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Optimising a Launch

Important factors affecting a new pharmaceutical launch in Sweden

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Abstract

Optimising a Launch - Important factors affecting a new pharmaceutical launch in Sweden

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This master thesis explores the launch process of new pharmaceuticals in Sweden. The path of a pharmaceutical from idea to innovation is a long and arduous process with only few new products actually reaching the patients in the end. Seeing as the drug development is also an expensive process, it is of importance that the products that get approval meet their expected revenue. New pharmaceuticals can also be life changing for the patient, and thus it is important that once approval is received the patients gain access to the new treatments. This study focuses on the post regulatory approval processes in Sweden, as well as activities carried out by the companies that affect the adoption of a new product.

By utilizing a qualitative study, this thesis aims to describe the internal and external factors that affect the pharmaceutical launch process in Sweden. As well as exploring what future initiatives and possible changes that might affect it. Ten interviews with different company representatives as well as six interviews with governmental and regional stakeholders were analysed using grounded theory to answer what factors affect the adoption of new pharmaceuticals. Factors that were found to be important were: Utilisation of cross-functional teams, clear and simple strategy that includes the whole organisation, communicating with national and regional authorities, and get feedback from these, communicate with patient representatives and organisations as well as developing utility services for the product. From a couple of these factors a trend towards the servicification of the pharmaceutical industry was discovered.

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Sammanfattning

Läkemedelsindustrin särskiljer sig från de flesta andra industrier. Den är högt reglerad och påverkas därmed av ett flertal intressenter. Att komma fram till ett nytt läkemedel är en lång och kostsam process för läkemedelsföretagen. Alla produkter får inte ett marknadsgodkännande och kan därmed inte säljas, och det är inte heller säkert att en potentiell produkt får alla kliniska faser godkända. Detta leder till en ökad press på de produkter som väl får ett godkännande när det kommer till den tänkta försäljningen. Produkten behöver inte enbart ta igen dess egna kostnad utan även delar av kostnaden från de produkter som aldrig får säljas. Därmed är det viktigt från företagens sida att genomföra en bra lansering av produkten för att få en god försäljning. I denna studie har vi tittat närmare på vad de är som påverkar själva lanseringen, både positivt och negativt. Detta för att se vilka möjligheter det finns till en förändring i lanseringsprocessen för att potentiellt öka försäljningen ytterligare. Rapporten fokuserar även på att få in ett framtidsperspektiv i bilden. Detta genom att se vad som kan komma att förändras inom de närmaste 5 åren som har möjlighet att påverka lanseringar för läkemedelsföretagen.

För att kunna titta närmare på hur företagen själva kan påverka, samt hur de idag genomför sina lanseringar, genomfördes 10 intervjuer på 9 företag. Intervjuerna var med personer involverade i lanseringsprocessen på företag som hade lanserat en produkt de senaste åren. Genom att analysera intervjuerna med hjälp av grundad teori kom vi fram till gemensamma teman för en generell lansering. Företagen använder sig utav tvärfunktionella team under lanseringsprocessen där övergripande strategier fås från det internationella huvudkontoret. Det är viktigt att verkligen förstå sin produkt och dess värde, samt att identifiera sitt marknadssegment. Intervjuerna gav också insikten att företagen ofta besitter kunskaperna för att genomföra bra lanseringar, men att det kan vara en resursfråga om en lansering uppnår sin fulla potential. Regleringarna för ett läkemedel är ett komplext system och det är viktigt med en god förståelse för detta system. Som en del av detta system läggs det stor vikt på att få en subventionering från TLV eller en positiv rekommendation från NT-rådet. En outnyttjad potential kring användandet av processer såsom *horizon scanning* för att optimera sin lansering i ett tidigt skede kunde också identifieras.

För att få ett helhetsperspektiv genomfördes även 6 intervjuer med parter som inte var läkemedelsföretag. Detta för att validera resultatet från företagsintervjuerna. Till att börja med är betalarna för läkemedel väldigt heterogena, vilket bidrar till komplexiteten i systemet som hanterar läkemedel. Myndigheterna är öppna för diskussioner med företagen, men de ser helst att kontakten initieras från företagens sida. Ett framtidsperspektiv som delas med företagen är oron kring att stadsbidraget till regionerna för läkemedelskostnader skulle generaliseras, utan att indexeras, vilket kan främja en ojämlik vård. De externa parterna behöver även vara redo att följa den utveckling som sker tekniskt idag. Denna utveckling leder till mer specifika läkemedel för mindre patientgrupper och ibland utan att fullständiga kliniska data finns att tillgå. För att inte begränsa tillgången för nya läkemedel i Sverige behövs system som är redo att hantera denna nya utveckling. Därmed ökar också vikten av tillgången till data och även modeller för att hantera denna, kallat *real world evidence*. Med de nya läkemedlen följer även nya kringtekniker, såsom diagnostikverktyg, samt andra kringtjänster. Kringtjänsterna är något som blir allt vanligare. Detta leder till en förändring i industrin som gör att den går mot ett mer tjänstebaserat utbud, med läkemedlet i centrum. Ett exempel på en kringtjänst är exempelvis SMS-påminnelser till patienten när de ska ta sina tabletter.

Läkemedelslanseringar är ett viktigt ämne att lyfta för att ge en ökad förståelse för hur tillgängligheten av läkemedel påverkas. I denna studie har vi fått en inblick i vilka svårigheter som finns och kan därifrån gå vidare med att se hur svårigheterna kan minimeras. En mer djupgående studie kring industrins externa intressenter hade varit intressant, men det är något som framtida studier får genomföra.

Acknowledgements

All of us working on the project went from basically knowing nothing about the industry, to discussing all kinds of concepts with senior industry professionals, and all this with a short time-frame. Such a rapid development of our knowledge, both as a group and as individuals, would not have been possible without the incredible support we have received from every single person we have been in contact with.

Thanks to all the representatives from the regional pharmaceutical committee we reached out to in the beginning of our project that all were very patient and helpful. Also a huge thank you to everyone that we interviewed! You are all busy people, but still took time out of your schedules to sit down with us and help create the foundation of our study.

Another person which really took time for us and our questions was our subject reviewer, Göran Lindström. You gave us really good ideas regarding how our research might fit in a broader scale. Our fellow students at the School of Entrepreneurship were also a constant source of inspiration.

We also would like to give a special thanks to all the incredible people at IQVIA that were all welcoming of us during our stay at their office. A special thanks to everyone in the client consulting group that we met on a daily basis. Another supporting role at IQVIA was everyone in our very own steering committee, that met with us at several occasions to discuss and listen to what we had to say, thank you for your time.

Finally, we would like to thank our supervisor at IQVIA during our project, Maaike Janssen. You always had time to lend a hand, whether it was discussing the next steps in the project, or helping us come in contact with the right people. You took a lot of time from your already busy schedule to make sure that our project became a great one. Without you we would not have been able to make this project the way we did!

Contents

Abbreviations

Alphabetical list of abbreviations used in the report.

EC ..... European Commission
EMA ..... European Medicines Agency
HTA ..... Health technology assessment
LIF ..... Swedish Association of the Pharmaceutical Industry
MPA ..... Swedish Medical Products Agency
NAS ..... New active substance
NPL ..... New pharmaceutical launch
RWE ..... Real world evidence
TLV ..... The Dental and Pharmaceutical Benefits Agency

Glossary

Drug	A substance that causes a physiological effect when introduced to a biological system.
Highly regulated market	"A market over which government bodies or, less commonly, industry or labor groups, exert a level of oversight and control." (Kenton, 2017).
LIF	The Swedish Association of the Pharmaceutical Industry (Läkemedelsindustriföreningen) is a trade association for the pharmaceutical industry in Sweden that performs research. The organisation represents approximately 90 members and associate companies whom are responsible for about 80% of the total pharmaceutical sales within Sweden. Their mission is to represent their members in questions regarding authorities, organisation, and decision-makers. As well as keeping up to date with the development within the industry and thus influence basis and framework for the members activity in Sweden.
MPA	The Swedish Medical Production Agency is an authority with the primary responsibility of enhancing the health of people and animals.
NAS	Refers to a new active substance. It is defined by the European Commission (EC)(2019) as "a chemical substance not previously authorised as a medicinal product in the Union" or "an isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously authorised as a medicinal product in the Union but significantly differing in properties with regard to safety and efficacy from that chemical substance previously authorised".

NPL	Refers to a new pharmaceutical launch, as in when a new active substance (NAS) is introduced to a new market.
NT-council	The council for new therapeutics is a group consisting of experts from the different regions in Sweden. They mainly give recommendations regarding the use of new requisition drugs, and operate under the same basis as TLV.
Pharmaceutical	An active substance used as a medicine with the right doses.
Pharmaceutical committees	Regional committees that are required by Swedish law (SFS 1996:1157). Their purpose is to help the regional healthcare system to establish a reliable and rational usage of pharmaceuticals.
RWE	Real-world evidence can be described as the clinical evidence that the usage of a medical product might produce in terms of risk/benefit analysis. This analysis can be done in different study formats and using different models, but uses clinical data, Real-world data, to come to a conclusion (FDA, 2019).
TLV	The Dental and Pharmaceutical Benefit Agency is the authority that makes decisions regarding subsidisation of pharmaceuticals as well as dental care and medical devices.

1 Introduction

The pharmaceutical industry is an important part of the health care system in Sweden. In 2017, its contribution to the Swedish GDP was about 0.7% (LIF 2019a, The World Bank 2018). Therefore, the continued growth of the industry is a topic of interest. The industry is constantly changing and developing, and to be able to present the best available healthcare it is important to continue adopting new innovations. New innovations keep expanding the lifespan of people and save lives. The industry is part of a highly regulated market, and in Sweden, a part of a complex value-based healthcare system. The Swedish pharmaceutical market is small compared to other markets, globally and within Europe, which makes it important to keep companies interested in launching new pharmaceuticals in Sweden.

In Sweden 40% of the volume of pharmaceuticals used today, excluding over-the-counter product, were launched over 40 years ago (Gustafsson & Troein, 2018). A failure in increasing the uptake of new pharmaceuticals would mean that patients will not have the best possible healthcare available to them. The production of a new pharmaceutical is both time consuming and comes with a high cost. Returning a good profit of new pharmaceuticals is hard, and according to research in the United States half of the new pharmaceutical launches (NPL:s) does not meet the expected revenue (Natanek *et al.* 2017). It has been shown that the most important time for a pharmaceutical launch is the first six months of sales (Murch *et al.* 2017) as that time-span heavily affects the product's continued growth. This makes it important for companies to focus on the pharmaceutical launch and the strategies surrounding it.

Getting a successful launch can be challenging, though. Multiple factors need to be considered that require specialised knowledge (Valid Insight, 2017) and future pharmaceutical launches need to be clever and differentiated in their marketing approach to reach success (Chierchia *et al.* 2013). Studies have shown that companies who are more satisfied with their sales tend to use newer marketing models and techniques (Mahajan & Wind, 1992), in regards to a general product launch. The same might be the case for the pharmaceutical industry. The research on this area

is limited for the pharmaceutical industry, especially when looking at the Swedish market in particular. Thus, it is of interest to look further into how the pharmaceutical companies perform their launches in Sweden and identify which factors in this process are the most critical.

1.1 Purpose Statement

The purpose with this study is to find factors among stakeholders in the pharmaceutical industry that affect the launch process of a new pharmaceutical.

The report discuss how launches within the highly regulated pharmaceutical industry might evolve and differentiate within the next 5 years. The results presented will aid the discussion around how to increase the adoption of diffusion in a highly regulated market, such as the pharmaceutical industry in Sweden. The goal of an improved launch process for pharmaceuticals would improve the quality of treatment for patients in the Swedish healthcare system. This would be achieved by opening up for an increased use of the latest technological advances in medicine. The project is also performed in collaboration with IQVIA.

1.2 Project focus

The project will be carried out by analysing how an effective product launch in the pharmaceutical industry is performed and joining it with theoretical backgrounds for such strategies. The study will look into what factors, both internally at pharmaceutical companies and external factors such as political ones, have an affect on a new product launch. How the industry launches new pharmaceuticals today, and possible influences that might change the effectiveness of this strategy in the near future, will be discussed. To ensure that the study keeps the right focus three research questions are specified below. These questions focuses on a company's view of important launch factors, how external stakeholders might affect a launch, and how current developments in the industry might change these factors in the coming years. The questions are formulated as:

- What are the frequent challenges for pharmaceutical companies when launching new treatments in Sweden?
- How do Swedish governmental stakeholders affect the launch climate for pharmaceuticals?
- What political and technological changes to the industry might affect the Swedish launch landscape in the near future?

Semi-structured interviews are used to answer the stated research questions seen above. Pharmaceutical companies have been interviewed as well as governmental stakeholders (that might affect the external factors). This primary data is compared and contrasted with secondary data sources to answer the purpose statement.

1.3 Delimitations

The project's scope is limited in time, spanning 21st of January 2019 to 24th of May 2019. This will ultimately result in a limitation in how much resources can be put on different topics covered in the report. The research only discusses the project specifications in regards to NPL:s in Sweden. The focus is on pharmaceuticals containing a new active substance (NAS) according to the European Commission (EC). Generic and biosimilar pharmaceuticals are thereby excluded.

2 An insight into the pharmaceutical industry

The pharmaceutical industry is ever-changing. New innovative ways of treating and managing diseases are constantly being developed. There is no wonder that fundamental changes to the industry have occurred in the past. Technological advances in biotechnology during the 1980s-1990s changed the research focus of pharmaceutical companies. In 1993, major pharmaceutical companies had one third of R&D-projects based on biotechnology. In 1980 that number was only two percent (Landau *et al.* 1999). This was a clear paradigm shift in the industry, and the complexity of research increased as a result of this transition from traditional organic chemistry to biotechnology (Au, 2014).

Today a new paradigm shift have been identified. The reason for this is the emergence of personalised medicine. Personalised healthcare focuses on preventing, and not only treating patients, something that is different from the traditional generalised treatment plans. As with the paradigm shift in the 80s- and 90s, new technologies in the market are the reason for this. A patient's genome and its environment can today be analysed and compared to other patients, tailoring treatments to an individual (GlobalData Healthcare, 2017). This approach of personalised medicine is as of yet mostly associated with oncology, with CAR-T cells being an example of this (Maciejko *et al.* 2017).

