

Mapping, Analysing and Reporting Barriers to Transnational Trade in Healthcare – SHINE project

SUMMARY

This report provides a detailed analysis of the drivers, barriers and support for the internationalisation of healthcare SMEs in Belgium, Scotland and the Netherlands. It uses a mixed methods approach combining secondary sources including project outcomes from EU funded projects, reports from commercial organisations and publications from business support organisations working in these three countries. The primary data collection based on semi-structured interviews in the three countries provides a vital insight into what is actually happening amongst SMEs in the healthcare sector and the organisations that support them. A wide range of motivators for internationalisation and an even wider range of barriers that restrain SMEs from pursuing an internationalisation strategy are identified from these interviews. External influences and future challenges provide a summary and overview of the key issues that SMEs need to consider, and that will be useful knowledge for the organisations providing business support for internationalisation in their strategic approach in the future.

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1. Introduction

1.1. Healthcare in Europe

The provision of healthcare in Europe is a complex and multi-faceted system that is highly confusing for those providing healthcare, those receiving and especially for those aiming to enter their products or services into the different health and care markets. The different systems range from the publicly funded NHS in the UK, to the systems led by the health insurance sectors, for example in the Netherlands, to those countries in which a mixture of types of provision makes up the healthcare system. Increasing challenges face those responsible for providing health and care to the people of this vast region, including the demands of ageing populations, increasing problems of providing for migrant populations who have particular health and care needs, increasing energy costs, the likelihood of diseases spreading into Europe from countries nearer the Tropics as climate change causes environmental changes to affect disease vectors, the impact of the Brexit situation and a myriad of other issues that present a frightening picture for policy makers, health and care service managers, clinicians, administrators and patients.

While there is recognition that business may have a significant role to play in meeting these challenges (Enders, 2008), businesses find it very difficult to penetrate the health and care systems in their own country let alone in managing to penetrate foreign markets. There is substantial acknowledgement of this as a problem, and there are many business support organisations including enterprise agencies, academic organisations, not-for-profit and other institutions that aim to help businesses to try and enter these markets.

Many healthcare providers are facing substantial budget cuts as the costs of providing ever more sophisticated and targeted treatments increases, and they are often pulled in different directions in trying to provide better healthcare for patients whilst identifying potential areas to cut costs. When businesses approach healthcare providers with new ideas, and innovations for new products and systems therefore, it is not a simple matter of accepting the technology, however excellent its outcomes are, as the many financial, administrative and political issues can mean that the healthcare provider will not be in a position to accept that technology into their procurement system, their management process or their clinical diagnostic and treatment systems. It is difficult for businesses to recognise this complexity, and difficult for healthcare providers to overcome or even to communicate the problems to businesses. As a result, there continues to be a disconnect between these two groups which even the business support organisations struggle to overcome. The willingness exists, but pragmatically it is not always to resolve the disconnect.

1.2. Transnational Trade in Healthcare Overview

That the healthcare sector is important to trade within the European Union is without doubt. FTI Consulting (2016) states that the sector drives a significant percentage of trade inside and outside the EU market, and that healthcare consumes, on average, 10 per cent of national budgets across the EU, making it a huge market sector providing a wide range of opportunities for businesses of all sizes and across product specialisms. It is argued that trade has a natural role in healthcare and that in addition to the wide range of products and services including thousands of items of medical equipment and

pharmaceuticals that form the basis of much of this trade, there is increasing opportunity for an expansion of trade both spatially and in relation to technological innovation (Erixon et al, 2015).

1.2.1. European Pharmaceutical Sector

The European pharmaceutical sector is regarded as one the EU's top performing high-technology sectors, and had an estimated E361500 million value in exports in 2015 (EFPIA, 2016). 23% of the world's new medicines were launched in Europe between 2010 and 2015 and E31500 millions was invested in pharmaceutical R&D in 2015 (EFPIA, 2016). SMEs are increasingly important in pharmaceutical innovation - SME applications for the marketing authorisation of new medicines comprise between 10 to 15% of the overall number of applications to the European Medicines Agency (EMA), and more than one in two medicines developed by SMEs (recommended for marketing authorisation) in the past 10 years contained a new active substance; showing that SMEs are an important source of medicines - 42% of these medicines being orphan medicines for rare diseases - with 1619 companies from across the EU being registered as SMEs with the EMA (EMA, 2016).

1.2.2. The Medical Technology Sector

Many businesses operate in the medical technology sector, which incorporates sticking plasters to syringes, wheelchairs to hearing aids, and blood glucose monitoring devices to replacement joints, and everything inbetween.

Globally, there are some 500000 medical technology products, and in Europe there are 26000 med-tech companies of which 95% are SMEs, most of which employ less than 50 people (i.e. are small and micro-sized companies (MedTech Europe, 2016). Around 10% of GDP in Europe is spent on healthcare and it is estimated that of this figure about 7.3% (or less than 1% of GDP) is spent on medical technologies, providing a market worth an estimated E115 billion in 2015 (around 28% of the world market) (MedTech Europe, 2016). Individual countries in Europe have varying sizes in their medical technology markets as shown below.

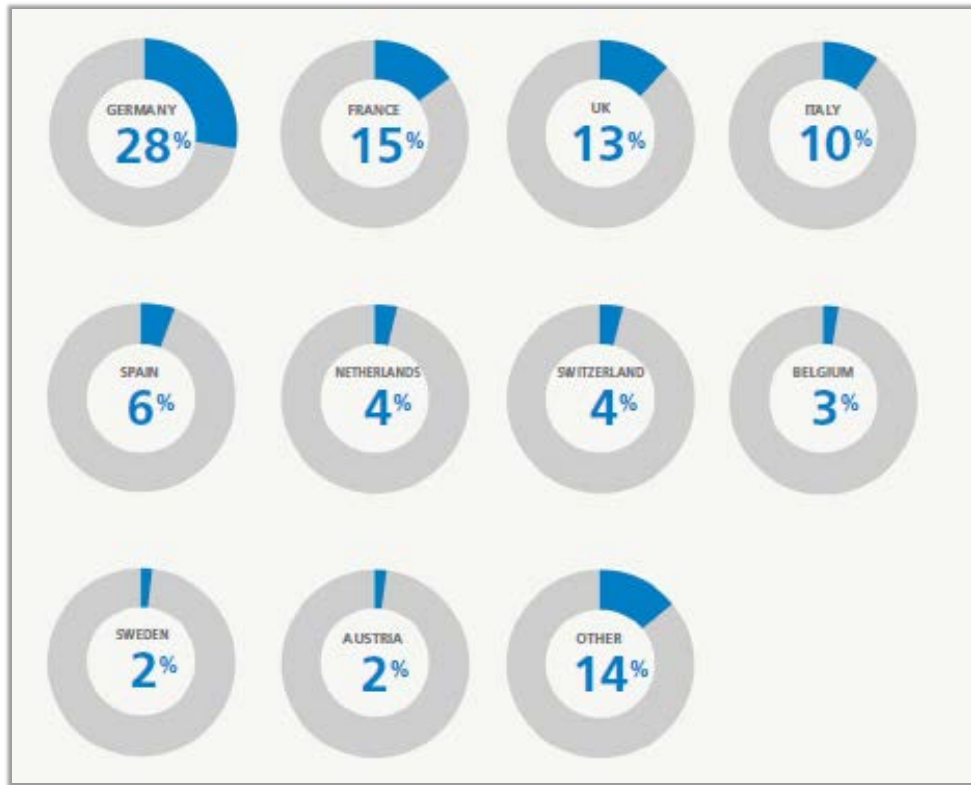


Figure 1 European Medical Technology Market by Country (based on manufacturer prices) 2015 (MedTech Europe, 2016:26)

Of these medical technologies, there are some sectors that stand out as being the most market dominant, with in-vitro diagnostics, cardiology and diagnostic imaging being the largest, although there are still substantial opportunities in many other areas including orthopaedics, dental and endoscopy, as the graph below shows.

