ACCESS & ACCELERATION

German-Danish network for innovation and cooperation in healthcare

Identification of market access barriers

Interreg Deutschland - Danmark

EUROPEAN UNION

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1 Management Summary

This report evaluates various barriers to entry for the Scandinavian and German healthcare market for innovative products. The evaluation covers reasons, challenges and entry barriers related to entering the Scandinavian and the German market, market trends, target groups, sales channels and cooperation with users and buyers. This report presents the results of qualitative interviews and workshops with partners from different institutions and companies (e.g. medical device manufacturers and software development companies).

The report identifies the common barriers to market access, and in later stages of the project, strategies for overcoming these barriers will be developed. Interviews and workshops with relevant stakeholders served to identify market access barriers. Companies, consultants and researchers from Denmark and Germany participated in both interviews and workshops.

Our experience so far shows that companies are often hesitant to support the Access & Acceleration (A&A) project with information, which can be attributed to the fact that companies fear to lose an advantage when giving out sensitive information. Involvement of companies in this early stage of the project was difficult due to the value of the knowledge companies can arrive. The interviewees were asked about current barriers to market entry, current trends, solutions and possible solutions on entering the Scandinavian/German healthcare market in the course of the interviews. According to the trends, the interviewees consider the Medical Device Regulation (MDR), pricing, E-Health and Artificial intelligence (AI) as important or of future importance.

The analysis has identified three main barriers to entry that companies struggle with: (1) implementation and handling of the medical device regulation and national legislation, (2) the different structure of the healthcare systems and (3) the language especially on description of healthcare structure and regulations. In the next phase in WP6: *Roadmap of market access strategies* we will use these three barriers and discuss how to overcome them.

2 Background

2.1 Aim of WP6 – Market Access

It is notoriously difficult to access the Danish and German markets for healthcare products with new technological solutions. It is especially hard for small and medium-sized enterprises (SMEs) that do not possess the necessary knowledge and market insight to enter the healthcare industry.

Being a part of an ecosystem that knows the healthcare sectors and has clear market access strategies supported by relevant partners, services, tools and methods, will be very valuable for Danish and German companies.

The purpose of this task in A&A is to establish an ecosystem based on existing knowledge and experience gained in e.g. Patient@home's ecosystem, which was operational from March 2012 to February 2018. This ecosystem supported the development of 49 new technological solutions in Denmark (including market access). The core partners in the Patient@home ecosystem (Odense University Hospital (OUH), University of Southern Denmark (SDU), WelfareTech (WT) and Southern Danish Health Innovation (SDSI)) are involved in this application as either partners or network partners. Universität zu Lübeck (UzL) and

Universitätsklinikum Schleswig-Holstein (UKSH) collaborates with all these partners in other healthcare projects.

The objectives of this task and report are:

- To identify barriers to market entry including regulatory standards, guidelines, health-economic opportunities and (lack of) financial incentives.
- To develop market access strategies as well as tactics for innovative healthcare solutions.
- To identify opportunities to support processes for adapting and disseminating new technological solutions in the health- and nursing care sectors.
- To attract health care providers such as hospitals, GPs and municipalities in Denmark as well as health insurance providers in Germany to facilitate market access.

These goals shall be achieved through three main tasks:

- Improving the innovation dialogue for identifying barriers to market access in Scandinavia and Germany. Possessing knowledge about barriers will enable companies to plan their product development processes better.
- Development of market access strategies in Scandinavia and Germany. The provision of a range of services, tools and methods will support companies in solving various challenges and tasks related to market access.
- Validation and dissemination of market access strategies. Through implementation in pilot projects, the usability of the developed market access strategies is dismantled, and the results are the basis for further dissemination of the strategy/roadmap and its application.

2.2 Description of tasks

Task 6.1: Identify market access barriers between Scandinavia and Germany

The result of this activity is an overview of the market access barriers facing innovative companies wanting to enter the German or Scandinavian markets with innovative healthcare solutions. The results are published on the project website and through the project's communication activities. Tasks 6.2 and 6.3 build on the findings and results of task 6.1.

Task 6.2: Roadmap of market access strategies in Scandinavia and Germany

The main goal of this task is to provide a roadmap of successful market access strategies for Denmark and Germany and will be developed on a result-focused workshop methodology. The *Roadmap for the management of innovative medical technologies* will similarly be published on the project website as well as through WP2. Task 6.2 will be the offset for the pilot study in task 6.3.

Task 6.3: Validating and marketing of the market access strategies

The validated roadmap can be used by companies who are interested in introducing new technological solutions on the Scandinavian or German markets. The developed method grants companies access to a complete online toolbox and services with case examples and a 'how to' guide in applying the strategies. Additionally, there will be a supportive partner network from which companies can follow concrete steps and tasks towards gaining access to the market and breaking down barriers.

2.3 Management

This part of the project is managed by CIMT in close cooperation with SDU MMMI, WT and UzL/UKSH. The network partners participate in the organising of the 1st, 2nd, 3rd and 4th workshop and also the dissemination workshops.

3 Stakeholder analysis

The stakeholder analysis was performed in collaboration between WT, CIMT, SDU MMMI, and UzL/UKSH.

The stakeholders were defined as relevant individuals possessing knowledge on market access barriers in Germany and Denmark, which could deliver the input to this report. To increase the number of participating German companies, the Scandinavian market is used instead of the Danish market, since the Danish market is often too small to be attractive for German companies. Further, the argument is that the different markets in Scandinavia have many similarities.

The stakeholders were identified as both companies and people from academia fitting to our specific interview requirements. The German companies should have considered or tried to enter the Scandinavian market or have experience with entering the Scandinavian market. Vice versa, the Danish companies, should have thought, tried to, or entered the German market. These stakeholders would provide input from first-hand experiences with entering the German and Scandinavian market. Similarly, consulting companies specialising in assisting companies in entering markets were identified. The researchers (academia) should preferably have knowledge in both markets to elevate the discussion of barriers and discuss the differences between the two markets.