Fundamental changes to a market causes inevitable challenges for the players on the market. For the pharmaceutical companies, personalised medicine means further specialisation of the product, with smaller patient groups as target segments. The challenge then becomes to get the expected return on investment from extensive R&D without raising prices for these treatments (Faulkner *et al.* 2012).

More advanced therapies and an increased specialisation of the products creates a more complex launch climate. These more complex products needs to be understood by the users, targeting the right, smaller, and patient group becomes more critical. Shifting technologies in an industry also means that supporting services needs to be in place to handle the new kinds of products that appear. If these do not exist,

the companies need to work with such issues as well during the launch of a product that might need additional diagnostic tools, other treatment guidelines, or any other infrastructure or education efforts that might not be in place.

2.1 A highly regulated market

In Europe, a framework exists governing how a pharmaceutical product can be sold and marketed. This framework also requires monitoring of negative side effects a product might have, and defines how severe these can be and still be allowed to be sold (EC, 2017). Such regulations on a market affects the pricing of pharmaceuticals, and ultimately their sales (Schulenburg *et al.* 2011). The pharmaceutical industry is a highly regulated industry (Jekunen 2014, Beemsterboer 2003), therefore an understanding of these regulations is important to begin discussing general topics in the market at large. This regulations has an impact on how the launches can proceed, what the companies are allowed to do and is therefore of interest to mention in this study.

"A regulated market is a market over which government bodies or, less commonly, industry or labour groups, exert a level of oversight and control" - Kenton, 2017.

2.1.1 Regulations in practice: Drug approval

It can take a pharmaceutical 15 years to go from R&D to its first sales. In general, this development cost is between 10-15 billion SEK (LIF, 2019b). The process is divided into separate sections with varying time-spans, as seen in *figure 1.* Starting with pre-clinical studies, screening for substances with good potential, the one(s) most likely to reach the market (and return a profit). A pharmaceutical has high safety requirements and substances with severe side effects or low clinical effects are screened out (LIF, 2019b). To continue with clinical trials an approval from a regulatory agency is needed for that specific substance (Läkemedelsutveckling - FASS Allmänhet, 2017). After a pharmaceutical product reaches the market the companies have a responsibility of monitoring for any long term side effects that turns out (LIF, 2019b).

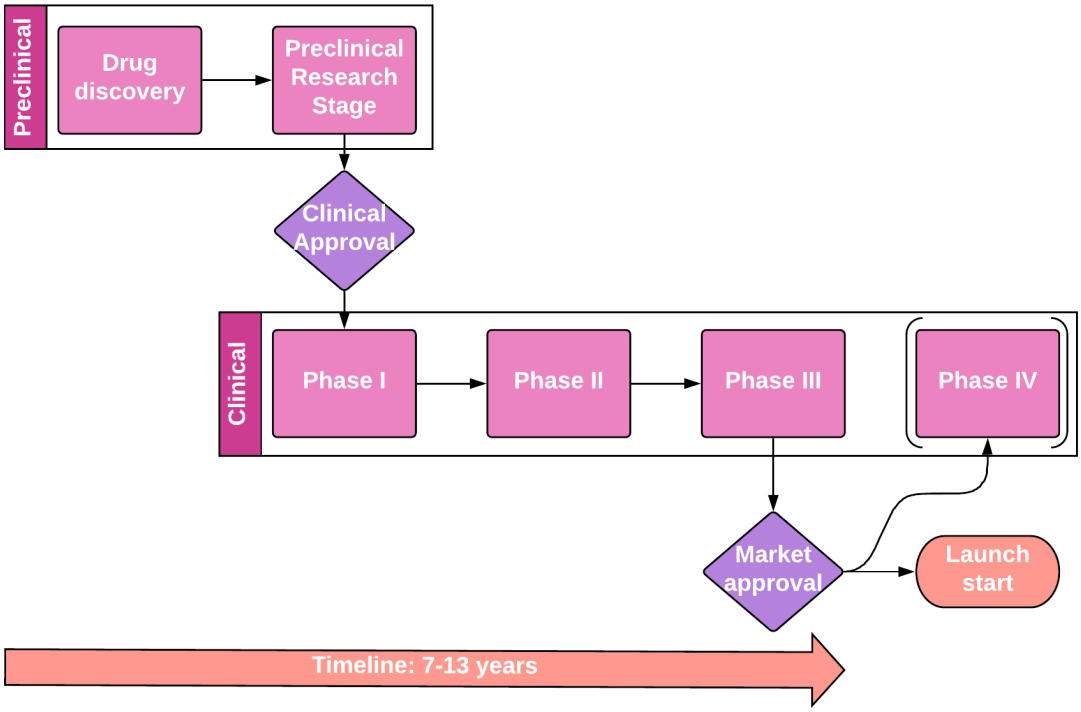

Figure 1: How a drug reaches the market, from screening for substances of interest, to market approval and monitoring the drug on the market. Adapted from LIF (2019b).

To receive a market approval in Europe, stating that the pharmaceutical in question is allowed to be sold and used, an application to the European Medicines Agency (EMA) have to be filed. EMA acts as a coordinator between pharmaceutical companies, national regulatory agencies (in Sweden, the Medical Products Agency (MPA)), and the European Commission (EC) (Dunder, 2016). EMA coordinates the job of evaluating the product together with the national regulatory agencies, ensuring that it has a desired therapeutic effect, and acceptable side-effects (Janusinfo, 2018a). The EC is then the one approving the pharmaceutical for market approval. The way this procedure is handled can vary, and within the EU two different regulatory paths are possible for a pharmaceutical to go through, with the end result being a market approval (EMA, 2018). One path is called the centralised procedure, where a single application is filed with EMA, and where a market approval in the end would be valid in all EU countries. Most new medicines for human use are processed through

the centralised procedure (EMA, 2018). If the pharmaceutical do contain a NAS for a specific indication, is considered to be significantly innovative, or is considered to be in the public health interest at the EU level, they are required to go through the centralised procedure.

If it is not required to be handled by the centralised procedure the pharmaceutical must go through the national procedure. Here, the request for market approval is sent to one or more national regulatory agencies. If a national agency approves the market authorisation, other EU member states can recognise that decision as well, making it valid in those countries too. This is called the mutual-recognition procedure. A pharmaceutical can also be processed and authorised by several EU member states at once, which would be called a decentralised procedure (EMA, 2018).

2.1.2 The Swedish reimbursement process

In Sweden, the state can reimburse the regional counties, those responsible for the healthcare costs, for prescription pharmaceuticals that have been deemed cost-effective by the Dental and Pharmaceuticals Benefits Agency (TLV) (Glenngård, 2019). This is part of a healthcare-system based upon the value-based healthcare approach, something that Sweden is one of a few countries in the world to implement (The Economist Intelligence unit, 2019). The Swedish agency for health technology assessment and assessment of social services (SBU) defines value-based healthcare as an overarching framework with the purpose of giving the patient the best possible outcome in relationship to the resources being used (SBU, 2018).

The regions in Sweden have initiated a collaboration for the introduction of pharmaceuticals (nationellt ordnat införande). The purpose of this process it to give equal and cost-effective healthcare in Sweden (Janusinfo, 2018b). An overview of the procedure can be seen in *figure 2*. The NT-council decides whether or not a pharmaceutical is to be handled by the cooperation procedure (Second step in *figure 2*). The degree of cooperation is described by three levels: one, two and three, which can be described as high, medium and low level of cooperation respectively. High level of cooperation is described by *figure 2*, excluding the dashed arrow, while the medium level follows a similar path with the exclusion of the introduction and monitoring protocols, see dashed arrow in *figure 2*. If the NT-council decides upon

cooperation level three, the lowest, it goes through a decentralised introduction that is driven locally in each of the regions (Swedish Agency for Health and Care Services Analysis, 2017).

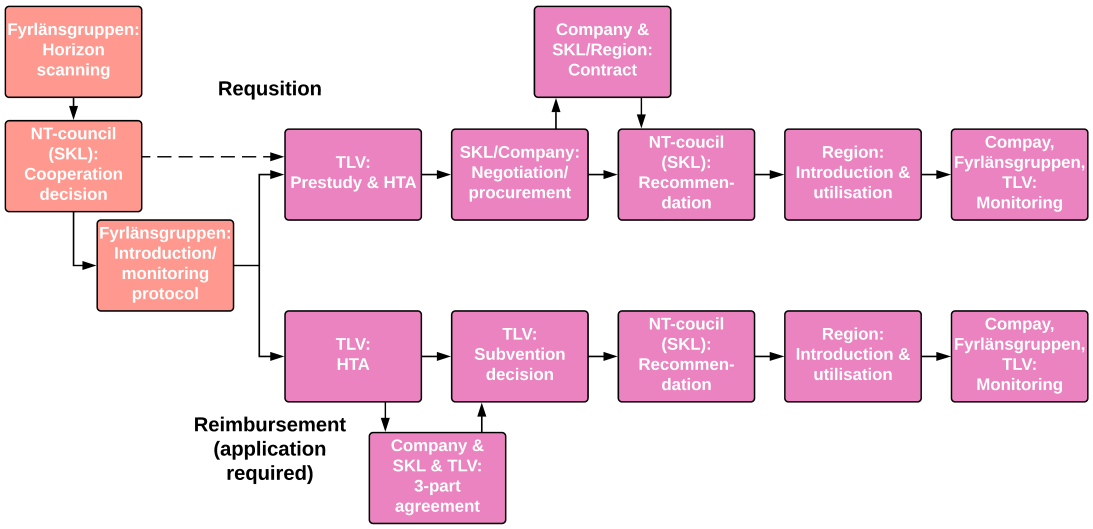

Figure 2: A schematic overview of the cooperation procedure for the introduction of pharmaceuticals in Sweden (Nationellt ordnat införande). The process is dependant on the type of pharmaceutical, and the payer of a products is ultimately the regions. Adapted from Bröstcancerföreningarnas riksorganisation (2017) and Swedish Agency for Health and Care Services Analysis (2017).

2.1.3 Marketing regulations in Sweden

According to Swedish law it is not allowed to advertise a pharmaceutical before it has received regulatory approval. When an approval is received, a prescription product can still not be marketed towards children, or the general public, with an exception for vaccines. Marketing efforts are only allowed to be targeted towards professionals that are allowed to prescribe pharmaceuticals (MPA, 2016). There are also restrictions affecting what advertisements can include. The information in the marketing needs to be precise and understandable for the target audience. This is different compared to the marketing regulations in for example the United States (US). Where it is legal to advertise prescription pharmaceutical directly to the patient (Ventola, 2011). In the US, it is also common to give out free samples and other gifts to influence

a physician's decisions (Connors, 2009). The restrictions set on the pharmaceutical market in Sweden tries to reduce the possible personal gains or opinions getting in the way of healthcare professionals prescribing the best possible pharmaceutical for their patients in any given situation.

These regulations on marketing can limit the use of otherwise common marketing strategies. Pharmaceutical companies have been reprimanded for using superlatives and wrongful time-estimates in their communication to the public (Brink, 2017). One company got fined for posting information that was regarded as marketing towards the public on social media (Walleskär, 2019). Using digital channels such as social media or blogs also requires a pharmaceutical company to identify possible reports of side-effects from their products on such channels, and report them to the proper authorities (LIF, 2017). This would mean that resources have to monitor such possible marketing channels if those exists, ensuring that any report gets documented.

Since more resources are required for every additional channel of communication compared to other industries, this could be a constraint in how many channels of communication are deemed possible to maintain for a company. And in every one of these channels of communication, bold, attention grabbing, communication might risk subjugating the company to fines for wrongful marketing of their product.

3 Factors affecting a product launch

This study looks into the pharmaceutical industry from a perspective of product launches. The intent of this section is to build a foundation from which the original data for this study can be analysed upon. In this study, theoretical models such as PESTEL can be applied. Also, the discussion regarding adoption and diffusion of innovations is relevant.

3.1 Knowing the surrounding environment

PESTEL is a method used to analyse the marketing environment at an external level from different angles. It is an extension of the PEST analysis, and often used in combination with both Porter's five forces as well as SWOT-analysis (PESTEL Analysis, 2016). The abbreviation stands for "Political, Economic, Social, Technological, Environmental, and Legal factors", where the "Environmental" and "Legal" factors are the extensions of PEST (Bates & McGrath, 2013). Political factors review what influence governments have on the industry of interest. The economic factors are in regards to how companies manage their business and the profit they make, which can fluctuate with inflation and economic growth. Social factors are dependent on where a company operates and what demographics are present, but also what norms and values there are as a result. Technological factors refer to the impact of technological innovations, R&D, and how it affects the industry. Environmental factors reviews the surrounding environmental effects of a market. This particular factor is getting more important as the awareness of climate changes is increasing. Legal factors include all the laws that may affect the company, and discusses the situation created from that (Bates & McGrath, 2013). The impact of each factor will vary depending on which industry the model is used in. The PESTEL analysis is good to use in decision making to create an understanding for the market position. In the context of launching a new product, these factors need to be taken into consideration when evaluating a product.

PESTEL can therefore serve as a framework for different viewpoints which are taken into consideration in the analysis of data. Ensuring that all viewpoints are covered

gives a more nuanced conclusion that falls at a lesser risk of missing a key part of a problem. In this report, only one viewpoint in the PESTEL-framework will be excluded, which is the ”Environmental” factor. This factor does play a big part in the regulation of pharmaceutical development, but is not a critical factor when reviewing the launch of a finished product. Given the current societal focus on the environment though, it is not far-fetched to assume that such a factor might become more important when looking at the launch of a pharmaceutical in the future, even if it is not covered in this report.

3.2 Adoption and diffusion of innovations

When studying the launch process of a product, the process of adoption becomes relevant to take into consideration. This is important since the goal of a launch is to optimise the initial adoption, and thus the continued adoption of the product. The process of adoption has been studied and built upon from before Everett M. Rogers first published his work ”Diffusion of Innovations” in 1963, which furthermore established the field by broadening its applications. The theories that have been developed include adoption both on a macro- and micro level of scale, and is applicable in countless areas of research. When studying the process of adoption, the term innovation appears as a keyword. Innovation being an invention that has been commercialised and adopted by an user. Technological innovation is often classified in two categories: radical, and incremental. Radical innovation is a shift in the dominant design, whereas incremental innovation is small changes in the dominant design that furthers the development of a product, or process. A process innovation referring to an organisations algorithms for improving effectiveness or efficiency of production (Schilling, 2016).