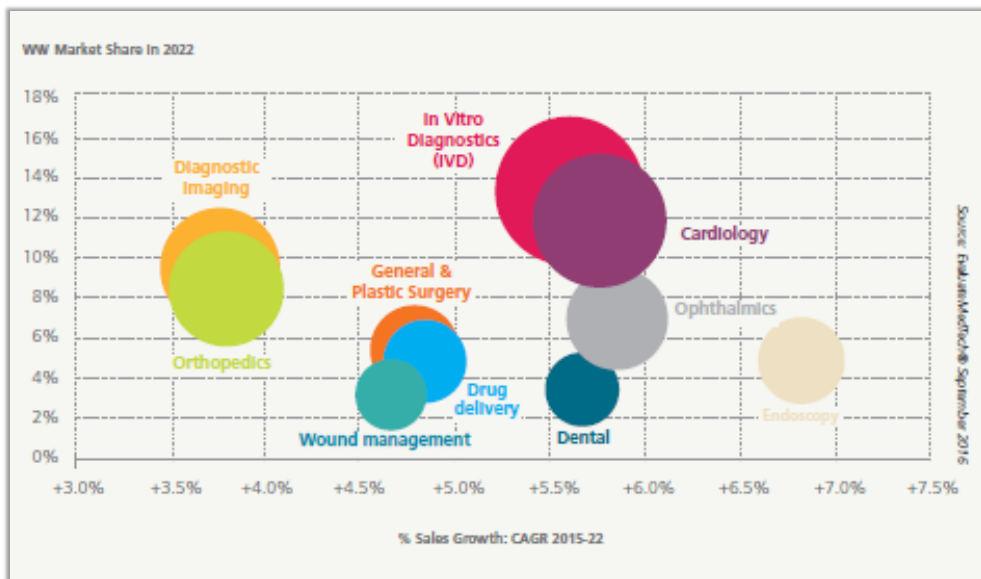


Figure 2 - World Medical Technology Market by Area and Sales Growth 2015 - 2022 (MedTech Europe, 2016:29)

1.2.3. The Digital Health Sector

The digital health sector is argued to be still 'young' with 82% of EU startups in a very recent eHealth Hub project survey of 300+ digital health SMEs stating revenues of under 100K€, with 39% of them being at the pre-revenue stage, and most of the trade being of the B2B type, because it is also argued the B2C trade is reliant on consumers being much more active in purchasing products for their own healthcare management, and this is not happening on a very large scale at the current time (Lardier, 2017).

2. Methodology

2.1. A Mixed Methods Approach

It was decided to employ a mixed-methods approach to the gathering of data to provide answers to the questions surrounding barriers to transnational trade in healthcare, especially in relation to SMEs. The methods therefore included a secondary data method – that of secondary data analysis from reports and academic papers focussing on this issue. This was followed by primary data collection in the form of semi-structured telephone and face-to-face interviews conducted with selected experts in Belgium, the Netherlands and Scotland.

The strengths of this method of data collection are that it provides a comprehensive overview, gathering a range of views from recent publications, which give a multi-perspective understanding of the key trends, issues and concerns that face businesses wishing to expand into international markets. The weakness of this method is that the rapid change in what is happening in the real-world outdistances the information provided in such documents.

2.2. Primary Data Collection

Consequently, it was decided to conduct some small-scale primary data collection to gather expert views on the current state of the barriers facing companies seeking to trade internationally. These expert views were obtained through a process of semi-structured interviewing; telephone interviews in the case of Belgian and Dutch experts, and face-to-face interviews in Scotland. Interviews generally lasted for 30 minutes and were professionally transcribed to ensure a high level of accuracy. Semi-structured interviews were used as the method as this approach is known to provide detailed views of a specific issue in some depth, and which can illustrate or disagree with the key points made in secondary data sources. The contact names for the interviews were provided by the relevant partners in the SHINE project. It was found that in the Belgian and Dutch cases not all of the contacts wished to participate in the interview process, and as a result the final number of interviews was 4 in Belgium, 4 in the Netherlands and 6 in Scotland.

3. Overview of Transnational Trade in Healthcare and the Benefits and Challenges for SMEs

3.1. The Policy Background

Getting SMEs to internationalise is an important EU policy objective, as it is seen that such a move can significantly benefit the European economy. Some of the objectives stated by the European Commission in the Communications 'Small Business Act' for Europe (EC, 2008) and 'Small Business, Big World' (EC, 2011) are to facilitate the internationalisation of EU SMEs. Supporting SMEs' economic activities outside the EU is integrated into the EU's overall competitiveness strategy as outlined in the Europe 2020 Communication on Industrial Policy and the EU 2010 Trade, Growth and World Affairs strategy (EC, 2010). This is especially true when considering the implementation and enforcement side of EU trade policy and the revised Market Access Strategy "Global Europe - a stronger partnership to deliver market access for European exporters" (EC, 2007).

3.2. Motivators for SME Internationalisation

The benefits of transnational trade can be substantial. The Transatlantic Trade and Investment Partnership (TTIP) in its 2015 Report on Opportunities for SMEs points out that companies with high-quality products can achieve substantial sales in Europe and the US, and that any action that reduced barriers will stimulate a rapid growth in these companies (TTIP, 2015). One aspect of trade and collaboration at which SMEs excel is in research, which in the medical technology sector typically occurs at the bedside and is usually a result of small or micro collaborations between SMEs, health professionals and academia. It is known that this research model brings rapid innovation, which quickly tackles current and emerging medical needs (Med Tech Europe, 2011). It is also known that international SMEs create more jobs and report higher turnover growth, for example, internationally active SMEs report growth of 7

% in employment versus only 1 % for SMEs without any international activities (European Commission, 2012).

The motivations for SMEs to move into an internationalisation strategy are varied, but include growth motives - where a company has a clear strategy to achieve growth it is more likely to move into international markets than companies that are not investing in growth; knowledge-related motives - where a company may be pushed or pulled into the international market because of the previous internationalisation experience of an owner or manager of the company for example (push), or because a company has a desire to obtain new knowledge or know-how and finds itself drawn to a foreign market (pull); and, network/social ties and supply chain links motives - here the process of collaboration and the exploitation of a company's 'soft' linkages such as its social or familial background may illustrate potential motives for entry into foreign markets (OECD, 2009).

3.2.1. Theories of Internationalisation

These motivators are at least partly recognised by theories of internationalisation. One theory sees this as 'stages of development' where firms become incrementally involved in foreign markets, from a point of no regular exporting, through exporting via agents and sales subsidiaries, and then to foreign production and manufacturing (Clark and Pugh, 2001). Network theory states that exporting occurs as a result of the development of networks and interactions within those networks through which trust and information are generated (Chetty and Blankenburg Holm, 2000). Finally, resource based theory which states that internationalisation decisions happen within the context of the strategic development of resources, both internal and external, and the physical, political and economic environments in which a company operates (Crick and Spence, 2005).

3.2.2. Characteristics of Internationalising SMEs

Research carried out by Pickernell et al (2016) using data from a Federation of Small Business survey containing responses from 4838 SMEs found that SMEs that export differ in their characteristics both relative to non - exporters and across business age boundaries. In terms of resources, they found that there was a consistently positive and significant linkage identified across variables, for example between degree - level education or higher and an export orientation within the business suggesting graduates play an important role in enhancing SMEs export performance. The authors also found that effective usage of website technology was linked to export behaviour which is an association with e -commerce trading to enhance trading (Pickernell et al, 2016). While this study did not focus exclusively on SMEs in the healthcare sector, it would appear that these findings would be applicable to SMEs working in the high-technology sectors that characterise healthcare SMEs in Europe.

3.3. Barriers to SME Internationalisation

For many companies the step up from trading in the domestic market to trading in the international market is fraught with challenges and difficulties, sometimes sufficient to deter that step being taken. When companies do take that step they can encounter a range of barriers that can derail the planned trading approach. Often these barriers apply commonly across all countries in Europe and beyond, and

are particularly difficult for SMEs to surmount. Some of these barriers are specific to healthcare, or to the healthcare markets in particular countries. SME knowledge of these barriers is often poor, and even with support from a range of business support agencies, enterprise agencies and other organisations, planned expansion into new markets can easily fail.

