INTERNATIONALIZATION AND INSTITUTIONAL CHANGE
AN INSITUTIONAL-BASED PERSPECTIVE OF INTERNATIONALIZING
SWEDISH SMES WITHIN THE HEALTHCARE INDUSTRY

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ABSTRACT

Internationalization of small to medium-sized enterprises (SMEs) in the healthcare industry has experienced rapid growth in the recent decade. Although research on understanding this process and what drives it has been conducted, previous studies are limited in recognizing the full influence of both domestic and foreign institutional environments. This study investigates the internationalization of four Swedish SMEs operating in healthcare markets through an institutional-based perspective, asking how and why SMEs internationalize and how they manage different institutional environments. By analyzing the empirical case findings in the light of a theoretical framework based on internationalization theory, institutional theory and institutional entrepreneurship we attempt to answer our research questions mentioned above. The thesis concludes that internationalizing SMEs experience a large range of barriers of which most can be effectively overcome by cooperation and access to networks with key opinion leaders. Findings on managing the institutional environment pointed to that the domestic institutional environment can act as a driver for internationalization, while the ability to influence and change foreign institutional environments were found to be near impossible for a single firm. However, our study shows that attempts at institutional change can be achieved through cooperation together with other firms, organizations and most importantly influential networks with key opinion leaders. Internationalizing SMEs within the healthcare industry might not be institutional entrepreneurs in its true sense; however they have the possibility of getting there.

Keywords: Internationalization, SME, Institutional-based perspective, Institutional entrepreneurship, Networks, Key opinion leaders, Healthcare industry.
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CHAPTER 1 - INTRODUCTION

The responsibility of healthcare has traditionally been the role of government, with the objective of providing access to an affordable and sustainable healthcare for their citizens (World Health Organization, 2010). In the last few decades, healthcare spending in developed countries as a proportion of GDP has significantly increased (OECD, 2013). In the 1990’s emerged the idea of “New Public Management” inspired from the private sector, stating that government alone are lacking in quality and efficiency (Hood, 1995). This idea opened up for a wave of privatization within several industries and allowed private actors to enter healthcare markets. Following this development, healthcare markets have experienced significant growth during recent years and have become more open which has further increased the opportunities for private actors (Anell et al., 2012). The growth and privatization of this industry is connected with an increase in lifestyle-related diseases; ageing populations and extended life expectancy which have created a greater demand for healthcare and has led to new challenges and opportunities within healthcare that governments alone will not be able to meet. These challenges must therefore be met together with both governmental and private actors (Orava, 2002). Hence there are growing opportunities for private actors within the healthcare industry to provide innovative and technological healthcare solutions to cope with these challenges.

Although these challenges and opportunities are a reality on a global scale, we have focused on the rapidly growing Swedish healthcare industry. The industry has experienced a rapid development both regarding privatization, growth and reform (Anell et al., 2012). It has during the past decade been one of the fastest growing industries in the country (Vårdföretagarna, 2014), with many innovative private firms entering the market, most of which are within the segment of small and medium sized enterprises (SMEs)¹(Vårdföretagarna, 2014). The growing demand for innovative healthcare solutions to meet the challenges of the future has been enabled by recent reform in healthcare markets worldwide, and provided opportunities for growth and expansion for SMEs in the healthcare industry (European Commission, 2012). This is true for domestic growth as well as possibilities for international expansion. Sweden, a small and open economy is dependent on foreign trade and exports of goods and services. The combined value of the export of goods and services have gone from 27% in 1975 to 49% of Sweden's gross national product in 2012 and accumulates to around 1 800 billion SEK (Business Sweden, 2013). Consequently, the

¹ Defined as enterprises employing up to 250 people or a turnover of 50 million euro (OECD, 2013)
healthcare industry is one of few industries that have not until recently started expanding into foreign markets, known as internationalization, and are now facing possibilities of growth in the global arena (Orava, 2002).

Internationalization is the process that organizations undertake in expanding their operations beyond the borders of their country of origin. Research on internationalization has foremost been focused on large multinational corporations. However due to a more integrated and globalized world economy in combination with a trend for more open markets, more and more SMEs are able to internationalize (Lu et al., 2001). Earlier research does not fully cover the process of how SMEs internationalize as well as how SMEs manage the pressures from foreign markets (Kostova et al., 2009; McDougall & Oviatt 1996; Lee et al., 2012; Lu et al., 2001). Internationalization presents an interesting arena for this phenomenon and, despite the increasing focus on understanding how SMEs internationalize, relatively few studies focus on how SMEs internationalize within highly regulated markets like the healthcare industry (c.f. Barnes et al., 2006; Holden, 2005). This is interesting in regards to SME’s in the healthcare industry, which just recently have started to be affected by globalization and international expansion. However, the field of international business has lacked in exploring the important relationship between SMEs and both the formal and informal institutions that are embedded in different market environments. These institutions can exert pressures on firms to act, operate and conform in certain ways; especially for SMEs (Peng et al., 2008).

Firms experience pressures from foreign institutional environments when internationalizing but there are also possibilities for firms to affect and sometimes change institutional environments (Kostova et al., 2009; Peng et al., 2008). This ability to change institutions is called institutional entrepreneurship and can be explained as the ways organizations not solely adapt to but instead affect and influence the surrounding institutional environment with a focus on change rather that continuity (Garud et al., 2007; Leca et al., 2008). Additionally, previous research of internationalization has not only lacked a clear focus on SMEs (Barringer & Greening, 1998; Kalantaridis, 2004; Le et al., 2012; Lu et al., 2001; McDougall & Oviatt, 2000; Nummela et al., 2006) but they have also lacked to fully recognize the impact of and ability to change the institutional environment (Peng et al., 2008).

Accordingly, there is a gap in research between theories of internationalization and institutional theory on how conformity and adaptation to institutional environments affect organizations entering new markets. Further, there are few studies on how SMEs within a
highly regulated field are able to affect the institutional environment in ways that enable successful internationalization.

1.2. Aim of the thesis

The knowledge about how SMEs within highly regulated industries internationalize and interact with the foreign institutional environment is limited. Therefore, this thesis aims to increase and widen our understanding of how the SME’s internationalization process unfolds with particular focus on why and how SMEs internationalize and how they are affected by the foreign institutional environment. Questions that need to be answered are therefore:

- Why and in what way do SMEs internationalize?
- How do they interact with the institutional environment at foreign markets?

The primary objective of this thesis is to study the internationalization process at a number of Swedish SMEs that operates within the healthcare industry. The healthcare industry has been chosen due to its high regulations, rapid growth and the recent changes that this industry has experienced, as well as limited previous research of how SMEs internationalize in a highly regulated industry. The thesis contributes to the field of international business in understanding why and how SMEs internationalize. Additional contributions will be empirical evidence of how SMEs operate in a highly regulated industry and how they interact with the foreign institutional environment. Lastly, the thesis contributes with managerial implications providing knowledge for managers of how a firm can successfully internationalize and manage the difficulties it entails.
1.3. Thesis disposition

Chapter 2: Literature Review

The theory section goes through internationalization theory from an institutional based perspective with the focus on SMEs. After an explanation of why an institutional based perspective is essential, a conceptual model will be presented. The model will go through key concepts of the literature review and explain how they are all interlinked and adequate to help answer our research questions.

Chapter 3: Methodology

Here we explain how the study has been conducted, why it has been conducted in that particular way and how we used the findings to be able to draw our conclusions. It also explains why and how we have chosen our cases. Furthermore, the limitations of the study and what actions we have conducted to minimize those limitations are presented.

Chapter 4: Findings

The chapter will give a short overview of the healthcare industry as a whole and the medical device industry in specific. Since this industry is global and highly regulated, an understanding for the institutional environment is vital, if the reader shall be able to fully apprehend the cases. For further understanding of the cases, a brief history will be presented for each case. Afterwards the main findings will be presented in a narrative way under separate but interconnected themes that have been decided by the theoretical framework.

Chapter 5: Analysis

The chapter presents and analyzes the findings in the light of the theoretical framework under three separate main themes in order to understand and answer our research questions.

Chapter 6: Conclusions

The chapter concludes the thesis by answering the research questions, contribute to existing theoretical frameworks, suggest managerial implications and also account for the thesis limitations in order to propose topics for future research within the field. We also connect to our previous theoretical model and revise it in accordance with our findings.
CHAPTER 2 - LITERATURE REVIEW

2.1. An Institutional-based perspective of the Internationalization Process

Internationalization has been studied and explored in modern organizational studies of international business area since it is a natural step in a firm’s evolution and one of the most important decisions for an expanding company (Barringer & Greening, 1998; Johnson & Vahlne, 1977; 1990; 2003; 2006; Johanson & Wiedersheim-Paul, 1975; Sommer, 2010, Zou & Stan, 1998).

Previously, studies on internationalization have focused on multi-national corporations (MNCs) (McDougall & Oviatt, 2000) since those organizations have possessed the capital and potential to go abroad and internationalize (Lu & Beamish, 2001). However, because of a more integrated and globalized world in combination with a trend of open market environments and technological improvements (Lu & Beamish, 2001) more small and medium sized enterprises (SMEs) have been able to internationalize. The subject have therefore become a popular research object among scholars (Barringer & Greening, 1998; Kalantaridis, 2004; Le et al., 2012; Lu et al., 2001; McDougall & Oviatt, 2000; Nummela et al., 2006). Despite the increasing focus on understanding how SMEs internationalize, relatively few studies focus on how SMEs internationalize within a highly regulated field like the health care industry (c.f. Barnes et al., 2006; Holden, 2005). Additionally, previous research of internationalization has not only lacked a clear focus on SMEs (Barringer & Greening, 1998; Kalantaridis, 2004; Le et al., 2012; Lu et al., 2001; Nummela et al., 2006) but they have also lacked to fully recognize the impact of the institutional environment (Peng et al., 2008).

As stated, many previous studies have lacked to recognize the institutional environment and are largely based on two main theories, one is proposed by Porter (1980) and has an industry-based view which proclaims that companies go beyond their domestic market due specific conditions within the particular industry (Peng et al., 2008). The other theory, represented by Barney (1991), has a resource-based view and claims that the strategies to move abroad are due to firm-specific differences. However, both of these theories view the formal and informal institutions that make up a markets institutional environment as a background context and not as one in which the firm is embedded in (Peng et al., 2008). A main reason for why two of the traditionally dominating theories lack to contemplate the institutional environment in the domestic and the foreign market is because these were designed long time ago. At that time,
when a company “moved to new markets” it often meant to another area in the same country and thus was not exposed to any significant institutional environmental differences worth considering (North, 1990; Peng et al., 2008). However, today in a prevailing integrated and global world, the institutional differences between the domestic and foreign markets can be very apparent and need to be considered when studying international business (Peng et al., 2008). However, in order to fully comprehend how institutions affect the internationalizing company we must first understand what institutions are.