When considering the adoption of a new pharmaceutical product the ideal situation would be one where the innovativeness and cost-effectiveness would decide the adoption of the new product. But since the efficacy and safety of new pharmaceuticals are often not fully understood until after a market introduction, this is not feasible. Also, complications arise due to the small improvements on new pharmaceuticals when compared to their older market counterparts (Alexander *et al.* 2011),

complicating the evaluation even further. Differences in when a company decided to launch a new pharmaceutical product is also a launch success factor, which is not easily understood or evaluated. An effect of this that not only the new innovative products are the ones that succeed on the market, as well as some product not being adopted by the market. Therefore it is of interest to further explore what factors are important when looking at the adoption of new pharmaceuticals.

3.3 Being successful with a new product launch

In previous literature several key factors have been identified when planning a successful launch of an innovative product. Di Benedetto (1999) found a strong correlation between a successful launch and two key factors in their study of key factors in product launch. One was the utilisation of multidisciplinary teams within decision making groups of the launch process. Also, a strong correlation was found between beginning the logistics planning early in the process and a successful outcome. The perception of superior marketing research, sales force, distribution promotion, R&D as well as engineering was also found to be correlated. Related to the previous statement, a correlation was also found between the quality of selling efforts, advertisement, as well as technical support, and the success of a product launch. Moreover, it was shown that utilising market research such as market testing, customer feedback, and advertisement testing within the launch process was vital for a positive outcome.

Other essential key factor that was found to be important in the launch process is timing. Factors to take into consideration when assessing launch timing are the timing relative to business unit goals, competitors, customers, different logistics and marketing channel cooperation and coordination, and execution of promotion in regards to a specific marketing channel and the sale of the launched product (Di Bendetto 1999, Schilling 2016).

It has also been shown that a product launch's financial success is dependent on structured launch objectives, well-positioned products in the target market, and good market segmentation (Talke & Hultink, 2010). These traits are in line with the STP-approach of target segmentation, where segmentation, targeting, and po-

sitioning of a product is done in a structured manner (Kotler *et al.* 2017). Also, a company's corporate mindset has been argued to be an influence regarding market success. The specific mindset required is then argued as being one of risk-taking with ambitious objectives, together with the above mentioned use of segmentation and positioning techniques. Introducing ways to internally reward and encourage a high-risk behaviour from employees at a company can therefore be seen as an effective method of increasing the odds of a successful launch (Talke & Hultink, 2010).

Hultink & Atuahene-Gima (2000) used a moderated regression analysis to correlate positive sales figures with market volatility, internal marketing of a new product, and outcome based control over the launch process. A schematic overview of the independent variables explored is shown in *figure 3*.

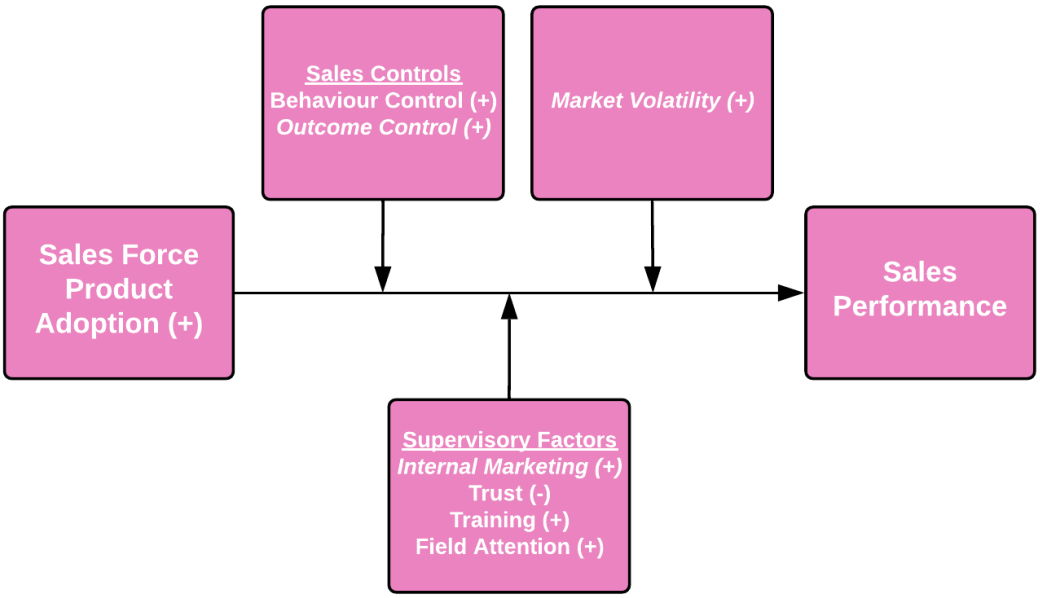

Figure 3: Schematic view of the independent variables explored by Hultink & Atuahene-Gima (2000). Italic variables had a significant effect on the sales performance, and the net effect is shown with +/-.

3.4 New pharmaceutical launches

Once a potential pharmaceutical has gone through the approval process, it can be argued that the product has been launched. A launch can also been seen as once the product reaches the patients, after it has been handled by the reimbursement and/or introduction processes at place. But the launch process starts before this with both the planning and other pre-approval activities, such as patent planning, actively working with horizon scanning initiatives, and starting the reimbursement process for example. Another unique launch aspect of pharmaceuticals is that a previously approved drug may get new indications introduced. This means that it can be argued that each new indication results in a new launch as well, furthermore complicating the definition of a pharmaceutical launch.

In the pharmaceutical industry it is possible to have a monopoly on a new product due to patent protection laws (Taylor, 2016). This makes time-to-market, and the planning and successful implementation of launch operations, a critical part of pharmaceutical companies strategic planning since patents expire a set time after the patent is filed and approved (Hansen & Grunow, 2015).

Patent protection is an important factor for innovation in the industry and therefore allows for diffusion of new technologies (Gawel, 2016). This is the case since patents in the pharmaceutical industry often cover the whole product, compared to other industries where they often only cover a small component of said product (Lehman, 2003). Lehman (2003) also states that while in other industries a product can be kept a secret up until the launch of a product, a pharmaceutical product have to disclose its technical details a long time prior to the actual launch of the product, which makes the filing of a patents occur before the launch of the product. The time on the market before a patent expires is therefore less for a pharmaceutical product than other products, making recuperating sales a more time-sensitive process.

Decreasing the time for projected sales can dramatically improve the attractiveness of that product from both an economic and a strategic point of view for a company (Robey & David, 2016). A strategy for the launch process which is optimised has

been suggested as a prerequisite for a successful pharmaceutical launch in emerging markets such as the Chinese pharmaceutical sector (Ching Gu & Burns, 2016). Furthermore, adapting the launch process plan to handle regional factors such as cooperation with non-governmental organisations have been suggested as a successful strategy in certain parts of Africa (Mukku *et al.* 2016).

A 2015 study in Finland suggested that the most important factors when optimising the strategy of an NPL had to do with a well-grounded pricing policy and a good marketing plan with the intention of accelerating and achieving customer acceptance of the new product (Matikainen *et al.* 2015). Involving key opinion leaders early in the launch process to increase interest of the product and incite information diffusion of the product also aids in achieving this (Matikainen *et al.* 2015). In the Swedish NPL-landscape, it has been indicated that a company's ability to allow decision-making from its employees in an autonomous and innovative way, with clearly defined objectives as a guiding tool, has been a successful sales force management technique for NPL:s (Fraenkel *et al.* 2016). Autonomy and allowing innovation from company employees increases the variables to be considered in a launch and could therefore be seen as an increase in risk-taking, thereby strengthening the indications of a risk-taking behaviour as positive for increased market performance.

Chierchia *et al.* (2013) states that launch success is dependent on having a detailed work plan of activities and deadlines to perform before a launch. Finding 3 to 5 key factors within the launch process in which one outperforms the competitors, and establishing a multidisciplinary team is also important. Lastly, launch success is dependant on the development of a winning corporate culture.

Another way of looking at doing a rigorous groundwork before a launch is the use of that groundwork for controlling uncertainty. Uncertainty management has its roots in risk management. The need for a broader perspective has caused shift in the focus from risk management, towards uncertainty management. This broader perspective has shown to improve project performance. Uncertainty management is about not only managing threats, opportunities, and implications but also about identifying and managing the sources of uncertainty. Focus then lays on identifying where and

why uncertainty is relevant, and where it can be ignored (Ward & Chapman, 2003).

Uncertainty is often managed through all the stages of a project, conception to support, in product life cycle model, and has to be kept in consideration for a success. Areas of uncertainty include: variability of estimate of project parameters, basis of estimates of project parameters, design and logistics, objectives and priorities, and the relationship between project parties (Ward & Chapman, 2003). Thus by planning the operational, financial and strategic processes in a product launch project, positive effects on the net results can be achieved (Hanlon 2015, Chierchia *et al.* 2013).

3.5 Political initiatives innovating the pharmaceutical market

There are several projects which are conducted within Europe, the Nordics, and Sweden that may affect the market development in the coming years. This is also true for political efforts aiming to catalyse the adoption of innovative therapeutics. The following sections describes a selection of these initiatives which might affect the Swedish pharmaceutical market in the coming years. One such initiative is an effort to early detect upcoming pharmaceutical products to better prepare for their arrival. This initiative is called horizon scanning.

3.5.1 Horizon Scanning

By working to detect early developments in technology for a research area, horizon scanning is a method used for finding possible future solutions to some kind of issue at hand. This is often done by desk research in all varieties by reading reports on the topic, searching the Internet, and talking to experts in the field. Successful implementations of horizon scanning might give a lead in the strategy planning of the future of that area (OECD, 2019).

In the field of healthcare, horizon scanning has been implemented in several countries to identify and prioritise potential future technologies, including emerging pharmaceuticals. This is done so that policy makers ahead of time can be informed about the costs of future treatment options and their impact on the patient care. It also facilitates early planning of introduction of new pharmaceuticals, or used to grant

such technologies early access to the market (Lepage-Nefkens *et al.* 2017). World Health Organisation (WHO) suggests that since future technologies might impact the budget of a given healthcare sector, horizon scanning works as a way to forecast best practices and analyse safety concerns to such emerging technologies before they reach the market (WHO, 2015).

Internationally there is a collaborative effort in EuroScan, an association that gathers interested parties with the mission of being a network for sharing information about innovative technologies in the health sector (EuroScan, 2019). In Sweden this function is performed by the Region of Västra Götaland, the Region of Östergötland, Stockholm County Council and the Region of Skåne in a collaborative effort under the name Fyrlänsgruppen (Sveriges Kommuner och Landsting (SKL), 2018a). In Sweden, continuous documentation on new pharmaceuticals are gathered, after which an expert in the group evaluate these findings and choose candidates to present for possible approval on the market based on a number of criterion (Swedish Agency for Health and Care Services Analysis, 2016). Between 2014 and 2018, 48 new pharmaceuticals were given a report and presented for further evaluation of approval (SKL, 2019). Horizon scanning also serves as the starting point for regions cooperation procedure (see *figure 2*).

As a tool for early evaluation of new products coming to the market, horizon scanning initiatives are one of the earlier assessments governmental authorities do on a product. It is not far-fetched to conclude that this assessment can lay the foundation for the general opinion of the product among key opinion leaders, affecting how the product eventually will be received when it reaches the market.

3.5.2 Collaborations

One of the challenges with new pharmaceuticals is to make sure it comes to Sweden in a reasonable time after it was first launched (Gustafsson & Troein, 2018). One attempt to reduce the time it takes and make sure the patients will have access to pharmaceuticals is in co-operations between countries. Sweden is involved in one such collaboration with a few other Nordic countries, and another collaboration with other EU countries.

FINOSE

FINOSE is a collaboration between the regulatory medicines agencies in Norway and Finland, and the Swedish Dental and Pharmaceutical Benefits Agency (TLV). Norway, Finland, and Sweden all uses the same evaluation method of looking at health- and economic effects that a new pharmaceutical brings to the society. The collaboration is a result thereof, and is used when considering a new pharmaceutical for approval of a nationally subsidised price (TLV, 2018a). Therefore, a company with a new pharmaceutical can send in an application for reimbursement to one of these agencies, after which the three agencies divide the application between one another, make separate analysis of the application, and later share their evaluation between each other. This makes the process for the application go faster and has the potential of making a new pharmaceutical reach the patient faster (FINOSE, 2018a). The application can be sent in before a drug approval is received, making the process even more time-efficient (TLV, 2018b).

EUnetHTA

European Network For Health Technology Assessment (EUnetHTA) is a collaboration for health technology assessments (HTA) in Europe. The aim with the collaboration is to get a more efficient sharing of information between countries in Europe regarding disease prevention and health care (EUnetHTA, 2018). HTA work with evaluation of health technologies which politicians turn to in their decision making process (Kristensen *et al.* 2009). This collaboration aims to minimise the differences in knowledge between the European countries.

3.5.3 Future Political Changes

The system regarding pricing and subventions of pharmaceutical drugs in Sweden was in 2016 deemed too complex when managing the current national healthcare system. A directive from the Swedish Ministry of Health and Social Affairs instructed an investigator to look into how the cost structure between the counties and the state were like. Also, how subventions and costs of pharmaceutical drugs for the public healthcare system should be handled going forward (SOU dir.2016:95).

Since public policy might change how the strategies surrounding the process of an NPL are done, analysing this report for a potential future impact on the area might

be of interest. Also, understanding the viewpoints of stakeholders within the industry covered by this report is of interest, seeing as it is a major political investigation of the pharmaceutical industry. Understanding different stakeholders' views on this investigation would also indicate what is likely to change in the future, with the basis in the final report from the investigation.

The investigation conducted by Toivo Heinsoo looking into the pricing of pharmaceutical drugs in Sweden was handed over to the Ministry of Health and Social Affairs in early January 2019 (Government Offices of Sweden, 2019), with some parts that might impact future strategic decisions regarding an NPL. The following section is a summary over that investigation.

The Toivo Heinsoo Investigation

The investigation suggests a possible change from the current system of regional Drug and Therapeutics Committees as well as the New Therapies Council to a single county-common governmental office, Läkemedelsrådet (National Pharmaceutical Council) (Swedish Ministry of Health and Social Affairs, 2018). This meaning, recommendations of new and old pharmaceuticals should be done by only Läkemedelsrådet (Swedish Ministry of Health and Social Affairs, 2018). At present these recommendations are performed by a regional Drug and Therapeutics Committee in each different county in Sweden (SKL, 2018b), and by the New Therapies Council (NT-rådet) for new pharmaceuticals (SKL, 2018c). This would mean that recommendations on pharmaceuticals to physicians would be performed in whole on a national level, instead of a regional one. The number of key opinion leaders at this level in a launch process would therefore go down from the current 21 (SKL, 2018b) to just one. Outreach to key opinion leaders would be simplified with such a change, and at the same time increasing the importance of influencing the opinion leader that would be the new National Drug and Therapeutics Committees.

