ACCESS & ACCELERATION

German-Danish network for innovation and cooperation in healthcare

Market access strategies

Interreg Deutschland - Danmark

EUROPEAN UNION

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1 Management Summary

This report describes the development of market access strategies to the healthcare systems 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.

- The objectives of this 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.

2 Access and Acceleration Project [1]

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), Welfare-Tech (WT) and Southern Danish Health Innovation (SDSI)) are involved in this application as either partners or network partners. Universität zu Lübeck(UzL) and Das Universitätsklinikum Schleswig-Holstein (UKSH) collaborates with all these partners in other healthcare projects.

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, UzL/UKSH and WT. The network partners participate in the supporting of the online survey and the workshop and also the dissemination workshops.

3 Online survey

3.1 Introduction

To further develop the market access strategies, an online survey was conducted in an attempt to secure input from a wide range of partners from industry, research and public institutions to help define an overall methodology.

More than 300 Danish companies and more than 100 German companies were contacted for this reason. Furthermore, a large number of institutions, business development associations and network partners were contacted as well, to assist with finding participants for the survey.

3.2 Design / Implementation

The aim with the survey was to verify the identified market entry barriers found in T6.1 and further investigate how to overcome these barriers.

First, a questionnaire were developed, consisting of questions about the company, the product, market entry barriers (already identified and further barriers) that a company has encountered when entering the new market, and finally questions about how to overcome them. Based on this questionnaire, an online survey in Danish, German and English was created with the tool surveyXact and distributed in August 2020.

3.3 Survey respondents

Within the framework of the Access & Acceleration project, the aim was to contact companies who could provide information on barriers and challenges that can arise when entering the Scandinavian or German market. The companies that have participated in the survey are listed below.

No.	Company	Business	Website
1	Advalight ApS	Advalight has developed patented laser equipment for effective treatment of a range of skin disorders	Website Advalight
2	VulCur MedTech ApS	VulCur MedTech is a medical device development company focusing on wound healing, using a novel combination of existing technologies.	Website VulCur MedTech
3	Bluewater Medical GmbH	Development partner for trauma, spine and orthopaedics	Website Bluewater Medical
4	MedNet GmbH	Service provider and supplier for the medical device and pharmaceutical industry	Website MedNet
5	CODAN DEHA ApS	CODAN is recognised amongst users as a manufacturer and distributor of medical devices	Website CODAN DEHA
6	Cercare Medical	Cercare Medical develops AI-powered imaging solutions that provide decision support for comprehensive assessment of brain CT and MRI.	Website Cercare Medical
7	Fluisense	Fluisense develops medical devices for use in preclinical and clinical biomedical research and diagnostics.	Website Fluisense
8	MedicQuant ApS	Medicquant provides diagnostic kit for blood anticoagulant properties. The company has developed a chip and instrument that can detect anticoagulants, directly from whole blood.	Website MedicQuant
9	MagCath ApS	We present a revolutionary medical device that will solve a range of major female urinary continence problems.	Website MagCath
10	InnoCon Medical	InnoCon Medical develops a neuromodulation healthcare solution for people with incontinence	Website InnoCon Medical
11	Miiskin	Photographic skin monitoring - App for patients to visually track moles and other areas of the skin for changes over time.	Website Miiskin
12	Roth GmbH	Handles and systems that help people whose mobility is restricted	Website Roth
13	Glove inSite	Glove inSite assists with the development and implementation of processes and routines to comply with the MDR	Website Glove inSite

No.	Company	Business	Website
14	Life Science Robotics ApS	ROBERT® is an innovative rehabilitation robot focusing on active resistive and assistive mobilization of the lower extremities.	Website Life Science Robotics
15	schwa-medico GmbH	Our main areas of focus include pain management, rehabilitation after injury, and incontinence therapy.	Website Schwa-Medico
16	Medbroker APS	Medbroker is a ISO 13485:2016 certified company with unique competencies within Medical device innovation & Market Access, Dietary Supplements, Regulatory Compliance and Strategy and Business Development.	Website Medbroker
17	Opitek International	We develop, design, manufacture and distribute devices and knowledge designed to facilitate a variety of procedures in the operating theatre.	Website Opitek
18	O2matic ApS	O2matic brings oxygen therapy into the digital age.	Website O2matic
19	NorDiaTech	The core business of the organization is the sale of medical equipment and consumables to hospitals and private clinics.	Website NorDiaTech
20	PRO Devices A/S	We add value to the laboratories by optimising manual workflow of weary routines, using automated resistance measurements, which is time-consuming and a routine task.	Website Pro Devices
21	Smiths Medical	Smiths Medical is one of the world's leading manufacturers of medical devices.	Website Smiths Medical
22	CAMPTON Diagnostics GmbH	The company develops and markets complete measuring systems for point-of-care diagnostics, i.e. for the on-site examination of patients.	Website Campton
23	sundhed.dk	At sundhed.dk you get an overview of your health. For example, you can consult the patient handbook, get an overview of your medications and register important decisions about organ donation, for example.	Website sundhed
24	Siemens Healthineers	Siemens Healthineers helps healthcare providers around the world achieve more: in expanding precision medicine, redesigning healthcare delivery, improving the patient experience and digitizing healthcare.	Website Siemens Healthineers
25	Cambio Healthcare Systems	Cambio Healthcare Systems is a company that delivers IT solutions and services to the health care market.	Website Cambio

No.	Company	Business	Website
26	Radiobotics	A company with a focus on developing algorithms for hospitals to automate reading of x-rays of bone and joints.	Website Radiobotics
27	Stryker DANMARK	The company manufactures orthopedic and surgical implants and instruments as well as products for patient transport.	Website Stryker

Table 1: Online survey – Participating companies

3.4 Results

In total 30 individuals from 27 different companies participated in the survey, see Table 1: Online survey – Participating companies. Below selected data is presented.

50% of the participants represent a micro-enterprise, with a representative distribution of primary operating country and product or solution. Primary target group of the products is hospitals (n=24). More than half of the companies (n=15) the product/solution is fully developed but waiting for finally CE-marking. 83,33% (n=25) of the companies considered entering other markets.

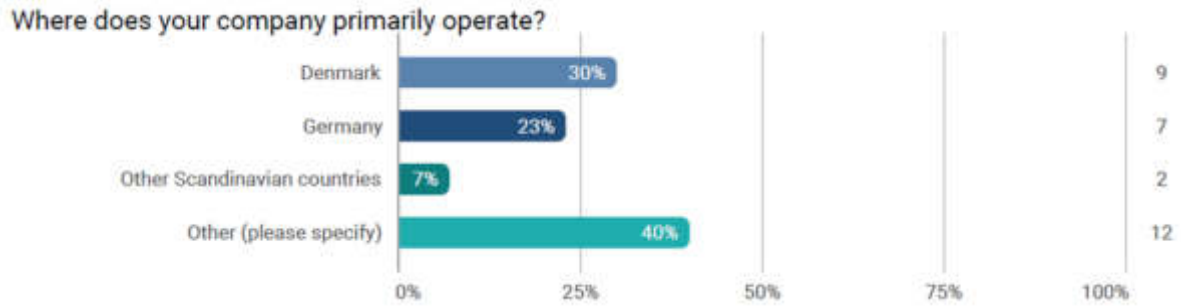

Figure 1: Online survey – Results – Where does the company operate?

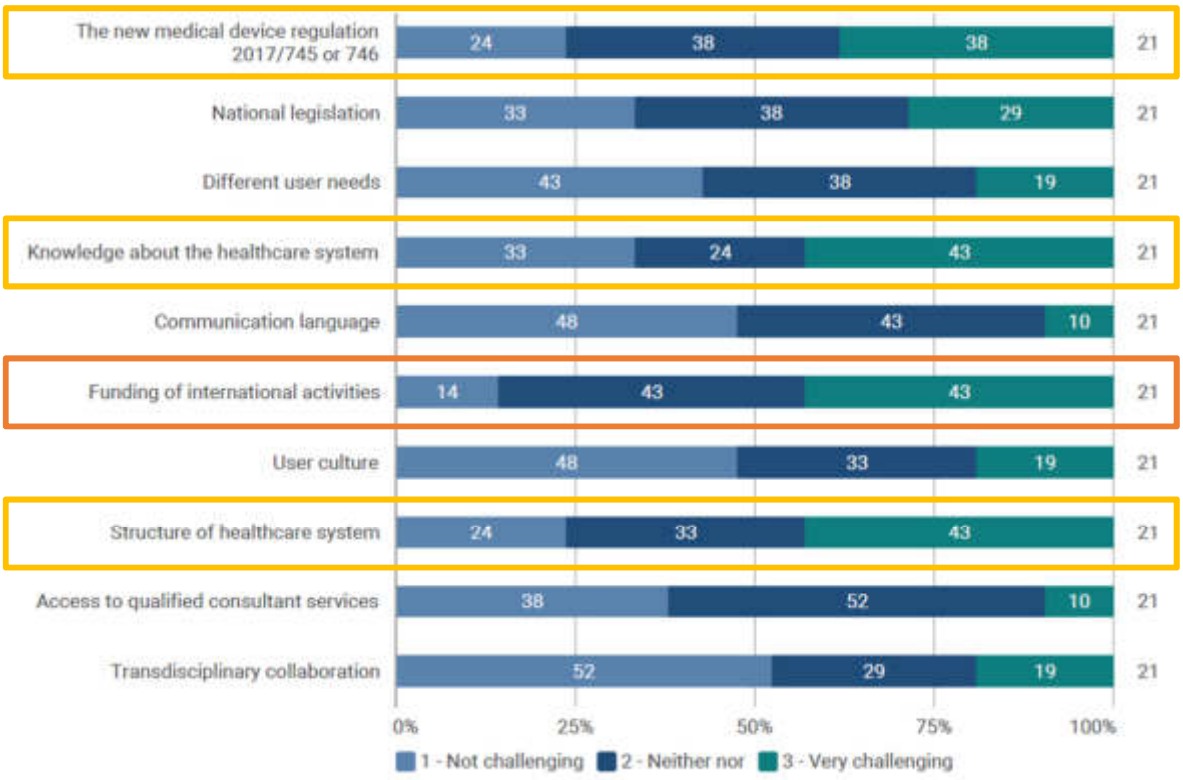

Figure 2: Please categorise the following challenges on a scale from 1-3 (1 is not challenging and 3 is very challenging). Orange and yellow show the most and second most mentioned tool to overcome the barrier.

Market entry barrier	Mean (on a scale from 1 to 3)
Funding of international activities	2,29
Structure of healthcare system	2,19
Knowledge about the healthcare system	2,10
The new medical device regulation 2017/745 or 746	2,14

Table 2: Online survey – Categorisation of market entry barriers

The 10 market barriers identified in T6.1 were further investigated in this survey. The four barriers defined as most important were:

1. The new medical device regulation 2017/745 or 746
2. Knowledge about the healthcare system
3. Structure of the healthcare system
4. Funding of international activities

Barrier 2 and 3 is similar and is therefore merged to one market barrier and named: the structure of the healthcare sector in home and target country.

In an evaluation of the three market barriers defined in T6.1 the structure of the healthcare system is most prominent barrier.

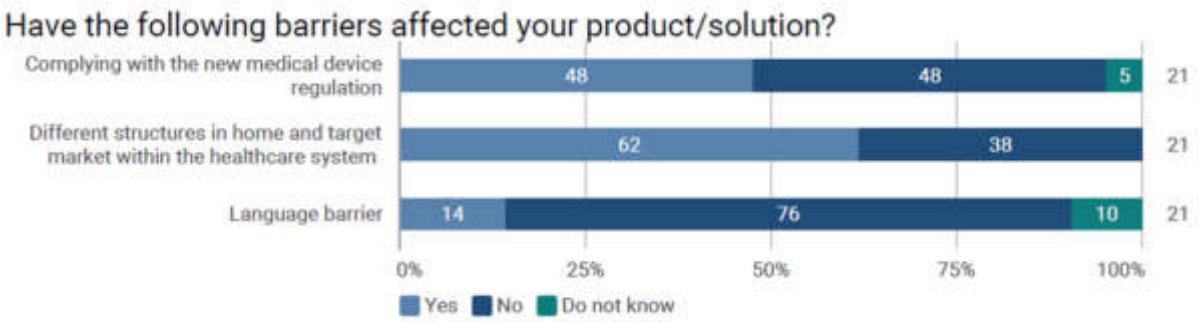

Figure 3: Online survey – Results – Have barriers affected the product/solution?

Companies which define the new medical device regulation as a barrier primary used knowledge sharing networks and specialised departments within the company to overcome this barrier, see Figure 4 and Figure 5.

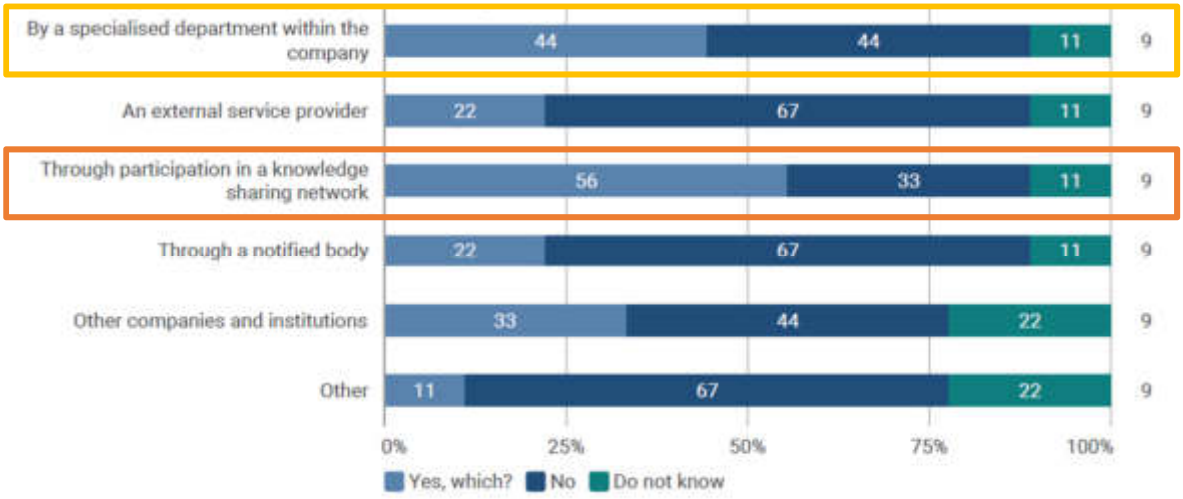

Figure 4: How did your company handle the following barrier: Complying with the new medical device regulation and/or national legislation? Orange and yellow show the most and second most mentioned tool to overcome the barrier.