Institutions are defined by North (1990) as “the humanly devised constraints that structure human interaction” but also by Scott (1995; 2007) as “regulative, normative and cognitive structures and activities that provide stability and meaning to a social behavior”. Thus institutions can be both formal and informal and can be an issue in both politics (e.g., corruption, trenchancy, policies), law (e.g., economic liberalization, regulations) and society (e.g., norms, attitudes, culture) all of which can affect the internationalizing company and its strategies (Peng et al., 2008). The field of international business has previously failed in highlighting the important relationship between these institutions that are embedded in the different market environments and the companies (Peng et al., 2008). Despite that, research is today starting to acknowledge institutions as embedded variables in the environment and is looking upon the dynamic interactions between institutions and companies as a part of firm internationalization (Peng, 2006; Peng, 2004; Peng et al., 2008). Therefore, one could argue that a companies’ strategic choices during internationalization is not only driven by specific industry conditions (Porter, 1980) or firm-specific differences (Barney, 1991) but are also influenced by the formal and informal institutions that exist, not only as background conditions, but instead directly determining companies strategies and their interactions with the institutional environment (Bruton et al., 2007; Carney, 2005; Chelariu et al., 2006; Delios & Henisz, 2000; Hill, 2007; Hoskisson, 2003; Ingram & Silverman, 2002; Khanna & Palepu, 2000, 2006; Lee et al., 2007; Lee & Oh, 2007; Lu & Yao, 2006; Meyer & Nguyen, 2005; Peng et al., 2008; Rodriguez et al., 2005; Teegen et al., 2004; Wan & Ring et al., 2005; Ma et al., 2006; Zhou et al., 2006).

2.2. The conceptual model

As previously argued, earlier studies of internationalization have not only lacked in explaining how this process unfolds for SMEs operating in the highly regulated healthcare industry (Barnes et al., 2006; Holden, 2005) but also lacked in recognizing the institutional environment as an important aspect (Peng et al., 2008). The institutional environment is an
important factor since it, with its normative, cognitive and regulatory rules together with all the physical actors, makes up the context where the company operates (Kostova & Zaheer 1999; Persson & Nagy 2011). Before the SME internationalize, it operates in its domestic market with its specific institutional conditions (Kostova & Zaheer 1999; Persson & Nagy 2011). Nevertheless, what makes the SME go abroad are specific internal factors and domestic or foreign market conditions that act as drivers and facilitates the SME’s expansion to a foreign market and thus acts as drivers for internationalization (Barnes et al., 2006). However, in order for the SME to successfully internationalize to the foreign market they face different barriers that might hinder the SME to set up business abroad (Evangelista, 2005; Hymer, 1976; Lu & Beamish, 2001; Mudambi & Zahra, 2007). In an effort to deal with these barriers, the SME can use different entry modes (Brouthers & Hennart, 2007; Schwens et al., 2011) as well as take advantage of the SME’s networks (Belso, 2006; Day, 1995 Chetty & Pattersson, 2002). If the SME succeeds in penetrating the barriers and establishing business in a foreign market, the difficulties are not over. Since the firm is used to operate at its domestic institutional environment with its specific conditions and actors, it now has to operate in a new institutional environment with other conditions, rules and actors. This institutional difference can cause legitimacy problems associated with the liability of foreignness (LOF); which also should be seen as barriers (Kostova & Zaheer 1999; Persson & Nagy 2011). Depending on entry mode and the use of networks, SMEs have the possibility to overcome or manage these problems. Nevertheless, these previous mentioned methods to overcome the institutional pressures which is caused by institutional differences are focused on the conformity of the firms to the foreign institutional environment which is often found to be costly or unmanageable (Chan & Makino 2002; Davis et al. 2000; Kostova & Zaheer 1999; Rosenzweig & Singh 1991; Xu & Shenkar 2002). New studies have shown that conformity is not the only way for an SME to face these problems; instead they can try becoming institutional entrepreneurs and attempt to influence or change the institutional environment after the firm’s needs and in that way try to deal with institutional differences and legitimacy problems (Peng et al., 2008). This reasoning is visualized below, in Model 1.
2.3. Institutional theory
Institutional theory has traditionally been concerned with how organizations establish their positions and achieve legitimacy in order to survive and make profit. This has been done by conforming to the rules, norms and social structure of the institutional environment (Meyer & Scott, 1994, Scott 2007). The institutional environment is set up of institutions, a term that refers to the regulatory, social and cultural aspects that exert pressures on organizations to adapt to the surrounding environment. These aspects define what is considered appropriate behavior and therefore exert conforming pressures on organizations not to act in an unacceptable manner (DiMaggio & Powell, 1983, 1991). The pressures of the institutional environment first identified decades ago have been summarized into three pillars by Scott (2007). These are regulative, normative and cognitive pillars. The regulative pillar guides organizations behavior by governmental legislation, industry agreements and standards for example. The normative pillar guides organizations in interaction with other actors by defining what is expected and appropriate in different situations, such as social or commercial situations. Values and norms are central to the second pillar, establishing the softer rules which organizations conform. The last and third pillar is derived from social behavior at a more individual level, such as cultural differences and language. This cognitive pillar is
important because it highlights the taken-for-granted and preconscious behavior present in the institutional environment that defines the right thing to do and is important for new actors to understand. These three pillars may resemble each other and often reinforce one another in a particular institutional environment (Bruton et. al, 2010; Scott, 2007). The importance of these pillars is significant due to if a company fails to understand any of them the company can risk losing legitimacy (Kostova & Zaheer 1999).

Organizational legitimacy is defined by Suchman (1995) as “a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate with some socially constructed system of norms, values, beliefs and definitions”. Therefore, in order to be successful, the SME need to fit in with different institutions (authorities, potential business partners, customers or governments) that defines the normative, cognitive and regulative rules (Kostova & Zaheer 1999; Persson & Nagy 2011). If the SME breaks the rules and thus do not obtain adequate legitimacy at the foreign market, it can hinder the company to survive or even enter the country (Kostova & Zaheer 1999). Also, it is argued that gaining legitimacy is the key for access to or taking advantage of market specific resources as governmental support, suppliers, customers, clients, capital and knowledge (Aldrich & Fiol, 1994; Meyer & Rowan, 1977; Oliver, 1991). The problem of legitimacy is a potential problem for every organization, however, it is especially critical and relevant to address for companies that operates in several different countries (Kostova & Zaheer 1999). Not only do these organizations have to deal with institutional pressure emitting from the domestic market; they need to co-op with several unfamiliar and different institutional pressures since every foreign market has its own specific institutional environment (Chan & Makino 2002; Kostova & Zaheer 1999). All these different institutional pressures restrain the company to act in different ways and if the company goes against any of the institutional rules, it can cause legitimacy loss that in turn could make it more difficult for the company to survive in the specific market. In order to deal with this legitimacy problem caused by pressure from the different institutional environments in each foreign market, some argue that the company need to isomorph (passively adapt the company and its action) to assimilate into the foreign environment; and only then can the company gain the much needed legitimacy (Chan & Makino, 2002; Davis et al., 2000; Kostova & Zaheer, 1999; Rosenzweig & Singh, 1991; Xu & Shenkar, 2002).

However, the view on how internationalizing companies manage legitimacy issues associated with the risks of being a foreign company has progressed to not only being seen as passive isomorphic behavior, but instead stating that an internationalizing organization can actively
manipulate, manage and alter the foreign institutional environment and in that way also the pressure upon the company (DiMaggio, 1988; Friedland & Alford, 1991; Greenwood & Hinings, 1996; Kostova et al., 2008; Lounsbury & Glynn, 2001; Oliver, 1991).

Legitimacy issues are as previously mentioned a dangerous reality for internationalizing firms. The term legitimacy is interconnected with the aspect of liability of foreignness (LOF) (Eden & Miller, 2004; Hymer, 1960) which during internationalization can create problems due to institutional differences between the domestic market and the foreign market of choice. This can cause a disadvantage for a foreign company relative to the domestic firms (Ashforth & Gibbs, 1990; Kostova & Zaheer, 1999). This disadvantage can lead to higher operating costs for the foreign company since they are unfamiliar to deal with local clients, customers, partners and other actors but moreover have specific knowledge about local institutions such as governments, authorities, potential business partners, norms or governments (Hymer 1976; Kostova & Zaheer 1999; Zaheer 1995). Both Kostova (1999) and Zaheer (2002) argue that these costs and risks of market failures are due to the liability of foreignness. Further, some institutional differences, and the costs related to them, are due to a lack of knowledge and experience and can be overcome by a steady accumulation of knowledge and in gaining experience of the foreign market (Johanson & Vahlne 1977; Zaheer 1995; Zaheer & Mosakowski 1997). Additionally, it can be overcome by developing trust-based relationships or be embedded in a network (Gulati 1995; Vahlne & Johanson 2009). Nevertheless, previously studies have been focusing on that isomorphic behaviors from the companies are the easiest way for them to avoid problems related to LOF and legitimacy. Today however, another concept has emerged as a response to these problems; institutional entrepreneurship which can help companies overcome LOF and legitimacy based problems without using an isomorphic behavior (Peng et al., 2008). New institutional research, especially tied to strategy in internationalization, highlights the interactive role of institutions in both enabling and constraining organizations ability to act. Institutions are much more than background conditions, rather they directly determine what means organizations have to affect the institutional environment and create a competitive advantage in new markets (Meyer et al., 2008; Peng et. al., 2008; Silverman & Ingram, 2002).

2.4. **Institutional entrepreneurship**

Institutional entrepreneurship represents the actions and activities of organizations in changing, influencing or affecting institutions (Levy & Scully, 2007). The concept can be extended to include actors who have a specific interest in particular institutional arrangements
or actors who use and/or leverage existing resources to create new institutions or change existing ones (Maguire et al., 2004). Early institutional studies have mainly considered the constraints under which organizations operates, while works on institutional entrepreneurship have aimed to build a theory of action based on the fundaments of institutional theory (Leca et al., 2008). The reason why institutional entrepreneurship is such an important aspect of both institutional theory as well as international business theory is because it enables companies to change the institutional environment instead of only changing the company after the institutional pressure (Leca et al., 2008). Thereby they can shape the institutional environment so it better fits the company’s needs and by doing so, the company can get an advantage over other actors at the arena (Leca et al., 2008). However, it has been widely debated among scholars of institutional entrepreneurship about what makes institutional entrepreneurship possible, where it is most likely to find an institutional entrepreneur and so on; however, no consensus can be drawn (Leca et al., 2008).

Despite that, it is argued that a company can rarely become an institutional entrepreneur by themselves, but must instead gather other key-actors behind their cause, and thus, by using the strength of multiple influences from different key-actors change the existing institution (Boxenbaum & Battilana, 2005; Fligstein, 1997; Greenwood et al., 2002, Leca et al., 2008). Foremost they must assemble a united group of actors that should consist of highly embedded agents (Lawrence et al., 2002), professionals and experts (Hwang & Powell, 2005). Thus, in order to become an institutional entrepreneur, the company must mobilize different key institutional and cultural actors if they shall succeed with the imposed change of the institution (DiMaggio, 1988; Fligstein 1997; Leca et al., 2008; Perkmann & Spicer, 2007; Rao, 1998).

Foremost, if the company wants to become an institutional entrepreneur, they must have a high level of empathy combined with social skills (Leca et al., 2008). They must then use these skills to be able to relate their goals with the interests of the identified key-actors (Fligstein, 1997). Those companies who succeed in using their social skills and uses empathy to convince the key-actors that changing the institution in a certain way is mutually beneficial, will have a chance of successfully becoming institutional entrepreneurs (Fligstein, 1997; Leca et al., 2008). Nevertheless, as one can understand that all institutional entrepreneurs can be considered as change agents, however, not all change agents can be considered as institutional entrepreneurs (Battilana et al., 2009). In order to be considered as true institutional entrepreneur a company must initiate a divergent change that breaks with the existing
institutional template as well as actively participate in the implementation of the changes (Amis et al., 2004; Battilana, 2006; Battilana et al., 2009; D’Aunno et al., 2000; Greenwood & Hinings, 1996). However, the underlying reason for this need for institutional entrepreneurship is the void between how the company operates and how the institutional environment is conducted (Peng et al. 2008). This void is often a result of an internationalization of a company into foreign markets and this internationalization is always sparked by one or several drivers that facilitate international expansion; as shown in Model 1.

