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Managing the Fourth Hurdle

Small medtech companies addressing the issue of reimbursement

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Abstract

Managing the Fourth Hurdle

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The rapid progress of medical technologies (medtech) today continuously generates innovative solutions to previously unmet needs. However, in many cases innovations in medical technologies, result in increased healthcare expenditures at least in the short term.
Worldwide the healthcare budgets are under heavy pressure and the cost consciousness among the healthcare providers has therefore increased. The impact on the medtech industry is that the regulatory requirements such as efficacy, quality and safety of the products no longer are the only hurdles to gain market access. The healthcare providers' expenses, arising from the treatments they perform, are covered, reimbursed, by a payer. This payer must be convinced of the clinical as well as the economic value of the product to be willing to pay for it. Therefore reimbursement is an additional issue that needs to be addressed by the industry and in particular by the manufacturers. This report investigates if and how small medtech companies integrate reimbursement activities in the commercialization process. Specifically the report focuses on how the companies deal with the reimbursement system in Germany. The reasons for choosing Germany are the large size of this market and its proximity to Sweden, making it particularly interesting to Swedish companies. The study was designed according to a Grounded Theory approach. The qualitative empirical data, that was initially collected, guided the researchers in the progress of their research. The information about the German system was acquired from interviews with experienced people within the industry. Interviews were also performed with six small companies and with one large company in order to build cases. Finally, the gained knowledge was used to build a model to be able to answer the research question.

The conclusions are that the companies do not actively integrate reimbursement activities in their commercialization process until they have received their regulatory approval. This means that the general product life cycle for medical technologies can be extended by an additional phase. This phase represents the reimbursement process, which must be gonethrough before full market access can be achieved. However, the characteristics of this phase are very much dependent on the technology, strategy and how well the companies are prepared for it.

Keywords: medtech, medical technology, medical device, reimbursement, early-stage companies, Sweden, Germany, DRG, marketing.

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Populärvetenskaplig beskrivning

Reimbursement är en faktor som blir allt viktigare i dagens sjukvård, inte minst när det handlar om att introducera nya behandlingsmetoder på sjukhusen. Reimbursement syftar på den ersättning vårdgivaren får från försäkringsbolag när de behandlar patienter. Ersättningen ska täcka alla omkostnader för behandlingen samt ge en viss marginal till vårdgivaren. I och med att kostnaderna för sjukvården har skenat iväg de senaste åren har emellertid försäkringsbolag och vårdgivare blivit mer medvetna om kostnaderna för nya behandlingsmetoder och tekniker. Det har skapat ytterligare ett hinder för innovativa medicintekniska företag då det inte längre räcker med att bevisa den kliniska effekten, kvaliteten och säkerheten av en ny produkt. Idag ställs det allt större krav från vårdgivare och försäkringsbolag att nya produkter ska ha ett ekonomiskt värde, dvs. de ska medföra minskade kostnader för sjukvården. Försäkringsbolag ser allt mer till de ekonomiska vinningarna av nya produkter när de beslutar om vilka behandlingar de ska betala för, medan vårdgivarna inte är villiga att introducera nya metoder som de inte får betalt för. Reimbursement ses därför inom branschen som det fjärde hindret för ett företag för att få full tillgång till marknaden.

I det här examensarbetet har vi studerat hur svenska medicintekniska företag hanterar reimbursement när de lanserar nya produkter. Studien bygger på sju fallstudier av olika företag i olika faser. Fyra företag är i lanseringsfasen, två företag är i en preklinisk fas medan ett företag har funnits ute på marknaden med sin produkt i flera år. Som en del av examensarbetet har även det tyska sjukvårds- och reimbursementsystemet kartlagts för att skapa en förståelse för hur det kan fungera i praktiken.

Resultatet av studien visar att de svenska medicintekniska företagen hanterar problematiken kring reimbursement i samband med den regulatoriska processen samt när de försöker etablera sig på marknaden. I väldigt liten utsträckning samlar de ekonomiska data under de kliniska studierna. Det innebär att företagen ofta inte är förberedda på den process där den färdiga produkten skall utvärderas på marknaden. De ekonomiska data måste då samlas in ute på marknaden innan försäkringsbolagen är beredda att betala fullt ut för produkten samtidigt som många vårdgivare inte är beredda att göra investeringen då de inte är säkra på att få tillbaka pengarna.

Vi föreslår att företagen skall integrera reimbursement tidigare i kommersialiseringsprocessen. De har då möjlighet att på ett tidigt stadium kartlägga skillnader mellan olika sjukvårdssystem och kan samla in ekonomiska data som visar hur de olika systemen kan spara in på kostnader med just denna produkt. En tidig utvärdering av den egna tekniken i jämförelse med konkurrerande och befintliga metoder är att rekommendera. På så sätt kan företaget bilda sig en uppfattning om hur det ska positionera sig på marknaden.

Preface

This report is a BET-project performed at the Unit for Bio Entrepreneurship, UBE, at Karolinska Institute, Sweden, in collaboration with Ecole Polytechnique Fédérale de Lausanne, EPFL, Switzerland. A BET-project brings together students with different academic background and let them work on a project performed in the interface between the Life Science industry and the academia. This BET-project is the Master Thesis of the authors. Since this study is a part of the researchers' education, each writer is going to be separately evaluated, approved and marked on this report. In order to make explicit individual distinctions, a system, that differentiates which author is behind each text part, is used. An individual symbol is used to associate the text to the author. The authors and their individual symbols are:

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Each heading is marked with the author's symbol. When the heading does not have any symbol at all, this means that the chapter has been co-written by the authors.

Several persons have been of great help in this project. First we would like to thank our supervisors Bo Norrman and Jessica Norrbom at UBE for their feedback, guidance and support during the process of writing this report. There are other persons at UBE that also deserves to be mentioned. A special thanks to Charlotta Dahlborg for her structured and valuable guidance in methodology. Thanks to Carl-Johan Sundberg for opening doors and providing contacts and Lena Hanson for facilitating our everyday work in several ways. We would also like to thank Mathias Kyhlstedt at Synergus for giving us useful inputs and providing contacts from the medical technology industry. Finally we would like to thank all the other people that have participated in the study by giving us a part of their time.

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	English	German or other languages
ANAES	National Agency for Habilitation and Evaluation in Public Health	Agence Nationale d'Accréditation et d'Evaluation en Santé
ASSR	Agency for Regional Health Services	Agenzia per i Servizi Sanitari Regionali
BMG	German Federal Ministry of Health	Bundesministerium für Gesundheit
BVMed	German Medical Technology Association	Bundesverband Medizintechnologie
CE-Mark	Conformity mark in Europe	
CEO	Chief Executive Officer	
COO	Chief Operating Officer	
CFO	Chief Financial Officer	
CTMH	Centre for Technology in Medicine and Health	
CW	Cost Weight	
IC	Integrated Care	
IQWiG	Institute for Quality and Efficiency in Health Care	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
EBM	Uniform Value Scale	Einheitlicher Bewertungsmaßstab
EU	European Union	
DKV	German Hospital Federation	Deutsche Krankenhaus Gesellschaft
DRG	Dignostic-Related Groups	
DIMDI	German Institute for Medical Documentation and Information	Deutsches Institut für Medizinische Dokumentation und Information
EUnetHTA	European Network for Health Technology Assessment	
FDA	Food and Drug Administration	

G-Ba	Federal Joint Committee	Gemeinsamer Bundesausschuss
GDP	Gross Domestic Product	
GKV	Statutory Health Insurance	Gesetzlischen Krankenversicherung
HTA	Health Technology Assessment	
ICD	International Classification of Disease	
IKK-BV		Innungskrankenkassen Bundesverband
INAHTA	International Network of Agencies for Health Technology Assessment	
InEK	Institute for the Hospital Renumeration System	Institut für das Entgeltsystem in Krankenhaus
ISPOR	International Society for Pharmacoeconomics and Outcomes Research	
KBV	Federal Association of SHI Physicians	Kassenärztliche Bundesvereinigung
KOL	Key Opinion Leader	
NICE	National Institute for Health and Clinical Excellence	
NUB	New examination and treatment methods	Neue Untersuchtungs und Behandlungsmethoden
OPS	Procedure Classification System	Operations und Prozedurenschüssel
SME	Small and Medium Enterprise	
PKV	Private Health Insurance	Privat Krankenversicherung
SGB	Social Code Book	Sozialgesetzbuch
SHI	Statutory Health Insurance	
R&D	Research & Development	
VC	Venture Capitalist	

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1 Introduction

The healthcare expenditures across the world almost doubled, from $2.6 to $5.1 trillion, between 1995 and 2005. The largest growth rate was seen in the latter half of this period; the expenditures then increased on average by $330 billion annually compared to the increase of $197 billion per year during the first five years. A general trend throughout the world is that healthcare expenditures are growing faster than the GDPs and also faster than the population growth.[1] The healthcare expenditures, as part of the GDP, have increased the last couple of years within OECD countries. In the 1970s the average annual expenditure across these countries was about 5% of their GDP. In year 2004 the expenditure had increased to about 9%.[2]

Demography in the form of an aging population is one of the reasons for these increasing expenditures.[3] Moreover, lifestyle diseases such as obesity and diabetes constitute additional costly expenses for the healthcare systems.[4] Today heavy demands are also made on the healthcare providers by the better informed patient groups. In addition, the expectation among the population that everyone should grow old, without suffering from any severe ill-health puts even more pressure on the providers. Fortunately, the frequent development of new improved medical technologies, medtech, increases the possibilities for healthcare providers to meet these high standards. Heart pacemakers, blood vessel replacements and other forms of implants are all examples of hightech medical technologies that have contributed to improve the well being of the population. The rapid progress also generates solutions to previously unmet needs. As a consequence, the groups of patients that can benefit from the innovations become larger. However, in most cases medical technology innovations also result in increased expenditures, at least in the short term.

The consequence of the increased expenditures worldwide brings the issue of how the continuing progress of medical technologies should be afforded in the future.[5] To manage the situation, people working in the healthcare sector have become more conscious about costs and expenditures.[6] This awareness has an impact on the demands made on the manufacturers and their development of medical innovations. The manufacturers need to carefully plan and take into account the costs in their commercialization processes in order to provide cost effective devices to meet these requirements. Today the cost aspect is an important factor when evaluating a treatment.[7]

Treatments, including medical technologies and drugs, are often expensive. The receivers (patients) therefore rely to great extent on different insurance systems, public or private, which reimburse healthcare providers for their expenses caused by the treatments they perform.[8] A universal payment system does not exist. Every country has its own

[1] World health organization, *The world health report 2008: primary healthcare now more than ever*, 2008, pp. 100-101.
[2] D. J. Johnston, *Increasing value for money in health system*, 2004, Eur J Health Econom, vol. 5, pp. 91–94.
[3] J.M. Schmitt, *Reimbursement and pricing of medical devices in Germany*, 2000, HEPAC, vol.1, pp. 146-148.
[4] Johnston, pp. 91-94.
[5] J.M. Schmitt, pp 146-148.
[6] A. Guhl, *Pricing and reimbursement system in Europe*, 2000, HEPAC, vol. 0, pp 8-10.
[7] J. Nixon, *The European Network of Health Economic Evaluation Databases (EURO NHEED) Project*, Eur J Health Econom, vol. 5, 2004, pp. 183–187.
[8] World health organization, pp. 100-101.

reimbursement system. The regulations and levels of reimbursement differ among the various systems.[9]

Reimbursement is one of the important issues for companies when marketing and selling their products. As the systems are not harmonized, the reimbursement is a complex issue to deal with for a medtech company when entering a new market. There is no way to build up an overall reimbursement strategy that fits all markets.[10]

Since Sweden is a small market, an early launching abroad is often necessary to reach more customers and thereby improve the possibilities of growth. Depending on the type of technology the marketing abroad may force the companies to understand and deal with each national reimbursement system. As mentioned the world market is fragmented concerning reimbursement systems and there is no possibility for us to understand them all. Germany is the biggest market in Europe, constituting around 31% of the total European medtech market[11]. The size of the German market, cultural similarities and the proximity to Sweden often makes Germany one of the first markets abroad for Swedish medtech companies. Germany is therefore in particular focus in this report.

1.1 Problem description

On the 27th of August 2008 we participated in a conference arranged by SEB, Skandinaviska Enskilda Banken. The event named *Taking the Next Step - Revenue Acceleration in Early-Stage Medical Device Companies* was about companies' general strategies and marketing and sales execution. An observation made was that medtech companies integrate the reimbursement issue very late in their commercialization process since they do not seem to be very conscious about its importance. This unawareness will be a problem for the companies when entering new markets, resulting in difficulties to find and convince payers, such as health insurance companies, county councils etc. The establishment of reimbursement can therefore be visualized as a fourth hurdle, beyond product quality, safety and efficacy to get full market access. The four hurdles are shown in Figure 1.

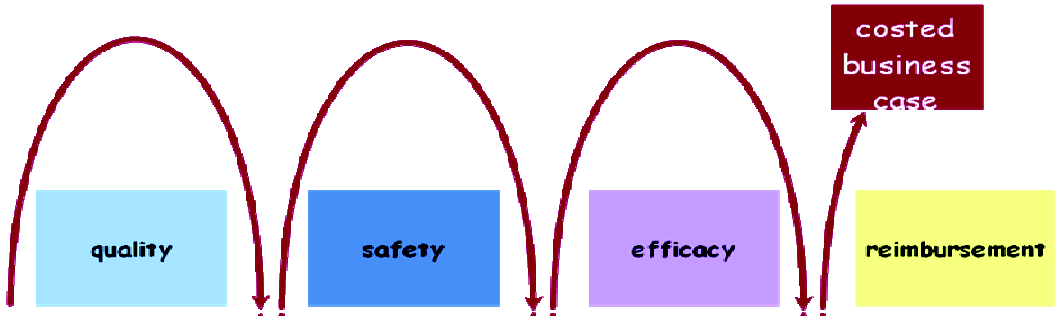

Figure 1 : The four hurdles for market access[12]

[9] C. Semple Piggot, *Optimising reimbursement submissions where procedure or device codes diverge*, Clinica 1322, 2008.
[10] C. Semple Piggot, Clinica 5th Sep 2008.
[11] Eucomed, *Competitiveness and Innovativeness of the European Medical Technology Industry -Evaluation of the Survey Results*, 2007. viewed on 2008-10-17, <www.eucomed.org>.
[12] M. Charny, *The foundation of a sound reimbursement strategy*, Transluency, 2008-08-27.

1.2 Aim

The aim of this project was to contribute to the awareness and knowledge about reimbursement of early stage medtech companies. By investigating how they deal with the reimbursement activities in their commercialization process, the aim was also to emphasize potential pitfalls and best practices. These experiences can be a valuable help for other companies, when trying to enter new markets and establish successful sales. In addition, the mapping of the German reimbursement system in this report can assist the companies when entering this market.

1.3 Research question

The specific question we were interested to address was the following:

Do small medtech companies integrate the reimbursement issue in the commercialization process, and if so, how do they operationalise it?

To be able to answer the question it was necessary to understand how a reimbursement system is working. As mentioned, the reimbursement system in Germany was chosen and used in this research both to specifically investigate how the companies are dealing with the German system but also to serve as a reference system. A working question was therefore defined as:

How does the reimbursement system work in Germany?

1.4 Limitations

The companies in focus are small Swedish medtech companies in their commercialization process in Germany. A small sized company in this report conforms to the definition of EU as a company with less than 50 employees[13].

In this report, the commercialization process includes all the phases a product needs to go through to enter and be sold on the market. It goes along the whole product life cycle except the early basic research. The process therefore includes parts of product development, clinical trials as well as the launching phase and marketing activities.

1.5 Structure of the report

The report is divided into three main parts. The first part is the background in chapter 2, which describes the medtech industry and its features. It also describes how medical treatments are generally classified and assessed. The aim of the background is to give the reader an understanding of the environment in which the medtech companies act. The second part consists of Chapter 4 and 5 and presents the results of the study. The study of the German system involves a description of the national healthcare as well as a mapping of the reimbursement system. The results from the case studies are also presented and analyzed in this part. The last part consists of Chapters 6-8. This part is where the results from the study are conceptualized and used to form a model.

[13] European Commission, SME Definitions, 2008, viewed on 2008-09-16, <http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/index_en.htm>.

2 Background

2.1 The Medtech Industry

2.1.1 Definition χ

The medical technology industry aims at extending and improving people's lives. It has an important role in today's healthcare. Medical technology is used daily in all the different sectors of the healthcare system. Medical technology appears in many forms in a hospital; it can be anything from hospital beds and bandages to pacemakers and X-ray machines. This makes the industry diversified with a wide product range. The products produced within the medtech industry have been classified into 12 categories and 10 000 generic groups by the Global Medical Device Nomenclature. In total the medtech industry consists of over 500 000 different products. Table 1 shows the 12 categories and what type of products they may contain. [14]

Table 1 : Categories of medical technologies with examples of the types of products [14]

1	Active implantable technology	Cardiac pacemakers, neurostimulators, etc.
2	Anaestethic and respiratory technology	Oxygen masks, gas delivery units, etc.
3	Dental technology	Dental floss, alloys, dentistry tools, etc.
4	Electromechanical medtech	X-rays, lasers, etc.
5	Hospital hardware	Hospital beds, etc.
6	In-vitro diagnostic technology	Pregnancy-, blood glucose-, genetic tests, etc.
7	Non active implantable technology	Hip and knee joint replacements, cardiac stent etc.
8	Ophthalmic and optical technology	Eye glasses, lenses, etc.
9	Reusable instruments	Various surgical instruments
10	Single use technology	Needles, gloves, syringes etc.
11	Technical aids for disabled persons	Hearing aids, wheelchairs, walking aids etc.
12	Diagnostic and therapeutic radiation technology	Radiotherapy units

However, this is a very broad definition of medical technology and from a reimbursement point of view it is of less importance to look at for example optical technology since this is often paid directly by the patient. We have therefore chosen to narrow our definition. In the *Action MedTech* report, written in collaboration between Karolinska University Hospital, Karolinska Institute and the Royal Institute of technology in Stockholm, 2007, the authors classify the medical sector in two areas, which are:

[14] Eucomed, *Medical Technology Brief 2007,*Eucomed, Brussels, 2007*,* viewed on 2008-10-06, <http://www.eucomed.com/press/~/media/pdf/tl/2008/portal/aboutindustry/medtechbrief2007.ashx>.

- High technology devices (equipment and supplies) and/or solutions/systems used to
    - Diagnose, prevent, supervise, treat or alleviate a disease/injury/handicap.
    - Examine, modify, or replace the anatomy or a physiological process.
- 'Lower'-technology devices mainly used to assist healthcare professionals in their care of patients, e.g.
    - Infection control, patient hygiene, etc.
    - Hospital beds, patient lifts, etc.[15]

Dental and ophthalmic/optical technologies are excluded since they are not of interest from a reimbursement point of view. In most healthcare systems these kinds of technologies are paid by the patients themselves. Furthermore, in our definition, we will not include the following:

- Lab equipment and analytical tools used outside the patient room.
- IT solutions.
- Technical services.
- Contract manufacturing.

2.1.2 History of Medical Technologies φ

History shows that different tools have been invented for medical use throughout human history. For example, archaeologists have found evidence of dental surgical operation and prosthesis that date from around 2500 BC.

From the beginning the development of medical technologies has been closely related to the appearance of new diseases, the development of medicines but also the evolution of cultural traditions of treating people. In the early stages of medicine, diagnostics were mostly based on the patient's descriptions of symptoms and doctor's personal observations.

However, the 19th century marked the starting point of an increasing development in medical technologies. This was mainly due to a change in the medical habits. A majority of practicians started using mechanical instruments and understanding the human body increased through the dissection of cadavers. From then on, medical technologies have been developed and introduced as a usual part of the medicine. The improvement and the interaction of different technological fields such as electrical, material and computer sciences as well as the increasing knowledge in medicine has allowed the great evolution of medical technology inventions.

The following chapter recounts some inventions and early breakthroughs among devices and diagnostic equipments that are still currently used in the traditional practice. Sweden has a particularly proud history of innovation in the discovery and development of medical

[15] P. Gudmundsson, B. Jakobsson & H. W-Henriksson, *Action MedTech – Key Measures for Growing the Medical Device Industry in Sweden*, CTMH, Stockholm, 2007, pp. 65 (appendix).

technologies such as the implantable pacemaker, the dialysis machine and the gamma knife mentioned in the following paragraphs.

In 1816, a French physician called René Laënnec invented the stethoscope, the first commonly accepted diagnostic medical breakthroughs. The microscope was invented many years ago in 1673 by Antoine Philips van Leeuwenhoek. However, the principles of optics were not for medical purposes, until 1851 when Hermann von Helmholtz developed the first ophthalmoscope to view the interior of the eye. Some years later in 1855, another optics-based technology was developed by Manual Garcia, namely the laryngoscope[16]. Diagnostics and treatments have undergone major improvements since the discovery of the X-rays in 1895 by Wilhelm Roentgen. The clinicians were then able to see inside the patient's body without any surgery. The sector of cardiology was strongly improved by the first electrocardiograph designed by William Einthoven in 1903. In 1920, Hans Berger began the study on human electroencephalogram (EEG). In 1938, the first hip replacement was performed by John Wiles, a British surgeon, thanks to the development of stainless steel used as the head of the joint.

World War II was a key period for the development of new medical technologies. Indeed, during this period many people suffered from different diseases and physical handicap and as a consequence numerous technologies and surgical procedures were developed to treat them.

Nils Alwall, a Swedish professor, developed a modified version of the kidney dialysis machine invented by Dr. Willem Kolff in 1943. The new version was more adapted to clinical use and between 1946 and 1960, 1500 patients were treated. The technology was the reason for the foundation of Gambro, a company that is still a worldwide leader in this field.

In 1950, John Hopps designed the first external pacemaker. After some years of development, the first clinical implantation into a human of an internal pacemaker was realized in Sweden in 1958. It was also in the 1950[s] that an artificial heart valve was invented by Charles A. Hufnagel, an American surgeon. The Gamma Knife which is a device used to treat brain tumors using radiation therapy was invented by Lars Leksell, a Swedish neurosurgeon, in 1967. 1980 was the year for the first use of magnetic resonance imaging (MRI) which made diagnostic substantially easier for clinicians. [17]

The development of medical technologies is growing fast and there are of course plenty of inventions not mentioned here. The next chapters describe the characteristics and the evolution of the medical technology industry. The aim is to provide the reader with a better understanding of the challenges that companies are facing today.

[16] Geocities, *Perspectives in Healthcare Technology - Timeline*, 2002, viewed on 2008-10-09, <http://www.geocities.com/kbeb3234/19.htm>.
[17] M. A. De Miranda, A. M. Doggett, J. T. Evans, *Medical Technologies, Contexts and Content in Science and Technology*, 2005, viewed on 2008-10-28, <http://teched.vt.edu/CTTE/ImagesPDFs/MedicalTech2005.pdf>.

2.1.3 Characteristics of the industry χ

The medical technology industry consist of about 80 % SMEs and a few big players within the different fields. Compared to the pharmaceutical industry, which only has a few big multinational companies and a long historical background, it can be characterized as quite young.[18]

The industry can also be characterized as very innovative and dynamic. Its relatively short product life cycles have an impact on the number of inventions created. In 2005, 14 700 patent applications were sent to the European Patent Office. This makes the medical technology industry the top leading one in this aspect, followed by telecom and EDP (Electronic Data Processing)[19]. On average the industry spends 9 % of its turnover on R&D and more than half of the industry turnover is constituted by products less than three years old.[20] That differs also from the pharmaceutical industry, where the product life cycle is typically long and the incremental improvements are few. Since medical technology is quite a broad definition the industry spans over large areas, and that makes it fragmented as well. As can be seen from the definition of medical technology in Chapter 2.1.1, it includes everything from active implants to hospital beds, and of course the technology bases that the different products rest on are quite different in these fields. Even though the medical technology products are not affected by the same heavy regulation as pharmaceuticals, the industry has its challenges and issues for sustaining growth in the long run. For the companies there are four characteristics of the industry that can be considered to make the journey to success more difficult. The first is the difficulty in achieving a feasible product differentiation. Today a lot of focus is put on improving existing technologies or methods and that has led to a decreased pace of differentiation. The decreased product differentiation makes the companies more dependent on marketing and sales, which raises their costs of doing business.

The complexity of the customer landscape has increased during the last years. Physician preferences, which before was the most important decision factor for purchasing new technology, has now lost its monopoly position. Today payers', providers' and patients' needs and preferences also play important roles. This makes the process of obtaining clinical data that satisfies this diverse group more challenging. In addition the market communication requires more effort since the single company must communicate the value to several actors on the market.[21] This can be seen as the fourth hurdle for a company to gain market access.

A fundamental prerequisite of entrance to the EU market is that the medical product carries a CE quality label. A CE mark certifies that the product is safe and presents a certain level of quality and efficacy. It is a licence that allows the product to be marketed within the whole of EU.[22] Responsible of this licensing are the notified bodies. Notified Bodies are authorized institutions, accredited by the federal authorities in each country, which inspect the evaluation

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[18] Eucomed, *Medical Devices Vademecum*, Brussels, 2006, viewed on 2008-10-06 <http://www.eucomed.org/~/media/pdf/tl/2008/portal/press/publications/vademecummedicaldevices.ashx>

[19] European Patent Office, *Filings growth forges ahead at the European Patent Office,* 2006, viewed on 2009-01-06 <http://www.epo.org/about-us/press/releases/archive/2006/19062006a.html>

[20] BVMed, *The German MedTech Market: A Growth Engine for the Health Economy*, 2007, viewed on 2008-10-06,<http://www.bvmed.de/themen/Medizinprodukteindustrie/article/The_German_MedTech_Market_A_Growth_Engine_for_the_Health_Economy.html>

[21] J. Wilkinson, *An Introduction to the Medical Technology Industry*, Eucomed, Cranfield, 2008 viewed on 2008-10-08, <http://www.eucomed.com/press/~/media/0C4ABA4A38E14D75BCC91C1FCA62288D.ashx>

[22] Eucomed, *Position Paper on Health technology Assessment* , 2008, viewed on 2008-10-9, <http://www.eucomed.org/press/~/media/49C306A47FE1424CBCA8ADC185F62554.ashx>

conformity of the production process. The validity of the evaluations performed by the Notified bodies is certified according to uniform national assessment factors.[23] A more uniform regulatory system in Europe, with the introduction of the CE mark in the 1990s along with overall increasing regulatory demands has raised the bar for market entry in many countries. This has had an effect on the investments needed for a company before the new product actually generates revenues.[24] The European Union Medical Device directive appoints four different classification levels for medical devices. The classification of a medical device depends on "the risk associated with the device, its degree of invasiveness, and the length of time it is in contact with the body." The classification of the medical technology will decide the type of assessment that must be carried out by the manufacture. However, the industry still enjoys a great deal of freedom when it comes to the regulatory issues. The process of getting a product out on the market is still relatively short, compared to pharmaceuticals.[25]

The hospital budgets and the cost pressure of the healthcare systems is another major challenge for the companies and the industry as a whole. Hospitals deal with margin and cost pressure from lower reimbursement levels and the payers are concerned with the rising healthcare costs.[26] This puts high demands on companies to prove the benefits of the product both to the providers and the payers of healthcare.

2.1.3.1 Product life cycle

Typically a medical device or technology completes its life cycle on the market in about 18 months. The R&D phase takes about four to five years and that means that a product has a life cycle of between five to ten years from when it is starting to be developed until it becomes obsolete.[27] The life cycles of the products within the medical technology industry are quite diverse. Many different technologies and applications make it difficult to put up a model that fits all over the industry. But there are common steps that most of the products face during their existence and phases that they all need to go through. The concept of product life cycle refers normally to the product's time out on the market. In this report a more extensive definition will be used, which also includes the development and other premarket phases (see Figure 2).

Usually the development phase of the product is long compared to its time on the market and typically takes many years with all the testing and modifications that is needed. Since the intellectual property and patents often are prerequisites for a given product to be unique and successful on the market this constitutes a problem for a lot of companies. Many products have, in comparison, a short market phase when they can actually create revenue and get the invested money back[28]. The product life cycle of a medical technology product can be divided into 5 phases, a development phase which also includes clinical trials/studies, the regulatory phase, the sales and marketing phase and the phase when the product become obsolete as

[23] Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM., 2006, viewed on 2008-10-15, <http://www.bfarm.de/cln_030/nn_425060/EN/medDev/marketAcc/marketacc-node-en.html__nnn=true>
[24] SwedenBio, *Focus Medtech Agenda – How to create a successful Medtech industry in Sweden*, SwedenBio, Stockholm, 2005, pp. 12.
[25] B. R. Riesberg A. *Healthcare systems in transition: Germany*, pp. 154, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004.
[26] SwedenBio, pp.12.
[27] J. Wilkinson, *An Introduction to the Medical Technology Industry*, Eucomed.
[28] A. Guhl, pp.8-10.

more competitive products have entered the market. Worthwhile to note is that the phases are overlapping and no distinct boundaries exist in reality. [29]

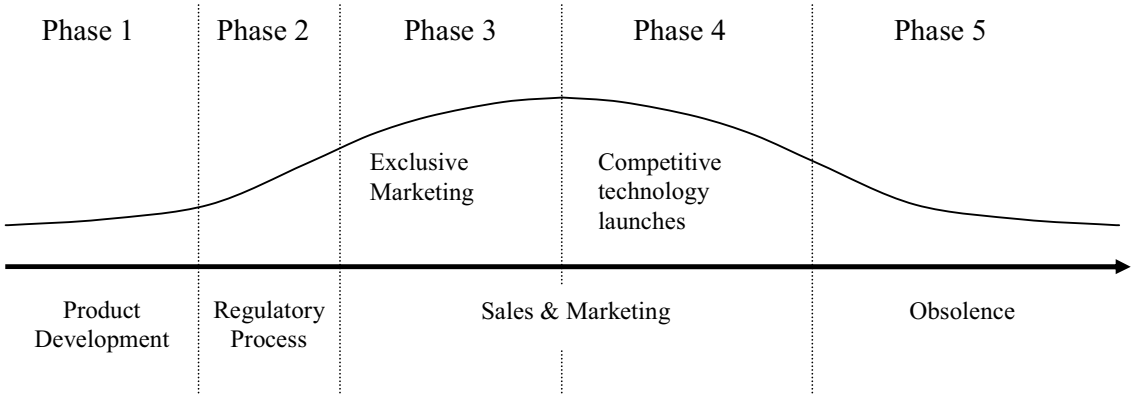

Figure 2 : Product life cycle of a medical device [29]

The two first phases constitute the main part of the life cycle and during these phases no or very small revenues are generated. The length of a patent is 20 years, and that means that a product's period on the market, as an exclusive product, is limited. But new technology threatens to shorten that time even more. All together the time on the market is usually not more than a few years for a new product. That implies that a high profitability during a short period of time is required. After that the revenues will decline as related products or new technologies enter the market and eventually the product becomes obsolete.

