more dynamic model which shares characteristics of spot trading. The contract outlines a specified timeframe for supply which creates a secure framework for the supplier. This framework allows the supplier to commit the required volumes to the Swedish market. Some suppliers distribute the products on a weekly basis while others distribute slightly more seldom.

Both PersonB and PersonC describe the relationship between the pharmacy chains and the largest PI as a close partnership, encouraged through the shared interests. Meetings are held at least on a weekly basis, in some cases even daily. There are continuous follow ups, both with long-term focus and less extensive meetings for specific short-term purposes. PersonB says that there is a continuous information flow between the importer and the purchasing department of the pharmacy, for example regarding availability. Both PersonB and PersonC describe the relationship as well functioning.

4.4.2 Risk Dynamics

PersonA describes how the risk of destruction is a major risk that the importer faces continuously. Mainly through how the PV-system works in combination with the right of return policy in place for outpatient

pharmacies. PersonE mentioned that PI companies have raised concerns to MPA that some pharmacies exploit this right and order more than planned, only to return the unsold products when they become obsolete. PersonC describes that some pharmacy chains use their own warehouses to which the products are transported to, while others use 3PL services directly to the outpatient pharmacy. There is only a right to return for a physical outpatient pharmacy, meaning that the risk dynamics vary depending on the organisational structure within the pharmaceutical chain. Also PersonE describes this aspect and highlights how this organisational structure is not common in Sweden and decreases the incentives for a pharmacy to return a product, which in practice moves the risk to the pharmacy.

PersonB and PersonC explain that the risk of destruction holds a greater significance within the PV-system than in the parallel exchange-system. PersonC describes that as the product that is prioritised can be changed on a monthly basis, there is a system induced challenge for the supply chain. Therefore, when managing the stock levels within the multi-echelon distribution system, one must also consider the possibility that the prioritised product changes.

PersonB explains that the destruction of obsolete products within the parallel substitution of patented originals is heavily limited by effective distribution policies at the pharmacies. The pharmacy chains has well functioning systems for planning purchases, choosing appropriate stock levels and finishing stocks in time in order to avoid destruction situations within this segment.

PersonA describes that the sourcing period often covers 1 to 3 months in order for the importer to reach high enough stock level to be able to assure availability for the whole period, which is needed in order to avoid fees from TLV. According to PersonA, one issue is that sometimes the importer cannot source the full amount before the products reach the point where they no longer can be sold because of the expiration date, which can force destruction of batches.

PersonC explains that there is a risk that importers cannot keep their promise of delivery, which for example could lead to a situation where no products are delivered at all for a long period of time. No matter how good the discounts promised per unit are, there will not be any financial gains for the pharmacy if no products are supplied. By committing to a contract with a supplier, the pharmacy might not be able to source from another PI, but are instead referred to the DI alternative.

4.4.3 Negotiation Power

The importer's ability to negotiate with pharmacies is highlighted by PersonA as a critical function for competing effectively on the market. This directly affects the margins for the importer, and also the volumes that are directed to the Swedish market.

According to PersonC, parallel importation is vital for the Swedish pharmacy market because of the additional trade margins the discounts can provide. The trade margins offered by TLV are simply not enough to cover the expenses in an outpatient pharmacy business. Without PI, PersonC states that many physical stores would be forced to close down, especially lower volume pharmacies, if not the trade margins offered by TLV are increased significantly. The financial importance of PI for the Swedish pharmacies is also emphasised by PersonB who describes its necessity in similar terms as PersonC. PersonB also explains that the upcoming raise of all trade margins within the national benefits scheme is welcomed, which could affect the pharmacies dependence upon PI.

PersonC states that the supply opportunities in general are similar in Sweden as in the rest of the EU. This means that the supply-securing effect that PI has on the Swedish market of pharmaceuticals in general is only marginal, even though PersonC says that PI sometimes has higher availability than the originals for certain product groups. PersonC means that PI will not be the solution to the current pharmaceutical supply issue where there is a shortage of around 900 products. However, PersonB mentions that one benefit with PI is that it can be used to cover up for shortages, which contradicts PersonC's statement of its insignificance in that aspect. PersonB means that sometimes PI is available in other strengths and package sizes which places it in a different substitution group than the DI. In such situations, PersonB means that PI can increase the availability even when the DI does not have a shortage. Lastly, PersonB states that it can function as availability ensuring during shortages from the DI. PersonE explains that PI holds a major position within certain substitution groups. Without the PI, DI would have to supply these volumes instead, meaning that it can be seen as a complement to DI with respect to availability assurement.

PersonB elaborates on the significant effect the general availability has on the negotiation dynamic, and explains that because of the regulatory requirements regarding availability on the pharmacy, the pharmacy is heavily dependent upon the PI in those situations. But in situations where the general supply is sufficient, the negotiations are rather held like a dialogue, according to PersonB.

Within the segment where there is generic competition, there is no possibility for the outpatient pharmacy to favour anything else than the product elected PV for the period. This means that there is no incentive for the PI to offer any discounts on those products. PersonC explains that the PI-products within the PV-system are mostly products that have previously been imported to compete during the patented phase, but then been moved to the system when the patent expired. According to PersonC there are also companies with an active generic portfolio that sometimes utilise the concept of parallel importation. Also PersonB explains how PI does not have any special role for the pharmacy chains when it is in the form of generic substitution, because of the PV-system.

PersonC describes how price per unit is an important factor for the pharmacies because of the direct influence on the financial potential of the procurement, also highlighted by PersonB. But both PersonB and PersonC also describe that the pharmacies try to estimate the actual sourcing reliability for the specific product, a procedure that is described as one of the main objectives within the purchasing for the pharmacy chain by PersonC. The characteristics of the demand for the drug and the predictions of future sourcing possibilities will define how the pharmacy decides to treat and categorise the product. This is important for how the pharmacy chain decides its position in the negotiations, due to its effect on the expected level of competition against other pharmaceutical chains.

PersonB also describes that the expiration date of the batch could be important, but that it is rather considered an order qualifier. Even if the pharmacy has the right to return, by using a FEFO-system the negative effects of a short expiry date can be limited for PI of patented originals, according to PersonB.

PersonC explains that PI often cannot supply all pharmacy chains simultaneously and that the PI is in a position where they can choose which chain they supply to. Price will therefore be an important aspect, but also the pharmacy chain's ability to sell the product according to estimations. PersonB describes how the currency influences the negotiation potential, where a weakened Swedish krona significantly narrows the scope for discussion.

4.5 Regulatory Environment

4.5.1 Regulatory Characteristics

According to PersonA, the regulatory environment affects the market in multiple dimensions. Firstly, it creates boundaries to what actions can be taken for business when it comes to responding to the market movements. In this way the organisations become less flexible.

Secondly, PersonB highlights the complexity of the regulatory environment with respect to the level of detail that is regulated, as well the multiple different organisations that regulate the market both on national and European level. This creates a complex regulatory environment that is difficult to get an overview of. PersonE agrees on the market being highly regulated in comparison to other free markets, but highlights that the pharmaceutical industry is highly regulated in general. In this context, the allowance of PI can be seen as relaxation within the pharmaceutical industry driving the industry slightly in the direction towards a free market. PersonE describes that the regulations on application procedures for PI can be seen as a simplification of the requirements related to DI, for example related to documentation.