2.5. Drivers and barriers of internationalization
In order to fully comprehend and understand the internationalization process of SMEs it is important to first understand the reasons for expanding operations outside of their respective domestic market. There are various reasons for an SME to internationalize, though common reasons are limited size of the domestic market, the spreading of risks, and new commercial opportunities due to market specific factors (Barnes et al., 2006).

Subsequently, by expanding internationally an SME has the possibility to take advantage of opportunities that otherwise would be limited and also heightens the SME’s chance of continued existence (Lee et al., 2012). The reasons for this are (1) the SME expands and broadens its market, customer base and chance for increasing sales (Lu & Beamish, 2001; Barringer & Greening, 1998), (2) spreads their risks across several markets and regions as well as improving production efficiency (Leonidou, 2004) and (3) the possibility to leverage different resources in several markets by taking advantages of market imperfections; for example setting up production in a country with lower wages, hence using the institutional environment to their advantage (Lu & Beamish, 2001).

Additionally, a factor that can drive the SME outside the domestic market is if they have a manager or another influential employee that has previous experience from internationalization (Reuber & Fischer, 1997). This previous experience is likely to contribute to the SME being more optimistic of the possibilities that exist abroad. Moreover, this person can act as a catalyst and transfer valuable knowledge and positive initiatives for internationalization to the rest of the company and thus facilitate international expansion (Sommer, 2010). Therefore, as visualized in Model 1, the drivers can be found in the domestic market, the foreign market or within the SME itself. No matter what the specific driver for internationalization is to an SME, when making the decision to internationalize the barriers to foreign market entry must be taken into account.
There are several barriers, or risks, associated with SME internationalization since these small organizations are vulnerable to foreign market failures (Evangelista, 2005; Hymer, 1976; Lu & Beamish, 2001; Mudambi & Zahra, 2007). The barriers can be difficult to handle beforehand since firms generally experience them at different stages and in different contexts of the internationalization process (Leonidou, 2004). SMEs in general, compared to larger MNCs, are exposed to a higher risk of failure in their market expansion (Lee et al., 2012). The foremost reasons for this heightened risk of failure for internationalizing SMEs are (1) rules and regulations (Ruzzier et al., 2006), (2) limited competence within the company (Erramilli & D’Souza, 1993), (3) limited financial resources (Fillis, 2001; Ruzzier et al., 2006) and (4) limited amount of human resources (Barringer & Greening, 1998). Moreover, a very important aspect for an internationalizing SME is the term psychic distance which can be conceptualized by the differences in culture, language, political system, level of education and the level of industrial development that exist between the domestic and foreign country (Johanson & Vahlne, 1977; 1990; Johanson & Wiedersheim-Paul, 1975). These differences can be barriers for the company when trying to gather knowledge and information about how the foreign market operates; something that is vital if the company shall succeed with the expansion (Barnes et al., 2006). Lastly, the previous mentioned issues with legitimacy and LOF must also be seen as barriers for internationalization since if a company is perceived as foreign or lack the legitimacy needed it can severely damage or prevent their expansion (Kostova & Zaheer, 1999). Barriers undoubtedly affect SMEs internationalization processes and it is up to the firm to find ways of minimizing the risk associated with them. One way of doing this is choosing different entry modes when internationalizing.

2.6. Entry modes
The term entry mode is referred to the way a firm chooses to expand into a new market (Brouthers & Nakos, 2004; Nakos & Brouthers, 2002). Four common modes of entry for SMEs found in the internationalization literature are (1) starting a joint venture with a local actor, (2) establishing a subsidiary in the foreign country, (3) signing a contractual agreement with a local partner giving them the right to sell the SMEs’ products or (4) by exporting their product (Brouthers & Hennart, 2007; Schwens et al., 2011). The advantages with these four different entry modes differ and are firm or/and market specific. It is important that the firm decides with care which entry mode it shall use since a faulty decision can have a great impact and cost for an SME (Nakos & Brouthers, 2002). Besides internal firm specific conditions, additional factors that determine which entry mode an SME should choose, depends on the
foreign market conditions (Brouthers & Nakos, 2004). For example, Brouthers and Nakos (2004) argue that a competitive foreign market with a large amount of rules and regulations can make it troublesome for the SME to enter the market through establishing a subsidiary. Instead it could be beneficial for an SME to try to enter a foreign market through a local distributor. As SMEs can be in a position of limited resources and restricted competitive advantages due to their size the type of entry mode might prove to be a vital decision (Nakos & Brouthers, 2002). Therefore, trying to find help or collaboration during this complex process from other actors can be of great importance for an SME.

2.7. Networks
Collaboration in business and organization is becoming increasingly more common (Belso, 2006). These collaborations have various terms such as networks, alliances, partnerships and relationships. The nature of these collaborations can range from formal ones such as joint ventures or strategic alliances, to more informal collaborations such as firm, organizational or individual relationships. Due to factors such as limited size, limited experience and different barriers for internationalization it is important for SMEs to be a part of such collaborations, or networks, as they are commonly referred to (Belso, 2006). Firms can use these networks to gain knowledge, resources and legitimacy, improve their strategic positions, or to create opportunities for entering foreign markets (Belso, 2006; Chetty & Pattersson 2002; Day, 1995). Research in international expansion and internationalization draws attention to the role of firm’s networks in contributing to successful internationalization. Researchers argue that a network perspective is valuable to complement older models of internationalization, and several authors have studied the use of networks and relationships in order to understand the process of internationalization (Johanson & Vahlne, 2003; 2006; 2009; Oviatt & McDougal, 1994). Therefore, it is important to understand the role networks play in the internationalization of SME’s.

Networks can be viewed as “intense business relationships that a firm has with its customers, distributors, suppliers, competitors and government – the actors in a business network”, and these business relationships are a significant part of a firm’s international context in which it operates (Johanson & Vahlne, 2003). These networks help in developing relationships with suppliers, distributors, customers and institutions but also with key individuals (Belso, 2006; Johanson & Vahlne, 2003; Madsen & Servais, 1997). By joining these networks firms can get a distinctive advantage to develop a rapid internationalization process. Research has shown that these networks helped internationalizing firms to identify foreign market business
opportunities and had a significant impact on the firm’s choices of which foreign markets to enter. Additionally, several studies have identified networks as one of the key factors of successful international ventures (Chetty & Blankenburg, 2000; Oviatt & McDougall, 1994; Servais & Rasmussen, 2000). Networks are often mentioned as one of the major factors that facilitate the internationalization process and an efficient strategy for SME’s to employ and are thus shown in the conceptual model as a part of the SME at the domestic market.

Concluding, the value and importance of networks in the internationalization process for SMEs is supported in previous research (Belso 2006; Chetty & Patterson, 2002; Johanson & Vahlne, 2003). Networks can also create opportunities for entering foreign market, aid in getting access to resources or give firms a possibility to gain legitimacy. But networks can moreover act as a platform for gaining experience and knowledge through interaction with other actors which is also a vital part in internationalization (Johanson & Vahlne, 2003).

2.8. Summarizing the theoretical framework

Earlier studies of internationalization have not only lacked in explaining how this process unfolds for SMEs operating in the highly regulated healthcare industry but also lacked in recognizing the institutional environment as an important aspect. The institutional environment is an important factor since it, with its normative, cognitive and regulatory rules together with all the physical actors, makes up the context where the company operates. Before the SME internationalize, it operates in its domestic market with its specific institutional conditions. Nevertheless, what makes the SME go abroad are specific internal factors and domestic or foreign market conditions that act as drivers and facilitates the SME’s expansion to a foreign market and thus acts as drivers for internationalization. However, in order for the SME to successfully internationalize they face different barriers that might hinder the SME to set up business abroad. In an effort to deal with these barriers, the SME should use different entry modes as well as take advantage of the SME’s network. If the SME succeeds in penetrating the barriers and establishing business in a foreign market, the difficulties are not over since it now has to operate in a new institutional environment with other conditions, rules and actors. This institutional difference can cause legitimacy problems associated with the liability of foreignness; which also should be seen as barriers. New studies have shown that conformity is not the only way for an SME to face these problems; instead they can try becoming institutional entrepreneurs and attempt to influence or change the institutional environment after the firm’s needs and in that way try to deal with institutional differences and legitimacy problems.
CHAPTER 3 - METHODOLOGY

3.1. Research Approach

Given that the purpose of this study is to increase the understanding and answer questions of how and why firms internationalize and interact with the institutional environments, an exploratory approach was chosen. An exploratory approach is desirable since the internationalization of the healthcare sector is a fairly new phenomenon (Holden, 2005a) and thus the research of understanding this specific field is fairly limited (Holden, 2005b, Orava, 2005). Moreover, since we want to comprehend and describe situations and contexts, which on the forehand are unknown, in an as accurate way as possible; an exploratory approach is recommended by, for example Eisenhardt (1989) and Saunders et al. (2009). As stated, an exploratory approach is suitable when, as we have done, trying to comprehend and understand an area where there lacks adequate research (Saunders et al. 2009), however, the approach have difficulties in explaining exactly how or why phenomenon occurs in an specific way (Babbie, 2012). Therefore our exploratory approach were complemented and combined with a descriptive approach so it is possible to both understand and describe situations and events in a context where you do not beforehand know the possible outcomes (c.f. Yin, 2009).

A qualitative research design was chosen since it allowed us to map out how different processes unfold and since it is an appropriate choice if the research purpose is to study organizational and institutional contexts (c.f. Pettigrew, 1997). Further, a qualitative study allows studying already established theoretical frameworks in a new context but also to discover and explore new explanations that can complement existing theoretical frameworks (Bryman & Bell, 2007; Eisenhardt & Graebner, 2007; Saunders et al., 2009). This study have tried to gain a broad understanding for how individuals and organizations act in specific contexts (c.f. Baxter & Jack, 2008) and searched for a deeper understanding for a situation or a phenomenon which is unexplored (Holme & Solvang, 1997). Lastly, a qualitative study is more suitable before other social science methods since it easier can describe and explain phenomenon and processes under social, institutional and environmental conditions (Yin, 2011).

Since this is a qualitative study, which combines both an exploratory and descriptive approach, a multiple case study was chosen (c.f. Bryman & Bell, 2007; Yin, 2009). A multiple case study is preferable before other qualitative methods since it allows to investigate complex phenomenon such as relations, processes and institutions (Yin, 2003) as well as to
study a contemporary phenomenon which is embedded in its context (Merriam, 2010). This is also appropriate when studying a contemporary event and when the purpose is to answer why or how a specific phenomenon occur (Yin, 2009). Moreover, a multiple case study increases the thoroughness of the study by exploring several empirical phenomena (c.f. Eisenhardt & Graebner, 2007) and thus the study’s analytical conclusions can be more accurate than if only one empirical case had been studied (Yin, 1994). Lastly, since we chose to study several cases that were chosen under similar criteria it was possible to analyze the cases either separately or be generalized as a group (c.f. Blumberg et al., 2008; Eisenhardt and Graebner, 2007) which is suitable if you want be able to illuminate patterns as well as differences among the different cases.

3.1.1. Case selection

In order to enhance the robustness of the study and increase the accuracy of the analysis the different case companies where chosen to fit the same criteria (Eisenhardt, 1989; Saunders et al., 2009). Namely the following 4 criteria:

1. SME’s as defined by the European Union (2003) as a company that has an annual turnover of maximum €50 million and employ maximum 250 persons.

2. Operate within the healthcare industry in general and the medical device industry in particular. As medical device industry the definition from according to European Directive 93/42/EEC has been applied².