The investigation by Toivo Heinsoo also suggests a more dynamic pricing over time for pharmaceuticals, where more resources would be given to TLV for renegotiating pharmaceutical pricing, as well as allowing different pricing for the same pharmaceutical used in monotherapies compared to combinations therapies (Swedish Ministry

of Health and Social Affairs, 2018). In the final investigation, it is also discussed how there is a need for subsidised advanced therapies, such as cell- and gene therapies. And that this ought to be done through a long-term agreement between the counties and state government (Swedish Ministry of Health and Social Affairs, 2018). This will serve as an initiative to stimulate the uptake of innovations.

When looking at the consequences these potential political changes have on the launch strategy of pharmaceuticals a couple of noticeable points of interest appear. Flexibility in the pricing of a pharmaceutical depending on treatment area, or time on the market, could mean that an NPL gets a greater degree of freedom regarding the internal pricing strategy. A higher level of flexibility would also suggest an increased complexity, since more potential pricing options could be available. When the complexity of deciding the internal pricing would increase, more time and effort for dealing with this part of the launch would be required, potentially delaying launches.

3.6 Summary

Many theories and methods have been considered as tools for the analysis of new product launches for this report, such as the Ansoff matrix, statistical analysis of sales data, and more. In the end, the theories and methods were ill-suited when analysing a NPL for various reasons and thus not included in this thesis.

Of the theories used PESTEL serves as a framework describing the viewpoint that have been analysed. Diffusion of innovation and the other sources on product launch served as theory for how product reaches a market as well as how launches are performed, in order to be compared during analysis. The section regarding political initiatives takes the future aspect into consideration. Recently an investigation of pharmaceuticals in Sweden by Toivo Heinsoo was presented which serves as a basis for potential future changes. Several trans-national collaborations might have a bigger effect in the future and thus these are discussed to describe their potential impact.

The theoretical background developed before the finalised results in this report con-

sidered pharmaceuticals as a product. This is of course the case for the industry. But at the same time, an analysis of the results gave rise to the hypothesis that the pharmaceutical industry have tendencies of servicification. Services surrounding a core product is becoming an increasingly important part for the success of the product launch. The theories surrounding this is not discussed in the section above. Later discussions will take this into consideration.

4 Methodology

To answer the specified research questions stated in section 1.2, a series of interviews were conducted. Interviews were chosen to gather deeper knowledge about how companies conduct their launches, and to identify possible challenges that can be averted or solved. Thus a qualitative study was performed, with the aim to describe and in different ways interpret a phenomenon in-depth. Interviews were also held with other stakeholders to further understand the problems, and contrast them with the company interviews.

The interviews were performed in semi-structured approach and were analysed using a form of grounded theory and abductive reasoning to reach a conclusion. A qualitative analysis is distinct from a quantitative one, since a quantitative analysis should always produce the same result if the exact same methodology is used. With a qualitative analysis on the other hand, even if this criteria technically is still true, it is harder to exactly reproduce the same study since human interpretations of the data in every step of the process means that slight variations might occur depending on who performs the study. The potential variables for error increases, where a researchers background, own beliefs, social context, and many more complex variables can affect the result slightly, even if the goal is to always be objective and methodological.

4.1 Prestudy

In addition to the desk research performed during the background research a few interviews were performed to validate information, as well as discuss the interview questions. These were held with senior personnel at IQVIA. The interviewees had several years experience in the Swedish pharmaceutical industry, and the interviews consisted of questions about how an NPL is planned as well as what external stakeholders are active in this process. The interviews together with the background research served as a basis for what questions were asked to the pharmaceutical companies, as well as a method for validating the relevance of the questions to be asked.

4.2 Interviews

There are some different ways to address an interview, qualitative data can be gathered using semi- or unstructured interviews (Bryman & Bell, 2013). With a semi-structured interview, the overall questions are prepared in advance but the way the interview turns out can vary depending on the interviewee via the use of follow-up questions and responses from the interviewer. In an unstructured interview, no formal questions are prepared beforehand, and the interview is more like a conversation. Another approach is structured interviews, the prepared questions are followed rigorously and might result in quantitative data from the respondents (Bryman & Bell, 2013). To make the interview more independent from prearranged questions but still deliver answers to the problem of interest, a semi-structured approach to the interviews was chosen for this project. This also increases the possibility of discovering new insights into the problem formulations that might not have been thought of beforehand.

The disadvantage with a semi-structured interviews is that they are a lot more demanding, both in time and workload, compared to a structured interview (Adams 2015). Advantages with this technique, though, are that the questions will give the interviewee an opportunity to answer with their own interests in mind, and more independently than with a completely structured approach. The semi-structured focus will make it clearer of whats important in the interviewees point of view because of the flexibility (Bryman & Bell, 2013). For this project, the available man-hours makes the benefits of conducting a semi-structured interview advantageous despite the increased time-consumption.

The interviews conducted were all audio-recorded. This method was chosen to enable a reliable data source for the analysis of subsequent interviews. Notes were also taken during each interview to allow for an initial analysis straight after an interview, where the main themes and topics during the interview were reflected upon without having to transcribe the interview.

4.3 Who were the interviewees?

Interviewees of interest were chosen among pharmaceutical companies that gained EMA approval for at least two NAS-pharmaceuticals between 2013-2017, and that had available sales data in Sweden beginning at the earliest 2015, and before 2018. The reasoning for having a cutoff-point of two NAS-pharmaceuticals were to focus the interviews on companies that from this dataset had more experience with launching products, since restrictions in the number of interviews had to be made because of time constraints on the project. To identify these companies of interest, a list of products with NAS' for that period was retrieved from the EMA. That list was then cross-referenced with sales data for Sweden, provided by IQVIA. The union of both these lists resulted in 75 products. For each of these 75 products, the company marketing the product in Sweden was identified using the Swedish National Registry for Pharmaceutical Products (NPL, 2019).

From this selection, 14 companies were identified as interesting entities for an interview. Out of these, 9 companies accepted the invitation to participate. These interviews ranged from 30 to 60 minutes, with the persons being interviewed having roles in market access, commercial, and medical positions at the company. The criteria was that the interviewees would in some way be involved in the launch process. Two interviews were group interviews, with two and three people participating respectively. At one company, two interviews took place, with two different persons. Details on identified companies, and which of them that were interviewed is presented in *table 2*, in the Appendix A.1. All interviews were performed in Swedish. All interviewees in the report are anonymous.

4.4 Grounded Theory

Analysis of qualitative data can be tricky as multiple methods are applicable to the same data. To help, there are guidelines for different paths to take. One of the most frequently used method is called grounded theory, described in *figure 4*, and was developed in the 1960s by Glaser and Strauss (1967). Bryman and Bell (2013) describes four components of grounded theory called: theoretical sampling,

theoretical saturation, data coding, and continuous comparison.

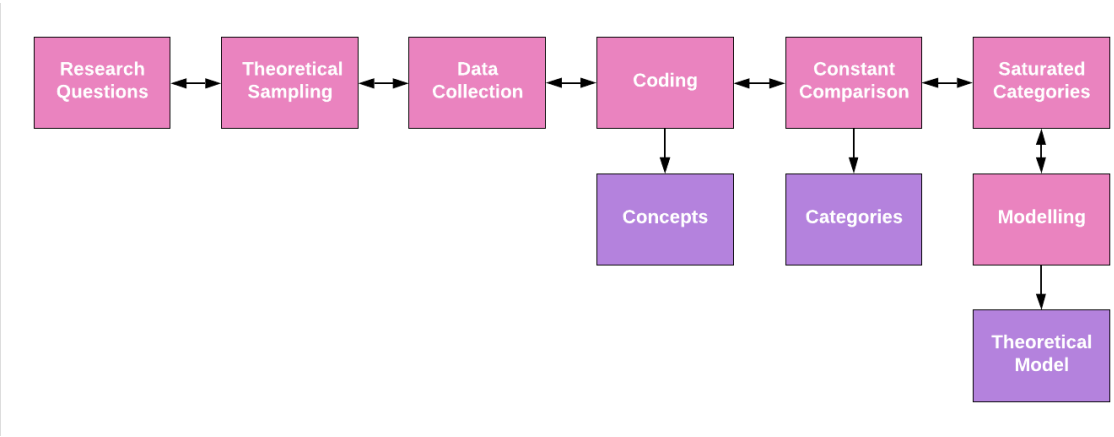

Figure 4: The process of working with interviews and grounded theory. The learnings from each process iterates on the previous process for the next stage of interviews, always adapting questions, conclusions, and the proposed models, until saturation is reached and one theoretical model is proposed. Adapted from Izvercian *et al.* (2016).

Theoretical sampling is an alternative to probability sampling, in which, instead of allowing probability to determine the sampling focused attempt to gather information is done. Glaser and Strauss (1967) argued that probability sampling is ill-suited for qualitative aimed researched as they are built upon statistical criteria instead of a theoretical criteria (Bryman & Bell, 2013). Another important aspect of grounded theory is theoretical saturation. This is the principle that sampling continues until no new relevant data appears in a category, and that the category has developed as such that its dimensions, characteristics as well as variation is described. Also, relationship between different categories should be established and validated (Bryman & Bell, 2013).

Coding is the process in which data is broken into parts and categorised. Data, which can be anything encountered by the researcher in grounded theory, is categorised in three forms, or ”levels”: Open coding, axial coding, and selective coding.

- Open coding, is the process in which data is broken down, studied, compared, conceptualised and categorised. The process produces codes that in turn can be categorised.

- Axial coding, is a set of procedures that structures categories by creating new links in between them. This is performed by linking codes with their context, consequences, causes, as well as patterns.
- Selective coding, is the process of selecting a core category (the central aspect or problem from which the others can be related) and systematically relating it to other categories. After relating them these relationships are validated and categories are developed if needed.

Coding in qualitative analysis differs from quantitative in that it is not only a method for handling data but the first step in generating theory, and starts after data collection has begun (Bryman & Bell, 2013).

The last central concept of grounded theory is continuous comparisons. By utilising continuous comparisons, a process for linking and conceptualising data to their codes and categories, central indications are not lost. This is performed by continuously comparing the data to the theory and thus attention is drawn to differences that appear in categories (Bryman & Bell, 2013).

A grounded theory approach makes it possible to build new theories based on the collected data (Bryant, 2017), something that is of use in exploratory research, such as this study. A semi-structured interview technique allows for constant comparisons and development of the theory until a theoretical saturation is achieved, something that is a characteristic of the grounded theory (Oktay, 2012).

4.5 How were the interviews analysed?

In this study, a grounded theory approach on the interview data was performed. Continuous comparisons were made between the interviews by discussing and reviewing the notes taken during the interviews. Important topics and new insights from each interview formed the basis for potential follow-up questions in the coming ones. The prepared questions are presented in the Appendix A.2. The questions defined so that the answers might give insight into the research questions present in section 1.2. In summary these questions covered:

- Basic information about the company and the interviewee
- How a launch in general is performed at the company
- Any examples of a successful and not successful launch in recent time at the company, and why that was the result of those launches
- The interviewees point-of-view on what makes the pharmaceutical industry unique, both when comparing countries to each other, and when comparing to other industries.
- Their thoughts on what makes a launch successful, and any difficulties the company usually faces when working with a launch

When all interviews were performed, each interview's transcript was analysed. Central concepts in the text were highlighted. This procedure was done twice, by different persons, to identify the central parts of each transcript. In grounded theory, this is referred to as selective coding (Bryman & Bell, 2013). A matrix was then created with columns representing the prepared questions, and rows representing the answers from each of the interviewees. Each cell was then populated by the answers to that question from each interviewee, where the answers were a summary of all relevant highlighted parts in the transcript. A concept of this matrix can be seen in *table 1.*

Table 1: Matrix to organise the selectively coded transcripts. The overall question topics functions as column headers, and each respondents answer is presented in the corresponding cell, based on the selective coding of the transcript. Each respondent have their fragmented answers in one row.

	Question 1	Question 2	Question ...	Question N
Company 1	Data/Concept	...	...	...
Company ...	...	...	...	...
Company M	...	...	...	Data/Concept

With the whole matrix filled, the contents of each column was compared, one-by-one, where the key concepts from each column was summarised, now representing the general conclusions from that column. These summarised columns were then compared to each other to identify any overarching themes present throughout the data. Common themes and subjects were deemed to be the concluding results for all the interviews. This workflow is visualised in *figure 5.*

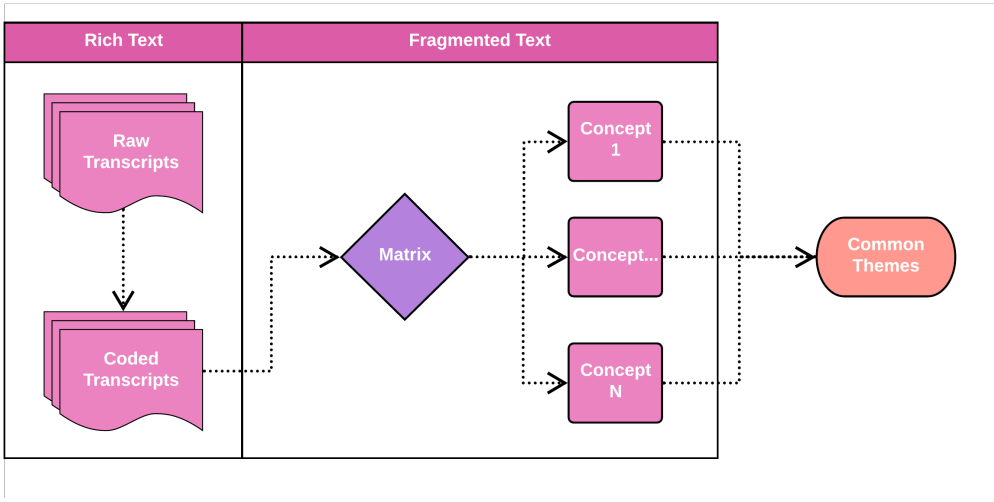

Figure 5: The adapted method for coding the interviews. 150+ pages of transcripts were selectively coded, by two persons. These coded parts were then fragmented and put in a matrix, from which common concepts for each topic was extracted. These common topics formed the consensus surrounding the overarching themes present in the interviews.