The previous mentioned hurdles for gaining legal market access, efficacy, quality and safety are mainly handled by the companies in phase 1 and 2. It is a prerequisite for companies to achieve a certain level in these parameters to have the product approved to be sold on the market. However, in this report it is argued that reimbursement is an additional hurdle to gain full market access and therefore it would be preferable to deal with that issue in phase 1 and 2.

2.1.4 Size of the industry ψ

The global medical technology industry had sales that represented about €187 billion in 2005. The largest market is the US, which constitutes about 42 % of the global market, followed by Europe, accounting for about 30 %, which is about €63.6 billion. Europe spent in 2005 €128 per capita compared to US's expenditure at around €270.[31] The countries that have the largest shares of the world medical technology market after US are Japan followed by Germany, France and Italy. The market share of these countries is shown in Figure 3. [30]

[29] C. Beever & M. Karbe, *The cost of medical technologies, maximizing the value of innovation,* Booz|Allen|Hamilton Inc., USA, 2003, <http://www.boozallen.com/media/file/137991.pdf>, pp. 4.
[30] J. Wilkinson, Eucomed *An introduction to the medical technology industry*, 2008.

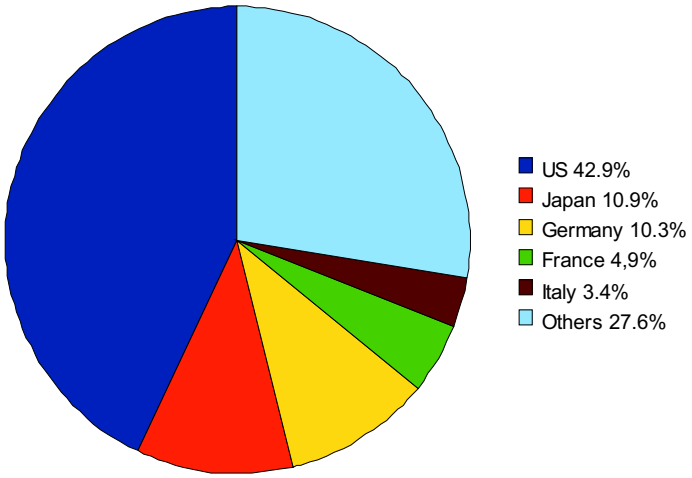

Figure 3 : Share of the global medical technology market in different countries in 2003 [31]

At a global level the medical technology industry employs about 800 000 individuals.[32] Europe counted in 2007 approximately 435 000 employees within the medical device industry. The largest part of them, about 25%, is employed in Germany. United Kingdom and France are also big players.

About 6-7 % of the total expenditures of the European medical technology industry were spent on research and development in 2003. This can be compared to the share spent on R&D in US, which is around the double, 12-13%.

The European medtech market is fragmented, since it consists of many countries. The medical technology industry constitutes about 6.3 % of the total healthcare expenditure in Europe. The largest market in Europe is Germany, which represents 31 % of total sales, followed by France, 16 %, United Kingdom and Italy, 11 % each, and Spain, 9 %.[33] Figure 4 shows different countries' share of the total European medical technology market in 2005. [34]

[31] Eucomed, *Competitiveness and Innovativeness of the European Medical Technology Industry -Evaluation of the Survey Results*, 2007. viewed on 2008-10-17, <http://www.eucomed.org/press/~/media/pdf/tl/2007/portal/publications/compsurvey.ashx>, pp.5.
[32] P. Gudmundsson, B. Jakobsson & H. W.-Henriksson, pp.1.
[33] Eucomed, *Competitiveness and Innovativeness of the European Medical Technology Industry -Evaluation of the Survey Results*.

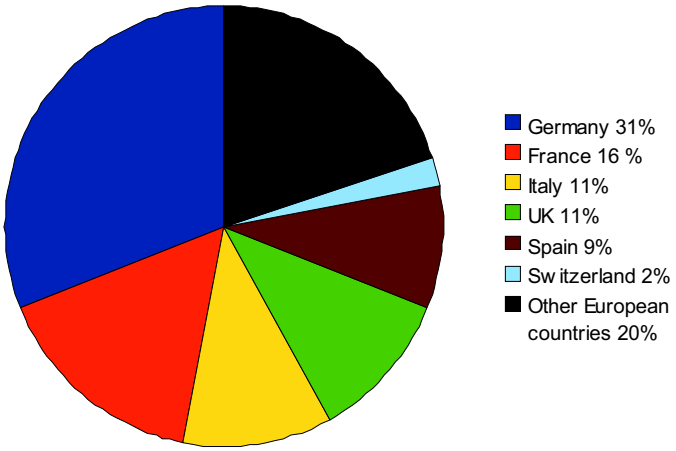

Figure 4 : European medical technology market shares in 2005 [34]

When it comes to companies the situation looks a little bit different. In 2007 there were around 11 000 medical technology companies in Europe. Due to favorable taxes and corporate laws United Kingdom has the largest share in Europe. [35] UK is followed by Germany, Spain, France and Sweden. All together they count for about 60% of the companies in Europe. Figure 5 shows the number of companies in different countries as percentage of the European total amount. [36]

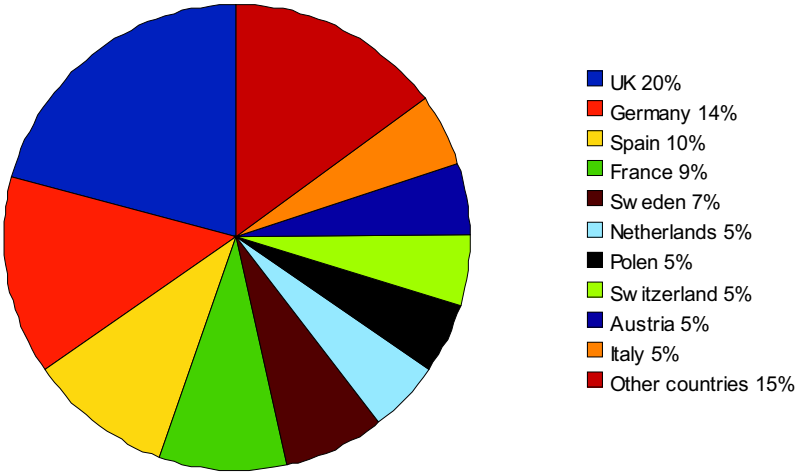

Figure 5 : Number of companies as % of European total in 2007[36]

[34] Eucomed, *Medical Technology Brief*.
[35] Eucomed, *Competitiveness and Innovativeness of the European Medical Technology Industry -Evaluation of the Survey Results*.
[36] Eucomed, *Medical Technology Brief*.

2.1.5 Revenue and growth of the medical technology sector ψ

Compared to other industries like automotive, pharmaceutical or cellular telephone industries the revenues in the medical technology industry are small. The three big American actors of the automotive industry, GM, Daimler-Chrysler and Ford, accounted together for an amount of $522 billion in 2003 compared to the revenues of the whole medtech industry, which was $165. The revenues of the pharmaceutical industry were in the same year about $492 billion.

The revenues of the medtech industry can be further split into $90 billion generated by "high technology devices" and $75 billion by the "lower technology devices" defined in Chapter 2.1.1. The growth and the profitability of the more technologically advanced medtech market have a pleasant history. It has a higher and more consistent growth than almost any other market. Figure 6 shows the evolution of the advanced medical technology market in terms of growth and revenues.

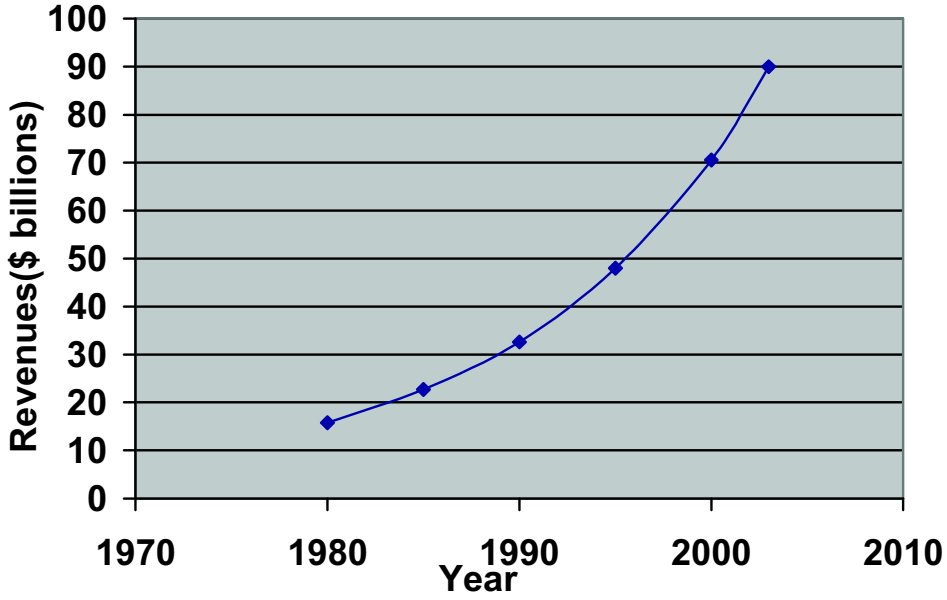

Figure 6 : Revenues and growth of the medtech market [37]

In most other industries the growth is slowing down when the market becomes mature and saturated. Profits above the average of a company are claimed to be something temporary, the revenues will become weaker as the competition from other manufactures enters and drives down the prices. This has not been the case for the medical technology industry yet. It finds a natural driving force in the demographic trends, constant emergence of illness cases and almost infinite absorbing capacity of the medical technology market. [37]

[37] L.R Burns, *The Business of Healthcare Innovation*, 2007, chapter 6, Cambride University Press.

2.1.6 The largest medical technology sectors ψ

The size and the growth rate of the major different medical technology categories are shown in Table 2. As can be seen, the orthopedic and cardiovascular are attractive sectors from a commercial perspective with large revenues as well as growth rates.

Table 2 : Size and growth of different medical technology industry sectors, 2003 [38]

	Revenues	**Growth rate**
	($ billions)	**(%)**
Major therapeutic sectors	**49.0**	**16**
Orthopaedics	16.5	15
Cardiovascular	16.2	24
Ophthalmology	5.7	5
General surgery	7.7	9
Neurological products	2.2	19
Urology	0.8	12
Diagnostics	**22.1**	**4**
Imaging and other	**18.9**	**5**

The orthopedic sector spending can be explained by the joint diseases, which represent half of all the chronic conditions in elderly people over 65 years old. The fractures related to osteoporosis have almost doubled the last few years and also contribute significantly to the orthopedic sectors large expenses. Spinal products used mainly to treat back pain account also for a large contribution.[38] The aging population, the less physical active lifestyle and the obesity also have an impact on this sector's growth. Cardiovascular diseases are the main cause of sickness and premature death and reduced quality of life. It kills over 2 million people every year within the EU. The annual cost for cardiovascular diseases in the EU is €169 billion, mainly due to productivity losses and the need for informal care. Germany and the UK account for 54% of these costs.[39] In the last years, the cardiovascular sector has seen a growth culmination due to the addition of drug-coated stents and electrical implantable devices to the production mix in order to treat congestive heart failure. The growth rate of the neurological sector is pointing to a future large field for the medical technology. Treatment of epilepsy, depression, Parkinson's disease and different kinds of pain are examples of advances of this sector. [40]

[38] L.R Burns, *The Business of Healthcare Innovation.*
[39] J. Wilkinson, Eucomed *An introduction to the medical technology industry*.
[40] Eucomed, *Medical Technology Brief.*

2.1.7 The largest companies on the global medical technology market ψ

According to FDA more than 20 000 companies are registered as medical device companies in the world. The medical technology sector is increasingly dominated by large companies such as Johnson & Johnson, Medtronic, Boston Scientific Corporation, St. Jude Medical, etc. These versatile companies have revenues of billions of dollars. In 1990, the top ten companies represented 48% of the world market revenue. In 2003, this percentage reached 66% which shows the tendency of the industry to go towards a more consolidated market. These large actors hold broad and skilled technology competences as well as extensive R&D and clinical research that make up the empire of medical technology excellence. The big actors in most cases enlarge their market share by acquisitions of smaller high-growth innovative companies even if some products in more rare cases emerge from internal development. Figure 7 shows medical technology companies, with the world largest revenues in 2006.

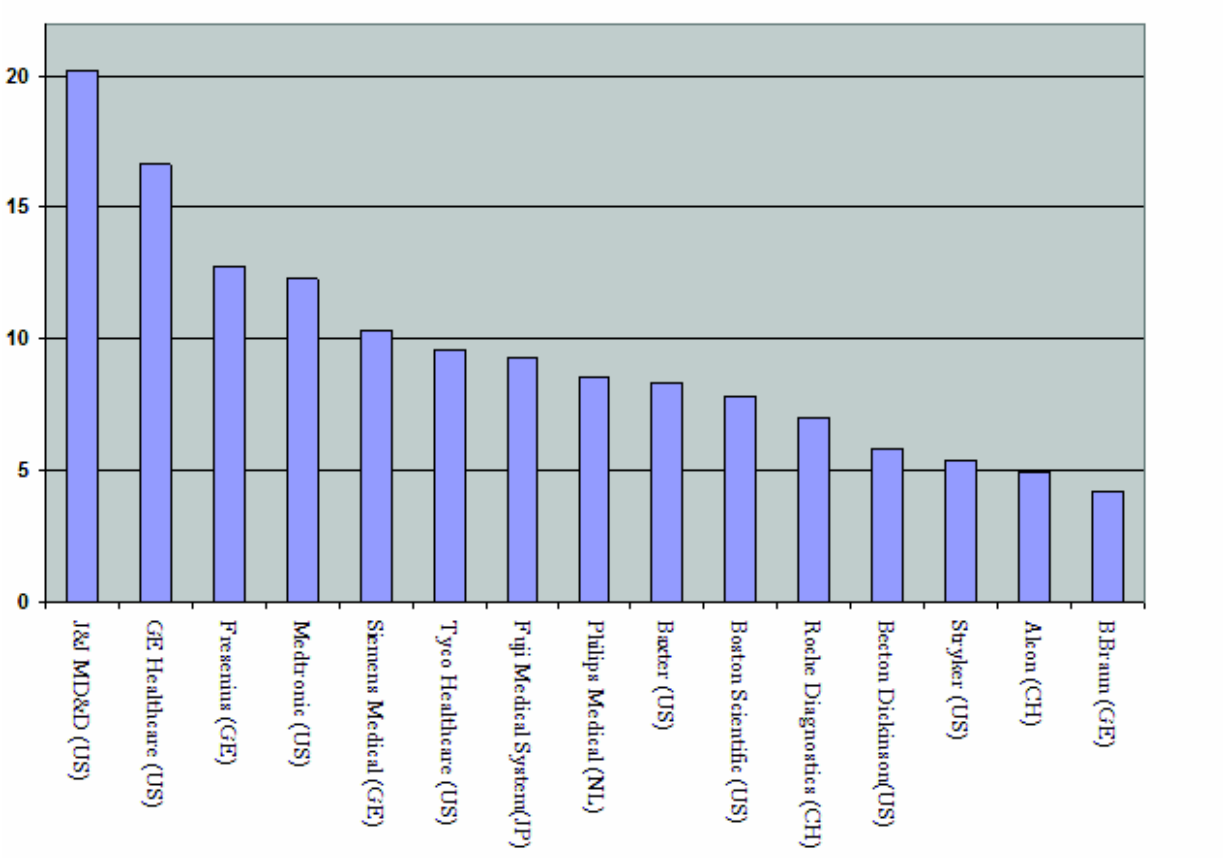

Figure 7 : The world largest medical technology companies in terms of revenues, USD billion in 2006 [41]

More than half of the 15 largest companies are registered in the US. The large companies' dominance on the market can be expressed by the fact that Johnson&Johnson, Medtronic and Boston Scientific in the period between 2001 and 2004 were involved in more than half of all the mergers and acquisitions.[42]

[41] P. Gudmundsson, B. Jakobsson & H. W-Henriksson, *Action MedTech – Key Measures for Growing the Medical Device Industry in Sweden.*
[42] Burns, chapter 6.

2.1.8 Technology trends ψ

The heavy cost pressure has an effect on the healthcare sectors all around the world and impacts the manufacturers in the medical technology industry. The price level that the manufacturers can expect for their products and the competition from alternative treatments procedures affect the companies' strategies. This means that a more direct focus towards developing cost-effective technologies is seen. This section aims to highlight the current technology trends within the medical technology industry. These trends presented further down are predicted to impact the outcome and performance of this industry in the nearest future. In Appendix 1 possible applications of these technologies are more comprehensively described.

2.1.8.1 Fading borders between the drug and the medical technology

The traditional boundaries between medical devices, drugs and diagnostics are becoming more diffuse. Hybrid systems, such as drug delivery technology systems, therapeutic devices that monitor and report on their own performance and devices covered by biologically active or compatible coatings, start to emerge on the market. The medical technology industry is undergoing an evolution and nowadays the converging sectors are developing intelligent and innovative solutions for medical problems.[43]

The attractiveness of the combined products is, among other beneficial properties, their multiple and complementary mode of acting. The multi-functional property might reduce the number of interventions or devices needed in a treatment. The product may itself also operate to counteract adverse effects, normally caused by certain devices, e.g. prohibit the thrombogenic effect. The commercialization of the combined products is thought to be a tough challenge. Regulatory issues include the classification of the product, which is situated in the interface between the categories of devices and drugs. These two groups of products are associated with different market applications, regulations and post-market reporting systems. This indistinct way of classifying the product entails uncertainty and extra workloads for the manufacturers that must put great efforts in dealing with different regulatory systems.[44]

2.1.8.2 Nanotechnology

Nanotechnology is often considered as activities that, in a controlled manner, can manipulate structures in the size of 5-100 nm. This means that controlling design and manufacturing structures down to atomic scale are possible. Within many different industry fields this technology has already had a strong impact on the development and the direction of the future research. The material science and the semiconductor industry are two examples. However, many observers assert that the medical technology industry is one of the sectors, where nanotechnology will have its biggest impact. The contribution of nanotechnology to the medtech sector is expected to be both scientific, with new improved 'smart' materials, medical devices and technologies, as well as economic. It is thought to accelerate the economic activities in the medical research and development.[45]

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[43] P. Driscoll, *Advanced Medical Technology, Beyond Technology: Other Medtech Market Forces*, 2007, viewed on 2008-10-27, <http://mediligence.com/blog/2007/04/26/medtech-market-forces>.

[44] Medical device link, *Drug and device combinations- Combination Medical Products: Capitalizing on Convergence*, 2007,viewed on 2008-11-02, <http://www.devicelink.com/mddi/archive/07/01/009.html>.

[45] Eucomed, *Innovation in Medical Technology- Nanotechnology*, 2006 viewed on 2008-10-27 <http://www.eucomed.org/press/~/media/pdf/tl/2008/portal/press/publications/booklet01nanotechnology.ashx>.

2.1.8.3 Replacement of organs and regenerative medicine

Regenerative medicine in general refers to the field of 'smart' biomaterials that promote self-repair or support the growth of biological tissue components. These products or technologies are usually based on interdisciplinary science, such a cell biology, biochemistry, material science, engineering and medicine. The US National Institute of Health, NIH, defines regenerative medicine/tissue engineering as:

"*a rapidly growing multidisciplinary field involving the life, physical and engineering sciences that seeks to develop functional cell, tissue, and organ substitutes to repair, replace or enhance biological function that has been lost due to congenital abnormalities, injury, disease, or ageing*".[46]

The research in this technology field hints to immense future treatment benefits since it is believed to enable shortened recoveries due to the stimulation of the body's own healing processes.[47] A human engineered tissue product may contain cells from humans, animals or bacteria and should have properties of regeneration, repair or replacement of human tissue. Biomaterials are important components in the human tissue engineering area. These materials may, physically or chemically, have an effect on the cell growth and the creation of the tissue. In addition, innate biomolecules such as growth factors, differentiation factors and other proteins are added to stimulate the growth or repair of tissue or to inhibit undesired responses.[48]

2.1.8.4 Information and communication technology

More than forty years ago Gordon Moore, one of the founders of Intel, stated that the number of transistors on a chip will double about every two years with the price held constant. His prediction agrees fairly well with the actual course of development.[49] The content of this statement, later called Moore's law of the semiconductor development, has entailed stunning consequences for the capacity of computing hardware. The law is illustrated in Figure 8. The medical technology industry has not escaped these advances that have occurred. Instead it has tried to derive advantages from the progress, for example from the faster computers with larger memory capacity. The integration of the two technology sectors has resulted in a new sub-sectorial industry, the healthcare information technology sector. The electronic medical record, EMR, is claimed to be the most important IT application in the healthcare so far. The Picture Archiving Communication and Storage system, PACS, enables digital storage of radiology examination and the integration of the examinations in the patient's EMR.[50]

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[46] Eucomed. *Innovation in Medical Technology- Regenerative medicine and human tissue engineering,* 2007, viewed on 2008-10-29,
<http://www.eucomed.org/press/~/media/pdf/tl/2008/portal/press/publications/booklet02humantissue.ashx>
[47] J. Wilkinson, Eucomed *An introduction to the medical technology industry*.
[48] Eucomed, *Innovation in Medical Technology- Regenerative medicine and human tissue engineering.*
[49] Intel, *More's law*, viewed on 2008-10-30, <http://www.intel.com/technology/mooreslaw/>.
[50] Burns, chapter 7.

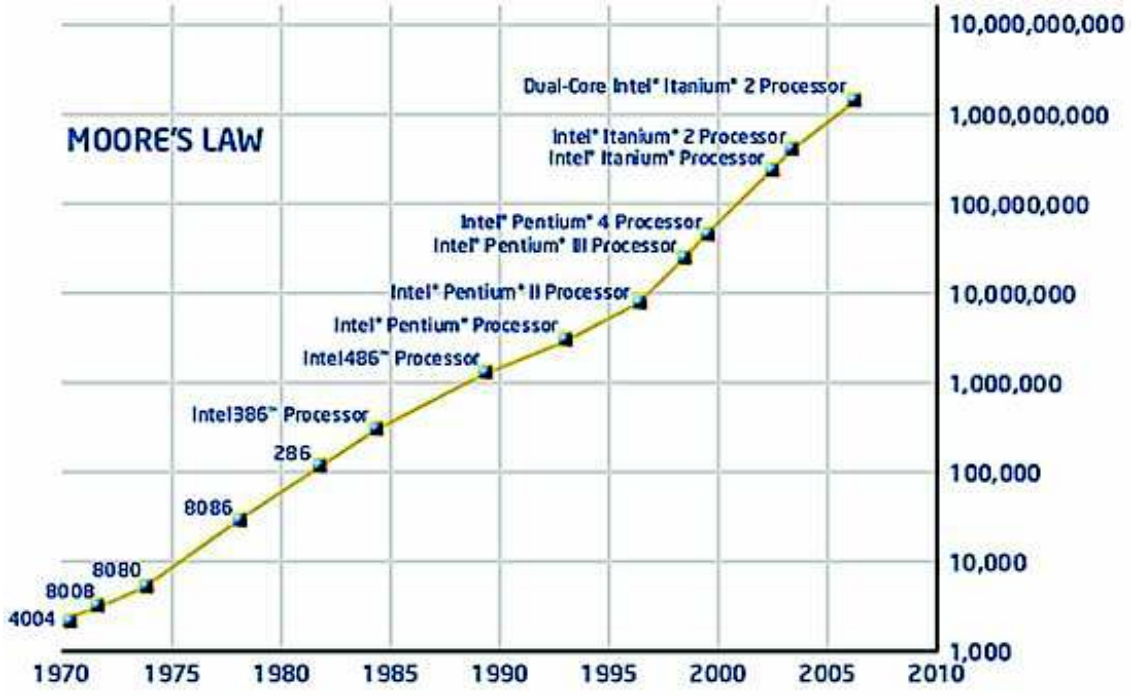

Figure 8 : Moore's law. Number of transistors on an integrated circuit in the period 1970-2007 [51]

2.2 Classification and assessment of medical treatments

Medical technologies are mainly used as parts of global treatments. As a consequence, the medtech industry is influenced by the medical environment and needs to follow the rules dictated by the healthcare system. Medical treatments are classified according to certain standards. A common system used for this is the Diagnostic-Related Groups, DRGs. Detailed information about the aim, the advantages and drawbacks of such a system, as well as the present situation in Europe is presented in this chapter. As a result of the increasing expenditures in healthcare as well as deficient budgets, the need for critical evaluations of medical technologies within a treatment has increased. The second part of this chapter aims to explain the concept of Health Technology Assessments, HTA, which analyses the clinical, economical and social impacts of a medical technology.

HTA is a factor to be considered by companies when dealing with reimbursement. However, the impact of HTA on DRGs differs between healthcare systems and the importance for the companies thereby vary.

2.2.1 Diagnostic-Related Groups φ

The concept of Diagnostic-Related Groups, developed by Professor Robert Fetter at Yale University in 1968 was initially used in 1983 by Medicare, the governmental social insurance

[51] A. Heavey, September 2007, Open Science Grid, viewed on 2009-01-07, <http://www.opensciencegrid.org/About/What_We%27re_Doing/Research_Highlights/NanoWire> .

in the US[52]. A DRG system provides a classification of hospital's patients into groups that are expected to use similar resources and are ensured to generate similar expenses (direct and indirect costs). The groups are defined according to diagnosis and surgical procedures as well as the patient's characteristics such as age and gender. [53]

The first aim of the DRG system was to assess, in an accurate and unbiased way, the treatment costs of a patient. The method was developed to adjust the performances of providers for the different mixes of patients they treat. In addition, DRGs provide a mechanism to reimburse providers. An amount of money is defined by the competent authorities and allocated to each DRG case and it is then used by the health insurance companies in order to reimburse the hospitals for inpatient care. [54]

The process of defining these groups is not easy and must be conducted carefully as it must take into account the economical and clinical issues. The DRG system has advantages as well as drawbacks. With the introduction of DRG, the main purposes are to decrease the costs and to improve the efficiency compared to a "fee for service" or "per day" reimbursement system. It has also the aim to increase the transparency of costs in a healthcare system as well as the quality of service.

The drawbacks and dangers of such a system are mainly the up-coding of patients when clinicians intentionally code patients with a more severe diagnose than it is in reality to get higher reimbursement. The priority might also be given to certain patients for financial reason instead of treating them equally. [55]

Since 1983, many countries have implemented DRG systems. Most of them have adapted it in order to suit their own healthcare systems to make people trust and accept it better.
In Australia for example, the DRG system was developed closely with the clinicians and has nowadays an international influence as Germany took it as a basis to develop its own system.

The current situation in Europe shows that most countries have introduced DRG systems. This is the case for Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Italy, Portugal, Sweden (Stockholm), Spain, Switzerland, The Netherlands and England and Wales in the UK. On the opposite, Luxembourg, Cyprus, Greece, the Czech Republic, Northern Ireland and Scotland in the UK do not use any DRG. As shown in Figure 9, the implementation of DRG can be a long process and can be realized in more than one step as for France, Belgium and Switzerland represented by the number (1) and (2) in the figure. Detailed information is presented in pages 32 to 34 of the HOPE report.[56]

[52] Office of Technology Assessment, *Diagnostic Related Groups (DRGs) and the Medicare program, Implication for medical technologies _ A technical memorandum*, Washington, DC, US Congress , OTA-TM-H-17, July 1983, viewed on 2008-10-10, <http://govinfo.library.unt.edu/ota/Ota_4/DATA/1983/8306.PDF>.
[53] HCUP National Statistics Archive, *Statistics From the HCUP-3 Nationwide Inpatient Sample for 1994: Diagnosis-Related Groups*, viewed on 2008-10-10, <http://www.hcup-us.ahrq.gov/reports/natstats.jsp>.
[54] R. Busse, *Hospital case payment system in Europe*, Healthcare Manage Sci (2006) 9: 211–213.
[55] K. Bhattacharjee, *Diagnostic Related Groups - Suitable Means to an End???,* 2007-12-19, viewed on 2008-10-10, <http://www.frost.com/prod/servlet/market-insight-top.pag?docid=115142822>.