3. Be a Swedish company as well as having its origin from Sweden.

4. Have undergone internationalization and thus be present at several markets.

The first three criteria were chosen since, as previously argued, Swedish SMEs operating within the highly regulated healthcare industry is a fairly unexplored subject and thus was of high interest. The last criteria was chosen because if the internationalization of the firm was undergone far back, the data collected from the interviews had a risk of being unreliable due to bad memory from the informants. Lastly, Swedish SMEs were also chosen as criterion as it granted us easier access to the companies.

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² “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).
The above mentioned criteria were made in order to identify appropriate cases from a larger pool of possible case companies gathered from extensive research by the authors. Several companies were deemed unfit to be included in the study due to that they did not fit all four criteria. However, several possible companies were identified and four were chosen to be included in the study. The case companies were chosen due to difference in size, starting modes and have chosen to internationalize in different ways. Table 1 shows the four chosen case companies. As presented in Table 1, the companies were all founded in Sweden during the last two decades; they have undergone internationalization and have different size and turnover. Vitrolife was chosen since it is a fairly large SME, operating in several markets and are profitable. Kibion was chosen due to its size as a medium SME but also due to success with their products both domestically and internationally. Biovica was identified as they were a reasonably newly founded company which had recently initiated their internationalization and Aprovix since they have experience from an unsuccessful internationalization venture and since they have chosen to focus their internationalization heavily on markets where special conditions prevail. Also, gained access to firms was naturally a part of our selection process.

Table 1 – Overview of case companies

<table>
<thead>
<tr>
<th>Company</th>
<th>Biovica</th>
<th>Kibion</th>
<th>Vitrolife</th>
<th>Aprovix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business description</td>
<td>A bio-diagnostic company focused on diagnostics, providing data and monitoring of patients with cancer.</td>
<td>Kibion is a supplier of breath tests for diagnosing stomach bacteria and diseases.</td>
<td>Vitrolife develop, produce and market products and systems for assisted reproduction.</td>
<td>Aprovix have created a reliable self-sampling process for testing and early detection of pre-stages of Cervix cancer.</td>
</tr>
<tr>
<td>Headquarters</td>
<td>Uppsala, Sweden</td>
<td>Uppsala, Sweden</td>
<td>Gothenburg, Sweden</td>
<td>Uppsala, Sweden</td>
</tr>
<tr>
<td>Employees</td>
<td>6</td>
<td>10</td>
<td>215</td>
<td>8-9 (2014)</td>
</tr>
<tr>
<td>Turnover</td>
<td>5 MSEK</td>
<td>42 MSEK</td>
<td>362 MSEK</td>
<td>10 MSEK (2014)</td>
</tr>
<tr>
<td>Internationalization</td>
<td>---</td>
<td>Germany</td>
<td>USA, Australia, France, Italy, United Kingdom</td>
<td>Russia</td>
</tr>
<tr>
<td>International market presence with subsidiaries</td>
<td>USA, Germany, Israel, Turkey, Japan, Estonia, Latvia, ext.</td>
<td>Europe, Middle-East, India</td>
<td>Asia, USA, Eastern Europe</td>
<td>Eastern Europe, Turkey, Finland, Portugal</td>
</tr>
<tr>
<td>International market presence with distributors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The selection was done with the purpose of trying to identify cases that could give us data that could be used to see trends, or if not, differences. Since the chosen companies are somewhat homogenous (they all fit the four criteria) but are still somewhat differentiated considered turnover, number of employees, starting mode and level of internationalization are we able to further ensure a high level of validity in the study (Barringer & Greening, 1998; Saunders et al., 2009). Moreover, data was also collected by conducting interviews with two additional organizations with significant experience and knowledge within the field of the study. The reason for these interviews was to gather data about the institutional context and more general knowledge about the industry as a whole. These organizations were Swecare and Business Sweden and are included in the Table 2.

Table 2 – Overview of organizations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Swecare</th>
<th>Business Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>A governmental industry organization with focus to facilitate international growth for firms within the fields of healthcare and life science.</td>
<td>Jointly owned by government and private sector, the goal is to support Swedish SMEs internationalization processes and reaching export markets with their products and services</td>
</tr>
<tr>
<td><strong>Headquarters</strong></td>
<td>Stockholm, Sweden</td>
<td>Stockholm, Sweden</td>
</tr>
</tbody>
</table>

3.2. Data Collection

The primary data were gathered by conducting semi-structured interviews with the chosen case companies. By conducting semi-structured interviews with open-ended questions, we were able to obtain a deeper knowledge, information, perception and experience from the informant and thus it is a reliable way to gather qualitative empirical data (c.f. Bryman & Bell, 2007; Eisenhardt & Graebner, 2007). Through asking open-ended questions, we also enabled a more detailed and objective answer from the informants and also minimized the risk for biased answers by affecting the informants with our view (c.f. Yin 2011). In order to conduct the semi-structured interview with open ended questions, an interview guide was constructed by applying the theoretical concepts and then adjusting them to be covered by the guide’s topics. However the guide was not structured in a detailed manner, but instead consisted of several topics that would be covered during the interviews. The topics chosen were to an extent based upon the theoretical framework in order to facilitate an easy and
accurate analysis (c.f. Eisenhardt & Graebner, 2007). In that way we were able to ensure that all the theoretical subjects were covered without trying to influence, steer or limit the respondents’ answers and replies. Nevertheless, the interviewers had, as a complement to the interview guide a larger set of questions that we wanted answers to and were used if the respondent did not explain a topic with sufficient detail.

The interviews were recorded and later transcribed, thus securing a more reliable set of data, which have facilitated a more correctly data analysis than if we only had access to notes from the interview (c.f. Saunders et al., 2009). Moreover, as mentioned previously primary data was also gathered from two additional organizations outside of the four case companies. Through collecting primary data from two different types of sources with two different perspectives, a more accurate analysis can be conducted and in the end a more valid conclusion (c.f. Baxter & Jack, 2008). Further, the respondents were chosen since they, through inquires, were the individuals in each organizations with the insight, information, experience and knowledge within the subject. When collecting data to describe the industry as a whole, the primary data from the interviews were complemented by data acquired from different reports, governmental websites and other secondary data sources found online. Likewise, some data about the case companies were also acquired from the different companies’ websites.

3.2.1. Interview process

One week before the conduction of each interview the respondent were given access to the interview guide in order to understand which subjects that would be covered and thus each respondent had time enough to research information and compile their thoughts before the interview. Before each interview, each respondent was again informed about the purpose of the study in order to be able to understand how to best respond to the questions as well as asked if we could record the interview in order to later transcribe it. Afterwards, the respondents were able to read through the transcribed interview and correct any misunderstandings or be able to clarify some important aspects, all in order to secure more valid data. The interviews and data collection are presented below in Table 3.
Table 3– Overview of data collection

<table>
<thead>
<tr>
<th>Company</th>
<th>Type</th>
<th>Length</th>
<th>Informants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biovica</td>
<td>Personal &amp; Complementary Questions</td>
<td>60 minutes</td>
<td>Chief Executive Officer &amp; Head of Research</td>
</tr>
<tr>
<td>Kibion</td>
<td>Personal &amp; Complementary Questions</td>
<td>60 minutes</td>
<td>Chief Executive Officer &amp; Researcher</td>
</tr>
<tr>
<td>Vitrolife</td>
<td>Telephone</td>
<td>60 minutes</td>
<td>Regional Director</td>
</tr>
<tr>
<td>Aprovix</td>
<td>Telephone &amp; Complementary Questions</td>
<td>60 minutes</td>
<td>Senior Advisor &amp; Chief Executive Officer</td>
</tr>
<tr>
<td>Swecare</td>
<td>Personal</td>
<td>60 minutes</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>Business Sweden</td>
<td>Personal</td>
<td>60 minutes</td>
<td>Vice President – Healthcare industry</td>
</tr>
</tbody>
</table>

3.3. Data Presentation and Analysis

The empirical data was, after the interviews, discussed and checked by the informants in order to ensure that the data was correct and not misunderstood or angled and thus the data was secured as reliable (c.f. Baxter & Jack, 2008). Some empirical data (more objective data about each case company’s background and current situation) is first presented case by case in order to give the reader a deeper understanding for each particular case. After that, the empirical data is presented in a more thematic and narrative way where every case were divided under different theoretical parts ensuring that we obtained the essential details and retained the specific complexity of each case (c.f. Langley, 1999). Furthermore, by using a continuously and iteratively way of processing the data and breaking it down to be sampled under different theoretical subheadings, a deeper analysis was attained; that could focus and grasp the most essential aspects of the empirical data (c.f. Eisenhardt & Graebner, 2007). Lastly, by presenting the data in illustrative quotes it facilitates a clearer overview that lies as a foundation for both the readers understanding but also to enable a more qualitative analysis since we can detect patterns and trends more easily (c.f. Eisenhardt & Graebner, 2007).

The data were continuously analyzed and were in an iterative procedure processed and viewed upon by different theoretical frameworks, and by doing so we have tried to ensure a more
precise analysis (c.f. Merriam, 2010). The main type of analysis was the above mentioned continuous text based analysis. The transcribed interviews were then analyzed with ATLAS.ti, a computer based qualitative data analysis programme which help us to categorize, analyze and spot relations in the data, all with the purpose of a more qualitative analysis. The ATLAS.ti analysis was conducted by uploading the transcribed interviews and then letting ATLAS.ti find patterns by coding keywords\textsuperscript{3}.

By transcribing the interviews and then analyzing the different cases together, with the help of ATLAS.ti, under different theoretical frameworks, we were able to analyze the different data against each other and by doing so enabled a more valid analysis by being able to detect patterns, differences and similarities between the different cases (Bryman & Bell, 2007; Eisenhardt & Graebner, 2007; Langley, 1999). This was done by coding the theoretical keywords of networks, key opinion leaders, change, influence, cooperation and see how often and in what settings they appeared. Furthermore, by comparing the cases between each other and also analyzing them in relation with relevant theoretical literature we were able to validate our results against existing theoretical frameworks or, if not being able to validate, being able to propose new theoretical findings.

3.4. **Research Limitations and Quality of the Study**

A limitation in this study is that we only have four different cases that we have studied. Despite that, since we have analyzed our findings with the help of our previous theoretical observations and literature reviews we can attain an analytic generalization (c.f. Yin, 2003). However, the reason for having four cases was firstly a question of limited access and time but by choosing cases that both complemented and contributed to each other we have tried to overcome this. Additionally, to compensate the number of cases and be able to triangulate our findings, we have conducted interviews with several kind of actors; both our case companies and the organizations Swecare and Business Sweden. Thereby we were able to limit the bias elements from both misinterpretations from the interviewers and informants views from the companies and thus adding to a more valid study (c.f. Eisenhardt & Graebner, 2007).

The fact that our study have focused on events of the past is also a limitation since the data then risk to be affected by the informants’ memory, impressions and cognitions which can mark the data in a subjective way (c.f. Langley, 1999).

