Understanding the internationalization process of Swedish SMEs operating in international healthcare markets

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Abstract

The widespread and rapid internationalization of small to medium-sized enterprises (SMEs) in the healthcare sector is outpacing our efforts to understand the motives behind this phenomenon and the processes that propel it. This paper investigates the internationalization processes of Swedish SMEs that operate in the international healthcare markets. Based on interviews from five SMEs, the study seeks to understand why these SMEs internationalize, and how and in what way this internationalization process unfolds. By developing a conceptual model based on previous literature for SME internationalization, knowledge and networks, and the regulatory environment in which the SMEs operate, the findings are analyzed in the context of the healthcare industry. The research concludes that product approval regulations have a small influence on the internationalization process; instead establishing relationships with local key opinion leaders to create awareness and legitimacy was essential to successfully enter a new foreign market. A further key finding identified was that each market is characterized by different national praxis and contrasting views on patient treatment methods, which was recognized as a challenge among the case firms.

Keywords: internationalization; SME; healthcare; network relationships; key opinion leaders; legitimacy
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CHAPTER 1: INTRODUCTION

With many countries experiencing an increase in lifestyle-related diseases, extended life expectancy and ageing populations, new challenges appear on the horizon for healthcare (Orava, 2002; European Commission, 2007; Waeger, 2008), all of which is a growing concern for governments and policy makers. These challenges, along with the deregulation and reforms in healthcare, have emerged as opportunities for enterprises in the private sector and has led to a rapid development of technological innovations regarding the promotion of health and prevention and treatment of illness and diseases (Outreville, 2007; European Commission, 2007).

Healthcare has traditionally been the role of governments, with the objective of providing access to sustainable and affordable healthcare for their citizens, commonly known as universal health coverage (World Health Organization, 2010). Looking back over the recent decades, healthcare spending as a proportion of GDP in many developed countries has rapidly increased (OECD, 2011). In light of this, the role of a government as a provider of healthcare became subject to scrutiny and from this there has emerged a growing need for controlling costs and improving efficiency (Anell et al., 2012). This critique of the role of governments led to a number of reforms in the early 1990’s known as “New Public Management” (NPM). Originating from the private sector, NPM emphasized, among other things, the implementation and use of performance measurement tools and accounting principles (Hood, 1995). This was followed by a wave of privatizations in several healthcare markets around the world, thereby opening up the healthcare industry to private sector solutions. Even though the delivery of healthcare may be delegated to private enterprises, governments are still responsible for the development and upholding of healthcare for their citizens. Thus, the mix of provision and financing between publicly and privately owned healthcare facilities varies among most countries.

Within the healthcare sector, the medical device industry is seen as a cornerstone, improving and saving lives by providing innovative solutions for diagnosis, prevention and treatment (European Commission, 2010). The industry covers a broad range of products, from items as simple as bandages to complex instruments for life-support, and during the last decades the pace of innovation in medical technology has accelerated dramatically (Cappellaro et al., 2010). The medical device industry also is a major employer within the European Union.
(EU), providing nearly 500,000 jobs at about 11,000 companies, while 80 percent of these companies are recognized as SMEs\(^1\) (European Commission, 2013).

Sweden, an EU member state, has a healthcare system that is primarily (80 percent) publicly financed by taxes and in year 2009 healthcare expenditure as a share of GDP comprised 9.9 percent, which is slightly higher than the EU average (Anell et al., 2012). Although it has higher healthcare expenditures, Sweden is recognized as having among the highest level of life expectancy in the world and its healthcare systems ranks highly in comparison to other EU member states (Anell et al., 2012; Björnberg, 2012). Further, the private healthcare sector in Sweden has been growing rapidly over the past decade; in fact, it is one of the fastest growing industries in the country (Vårdföretagarna, 2013) and the focus of the Swedish healthcare sector for the future is more attention to cost control, cost-effectiveness and quality of care (Anell et al., 2012). Most of the private companies in this sector consist of SMEs (Almega, 2013) and as both the domestic and foreign markets grow, so do opportunities for international expansion for these SMEs. In a survey conducted jointly by Business Sweden and Swecare, two export oriented trade associations, 40 percent of the polled companies in the healthcare industry anticipated a 50 percent growth in the following three years (Dagens Möjligheter, 2012). This is indicative of high expectation of future growth due to the export potential in the industry. Overall, for the Swedish economy the EU is Sweden’s largest export market, with close to 60 percent of all Swedish goods exported to countries within the EU (SCB, 2012). Therefore, for Sweden, being an export and import intense country, it is highly important to deliver competitive products to the European market.

International expansion, in the international business literature also known as internationalization, is described as “the process in which the firm gradually increases their international involvement” (Johanson and Vahlne, 1977, p. 23). Historically, research on international business has mainly focused on large and established multinational companies (McDougall and Oviatt, 2000), however, during the past decades there has been a growing interest in studying the internationalization of SMEs (Barringer and Greening, 1998; Kalantaridis, 2004; Leonidou, 2004; Lee et al., 2012). This is viewed as due to the acceleration of internationalization of SMEs (McDougall and Oviatt, 2000; Nummela et al.,

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\(^1\) SME stands for small or medium-sized enterprise, and is defined by the European Commission (2003) as a firm with less than 250 employees and with a turnover of less or equal to €50 million.
2006) and their growing impact on the international market (Barringer and Greening, 1998; Lu et al., 2001; Ruzzier et al., 2006).

Nevertheless, the healthcare sector is one of the remaining industries that have yet to be fully affected by trends in globalization (Smith, 2004; Orava, 2002) and not until recently has the healthcare sector experienced widespread internationalization and growth in trade in the various markets (Holden, 2005; Outreville, 2007; Herman, 2009). Furthermore, researchers have attempted to provide initial insight into the internationalization process of firms within the healthcare industry. However, these findings are limited to particular countries and therefore there is a call for further research in other countries in order to broaden the understanding of SMEs in the healthcare industry (Barnes et al., 2006). Which leads us to our research question:

*Why do small to medium sized enterprises in the healthcare industry internationalize and how- and in what way does the internationalization process unfold?*

### 1.1 Research purpose and contributions

The widespread and rapid internationalization of healthcare that has occurred is outpacing our knowledge and understanding of the processes, methods and motives that SMEs in this industry experience and practice when they expand internationally. The main purpose of this research is therefore to study the internationalization process to increase our knowledge about how these firms internationalize, what challenges they face and what motivates them to enter the international arena. Furthermore, SMEs within the healthcare industry are shaped by rules and regulations, policies and institutional actors, which influence the internationalization process. As current academic literature reflects little about this area, a further purpose of this research is to increase our knowledge about what affect the political institution has on the internationalization process for SMEs in the healthcare industry.

In order to provide further insight, the primary objective of this paper is to undertake research on a number of SMEs operating within the healthcare sector, specifically in the medical device industry, and by investigation broaden our understanding of the internationalization process that these SMEs experience. The study contributes to the international business literature in the field of internationalization, specifically in the field of SME internationalization. From the healthcare environment in which SMEs operate, the study
provides further empirical evidence that lacks in today's academic literature. Additionally the study contributes with theory development by providing a conceptual model, which includes the political and regulatory environment in light of the existing literature on SME internationalization. Lastly, by disclosing important managerial implications, the study contributes with insight to managers with a better understanding how the internationalization process proceeds and the important factors to consider before and during internationalization.

1.2 Thesis disposition

Chapter 2 - Literature review

This chapter provides a review of the international business literature covering SME internationalization and literature regarding the political and regulatory institution. Furthermore, the chapter develops and presents the conceptual model.

Chapter 3 - Methodology

This chapter provides a detailed overview of the methodology used in this study, specifically describing the process of how the data was collected and the selection of cases, followed by a discussion of the limitations and the quality of the study.

Chapter 4 – The healthcare industry

This chapter presents an insight into the healthcare industry in order to gain an understanding of the surroundings in which the case firms operates within. The regulatory and political setting is described followed by an outline of the procurement process. Lastly, a clarification of the terms reimbursement and coverage is provided.

Chapter 5 - Case findings

This chapter presents the findings from the empirical data. The international growth patterns of the case firms are illustrated, with an explanation of the early development and establishment of the case firms.

Chapter 6 - Analysis

This chapter analyzes the findings and provides an explanation of why SMEs in the healthcare industry internationalize and further how this internationalization process unfolds.

Chapter 7 - Conclusion

This chapter answers the research question, summarizes the key findings and highlights the papers theoretical and managerial contributions, and suggestions for future research.
CHAPTER 2: LITERATURE REVIEW

Internationalization is today a general means of growth for a firm and has consequently become a well-researched area within the international business field (Johanson and Wiedersheim-Paul, 1975; Johnson and Vahlne, 1977; 1990; 2003; 2006; Zou and Stan, 1998). Over the last decade the interest in studying internationalization of small- and medium sized firms (SMEs) has increased considerably (Barringer and Greening, 1998; Kalantaridis, 2004; Leonidou 2004; Ruzzier et al., 2006; Lee et al., 2012). This can on the one hand be seen due to the increase of internationalization among SMEs (McDougall and Oviatt 2000; Nummela et al., 2006) and on the other hand their growing impact on the international market (Barringer and Greening, 1998; Lu and Beamish, 2001; Ruzzier et al., 2006). Despite considerable interest in the field of internationalization and the growing attention towards understanding the internationalization process among SMEs, little has been accomplished in terms of examining the internationalization among firms that operate in the healthcare industry (Holden, 2005; Barnes et al., 2006). As to date, and to the researchers knowledge, there exist no unified model or framework that unfolds the process that occurs when SMEs internationalize within the context of the healthcare industry. Therefore, the intent of this literature review is to set forth a model (see Figure 1) that attempts to understand, in the context of firms operating in the healthcare industry, and explain the central elements of the internationalization process of these firms. The aim of the model is not to give an exact description of reality; rather the intention is to explain the central elements of internationalization of firms operating in the healthcare industry to increase our understanding in this field. In order to fulfill this, the literature review explains the elements in the model, one by one, and describes how these elements are interconnected. The following section is a disposition of the literature.

Figure 1.
The internationalization process of small to medium sized healthcare firms.
2.1 Literature review outline

The disposition of the literature review is as follows. First, a review of the international business literature in the context of internationalization of SMEs is presented, which involves a description of the internationalization process of SMEs in terms of, drivers, barriers and entry modes. Second, the review clarifies two additional elements, network and knowledge, and how these effect and influence the internationalization process of SMEs. Third, as these firms operate in an environment and industry that is heavily regulated, consisting of many policies that shape and influence how the firms must and can act, a section describing the political and regulatory environment is set forth. Finally, all of the above mentioned elements are connected and described in the conceptual model.