Thirdly, PersonA also describes that because the national regulations have differences, different competition strategies are possible in different countries. As the Swedish parallel importation competes with importation to other countries on the finite sourcing market, this creates an uneven competitive advantage. This is also highlighted by PersonC, who also links this to how countries created trade barriers during the COVID-19 pandemic in order to secure national supply. At the same time, the market is driven by traditional marketing dynamics where price and volume allocations are affected by supply and demand.

4.5.2 Regulatory Authorities

PersonE describes how the regulatory authorities can be divided into two main levels: EU- and national level. The regulations on EU-level can be separated into two groups based on if they apply to states or members within the union. Regulations that apply to states are required to be included in the national regulations and will not have to be considered in detail by professionals.

PersonD describes how the general legislation on pharmaceuticals for humans on EU-level is currently being reviewed and developed, and that the new directive and regulation will cover PI explicitly.

The main regulatory authorities in Sweden are MPA and TLV. Pricing is an aspect that is regulated almost exclusively on a national level, creating the differences seen between different member states. But PersonD also describes how many aspects of how PI is carried out in practice today can be linked to judgments in cases in the CJEU. While there are national regulations such as The Medicinal Products Act (Läkemedelslagen), provisions on the area are adjusted based on these CJEU judgements meaning that the practical application of national legislation are also affected by decisions on EU-level.

Lobbying organisations play a role in affecting policy makers on a national level, according to PersonC. The PI-supporting lobby organisation *Läkemedelshandlarna* is not very powerful because of its small size, so when it comes to affecting the politicians, the direct importers have much greater possibility to do so through *Lif*, according to PersonC.

PersonA describes that the general attitude towards PI amongst politicians and policymakers might have been negatively influenced by direct importers, which could in turn affect the national regulations. This would make regulations more shifted towards the interests of the direct importer. Except for the importers themself, the financial gains from PI mainly only benefit the pharmacies. This creates a business environment where there are limited financial incentives for other stakeholders on the market to support the industry. Also PersonB considers the regulatory environment more adjusted towards the interests of the DI, rather than to stimulate PI. The regulations on pricing are highlighted as a limiting factor and an example of this.

4.5.3 Regulations on Parallel Importer

4.5.3.1 Wholesale Permit

PersonE describes how any company involved in wholesale trade of pharmaceuticals in Sweden must possess a wholesale permit issued by MPA. The only exception is manufacturers, as they can wholesale their own products without specific authorisation. The wholesale permit authorises the company to trade with pharmaceuticals both in Sweden and other countries within the EU.

PersonE also describes how most companies with wholesale permits in Sweden have both a company and physical premises in the country, and that MPA monitors these from a regulatory perspective. The companies are inspected with respect to their procedures when sourcing, storing and selling goods, continues to fulfil the requirements of a wholesaler, follows GDP, has a responsible person for wholesale trade etcetera. For permit holders specifically involved in PI, some inspection areas are of extra interest. These are for example the sourcing and regulations related to contact with other parts. Inspections are done on the company's physical premises in Sweden, and focus not only on the products, but also on their internal procedures.

PersonE explains that GDP-inspections in recent times often result in remarks regarding how the PI assures that batches have been released to the market. There exists physical certificates that the manufacturer signs and sends along the products upon market releases, but these certificates often get lost in the transactions. This means that the regulatory authorities cannot require this certificate as proof, but it is up to the PI to prove that the products have been released. The PI has different strategies for this, such as reasoning about high reliability of the suppliers, even though the PI might not be fully aware of the sources of the suppliers. The 2D safety details however can provide proof of the batch being released which is a part of assuring the legitimacy of the batch. There has also been some remarks regarding the PI’s internal system for assuring that changes in the originals package leaflet is noticed and adjusted for.

4.5.3.2 Parallel Importation Application

PersonD describes that in order for a pharmaceutical product to be considered for parallel importation, the product must first be a pharmaceutical authorised for sale in Sweden, meaning that the patent holder is required to have introduced the pharmaceutical to the Swedish market. If it is, a parallel importer with a wholesale permit can apply for authorisation to import a specific pharmaceutical product from another EU-country. MPA assesses these applications, renewals of applications and changes in the applications. These controls are done with both a pharmaceutical- and regulatory perspective.

PersonD describes that the application procedure begins with MPA receiving an application. This application is then being verified, registered and distributed to the proceedings group. The initial regulatory quality assuring measures taken revolves around controlling authorisations, such as the wholesale permit for the PI and the manufacturing permit for the repackaging-company. A control of the permit for the product in the export

country is made, as well as a control of the corresponding product in Sweden. What the PI does is referencing the product they want to import to the already approved DI, resulting in a simplified application procedure.

A physical sample of the suggested packaging is also assessed. This could be with new labels or a full repackaging, and a Swedish package leaflet is also required. The assessment is therefore done on a product level.

There is always a dialogue with the medicinal authority in the export country, from which information on the product is shared regarding detailed composition. This is then compared to the already approved DI. The active substances must of course be the same, but the composition in general must also result in a product that is therapeutically identical which requires a pharmaceutical assessment when comparing the two products.

MPA controls how the PI means to treat the product during transport, storage and repackaging in relation to any product specific requirements such as temperature- or light-sensitivity. During the whole process, MPA has contact with the applying PI. Questions might need to be clarified, or there might be comments on the packaging or package leaflet. Most remarks relate to suggested packaging and package leaflets, according to PersonD.

Being approved for wholesale requires the PI company to take responsibility for the product and any changes related to the product. This means that the PI must apply for approval of changes, for example related to the content on the package leaflet, repackager or adjustments to the package. Renewal applications must also be sent five years after the first approval.

4.5.3.3 Licence Suspension

Another factor highlighted by PersonA is the lack of possibility to suspend a licence for PI products for a limited period of time, which for example is possible for the parallel distribution. While there are no regulatory requirements for the importer to use the licence, the fees must be paid either way, or the licence will be withdrawn. This creates a system where the importer must consider the yearly licence fees and expenses related to the appliance procedure in a longer time period. In practice this means that the long term sourcing and demand possibilities must be predicted and considered when deciding to apply for new licences.

4.5.3.4 2D-Labelling

PersonD describes how transferring counterfeit pharmaceuticals into the legal supply chain to become PI has historically been the most effective way

to generate income. The actors within the originals are large and there are only a limited number of well known actors which the pharmaceutical companies have close partnership with, making leakage into the system very difficult. In contrast, the number of companies involved in PI are much greater which increases the risk of allowing counterfeit products to enter the SC.

Prior to the introduction of 2D-labelling, counterfeit cases were identified almost exclusively by PI, as they were the only entity performing thorough inspection of the packages. There are examples of how PI-companies have detected exceptionally well performed falsifications with only subtle alterations in nuances on prints. While it is essential for the PI to report in such cases, PersonD explains that doing so also has a major negative impact on the financial results. The expensive pharmaceuticals that have been sourced and re-packaged in good faith, will now be withdrawn by MPA and directly affect the margins. Because of the patient risks associated with falsified pharmaceuticals, disregarding the reporting is of course not an option for the PI, which is also why reporting is a requirement in the regulations.