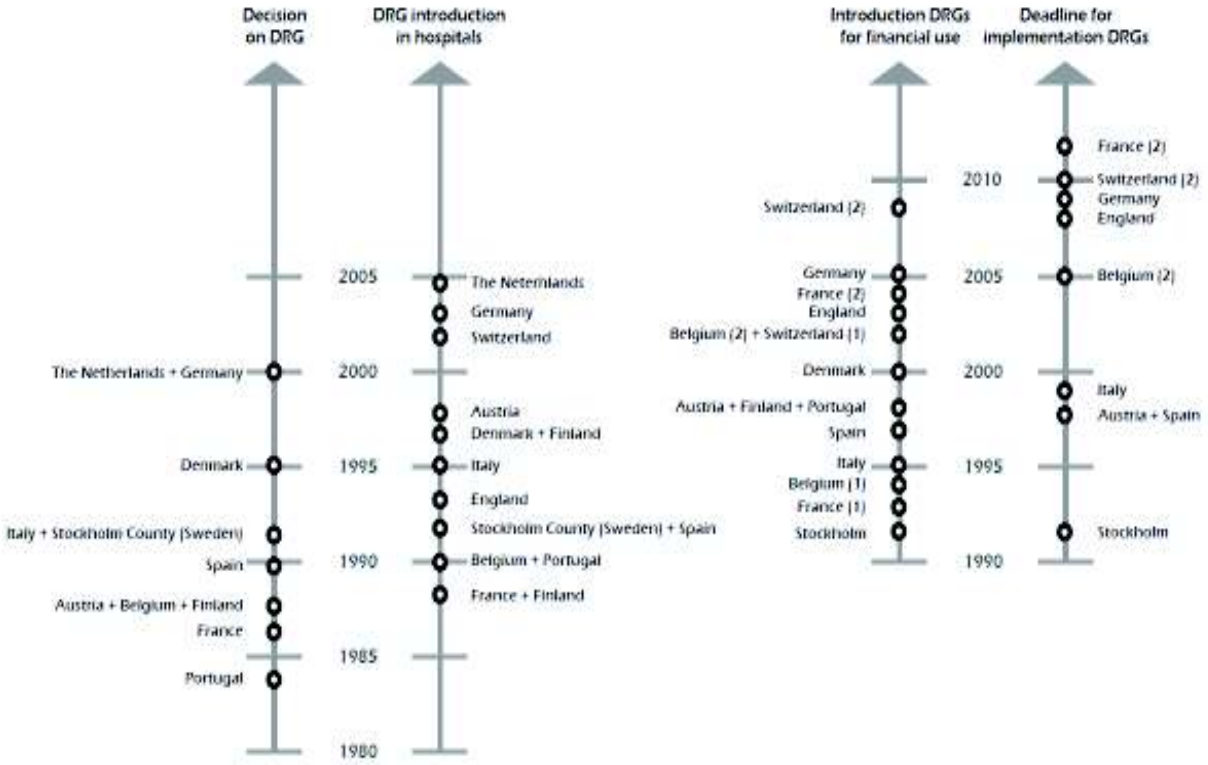

Figure 9 : Timetable of the implementation of DRG systems in Europe [56]

DRG has a major impact on medtech industry. Some companies can no longer build their marketing strategy on a single product. They need to integrate it in the overall treatment process and in a DRG case to receive more prominence. [57]

As mentioned previously, the purpose of a DRG system is to decrease costs, which is mostly achieved in closing inefficient hospitals and in decreasing the number of beds. In doing so, the impact of the medtech industry is obvious. For example, sales of bedside patient monitors and equipments in operating rooms decreased drastically as they are directly affected. On the other hand, as the length of stay in hospital tends to decrease, an increasing demand for home-care products can be observed. For example there is a rise in the demand for blood pressure monitors. The surgical instruments segment is also expected to grow related to the increase of ambulatory or day-surgeries. [58]

Positive and negative impacts on the industry can be seen depending on the focused segment and types of products. However, most of the players in the medtech industry see the implementation of a DRG system as a negative influence on technology diffusion, and thus growth of the medical technology industry. Some of them have concerns about the impact of

[56] HOPE, *DRGs as a financing tool, European Hospital and Healthcare Federation*, December 2006, viewed on 2008-10-10, <http://www.hope.be/05eventsandpublications/publications_chronologicallist.html>.
[57] BVMed DRG workshop, *Away from product consideration towards process and case considerations*, 2005-01-25, viewed on 2008-10-10, <http://www.bvmed.de/themen/DRG-System/pressemitteilung/DRG-Workshops_von_MedInform_Weg_von_der_Produktbetrachtung,_hin_zur_Prozess-_und_Fallbetrachtung.html>.
[58] K. Bhattacharjee, *Diagnostic Related Groups - Suitable Means to an End???*

DRGs on revenues of products already present on the market as well as the introduction in terms of adoption and reimbursement of new technologies.[59]

2.2.2 Health Technology Assessments ψ

A HTA evaluates the clinical as well as the economic effectiveness of the medical technology. One of the aims is to help the decision-makers in their reimbursement decisions. The objective of the assessments is to map the different alternatives of treating a certain clinical state of ill-health and to evaluate them. Furthermore, the assessment should contribute to provide to the patients the best products or treatments on the market. In addition, they are supposed to entail a positive view of the 'best in class' products giving them a better starting-position for example to establish reimbursement. Conversely, obsolete and inferior devices and treatments are thereby thrown into the shade for their superior peer counterparts. HTAs intend to adopt a broad perspective and capture the impact of the new medical intervention on all stakeholders; i.e. patients, care providers, payers and society as a whole.[60]

In order to capture the actual clinical effectiveness of a medical intervention and to create a reliable evaluation, robust for comparisons, the information should preferably, according to the 'gold standard', be collected from randomized trials.[61] However, the design of the assessments must be modified when evaluating medical technologies. The usage of medical technologies might prohibit a randomized performance of the study.[62] Although the non-randomized methods are considered less evidence-based, they are still appropriate to evaluate the quality of the technology and to inform the decision makers.[63] Moreover, due to the nature of the procedure, the possibility of performing a double blinded study might be difficult when testing medical devices.[64]

2.2.2.1 International situation of HTA

In general, most countries of the European Union, the US and other industrialized countries have HTA programmes. Departments and agencies, independent or coupled to universities, governmental or non-governmental institutes carry out the assessments and constitute together a heterogeneous health technology assessment situation worldwide. There are various general frameworks and guidelines for conducting HTA but no international standard of a methodological approach exists. The HTA bodies around the world are mainly funded by national healthcare systems or by research and development budgets. The assessments might be commissioned by governmental or non-governmental health policy-makers, third-party payers, patients' advocate or health technology assessment institutions.[65] A general trend

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[59] HBS consulting, *European Hospital Financing Reform - Developments and Business Implications for the Medical Device Industry*, viewed on 2008-10-15, <http://www.researchandmarkets.com/reports/28611/european_hospital_financing_reform_developments>.

[60] Eucomed, *Eucomed HTA Position Paper,* 2008, viewed on 2008-10-13, <http://www.eucomed.org/press/~/media/49C306A47FE1424CBCA8ADC185F62554.ashx>.

[61] Eucomed, *Supplement to the Eucomed position paper on Health Technology Assessment* , 2007, viewed on 2008-10-13 <http://www.eucomed.org/press/~/media/pdf/tl/2007/portal/publications/position_papers/supplement_hta_paper%20pdf.ashx >.

[62] IQWiG, *General Methods, Version 3.0*, 2008 viewed on 2008-10-13, <http://www.iqwig.de/download/IQWiG_General_methods_V-3-0.pdf>

[63] Eucomed, *Supplement to the Eucomed position paper on Health Technology Assessment.*

[64] IQWiG, *General Methods, Version 3.0.*

[65] M. Velasco-Garrido*, Health technology assessment***,** *An introduction to objectives, role of evidence, and structure in Europe,* 2005, European Observatory on Health Systems and Policies.

observed is that the health technology assessments have shifted the decisions about the technologies that should be used from the clinicians to HTA bodies. Furthermore, the manufacturers are facing a situation where they are expected to provide larger amounts of data to demonstrate the clinical as well as the cost benefits of their innovations. It results in increased costs for the manufacturers that might need health economical expertise to meet these requirements. Some of the most renowned and influential European HTA bodies are the UK institution NICE, the French ANAES and the Italian ASSR. These organizations have different roles in guidance, decision-making and implementation of HTA in the healthcare system.[66]

HTAs have, so far, focused mainly on the economic analysis and the patient benefits either through the life extension or quality of life. The assessments have, in general, been performed when the data needed is available. Recently, a general opinion has express the need of earlier assessments. The cost and performance of the technology should be analyzed already during the design and the development in order to reduce uncertainties. This assessment structures the situation and demonstrates the probabilities for different scenarios and the associated consequences. The development of a new medical technology is recognized as uncertain and costly. Decisions about management and design have to be done by medtech companies or their investors even before the clinical performance of the product is clear. The assessments can support the decision-makers, at this early stage, by providing information but also by identifying the most relevant performance and outcome measures for later evidence-based assessments.[67] Different European and international HTA organizations are presented in the Appendix 2.

[66] J. Wilkinson, Eucomed, *An introduction to the medical technology industry*.
[67] J. B. Pietzsch , *Early technology assessment of new medical devices,* 2008, International Journal of Technology Assessment in Healthcare, 24:1, 36–44.

3 Design of the study

The method used in this paper is influenced by the Grounded Theory methodology. Grounded Theory is a method suited for phenomena that cannot be described sufficiently using existing theories or to enhance the existing ones and give them new meanings[68]. The method aims at building new theories based on the empirical observations done. This requires that the researcher approaches the problem area as a "blank sheet" and has no or little theoretical prejudice about the phenomena of study. The researcher makes empirical observations about the reality and let the theory evolve gradually as the gathered data is increasing.[69] The method is an iterative process where the collected empirical data guides the researcher and forms the ground for how the study should progress. In contrast to traditional deductive methods the theoretical prejudice acts as a guideline for what questions to ask and what the researcher should focus on in his/her study. The result from the study is then analyzed and coded. The purpose of this is to put together a theory that can explain and predict the studied phenomena. The last part of the study consists in doing a theoretical literature study and in comparing the grounded theory with established ones. This is done in order to put the model in a scientific context and put forward critiques to both the established models and the one just created. For further reading about the Grounded Theory methodology, the book *Metod: Grundad Teori för ekonomer* written by Bengt Gustavsson is recommended.

The choice of this Grounded Theory approach was due to the very limited knowledge and unfamiliarity of the medical technology industry when this project was assigned. A way of becoming familiar with the industry and to get knowledge about the problem areas within it was needed in order to define the research question. The method also means that we have built a model that describes the phenomena of how small medtech companies integrate the reimbursement issue in the commercialization process. From that we will then discuss how the awareness of the companies affects the integration of reimbursement related issues in the overall strategy.

The rest of this chapter will describe more precisely how the Grounded Theory method has been used in this study.

3.1 Defining the research question

In the very beginning the framework for the project was quite broad and open. The initiators of the project described the scope with the sentence:

"*The focus of the project will be on medical technology, studying how innovative medtech companies address such questions as international regulatory systems, reimbursement and intellectual property issues."*

A particular, predetermined, research question for the project was, in other words, not clearly defined. The aim of the project was partly that the result in some way should contribute to a deeper knowledge of the medtech industry for the ones actually working in it. The ambition

[68] B. Gustavsson, *Metod: Grundad Teori för ekonomer – Att navigera i empirins farvatten*, Academia Adacta, Lund, 1998, pp.37
[69] Ibid, pp.9 ff.

was therefore to find within this frame a specific topic that is an important and immediate issue for the industry today. Consequently, a general mapping of the industry situation was performed to find out possible issues. The information was gained in several different ways but also from different perspectives. The attendance at *Taking the Next Step – Revenue Acceleration in Early stage Medical Device Companies,* an event arranged by SEB, one of Northern Europe's leading financial groups, on August 27th, 2008, highlighted major obstacles small and medium sized medtech companies experience on their way to become successful players on the market. Some interesting points of importance for possible research questions emerged already at this point.

In connection to the event we were assigned to document what was said during the seminars and discussions that were held during the day. The documentation was then used to put together a toolbox for how small Swedish medtech companies should accelerate their revenue. The toolbox can be found in Appendix 3. The toolbox was made on the behalf of SEB with help from Synergus, a Swedish medtech consulting company dealing with regulatory, quality and business development.

After that, interviews with experienced people from the medtech industry were performed. The interviewees' different kind of professional assignments gave several different perspectives of what the most important issues actually are. The subjects of interview were:

- Anders Qvarnström, Executive Vice President and COO at Radi Medical System, here representing the perspective of a large Swedish medtech company.

- Ola Magnusson, Managing Director at Sedana Medical, here representing a small Swedish medtech company's perspective.

- Otto Skolling, Investment Manager at Karolinska Development, with a venture capitalist's ,VC, perspective of the industry.

Informal meetings with Mathias Kyhlstedt, CEO at Synergus, also helped us in the process. The mapping was supplemented with literature studies and the whole industry mapping resulted in the research question of this report.

3.2 Acquiring knowledge about the German reimbursement system

The German reimbursement system was studied in two different aspects. The German reimbursement system was investigated in order to find out how it works and the different pathways through it. The system was mapped according to what the rule book said about it. The other view of investigating the system was to understand how it works in practice from a company's point of view, e.g. unwritten rules, the practical procedure, etc. To acquire knowledge about the German reimbursement system and to understand it in depth, from both perspectives, an extensive literature study was performed. The articles used were mainly found on homepages of the various organizations or federal institutes working with the reimbursement system in Germany. The homepages of European and German medtech organizations, such as Eucomed and BVMed respectively, were also used.

To get an understanding of the system from the markets point of view, two interviews were performed. The respondents of the interviews were:

- Thomas Seeger, Managing Director of Medalliance GmbH, a consultant firm in Germany, specifically working with reimbursement questions in Germany.

- Stefan Zenk, Senior Reimbursement Manager at Medtronic, one of the largest medtech companies in the world, based in the US. Stefan Zenk is based in Germany and is specialized on the German reimbursement system.

To get the companies' perspective of the reimbursement system the ambition was to talk to a few Swedish companies that already have established reimbursement in Germany. These companies should have been treated as backtracking companies and their stories should elucidate possible characteristics, pitfalls and procedures of the reimbursement process.
This knowledge should then have been used, together with the other information, in order to make highly relevant questions for the small medtech companies, which in the end should form the basis for answering the research question. Unfortunately, just one such company, that was willing to co-operate, was found. Therefore the reliability in this part of the study can be questioned.

3.3 Screening study

A screening study of small Swedish medtech companies was done to enable the choice of companies for the case studies. The aim was to find around three companies that plan to launch their products in Germany within the following 12 months. The study should also ideally sort out an additional three companies that were in an earlier stage phase, developing their technology or performing their clinical studies. The strategy and involvement of these companies, at their different stages in the product development or commercialization should form the basis of analysis.

55 companies were asked by e-mail to participate in the screening study by taking part in an interview of about 20 minutes. 28 companies accepted and joined the screening study. The interviews were performed over the telephone. The purpose of the questions was to get general information about the company, its technology or products it is focused on, the phase of the product life cycle, etc. The questions also included how the companies perceive the possible challenges, the reimbursement issue as well as the competition. The full questionnaire used for the screening can be found in Appendix 4.

3.3.1 Criteria for the companies in the screening study

The aim was to find a coherent set of companies that develops 'innovative' products, which fit with the definition of high technology devices in Chapter 2.1.1. Products that are directly used on the patient or closely related to the patient were also taken into account. Thereby, all diagnostic products for laboratory use were excluded. Furthermore, the products had to be intended for either the hospital or the ambulatory sector in Germany.

3.4 Case studies

From the screening study, six companies were chosen for deeper studies and as a complement to this we also, as already mentioned, included a larger Swedish medtech company. This company has been established in Germany since the early nineties and has been struggling with the reimbursement issue for many years. The study thus consisted of a total of seven interviews, each of about 1-2 hours duration. The interviewees were key persons at the managerial level in the companies. We were referred to them as they were the most knowledgeable persons about reimbursement in the companies. After the interviews the information was extended with follow up questions sent by e-mail.

3.4.1 Choice of companies for the in deep studies

Out of the initial 28 companies, two reported at a second inquiry regarding further co-operation that they could not participate anymore. Two other companies were excluded since they mainly were active in the dental field, which are under completely other financial administrators. Seven companies were excluded since their products were mainly intended for laboratory use, not really innovative or used in direct contact on the in-patient. One company was excluded since they were subcontractors and did not supply their product directly to the hospitals. Two companies were not dealing with the German market by themselves. They had partners that managed the issue and they were therefore excluded. One company did not focus on Germany at all due to the immature market situation for their product. In total ten qualified companies remained, seven in the launching phase and three in an early stage. Four launching companies and two early stages were picked randomly.

As mentioned earlier, one case was also built on the story from a large Swedish medtech company. This company was the only one among the potential backtracking companies that agreed to participate.

3.4.2 Interviews of the companies under study

The questions for the companies were elaborated from the general background information and the knowledge acquired from the study of the German system. Three different questionnaires for the early stage, the launching as well as the backtracking companies can be seen in Appendices 5, 6 and 7 respectively. The interview consisted of three parts. The first part considers general information about the company e.g. the structure, history and current phase of the company as well as the product or technology and its value. The second part investigates the marketing strategies in terms of how the company plans the marketing and its considerations about the German market. The last part deals with the reimbursement questions. Each researcher was responsible for one of these parts during the interviews.

The interviews were performed in a semi-structured mode. This approach was chosen since it was thought to be the best alternative to gather important information about the companies' strategies and work concerning reimbursement issues. With this approach the subject of interview was guided to talk about the relevant subjects but was at the same time allowed to talk about additional incidents and characteristics from the companies' history as well as possible future obstacles. Such circumstances might not have been discerned in a structured interview.

The interviewee was at the beginning of each interview informed about their right to be anonymous in the report. The majority of the interviewees gave their acceptance for us to

publish their name; however, there were companies that wished to be anonymous. This is the reason why we have chosen to exclude all the names in the presentation of the cases.

3.4.3 Presenting the cases

The companies and their products are named after the Greek alphabet. The interviewees are named according to the order of the case, e.g. Person 1, Person 2, etc. The order of the cases in the report is not consistent with the order of the interviews. In the report the launching companies are presented first, following by the early stage companies while the case with the large company is presented last.

3.4.4 Analyzing the cases

The case analyses are presented in connection with each case. In these analyses the main observations about the possible integration of reimbursement in each company are highlighted. Moreover a discussion about the companies' overall strategies and how well they agree with the reimbursement system in Germany is put forward. In this part the cases are more freely discussed according to the German system but also in relation to how the companies deal with the reimbursement in general.

3.5 Building the model

In consistency with the Grounded Theory methodology, a model is created based on the empirical observations made in this study. The model describes when and how the interviewed companies integrate the reimbursement activities in their commercialization process. A figure representing the product life cycle is used in order to categorize our observations according to the time and the phase they appear in. This can be problematic from a Grounded Theory point of view since the product life cycle actually is a model of how the demand for a medical device changes over time. However, the model has not been used when designing the study. The purpose of using it is that it allows a categorization and a conceptualization of the observations according to an existing theory. Therefore it can be argued that this is a credible way of doing it.

To build the theory from the study much focus is put on the launching companies. Since the issue is most current for them, it is of most interest to see how they deal with it. The backtracking company is used into the model to see the commercialization process from a perspective of a bigger company that has already gone through it.

The early stage companies are used to see how they stand in comparison to the launching companies, if there are differences in their behavior that cannot be explained by the model and call for an extension of it. The large medtech company is used in the latest part when the model is discussed to see how well it can explain that particular situation.

4 Study of the German system

4.1 Size of the German medtech market ψ

As can be seen in Figure 3, Germany is the third largest medical technology market after the US and Japan. The German market is by far the largest market in Europe. It is about twice as large as the French market and three times as large as the British and Italian markets. The sector of medical technology has a positive impact on the German economy and on the labor market.[70]

In 2007 the medical technology market in Germany accounted for:

- 3.9% of all the healthcare expenditures
- 0.4% of German GDP [71]
- 90 000 employees in 1200 companies

In addition, 75 000 employees were working in 10 000 companies in related businesses.[72] Germany spent 20 billion Euros in total in 2006 on medical technologies. From this amount about 7 billion were spent in the hospitals and about 13 million in the out-patient care.[73]

A stagnation of the domestic sales in Germany has been seen in the last couple of years. A possible reason might be that the normal drivers usually fueling the market growth, e.g. demographic changes in terms of an ageing population and increased health awareness among the population, are counteracted by the restricted health budget. However, a forecast conducted in 2006 by Deutsche Bank Research estimated the annual growth of the German medtech market to 8% until 2015. The sustained need for healthcare is thought to prevail over the cost issue. Particularly, "innovative products" within some areas are predicted to impact on the growth of the German medical technology industry. These areas are for example computerisation, which includes computer-based diagnosis and therapy, biotechnology, cell and tissue engineering as well as the miniaturisation of systems, including micro, nano and optical technology.[74]

Germany is considered to have short approval times as well as cost-effective and efficient clinical research. To bring an idea to an available technology on the market costs on average 8 to 10 million Euros. In the US the corresponding expenditures are much more costly, about 80 million dollars. However, the German system has some drawbacks when it comes to introducing innovative products into the reimbursement system. The delay caused by this

[70] BVMed, *The German MedTech Market: A Growth Engine for the Health Economy.*
[71] Business Intelligence, *The Medical Device Market: Germany Opportunities and Challenges*, 2007, viewed on 2008-10-21, <https://www.espicom.com/Prodcat.nsf/Search/00000549?OpenDocument>.
[72] BVMed, *The German MedTech Market: A Growth Engine for the Health Economy*.
[73] J. M. Schmitt, Marketing Policy*, Communicating the value of medical technologies: Best practice cases from Germany*, 2006, Journal of Medical Marketing, Vol. 6:3 203–208.
[74] L. Kelly, *Germany Invests in Innovation*, 2008, viewed on 2008-11-04 <http://www.medicaldevice-network.com/features/feature42882/>.

process prohibits a fast availability of new products to the public and makes the market less dynamic than it potentially could be.[75]

A German industry survey was conducted by the medical technology trade organization, BVMed, in 2007. The organization presents its members' opinions about the environment of the medtech sector in Germany. The main drawbacks of the market were according to the members the low level of reimbursement in Germany compared to other European countries. The scarcity of coverage is most evident in the implant sector where Germany provides the lowest level of reimbursement. In addition, an increased flexibility of the system was desired.[76]

4.2 Healthcare system in Germany φ

As mentioned previously Germany is the biggest market in Europe for medical technologies. Most of the European medtech companies choose to establish their sales there, but in order to enter a market successfully it is essential to understand how its system works. In this study, healthcare system is playing an essential role because of its interactions and its influence on the medtech industry.

The focus of this chapter is to understand how the German healthcare system works with the aim of highlighting how a product can get reimbursed. The study considered the different actors and their interactions as well as the procedures required by the responsible organizations or authorities.

4.2.1 Evolution, expenditure and trends

Germany has a long tradition of healthcare systems. The first system was introduced in 1883 by the general Otto von Bismarck and was mainly based on the fundamental principles, which are solidarity and individual responsibility. Since then many reforms have taken place in order to improve and adapt it to the evolution of the society but keeping in mind the main principles.

The German healthcare system has a worldwide reputation of being one of the best in terms of quality of care. It is also one that expends the most as a part of its GDP as it is shown in Figure 10. In 2006, Germany was number four after US, Switzerland and France with 10.6% of its GDP which represents about € 250 billion.[77]

[75] BVMed, *The German MedTech Market: A Growth Engine for the Health Economy*.
[76] BVMed, *Annual report 07/08*, viewed on 2008-11-04,
<http://www.bvmed.de/stepone/data/downloads/d4/bc/00/annrep0708.pdf>
[77] OECD, *Growth in health spending slows in many OECD countries in 2006, according to OECD Health Data 2008*, 2008-06-26, viewed on 2008-08-30,
<http://www.oecd.org/document/27/0,3343,en_2649_34631_40902299_1_1_1_1,00.html>.

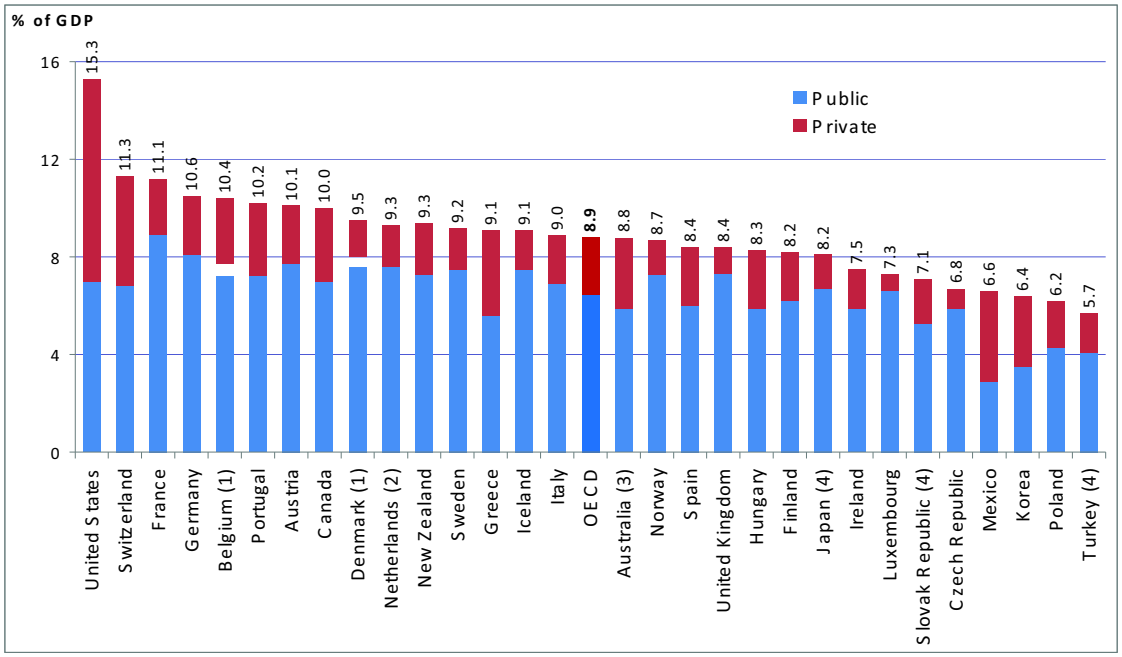

Figure 10 : Heath expenditure as a share of GDP, 2006 [78]

As many other industrial countries, Germany is facing new demographic issues such as the ageing of the population as it is shown in Figure 11. The percentage of people financing the healthcare system, mostly the working people between 15 and 64 years old, is decreasing comparing to the retired, above 65 years old. The tendency is projected to be became even more pronounced in the following 50 years.[79]

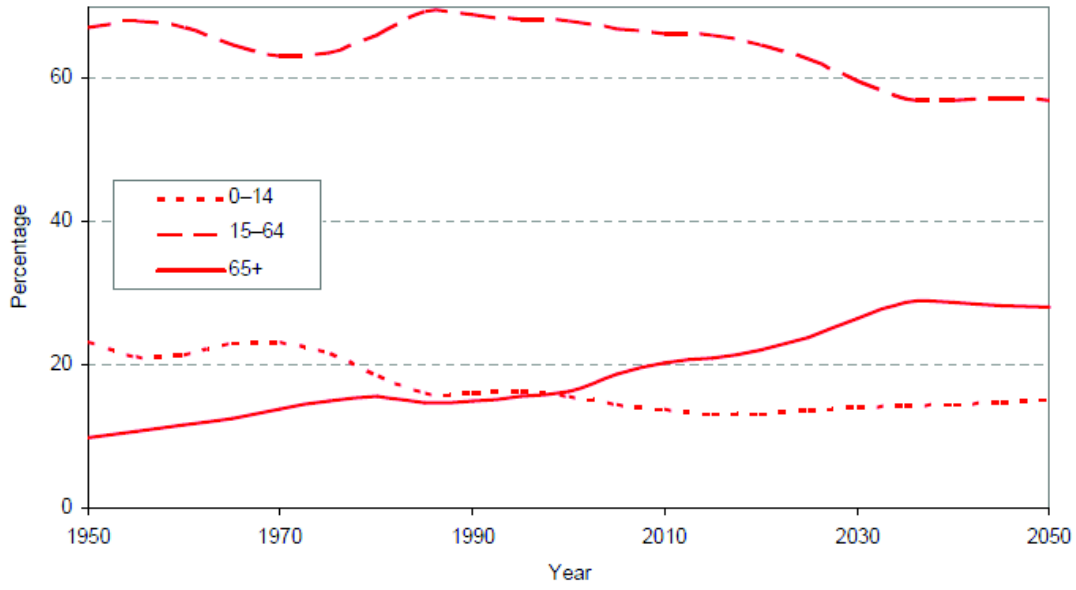

Figure 11 : Percentage of the population aged 0-14, 15-64 and 65+ years, Germany, 1959 to 2050 (projected) [79]

[78] OECD, *Growth in health spending slows in many OECD countries in 2006, according to OECD Health Data 2008.*

Moreover, standards of health is also improved, mainly thanks to the development of new technologies and drugs, but also due to an increasing demand on quality from the population that desires to live longer and healthier.

These two main issues result in the increase of the expenditures on healthcare, which has been seen also over the past years and will probably follow the same trends. The government needs therefore to find new strategies to finance the system and at the same time to reduce the costs.[80]

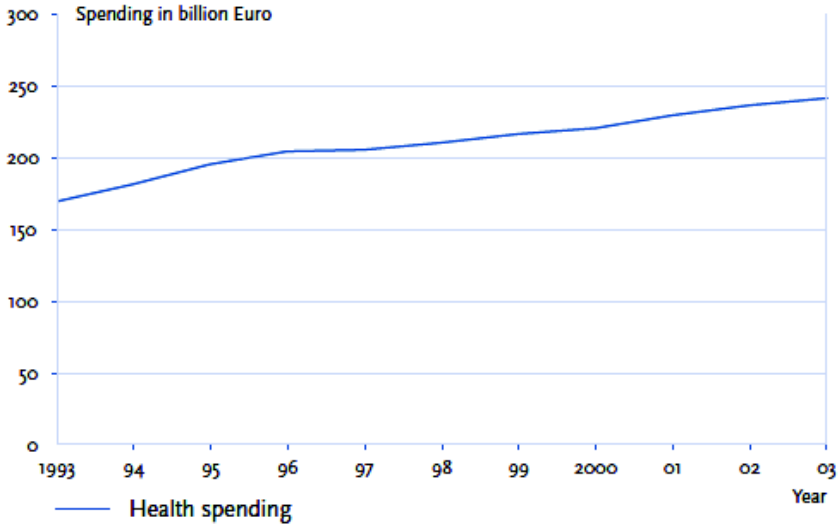

Figure 12 : Development of health expenditure in Germany (nominal) [80]

4.2.2 General framework

The German healthcare system is highly decentralized. The legal framework of the healthcare system is described in the Social Code Book, SGB, defined by the government. However, the decision-making process is split among different actors which are self-regulated bodies. They are organized at different levels and supervised by the Federal Parliament, the Federal Ministry of Health as well as each of the 16 state ministries responsible for health. Two main sectors are active in the healthcare system. On one side, there are the providers of healthcare which are the physicians and the hospitals and on the other side there are the payers, mainly constituted by the sickness funds.

4.2.3 Payers

The German healthcare is financially supported by the payers. This sector is divided between public and private health insurances. 87% of the population is insured by the public service called Statutory Health Insurance, SHI (Gesetzliche Krankenversicherung GKV). This

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[79] WHO Regional Office for Europe, *Highlight on health in Germany 2004*, Copenhagen, viewed on 2008-09-30, <http://www.euro.who.int/highlights>.

[80] Robert Koch Institute, *Health in Germany*, Federal health reporting, July 2006, Berlin, pp.13, viewed on 2008-10-03, <http://www.gbe-bund.de/gbe10/owards.prc_show_pdf?p_id=11094&p_sprache=E&p_uid=gast&p_aid=36469923&p_lfd_nr=1>.

insurance is compulsory for people fulfilling the following criteria, which represent around 75% of the population:[81]

- Employees whose regular income before deductions exceeds €400 per month and remains below a set annual limit. In January 2007, the general annual gross income limit for mandatory state insurance was €47 700[82].

- Students at state and state-approved universities.

- People in work experience programs (internships, trainee) or in secondary education.

- Old-age pensioners who have been in a statutory health insurance scheme or insured as a family member for most of the latter half of their working life.

- Unemployed people receiving benefits from Federal Employment Services (with some exceptions).

However, each person can have supplementary private insurance packages which cover additional services in hospitals such as treatment by the chief consultant and allocation of a bed in a single room. The remaining 12% insured by the SHI are called voluntary members. They are not included in the previous list but have chosen the public insurance.