In general terms, all SMEs, inside and outside of the healthcare market, have long reported common barriers to internationalisation. In 2009, an OECD report on this issue identified the following as the key barriers:

- A shortage of working capital to finance exports
- Inadequate knowledge of overseas markets
- An inability to find contacts or communicate with contacts in overseas markets
- Lack of managerial time, skills and knowledge

(OECD, 2009)

Some other barriers identified in the report were administrative and technical difficulties, issues with exchange rates, documentation and payment problems and existing competition in foreign markets. The findings of this report also indicated that one of the most effective ways of supporting SMEs into penetrating foreign markets was to integrate them into the value chains of larger companies (OECD, 2009).

SmartInno, a EU funded project comprising a number of development agencies and supporting organisations, has carried out a survey of 12 National Industry Associations (including all the major medical technology exporters) across Europe. It has identified that the 7,000 SMEs that design and manufacture medical devices and diagnostic products in Europe, face “significant barriers that prevent them from reaching their potential” (SmartInno, 2015). Specifically, they found that SMEs have difficulty with product registration, reimbursement, procurement, distribution channels, health technology assessment and access to R&D incentives, all of which are compounded when the company seeks to move into other countries.

3.4. Provision of Business Support for SME Internationalisation

There are a number of initiatives and programmes across Europe that focus on supporting healthcare SMEs in their aim to grow and trade with other countries. It is not the function of this report to provide a list of the many large and small initiatives and programmes that exist across Europe to provide such support. However, it is clear that while national governments and the European Union have developed policy and programmes to help SMEs in this sector through knowledge exchange, funding, business technical skills support and many other aspects, the support landscape and the innovation landscape is crowded, difficult to navigate and lacking integration. In addition to the government and EU funded support, there are also initiatives provided by industry trade associations, member schemes and a variety of other organisations. Together all of these sources provide a lot of potential support for the healthcare SME that wishes to internationalise, but not always in the most accessible package.

3.5. The Impact of Brexit on Healthcare SME Internationalisation

The impact of Brexit on international trade in healthcare is likely to be substantial and surrounded by complexity. FTI Consulting points out that the health and Life Sciences are heavily regulated sectors, which directly employ a significant proportion of the workforce across health and care delivery, pharmaceuticals, research and development, education, and a wide variety of other activities. It also indicates that there is likely to be some substantial changes in the infrastructure currently governing the product approval activities - for example, the European Medicines Agency (EMA), the EU's one-stop shop for a centralised marketing authorisation (MA), which allows medicinal products to enter all EU and European Economic Area (EEA) and European Free Trade Association (EFTA) states (Iceland, Liechtenstein and Norway) is currently located in London, but this is likely to move to one of the Member States staying in the EU (FTI Consulting, 2016).

The position and views of some of the key organisations that support businesses in internationalising their products or services point to the lack of clarity and the uncertainty surrounding the whole Brexit process as unnerving some companies, and causing them to rethink internationalisation. For Scotland, at the current time (in Spring 2017) it is seen as a good position for exporting into Europe and the US, and there are short-term gains, but this is unlikely to be the case for long. It might be for UK companies that following Brexit it will be easier for Scottish companies to trade with Europe because there will be fewer rules and regulations for business support organisations to be concerned about. Some of the restrictions that exist in Europe are about the amount or level of support that companies are allowed to receive from business support organisations, and in Scotland it is thought that Brexit might allow that restriction to be changed or lifted, but everything is in all European countries a time of insecurity about the future.

4. Perspectives on Healthcare SME Internationalisation in Belgium, the Netherlands and Scotland

4.1. Introduction

This section of the report provides the responses from the expert interviews gathered during the primary data collection stage of the research. It presents the findings for each country, and divides it in each case into a section focussing on the general patterns of healthcare SMEs, their motivations for wanting to internationalise, the barriers, both perceived and actual, that prevent them for internationalising, and the support that is available to try and overcome these barriers.

4.2. West Flanders / Belgium

4.2.1. Healthcare SMEs in West Flanders and in Belgium

SMEs in Belgium are largely in the 1 to 5 employee bracket (70 – 80%), but the range between 20 – 100 employees is also quite well represented. Services represents about 25%, 15% are in what are known as the free professions (lawyers, architects, pharmacists and the like), while construction is also a big sector.

There is a wide variety of other sectors represented in SMEs in Belgium – retailing, manufacturing, food production, transport logistics and others. There are also a lot of SMEs that are involved in machinery, logistics and IT solutions in farming and in healthcare. In the healthcare sector, there are a lot of SMEs that are really active worldwide i.e. in 20 to 60 countries, with some 80 to 90% of their turnover from export goods or services. A lot of these companies have followed a strategy of developing themselves as a ‘niche player’ because their products or services are quite specialised – while this means that they need to look worldwide for their customers, it also means that they tend to be quite robust in international markets. The healthcare sector is acknowledged politically as being of importance because of the investment made by the government in a range of projects and programmes. The size of the healthcare sector itself in Belgium is substantial with at least 200000 people working in it.

The SME sector is strong in the West Flanders region, not only in the healthcare sector but also in other sectors that deliver products and services to healthcare organisations. The healthcare sector in West Flanders does not have many pharmaceutical or life sciences companies, instead having companies that are involved more generally in the healthcare economy. For example, one company in the region makes audio-visual solutions and screens that are commonly used in healthcare provider organisations, whilst another company provides a range of audio services – so they are not actually making health products or services – rather they are providing products and services that are used widely by the healthcare providers in the region. The healthcare economy as a sector is considered to be growing in importance in the region, and in Belgium as a whole, because of the ageing population of the country meaning there is a growing demand for healthcare services and products.

4.2.2. Drivers for Internationalising Trade for Belgian Healthcare SMEs

There is a clear link between the desire for growth in Belgian healthcare SMEs and the likelihood of their intention to internationalise - either through export trade or through collaboration with organisations and business abroad. Many Belgian healthcare SMEs are in specialised sectors, for example, in digital health, web-based solutions, and highly specialised medical technologies so they have the potential to access markets worldwide. The products and services they provide change and improve rapidly, so they try to add value to their products on a continual basis to keep them attractive to their customer base. Of course, they wish to grow to increase profits, but are also very passionate about contributing to the overall healthcare of patients and to help prevent disease and illness in the healthy population.

In West Flanders the whole economy is made up of SMEs – they are the driving force for the regional economy. Many of these businesses are small, and are often family owned businesses, but are nevertheless innovative, and it is recognised as a very entrepreneurial region. In general the SMEs in Belgium or at least in the West Flanders region are well organised to move into international markets – this is partly because of the crowded, small nature of the Belgian nation market – SMEs quite quickly understand that they may need to move into international markets. It is slightly different for start-ups as they are not generally well set up for international markets to begin with and it takes time and experience for them to grow into a more prepared position.

4.2.3. Barriers to Transnational Trade in Belgian Healthcare SMEs

4.2.3.1. Lack of Knowledge

The main barriers that have been identified include a lack of knowledge about a variety of aspects. First, there is a general lack of knowledge of markets especially those in other countries, not only those at distance, but also markets in very nearby countries. Next, a lack of knowledge of how companies in other countries operate, in other words, what their corporate culture is like. This definitely acts as a barrier to those companies wishing to develop their export activities. While large companies may have subsidiaries in other countries, this is uncommon for SMEs, and if they are not familiar with the different ways of doing business that characterise markets in other countries, they can find it very difficult to start this process.

Another lack of knowledge is that regarding innovations happening within sectors or within markets more generally, and the opportunities that might be available for companies seeking to internationalise – some innovations being cross-sectoral in nature. Without this information, some of companies are missing out on these innovation opportunities. A lack of knowledge about the structure of the market is also an important deterrent. For example, in the UK people can visit Boots the Chemist and speak to a pharmacist for advice, obtain their prescription and buy off the shelf medicines, but they can also buy a wide range of other products including food, beauty products, and electrical items. In Belgium, a pharmacy operates similarly to a doctor, and only sells medication (that can be delivered up to five times a day because most of these businesses are very small). If a company is not aware of these differences they would not know to contact the big pharmacy retailers if they have a product to sell into the UK – and they may also not know the highly complex structure of regulations that have to be observed if they wish to sell their products or services in the UK.