- Medicoindustrien
- HTHC, HTN, MTB
- Medico industrien
- IVAM, Life Science Nord, Diagnostik.Net BB

Figure 5: Through participation in a knowledge sharing network – Yes, which?

The use of knowledge sharing networks was further mentioned as the main tool for overcoming the barrier with regards to different structure of home and target market, see Figure 6.

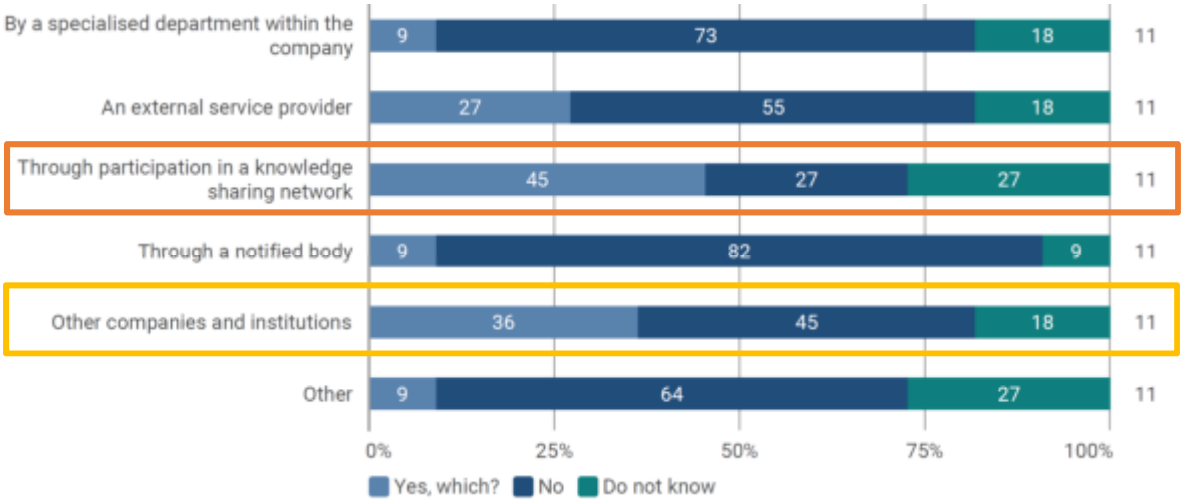

Figure 6 - How did your company handle the following barrier: Different structures in home and target market within the healthcare system. Orange and yellow show the most and second most mentioned tool to overcome the barrier.

The mentioned knowledge sharing networks for overcome the barrier of different structure is seen in Figure 7.

- Medicoindustrien
- HTN, HTHC, MTB
- Danish Care
- EIT health
- EU projekter

Figure 7 - Through participation in a knowledge sharing network - Yes, which?

One company found that language barriers affected their cross-border market entry, this was overcome with help from an export organisation.

3.5 Discussion

The survey confirmed the previous identified market entry barriers from task 6.1 to be:

- The new medical device regulation 2017/745 or 746 (MDR)
- The structure of the healthcare sector in home and target country

Further, was the *Funding of international activities* also identified as a market barrier. The *Language* was in the survey not found to be a significant market barrier. See this on Figure 2.

The market entry barriers of the MDR and different market structures were mainly overcome with participating in knowledge sharing networks, see Figure 5 and Figure 7. The Danish organisation *Medicoindustrien* is mentioned here. *Medicoindustrien is industry association for companies in Denmark which develop, manufacture, sell or otherwise take an interest in medical devices. Medicoindustrien* has more than 200 member companies which have access to network, MedTech Academy and regulatory advisors. It should be noted that the survey can be biased since all of the contacted Danish companies were members of the *Medicoindustrien*.

Also HTN, HTHC and MTB were mentioned as common knowledge network sharing.

- **MTB**: M&T Bank describes themselves as having the financial strength, industry knowledge and creative solutions to help meet your healthcare organisation's banking needs
- The M&T Healthcare Services Group has helped a diversity of clients in your industry meet their goals, thanks to a strong working knowledge of the sectors and operating environment within the healthcare industry.1
- **HTN** is an innovative platform for the health tech community. Through our website, newspaper, HTN Digital Week, Health Tech Awards and Features, HTN offers a unique depth, breadth and perspective on health technology.2
- **HTHC**: High Tech Home Care AG or HTHC is a Swiss company that has been active in the area of specialized drug applications since 2004.3

3.6 Conclusion

Based on the work in T6.1 and the survey in T6.2, the following strategy paper should focus on developing tools to address the following barriers:

- The new medical device regulation 2017/745 or 746
- The structure of the healthcare sector in home and target country (compiled barrier)
- Funding of international activities
- Language

4 Market entry barriers / Roadmap

4.1 Market entry barriers

Our project evaluated various barriers to entry for the Scandinavian and German healthcare market for innovative products. The evaluation covered reasons, challenges and entry barriers related to entering the Scandinavian and the German market, and also market trends, target groups, sales channels, and cooperation with users and buyers.

We identified the common barriers to market access and developed strategies for overcoming these barriers. Interviews, workshops and an online survey with relevant stakeholders were used to identify market access barriers and served as the main input for the developed strategies. Companies, consultants and researchers from Denmark and Germany participated in these activities.

Tools, Information, Downloads

Description		Language	Link
Downloads	Access & Acceleration - Report on market access barriers	EN	Link
Webinars	Welfaretech - Digital health & care 4.0 you find a series of 4 webinars from 2019	EN	Link
	Digital Health in Scandinavia. Business opportunities.	EN	Link

Table 3: Market entry barriers – Tools, Information, Downloads

[1] https://www3.mtb.com/commercial/industry-solutions/healthcare
[2] https://htn.co.uk/
[3] https://www.hthc.ch/de/

4.2 Roadmap to market

English version of the Roadmap: https://www.accessinnovation.eu/roadmap.html

Danish version of the Roadmap: https://www.accessinnovation.eu/roadmap_dk.html

German version of the Roadmap: https://www.accessinnovation.eu/roadmap_de.html

Figure 8: Roadmap – Print screen graphic

A webbased roadmap on market entry strategies in English, Danish and German for companies were developed, enabling them to obtain information on market barriers in the healthcare market in Denmark and Germany and to derive strategies from this information. It is an excerpt from the strategy paper that provides the information for the companies in a more convenient way.

The Roadmap is a tool for small and medium-sized enterprises (SMEs) and other companies who wish to enter the Danish or German healthcare market with their innovative product(s). It is notoriously difficult to access the Danish and German markets for healthcare products with new technological solutions and it is especially hard for SMEs that do not possess the necessary knowledge and market insight to enter the healthcare industry.

The content of the Roadmap is centered on the three most common barriers to entering these markets as identified in a stakeholder analysis from 2019.

The barriers identified in the analysis were:

1. Complying with european and national regulations and legislation (MDR)
2. Understanding the structure of a foreign healthcare system
3. The knowledge about funding opportunities to support companies

The Roadmap addresses each of these barriers and gives helpful information about the Danish and German markets as well as tips to succeed in entering these markets. The user can use

the links in the interactive Roadmap to navigate directly to a specific topic or scroll down to start reading and familiarise themselves with the different topics.

How does the Roadmap work:

The roadmap contains a graphic with the identified market entry barriers. As soon as the user moves the mouse over the individual icons and texts, topic-specific questions are displayed (see Figure 8 – Funding of international activities). Clicking on an icon the user jumps to the corresponding place in the text below containing information regarding this topic (see Figure 9 . Funding chapter).

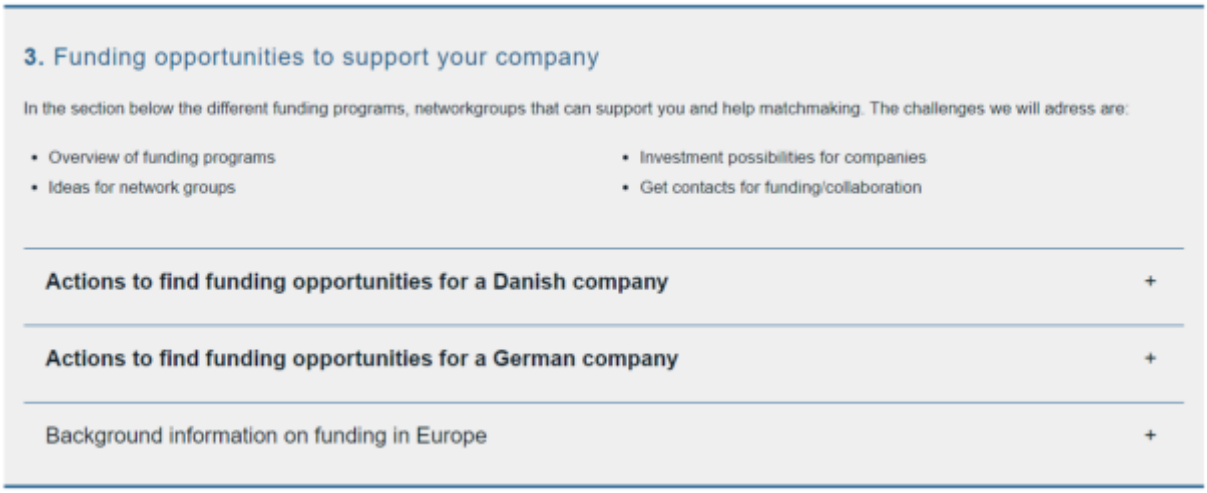

Figure 9: Roadmap – Print screen funding section

Below the graphic is a longer box. This consists of paragraphs on the various market entry barriers identified in advance, each with a different background colour, so that the user can also see visually where a topic begins and where it ends.

The different text boxes are structured in the same way. First there is an overview of the topic (the market barrier) with bullets on which kind of information you will find related to this topic/market barrier. Below there is the possibility to expand the box with information related to specific actions to overcome this barrier. These specific actions are divided into two sections depending on whether the target market is Denmark or Germany. The user can open and close these with a mouse click. At the end of each chapter, there is also more background information on the barrier, if needed.

Taking the identified market entry barriers into account, a digital roadmap was developed that has been integrated on the project website. With the help of this Roadmap that presents an overview of information needed to overcome the most significant challenges in entering the Danish or German market, it should be easier for companies to be able to develop a strategy that helps them overcome these.

National institutions and local institutions can contribute to barrier identification and strategy development and use the roadmap developed for consultation purposes. As potential users, the roadmap will provide companies with the necessary tools to access the German or Danish healthcare market.

The following chapters provide further information on the identified market entry barriers and the target markets. Actions for successful overcoming, tools, links to networks and cluster organisations, webinars, publications, partner cooperation exchange, funding databases and more are listed and described.

5 The new MDR and national legislation

The Medical Device Regulation (MDR), European Regulation for Medical Devices, together with the Regulation for In Vitro Diagnostics (IVDR) officially came into force on May 25, 2017. After a four-year transition period, the MDR is mandatory as of May 26, 2021. Initially, the entry into force of MDR was planned for 26 May 2020 (see Figure 10).

However, the European Parliament and the Council decided by means of a regulation to postpone the date of application by one year (Regulation (EU) 2020/561 of the European Parliament and of the Council amending Regulation (EU) 2017/745 concerning medical devices as regards the date of application of some of its provisions, 23 April 2020. This was a response to the tight situation on the medical devices market due to the lack of notified bodies, the challenges of the Covid 19 crisis, and the threat of supply shortages. [2]

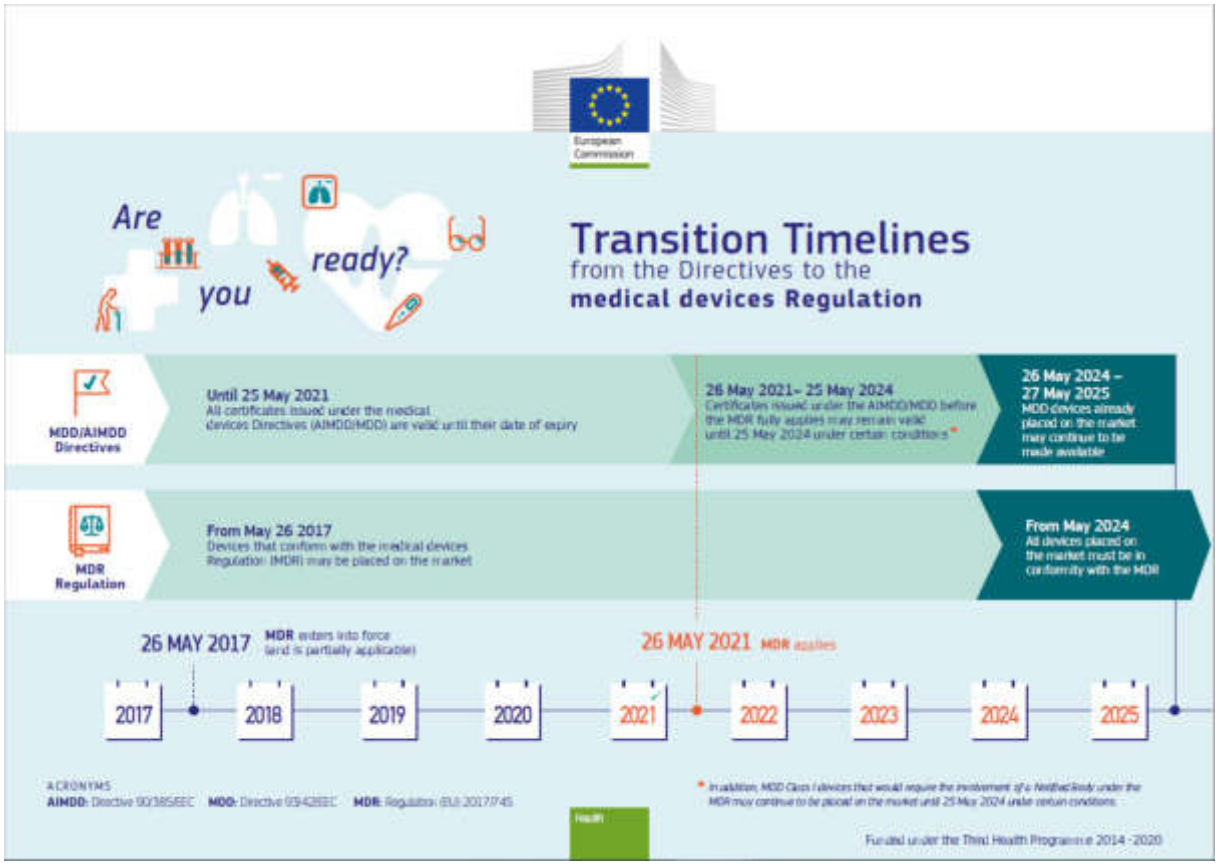

Figure 10: Transition timelines from the Directives to the medical devices Regulation [3]