There are three types of customers that use private insurances, which account for approximately 10% of the population. Firstly, it is the people that do not belong to the previous list and have a salary higher than €47 700. They can choose either a public or a private insurance. Secondly, the self-employed that are forced to have a private insurance because they are excluded from the SHI and finally the employees of the public sector such as teachers and policemen. A part of their health costs are covered by the state, but for special services, they need to be privately insured.[83] The remaining 3% of the population are without any type of insurance, neither private nor public.

In both systems, the contributions are equally split between the employer and the employee. However, they are based on different criteria. With a public insurance, the contribution is based on the income, which represents about 14% of the gross salary, while the privately insured pays according to his risk profile, for example age, gender, state of health, etc.

The SHI has the advantage to provide insurance for the whole family without any extra costs. The partner and the children are also insured as long as they do not have a salary that exceeds a fixed amount per month (€ 345 in 2005[84]) and are not covered by their own insurance. The list of the treatments covered by the SHI can vary but usually includes physician, hospital and some dental treatments. It also includes some preventive measures and the free choice of doctors contracted and recognized by their insurance provider.

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[81] Health Guide Germany, Just Landed, viewed on 2008-10-08, <http://www.justlanded.com/english/Germany/Tools/Just-Landed-Guide/Health/Health-insurance>.
[82] Gemeinsame Bundesausschuss, *The German Health Care System and the Federal Joint Committee - a general presentation*, viewed on 2008-10-08, <http://www.g-ba.de/downloads/17-98-2449/2007-10-08-G-BA-General_Presentation.pdf>.
[83] S. Grant, *Health in Germany*, 2004-07-09, Spring 2003 issue of MedHunters Magazine, viewed on 2008-10-01, <http://www.medhunters.com/articles/healthcareInGermany.html>.
[84] Health Guide Germany, Just Landed.

In certain cases, the patient has to pay a portion of the cost, the co-payment, especially in prescription drugs, bandages, dental treatment and glasses[85]. The last years, the part of the co-payment has increased significantly to face the increase of health costs. Both hospital and physician bills are settled directly through the insurance.[86]

The Statutory Health Insurance is composed of seven state-regulated plans or sickness insurance funds that work with the state to provide health programs to the population. Those are non-profit companies and the members are[87]:

- Allgemeine Ortskrankenkasse, AOK
- Betriebskrankenkasse, BKK
- Innungskrankenkassen, IKK
- Arbeiter-Ersatzkassen-Verband, AEV
- Verband der Angestellten-Krankenkassen, VdAK
- Knappschaft
- Bundesverband der landwirtschaftlichen Krankenkassen, LKK

These organizations have self-administered corporate bodies in different regions which represent a total of about 220 regional insurance companies. From 1997, Germans are free to choose between those companies. Most of the benefits are similar but some variations can be found in the contribution.

The private sector represents only a small part of the population. The services are provided by Private Health Insurance, Private Krankenversicherung PKV, which represents about 50 companies which is known to be more expensive. In exchange, the patient receives a more extensive cover, for example the choice of the hospital and the conditions (1-2 beds), some alternatives therapies depending on the chosen insurance company. It has been shown that a private insurance allows a reduced waiting time to access care as an outpatient mainly due to a higher reimbursement rate, 25-35%, for physicians[88].

[85] Ch. A. Gericke, M. Wismar, R.Busse, *Cost-sharing in the German Healthcare System*, 2003, viewed on 2008-10-01,<http://www.ww.tu-berlin.de/diskussionspapiere/2004/dp04-2004.pdf>.
[86] Grant, *Health in German.*
[87] GKV website, viewed on 2008-09-29, <http://www.gkv.info/gkv/index.php?id=73>.
[88] M. Lungen, B. Stollenwerk, A. Gerber, *Waiting times for elective treatments according to insurance status: A randomized empirical study in Germany*, International Journal for Equity in Health, 7:1 January 2008, BioMed Central Ltd, Lungen.

4.2.4 Providers

The providers of healthcare are mainly classified in two sectors according to the following[89]:

- Hospitals sector, where the patient is considered as an inpatient:
    - Public hospitals supervised by local authorities, towns, states or government which represent about 53% of the hospital sector.
    - Private non-profit making hospitals run by churches or non-profit making organisations such as the German Red Cross with the help of the government and the states, 39%.
    - Private profit hospitals owned by private companies, 8%.
- Ambulatory sector with independent doctors that provide consultations such as check-up and treatments. The patient is considered as an outpatient.
    - General practitioners on contact, which represent about 50% of the ambulatory.
    - Specialists in private practice for example dermatologists, gynaecologists, etc... They count for the other 50% of the ambulatory sector.

In 2003, Germany counted 2 197 hospitals with a total of 542 000 beds. 3.6% belonged to the public hospitals, 36.4% to the private non-profit and 10% to the for-profit. The tendency is a decrease in the share of public hospitals and an increase of the for-profit hospitals one.[90]

In 2003, among a total of 304 100 active physicians, 132 400 of them were working in the ambulatory sector. A large majority, 117 600, worked in collaboration with the SHI and 6 600 of them practised for private clientele[91]. Patients can choose freely their ambulatory providers.

The distinction between these two sectors might sometimes be a little bit fuzzy. Ambulatory treatments can also be provided in a hospital as an ambulatory service. In that case, the patient is not hospitalized and is considered as an outpatient. It is important to make the distinction since the hospital administration deals with both in and outpatient sectors. This can be sometimes confusing when defining in which sector a medical technology is used.

4.2.5 Financing and expenditures of the healthcare system

As shown in Table 3, in 2002 the main part of the financing of the German healthcare system, 75%, came from public sources. Statutory Health Insurance represented the largest input with about 57%. Other sources included taxes and other different types of additional insurances.

The private sources represented about 25% of the financing. Payments made directly from the patients (out-pocket payment) were the main income followed by the private insurances and the employers contributions.[92]

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[89] Bundesärztekammer, 2007-08-23, viewed on 2008-10-01, <http://www.bundesaerztekammer.de/page.asp?his=1.109.112.3>.
[90] WHO, *Highlight on health in Germany 2004.*
[91] Georg Baum, Director general of the DKG, *Basics of the Financing System for Hospital in Germany, 2007-05-07*, viewed on 2008-07-10, <http://www.haiglateliit.ee/UserFiles/File/Tallin%20fini.ppt>.

Table 3 : Main sources of finance, in percentage of total, 1992-2002 [92]

	1992	1994	1996	1998	1999	2000	2001	2002
Public sources	**77.7**	**77.0**	**77.2**	**75.3**	**74.8**	**75.5**	**74.9**	**75.2**
Taxes	13.0	12.9	10.8	8.1	8.0	7.9	7.8	7.8
Statutory health insurance	60.7	59.7	57.4	56.7	56.8	56.9	57.0	56.9
Statutory retirement insurance	2.3	2.4	2.4	1.7	1.7	1.8	1.8	1.7
Statutory accident insurance	1.8	1.9	1.7	1.7	1.8	1.7	1.7	1.7
Statutory long-term care insurance	n. a.	n. a.	4.9	7.0	7.1	7.2	7.0	7.0
Private sources	**22.3**	**23.0**	**22.8**	**24.7**	**25.2**	**24.5**	**25.1**	**24.7**
Out-of-pocket payments/NGOs	10.7	11.1	11.3	12.6	12.3	12.2	12.3	12.2
Private insurance	7.3	7.6	7.3	7.8	8.3	8.2	8.2	8.4
Employer	4.3	4.3	4.2	4.2	4.1	4.1	4.1	4.1

According to the data of the Ministry of Health, the expenditures on statutory health insurance in 2005 reached €143.81 billion[93] and could be split in the different area represented in Figure 13. The hospital sector was the one with the biggest expenses and counted for 33% of the total, followed by the pharmaceutical (18%) and the ambulatory (16%).[94]

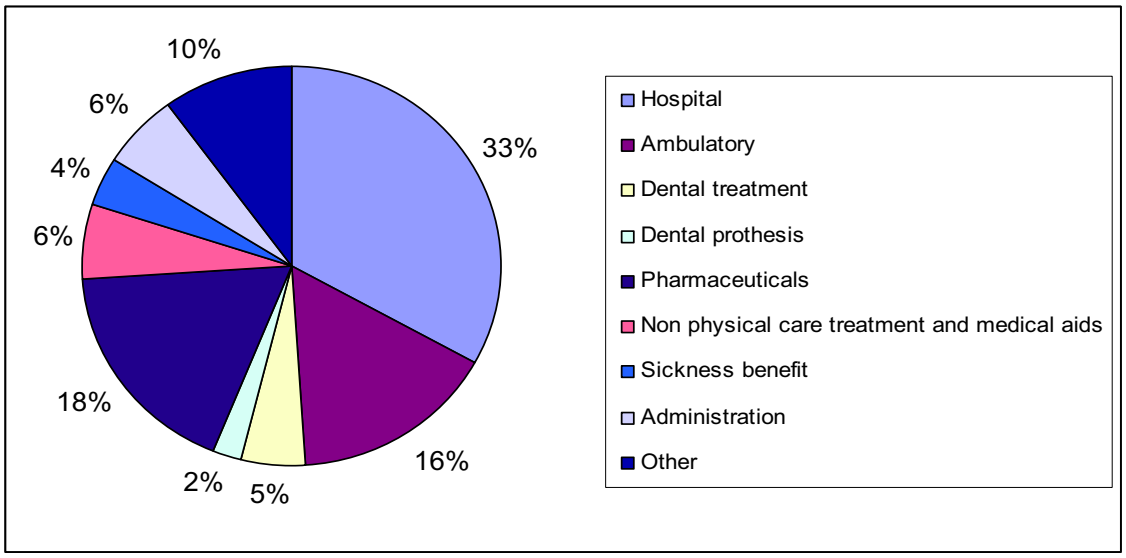

Figure 13 : Expenditure of Statutory Health Insurance in 2005 (%) [94]

[92] R. Busse, A. Riesberg, *Healthcare system in transition: Germany*, Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, pp.58.
[93] Ministry of Health, *Entgültige Rechnungsergebnisse der gesetzlichen Krankenversicherung*, 2005, viewed on 2008-10-09, <http://www.bmg.bund.de/cln_110/nn_1168248/SharedDocs/Downloads/DE/Statistiken/Gesetzliche-Krankenversicherung/Finanzergebnisse/KJ12005,templateId=raw,property=publicationFile.pdf/KJ12005.pdf>.
[94] R. Busse, *Health Insurance in Germany, Benefits and Reimbursement*, Technische Universität Berlin viewed on 2008-10-24, <http://www.mig.tu-berlin.de/fileadmin/a38331600/2006.lectures/2006.10.02_rb_Hakone.pdf>.

4.3 Impact of HTA ψ

In the past the health technology assessments was not a big issue in Germany. Today the assessment's impact on the reimbursement decisions depend on whether the medical product is used directly by the patients, i.e. medical aids, or as a component in a treatment procedure in the hospital or ambulatory sector.[95] Depending on the application area of the medical device under study, the recipients of the HTA report differ and could be the hospital, the Joint Federal Committee, the Institute for Quality and Economic Efficiency in Healthcare (IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen), the German Medical Associations, or health insurance funds.[96]

There are mainly two institutes in Germany with assignments of involving health technology assessments. These are the DIMDI (Deutsches Institut für Medizinische Dokumentation und Information, German Institute of Medical Documentation and Information), and IQWiG. However, neither of them assesses devices in the sense of apparatuses. Rather, 'interventions' are assessed and these may include the usage of medical devices, which in that case are included.[97]

4.3.1 DIMDI

DIMDI was founded in 1969 and is an institute within the scope of the German Federal Ministry of Health, BMG. Its main task is to provide information in all fields of the life sciences to the interested public. The German Agency for HTA at DIMDI, DAHTA@DIMDI, was established in 2000. The agency runs under DIMDI's regime and is responsible for the development and implementation of information systems, specialised databases and HTA reports. The topics are chosen according to priority in need of health policy decisions and the reports include the following aspects:

- Experimental efficacy
- Effectiveness under practical usage in everyday condition
- Comparisons of effectiveness showed by different technologies or devices
- Health economical assessments, which is efficiency
- Social, legal and ethic impacts of the technology

The topic identification is public and anyone can propose a research question. Afterwards, the HTA Board of Trustees determines the topics for future reports. The board is constituted by representatives from physicians, hospitals, insurance companies, nurses, patients and observers from IQWiG and the industry[98]. DIMDI can carry out studies for third parties e.g. manufacturers. DIMDI can also be commissioned by IQWiG. From 2009 the Federal Joint Committee, (Der Gemeinsame Bundesausschuss, G-Ba) will also have this possibility.[99]

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[95] Riesberg, *Healthcare systems in transition: Germany,* pp.153-160
[96] BVMed, *Annual report 07/08*, pp. 9.
[97] A.S. Ernst, information in e-mail from representative of IQWiG, 2008-10-24.
[98] DIMDI, *HTA at DIMDI*, 2007,viewed on 2008-11-27, <http://www.dimdi.de/static/en/hta/basisinfo_en.pdf>
[99] A.S. Ernst.

4.3.2 IQWiG

IQWiG is an independent institute, established in 2004 as a result of the healthcare reform. The institute evaluates the quality and efficiency of healthcare and undertakes commissions from the Federal Joint Committee and the Federal Ministry of Health. The institute gets a share of the reimbursement for inpatient and outpatient healthcare services to finance its activities. The Federal Joint Committee chooses the topics of its assessments.[100] In the ambulatory sector, the KBV (Kassenärztliche Bundesvereinigung) innovation service might assess the technology and if the result is positive, they file in an application to the G-Ba, which commission IQWiG to perform a health technology assessment.[101] However, in the hospital sector IQWiG does not perform classical HTAs; just the medical benefit is assessed. The recommendations from IQWiG though have to be considered by the Federal Joint Committee before decision making.[102]

4.3.3 Voices of the business sector

Thomas Seeger, Managing Director at Medalliance, considers the role of health technology assessments in the hospital sector today as an assessment not officially included in the reimbursement decision making process. Only in rare cases health technology assessments play a role for the reimbursement decisions. HTAs have in these cases contributed in the exclusion by G-Ba of procedures from the system. These have been listed in a catalogue which prevents them from being reimbursed. He mentions that there is a possibility that the G-Ba in the future decides to look more intensively into the hospital sector and to a larger extent limit reimbursement. Thomas Seeger however considers the limited capacity and wide range of responsibilities of G-Ba as a restraint on its ability to increase its exertion to exclude. Around 0.3% of the technologies are at the moment assessed by the G-Ba.

'It could be by chance that your technology is now the one that G-BA is looking at in the hospital sector, and then you have a problem.'

Stefan Zenk, Senior Reimbursement Manager at Medtronic also emphasises the risk when being assessed in an official HTA in an early stage, when sufficient data does not exist.
However, a recommendation could be to perform an internal HTA to better understand the situation the company is facing. In an early stage of the product life cycle there are a lot of approximations about for example the future market situation and the clinical performance of the product. Stefan Zenk discusses the increased consciousness of the situation that could be achieved in such an 'in-house' HTA that e.g. could be a SWOT analysis (Strengths-Weaknesses-Opportunities-Threats).

4.4 Reimbursement system in Germany

4.4.1 Framework of the reimbursement system φ

In the SHI system, in which the majority of the population is insured, different organizations in the respective sectors play an important role to define the acceptance of reimbursement of new products.

[100] IQWiG, *The Institute*, viewed on 2008-11-27 <http://www.iqwig.de/about-us.21.en.html>.
[101] E. Maldonado-Holmertz, Aerocrine, *International Reimbursement for Outpatient Products : Working within the EU Healthcare Market*, presented 2008-06-17.
[102] A.S. Ernst.

The different organizations involved always work under the legal framework provided by the Federal Parliament with the Social Code Book. The general framework of the whole reimbursement system is supervised by the Ministry of Health under the responsibility by the Federal Joint Committee, Gemeinsamer Bundesausschuss, G-Ba. G-Ba was founded in 2004 and is composed of representatives of the sickness funds (9), providers (9), neutral parties (3), and patient (9 but without voting rights)[103]. It is the main institution that is authorised to issue general directives for the implementation of new pharmaceuticals principally, but also diagnostic and therapeutic procedures, medical devices and non-medical treatment in the area of in and out patient cares. The directives can reduce or exclude SHI reimbursement if the assessment does not prove medical necessity and efficiency.

The evaluation differs between medical aids, treatment of patients in ambulatory or in hospital and the distinction between the sectors is a key factor to understand how the reimbursement system is working.

4.4.1.1 Hospital sector

Before 2004, each hospital negotiated its budget with the sickness funds and was usually reimbursed on the basis of per diem (per day) and per case. Each hospital could by itself manage the introduction of new procedures and technologies.

The implementation of the German DRG system, G-DRG, was initiated in Germany in 2004. It is based on the Australian Refined DRG system which was thought to suit best to summarise sicknesses, indications and treatment methods in specific groups and to reflect their costs in an appropriate way. [104]

The initiator of this new system was the German self-administration board which is composed of the German Hospital Federation, Deutsche Krankenhaus Gesellschaft DKV, the Statutory Health Insurance funds, GKV, and the association of Private Health Insurers, PKV.
Different institutions have an impact on the G-DRG definition. However they all work in the framework of the SGB, which rules that medical care in hospitals shall be “adequate, expedient and cost-effective. [105]

The Ministry of Health may reject or define substitutive execution and G-Ba has the power to define directives which exclude new methods from the DRG case. However, the main institution involved in the definition of the G-DRG is the Institute for the Hospital Remuneration System (InEK, Institut für das Entgeltsystem in Krankenhaus). It is directly supervised by the Committee of Hospital Payments which is composed of people from sickness funds and members of the German Hospital Association. [106] InEK is responsible for annual adaptation of the G-DRG system. Its main roles are to collect data from the hospitals in order to calculate the price of each DRG, to adapt of diagnosis and procedure coding in

[103] R. Busse, *German Healthcare 2008 - Learning for others or to learn from?,* viewed on 2008-10-18, <http://www.lse.ac.uk/collections/LSEHealth/ppt/MerckFoundationLecture2008/London080508-GermanHealthCare2008.ppt>.
[104] J.M. Schmitt, BVMed Director General, *Medical Technologies and the German Healthcare System: State and Future*, May 2003, viewed on 2008-10-06, <http://www.bvmed.de/pdf_temp/Medical_Technologies_and_the_German_Healthcare_System_State_and_Future.pdf>.
[105] R. Busse, T. Star gardt , J. Schreyögg, *Determining the “Health Benefit Basket” of the Statutory Health Insurance scheme in Germany*, Eur J Health Econom 2005 · [Suppl 1] 6:30–36, 2005-11-04
[106] R. Busse, *Health Insurance in Germany, Benefits and Reimbursement.*

collaboration with DIMDI and to integrate the change of the DRG mainly asked by the hospitals.

Hospitals get reimbursement according to the price defined in the "DRG case fee catalogue" published by InEK each year. The actual number of cases defined in the 2008 catalogue is 1137[107]. Coding guidelines as well as billing regulations have also been defined. The calculations of procedures in catalogue 2008 were based on 221 hospitals which represent about 2.8 million treatments[108]. These hospitals are volunteers to collect the data and it can change from year to year.

4.4.1.2 Ambulatory sector

The ambulatory sector is more regulated than the hospital sector. According to the SGB, for ambulatory care, the criteria for a medical technology that are necessary are "diagnostic and therapeutic expedience, medical necessity and cost-effectiveness". A Sub-Committee of G-Ba is responsible for assessing reimbursable medical technologies. It decides which technologies need to be evaluated first. Based on the quality of the evidence presented by the applicant and the medical association as well as the results of its own literature studies and assessment made by IQWiG, the Sub-Committee takes the decision to include or exclude a technology in the SHI reimbursement package.

In the second phase, a Valuation Committee, composed of members of sickness funds and federal SHI physicians associations, is in charge of the elaboration of the Uniform Value Scale, EBM, which gives the relative value of the technology compared to other ones. It is also responsible to define exactly the technology and the procedures to use it. A physician that claims reimbursement should fulfil specific requirements determined previously by the Valuation Committee[109]. The EBM list is published by Federal Association of SHI Physicians, KBV.

4.4.1.3 Integrated Care

The consequence of the strict distinction between hospital and ambulatory sectors can be measured in a massive duplication of services, procedures and lack of coordination. The concept of Integrated Care (IC) was elaborated in order to better link up hospital and ambulatory care. IC projects involved different types of providers but there are no special pre-conditions for entering such a program. It is however always better to be able to show the benefits of the IC project in terms of patient care and cost savings, but also the number of patients treated. [110]

The rate of reimbursement is negotiate directly with the sickness funds which are allowed to allocate 1% of the amount of the resources for ambulatory physicians and hospital care to IC projects once contracts have been concluded.[111]

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[107] BVMed news, *DRG-Katalog 2008 published*, 2008-03-19, viewed on 2008-10-13 <http://www.bvmed.de/Start/Aktuell/article/Neuer_DRG-Katalog_2008_erschienen.html?search=DRG>.
[108] BVMed Report, *German DRG-Katalog 2008 published*, No. 11/07 – November 2007, viewed on 2008-10-13, <http://www.bvmed.de/stepone/data/downloads/28/b8/00/report1107.pdf>.
[109] World Health Organisation for Europe, *Country profile: Germany*, viewed on 2008-11-27, <http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020425_2>.
[110] R.Busse, A. Riesberg, *Heathcare in Transition - Germany*, pp.114-115.
[111] A. Inbar, *Alternative Reimbursement Mechanisms for Medical Devices in Germany (Part 1),* Trendlines International Ltd, viewed on 2008-10-31, <http://www.trendlines.com/reim-inbar2.asp>.

4.4.1.4 Medical aids

The medical aids are mainly 'lower'- technology devices and are used directly by patients such as wheelchairs, glasses, respirators etc. Medical aids that are reimbursed by the SHI are listed in the catalogue of handicap aids and medical appliance, Hilfmittelskatalog. The Federal Joint Committee elaborates the general directives. The manufacturer needs to fill in an application that will be sent to and evaluated by the association of the sickness funds, IKK BV, which makes the coverage decision of integrating a medical device into this catalogue. In case of acceptance, the device is classified into one of the 34 product groups and also described under specific designations. The whole procedure can take between four and six months.[112]

4.4.2 How to get into the G-DRG system φ χ

The process for getting a product represented in the G-DRG system is different depending on the type of product and how inventive it is. If the benefit from the product is already financed within the system it is not an issue getting into the system. The hospitals will be reimbursed for the treatment, and this refers to the 'me-too' pathway in Figure 14. For products not covered by the G-DRG system the process is more complex. An application then needs to be sent to the InEK, suggesting a development of the G-DRG system involving the working procedure. However, InEK cannot proceed with the application if the product does not have an existing procedure code, called OPS (Operations und Prozedurenschüssel), that classifies the product within a specific procedure or diagnostic method. This means that, in case the product does not have an OPS code, an application first has to be sent to the DIMDI to get a procedure code. Not until the product has the code issued by DIMDI is it visible to InEK.[113] The coding has actually nothing to do with the reimbursement system directly; it is more a way of classifying and describing different procedures used in the hospitals[114]. To get the code DIMDI evaluates the product and some of the criterions they look at are:

- Whether the method is accepted in other countries?
- The number of patients treated that is affected by it?
- How would it be coded?
- Is the price high enough to motivate a new code?
- Would it be a necessary part of the DRG system?[115]

DIMDI overlooks the existing codes once a year and the deadline for handing in the application is on 28th of February in order to get an OPS code the following year.[116] Important to know is that an OPS code do not necessarily mean that the procedure will be included in a DRG. The OPS codes is for describing the procedures that is used in hospitals and the DRG is

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[112] *EU pricing and reimbursement for medical devices and diagnostics*, 2006, Clinica, Chapter 12, Germany, pp.76-77.
[113] BVMed, *Health System Guide - Introduction of innovative and new medical products into the G-DRG system*, 2007, pp. 9.
[114] DIMDI, *Procedures*, 2008, viewed on 2008-10-30, <http://www.dimdi.de/static/en/klassi/prozeduren/index.html>.
[115] J. Malzahn, *The German Healthcare System and Reimbursement of Innovation,* Hospitals and Rehabilitation Federal Association of the AOK, Brussels 2008, pp.69.
[116] C. Semple Piggot, Optimising *reimbursement submissions where procedure or device codes diverge*, pp.6-8.

a code that the hospitals use for charging the sickness funds for the costs related to those procedures.

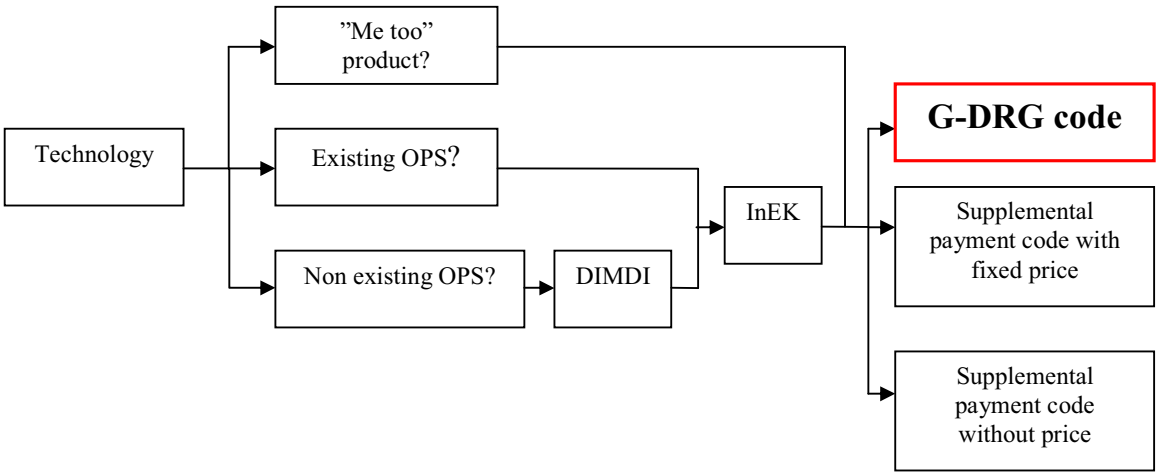

Figure 14 : The pathways to enter the DRG system depend on the type of technology.

‘Me too’ products are already included in a DRG code, no special application is required. Products with an existing OPS code need to be submitted to InEK before being included in a DRG code. The longest pathway is for products without any existing OPS code. Such a code is established by DIMDI, and then InEK can decide to include the OPS in a DRG code.

When the InEK receives a suggestion for representation within the G-DRG system it initiates a calculation of cost and representation procedure. The procedure involves collecting economic data from hospitals in order to assess the costs of the procedure and put a cost weight (CW) on it.[117] In 2006 the number of hospitals that was participating in the data collection was 284, which account for approximately 16 % of all the hospitals using DRGs in Germany. The cost for the whole treatment including personnel, material and infrastructure cost are considered when calculating the CW. The capital cost, such as interest charges, is however not included.

Some DRGs are represented without any CW associated to them. The reason for this is that the data collected either was insufficient for calculation or that the cost variance was too large. There is also something called supplemental fees that are negotiated between the self governed bodies. These are used for reimbursement of very cost intensive procedures. This means that a product can be represented permanently within the G-DRG system in three different ways.[118] The process of including new treatments is initiated once a year when the new OPS codes are made available to InEK. This process then takes about two years, the data is collected during the same year but the calculations takes place the year after and the inclusion of a DRG in the third year. The deadline for handing in suggestions for new representations is on the 31st of March[119].

The process of getting a product into the G-DRG system is usually initiated by the individual hospitals, or working groups at the hospitals, that wants to use the product. Applications can

[117] Malzahn, pp. 36.
[118] J. Schreyögg, *Cost accounting to determine prices: How well do prices reflect costs in the German DRG-system?*, Healthcare Manage Sci (2006) vol. 9, pp.269–279
[119] BVMed, *Health System Guide -Introduction of innovative and new medical products into the G-DRG system*, pp. 9

however also be sent in through the BVMed in collaboration with service providers and specialists.[120] In the case that a product belongs to an already defined procedure or method the manufacturer can file an application in order to get the product represented in the DRG catalogue[121].

As mentioned the time it takes for a product to be represented within the G-DRG system from that the OPS code application has been sent in is between 3-5 years. The first year is for establishing the OPS code and the following years are for the DRG data collection and calculations[122]. During that period the system has another way of introducing and financing new innovations in hospitals, the NUB.

4.4.2.1 Pathway for new examination and treatment method, NUB

The innovation payment has been introduced in Germany in 2005. It is a special transition pathway for new examination and treatment methods called "NUB" (Neue Untersuchtungs- und Behandlungsmethoden). NUB suits for innovation that are not yet included or not correctly reimbursed in the DRG system. The aim with it is also to decrease temporal losses, resulting from the introduction process into the DRG system.

The on-line application for such payment must be filled by the hospitals interested in using the innovation and submitted before 31st of October to InEK. The answer is provided by the end of January for the following year. Even if a method is commonly used among different hospitals, each of them needs to apply separately to obtain a NUB payment which increase significantly the number of inquiries sent to InEK. In the application form, hospitals must describe the new method and answer different types of questions such as:

- What kinds of patients are treated with this method?
- Which present methods will be replaced by the new method?
- Is the method completely or only partly new? Why should it deserve an examination?
- When has the method been introduced in the Germany? In the hospital?
- How many hospitals are actually using it?
- How many patients are treated right now with the new method and how many will be in the future?
- Is the method more expensive than other conventional methods? If yes, provide a description of costs.
- Is the method already adopted in the DRG-System? If yes, which DRG are affected?

[120] BVMed, *Health System Guide -Introduction of innovative and new medical products into the G-DRG system,* pp. 7
[121] Clinica, *EU pricing and reimbursement for medical devices 2006*, p.76
[122] BVMed, *Health System Guide -Introduction of innovative and new medical products into the G-DRG system,* pp. 9

An evaluation is then made by InEK to show if the method is really new in the context of the DRG system. The method receives then a number between 1 and 4[123] .

1. If the method fits into NUB criteria, a reimbursement price can be negotiated between hospitals and sickness funds. Once approved, the reimbursement is valid only for one year. At the same time, InEK will check if the method can be introduced into the DRG system.
2. If the method does not fulfil NUB criteria, there will not be any possibility to negotiate with sickness fund and therefore no payment will be allocated for it.
3. If InEK does not have enough time to check the method before the 31th of January, then it will be part of the negotiation between the sickness fund association and the hospital to get reimbursement.
4. If the application is not clear enough, implausible or not correctly filled, inquire is excluded from NUB procedure and no additional payment will be allocated. [124]

Table 4 gives an overview of the number and the classification of NUB's applications from year 2005 to 2007. In 2007, the number of inquiries from the hospitals was 5 064 which represented 618 different methods.