2.2 SMEs moving abroad

2.2.1 Taking the first step

The choice to internationalize is recognized as one of the most important growth paths for SMEs (Barringer and Greening, 1998; Sommer, 2010), through internationalization the firm is exposed to opportunities that increases the firms ability to survive (Lee et al., 2012), such as finding ways to broadening the customer bases (Lu and Beamish, 2001 and Barringer and Greening, 1998), spreading the risk across different markets, improving production efficiency (Leonidou, 2004) and increasing the ability to leverage on resources in different markets (Lu and Beamish, 2001). These aspects are recognized as potential effects of internationalization rather than a motive or driver for internationalization. In order to fully understand the internationalization process, it is important to study the reason behind the decision to internationalize and the motivation behind the choice of market.

Opportunities, triggers, motives or drivers are all academic labels used to explain the SMEs decisions to enter or expand its operations to the international arena (Barnes et al., 2006; Erramilli and D' Souza 1993; Leonidou, 1995) There are several influential motivators for internationalization, however, among the most influential is the stability of the export market, the potential for an increase in business growth and the size of the domestic market (Barnes et al., 2006). Reuber and Fischer (1997) elaborate further on how the size of the domestic market drives the SMEs to internationalization and divides it into a strategic or a necessary decision. For SMEs operating in a large domestic market, the decision to internationalize is mostly strategic; contra if the firm is operating in a small domestic market the decision is
more of a necessity for survival due to the limited capacity of the home market. Recognized as another influential driver for internationalization among SMEs are managers with previous international experience (Reuber and Fischer, 1997), as they are generally less afraid of pursuing opportunities abroad and their positive attitude towards internationalization contributes to an open-mind towards internationalization inside the firm (Sommer, 2010). Therefore, choosing a manager with relevant experience is imperative for SMEs that wish to internationalize. Although internationalization offers opportunities for SMEs, it is also characterized by a number of barriers in addition to the common ones associated with domestic growth (Lu and Beamish, 2001), which are important to discuss when studying the internationalization process.

2.2.2 Barriers for internationalization

There are many barriers related to internationalization of SMEs, and where these barriers appear is dependent on the industry in which the SME operates (Leonidou, 2004). In general, smaller firms have a lesser ability to export products or services to foreign markets (Sommer, 2010; Ruzzier et al., 2006) and a higher risk of failure in such efforts (Lee et al., 2012). The underlying reason for this are the challenges related to internationalization of SMEs; limited competences (Eramilli and D’Souza, 1993) and limited resources, both financial (Fillis, 2001; Ruzzier et al., 2006) and human resources (Barringer and Greening, 1998), as well as legal regulations (Ruzzier et al., 2006). Another disrupting issue for internationalization is the cultural aspect, which includes differences in language, culture, political system, level of industrial development and level of education. These aspects are often summarized under the concept psychic distance, seen as a set of factors such as, that prevent the flow of information between markets (Johanson and Wiedersheim-Paul, 1975; Johanson and Vahlne, 1977; 1990). The larger the psychic distance the more challenging it becomes for firms to gain knowledge about the foreign market and consequently hinder the internationalization process. Therefore, knowledge about the foreign market can affect the barriers regarding the internationalization process. With regards to the EU, where markets are geographically close, Barnes et al. (2006) argues that cultural gaps exist and that they could complicate the internationalization process for the firm. In addition, SMEs operating in industries that require high levels of capital are less likely to enter culturally distant markets (Eramilli and D’Souza, 1993). In contrary, Sandström, (1992) argues that cultural differences only influence the internationalization to the extent of the firm’s awareness of the cultural distance. In other words, the challenges
associated with psychic distance could be overcome by increasing the knowledge about the foreign market.

Accordingly, internationalization of SMEs offers both challenges and opportunities and the motivation behind the decision to enter the international arena are many. However, it is not just important to understand what drives the SMEs to internationalize and what barriers they face; it is equally important to understand how these firms choose to enter the international area.

2.2.3 SMEs entering the international market

The choice of entry mode is an important decision for the SME as the outcome of the choice can lead to consequences that can cost the firm both time and capital (Nakos and Brouthers, 2002). When entering a foreign market there are several types of entry mode to choose between, for example, through a joint venture, establish a subsidiary, sign contractual agreements with partners or simply export the products (Brouthers and Hennart, 2007; Schwens et al., 2011). The choice of entry mode is on one hand dependent on the foreign market specifics (Brouthers and Nakos, 2004), for example markets characterized of having excessive regulations might limit the SMEs ambitions to establish a subsidiary and therefore the SME instead decides to sign an agreement with a distributor in the foreign market. On the other hand, knowledge about the foreign market will also influence the choice of market entry mode (Sharma and Blomstermo, 2003). Furthermore, the decision is dependent on what type of product or service the company offers. SMEs that produce and manufacture innovative products are more protective of their proprietary know-how and therefore prefer to establish a subsidiary were they can have control of the product instead of licensing to a third party (Nakos and Brouthers 2002). In other words, there is no general agreement on SMEs modes of entry because the choice is dependent on varies of issues.

All of the previously mentioned elements: drivers, barriers, entry modes are important to study in order to conceptualize the internationalization of SMEs in this study. Together these elements lay the foundation of understanding the internationalization process of SMEs. However, there are another elements that impact the internationalization process, which is the interplay among actors and the influence of knowledge. Hence, the next section will discuss the role of the networks and how the network relationships are an important part in internationalization and in what way knowledge influence the internationalization process.
2.3 Network and knowledge

2.3.1 The role of networks and relationships for SMEs

For SMEs it is important to be a part of an international network, as the knowledge gained through the networks relationships can assist the SMEs in their internationalization. The network relationships consist of both organizations and individuals, proclaiming that both employees and firms are considered to be actors in the network (Sandström, 1992). By understanding that networks are a platform for a firm’s knowledge acquisition (Chetty and Patterson, 2002; Gulati et al., 2000) and provide opportunities for firms entering foreign markets (Arbaugh, 2008), the relationships within these networks are a contributing asset for the firm success. Because of this it is vital to understand and analyze the influence networks has on the internationalization process of SMEs.

Multiple authors have investigated the use of networks and business relationships in order to understand a firm’s internationalization process (Johanson and Vahlne 2003; 2006; 2009; Coviello and Munro, 1997; Hilmersson and Jansson 2011). Welch and Welch (1996) define the creation of a firm’s network as: “When firms establish and maintain relationships with customers, partners, suppliers, government officials they create networks which can prove to be powerful and strategic for the firm” (Welch and Welch, 1996 p.13). The network relationships are imperative to the SME, as the knowledge gained in the networks influences the SMEs decisions. Coviello and Munro (1997) identified that the internationalization process is influenced by a set of formal and informal network relationships, and that furthermore these relationships impact foreign market selection and mode of entry. As the network relationship have an influence on the decisions taken by the SME, it is important that the organization is attentive when choosing which networks to be a part of.

Coviello (2006) identified that network relationships emerge even before the internationalization of the firm begins. A notion that has progressed over the recent decades concerning the internationalization of firms is the theory of international new ventures (INV), which distinguishes INVs from other firms in the view that they have a proactive international strategy from or near their inception (Oviatt and McDougall, 1994; Madsen and Servais, 1997; Evangelista, 2005; Crick, 2009). Another distinguishing feature of INVs is that they have an involvement in networks in order to enable rapid internationalization. Because these
relationships where bound before the inception of the firm they have a fundamental input in the decision of the firm whether to move or grow their operations abroad (Coviello, 2006).

Furthermore, the network relationships do not form themselves; rather it is a configuration of both intended and unintended components (Welch and Welch, 1996). The intended aspect, for example marketing activities, involves a deliberate action by the firm intending to establish personal relationships with a foreign agent. Unintended network development is the result of relationships and connections that have evolved without anticipation. In general Welch and Welch (1996) state that it is difficult for firms to determine the value of networks as they cannot be measured in financial terms nor are they a predetermined criterion in a firm's strategic planning cycle.

2.3.1.1 Moving from outsidership to insidership

Establishing new networks can be challenging for SMEs, as they are unknown and unfamiliar with the different actors in the market. Johanson and Vahlne (2009) reviewed the access of networks and addressed the subject in the terms insidership and outsidership. They defined insidership when an SME collects knowledge and information in its networks and outsership when an SME suffers from the liability of outsidership. In other words, being an outsider could have severe consequences, such as not having access to valuable market specific information or establishing win–win relationships with respected actors. This further enhances the importance of networks in the internationalization process. Johanson and Vahlne (2009) claim that the challenges and opportunities for firms lie not in the matter of country-specificity but more in the relationship- and network-specificity, meaning that as firms internationalize the challenge is to know and identify relevant business actors in the foreign market.

Firms gradually pass through three distinct stages when becoming an insider (Hilmersson and Jansson, 2011). In the first stage, the exposure network, were the degree of insidership in this stage is low, firms aim to find hubs that provide information and contacts, through which they can expose themselves to potential customers and intermedaries. While the firm gradually strengthens its position in the network and starts establishing ties with partners and customers it moves on to the second stage, the formation network. This stage consists of both information and social exchange where the aim for the firm is to identify which partners to commit to and go forward with. The third stage, the sustenance network, concerns how the
firm sustains an insidership position in the network and form structured and strong relationships with key partners.

Consequently, if firms succeed in entering a new market it is highly dependent on its position in the network and the relationships within the current market (Coviello and Munro, 1997). In addition, companies will gain a level of credibility if they are inside a network that they would not have if they were outsiders (Chetty and Patterson, 2002). In short, networks provide a platform for knowledge sharing and to further elaborate on the importance of knowledge the following section describes the impact knowledge and experience has on the internationalization process.

2.3.2 Knowledge and experience

While internationalization is a process characterized by uncertainty, the degree of knowledge in the firm affects the internationalization commitment (Johanson and Vahlne, 1977; 1990; Welch and Welch, 1996). However, knowledge can be viewed on two different levels, firm level and individual level. Within smaller firms, the knowledge that each employee holds can be seen to have a greater impact on the firm compared to knowledge among employees in larger firms. This is possible to assume because SMEs consists of reduced number of employees, in some cases only a handful, and therefore each employee could have a greater ability to influence the orientation of the firm. According to Sommer (2010), managers in SMEs should see internationalization as an opportunity rather than a threat and have the self-confidence to believe that they are able to conquer the market. This is further emphasized by Westerberg et al., (1997) who argue that CEOs characteristics matters significantly and play a dominant role in the orientation and direction of the firm. Therefore, it is not only the knowledge among employees that influence the internationalization it is also how employees perceive internationalization. For example, managers that have previous positive experience from internationalization can have a progressive influence on the firm’s direction. Moreover, as internationalization is characterized by uncertainty (Johanson and Vahlne, 1977) it is especially important that the CEO have a high tolerance for ambiguity (Westerberg et al., 1997).

When studying the internationalization process of firms that operate in the healthcare industry it is imperative to study the relationship between the firm and the political and regulatory actors (Welch and Wilkinson, 2004; Hadjikhani and Ghauri, 2001; Hadjikhani et al., 2008).
Hence, the next section will discuss the political and regulatory environment of SMEs, with regards to network and knowledge and how it affects firm’s internationalization process.