Based on the identification of the types of stakeholders, individuals from companies were identified in Denmark by WT and researchers were identified by CIMT and SDU MMMI.

The individuals participating in interviews in Germany were identified by UzL/UKSH in collaboration with Life Science Nord (LSN).

4 Interview respondents

A&A aims to promote the innovation dialogue to identify market access barriers, because knowledge about potential barriers enables companies to plan their product development and strategy better to enter the different markets. In order to gain a broader picture of their interests and current barriers to market entry, we sought to initiate a dialogue with other stakeholders as well.

Within the framework of this Interreg project, the aim was to identify interview partners who could provide information on barriers and challenges that can arise when entering the Scandinavian or German market. The contacted companies were already successfully offering their products/solutions on the Danish or German market. Companies beginning to discover the Scandinavian or German market, and companies that tried to enter these markets but failed, were included.

In both Denmark and Germany five qualitative interviews were conducted with partners from different industries and institutions. Table 1 gives an overview of the participating companies and organisations (Table 1).

Company / Institution	Core Business	Website
Acumed GmbH Germany	- is a global market leader, providing orthopaedic and medical solutions	www.acumed.net
litos/ GmbH Germany	- engineers, manufactures and distributes multidirectional locking systems for internal and external fixation of bones and joints	www.litos.de
soventec GmbH Germany	- is a software development partner for companies and scientific institutions in the laboratory automation environment in biotechnology, medicine and life science	www.soventec.de
Stryker GmbH Germany	- is one of the world's leading medical technology company. The company offers innovative products and services in Orthopaedics, Medical and Surgical	www.stryker.de
WTSH Kiel Germany	- is the central business development agency in Schleswig-Holstein	www.wtsh.de
Cambio Denmark	- The leading Scandinavian supplier of e-health solutions. Provides IT solutions to improve health care and patient safety.	www.cambiogroup.com
Center for innovative medical Technology (CIMT) Denmark	- research and innovation centre for Odense University Hospital (OUH) and the University of Southern Denmark	www.cimt.dk/gb
GDV Technology A/S Denmark	- manufacture with unique and innovative equipment for daily mobilization and repositioning of the patient	www.careturner.com
University of Southern Denmark (SDU) Denmark	- is a highly approved University in the region of Southern Denmark	www.sdu.dk/en
Welfare Tech (WT) Denmark	- is a Danish national cluster and hub for innovation and business development in healthcare, homecare and social services	en.welfaretech.dk

Table 1: List of German and Danish interview partners

In order to obtain information from different perspectives on the challenges and barriers to entering the Scandinavian and German health care market, different organisational positions were included in the interviews, see Table 2 below.

Work position
International Business Manager
Head of Quality Management and Regulatory Affairs
CFO, Managing Director
National Sales Manager Trauma & Extremities, Denmark and Norway
Foreign trade consultant
Product Manager
Chief consultant
Commercial Director & Co-Founder
Professor
Consultant

Table 2: Work position in German and Danish company / institution

4.1 Product / Solution

The products and services offered by the interviewees are very different from one another (see Table 3) and so are the target groups and sales channels.

Product / Solution
Wrist prosthesis
External and internal fixation systems for bone surgery
Software development services, sample management software
Orthopaedic products such as plating, IM nailing, external fixation and small joint replacements
Bone substitutes
Support of SMEs and research institutions in their internationalisation efforts
Add-on to beds for improving the comfortability of the patient, and being resource- and timesaving

Table 3: Examples of Products / Solutions

4.2 Target Group

Since the interviewed companies offer a wide variety of products and services, there are practically no converging target groups. The overview (Table 4) compiles the target groups that the companies named.

The participating consulting companies' target group are the companies that aim to enter the markets, so primarily manufacturing companies. The target groups for the manufacturers of orthopaedic products are hospitals and clinics.

Target Group
SMEs
Start-ups
Research institutions
Industry
Medical device manufacturers
The Region (Denmark)
Hospitals and clinics

Table 4: Target Groups

4.3 Sales Channels

The sales channels through which the products and solutions reach the target groups are not uniform. This is because of the different products and services offered by the companies/institutions. An overview of the sales channels mentioned by the interview participants is given below (see Table 5).

There are products that can only be sold by a specialised and well-trained team because they require a lot of explanation, such as wrist prosthesis or orthopaedic products. On the other hand, some products require less explanation to use because they are more generic, and are used by trained health professionals. As an example, surgeons have already learned to use special surgical instruments and products during an operation so it does not matter which manufacturer supplies the product. Another big difference, especially in medical products sold in Denmark is if a product is part of a centralised procurement plan like many products are in Denmark, where the regions and hospitals have the decision power to choose between products.)

Sales Channel
Direct specialised sales team
Events
Mailings
Own website
Social media
Word-of-mouth propaganda
Tender process

Table 5: Sales channels

4.4 Current status of the product

Almost all products and solutions offered by the German interviewees are already successfully established on the German market and are, for the most part, offered on the Scandinavian market.

A selection of answers regarding the status of the product is listed below:

- It is implemented in the home market and present in the Danish/Scandinavian market
- Launched on the German market (services and products) and software development services in Sweden
- The product has been successfully launched on the German market, product is sold in Sweden and Norway

The Danish interviewees working in manufacturing companies do not have their product on the German market yet but are very interested in gaining access.

4.5 Cooperation with users

All ten interviewed companies and institutions work together with the end-users of their products either during the early or later phases of the product development process. Especially the Danish companies had a substantial active involvement of the end-user, hospitals and researches.

Some of the answers in relation to user cooperation are listed below:

- Depending on the product; in the case of medical equipment, possibly with the direct users (clinics)
- Development together with future users
- Doctors give feedback, pass on their ideas for product improvement, suggest new products
- We do try to incorporate feedback and input in our R&D process in the early stages of innovation
- Yes, early phase
- Yes – normally at a late stage for early product surveillance

4.6 Cooperation with buyers

Several companies cooperate with the subsequent buyers, and others do not. Such cooperation concerns both product development and the sale of the product. In some cases, the buyers are the purchasing departments in hospitals and clinics.