There are shorter deadlines for reporting serious incidents and medical devices receive a Unique Device Identification (UDI). This unique product number is intended to help identify and trace medical devices. The UDI will be stored in the central, European database for medical devices, Eudamed, where it can be accessed. A staggered start is planned:

- for Class III products and implants: from May 2021
- for Classes IIa and IIb products: from May 2023
- for Class I products: from May 2025

Eudamed is intended to serve the central administration of medical devices. Access to data documenting the safety of medical devices enables regulatory authorities to react quickly to

incidents. Certificates of conformity and data on clinical trials must therefore be stored in the IT tool. [4]

The module on Actor registration is available since December 2020. The module on UDI/device registration (second module) and the module on Certificates and Notified Bodies (third module) will become available in September 2021 except for the mechanism for scrutiny and the clinical evaluation consultation procedure (CECP) functionalities. Afterwards, the remaining modules as well as the mechanism for scrutiny and the CECP will be released when EUDAMED is fully functional. [5]

Tools, Information, Downloads

Description		Language	Link
Tools	European Commission: MDR – Getting ready (Factsheets for manufacturer, healthcare professionals, health institutions…)	EN	Link
	Notified bodies for MDR 2017/745 – NANDO database	EN	Link
	Eudamed – Actors registration	EN	Link
Information	Regulation (EU) 2017/745 on medical devices	EN	Link
	European Commission: Eudamed – Overview	EN	Link
	European Commission: CE Marking	EN	Link
Downloads	European Commission: MDR – Timelines	EN	Link
	European Commission: MDR – Step by Step Guide	EN	Link
	Eudamed – Actors registration FAQs	EN	Link

Table 4: The new MDR – Tools, Information, Downloads

5.1 Actions to overcome this barrier

In this section the new medical device regulation is shortly described and we will provide you with information and tools that will help your company to solve the challenges:

- Understand and get an overview of the MDR/IVDR
- Share and get knowledge
- Get contacts for clinical investigation/collaboration
- Getting access to a notified body

Actions to comply with European legislations (MDR)
Exchange experience with companies from your own network
Register in cluster organisations
Participate in a knowledge exchange through networking
Organise workshops for knowledge exchange
Appoint an adviser
Found a special department

Actions to comply with European legislations (MDR)
Find and hire a specialist for the company
Hire an external service provider
Obtain an overview of MDR, Notified bodies and Eudamed
Participate in webinars

Table 5: The new MDR – Actions to comply with European legislations (MDR)

5.2 MDR / National regulations in Denmark

The capacity of the notified bodies (NB) is significantly decreased under the MDR compared to earlier under the directives. The Danish notified body, Presafe, is not certified for the MDR, which means that the lack of NB is increasing in Denmark.

In December 2020 TÜV SÜD becamethe winner of the Ministry of Industry, Business and Financial Affairs' tender of 14.7 million.

Tools, Information, Downloads

Description		Language	Link
Tools	Find a notified body in the NANDO database	EN	Link
	Participate in international matchmaking events and trade missions	EN	Link
Networks	Find international partnership in Enterprise Europe Network	EN	Link
	Find the perfect network in Denmark	DK	Link
Service provider	Become a member of Medico Industrien	DK	Link
	Become a member of BSI group	EN	Link
Information	Introduction to MDR (Danish medicines agency)	DK	Link
	Get ready for the MDR (factsheets)	EN	Link
Webinars	Safe and performant Medical Devices for all (EC webinar)	EN	Link
	WelfareTech webinars	DK	Link
	A Danish angel on the MDR	DK	Link
	Different angels on the worldwide regulatory process	EN	Link
	Webinars and lessons learnt by BSI	EN	Link

Table 6: The new MDR Denmark – Tools, Information, Downloads

5.3 MDR / National regulations in Germany

At national level, the adaptation of national law to MDR also began in October 2019 with the Medical Devices EU Adaptation Act (MPEUAnpG). In particular, the current German Medical Devices Act is still being adapted to the MDR and the opening clauses by the MDR are being regulated in more detail. This is followed by the revision of the Medical Devices Tax Ordinance, the Medical Device Operator Ordinance and other ordinances by the Federal Ministry of Health (BMG) in the context of the conversion to MDR.

In doing so, the German legislator is also taking into account the postponement of the entry into force of the MDR, so that the previous national medical device law will be retained until May 2021 and the entry into force of the MPEUAnpG will be postponed until 26 May 2021. [6]

Tools, Information, Downloads

Description		Language	Link
Tools	Find a notified body in the NANDO database	EN	Link
	Participate in international matchmaking events and trade missions	EN	Link
Cluster	Federal Ministry for Economic Affairs and Energy - Cluster Excellence in Germany	EN	Link
	Life Science Nord (LSN) – Clusterorganisation	EN	Link
Networks	Find international partnership in Enterprise Europe Network – Germany	DE	Link
	Become a member of Forum MedTech Pharma - Network for innovations	EN	Link
Information	DIMDI – EUDAMED (MDR)	DE	Link
	Get ready for the MDR (factsheets)	EN	Link
	EUDAMED - The European Database for Medical Devices	EN	Link
Service provider	Emergo consulting - Global medical device consulting	EN	Link
Webinars	Safe and performant Medical Devices for all (EC webinar)	EN	Link
	Different angels on the worldwide regulatory process	EN	Link
	Webinars and lessons learnt by BSI	EN	Link

Table 7: The new MDR Germany – Tools, Information, Downloads

5.4 Notified bodies

All European notified bodies (NB) for medical devices will lose their designation atthe date of the application of the MDR and IVDR due to the change in the legal framework, and must therefore be redesignated under the MDR.

All notified bodies are published on the NANDO homepage. Many products that could be placed on the market without consulting a NB up to now are reclassified or highly classified under the MDR (e.g. reusable surgical instruments, software, material medical devices etc.) and are therefore for the first time subject to mandatory certification from the date of validity (as are the large majority of IVDs). All these circumstances inevitably lead to a "bottleneck" for notified bodies and manufacturers. [7]

Naming under the MDR is still slow. So far (August 2021) only 22 notified bodies have been notified and listed in the NANDO database according to Regulation (EU) 2017/745 (MDR). Currently six notified bodies are listed in Germany and four in Scandinavia (see Table 8).

Notified bodies	ID	Link
DEKRA Certification GmbH, Stuttgart, Germany	NB 0124	Link
DQS Medizinprodukte GmbH, Frankfurt am Main, Germany	NB 0297	Link

Notified bodies	ID	Link
mdc medical device certification GmbH, Stuttgart, Germany	NB 0483	Link
MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH, Hamburg, Germany	NB 0482	Link
TÜV Rheinland LGA Products GmbH, Nürnberg, Germany	NB 0197	Link
TÜV SÜD Product Service GmbH, München, Germany	NB 0123	Link
DNV GL Presafe AS Norway	NB 2460	Link
Intertek Medical Notified Body AB Sweden	NB 2862	Link
Eurofins Expert Services Oy Finland	NB 0537	Link
SGS FIMKO OY Finland	NB 0598	Link

Table 8: The new MDR – Notified bodies

5.5 Medical devices

Chapter V of the Regulation "REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC" classifies medical devices in classes I, IIa, IIb and III, taking into account their intended purpose and the associated risks. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII. The application of the classification rules depends on the intended purpose of the products and is the responsibility of the manufacturer.

Definitions specific to classification rules [8]

Medical devices are classified in terms of the "vulnerability of the human body". This ranges from no existing risk for the human body to a high risk and danger potential. The following criteria help to classify a medical device in one of the risk classes.

- Duration of use
  - transient: continuous use for less than 60 minutes
  - short term: continuous use for between 60 minutes and 30 days
  - long term: continuous use for more than 30 days
- Invasive and active devices
  - degree of invasiveness (invasive, surgically invasive, implantable)
  - Central circulatory system or central nervous system (Wiederverwendbares chirurgisches Instrument)
- Active medical device
  - active therapeutic
  - active diagnostic
- Use of biological material (human or animal)

Risk classes

Based on these and other criteria listed in Annex VIII of the MDR, medical devices can be assigned to one of the four currently valid risk classes. Classification into a risk class is the responsibility of the manufacturer with the intended use. Neither the EU directive nor national

legislation makes such a classification. There are four risk classes in total, which carry a different risk potential (see Table 9).

Class I	Class IIa	Class IIb	Class III
Low risk Non-invasive Reusable	Medium risk Invasive or non-invasive for short term use	Increased risk Systemic effect Implantable and/or invasive for long term use	High risk Direct application to the heart, central circulatory or nervous system Implantable and/or highly invasive for long term implantation application
Bandages Crutches Patient beds Support stockings Wheelchairs	Contact lenses Dental materials (dental fillings, dental crowns) Diagnostic ultrasound devices Disposable syringes Hearing aids	Dialysis devices Defibrillators Dental implants Infusion pumps Respiration devices	Absorbable surgical sutures Cardiac catheters Cardiac valves Implants Stents

Table 9: Classification of devices – Overview

5.5.1 Medical devices – The path according to the new MDR

The long way that a medical device has to go, from the idea to the application on the patient is summarised in the following figure (Figure 11: BVMed – The long way of a medical device from the idea to the application on the patient). The requirements that the new MDR brings with it were taken into account.

After the product idea and the examination of the technical feasibility, the manufacturer has to define the purpose (medical indication), which is accompanied by the development of a prototype plus instructions for use. The medical device must then be assigned to one of the four risk classes. Afterwards, technical documentation for the proof of safety and clinical documentation for the proof of performance and efficacy are prepared. Depending on the classification in the risk class, either the company itself (self-certification for Class I) or a Notified Body checks the safety and performance. In some cases (class III) the BfArM is also consulted within the scope of a consultation procedure if the medical device contains pharmaceuticals.

CE marking is required before a medical device can be placed on the market for the first time. For this purpose, a written declaration of conformity must be submitted and a notification must be made to the competent authority.

In the market introduction phase, an audit of the production facility must be carried out and the manufacturer must ensure reimbursement, e.g. in-patient: DRGs, NBUs, out-patient: G-BA, HMV). Afterwards the users must be trained.

In the phase of market surveillance, the state authorities are responsible for monitoring the medical device on the market and at the manufacturer. The manufacturer has been made responsible by the new MDR for the long-term monitoring of his product, which is carried out and documented by clinical studies, registers, safety and metrological controls, among other things.

In the downstream re-audit phase, an annual re-audit of the quality management system by the Notified Body and a re-certification of the medical device by the Notified Body is required at least every 5 years. [9]

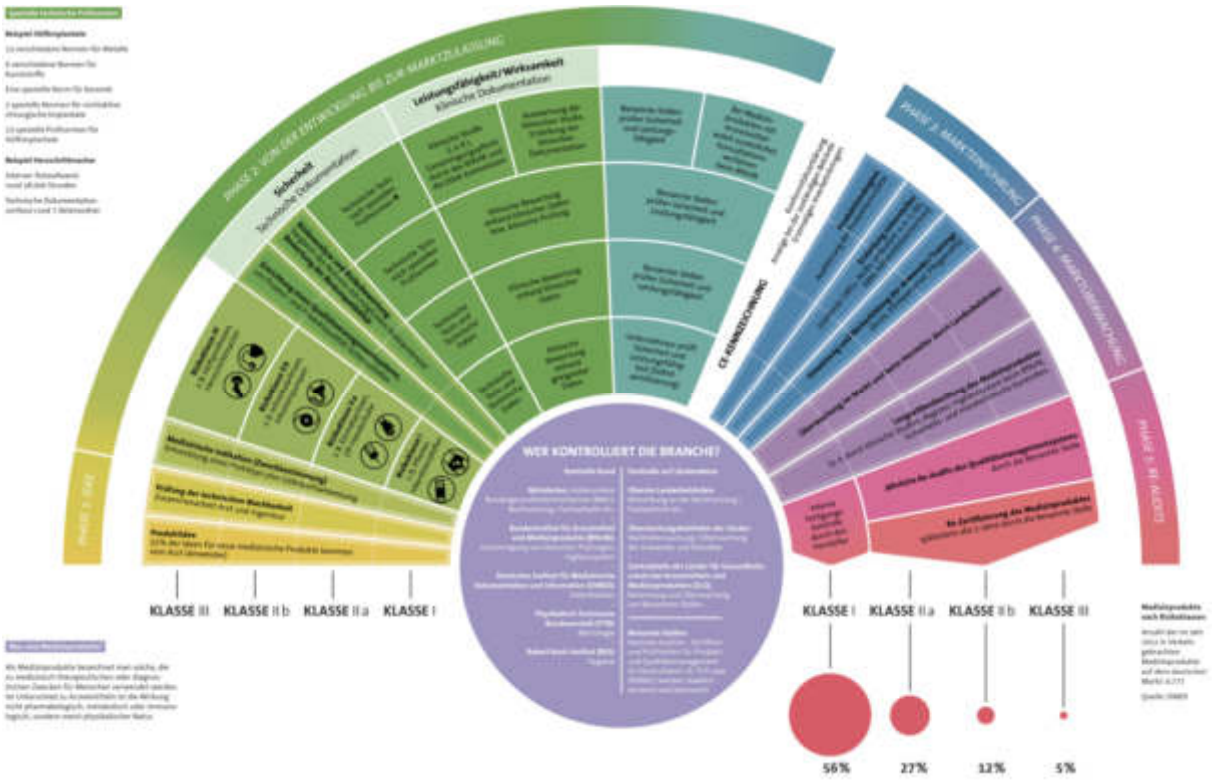

Figure 11: BVMed – The long way of a medical device from the idea to the application on the patient (DE)

Medical devices	Language	Publication (P) Website (W)	Link
BVMed – Infographic	DE	P	Link
Reimbursement Institute - General information	DE	W	Link
BfArM – General information	DE	W	Link
BfArM – General information	EN	W	Link
BMG – General information	DE	W	Link
European Commission: Medical Devices – Overview, Current Directives, New Regulations	EN	W	Link

Table 10: Medical devices – Websites and Publications

5.5.2 CE Marking

Medical devices must have the CE marking in order to gain access to the European market. CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU. CE marking is only

obligatory for products for which EU specifications exist and require the affixing of CE marking. Some products are subject to several EU requirements at the same time. The manufacturer must make sure that the product meets all relevant requirements before affixing the CE marking to it. [10]

The manufacturer must carry out a conformity assessment, set up a technical file, and sign a Declaration stipulated by the leading legislation for the product. The documentation has to be made available to authorities on request. Depending on the level of risk of the product, the CE marking is affixed to a product by the manufacturer or authorized representative who needs to ensure that the product meets all the CE marking requirements. [11]

CE Marking	Language	Publication (P) Website (W)	Link
European Commission – General Information	EN	W	Link
European Commission – Information for manufacturers – procedure	EN	W	Link
European Union –General information - When is CE marking mandatory? How to obtain CE marking? Do you need an independent assessment?...	EN	W	Link

Table 11: CE Marking – Websites and Publications

6 Different healthcare structure

German hospitals can be compared to a profit centre, whereas in Denmark it is more a social institution. Germany has over 200 health insurances compared to only one in Denmark.