2.4 The political and regulatory institution

SMEs operating in highly regulated environments are continuously affected by constraints that are set in the landscape of the political actors. Salmi (1995) defines the political institution as a provider of frameworks consisting of rules and regulations that private actors must accept and follow. The private actors could benefit from having a close relationship with the political institutions as the actions the institutions practice can affect the private firms market access and competitive position, implying that for example, governmental actors can act as an introduction to the foreign market as they play specific economic roles as buyers and suppliers of products and services (Welch and Wilkinson, 2004). In contrary to business-to-business relationships Hadjikhani et al. (2008) claim that firm and political relationships are not based on financial exchange, rather on sociopolitical values that are defined depending on the legitimacy of the firm and have a long-term and mutual nature. Legitimacy is the perception of a firm’s position in society and can be seen as a driver for firms aiming to influence the political actors in their environment (Hadjikhani et al., 2008). In other words, firm’s relationships with different political actors could influence the internationalization of firms by providing them with legitimacy and helping them overcomes barriers regarding internationalization.

Welch and Wilkinson, (2004) outline the political embeddedness in business networks by describing four institutional dimensions that influence the ways in which political relationships and networks develop. The first dimension, political institutions, focuses on how organizations such as ministries, research institutes, media and pressure groups affect the social values and political ideologies that shape the rules and regulations the firm has to operate by. Hallén (1992) describes that the firm’s dependence on the political institutions takes the form of adaptions to the rules of the game and framework for action. This is in line with Salmi (1995), who argues that institutions defines the roles and norms for behavior and provide the framework for interaction. Changes in the rules and regulations can trigger a reconfiguration of business networks (Welch and Wilkinson, 2004), some firm’s rebuild their existing networks to fit the new rules for interaction, meanwhile for other firm’s this change could be a window of opportunity to extend their business and build new relationships in new
markets. Consequently, the political institution offer both constrains and, if managed in the right way, opportunities for action.

The second dimension, political actors, includes bureaucrats, government ministers, and special interests groups that help shape or change business networks through facilitating or disrupting activities (Welch and Wilkinson, 2004) and consequently represents important assets to the firm (Hallén 1992). Without having any business relationships with competitors, government agencies, or opinion leaders, firms depend more on themselves to actively seek for market-specific information. In addition, Hallén (1992) asserts this facilitating role as social ties of, for example, a government official participating in a business network and acts as a vehicle for information, communication and influence. In other words, political actors are important assets to the firm, as they both support and constrain the firms’ actions.

The third dimension, political activities, includes actions taken both by political actors as they deal with businesses and also by firms when they take the function of lobbyist of governments and influencers of public opinion (Welch and Wilkinson, 2004). Hallén (1992) describes market relationships as a connection of resources, activities and actors of two or more parties. However, lobbying is described as a non-market relationship as it does not connect any resources to the market relationship. In other words, lobbying only connects the activities and the actors of the involved parties. Hadjikhani and Ghauri (2001) clarify that the size of the firm has an impact on the ability for the organization to craft a policy agenda; the generation of creating and exchanging political ideas that aim to influence and persuade political actors. The uniqueness and effectiveness of the political agenda depends on the management’s capability to incorporate the firm’s resources into the needs of the political actors. Smaller firms generally act as followers of the political rules, as they have limited resources and knowledge about how to influence the political agenda. This is in contrast to larger firms, which engage in political activities in order to gain political support, as they already possess the knowledge and necessary resources to influence the decision-making process even before decisions are being made. However, the level of political achievement is determined by the firm’s commitment in the foreign market (Hadjikhani, 2000) and its legitimacy among the actors in the foreign market (Hadjikhani and Ghauri, 2001).

The fourth and last dimension, political resources, explains the gains firms wish to acquire through the political activities. Here governments are seen as a pool of political goods that are desired by firms, for example public sector contracts, licenses and funding for research.
Furthermore, governments are also an important source of market-specific information for firms that lack knowledge about foreign markets. The dimension includes all types of resources that firms have, and currently benefit from and the resources that firms wish to gain (Welch and Wilkinson, 2004). Hadjikhani and Ghauri (2001) raised that some firms do not have the resources to engage a specific person or unit to manage the political relationships, rather they turned to intermediary organizations which offered assistance regarding information about the foreign market, establishing contacts with other firms, and provide information about supporting funds. Aspelund and Moen, (2005) who discusses the impact of policy makers on SMEs internationalization, argues that governments should implement support programs to help firms overcome shortcomings related to resource gaps and knowledge about the market place. Accordingly, SMEs are limited to the extent of the rules and regulations that are in place. Despite this, it is possible for SMEs to overcome the barriers related to regulations by utilizing their political and business networks or knowledge gained through experience and intermediaries.

To summarize, the literature review has up till now discussed the important elements in the internationalization process of SMEs, from their initial drivers of internationalization, to the barriers they face throughout the internationalization process and the alternative ways of entering the international arena. Furthermore, in the light of networks and knowledge it was reviewed how the two elements are affecting the internationalization process. Finally, the political and regulatory landscape was discussed due to the unique aspects that are evident in highly regulated industries. The next section further describes the conceptual model by explaining how all of the above-mentioned elements: drivers, barriers, entry modes, knowledge, networks and the political landscape, are interconnected and provides a deeper understanding of the internationalization process of healthcare firms.
2.5 The conceptual model

The conceptual model acknowledges the premise that the healthcare industry is highly regulated and that this has a direct affect on the internationalization process, as the firms must adapt and follow the rules and regulations that are set (Salmi, 1995). The model also illustrates that networks and knowledge, at both a firm and individual level, influence and affect the SME internationalization process. The knowledge stimulation includes all types of knowledge an SME possess, both in the form of the degree of current and previous international experience (Johanson and Vahlne, 1977), its management (Reuber and Fischer 1997) and knowledge about foreign markets (Johanson and Vahlne, 1977; 1990). The network stimulation consists of the relationships that an SME creates by way of interactions with business actors, such as customers, partners and suppliers (Welch and Welch, 1996) as well as political actors in the form of government officials and regulatory authorities and special interest groups (Welch and Wilkinson, 2004; Hadjikhani and Ghauri, 2001; Hadjikhani et al., 2008). The networks further enable SMEs to realize potential opportunities that it could not have achieved on its own (Coviello, 2006; Chetty and Patterson, 2002; Gulati et al., 2000). More specifically, the model explains how the two elements, networks and knowledge, influence the selection of a foreign market and mode of entry (Coviello and Munro, 1997), the drivers for internationalization (Barnes et al. 2006; Erramilli and D’ Souza 1993; Barringer and Greening, 1998; Lee et al., 2012) and how a firm can tackle the barriers (Barnes, et al., 2006; Ruzzier et al., 2006) that they encounter during the internationalization process.

Overall, the internationalization process of SMEs is characterized by a set of activities that indirectly affect internationalization (Hadjikhani et al., 2008; Hadjikhani and Ghauri, 2001; Welch and Wilkinson, 2004). Consequently, knowledge helps a firm identify networks (Johanson and Vahlne, 2009) and through the networks the firm acquires knowledge (Chetty and Patterson, 2002; Gulati et al., 2000), which in turn, has an affect on the internationalization process.
CHAPTER 3: METHODOLOGY

3.1 Research approach

As the intention of the present study is to understand why small to medium sized enterprises in the healthcare industry internationalize and how this process unfolds an exploratory approach was found appropriate. Despite the amount of research conducted in the field of internationalization there exists limited research regarding the internationalization of SMEs in the healthcare industry and consequently, as this is a new phenomenon, few empirical studies and contributions have been made. Therefore an exploratory approach was suitable for this study as it helps to understand what is actually happening (Saunders et al., 2009). However, it has been argued that an exploratory study does not provide full or satisfactory answers to the research questions why and how. Therefore a descriptive approach complements the exploratory approach in order to gain a holistic picture (Babbie, 2012). Saunders et al. (2009) states that through a descriptive approach it is possible to portray an accurate profile of the situation. By applying a mixed approach it is achievable to investigate a situation where there is no clear single set of outcomes, as well in order to describe a phenomenon and the real-life context within it (Yin, 2009).

When applying a methodology based on an exploratory and descriptive approach a qualitative research design is suitable. The qualitative standpoint is motivated for this study as it brings a richer understanding for the researchers when studying individuals and organizations and in the effort to explore a phenomenon within its context (c.f. Baxter and Jack, 2008). As the purpose of this study is to deepen the understanding of an unexplored phenomenon, a qualitative standpoint was pivotal (Holme and Solvang, 1997). Furthermore, considering the focal position of the contextual conditions in this study, a qualitative approach is explicit, as other social science methods have difficulties in addressing the social, institutional, or environmental conditions (Yin, 2011).

3.2 Research design: multiple-case study

This study employs both an exploratory and descriptive approach from a qualitative perspective, and therefore a case study methodology was found appropriate (Yin, 2009; Bryman and Bell, 2007). Eisenhardt and Graebner (2007) emphasize the use of a case study method when trying to understand a phenomenon in a real-world context and also where the
objective is to cover contextual conditions that are relevant to the phenomenon under investigation. This is vital as without considering the unique context of the healthcare industry, the study will be insufficient in order to achieve the purpose of the research in this paper. Additionally, Yin (2009) emphasizes a case study approach as appropriate when examining contemporary events and where the purpose is to answer how and why questions, which are viewed as foundational to research of this nature, and thus it provides further motivation for use of a case-study approach.

When conducting a case study, there is a choice for researchers to choose between applying a single-case study or a multiple-case study approach (Saunders et al., 2009). While the aim of the study is both to contribute with empirical knowledge on the subject and theory development, the choice of a multiple-case study is viewed as essential. An advantage of a multiple-case study approach is that it generates a more robust, generalizable and testable basis for theory building and further the research can be grounded more deeply in varied empirical evidence (Eisenhardt and Graebner, 2007). Furthermore, as to date little attention has been given to understanding the internationalization process of SMEs in the healthcare industry, there is a need for research that can provide a sound basis for theory building, which fortifies the application of a multiple-case study approach.

In this study, each individual case has been selected using the same criteria, such that the findings can be either analyzed on a general or a case-specific basis (Blumberg, et al., 2008; Eisenhardt and Graebner, 2007). This method is often applied in multiple-case studies, which will enhance the empirical knowledge contribution. Additionally, conducting a multiple-case study enables application of replication logic with the units of analysis, as described by Eisenhardt and Graebner (2007). In this study the case SMEs are the analytical units and the internationalization process is the unit of analysis. As in line with Yin (2009) the unit of analysis should be related to the research question in order to avoid incorrectly defining it.

3.2.1 Case selection

The basic criteria for the selection of case firms are related to firm size, sector, location and the foreign markets where the firm has established operations.
First, a case company must fit within the definition of a small or medium-sized enterprise according to the European Commission (2003), which means having 250 or less employees and an annual turnover of €50 million or less.

Second, the case firm must operate in the healthcare sector, specifically the medical device industry. The operational definition of a medical device, according to European Directive 93/42/EEC, is

“Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of (a) diagnosis, prevention, monitoring, treatment or alleviation of disease, (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, (c) investigation, replacement or modification of the anatomy or of a physiological process, (d) control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.” (European Directive on Medical Devices, 1993).