4.6 Validation or rejection of conclusions

The conclusions from the initial interviews were based solely on one type of stakeholder's views on the launching of new pharmaceuticals, the companies'. To get another point of view on possible conclusions, another round of interviews were performed. In these, representatives from TLV, the NT-Council, regional pharmaceutical committees, regional representatives, and LIF were interviewed. A total of 6 interviews were done, with representatives shown in *table 3* in the Appendix A.3. These interviews were also semi-structured, and the prepared questions were based on conclusions drawn from the first round of interviews. Each organisation in this round of interviews are different in their role and function, so the prepared questions could not be identical for all of them but was only altered slightly between each interview to fit in with the organisation. These interviews were then analysed in the same way as the interviews in round one, see section 4.5.

4.7 The Responsibility of Research

One of the main stipulations when conducting research is that it should be done so in an ethically defensible manner. This requirement is even a part of The Swedish Higher Education Act (SFS 1993:100). A part of this is that considerations to societal values should be considered when doing research (Uppsala University, 2018). Therefore, it is important to evaluate and discuss any research that is performed, including this report. This way, insight might be given into how resources are allocated when furthering the knowledge of mankind, and if this allocation of resources are the most ethically viable. If not, one can always have a discussion regarding how similar results might be produced but with a more stable grounds in ethics. Since the discussion regarding ethics are a part of the Master Programme of Molecular Biotechnology Engineering (Henriksson *et al.* 2017), it is only natural to include a comment about the research in this report from an ethical standpoint, and what thoughts it raises.

To begin with, the healthcare industry is more sensitive to ethical dilemmas than most other industries in society. This is made clear, for example, by the presence of a national Ethical Review Authority in Sweden, with the purpose of evaluating and approving all tests done on humans, which would include clinical trials of new pharmaceuticals. A consequentalist approach to which pharmaceuticals are worth investing in is something that governmental agencies use to evaluate new pharmaceuticals entering the market (TLV, 2019). This also extends to all aspects of the use of medicines in the healthcare system, where inappropriate use of a pharmaceutical can impact a patient's quality of care, as well as an economic waste (Moynihan *et al.* 2002). From a governmental point-of-view, Sweden defines the obligation to be as effective as possible with public funds in the existence of The Swedish Agency for Public Management (2018), which purpose includes the evaluation and improvement of the use of tax funds. Society has therefore defined an interest in an ethically sound use of pharmaceuticals, with the goal of being as utilitarian as possible with the resources at hand. As part of the society pharmaceutical companies and its affiliates in Sweden operate in, it is therefore inferred that it is in those companies' best interest to adhere to an approach of utilitarianism.

The question then arises; is it possible for companies to be socially responsible and at the same time improving the economic end result? Porter & Kramer (2006) argues that strategic implementation of corporate social responsibilities (CSR) can increase a company's long-term competitiveness and improve their public image by resonating with the local community. Social responsibility and future sustainability could even be argued to be a part of a modern definition of economic well-being (King, 2008). An economic interest for companies to work with CSR, and to think of how new research is conducted and presented, is therefore completely viable with the underlying objective of a company creating value for its stakeholders. And from a view oriented around strategic launch planning, effective CSR has been shown to improve relationships with stakeholders (Min *et al.* 2017). The importance of social responsibility is something that some of the largest pharmaceutical firms in the world have easily accessible information about on their websites (Grantham *et al.* 2009). Its also seen that younger generations say they are more likely to support and stay loyal to a socially responsible business (Murray, 2018).

So how does this reflect on the research presented in this report? The report aims to inform stakeholders in the pharmaceutical industry in how new pharmaceuticals can reach a larger number of patients. Ethically, this is a legitimate purpose since newer technologies probably will increase the quality of care for the patients. The underlying definition on how a successful pharmaceutical launch is perceived could be more in line with this purpose than the current one. In this report, a successful launch is defined with a certain amount of sales in a limited time span, which only evaluates the return of investment rate for the pharmaceutical companies. Instead a successful launch could be defined as a new pharmaceutical reaching a certain percentage of patients in need of this new therapy. The change in definition would probably reach the same kind of conclusions as in this report, but would illuminate the ethically beneficial actions of implementing some of the discussed strategies more.

If social conditions can be assumed to be improved by positive examples, it would be in line with the theories of virtue ethics (Hursthouse & Pettigrove, 2018) to heavily reflect on how to produce this report in a way that also becomes an example on that

positive change. By including this part about the ethical dilemmas facing the pharmaceutical industry, this responsibility could be considered to be, at least partially, fulfilled.

5 Summarised interviews - Stakeholder viewpoints

The results from the interviews is described in two parts. The common themes identified by the method described in the workflow diagram, in *figure 5* on page 32, from the interviews with the pharmaceutical companies are categorised as the internal point of view, together with LIF. Round two of interview consisted of the six interviews conducted with stakeholders representing other organisations than pharmaceutical companies. These interview (excluding LIF) are categorised as the external point of view. These different rounds of interviews are compared both individually and in tandem with each other.

5.1 Internal point of view

From the interviews with the companies, common themes were extracted. The following text summarises the general thoughts and comments of the interviewees. The interview with LIF is described under a separate heading, since the interview is not comparable with the pharmaceutical companies directly, being a different kind of organisation.

The launch process
The local affiliates start planning the launch around two years before they get an EMA approval for a product. The time might vary depending on if the product is a first entrant or a me-too product. This also affects the main focus of the launch process. With first entrants, the main focus is to get a good segmentation, to find the right patient group, and to optimise the market positioning. The focus is also on gathering knowledge and opinions on the product or patient group from key opinion leaders, physicians, and other stakeholders. For a me-too product the main focus is instead to differentiate the product, and understanding the value of the product compared to other products already on the market. In this case the focus is more on a commercial level than an access level. How to approach the launch is also determined by the therapeutic area; if it is a new one, or if it is an established one. New therapeutic areas requires more groundwork in regards to market research to have a successful launch. Most launches are managed by cross-functional teams, often

involving roles as market access, medical and commercial. Other roles taking part in the launch varies depending on where on the timeline the launch is currently at.

Overall launch strategies are given to the affiliate offices by their headquarters (HQ). In most cases, HQ seem to understand that the Swedish market may differ from others, regarding the value-based healthcare system. Therefore, the local affiliates are free to adapt the strategies to the local market. In some cases the affiliates need to negotiate and motivate why adaptations should be done. One key factor for HQ is the product's price. A high price can in some cases be difficult to motivate in Swedish market because of the value-based pricing, creating an internal discussion about the pricing between HQ and the affiliate.

Contact with external stakeholders

The first contact with the horizon scanning group is around 2 years before market approval, and is one of the first external stakeholders to be involved in the launch. The usage of this opportunity differed between interviewees, from seeing it as a good kick-off for the launch team, to use it as an evaluation tool for the coming process. The one seen as the most important external stakeholder is TLV. When applicable, all of the interviewees sent in applications to TLV to get a reimbursement. One thing that differed between the companies was the amount of discussion, or dialog, they had with TLV. The interviewees viewed it as their responsibility to invite to these discussions.

If the new product is a pharmaceutical for hospital use, a requisition pharmaceutical, the NT-council is of interest, and an application is sent to them. Some contact may be done directly with the county councils to get them to prepare their budget for the new pharmaceuticals to come. A perceived problem with the governmental stakeholders is that they are slow at adapting to current developments, especially regarding orphan drugs and advanced therapeutics. Some interviewees mentioned hardships in understanding how different governmental stakeholders evaluate an application, with many mentioning NT-council's role as a pseudo-governmental agency resulting in transparency problems.

It is important to reach out to key opinion leaders to get their opinion and thoughts about a specific product or therapy area. An extension of this is talking to physicians to garner attention and to educate healthcare professionals about new pharmaceuticals. Contact with patient organisations is maintained at most companies, and is essential for spreading awareness on therapeutic area of interest. This contact is not utilised as a tool in the launch process, though. The companies need to be aware of when the different roles can communicate what information and towards whom, since marketing laws regarding pharmaceuticals are strict.

Important

During the launch process some parts are seen as vital to keep in mind. Without a well-defined positioning and mapping of the market the product will not succeed. Secondly, a strategy that is easily understood and has a clear message makes it easier to engage and involve the whole organisation, optimising internal collaboration. The product needs to have good credibility and healthcare professionals should know how to use it. The company needs to have a deep understanding of the regulatory framework to allow for flexibility during the launch. The interviews showed that this understanding is not always present. Again, this plays into the fact that governmental stakeholders are regarded as lagging behind the industry. Governmental agencies' methodology surrounding the evaluation of orphan drugs and advanced therapeutics are seen as outdated, leading to a feeling of miss-communication between stakeholders within the industry.

A rapidly changing pharmaceutical industry have brought up opinions that there is a need to produce services alongside the pharmaceutical product. These satellite services surrounding the core product are meant to inform patients and healthcare professionals, aid in self-administration of drugs, or have other supporting effects for the patient. Also, pharmaceuticals are today regarded more as a therapy program, and not just as a treatment, it is a result of their increasing complexity. This leads the industry towards more innovative thinking, the use of more creative solutions, as well as new collaborations. Another technological aspect that is getting more important for companies is the increasing availability of large datasets of different kinds. This is also an increasing challenge, since the competency to use this available data is not al-

ways present at pharmaceutical companies. The interviews, though, identified cases where big data solutions have been applied as an innovative problem solving strategy.

Future
The industry is progressing towards being more patient-focused, strengthened by the fact that patients today are more knowledgeable and can therefore be more demanding than previously. This correlates with the availability of data in Sweden, an availability that has an unused potential at the moment. How this data is accessed, and by whom, is something that will be a big talking point in the future, something that is of interest to the pharmaceutical companies interviewed.

The interviewees got to comment on the Toivo Heinsoo report. They agree that it is positive that the questions covered are brought up, facilitating discussion. They hope that it will result in more transparency and a simpler system, in regards to the NT-council turning into an agency. Generalising the states pharmaceutical reimbursement to the regions was not seen as positive. There appeared to be some skepticism regarding how much of the investigation that would actually be implemented due to the current political climate.

Swedish Association of the Pharmaceutical Industry (LIF)
During the interview with LIF one of the themes that could be identified were that of cooperation and attitudes within the industry. In the current market access landscape the evaluation of the cost effectiveness of a product takes place at the same time as the negotiations for it approval or recommendation. This leads to an uncertainty in regards to what the driving factors are when evaluating new pharmaceuticals. Whether or not decisions are made due to the additional health value of the therapeutic, or budget driven constraints. The questions about pharmaceuticals can be seen as non-political because it is steered by public officials, instead of politics because of the complexity of many issues. In addition, the cooperation between different governmental stakeholders is limited. Although the cooperation is limited, an increase in trans-European cooperation have been seen. A challenge here is that there are differences in how the authorities in these countries operate, and companies think that this might be problematic if these differences are ignored.

LIF largely works questions at large for the pharmaceutical industry, but there are moments when the companies lack adherence to the principles that are developed and instead only focus on succeeding with their launch. When asked about the future and Toivo Heinsoo's investigation, several topics were discussed. The investigation was seen as ambiguous, with inconsistencies between the summarised propositions, legislative text, and the report's body text. Also, many had higher hopes for what would be presented. There is also a worry that by generalising the reimbursement for pharmaceuticals, that part of the healthcare system will eventually become underfunded.

Some general challenges that the industry is facing are in regards to that innovation within the sector is largely driven by the private sector. This have resulted in a challenge where the knowledge-gap between the private and public sector is increasing. Also, the uptake of new products is largely driven by the regions.

5.2 External point of view

Following the interviews with the pharmaceutical companies, other stakeholders participate in the study. These interviews could not be summarised into common themes the same way as the pharmaceutical companies was. Seeing as these were not as homogeneous as the company interviews, they are split into each stakeholder separately.

New Therapies Council (NT-council)
When the NT-council decides upon a new recommendation, it is communicated to the separate regions by a representative from each region. When the information reaches the regions it is up to them to act on it. Since the regions are heterogeneous, there is no mutual process for handling the recommendations the NT-council gives. Due to more specialised high-cost treatments, task forces for some new treatments have been introduced (behandlingsråd). These work with patient selection on high-cost treatments to assert that patients who need these high-cost treatments get access to them. This work is done on a patient-by-patient basis.

The council does not have discussions with individual companies. All communication with companies are formal in the form of the necessary communication during an evaluation of a product. Questions of principle or general practises are instead discussed with LIF. How to follow up the usage of a treatment is seen as a challenge, referencing a lack of infrastructure in Sweden or a lack of resources to effectively do such evaluations. Also, methods for analysing RWE are also uncertain. The NT-council sees a need for collaborations between stakeholders to tackle these challenges. The collaborations with patients are also increasing, with patient representatives as a part of the council and other forms of patient cooperation being a focus.

Regional

From the regions there was clear that the smaller regions follow the bigger ones, often copying decisions and actions. The decisions made in the regions are mainly based on the information from TLV, NT-council, and other official governmental sources. The pharmaceutical committees have a network called LOK, where all the chairpersons of the pharmaceutical committees cooperate. This is the channel used to discuss strategic decisions. There are collaborations between regions which co-operates regarding the procurement of pharmaceuticals. Beyond that each region forwards information regarding recommendations, strategies, or such, to interested parties in the region (physicians, clinics). Larger regions have a more structured way of reaching out with this type of information. A problem expressed is the increased amount of delayed deliveries of pharmaceuticals. The regions can not be sure to get all the supply they need, even when a contract exist. This leads to an uncertainty which decreases credibility of the suppliers (companies).

When talking about the future, discussions taking place in the future can be believed to become more infected, as a result of patients possessing more knowledge on specific topics, leading to more interest gathered in the media. The use of real world evidence will need to show the real value according to the quality adjusted life years (QALY), just as traditional evidence is presented. Regarding the Toivo Heinsoo report, a positive attitude towards generalising the states pharmaceutical reimbursement could be seen, as long as it gets indexed. Another general opinion is the high probability of the NT-council turning into a governmental agency, even if

this makes their work more time-consuming.

The Dental and Pharmaceutical Benefits Agency (TLV)
The system with product of the month, where pharmacies have to substitute medicines to the cheapest available generic competition, is viewed as an effective way of lowering pharmaceutical costs. This in turn frees up funds that can be used in cases where new and innovative medicines have to be used.