The risk of a counterfeit product passing through an importer has now been reduced through the introduction of 2D-labelling, which is good for both the PI and the patients, according to PersonD. By deactivating the previous code and applying a new in the repackaging phase, the importer can assure that the product has been released onto the market and is not falsified.

PersonD describes how MPA saw a direct relation between the introduction of FMD in 2019 and an increase in adjustment applications for the packagings, where the PI in a higher degree applied for full repackaging after the introduction. After a CJEU decision in autumn 2022 made clear that it is allowed for the PI to resell a product with apparent seal breakage if a new seal is added, which also included the 2D-labelling, an increase in adjustment applications were once again seen at MPA. This time PI primarily applied for relabeling the packages instead of repackaging.

4.5.3.5 Regulatory Authorities Relation with PI-companies

PersonE describes the relation between the PI and MPA as adequate and well developed. The MPA tries to be clear in instructions and communication, and has meetings with lobbying organisations to discuss implications of judgements on EU-level, for example regarding the safety details or labelling of packages. Some aspects are seen as critical for the PI-

organisations and MPA will then try to be clear with their perspective on the issue, which can direct tactical and strategic decisions for the importer.

Both MPA and the importer want the operations to comply with the regulations, meaning that there is also an educational perspective in the relationship. It could be anything from how to fill a form correctly, to how the agency reason related to certain aspects. But at the same time, as MPA has a task to monitor certain aspects of the pharmaceutical system, they have their own procedures to follow internally.

4.5.3.6 Future Regulations

PersonA and PersonC explain that changes within the regulatory environment are continuously reviewed. One such example is the introduction of a requirement of contributing to a national safety stock. This regulation would force the PI to keep extra stockage of products which would decrease Sweden's dependence upon other countries under widespread shortages. This would however be devastating for the PI industry as the current business builds on a high turnover rate.

4.5.4 Regulations on Customer Interaction

PersonA describes how the inflexible pricing structure of TLV creates hindrances for the importer and that a more flexible pricing structure on a national level could create better opportunities for the importer. This refers more specifically to the price ceiling set by TLV and that prices are defined for one month at a time. The current regulations limit the possibilities for prices to fluctuate based on supply and demand which forces the importer to commit to the prices for a longer time period. Both PersonC and PersonB describe how the pricing principles from TLV create a hindrance that affect the flexibility and responsiveness on the market.

PersonC describes how TLV during recent years have realised the necessity of PI for the customers in terms of how it increases the trade margins. This, according to PersonC, led to the review of the trade margins offered by TLV within the reimbursement scheme, as the current market of PI is not as profound as it was previously.

4.5.5 Regulations on Customers

PersonA highlights how the current regulations which allow outpatient pharmacies to return unsold products create a business environment where the risk is held by the importer for a longer time period. This holds for pharmacy chains that do not have their own centrally managed storage

organisation. When the organisational structure within a pharmacy chain creates formal transactions between the outpatient pharmacy and the central warehouse organisation when orders are placed, the right of return means that the outpatient pharmacy can return products to the central warehouse. Because of this, the outpatient pharmacy will not have any direct financial incentive to not order a product. This also means that outpatient pharmacies might order larger quantities than necessary in order to assure a high availability rate even under uncertain demands.

PersonC explains that the regulations force the pharmacies to supply the product with the lowest list price for the month to its customers, even if it's only slightly lower than the alternative. This means that they will have to adjust the stocks if a DI or PI changes its price point from one month to another. Even though the pharmacy might gain more from selling the PI-alternative, the regulations forces them to not do so. The adjustment of stocks comes with higher costs for storage and a risk of the alternative product becoming obsolete before it has a chance to be sold.

PersonC explained that the regulations also lead to a requirement on the pharmacies to have advanced information systems in order to avoid distributing the wrong alternative, as this would result in fees from TLV. But PersonB explains that the limiting factor is rather how the regulations by TLV prohibits continuously updating pricings, as the current system in use can support price changes also during the month.

PersonB describes that the pharmacies are required to stock available pharmaceutical products, and that a customer request must be answered in 1 day. This forces the pharmacies to have sufficient stocking also for rarely used products or products with high variability in demand.

4.7 Competitive Environment

4.7.1 Overview of Competitive Environment

The competitive environment consists of mainly two parties, manufacturers/direct importers and other parallel importers. PersonC explains that the organisational structure of a direct importer on a European level affect its attitude against parallel importation. Some direct importers track financial performance of each marketing area independently, while others track performance on a European level. A direct importer that tracks financial performance on a European level will not be as concerned by parallel importation to Sweden, as the products have already been sold by

the direct importer in another country within the EU. However, when the different national markets are treated as independent companies, a Swedish branch within a direct importer will see PI as a threat as it negatively affects its market shares. The organisational structure's effect on the position against the PI is also explained by PersonB.

While many aspects within the industry are controlled on a EU-level through judgements in the CJEU, PersonD describes how the national regulations create different competitive environments in different member states.

4.7.2 Competitive Effects Related to Suppliers

There is a current discussion regarding introducing an environmental bonus scheme that would benefit low environmental impact. PersonA describes that an introduction of such a bonus scheme could enable the DI to withhold specific environmental information to the suppliers, which in turn would have a significant competitive effect on the PI through the supplier channel. This information would be needed for the PI company to apply for benefits from the government, which in practice would make it more expensive to distribute PI. This is also mentioned by PersonC.

PersonE explains that because of the competition and existence of PI within the EU, the DI is limited in which prices are set within the union for identical products. This means that the competition affect the suppliers through which prices they have, which would have been more diversificated if not for the PI. While this can be directly linked to PI in the patented originals segment, the same effect is seen after patent expiration when introducing generic alternatives, where the prices are also reduced.

4.7.3 Competitive Effects on Parallel Importer

The threat from DI to sue PI-companies for trademark infringement is always present, according to both PersonA and PersonC. Doing so can have a devastating affect on the PI, because of the high costs related to going through the legal procedure.

4.7.4 Competitive Effects Related to Customer Interaction

PersonC describes how parallel importation creates incentives for direct importers to decrease the prices on patented pharmaceuticals in order to protect its market share. Without this dynamic, PersonC argues that there would not be any reason for a direct importer to adjust its prices as this would mean that the margin decreases. But because of the prevalence of PI,

the direct importer and the parallel importer will decrease their prices marginally on a monthly basis until any of the parts cannot continue to decrease the prices. This is also brought up by PersonA.

4.7.5 Competitive Effects Related to Customers

Within the generic segment, the competition and purchasing decision is strictly regulated through the PV-system. Out of the products with reported availability, the cheapest alternative must be prioritised by the pharmacy. This means that in the PV-system, the competition revolves around providing full coverage for demanded volume at the lowest price possible.

Within the segments of originals, the competition arises when there are available products that can be substituted through the parallel substitution system. PI will then be preferred by the pharmacies as they are purchased with discount.

5. Analysis

Chapter 5 covers an analysis of the gathered information, both from literature review and the empirics, in the context of competition theory. Lastly, speculations on the future are presented.