Third, the case company must be headquartered in one country, Sweden, in order to minimize the potential for country specific biases. Sweden was selected because it is home to a significant number of healthcare firms that fit within the SME definition and the Swedish healthcare system is ranked high on a worldwide basis (Björnberg, 2012, Symbiocare, 2013). There also was a practical reason for choosing Sweden, the geographic accessibility of the case firms by the researchers.

Fourth, a case firm must be undergoing internationalization and have market presence in European Union member states. The application of these criteria resulted in the elimination of many firms from the study, but a meaningful number of firms still qualified for inclusion and were selected after they expressed a willingness to participate in the study.

Out of the above selected criteria five case-firms were chosen for this study. Table 1 specifies these five firms, including their business concept, starting year, financials, first international activity and market presence outside Sweden. All of the five case SMEs product or invention originate from university research projects, although three of them derive directly from the university, so called university spin-offs, and the two other companies are corporate spin-offs. All of the firms originate from Sweden and have established sales abroad during the past
decade. Furthermore, all of the case-companies have to date sales in several EU countries, either through own subsidiaries or contracted distributors. In order to preserve the desired anonymity of the informants and the case firms, they are in this study replaced with fictional names.

Table 1. Profile of case firms

<table>
<thead>
<tr>
<th>Firm</th>
<th>AnnoMed</th>
<th>Binava</th>
<th>Cearus</th>
<th>Lavace</th>
<th>Nione</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Business description</strong></td>
<td>Delivers products for the diagnosing and monitoring of inflammatory airway diseases</td>
<td>Develops and manufactures biomaterial products for the spinal and orthopedic market.</td>
<td>Develops and markets products for the use of blood cell analysis.</td>
<td>Provides point-of-care diagnostic instruments</td>
<td>Delivers and markets monitoring and management tools for the obstetric care market.</td>
</tr>
<tr>
<td><strong>Headquarters</strong></td>
<td>Stockholm, Sweden</td>
<td>Lund, Sweden</td>
<td>Lund, Sweden</td>
<td>Lund, Sweden</td>
<td>Göteborg, Sweden</td>
</tr>
<tr>
<td><strong>Origin</strong>*</td>
<td>USO</td>
<td>USO</td>
<td>USO</td>
<td>CSO</td>
<td>CSO</td>
</tr>
<tr>
<td><strong>Employees</strong></td>
<td>71</td>
<td>21</td>
<td>59</td>
<td>10</td>
<td>26</td>
</tr>
<tr>
<td><strong>Turnover</strong></td>
<td>95 MSEK</td>
<td>18 MSEK</td>
<td>155 MSEK</td>
<td>2 MSEK</td>
<td>39 MSEK</td>
</tr>
<tr>
<td><strong>Market presence with subsidiaries</strong></td>
<td>Germany, UK, Switzerland</td>
<td>Germany, the Netherlands, USA</td>
<td>Canada, Japan, Finland, Denmark, USA</td>
<td>Austria, Spain, Italy, UK, Germany, Eastern Europe, Korea, Taiwan</td>
<td>France, USA</td>
</tr>
<tr>
<td><strong>Market presence with distributors</strong></td>
<td>World-wide</td>
<td>Italy, Benelux, Poland, Spain, UK</td>
<td>Europe, Middle East, USA, China</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Origin: CSO = Corporate Spin-Off. USO = University Spin-Off

3.3 Data collection

For the present study the use of multiple data sources has been applied, with interviews as the primary data source, complemented with secondary data. The secondary data was collected from each case firms website and through other Internet sources, such as annual reports, trade association reports, governmental publications, news articles and research articles. This type of data has been gathered as additional information to the case interviews and the pre-study interviews. In order to perform vigorous case study research the use of multiple data sources is preferable as each data source acts as one piece of the puzzle, the convergence supports the research in achieving a greater understanding of the phenomenon (cf. Baxter and Jack, 2008).
3.3.1 Primary data

The collection of primary data has been conducted through personal- and telephone interviews with informants from the selected case firms. Table 2 presents the conducted interviews, which is the foundation for the empirical findings. Before the interviews were conducted a pre-study was formed with the aim to gather a deeper understanding of the healthcare industry. This was found pivotal due to the high complexity of the industry and helped to develop a framework for the interview guide. The pre-study has been conducted with representatives from the trade associations Swecare and Business Sweden, and also with the Swedish Ministry of Health and Social Affairs. All of the interviews, both in the pre-study as well as with the case firms, were conducted with a semi-structured disposition tailored by a number of pre-set themes, providing the interviewee with open-ended questions. According to Saunders et al. (2009) this approach is favorable when the study is of an exploratory nature. Furthermore, this disposition enables the researchers to incorporate follow-up questions (c.f. Bryman and Bell, 2007) during and after the interview.

Table 2. Overview of interviews

<table>
<thead>
<tr>
<th>Case</th>
<th>Interview type</th>
<th>Length</th>
<th>Informant</th>
</tr>
</thead>
<tbody>
<tr>
<td>AnnoMed</td>
<td>Personal</td>
<td>60 - 90 min</td>
<td>Chief Technical Officer (CTO)</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>60 - 90 min</td>
<td>VP Commercial Operations EU and Asia (VP)</td>
</tr>
<tr>
<td></td>
<td>Telephone</td>
<td>30 - 60 min</td>
<td>Medical Director (MD)</td>
</tr>
<tr>
<td>Binava</td>
<td>Personal</td>
<td>30 - 60 min</td>
<td>Chief Operations Officer (COO)</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>90 - 120 min</td>
<td>Co-Founder (CoFo)</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>30 - 60 min</td>
<td>Head of R&amp;D (HRD)</td>
</tr>
<tr>
<td>Cearus</td>
<td>Telephone</td>
<td>30 - 60 min</td>
<td>Chief Executive Officer (CEO)</td>
</tr>
<tr>
<td></td>
<td>Telephone</td>
<td>30 - 60 min</td>
<td>VP Sales and Marketing (VP)</td>
</tr>
<tr>
<td>Lavace</td>
<td>Personal</td>
<td>60 - 90 min</td>
<td>Chief Executive Officer (CEO)</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>60 - 90 min</td>
<td>Head of R&amp;D (HRD)</td>
</tr>
<tr>
<td>Nione</td>
<td>Telephone</td>
<td>30 - 60 min</td>
<td>Chief Executive Officer (CEO)</td>
</tr>
<tr>
<td></td>
<td>Telephone</td>
<td>30 - 60 min</td>
<td>Medical Director (MD)</td>
</tr>
<tr>
<td></td>
<td>Personal</td>
<td>30 - 60 min</td>
<td>Technical Director (TD)</td>
</tr>
</tbody>
</table>

One of the challenges of interviews as a data source is to design data collection approaches that limit bias. For the present study we have in line with Eisenhardt and Graebner (2007) used several and highly knowledgeable informants who have viewed the phenomenon from different perspectives. By interviewing the executive management with diverse functions and
areas of expertise, for example, CEOs, Head of R&D etc., the aim is to gain a deeper insight and a more balanced view of the internationalization process, as these employees typically have had a prominent role in this process. Furthermore, the number of years the informants have been working for their firm differs, illustrated in Table 3, ranging from recently employed to the foundation of the firms. The range of the informants’ employment with their firm provided an overview of the firms internationalization process viewed from different perspectives, which furthermore limits the potential bias that could appear if, for example, only the founders were interviewed.

3.3.2 Interview guide and process

Prior to the interviews an interview guide was prepared (see Appendix) with the purpose to assure that certain themes were touched upon during the interviews, and furthermore also to guarantee that all interviews covered equal subjects. Before the interviews took place, the pre-set themes were e-mailed to the firms’ in order to make sure that suitable candidates with relevant competence participated in the interview, and also so that the informants could prepare for the interview.

Pre-set themes that guided the interviews:

(a) How has the firm internationalized and why is the firm established in the countries it is present in today?

(b) How and to which degree has aspects of regulations, patents, certifications, etc. affected the internationalization process?

(c) Throughout the internationalization process, what have been the foremost challenges?

(d) How and to which extent has the firm and its management used business and personal networks to influence the internationalization process?

<table>
<thead>
<tr>
<th>Table 3. Informant's year of employment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case (year founded)</strong></td>
</tr>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td>Binava (1999)</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Cearus (1994)</td>
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<td></td>
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<tr>
<td>Lavace (2000)</td>
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<td></td>
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<td>Nione (1997)</td>
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<tr>
<td></td>
</tr>
</tbody>
</table>
All interviews, both in person and by telephone, were recorded after consent from the interviewee in order to be able to use the interviewees’ full responses and conversation with the questioner, this further strengthens the ability to produce reliable data for the analysis (Saunders et al., 2009).

### 3.4 Data analysis

All the case interviews that were conducted were transcribed in order to enable a comprehensive review of the compiled data. Responses in personal interviews can tend to be influenced by thoughts and feelings by both the interviewees and the researchers, which can lead to difficulties in analysis of the data (Langley, 1999). By transcribing the interviews, however, these personal interpretations and bias can be filtered out. Each transcription has been carefully reviewed and the relevant sections and quotes were highlighted, and gradually divided into categories (Langley, 1999). In other words, transcribing the interviews helped facilitate the data presentation and the identification and categorization of the different aspects in the internationalization process, which made it easier to target important findings (Bryman and Bell, 2007).

### 3.5 Data presentation

The empirical findings from the case interviews are presented within a set of pre-defined categories, which enabled an easier detection of specific incidents (Langley, 1999) and a richer dialogue, due to the high number of cases covered (Eisenhardt and Graebner, 2007). The categories are constructed upon the basis of themes from the interview guide in order to ensure that all aspects of the internationalization process are covered. Structuring the data within these categories made it easier to focus on the important empirical findings and to exclude the less important aspects. The findings were also discussed among the research team in order to further ensure that the data was correctly interpreted and that sufficient data was reviewed in order to answer the research question (Baxter and Jack, 2008). Following this, the findings were systematically re-read in order to distill the data into a smaller and more manageable number of categories, focusing on the most important aspects (Eisenhardt and Graebner, 2007).

In order to fortify the important aspects, the data is presented in the form of quotations from different interviewees (Eisenhardt and Graebner, 2007). Additionally, there is no
differentiation made between the interviewees, with regards to their position within a case firm, but instead the data is classified around different groups of interviewees based on similarities in their opinions in order to understand the most important aspects (Baxter and Jack, 2008). This approach was suitable because our purpose is not to compare opinions that are dependent on an interviewee’s position in a case firm, rather to find similarities among their responses in order to explain the internationalization process.

As the study covers multiple cases, tables were used in order to summarize the case evidence with the intention to provide more depth in the research (Eisenhardt and Graebner, 2007). Furthermore, Even though the use of tables may reduce the richness of the empirical evidence, it is important to remind reviewers that the objective of the present study, besides contributing empirically, is to develop theory. The above-described methodology ensures the integrity of the data in order to undertake a critical analysis in answering the research question.