A selection of answers regarding the cooperation with buyers is listed below:

- The buyer is the purchasing department, i.e. a department and usually not a doctor.
- Abroad, certain products are explicitly requested, and then the hospital orders them from the purchasing department.
- Yes, cooperation already in the development phase, no special challenges, regular exchange necessary.

- Depending on the product; in the case of medical equipment, possibly with the direct users (clinics), otherwise rather with the partner (distributor, dealer) than a local buyer, possibly cooperation with local manufacturers in the area of research and development.

4.7 Reasons for entering the German / Scandinavian market

The interviewed companies and institutions gave various reasons why they decided to offer their product on the German/Scandinavian market.

Some of these arguments are listed below:

- Few cultural differences
- Germany is quite close to Denmark – geographically but also mentally/culturally
- Good prospects in the field of care for the elderly (demographic change)
- High level of prosperity
- In Scandinavia, we have the registers which make the market highly attractive despite the low reimbursement pricing
- Neighbours, comparable mentality, (high English language proficiency)
- Regional proximity
- Strong health market
- Large market size

5 Method

5.1 Interview

The interview questions were constructed in collaboration with project partners from hospital, university and the cluster organisations. From the broad experience and close contact with the Danish and German market, the cluster organisation knows the entry barriers. All questions addressed both the barriers to market entry in Scandinavia and in Germany. The questionnaire was divided into three parts: (1) Introduction with questions about the company position, (2) “product/service” with questions about the target group, sales channels and the cooperation with users and buyers and (3) “the market” with questions about barriers to market entry and trends.

The interviews were conducted as semi-structured interviews by phone and were afterwards confirmed by mail. Most of the interviews were recorded with sound and saved. Some were not given consent to record. The main points of the meetings are analysed and evaluated corresponding to other interviewers and the workshop.

Within the framework of the questionnaire, some market access barriers were already pre-defined and listed in the interviews, but it was also possible for the interview participants to name others.

5.2 Workshop

The procedure of the workshop was based on the barriers (or challenges) mentioned in the interview guide. The workshop was divided into 3 stages:

1. Prioritise the challenges
2. Elaborate and discuss the top 3 challenges in groups

3. Presentation and plenum discussion on the challenges

5.2.1 Prioritise the challenges

The challenges are evaluated with the steps below:

The most significant challenges are appointed maximum point.

- Each group has 8 points
- Choose maximum 4 challenges (or less), that you believe to be most significant
- The group appoints points to the 4 (or less) most significant challenges, **the total number of points must add up to max. 8**
- 1 challenge can receive a maximum of 3 points

The total amount of points for all challenges is calculated and the three highest prioritized challenges form the basis for the 2nd stage.

5.2.2 Poster discussion

The groups are asked to elaborate on the top three challenges based on three questions:

A. Describe the challenge
B. Why is this a challenge?
C. Possible solutions

The discussion and key points are written down by the facilitator on a poster for each challenge (see annex). Each group was given 15 min to elaborate on each challenge before rotating to the next challenge.

5.2.3 Plenum presentation and discussion

The conclusion of the posters is presented by the participants or the facilitator and the results are discussed in plenum.

Additionally, the challenges that were not prioritised within the top three were part of the discussed in plenum (see annex).

5.2.4 Data collection and analysis

The facilitators collect the information of the top three elaborated challenges and the results are described in section 5.2.

6 Results

The results are based on input from the qualitative interviews conducted in Denmark and Germany and from a workshop where relevant stakeholders discussed barriers to entry for the German/Danish market.

The barriers used as examples in the interviews were identified in collaboration between CIMT, SDU MMMI and WT, which have previously worked extensively with this area, and then served as input for the interview questions and the format of the workshop.

6.1 Interview

The results mentioned below are based on the approach described in *4.1 Method - Interview* and further divided into challenges for entering the Scandinavian and the German market.

In total, 4 consultants and 11 manufacturers participated in the interviews. The interviews lasted from 18 to 43 minutes and were performed by two different individuals. The companies participating in the interviews were manufacturers of IT-solutions, hip replacement technology and developers of supporting/prevention equipment. The consultants that were interviewed represent the Danish and German side, both with close contact to companies and clinics.

6.1.1 Regulations and national legislation

The interviewees mentioned that it can be difficult to enter the market due to the fact that each country has its own legislation on medical devices. This concerns finding the national legislation on the website of the health authority in the target country. The national legislation was stored in the national language and could not be found in English. The challenge did not occur in the application or observance of the regulations, it was a language barrier problem rather than a problem with the existing national legislation.

Furthermore, the tender process and the high demand for evidence-based products is problematic e.g. in Denmark. For a successful sale or launch of products, it is essential to have specific knowledge about the tender process. Companies must acquire this specialised knowledge themselves or they can obtain it through the support of agencies or partner companies in the respective country.

Before a company can launch a product on the market there is a great need for clinical documentation that documents that the product creates value. In Denmark, the strong collaboration between the private sector (suppliers) and the hospitals (buyers) supports companies in launching their products faster and with more certainty. The hospitals in Denmark are willing to participate in research or innovation projects that can secure the clinical documentation needed for the suppliers. If the hospitals were not willing, it would be very difficult to secure the needed clinical evidence that the product creates value, which has a great impact on the survival of the product.

Some highlighted points from the respondents include:

- For market access in Scandinavia and Germany, the requirement for evidence-based documentation is high. This increases the need for collaboration with Scandinavian- and German hospitals, to accept clinical evidence gathered in the other country. The market tends to favour the evidence gathered only in their own market.
- For both countries, people tend to underestimate the work and implementation of AI-algorithms, due to the comprehensive need for documentation.
- The German legislation concerning data security, sharing of data, and privacy regulations is a bit sharper compared to Danish regulations. In Germany, there is a very restrictive approach to sharing data.