\textsuperscript{3} Example of keywords: network, KOL, drivers, barriers, problems, relations
In addition, some interviews were conducted by telephone since the informants were unable to personally attend or they were physically too far away. This could affect the quality of the data since the interviewers in those cases were not able to read the informants’ different body expressions or other visual observations (c.f. Bryman & Bell, 2007). Despite that, this factor was limited by letting the informants read the transcribed material after the interview was conducted and then able to complement, alter, or extract information with the purpose of making it more reliable (c.f. Baxter & Jack, 2008). Also, some data collection was in the form of complementary questions via email to a few informants. This is also a limitation for our study; however we tried to ask questions that provided the possibility of answering in writing that limited too much interpretation. A limitation can also be found in that the companies differ some in size, start-up mode and market presence, which can make it more difficult to spot certain patterns in the empirical data. However, these differences also add to the depth of our study by letting us investigate if small differences affect how the internationalization processes unfold. Lastly, this study has as previously stated, was conducted in retrospective. As argued, this was a precondition but it is also a limitation since the long time span from the actual events to the interviews can have had a negative effect upon the informants. We thus cannot guarantee that the data given by the informants are historically accurate but we have tried to validate it by letting the informants check their memories against other persons at the companies as well as other company documents.
CHAPTER 4 – FINDINGS

4.1. Empirical context
According to the World Health Organization (2000) a health system can be described as all organizations, institutions, actors and resources that are devoted to produce health actions to a country. However, these systems can be built differently in different countries (WHO, 2000; Svensk Försäkring 2013) though the structure is dependent on economic, social, demographic factors as well as different values and traditions (Anell et al., 2012; Gottret et al., 2008; Kamp and Hvid, 2012). During the last decades, the financial size of the healthcare industry, which the medical device industry is a part of, has risen to new levels which has had a major impact for the opportunities for firms within the industry (Sorenson & Kanavos, 2011). What makes this industry special and complex is that it is often not the patient that pays for the treatment or the device but instead is it a third party as the government or an insurance company that pays for the purchase (Casto & Layman, 2006). More so, the government and other institutions in each country plays a huge role since it is often they that sets the guidelines for the healthcare providers in what equipment and which methods to use in the treatments of the patients (Casto & Layman, 2006).

In order for a company to get their product approved for the markets in Sweden, European Union as well Iceland, Lichtenstein and Norway is to obtain the CE-label approval; which is applied for in one country but valid in all (European Commission 2013). Due to the rapid pace of innovations within the medical device industry, the directives from the European Union are by many countries considered out of date. In order to deal with the many innovations and the slow directives, many member states have chosen to implement the directives in a way that they think is appropriate (European Commission, 2013); something which further improves the gap (that should not exist) between the member states regulations (Kramer et al., 2012).

Compared to other markets as the American, the European markets are easier to penetrate and establish a presence in; something that is advantageous for the companies but more debated if it is beneficial for the patients (Kramer et al., 2012; Greer et al., 2013). The strongest criticism says that the devices that makes it into the European markets are not adequately tested since they absence of oversight during the clinical testing and use but also lacks transparency when the companies publish their research of the benefits of their device as well as the supposed complications related to the use of the device (Cohen & Billingsley, 2011; Wilmshurst 2011).
In the most countries there exist both privately own and governmental healthcare providers (Greer et al., 2013). However, no matter the ownership of the provider, most of them use a procurement process when they decide which type of medical device that shall be used in their service (Sorenson & Kanavos, 2011). Therefore it is extremely important that the companies that produces this devices to become accustomed with these processes so that they can promote and expose their product in a favorable way as possible (Sorenson & Kanavos, 2011). More so, the procurement processes often differ if they are funded by the private or public initiative. The public procurement processes are usually characterized by a slower and more complicated process compared to the private. However, the level in the hierarchy where the procurement process is handled differs between countries. If we look upon the European Union, some countries have a more decentralized process that occurs at the relevant hospital while others have a more centralized process that applies for a whole country or region and is managed at a higher level (Sorenson & Kanavos, 2011). The reform of the Swedish health care industry has enabled more private actors to emerge; and this is also true for several other healthcare markets as well (Anell et al. 2012). Some of the consequences following this have been that it is possible for small companies to emerge and prosper since they now have the ability to approach private medical actors without having to deal with large scale public healthcare procurements. Additionally, small to medium healthcare firms can expand alone and do not need to be acquired or funded by a larger corporation before they internationalize (Business Sweden; Swecare). Swecare stated that there are plenty of innovative healthcare firms in the industry that are naïve in pursuing an internationalization attempt without having a clear business model or even lacking the competence needed. These findings were supported by Business Sweden for healthcare industry SMEs and it was clearly stated that the right competence is needed in order to succeed with this endeavor.

Business Sweden, in itself an organization dedicated to help firms establish business networks, clearly stated that it is vital for a firms survival, success and legitimacy to choose the right network and key individuals. These networks also provide incentives for firms to expand their business to new markets. Business Sweden and Swecare work with networks by the principle of Triple Helix, which is the idea to put the three worlds of academia, governmental and business together. The synergies with this approach are especially important in an industry such as healthcare, where the knowledge and influence lies within all three fields. Being associated with these actors was according to Swecare a necessary prerequisite in some markets in order to receive legitimacy and not being an outsider, but they
also lifted the use of different networks as one of the most effective ways of bringing about change.

Lastly, Business Sweden and Swecare argued that the existing institutional environment on the Swedish market provided a difficult context for healthcare SMEs to operate in. This was largely due to the complex procurement processes where firms have to go through different processes for the 21 counties in Sweden who are responsible for healthcare in their regions. These processes could be time-consuming, complicated and financially expensive to participate in and therefore could act as incentives for SMEs to expand internationally (Business Sweden; Swecare).

4.2. Foundation and commercialization of the case companies

4.2.1. Aprovix

Aprovix started their business with the creation and development of a self-sampling process combined with HPV testing for early detection of pre-stages of Cervix cancer, which is the second most common cancer among women. The product was an invention of the Swedish professor Erik Wilander at Uppsala University hospital. Aprovix was founded in 2001 and they started developing the product in 2004 and they had the product completed for market in 2008. During this period there were a few pilot studies together with Uppsala University hospital and cooperation with a few Swedish counties. In 2008 Aprovix initiated an attempt at launching the product on several international markets but failed. This was the consequence of a number of reasons, but largely due to a combination of the lack of a clear internationalization strategy and the relatively new field of HPV-cancer.

Today a second business development plan and internationalization strategy is ongoing after a new CEO, with experience in both internationalization and the industry, backed up by new investors have taken over the management of the company. The product is CE-labeled and the focus markets are Europe and the Middle East.

4.2.2. Biovica

Biovica was founded in 2005 by a researcher at Uppsala University and is a bio-diagnostic company that is focused on improving diagnostics of cancer. Biovica has developed a highly sensitive blood test for the detection, prediction and therapy monitoring of abnormal cell division. The company has since its inception received several grants, awards and funding for research and studies to further develop their product. A significant development in their growth has been a clinical study together with Karolinska Institutet in Stockholm which
provided qualitative and promising results that has enabled them to leverage this in their internationalization. Biovica’s product is CE-labeled as of 2006 as well as ISO 13485-certified\(^4\) and the company is currently working for obtaining higher sales and internationalizing to new markets. Market presence includes countries as Germany, Czech Republic, Japan and Turkey to highlight some key markets. The company is in the early stages of establishing their product internationally and has a promising future. Their vision is to be part of the standard in cancer diagnostic process with their products.

4.2.3. **Kibion**

The starting point for Kibion was 2005 when the company was founded with a clear focus on their specialized product for diagnosing stomach bacteria and diseases. The foundation of the company followed breakthrough discoveries that the stomach bacterium Helicobacter pylori have a significant part to play in stomach ulcer disease, which earned the discoverers the Nobel Prize in 2005. The product that Kibion provides is a breath test that helps in diagnosis of stomach diseases, ulcer and Helicobacter pylori testing. The company is a subsidiary of the Swedish pharmaceutical company Orexo AB and has grown organically as well as from acquisitions. 2006 and 2011 Kibion acquired companies on the European market. Kibion has international market presence in over 40 countries. Kibion and its product are CE-labeled and they are also certified according to ISO 13485.

4.2.4. **Vitrolife**

Vitrolife originally started as a university spin-off from the University of Gothenburg and began its operations in 1994. Since then the company has experienced both domestic and international growth and the company is since 2001 listed on the Stockholm Stock Exchange. Vitrolife is today an international medical device group with expertise in the fertility product area. They develop, produce and market products for assisted reproduction. The company has had positive growth since inception but is aiming for stronger internationalization and activity in international markets. Compared to the other companies in the case study, Vitrolife has reached the farthest on their internationalization journey.

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\(^4\) International Organization for Standardization (ISO) standard that represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
4.3. Findings on internationalization

4.3.1. Starting the internationalization process

The decision to pursue international activity and internationalize was the idea since creation for all of the four case companies. The main reasons for this were that the size of the Swedish market was too small and therefore would not be able to sufficiently support the companies from a financial standpoint. Additionally, the types of products these companies offer had global potential since the problems the products solve extend outside of the home market. Kibion and Vitrolife maintain a strong focus on the home market at the same time as the internationalization process. Kibions product however has not succeeded in the same way on the domestic market as foreign markets, due to low demand. Vitrolife, the most internationally active of the case firms, established their products on the home market initially and then slowly started to expand onwards to foreign markets. The following quotes put forth the case companies’ intentions on internationalizing.

“We have a product with global potential, and the size of the Swedish market was too limited, so there was never any doubt about internationalizing, only what strategy to use”

“The international focus was always there, but there was a lack of focus on how to execute a viable business strategy”

“To go international was the idea from the beginning”

“International expansion has always been on the table. If the company was to grow, we needed to move outside of Sweden’s borders”

It was also found that yet another driving force for internationalizing was the complexity of the home market. Sweden’s complex healthcare market with twenty one counties responsible for healthcare services and products all have different procurement processes which makes it costly, both financially as well as time spent trying to manage these difficulties. This aspect, together with the limited size of the Swedish markets and its limited commercial possibilities, was key drivers for internationalizing.

The determinants for market selection by the four firms in the study were a combination of several aspects. Firstly, demand for the product was a major factor in determining which
markets to enter. Additionally, market size and relation to the market were also important criteria. Lastly, regulatory aspects and the complexity of the foreign institutional environment were also part of the process of foreign market selection.

For Kibion, it was outside demand for the product that triggered internationalization. This was enabled by exposing the company and its products in settings that could lead to business opportunities. Initially for Kibion, the rationale behind foreign market selection was characterized by a random factor meaning that the actors you created a relationship with determined market selection. To illustrate this is a quote from the CEO of the firm:

“In the beginning it was entirely up to who you met for determining where you ended up”

This contributed to the development of Kibion establishing their first international activity in a randomized way with initial markets such as Australia, England, Finland and the Middle East. The process of internationalizing has since then shifted heavily to an increasingly more structured way of beforehand identifying which markets and which actors they want to work with, and approaching them in a professional manner.

Vitrolife and Aprovix on the other hand both focused on nearby markets initially. The main focus for market choice was the Nordic countries. This was due to the market similarity (market size, procurements processes and regulations), the perceived limited cultural differences (norms and values) and established relationships. However, the two cases took different turns in the following development where Vitrolife furthered their products to new markets directly and with Aprovix terminating their first attempt at internationalization. For Vitrolife, the key to accomplishing entry into additional foreign markets was the cooperation with individuals, clinics and companies in combination with the important factor of an already existing demand for their products illustrated by the following quote.

“We started out in the Nordics because we wanted to keep it close, however demand was already out there so it didn’t take long for us to target new markets”

Aprovix, equipped with a new business model and new leadership in the company, initiated a second internationalization attempt focusing foreign market entry to Finland, Eastern Europe and Russia, mainly due to newly gained access to the right individuals and networks enabling
them to gain access and publicity in those markets. Equally important in the choice of market entry was identifying the markets with demand and viable commercial possibilities, which consequently has led them to largely focus their efforts on Eastern Europe and Russia.