3.6 Research limitations and quality of the study

One of the greatest challenges with a case study is that the outcomes are not generalizable for an entire population (Yin, 2009). In order to strengthen that the phenomenon in the present study has been portrayed in an accurate way with high validity, numerous actions were taken. The number of informants influences the validity of the data (Yin, 2011), and in order to attain a high validity it should be noticed that in the study the researchers interviewed between two to four informants at each firm. However, five of the interviews were conducted by telephone and therefore various personal impressions and observations might have been lost which can affect the validity (Bryman and Bell, 2007). The data was collected and thereafter transcribed and thereafter the researchers shared the data with the informants in order to give them the opportunity to review the researchers interpretations of the data. The informants therefore had the possibility to discuss or provide further perspectives on the topic, as a cautionary step to further strengthen the reliability of the data (Baxter and Jack, 2008).

Furthermore, one limitation that must be taken into consideration with regards to the validity to the research is the fact that one of the firms in the present study manufactured devices for both the human and veterinarian market. This could complicate the generalization, as their internationalization experience on one hand does not encounter the same challenges. Closely linked to the concept of validity we find the term reliability. While validity measures the
integrity of the conclusions drawn from the research, reliability is concerned with the question of whether the results of a study are repeatable (Bryman and Bell, 2007). As this study only investigates Swedish SMEs the findings may not be used consequently for all SMEs around the world in this industry. In addition, as Sweden is a part of the European Union, the internationalization process might be different for Swedish firms, compared to those firms that origin from countries outside the EU.

Lastly, one limitation that needs to be taken into consideration is that neither of the two informants from Lavace has been employed with the firm from or close to inception, which therefore required a larger emphasis on secondary data, specifically annual reports, in order to gain an understanding of the internationalization process.
CHAPTER 4: THE HEALTHCARE INDUSTRY

This chapter presents an insight into the healthcare industry in order to gain an understanding of the surroundings in which the case firms operates within. First, the regulatory and political settings will be described. Second, an outline of the procurement process is presented. Third and lastly, a clarification of the terms reimbursement and coverage is provided. All of the above terms are important in order to understand the commercial side of the healthcare industry.

4.1 Medical device regulations in the European Union

At its origins, the European Union (EU) constituted six western European countries to reduce trade barriers between these countries. Today, the EU has expanded into an influential and important supranational body, consisting of 27 member states. The actions and policies of the EU affect almost all aspects of the citizens within the union. This influence involves an extensive body of legislation, which extends to the healthcare sector and has a large impact on the industry (Greer et al., 2013). In the healthcare sector the medical device industry is regulated at a EU-level out of three directives:

- Active implantable medical devices (origins 20 June 1990)
- In vitro diagnostic medical devices (origins 27 October 1998)
- (Other) Medical devices (origins 14 June 1993)

Directives are the most common EU legislative mechanism, where the objectives of the directives are agreed upon together amongst the member states and becomes binding. However, it is every member states own responsibility to establish the means to achieve them (Greer, et al., 2013). For instance, Sweden has transposed these directives into different parts of a Swedish Act (SFS 1993:584), Ordinance (SFS 1993:876) and Regulations LVFS 2001:5, LVFS 2003:11 and LVFS 2001:7 from the Medical Products Agency (MPA). Each directive has been implemented almost directly into these laws. The Medical Products Agency is a national authority (the Competent Authority in Sweden) with responsibilities for regulation and surveillance that producers of medical devices meet the requirements from the legislations in development, manufacturing and sales of their products (Läkemedelsverket, 2013).
The procedure to receive an approved product for the Swedish market, the CE-mark approval, is the same as for all EEA-countries (EU plus Iceland, Lichtenstein and Norway), and an approval by one country’s competent authority grants approval for the whole EEA-market. Typically the procedures within Europe are the same, even if every national authority has their own legislation (Läkemedelsverket, 2013; Kramer et al., 2012). However, as the innovation pace in medical technology has accelerated in the last two decades the existing directives, even though they have been revised, are seen as out of date. This has lead member states within EU to interpret and implement the current rules in different modes (European Commission, 2013).

An ongoing debate is whether the European approval procedures are adequate or not. Reports suggest that European patients are exposed to certain high-risk medical devices earlier than American patients, arguing the European system of device-approval is quicker than the American and also more open for innovation (Kramer, et al., 2012; Greer, et al., 2013). However, the European approval system has received criticism, claiming to be unscientific. The criticism highlights the failures in regulatory oversight during clinical use and the lack of transparency when publishing research findings and device related complications (Wilmshurst, 2011; Cohen and Billingsley, 2011).

4.2 The procurement processes

Healthcare expenditures have increased over the past decades in which the financing of medical technology has become an increasingly important part of policy making by decision-makers (OECD, 2011; Sorenson and Kanavos, 2010). Many countries have implemented tools for measuring healthcare costs in order to assure that the procurement processes are aligned with national healthcare priorities and guide the usage of technologies. These mechanisms often correlate with policies on healthcare coverage and reimbursement, and are two key aspects that have a bearing on the financing of healthcare solution. Several European countries have established procedures for the approval of sale of medical devices within their country and have published directories of approved medical devices.

The procurement process for medical devices is highly complex and it is vital for the manufacturers to become familiar with these processes in order to make the procurement favorable to their devices (Sorenson and Kanavos, 2011). The procurement process can differ between different health service providers depending whether they are privately or publically
funded. In general, the procurement process is shorter and less complicated in health service providers that are privately funded. The main actors involved in the procurement process differ between countries. In general health service providers, such as primary care physicians, hospitals, elderly care etc., and manufacturers, distributors and suppliers are the base for the procurement process, although governments and interest groups play an indirect, or sometimes direct part in the process. In countries characterized by a decentralized procurement process, such as France and Germany, hospitals purchase technologies and solutions directly from the manufacturers, while countries such as England, Italy, Spain and Sweden apply a centralized approach, which implies local or regional bodies taking a greater role in the procurement process (Sorenson and Kanavos, 2010).

4.3 Reimbursement and coverage

Tightly connected to the procurement process are the terms reimbursement and coverage. As few patients are able to pay for their healthcare directly, third-party payers play an important role in determining which procedures and medical devices that are to be used. As previously mentioned, the actors involved in the procurement process range from the manufacturers and hospitals to regulators and policy makers. To add to this list, insurance companies have come to play an influential role during the last decade (Raab and Parr, 2006). Reimbursement is a term used from both a private insurance standpoint, as well as from a public national health plan standpoint. The reimbursement and coverage policies from public and private actors affect which devices that are available for public purchase and use and at what level they are financed (Sorenson and Kanavos, 2011). Therefore, as reimbursement can shape medical practice and create technology winners and losers (Raab and Parr, 2006), the inclusion of reimbursement in a medical device firm’s business strategy is imperative.

When a new medical technology or treatment is introduced into a new market, private insurers and public healthcare providers must decide whether these new solutions should be covered by their plans. The first consideration is whether a new solution is beneficial from an added value perspective; in other words, what will be gained by utilizing the new method. The next is to decide whether it should be covered or reimbursed and, if so, at what level (American Academy of Actuaries, 2008). Reimbursed refers to how healthcare providers, for example hospitals, will receive payment for using a certain procedure or medical device. This pressures the reimbursement actors, as they need to assess whether the new technology adds value, through quicker and more precise diagnosis or more efficient
treatments. Typically private insurers have several resources they base their reimbursement
decisions on, such as subscriptions to health technology assessment organizations, which
evaluate the scientific evidence of the new technologies, as well as in-house analyses and
reports from state funded assessment centers. Public payers also use similar solutions to
assess their coverage and reimbursement policies, however, they also have existing legislative
requirements that need to be accounted for (American Academy of Actuaries, 2008).
CHAPTER 5: CASE FINDINGS

The findings from the collected data are presented in this chapter. First, a description of the establishment and early development of each case firm is presented, with emphasis on the firms’ international growth patterns. Second, the influence of network relationships is described, from the perspective of how both the business and political actors influenced the internationalization process.

5.1 Foundation and commercialization

5.1.1 AnnoMed

AnnoMed is a spin-off from research departments at Karolinska Institutet, Stockholm, primarily from pre-clinical research carried out by research groups at the Department of Physiology and at the Department of Pharmacology. The research groups had several avenues for how they could develop the product concept into a commercially innovative product. Initially, they considered licensing the concept to a large medical or biotech firm, but after being unable to find a suitable partner or licensee, they decided to instead start their own company. In 1997 the company was founded, under the name AnnoMed, for the purpose of commercializing the treatment of airway inflammation.

A contact and friend to the research group, who worked in the venture capital business, assisted the researchers in establishing the company and raising the necessary start-up capital. As a condition to assisting the researchers raise capital, the venture capital firm required someone to take care of the commercial and business aspects of the company in order for the company to become financially viable. Furthermore, due to contacts arranged by the venture capital firm, AnnoMed was able to recruit a board of directors with extensive experience in senior management positions at multinational pharmaceutical and medical firms. AnnoMed quickly received CE-mark approval in 1999, while the FDA approval for the US market was not granted until 2003.

5.1.2 Binava

Binava, formed in 1999, evolved from a research project at Lund University headed by a leading professor in orthopedic surgery. Due to the unique nature of the product, it was necessary to conduct pilot and clinical trials in order to support applications for approval by the EU and US regulatory authorities. The trials could not be conducted in Sweden due to a
lack of available patients, which led the researchers to turn to Germany for their trials. The trials were conducted in Germany from 1999 to 2003, thus being the first internationalization step for Binava.

Once the trial produced positive outcomes, Binava applied for CE-mark and FDA approval. The product that was submitted to the regulatory authorities was not the principal product that Binava intended to commercialize, but rather the board of directors suggested a strategy to file for a product that was to some extent less complex and therefore could be more quickly approved. FDA approval for the product was granted in 2005, only two months after Binava filed for an application. In contrast, the European authorities, which were not familiar with the product’s technology, took several years before it granted CE-mark approval in 2008.

5.1.3 Cearus

Cearus was founded in 1994 as a research project with the intention to develop automated microscopy analysis. A doctoral student at Lund University’s Neurophysiology department originated the idea. This student was the company’s initial CEO until 1998, when the present CEO took over the post. Although the company was founded in 1994, it did not have any employees until 1997.

During the first three years the present CEO focused entirely on bringing the product to market. Even though software formed the core product, certain hardware was necessary in order for the product to be functional. This specific hardware was not available on the market, which led Cearus to make the decision to develop its own hardware. The first product system was launched in 2000 and it was first sold on the Swedish market. In parallel to the product launch in Sweden, the product received approval by the FDA and subsequently a sales subsidiary was established in the US; consequently, Cearus first internationalization experience began in the US market.