Some of the answers to the question: “Which and how do the regulations specifically affect your organisation?” are listed below:

- We are quite well informed about the process in Denmark, but mostly it is the tender process and the high demand for evidence-based products that cause problems
- EU, so far no problems, rather fewer obstacles than national
- The first obstacle is to find this legislation (the availability of the legal basis)

- The Scandinavian countries have a good internet presence of the health authorities, where also the regulations are published
- This is where the language barrier comes into play, because the legislation is usually only available in the national language
- The legislation and structure for the "*Hilfsmittelverzeichnis*" in Germany.
- The new medical device regulation increases, e.g. the need for clinical data.

6.1.2 Different user needs

The healthcare system in Germany is insurance-based, which contributes to less interest in supporting and prevention equipment since the insurance companies want to cover only necessary equipment. The difference in healthcare structure affects the user needs. Therefore, some products have more or less market potential in Germany compared to Denmark. Especially prevention equipment for the primary sector is known to have a limited market potential in Germany.

Involvement of the user is vital in an innovative product development process and to ensure a successful implementation. The user's willingness for participation in the development and implementation phase of the product is very different from Denmark and Germany. In Denmark innovation and user involvement is a large part of the development process. Many companies aim to facilitate this user involvement in the development of innovative products. These companies also have an extensive network in the primary and secondary healthcare sector to improve the understanding of the user.

One company pointed out that language is an important factor in understanding the user's needs. Since it cannot be expected that knowledge of the respective national language exists, it should be expected that English is spoken as a common language. For some users and healthcare staff this poses a challenge when discussing with a potential supplier from a different country,

Some of the interview answers to the question: "How have you encountered this issue?" are listed below:

- As we are working in an almost standardised training profession - trauma surgeon - we do not really have user requirements
- Yes, different coding systems were considered (reprogramming, language)

6.1.3 Lack of knowledge about the organisation of the healthcare system

German companies do not necessarily need to know the healthcare sector in Scandinavia in order to sell their products successfully. In the simplest case, a company receives a request for a certain product directly from a hospital in Scandinavia (in this example: Sweden). An offer is sent to the hospital and if it is accepted, delivery can take place. In this case, the knowledge of how the healthcare system is organized in that country is not important.

Some of the answers from the interviewees to the question: "Do you have knowledge of any intermediaries that you could contact about this?" are listed below:

- Maybe "MedicoIndustrien" would be a good start in Denmark.

- Usually the company receives an order, which is preceded by an inquiry and an offer, at this point it is then almost irrelevant how the healthcare system is organized.

Danish companies find the German healthcare system rather complex, also more than they expected. One challenge is that the companies that wish to enter the German market need to have extensive knowledge about the German market prior to entry. Furthermore, the "*Hilfsmittelverzeichnis*"-system is difficult to access, especially with preventive products. The "*Hilfsmittelverzeichnis*"-system contains all equipment covered by the insurance. Since the insurance companies' main focus is treatment and inexpensive solutions, preventing equipment is difficult to get accepted in the "*Hilfsmittelverzeichnis*"-system. Information about the structure of the system is difficult to access because most of it is only described in German. This results in a long acceptance process and needs for knowledge. The knowledge can be provided by a qualified consulting company, which is often expensive.

6.1.4 Language

Four of the five German companies cited language as a barrier to market entry. For some products sold on the Scandinavian / German market, labels in the local language are a requirement that is applicable in EU and include the instructions of use. It is recommended to involve translation agencies or native speakers in the translation of the instructions of use as these problems can be addressed rather merely by a native speaker.

Another example of language as a barrier is the difficulty in finding important information on, e.g. national healthcare structure on the webpages of the health authorities. These pages are often not written in English but only in the national language. To reduce this barrier most companies have one or more Scandinavian/German speaking employees.

Some of the answers to the question "How have you encountered these barriers?" from the interviewees are listed below:

- The language barrier in Germany can be an issue since some German surgeons do not like to speak English. Otherwise, we have not had any issues.
- Usually there is no English language site
- Finding the relevant information on the linked pages, which are available in the national language, was the real problem
- Germans prefer to speak German
- This is not a problem for the companies

6.1.5 Access to funding, specifically funding for the internationalisation activity

Danish companies find it rather easy to find partners and national funding, but the difficulties of international collaboration and funding were addressed. The company found it hard to find information about the process and how to find the right partners for a funding project.

6.1.6 Culture

The German and Scandinavian cultures are quite similar - there is similar mentality. Conformities between the German and Scandinavian cultures are mentioned, and the culture is not seen as a barrier. The German respondents pointed out that language rather than culture is a problem.

Danish companies experienced that the German healthcare system is very hierarchal compared to the Danish system. The knowledge about the right stakeholders and the culture is, therefore, more important and a decisive factor for entering the market. If these differences are known and handled, it is not observed as a challenge.

6.1.7 Differing structures

The different healthcare structures affect some companies and others are not affected, this is product dependent.

The differences between the public health sector and the private sector affect the market accessibility because they work in different ways and have different demands. A downside as a supplier is the tender process because companies are either in or out depending on the price agreements. Denmark has a relatively strict tender process and companies can therefore not be certain to get the sale even though they have developed the product together with a hospital, which also can cause negative relations and unmet expectations if you are not used to or familiar with this process. In Denmark, solutions are usually bought on a national or regional level, which is opposite in Germany where there is a higher degree of decentralization in the health sector and therefore a higher number of sales directly to the hospitals making the sales process extremely different. In Denmark, the hospitals are larger and highly specialised, which results in more influence on prices and development.

It can be problematic for German companies to understand how the Danish health IT infrastructure is built and that you need to follow and adapt to Danish standards to be able to communicate and integrate with the Danish IT system. Consequently, German companies need to reprogram software to other programming-language to ensure integration and implementation. The high degree of digitalisation in Scandinavian countries is a problem for German companies because Germany still has some catching up to do in this area.