Table 4 : NUB-Status, results 2005 – 2007 [125]

Year	2005	2006	2007
Inquiries of all hospitals	3 464	3 857	5 064
Inquiries of different methods	983	705	618
Hospitals	386	552	n/a
Status 1 (in brackets: diff. methods)	809 (26)	1 507 (55)	2 312 (70)
Status 2 (in brackets: diff. methods)	1 752 (444)	2 141 (631)	2 340 (528)
Status 3 (in brackets: diff. methods)	903 (513)	- (-)	- (-)
Status 4 (in brackets: diff. methods)	- (-)	93 (16)	332 (16)
Split status (in brackets: diff. methods)	- (-)	116 (4)	80 (4)

About half of the requests (2 312) received a Status 1, which represented only 70 different methods that were integrated in the NUB procedure. Another half (2 340) were excluded of getting reimbursement, Status 2. A minority of inquiries (332) received the Status 4.

NUB is a new process with different advantages such as having reimbursement during the DRG procedure and the fact that a negative reply does not affect the chances of establishing reimbursement in the future. Even if the NUB is valid only for one year, it can be renewed to ensure reimbursement until they get represented in the DRG case fee catalogue. However it has shown some drawbacks. NUB is available only for hospitals asking for special innovations. Moreover, applications for NUB reimbursement are submitted only once a year, which does not help to introduce new innovation quickly. The medtech industry with the help of BVMed is trying to improve the system to make it more dynamic and reactive so the procedures might still evolve during the following years. They try to obtain the right to apply

[123] A. Inbar, *Alternative Reimbursement Mechanisms for Medical Devices in Germany (Part 1)*.
[124] J. Malzahn, *The German DRG System and Medical Innovations*, AOK, 2006-11-17, Düsseldorf, viewed on 2008-11.12, <http://www.swedishtrade.se/medica-06/DocFile/edicaeminar2006__11f6c88a-7100-4a47-8571-4330a7dd8d0a.pdf>.
[125] J. Malzahn, The German Healthcare System and Reimbursement of Innovation.

for NUB during the whole year, to facilitate the introduction of cross-hospital innovations and to reduce bureaucracy in term of time and costs. Another issue is that the NUB is not included in the current cost calculations. The therapies included in the DRG catalogue are based only on past data. As a result, innovations represent only around 0.1% of hospital expenses[126].

4.4.3 How to get into the ambulatory sector φ

The normal pathway, shown on Figure 15, as a manufacturer is to make an application to the Federal Joint Committee, G-Ba for the new technology. A Sub-Committee of G-Ba, which is especially in charge of the process, is responsible for classifying the therapeutic and diagnostic procedures respectively into five and four categories that follows the scheme of evidence-based medicine. However in both cases, at least one study showing level I of evidence is necessary.

Categories for therapeutic procedures:

- I. Randomized controlled trials
- IIa. Other prospective studies
- IIb. Well-designed cohort or case-control studies
- IIc. Temporal or regional comparisons
- III. Other studies and opinions

Categories for diagnostic procedures:

- Ia. Studies demonstrating a benefit in patient outcome
- Ib. Controlled study under routine conditions, allowing the calculation of sensitivity, specificity and predictive value
- II. Other studies allowing at least the calculation of sensitivity and "specificity"
- III. Other studies and opinions.

This classification is based on assessment made by IQWiG, which include benefit, medical necessity and efficiency. According to this classification, the Sub-Committee elaborates directives whether the technology should be included or not in the SHI benefit package. In case of a positive answer, the Valuation Committee elaborates the level of reimbursement. [127]

[126] BVMed, Press release*, Industry wants improvement of innovation clause*, 2008-03-28, viewed on 2008-11-15, <http://www.bvmed.de/presse/pressemitteilung/BVMed_setzt_sich_fuer_Verbesserung_der_DRG-Innovationsklausel_ein.html?language=2>.

[127] World Health Organisation for Europe, *Country profile: Germany.*

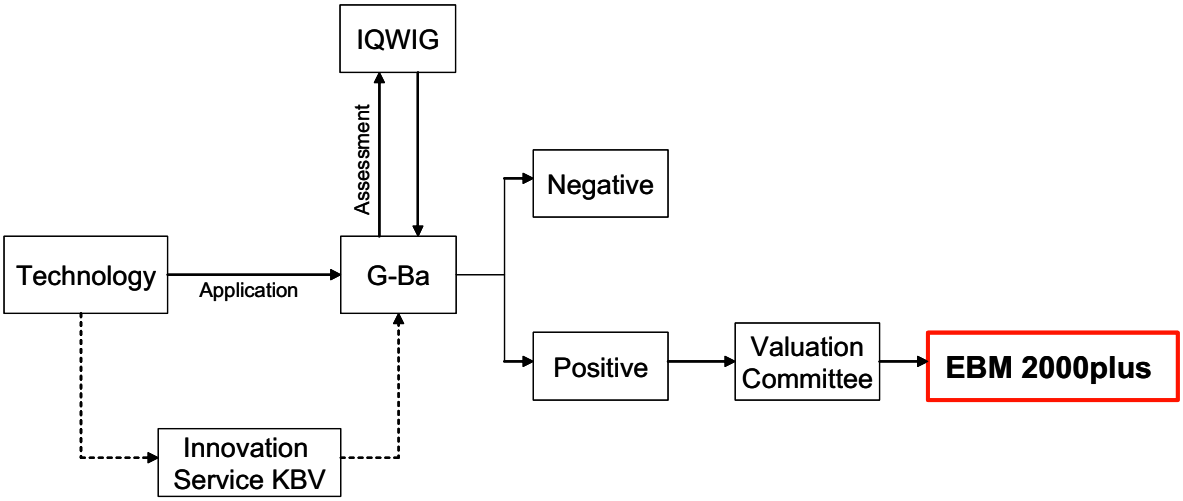

Figure 15 : Scheme of the paths to enter the EBM catalogue.

Application at G-Ba for a technology is made by the manufacturer. IGWIG assesses the technology for G-Ba, allowing the organization to take a decision. In case of a positive answer, the Valuation Committee decides of the level of reimbursement. Innovation Service KBV can be used in order to facilitate the application at G-Ba.

Another pathway is also possible in order to accelerate the whole procedure. The manufacturer needs in that case to enquire at the Federal Association of SHI Physicians, KBV (Kassenärztliche Bundesvereinigung) and its Innovation Service.

4.4.3.1 KBV Innovation Service

In order to accelerate the process of introducing a new medical technology into the EBM catalogue, KBV introduced in 2005 an innovation service[128]. This service is free of charge and is basically an initial assessment to determine the potential of the innovation. The evaluation is made on the quality of the available information and data with respect to benefit, medical necessity and economic rationale of the procedure under the following questions:

1. Is there a clear definition of the disease/condition for which the innovation should be used?
2. Are clear inclusion and exclusion criteria defined for use of the innovation in that disease/condition?
3. How many patients are affected?
4. Which data/evidence is available to show the efficacy of the new method (case reports, cohort studies, randomised clinical trials, HTA etc.)?
5. Are the used endpoints relevant for the patients?
6. How many patients are documented in the "scientific core" data?
7. Which data concerning safety is available?
8. Which diagnostic or therapeutic alternatives are currently available for patients provided by the public health insurance companies in Germany?
9. Which health economic data is available? [129]

[128] E. Maldonado-Holmertz, Aerocrine, *Reimbursement in Germany*.
[129] R. Schiffner, *Criteria used by the KBV-innovation service for decision on proposals of medical, non-pharmaceutical innovations to the German Federal Joint Committee (G-BA),* Poster, 2008-04-07, viewed on 2008-11-10<http://www.kbv.de/innovationsservice/innovationsservice.html>.

The time for KBV to perform this assessment depends on the degree of sufficiency of the documents available but also the degree to which the information is based on scientific literature. If the assessment is positive, KBV can decide to fill an application for G-Ba which will then ask for the official HTA, provided by IQWiG, and take the final decision to include the device into the EBM. This is approximately a three months process. [130]

[130] E. Maldonado-Holmertz, *Reimbursement in Germany*.

5 Results and analysis of the case studies

The cases are based on information from the interviews, the companies' homepages and product brochures as well as from articles about the companies.

5.1 Launching companies

5.1.1 Case study 1 φ

The interviewee, Person 1 was the CEO of Company Alpha. He has a financial background and has worked in different part of the industry, first with retailing and later for one of the largest Swedish healthcare providers. He worked as a consultant until the beginning of 2006 when he joined Company Alpha. He started as CFO and later became the CEO.

Company Alpha
Company Alpha was founded in 2003. The two founders were working with a technology similar to the one that is currently marketed by the company, here called Product α. They found a way to improve it thanks to a family member that was an engineer. From the start, Company Alpha was financed by four Swedish VC firms which gave it the first financial round in 2004. At that time, the people working in the company was mainly persons close to the two founders. Company Alpha was a kind of a family business. This structure has changed during the years due to internal issues but also due to that the company was in a lack of know-how and experience about the medical industry. The present management team was appointed in 2006 and the new CEO in 2007.

Nowadays Company Alpha consists of seven persons; the CEO, Person 1, which is in charge of quality and training, a person responsible for the sales in Europe and customer education, a marketing manager, an engineer, a regulatory manager, two persons that works in the United States, a sales manager and an assistant. The current team raised the latest round of financing in mid-June 2008.

Product α
The technology was patented in the end of 2004. The company received a CE-mark in mid-June 2005, as well as a FDA approval, in October 2006. This was done without any clinical trials, just using a literature study.

Company Alpha started the production of Product α directly after the foundation. The production site is located in Sweden. Product α is mainly in competition with the traditional system, Product T. The main difference is that Product α gives objective measures of pressure and flow whereas Product T is more subjective since it the clinician needs to do a visual evaluation. In case of doubt in this evaluation the patient is kept in hospital to prevent any problem.

Clinical studies have been performed in different places to point out different advantages. The first study was performed in Sweden to prove the safety and the efficiency. Then two studies, in the US and Italy were used to prove that the use of Product α reduces the number of days the patient needs to stay in the hospital by one. The length of hospital stay is currently between four and eight days for this kind of health problem. A third clinical study was done to compare Product α and Product T and their inter-variability. The last clinical study just started

in the US and will probably be finished in October 2009, with mid-term results expected for May 2009. In the long term, Company Alpha wants also to show that Product α can reduce the number of X-ray examinations needed to check the patient health status.

Marketing strategies
Product α were first used in the sites where Company Alpha did their clinical studies. The company is now in a launching phase with 130 units sold in the US and 200 units ordered in Italy. The main strategy is to build its cases with physicians it already has contact with and focus on centres of excellence in order to be able to spread the products on the whole market. Person 1 mentioned that this phenomenon already can be seen in Italy. The two Italian clinics that ordered the product are not the ones where the trials were performed. Word of mouth of the physicians has been useful.

The case in Germany was a little bit different from the cases in other countries. Company Alpha did an attempt to enter the German market 2.5 years ago, in 2006. However it failed because of technical issues of the product. In 2007, the company tried again and was then focusing on a specific site near Munich. The attempt was unsuccessful for different reasons. In 2007 the German payment system was still in transition and the habits of the former German system were kept and these gave no incentives to reduce the number of hospital days of the patients. Therefore, the argument used by Company Alpha was not beneficial for the clinicians. At the beginning of 2008 the company decided to focus on centres of excellence and key opinion leader in Vienna, Austria and Zurich, Switzerland. The aim was to use these German-speaking countries to build a case and convince German clinicians. Person 1 plans to start the first sales in Germany within a year from now, at the end of 2009.

From experiences Company Alpha realized that the clinicians needed to use Product α between 15 and 20 times to be convinced of it. Therefore, as a strategy, the company provided some products at a 'lower price' during the first months when the clinician tried the product. Company Alpha is at the moment looking for collaboration with an industrial partner as it will cost them a lot of money to gain market access.

Reimbursement issue
Company Alpha ordered a report from an American consultant firm about reimbursement in the US. The conclusion was that the medical procedure of Product α was fairly similar to the one currently used in the US. Therefore, Product α will not have any difficulties to be included in a DRG there. Related to that, the interviewee did not think that it will be an issue to get reimbursement for the product in Europe either.

"It's not so much about the reimbursement system in Germany, it's more to get experience in one hospital and getting in there and show them that they are saving money."

He thinks that for Product α, *"it is only more costly and more time consuming to walk into the reimbursement system to get our own code"* than using the present one. Therefore the company has not planned to apply for a new procedure code. The pricing of the product was not clearly defined when the interviewee entered the company. The first estimation was to price Product α 10% higher than the products on the market such as Product T. However, Company Alpha realized that it would not be able to cover the production costs with such a price. Nowadays, the price of Product T is on average €50. Company Alpha intends to price Product α between €120 and €200.

Some brief cost-saving calculations have been made by the company to be able to convince the clinicians of the benefit of the product. One day in hospital corresponds to around €400-500 according to the interviewee. The argument is that using Product α saves at least one day. Even though Product α is more expensive, the hospitals will save money at the end. Company Alpha is planning to use the studies performed in order to convince the clinicians.

5.1.2 Case analysis 1

The company was founded around an existing product that the two founders wanted to improve. The development of the technology did not take so much time as the basic concept was already proved. The challenge was more to bring Product α to the market.

The structure and the people involved in the company have been completely reworked compared to the start. It has changed from being a "family business" with limited experience in the medtech industry and with informal network to become a team of more experienced people. For example the current CEO has a background as a consultant as well as an employee in the healthcare sector. His network can be an advantage for the company.

Alpha is VC financed. However, it appears from the interview that the owners do not influence the decisions taken in the company. They do not put too much pressure on the company in the sense of an acquisition as can be seen in other cases. However, Alpha believes that it might be difficult to reach the market by itself. Therefore the company plans for a partnership as it seems to be the best alternative according to Person 1.

The strategy of the company changed several times during its early years. This was due to that the people involved were exchanged. The current marketing strategy is quite well defined in terms of which markets the company aims for. The focus is on the US and Italy where some products already have been sold or ordered. It was also in these two countries where Alpha did the clinical studies about the reduction of the length of stay. In Europe, the current aim is to gain the German speaking countries by first entering Austria and Switzerland. After that it will be able to reach Germany, where it has already failed twice.

Nowadays Company Alpha seems to only focus on these markets since no other countries were mentioned as future markets in the interview. As many companies, Alpha aims for the recognized centres with key opinion leaders, KOLs, to be able to reach other hospitals. It can already see the spread of the technology across Italy which might indicate that the choice of the first two centres was a strategy that worked for Alpha. The strategy to sell Product α is mainly based on showing the clinicians the value of Product α compared to Product T. The arguments about its benefit are essentially based on the fact that Product α is cost-effective as it decreases the number of days spent in the hospital by one but also since it could reduce the number of X-ray examinations. The latter still needs to be supported by more clinical data.

The pricing of the product was an issue when Person 1 joined the company. No real pricing strategy was established. The price was set, 10% higher than Product T, but without having made basic calculation on the costs. Nowadays the calculation for the pricing strategy is based mainly on the benefit provided by saving one day in hospital. However, in order to encourage the clinicians to test Product α, the company gives 'special discount' to promote the product.

Person 1 seems to be aware of the reimbursement issue since Alpha ordered a report from an American consultant firm. The report examines in deep the question of reimbursement for Alpha in the US. Moreover, when Alpha tried to enter the German market in 2007, the interviewee experienced that the payment system affected the clinicians' decisions. The

argument presented at that time, which was the reduction of hospital stay, made clinicians losing money in the German system. As the German system has changed with the introduction of the DRG, the argument now fits better.

5.1.3 Case study 2 ψ

Person 2 at Company Beta is an international director of marketing and sales. The interviewee was employed in 2006, as employee number twelve in the company and was the first sales oriented person. The interviewee has a long and international experience from marketing and sales in medical technology businesses.

Company Beta
The background of Company Beta's first product goes back to the year of 1996 when the basic science and the development of the technology behind it was started by a professor and his PhD students at the University of Lund. The company was founded in 1999 and is still situated in Lund. Very recently, Beta acquired another small company and today Beta holds a personnel force of 29 persons. The aim of the company has been, from the very beginning, to be a major market player and to build the company in a structured way.

The Product β is an implant and there are other companies trying to solve the same health problem as Company Beta's product does. The particular properties of Beta's product are mainly the new material that has been developed but also the simplified procedure for the doctors. The focus of this case is Product β, which is the second product of this company. It is based on the same technology as the first product but slightly modified to better fit its new application.

A multi centre clinical study was performed in Germany. Six hospitals investigated in total 41 cases, which was more than anyone else had done before to treat the same health issues. The study was initiated in 2005 when the recruitment of clinical centres, doctors and patients started. Initially, six months were planned for the study but that changed to 18 months. The study was finished in February 2008. The final report for regulatory approval was filed in for assessment in September the same year. Product β received the CE mark in November 2008, and was at that time about one year late compared to the original plan.

Marketing strategies
As Company Beta is a small company with limited resources they will focus on just a couple of markets. Germany is one on those. The US are by far, the biggest market for this product. Annually, around eight times more procedures are performed there than in the second largest market, Germany. The company has one marketing and sales person established in Germany, compared to two in the United States. The aim is, with the establishment in Germany, to also reach other German speaking markets such as Austria and Switzerland. A set up of distributors in Italy already exists but since the delay of the regulatory approval they have not sold any product yet. The delay of the CE mark also put off the launching plan at the German market until the beginning of year 2009.

The strategy is to try various sales models. A direct approach will be used in Germany where they want to employ direct sales people. The reasons for choosing Germany was partly because of its market size but also because the clinical study was performed there. Therefore contacts have already been established with university hospitals and physicians in these sites

where the studies were performed. The very structured reimbursement system in Germany was another reason for the choice.

Though Sweden is the home market of Company Beta it is not in focus. One reason is the limited market size but the main reason is that the healthcare system is not setup to perform the procedure; only two or three doctors are doing it on their regular basis. The general practitioners are partly unaware of the underlying reasons of the health problem and therefore no patients are referred to the doctors that perform the procedure.

Present reimbursement situation

The product already has an existing OPS code in the German DRG system. The traditional procedure is not approved for out-patient treatment, only in-patient procedures are allowed and are reimbursed at about €3700. Another competing product, Product C, has its own code and the level of reimbursement for its procedure is around €7800. Multiple procedures are needed for some patients. The reimbursement level is almost the doubled when the patient is treated with Product C but the traditional procedure, including Product β, remains on a fixed level. The hospitals are therefore very much interested in the product C since the cost, in this case, does not go up proportional to the reimbursement level.
Globally, the pricing of the traditional procedure is around €500 compared to the Product C's procedure that is around €2700.

According to the interviewee, it is possible for Company Beta to work on a lower price level than the competitors. The intervention of all the competing technology is much more of an operation. In fact, the technology of Company Beta might enable the transform of the procedure from in-patient to out-patients. However, the German system requires a minimum of stay of around seven days for patients treated according to this existing procedure. The hospitals try to keep their patients because if they leave earlier the level of reimbursement goes down.

The late date of when the regulatory approval was achieved resulted in that Beta just missed the deadline for the NUB application. The admission to get into the DRG system needs to be filed in the end of February and the considerations within the company is that they will not manage that. A realistic plan is then that Product β, or a modified version of it, will be included in the German DRG system in 2011.

Dealing with the reimbursement issue

The person employed in Germany is involved in the reimbursement issue, but Company Beta does not have any particular employee that specifically deals with the reimbursement. A consultant was commissioned specifically to look at the German market and how the existing procedure works. Right now they are looking for various options to use consultants to work with the issue. But according to the interview respondent it is more a question of time before they will need in-house resources. During the nearest one to three years probably one person will be needed. Two or three more employees are estimated to be needed in the future three to five years.

The challenge of Company Beta, as they see it, is to play at the higher price level. They do not want to be in the traditional €500 class since they believe that they have a superior offer. In Europe they are thinking of pricing the product at around €1700. To reach this higher price level Company Beta must provide more than just the material as they basically think that they do today.

"We want to be able to say that here is the Beta procedure or solution and we want to get a specific code for that. So that is our basic strategy, but we don't have the technical solution for that yet."

Company Beta aims at having its own specific procedure. At the moment Company Beta is at the stage where the clinical studies have shown the safety and efficacy of Product β. However, health economic data collection was not in the focus of this study, some standard protocols assessing the quality of life, was filled in. The next challenge for Beta will be to prove the health economic benefits of Product β compared to the other procedures performed today. The data that exists today is not considered strong enough to build a health economic case. An advantage is that the clinical series now can be performed as post marketing studies, which means that revenues can be generated at the same time.

A small study in which the focus was to assess the quality of life has already been performed in Sweden. The study was not big enough to prove anything significantly. Though a clear trend is that Product β, compared to the different competitors' alternatives, added benefits in terms of quality of life could be seen. To get the evidence of the health economic benefits Company Beta thinks that they must perform a large study, which would be very costly. Therefore, the company is instead now trying to encourage doctors to use Product β and at the same time test it. These doctors are partly financially supported, and in the end it might be a break even deal for Company Beta. The gain for Beta is the clinical evidence that is gathered and documented in the doctor's clinical papers.

The actors that are most important to convince about the benefit of the product are, according to the representative from Beta the doctors that actually carry out the procedures but also the health authorities and the health technology assessors. Since they have their CE mark and have started to work on the market the respondent says that "*we will certainly soon be on the radar screen".* The interviewee also emphasized the importance of building relationships with the key opinion leaders, who sometimes are desired in an advisory board. They are of particular importance for a company that wants to bring in a new technology into the system. "*They are the ones that actually encourage the system to change".* To get advice and to be recommended by them is important, especially for small companies that do not have the heavy lobbying strength as the big companies do.

5.1.4 Case analysis 2

Company Beta started, like many other companies have done, as a university project, which was considered to have a great potential and was therefore commercialized. Product β is not the first commercialized product of Company Beta. The experiences from the first product's market entry seem to have influenced the awareness of the different steps in the commercialization process. In addition, these experiences might have counteracted the risk of becoming infatuated with pride of the own product. Even though Beta is restricted in its activities due to limited resources the company seems to have enough money to be confident about planning future activities. Company Beta has tried to structure itself so it looks as much as possible like the organization of a big company. The first person focused on marketing was however not employed until one year after the start of the clinical trials. This person was also the one that started to deal with the reimbursement issue. Today it looks like Beta, to some extent, affords to employ or consult specialists for particular assignments within the company. Usage of specialists also allows Beta to eliminate some of the uncertainty in the planning,

since decisions might be based on experiences from these persons. Such experiences increase the awareness of the different alternatives available but the potential pitfalls might also easily be predicted.

Company Beta chose its markets mainly due to their size. US were prioritized as well as the biggest markets in Europe. Germany was also referred to as having a structured system. To enter the European markets Beta believes that the physicians and health technology assessors are the most important actors to convince. When these physicians have been convinced by the product's value and when there is enough data, the larger group is thought to adapt the new product. Beta wants to create a new DRG code. For that purposes Person 2 thinks that it is of particular importance to convince the KOL of Product β's value. In Germany, Beta aims to enter the market through a NUB.

Company Beta believes that Product β has a superior value and that it therefore should have a higher price than the competitors in the traditional procedure. However the current level of reimbursement for the DRG code that Product β fits in today is not enough to cover this increased price. The long term objective is therefore to create a new DRG code with higher reimbursement level than the one today. The reason is that they want to be able to charge the hospitals a higher price. The company behind Product C created successful such a new code, which allows them to charge a higher price. It seems like Beta wants to imitate this competitor's strategy but are not, however, expecting that high level of reimbursement.

Product β's history shows signs of underestimation about the time needed for getting a regulatory approval. This process was delayed by approximately one year. Person 2 seems to be more pessimistic in his estimations about when Beta will establish reimbursement in Germany for Product β. The application deadline to DIMDI, that was four months after the regulatory approval, is not expected to be reached. The plan is instead to file in the application before February 2010. Company Beta mentions different German organizations involved in the reimbursement process and seems to be aware of the different pathways into the DRG system. In addition, the pessimistic considerations about when they will establish reimbursement also show an awareness of the potential difficulties that might be faced in the reimbursement process. Person 2 also mentioned that a few persons will be needed soon in the company with the purpose of dealing with reimbursement.

It was not prioritized to gather health economic data during the studies that have been performed. Some basic forms have though been filled in. However, Beta has an aim to collect evidence of the health economic benefits but the costs restrict the company from performing a study for this specific purpose. The data will be gathered when the product is tested by interested physicians.

5.1.5 Case study 3 χ

The interviewee, Person 3, is a sales and marketing director at Company Gamma. Person 3 was employed by Gamma in April 2007 and has a long and international experience from marketing within the pharmaceutical industry.

Company Gamma

The history of the company goes back to year 2000 when the first idea of the product came up. It started with an expressed need from the market, the head nurse of the county hospital in Halmstad had some incidents with patients and she was surprised that the monitoring devices

did not indicate that something had gone wrong. She thought that something had to be done about this, so the hospital contacted an external innovation company to bring forward a solution to the problem, which it did. Company Gamma was formed in 2006 and was set up as a spin off from the innovation company. Today Gamma employs about 25 people and has their head office situated in Sweden. They also have an office in the US and a production facility in Malaysia. At the managerial level in Sweden they have four people; the CEO, the CTO, the sales and marketing director and a product marketing manager. The company is owned and financed by local investors from Sweden and the goal of the company is to grow by itself and not be acquired by a larger company.

The product that the company sells, Product γ, is for monitoring purposes. It is used as a complement to a treatment used mainly in the outpatient sector. The treatment can be done both in hospitals or smaller clinics, as well as in the patients' home. The product is split in two parts; one consumable part that is attached to the patient and one alarm unit, which also contain all the intelligence of the product. The value that the product brings to the clinics is that the nurses do not have to be in the same room as the patient during treatment as long as they are in the reach of the alarm signal, so they can act on a mishap. The device will alarm with a sound as soon as something has gone wrong and the patient is in danger. The nurses will then be able to abrupt the treatment in time so the patient is relieved from longer hospital stay or in worst case death due to the mishap. The number of treatments done each year, in which this product could be used, is about 200 million throughout the world and in 1 out of 5000 there is a mishap that endangers the health of the patient.

Gamma has performed several clinical trials with Product γ in Sweden. These were limited to six weeks and the aim of them was to test different parts of the product and to see if they worked as intended. Besides that Gamma has also done studies in other countries, Glasgow for example, to evaluate the reception of the product from nurses and patients. In total they have 352 treatments in their studies. Product γ was CE-marked in 2006.

Marketing strategies

Today Gamma is present and selling their Product γ in Scandinavia, UK, Ireland and the Benelux countries. They have also begun selling the product in the US and the company has focused a lot on that, which has meant that they have not had the time collect knowledge about other markets. Now Gamma has started to deal with other markets such as Germany, Italy and France. Germany they consider to be an important market due to its population of about 80 million. For Germany they started the process in September and they expect to have their first sales within 6 months from now. Their strategy in all of their markets is to use established distributors and let them take care of the market specific issues. The criterions on which they choose their distributors are that they should have a good network and are selling other products within the same area already. Person 3 thinks that this will help promoting Product γ to the hospitals. Right now they are working with a consultant from Germany that is screening the market for possible distributors Gamma can work with and set up meetings with them.

Present reimbursement situation

There are reimbursement codes for this kind of treatment in Germany today. The procedure is included within the outpatient sector and therefore not a part of the German DRG system. However, the reimbursement codes do not explicitly include this monitoring device. Gamma has not looked into the specific reimbursement levels in Germany but will be using just about the same pricing of the product in all the markets. The product is quite cheap compared to the

whole treatment and costs about €300-400 for the alarm unit and €2-3 for the consumable part. There are differences between countries, and they were described by Person 3:

"…the alarm unit is like a cell phone for the cost, you know it changes depending on the market and so. The patch, which is a single use, is more like a cup of coffee."

Dealing with the reimbursement issue
Gamma sees the German market as complex and that is also one of the reasons why they have waited to deal with it. One of the major difficulties will be to get the hospitals to give away a little bit of their profits from the reimbursement for the treatments done and invest in Product γ as safety for the patients. The strategy Gamma will use to make this happen is to try to change how the hospital administration and other decision makers look at the product. Gamma will try to show them how they actually may make money from it instead. This can be done in several ways.

The focus will initially be on selling the product to bigger reference centres in Germany and start clinical evaluations there to see how they work with the product and get references that Gamma, or the distributors, can use in their contacts with other hospitals.
Gamma has not yet made any health economical studies about Product γ but might consider doing that in the future. The resources of the company have not, so far, allowed them to start such studies;

"We need to reach breakeven, and then, when we have more money, we can do those studies that I want to do to show this business case."

As of now Gamma is collecting knowledge about the German system and cannot today say if they are going to go for their own coding or not. In the US they have applied and got their own coding and as for Europe Person 3 says:

"…that would be a route that we could run from the head office, that we could sort out the coding in one country and let other countries look at how they do in Sweden for example."

The main strategy, as mentioned, will be to run the market through distributors and let them handle the local market issues, such as reimbursement. Within the company Person 3 estimate that they spend about 20 % of their marketing budget on reimbursement related issues. As for the time frame Person 3 estimates that they will have sorted out the reimbursement process in about six months, but she points out that she is not really aware of the situation in Germany yet.

5.1.6 Case analysis 3

Company Gamma cannot be considered to be a spin-off from a hospital or the university. The idea indeed emerged from these settings, but the actual development of the technology and the commercialization of the product is something that was done by a company specialized in bringing forward new technology. That has had an impact on the development and the financial situation as the innovation company already must have had an established network and procedures for how to deal with the commercialization process. That might be a reason that Company Gamma is not owned by venture capitalists today. The company has a managerial group that to a great extent is marketing focused, two of the persons are working

with marketing oriented issues. This means that the company has overbridged the problem with the entrepreneurial product/technology focus the last couple of years.

Product γ is the first product of its kind out on the market and therefore Gamma might have the advantage of signing up the important distributors and hospitals which can help them. It seems that the company has been focusing on close markets in Europe to begin with, and the size has had little to do with their decision of where to go. The US are an exception of course. As Gamma will use distributors as a sales channel out to the market they do not have any specific plan for which hospitals they will turn to at the beginning. However, they seem to have thought about the issue and they picture that the distributors will go for the big centres first. The choice of markets has affected their knowledge about the reimbursement system in Germany. They are not aware of how it works but are looking into that now. The question is whether the product can be included in the ambulatory reimbursement system. According to the 9 bullet points that the KBV assess at when they evaluate new devices there is a lack of health economic data of the product today. However, on many of the other points Gamma seems to be able to provide answers. For example there is a clear definition of the condition, it is known how many cases there are per year, and statistics on the number of mishaps exists. The health economic studies that Person 4 said she wanted to do might be important for their reimbursement process in Germany since it would strengthen the economic case of the product. The company seems to have a good picture of what value the product bring to the market, less liability processes, extra safety and the opportunity to make money out of the product. What they need is economic data showing the actual numbers.