5.1.4 Lavace

Lavace was founded in 2000 as a subsidiary of a research and development facility in Sweden. The facility identified and exploited new ideas within the fields of medical technology and biotechnology, with the successful projects being later spun-off as independent companies. This became Lavace origin, and after it was listed on the Swedish stock exchange in 2002, it became an independent entity from the research and development facility. The technology underlying Lavace’s product was developed at Lund University and
during the first few years after its formation it focused primarily on developing a viable, marketable product. Patents for Lavace’s products were granted in the US in 2000 and in Sweden 2002/2003.

Lavace first exposure to the practice of establishing sales and distribution channels began in 2006 when the firm attended technology fairs and exhibitions. At these events, potential distributors proactively approached Lavace by expressing interest in representing its products. The company signed distribution agreements for its products with several companies awaiting the CE-mark of the instrument and subsequent registration of components according to the medical device directive. Parallel developments aimed at the veterinary market where a CE-mark is not required made it possible for the company to start commercial activities when the instrument was CE-marked in 2008.

5.1.6 Nione

The invention upon which Nione’s products are based traces back to the mid 1980s, when it was produced and marketed under another company and marketed in Europe and Asia. However, due to lack of sufficient funding the company was unable to sustain operations and as a result the business was closed down and the company’s rights and patents were sold to another firm.

After a period of dormancy, in 1996, one of the original co-inventors made an effort to revive the company with new investors and also under a new name, Nione. From 1996 to 2000, Nione was a purely research driven company focusing on improving and developing the original products from the mid 1980s. When Nione received CE-mark approval in 2000, it enabled the company to further become a commercially driven company. Although it had the CE-mark approval, by which it could have sold its products throughout the EU, the company remained domestic until it was granted FDA approval in 2005. This motivated the firm to attend fairs and exhibitions in the US in order to raise awareness about its products and to identify market opportunities. Its first sale in a foreign market was in 2007, when it sold a system to a US company. That same year Nione established a US subsidiary responsible for sales and marketing of the products in the US.

5.1.7 General findings

Table 4 is an overview of the five SMEs that are included in this study; including the year each was founded, their first international activity and market presence outside of Sweden.
All of the five firms have established sales abroad during the past decade and have sales activities currently in several EU countries, either through own subsidiary operations or by way of sub-contracted distributors.

Table 4. Profile of case firms

<table>
<thead>
<tr>
<th>Firm</th>
<th>AnnoMed</th>
<th>Binava</th>
<th>Cearus</th>
<th>Lavace</th>
<th>Nione</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market presence (subsidiaries)</td>
<td>Germany, UK, USA, Switzerland</td>
<td>Germany, Netherlands, USA</td>
<td>Canada, Japan, Finland, Denmark, USA</td>
<td>France, USA</td>
<td></td>
</tr>
<tr>
<td>Market presence (distributors)</td>
<td>World-wide</td>
<td>Italy, Benelux, Poland, Spain, UK</td>
<td>Europe, Middle-East, USA, China</td>
<td>Austria, Spain, Italy, UK, Germany, Eastern Europe, Korea, Taiwan</td>
<td>Europe, Middle-East</td>
</tr>
</tbody>
</table>

5.2 International activity

For AnnoMed, Binava, Cearus and Nione, the decision to internationalize was obvious from their inception, for the simple reason that the Swedish market alone would be insufficient to support the companies from a financial perspective. In regards to the intention of internationalization for Lavace it was stated in the 2002 annual report that internationalization was part of the firm’s vision. Table 5 cites the case firms’ aim to pursue operations abroad.

Table 5. Intention for internationalization

<table>
<thead>
<tr>
<th>CTO, AnnoMed</th>
<th>CoFo, Binava</th>
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<tbody>
<tr>
<td>&quot;We never made this company just for the Swedish market&quot;</td>
<td>&quot;It was self-evident that this type of product wouldn’t be sold in Sweden, the market here is very conservative, you have to have a lot of evidence and support in order to succeed, therefore we took the decision early that Sweden wouldn’t be an interesting market&quot;</td>
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</table>

<table>
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<tr>
<th>CEO, Cearus</th>
<th>TD, Nione</th>
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<tr>
<td>&quot;We decided from early on that this would be an international company, it was crystal clear...The founder, who had previously listed two other firms on the stock exchange had very high ambitions for Cearus for it to be a global and profitable firm&quot;.</td>
<td>&quot;Even before Nione existed there was an awareness of the product since it had been used earlier, primarily within Asia, so there already was a network for the product overseas. This has been fortunate considering that Sweden and the Nordic market is too small for this type of product.&quot;</td>
</tr>
</tbody>
</table>

Annual Report, Lavace

"Lavace vision is to establish its technology on the world market"
In other words, internationalization was essential in order to guarantee a future survival for the firms. Both AnnoMed’s CTO and Nione’s TD, who had been with their firms from inception, stated that it would not be financial viable to only commercialize in the domestic market. From another perspective, Binava’s CoFo stated that the Swedish market was too conservative in accepting their technology, which made it problematic to market their products in Sweden.

5.2.1 Foreign market selection

Among the case firms it was found that there are three different criteria in choosing a foreign market: commercial size of a market, geographic distance from its headquarters and previous relations to the market.

For AnnoMed the commercial size of the market was an important driving criterion, leading them to identify Germany as their first international market. Both Cearus and Lavace stated that the distance from their headquarters was influential in their choice of foreign market. Cearus CEO reflected upon her previous experience when marketing a new product it is important to be able to quickly respond to customer inquiries and make sure that they are satisfied, and this motivated them to start Cearus operations in the Nordic market and then Germany before launching their product in the rest of Europe.

Lavace had a similar experience and motivation. Its CEO stated that even though half of their potential sales was in the US, they preferred to begin their sales effort in geographically close markets because this enabled them to control the initial commercialization phase and make sure that the products function correctly and lived up to customer expectations.

For Binava the selection of its first foreign market was decided upon during the research and development phase, a period when the company was conducting its patient trials in Germany. Binava’s CoFo commented that the company could have done its trials elsewhere, but Germany was a good market for launching their product after the trials, and consequently had a significant market potential. The CoFo therefore knew Germany would be an important market in the future and chose to conduct their patient trials there. Although its intention was to initially market the product in Germany, Binava’s CoFo further commented that the first international market was the US due to a contact that proactively approached the CoFo after Binava received its FDA approval. Within the EU the Binavas’s first country came to be Italy,
due to the same reasons as in the US, with a distributor contacting them desiring to sell their products.

5.2.2 Compliance with legislation

AnnoMed, Cearus and Nione did not view the CE-mark approval process as an obstacle, but rather all three identified it as a positive process that would grant them permission to market and sell their devices throughout the EU, as the procedure requires the filing of only a single application. The same three firms also declared that when viewed in relation to the other regulatory and license requirements necessary to marketing devices in Europe, the CE-mark approval process is not the most demanding in nature. Table 6 cites the case firms’ view of the CE-mark approval process.

<table>
<thead>
<tr>
<th>Table 6. View on the CE-mark approval process</th>
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<tbody>
<tr>
<td>VP, AnnoMed</td>
</tr>
<tr>
<td>“It's not that hard to get CE-mark approval. It's not easy, but it is not the hardest part either.”</td>
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<tr>
<td>CEO, Cearus</td>
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<tr>
<td>“...I believe it’s only a few countries were the manual can be in English, elsewhere the manual has to be in the local language for the CE-mark. The language barrier is a challenge for us; it’s very expensive to make sure that all the manuals are up to date and in the right language, we translate them to around 16 different languages...”</td>
</tr>
<tr>
<td>CEO, Lavace</td>
</tr>
<tr>
<td>“The CE-mark is for the present management not a certainly complicated procedure. It is known what needs to be done.”</td>
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</table>

In contrast, Binava found the CE-mark approval process burdensome, they anticipated that the process would be much more expedient and therefore they began to establish contacts and sign distributor deals in potential markets even before their devices was CE-mark approved. Additionally, two other aspect of the CE-mark approval process that have been considered burdensome for some of the case firms is that the manual for a medical device must be translated into the local language of each EU member state and that in certain markets, for
example Italy, the device must be registered with the national authorities stating that the product is available on that market.

5.2.3 Foreign market entry

Among the case firms there are two alternative sales methods when establishing operations abroad: by establishing a firm-owned sales subsidiary or by way of distributor arrangement, which is described in Table 7 below.

<table>
<thead>
<tr>
<th>Subsidiary</th>
<th>AnnoMed</th>
<th>Binava</th>
<th>Cearus</th>
<th>Lavace</th>
<th>Nione</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK, USA, Switzerland</td>
<td>Germany, UK, USA, Netherlands, USA</td>
<td>Canada, Japan, Finland, Norway, USA</td>
<td>-</td>
<td>France, USA</td>
<td></td>
</tr>
</tbody>
</table>

Table 7. International market presence

AnnoMed, Binava, Cearus and Nione all stated that their primary motivation for forming their own subsidiary in a foreign market, instead of using a distributor, was that they had identified particular countries as having a high potential for them to become key markets for future sales, and therefore using a subsidiary would enable them to establish a stronger local presence. For other markets with lower sales potential, the four case firms tended to lean towards partnering with a local or multinational distributor, as that approach would provide the firms expedient access to a broader range of potential customers in the market. Lavace’s CEO stated that their sales method is entirely dependent on distribution networks.

Distributors differ in size ranging from small regional distributors to large multinational distributors. Binava, Lavace and Nione chose to partner with local distributors, while AnnoMed and Cearus made arrangements with larger multinational actors. Even though marketing through distributors is the most common way for the firms to establish sales operations abroad, they must proceed with caution when using this type of sales channel. According to Binava and Cearus, one challenge is finding a distributor with the right profile to market their products. The firms needed to find suitable distributors that have a strong portfolio of complementing products that the physicians desire as well as requiring that the distributors have knowledge about the medical field in which the case firms products operate in. Finding the right distributor is according to Lavace’s CEO, a process that requires multiple
marketing and networking activities. Then, once a local partner is found, educational and supporting activities are necessary in order for the distributor to become familiar with the products in order to sell them.

Typically, many distributors represent several competing products and the sales representatives, who work on commission, can choose for themselves which product that they think can most easily be sold. Both Binava’s CoFo and Lavace’s CEO saw this situation as giving rise to the need of aligning the goals of the distributor with their own. Cearus VP further stated that one downside of using a distributor is that the firm looses direct contact with the end customer and this can have an effect on information flow, both to customers as well as feedback to the firm.

A shared view among the case firms’ is that when establishing a subsidiary in a foreign market, it is important to hire local employees in order to avoid language barriers and to recruit employees that have previous experience with similar products. Relevant experiences includes a familiarity with the technology and treatment method or having experience from a position from either large or small firms that have successfully conducted operations abroad earlier. Beyond language skills and relevant experience, employees were recruited on the basis of their value in terms of both their personal and business networks. For example, Nione’s MD was recruited in the beginning of the firm’s internationalization phase and partly on the basis of relevant prior experience and also for the MD’s contacts and previous relationships with distributors which proved to be valuable for Nione at the time.