Most of the West Flanders or Belgian healthcare SMEs are too small to gather information on such barriers or on markets by themselves, so even though there are a number of companies that have products or services likely to be of interest to foreign markets they see the knowledge and informational barriers as too difficult to overcome and don't even try to go down the route to internationalisation.

4.2.3.2. Language and Culture

Another barrier is that of language and culture – not only the fact that people may be speaking a language different to that of the SME's employees, but sometimes in relation to the terminology used. Cultural difference is also a potential barrier – not only between countries but sometimes within a company or between regions. For example, in Belgium, it has been stated that there is a very different culture in business and the desire to internationalise between the Flemish entrepreneurs and the Wallonian entrepreneurs. The problem becomes greater the further away from the home country.

4.2.3.3. Perceptions of Competition

A further barrier is the perception of competition held by some of the owners or managers of healthcare SMEs. They can perceive selling to other markets as high risk. One useful example is of a Belgian company who were afraid to import a resource from another country even though it would have improved their

product; they were concerned if they followed this path they would cause their relationship with their local suppliers to be negatively affected. Often it is just taking the first step that causes anxiety.

4.2.3.4. Investment Risks

Perception, this time of the risk engaged in investment, is another barrier that deters SMEs from developing their export markets. There is a need to invest substantially in the preparation of a new market, and developing a company's products and processes long before any sale is possible, and before it is apparent that this new market might actually be useable and profitable for the exporting company. This means that healthcare SMEs, both in West Flanders and in Belgium more generally, tend to develop their foreign markets in a linear fashion – one after the other, as developing 4 or 5 markets concurrently is likely to be far too expensive for a small company. One example provided for the healthcare sector in Belgium, is a company involved in providing logistical solutions is exporting to South Africa, but the turnover they have in this market is only around E100000 meaning that after investment there is not much margin to be obtained especially if adaptations are required. Such companies have to balance the risk and level of investment against the potential revenue. It is often about risk and perception of risk, and it is suggested that if a company is not absolutely sure that the risk is worth it or are risk averse, then it is better for them not to seek to start exporting to foreign countries. Selling into Europe has some level of protection and familiarity, but there is greater risk exporting into countries further afield with very different cultures, into China, for example, in terms not only of the culture but also the political stability of such countries and their administrative infrastructure that is difficult to deal with.

4.2.3.5. Contacts in Foreign Markets

Fact finding missions overseas can be costly in terms of finances and also personnel, especially for those companies who have only 3 or 4 staff, none of whom is in marketing or sales. In fact, this is often the case with University spin-out companies – they have the personnel to design and develop a product but are very poor at selling it. One possible response is for SMEs to cluster so that they can share a sales person. This relates to a lack of contacts in foreign markets that characterises SMEs, again this goes back to lack of knowledge but specifically here it is in relation to having a known person that can support their entry into the new market. It is a big step to try and move into an export market without any support, and without identified contacts, and many SMEs will therefore defer decision-making about developing into export markets. This lack of contacts and the difficulty in developing them if the company is not using any form of organisational support is a common response from the experts interviews, who also point out that there is a lot of interest in finding out how to approach business people in 'other' cultures. Flanders In Trade (FIT) carry out an annual survey and the biggest problem identified in relation to internationalisation is 'finding the right partner' and this is often because of the partners available very few are seen as 'really competent'.

As a result sector specific contacts in each country are really important. The key issue is that SMEs do not have the resources to build big networks in foreign countries, and governments can have a broad network but not a highly developed network. There has to be choices made by all concerned about how much time and effort they can spend on one sector and the development of contacts, and these decisions have to be rational and take into account the resources available.

4.2.3.6. “Red Tape” and Customs

Red tape, especially in relation to customs, is another barrier often referred to. One of the experts interviewed quoted from UNIZO research survey of 400 Belgian exporting companies in 2015. This survey found that 34% of companies spent more than one hour for working on ‘custom’ formalities i.e. preparing and assembling customs documentation. They also asked whether these companies had any difficulties with their customs declarations at any borders, and 38% of companies had goods retained at a border as a result of customs concerns. 23% stated that they had spent more than E1000 a year because of extra costs generated by problems with customs, 24% had spent more than E100 and 10% more than E5000, and 31% needed at least half a day to solve these problems. The expert pointed out that it is not just the customs authorities that make mistakes, however, it is also the SMEs, as they may miss completing the documentation accurately.

4.2.3.7. Rules of Detachment

Another barrier is the lack of knowledge that SMEs have about the rules of detachment. This relates to companies that wish to pursue small assignments in foreign countries for up to a duration of a year. In this situation, a company is required to have a copy or proof of paying social security payments in their home country, and if this is not proved the company can be fined up to some thousands of Euros even if they have only been working in the foreign country for a few days. As the rules can be slightly different in each European country this is a challenge for SMEs, and there are added complications if the foreign country’s sector regulations are also different i.e. regulations relating to overtime, minimum wages or other such issue. Even small irregularities can cause problems if the SMEs are not aware of them, and if they need to engage lawyers to sort out any infractions that can increase the cost of such a lack of knowledge.

4.2.3.8. Regulation

In relation to regulation, it is argued that it is not sufficient to have a high quality product or service, it is more a need to be responsive to the national regulation of the countries in which a company is aiming to develop its market. Products may have to be adapted to the regulations of an individual country, and as every country has differences in its regulations this means that a company may have to go through a number of adaptations which is easier for SMEs than for larger companies that do not have the ability to be so flexible, but it still involves substantial time and resources.. On the positive side, if an SME is willing to invest in the time required to get to know a market thoroughly and the regulations that are specific to it, if that company becomes the only one that is able to meet the regulatory requirements and has a product or service that will be well received in that market, then it could have a very positive experience and outcome. However, it is stated that the healthcare sector has a level of regulation that is difficult for companies to understand and comply with. In fact, there are multiple levels of regulations – about products, about services and about financing.

4.2.3.9. Nomenclature

One of the first questions SMEs ask is what is the structure and process of social security in the country they wish to sell into, what is paid for by the government and what is paid for by the patient, and what products and services can be at least partially reimbursed by the government. This is known as 'nomenclature' and is the list of medical aids, pharmaceutical products, and services that medical professionals can use that will be partially reimbursed by the government or health administration. If not on this list a product or service will have to be fully paid for by the patient, and this clearly is likely to deter some companies as they may feel that their product will be too expensive for patients to pay for regardless of how effective it is. An example in Belgium is that the cost of cancer treatments are supported but the cost of diabetes treatments are not because it is not such an important problem in Belgium. This information is very difficult to obtain, not just for SMEs but even for organisations like FIT even though they have networks developed in foreign countries. The difficulty is that they are covering all sectors not just healthcare so they do not have the capacity to develop very deep understanding or knowledge in any one sector.

4.2.3.10. Financial Resources

Financial resources, or the lack of these, can also act as a barrier. Especially the smaller companies, as these do have a lack of access to financial resources that would support them in exploring foreign markets – whether this is in attending international trade fairs or even becoming more organised and geared up to develop an export process.

4.2.3.11. Impact of Brexit

There is undoubtedly concern about Brexit and the impact that this will have on their business. Companies are already exhibiting signs of concern and anxiety about what Brexit will mean, for example, about customs rates. It is the uncertainty of what the changes will bring, and because it is not possible to obtain answers from anybody at the current time, this uncertainty grows and presents companies with a barrier to internationalisation. If they regard moving into international markets already as a difficult process, the addition of a large scale change which has limited detail associated with it at the current time can substantially reduce the company's desire to move into other markets.

On the positive side, research has shown that those companies that do manage to export to foreign countries are generally stronger as companies than those that remain selling in their own home country. However, it is suggested that companies do not start with the difficult markets first, but instead follow a progression of trying to start with exporting to neighbouring countries, and then, having built up a level of skill and confidence, start to move into the more challenging markets. It helps companies to streamline their structure as well as stimulating their growth but it does require companies to be much more flexible and there are a lot of unknowns that they don't get in Belgium.