5.1 Introduction to Analysis

Because of the detailed regulations, the pharmaceutical industry is monitored and surveilled through the scope of regulations - in all dimensions of the business. One way would be to see the regulations as something that is affecting the business as an external part which disrupts the operations and puts pressure on the importers. Another way would be to see the regulations through the scope of standard market dynamics, where the market is still driven by customer preferences. With this scope, the regulatory authorities in the role of customer clearly state its requirements on the supply chain - through the regulations. The interesting addition this perspective gives is that it allows the regulations to be defined in terms of order winners and qualifiers, which in turn can be used to support strategy decisions and assure alignment in operations. With this perspective in mind, the aspects covered in Chapter 3 and Chapter 4 are analysed, structured and grouped with a focus on how it can be described as the market requirements. This analysis adapts the *Hill's model* by applying it throughout a supply chain which also shows how the model can be extended to include regulations. Furthermore, it shows how the concepts can be used to explain incentives for market actors.

5.2 Market Qualifiers

5.2.1 Overview of Market Order Qualifiers

There is one way to distinguish the market order qualifiers that exists through the regulations. Permits are clear market entry barriers that are required to qualify for the market. Because of how the compliance with the permit requirements are continuously monitored by regulatory agencies, they will continue to work as market qualifiers even after the permits are first granted.

5.2.2 Permits

The regulatory requirements related to the market entry includes preparing the organisation for parallel import operations throughout the SC with systems, procedures and processes. There are two areas that are especially important in the regulatory environment related to market entry, namely those related to the wholesale permit and the permit for PI of a product. These regulations work as barriers to entry and can be seen as well defined market qualifiers. Failure to comply with these regulations will directly hinder the importer from operating on the market.

Wholesale trade permit

The Act on Trade in Medicinal Products will be especially important because of how it affect the requirements for acquiring the wholesale trade permit. The requirements stated can be structured into three main themes:

1. Follow GDP
2. Internal resources
3. Trade with authorised actors

Because of the wide coverage of GDP, both theme two and theme three are regulated in GDP, creating an overlap in terms of market qualifiers. A speculative explanation to this could be that a company without a wholesale permit will have difficulties with providing proof of following all aspects in the GDP directives, as all aspects might not be applicable without actual operations. However, the requirements for the wholesale permit highlights what aspects must be treated also before acquiring the permit. When evaluating the market in terms of market qualifiers, GDP compliance will be sufficient to describe the requirements that are enforced through the wholesale permit. The responsible person will have an important role in ensuring alignment with GDP in operations. The requirement on providing the responsible person with sufficient resources and power to assure that the directive is fully implemented will be important for fulfilling this criteria continuously.

Permit of Single Product

MPA Regulation on Parallel Imported Pharmaceuticals regulates the approval for PI of a unique product, and will thus be important when it comes to the permit of a specific product.

There are four main areas that are covered through this permit:

1. Control of necessary permits
2. Internal processes related to the specific product
3. Package design
4. Pharmaceutical similarity

Through the requirements in the permit, market order qualifiers can be formulated as:

1. Authorised SC
2. Quality
3. Package
4. Pharmaceutical characteristics

Just as regular order qualifiers, such as quality conformance, can these qualifiers be further described. In this case the descriptions are detailed and multifaceted, and even have their own directives - such as for the package design. The details will provide further guidelines on how the importer will need to act in order to fulfil these market order qualifiers. By defining the qualifier at a high level perspective, rather than delving deep into the details of specific requirements, the risk of getting overwhelmed is reduced. The order qualifiers can be assessed through the following questions:

1. Authorised SC: are the repackager and importer approved, and the product in both the export country and import country?
2. Quality: has the product been handled according to product specific requirements throughout the SC?
3. Package: has the package been designed in accordance with regulations with respect to labelling, safety features, trademark and package leaflets?
4. Pharmaceutical characteristics: is the PI pharmaceutically identical to the DI already on the market?

5.2.3 Qualifying in Substitution Systems

The substitution system includes the products within the benefits scheme. To compete within these systems, being included in the benefits scheme can be considered a market order qualifier. The lifecycle phase of the pharmaceutical dictates which substitution system will be used (patented/generics).

While there is a qualifying aspect through the price ceiling established within each product substitution group, price will be better described as an

order winner because of how it dictates which product is chosen for the month. For a product to be considered as the product of the month, a 100% delivery availability must be promised by the importer, even under volatile demand (*Monthly availability*).

Parallel substitution is dependent upon the product being available for substitution at the pharmacy, which is a decision by the pharmacy chain. The market qualifying factors through the downstream dynamics are therefore experienced partly through the regulations on the system, and partly through the pharmacy chain as a customer. The system requires the list price to match that of the DI (*List price*), which is a requirement that will be utilised by the direct importer in competition. The parallel substitution will be used for a product with an active patent (*Life cycle*). The pharmacy chains will value the expiration date of the batches when evaluating the offer, as there are directives regulating how close to the expiration date the patient is allowed to be given the product, depending on the intended use (*Expiration date*).

5.2.4 Competing Through Order Qualifiers

The regulations create order qualifiers in the sense that they dictate the consideration of a product or company as a possible alternative. Because of its qualification status, and the ability for competitors to influence the performance in these dimensions, competition will take place also in these dimensions.

The trademark proprietor will try to find reasons to question the importer's measures to fulfil the packaging requirements, with reference to trademark infringements. In this way, the importer will experience competition in a dimension that is binary in terms of how it can effectively remove the access to the market. The importer's ability to fulfil the qualifier related to packaging can therefore be described as a dimension that is partly assessed by a competitor, which is unique for the market.

Withdrawal from markets or not entering a national market are also measures that can be taken by the patent holder to remove access to the market for the PI, this time through the regulations on product importation permit.

Because of the design of the parallel substitution system, adjusting list prices will be a measure taken by the DI in order to make matching more difficult for the PI. This is possible because of how the price point of the qualifier is dependent upon the price listed by the DI. While list price could

potentially be seen as an order winner, this interpretation does not capture how perceived value is not affected by an even lower price. Instead, the market only values that the PI is as cheap as the DI. In direct contrast to a regular market, the perceived value of the product decreases after the qualifying level is achieved. This is a result of the system where the pharmacy receives its trade margins based on the list prices - lower list prices results in less compensation. Furthermore, and even more important, is how a lower list price results in a decrease of the effect from the discounts offered by the PI. When the list price reaches the point where the discounts only cover the decrease in trade margins from TLV, there is no additional financial gain for the pharmacy. This is visualised in *Figure 8*.

Figure 8: Perceived value v. List price

Because of how the value of the product is decreasing when passing the list price of the DI, the PI is incentivised to target the list price of the DI. From the perspective of the DI, disrupting this by adjusting the price will allow the DI exclusive right to the market one month at a time. This can be seen in *Figure 9* as a situation where the DI jumps vertically from the filled line to the dotted line. Without the regulation on how often prices can be adjusted, there would be no incentive for the DI to decrease the list price as it decreases the margins and the PI would match the price directly anyways. In this way, the regulations create a business environment where the involved parts are incentivised to slowly decrease the list price on the patented product.