The German and the Danish healthcare systems are notable different for two essential characteristics:

- The sharing of decision-making powers between states, the federal government and self-regulated organisations of payers and providers; and
- The separation of Public/Statutory Health Insurance (SHI) (including the social LTCI) and Private Health Insurance (PHI)(including the private LTCI).

SHI and PHI use the same providers. Hospitals and physicians treat both statutorily and privately insured patients, unlike hospitals in many other countries. Private insurances have some influence on the German market, whereas they play a minor role in the Danish market.

Especially the insurance differences can lead to difference in treatment. The Danish primary sector is focused on the rehabilitation and preventive treatment, as well as home treatment and telemedicine, since this is more cost-effective than admission of the patient. In Germany the focus on prevention is less because these products are not on the Hilfsmittelverzeichnis list, and therefore will the prevention treatment not be covered by the insurance to the same extent.

Further, Denmark is an international front-runner of digitalisation of the healthcare sector. Denmark is more developed and predecessors for the digitalisation in Europe and the rest of the world. [12]

6.1 Actions to overcome this barrier

In the section below the structures of the healthcare systems in Denmark and Germany are shortly described and we will provide you with information and tools that will help your company to solve the challenges:

- Understand the reimbursement process
- Get an overview of the tender process
- Share and get knowledge
- Improve your development through collaboration
- Get access to the catalog of assistive devices
- Purchasing managers/departments for the medical equipment

Actions to understand the structure of the healthcare system
Gain knowledge about the structure of the healthcare system
Contact potential customers (doctors, pharmacies...) at fairs, events
Obtain information about the catalog of assistive devices (Hilfsmittelverzeichnis)
Get access to the catalog of assistive devices (Hilfsmittelverzeichnis)
Aquire knowledge about the reimbursement process
Take part in the tender process
Find and hire an expert of/for the tender process
Register at international cooperation exchanges for partner search
Find a partner for the distribution of your product

Table 12: Structure of the healthcare system – Actions to overcome this barrier

6.2 Structure of the healthcare system in Denmark

Denmark has a decentralized health system where the national government provides block grants from tax revenues to the regions and municipalities, which deliver health services.

The five regions are responsible for the secondary care and the 98 municipalities are responsible for the primary care.

At all levels in the health system Information technology (IT) is used and part of a national strategy supported by the National Agency for Health IT.

All citizens in Denmark have a unique electronic personal identifier, appearing in all public registries, including health databases and electronic medical card. Danish general practitioners were ranked first in an assessment of the overall implementation of electronic health records in 2014.

All residents are entitled to public financed care, including largely free primary, specialist, hospital, mental health, preventive, and long-term care services. Residents may purchase voluntary complementary insurance to cover co-payments for outpatient drugs, dental care, and other services. Supplemental insurance, provided mainly by private employers, offers expanded access to private providers. Cost-sharing limits for adults and for children create a safety net.

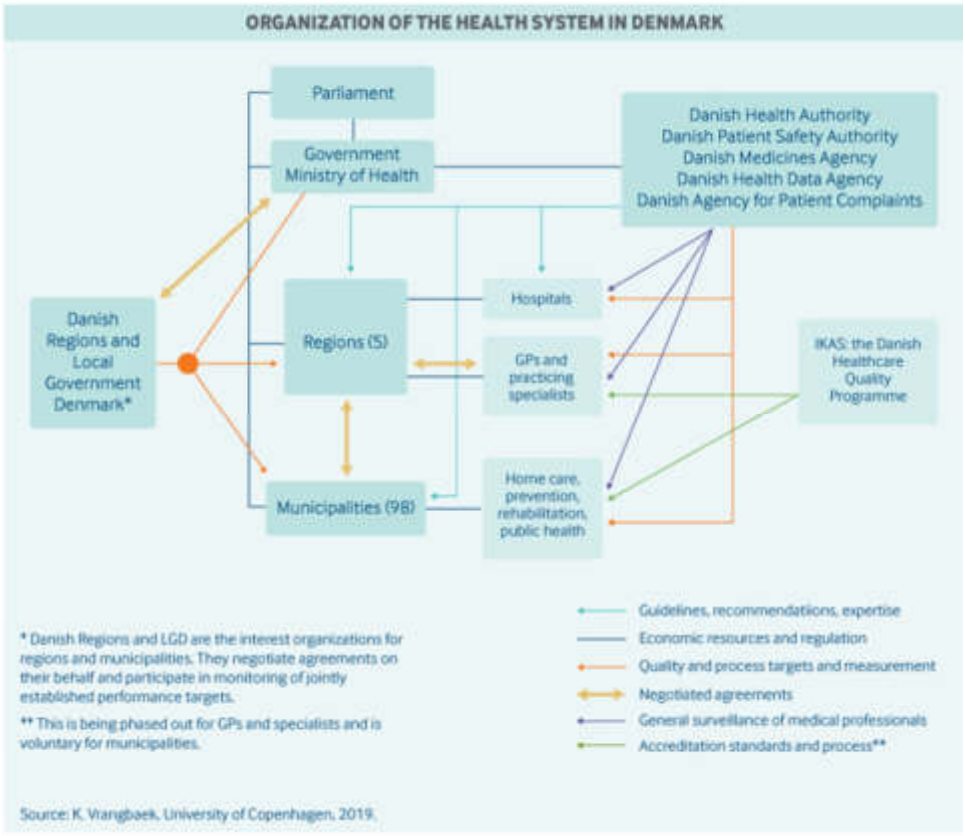

Figure 12: Structure of the healthcare system in Denmark – Organisation [13]

Principle	Description
Public health insurance	Health care is financed mainly through a progressive national income tax. The national government allocates health care funding to regions and municipalities, mostly as block grants, with amounts adjusted for demographic and social differences. These grants finance 77 percent of regional health functions. A minor portion of state funding for regional and municipal services is tied to specific priority areas and targets, usually defined in the annual economic agreements between the national government and the municipalities or regions.
Governant	The national government sets the regulatory framework for health services and is in charge of general planning, monitoring care quality, and licensing health care professionals. The national government also collects taxes and allocates funding to regions and municipalities based on sociodemographic criteria and activity.
Solidarity	Everyone in Denmark are covered be the public health to go to the hospital. Regardless of their job, insurance etc. They will recieve full care at the hospital. Another aspect of this solidarity is that those in work continue to receive their salary if they become ill.
No direct payment by patients	There is no direct payment when recieving medical treatment. Every cost will be govered by the government.

Table 13: Structure of the healthcare system Denmark - Principles

Tools, Information, Downloads

Description		Language	Link
Tools	Contact the experts in innovation and technological development	EN	Link
	Find a partner abroad for your business	EN	Link
	Access to the Danish healthcare market	DK	Link
Information	Get an overview of the Danish healthcare system	EN	Link
	Information about innovation of new medical technologies	EN	Link
	The tender process - step by step	DK	Link
	Compete in the tenders	EN	Link
Networks	Get in contact with specialists in public tenders and B&B sales	DK	Link
	Find experts in the network for business contacts and connections	DK	Link
	Stay updated on the Danish healthcare system	EN	Link
Downloads	Read about healthcare in Denmark	EN	Link
	An overview of the reimbursement process in Denmark	EN	Link
	Access & Acceleration Report	EN	Link

Table 14: Healthcare system Denmark – Tools, Information, Downloads

6.3 Structure of the healthcare system in Germany

In Germany, the principle of self-administration applies: Although the state sets the legal framework and tasks, the insured and contributors as well as the service providers organize themselves in associations that are responsible for providing medical care to the population.

The state holds most university hospitals, while municipalities play a role in public health activities and hold about half of all hospital beds. Patients health insurance covers costs that are directly associated with the treatment in the hospital. The federal state in which the hospital is located finances so-called ‘investment costs’ such as diagnostic machinery, ambulance vehicles, and building maintenance.

The German health care system is supported and self-managed by many institutions and actors. The core area, also known as the first healthcare market, comprises the area of "classic" health care, which is largely financed by statutory health insurance (SHI) and private health insurance (PHI) including nursing care insurance. All privately financed products and services related to health are referred to as the second healthcare market. [14]

Tools, Information, Downloads

Description		Language	Link
Tools	Overview trade fairs by sectors of activity	EN	Link
	Develop international business relationships	EN	Link
	Obtain an overview of the tenders in health economy	DE	Link
	Find international cooperation fairs	DE	Link
	Search directly in the catalog of assistive devices	DE	Link

Description		Language	Link
	Watch the healthcare webinar series „Succeed in Germany's Healthcare Market" 2014 – 2020	EN	Link
Information	International healthcare system profiles - Germany	EN	Link
	Health care in Germany	EN	Link
	Get on overview of the Catalog of assistive devices	DE	Link
	Apply to have your medical devices included in the catalog of assistive devices	DE	Link
	What is a tendering process and what do you need to consider?	DE	Link
	Market access in the light of the health and certification system	EN	Link
Downloads	An overview of the German healthcare system	EN	Link
	Have a look at the figure of the German healthcare system	DE	Link
	Find your way into the German medical device market	EN	Link
	Read about the German pharmaceutical market	EN	Link
	BVMed Branchenbericht	DE	Link
	Access & Acceleration Report	EN	Link
Networks	Find experts in the network for business contacts and connections	DE	Link
	Contact specialists at the platform for business networks	DE	Link
	The list of German cluster initiatives and links to their websites	EN	Link
	Become a member of the network for medtech and pharma	EN	Link

Table 15: Healthcare system Germany – Tools, Information, Downloads

Healthcare in Germany is based on five principles. A brief explanation of each of the basic principles can be found in the following overview (see Table 16).

Principle	Description
Mandatory insurance	All citizens are obliged to be insured in a SHI - as long as they do not earn more than a certain amount gross ("compulsory insurance limit"). Those who earn more can take out PHI.
Financed by contributions	Both SHI and PHI are funded by contributions or premiums from their members. Whereas contributions to PHI depend on a person's health, the age at which they take out the insurance, their individual risk, the type of coverage and any excess, contributions to the SHI are based on a person's salary. With the SHI, all the insured receive the same level of services. Those who earn more pay higher contributions. This is what is meant by solidarity in the statutory health insurance system.
Solidarity	All those with statutory health insurance bear the costs for the treatment of individual members. Everyone covered by SHI is entitled to medical care, regardless of their income and therefore their health insurance contributions. Another aspect of this solidarity is that those in work continue to receive their salary if they become ill. Employers pay them their full salary for the first six weeks. Anyone who is off work for longer receives an allowance of 70 percent of their gross pay from their health insurance fund.

Principle	Description
No direct payment by patients	Those covered by SHI receive medical treatment without having to outlay the costs themselves. Doctors, hospitals and pharmacies charge the cost of treatment and medicines directly to the health insurance funds. The insured are entitled to free treatment, apart from any individual extra charges defined by law.
Self-administration	This means that the state defines the framework for medical care and its responsibilities. It enacts legislation and regulations for this purpose. Its supreme decision-making body is the Federal Joint Committee (G-BA). Representatives of patient organisations have the right to table motions in and take part in G-BA sessions. The G-BA defines in binding guidelines the healthcare services to which those covered by statutory health insurance are entitled, e.g. what treatments are covered by the statutory health insurance. As a rule, new medicines are covered.

Table 16: German healthcare system – Basic principles [15]

Structure of the health system [16] [15] [17]

The German healthcare system is divided into three levels:

1. A framework defined by the state – at federal, state (Land) and municipal level
2. A healthcare structure as defined by the system of self-administration, with its bodies and associations
3. Provision of care by health insurers, doctors, many different healthcare professionals, hospitals and pharmacies, whose interests are represented by associations

The legislative framework

At federal level, the Federal Ministry of Health (BMG) shapes health policy. This means it is in charge of drawing up the corresponding legislative proposals, ordinances and administrative regulations. The BMG supervises a number of institutions and authorities that deal with overarching aspects of health policy. These include, for example, the Federal Institute for Drugs and Medical Devices (BfArM), the Robert Koch Institute (RKI) and the Paul Ehrlich Institute (PEI). The BfArM is responsible, among other things, for the approval of drugs. The PEI's tasks include the approval of vaccines, for example.

Alongside the German Bundestag and the Federal Government, the Bundesrat is the third key driver of health policy at the federal level. As the “second chamber of parliament”, it is the institution where the governments of the individual German states can debate matters of health policy. The legislature and state health policy define the framework in which the various partners in the healthcare sector can make their decisions.

Self-administration

Within the framework of statutory health insurance, the Federal Joint Committee (G-BA) is the most important body in the joint self-administration of healthcare. It consists of members of the National Association of Statutory Health Insurance Funds, the National Association of Statutory Health Insurance Physicians, the National Association of Statutory Health Insurance Dentists and the German Hospital Federation. Patients are also entitled to make their interests heard, so organisations representing patients and people with disabilities have the right to take part in and table motions in G-BA sessions.

The health insurance funds and the service providers (doctors, dentists, hospitals, psychotherapists) jointly discuss within the G-BA the content of health care and the medical services that are covered by the statutory health insurance. The G-BA issues guidelines that are binding for all insured persons, the statutory health insurance funds and the doctors and other service providers involved in the provision of health care. As the central organ of self-government at federal level, the G-BA decides, among other things, which medical services are paid for by the statutory health insurance funds and in what form they are provided.

The statutory health insurance funds are represented at the federal level by an umbrella organisation, the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband). Via this or its regional branches, they sign contracts with medical associations, hospitals and pharmacies and agree on how much they will pay for individual medical treatments. It is thus the sole statutory association of the SHI at the federal level and regulates in particular the framework conditions for the competition for quality and efficiency of care. The contracts concluded by the GKV-Spitzenverband and its other decisions apply to its member funds, the regional associations of the health insurance funds and to the insured.