The pricing of the product seems not be a parameter that Gamma will use explicitly to build the reimbursement case in each country. The pricing will be just about the same everywhere. Whether or not that is a good strategy is hard to say, but since there are no competitors out on the market and there are differences in payment systems and liability processes between countries the value of the product might be different. They might therefore miss the opportunity to optimize the pricing of the product on each market.

The fact that Gamma has been working with reimbursement and has established a new coding in the US shows that they are aware of the issue. However, the experience they gained from that process is not a guarantee for success in Germany. Their consideration to establish reimbursement in one country and use that as a reference relies very much on what country they choose. Since the healthcare systems in Europe are different from one another the result from the reference country might not be applicable everywhere.

5.1.7 Case study 4 χ

This case, describing the situation for Company Delta is built on an interview with the CEO, Person 4, of the company. Person 4 was employed by Delta in 2006 and has a long and international experience from medical technology business.

Company Delta

Company Delta was founded in Umeå in 1998 by two medical doctors at Umeå University hospital. They saw the need to improve the existing treatment done at their department and came up with a solution to minimize the side effects of it and make it more effective. The two doctors developed the idea and the technology in Delta and thereafter they sold the company to a group of entrepreneurs, also situated in Umeå. These entrepreneurs started to develop the concept and brought it to the Swedish market, but they lacked the financial resources to enter

larger markets abroad. Therefore they sold the company to its current owner, a large Swedish medtech company. The original founders are, however, still involved in the company as scientific advisors.

The company has only two employees, the CEO who sits in Sweden and one employee in Finland. Otherwise the company is working with consultants at the managerial level. It has one that deals with quality, one for finances, one for production and another one for R&D. The reason for this, according to Person 4, is that they do not want to spend resources internally on hiring full time people until they know where they will be in the future.

The company's first product was launched about ten years ago and has been sold in Scandinavia until now. However, the product has become obsolete and therefore Delta launched a new version, Product δ, in 2006 that they plan to market also outside Scandinavia. The health economical value of the product is that it makes the overall treatment up to five times as effective as it would have been without the device. Fewer hospital visits along with less side effects for the patient is the value the product brings to the market. But there are competitors doing just about the same thing and that have an impact on the marketing strategies for Delta. Some of these competitors are already established in Germany.

Delta has a good market share and a strong position in Scandinavia. This is the strategy of the company according to Person 4, because since Delta is a small company it needs to have a strong base to rely on when entering new markets.

Marketing strategies

Delta's first market outside Scandinavia was Spain. However, according to Person 4 the market is not mature enough for Product δ and the sales have therefore been low. When choosing the target markets Delta has prioritized after what Person 4 sees as mature enough markets. By that he means that the hospitals have invested in the technology that Product δ requires and if they have the knowledge to use it. The countries that Person 4 considers to be the most mature ones in Europe within this field are, besides Scandinavia, Germany, UK and that is also the next countries they will enter.

Delta started the process of marketing the product in Germany in February this year and plan to have the first sales in the beginning of next year. The strategy will be to go direct in Germany without any distributors. The person who will handle the first contacts is Person 4 himself since he has experience from selling medical devices in other companies and can use his network to get hold on the right persons. After a while when the market has been penetrated and the contacts has been established Delta will hire local sales people to take care of the selling. When that will be is up to Person 4 to decide.

Present reimbursement situation

Product δ is a part of an existing treatment that is reimbursed in Germany today. The treatment is considered to be an outpatient treatment in Germany and is therefore not a part of the German DRG system. The product is not yet on the German market and can therefore not officially be considered as included in the outpatient sector either. But that is however not a problem according to Person 4 since consumables are quite easy to get reimbursed compared to more capital intensive equipments. Therefore Delta has not and do not intend to put any effort into the reimbursement issue. Since all the coding is there and the product has a clear health economical value Person 4 does not see the need for it. Implicitly he will deal with it when marketing Product δ.

Dealing with the reimbursement
The strategy Delta will use for marketing Product δ is to go to the big hospitals in Germany and get them to start using the product. The reason for this is that Person 4 has heard from the smaller hospitals that they might have some problems with reimbursement for this device. That means that Delta would have a hard time getting in to those hospitals and start selling. If they instead concentrate on the bigger hospitals which are not affected by the reimbursement issue in the same way and start selling to them it would be an easier entry on the market. This approach will also help Delta to market Product δ at the smaller hospitals later on. When the clinicians in the big hospitals start using the product Delta will use them as references to the small hospitals to see how to solve the issue of reimbursement. Then the company will be able to provide both numbers about codes and pricing as well as contacts at the bigger hospitals.
The price of the product is something that Person 4 does not want to give away. He points out that:

"*…the pricing is always a question of the quality, your competitors, your production cost…so that's by what I put up the price.*"

As sales argument for the hospitals Delta relies on 5 years of clinical and follows up studies from the former product, and since Product δ is basically an upgraded version of that one the results can be applicable to great extent. Besides that Delta has done its clinical studies, they also have results from treatments and references from experts within the actual area.

5.1.8 Case analysis 4

Company Delta is like many other small medtech companies a spin-off from a hospital. In this case the inventers were the medical doctors that invented and developed the technology, but they were not the same as the entrepreneurs that commercialized the product, as the company were bought by a group of entrepreneurs. For the company that meant that the lack of market knowledge, important networks and manufacturing capabilities to some extent could be overlapped. It is not that farfetched to believe that the founders of the company lacked the necessary knowledge to develop a product for the market as they were medical doctors with no experience from commercialization activities. However, the takeover was not enough to bring out the product on a broader market. The new owners did not have the finances to go outside Sweden and since Sweden is not a big enough market for sustainable growth of a SME this became an obstacle for the company. The final takeover by the large firm solved this problem as the financial situation then improved. Today the company aiming at going abroad, but the lack of resources are still apparent and a sign of this can be seen in the fact that they mainly have consultants working at the managerial level.

The CEO of today faces a completely new situation than his predecessors. The company has now got a commercialized product that it can bring to the market and it has the financial resources to do it abroad. In this the CEO has taken the role of a marketing manager as well. In this role he is very much relying on his own informal networks and experience gained when marketing the product, instead of using the companies established channels out on the market. This has of course a lot to do with the fact that the company hasn't been abroad before and have no channels, they need to be built up. He does not seem to put too much value into the own technology, but are aware that there are other products with approximately the same value. This has an impact on the marketing activities that he performs. Person 4 is aware that the competition with other products is not just about having the best technology, but also to communicate the value to the market. His strategy for doing this is to go for the

early adopters, both countries wise and within the specific markets. The decision of where to go is based on the maturity of the markets, if they are ready for the product and if they can handle the reimbursement issue today. The time plan might be more uncertain as he today do not know when he will expect to have established sales enough to build a sales force around, he relies here on his experience for knowing when that will happen. The pricing was an issue that Person 4 did not want to go in to more specifically. Since there is competition on the market there is a need to position the product according to the competitors. The experience the company has gained from other markets is mainly from Spain and Scandinavia. For Product δ however, the sales in Spain has been low.

The reimbursement is nothing that Person 4 considers in his pricing strategy. But the strategy of going to the bigger hospitals first and start the sales there is a marketing strategy that handles the reimbursement issue. The bigger hospitals will then work as early adopters of new technology that the majority of the hospitals then can use as examples for how to deal with the issue. That also means that the economic data required to handle the reimbursement is limited to what is needed to convince the clinicians and the hospital administrators.

5.2 Early stage companies

5.2.1 Case study 5 ψ

Case 5 is built on the interview with the CEO of Company Epsilon, Person 5. The employment at Company Epsilon was the first position for the young interviewee after obtaining his Master degree from a bioscience business school.

Company Epsilon

The background of the company goes back to year 2000 when the research behind Epsilon's technology started as a PhD project. In 2003, a research collaboration between university hospitals and Chalmers was created. Person 5 was the one building the business case that pushed the academic research into a commercial project. Company Epsilon, today situated in Gothenburg, started as a commercial project in mid 2005 and became a registered company in 2006. The company is privately held and owned by its founders and a company portfolio holder. Epsilon has three full time employees, two of them are mainly working with the management of the company and the third person performs the laboratory tasks. Epsilon has so far mostly leaned on grants from governmental funds, subsidizing the development and commercialization of innovations in Sweden. Some financing is also assured by advantageous loans. Right now, with the present capital, the company can manage to stay alive until about March 2009. Company Epsilon has managed the first years of existence without involving venture capitalists. This has been a somewhat deliberate choice, since the belief is that they will get a better deal if they perform more academic research and thereby increases the value of the company before approaching the venture capitalists. This is not to say that all early offers from venture capitalists directly will be turned down, the right deal will be accepted. According to the interviewee, a realistic prediction is that Epsilon will be acquired by a big company before they even start their sales. A feasible opportunity for this take over could be when Epsilon has shown that Product ε works in humans.

Product ε

The product developed by Company Epsilon is an implant. Even though the application in focus for Product ε is in a particular anatomical region, there are possibilities to use it in various parts of the human body. The main advantage of Product ε, when used in the intended

part, is the avoidance of surgery, which otherwise needs to be done. This surgery often causes further complications including for example inflammation and healing problems of the cut.

The new features of Epsilon's product compare to the competitors are the better adapted, engineered biomaterial and its small size, which has a strong influence on the applicability in this particular part of the body. This material has been used before in totally other medical applications and is from these interventions known in the literature to work within the body. There are competitors developing the same kind of product from other materials, but many of them are not intended for exactly the same patient group. They are either intended for usage within other anatomical regions, due to its larger size, or designed very individually by tissue engineering for each patient, mostly for usage in severe cases.

The company has performed small studies in animal; one was done on three animals, showing that the product works for at least one year in the animals. The plan is to start the clinical trials in two years. This study is planned to last for about two years for one type of application and three years for the more complex main application.

Marketing strategies
Company Epsilon is planning to first focus on the Swedish and Danish markets, and then they will get Europe as a bonus, thanks to the common regulatory system. US are due to its size an obvious choice. In Europe, Germany and France are the biggest markets. The interviewee points out that the choice of markets, to some extent, is already done when the patents are filed. Epsilon believes that they, or the ones that will own the company at that time, will go through the established wholesalers and distributors, which already have contacts with the surgeons within this field, to enter the markets.

The sites of the clinical studies are not determined yet but they might be performed at clinical centres, which Epsilon already has established contacts with. The company has focused on getting in touch with and involving the big clinical centres and its key opinion holders. In these clinical centres, with the key opinion leader on their side, Epsilon will try to build its cases and then spread the product to other, smaller hospitals. Contacts have been established through friends with key opinion leaders in Sweden, U.K, South Africa and partly in Denmark. In Germany no such contact has been established yet. The first customers will probably be the hospitals, which have been involved in the clinical studies, but also other hospitals, that perform similar operations, already familiar with the procedure.

Person 5 emphasizes the importance of all the contacts that Epsilon has. The contacts have been made partly due to the company’s background at the university as well as the environment of network it is in right now.

Present reimbursement situation
There are no existing codes in the German DRG system today that fit Product ε. Epsilon, its future owners or a competitor will be the first one that build the reimbursement case. The best possible way for approaching the situation, as it is right now, is to look at the OPS codes of similar procedures done in other parts of the body. Person 5 got some additional information from calculations about the current situation in Germany from a friend that has used consultants in Germany. The most common DRG code, in which this OPS procedure was performed, is reimbursed at around €6600. About 12% of this amount, which is equal to €770, should cover the cost of the materials, 35% should cover the surgeons work, and 39 % cost for the general care.

With a great emphasis on the word, 'estimation', the price of the product is said to be around €1000. The estimated price of the product seems to force up the material costs if it is compared with costs calculated for the similar procedure. However, by using Product ε, the need of one more surgical operation is avoided. According to a study about an alternative minimal invasive surgery, which can replace the surgery that Epsilon totally avoid, the cost savings for this less severe surgery is around €2000. Epsilon expects thereby that Product ε also can save at least €2000. The net cost savings for the hospital when using Product ε is then around €1000. However, the department of the hospital paying for products such as Product ε does not always see the benefits from that avoided surgery, since the care of the cut is taking place in the ambulatory care.

"*The ones paying for it initially don't see the cost savings in the end. Therefore we need to address the reimbursement so they will get money from the government."*

Dealing with the reimbursement issue
The interviewee says that investors always ask questions about the reimbursement situation in US. A common view among these seems to be that:

"*If you can handle the US reimbursement system you can pretty much handle the rest of the world."*

Epsilon was therefore focused on the US system in the beginning. The interviewee agrees on the fact that there are a lot of things to learn from the US but also remarks that there are differences among countries. The reimbursement situation in Germany and France has been surveyed to some extent.

A competitor is one step ahead in its development, making their clinical trials right now. Its focus is on the US market and they will probably be there first, building the case. In Europe their market entries will be more even, but the competitor might be there first as well. Epsilon has got information that the competitor plans to price its product approximately the same, which makes Epsilon confident that they are on the right track, since they have some margins in the pricing.

Epsilon is thinking of hiring Swedish consultant firms, which would assert that they have reimbursement professionals in all big European countries, helping them. Epsilon might be able to reach many markets through these consultants. The usage of them will though not take place before more money has been raised.

The interviewee started to consider the reimbursement situation of the product about one year ago, which was in 2007. That was actually the time when the company realized that it could be an issue.

"I think that these issues are way behind. You always talk about the regulatory approval but you hardly never speak about the reimbursement issues until it is really late in the development process."

During the first years, no particular amount of money was spent on the reimbursement issue. However, the plan is to allocate more resources for it when the clinical trial will start to take

form and Product ε will be closer to the launching. About one fourth to one third of the regulatory costs is estimated to go for reimbursement issue.

5.2.2 Case analysis 5

Company Epsilon started, as many other companies, as a spin-off company from the university. The CEO came directly from his undergraduated education and did not have profound experiences of the industry from other similar employments. Epsilon's network tends to be important in supporting and supervising Person 5 in his decision makings. He is surrounded by experienced people and the network might introduce a confidence of Epsilon's managerial capacity to potential investors and co-operators, which otherwise could have maybe been doubtful due to the CEO's relatively short job experience. The network's support also leads to that Epsilon have bigger chances to be more conscious in its decisions without investing any money for that purpose.

The company has not involved VCs yet, instead it is owned by its founders and a company portfolio holder. Company Epsilon's financial situation restricts it in their activities. For example they have to wait with the usage of consultants for investigating the reimbursement situation in Europe until more resources have been raised. This is however a sign of awareness of that reimbursement could be an issue. Person 5's contacts are an alternative resource for Epsilon. Unofficial information about the German reimbursement situation has for example been gained through a contact.

Person 5 said that Epsilon will get 'Europe as a bonus' after they have been established on the home market, as Europe has a common regulatory system. However, nothing was mentioned about that the differences between the reimbursement systems in Europe might be an obstacle for entering these 'bonus' markets.

Person 5 believes that Epsilon will be acquired before they even sell a single product. He will therefore not personally be the one that finally will establish the reimbursement for Product ε. This fact might not motivate Person 5 to prioritize the reimbursement issue as if the aim had been to build the company independently. Person 5 is however showing awareness of that reimbursement might be an issue for the market entrance. He mentioned for example reimbursement as an issue 'way behind', which is often forgotten because of the focus on the regulatory. Moreover, the plan to use consultants to look at the reimbursement systems in Europe is also a sign of awareness. Person 5 expressed that the investors not stimulates the companies to look at the different reimbursement systems in Europe. The environment of Epsilon with its contacts might have had an impact in making Epsilon, which still is in an early stage, partly aware of reimbursement.

The plan of where Epsilon is thinking of doing their clinical studies is influenced by the location of the people they know. Through friends, KOL has been reached at some clinical centres. However, it is not decided where to perform the clinical studies, it might be at the sites where contacts with KOL already are established. The biggest markets are according to Person 5 important. The sites of where the clinical trials are planned to be performed are however mainly not in these big markets.

Person 5 has information about the level of reimbursement of the DRG code where the future procedure for Product ε is expected to be included. When the price is discussed, this level is considered as well as the information about how much the competitors will price their

products. The price of Product ε will increase the material costs of the procedure but will be approximately at the same level as the competitor's price. Person 5 thinks that Epsilon will enter the European market, more or less, at the same time as a competitor. This means that the differentiation of Product ε, compared to the competing product, might be crucial for gaining big market share. However, Person 5 mentions that Epsilon though has margins to undercut the price in case of competition.

5.2.3 Case study 6 φ

The interviewee is a consultant responsible for the business development working half time at Company Zeta, Person 6. This person has an engineering background and has worked with corporate capitals funds, acquisition and business strategy teams. He finally joined Company Zeta in 2005.

Company Zeta
Company Zeta is a start-up company founded in 2002. It is VC funded and based in Lund, Sweden. The idea for developing the product emerged from a doctor in the United States between 1996 and 2000. The first patent on this technology was submitted in 2001 and approved at the beginning of 2002. The doctor then looked for companies ready to buy the patent and that were interested in investing and developing the technology. The company where the present CEO was working was not interested because the technology did not fit with its product's goal. However, the present CEO was certain of the potential benefit of the technology so he bought the patent himself and created Company Zeta.

He started rapidly a partnership with another company to benefit from its network and build a strategic case. He also approached different investors from the start to raise funds and it took him more than a year to receive the first investment in 2003 from three different sources, mainly venture capital firms but also industry's funds. The first resources obtained were mainly allocated to improve of the technology as well as to prove the basic concept, the clinical and market viability. This was done mainly with animal studies. After about two years in 2005, as the first studies showed promising results, they started looking for potential acquirers and showed the technology to major medtech players in their field. At that time, the technology did not really fit acquirer's interests who were mostly focused on alternative technologies.

In the meantime, the alternative technologies showed some bad pre-clinical and clinical results so the medical community became cautious. However actors within this community started to become interested in Company Zeta's technology. Company Zeta used this opportunity to talk to them to better understand their needs and interests. This enabled Zeta to bring forward an appropriate design of Product ζ.
One year later in 2006, the investors provided an intermediate financing of about €450 000 to support the company in these developments. During these years, the company also enlarged its patent portfolio. At the same time, Company Zeta spent a lot of time trying to raise money, and finally this year in 2008, an additional investor decided to invest in Company Zeta. As the business development consultant says:

"Small medical device companies in Europe are very hard to finance, most people are looking for big, €20 million, investment, but we were looking for only few millions. We had a hard time to get attention from the large funding companies for small fund to invest."

During the development phase the company had a few full time employees, mainly engineers. Nowadays, Company Zeta counts only one fixed employee which is the CEO and about five consultants that are employed part time in the field of R&D, clinical studies, regulatory affairs, quality assurance and business development. The board is composed of six people. The last member is a renamed German surgeon that has experience and contacts in the German-speaking countries. The company is focused on product, but as the mechanical part is fairly complete, the CEO decided to employ consultants so that the company does not have to pay every month fixed salary and thereby saving money.

Product ζ

The main value of Product ζ is to reduce the time of surgery of approximately 50% compared to the current procedure used in hospitals. The procedure associated with Product ζ will be easier than the actual one, which is highly skilled oriented with a limited number of surgeons qualified to perform it. However, the actual procedure is still the 'gold standard'. Company Zeta provides a technology that is according to the interviewee *"better, quicker, safer and more reliable"* and can be used in different types of surgery (open, minimally invasive and percutaneous).

The price of the device is approximately the same as for the ones existing on the market. However, the plan is to introduce it as a 'premium' price (€1800 - €2200) instead of an average sales price (€1200).

Plans for the future

Company Zeta is in a phase where they have pre-clinical data and have already started gathering some data from humans (early clinical trials). Thanks to this data they plan to receive the CE-mark in 2010. This data would be enough to go directly into human trials. However, Zeta prefers using the last investment, received this year, to perform first deeper pre-clinical studies on animal before clinical on humans. The company has from now a capital for about 2.5 years. Company Zeta's general strategy as most of the VC funded companies is to build value in order to sell it. As the business development consultant says:

"We build the patent portfolio, ... , Company Zeta is a small start-up and our chance of success in delivering and distributing the product ourselves is very low… it will cost as much as the clinical and development we have done in the past. It is double money to build a marketing team, so our objective is really to sell the company."

Company Zeta is dependent on the financial resource so they want to fix milestones they are sure to achieve and then look for acquirers for Product ζ. The next step as mentioned is to perform clinical trials with the money recently raised. They plan to have data from the first patients at the end of 2010 with the follow-up and the whole study might be finished by the end of 2011. Hopefully at that time they will be successful in finding an acquirer for the whole platform product. As the interviewee said:

"In term of selling the company, the best we can do is actually is to achieve certain milestones like clinical trials. We could actually begin to do sales through distributors or directly with very small marketing team. Those don't tend, until you get a big number, to affect the sale price of the company."

In case nobody is ready to buy the company by 2011 Person 6 thinks that the investors will not shut it down if there is nothing wrong. The company will therefore have to survive in

marketing the product by itself. In that case, they see different possibilities. Firstly they can licence the technology or part of the patent portfolio. Secondly they can market Product ζ by themselves. In any case, they would prefer to keep control of the product. If they have to go forward on their own, they will have to hire a vice president of marketing who will handle the sales in the first sites using distributors or direct forces. They estimate a financing between five and ten million Euros to build this marketing team.

Nowadays, the first markets they have in mind are some centres in Nordic regions but the focus will then be put in targeting the biggest market: Germany, France and Italy. According to the interviewee, those markets are interesting in term of volume, budget and approval processes, but also because they have champion and leader clinicians as well as medical sites recognized around the world. Germany is mainly interesting as it is a gateway into the eastern countries. In Germany they want to focus on the key recognized centres and build volume from there.

Dealing with the reimbursement issue
Product ζ is not completely new to the market. However, the procedure to introduce the device into the body is slightly different from the current one. According to the interviewee, the technology falls under current reimbursement codes. He said about it:

"That is good news for getting the product out on the market, but bad to sell it at a high price. However, it turns out that we can currently make money at the current pricing."

He also said that looking into the reimbursement system in each country will take time.

5.2.4 Case analysis 6

The existence of the company is essentially due to the present CEO, who bought the patent, believing in the technology. He started the company and developed the idea to a marketable product. He hired consultants to help him in his task such as Person 6.

The general strategy of the company and the decisions taken seems to be mainly guided and influenced by the aim of their owners which is the acquisition. Indeed Zeta is financed by VC firms that want to build value into the company as quickly as possible to be able to sell it and have a return on investment. In order to conclude a good deal and increase the value, the aim is to achieve different milestones. Zeta has already finished the early pre-clinical trials but was unsuccessful in finding an acquirer. Nowadays, the company is focusing practically only on the next milestone which is to perform the clinical trials to get the CE-mark in order to sell the business, which hopefully will happen in 2011. Most of the efforts and the resources of the company are put on that issue right now as they only have capital for that period of time.

If the aim to be acquired cannot be achieved, and if Zeta still has resources, the company will have to enter the market by itself. However, its marketing strategy does not seem to be well established yet. The markets where Zeta wants to enter are Nordic countries, Germany, France and Italy according to Person 6. In the criteria mentioned by the interviewee for the choice of those countries, the reimbursement issue was not an argument. However, other parameters of the strategy seem diffuse. Even if Zeta has an idea where to go, the plans concerning the timeline about the different market are not defined specifically. They are aiming at the recognized centres especially in Germany to try to build sales from them where one hospital has already been chosen for the clinical trials. An agreement between the

company and the clinic is pending. For Germany, Person 6 said they use the advice and contacts of the German surgeon that is on Zeta's board. It seems that his network might play an important role. In term of how they would enter the different market, the interviewee gives an overview of the different possibilities they have; licensing the technology, using direct or distributor channels to sell the product. However, it does not seem like Zeta has a clear idea of how to do it. If Zeta has to employ a marketing team, it will cost a lot of money. However they do not seem to include that in their strategy as their main focus is to be acquired. Company Zeta knows that the price of their device is similar to the ones that are present on the market. The strategy, even if it is still vague, is to price Product ζ not on the average sale price but on a higher level.

It appears that since the aim of Zeta is to be acquired, they are not focusing on the marketing phase of their device. Moreover, the financial situation allows Zeta to survive 2.5 years. Therefore, questions such as how to enter the market and pricing of the product do not seem to be a priority for the company at the moment of the case. The reimbursement issue has not been examined specifically as they seem to consider it as a marketing issue and also probably because they think that the device falls under current reimbursement codes.

5.3 Backtracking company

5.3.1 Case study 7 χ

This case describes the history and present situation for company Eta. The case is based on an interview with a marketing director responsible for the product of interest at company Eta.

Company Eta
Company Eta is a large Swedish company within the medical technology field. It was founded in the 1970s as an R&D company. Since then it has evolved and today employs more than 2000 people. The company headquarter is situated in Stockholm, however it has corporate and regional offices throughout the whole world.

The company was originally built around one technology invented by the founder. He started to develop the technology during the late 1940s and in the late 1960s the first prototype of today's product was built. The actual launch of the product took place almost 20 years after that. Since then the company has grown and made a number of acquisitions that has helped to expand its product portfolio. The focus in this case will be on the original product, herein named Product η.

Product η is protected by patents and the only one of its kind in the world. It constitutes a major investment for hospitals and costs millions of Euros to buy. The product offers a non invasive treatment as an alternative to surgery, which results in shorter hospital stay for the patient. This of course has an economic impact for the payers too.

Marketing strategies
Product η was launched by Eta on the international market in the year 1986. Eta was by then quite a small company and had no or small resources to invest heavily on a single market. Instead they sent out sales people to sell the product to single hospitals throughout the world. The hospitals were chosen more on the criteria if they were interested in trying the product than from a strategic point of view, or as Person 7 describes it:

"*It was more some kind of entrepreneurial guerrilla attack to get out on the market.*"

In the US they were able to establish reimbursement for the product with their first customer and it has been reestablished several times since then. Today the reimbursement issue is not a problem in the US, or in other countries like Japan. In Germany the first Product η was introduced in 1994. As in the first launch of Product η in 1986 Eta did not use any specific criteria to choose which hospitals to sell to. It just looked for the ones that were interested in the product. In the case of Germany that meant that they went to the private hospitals which focused on outpatient care. This kind of treatment did not need any reimbursement at that time; the hospitals negotiated prices with the specific sickness funds or got paid by the patient. The public hospitals were not targeted as they could not decide about the investment by themselves. It had to be decided on a national level. The reimbursement was not an issue in the German system at the time of the product's launch. The hospitals bought their equipment and financed it either from the hospital budgets or, if it was a large investment, from federal budgets. This meant that Eta did not establish reimbursement for the product from the beginning in Germany.

Present reimbursement situation

Today Product η is not included in the German reimbursement system. Since the procedure that the product represents is typically an outpatient procedure that replaces an inpatient procedure, it makes the situation more complex. Until now Eta has focused on getting the product represented within the ambulatory sector and the EBM catalogue. The strategy has been to apply to KBV for their innovation service. KBV has helped Eta to establish a procedure and related procedure codes for Product η. It has also assessed the publications' clinical data about the product. Since more than 50 000 people are treated with Product η each year, there is quite an extensive set of data and publications. The problem is, however, that most of the data and publications do not live up to the standards that are required, the evidence levels are not enough. Eta has been working with KBV about this issue for approximately 1.5 years and has now come to the conclusion that this is not the right way to go. The level of evidence is too low to be accepted by IQWiG. KBV have recommended them to not apply for representation within the outpatient sector, but instead go for representation within the German DRG system. So Eta will now focus on establishing reimbursement for the procedure within the hospital sector.

Dealing with the reimbursement issue

In working with the reimbursement issue Eta has used consultants that have guided them through and advised them about the system. The consultants have especially been important for Eta to be informed of the changes in the reimbursement system that has undergone the last years. The consultants that Eta uses have advised them what different bodies there are within the system that is of importance for the process.

Eta expects that it still has to get the product accepted by IQWiG, which assesses the medical benefits of the product, to get the proper coding and the product into the G-DRG system. In this process Eta also rely very much on their customers to apply for the reimbursement and promote the procedure to the insurance companies. Eta supports them with clinical data and information about reimbursement levels in other sites and countries, which they can use in their negotiations.

The reimbursement level in Germany is low compared to other countries. What the private users of Product η in Germany get today is about half of what they get in other countries. That

has a negative effect on the selling in Germany and it is considered as a less attractive market by Eta as the situation is today. The reimbursement level that Eta aims at is in parity with the level of alternative treatments and since Product η shortens the hospital stay that should become an incentive for the hospitals to buy the product. This argumentation is something that Eta has been successful with in other countries and therefore they hope it will work in Germany too.

Internally they have not recruited any local experts on the reimbursement systems in different countries. It has mainly been dealt with by people in Sweden, the local business units and customers.

5.3.2 Case analysis 7

Company Eta differs a lot from the other companies studied in this project. It is first of all a large international company with established sales in many of the major markets. It also has several products in its portfolio, which mean that it is not as dependent of success with one single product as the other smaller companies. However, the success or failure of one product might affect the growth of the company. The size of Company Eta also means that it also has better access to financial resources to deal with market reimbursement issues.

But the differences set aside; Company Eta has once been a small company and was forced to deal with the marketing process of Product η while they did not have the resources they possess today. The scarcity of resources affected their marketing of Product η as they did not have the resources to penetrate a market properly from the beginning. In the US and other big markets the strategy turned out well in terms of sales and reimbursement. They managed to establish reimbursement codes and get the sales going. But for Germany it looked different, the system was different and worked in another way at that time, still however Eta used the same strategy as they did in other countries. In the US, reimbursement was established and the volume of sales had increased. The experience it gained from entering that market it probably thought it could apply in Germany as well. The problem was however that Germany had not introduced the DRG system at that time and the reimbursement was based on the number of hospital days. Today the system is different and maybe the situation would have been different if Eta had approach the system as it looks today. Eta has made approaches to get into the reimbursement system recently and then they have gone for the outpatient care. The problem seems to be that level of evidence needed to establish the treatment within the outpatient sector high and Eta does not live up to the requirements of the evidence when it comes to Product η. Therefore the approach taken by Eta has made the reimbursement process long.

When dealing with the reimbursement in Germany Eta has worked with consultants. No internal expertise seems therefore to have been acquired. This might have had an impact on the situation. The person handling the situation within the company has been working in Sweden and that means that the company loses the near presence to the decision makers in Germany. A consultant is often very knowledgeable about the system and can advise on how to proceed through it, but when it comes to negotiations and presenting the company and the product to the market it is preferable to have a person from within the company. That person should then preferably possess knowledge about reimbursement and also speak the native language.