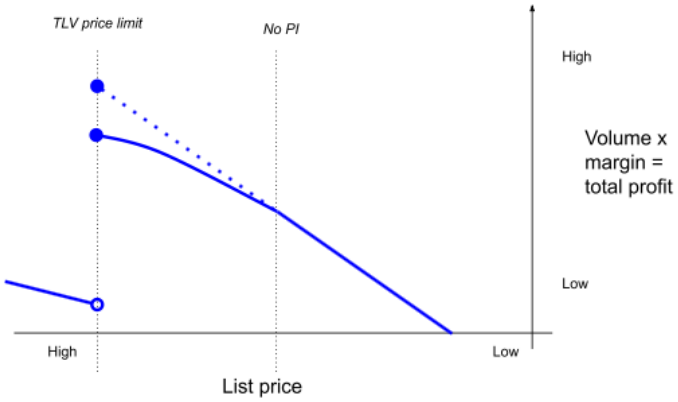

Figure 9: Total profit v. List price

5.2.5 Summary of Order Qualifiers

Table 2 shows the two permits essential for qualifying on the market. They play a central role for the company and it will therefore be of highest priority to support these qualifiers through operations.

Table 2: Qualifier ranking, PI in general

Qualifier	**Ranking**
Wholesale permit	QQ
Product specific PI permit	QQ

Monthly availability will be important as it is a prerequisite for being prioritised within the PV-system. However, the importer can decide to promise delivery, be selected, and not fulfil its obligations, even if it will be associated with a fee. This promise will be stated with the expiration date in mind, which makes it a qualifier as well. The qualifiers and their respective ranking within the PV-system are summarised in *Table 3*.

Table 3: Qualifier ranking, generics

Qualifier	**Ranking**
Monthly Availability	Q
Expiration date	Q

When qualifying for the PI substitution, it will be important to match the list price of the corresponding DI. Not doing so will create a short term

exclusion from the market. The qualifiers and their respective ranking within the PI substitution system are summarised in *Table 4*.

Table 4: Qualifier ranking, patented segment

Qualifier	**Ranking**
List price	Q
Expiration date	Q

5.3 Market Order Winners

5.3.1 Overview of Market Order Winners

When the PI has entered and qualified for the market through fulfilling the dimensions described as order qualifiers, the company will need to consider the regulations and preferences that affect the ability to compete effectively. Even if the regulations themself not always create competition, competitors often utilise regulations to compete in a way that is unique for highly regulated industries. In free markets, competition often arises through an increase of perceived value offered to the customers. As the PI in terms of product characteristics are very similar to the DI, the product characteristics will not play a role in competition. Instead, other aspects will create the fundament for competing after qualifying for the market.

5.3.2 Market Order Winner Dimensions

When a product has qualified for the PV-system, the product with the lowest list price available will be prioritised for the period. In this way, price will be considered the order winner within the generics segment in the benefits scheme (*List price*). Because of how the patient is allowed to pay for receiving the prescribed alternative even if it is not the prioritised product, the perceived effectiveness and side effects for the patient can have an impact on the demand for the product (*Pharmaceutical effect*). This choice is enabled through the PV-system, and incentivises the producers to value high quality alongside low production cost in the development of generics.

The purchasing of the PI has a specific purpose for the pharmaceutical chains, namely to increase the trade margins through discounts. Because of this purpose, the order winners within the patented segment will be the aspects that increase this effect. Promised volume, discount in SEK per unit, and the delivery reliability. Multiplying the volume with discount per unit creates a variable which describes the total financial gain from the PI (*Total*

discount). With an uncertain SC, the delivery reliability decreases which limits the realised financial gain. This will of course be more important for longer supply contracts. When the general supply for a product line is limited, the delivery reliability becomes increasingly important, because of the regulations on the pharmacies (*Delivery reliability*). In this way, the design of the contract between the pharmacy chain and importer, and the external factor of general supply within the product line, will affect how the order winners are prioritised.

5.3.3 Summary of Order Winners

While the list price will be essential for a product to be chosen as the product of the month, the pharmaceutical effect might have an impact on the demand if there is a better alternative that is not extensively more expensive. Patients can be assumed to be willing to cover this additional cost if it is small and there are perceived benefits with the other alternative. This might be even more relevant for some product groups, for example regarding drugs often taken over long periods of time, as these patients can be assumed to have better insights into their preferences regarding various producers. With this said, the weighting of order winners within the generics segment are summarised in *Table 5*.

Table 5: Order winners, generics

Order Winner	**Ranking**
List price	90
Pharmaceutical effect	10

For the patented segment, the order winners are presented in *Table 6*.

Table 6: Order winners, patented segment

Order Winners	**Ranking (shortage)**	**Ranking (no shortage)**
Total discount	10	50
Delivery reliability	90	50

Bonus schemes such as the environmental premium currently under discussion, provides an example on how competitors can significantly decrease the importer's ability to create an offer with a competitive total discount. This would be executed through withholding of environmental impact information after releasing the product to the target customer, which

decreases the attractiveness to reroute these products through wholesalers or European pharmacy chains.

5.4 Market Drivers

As explained previously, the market driving factors are heavily dependent upon the regulations on the area. These regulations create a framework for the business, mainly in terms of qualifiers, that the importer must consider and support through its operations. While the customer and its preferences are suggested to be in focus when designing an operations strategy, the somewhat diffuse customer in this industry makes this difficult. While the market demand is driven by patients suffering from various conditions, the demand for a product is dependent upon a prescription ordinator considering that being appropriate treatment. This will in turn be dependent upon the product characteristics, both in terms of positive effect, side effects and cocktail effects. Because of the exposed position of the patients, and how the government subsidies pharmaceuticals in Sweden, the market is regulated through governments, agencies and politicians. This can be considered reasonable because of how these institutes are meant to represent the people and their best interests. With this interpretation the customer in this industry will be the people, expressing its will in qualifiers and order winners, explicitly formulated in regulations, dictated through its democratically elected representatives. Lastly, the representatives of the people are in turn influenced by the big players such as the lobbying organisations and Big pharma.

The Swedish market is limited and exists in a global context. Because of how sourcing takes place on the European market, this context will also be important when describing the market drivers and dynamics. Currency will be important and affect the competitiveness on a national level in comparison to other European import countries. The global, high level supply will also affect this dynamic - which also has a direct impact on the power dynamics within the negotiations on a national level.

Figure 10 provides an overview of how the different market driving factors relate to each other.