At the regional level, hospitals are organised in associations for their specific Land or state. The regional associations in turn send delegates to the federal body, the German Hospital Federation (DKG). The DKG has a number of duties assigned to it by law in line with the self-administration system in the healthcare sector. Along with the National Associations of Statutory Health Insurance Physicians (KBV and KZBV) and the GKV-Spitzenverband, it is one of the supporting organisations of the G-BA. In addition, the DKG, together with the GKV-Spitzenverband and the Verband der privaten Krankenversicherung, is a shareholder of the Institute for the Remuneration System in Hospitals (InEK GmbH).

The local associations of SHI doctors and dentists and their umbrella associations at the federal level are responsible for the area of contractual medical and contractual dental care to people with statutory health insurance. They represent the doctors in the respective federal states who are licensed to treat patients covered by health insurance. Their organs are the representative assemblies, which are in turn elected by the members, and the executive boards.

Individual actors and their lobby groups

To ensure that those involved in providing treatment directly to patients also have a voice and can make themselves heard by policymakers, they have formed professional organisations and trade associations. These include the federal and regional associations of various medical professions, as well as the Federal Union of German Associations of Pharmacists (ABDA). In addition, there are patients' organisations, the medical associations, the associations of other healthcare professionals, the association of private health insurance funds and the associations of pharmaceutical companies.

Actors in the health system

Important providers, institutions and associations in the German health sector are listed in the following table. Further explanations of the important players and their tasks in the health care system have been compiled in the following overview (see Table 17).

Actor	Description
Health insurance companies	The statutory health insurance funds have a duty to insure citizens and ensure that they receive medical services. The association of all statutory health insurers at the federal level is called "GKV-Spitzenverband The private health insurance companies offer their customers either full, partial or supplementary insurance. Their lobby is the "PKV Association". Link GKV-Spitzenverband: https://www.gkv-spitzenverband.de Link PKV: https://www.pkv.de/
The national associations of SHI doctors and dentists	All doctors and psychological psychotherapists who settle accounts with the statutory health insurance are organized in the federal states in associations of panel doctors (KV), the dentists in associations of panel dentists (KZV). The responsible associations at the federal level are the Kassenärztliche Bundesvereinigung (KBV) and the Kassenzahnärztliche Bundesvereinigung (KZBV). The tasks of the associations are defined by law. Link KBV: https://www.kbv.de/html/ Link KZBV: https://www.kzbv.de/
German Hospital Federation	The German Hospital Association (DKG) represents central and regional associations of the various hospital operators such as cities and municipalities, churches, non-profit associations and other private operators. Link: https://www.dkgev.de/
Chambers of doctors, dentists, psychotherapists and pharmacists	On the level of the federal states, all physicians, dentists, psychotherapists and pharmacists are compulsory members of their respective state chamber. The tasks of the chambers include the monitoring of professional obligations and compliance with the X-ray and radiation ordinance. They are responsible for the recognition of the profession, the specialist examination as well as the assessment and arbitration in case of allegations of treatment errors. The state chambers have formed corresponding federal chambers at the federal level.
Public Health Service (ÖGD)	The task of the ÖGD is to protect the population from health hazards. The municipal health authorities in particular are responsible for hygiene in community facilities, protection against infection and general health promotion. Link BVÖGD: https://www.bvoegd.de/
Associations of Pharmacists	Pharmacies are responsible for dispensing medicines to consumers. To ensure supply, their associations must conclude contracts with the GKV-Spitzenverband and the health insurance funds. The Bundesvereinigung Deutscher Apothekerverbände e. V. (ABDA) is the central organization of German pharmacists. Members of the ABDA are all 17 state chambers of pharmacists and all 17 state associations of pharmacists. Link ABDA: https://www.abda.de/index/
Non-medical health professions	These include, for example, physiotherapists, speech therapists, nurses or midwives. Insofar as they offer health insurance services, their associations also conclude contracts with the GKV-Spitzenverband and the health insurance funds.
Patient organisations and support groups	Many people have joined together to form self-help groups and patient organisations that advise and support patients. Various patient organisations also represent patients' interests in health policy issues.

Table 17: German healthcare system – Important actors [16]

6.3.1 The first, second and third healthcare market

The First healthcare market [18] [19]

The First Healthcare Market covers the area of "traditional" health care and includes those health-related products and services that are reimbursed under a solidarity-based financing system. Financing is largely provided by the statutory health insurance (SHI) and private health insurance (PHI) including insurances such as nursing care, pension and accident insurance. Employers, the state and other social security institutions are also involved, but make a much smaller contribution.

The goods and services currently used and reimbursed in the health care sector, such as pharmaceuticals and other medical devices, medical and nursing services, hospital treatment, etc., belong to the first health care market. They are subsumed under the term "core area of the health care industry".

Due to the tight financing system, the primary healthcare market is a highly regulated market. Numerous laws, which limit the expenditure of the statutory health insurance funds for pharmaceuticals, hospitals and medical services and have continued to do so for decades, significantly impede the development and growth of the primary healthcare market.

The Second healthcare market [18] [20]

The second health market is defined as all privately financed products and services related to health. The classification of which goods and services have a connection to health is not clearly defined and is sometimes controversial. The second health market is generally understood to include over-the-counter medicines and individual health services, fitness and wellness, health tourism and - in some cases - the areas of sport/leisure, nutrition and housing.

The Third healthcare market [21] [22]

The third health care market offers numerous opportunities for improving health care. The third health market sees health care as a sharing economy, it is characterised by the sharing of health data. New forms of cooperation have emerged. This means that consumers organise themselves according to the principle of non-profit making; this can be done, for example, through consumer initiatives in which those affected or interested share their experiences with each other.

6.3.2 Healthcare fund [23] [24] [25]

The healthcare fund is a money collection point for the contributions collected by the health insurance companies. When the healthcare fund was implemented on 1 January 2009, the Federal Government set a uniform contribution rate for all those with statutory health insurance. In future, contributions, which will continue to be financed to around 95 percent from employee and employer contributions, will flow directly into the healthcare fund. This healthcare fund will also be financed by tax revenues, which will increase gradually.

Since 1 January 2009, all revenue from contributions of the individual health insurance companies and the federal subsidy from tax money have been flowing into the healthcare fund. It is administered by the Federal Office for Social Security. Since 1 January 2015, the health insurance companies have also been deducting the additional contribution rates together with the general health insurance contribution, which is financed on a parity basis, at source and paying both parts of the contribution in full to the healthcare fund.

The money collected in the health fund is then transferred back to the health insurance companies for the health care of their insured. The statutory health insurance companies receive a fixed share from the fund each month. From this financial pool, the insurers receive a standard amount for each insured person plus supplements for the age structure and risks of their

insured persons. Health insurance companies with older and sick insured persons receive more funds than health insurance companies with a large number of young and healthy insured persons. In addition to the risk-adjusted allocations from the health fund, each health insurance company also receives the amount resulting from the application of its individual health insurance company's additional contribution rate to the average basic wage of the statutory health insurance company multiplied by the number of its members.

6.3.3 Reimbursement

The German healthcare market is characterized by a complex reimbursement system. The reimbursement of medical devices by the various cost units is very complex and subject to numerous regulations and requirements. A prerequisite for inclusion in the catalog of services offered by the statutory health insurance funds is the successful evaluation of medical methods. For medical device manufacturers, especially when introducing new innovative medical devices to the healthcare market, access to the reimbursement system is of fundamental importance for economic planning.

The basis of the diverse regulations are the legal provisions of the Social Security Code 5 (SGB V) and the Rules of Procedure of the Joint Federal Committee (G-BA). The latter specifies the requirements for evaluation methods and the system of the scope of services in the outpatient and inpatient sectors.

The evaluation of examination and treatment methods in the outpatient sector (according to Section 135 SGB V) and in the inpatient sector (according to Section 137c SGB V) are supplemented by further regulations (according to Section 137e SGB V and Section 137h SGB V). [26] [27]

Medical devices

In Germany, medical device manufacturers encounter an established, consolidated health care system that is based on a contribution-financed compulsory insurance scheme for the population. The model of statutory health insurance and the model of private health insurance are anchored in legal regulations. The statutory health insurance is a compulsory insurance that can only be left in favour of the private health insurance if certain conditions are met. The SHI represents the largest community of cost bearers and is of central importance for the German medical device market, also due to its influence on the reimbursement environment.

Especially in the area of statutory health insurance, there are clear rules for the reimbursement of medical services and medical devices by the insurance companies.

In the outpatient sector, there is an authorization right [pursuant to Section 135 § 1 of the Social Security Code V). This means that new (medical) services form part of the liability of the statutory health insurance only after examination and approval. In contrast to this, the inpatient segment has a prohibition right (pursuant to Section 137c of the Social Security Code V), that allows provision of new (medical) services and their reimbursement by the statutory health insurance as long as the fundamental principles of quality and cost-effectiveness are not violated (see Figure 13: Reimbursement in the statutory health insurance). The aim of the prohibition right is to ensure that insured patients are quickly able to take advantage of innovative methods of treatment. The rules are adopted implicitly by the private health insurance.

Therefore in the inpatient sector innovations in medical devices find conditions that enable their rapid application in clinical practice. The pricing of medical devices by the manufacturer is subject to the market and competitive mechanisms to a significant extent. Whether the service providers who obtain the medical device from the manufacturer accept the intended purchase price depends on the financing of the services sector and the reimbursement options. [28]

In principle, innovative procedures based on medical devices are more easily reimbursed in the inpatient sector than in the outpatient sector.

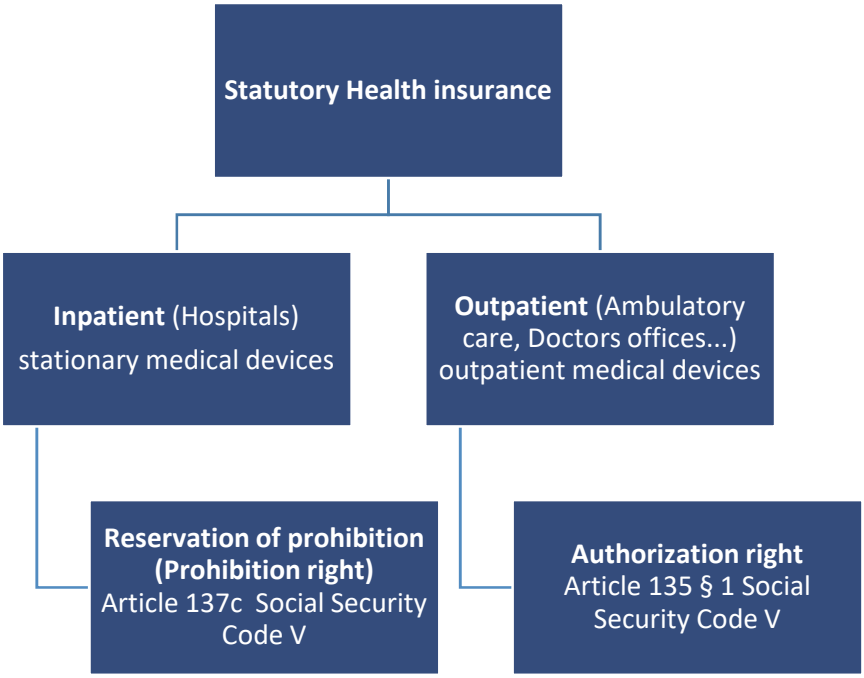

Figure 13: Reimbursement in the statutory health insurance

Pharmaceuticals

Most EU countries use price referencing systems to set pharmaceutical prices. Pharmaceutical prices in individual countries can therefore have a significant impact on prices in other countries. Companies must strategically consider pricing in individual countries and its impact on other countries.

There are various requirements for innovative drugs and medical devices that must be fulfilled in order to be recognized as a benefit of the statutory health insurance (GKV). A distinction is made between inpatient and outpatient care in accordance with the sectoral division of the German health care system. [29]

6.3.4 "Hilfsmittelverzeichnis" – HMV [30] [31]

The HMV of the statutory health insurance in Germany contains a list of those aids whose costs must be covered by the German statutory health insurance according to the aids directive of the Joint Federal Committee. In principle, the costs for aids can only be covered by the statutory health insurance if the products are listed in the HMV. In addition to the aids (rehabilitation), the HMV also contains a list of nursing aids according to the statutory nursing insurance.

The directory is compiled by the German Federal Association of Health Insurance Funds and is continuously adapted to medical and technical progress. New products are included after the Medical Service of the German Federal Association of Health Insurance Funds has been informed.

The products available on the market are assigned to specific product groups in the HMV according to their functions and their areas of application/indications. The HMV provides comprehensive information on the health insurance companies obligation to provide services and on the type and quality of the products, creates market transparency and serves the health insurance companies and other parties involved in the provision of care as an interpretation and orientation aid.

At the request of the manufacturers (or third parties authorized by them), products are entered in the HMV if they have certain properties and quality characteristics. Product-specific application forms are available for this purpose. The application for inclusion in the medical aids directory must be submitted in writing by mail or can also be submitted digitally. The Rules of Procedure contain explanations of the application procedure. These can also be downloaded from the website of the GKV-Spitzenverband.

For medical devices in the sense of § 3 No. 1 of the German Medical Devices Act (MPG), proof of functional capability and safety is generally deemed to be provided by the CE marking. The GKV-Spitzenverband decides on the inclusion in the HMV or "Pflegehilfsmittelverzeichnis". The products that meet the requirements for inclusion in the list are each listed with a reference to the manufacturer as well as specific design features and are given an individual ten-digit item number. The applicant is informed in writing by the GKV-Spitzenverband about the result. The official announcement is made in the "Bundesanzeiger".

However, aids that are not listed in the HMV could also be reimbursable by the GKV. Since the health insurance companies are responsible for the securing of medical aids, only they can make a statement on the obligation to perform in individual cases.

The assistive device shall be included in the HMV if the manufacturer has demonstrated its functional capability and safety, the fulfilment of the quality requirements according to §139 paragraph 2 SGB and, if necessary, its medical benefit and if it is provided with the information in German language required for proper and safe handling. If a product cannot be included in the HMV because, for example, it does not have the properties of a assistive medical device, it will then be examined whether it can be included in the Register of Care Devices. So far, more than 32,500 products have been included in the directory.