5.3 Understanding foreign market praxis

A barrier encountered by AnnoMed, Binava, Lavace and Nione was gaining an understanding of the praxis in the foreign markets. With praxis they refer to the methods of treating patients and which devices were applicable in the treatment method.

The four case firms all experienced difficulties in understanding the methods practiced in different countries and, in particular, the best ways of presenting or marketing their products in order for them to be adopted as a tool utilized by, for example, a physician at a hospital or clinic. Table 8 cites the four case firms’ view on foreign market praxis.
Table 8. View on foreign market praxis

<table>
<thead>
<tr>
<th>MD, AnnoMed</th>
<th>CoFo, Binava</th>
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<tbody>
<tr>
<td>”...You have to find the specifics, which are different in every country. For instance asthma in UK is treated by nurses, in Germany by general practitioners, and in Italy patients go to specialists...You have to really adapt the medical message to what is interesting to the local culture, behaviour, and also find out what are the regulations, what we can say, whom we can approach. This process is really complex.”</td>
<td>”...You have to take one country at a time and use consultants that can help you understand how things work in each country...first we educate the consultants on our product then they hold our hand when we enter the market.”</td>
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</tbody>
</table>

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<tr>
<th>HRD, Lavace</th>
<th>CEO, Nione</th>
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<tbody>
<tr>
<td>”...We first approach a hospital in the region and contact a doctor, to identify the conferences he or she usually attends. Then you try to generate interest by some of the doctors there by saying that we’ll have a commercially viable product and that you are willing to let them test it. You maybe have to repeat this a few times and cover a few costs, but that is what it takes to become established abroad.”</td>
<td>”In every active market we have established at certain hospitals so called Competence Centers, a type of reference site for our technology, in order to spread the knowledge of our method to physicians and practitioners. We have these Competence Centers all over Europe.”</td>
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</table>

Cearus CEO declared that they were aware of the importance of understanding that each foreign markets had a different praxis. However, they did not view this as a barrier, as they early on had decided that it would be the responsibility of their distributors for dealing with the challenge of understanding their local foreign market and how the product should be marketed there.

All of the case firms have utilized assistance from the trade organization Business Sweden at one point or another during their internationalization towards new foreign markets. In terms of gaining knowledge about the healthcare sector in a foreign market, for example, Binava’s COO explained that Business Sweden helped them understand the complexity of the French healthcare market and provided insight in the process of deciding whether Binava should enter the French market.

In other ways Business Sweden can also function as an extended sales and marketing resource. AnnoMed’s VP explained that when AnnoMed entered the German market they used Business Sweden to help them reach out to new customers. Lavace’s HRD revealed that Business Sweden is commonly used as an intermediary when attending fairs and exhibitions in foreign markets. In Lavace’s case, it is a small firm with limited financial resources that precluded them attending all fairs and exhibitions on their own; therefore, they were represented by Business Sweden at some fairs. Another important dimension is the
relationship between Business Sweden and the Swedish Embassy in the foreign markets. Both AnnoMed’s VP and Lavace’s CEO explained that they had utilized the relationship between Business Sweden and the Swedish Embassy in foreign markets. When AnnoMed hosted an activity, such as an advisory board meeting, it chose the Swedish Embassy as the venue in order to attract representatives to attend.

5.4 Creating awareness and legitimacy

In order for a medical device to be successfully sold in a new market, all the case firms confirmed that it is necessary to generate awareness and recognition of the product and how practitioners and physician can use it for patient treatment. All the case firms refer to this process as creating “legitimacy”. Absent legitimacy, it is an uphill battle to sell medical devices, as practitioners and physicians tend to avoid using devices that they are not familiar with or do not know precisely how they function. Generating legitimacy is viewed as something that a medical device manufacturer cannot accomplish by itself, but instead, it must be established by way of local relationships and endorsements that vouch for the legitimacy of the product. Binava’s CoFo emphasized this, which is acknowledged by all the case firms:

“It is a relationship industry, so if you haven't worked up a trust with the customers it will be very hard to come there and sell a product.”

These local endorsers, referred to by the case firms as “Key Opinion Leaders” (KOLs), must have an established network and have influence in the particular medical field of the firms’ products, and all the case firms’ were also unanimous in the view that use of KOLs is the main tool employed to create legitimacy for their products. Table 9 illustrates the case firms’ view and use of KOLs in their pursuit of creating legitimacy.
Table 9. Comments on the use of KOLs

<table>
<thead>
<tr>
<th>VP, AnnoMed</th>
<th>CoFo, Binava</th>
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<tr>
<td>“The doctors (KOLs) are an important network for us, we keep them active in different ways by establishing advisory boards...I sit down and tell the KOLs that we have a really good method [device] that everyone should use, the question is how are we going to make that happen? A typical KOL activity is that they write a joint consensus letter explaining and agreeing on the clinical method and how it should be applied in practice.”</td>
<td>“First, it’s about approaching the early adopters, who are willing to test a new product. Then you advance towards the old-fashioned and conservative doctors, once you convince them then you have the best ambassadors [KOLs] out there for the product.”</td>
</tr>
<tr>
<td>VP, Cearus</td>
<td>MD, Nione</td>
</tr>
<tr>
<td>“We use KOLs to compose local publications...You can’t publish an American study in Germany, or a German study in France, it has to be local and preferably include a reference to a local KOL.”</td>
<td>“The KOLs are very important but you have to be careful not to overuse anyone so that its not at all times the same person saying the same things, instead you need several people [KOLs] for it to work.”</td>
</tr>
<tr>
<td>HRD, Lavace</td>
<td></td>
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<tr>
<td>“It's critical to be acknowledged in each market, both regulatory [CE-mark] and with the KOLs. In Europe there are a few KOLs in each country, in the Nordics maybe two if we are lucky, so you have to find a way to approach and convince the KOLs.”</td>
<td></td>
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</table>

It was found among the case firms that when entering a new market it is important to quickly build up a network of KOLs and that the KOLs publish studies about the products, hold presentations at conferences and are active on advisory boards (a type of network of KOLs). By way of these activities, the KOLs generate an awareness of the product and its features, as well as boosting legitimacy and influence the buying decisions of potential customers.

All of the case firms acknowledged that creating legitimacy is a country specific activity, for example, Cearus VP stated that a KOL study, which gives legitimacy to a product or a method in Germany does not confer any legitimacy of the product in France, and vice versa. The local approach is something that all the firms recognized as necessary in order for a KOLs to have the desired influence. AnnoMed’s VP took this view a step further, explaining that the approach varies when creating legitimacy as it is almost regional instead of national. In contrast to a national or even regional approach, AnnoMed established a pan-European advisory board with KOLs to create legitimacy among countries.

Generating legitimacy is the main purpose of utilizing KOLs, the firms use these relationships in order to create a buzz about their products, or lobbying as AnnoMed’s MD referred it to.
This was a term, however, that the firms were unwilling to associate with their networking activities. Accordingly, both Lavace’s HRD and Binava’s CoFo decided to maintain the relationships with their KOLs at an arm’s length. Apart from the risk of a KOL loosing his or her credibility, and thereby negatively affecting a product’s legitimacy, a too cozy relationship with a network of physicians and procurers might also expose the firm to the risk of a bribery situation. According to Binava’s CoFo, previously they could pay for trips for the KOLs, which would be forbidden today, and thus some legitimacy activities are more limited today than earlier.

5.5 Reimbursement and coverage

When entering a new foreign market AnnoMed, Binava, Cearus and Nione stated that they needed to establish a relationship with each markets competent authority as well as the private insurers in order for the case firms product or method to be part of the reimbursement and coverage system. For instance, AnnoMed argued that the British competent authority was revising the cost benefits in the national public health plan and therefore it was a great opportunity for AnnoMed to establish a relationship, through consultants, with the British competent authorities and introduce their product. AnnoMeds’ VP stated that if the review is positive, their products would be reimbursed to a level that will increase their possibilities for growth in markets shares of significance in the future. Further, Niones’ CEO did also point out England as a rising market for their product as the reimbursement policies have shifted in their favor.

All the firms recognized that the coverage systems and reimbursement procedures differs from market to market, and that some systems and procedures are very complicated and thus difficult to understand. Binava’s CoFo, expounded on this, saying that seeking insurance coverage in new foreign markets is somewhat of a catch-22-moment, explaining:

“First, you have to show that the you have done a hundred treatments, then you can apply for the coverage. In order to do these hundred treatments the physicians have to buy the products and they won’t buy the product in case they aren’t covered by the insurance.”
CHAPTER 6: ANALYSIS

6.1 SMEs intention for internationalization

For all the case firms, to internationalize was an obvious course of action from, or near, inception. This was, to a large extent, due to the fact that the domestic market was too small for their future growth. In other words, internationalization was essential for the future survival of the case firms. When considering the characteristics of healthcare firms, it is important to acknowledge that medical devices are highly expensive to develop and market. Therefore it could be argued that in order to be profitable the case firms had no choice but to enter the international arena. This reinforces the premise that the inadequacy in size and potential of domestic markets influences a SMEs decision to internationalize (Reuber and Fisher, 1997; Barnes et al., 2006). Furthermore, the decision to internationalize is in line with Reuber and Fisher’s (1997) explanation that internationalization, for firms with a limited domestic market, is a matter of necessity, if not survival, rather than a strategic choice.

However, it could be assumed that the decision to internationalize for these firms comes as a natural step given the origin of the firms. All of the firms had been spawned from research projects, with the founders coming from Sweden’s top universities, by which they were exposed to networking and knowledge activities such as publishing research papers and attending international conferences. Hence, it can be assumed that the founders’ comprehension of the domestic and foreign markets led them to conclude the limitations of Sweden as their only market, providing another obvious driver to internationalize. This could further imply that the language barriers, as a hinder for internationalization, is somewhat minimized, as the recognized language in academia is English.

6.2 Grounds for foreign market selection

Selecting a new foreign market to enter is a decision primarily driven by network relationships, which is consistent with Coviello and Munro (1997). Furthermore, it has been found that employees’ previous experience in the foreign market and knowledge about its specifics was also two influential drivers. Since the majority of the case firms founders and employees had prior international experience, either on a research or commercial level, it could be argued that the decision of which foreign market to enter is highly influenced by relationships that emerged in the founders and employees previous careers. Consequently, in
order to internationalize in the healthcare industry previous international experience is imperative.

Commercial size of a foreign market and geographic distance from a firm’s headquarters were also two significant criteria identified as important when selecting which foreign market to enter. These findings demonstrate that the decision of which market to choose is also strategic. However, it can be maintained that the decision of which particular market to choose might not be the most critical decision in the internationalization process, as a majority of the markets in the EU are geographically close and of considerable commercial size. This is supported by the fact that many times the decision of which market to enter is also influenced by distributors, who approach the firms with business propositions to partner with them in their home market.