Communication between TLV and other stakeholders are mainly done via their website and through a newsletter. Regional representatives are also present at a meeting once a month, as well as a monthly meeting with the NT-council. Patient representatives are part of their board, and meetings with patient groups of interest are also held when necessary. Patient opinions leaders are valuable in giving their perspective on things, that later can be used when evaluating a pharmaceutical, that is evaluated on two metrics: quality of life, and life expectancy. TLV is also involved in trans-national cooperations. They are the one of the utmost contributor in EUnetHTA. FINOSE is also looking out to be a project with good potential, with a worst-case-scenario of at least making the time to evaluating a new application to one of the members of FINOSE the same as the other partnering agencies'.

When talking about the companies handing in their applications to the agency, larger companies are more used to the process and that could factor in how well the application is written. In the end it has to do with how well the company can express their product's value. Evaluating RWE in these applications is something TLV is trying to improve on, and pilot studies on this is on-going. This is also something that TLV sees as getting more important. Scanning the horizon for new pharmaceuticals is also a challenge, and here companies are a welcomed aid when they communicate early what they have in their pipelines.

The large shift towards personalised medicine will make RWE, real-world data in good databases, and models for using these increasingly important. Large amounts of data going in a decision in the future will require analysis using artificial intelligence, and technologies in information technology, medicine, and medical technology

will merge even further, requiring new collaborations between stakeholders tasked with evaluating and deciding upon such technologies. These collaborations that are looking at the healthcare industry as a whole is today lacking and needs to be developed.

The current legislation does not consider pharmaceuticals different from each other. New innovative and old medicines follows the same legislation, the same goes for antibiotics or gene therapies. This causes problems when for example new gene therapies having a large non-recurrent cost, and are thus not suited to the comparisions that are made today.

6 Reflections on the launch topic

Some common themes can be identified from all the interviews put together. Most of what the pharmaceutical companies view as important and challenging are shared with other stakeholders. Some critical themes are also only discussed by the companies, but might impact the industry in a big way regardless. One of the themes companies have discussed is covering the topic of servicification.

6.1 What do the interviews say?

Some common themes between the different stakeholders interviewed can be identified. Some of these themes are discussed below, where also the views of the pharmaceutical companies and other stakeholders are compared.

6.1.1 What is important for succeeding with your launch?

In order to be successful with the launch process, the following factors are the most important according to the interviews performed. You need to have a clear positioning in the market, something argued by Talke & Hultink (2010) and Kotler *et al.* (2017) as well. An understandable launch strategy, adopted to the Swedish market is also seen as vital, just like previous literature had identified as an important factor in African countries (Mukku *et al.* 2016). In practice this means segmenting a patient group with precision, targeting only the patients that can benefit the most from the pharmaceutical. It also means keeping in mind how the Swedish system differs from other countries and playing on these differences, while still maintaining a simple executable plan for the launch.

Just as Lepage-Nefkens *et al.* (2017) suggests that horizon scanning can be used by payers of pharmaceuticals as a planning tool, some companies represented in the interviews saw the horizon scanning group as a good potential evaluation tool during the launch, helping them in planning their subsequent strategy. Utilising this early assessment tool to its full potential can therefore be in the companies' best interest.

The industry is constantly changing and some future changes will require adaptations from the companies. What have been seen is that the Swedish pharmaceutical

market has an advantage due to the massive data that is available. Today's society is formed by an information driven era and therefore it is important to know how to use the data that is available and keep innovating in this area. From the interviews the usage of new data models to handle aspects of the launch process, such as health-economic modelling and clinical data evaluation, have been identified. This might be an ongoing trend and will continue to increase in importance. Even in a highly regulated market, such as the pharmaceutical industry, a trend that leans toward big data and also products as a service can be seen. This might be driven by the paradigm shift that is towards personalised healthcare (GlobalData Healthcare, 2017).

6.1.2 Two kinds of products - New entrants & me-too products

From the interviews it was clear that the strategy that one applied differed when a product was a new entrant and when it was similar to previous products on the market, a me-too product. When a company launched a product similar to others on the market, in a market they were knowledgeable in the strategy was focused on differentiating your own product over the other and more classical marketing than market access.

While a first entrant launch focuses more on market research and/or developing knowledge regarding your product on the market. Thus being more related to either product development or diversification, depending on if the market can be seen as a new one for the company or not. Most companies tended to keep their portfolio to certain therapeutic areas, which can be seem as already established markets.

As most established companies are quite knowledgeable about the market (if regarded as a single market), as well that there are differences in therapeutic areas. Then there are models, like the one put forth by Ahlawat, et. al (2013) in Beyond the Storm, in which archetypes are categories by the perception of the therapeutic area, as well as the differentiation of the pharmaceutical, which in turn forms the strategy.

6.1.3 What do the different stakeholders (dis)agree on?

The fact that the payers of the pharmaceuticals, the regions, are very heterogeneous seems to be an opinion shared among both companies and other stakeholders. This adds a complexity to the whole system, verifying the views of the Swedish government in 2016 (SOU dir.2016:95). An interest in securing future financing for pharmaceuticals via state reimbursement is also something most parties raised as a concern, even though discrepancies in how the best way to move forward in this question deviated between company representatives and other stakeholders.

The emergence of RWE is seen as a challenge for all parties in the industry. Here, companies have shown initiatives in trying new models and methods and seem to be further ahead than governmental stakeholders. Many companies regarded the quality and availability of data in Sweden as an asset, something other interviews have pointed out as well.

Both regional stakeholders and the NT-council expressed a desire to enhance their interaction with patient representatives. This furthers the importance of reaching out to patient representatives for companies if these key opinion leaders' position is further strengthened in the future. Working with those opinion leaders is something the companies are doing already, though.

6.2 Servicification of the industry

The analysis of the interviews in this report indicates that tendencies towards offering more services surrounding a core product can be seen. An increase in services, that today are given away for free, could create new revenue sources for companies that find ways to make someone pay for such services. Increasing surrounding services and expecting the core product to pay for these is not sustainable, meaning that sooner or later these services have to be paid for somehow. To develop such an infrastructure, knowing how to create a management system for these services is a key skill in the future.

Richard Normann (1983), proposes that innovation in service management systems

depend on Social innovation, technical innovation, and reproduction innovation. Social innovation is characterised by customer participation, distribution of roles in a system, new connections, and new sources of human energy.

According to the results of this report's study, involving physicians in the launch process is regarded as essential to a pharmaceutical product's success. Also, in the pharmaceutical industry it is not entirely clear who should be defined as being a customer; the physicians, or the patients. In the conducted interviews a trend can be seen that there is an increased interest in discussing more with patient representatives, which would suggest the importance of both types of customer definitions.

The second round of interviews also identified a need for more movement, collaboration, between academia, industry, and the public sector, to be able to advance research in the field of RWE for a successful future. This would be "new sources of human energy". Advancements in new technologies and personalised medicine also means that an aspect of the role distribution in the system needs to be taken in consideration. Diagnostics, treatment, follow up, and control systems surrounding a patient will get further divided in the future, meaning this distribution will be of an increasing importance.

Richard Normann (1983) states that reproduction innovation comes from three steps. First, a few success factors for the service management system are identified, the system's "simple logic". Next, methods for recreating these factors are identified, after which the final step is to develop a support system that enables the reproduction of this "simple logic".

In the case of the pharmaceutical industry, if a pharmaceutical would be looked at as part of a service package, there would be a need of identifying this "simple logic" for a pharmaceutical to succeed. Ways to incorporate a new product in an already existing network of satellite services would help in this regard. Creating an ecosystem for a product to exist in is something that has been proposed by others as a way of innovating in 2019 (Ringel *et al.* 2019), and is in-line with the idea of customer focused system development (Normann, 1983).

In the interviews from both pharmaceutical companies and other stakeholders, a negative attitude towards the viewpoint of other stakeholders was often present, even though as a whole most stakeholders came to the same type of conclusion on a topic, regardless of whether they came from industry, state government, or regional government. The image of these different stakeholders within the sector itself might therefore be skewed, and a better cooperation between stakeholders might be achieved with an improved image for all stakeholders towards each other.

Segmentation of patients, of the market, is critical according to the perspective of the industry, as well is the emerging concept of having services surrounding a product that might aid a patient, or healthcare professionals. Discussions by other stakeholders regarding how to finance future pharmaceuticals, and how to segment patients by evaluating which patients should receive which treatment, shines light at the importance of reflecting over the delivery service of the product, the pharmaceutical.

In "Service management system" (Richard Normann, 1983), these concepts are summarised in a model visualised in *figure 6*. Since many common factors exists between this model and what can be argued for from this report's research, this model could be seen as a validation to the fact that part of the pharmaceutical industry might go towards a servicification. Also in *figure 6*, the culture of a company is regarded as a vital factor, something that Chierchia *et al.* (2013) proposed as an important factor when looking at pharmaceutical launches. Having a culture that enables creative thinking is also validated by (Fraenkel *et al.* 2016).

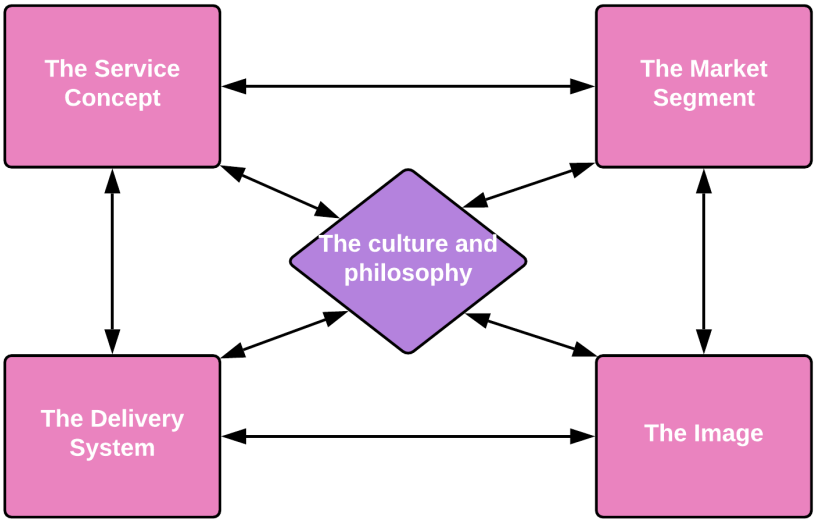

Figure 6: Service management system visualised as an interaction between 5 parts. Image adopted from Norman (1983, p.33-36)

6.3 Validity of the research

Theoretical saturation was not taken in consideration. as many interviews as possible were conducted in the given time frame. It is worth mentioning though that common themes could be identified in all interviews in round one. Also, a majority of the major pharmaceutical companies in Sweden were interviewed. Since there is no certain way of defining when the data is considered to be saturated for an interview-based approach, a good saturation can still be argued was achieved. This is because one of the ways of defining a good saturation is when the same answers are starting to appear in the interviews (Bryman & Bell, 2013), something that was observed.

The interviewees have all been seen as a representative for the entity (company/organisation) they represented, even though most entities are only represented by a single individual. This individual's viewpoint of the questions asked might not represent the common viewpoint of the whole entity, or be a good mean of all the people working there, something to keep in mind. In tandem with other studies surrounding the

subject, though, the external validity of the research conducted should be sufficient regardless, though.

Furthermore, the authors of this report all have a background as engineering students in biotechnology or chemical engineering. The discipline of engineering can be viewed as using all tools necessary to solve a problem, both theoretical and practical (Nair & Bulleit, 2019). The problems an engineer might feel comfortable with solving are often called puzzles (Udwadia, 1986), structured problems that can be taken apart and tested for a solution. The contrast to these structured problems are called ill-structured problems, and is characterised by having several possible solution, each with their own strengths and weaknesses (SERC, 2018).

This report handles a subject of business development and strategy, of which no definitive solution can be proposed. These types of problems are more akin to the Social Sciences than traditional STEM research. Therefore, the authors for this report might have a different viewpoint of how to solve the research questions proposed than what might traditionally be expected from a report like this.

7 Final remarks

To view the pharmaceutical industry as a service industry is not correct in a strict sense. A pharmaceutical is in the end a product, with production lines and logistical transports and the consumer using a physical product. But parts of what makes a launch of such a product successful is in tandem with research regarding the service industry, which might suggest that looking there for inspiration might be a recipe for success. In this report there was no intent to validate this industry as a service industry. Looking further into this phenomenon is a possibility though, and something that might be a topic for future research.

For a pharmaceutical launch to be successful, a few concepts that this report has identified as important are:

- Internal communication: Have it being simple, concise, and engaging for all company members
- Stakeholder utilisation: Know what is allowed, and maximize collaborative efforts and discussions
- Usage of data: Know how to handle data, know what is available, and how external stakeholders view such evidence
- Servicification: Extend the value-proposition using satellite services to enhance perceived value, and improve relations with key opinion leaders

Utilising stakeholders to their full potential is something that many companies had challenges with, especially looking at governmental stakeholders. This also means that these governmental stakeholders affect the launch of a product in a major way, something that the companiy interviews showed when talking about the importance of getting a positive reimbursment/recommendation decision.

Also, concepts such as developing the cooperation between different stakeholders, ensuring movements throughout the sector, and valuing innovation in general for pharmaceuticals are not isolated conclusions from conversations with stakeholders

from this report only. Government initiatives in the form of workshops have reached similar conclusions in the past (Idéplattform för en stärkt svensk life science-sektor, 2014). An improved collaboration between industry and academia, different stakeholders, have also been previously mentioned as a need for the sector (Vasco Adviser, 2019). This is also the case with the importance of RWE and the development research on that front (FINOSE, 2018b). Ideas proposed in this report are therefore a validation of the broader picture the industry seem to be in agreement of.

References

1993:100, SFS. *Högskoleförordning (1993:100) | Lagen.nu*. URL: https://lagen.nu/1993:100#K6 (visited on 01/25/2019).

1996:1157, SFS. *Lag (1996:1157) om läkemedelskommittéer | Lagen.nu*. URL: https://lagen.nu/1996:1157 (visited on 02/27/2019).

Adams, William C. (2015). *Handbook of practical program evaluation*. Ed. by Kathryn E. Newcomer, Harry P. Hatry, and Joseph S. Wholey. 4 th. Jossey-Bass, A Wiley Imprint. 493–494. ISBN: 978-1-118-89360-9.