Consultation

With the resolution on the medical device European Union adjustment law on 5 March the German Bundestag creates the legal framework, in order to establish for aid manufacturers a consulting consultation with the GKV-Spitzenverband.

Previously, the GKV-Spitzenverband did not have to advise the applicant personally on the formal and substantive requirements. General information on this subject is provided on the website of the GKV-Spitzenverband.

With the resolution on the Medical Devices EU Adaptation Act on March 5, an amendment to §139 SGB paragraph 4 was made as follows.

Upon request of the manufacturer, the German Federal Association of Health Insurance Funds (Spitzenverband Bund der Krankenkassen) will advise the manufacturer on the quality and scope of the application documents to be submitted in the context of an application procedure for the inclusion of novel products in the list of medical devices. The consultation extends in particular to the basic requirements for the proof of the medical benefit of the aid. If products are an integral part of a new examination and treatment method, the consultation does not refer to the procedure according to § 135 (1). [32]

Temporal sequence

The following two tables show the temporal sequence for an application submission with a complete application (see Table 18) and with an incomplete application (see Table 19). The compilation was carried out in accordance with Section III of the Rules of Procedure.

Deadline	Step	Responsibility
	Submission of the application	Applicant
+ 10 working days	Acknowledgement of receipt to the applicant	GKV-Spitzenverband
+ 10 weeks	Decision on formal completeness of the application	GKV-Spitzenverband
+ 3 month	Decision on the application and sending a written decision to the applicant	GKV-Spitzenverband
	In the event of a positive decision, publication in the Bundesanzeiger and listing in the HMV	GKV-Spitzenverband

Table 18: HMV – Procedure for a complete application

Deadline	Step	Responsibility
	Submission of the application	Applicant
+ 10 working days	Acknowledgement of receipt to the applicant	GKV-Spitzenverband
+ 10 weeks	Determination of the incompleteness of the application	GKV-Spitzenverband
+ max. 6 months	In case of incompleteness submission of missing documents / completion of information	Applicant
+ 3 month	Decision on the application and sending a written decision to the applicant	GKV-Spitzenverband
	In the event of a positive decision, publication in the Bundesanzeiger and listing in the HMV	GKV-Spitzenverband

Table 19: HMV – Procedure for an incomplete application

The following table (see Table 20) lists links to websites and publications that are thematically related to HMV.

Hilfsmittelverzeichnis	Language	Publication (P) Website (W)	Link
Wikipedia – General information	DE	W	Link
GKV Spitzenverband – Application procedure	DE	W	Link
GKV Spitzenverband – HMV Overview of product groups	DE	W	Link
GKV-Spitzenverband – HMV Rules of Procedure	DE	P	Link
Bundesamt für Justiz – German social security statute book	DE	W	Link

Table 20: HMV – Websites and Publications

6.3.5 Tender process

In Germany, about one third of hospitals are in **municipal** and thus **public hands** and are therefore subject to the obligation to tender, as are all public contracting authorities. The introduction of the procurement regulations has an enormous economic impact and represents a significant budgetary advantage for many companies.

Public contracting authorities are subject to a fundamental obligation to invite tenders. This means that all planned procurements of goods and products as well as services must be published. This initially applies from a net contract value of 209,000 euros for supplies and services and 5,225,000 million euros for constructions. Above this limit, contracts must in principle be put out to tender EU-wide.

This obligation is regulated by law in the Procurement Ordinance (VgV). This describes the basic procedure for awarding public contracts.

If the hospital is **privately or denominationally** run, a tender is not obligatory. In this case, the market enquiry procedure is used to find suitable contractors. This means that the hospital issuing the invitation to tender obtains non-binding offers from several providers and compares them, just as a private person would do. In this case, the project does not have to be put out to public tender and the selection process can be carried out individually. [33]

Websites and Publications

Tenderprocess	Language	Publication (P) Website (W)	Link
Tenders Electronic Daily – EU-wide tenders	EN	W	Link
Federal Office of Economics and Export Control – Tenders	DE	W	Link
GTAI database – Tenders in health economy	DE	W	Link
Portal Deutsche eVergabe	DE	W	Link
Tenders of the public sector	DE	W	Link
Portal service.bund.de – Administration Online	DE	W	Link
Krankenhaus GmbH – Current tenders	DE	W	Link
B_I MEDIEN GmbH – Tender platform	DE	W	Link
B_I MEDIEN GmbH – Award platform	DE	W	Link

Table 21: Tenderprocess – Websites, Publications

6.4 Comparison of the healthcare systems

In the interviews, workshops, and online survey, companies repeatedly pointed out a barrier that makes it difficult for them to access the market. This is the lack of knowledge about the structure of the healthcare system in the target market. The facts describing the healthcare system in Denmark and Germany were listed below. (see Table 22)

	Denmark	Germany
Inhabitants	5.81 million Inhabitants	83.2 million Inhabitants
Hospitals	32 Hospitals	1,925 Hospitals
Facts & numbers	5 regions 2,5 beds per 1000 inhabitants	**2018** [34] 391 bn € Health expenditure 4,712 € Health expenditure per inhabitant 498,192 Beds provides 19.4 mn Patients 108.9 bn € Cost of hospitals
Health insurance companies	1 National health insurance	103 statutory health insurance companies (as of January 01, 2021 [35]) 43 private health insurance companies (as of December 31, 2015 [36])
Financing	Tax revenues	Insurance contributions of the insured persons Tax revenues Employer contributions
Structure	*3 levels:* 1. National level 2. Regional level 3. Local level	*3 levels:* 1. The legislative framework 2. Self administration 3. Individual actors and their lobby groups
Core areas	100% are covered by public health	*1st Health care market* Financed by statutory and private health insurance. *2nd Health care market* Financed by privately financed products and services
Digitalisation	Significantly higher than in Germany	Significantly lower than in Denmark

Table 22: Comparison of the healthcare systems in Denmark and Germany

7 Funding

The European Union supports companies and research institutions with a variety of funding programmes and financing instruments. In addition to research and development projects, the EU also funds projects in the area of opening up new markets. On the website of the European Commission specifically on financing and tendering, companies can find a wide range of information about the tendering process and opportunities for doing business with the European Commission. There are open and upcoming calls for funding proposals, background information on funding processes and programmes, information on the different types of EU funding available, the application process, eligibility and rules.

Horizon Europe is the research and innovation framework programme running from 2021-2027. The EU institutions reached a political agreement on Horizon Europe on 11 December 2020. On this basis, the European Parliament and the Council of the EU proceed towards the

adoption of the legal acts. The first Horizon Europe Strategic Plan (2021-2024) is expected to be adopted in February 2021. The first work programmes are expected to be published by April 2021. [37]

Tools, Information, Downloads

Description		Language	Link
Tools	European Commission: Funding and Tender Portal	EN	Link
	European Union: The finance portal	EN	Link
	Innovative medicines initiative - Europe's partnership for health	EN	Link
Information	European Commission: Funding and Tender	EN	Link
	European Commission: How EU funding works	EN	Link
Downloads	Horizon Europe - EU Research & Innovation Investment Programme	EN	Link
	European Commission - EU4Health Factsheet	EN	Link
	European Commission - European Investment Funds Programmes	EN	Link

Table 23: Funding – Tools, Information, Downloads

7.1 Actions to overcome this barrier

In the section below the different funding programs, networkgroups that can support you and help matchmaking. The challenges we will adress are:

- Overview of funding programs
- Ideas for network groups
- Investment possibilities for companies
- Get contacts for funding/collaboration

Actions to find funding opportunities
Get an overview of funding programs
Obtain an overview of foreign trade promotion
Become a member in networks
Get in contact with economic development associations
Participate in Webinars

Table 24: Funding – Actions to overcome this barrier

7.2 Funding in Europe

To have the right product idea is not always enough. The product will often need adjustments to fit the content. There are different funding programs that support public and private innovation both nationally but also internationally. To navigate in the different funds, search for relevant network etc. is difficult for SMEs, this section will provide you with an overview of relevant funding programs, relevant networks, and where get the support for cross boarder collaborations.

The European Union (EU) supports companies and research institutions with a variety of funding programs and financing instruments. In addition to research and development projects,

the EU also funds projects in the area of opening up new markets. Horizon Europe is the research and innovation framework programme running from 2021-2027.

EIT Health is one of the largest healthcare initiatives worldwide. Its goal is to sustainably advance the fundamentals of healthcare and thus promote suitable future conditions for healthy living of people across Europe.

Tools, Information, Downloads

Description		Language	Link
Tools	European Funding possibilities	EN	Link
	Innovative medicines initiative for SMEs	EN	Link
	Partnerships if you are interested in Crowdfunding	EN	Link
Information	EIT Health - One of the largest healthcare initiatives worldwide	EN	Link
	The EU funds projects in the area of opening up new markets	EN	Link
	Horizon Europe - The research and innovation framework programme	EN	Link
Downloads	Short presentation of Horizon Europe (2021-2027)	EN	Link
	Improve and foster health in the Union - Factsheet	EN	Link
	Calls for European projects - Horizon Europe	EN	Link

Table 25: Funding Europe – Tools, Information, Downloads

7.3 Funding in Denmark

Denmark is among the world's leading countries within innovation, especially concerning international partnership collaborations, high quality research outputs and networks at an international level, innovative-friendly environments and finance, according to European Innovation Scoreboard 2020.

The fundamental elements to achieve a high-level innovation performance comprises a balanced innovation system that is built from highly educated labour and public-private collaborations. However, one of the main parts of the innovation strategy is to ensure funding, which is done through both local, regional, national and international funding programmes.

Tools, Information, Downloads

Description		Language	Link
Tools	1:1 consulting on your idea and matchmaking	DK	Link
	Connect with German companies from the healthcare industry	EN	Link
	Free counselling about EU funding	EN	Link
Networks	Syddansk Sundhedsinnovation	DK	Link
	Innovation Fund Denmark - Grand Solutions	EN	Link
	Export and expand internationally	EN	Link
Information	Eurostars - projects with international marked potential	EN	Link
	To researchers with initiativers	EN	Link
Downloads	Panorama - Denmark: investing in an innovative future	EN	Link

Description		Language	Link
	Funding possibilities all year around	EN	Link
	Invest in an innovative future	EN	Link

Table 26: Funding Denmark – Tools, Information, Downloads

7.4 Funding in Germany

Research into the financing of international activities in relation to the German healthcare market revealed the following composition. Funding for corporate activities can be provided at the European level. There is also support for companies through funding programs at the federal level. The federal government has launched the Export Initiative for the German Healthcare Market, which is supported by Germany Trade & Invest.

At the state level, there are economic development agencies that are state-owned institutions that have the task of supporting investment projects of foreign or domestic investors in the region. Every federal state in Germany has its own economic promotion agency.

In addition, there are other opportunities for companies to obtain financing from organisations, associations and networks. A detailed explanation of the individual forms of financing can be found in the following chapters. An overview of the various financing options is provided in the figure below (see Figure 14).

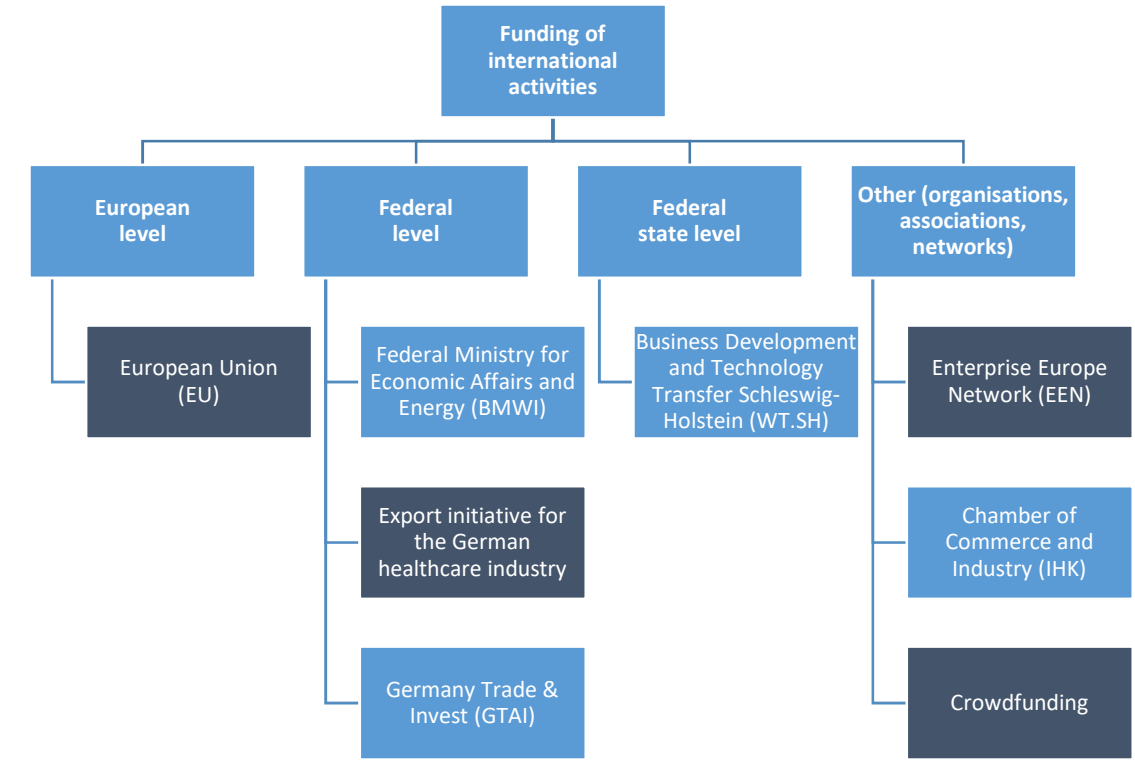

Figure 14: Funding of international activities – Overview Germany

Caption for Figure 14.