5.4 Summarizing the case studies

This section provides a short summary of the seven cases presented. In Table 5 the size of the companies, the types of products and the backgrounds of the interviewees are presented. The three last rows provide our subjective view of how the companies see the reimbursement issue. Especially the judgement of the companies' awareness is subjective in that sense that it is based on the impressions that the authors have from the interviews and from interpreting the material. The two last rows are also based on the subjective judgement of the authors, however, it can be argued that the judgement relies more on the result presented in the cases.

Table 5 : Summary of the cases

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7
Company	Alpha	Beta	Gamma	Delta	Epsilon	Zeta	Eta
Status	Launching	Launching	Launching	Launching	Early stage	Early stage	Backtracking
Founded	2003	1999	2006	1998	2006	2002	1970s
No employees	7	29	25	2 + consultants	3	1 + consultants	
Product used in	Inpatient sector	Inpatient sector	Mainly outpatient sector	Outpatient sector	Inpatient sector	Inpatient sector	Both inpatient and outpatient sector
Title of the interviewee	CEO	International Marketing & Sales Director	Sales & Marketing Director	CEO	CEO	Consultant: VP of Business Development	Marketing Director
His/her background	Financial	Engineer + experience in marketing & sales	Business + marketing	Engineer + management	Engineer + bioscience business school	Engineer + business work in consultant firms	Engineer
Field of his/her previous experience	Medtech industry (retailing + healthcare provider)	Construction + medtech industry	Pharmaceutical industry	Medtech/ Pharmaceutical industry	None	Medtech industry	Medtech industry
Aware of the product's reimbursement situation	Partly	Yes	Partly	No	Yes	No	Yes
Do the interviewee see reimbursement as a hurdle for market access	No	Yes	No	No	Yes	No	Yes
Do they have an explicit strategy for dealing with reimbursement	Partly	Yes	No	No	Partly	No	Yes

The argument for why only two companies, Beta and Eta, are considered to have an explicit strategy for dealing with reimbursement is that these two companies have gathered information about the German reimbursement system, they have a time plan, they are aware of the reimbursement levels of both their own and competing products and they have performed or are planning to perform studies showing the health economic value of the product. The authors of this report only consider Companies Beta and Eta to live up to these requirements. Company Eta is however a big company that has been out on the market with its product for many years and it has experienced the difficulties of getting the product reimbursed. Its strategy has therefore evolved and changed over the years out on the market. At the time of the launch there was no explicit strategy in the company. Beta on the other hand is in its launching phase and has a strategy fairly well worked out. This distinction between the two companies is important to make.

From the table it can be concluded that the companies that see the reimbursement as a hurdle are also those who have a strategy for dealing with it. Company Epsilon only partly integrates the reimbursement as a strategy, but that might be explained by the early phase the company is in. So far the company has gathered information about reimbursement levels and done calculations about how to price the product. How this gathered information is used in the clinical trials or to perform other studies will decide if they develop an explicit reimbursement strategy.

6 Reimbursement integration model

The model in this report is built from the seven cases presented and the study of the German system. The model is based on the life cycle of a medical technology, Figure 16, and the aim is to relate how the companies deal with reimbursement within the different phases of the cycle. The purpose of building this model is to visualize and describe the actions taken by the companies concerning reimbursement. The model forms the basis of the discussion in this report and also lays the foundation of further research presented in Chapter 11.

In phase 1, the market in general is not yet conscious about the existence of the product since it is still in an early stage. The small companies do not have the resources or the focus of promoting the new technology. Focus is put more on the development and proving the safety, efficiency and quality of the product. Therefore the market demand for the product is low. When entering the regulatory process in phase 2 all the clinical data is available for communicating the clinical value of the product to the market, this can be done in for example premarketing activities. This increases the consciousness of the technology on the market and the demand curve rises as well. At the same time the evidence of the product's quality, safety and efficacy is collected during the clinical trials. This is evaluated by regulatory bodies and when (or if) the product is approved this increases the interest in the product. Still however the knowledge about the economic value of the product is not complete. This is what the companies are trying to establish in phase 3. In phase 3 most of the innovative products are unique on the market. The competition is low for innovative products during this phase. In the next phase more competitors start to enter the market and the demand for the product is therefore decreasing. In phase 4 the product is driven out of business as more competitive products have entered the market. The two last phases were not covered by our study and therefore are not described sufficiently in this model.

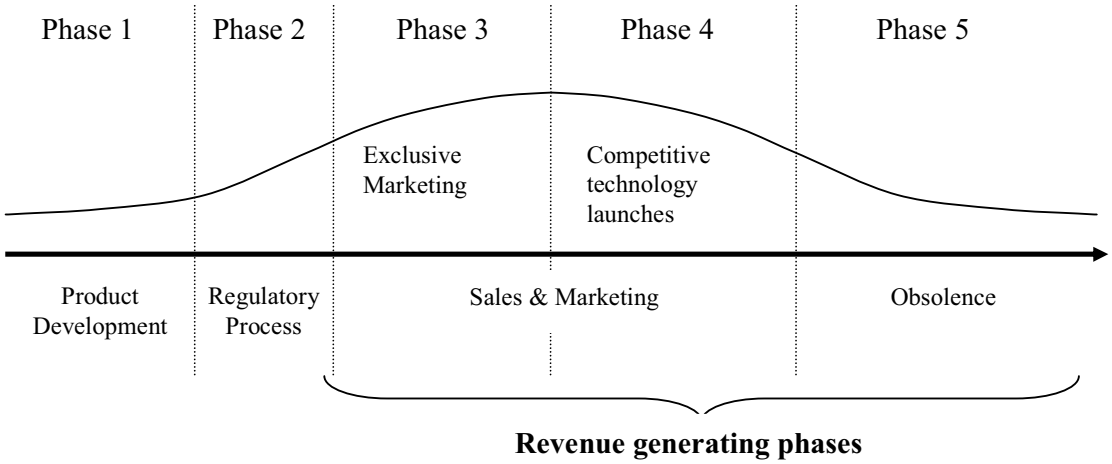

Figure 16 : Demand curve for a medtech product

A medtech company can generate revenue in phase 3 to 5 in the product life cycle. The start of phase 3 is characterized by the product getting its regulatory approval and it is then allowed to be sold on the market. However, the regulatory approval is not equivalent to full market access. If reimbursement is not established it will affect the volume of the sales. The optimal situation would therefore be to have established the reimbursement case, with the best

possible coding and pricing at the beginning of phase 3, at the same time that the product is regulatory approved. However, this is just in theory, since the OPS coding requires that the product is at least certified with a CE mark. This in turn means that the company has to go through the regulatory process before they can start applying for representation within the reimbursement system. But the sooner a complete and proper application is made in phase 3 the better. The risk of filling in an inadequate application too early in the case of the ambulatory sector is that the product might be excluded from the reimbursement system altogether.

6.1 Integration of reimbursement activities for launching companies

When planning the interviews we were asking for the person within the company that knew most about reimbursement. An observation made was that a majority of the people we were referred to was marketing managers or was at least working with marketing in the launching companies. This might be a sign of that the companies see the reimbursement process as a marketing activity. This means that they mainly involve it in phase 3 in the life cycle of the product. However the companies are hiring the marketing people before entering that phase and might therefore also include reimbursement activities earlier on. We mainly saw that the issue was dealt with in phase 2 and 3, which is shown in Figure 17.

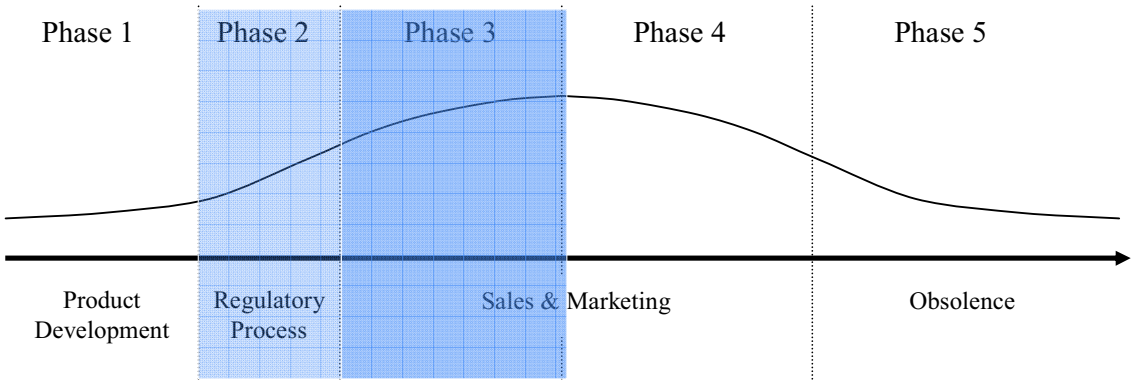

Figure 17 : Integration of the reimbursement activities in the product life cycle

These earlier activities involve mapping of reimbursement systems, collecting information about reimbursement codes and levels. The companies mainly work with consultants that provide them with this information. For example Company Gamma is working with a consultant right now to map the German market. Company Beta also hired a consultant to specifically map the German reimbursement system. Company Alpha has ordered a report from a consultant about how to integrate their product in the US reimbursement system. An exception would be company Delta that is more relying on Person 4s own experience in dealing with the issue. What the companies in general seem to be interested in is information about the reimbursement levels, how the system works, how and where the product can be included and to what hospitals they can turn to. From this the companies can formulate their strategies for how to get their product into the reimbursement system. This is something that has been seen from companies Alpha, Beta and Delta. Company Gamma has not yet worked out its strategy since it is not yet aware of the situation in Germany. The level of details in the

acquired information about the reimbursement situation depends mainly on the market in focus. Company Alpha is a good example; it has collected quite detailed information about the situation in the US, but not in other markets as they have not been in the same focus.

The next step for the companies is to launch the product in phase 3. The general strategy among the companies is to go for the KOLs in different markets. They see it as an opportunity to build up a good reputation and open up the market for the product to be sold in other hospitals. This general strategy is illustrated in Figure 18 where the hospitals are designated H. An exception is Company Gamma that plans to use an intermediate distributor to reach out on the market. The model described below could in that case simply be extended with a box in the picture for the distributor.

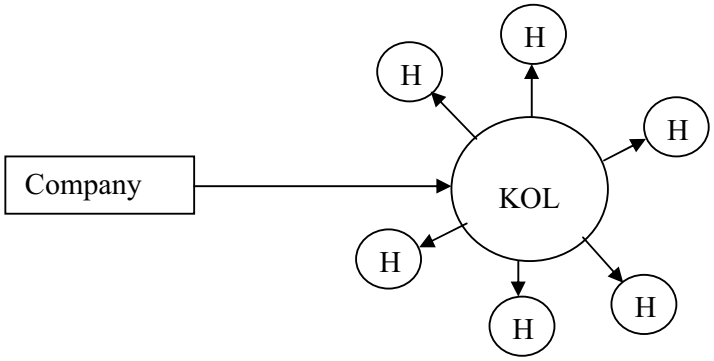

Figure 18 : Penetration strategy

This is a strategy that also has an impact on the reimbursement situation. In the German system, the decision makers of reimbursement such as the InEK for the DRG groups and the Valuation Committee for the EBM catalogue are partly composed of physicians' associations influenced by KOL. These might have an influence in the reimbursement acceptance. The companies seem more or less aware of this advantage. Even so, only one company, Beta, has specifically pointed out this issue and integrated it in its strategy, the three others have not explicitly mentioned it. Case 7 is an example where the company did not go for the KOL when launching the product in Germany. Instead it focused on the private hospitals that could afford the product. Thereby they missed the opportunity to build the reimbursement under SHI, which represent the largest part of the healthcare purchasers.

Phase 3 is also the phase when the companies try to execute the plan they have come up with from the knowledge they gathered in phase 2. The two different ways to deal with the German system for the companies are to either like Company Beta establish a new code or like Company Alpha and Delta try to make money out of the existing one. When creating a new code the pricing of the product is important since that has an impact on the calculated level of reimbursement for the provider. Company Beta is for example aiming at creating a new DRG code to be able to put a higher price on its product than the traditional procedure. The strategy of pricing when it comes to use existing codes is more about integrating the knowledge about the reimbursement level so that the company can price the product optimally. The knowledge is about what monetary value the product brings to the providers compared to the competing products and how high the company can price the product according to that.

The gathering of economic data to build the reimbursement case seems to take place after the regulatory process and the product is being launched. For example Company Alpha

performed a special study that proved the reduction of hospital stay. Companies Beta, Gamma and Delta however are planning for collecting economic data while they are out on the market. This can be seen as if they are in a separate phase between phase 2 and 3 in the product life cycle where the actual reimbursement activities take place. It is characterized by relatively low sales as the companies are building their economic case in order to establish reimbursement. This extra reimbursement phase is illustrated in Figure 19 as phase R. The beginning of the phase is defined by achieving the regulatory approval and gaining a legal market access. The end is defined by the first establishment of reimbursement.

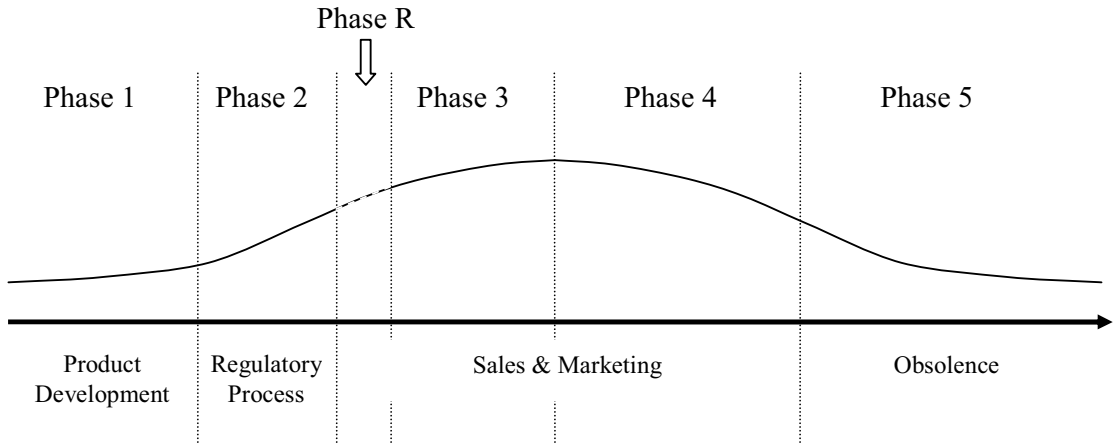

Figure 19 : Illustration of the reimbursement phase

In Figure 19, the slope is the same as before in phase R. This is a conscious choice to keep it that way since the study performed has not given any data that could help determine the change of it. However, it is reasonable to believe that the slope of the curve would actually flatten out in phase R. During that phase the permanent payment of the product is not established and that can affect the demand for the product. Moreover the length of the phase can be discussed. In the figure the reimbursement process takes much shorter time than the regulatory process. This is however not always true. Depending on the technology, strategy and preparations made by the companies the length of phase R can vary. Applying for a new code would extend the reimbursement phase with several years. On the other hand, using existing codes when marketing the product would probably make the phase shorter. The relative length between phase 2 and R is much depending on the system differences that exist between countries.

6.2 Integration of reimbursement activities for early-stage companies

Both of the early-stage companies are according to our model just in phase 1 since they have not yet started their clinical trials. Company Epsilon and Zeta have therefore not even reached the phases in which the launching companies more deeply started to deal with marketing related issues, including reimbursement. Both of the companies believes that they will be acquired before phase 3 is entered and the people within these companies will probably not establish the reimbursement by themselves. At least phase 4 and 5 is therefore beyond the horizon of these companies. However, these two companies more or less extensively make up plans for how they can integrate reimbursement related activities in the phases after the

expected acquisition. These plans together with further investigations of potential future opportunities and obstacles in phase 3, the time of intermission in phase R might be shorten down and additional value can thereby be built within the company. For Company Epsilon the current gathering of reimbursement information seems to be such a preparing activity to create value. Contradictory, Company Zeta seems to leave the reimbursement issue to the future owners. Instead they are currently more focused on developing the product and proving its clinical benefits. The majority of the launching companies did not thoroughly collect health economic data in phase 2. The early stage companies do not have plans for doing that either. Instead, that is something that is postponed for the phases beyond phase 2. As it seems right now, Company Epsilon is gathering information about the reimbursement situation but does not have a particular plan for how to use it. The early-stage companies therefore seem to address the reimbursement issue similar to as the launching companies have done it so far. However, the fact that these two companies are in an early-stage, they still have a couple of more years in phase 1. This means that Company Epsilon for example still have time to plan the integration of the reimbursement activities, based on its acquired knowledge.

7 Explaining the integration model

During this study, different characteristics, factors and activities have emerged that seem to explain the behavior of the companies. Some specific theories have therefore been chosen in order to discuss the phenomena observed.

7.1 Characteristics of SME impacting the decision making ψ

7.1.1 The entrepreneur

The general characteristics of an SME, e.g. the management's execution and its activities, are highly influenced by the entrepreneur behind the company. The word 'entrepreneur' derived from the French word 'entreprendre' means 'to undertake'. There are many interpretations of the term and a large number of definitions of what an entrepreneur is can be found. Coulters defined, in 2001, entrepreneurship as:

"*The process whereby an individual or a group of individuals use organized efforts and means to pursue opportunities to create value and growth by fulfilling wants and needs through innovation and uniqueness, no matter what resources are currently controlled."*[131]

The entrepreneur of today, and also the view that is used henceforth in this chapter, is an innovator or someone else, who develops an idea that he/she appraises as promising, converting it into a marketable product or service.[132] The personality and attributes associated with entrepreneurs is that they in many contexts are considered as being individualistic, risk-taking and highly focused on the well-being of the company. The personal attributes of the entrepreneurs might impact the SME's activities and permeate the decision makings in the companies.[133]

Many SMEs stem from research projects, started at university labs. Promising technologies might result in a spin-off and a new enterprise is founded in order to develop and commercialize the invention. The entrepreneur therefore often has a background as a scientist/researcher, who wants to follow the research project until it is put into practice and commercialized. To make this journey the researcher has to transform and become an entrepreneur. In the new role the entrepreneur must learn a lot in order to be successful on the market. Besides the knowledge of the product and the endeavor to innovate, knowledge about e.g. the market, how to recognize opportunities, how to effectively employ and organize resources must be acquired. The competitive advantage is gained through skilled management of intellectual property based on pioneering science.

A start-up company's technology is rather often in a phase where only a 'proof of concept' or a lab-scale prototype exists.[134] The entrepreneur of such an early-stage company might have to act in uncertainty, e.g. the commercial applications might not be fully established and the

[131] B. Bjerke, *Understanding entrepreunship*, 2007, Edward Elgar Publishing Limited, pp. 16.
[132] D. Hine and J.Kapeleris, *Innovation and etrepreneurship in Biotechnology an international perspective*, 2006, Edward Elgar Publishing Limited, pp. 19.
[133] M.J. Baker, *The Marketing Book*, 5th Edition, Butterworth-Heinemann, 2002, chapter 29, pp. 758-759.
[134] R.A. Lowe, A.A. Ziedonis*, Overoptimism and the Performance of Entrepreneurial Firms*, 2006, Management Science 52(2), pp. 173–174.

scarcity of available resources restricts the possibilities. The indefinite situation is considered to be tackled through an exploratory approach, which means that the entrepreneur needs to explore the opportunities and make decisions about what are worth trying.[135] An often desired factor in the entrepreneurship is therefore the talent of calculating and judging risks.[136] However, the entrepreneurial propensity and willingness of risk taking compared to 'nonentrepreneurs' are much debated.[137]

The entrepreneur in start-ups, due to his/her new role as business executive, might often lack significant assets such as market knowledge, manufacturing capabilities, important networks through which the customers can be reached or necessities for bringing a product to market. Furthermore, these companies are typically single-product companies. The dependence on this product's development is therefore critical, since the company is unable to spread its risks across several projects, like more established companies can do. [138]

7.1.2 The financial situation

Besides the number of employees and the turnover which, in this report, define SMEs there are several other characteristics of such companies that have an impact on for example how they are managed and their decisions. For instance, a fundamental difference between SMEs and big companies is the lack of resources, both financial as well as human, in the smaller ones.[139]

One central task of an entrepreneur is therefore to find finances that support the activities in the early-stage SMEs. There are many ways to raise money to support the business, each of them associated with advantages and disadvantages. The most common financing models for SMEs in medical technology industry include:

- **Venture capital:** Equity or stock is sold to a venture capitalist. Venture capitalists, VCs, are professional investment managers that invest in small companies, that they predict will give high returns. The VC's money originates from institutional investors including pension-fund managers, charity funds and wealthy individuals. Borrowing funds are capital borrowed from the bank.

- **Business angel:** Wealthy individuals, 'angels' make investments. This kind of financing is most common at the very early stage when only small amounts of money are needed.

- **Investment banks:** Capital is received from the investment bank but in return a portion of the raised money is debited. The investment bank sometimes assembles a group of investors, usually called a 'private placement'.

[135] D. Politis, and J. Gabrielsson*, Entrepreneurial Decision Making: Examining Preferences for Causal and Effectual Reasoning in the New Venture Creation Process*, 2006.
[136] D. Hine and J.Kapeleris, pp. 25-26.
[137] K.D. Miller, *Risk and rationality in entrepreneurial processes*, 2007, Strategic Entrepreneurship Journal, 1, pp. 59–60
[138] B. Bjerke, pp 16.
[139] M.J. Baker, pp 758-759.

- **Corporations:** Credibility can be added to the SME by the corporate investors. However, their objective is usually to get the distribution rights for the product or a way to acquire the company if it is successful. Other potential customers tend to lose the motivation.

- **Customers:** If the product solves a problem for a customer, the customer might be willing to financially support the company.[140]

The scarcity of capital has an impact of the small enterprises in many perspectives such as its decisions and the ownership. Until a certain threshold of expansion is reached, the financial constraints tend to dominate the decision making.

All enterprises might have capital limitations restricting the activities within the companies. However, for the bigger ones there are, to a greater extent, possibilities to move around the staff where it is most needed, buying in expertise temporarily for specific tasks and fund projects. Accordingly, the human resources within a SME are often limited. The company cannot afford to employ a specialist for every specific task. The employees in a SME tend to carry out a wide variety of tasks, not within the frame of their supposed responsibilities, among those the decision making.[141]

7.2 Decision making models: rational choice theory and bounded rationality ψ

The 'rational choice paradigm' proposes that principle behind human choices is an effort to maximize their utility.[142] The theory assumes that the decision is made when all the alternatives, which are available for the choice, are known and that the decision maker can compute the expected value of utility associated with each alternative. Further, the alternative that maximizes the expected utility is then chosen. An underlying assumption is therefore that a comprehensive knowledge is necessary for optimizing the decision making.[143] However, during the last three decades, studies have ended in result that violates the theory's principles of human choice behaviour. Especially, decision making with high degree of risk and uncertainty are considered to be influenced also by biases and emotions.[144] Bounded rationality is a term used when information is not fully and rationally considered in decision making. Cognitive constraint of the decision maker's perception of the situation prevents him or her from seeing, seeking or sharing relevant and accessible information. The concept challenges the traditional rational perspective and suggests that the rationality of a human behaviour is partly limited by the human constraints. For decision making theory this implies that decision making takes place in situations of uncertainty and incomplete information.[145]

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[140] L. Bottorff, *Funding a Medical Device Start-Up, 2000,* Medical Device & Diagnostic Industry Magazine, viewed on 2008-11-26, <http://www.devicelink.com/mddi/archive/00/01/004.html>.
[141] M.J. Baker, pp 758-759
[142] B.Yang, D. Lester, *Reflections on rational choice-The existence of systematic irrationality*, 2008, The Journal of Socio-Economics, 37, pp 1218–1219.
[143] I.Horide, *Emotion and Bounded Rationality in Entrepreneurial Decision Making: An Interdisciplinary Approach*, 2003, Reitaku International Journal of Economic Studies, Vol. 11, No. 1.
[144] B.Yang, D. Lester, pp.1218–1219.
[145] 12MANAGE, citing Rüdiger F. Pohl in Cognitive Illusions, 2008, viewed on 2008-11-25, <http://www.12manage.com/description_bounded_rationality.html>.

For over 50 years it has been recognized that managerial decision-making often deviates from the rational decision making model. Different researchers have identified factors that prevent the managers of various companies from making their decisions according to this rational model. These are for example:

1. High cost of such decision making efforts
2. Information-processing limits of the decision makers
3. Differences in the value perception of the decision makers [146]

Entrepreneurs that develop and introduce new products into a sometimes not even yet existing market have to make decisions under uncertainty and ambiguity. Even if they try to collect all the available information it might be difficult to obtain complete information. The future is intrinsically uncertain, and accurate prediction is almost impossible. This results in a chosen strategy that tends to be different from the one that should have been rationally chosen, rather the decision makers are acting according to their bounded rationalities.[147]

7.3 Differences in prerequisites and execution of decision making between entrepreneurs of SMEs and large organizations' managers ψ

The level of uncertainty faced in a decision making situation is, in general, greater for the entrepreneur than for the manager at a higher organizational level. The latter often have access to internal documented experiences and performances of the company from the past. This information might reduce the uncertainty associated to a decision making and, in addition, can be done at relatively low costs. The entrepreneur has no such information to rely on. Large firms have often developed policies and procedures for the decision making process. Entrepreneurs usually lack such a structured model, and the biases and heuristics may then have a great impact. Entrepreneurs, developing innovative technology, are often faced with situations where they have to, quickly and with limited information, convince financiers and other stakeholders of the company's opportunities. In such situations the entrepreneur is forced to rely on experiences and intuitions in order to make fast decisions. Furthermore, the 'not established' market acceptance of a new pioneering innovation adds more uncertainty to decisions that have to be made.[148]

It has been found that entrepreneurs, introducing pioneering innovative products on new and uncertain markets, to a greater extent exhibit overconfidence compared to managers that introduce incremental products,. For example, in a study of the commercialization of three medical products (artificial heart, cochlear implants and an immunosuppressive drug) emerged from university researchers, it was found that the product developers' overconfidence resulted in underestimation of the time and costs needed for the technology development and FDA approval. Factors that could delay commercialization such as production problems and quality of life issues were to a large extent ignored by the researchers. Conversely, the patient benefits and the uniqueness of the technology were

[146] L.W. Busenitz and J.B. Barney, *Differences between entrepreneurs and managers in large organizations: bias and heuristics in strategic decisionmaking*, 1997, Journal of Business Venturing 12, pp 12-13.
[147] I.Horide, *Emotion and Bounded Rationality in Entrepreneurial Decision Making: An Interdisciplinary Approach*.
[148] L.W. Busenitz and J.B. Barney, pp13-14.

overestimated. Decision making regarding market entry has been demonstrated to be impacted by overconfidence.
Other studies show that the cognitive bias is more significant among entrepreneurs than managers of more solid established firms.[149] The cognitive bias that affects human minds, is hard to avoid and leads to a perception, which might deviate from the 'reality' in decision making.[150] A manager of an established firm might compare a new innovation with the existing similar ones. Entrepreneur minds are rather concerned with early-stage technologies and their prospect are along the track of this pioneer technology.[151] Studies have demonstrated that entrepreneurs value their own ventures higher compared to the competing ones. This is consistent with the unreasonably high level of confidence in their own decision-making ability.[152] Overconfidence by the entrepreneur might therefore lead to greater difficulties than expected when developing and commercializing the technology. [153]

7.4 Entrepreneurial networks ψ

The personality of the entrepreneur might add various strengths to the small company, limited in its business and constantly struggling with the finance deficits. By using the skills in building entrepreneurial networks and through them doing business, the entrepreneur is more or less able to impact the situation of the small firm.[154] The 'network' metaphor used to describe social or businesslike contacts emerged in the 1970s and today represents a part of the new entrepreneurial society. The network of SMEs has primarily been seen as a supporting structure for start-ups and as a key resource for further development and growth of the small firms. There are different levels of network and they can be found in different context. Shaw and Convay (2000) present five broad categories of network types, in which entrepreneurs can be found.

1. Networks gathered around a scientific or technical subject or field.
2. Professional networks of persons within the same profession such as medicine or education.
3. Networks developed with the end-users of the company's product.
4. Friendship networks.
5. Recreational networks in which the members have a mutual interest of an activity. This is a particular type of friendship network.

Due to the characteristic properties of a SME, like the uncertainty of the company's future, it is likely that resource holders, such as potential investors, use the networks to gain information, which helps them in their investment choices. The entrepreneur tries to avoid the risk of information leakage to the investor's party by associating with well-regarded actors and organizations. In such a situation, the company's network linkages might, if positively perceived by other parties in the network, result in subsequent beneficial resources exchanges.

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[149] A. Arora, *Contracting for tacit knowledge: the provision of technical services in technology licensing contracts*, 1996, Journal of Development Economics, 50, pp. 234-236,
[150] 12MANAGE, citing Rüdiger F. Pohl in Cognitive Illusions, 2008, viewed on 2008-11-25, <http://www.12manage.com/description_cognitive_bias.html>.
[151] A. Arora, pp. 234-236.
[152] L.W. Busenitz and J.B. Barney, pp14-15
[153] A. Arora, pp. 234-236.
[154] M.J. Baker, pp 758-759

The type of relationship in a network might be of different significance. There are two different types of relationship. The informal one built on, for example friendship, is referred as 'strong ties'. Formal relationship such as joint ventures, licenses and business relationships are considered as 'weak ties'. A relationship based on weak ties has low density but can reach a large group. Strong ties on the other hand are dense but have a shorter range. There is no uniform opinion about how an optimal entrepreneurial network should be constructed. However some conclusions from researchers sound as follow:

- Granovetter (1985) considered that successful entrepreneurs have large networks built on weak acquaintances. These can provide the right information at the right time, introduce potential investors and give access to potential customers. In a business context this network seems more important than a strong friendship or kindship.

- Convay (1994) made the conclusion from a comparative study of small and large successful technology companies that external ideas about the best course of the development process mainly consisted of strong ties between the SMEs.

- Bruderl and Preisendorfer (1998) found that strong ties were more important for the company's success. For sales growth they were however not so critical. [155]

7.5 Marketing theory χ

To be successful in marketing a new product any company needs to decide on four different parameters. The commercialization phase of a new product is expensive and it is therefore essential that the company carefully consider these decisions. The first parameter the company needs to decide is *when*. Timing is critical when launching a new product and basically the company have three choices:

- **First entry:** The company first on the market will usually have the advantage of building up relationships with important customers and other key actors on the market. But if the product is not working properly or has not been debugged thoroughly it can destroy the whole marketing phase.

- **Parallel entry:** Another approach is to time its entry with a competitor. This might have a synergy effect as the market will pay more attention when the companies communicate their products.

- **Late entry:** The last approach is to wait with the entry until a competitor has entered the market. In that way the company will not have to bear the cost of educating the market and it can learn from its competitor.