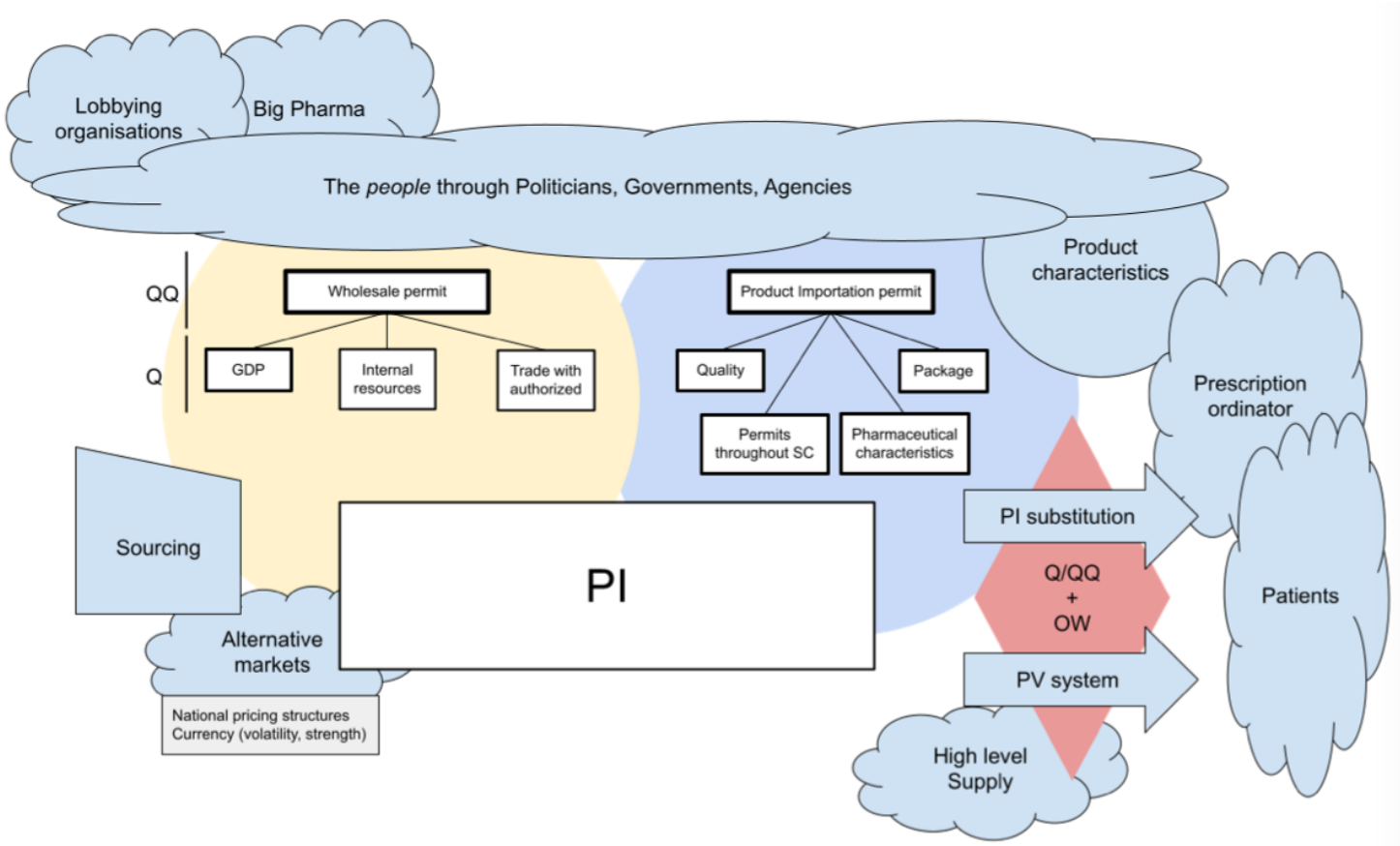

Figure 10: Overview of market drivers

Table 7 summarises the order winners and qualifiers within the industry, and illustrates some main differences in market requirements for the different segments. However, it will also be important to remember that further categorisation can be made, for example in high/low volume products.

Table 7: Summary of order winners and qualifiers

Dimension	**Generics**	**Patented**	**Patented with high shortage**
Wholesale permit	QQ	QQ	QQ
Product specific PI permit	QQ	QQ	QQ
Monthly availability	Q		
Expiration date	Q	Q	Q
List price	OW90	Q	
Pharmaceutical effect	OW10		
Total discount		OW50	OW10
Delivery reliability		OW50	OW90

5.5 Implications on Operations

An important task for the importer will be to align the operations and construct a setup which supports the qualifiers and performs well on the order winners. Independent upon the strategy chosen, operating on the market will require the importer to consider the order-losing sensitive qualifiers (QQ) which are displayed through the two needed permits. Being able to do so will require deep understanding and thus regulatory competence as an internal resource. The responsible person will have an important role in ensuring this throughout the organisation, and it will therefore be important to supply this person with required resources. The measures taken will create a fundament for quality assurance within the organisation, but also extended to control of connectors in the SC.

Because of how the other requirements within the three presented segments differ, there will be different implications on operations to support these. Availability is present for all three segments, but the purpose and therefore the nuance in the requirement is not the same.

For generics, the requirement on monthly availability will put pressure on either purchasing or warehousing. Purchasing can support this Q by targeting safe and reliable sourcing options, with transportation choices that limits the induced delivery uncertainty. An alternative is to support the Q with extensive warehousing, where the expected monthly demand will be supplied solely from current stockage.

When it comes to delivery reliability for the patented segment, the aspect will be more important for product lines with a limited supply. For those products, the choice of supplier and how developed the relationship is will be especially important. Purchasing will have an important role. In contrast to the generics segment, this OW cannot be solved through warehousing, as there is no necessity in being able to supply during a whole month. With no significant global shortage, the aspect will be important for assuring that the discount is actually possible to utilise. Building storage and releasing larger batches will in this case assure the pharmacy chain that the discounts actually will be used.

While it can be tempting to source all products that the importer can get hold of, it might be better from a strategy alignment perspective to focus on products with similar sourcing reliability levels, or at least differentiate in between them. Because of the importance of sourcing reliability in competition, there is a risk that the importer gets stuck in the middle when it comes to the strategy implementation. Product lines with a high delivery reliability might not be recognised as this by the pharmacies if the PI also source from uncertain suppliers which affect the experienced delivery reliability. As functional strategies and targets throughout the organisation should be directed and aligned with the overall company strategy, it will be especially important to consider which implications the strategy have on the delivery reliability requirements.

The warehousing or safe sourcing decision will have to be taken with consideration to the expiration date qualifying requirement, as this is also important for all product lines.

The list price will be important as an OW within the generics segment, which puts pressure on minimising the costs per package throughout the operations. Depending on the exact cost-driving factors for the PI operations, this might result in decisions such as focusing on large volumes, high value pharmaceuticals or increasing the inventory turnover rate. Further analysis can be done in the sourcing dimension, which might open up for decreasing the cost of purchasing. Instead, the importer can increase the value in purchasing through collaborations or flexibility in accordance

with supplier preferences. This will also be important for the patented segment, especially for products without extensive shortage. However, this will be for the purpose of providing competitive discounts.

As the pharmaceutical effect might have an effect on the product demand within the substitution group, this aspect could be important to consider in the context of sourcing decisions.

5.6 The Future of PI

The main driving factor that enables PI is the price differentiations that can be seen within the internal markets of the EU. The reason for regulating prices of pharmaceuticals on a national level is related to the mono-/oligopolistic market features in combination with a demand that is not driven by regular market forces. Instead the government covers a large portion of the direct cost, and medical professionals dictate the usage through prescriptions to the consumers. This means there are limited incentives for the patent holders to decrease prices, if not for the regulations.