Advisers, Vasco. *Samverkan mellan sjukvård, akademi, och näringsliv*. 4. Vasco Advisers, p. 47. URL: https://www.lif.se/globalassets/pdf/rapporter-externa/samverkan-mellan-sjukvard-akademi-och-naringsliv.pdf (visited on 05/02/2019).

Ahlawat, Hemant, Giulia Chierchia, and Paul van Arkel (2014). *The secret of successful drug launches*. Mckinsey & Company. URL: https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-secret-of-successful-drug-launches (visited on 01/25/2019).

Alexander, G. Caleb, Alec B. O'Connor, and Randall S. Stafford (2011). "Enhancing Prescription Drug Innovation and Adoption". In: *Annals of Internal Medicine* 154.12, p. 833. ISSN: 0003-4819. DOI: 10.7326/0003-4819-154-12-201106210-00012. (Visited on 02/12/2019).

Au, Regina (2014). "The paradigm shift to an "open" model in drug development". In: *Applied & Translational Genomics*. Global Sharing of Genomic Knowledge in a Free Market 3.4, pp. 86–89. ISSN: 2212-0661. DOI: 10.1016/j.atg.2014.09.001. (Visited on 02/11/2019).

Bates, Bob and Jim McGrath (2013). *The Little Book of Big Management Theories*. 1:a. Pearson. ISBN: 978-1-292-20062-0. (Visited on 05/02/2019).

Beemsterboer, Bas (2003). "The Hidden Economic Value of Calibration Management". In: *Pharmaceutical Technology Europe* 15.12, pp. 33–35. ISSN: 17537967. (Visited on 03/18/2019).

Brink, Torsten (2017). *Aktuella avgöranden i IGN*. Pharma industry. URL: http://www.pharma-industry.se/aktuella-avgoranden-i-ign/ (visited on 03/18/2019).

Bryant, Antony (2017). *The Grounded Theory Method: An Overview*. Oxford University Press. ISBN: 978-0-19-065254-8. (Visited on 03/18/2019).

Bryman, Alan and Emma Bell (2013). *Företagsekonomiska forskningsmetoder*. Trans. by Björn Nilsson. 2:2. Liber. ISBN: 978-91-47-09822-4.

Bröstcancerföreningarnas riksorganisation, (BRO) (2017). *Introduktion av nya läkemedel*. Stockholm: Bröstcancerföreningarnas riksorganisation, p. 8. URL: https://brostcancerforbundet.se/documents/79/Introduktion_av_nya_lakemedel.pdf (visited on 03/18/2019).

Chierchia, Giulia, Johannes Doll, and Paul van Arkel (2013). *Beyond the storm - Launch excellence in the new normal*. Mckinsey & Company, p. 76. URL: https://www.mckinsey.com/~/media/mckinsey/industries/healthcare%20systems%20and%20services/our%20insights/the%20secret%20of%20successful%20drug%20launches/beyond_the_storm_launch_excellence_in_the_new_normal.ashx (visited on 01/25/2019).

Ching Gu, Vicky and James R. Burns (2016). "The launch strategy choices in China's pharmaceutical market". In: *International Journal of Pharmaceutical and Healthcare Marketing* 10.3, pp. 339–356. ISSN: 1750-6123. DOI: 10.1108/IJPHM-06-2015-0030. (Visited on 01/25/2019).

Connors, Amanda L (2009). "Big bad pharma: An ethical analysis of physician-directd and consumer-directed marketing tactics". In: *Albany Law Review* 73.1, p. 40. ISSN: 0002-4678. (Visited on 01/25/2019).

Di Benedetto, Anthony C (1999). "Identifying the Key Success Factors in New Product Launch". In: *Journal of Product Innovation Management* 1999.16, pp. 530–544. ISSN: 0737-6782. (Visited on 01/25/2019).

Dunder, Kristina (2016). *Godkännande av läkemedel*. Läkemedelsboken. URL: https://lakemedelsboken.se/kapitel/regelverket_och_it-stod/godkannande_av_lakemedel.html (visited on 01/25/2019).

EC (European Commision) (2017). *Legal framework governing medicinal products for human use in the EU*. Public Health - European Commission. URL: https://ec.europa.eu/health/human-use/legal-framework_en (visited on 03/18/2019).

EC (European Commision) (2019). "Marketing Authorisation". In: *Procedures for marketing authorisation*. Vol. 2A. URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/vol2a_chap1_en.pdf.

EMA (2018). *Authorisation of medicines*. European Medicines Agency. URL: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines (visited on 04/01/2019).

EUnetHTA (2018). *About EUnetHTA – EUnetHTA*. URL: https://www.eunethta.eu/about-eunethta/ (visited on 01/25/2019).

EuroScan (2019). *About*. EuroScan International Network. URL: https://www.euroscan-network.global/index.php/en/about (visited on 01/25/2019).

Faulkner, Eric, Lieven Annemans, Lou Garrison, Mark Helfand, Anke-Peggy Holtorf, John Hornberger, Dyfrig Hughes, Tracy Li, Daniel Malone, Katherine Payne, Uwe Siebert, Adrian Towse, David Veenstra, and John Watkins (2012). "Challenges in

the Development and Reimbursement of Personalized Medicine—Payer and Manufacturer Perspectives and Implications for Health Economics and Outcomes Research: A Report of the ISPOR Personalized Medicine Special Interest Group". In: *Value in Health* 15.8, pp. 1162–1171. ISSN: 1098-3015. DOI: 10.1016/j.jval.2012.05.006. (Visited on 02/11/2019).

Finansiering, subvention och prissättning av läkemedel (2016). In collab. with SOU dir.2016:95. URL: https://www.regeringen.se/4ac877/contentassets/d2ddae7622a44cb0a04278fe70f1dc74/finansiering-subvention-och-prissattning-av-lakemedel-dir201695.pdf (visited on 01/25/2019).

FINOSE (2018a). *FINOSE - Proccess for joint assessment*. URL: https://www.fimea.fi/documents/160140/1454518/FINOSE+prosessikuvaus/5bcd54a5-ed1a-d629-26bb-74cd0c8cdca1 (visited on 04/08/2019).

– (2018b). *Summary from FINOSE Strategic HTA and Industry Meeting*. Stockholm: FINOSE. URL: https://www.tlv.se/download/18.500ea4181641067957aeb15/1529322046523/summary_from_finose_strategic_hta_and_industry_meeting.pdf (visited on 05/02/2019).

Food & Drug Administration, FDA (2019). *Real World Evidence*. FDA. URL: /science-research/science-and-research-special-topics/real-world-evidence (visited on 05/14/2019).

Fraenkel, Stefan, Darek M. Haftor, and Natallia Pashkevich (2016). "Salesforce management factors for successful new product launch". In: *Journal of Business Research* 69.11, pp. 5053–5058. ISSN: 0148-2963. DOI: 10.1016/j.jbusres.2016.04.079. (Visited on 01/25/2019).

Gawel, Claus Roland (2016). "Patent protection as a key driver for pharmaceutical innovation". In: *Pharmaceuticals Policy & Law* 18.1, pp. 45–53. ISSN: 13892827. DOI: 10.3233/PPL-160431. (Visited on 01/25/2019).

Glaser, Barney G. and Anselm L. Strauss (1967). *The discovery of grounded theory: strategies for qualitative research*. 4. paperback printing. OCLC: 553535517. New Brunswick: AldineTransaction. 271 pp. ISBN: 0-202-30260-1.

Glenngård, Anna (2019). *Sweden : International Health Care System Profiles*. International Commonwealth Fund. URL: https://international.commonwealthfund.org/countries/sweden/ (visited on 03/18/2019).

Grantham, Susan, Morgan Sones, and Edward T. Vieira (2009). "Communicating CSR via pharmaceutical company web sites: Evaluating message frameworks for external and internal stakeholders". In: *Corporate Communications: An International Journal* 14.2, pp. 144–157. ISSN: 1356-3289. DOI: 10.1108/13563280910953834. (Visited on 01/25/2019).

Gustafsson, Ida and Per Troein (2018). *Nya läkemedel - Når de patienten i Sverige?* Solna, Sweden: IQVIA, p. 20. URL: https://www.lif.se/globalassets/pdf/rapporter-externa/iqvia-nya-lakemedel-i-sverige.pdf (visited on 01/25/2019).

Hanlon, David (2015). "10 key activities in measuring and communicating pharma product launch excellence". In: *Quirk's Marketing Research Review* 2015. URL: https://www.quirks.com/articles/10-key-activities-in-measuring-and-communicating-pharma-product-launch-excellence (visited on 01/25/2019).

Hansen, Klaus Reinholdt Nyhuus and Martin Grunow (2015). "Planning operations before market launch for balancing time-to-market and risks in pharmaceutical supply chains". In: *International Journal of Production Economics* 161, pp. 129–139. ISSN: 0925-5273. DOI: 10.1016/j.ijpe.2014.10.010. (Visited on 01/25/2019).

Health, Swedish Agency for and Care Services Analysis (2017). *Ordning i leden?: utvärdering av ordnat införande av nya läkemedel*. 2017:5. OCLC: 1023263239 ISBN 978-91-87213-73-1. Swedish Agency for Health and Care Services Analysis

(Myndigheten för vård- och omsorgsanalys). URL: https://lakemedelsverket.se/upload/om-lakemedelsverket/NLS/Ordning-i-leden_MYVA.pdf.

Health {and} Social Affairs, Swedish Ministry of (2019). *Tydligare ansvar och regler för läkemedel (SOU 2018:89)*. URL: https://www.regeringen.se/rattsliga-dokument/statens-offentliga-utredningar/2019/01/sou-201889/ (visited on 01/25/2019).

Healthcare, GlobalData (2017). *Personalised medicine: a paradigm shift in treatment*. Pharmaceutical Technology. URL: https://www.pharmaceutical-technology.com/comment/commentpersonalised-medicine-a-paradigm-shift-in-treatment-5771494/ (visited on 02/11/2019).

Henriksson, Lena, Tobias Jakobsson, Jessica Nihlén Fahlquist, and Jan Andersson (2017). *Etik på civilingenjörsprogrammet i molekylär bioteknik*. (Visited on 02/11/2019).

Hultink, Erik Jan and Kwaku Atuahene-Gima (2000). "The Effect of Sales Force Adoption on New Product Selling Performance". In: *Journal of Product Innovation Management* 17.6, pp. 435–450. ISSN: 1540-5885. DOI: 10.1111/1540-5885.1760435. (Visited on 02/13/2019).

Hursthouse, Rosalind and Glen Pettigrove (2018). "On Virtue Ethics". In: *The Stanford Encyclopedia of Philosophy*. Ed. by Edward N. Zalta. Winter 2018. Metaphysics Research Lab, Stanford University. ISBN: 978-0-19-823818-8. (Visited on 01/25/2019).

Insight, Valid (2017). *Launch factory: Improving market access to new therapies*. Valid Insight. URL: https://www.validinsight.com/launch-factory-improving-market-access/ (visited on 01/25/2019).

Izvercian, Monica, Sabina Seran, and Larisa Ivascu (2016). "Job Satisfaction Variables: A Grounded Theory Approach". In: *Procedia - Social and Behavioral Sciences* 221, pp. 86–94. DOI: 10.1016/j.sbspro.2016.05.093.

Janusinfo (2018a). *Beslut om samverkansnivå*. URL: https://janusinfo.se/nationelltordnatinforande/saarbetarvi/arkiv/beslutomsamverkansniva.5.4771ab7716298ed82ba97add.html (visited on 05/09/2019).

– (2018b). *Godkännande*. URL: https://janusinfo.se/nationelltordnatinforande/saarbetarvi/arkiv/godkannande.5.4771ab7716298ed82ba97b0d.html (visited on 02/11/2019).

Jekunen, Antii (2014). *Decision-making in product portfolios of pharmaceutical research and development – managing streams of innovation in highly regulated markets*. Drug Design, Development and Therapy. (Visited on 03/18/2019).

Kenton, Will (2017). *Regulated Market*. Investopedia. URL: https://www.investopedia.com/terms/r/regulated-market.asp (visited on 03/18/2019).

King, Mary C. (2008). "What Sustainability Should Mean". In: *Challenge* 51.2, pp. 27–39. ISSN: 0577-5132. (Visited on 01/25/2019).

Kotler, Phillip, Anders Parment, and Gary Armstrong (2017). *Marknadsföring - Teori, strategi, och praktik*. 2nd ed. Pearson. ISBN: 978-1-292-21113-8.

Kristensen, Finn Børlum, Marjukka Mäkelä, Susanna Allgurin Neikter, Nina Rehnqvist, Lise Lund Håheim, Berit Mørland, Ruairidh Milne, Camilla Palmhøj Nielsen, Reinhard Busse, Sun Hae Lee-Robin, Claudia Wild, Mireia Espallargues, and Julia Chamova (2009). "European network for Health Technology Assessment, EUnetHTA: Planning, development, and implementation of a sustainable European network for Health Technology Assessment". In: *International Journal of Technology Assessment in Health Care* 25 (S2), pp. 107–116. ISSN: 1471-6348, 0266-4623. DOI: 10.1017/S0266462309990754. (Visited on 01/25/2019).

Landau, Ralph, Basil Achilladelis, and Alexander Scriabine (1999). *Pharmaceutical Innovation: Revolutionizing Human Health*. Google-Books-ID: IH4lPs6S1bMC. Chemical Heritage Foundation. 118–120. ISBN: 978-0-941901-21-5.

Lehman, Bruce (2003). *The Pharmaceutical Industry and the Patent System*. International Intellectual Property Institute, p. 14. URL: https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf (visited on 05/14/2019).

Lepage-Nefkens, Isabelle, Karla Douw, GertJan Mantjes, Gimon de Graaf, Roos Leroy, and Irina Cleemput (2017). "Horizon Scanning for Pharmaceuticals". In: *Belgian Health Care Knowledge Centre*. Kce Report 2017. ISSN: 24666459.

Läkemedelsindustriföreningen, LIF (2017a). *etik:LER i läkemedelsbranschen*. URL: https://www.lif.se/contentassets/2dbb42377ace42b0bbd2ec07d1605558/anvandande-av-digitala-kanaler-utifran-lakemedelsbranschens-etiska-regelverk-1709.pdf (visited on 03/18/2019).

– (2017b). *Forskning och utveckling av läkemedel i Sverige*. Läkemedelsindustriföreningen [LIF]. URL: https://www.lif.se/statistik/forskning-och-utveckling-av-lakemedel-i-sverige (visited on 01/25/2019).