Funding for **German and International** companies

e ko Funding for **German** companies **nden werden.**

Tools, Information, Downloads

Description		Language	Link
Tools	Gain an overview of funding possibilities in Germany	DE	Link
	Increase the visibility of your company	DE	Link
	Apply for funding for German projects	DE	Link
Webinars	Digital Health in Scandinavia. Business opportunities and recommendations for sales	EN	Link
	ECN: Webinars	EN	Link
	Horizon Europe for beginners	DE	Link
Funding	Get motivation to think international	DE	Link
	Description of alternatives to funding	DE	Link
	Research funding	DE	Link
	Get a private investor on board	DE	Link
Information	Get your company promoted	DE	Link
	Online Portal for German companies	DE	Link
	Health made in Germany	EN	Link
Downloads	Market development program for SMEs	EN	Link
	The European Business and Innovation Support Network	DE	Link

Table 27: Funding Germany – Tools, Information, Downloads

7.4.1 Federal level [38]

7.4.1.1 Federal Ministry for Economic Affairs and Energy (BMWI)

The BMWI provides a funding database that gives an overview of funding programs of the federal government, the states and the European Union. Companies can use the search function and browse through the current range of funding - tailored to the company's project. All information and links to the most important federal, state and EU funding organisations are available on these funding database websites. (see Table 28)

Websites and Publications

Funding	Language	Publication (P) Website (W)	Link
BMWI – Funding Database	DE	W	Link
BMWI – Promotion of foreign trade and investment	DE	W	Link
BMWI – Promotion of foreign trade and investment	EN	W	Link
BMWI – Market development program for small and medium-sized enterprises (Flyer)	DE	P	Link
BMWI – Program to promote the participation of young innovative companies in leading international trade fairs in Germany	DE	P	Link

Table 28: Funding – Federal level – Websites, Publications – BMWI

7.4.1.2 Export Initiative for the German Healthcare Industry

The German system of promotion of foreign trade and investment is characterised by a division of responsibilities between the state and the private sector. Various institutions, such as German chambers of commerce abroad, foreign missions, and Germany Trade and Invest (GTAI), work closely together to deliver the best possible backing for German firms.

With the Export Initiative for the German Healthcare Industry, the BMWi supports the German healthcare industry in opening up foreign markets. The aim is to secure and expand Germany's position as one of the leading exporters of health industry products and services.

The Export Initiative supports companies in entering foreign markets and in networking at home and abroad. The focus is on the pharmaceutical, medical technology, medical biotechnology and digital health industries. In particular, the ministry offers services to help companies develop foreign markets along the entire chain of export business.

The market development programme is targeted at SMEs in all sectors; the export initiatives (for energy, environmental technology, healthcare, civil security technologies) focus on specific industries. These services are now better coordinated, in terms of both content and structure, and can have a more targeted impact. This combined strength can also be seen in the new brand “Mittelstand global”. It brings two approaches together: on the one hand, the horizontal SMEs market development programme and export initiatives in key forward looking fields like green technology, healthcare and civil security.

HEALTH MADE IN GERMANY is the export initiative for the German healthcare industry. It supports international companies and organisations that are interested in establishing contact with potential German partners and suppliers. Set up by the German Federal Ministry for Economic Affairs and Energy (BMWi), the initiative bundles expert market intelligence for easy industry access.

The Export Initiative for the Healthcare Industry provides companies with comprehensive information on foreign markets, market entry abroad and other important topics in the export business. In the Info desk, companies can find free information available in various sections, studies on important export markets, recordings of webinars made by the export initiative, newsletters, presentations, company directories, profiles of different sectors for marketing abroad and other materials for successful export business.

Digital Health in Scandinavia – Business opportunities and recommendations for sales. Companies can find out at any time about the digital health markets in Denmark, Norway and Sweden, about possible business opportunities and important tips for market entry in the countries.

Websites and Publications

Funding	Language	Publication (P) Website (W)	Link
Export Initiative for the German Healthcare Industry – Online portal for German companies	DE	W	Link
Export Initiative for the German Healthcare Industry – Online portal for International companies and organisations	EN	W	Link
Export Initiative for the German Healthcare Industry – Information desk	DE	W	Link
Export Initiative for the German Healthcare Industry – Sector reports	DE	W	Link

Funding	Language	Publication (P) Website (W)	Link
Export Initiative for the German Healthcare Industry – Tenders and projects	DE	W	Link
Digital Health in Scandinavia. Business opportunities and recommendations for sales – Webinar	DE	Webinar	Link

Table 29: Funding – Federal level – Websites, Publications – Export initiative

7.4.1.3 Germany Trade & Invest (GTAI)

The GTAI offers German and foreign companies a comprehensive range of information and professional support. Trade and commerce with other countries is a major factor in Germany's economic growth and prosperity.

In times of increased international competition, successful economic promotion is more important than ever. GTAI is the country's national agency for doing precisely that. GTAI supports both foreign companies and helps them expand their business. Moreover, GTAI promotes Germany's advantages as a business location and the internationalisation of the economy in German regions undergoing structural change. It also assists German companies looking to do business abroad.

Websites and Publications

Funding	Language	Publication (P) Website (W)	Link
GTAI – Website	DE	W	Link
GTAI – Denmark – Contact points for companies	DE	W	Link
GTAI database – Tenders in health economy	DE	W	Link
GTAI database – Projects in health economy	DE	W	Link

Table 30: Funding – Federal level – Websites, Publications – GTAI

7.4.2 Federal states level

7.4.2.1 Schleswig-Holstein business development and technology transfer corporation (WTSH) [39] [40]

The Schleswig-Holstein business development and technology transfer corporation (WTSH) provides the service required for founding, expanding or relocating businesses. It is a corporation of the state of Schleswig-Holstein, the chambers of industry and commerce and the chambers of handicrafts and the state's universities. WTSH is a competent partner for all aspects and all phases of the process – offering customised and targeted expertise.

WTSH is particularly in demand when small or medium-sized companies are faced with challenges that they can only overcome with the greatest effort or not at all. In such cases, WTSH provides advice and support and attaches particular importance to open and trusting cooperation with customers, shareholders and partners.

The WTSH is integrated into the Enterprise Europe Network (EEN), the world's largest network for business development. The network promotes cross-border cooperation between business and science, offers access to EU funding programs and provides information on European economic issues.

Websites and Publications

Funding	Language	Publication (P) Website (W)	Link
WT.SH – Website	DE	W	Link
WT.SH – Enterprise Europe Network	DE	W	Link
WT.SH – Medical Engineering and the Pharmaceutical Industry (Overview of the "Medical Technology and Pharmaceuticals" industry in Schleswig-Holstein, figures, data, facts…)	EN/DE	P	Link

Table 31: Funding – Federal states level – Websites, Publications – WT.SH

7.4.3 Organisations / Associations / Networks

7.4.3.1 Chamber of industry and commerce Schleswig-Holstein (IHK) [41]

The IHKs promote the local economy and support it with a wide range of advice and tailored services. For example, they support company founders, provide information on legal and tax issues, and advise on expansion into international markets.

The IHK provides comprehensive help and advice for start-up entrepreneurs by supporting them during their first steps into self-employment. The IHK in Schleswig-Holstein offers assistance in drawing up a viable business plan and when it comes to funding issues. The services range from the planning stage to the successful completion of a funding application.

At the information day for start-up entrepreneurs ("Info-Tag Existenzgründung"), held every month, the IHK offers important entrepreneurial guidelines and a host of expertise and resources. With the "Chamber Mentor" ("IHK-Mentor"), an online information and planning tool, companies can use to get extensive additional information and to draw up the business plan interactively online.

The IHK is a reliable partner in times of crisis as well. Thanks to the cooperation with the German promotional bank "KfW Mittelstandsbank", and other competent financial institutions, the crisis management team can offer companies valuable support in times of economic difficulty.

At the financing consultation day, the Chamber of Industry and Commerce (IHK) and the Investitionsbank Schleswig-Holstein's funding guides discuss their specific financing plans. In an individual one-to-one meeting, the companies are informed about the current funding programmes from the federal government, the state and the EU.

The consultation day for business support and funding is aimed at start-ups and existing businesses who would like to find out about the possibility of public funding programmes to finance their project. In an individual one-on-one meeting, you will learn all about public funding products offered by the state of Schleswig-Holstein, KfW-Mittelstandsbank and the European Union. The aim of the discussion is to develop a concrete financing proposal for your project.

The website of the IHK Schleswig-Holstein presents various financing alternatives in more detail, such as forms of financing with the crowd, financing by investors or the capital exchange "EuroQuity".

7.4.3.2 Baltic Business Angels Schleswig-Holstein

The Baltic Business Angels Schleswig-Holstein unite private investors who support young innovative companies with capital and know-how.

With the foundation of the Baltic Business Angels Schleswig-Holstein e.V., experienced entrepreneurs have come together for the first time in Schleswig-Holstein to support start-ups with capital and know-how. The association's ambition is to close the gap between start-ups and business angels in order to firmly establish Schleswig-Holstein on the start-up map in Germany. With the Baltic Business Angels network, the already good conditions are to be used and entrepreneurship, entrepreneurial spirit and start-up culture in the true North are to be further strengthened.

The development and establishment of the Baltic Business Angels Network is supported by WTSH - Wirtschaftsförderung und Technologietransfer Schleswig-Holstein GmbH within the framework of the state-funded project "Innovationsorientiertes Netzwerk StartUp Schleswig-Holstein".

7.4.3.3 Enterprise Europe Network (EEN) [42]

The Enterprise Europe Network helps businesses innovate and grow on an international scale. It is the world's largest support network for small and medium-sized enterprises (SMEs) with international ambitions. The Network is active in more than 60 countries worldwide. It brings together 3,000 experts from more than 600 member organisations – all renowned for their excellence in business support.

Teams of Network experts in each member organisation offer personalised services to businesses. They know the local business environment and have contacts for business opportunities worldwide. The Network can also offer a targeted approach aimed specifically at your business sector. Its expert groups cover all key economic sectors, from healthcare to agrofood, from intelligent energy to fashion and textile.

The Network manages Europe's largest online database of business opportunities. It contains thousands of business, technology and research cooperation requests and offers from companies and research and development institutions. The database is accessible for free.

7.4.3.4 European Crowdfunding Network (ECN) [43]

The ECN promotes crowdfunding as a viable offering of job creation, social innovation and boost to entrepreneurship to the European public, policy makers and stakeholders. ECN is providing resources, professional support and a forum for collaborative action regarding crowdfunding.

The ECN is engaging in a discourse with policy makers and industry regarding professional standards, best practice and data provision and is providing opportunities for members from across Europe to meet together, exchange information and ideas, and discuss the latest industry trends and issues. The ECN is promoting, conducting or commissioning a wide variety of research on crowdfunding and its impact on economy and society.

The ECN offers webinars, to inform companies in a short and straightforward way about the most important facts about crowdfunding and to provide insights on how to take advantage from the crowd at different company life cycle stages.

7.4.3.5 EIT Health Germany [44]

EIT Health is one of the largest healthcare initiatives worldwide. Its goal is to sustainably advance the fundamentals of healthcare and thus promote suitable future conditions for healthy living, active ageing and improved wellbeing of people across Europe.

EIT Health leverages the expertise of over 135 member organisations from the pharmaceutical, diagnostics, and medical technology fields, as well as insurance groups, payers, research institutes, and universities. As one of the EIT's Knowledge and Innovation Communities (KICs), the initiative benefits from some of the world's best-in-class academic and research organisations and offers both higher education and business expertise.

EIT Health Germany is one of a total of six EIT Health Centers in Europe and currently serves 35 leading companies and public health care institutions in Germany, Austria and Switzerland as well as renowned universities and research institutions in the spirit of the EIT Health Mission in a "public-private partnership". The aim is to jointly address the urgent health challenges of our time with concrete measures and programs in order to open up new resources for established and young companies and to realize their ideas in common products and services for the European market.

The EIT Health 'Accelerator' is targeted at all startups, spin-offs, scaleups and SMEs involved in health in Europe. The stated goal is to bring together the best young entrepreneurs in the healthcare industry and to provide them with the support, skills and services they need to bring their ideas to market. To accompany these young companies at every stage of their growth, the EIT Health Accelerator offers programs in three phases.

7.4.3.6 VDI Technology centre [45]

On behalf of the Federal Ministry of Education and Research (BMBF), the VDI Technology Centre has taken over the project management of medical technology in the fields of medical devices, regenerative medicine and health-related services and is the contact for research and innovation funding.

Within the Federal Government's Medical Technology Framework Programme, the BMBF is concerned with all facets of health research and is particularly active in promoting innovation in the field of health economy. As the responsible project management agency, the VDI Techology centre is in charge of a broad spectrum of funding measures and is responsible for reviewing, evaluating and monitoring the research and development projects and support the BMBF in all matters.

Websites and Publications

Funding	Language	Publication (P) Website (W)	Link
IHK Schleswig-Holstein – Business Start-up and support	EN	W	Link
IHK Schleswig-Holstein – Financing and funding	DE	W	Link
IHK Schleswig-Holstein – Financing alternatives	DE	W	Link
IHK Schleswig-Holstein – Website	DE	W	Link
IHK Schleswig-Holstein – Consultation days 2021	DE	P	Link
Capital Exchange "EuroQuity"	DE	W	Link
Baltic Business Angels – Website	DE	W	Link
EEN – Englisch Website	EN	W	Link

Funding	Language	Publication (P) Website (W)	Link
EEN – German Website	DE	W	Link
EEN – Hamburg/Schleswig-Holstein	DE	W	Link
EEN – International cooperation fairs	DE	W	Link
EEN – Services (Matchmaking)	DE	W	Link
ECN – Website	EN	W	Link
ECN – Webinars	EN	W	Link
EIT Health – Accelerator	EN	W	Link
VDI – Research funding	DE	W	Link

Table 32: Funding – Organisations / Associations / Networks – Websites, Publications

8 Target markets

The Danish medical industry in numbers: About 250 companies in Denmark work dedicatedly with the various branches of the medical industry. But in total, just over 1,000 companies are to a greater or lesser degree employed in the medical field. The 20 largest companies account for approx. 75 pct. of revenue and 2/3 of the companies in the industry have less than 50 employees. The Danish market for medical devices accounts for 0.5% of the global market. Expenditure on medical equipment amounts to approx. 5 pct. of the total public expenditure on our healthcare system. [46]

The public health service via the five regions is the largest buyer of the industry's products. Other customers are municipalities (e.g. in connection with care and rehabilitation), private hospitals or private citizens. USA was Denmark's largest export market for medical equipment with 25% of exports in 2014. This was followed by Germany (15%), Sweden (6%), Japan (4%) and China (4%). [46] Over 95 pct. of Danish production is exported.

Germany as target market: Compared with the economy as a whole, the healthcare industry is showing above-average growth rates. At 4.1 percent per year, it has grown faster than the German economy as a whole over the past ten years. The German healthcare industry employs 7.6 million people and generates almost 370 billion euros. This corresponds to a share of 12.1 percent of gross domestic product (GDP). The industry makes a significant contribution to achieving key economic policy objectives and influences them in terms of adequate and steady economic growth and high employment levels.