Biovica, the smallest of the case companies present in the study and also the firm that is currently in the earliest phase of the internationalization process started out with trying to build up domestic scientific support for their product before initiating any attempt at internationalizing. Being backed up by clinical studies and trials are of major importance for Biovica as well as the other firms’ products. By collaborating with a large, internationally influential scientific actor in the home market, they have built up proof of possessing a viable product and this has been critical for their market selection process. Biovica has used a combination of networks and relationships to enter foreign markets along with as well as being contacted by distributors directly.

General findings regarding foreign market selection has been that all firms have been significantly influenced by networks and relationships when decided what markets to enter. This has been done either through an intentional effort in trying to identify and establish relationships with a certain individuals or actors, or been characterized by a randomized factor with the firm being approached by other actors.

4.3.2. Barriers to foreign market entry

Regulatory aspects and compliance with legislation were aspects that each firm highlighted as a barrier to enter foreign markets. The perceived issues with regulatory aspects were that different markets can have processes and legislative demands that differ significantly and therefore make it demanding. The case firms all viewed the European regulatory process for CE-label as not a particularly complicated procedure. But markets that were more culturally and institutionally different posed a greater challenge. However, it was highlighted by all firms that regulatory difficulties do pose as barriers to a large extent. Especially for the smaller firms in the earlier stages of internationalization, regulatory aspects greatly influence the strategy and decisions for internationalizing as illustrated here by quotes from Biovica and Kibion;

"Internationalizing to markets with tough regulatory processes is postponed".

“A lot of markets have their own strict regulatory processes, which is very demanding to handle and is always taken into account when evaluating to internationalize”
A key finding in regards to the barriers to internationalization was that limited competence and limited financial resources pose strong challenges for small and medium-sized companies. All of our case firms mentioned the importance of having access to the right competence in order to succeed with an international venture. Aprovix failed their first attempt at internationalization due to lack of competence in developing a viable international business strategy and illustrated the problems with an interesting quote from the CEO followed by the same finding from Biovica;

“The inventors behind these products are great at medical devices, but not at business strategy. There was a lack of a clear focus on what can we do, which market can we enter and why, how do we enter that market, and how do we charge and how much do we charge.”

“The key and a prerequisite to succeed with international expansion is that you possess the right competence in the firm, especially experience on the business side”.

Limited financial resources were also a barrier. It is costly to enter new markets, especially in regards to managing all the risks entailed with slow regulatory processes and trying to create a demand for the product. Therefore the case companies were reluctant to enter markets that they knew would include risking to not get a quick return on investment. During internationalization, the firms tried to overcome this barrier and focused on attracting more investors, financial research contributions and maintain a strong focus on achieving a positive cash flow in the firm.

Cultural differences and understanding of the local market conditions was another vital aspect of internationalization brought forward during our case study. Kibion, Aprovix and Vitrolife stated that language barriers is important to overcome, as both market actors and regulatory actors tend to put great importance in communicating in the native tongue. But language was only one part of the cultural barrier, it was equally important to have local cultural knowledge for the specific market which you are to enter. New markets are often complicated to understand and also how to act in order to overcome the barrier they pose, hence possessing knowledge regarding cultural business aspects is vital and was stated by the case firms as the following quotes highlight.

“You have to have someone in the specific country that will help you, understanding new markets and culture is a vital thing. For example, In Japan it is was important to be perceived as a local actor because of the cultural context where it is incredibly important to support local businesses”
“When entering the Russian market, we needed Russian speaking employees and competence”

“It is a must to possess the right cultural competence for a market”

4.3.3. Entry modes

Both distributor and subsidiary arrangements were the choice of entry modes by the case firms in the study, with distributors being the choice for the early phases of internationalization. All of the firms have distributors in several markets, however Aprovix have set up a subsidiary through a joint-venture in their key market Russia where they are majority owners and Vitrolife has several firm-owned sales subsidiaries in different markets. Subsidiaries was seen as a more costly and more complicated mode of entry, due to significant investments for the right competence but also the risks associated with lack of cultural knowledge. However, when identifying a key market with potential demand and future opportunities setting up a subsidiary would help them establish a stronger local presence and control compared to distributors. For markets with less potential and not necessarily key markets, a distributor partnership was a more common method of choice. This was also true for the firms in the study who are in the earlier phases of internationalization with a limited international presence and firm resources, meaning Biovica and Aprovix. Biovica’s CEO stated that they let distributors in some markets get exclusive rights and try for themselves, where Biovica as a firm does not see potential or have the resources, knowledge or the right relations to take part.

The strengths of the more common distributor model of establishing international presence were local market knowledge, access to important individuals, actors and networks and limited financial investment requirements. Of the challenges identified by the case firms the importance of finding suitable distributors was mentioned as a key issue. A suitable distributor was characterized as possessing experience and competence within the field, having access with vital network and business actors, local market and cultural knowledge and dedicated human resources. The process of finding the right distributor can be a lengthy and challenging process. Kibion, who at the first stages of launching their product internationally randomly entered in distributor agreements, now has a rigorous evaluation process that together with experienced organizations such as Business Sweden establishes criteria such as market demand, commercial possibilities, regulatory market aspects and potential partners. They subsequently identify suitable distributors with which contracts can be entered. Vitrolife, the most internationally experienced of the case firms, have employed
an entry mode strategy based upon initiating with distributors then gradually moving towards setting up firm-owned sales subsidiaries, as described from the following quote.

"We have initially always used local distributors for the simple reason that they have possessed the local competence and knowledge that we do not. Once we attained the local competence needed, setting up our own entity gives us more control and possibilities for higher sales”.

4.3.4. Networks and knowledge

Among all the case firms the main concept that was recurring and mentioned over and over again was the absolute vital importance of having access to networks and key individuals within respective markets. Additionally, to be associated with the right partners who in turn possess access and influential ability on key networks and key individuals was also equally important. The key individuals and networks were characterized as having large amounts of local knowledge and expertise, both country-specific and industry-specific. But also having the ability to contact, create relationships and influence decision makers and other institutional market actors such as organizations, governments, firms, customers, suppliers and last but not least medical professionals and experts. Gaining access to these networks and consequently paving the way for successful internationalization was made possible by the use of key individuals referred to as “Key Opinion Leaders” (KOLs). KOLs can be defined within this context as being individuals that are recognized within their field of expertise and often have strong academic/institutional/professional connections with the power to influence. The following opinions of the four case firms develop the importance of KOLs.

“It is of major importance to have relationships with KOLs within our field that are internationally recognized, they work as spokespersons for our products and open new possibilities”.

“When we enter a market we want a KOL, in our case a widely respected oncologist, who are willing to use our products in his work and through that process put our name on the map.”

“When we entered Russia, we went directly for those who were the leading individuals within the field in each region and worked hard to establish a relationship with them”.

“We have worked extremely hard in establishing strong relationships with local KOLs who themselves have a much better ability to influence local clinics to use our products”.
Aprovix stated that they focus especially on working together with KOLs within their specific field with the argument that they beforehand are aware of the problem, understand the benefits and does not have to be persuaded to a great extent. Additionally, they have the influence and resources to drive change and put in motion developments that benefit Aprovix. Moreover, these networks were explained as never static but working as links in a chain, always extending and creating new relationships. Vitrolife first establishment in USA arose from collaboration with a KOL, a renowned and influential professor within the field, which created possibilities for Vitrolife to set up production, gaining access to the market and created awareness within the industry. Biovica uses a KOL from a local, domestic setting to aid them in influencing international markets to open up for their product. The international network provided by this KOL has been very important and have enabled Biovica possibilities to get international studies to strengthen their product. All of the firms, especially Kibion, work closely with domestic organizations that aid them in providing access to these networks and KOLs. These organizations were defined as well connected within the healthcare and life science industries worldwide mainly due to governmental relationships but also from insights, competence and experience from market-specific conditions. As such, the right networks provide access and knowledge about markets that are not easily attained. One aspect that was mentioned here yet again was that the firm needs the right competence and knowledge from someone with experience to get ahead in the internationalization process. Additionally, the case firms stated that being connected to KOLs and networks, both domestic and international, provides legitimacy and decreases several of the risks with entering foreign markets.

4.3.5. **Legitimacy issues and the liability of foreignness**

An effect of being associated and connected with the right individuals, networks and organizations was that it increased the legitimacy for the case firms. As far as risks with internationalizing goes, not having legitimacy and credibility can be devastating for a firm and that was highlighted from all of the case firms. In the pursuit of legitimacy, and in turn not being subject to the risks associated with liability of foreignness, Biovica stated that KOL networks in combination with data and evidence that supports the product is a key factor. The importance of having the right data to prove your products viability was strongly emphasized in being perceived as legitimate. Kibion and Aprovix both put forth that the right partner and network was essential to not being perceived as an outsider and gaining the legitimacy required for being successful on the market. The process of convincing the market that you
and your products are needed was lifted as one of the toughest challenges if the firm lacked legitimacy or was viewed as an outsider. One case firm lifted an example of the Indian market where the importance of being perceived as legitimate was a prerequisite before business could be initiated. It was a necessity for firms to first establish a relationship, often under informal circumstances, with the right network or individuals before even beginning to discuss business. For a Swedish firm and their western style of operating a business, this could sometimes be seen as a waste of time or unnecessary effort.

4.3.6. **Institutional environment and institutional entrepreneurship**

With the institutional-based perspective on internationalization it is argued that firms experience pressures from the institutional environment and its actors. These pressures constrict firms’ ability to operate, affect them in various ways and force them to conform to certain political, normative and cognitive structures. But there are also possibilities for firms to influence institutions and actors in an attempt to drive beneficial change for successful internationalization. Biovica and Kibion stated that political regulatory factors are hard to change for a single firm and therefore you must conform to the often strict and lengthy processes. Additionally, all case firms clearly defined the importance of cultural conformity. When internationalizing, adapting to how business was done in the specific cultural context of the chosen market was crucial. In general, conformity was needed on several levels such as regulatory, cultural and normative guidelines on doing business. However, as the following empirical examples from all case firms will show, the ability to influence the institutional environment and its actors is possible.

Vitrolife have attempted to influence the institutional market context in several ways. Firstly, as regulatory processes pose a barrier and require conformity for firms when entering markets, they can also be used to benefit already established firms. Vitrolife and Kibion have tried to influence political institutions to an increased demand for regulations. Vitrolife stated that they have been actively promoting the demand for CE-labeling in markets where it was not a regulatory demand in order to do business. This was done with the intention to strengthen the competitive advantage for the Vitrolife as illustrated by the quote below.

"We have used our ability to influence markets to push through a demand for CE-labeling in order to do business. Some markets lacked this requirement for our product field, and we saw opportunities that a change for reinforced regulation to benefit us and shut out competition".
Biovica have tried to influence more informal regulations such as local guidelines of how the industry manages the use of cancer diagnostics, in attempts to loosen and change the guidelines to be more in line with their products. However, this is not easily done and as stated above it is a difficult task to influence change for a single SME. The following quote from Biovica shows how they have focused on influencing KOLs of the need for change and together through cooperation tried to initiate the same.

"We use KOLs with whom we together try to affect local guidelines in specific markets, such as guidelines that define what type of diagnostics test and methods professionals are expected to use. To goal is to change these local guidelines to benefit the use of our product”

The main findings in regards to the ability to influence and change institutional and industry structures are in line with the above quote. It is the use of cooperation together with other actors, be it key individuals such as KOLs, networks, customer, institutions, organizations or other firms.