Some of the answers from the interviewees are listed below:

- Yes, different coding systems were considered (reprogramming, language)
- The major difference is between the public healthcare system and the private sector. They work in different ways and have different demands.
- Also during the last decade, a higher degree of specialization at the Danish hospitals has occurred meaning larger units.
- As a supplier you are in or out depending on tender outcome / price agreements with the larger units.

In extension, the German insurance-based healthcare structure is a large barrier for the Danish companies. If the company is not in the "*Hilfsmittelverzeichnis*"-system the sale to the primary sector is difficult and the company will have to focus on sales to private users, which requires a different market approach.

The German system (insurance/reimbursement) tends to choose the cheapest solutions, which can cause problems for newly developed solutions that tend to be comparatively more expensive than older solutions.

6.1.8 Access to qualified counselling

Some companies use the support of consulting companies or partner companies, which are offering a wide range of compliance and market access services to be successful in the German/Scandinavian market. Access to qualified consulting services is available to all companies, although only some take advantage of this. Access to adequate counselling was not seen as an obstacle, but perhaps more a question of whether a company can afford such a consultancy firm. These consulting companies offer a wide range of regulatory compliance services, e.g. product registration, quality management system compliance and in-country distributor qualification.

Some of the answers from the interviewees to the question “Do you know where to approach when needing help?” are listed below:

- We use EMERGO
- On-site consultation was not necessary, neither from authorities nor from other institutions
- EU: free movement of goods, practically no trade barriers, no customs
- Yes, Med Tech branch org Denmark

6.1.9 Collaboration with Danish/German partners

Some companies cooperate with local partners in the respective countries, and others cooperate with other companies or service providers. One company mentioned that it is difficult to find funding for this cross-border collaboration and development.

Collaboration between manufacturers from Scandinavia and selling partners in Germany can improve the potential for success on the German market because the German partner has extensive knowledge and a wide network within the field. This can improve the development, implementation and sale after the product is launched on the market.

A selection of the answers to the question “Which sales models did you consider/choose?” is shown below:

- Distributors
- There was no collaboration with other partners
- Personal contact, if necessary, a local language representative
- Looking at the size of the sales direct channels are preferred

6.1.10 Other

It takes a significant investment to enter the German market, and it demands that you are part of an organisation that is highly committed. Moreover, you need to know the right stakeholders, the health system and the clinicians. In Germany, a doctor is reimbursed based on the DRG registrations, which is very different from the reimbursement process in the Scandinavian countries. For companies participating in tenders in Scandinavia, it is essential to have detailed knowledge of the process. This knowledge can be acquired by the companies themselves or they can use the support of consultants or partner organisations. One company mentioned: “If products are within tenders then the tender process will need to be investigated and understood”.

Another point to which companies have drawn attention is the General Data Protection Regulation (GDPR), which has come into force since May 2018, and is a regulation by EU law on data protection and privacy in the EU and the European Economic Area (EEA). The GDPR is only of interest to manufacturers of medical devices if there are customised products for individual patients that require the usage of personal data. As a manufacturer of medical products, these must ensure a GDPR compliant working method. In the context of anonymous sales, the GDPR does not play any particular role.

6.2 Trends

The table below outlines the interviewees' answers to the question about developments / trends on the Danish/Scandinavian and German market (see Table 6).

Trends	Description
AI, E-Health	Advantages Scandinavia: faster on the market - "entrepreneurial mentality", on the other hand in Germany: "sceptics" Decision support in diagnostic is a big development area in the future. Important part of these algorithms is a large amount of data. The potential of these algorithms is especially high in Denmark, due to the long-range of patient records. These products are still on a research basis and not tested and implemented.
MDR	Many manufacturers are currently revising their current product portfolios and deleting low-turnover product groups because the regulatory burden of MDR is far too high to keep low-turnover products alive. A withdrawal of many American companies from the German/European market can be observed, as there is no more money to earn. The large suppliers (system suppliers) are becoming fewer and fewer. At this point the Asian manufacturers come onto the market, who offer relatively cheap products, whereby the question arises as to how safe these products are. One increasingly sees company-closures or mergers, such as the formation of competence centres (one company does the preparation; another company does the development; another company does something else).
Notified Bodies	Currently there are only 5 notified bodies in Europe that have an MDR accreditation, one is in England (leaves with Brexit), one in Italy, three are in Germany. In contrast to thousands of companies in Europe, there is a shortage of supply. Currently, when you ask for certification, you get the answer that there is an acceptance stop until an undefined date. One can only hope that the notified body one is currently with, will get a corresponding MDR accreditation as soon as possible. At present, no notified body in Europe knows how to implement MDR in companies. There are many guidelines for the Medical Device Directive (MDD), but not for the MDR. No company knows exactly

Trends	Description
	how to do something, there are a lot of regulations, but no help how to do things. Consequence: From May 2021, there can/will be a shortage of products.
Pricing	Pricing is a huge issue, and the trend is that all implants will have to be offered sterile within a few years. Currently it is nice to have but not need to have, which will change soon. The prices cannot be increased when the products are offered sterile.
Automation	Automation of treatment and diagnostic does only include small processes in the healthcare system. This includes automation of the blood samples: from sending the sample from the department and to an answer in the patient record.
Welfare technology and daily supporting equipment	Technology for supporting daily living at home for elderly and inhibited patients. This technology can be all from robot vacuum cleaner to rehabilitation robots. Due to the healthcare structure in Denmark the potential of preventing and supporting technology is high.

Table 6: Overview: Trends on the German / Scandinavian healthcare market

6.3 Workshop in Denmark

The first workshop was held in Odense, Denmark, November 19th, 2019, with a total of 15 participants from Denmark and Germany: 6 participants from Universities, 3 from the hospital (OUH), 5 from different companies and 1 from the cluster organisation (WT).

The method for collecting data in the workshop is outlined above in 5.2.