The medtech sector in Germany is dominated by small or medium-sized companies. 93 percent of medtech companies employ fewer than 250 people. There are 13,000 micro-enterprises alone with around 60,000 employees. Only 90 medtech companies in Germany have more than 250 employees. The medtech industry is innovative and has very short product cycles. German medical technology manufacturers generate about one third of their turnover with products that are not older than 3 years. [47]

8.1 Target market Denmark

Healthcare in Denmark is provided by the local governments of the five regions, with coordination and regulation by central government, while nursing homes, home care, and school health services are the responsibility of the 98 municipalities.

Danish government healthcare expenditures amount to approximately 10.4% of the GDP, of which around 84% is funded from regional and municipal taxation redistributed by the central government. Because necessary healthcare is taxpayer-funded (public funded), personal expenses are minimal and usually associated with co-payments for certain services, as medication, physiotherapy etc.. These expenses are usually covered by private health insurance.

Use of electronic health records (EHR) is widespread, and efforts are underway to integrate these at the regional level. For every 1,000 people in Denmark, there are about 3.4 doctors and 2.5 hospital beds. Spending on hospital facilities are 43% of total health care spending, which is above the average for OECD countries, even though the number of beds has decreased considerably.

Tools, Information, Downloads

Description		Language	Link
Cluster	Welfare Tech - A Danish national cluster	EN	Link
	Life Science Innovation North Denmark	DK	Link
	Medtech Innovation Consortium	DK	Link
	Copenhagen Healthtech Cluster	DK	Link
Networks	Danish Healthtech - A national innovation network	EN	Link
	Medico Industrien - Industry association	EN	Link
	Enterprise Europe Network (EEN) – Denmark	DK	Link

Table 33: Target market Denmark – Tools, Information, Downloads

8.2 Target market Germany

The MedTech industry is an important economic and labour market factor. The industry employs over 215,000 people in Germany. Over 12,000 new jobs have been created in the last 5 years alone. Each job in the industry also secures 0.75 jobs in other sectors. The total turnover of the MedTech sector in 2019 was 33.4 billion euros. The export ratio is around 65 percent. The medtech sector is dominated by medium-sized companies. [47]

In 2019, health expenditure in Germany amounted to 410.8 billion euros, or 4,944 euros per inhabitant. To mark World Health Day on 7 April 2021, the Federal Statistical Office (Destatis) also reports that total health expenditure rose by 19.3 billion euros or 4.9% compared with 2018. In 2019, health expenditure accounted for 11.9% of the gross domestic product. By far the largest share (56,7%) of this amount is accounted for by spending on statutory health insurance. The next largest item, 13.3% (Euro 54,8 billion), is for private households and private non-profit organisations. The third position in the list of expenditures is for statutory long-term care insurance with 10.3% (Euro 42,1 billion). [34]

In 2020, around 73.36 million people in the Federal Republic of Germany were covered by statutory health insurance (GKV). Of these, around 57.14 million people were contributory members and 16.22 million non-contributory members, e.g. family members. The private health insurance companies (PKV) had a total of 8.73 million fully insured persons. In 2018, the premium income of private health insurance amounted to around 37.2 billion euros, while benefits expenditure amounted to 27.1 billion euros. [48]

The German healthcare market is characterized by a complex reimbursement system. The reimbursement of medical devices by the various cost units is very complex and subject to

numerous regulations and requirements. A prerequisite for inclusion in the catalogue of services (HMV) offered by the statutory health insurance funds is the successful evaluation of medical methods.

For medical device manufacturers, especially when introducing new innovative medical devices to the healthcare market, access to the reimbursement system is of fundamental importance for economic planning. [27] [26]

Tools, Information, Downloads

Description		Language	Link
Webinars	GTAI - Webinar: Market Access and Regulatory Update for Medical Device Manufacturers	EN	Link
	GTAI - Webinar: Germany's Medical Device Market. How to Commercialize Innovative Medical Devices in Germany	EN	Link
	Insight into the German Market for healthcare technologies	EN	Link
Portals & Databases	Export Initiative for the German Healthcare Industry - Information center	EN	Link
	European Commission: Funding and Tender Portal	EN	Link
	Bundesministerium für Wirtschaft und Energie (BMWI) – Funding Database	DE	Link
Networks	Federal Ministry for Economic Affairs and Energy - Cluster Excellence in Germany	EN	Link
	Life Science Nord (LSN) – Clusterorganisation	EN	Link
	Enterprise Europe Network (EEN) – Germany	DE	Link
	Forum MedTech Pharma - Network for innovations	EN	Link
Downloads	BVMed Branchenbericht	DE	Link
	Federal Ministry of health - The German healthcare system	DE	Link
	WT.SH - Publication Medical Engineering and the Pharmaceutical Industry	EN	Link

Table 34: Target market Germany – Tools, Information, Downloads

9 Language

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. 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.

Regarding a report from Effects on the European Union Economy of Shortages of Foreign Language Skills in Enterprise (ELAN), recruiting native speakers with language skills appears to be widely used as a language management technique, with 22% of businesses drawing on this resource and need for language skills will increase in future. In 13 of the 29 countries surveyed, at least 50% of respondents believed they would need additional language skills in the next three years. (page 5) [49]

9.1 Actions to overcome this barrier

Actions to overcome the language barrier
Commissioning of a translator or a translation agency
Identifying and hiring additional staff, such as bilingual sales people
Commissioning a native speaker
Native speaking employees
Appointing advisers

Table 35: Language – Actions to overcome this barrier

9.2 Denmark

It was not detected that companies in Denmark had an issue with language as a market access barrier. This will therefore only be discussed from the German business' side.

9.3 Germany

The Federal Association of Interpreters and Translators (BDÜ) is the industry's largest professional association. BDÜ represents about 80% of all translators and interpreters who belong to a professional association in Germany. On the website of the BDÜ a Membership database is provided, which contains the contact data of more than 7,500 qualified interpreters and translators covering more than 80 languages. [50]

For those needing translation services ADÜ Nord – associated interpreters and translators in northern Germany – provides a trade association for professional providers of language services, with its geographical base and point of emphasis in northern Germany. In the online database, potential clients will find language professionals able to address their needs. [51]

The Schleswig-Holstein Chamber of Commerce and Industry (IHK) will be glad to assist companies in the search for and placement of qualified interpreters and translators. [41]

Tools, Information, Downloads

Description		Language	Link
Tools	BDÜ - Membership Database	EN	Link
	ADÜ Nord - Online Database	EN	Link
	DeepL Translator (German – English – Danish)	EN	Link
Associations	BDÜ - Federal Association of Interpreters and Translators	EN	Link
	ADÜ Nord - Associated interpreters and translators in northern Germany	EN	Link
Information	IHK Schleswig-Holstein - Interpreters and translators	DE	Link
Downloads	ADÜ Nord - Grüne Liste (List of interpreters and translators)	DE	Link
	BDÜ - Press Information - About BDÜ	EN	Link
	BDÜ - Media Information - Profile of the BDÜ	EN	Link

Table 36: Language Germany – Tools, Information, Downloads

10 Conclusion

In summary, there is no one perfect strategy for overcoming the various market entry barriers. Every company has different prerequisites and consequently needs a different strategy. Not every company that wants to enter the other market necessarily has to struggle with all the barriers mentioned in this document. The content of this document focuses on the four most common barriers to entering these markets identified in a 2019 stakeholder analysis and various interviews. To complement this document, a digital roadmap to market has been developed to enable companies to access the information they need to develop a successful market entry strategy as easily as possible.

With our document we try to cover as many options as possible with the proposed actions. Companies can put together the appropriate mix of actions themselves, depending on the circumstances and the goal they are pursuing. For each identified market entry barrier, companies will find suggestions in this document on what actions they can take to overcome existing barriers. In addition to the measures, companies will find valuable links to

- webinars that provide guidance on the different problems
- documents and illustrations that explain structures and processes in more detail
- databases and portals that facilitate access to calls for tender or cluster intelligence
- cooperation exchanges and networks to better discuss and solve problems with each other
- web pages with more in-depth and further information, so that a topic can be examined from many different angles and the user can build up a broad knowledge for themselves

In the interviews and online surveys, it was repeatedly emphasised how extremely important and valuable a well-functioning network is. It facilitates the exchange of knowledge and ideally enables joint action and mutual support in the attempt to access the German or Danish market with their own innovative products.

11 Useful links and more information

Links to the Access & Acceleration Roadmap to market

Language	Link
English	Link
Danish	Link
German	Link

Table 37: Roadmap to market – Links

MDR

MDR	Language	Publication (P) Website (W)	Link
Regulation (EU) 2017/745 on medical devices	EN	W	Website EUR-Lex MDR Current consolidated version: 24/04/2020
Regulation on medical devices	DE	W	Website BMJV
Wikipedia - Regulation (EU) 2017/745 on medical devices	DE	W	Website Wikipedia
Medical Devices – Overview, Current Directives, New Regulations	EN	W	Website European Commission
MDR – Getting ready (Factsheets for manufacturer, healthcare professionals, health institutions…)	EN	W	Website European Commission
MDR – Step by Step Guide	EN	P	Website European Commission
Guidance - MDCG endorsed documents	EN	W	Website European Commission
Medical Devices EU Adaptation Law – MPEUAnpG	DE	W	Website BMG
National Working Group (NAKI)	DE	W	Website BMG
Unique Device Identification (UDI) System - FAQs	EN	P	Website European Commission
MDR – Timelines	EN	P	Website European Commission
MDCG 2019-15rev.1 GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES	EN	P	Website European Commission

Table 38: MDR – Websites and Publications

German healthcare system

The following table (see Table 39) contains a compilation of various publications (P) and websites (W) that provide further information on the German healthcare market.

Topic	Publication (P) Website (W)	Language	Link / Title
German healthcare system	P	DE	Figure - Our healthcare system
	W	EN	The German healthcare system
	W	DE	BPB - The Healthcare System in Germany - An Overview
	W	DE	Wikipedia - Healthcare system in Germany
Basic principles	P	EN	BMG - The German healtcare system
	W	DE	Gesundheitsinformation - Overview
	P	DE	German Parliament - Information to the German healthcare system
Structure	P	DE	BMG - The German healthcare system
	W	DE	Gesundheitsinformation - Overview - Structure
Actors	P	EN	BMG - The German healthcare system
	W	DE	Gesundheitsinformation - Overview - Actors
Healthcare Fund	W	DE	BMG - Financing of the SHI
	W	DE	Krankenkassenzentrale - Healthcare Fund
	W	DE	VDEK - Healthcare Fund
	W	DE	GKV-Spitzenverband - Healthcare Fund
Reimbursement	P	EN	AIM Germany - Reimbursement of medical devices
	P	EN	IFGV - Reimbursement of pharmaceutical products
	P	EN	OECD - Pharmaceutical-Reimbursement and Pricing
	P	EN	IGES - Reimbursement of Pharmaceuticals
	P	EN	Exportinitiative Gesundheitswirtschaft - Reimbursement of medical devices
	P	DE	Spectaris - Access to the German reimbursement system
Hilfsmittel-verzeichnis	W	DE	Wikipedia - "Hilfsmittelverzeichnis"
	W	DE	GKV-Spitzenverband - Hilfsmittelverzeichnis Overview
	W	DE	GKV-Spitzenverband - "Hilfsmittelverzeichnis" - Online portal
	P	DE	GKV-Spitzenverband - "Hilfsmittelverzeichnis" - Rules of procedure

Topic	Publication (P) Website (W)	Language	Link / Title
	P	DE	GKV-Spitzenverband - "Hilfsmittelverzeichnis" - Notes to the application
	P	DE	Handbuch Hilfsmittel GKV-Spitzenverband
Facts and Figures	P	DE	VDEK
	W	DE	BMG
	W	EN	DESTATIS
	P	DE	BMWI
	P	EN	BMG
	W	DE	Gesundheitsberichtserstattung des Bundes
	W	DE	Statista
Trends	P	DE	Dostal Partner
	P	DE	Zukunftsinstitut Gesundheitswirtschaft
	P	DE	Healthbank
	P	DE	HBSN AG

Table 39: German healthcare system – Publications and Websites

Funding in Germany

Exportinitiative Gesundheitswirtschaft
c/o Germany Trade and Invest GmbH
Friedrichstraße 60, 10117 Berlin
Phone: +49 30 200099-0
Email: info@exportinitiative-gesundheitswirtschaft.de

Geschäftsstelle Markterschließung KMU
c/o Bundesministerium für Wirtschaft und Energie
Villemomblerstraße 76
53123 BonnPhone: +49 228 99 615 4291
Email: markterschliessung@bmwi.bund.de

WTSH Wirtschaftsförderung und Technologietransfer Schleswig-Holstein GmbH
Lorentzendamm 24
24103 Kiel
Phone: +49 431 66 66 6-0
Email: info@wtsh.dewww.wtsh.de

IHK Flensburg
Phone: +49 461 806-806
Fax: 0461 806-9806
Email: service@flensburg.ihk.de

IHK zu Kiel
Phone: +49 431 5194-0
Fax: 0431 5194-234
Email: ihk@kiel.ihk.de

IHK zu Lübeck
Phone: +49 0451 6006-0
Fax: 0451 6006-999
Email: service@ihk-luebeck.de

VDI Technologiezentrum GmbH
VDI-Platz 1, 40468 Düsseldorf
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Phone: +49 (0) 211 62 14 – 401
Fax: +49 (0) 211 62 14 – 484
Email: vditz@vdi.de

12 Abbrevations and terms

Abbrevation / Term	Description
AI	Artificial intelligence
BMBF	Federal Ministry of Education and Research
BMWI	Federal Ministry for Economic Affairs and Energy
EEA	European Economic Area
ELAN	Effects on the European Union Economy of Shortages of Foreign Language Skills in Enterprise
EU	European Union
DKG	German Hospital Federation
DRG	Diagnosis Related Groups
G-BA	Federal Joint Committee
GTAI	Germany Trade and Invest
HMV	"Hilfsmittelverzeichnis" – German technical aids listing
IGES	The IGES Institute is an independent research and consulting institute for infrastructure and health issues.
IHK	Chamber of industry and commerce
MDD	Medical Device Directive
MDR	Medical Device Regulation
MPEUAnpG	Medical Devices EU Adaptation Law
NUB	New examination and treatment methods
PHI	Private health insurance
R/D	Research/Development
SHI	Statutory health insurance
SME	Small and medium-sized enterprises
UDI	Unique Device Identification
WTSH	The Schleswig-Holstein business development and technology transfer corporation

Table 40: Abbrevations and terms

13 List of literature

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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)
- Danish Life Science Cluster
- 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

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