4.2.4. Support to Overcome The Barriers to SME Growth and Export in West Flanders and Belgium

4.2.4.1. POM West Flanders

It would seem natural to assume that supporting SMEs to move into foreign markets would be the role or responsibility of the Belgian Government funded organisations. One organisation that provides support to SMEs in West Flanders in terms of their internationalisation is the Provincial Development Agency (POM) which is funded through the provincial level of government, and has as its focus the economic development and promotion of business for the region. POM assists in hosting international delegations and international companies and networks them with local companies, as well as having a presence abroad in promoting the West Flanders region to companies in foreign countries. The organisation focuses on a selected number of clusters, one of which is the health and healthcare cluster. It does this because it finds it is more effective to focus on a small number of niche clusters especially when assisting start-ups and SMEs that have no experience of moving into international markets. POM tries to foster the possibility of internationalisation early on with SMEs; seeking linkages abroad, and sometimes encouraging them to internationalise immediately, rather than following the classic route of getting the national market successfully developed first and then internationalising. POM tries to support companies by financial assistance with attendance at trade fairs, with cluster companies sharing a stall and heading it up with a cluster name. It also facilitates developing contacts between businesses sometimes using a type of 'match-making' approach.

4.2.4.2. Flanders Investment & Trade

Another organisation in West Flanders, is Flanders Investment and Trade (FIT) that is facilitated by the Flemish Government – an enterprise type agency that is focussed on internationalisation. Each county in Flanders has a FIT office, which provides businesses with the first level of information about internationalisation, foreign markets and many other issues – FIT helps businesses to take the first steps. It also provides them with a broad understanding of what it means to internationalise and they can return to obtain further advice and support even when they have begun to sell abroad. They provide substantial support for SMEs, for example, by assisting them to attend trade missions. They have offices in other countries as well (50% in Europe and 50% further afield) and up to 30 years of experience in some countries so provide a very well supported service. Flanders in Trade has a KPI that relates to the numbers of exporting SMEs supported with information, appointments, contacts, and these activities are known to be appreciated by the SMEs that use them. It provides market information, lists of distributors, possible partners, information on regulations, and introductions to useful contacts including relevant ministries and administrators, participation in trade missions, networking events. They offer subvention for market prospecting activities: SMEs can get up to 50% of their travel and accommodation costs for up to four times a year, which is a substantial contribution financially that can benefit SMEs and can make the difference between whether they decide to look at expanding into export markets or not. It is difficult and expensive for SMEs to independently to obtain the type of information that they can get from FIT or other similar sources. However, it is also stated that if SMEs make an effort to do some of the investigation of the market and of relevant contacts themselves, then they are likely to be better supported by the export support agencies.

4.2.4.3. UNIZO

Further support in Belgium is provided by UNIZO which is an SME organisation that represents around 85000 members, mainly small and micro SMEs. It has an international department which exists to help members with information, advice and networking services worldwide for goods and services both for import and export. UNIZO provides courses and information, aids contact for companies to other individuals within their network that can support them with such issues as regulation, and has networks and individual experts to provide support that is vital for SMEs. UNIZO also has an entrepreneur's hotline that receives over 1000 calls a year, and if their question cannot be directly answered the organisation puts them into contact with an appropriate expert, for example, a lawyer.

4.2.4.4. Overview of Business Support for the Internationalisation of Healthcare SMEs in Flanders and Belgium

While the work of these organisations is appreciated, one of the experts interviewed felt that the barriers to internationalisation in relation to lack of information or knowledge about the differences that exist in foreign countries, were made worse because there was a limited specific focus on healthcare internationalisation within the Belgian government. It was felt that while all sectors were generally supported for SMEs, healthcare had a much greater level of regulation so generated a greater barrier than for some other sectors. It was felt that while Government support could very useful, it was often rather broad and perhaps could not provide help at the level of identifying specific contacts for specific SMEs. Another issue is that while there are many SMEs that do use the services of FIT, POM and other organisations, there are many more companies that appear to be unaware of this support and the services it provides, so these business support organisations have some work to do rectify this situation.

Two of the other experts interviewed suggested that there is plenty of general support available, but much less for specific sectors and even less for specific companies. They argued that market specific support is the real necessity, because issues of legislation, customs, regulations and other matters are very different from sector to sector. It was suggested that it might be useful if sector federations could provide some more of this targeted support, as there is a limit to the resources available for Government funded programmes. It was further argued that it would be useful if there could be more consistency across Europe in relation to how information about differences in national systems is obtained and how it is provided to businesses. An example was provided of there being at least 35 ICT companies in West Flanders that do not currently work in healthcare, but who have products or services that would fit well with healthcare and could internationalise in this sector, but they do not have any knowledge and have a perception of the regulatory background being so complex that they have decided not to pursue this kind of opportunity, especially as it would require substantial investment to enter into these new more complex markets.

It would be useful for companies to have regularly updated information about what is happening within a sector as a whole, to see the trends, the differences between countries and other sectors. This kind of broad overview would allow companies to have a much better understanding of their place within the sector, and other sector, to assist them in making decisions.

4.2.5. Conclusion

While these business support organisations can provide some support, even some financial support, to ease the internationalisation process, it is really with the healthcare SMEs themselves to decide whether they move towards internationalisation – if they don't have the will or the interest they will not make this move. A lot of West Flanders SMEs are seen as having a pioneering spirit, but it would be difficult to put a number on those who felt able to develop their export market regardless of the barriers that faced them, and the number who would struggle. The views of the experts is that healthcare SMEs have a persevering spirit in this region, so they would not give up immediately, but might eventually decide it is too difficult to internationalise.

4.3. The Netherlands

4.3.1. Healthcare SMEs in the Netherlands

SMEs in healthcare are important to the Dutch healthcare system because they not only offer services to the healthcare providers i.e. the hospitals but also to manufacturers engaged in producing healthcare products as the SMEs may form part of their supply chains. This means there are a number of very expert or niche teams in SMEs. There is no longer a large pharmaceutical sector in the Netherlands, but there has been a growth in biotech and SMEs are very much part of this.

There is quite a wide definition of the term healthcare, used by the expert interviewees as some of them include companies that are not necessarily focussed primarily on healthcare, but instead provide products or services to healthcare institutions, those products and services not being medical, biomedical or healthcare devices, drugs, therapies or similar items; instead being such things as cleaning systems, food products or the like.

There has been a substantial growth in the healthcare sector as a whole as evidenced by the increasing number of businesses and other organisations that participate in the missions organised by different business support organisations. Other evidence is provided by the large number of incubators, life science and healthcare hubs that have been established across the country, and the number of new start-ups, SMEs and other organisations that have recently emerged in the sector.

4.3.2. Drivers for Internationalising Trade for Dutch Healthcare SMEs

From an SME perspective, the opportunities to get products into a range of markets and to achieve increasing sales is the key motivator. Some SMEs have found it possible to work closely with healthcare providers to develop their products and services in the Netherlands. This is especially the case where a business includes a clinician or other healthcare professional as one of the start-up founders. This provides a route to clinicians in other countries making it easier to start discussions about selling products in those countries, so gaining a clinician as a partner in the early stages of a business is a big motivator to move into foreign markets at a relatively early stage.

In terms of internationalisation for SMEs in the sector, most companies are likely to start with the countries that are nearest. In the top ten export destinations for Dutch companies, number one is Germany, two is Belgium, three is the UK and then the US, France and Switzerland.

4.3.3. Barriers Facing Dutch Healthcare SMEs in Internationalisation

4.3.3.1. Contact in Foreign Markets

One of the main barriers for SMEs is the amount of time they have available to reach out into new markets and find new contacts. Most SMEs will choose to start slowly. One company interviewed from the region explained that they had a clinician as one of the founders of the business, so the advantage of that was they had been able to access clinicians in other countries because they had the clinical contact. All that SMEs really want to know is does the market want their product, are they willing to pay for it and will it work in the foreign systems, and if the answers can be established then at that point it might be possible to identify a useful contact, but getting the answers to these questions can be very difficult.

4.3.3.2. "Red Tape" and Customs

A further major barrier is the problem that many companies have with customs. In its annual survey of the whole of the life sciences and healthcare sector in the Netherlands, Task Force Healthcare found that 44% of respondents identified export issues around customs as problematic. Specific issues were the bureaucracy, the completion of paperwork, and the compliance with regulations. Businesses pointed out that the actual completion of all these requirements was not difficult, but it was the time that it took which definitely hampered them in getting their products to customers.