Challenges	Group 1	Group 2	Group 3	Total
Different laws and regulations	2	3	2	**7**
Language barriers				
Different healthcare systems structure		3	3	**6**
Different user needs	2	1		3
Access to funding for internationalization activities				
Access to qualified counselling		1	1	2
Lack of knowledge of how the healthcare system is organised	3		2	**5**
Different culture	1	1		2
Difficulties in collaborating with DK/DE partners				

Table 7: Rating of the challenges in Danish workshop

The top three challenges were defined as (see Table 7):

1. Different laws and regulations
2. Different healthcare systems structure
3. Lack of knowledge of how the healthcare system is organised

6.3.1 Results from the workshop

In this section, the results from the workshop will be presented.

Different laws and regulations

Until May 2020, medical devices are regulated with the medical device directive 92/42/EEC, which results in countries' specified laws and need for documentation. The new regulation for medical device 2017/745 is effective from May 2021, and the effect of the challenges is therefore unknown in the future and not further discussed in this report.

The key points from the discussion are found below.

Describe the challenge (why)

- Different understandings and applications of EU regulative
- (Lack of) transparency in the approval process between the countries.
- Administrative barriers and the number of administrative tasks.
- German hospitals primary earn money when patients are admitted and therefore often less focus on prevention.
- Laws and regulations are not that different in DE and DK (contrary proposition - no. 1)
- One product can be positioned as different things (e.g. Medical device, caregiving device) – result in different regulations.
- Limited access to patient data, especially DE is more restricted in using personalised data and in the collection of data.
- Laws and regulations are changing (especially in DE)

Why is it a challenge?

- No incentive for hospitals and the healthcare system to avoid admissions of patients in Germany.
- Difficult for a foreign company to understand how to act on the market and in the system.
- The requirement of evidence/experience/documentation is large and the evidence collected will not automatically be approved in another country. This is a mutual challenge between countries and sections.
- Not enough data to provide evidence, topic dependent e.g. collection of patient data in Germany. Further, this is a very time- and cost consuming task.
- Difficult to stay updated on changes in regulations and laws.
- Different laws and regulations have an impact on products and business cases, difficult to access a new market.
- Laws are interpreted differently even on hospital level

- The different laws and regulations can also be a huge opportunity to move to "a better" market and room for interpretation.
- Different opportunities for innovation, this can be a disadvantage and advantage.
- Hospitals in DE and DK have different incentives for means for prevention.

Possible solutions

- Develop examples and show to regional governments, e.g. Decision processes or pitfalls when launching products on the market. Examples of success and not a success.
- Change laws
- Generalisation of the EU regulations in healthcare, improve the transparency of CE-marking
- On the political level, especially DE is talking more about "open" the use of data (decrease the impact of data protection laws)
- DK can be used as a showcase for how to use health data in DE.
- Telling success histories from the Scandinavian and German market.
- Provide help to companies on how to approach the market and how to adapt the product, comply with standards, etc.
- See the differences as opportunities rather than challenges
- Collaborative approach

Different healthcare systems structure

Describe the challenge

Specific barriers to market access in Germany:

- Different reimbursement – *Who pays the bill*?
- Germany does not have the patients in mind when thinking healthcare
- If you create a business model in Germany, the patients are not included
- Germany: complex system – should be updated (specifically the reimbursement numbers)
- Problem: the buyer is not the end-user (General)

Specific barriers to market access in Scandinavia:

- Requires extensive knowledge of tenders
- Very long tender process

Why is it a challenge?

- The German market is not interested in new innovative ideas because of how the reimbursement system works
- The different health care systems mean different financial incentives in terms of treating patients
- There is a mismatch between the healthcare organisations and the patients
- General barrier: Lack of knowledge on tender processes across borders
- Creating a proof of concept is easier in Denmark than Germany

- The German system performs too many operations due to the reimbursement system
- Public health insurance companies. The companies are not interested in new ideas
- "Patients are investments". E.g. if the success criteria states that a patient with a hip replacement should be able to walk within 3 months, then if a doctor can see that a patient will not be able to walk before 3 months, but perhaps later, the patient will not receive this treatment.
- In Denmark, there is an open innovation environment. However, DK struggles with scaling
- Denmark: Need to know about the call for tender before they formulate it
- Denmark: The system is built so the tenders call for big companies. This kills small companies.

Possible solutions

- Possible solutions should be done on national level.
- The companies should acquire more knowledge of the healthcare system. A more thorough business case.
- Need to figure out how to transfer learnings between hospitals
- Need to learn more knowledge on the German market
- Team up with partners/other companies that are already on the German market.

Denmark:

- SKI[1]: if you get your product in here, you do not have to go through the tender process
- SKI: You have to do it every 4 years and then municipalities can buy the products without tenders
- SKI: Easier to do it next time. Have to find partners because of a big process.
- In Denmark, you need to access the market through projects
- Denmark: Quantity makes the statistics better: closing of the smaller hospitals.

Lack of knowledge of how the healthcare system is organised

Describe the challenge

- DK: The structure of the tax-finalization system vs. "*Hilfsmittelverzeichnis*"-system is very different.
- Knowledge can be very expensive
- The systems in DK and DE are not transparent, and the information is on national language. The knowledge is therefore hard or almost impossible to access for SMVs.

Why is it a challenge?

- Missing early collaboration between cross-border companies

[1]Staten og Kommunernes Indkøbsservice, https://www.ski.dk/Sider/Forside.aspx

- The public-private collaboration can provide the companies with the information. But it is hard to start the process and establish contacts with relevant partners. The private-public network is more developed in Denmark compared to Germany, but especially the cross-border network is insufficient.
- Information and knowledge are in the national language.
- The reimbursement catalogue ("*Hilfsmittelverzeichnis*"-system) is only available in German. Equally the tender-process is only available in Danish. For both systems, only a limited amount of data is accessible in the opposite language or English.
- Consulting companies are expensive and advocating for a complex system.
- There is a hidden agenda (political or consulting companies) and the system is not transparent.