Pharmaceutical development is currently, and has always been, a very expensive process. Extensive testing and documentation is required over a long period of time before a product reaches the market, and it is only a few of all tested candidates that will ever do so. These R&D costs must of course be covered through the sales of the products, in order for the pharmaceutical company to continue to develop new medicines that are safe and effective. The situation when a patent expires and new generic alternatives are introduced, probably comes close to where the research is excluded from the financial calculations in pricing. What is seen is decreased production costs and lower prices in the benefits programs.

New technologies and innovation, for example through digitalisation of the development and increased usage of machine learning or AI, begins to make the research process more effective. When better and safer products are researched in a cheaper and faster research process, the regulatory environment can be expected to change and adapt. Also, development in treatment technologies such as advanced therapy medicinal products (ATMP) might affect the industry significantly.

Patents exist to protect the researcher’s findings and reward innovation and all investments and risks that have been held by the organisation. The current level of research that is behind each new medicine, in order to increase efficiency, could be seen as a certain level that the government has agreed on covering the costs for through the pharmaceutical benefits

scheme. As patented products in a way compete with alternative treatments, significant improvements of research technologies could increase the competitiveness on the market - which in turn could pressure the prices. With increased competitiveness and lower prices, the need for pricing regulations on national level could be decreased. This could lead to a decrease in the price spread and make pricing more homogenous throughout the EU. If this would happen, the driving force of the market of PI would decrease significantly, which could have the potential to threaten the whole existence of the PI industry. From that perspective, the future of the PI industry is dependent upon staying relevant and adding value to the value chain so that stakeholders are willing to pay for the costs related to operations in PI, such as repackaging.

6. Conclusion

Chapter 6 summarises the results from the analysis and present reasoning regarding the choice of methodology. Finally, the contribution to the academy and suggestions on further research is presented.

6.1 Conclusion of Results

The regulations create a business environment where competition often is seen through and supported by the regulations, in contrast to the market dynamics on free markets. In traditional markets, organisations compete with perceived value with aspects such as price, product, location, supporting functions or anything else that the customers value. The competition seen on the market of PI is often deployed through support and clever usage of regulations. Because of how some qualifiers on the market are dependent upon competitors, competition can arise in a binary way where products are excluded from the market.

Regulations on different areas create incentives to drive the market in a desired direction, which highlights the importance of a systems perspective when adjusting the regulations. Realising how the market driving dynamics can be expressed in terms of OW and Q will give insights to how the operations for the importer can be improved. It can also give insights to regulatory development so that the regulatory environment can be designed to incentivise the market actors to act in accordance with desired outcome. The driving factors behind the micro adjustments of list price for patented pharmaceuticals is an example of this.

6.2 Results in the Context of Study's Goal

6.2.1 Answering RQ1

Which dimensions are most important when describing the business environment?

The most important factor when describing the market is the regulatory environment. Regulations affect the importer in all phases of the company, but also the SC connections and interactions, as well as internal resources needed. Regulations dictate the requirements for entering the market, the

requirements for daily operations but also how competition arises within the market.

The implications of the permits on the operations is of course essential for all organisations in the PI industry. Adjustments in these regulations will have a direct effect on the importers. Furthermore, the totality of the OW and Q within the segments investigated will of course also be important dimensions in describing the business environment.

6.2.2 Answering RQ2

How can insights from RQ1 be applied in practice?

Realising how different segments require different support from operational strategy to sufficiently and competitively be delivered to the market, will be highly important. Treating the product lines in accordance with the requirements in terms of OW and Q will be important for effective PI. The OW and Q will have to be evaluated with the context, reason and/or purpose in mind.

6.3 Effect of Delimitations

The delimitations of the thesis are constraining how the conclusions can be used. Limiting the market to the Swedish market affect how the details in the analysis can be transferred to other European import markets. While the details are based on Swedish regulations, the concepts and thought process will be applicable to other markets as well.

Constraining to only investigate the pharmacy sector when it comes to the customers, only a part of the PI industry is investigated. It may very well be other aspects that are important for the regions when they purchase for the hospitals. However, this thesis shows how the principles of order winners and qualifiers can be used to describe driving factors in a highly regulated industry. Furthermore, it points in the direction of how these insights can be used in constructing a corporate strategy.

6.4 Alternative Methodology

An alternative methodology would be to assess the market dynamics within the system directly from the importers perspective and use this perspective to explain the industry. This could be done with a focus on a few key personnel within the company through a case study of an importer. With this approach, more precise and accurate descriptions could have been achieved,

and also an opportunity to observe actual behaviour rather than explanations of the dynamics. However, there is a risk of focusing on what is already known within the organisation being studied, and missing the overall perspective.

6.5 Contribution to Academy

This thesis explores how the regulations within a highly regulated industry affect the business environment, and how they can be explained and investigated under the concepts of order winners and qualifiers. The thesis also shows how these insights can be utilised to direct high level strategic decisions within the industry.

Furthermore, the mapping of the PI-industry through the literature review and empirics, provides insights and an overview of this niche market. A contribution has also been made in terms of creating an overview of the regulatory environment - which has been described as highly complex and difficult to overview.

6.6 Suggestions to Further Research

While this thesis introduced a perspective on regulations through the scope of competition, further research could be done to better understand how different product lines could be grouped together in terms of market requirements. This could for example be related to newly approved pharmaceuticals, and what characteristics the operations must be able to support in order to compete on that market.

As this thesis mainly focuses on the internal- and customer side, and related regulations, the corresponding application to the supplier side could be further elaborated on.

To confirm the results, a quantitative study could be conducted where segments of pharmaceuticals are more deeply investigated.

Other aspects in the industry that can be further investigated is how a model for multi-echelon product allocation can be adjusted for the dynamics within the PV-system. This could for example be an extension to a closed form approximation model based on the induced backorder cost (Berling & Marklund 2006).

The demand pattern for pharmaceuticals can be analysed with a multi-echelon perspective, and how this can be used to improve collaboration between the pharmacy chain and the importers.

While there is currently competition between DI and PI, is there a way for the MAH and PI to collaborate? For example, a flexible PI could cover demand spikes for a DI that gains from a certain demand.

Finally, the development of new technologies such as Industry 4.0, AI and machine learning will impact the industry. Further research could investigate these effects and how the PI industry can benefit from these new technologies.

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Appendix

Appendix 1 – Interview guide

Intro:
Describe and promise anonymity, and the level of details presented in the report.

Present the structure of the interview:
- The purpose of the thesis and current progression
- Goal of the interview
- General questions
- Your view on the market as a whole
- Your view on the regulatory pressure

Purpose of the thesis:
Explain:
- The fundamental view that the project is built upon
- The perspective of regulations and how it affects the business environment
- The research questions
- Focus and delimitation of the study

Progression:
- Show a draft of a constructed model
- Some possible outcomes or conclusions
- Explain the progression and what is left to do

Goal of the interview:
- Assure correct understanding and overall focus of the thesis
- Input for the empirics

General questions:
I believe I have a good understanding for the principle. Would you like to comment on, or confirm, my understandings of the general PI:

1. Importer identifies a sourcing opportunity
2. Importer applies for permission for importing a specific pharmaceutical
3. Importer informs the MAH of the intentions
4. Importer prepares the products for the Swedish market
5. Importer negotiates with pharmacy chains
6. Pharmacy chains purchase the products at a discount price

Which of the two segments *Generics* and *Patented* is most important for the importers? Do you believe I should limit myself to focus on only one of the two segments?