4.3.3.3. The 'Selling Circle'

Another key barrier facing SMEs is the challenge of entering the 'selling circle' within a big organisation such as a hospital, and the same applies for trying to sell to the NHS in the UK even though a company's product or service has already been well validated in the Netherlands. For example, one expert interviewee knew of a case where it had taken up to 4 years for an SME to manage to even talk to the NHS with a product that had already been validated in the Netherlands, and that is a very long time in the life of an SME.

4.3.3.4. Customer Size

The size of a customer may also be a barrier because as an SME if a big customer is interested in their product or service, the size of the contract required by the customer may be so large that an SME will never be able to meet the requirements, and this puts some businesses from seeking out possible contracts with large customers. Alternatively, it might be that this customer becomes the only customer for the SME due to the size of the contract, and that can be a risky situation as 'putting all the eggs in one basket' is sometimes a dangerous strategy. Also scaling up production for such an eventuality means that you have to be able to grow very quickly as a company.

4.3.3.5. Capacity

SMEs need to have sufficient capacity i.e. they need to have enough manpower to deal with contracts abroad, as well as satisfying the customers in the home country, and that can be a difficult balance to achieve. This is often easily achieved by large companies but not by SMEs, and the accepted wisdom is that companies need to get to a certain size to survive if they want to grow internationally. The expectation by customers abroad is often that the SME approaching them is a 'big player' because the healthcare sector and the major providers of healthcare, is really only used to dealing with big companies.

4.3.3.6. Attracting Investment

A further challenge is trying to attract investment particularly from venture capitalists, as these are often interested in hi-tech companies who are cutting edge, but may not be interested in companies that have a good product but have been around for some years - and that is likely to be the majority of SMEs. It is easier in the software sector as it is relatively easy to scale up rapidly, but that is not the case with other subsectors in healthcare. It is also a matter of timing as there is rarely a rapid time frame for investment, and SMEs find it difficult to hold on whilst decisions are being made. What this means is that most SMEs will stay within their own region because they just cannot afford to grow even if their value proposition will work somewhere else just as effectively.

4.3.3.7. Culture

Culture in foreign countries can be a substantial problem as well as in the home country, especially around an acceptance or understanding that SMEs can make a valuable contribution to healthcare provision, service and patient improvement. In the Task Force Health Care survey some 20% of businesses indicated that culture was a barrier to their internationalisation. In the healthcare industry SMEs feel that they need to have been around for at least 20 years before the healthcare providers will allow them into their circle of suppliers.

4.3.3.8. Procurement Systems

Procurement departments are stated to often have no idea about solutions that are provided by SMEs, and the improvements that they can bring about, because procurement departments often focus on the size of companies approaching them. This can be a huge barrier, and can cause a lot of frustration amongst SMEs, who do not want to waste months of time while the relevant people in the healthcare provider organisation are identified, and then persuaded to meet with the company. It is likely that there are a lot of innovations that do not get picked up and are only available to a limited number of people within a geographical area.

4.3.3.9. Credibility

The issue of credibility is an associated barrier to that of culture, because in the healthcare sector quite often people only buy from 'who they know', unless it is a large company that has an internationally recognised brand. For SMEs that are not known by potential customers, breaking through this barrier can be quite difficult. Questions are often asked by a potential first customer in a new country about who else

in (that country) is using an SME's product or service, because nobody wants to be the first. This can cause a substantial barrier relating to the time involved as SMEs do not have the time and money available to wait for these kinds of decisions to be discussed over a long period.

4.3.3.10. Contacts in Foreign Markets

Identifying the right people in a new market is always a challenge, as that person needs to have sufficient experience to be able to support the company, and it can be very difficult if the SME invests their time and money in the 'wrong' person. SMEs do not have the resources to spend 6 months investigating an individual to find out if they are the 'right' person, but if they don't try and find out it can end badly. Specifically finding local distributors, agents and trade partners can be very difficult, and the Task Force Healthcare survey showed that 35% of respondents highlighted this as a barrier. It is well known that in certain countries that the risk of being 'duped' is quite high, and this can deter movement into these markets.

4.3.3.11. Payment and Currency Risks

Another risk area that is very problematic for SMEs seeking to internationalise is around payment and currency risk. This occurs when a SME begins to sell abroad, but perhaps into countries in which payment is an issue or there is a high level of corruption, and the expected payments do not occur. While large companies can weather this issue, for SMEs it can be a huge problem, because they do not have the financial capacity to absorb long periods of non-payment. While profits may be high in countries which need new healthcare technologies, it is in these same countries that payment risk may be high. The perception of this issue is sufficient to deter some SMEs from seeking to internationalise.

4.3.4. Support to Overcome The Barriers to SME Growth and Export in The Netherlands.

Support for healthcare SMEs to progress towards internationalisation in the Netherlands is thought to be generally very good. The Government is seen as very supportive, and every Dutch embassy in foreign countries has a technology adviser, and a person that supports start-ups and scale-ups, to facilitate contact with the right people in a new market.

4.3.4.1. Task Force Healthcare

One example of a business support organisation that focuses on internationalisation is Task Force Healthcare. This is a public-private platform, a not-for-profit privately financed organisation that aims to improve healthcare internationally with the input and expertise of Dutch organisations. It currently has 120 members from the healthcare and life sciences sector including large companies, large institutes, university medical centres, NGOs and SMEs. These members provide a third of Task Force Healthcare's funding, the rest of which is made up of money obtained through the completion of Government contracts, and from the provision of missions to other countries. The organisation is seen as a strategic partner in the healthcare economy. It provides facilitation of knowledge exchange between the members, ensures the healthcare sector is connected globally through its network of contacts, and organises

missions for business to visit other countries for the purpose of internationalisation. It is also a partner of the Dutch Enterprise Agency and fulfils a role in representing the healthcare economy if visits abroad are made by state officials. It also organises the Holland Pavilion for events abroad such as Medica enabling businesses to visit these events or be represented at them. In addition, it organises visits for people from other countries to the Netherlands to see the Dutch healthcare system and the landscape of active organisations.

Task Force Health Care is a partner with the Dutch Government in a programme called Health Holland International Starters. This focuses on coaching young businesses in developing their internationalisation strategy. It also facilitates mentoring with larger companies, and in the Netherlands Philips is one such company that provides insight, experience and knowledge to these young businesses.

4.3.4.2. Health Holland

Health Holland is another organisation set up to provide business support to the sector. It is a government funded foundation whose aims are to represent the life sciences and healthcare sector, to stimulate competitiveness in the businesses in the sector, to fund research projects between industry and research institutes or university medical centres, to provide accelerator programmes for life sciences and healthcare start-ups, and to support businesses in the sector from start-up to internationalisation.

4.3.4.3. Overview of Business Support for the Internationalisation of Healthcare SMEs in the Netherlands

While it appears that the provision of business support for Dutch healthcare SMEs is seen as well-organised, integrated and has commitment from central and regional government, there continues to be concern amongst healthcare SMEs that the barriers to overcome are substantial. Of most concern is the amount of time and money that they perceive is required to obtain knowledge about new markets, to get contacts, and to avoid risk.

4.3.5. Conclusion

Essentially, one of the main barriers is that companies 'don't know what they don't know', and it is not until they start to consider how they will sell their products to foreign markets that their lack of knowledge becomes apparent. Many SMEs have very good ideas for products, very good innovations and healthcare solutions but very little knowledge about business management at all, let alone managing that business to sell abroad. As Task Force Health Care stated, it warns SMEs that internationalisation is 'a marathon not a sprint'. If the process is to be done properly it has to be given sufficient time and resources, and requires a lot of effort and commitment, and some SMEs do not have this type of capacity.

4.4. Scotland and the Highland Region

4.4.1. Healthcare SMEs in Highland and in Scotland

In the healthcare sector in Scotland there are 37000 employees across 700 organisations, which contribute a turnover of £4.2 billion annually to the economy, and this represents a significant added value for the country. Businesses include both multi-nationals and SMEs, and the culture of entrepreneurship in Scotland which has long been recognised, is replicated in the healthcare sector which is seen as buoyant and increasingly important for the Scottish economy. Currently a lot of the investments which are made by both the public and the private sector are into companies that have links to healthcare because it is seen as a growing market.