Possible solutions

- WT videos and webinars provide knowledge about the German market to the companies.
- Companies must use the time to get familiar with the market. It is important that this is not assigned to the distributor only.
- Get a network of different shareholders in Germany (or Denmark) and use this especially in the early stages. It is important to use the network from the development to implementation and sale.
- Use a living lab (Public intelligent/SDSI) to test the product and build an ecosystem with relevant stakeholders. The living lab is most accessible in Denmark.
- A business model where SMV (developer) can collaborate with a consulting company. The consulting company will get some percentage in the company for implementing the product on the cross-border market. If the consulting company is not successful in obtaining market access, they will not charge anything.
- A database where companies can register and automatically get knowledge about relevant projects, research, changes in the market or others.
- A&A must provide this knowledge, portfolios, maps (mast), and a visible ecosystem.
    - It is important that the platform facilitates collaboration and innovation and not only sale.

6.4 Workshop in Germany

A workshop was held with the two institutions IHK Lübeck and WT.SH Kiel in Germany to evaluate the results on market entry barriers from the conducted interviews. Both institutions have many years of valuable experience in foreign trade consulting on how companies are supported on their way abroad (Scandinavia) and also concerning industry support, medical technology/life sciences, and the Scandinavian economy.

The aim of the workshop was to find out whether there is actually market access restrictions for German companies on the Scandinavian market, if so, to describe this challenge and to identify a solution. The workshop focused on the market entry and featured an in-depth discussion of the market barriers for entering the Scandinavian market.

6.4.1 Results from the workshop

Reasons for entering the Scandinavian market

During the workshop it was discussed why German companies should be interested in the Scandinavian market at all, because compared to the European or American market, the sales potential is relatively small. In the end, the idea was that if a company has to certify its medical device for the entire European market and subject it to a conformity test, then the effort required to enter the Danish market is limited and can be done with manageable means. The cultures are similar, the user-specific requirements for the products do not differ greatly from those of German users and the different structures do not represent obstacles that cannot be overcome.

Language

Four of the five surveyed companies cited language as a barrier to market entry.

For some products sold on the Scandinavian market, it is very important that the labelling is in the local language. There are also regulations that require instructions for use to be written in the national language and enclosed with the product.

Another example of language as a barrier is the difficulty in finding important information on the webpages of the health authorities, because these webpages are not necessarily in English but in the national language. Finding the relevant information on the linked pages, which are available in the national language, was the real problem.

The national language is not such a big challenge that a company cannot solve it when entering the market. For certain requirements, e.g. as soon as documents must be available in the national language, a native speaker or a translation agency can be engaged. Otherwise, the English language is very widespread in the Scandinavian countries, is very well mastered and can be used for communication without any problems.

Regulations, Notified bodies, Medical Device Regulation (MDR)

IHK Lübeck and WT.SH Kiel were not surprised to hear that the regulations are not a practical hurdle. In their opinion, they should not necessarily be a problem either. There are indeed European-wide regulations and directives that have to be subsequently transposed into national law, such as the Medical Device Directive (MDD). But with the Medical Device Regulation 2017/745 (MDR), this is not necessary because it is a regulation that is valid throughout the EU when it comes into force and does not require separate implementation in national laws. This means that all European countries are affected equally and the regulation applies to all companies in these countries.

It has been discussed that a company applying for CE certification/conformity testing for its medical product does this for practically all countries of the EU and thus there is no hurdle. If documents have to be submitted in the respective national language, they can probably be easily produced by translation agencies.

However, there is a problem concerning notified bodies with MDR accreditation. There are still far too few of these throughout Europe. However, companies are dependent on these notified bodies for the conformity testing of their products.

Notified bodies:

- In the meantime, there are about 13 notified bodies with MDR accreditation
- It is becoming more expensive and more complex for companies to have their products certified
- Niche products pose a problem (finding a sufficiently large patient group for clinical studies)

MDR:

- MDR is now considered a barrier to innovation in Europe
- New companies with innovative products have a problem to find an appropriate notified body and to pay for it
- The US with FDA regulation might seem more attractive for some of these companies

Tender processes and pricing

According to the surveyed companies, the recent specialisation and merging of clinics and hospitals in Denmark has simultaneously led to the merging of purchasing departments and thus led to a certain increase in market power. This means that German companies struggle to participate in tenders and meeting the desired low prices. Neither the IHK nor WT.SH could confirm this direction of development.

From the Danish point of view, the question is whether to sell the products on the first or the second healthcare market in Germany.

6.4.2 Remarks from the workshop in Germany

At the end of the discussion round, the question arose as to whether the already mentioned barriers to market entry are actually barriers, because at least the surveyed companies have successfully mastered the challenges that have aroused and now offer their products on the Scandinavian market.

- There are no significant barriers to market entry for German companies, making it possible for them to enter the Scandinavian market.
- There are challenges in the European healthcare market that affect German and Scandinavian companies equally, such as MDR and Notified Bodies.

7 Concluding remarks

The key points from the interviews and the workshops will serve as the basis for the next task in the project: the development of market entry strategies.

The main market access barriers identified through the interviews and workshop are:

- Overall national legislations and the new Medical Device Regulation 2017/745
- Differences in the healthcare sector structure
- Language barriers

Further reasons for entering a new market and trends in health care was discussed. These topics will not be discussed further, since the target group for this report are interested in entering a new market (Scandinavia or Germany) and already have a product available.

Below the main market access barriers will be presented.

7.1 Overall national legislations and the new Medical Device Regulation 2017/745

The legislation on medical devices until May 2021 is national legislation based on the Medical device directive 93/42/EEC and Active implantable medical device 90/385/EEC. From May 2021 the new medical device regulation 2017/745 (MDR) comes into force and the differences in CE-marking legislation are expected to be reduced. Hopefully, this will improve the single-market approach and reduce this particular market entry barrier, but with the new MDR the expectation is an increasing number of challenges, especially regarding getting new medical device CE-marked.