– (2019). *Our industry*. Läkemedelsindustriföreningen [LIF]. URL: https://www.lif.se/en/about-lif/ (visited on 01/25/2019).

Läkemedelsutveckling - FASS Allmänhet (2017). FASS. URL: https://www.fass.se/LIF/menydokument?userType=2&menyrubrikId=3204 (visited on 04/08/2019).

Maciejko, Laura, Munisha Smalley, and Aaron Goldman (2017). "Cancer Immunotherapy and Personalized Medicine: Emerging Technologies and Biomarker-Based Approaches". In: *Journal of molecular biomarkers & diagnosis* 8.5. ISSN: 2155-9929. DOI: 10.4172/2155-9929.1000350. (Visited on 02/11/2019).

Mahajan, Vijay and Jerry Wind (1992). "New product models: Practice, shortcomings and desired improvements". In: *Journal of Product Innovation Management* 9.2, pp. 128–139. ISSN: 0737-6782. DOI: 10.1016/0737-6782(92)90004-V. (Visited on 01/29/2019).

Matikainen, Minna, Tarja Rajalahti, Marikki Peltoniemi, Petri Parvinen, and Anne Juppo (2015). "Determinants of New Product Launch Success in the Pharmaceutical Industry". In: *Journal of Pharmaceutical Innovation* 10.2, pp. 175–189. ISSN: 1939-8042. DOI: 10.1007/s12247-015-9216-7. (Visited on 01/25/2019).

Min, Maung, Francois Desmoulins-Lebeault, and Mark Esposito (2017). "Should pharmaceutical companies engage in corporate social responsibility?" In: *The Journal of Management Development; Bradford* 36.1, pp. 58–70. ISSN: 02621711. (Visited on 01/25/2019).

Moynihan, Ray, Iona Heath, and David Henry (2002). "Selling sickness: the pharmaceutical industry and disease mongering". In: *BMJ : British Medical Journal* 324.7342, pp. 886–891. ISSN: 0959-8138. (Visited on 01/25/2019).

MPA (2016). *Marknadsföring av humanläkemedel - Läkemedelsverket / Swedish Medical Products Agency*. Läkemedelsverket [LV]. URL: https://lakemedelsverket.se/malgrupp/Foretag/Lakemedel/Marknadsforing-/ (visited on 01/25/2019).

Mukku, S, A Edathodu, B Battepatti, and R Dass (2016). "PHP39 - Opportunities For Pharmaceutical Companies To Successfully Launch Products In African Countries". In: *Value in Health* 19.7, A446. ISSN: 1098-3015. DOI: 10.1016/j.jval.2016.09.577. (Visited on 01/25/2019).

Murch, Lisa, Sarah Rickwood, Bill Mcclellan, and Dr SImone Seiter (2017). *Launch Excellence V*.

Murray, Seb (2018). "Why giving back is the best way forward for businesses". In: *The Guardian*. ISSN: 0261-3077. (Visited on 01/25/2019).

Nair, Indira and William M. Bulleit (2019). "Pragmatism and Care in Engineering Ethics". In: *Science and Engineering Ethics*. ISSN: 1471-5546. DOI: 10.1007/s11948-018-0080-y. (Visited on 04/09/2019).

Natanek, Rafael, Christoph Schlegel, Michael Retterath, and George Eliades (2017). *How to Make Your Drug Launch a Success*. Bain & Compay. URL: https://www.bain.com/insights/how-to-make-your-drug-launch-a-success/ (visited on 01/25/2019).

Normann, Richard (1983). *Service Management*. 1:1. Malmö: LibrFörlag. ISBN: 91-38-61148-1.

NPL (2019). *Nationellt produktregister för läkemedel (NPL) - Läkemedelsverket*. URL: https://npl.mpa.se/ (visited on 04/08/2019).

OECD (2019). *Overview of Methodologies*. The Organisation for Economic Co-operation and Development [OECD]. URL: https://www.oecd.org/site/schoolingfortomorrowknowledgebase/futuresthinking/overviewofmethodologies.htm (visited on 01/25/2019).

Oktay, Julianne S. (2012). *Introduction to Grounded Theory and Its Potential for Social Work*. Oxford University Press. ISBN: 978-0-19-993262-7. (Visited on 03/18/2019).

PESTEL Analysis (PEST Analysis) EXPLAINED with EXAMPLES | B2U (2016). B2U - Business-to-you.com. URL: https://www.business-to-you.com/scanning-the-environment-pestel-analysis/ (visited on 02/27/2019).

Porter, Michael E. and Mark R. Kramer (2006). "Strategy & Society: The Link Between Competitive Advantage and Corporate Social Responsibility". In: *Harvard Business Review* 84.12, pp. 78–92. ISSN: 00178012.

Public Management, The Swedish Agency for (2018). *Den statliga värdegrunden – professionella värderingar för en god förvaltningskultur*. The Swedish Agency for

Public Management [Statskontoret], pp. 17–18. URL: http://www.statskontoret.se/globalassets/publikationer/2017/vardegrunden.pdf (visited on 01/25/2019).

Ringel, Michael, Florian Grassl, Ramón Baeza, Derek Kennedy, Michael Spira, and Justin Manly (2019). *The most innovative companies 2019*. Boston Consulting Group, p. 18.

Robey, Seth and Frank S. David (2016). "Drug launch curves in the modern era". In: *Nature Reviews Drug Discovery* 16, pp. 13–14. ISSN: 1474-1784. DOI: 10.1038/nrd.2016.236. (Visited on 01/25/2019).

Rogers, Everett M. (1962). *Diffusion of Innovations*. 3rd. New York: The Free Press. 453 pp. ISBN: 0-02-926650-5.

SBU (2018). *Värdebaserad vård - kartläggning av kunskapsläget*. 285. Stockholm: Statens beredning för medicinsk och social utvärdering. URL: https://www.sbu.se/contentassets/96ae32a02adf4ad6bdf4aca518c3a096/vardebaserad-vard_285.pdf (visited on 03/18/2019).

Schilling, Melissa A. (2019). *Strategic Management of Technological Innovation*. 5th. New York: McGraw Hill. ISBN: 978-1-259-53906-0.

Schulenburg, Fritz von der, Sotiris Vandoros, and Panos Kanavos (2011). "The effects of drug market regulation on pharmaceutical prices in Europe: overview and evidence from the market of ACE inhibitors". In: *Health Economics Review* 1.1, p. 18. ISSN: 2191-1991. DOI: 10.1186/2191-1991-1-18. (Visited on 03/18/2019).

SERC (2018). *Well structured versus Ill structured problems*. the Science Education Resource Center at Carelton College. URL: https://serc.carleton.edu/sp/carl_ltc/quantitative_writing/wellversusill (visited on 04/09/2019).

SKL (2018a). *Horizon scanning*. Janusinfo. URL: https://janusinfo.se/nationelltordnatinforand managedintroductionthisishowitworks/inenglish/horizonscanning.5.4771ab7716298ed82ba html (visited on 01/25/2019).

– (2018b). *Läkemedelskommittér*. Sveriges Kommuner och Landsting [SKL]. URL: https://skl.se/halsasjukvard/lakemedel/kontaktuppgifter/lakemedelskommitter. 1934.html (visited on 01/25/2019).

– (2018c). *NT-rådet (nya terapier)*. Janusinfo. URL: https://janusinfo.se/nationelltordnatinforande/saarbetarvi/rollerochkontaktuppgifter/roller/ntradetnyaterapier.5.4771ab7716298ed82ba5e87.html (visited on 01/25/2019).

– (2019). *Horizon scanning - Janusinfo*. Janusinfo. URL: https://janusinfo.se/nationelltordnatinforande/horizonscanning.4.728c0e316219da813569ab4.html (visited on 01/25/2019).

Sweden, Government Offices of (2019). *Läkemedelsutredningen överlämnad till regeringen*. Regeringskansliet. URL: https://www.regeringen.se/pressmeddelanden/2019/01/lakemedelsutredningen-overlamnad-till-regeringen/ (visited on 01/25/2019).

Swedish Agency for Health and Care Services Analysis (2016). *Utvärdering av ordnat införande av läkemedel - En förstudie*. 4. Swedish Agency for Health and Care Services Analysis [Vårdanalys], p. 21. URL: https://lakemedelsverket.se/upload/om-lakemedelsverket/NLS/Forstudie-Utvardering-av-ordnat-inforande-av-nya-lakemedel.pdf (visited on 01/25/2019).

Talke, Katrin and Erik Jan Hultink (2010). "The Impact of the Corporate Mindset on New Product Launch Strategy and Market Performance". In: *Journal of Product Innovation Management* 27.2, pp. 220–237. ISSN: 07376782. DOI: 10.1111/j.1540-5885.2010.00711.x. (Visited on 01/25/2019).

Taylor, David (2015). "The Pharmaceutical Industry and the Future of Drug Development". In: pp. 1–33. DOI: 10.1039/9781782622345-00001. (Visited on 01/25/2019).

The World Bank (2018). *GDP (current US$) | Data*. The World Bank. URL: https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?end=2017&locations=SE&name_desc=true&start=1960&view=chart (visited on 01/25/2019).

TLV (2018a). *FINOSE - a Nordic cooperation - Tandvårds-Läkemedelförmånsverket*. TLV. URL: https://www.tlv.se/in-english/international-collaboration/finose---a-nordic-cooperation.html (visited on 01/25/2019).

– (2018b). *FINOSE - Process for joint assessment*. URL: https://www.tlv.se/download/18.500ea4181641067957aeb13/1529322046472/finose_process.pdf (visited on 01/25/2019).

– (2019). *Så beslutar vi - Tandvårds-Läkemedelförmånsverket*. URL: https://www.tlv.se/lakemedel/ansok-om-pris-och-subvention/sa-beslutar-vi.html (visited on 04/24/2019).

Udwadia, F. E. (1986). "Management situations and the engineering mindset". In: *Technological Forecasting and Social Change* 29.4, pp. 387–397. ISSN: 0040-1625. DOI: 10.1016/0040-1625(86)90024-7. (Visited on 04/09/2019).

Unit, The Economist Intelligence (2019). *Value-based healthcare in Sweden*, p. 30. URL: https://eiuperspectives.economist.com/sites/default/files/value-basedhealthcareinswedenreachingthenextlevel.pdf (visited on 03/18/2019).

University, Uppsala (2018). *Forskningsetik och god forskningssed - Uppsala universitet*. URL: https://www.uu.se/forskning/forskningsetik/ (visited on 01/25/2019).

Ventola, C. Lee (2011). "Direct-to-Consumer Pharmaceutical Advertising". In: *Pharmacy and Therapeutics* 36.10, pp. 669–684. ISSN: 1052-1372. (Visited on 01/25/2019).

Wallskär, Helene. *Novartis fälls för inlägg i sociala medier*. URL: https://www.lakemedelsvarlden.se/novartis-falls-for-marknadsforing-i-sociala-medier/ (visited on 03/18/2019).

Ward, Stephen and Chris Chapman (2003). "Transforming project risk management into project uncertainty management". In: *International Journal of Project Management* 21.2, pp. 97–105. ISSN: 0263-7863. DOI: 10.1016/S0263-7863(01)00080-1. (Visited on 01/25/2019).

WHO (2015). *Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research (2015)*. World Health Organization [WHO], p. 47. URL: http://apps.who.int/medicinedocs/documents/s21793en/s21793en.pdf (visited on 01/25/2019).

Appendix A - Additional information from main study

Contents

A Interviews

Here additional information is presented that were used leading up to or during the interviews.

A.1 Identified companies of interest

Table 2: Companies identified for interviews, in total 9 out of 14 companies participated in an in-depth interview. On 3 occasions more than one person was interviewed at a single company.

Company	**Interview**	**Note**
Amgen	Participated	
AstraZeneca	Declined	
Biogen	Participated	
Boehringer Ingelheim	Participated	
Bristol-Myers Squibb	Participated	Group interview, two persons
Eli Lilly	Declined	
Gilead	No response	
GlaxoSmithKline	No response	
Janssen-Cilag	Participated	
Merck, Sharpe & Dome	Participated	
Novartis	No response	
Pfizer	Participated	
Roche	Participated	Group interview, three persons
Sanofi	Participated	Two interviews, different persons

A.2 Company interviews - Questions

The following questions (in Swedish) was used as a template during the semi-structured interviews with the companies.

Introduction

- As a start, could you give a short introduction of the company? (Where is your head office? How many employees do you have in Sweden? What therapeutic areas do you focus on?)

- What is your role and responsibilities at the company?
- How long have you worked here?

Generally about the launch process

- In general, when does the company start planning the launch process of a new pharmaceutical in Sweden?
- During the planning as well as during the launch, what directives are received from corporate headquarters?
- Which roles at the company are included in the planning of the launch process?
- Which roles carry out the launch?
- What stakeholders do you focus your communication towards during the launch process? Why? How? (TLV, new pharmaceutical council, physicians, regions, other governmental stakeholders, patient representatives)
- What was your latest new pharmaceutical launch?
- How was that launch performed? What stages or processes were included?
- Did you run into any problems?
- Is there anything from this launch you take with you to future launches? Positive/Negative?
- Are there any difficulties which are common during the launch of a new product? What difficulties?

Successful and no successful launches

- Can you recall any launch that were extraordinarily successful? Which was that?
- Did you do anything different then from your usual launch process?

- According to you, what made the launch so successful? (If the answer is "good product", ask if there is an example where the product was not extraordinary by itself.)
- Can you recall any launch that ended up being not so successful? Which one?
- Did you do anything different then from your usual launch process?
- According to you, what made the launch fail?

General questions

- What is important to think about during the launch process of a new pharmaceutical?
- Do you think there is something unique to the pharmaceutical industry, compared to other industries, when it comes to launching a new product? What?
- Do you think there is something unique with the Swedish market compared to other countries? What?

A.3 Other interviews

Table 3: Interviews in "round two" and prestudy. In total ten persons participated, representing seven stakeholders other than pharmaceutical companies.

Stakeholder	**Interview**	**Note**
Expert	Participated	Senior expert at IQVIA
Expert	Participated	Senior expert at IQVIA
Expert	Participated	Senior expert at IQVIA
Expert	Participated	Senior expert at IQVIA
LIF	Participated	2 persons
NT-council	Participated	
TLV	Participated	
Region of Gotland	Participated	Pharmaceutical committee
Region of Kronoberg	Participated	Pharmaceutical department
Region of Stockholm	Participated	