One example describes how a proactive distributor showed interest in marketing Binava’s products in the distributors home market and that this interaction later led to a partnership. Welch and Welch (1996) explain that this type of partnership is created by unintended network development caused by an unanticipated evolvement of an actor that becomes part of a firms network. It can be argued that when SMEs, such as the case firms, become involved with distributors through unintended network development, they can influence the selection of which foreign market to enter, and furthermore the level of success in the market, which is in line with Coviello and Munro (1997) who claim that a firm’s success is highly dependent on the firm’s network and relationship when entering a new foreign market. Given this example it could be argued that a firm’s attractiveness in a foreign market has an impact on the choice of which market to enter, implying that highly attractive firms are regularly approached by distributors that desire to represent their products.

6.3 Foreign market prerequisites

6.3.1 Regulations

The CE-mark approval process is imperative for healthcare firms in their internationalization process in the EU. AnnoMed, Cearus, Nione and Lavace did not experience the process as a hindrance, but instead as an industry wide requirement that all firms within the medical device industry face whether on the international or domestic level (within the EU). Considering that the firms themselves control the CE-mark approval process, it is not
surprising that it does not present any challenges as many of the case firms’ employees had experience from earlier product approvals and are familiar with the technical requirements. One of the case firms, Binava, viewed the approval process as a time consuming and costly process, thus it is natural that some firms, especially SMEs with limited resources (c.f. Barringer and Greening, 1998; Fillis, 2001; Ruzzier et al., 2006), consider certain international regulatory activities as burdensome. For instance, in order for the firms to sell their products in foreign countries they need to have the product manual in each specific country’s language.

Furthermore, even though the CE-mark is not a arduous barrier today, it should be noted that the process has been criticized for its lack of transparency (Wilmshurst, 2011; Cohen and Billingsley, 2011) and therefore in the future it is likely that the case firms will be subject to further regulatory oversight.

6.3.2 Local praxis and legitimacy

In all the case findings, it was imperative for the case firms to create awareness and establish legitimacy of their products or method in order to generate sales in a new market. This was accomplished by fostering activities with local key opinion leaders (KOLs), who influenced the national competent authorities decision of which products are to be covered by the reimbursement and coverage system. This verifies the importance of firms working within the healthcare industry to use their relationships with KOLs to signify for the national competent authorities how society can leverage on a socio-economic level by using their products. This is in accordance with Hadjikhani et al., (2008) who argue that legitimacy is the perception of a firms’ position in society and further can be seen as a driver to influence the firms’ political standing. Therefore it could be argued that it is crucial for firms operating in the healthcare industry to create awareness and legitimacy in relation to the political scene and private insurers in order to sell their products.

A challenge to achieving success in the healthcare sector is that each market is characterized by different national praxis and contrasting views on patient treatment methods. To overcome this, the case firms utilized their relationships with local KOLs to get endorsements of their products on a national level, which subsequently led to an enhancement of the firms’ credibility. This signifies the importance of being an insider in the local networks, and the firms achieve this by way of introductions and endorsements facilitated by the KOLs, which
is in accordance with Chetty and Patterson (2002) who argue that firms inside a network gain a level of credibility that they would not otherwise have. It also implies that the KOLs have a significant bearing on a firms’ success when entering a new market and they should therefore be carefully selected with regard to being a respected authority within his or her medical field in order to have a significant impact.

It can be argued that the compilation of network relationships identified in this study are entirely market specific, which contradicts the view of Johanson and Vahlne’s (2009) view that firms are part of global networks and are not bound to specific countries. This is a characteristic unique to the healthcare industry, as legitimacy must be created locally. Furthermore, the KOLs create legitimacy for the firms to interact with local physicians or procurers, claiming that legitimacy is created easier when the KOL and the physicians share the same nationality, language and culture.

Welch and Welch (1996) argue that networks are not a predetermined criterion in a firms’ strategic planning cycle. This view can be contradicted as found in the case findings; the case firms are dependent directly on the KOLs, which are important components of the firms’ strategic planning when internationalizing. A majority of the case firms declared that interconnecting with KOLs in order to educate physicians and procurers in a specific market was necessary before a product could be successfully distributed in a new market.

Overall, these findings confirm that, before a firm can sell their products in a market, firms within the healthcare industry must establish relationships with prominent physicians and researchers, specifically KOLs, which can influence the choice of device and patient method that is utilized is their home market. Furthermore, a failure to understand the praxis and routines in a foreign market creates a barrier for an SME’s internationalization effort.

6.3.3 Sales through distributors and subsidiaries

As shown in the case findings, the firms’ sales channels were established either by forming a subsidiary or by way of partnering with distributors. Upon commencement of the internationalization process the case firms migrated to the use of distributors instead of subsidiaries when venturing into new markets. By partnering with a distributor that had local presence in a foreign market the case firms gained access to market knowledge as well as access to the distributor’s network, which included useful KOLs contacts. It is therefore rational that by contracting with a local distributor when entering a foreign market, SMEs in
the healthcare sector can avoid many of the barriers of internationalization that are recognized in the SME internationalization literature. Importantly, the problems associated with limited competences (Eramilli and D’Souza, 1993), limited resources, both financial (Fillis, 2001; Ruzzier et al., 2006) and human (Barringer and Greening, 1998) can all be avoided or minimized by using a local distributor, provided, of course, the distributor has a sufficient presence and a established network of valuable contacts in the foreign market.

As earlier mentioned, the case firms recruited local employees when establishing sales channels. Considering that the products and devices the case firms produce are highly complex, it can be taken for granted that the recruitment of local employees is a matter of necessity as it would be difficult for non-native speakers to fully espouse on the features of a product in a convincing manner. It is therefore self-evident that by recruiting local employees SMEs can reduce the liabilities that come with outsidership (Johanson and Vahlne, 2009) when entering a new foreign market. Even though the current literature does not provide an understanding of the challenges SMEs face in terms of market praxis, it can provide arguments that relate to cultural gaps as Barnes et al. (2006) or psychic distances as Johanson and Vahlne (1975; 1990) defines it.

6.4 Relating to the conceptual model

The conceptual model in this study takes into consideration that internationalization in the healthcare industry is influenced by the elements network and knowledge within the context of the political institutions. The empirical findings show that these elements and the political context have additional aspects that were not explained earlier, thereby creating a need to supplement the comprehension of the internationalization process in relation to the conceptual model.

The utilization of KOLs is vital to the internationalization process, as they have assisted the case firms in realizing potential opportunities that the firms could not have achieved on their own. In relation to the network element, however, arguable the KOLs are not part of the SMEs network, as they are neither business nor political actors. Rather, the KOLs should be seen as intermediaries, working outside a firms’ network, and that they act as a resource to help create legitimacy within the firm’s network, among both the business and political actors.
The model can be further developed to categorize KOLs as an additional institutional layer, equivalent to how the political context is described in the original model, since the KOLs are ubiquitous in the healthcare industry. In the internationalization process, how successful an SMEs is can be dependent on how well they establish and manage relationships with KOLs, implying that KOLs can have a significant impact on the success or failure of SMEs in their attempt to enter the international market.

Furthermore, the model describes how the political context influences and creates the framework for how SMEs in the healthcare industry must operate. This study however, reveals that the rules and regulations had limited impact on the internationalization process, which earlier has been argued as a central issue in the conceptual model. The political context therefore indicates that the regulatory requirements are not exclusively related to the internationalization process itself, but rather should be seen as an industry wide necessity applicable to all SMEs in the healthcare industry regardless of whether they internationalize or not.
CHAPTER 7: CONCLUSION

The purpose of this study was to investigate why Swedish SMEs within the healthcare industry internationalize and explain how and in what ways the internationalization process unfolds. Previous academic research on the subject is scarce, and thus the aim of this study was to contribute to the international business literature by crafting a theoretical model of the internationalization process and to investigate on an empirical level the activities that SMEs in the healthcare industry undertake when internationalizing. Finally, the intent was to provide insights for managers within the healthcare industry to enable them a better understanding of the environment, challenges and opportunities that must be undertaken or confronted in the internationalization process.

The internationalization process for SMEs in the healthcare industry is by many ways unique and several aspects have been identified as imperative. On the aspect of why to internationalize, the primary driver is that the domestic market has limited potential for future growth. Consequently, for the SMEs studied it was never a question of whether they should internationalize, but rather it was seen as a necessity, if not a matter of survival, for SMEs originating from smaller markets such as Sweden. Additionally, the case firms founders previous experience and international relationships provided a further motivation for internationalization.

A key finding identified when understanding the internationalization process was that each market is characterized by different national praxis and contrasting views on patient treatment methods, which was recognized as a challenge among the case firms. In order to overcome these barriers it is imperative for SMEs to create and utilize their relationships with key opinion leaders (KOLs), as they endorse and create legitimacy for the firm’s product or device among practitioners and physicians. Consequently, the KOLs have a significant bearing on a firms’ success when entering a new foreign market.

Considering the regulatory requirements, the CE-mark approval process is a necessary step for the internationalization of medical device manufacturers in the healthcare industry, although it is not to be recognized as a barrier for the internationalization process itself as this is a industry wide requirement that all firms face whether on the international or domestic level (within the EU).
7.1 Managerial implications

Our investigation of the internationalization process of healthcare firms can provide firms with a better understanding how this process proceeds and the important factors to consider before and during the internationalization process. From a managerial perspective, managers of SMEs must be aware of the impact that KOLs have when venturing to new foreign markets, and should therefore identify and utilize local KOLs early on in the internationalization process. This can be done by constantly engaging in networking activities, such as attending conferences, exhibitions and trade fairs, but also through utilizing the networks of the distributors.

7.2 Limitations and suggestions for future research

All the above-mentioned elements have been highlighted as foundational in the internationalization processes. Due to this, and as a limitation, this study does not provide a completely generalizable landscape but instead should be viewed as an initial research of the internationalization process of SMEs acting in the healthcare industry. Further, as the research only covers SMEs in the Swedish market, these findings might not be generally applicable to firms that have other home markets. Therefore, we encourage future research to aid insight of SMEs internationalization in this field by investigating firms originating from other countries to establish a more generalizable picture of the internationalization process. Further, while conducting the research, it became clear that in this industry small firms contra medium sized firms differ from each other significantly in terms of how they encounter the internationalization process and therefore it would be interesting for future research to investigate how the firms size impacts the internationalization process. Lastly, considering the unique characteristics of this industry, it would be interesting to further examine the procurement process that occurs in other healthcare markets.
References


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APPENDIX

INTERVIEW GUIDE

(a) How has the firm internationalized and why is the firm established in the countries it is present in today?

- Reasons behind the internationalization, market choice, activities to facilitate internationalization and the use of trade associations.

(b) How and to which degree has aspects of regulations, patents, certifications, etc. affected the internationalization process?

- Regulatory inferences, product approval process (CE-mark), certification, product trials, dialogue with domestic and foreign regulators and policy makers.

(c) Throughout the internationalization process, what have been the foremost challenges?

- Difficulties and barriers for internationalization.

(d) How and to which extent has the firm and its management used business and personal networks to influence the internationalization process?

- Informant’s background, previous experiences and role in the firm, employees’ previous networks and relationships.