The new MDR is postponed one year due to the coronavirus. This gives companies one extra year to meet the requirements. However, the new MDR significantly increases the requirement for technical documentation, including post-market surveillance. The requirements and structure of technical documentation under the MDD have earlier mainly been up to the manufacturer. The new MDR will, therefore, affect new and already market medical devices. Further, the requirement for clinical data is significantly increased by the MDR, which is a big challenge for many new and innovative products. National differences for compliance with the MDD are for some devices beneficially. With the MDR the national differences are expected to be reduced or eliminated.

The implementation of the MDR is not the primary challenge for the cross-border market entry or sale but more related to the approval process and documentation needs in general, of the CE-marking process. The implementation of the MDR will be one of the most substantial challenges for the medical device industry in the coming years and will affect both innovative, new and original products. Especially for SME's the MDR will result in a significantly increased workload due to the new regulatory requirements.

The cross-border market entry barriers of legislation are or some language-related. National implementation of the MDD is only available in national language, which complicates the way to meet the requirements. In most EU member states, national language documentation is further a requirement for compliance with the legislation. This challenge can rather easily be accommodated with a national speaking employee or a translation company. Further, national legislation of the healthcare sector and the structure is only available in national language, which introduces a barrier for cross-border sale.

Legislation on the German healthcare market is frequently changed, especially with regards to digitalisation in the healthcare sector. The market and political landscape are being developed with an increased focus on this area. For example, the access to patient journals and information in Germany is very strict and difficult. Therefore, data-driven innovative products, such as decision-support, can be challenging.

7.2 Differences in the healthcare sector structure

Insurance-based and regional-based health care structure:

In Denmark the residents can freely access to the healthcare system for examinations and the treatments, without payments.

The Danish tender process is often a significant market access barrier for out-country companies such as companies in Germany. This is a problem and costly for companies, which have been involved in the development process and later not win the tender process. Since the hospitals are not able to favour any company, which a development cooperation would be, they cannot promise that they will buy the product that they have been part of developing. The procurement process needs to be available for all companies, and it is, therefore, possible that the supplier becomes a different company, that either is able to provide a better product or at a better price. This can be difficult to understand for e.g. German companies since it would be reasonable to assume that the hospital would buy the product they have been part of developing. However, due to Danish regulations, all procurement is done on a national or regional level, and the hospital can therefore not make any procurement decisions alone.

In Germany the residents have both a public and a private health insurance. The German insurance-based healthcare structure is based on the *Hilfsmittelverzeichnis*, which is a list of reimbursable products. The system structure motivates for the doctors that reports the service (operation, treatment, etc.), to report the more expensive service because the more this will make the hospital earn more money, which can in some cases create a bias in the healthcare structure. Furthermore, some of the more significant difference between the Danish and German structure is that the German structure is not incentivized to push and implement the preventative solutions that are on the market, because the patients are clients and the preventive means would mean less income for the hospitals.

In Denmark there is a significant focus on these preventive solutions, because the hospitals are focusing on lesser beds and a shorter stay in the hospitals. This can also cause a bias in Denmark, since the patients can be sent home too early. The Danish municipalities are responsible for the rehabilitation and preventive solutions and treatments, further, is the regions responsible for the acute- and illness examination and treatment. This results in different interests and in some cases, different preferred treatments, which can result in a negative- and prolonged treatment plan for patients. But this also results in a larger marked potential for preventive solutions and less pronounced barriers for these solutions in Denmark compared to Germany.

7.3 Language barriers

Information about the healthcare structure, tender and the legislation is only provided in the national language. The language barriers were mentioned in various situations, and especially in Germany, this was highlighted as a barrier by more than one respondent. In Germany this was mentioned as a challenge in 4/5 companies; however, the barrier was not seen as the

most significant challenge due to the simple way that the problem could be overcome: by hiring a Danish native speaker or by using a translation company.

As mentioned in the discussion above in section 7.1*7.1 Overall national legislations and the new Medical Device Regulation 2017/745,* the transition from the MDD to MDR reduces the national translation and differences in the legislation regarding the CE-marking. Further, the instructions for use and labels are still requested on the local language; however, as mentioned, this challenge can easily be solved in the company with a translator.

The language barrier is similar perceptible in finding information on the healthcare structure and other relevant information from the healthcare authorities, e.g. tenders. This knowledge is frequently only found in detail in the national language, with a short version in English. This barrier can be reduced with having an employee that possess in-depth knowledge of the healthcare structure, tendencies, community, and language. For minor companies this could be difficult due to economic resources or interests.

7.4 Next steps

There seem to be overall similarities in what is perceived to be market entry barriers in Germany and in Denmark; however, the Danish companies perceive the challenges more significantly than the German companies. The common barriers are identified as 1) Overall national legislations and the new Medical Device Regulation 2017/745, 2) Differences in the healthcare sector structure, and 3) Language barriers. The barriers are both of concern on the national level, and on EU level, which applies to all companies operating in EU.

Conclusively, this report has highlighted the barriers and its features, which will serve as a starting point for the next phase: to develop strategies to enter the Scandinavian or German market. The barriers will then serve as elements to overcome with the strategies.

Key facts

- Total budget: 2.9 million Euros
- Around 1.7 million Euros funding granted by Interreg Deutschland-Danmark
- Project duration: April 2019 – March 2022

Project partners

- Centre for Innovative Medical Technology (CIMT)
- Kiel University, Institute for Innovation Research (Technology Management)
- University of Lübeck, Clinic for Orthopaedics and Trauma Surgery (University Hospital Schleswig-Holstein), Campus Lübeck
- University of Southern Denmark, Mads Clausen Institute
- University of Southern Denmark, Maersk Mc-Kinney Moller Institute
- Welfare Tech

Network partners

- Business Development Agency Kreis Plön GmbH
- Exoprosthetic network.SH
- Hochschule Flensburg
- Kalundborgegnens Erhvervsråd
- KiWi, Kiel Economic and Structure Development Corporation
- Life Science Nord Management GmbH
- ScanBalt
- Sorø Erhvervn, Sorø Kommune
- Syddansk Sundhedsinnovation
- Sydvestjysk Sygehus, AK- og Tromboseklinikken