Aprovix have in cooperation with KOLs managed to influence the academic arena in one of their key markets. Through a key individual with access and influence on decision makers they have managed to get information about Aprovix and their products into the textbooks of medical school students. They highlight that when trying to make change happen institutions and the actors involved such as politicians and medical professionals can be very resistant to change. It is through building strong lasting relationships with KOLs that have the power to change guidelines and rules that change comes about. An interesting take on another way of influencing the institutional environment of foreign markets is to first target the domestic institutional context. Aprovix are currently trying to affect the way the politically decided processes in Sweden regarding cervix-cancer testing. This is again done in cooperation with a professor with political influence on the counties in charge of healthcare in Sweden. The idea is to if you are successful changing your domestic institutional environment, Aprovix can then bring about the same type of change on new markets.

“...we focus on changing the political processes regarding the procedure for HPV-testing, to change the entire institutional process from its current state into a self-testing process that would benefit everyone, not only our firm. We are currently trying to do this in Sweden where we cooperate with KOLs to influence the Swedish counties that have responsibility for the medical process regarding HPV-testing for women”.

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Additionally, Aprovix used an approach for the Turkish market by directly focusing on the governmental decision maker, the female healthcare minister who just happens to be a woman with and interest and knowledge in the field of HPV-cancer, regarding the national testing process and hope to be the provider for the change in cancer testing that they are trying to influence.

Another form of influencing institutional actors to change through cooperation is for firms to work together with not only their distributors but also with their customers. Kibion stated that in order to influence markets to adopt new medical solutions this type of cooperation is vital.

"Cooperation between Kibion, our distributors and our customers is required for us to influence markets".

Vitrolife supported this view mentioning that the firm cooperates closely with the clinics where their products are used with the aim to be directly involved in institutional decision making for the industry. This was used both at specific firm and market level contexts, but also on a larger scale. Membership in organizations spanning over several markets allows for greater influential power in the institutional environment, as illustrated by this quote;

"By being active members of larger organizations we can together with other members get far greater power to influence the institutional environment. A vital part to this is that customers are a part of these organizations so they can be involved in the process of changing the industry, institutions and regulations”.

The case firms stated that as a single SME you have a small chance to influence and affect the institutional environment when internationalizing. But by cooperation with other actors such as organizations, firms and government firms can in the right settings bring up issues that could be changed for the benefit of the internationalizing firms. Kibion lifted an example of ongoing change regarding issues with Brazilian market regulations; a potential cooperation between Swedish and Brazilian authorities controlling regulation for the healthcare industry has arisen. Previously a delegation from Brazil had to travel to Sweden and perform an observatory inspection of production facilities and headquarters, which is a financial as well as a time costing barrier. Now, after these issues have been lifted by internationalizing firms, change is underway. Possibilities are in place for the Swedish regulation agency to perform the inspection in cooperation with the Brazilian authorities instead of the firms having to put
in the timely and costly resources. This is one example of ongoing institutional change during internationalization.

The other firms also viewed the possibilities to influence the institutional environment as a lone firm rather limited. However through cooperation it was a possibility. An interesting example came forth here that illustrate the complexities of institutional change. Internationalizing SME firms, together with Business Sweden, was experiencing difficulties getting access to a market because of a lengthy and bureaucratic two year regulatory processes. When trying to influence and pressure for change on how these processes were undertaken, the politically elected government official in charge of these issues at the foreign market recommended that they should legally sue them. The recommendation was that the Swedish SME firms join together with the host market medical technology organization and sue the governmental institution in power to bring about change, explaining that legal action was the means by which you could force the officials to respond to the matter.

Concluding, adapting and confirming to the institutional environment of foreign markets when internationalizing were an empirical reality for the case firms. However, the possibility to influence and change the institutional environment do exist which connects the concept of institutional entrepreneurship closer to our findings. In the following chapter, the analysis of our theoretical framework and empirical findings is presented.
CHAPTER 5 - ANALYSIS

In the following analysis we begin with discussing the drivers of internationalization related to our conceptual model and the question of why. Secondly we analyze the question of how SMEs internationalize and lastly we relate to the domestic and foreign institutional environments during internationalization and the ability to act as an institutional entrepreneur. Lastly we revise our conceptual model according to our findings.

5.1. Home market conditions can push SMEs to internationalize

A key driver for the case firms’ internationalization was that the Swedish market is limited concerning size, demand and profit potential (c.f. Barnes et al., 2006; Barringer & Greening, 1998; Lu & Beamish, 2001). However, an interesting finding was that several of the case firms experienced a push to expand to foreign markets due to the specific institutional environment that exist in the Swedish market. The underlying reason here was the complicated, time consuming and costly process connected with the procurement processes that exists in the government provided part of Swedish healthcare. To penetrate the entire market which is important in a small country as Sweden, the firm needs to take part in separate procurement processes connected with each county responsible for healthcare in specific regions. Hence, when the companies are newly started, small and need to gain revenues, it was not seen as worth it to compete at the Swedish market. Together with the size and low demand of the Swedish market this can drive the experience of being pushed out of the Swedish market and to internationalize.

As previously concluded, the companies are driven to internationalize to new and foreign markets and must therefore chose which one to enter. One company did not initially choose which markets to enter first; instead they intentionally promoted their company in international settings and got approached by companies that were willing to distribute their product at their markets. Thus it can be argued that they did not use their current network and contacts but rather obtained new contacts and thus expanded their network to help them internationalize (c.f. Belso, 2006; Chetty & Blankenburg, 2000; Johanson & Vahlne, 2003; Madsen & Servais, 1997; Oviatt & McDougall, 1994; Servais & Rasmussen, 2000). Further, it can be argued that a company, when their KOLs presented them for other actors that became incorporated in the company’s network, expanded their network accordingly with Welch and Welch (1996) as they argue that networks can derive from personal or professional relationships that have evolved without anticipation or deliberate intention; just as links in a
chain with one link connecting with the other. Nowadays they instead choose the markets to enter more methodically, using more of a business strategy mindset, where they scout and research for markets with maximum potential, (Barnes et al., 2006), low barriers (Evangelista, 2005; Hymer, 1976; Lu & Beamish, 2001; Mudambi & Zahra, 2007) and use their established networks to penetrate the market. Several case companies chose to internationalize to the Nordic countries first due to market familiarity and similar culture. This can be traced back to the concept of psychic distance that Johanson and Wiedersheim-Paul (1975), Johanson and Vahlne (1977; 1990) and Barnes et al. (2006) discuss; that firms can, or rather should, expand to those countries with similar ways to operate and think since it limits the physical distance and thus lower the market barriers for firm internationalization. Furthermore, all of the case firms have one common factor when deciding which markets to enter and this was where they had or could establish access to key networks including the right KOLs. This is in line with Day (1995), Chetty and Patterson (2002) and Belso (2006) that states that networks and especially key opinion leaders are hugely important if firms need to gain knowledge, resources, and legitimacy but also to improve their strategic positions, or create opportunities for entering foreign markets.

5.2. The importance of selecting a correct entry mode and using the network

Out of the four entry modes (c.f. Brouthers & Hennart, 2007; Schwens et al., 2011), the most used way to enter a new market was using local distributors. In that manner the case firms did not only avoid heavy investment or risk associated with starting up subsidiaries or engaging in a joint venture, two modes of entry that can be troublesome for an SME. Thus, by working with a local distributor, making the end-users unaware of the foreign and unfamiliar companies, they succeeded in avoiding a lot of the initial problems and barriers related to LOF and legitimacy. An additional benefit with an already established local actor was that the companies were also able tap into their networks and thereby new sales opportunities. Additionally, in accordance with Brouthers and Nakos (2004) the case companies expressed one more great advantage by using local distributors when entering a new market; their knowledge of the local market conditions and the often complicated regulatory frameworks.

Though the companies did at first only enter new markets by using distributors; some firms later on chose to established subsidiaries. One company did at several occasions start up subsidiaries at their new markets and another case company has recently set up a subsidiary at the Russian market, jointly owned, together with a local company. The reasons for both companies to use subsidiaries, despite the heavy costs and risks, were that they had the
knowledge, capital and network to support it as well as wanting the high degree of control that is not associated with using distributors (c.f. Brouthers & Hennart, 2007; Schwens et al., 2011).

Therefore we argue that the companies’ networks, together with firm specific factors, are the two major forces that decide which markets to enter and specific entry modes. Local market factors as size, regulatory rules and physical distance, however still important, play lesser roles for market selection and entry mode. We argue that the sometimes seemingly arbitrary entry modes and market selections illustrated by the case firms are in fact not random but instead, although often unconsciously, are a result from the companies' internal factors as size and capital as well as their network.

The factor that all of the case firms have highlighted their international success most to is establishing access to networks in general and especially establishing relationships with crucial KOLs. All case companies have expressed that their network has helped them developing relationships with suppliers, distributors, customers and institutions but also with key individuals (c.f. Belso, 2006; Johanson & Vahlne, 2003; Madsen & Servais, 1997) Furthermore, these networks have helped them to identify foreign market business opportunities and have had a significant impact on the firms’ choices of which foreign markets to enter (c.f. Johanson & Vahlne, 2003). Additionally, the networks and KOLs have helped the SMEs to gain legitimacy and overcome the obstacles related to LOF (c.f. Belso 2006; Chetty & Pattersson 2002; Day 1995) since they often are local actors with a local network that is needed to reach the local business opportunities. However, the networks have not formed by themselves, all of the companies have had a clear goal working towards getting access to these in order to obtain the right contacts, becoming a part of the right network and influencing the right KOLs (c.f. Welch & Welch, 1996).

The two biggest barriers for entering a new market was (1), limited financial resources (c.f. Fillis, 2001; Ruzzier et al., 2006) or (2) the often high regulatory network that was stipulated at the foreign market (c.f. (Ruzzier et al., 2006). Nevertheless, since the rules and regulations within the healthcare industry often hindered the firms to enter a specific market could after their entry be used to their advantage since they also hindered their competitors to enter the specific market. Further, not only were the existing rules to their advantage, one company even tried to enforce regulatory rules by attempting to introduce CE-label requirements to do business in markets where it was not needed, both before and after they entered a new market. Thereby it can be argued, they took steps in trying to change the institutional environment of
those particular markets in order for it to benefit the firm and be a disadvantage for competitors. Thus one could argue that they in that particular example showed tendencies of trying to act as an institutional entrepreneur. Consequently, the conceptual model also needs to be adjusted. The barriers are described in the literature as something that is only negative and will prevent the SME to be successful. Our study can instead show that these barriers do not only have to be an obstacle to overcome; they can also be used as a competitive advantage towards competitors.

As stated, one case company failed their first internationalization and named the lack of business strategy as the key factor behind this. They lacked the needed competence and knowledge to successfully internationalize (c.f. Erramilli & D’Souza, 1993). After they replaced senior management and placed a CEO with international knowledge and experience along with a clear and valid business strategy, their new internationalization attempt was successful.