In the Highlands, whilst there are a reasonable number of companies working in the health and care sector, many are micro businesses, and the main contributors to the economy are the Universities, the NHS and one large scale business - Lifescan, which is owned by Johnson and Johnson, and is located in Inverness. The role of the NHS and Lifescan in stimulating innovation and ideas for new products and services is seen as central to the continued growth of the region.

One of the overall weaknesses of the Scottish economy is the lack of medium sized businesses. There is a small number of very large companies, mostly multi-nationals, and a large number of small and micro-sized businesses, but much fewer businesses of medium size i.e. companies employing hundreds of people. This is in direct contrast with some other EU countries, Germany, for example, which has a Mittelstand of businesses - medium sized business, often family owned. The reason the German economy is so strong is because the companies take a long term view, and invest and reinvest in the business. In the UK the model is different. It follows a pattern of aiming to grow to a significant size and then selling out - there is, therefore, little incentive to get to a medium size, and there is really no long-term view, resulting in a lack of medium sized companies. One of the problems for micro businesses under this model is that the people who start these businesses are encouraged to think of themselves as entrepreneurial, and are led to believe that they are failing unless they want to 'get rich' - and the only way to do that is to sell the business. The Scottish Government has recognised this issue and are searching for the best ways to address it.

4.4.2. Drivers for International Trade for Scottish Healthcare SMEs

it is known that one of the drivers for advancement into the international markets is when those businesses are aware that there are mechanisms for connecting people, and ensuring that the 'right' people are connected. This allows a business to have confidence in moving forward into new markets, especially where companies from different countries collaborate to produce a product that might be a niche product in one country, but becomes a more widely used product as the number of countries involved increases.

4.4.3. Barriers Facing Scottish Healthcare SMEs in Internationalising

There are different levels of barriers that appear to face SMEs in the healthcare sector. One of the main barriers is a lack of international aspiration, and it appears that many companies are quite blinkered in terms of regarding the NHS in the UK as 'the market' which can be risky as reliance on one market can be

affected by a wide range of factors. SMEs can also be quite naïve in perceiving themselves without any competition – thinking that their product or service is unique – when in reality there are companies in competition, but the SME has not had the ability to identify them. This attitude means that when these companies come to the point of moving into international markets, it can be more challenging because they can find that there are competitors that they were not aware of.

4.4.3.1. Distance

A specific barrier for businesses in the Highlands is the sheer distances involved. For many companies this is not an issue because their product or service is Internet based or a digital product. Even so, the distance between Lerwick in Shetland and London is the same distance as between London and Milan, and the transport infrastructure is not very comprehensive especially for the more remote areas, so physically moving products is not easy.

4.4.3.2. Cost of Energy

A similar type of problem for businesses in the Highlands is the high cost of energy in the region, and the high cost of living which can translate into difficulty in attracting people to work in a business in a remote area. One example provided was that of an IT business located in a very remote area having difficulties in recruiting coding staff, because quite often those kind of people were more attracted by city life, not by living in very remote countryside. These types of barriers are not obvious, they can be 'below the radar' but they can still prove a hindrance to growth and to internationalisation.

4.4.3.3. Proving Their Solution

Another barrier for healthcare SMEs is for them to try and prove their solution in a relevant environment. The NHS is often the likely customer, and engaging with the NHS is difficult. When the NHS does engage with a new product it will often be on a pilot basis, but moving from pilot to implementation in the NHS, putting aside the difficulties of the NHS procurement process, is quite a challenge. This is partly because there needs to be a clinical champion within the NHS to support that product or service, and for clinical people it is quite difficult to find the time to commit towards supporting products in this way. There are also many clinicians who will not be interested in a product unless it represents a 'quantum step' in improving patient health, and who will lack knowledge or understanding about savings to the NHS - although services managers might. There is also some difficulty if a company is aiming to internationalise, as if it hasn't demonstrated that its product or service has been proven in a relevant environment, and in the UK that is most likely to be in the NHS, then it will face potentially huge barriers when try to enter other markets.

4.4.3.4. Accessing Funding

In relation to accessing funding, one of the challenges facing healthcare SMEs is in deciding what the right scheme for them is. They need some guidance as these schemes can be complicated. While the 'local' University in the Highlands, the University of the Highlands and Islands, is quite active in the European funding arena, and can act as a facilitator for obtaining access to other organisations in Europe, it has not

found it easy to engage with SMEs in terms of providing support. Interreg funding, which is what UHI mostly deals with, is not structured for easy engagement with SMEs as it lasts for too long and SMEs are not allowed to lead these projects, meaning that if an SME comes up with an idea for a project, it cannot take it forward by itself under this programme. There has been money in the past from the European Regional Development Fund (ERDF) and for those business that were looking for funding for equipment or for CAPEX more generally this funding was more relevant, but was always very competitive and is even more so at the current time. There are also State Aid restrictions on a number of funding streams and programmes, and while funding is often seen as a necessary facilitator for these SME businesses, it is often not as accessible as people think it is and that can also cause a barrier.

4.4.3.5. Knowledge and Information

One of the main barriers is not having enough information about market dynamics or market opportunities i.e. how does the foreign country operate? In the UK it is a very UK centric publicly funded healthcare system, and in Scotland there is an integrated health and social care system. In other countries there may be a mix, it may be regionally driven, or a mix of private care providers and private health providers. So a product might be developed for the NHS system, although it might also be adaptable for a systems based on healthcare organised through insurance providers. But being able to understand the differences in these markets is vital. In the UK, and in Scotland specifically, it is difficult for healthcare SMEs, even those based in Scotland, to sell to the NHS, as the procurement system of the NHS is renowned for being difficult to penetrate, especially for SMEs. This is despite a commitment by the Scottish Government and National Services Scotland, the arm of the NHS responsible for procurement, to try and include SME products and services more effectively into the procurement process. This is partly because a huge organisation like the NHS is often going to be purchasing on a fairly large scale, and will want to assure itself that the financial position of the supplier is credible and robust and it is easier for large companies to demonstrate this. When trying to internationalise this becomes an issue of importance for SMEs because possible customers in other countries will look to see if the product or service has been accepted by the NHS, because the NHS is viewed generally as an important market and judge of product value.

Another problem is that many healthcare SMEs are simply not aware of the support in their own country that can be accessed to support their business, especially in relation to internationalisation. Some SMEs also try and pursue their internationalisation process by themselves, and then only access the support organisations if something goes wrong, or a relationship between the Scottish and the foreign business breaks down for some reason.

4.4.3.6. Contacts in Foreign Markets

The lack of relevant contacts in foreign markets is another barrier. SMEs find it very difficult to identify the most important people in other countries who might be interested either in their product or service or in some form of collaboration.

4.4.3.7. Recruitment of Staff

For healthcare SMEs in particular, the difficulty in recruiting individuals who have a range of relevant skills for internationalisation can prove a barrier. For example, it may be relatively easy to recruit somebody to work in an SME who has technical expertise, but it is much more challenging to find somebody who has technical skills, and who also possesses sales expertise and experience. Because an SME is unlikely to have the financial resources to employ more than one person, this issue can become quite a substantial barrier.

4.4.3.8. Regulation

Finally, regulatory barriers can be problematic. Understanding regulations and aspects such as CE Marking is challenging, as while healthcare SMEs can be quite quick to pick up on these issues in their home country i.e. the UK,, it can be much more difficult for them to find their way through the regulatory approvals process in other nations.

4.4.4. Support for Internationalisation for Scottish Healthcare SMEs

4.4.4.1. HIE

It is argued that in the Highlands, and in Scotland more generally, there is a range of interconnected agencies that do much to facilitate the growth of Scottish businesses and their internationalisation. Highlands and Islands Enterprise is one such facilitator and works closely with Scottish Development International to support this process, but also with Scotland Europa, which has long had a presence in Brussels to assist in raising the profile of Scottish business in Europe. Even when companies do not meet the criteria to become one of HIE's account managed companies - perhaps due to their small size - they are still able to access some of the functions and events HIE provides. HIE is really interested in those companies that are growing fast and wanting to export, and it is those companies that become account managed by HIE and that are given extra support and facilitation. The size of the company is seen as irrelevant - it is more about the culture and strategic aims of the company.