Except for how a pharmaceutical is approved, what differentiates between *Parallel importation* and *Parallel* distribution?

Show investigated regulatory agencies and regulations. Anything I should add or remove?

Show investigated market actors. Any actor I should add or remove?

Your view on the market as a whole:

Do you agree with describing the market as complex, and if so, why?

Show positive aspects with PI as a concept. Could you elaborate on how and why these are valid?

What negative consequences could there be related to PI?

What aspects are most important when operating a PI business?

Which are the largest risks associated to PI?

Show the most common sourcing counties. Why do you believe these countries to be the largest exporters to Sweden?

How could the business environment be improved to better support PI operations?

In what ways do manufacturers disrupt or threaten PI operations?

Your view on the regulatory pressure:
To what extent do you feel like the regulations are assuring quality throughout the SC?

How do you believe importers in general view the regulatory pressure within the industry? (positive, limiting, controlling, quality assuring?)

How has the regulations developed in recent years? Any thoughts or insights on future regulations?

How do you think the regulations work as a barrier to entry?

To what extent do importers regulate themselves?

What do you believe is the most common deviation when it comes to regulatory compliance?

What do you believe would be the effect if the regulatory pressure decreased?

End:
Is there anything you think we should have talked more about? Or something we might have missed?

Is it OK if I contact you if there is anything I would like you to clarify?

Appendix 2 - Content of GDP

Quality Management

The quality management at a parallel importer should define responsibilities, processes and risk management principles with respect to the distribution activities. It is the management of the organisation's responsibility to maintain and monitor the quality system through active participation and have to be supported by staff throughout the organisation. The quality system should be fully documented and constructed to ensure confidence that the quality and integrity of the product remains intact throughout the supply chain. This must be done with the organisational structure, procedures, processes and resources in consideration and do also extend to any outsourced activities. (EMA, 2013)

In order to ensure implementation and maintenance of the established quality system, a responsible person should be appointed with clear responsibility and authorisation to control the operational adherence. (EMA, 2013)

The quality system should be periodically reviewed through a formal process established by the management. This includes measuring and assessing the performance of the system with the help of key performance indicators and objective achievements. Management should also consider changes in the business environment, such as new innovations, emerging regulations or guidances, and quality issues that might affect the quality system. (EMA, 2013)

Quality risk management is a process for systematically addressing the risks related to quality of medicinal products. It concerns how management should assess, control, communicate and review the different risks, both proactively and retrospectively. (EMA, 2013)

Personnel
Personnel within the organisation are the ones executing the standards for assuring quality, therefore being of great importance. GDP touches on this subject through four areas: responsible person, other personnel, training and hygiene. (EMA, 2013)

The responsible person holds a personal responsibility for the wholesalers compliance with GDP and public service obligations. This designated person should qualify for all requirements present in the member state, and preferably hold a degree in pharmacy. Furthermore, this person should have appropriate experience and competence with respect to GDP and be assigned appropriate authority in relation to the responsibilities. Concrete areas of responsibilities are further elaborated on in GDP. (EMA, 2013)

GDP states that there should be enough competent personnel involved in all stages of the distribution activities, with responsibilities clearly documented throughout the organisation. Appropriate training on GDP should be given, and personal hygiene procedures covering health, hygiene and clothing should be established and controlled for relevant activities. (EMA, 2013)

Premises and Equipment
The wholesaler must have appropriate premises and equipment to ensure proper distribution of medicinal products.

GDP describes how facilities should be secure, structurally sound, large enough and equipped with sufficient lightning. If the premises are operated by a third part, a contract must be in place. Furthermore, the guidelines state how, when and when not products must be physically segregated. There is also guidance on how temperature and environment should be controlled through aspects such as temperature, light, humidity and cleanliness. (EMA, 2013)

According to GDP, all equipment must be designed, located and maintained in an appropriate way so that safe storage and distribution can be assured. Maintenance, calibration, alarms, repairs and documentation of this should be conducted according to standards. IT systems are also covered in this context. (EMA, 2013)

Documentation
Through written documentation, errors can be limited and it allows for backtracking of the information flow. GDP provides guidelines on personal data, language, signing, alternations, retention, access, structuring of documents and records. (EMA, 2013)

If the medicinal products are relabeled or repackaged by the importer, national legislation related to batch numbers should be guiding the numbering on the parallel distributed packs. If specific national guidance or legislation do not exist, GDP provides guidelines to how batch numbering shall be done. (EMA, 2023e)

Operations
Through operations, the wholesaler can take actions to ensure the identity of the medicinal product and that the distribution is performed in accordance with the information on the package. A distributor who imports medicines must notify the marketing authorisation holder and the competent national authority of the intention to import the product. The wholesaler must assure that the suppliers and customers are qualified and follow the requirements from national and EU regulations. Which requirements and how to control them are further explained in the guidelines. Operational principles regarding storage, destruction of obsolete goods, picking, supply documentation and exports to third countries are also mentioned. (EMA, 2013)

Complaints, Returns, Suspected Falsified Medicinal Products and Medical Product Recalls
GDP describes principles for the wholesaler to follow regarding complaints, returned products, falsified products and medicinal product recalls. Complaints should be treated differently if it regards the quality of the product or the distribution provided. Requirements for when a returned medicinal product can be returned to the saleable stock are presented. Procedures for how suspicion of falsified products should be treated is explained. Finally, product recalls must be promptly dealt with. The procedures for this must be well documented and evaluated regularly. (EMA, 2013)

Outsourced Activities
Any outsourced activity must be defined, agreed and controlled by the wholesaler. The wholesaler holds responsibility also for activities contracted out. This means that the competence of the contract acceptor must be assured and controlled through audits. All necessary information, for the acceptor to fulfil their obligations, must be shared. The acceptor is not allowed to use a third party for any of the obligations entrusted through the contract. (EMA, 2013)

Self-inspections
The wholesaler should conduct self-inspections covering all aspects of GDP and compliance with other regulations, guidelines and internal procedures.

These inspections should be done according to a defined program, assuring compliance over time. (EMA, 2013)

Transportation
As the wholesale distributor is responsible for correct handling during transportation, actions must be taken to limit the risk of breakage, alterations and theft. The wholesaler must also be able to assure temperature conditions have been held within acceptable limits during transportation. In GDP, further responsibilities for the wholesaler are detailed. These concern actions if deviations are identified, equipment, maintenance, route risk assessment, dedicated vehicles, delivery addresses, emergency deliveries, third party relations, containers and products requiring special conditions. (EMA, 2013)

Special Provisions for Brokers
A broker is a person negotiating sale or purchase of medicinal products on behalf of another part. This section explains what parts of Directive 2001/83/EC apply to brokers and which does not. Furthermore, special provisions related to quality system, personnel and documentation are presented. (EMA, 2013)

Final Provisions
As final provisions, it is stated which previous guidelines the directive replaces and when the directive will be applied. (EMA, 2013)