Corresponding to Leonidou (2004), our case companies experienced different barriers at different stages in the internationalization. Before entering the market, a main barrier was complex regulatory frameworks that were in place. However, after penetrating those barriers and entering the market, the foremost barrier to work with was the issues of LOF, mentioned under the institutional environment chapter in our previous literature review; (c.f. Hymer, 1976; Kostova, 1999); Zaheer, 2002) and legitimacy (c.f. Kostova & Zaheer, 1999; Suchman, 1995). All of the case companies expressed that the prevalent issue when establishing your internationalization was that they were easily viewed as a foreign company and lacked the legitimacy needed to be successful. The particular reason for this was that customers, suppliers and institutions did not take notice, trust or listen to the firms since they were foreign and unknown. The solution to this problem was not as according to (c.f. (Johanson & Vahlne 1977; Zaheer 1995; Zaheer & Mosakowski 1997) continue operating at the foreign market and thus attain a steady accumulation of knowledge and experience but instead to develop trust-based relationships and becoming embedded in a network with the right KOL (c.f. Gulati 1995; Vahlne & Johanson 2009). The literature states that the later solution (of which the companies actually used) is only proficient against those costs that are related to a lack of experience or knowledge and is not proficient against those barriers associated with LOF and the institutional differences that are caused by a lack of legitimacy (as of this case) (c.f. Eden & Miller 2004; Hymer 1960). However, all of the case companies in our study have shown that being in the right network with the correct KOL can also resolve the problems
related to both legitimacy and LOF. Additionally, these local networks could help the companies to overcome the barrier that was put up by the psychic distance (c.f. Barnes et al., 2006; Johanson & Vahlne, 1977; 1990; Johanson & Wiedersheim-Paul, 1975) that was illuminated by the cultural distances as well as the problem of having different primary languages.

5.3. How to change the institutional environment

First, similar to what Kostova and Zaheer (1999) argues, all of the case firms understood that they can be seen as foreigners and thus have a problem with legitimacy when trying to enter a new market. Just as Davis et al. (2000) and Kostova and Zaheer (1999); argue, the case firms often conformed in order to better fit the foreign institutional environment. Further, the companies also expressed that it is very important to be perceived as locals in order to obtain legitimacy. In order to do so, it was very important to work close with local actors, KOLs and distributors with the purpose of broaden their foreign network and thereby perceived as less foreign.

As argued, all of the case companies tried to adapt their organization or their conduct after the foreign institutional environment in order to not break any regulatory, cognitive or normative rules or lose legitimacy. The fact that they needed to conform to the specific cultural in each country in order to not loose legitimacy illustrated this clearly. Every company also expressed that they could not or would not dare to try to change the cultural rules that were part of the foreign institutional environment. Nevertheless, in several occasions, our case companies tried to influence KOLs and other institutions in order to change the regulatory rules and introduce the CE-label requirement, i.e. put up higher regulatory rules, in order to shut out competitors and thus gain a market advantage. However, these attempts have not been successful since they have been too small and to have enough power to influence real change. Therefore it can be argued that they in their attempt to change existing institutional regulations did try to act as an institutional entrepreneur. The sense that they were too small to influence is something that is backed up by both Business Sweden and Swecare which both states that a single firm in this business have little possibility to change these very static and tough regulator networks. Therefore, we argue that, in order for SMEs in the healthcare industry to really change the very static and specific regulatory institutions that exist in each separate foreign institutional environment, the companies need to, together with other organizations, come together and collaborate and thereby making a more powerful entity that can truly influence.
All the companies have shown tendencies to act as an institutional entrepreneur. At one occasion, a case firm managed to influence a very important KOL, and together, they saw to influence the education of medical students in the particular country, and managed to get their method of diagnosing cervix-cancer into textbooks. This is an example of how the companies can influence the existing foreign institutional environment and to use it as an advantage towards competitors. Furthermore, the firm is currently trying together with KOLs, to influence the Swedish counties in their guidelines for self-testing cervix-cancer so that it is advantageous for them. Not only that, maybe the clearest example for using KOLs to influence the institutions was when the same company approached the Turkish health minister, who happened to be a woman with insights into this particular medical field and tried to influence her. Another company used their KOLs that where in their network to change the local guidelines that define what type of diagnostics test and methods professionals are expected to use. Lastly, two companies tried to influence and change the foreign institutional environment by working close with KOLs, distributors and customers to develop and adapt their products to better fit the specific market preferences. You can argue that they, by doing so, were not changing the institutional environment but merely adapting and conforming themselves to the institutional pressure. However this is not the case, since they during collaboration also are affecting both the actors and norms at the foreign institutional environment. We can thus argue that they are indeed being affected themselves, but more importantly, they are changing the institutional environment that previously restrained their product, to now embrace it instead. Moreover, the companies did not only try to change the foreign domestic environment. One case company has approached several Swedish politicians in order to try to change the complicated institutional environment and guidelines that exists today.

Therefore we argue, relating to our conceptual model, that all of our case companies in several examples showed attempts of acting as institutional entrepreneurs since they initiated divergent changes that broke with the existing institutional template as well as actively participated in the implementation of the changes (c.f. Amis et al., 2004; Battilana, 2006; Battilana et al., 2009; D’Aunno et al., 2000).

5.4. Revising the conceptual model
After the above analysis, several aspects of the conceptual model presented in Chapter 2 must be revised. Firstly, we argue that the drivers as described in the literature are not only market opportunities on a foreign market elsewhere or by internal factors. Instead we have found that
specific market conditions (Sweden’s limited market size and the 21 counties with separate procurement processes which are both costly, time consuming and complex) can exert pressure on SMEs and push them to expand internationally where they need to find new markets to be successful. Further, we argue that the best way a company can do so is by facilitating their network to seek market opportunities elsewhere.

Secondly, these home market opportunities should not only be seen as a driver/pusher but should also be looked upon as a barrier that hinders the company to operate at the home market. Therefore we argue that the barriers do not only exist as an obstacle to penetrate a foreign market but instead surrounds the SME no matter in which market or institutional context it operates in. We also argue that the way to overcome this barrier, just like any other institutional barrier, is either conformity or, as we have seen all of our case companies try to do, to act as an institutional entrepreneur and thus try to change the institutional environment.

Lastly, we have shown the importance of the SME’s network, not only to overcome barriers associated with LOF and legitimacy but also to find and penetrate new markets. Furthermore, the SME cannot only use their existing network in hope of this but must instead seek out new networks and KOLs that exist at foreign markets. These three findings results in the revised conceptual model presented below.

Model 2 – The revised conceptual model
CHAPTER 6 – CONCLUSION

6.1. General conclusions

As stated, the purpose of this study was to increase and widen our understanding of how the internationalization process of SMEs’, operating in a highly regulated industry, unfolds with particular focus on how they interact with the foreign institutional environment. Therefore, after the presented empirical findings with corresponding analysis, several conclusions can be drawn.

Firstly, the main driver for internationalization among the case companies was not internal firm-specific conditions, to spread risk on several markets or make use of market imperfections. Instead the main reasons were because of Sweden’s limited market size and foremost, that Sweden’s institutional environment is costly, time consuming and complex to operate within due to their many procurements processes and county controlled healthcare.

Secondly, it is important that the SMEs determine an entry mode that is adapted after the foreign market conditions, regulatory framework, size and complexity, as well as the companies’ internal conditions, knowledge, financial resources and networks. Specifically, the companies’ networks are one of the most important factors for successful internationalization. The networks can help the companies both to expand and facilitate the correct entry mode by for example connect them with the right distributor, help them overcome the problems associated with legitimacy and LOF, help them overcome different barriers and also by aiding the companies to obtain new market opportunities. However, we argue that it is not specific foreign market conditions that decide which market the companies chose to expand to, nor which entry mode to us. Instead we argue that it is the firm’s internal factors as well as their network that are the two major forces.

The barriers that the companies face during the internationalization process should not only be seen as obstacles but instead they should be seen as potential advantages. If the companies succeeds to overcome the obstacles they can be used as a competitive advantage and hinder other firms from penetrating the particular market. Moreover we argue that the barriers do not only exist in front to foreign market but instead are a constant obstacle that always surrounds the SME, no matter in which market it operates.

Lastly, we can show that the companies in this study can act as institutional entrepreneurs since they initiated divergent changes that broke with the existing institutional template as well as actively participated in the implementation of the changes. However we will also
argue that they cannot be seen as true institutional entrepreneurs since the attempted changes to institutions are minor and not definite. We found that the reason for not being able to bring about major changes to the institutional environment in a highly regulated industry as healthcare is because the SMEs are too small to have the power to influence and thus need to organize themselves together with other actors if they shall have the possibility to perform major changes in the institutional environment, in other words cooperation is key.

6.2. Academic and managerial contributions

From an academic perspective, our study has contributed in the field of international business by adding to the comprehension and understanding of (1) what drives SMEs to internationalize, (2) which aspects are important when selecting entry mode, (3) that the SMEs’ networks has a much more multifaceted purpose then previously explained, (4) that the barriers internationalizing SMEs face can also be seen as possible advantages and (5) that SMEs can act as institutional entrepreneurs but it can be discussed if they can be considered true institutional entrepreneurs since they only make minor changes to the institutional environment.

Moreover, from a managerial perspective, our study has made contributions by showing that SMEs are able to not only conform, but also have a possibility to influence the institutional environment. Also, our study has shown that the managers must understand that they need to adapt their entry mode after both internal and external condition and that using their network it key and should be used to gain legitimacy as well as creating new market opportunities. Lastly managers can take lessons from this study by not only recognizing the barriers as obstacles but instead use them as a competitive advantage.

6.3. Limitations and Suggestions for future research

Since our study only cover Swedish healthcare industry SMEs, we cannot sufficiently enough say that these conclusions are valid to be generalized to include foreign firms or other industries. Therefore we encourage future research to have a similar purpose of their study but focus on domestic or foreign firms in other industries or markets. Further, if similar studies are performed, it could possibly be discovered what factors determines a true institutional entrepreneur or in which way firms can change institutional environments. Additionally, since this study lifts the importance of networks, it would be beneficial if future research focused on how firms obtain key networks, how they maintain them and use networks in the best possible way. Furthermore, since this study only focus on the companies within the healthcare industry, and their perception of their internationalization process, we suggest that a future
subject for research would be to focus on another actor in the arena; for example how hospitals and doctors perceive the matter or how politicians and lawmakers see the process of internationalization and companies attempts to change the institutional environment.
CHAPTER 7 - REFERENCES


Business Sweden, (2013) [link](http://www.business-sweden.se/PageFiles/11619/Svensk%20export%202012.pdf)


CHAPTER 8 - APPENDIX

8.1. Interview guide

1. Questions regarding the informant and the firm’s background, previous experience and current situation.

2. How and why has the firm internationalized?
   (From decision to action, drivers behind internationalization, what markets and why, entry modes)

3. What challenges did the firm face throughout the internationalization process?
   (Difficulties and barrier for internationalization, how did the firm handle these barriers, would you act differently today)

4. How did aspects of regulations, patents, certifications, etc. affect the internationalization process?
   (Regulations, institutions, policies and product approval process, action to handle these aspects?)

5. How did the firm use personal and professional networks, organizations, partners and cooperation throughout the internationalization process?
   (Achieve legitimacy and credibility on foreign markets, the creation of relationships and access to networks, influence of other actors.)

6. Did the firm in any way try to influence, affect or change the institutional environment of foreign markets throughout the internationalization process, or was there a pressure to conform to the existing regulatory, normative and cognitive structures prevalent in the market?
   (Direct or indirect influence or change on for example political, academic or business institutions, regulatory aspects, organizations, customers, partner or competitors.)
Changes / Additions to questions for interviews with Business Sweden and Swecare

2. How do you help in the internationalization process for Swedish SMEs in the healthcare industry?

3. From you experiences, what are the foremost challenges throughout the internationalization process for these firms?

   (How do the firms overcome these challenges, how do you help and why do you handle barriers differently?)

4. Regulatory question rephrased to ask them what they experience is the impact on firms.

5. How can firms use personal and professional networks, organizations, partners and cooperation throughout the internationalization process and how can you help with this process?

6. Can firms in any way influence, affect or change the institutional environment of foreign markets throughout the internationalization process, or is there a pressure to conform to the existing regulatory, normative and cognitive structures prevalent in the market? Can you?