4.4.4.2. SE

Within Scottish Enterprise (SE) there has been a strong focus on digital health activity. In terms of Scotland, the field of digital health is currently a focus for economic development and the aim is to attract inward investment and especially the big players in digital health. There are a number of companies operating in this area directly i.e. developing solutions or developing technology that could be applied to the healthcare domain. There is also a range of companies that have products or services that can be indirectly applied. These include companies working in the fields of informatics and big data, sensors and monitoring that may or may not be directly applied to the area of health. While the SE focus is on trying to attract big digital health companies to invest in Scotland, the indigenous SME has perhaps had slightly less support from SE than it had previously. However, it has been suggested by Highlands and Islands Enterprise that it is sometimes too easy to become focussed on those SMEs that provide either IT solutions or equipment that is directly relevant to health or care issues. Instead the net should be cast wider, as there is a huge range of enabling organisations which are involved in the health and care supply chain. Even in the Highlands of Scotland there are over 100 companies that operate within these supply

chains, and some of these are very small companies, micro businesses, that nevertheless have managed to become suppliers to the NHS and to care homes and other facilities, and which in time may grow.

4.4.4.3. EEN

One of the key organisations providing support for Scottish healthcare SMEs is the European Enterprise Network (EEN), which is supported by Scottish Enterprise. EEN works with the account managed businesses that SE provides support for on an ongoing basis. EEN is funded by the Scottish Government and by the European Commission to support Scottish companies to engage in international innovation activities. It acts as an advisor and as an interface organisation for companies seeking partners or funding. The organisation divides business into sectors, but it is fully aware that there is a lot of cross-over between sectors so it works very flexibly for, and with, businesses. For example, the Scotland contact for digital health in EEN also has experience of ICT, software and other tech companies more generally. EEN not only covers European countries but also further afield including Mexico, Japan and the US, although the main activity is around Europe. especially for those companies that are 'account managed' in Scotland. It has a specific role for the international collaboration and support of companies seeking to innovate and develop new products, and those seeking access to new markets. EEN plays a key role in this as it looks at European funding and helps companies understand the schemes and programmes, and decides which would be the 'best-fit', whether they are at the right stage of development and whether they should focus their energy on that funding at that time.

EEN facilitates the delivery of funding as well. For example, there are a number of SBRI calls for funding applications. These often look at technologies to increase efficiencies in clinical areas, and they are essentially pre-commercial procurement competitions. The scope of the calls is worked out closely with the NHS, and then the call goes out to companies to submit ideas. It provides an early understanding of what the key challenges are, and allows companies to pilot their ideas or products in a contained way with commitment and funding. EEN also delivers thematically driven matchmaking events. EEN encourages SMEs to participate in these types of events if they are relevant to the company and to the specific market.

4.4.4.4. SDI

Scottish Development International (SDI) is the international development arm of the two enterprise agencies in Scotland, so is funded by the Scottish Government. It employs trade advisers that have portfolios of life science and healthcare companies, and it advises and supports those companies in their international activities - through soft support and sometimes financial packages. SDI has 35 global offices overseas with six offices in the US, four in Europe, five in Asia, and some in Africa, Australia and other countries. The service covers all sectors, and some sectors have specialist staff assigned, although the overall resource is limited. SDI will help a company prepare a Strategic Plan which may include a number of conferences, exhibitions, workshops or receptions, and can also provide up to 30% of the cost of travel, registration and associated activities. One of the problems for SMEs aiming to access SDI services is that the companies they assist have to have a certain level of revenue, around £1 million over 3 years, to be considered for participation. However, the Business Gateway service in Scotland which supports start-up companies does pass a small number of smaller companies that they consider suitable along to SDI.

Healthcare is a key priority sector for SDI, and it works with SE generally to help access funding for SMEs who it estimates need between £500000 and £2 million to be able to enter into the European market effectively. Support from SDI very much depends on the background of each SME approaching them for support. It depends on how much money the SME already has available, as if they come to the point of internationalisation with some financial backing then it is a lot easier than it is for companies who have very little funding. In most cases it is one of the key areas for SMEs trying to internationalise - trying to secure additional funding. Another aspect is providing knowledge of international markets for companies; SDI provides a number of international strategy workshops for companies - which helps them gain market knowledge and an understanding of the landscape which is a crucial area. Companies find that support from SDI operatives in foreign locations is a considerable help in understanding the markets, as well as providing them with contacts. It has been found that help with contacting potential distributors is particularly valued, as this is a challenge for SMEs to carry out on their own. SDI runs around 7 events annually for the pharma and medtech subsectors of health, and will invite Scottish companies to participate on the SDI stand, for example at Medica, which is of great financial benefit to the companies. SDI target new companies, but also companies that are well established but not making significant sales. It also supports companies that are already selling internationally, if they are bringing a new product to the market

One particular service that is provided is through the Global Scots programme which is part of SDI based in Glasgow, which is a worldwide network of business contacts who are experts in their field, and who are driven to help Scottish companies develop, expand and thrive in a competitive international market. The motivation of these experts is from a familial, historical, cultural or other connection with Scotland, and their time is generally provided for free. This has been found to be a very effective way to help businesses, as their local knowledge of regulatory issues, market issues or many other aspects of doing business in foreign countries, is very valuable and reduces a number of barriers through their personal knowledge and contacts.

4.4.4.5. Overview of Business Support for the Internationalisation of Healthcare SMEs in Scotland

It is clear that there is plenty of support for healthcare companies based in Scotland if they are aiming to internationalise, although less for healthcare SMEs than for larger companies. One of the issues that faces companies aiming to access this support is the complexity of the support landscape, which is further crowded with a raft of agencies and initiatives directly supporting innovation within the healthcare sector. This confusion causes some SMEs to put off the decision to internationalise because they do not have sufficient time to work out which organisation will best serve them.

4.4.5. Conclusion

As the UK exits from Europe the key challenges facing healthcare SMEs in Scotland will be access to European markets, and the need to factor trade barriers into their decision-making about their internationalisation strategy. It is difficult to predict exactly what leaving the EU will mean for these businesses, but at a minimum it is clear that the cost of internationalisation with European countries is likely to increase.

There are also many other barriers facing SMEs in the Highlands and in Scotland more generally in their attempts to internationalise and sell into new markets. These barriers are often seen as quite significant by the companies themselves but also by the organisations that exist to support them in their internationalisation processes. However, it is also noted by some of these organisations that perception is what often holds back some companies from pursuing the internationalisation route - if they feel that expanding into these markets is likely to be too difficult, or very expensive or time consuming they are unlikely to pursue that pathway. Developing sector specific knowledge and contacts has repeatedly been raised as a possible response to the concerns voiced by SMEs. It is also felt that by providing SMEs with more activity to support them in understanding the ways in which different European territories are set up, what the current status of innovative healthcare solutions is, and where new opportunities are likely to occur, and what non-traditional routes to market might exist, would provide these companies with the kind of support they require to develop a positive internationalisation strategy.

5. Overall Findings

Healthcare SMEs in Europe face a complex mixture of challenges to growth and to internationalisation both within their home countries but especially when they start to try and develop into foreign markets. Healthcare SMEs, whether in pharma, biotech, digital or medical devices, are often found to be very innovative and highly skilled producing high quality high value products. Many organisations – Government and commercially funded – exist to support these SMEs to export abroad or to collaborate with foreign partners, and there are many examples of success. However, it is clear that many barriers still exist at all levels, and thousands of SMEs with innovative healthcare products have yet to seek to internationalise because of these barriers – whether perceived or actual. It seems that it is timely for further integrative models of support to be developed to move these companies forward.

6. Tables and figures

Figures

Figure 1 European Medical Technology Market by Country (based on manufacturer prices) 2015 (MedTech Europe, 2016:26)..... 6

Figure 2 - World Medical Technology Market by Area and Sales Growth 2015 - 2022 (MedTech Europe, 2016:29) 7

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