The second parameter the company needs to decide about is *where*. The geographic strategy of the company should consider in which areas it wants to be and how large these areas should be. This decision is very much effected by the size of the company. The bigger the company is the larger area it can, and it needs to, cover. Commonly companies develop products for the domestic market and start selling them there before they expand their territory to new markets. The main criteria when choosing these new markets is the market

[155] B. Bjerke, p. 141-152

potential, but also the local reputation of the company and costs of distribution and market communication are important factors.[156]

The third decision parameter is to *whom* the company should turn within the markets it enters. It must find and choose the group of customers that give the company the best prospects. There are typically early adopters, heavy users and key opinion leaders and they should preferable be reached at a low cost. The company must rate the groups and prioritize among them so that it can target the group that suits best. The aim is to generate strong sales as soon as possible and attract other groups.

The fourth decision to be made is *how* the company should proceed for introducing the new product into new markets. This can for example be done with critical path scheduling in which the company management involves all the activities that must take place when launching the new product. The estimations of time that each activity will take give the company an overview of the completion time for the project. Any delay in any activity within this schedule will cause a delay of the entire project.[157]

7.5.1 Customer adoption process

To be able to make the above discussed decisions the company needs to be aware of how the market looks and what groups of customers there are that it can turn to. The adoption process is a helpful tool when identifying the customers. It explains their behavior as they purchase and start using new products. The customers go through five stages when adopting new products; awareness, interest, evaluation, trial and then adoption.

There are individual differences between customers to try new products and this has an impact on the diffusion of a new product on the market. Basically there are five groups of customers ordered by their readiness to adopt new products.

- **Innovators:** Customers that are buying products in a very early stage at the product life cycle. They always want to be long ahead of the average customer. Typically there are very few in this group.

- **Early adopters:** Customers that also are quick at purchasing new products and often act as KOLs. This group is also quite small, but larger than the former.

- **Early majority:** This group of customers looks at the earlier groups to see if the new product works, and if does they start purchasing it. In this group large quantities of purchasing start to evolve as the group is relative big.

- **Late majority:** This is another big group of customers. However the customers in this group tend to purchase products later than the average customer and are slow to pick up new trends. The mass consumption is still going on, but starts to decline.

- **Laggards:** Relative small group of customers that very late or never purchase the new product.

[156] P. Kotler, *Marketing Management,* 12 e., Pearson Prentice Hall, Upper Saddle River, 2006, pp.96
[157] Ibid, pp.658

Also the characteristics of the product have an impact on the adoption process and the time it will take for a product to gain market acceptance. The perceived value by the customer, the compatibility with existing experience and values, the complexity, the divisibility and the communicability are all factors that together decide how the adoption process will proceed.[158]

7.6 Pricing φ

When trying to position its product on the market, a company should usually use a strategic approach called marketing mix, which uses the 4P concept, price, product, place and promotion. The price is the amount of money that the customer will pay for a product. It is a key parameter of the marketing mix as it is the one that brings income into the company, the three other Ps only concern the costs. The defined price also determines the level of reimbursement that a company plans to obtain. It can be in the same range of its competitors or different. In the latter case, the company needs to have arguments to convince the customers that its product needs to be reimbursed at a different, generally higher price.

A way to determine the price is to build a strategic approach using different steps. The first one is to develop a marketing strategy defining the segmentation, the positioning and the target market. Then an analysis of the 4Ps of the marketing mix should be performed. Then it is essential to estimate the market demand curve. To be able to calculate the costs, the company must take into account the fixed and variable costs.

It is necessary to understand how the environment looks to be able to set the price objectives that will allow the company to define its pricing strategy to achieve them. A company needs to be aware of how much the customers value the product, what price the competitors are charging for their product and how flexible the company can be in pricing to be able to price it correctly[159]. Common objectives can be a maximization of: the current profit, the current revenue, the quantity or the profit margin, but also a quality leadership, a recovery of the partial costs, the survival or the status quo of the company. For a new product it is generally the two first objectives that tend to be achieved.

Analysing the different points mentioned in the previous paragraph helps to define an appropriate price strategy according to the objectives. Different strategies are presented and all of them are based on customer demand.

- **Penetration pricing:** The prices are set relatively low in order to gain market share in selling a large amount of products. Once achieved, the aim is then to increase the price. This strategy can be applied when the customers are highly price-sensitive, when the costs decrease as the volume produced increases, when the product can gain mass market quickly and also when there is a threat from the competitors.

- **Skimming pricing:** The prices are set high for the customers that are not price-sensitive. However, the prices tend to increase as new competitors enter the market. The strategy can be used when the product has a substantial competitive advantage.

[158] Ibid, p.659-661
[159] Wikipedia, *Pricing*, August 2006, viewed on 2008-12-01, <http://en.wikipedia.org/wiki/Pricing>.

- **Premium pricing:** The prices are set really high most of the time in the case of luxury goods. It is possible to use this approach when the product is unique and has a substantial advantage.

- **Economy pricing:** The prices are kept at a minimum thanks to the low manufacturing and promotional costs. That kind of pricing is often associated with poor quality.

- **Competition pricing:** Setting a price at competitors' level.

- **Product Line Pricing:** Selling a range of products where the price reflects each benefit of the range.

- **Bundle Pricing:** Selling different products in the same package.

The four first pricing strategies are the most commonly used. The two first ones are generally applied in the introduction of a new product. Pricing strategies can also be split with the method used to price the product as follows:

- **Cost-plus pricing:** Setting the price at the production level and adding a certain profit margin.

- **Target return pricing:** Setting the price to target a return on investment. [160]

- **Psychological pricing:** Trying to base the customer's choice on emotional and not rational buying.[161]

- **Value-based pricing:** Selling prices on the perceived value to the customer. This can be used when the clearly-defined benefits give an advantage compared to the competitors[162].

If focusing on medtech industry, specific questions need to be in the mind of the company's members. It is essential to understand the environment, the pressure that affects the pricing of a medical technology and the risen questions that are related to these different parameters:

- Competiting technology: is it as effective as ours?

- Competiting price: should we match it or can we price higher than the competitor due to a specific advantage?

- Reimbursement situation of the market being entered: what will be the level of reimbursement system of the country entered? What are the parameters that influence the price of reimbursement of the product?

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[160] Net MBA, Knowledge Center, *Pricing Strategy*, viewed on 2008-12-04, <http://www.netmba.com/marketing/pricing>.
[161] Learn Marketing*, Pricing strategies*, viewed on 2008-12-04, <http://learnmarketing.net/Price.htm>.
[162] Business Link, *Price your product or service, G*uide developed by BERR, Dpt for Business, Enterprise and Regulatory Reform, England, viewed on 2008-11.26, <http://www.businesslink.gov.uk/bdotg/action/detail?type=RESOURCES&itemId=1073790697>.

- Price trends within the sectors: is there a price tendency of increasing or falling?
- Medical need for the product: can a greater need be enough to charge a higher price?
- Company's market share: is it large enough to be protected if an aggressive pricing is chosen?
- Company's economic strength: can we undercut the price in a situation of the competition?
- Brand's strength of the product: can the brand protect the price of the product?

Factors of different natures can affect the price of a medical technology, it is therefore necessary for a company to take all these parameters into account to define its pricing strategy. The company needs to assess the costs, the medical need, the competition and the customer market. The assessment of the costs allows the company to define the minimal price they can offer thanks to the definition of the cost of manufacturing and marketing of the product. A commonly used strategy with innovative technologies is the skimming pricing. This is mainly due to the life cycle and the entry of new competitors. The assessment of the medical need can provide information about the possibility to charge a higher price for the product due to the demand. The assessment of the competition allows defining if the competitor leads the market with its pricing but also if a segment is price-sensitive or not. It allows the positioning of the company compared to its competitors. The assessment of the customer market shows the emphasis the customers put on price and quality. It also allows understanding the target market in term of legal requirement, the type of payment and the favourite products.

This section summarizes the different issues that need to be addressed. The company needs to evaluate if the severity of the disorder affects the price sensitivity as well as the position of the disease/treatment in the perception of payer, physician and population. They should also look at the costs, direct, indirect and quality of life, for the healthcare system and the society that are related to the disease. The more the medical technology can reduce costs, the greater the potential to increase its price. The company also needs to keep in mind the documents and information needed to prove the cost savings, which can be obtained from clinical trials as well as comparisons with other technologies and economic data. The product sometimes can be used in a combination therapy. It is important to consider the cost and the price of the therapeutic process as a whole. Last but not least, the company needs to understand if the product's value is different for the various potential applications. In such a case, the price better needs to be adapted to the perceptible value.[163]

Depending on the market segments and their tendency, the price of a medical technology needs to be set differently. In a mature segment such as pacemakers, it is difficult to price new products with additional features much higher than the standard. However it is not a generality. In the example of orthopaedics, knee and hips implants have fashioned and lots of special features with high standards, which give another perception to the product and allow

[163] HBS Consulting, *Pricing Strategies – the outlook for Medical Devices and Diagnostic Companies*, Strategy review, 2006, London, viewed on 2008-12-05, <http://www.hbs-consulting.com/HBSStrategyReviews/pricing.pdf>.

companies in that field to price new generation of products higher. However, a company should keep in mind that these actual tendencies might change in the following years. [164]

7.7 Discussing the integration model

This section relates the theories presented above with our own model illustrated in Figure 19. The purpose is to explain why the integration of reimbursement activities does not take place earlier among the companies in this study.

Phase R is a critical phase and companies can be stuck in it as long as they have not established reimbursement. As it can be seen in case 7, the consequence of not having reimbursement for the product is that the sales are negatively affected.

The aim for a company should be to reduce as much as possible the length of phase R to be able to benefit from the advantages in phase 3, when the product is 'unique' on the market. The key factor is therefore to integrate the reimbursement issue as early as possible in the product life cycle in order to be well prepared when approaching phase R. This might reduce the length of the reimbursement phase. As mentioned, the launching companies do not integrate the reimbursement activities until phase R even if some of them have collected information about it earlier.

A possible reason why these companies do not start the reimbursement activities in phase 1 is that they, at this early phase, are not aware enough of the reimbursement and the issues that may be associated with it. Awareness is a state of mind that is hard to measure with quantitative parameters. However, a few common reasons for why some companies seem to be more aware than others emerged from the case studies. The phase in which the companies are seems to explain part of the differences. Since many of the companies emerge from university projects, researchers are often on the management positions in phase 1. Therefore the companies cannot rely on experiences in their decision makings from previous commercialization processes. When taking decisions the reimbursement issue might be left behind since the possible obstacles in practice might be unknown. When allocating the resources within the company, reimbursement might not cross the decision makers' mind. The bounded rationality of the decision maker is then, according to these arguments, one reason for why reimbursement sometimes is 'forgotten' in phase 1. The decisions can however become more rational if the decision maker can benefit from other's experiences, for example from other companies, products or markets. An example where the experiences of the people within the company seem to have had a large impact is Company Beta. Person 2 has a long experience from working with market related issues within the medtech industry. His entrance in the company changed the general view of the reimbursement issue and that is a sign of his awareness.

The network of the entrepreneur of the company can also influence him in term of becoming more aware and knowledgeable about the reimbursement issue. This is an explanation why Company Epsilon has such a high degree of awareness that it starts gathering specific information about reimbursement at an early stage, while Company Gamma does not collect the information until just before the launch. Person 5 from Company Epsilon exemplifies this as he has no previous experience from commercialization of medical technology since this

[164] L.R. Burns, *The Business of Healthcare Innovation*, Cambridge University Press, 2007, pp. 308.

company is his first mission outside academia. He pointed out that it was his network of people that brought his attention to the matter.

The network of the companies evolves and has specific characteristics in the different phases. In phase 1 the link to a larger network is reached through informal contacts, like physicians which are friends or friends of a friend of the entrepreneur. The centres where the clinical studies are performed might for example be reached through these contacts. In phase 3 when the marketing and sales start the network seems to become more formal. As the model describes the penetration strategy of the companies are to focus on targeting the KOL to reach the larger market.

As described in the model, even if awareness about the issue and some knowledge gathering can be seen earlier on in phase 1 and 2, the integration of reimbursement activities does not seem to take place until reaching phase 3. The lack of resources, in terms of capital, is a main obstacle that restricts the companies from using the knowledge they have acquired and from accomplishing the plans they in some cases have. The companies are often partly aware of that reimbursement might be an obstacle to gain full market access and in addition also have plans for which market they want to enter. They may for example want to investigate the reimbursement system more deeply in these markets by hiring consultants. However, the limited resources restrict them from doing it. The type of financing might also affect the companies when prioritizing among different activities to focus on. VCs are mainly involved in the early phases like 1 and 2 and may therefore not bother too much about the later phases where an exit probably already has taken place. However the value in the company might increase if the reimbursement situation is clear.

Former experiences as mentioned in the paragraphs above might influence the company in dealing with the reimbursement issue. However, it can be discussed if those influences have always a positive income. In general, former experiences seem to have a good impact on the reimbursement awareness. It can however have a negative influence in the sense that people might rely too much on what was done in other markets with other type of products. The payment systems differ from countries to countries and the acquired knowledge on a market might therefore not be valid on another one.

Moreover, reimbursement is an on-going process. For example the German DRG prices are recalculated each year which makes the process continuous. Reimbursement processes also take place in changing environments. In the hospital sector for example, from 1990s until today, DRG payment systems have been introduced across Europe, as presented in Figure 9. The phase of introduction takes in general a couple of years during which the rules are not always well defined. Therefore, it might be a mistake from people not updating their knowledge and just rely on past experiences.

The behavior of the companies, when marketing their products, can also be explained by Kotler's model of what decisions needs to taken and the early adoption process. The model describes how the decisions of when, where, to whom and how are affected by the resources of the company. What Kotler's model however does not explain is how the decisions made affect the reimbursement situation for the company. For example the 'whom' decision in that model is about optimizing the sales. That is consistent with the reimbursement integration model also, but it lacks the explanation of how to optimize the sales by establishing reimbursement. In the integration model is described that the companies go for the KOLs to penetrate the market and build a reimbursement case that later will help them to reach out to

the rest of the market. The how decision, in the reimbursement integration model, should be about when processes should be started and activities performed as well as what strategies to use, e.g. if applying for new coding and price level. As for the when and where decision we see that they are quite consistent between the different models. The 'when' decision affect the resources a company needs to put on convincing the market of the product's benefit. In the reimbursement case several parallel entries of similar products might ease and/or speed up the reimbursement process. The markets in focus also play a role as a company has limited resources and cannot collect market specific information from all the markets at the same time. That means that the reimbursement phase can be of different length in different markets as the preparations are different.

It can be observed in the case studies that the pricing strategy of the companies vary according to the strategy. Differences seem to appear, in the launching companies, depending on if they want to apply for a new code or if they aim to fit in an existing one. It seems that, when using an existing code, the companies cannot price their product at a much higher level than the competitors because the level of reimbursement would not be sufficient. The pricing strategy can be related to a competition pricing.

Creating a new code gives the company a chance to price it differently, generally higher, from its competitors and therefore using a Premium pricing strategy. The example of Beta shows the application of it as it is aiming at charging a much higher price for its procedure than the actual one.

The early-stage companies have not a pricing strategy clearly defined yet. However, since these companies will probably have to apply for a new code, they might follow a Premium strategy in the future.

Most of the companies present a common method of pricing which is the value-based pricing. Independently from the strategy, they try to obtain a price as high as possible. In order to convince the customers they mainly argue with clearly-defined benefits that the customers' value and which give them an advantage compared to their competitors. The promoted value is not similar in each case and can be for example reduced costs like for Company Alpha, unmet needs like for Company Gamma, some technical improvements like Company Delta, as well as time saving or a mix of these argument as for Company Beta, Epsilon, Zeta.

8 Comparing the integration model with the value chain concept

8.1 The value chain χ

All firms are involved in a wide range of activities that allow them to design, produce, market, deliver and support its product. The activities together form a value chain in which the company creates value. The concept was introduced by Michael Porter in his book *Competitive Advantage; creating and sustaining superior performance*[165]. The value chain represents the total value to the buyer, created in these activities. The activities in the chain are firm specific and each of them employs purchased inputs, human resources and technology to function. The chain is divided into 'Primary activities' and 'Support activities'. Primary activities are directly performed to increase the value offered to the buyer. The support activities are supporting the primary activities with internal services in order for them to function properly.[166] The Primary activities consist of:

- **Inbound logistics:** Activities performed within the company aiming at handling inputs to the product.
- **Operations:** Activities performed aiming at transforming the inputs to the final product.
- **Outbound logistics:** Activities performed aiming at delivering the final product to the buyer.
- **Marketing and Sales:** Activities performed aiming at providing the buyer with incentives and means for buying the product
- **Service:** Activities performed aiming at providing after sales services to the buyer.

The Support activities are on their part divided into four different categories;

- **Procurement:** Purchase function of inputs to be used in the firm's value chain.
- **Technology development:** All the activities the firm is involved in, in order to improve the product or the process.
- **Human resources management:** All the activities involved in employee recruitment, hiring, training etc.
- **Firm infrastructure:** All the activities in the firm involved in planning, management, finance, etc.

[165] M.E. Porter, *Competitive Advantage; creating and sustaining superior performance*, New York Free Press, New York, 1985.
[166] Ibid, pp. 37-38.

In each of the above categories three different activity types play different roles. The direct activities create value for the buyer, for example the assembly of a product. Indirect activities enables the direct activities to be performed, an example is maintenance of production equipment. The quality assurance activities finally, assures the quality of the before mentioned.[167]

Figure 20 shows the concept of the value chain presented by Porter. Important to bear in mind is that even though it is shown as a linear process in reality it seldom is.

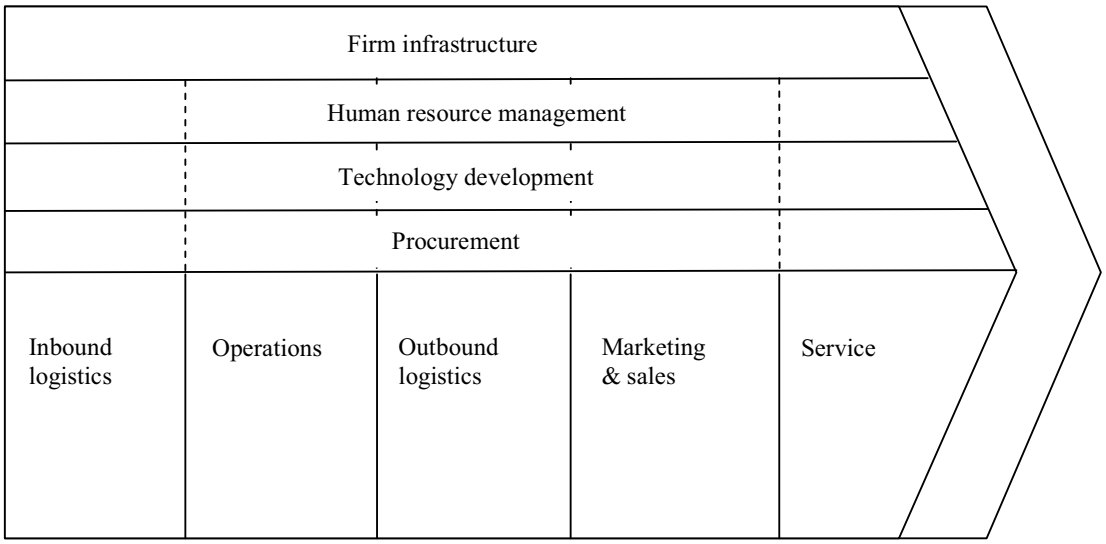

Figure 20 : Porter's value chain [168]

Buyers also have value chains and the output from a firm's chain serves as an input to the buyers' own chain. Companies become competitive by differentiating their value chains from their competitors and change the way it affects the value chain of the buyers. This is not only done by product delivery to the buyer but also through all other interactions between the firm and the buyer, shown in Figure 21. The firm can affect the buyer's value chain either by lower its costs or raise its performance. If buyers perceive the value created from the firm they are willing to pay a premium price.[169]

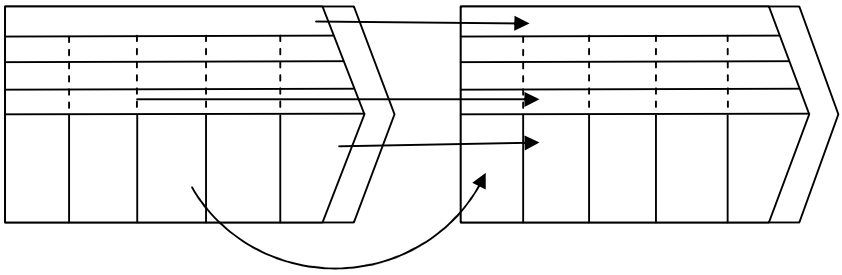

Figure 21 : Schematical representation of the interactions between the firm and the buyer according to Porter [170]

[167] Ibid, pp. 39-44.
[168] Ibid, pp. 37.
[169] Ibid, pp.52-53.
[170] Ibid, pp. 133.

Lowering of buyer costs can be done in many different ways. Beside the fact that the product characteristics have an impact it can also be influenced by logistics, ordering procedures, etc. Raising the buyer performance is somewhat different because it will depend on the firm's understanding of the buyer's desired level of performance. This requires analysis of the buyer's activities as well as of the buyer's buyer. A problem for the firm in providing value to a buyer is that not even the buyer itself is always capable of assessing the value in advance. That makes it difficult for the firm, and the buyer, to understand fully how the value provided actually affect the value chain of the buyer. This can also be difficult to fully understand even afterwards. The buyer's incomplete knowledge and the fact that he will not pay for a value that he does not perceive has an impact on how the firm mediates the value provided to the buyer. [171]

The buyer values the product from two different criteria, the use criteria and the signaling criteria. The use criterion is how the firm actually affects the buyer value. Examples of use criteria might be product efficiency, quality, support, etc. The signaling criterion is about signals of value to the buyer, it might be such things as reputation and advertising. [172]

When identifying the buyer criteria it is always important to identify the decision maker of the buyer. It is always people who buy something, not organizations. [173] The user criteria should then be identified first, because it is from that criterion what the buyer value can be derived from. It is also a determinant of the signaling criteria. .Furthermore a precise description of the use criteria is essential when developing a differentiation strategy. The performance of the product in meeting the criterions should be quantified. This allows the firm to position itself from its competitors and do comparative studies. The value of meeting the criterions is assessed by looking at how it affects the buyer's cost or performance. The criterions can from this then be ranked after importance. This will help the firm develop a strategy that is efficient and focuses on the right purchase criterions. The use criterions will eventually reach a point when it is no longer feasible to meet them. Any further improvements or measure of them will not increase the buyer value and the returns will diminish. The measurability of the criterions is also something to consider. The more difficult a criterion is to measure, the more expensive it becomes to collect data. This has an impact on how to rank the criterions and how to make up the strategy. The cost of measuring it and the importance of the buyer value should be put against each other.[174]

8.2 Comparing the two models

Our model is based mainly on small startup companies, built around only one technology. That means that they are building value into the product and to the customers as they develop it. In Porter's value chain theory the technology development is seen as a support activity that supports the primary activities in the company. We argue that this is not applicable to a medtech company of the size studied. Or at least it is more feasible to look at it from another perspective. As the companies are much focusing on developing a new product and not yet manufacture it, it becomes a Primary activity according to Porter's concept. More precisely we argue that the product development in the company is the operation that transforms the inputs of ideas to a final product. Seen from this perspective the inbound logistics then

[171] Ibid, pp. 137-140.
[172] Ibid, pp. 142.
[173] Ibid pp. 140.
[174] Ibid, pp. 146-149.

become the activities the company performs in order to get new ideas and its way of handling these. The outbound activities that are more about delivering the final product would in this case then be to set up the manufacturing and produce the product. This is what the company needs to do to be able to supply the market with the technology. Finally, marketing and sales is about convincing the market to invest in the new medical technology.

In the model presented in this report we conclude that companies mainly integrate the reimbursement activities in the marketing phase. Compared to Porter's value chain concept this means that they are a part of the Primary activities in the form of sales and marketing. Thereby the companies build value for the users when they manage to establish reimbursement for the procedures. This means that the companies have to convince one type of customer, the insurance companies, to be able to sell to the actual user.

In Porter's model the use criterion on which the buyer decides to buy the product or not is based on parameters such as the efficiency, quality and safety of the product. In the medtech industry however, the customer landscape is more complex as it is not the same customer that pay for the product that actually use it, and to make it even more complex there is a third party that receive the benefit of the product. This has implications on the parameters that the company must address when marketing a product. Not only have the technical features of the product become important to show, but also how it economically affects the customers, especially the payer and the user. In Porter's model this can be seen as if the company needs to affect the value chain for both of these parties. For the user it does that with more efficient products that can make the activities performed more effective or make the outcome better. This would then reduce the costs for the user while the reimbursement levels are the same or at least do not decrease with the same rate. For the payers it is also about reducing the costs, but in overall. It is more about improving the outputs of the activities of one user to be able to reduce the costs of another user.

According to Porter, a buyer is always uncertain about the real value of a new product. This uncertainty can be hard to overcome completely, but is decreased as the provider of the product is able to identify the criteria on which the buyer bases his decisions and address them. Evidence on how these criteria are fulfilled is needed to make the buyer overcome his uncertainty. Related to the model in this report the companies try to overcome this uncertainty by building up evidence of the economic value on the market.

9 Method discussion

The Grounded Theory used during this investigation entails some problems which spring out of the nature of the method and its inherent properties. The iterative process by which the researcher continuously enlarges his/hers knowledge forms the acquired empirical data. This results in the fact that the consistency during the process is affected. The case interviews were performed during a period of a few weeks and each of the interviews informed the researcher that became more and more knowledgeable during the process. For example the interview technique evolved and the increased knowledge resulted in deeper questions that were not asked during the first interviews.

For the seven company interviews, we asked for the most knowledgeable person about reimbursement. However, this might not always have been the case. In addition, we can never be sure that the statements made by the interviewees represent the general opinion within the company.

The results derived from these interviews might have been influenced by the situation the interviewees were facing. When preparing the questions we did not take into account the risk that the respondent would not know anything about reimbursement. The outline of the questionnaire might therefore have unintentionally influenced the answers of the respondent. In addition there is a possibility that a respondent which is faced with three students might want to seem knowledgeable and give answers that agree with that agenda. We have therefore held ourselves sceptic and looked upon the answers with critical eyes in order to not be too much influenced by the respondents' personality. This gives more credibility to the study. However, it is hard to be completely objective. The results must always be interpretated in one way or another.

Due to limitations of time for this project it was not possible to investigate a larger number of companies. A greater sample size would have made the study more reliable but may also have resulted in that more similar characteristics would have been perceptible. It would have been feasible with more backtracking companies but it was not possible as mentioned earlier.

The case studies could also have been more profound in order to capture all the details that could have been of interest. However this would have required further interviews with the same or other people within the companies. Since several of the companies were located in other parts of Sweden more travels would then have been required for these additional interviews, which the resources did not allow.

10 Conclusions

From the study performed and the reimbursement integration model, four conclusions can be drawn.

- Small Swedish medtech companies seem to handle, when at all, the reimbursement issue within their marketing departments. This means that the reimbursement is seen as a marketing activity and is therefore handled by marketing people in phase 3 of the product life cycle. We would like to argue that this is too late and can be seen as a major pitfall for the companies. Sales will in most cases not escalate until reimbursement is established and companies therefore miss out on potential revenues. Instead they should integrate it in the earlier phases.

- The companies do not, however, address the reimbursement in these earlier phases, by collecting economic data parallel with the clinical trials. This should be done in order to fully assess the impact of the product on the healthcare. An 'internal' HTA could be feasible to perform to be sure that the company understand the challenge they face. It is also essential that the company in an early stage chose the target markets and gathers information about the appropriate target market as a basis for the price setting strategy. The gathered information should for example identify important actors within the healthcare/reimbursement system, reimbursement levels and potential competition on that market.

- The life cycle of a medical technology product can be extended by adding a reimbursement phase, Phase R, which follows the regulatory process. The length of this phase is influenced by how a company addresses the above points.

- The reimbursement issue has various importances for different type of products. For radical new innovative products, which do not fit within an existing reimbursement code, it has a bigger impact on the market access and thereby the sales. On the opposite, for companies with products that represent incremental improvements the reimbursement issue is not that problematic. This means that not all companies need to invest the same resources in their reimbursement activities.

An anecdote...

A thing that deserves to be mentioned is that there seems to be no well recognized translation of the word 'reimbursement' in Swedish among the medtech companies. The closest word is 'ersättning', however that seems not to be an established word in the mind of the people working in these companies. This might influence them in their state of mind since they do not have any commonly used word to refer to in their own language. It might have an impact on their awareness and judgement of the importance of the issue.

11 Further studies

In this report a descriptive model has been built. However the model only touches the surface of how the companies deal with the reimbursement issue. Therefore it would be of interest to further develop it and look at different aspects of what affects the awareness and the activities performed by the companies. It would also be interesting to see if the model also fits companies from other countries. We have briefly discussed how the network and experience of the people within a company can affect its awareness. A suggestion would be for instance to more specifically look at how the experience and knowledge from one market affects the activities in another. Moreover it would be of interest to actually try to measure the awareness of the issue within the company and classify it in different levels. The first level could for example be that they just are aware of reimbursement existence and the last level could be that they have full understanding about the complexity of the issue and have developed a specific plan to deal with it. The awareness is a difficult concept to measure and it would put the researchers' creativity to test and to come up with a good way to quantify it. It would, however, be of interest to know more about this since the awareness is a prerequisite to start dealing with the reimbursement issue at all. Also, it might be of interest to study the impact of the reimbursement awareness/competence among owners and board of directors on the company strategy.

This study has taken the perspective of the small companies to see how they integrate and deal with reimbursement in their activities. But the lack of resources within the companies can make the issue too large for them to handle. They would therefore probably benefit from external support in both becoming more aware and put up a strategy for dealing with it. It would be interesting to see what could be done on a national level to support small medtech companies in their commercialization process. That would then also include support and advice of how they should deal with the reimbursement issue.

From another point of view it would be interesting to see if and how the diverse reimbursement systems in Europe could become more uniform. The different systems have different requirements and the routes to get into them vary. This makes the landscape more complex for manufacturers of medical technologies and market access in the whole of Europe harder to gain. Therefore a more uniform system might make it easier to bring new technologies to the market. This could maybe be split into two research questions:

- What are the obstacles for unifying the reimbursement systems in Europe?
- How can the reimbursement systems in Europe become more uniform?

The first question would then identify the factors that constitute the hurdles for a more uniform system, while the second one would investigate how these hurdles can be overcome.

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Appendices

Appendix 1 : Technology trends ψ

Using medical technology for drug delivery

The history of the pharmaceutical industry shows mainly contributions of drugs that consisted of fast-acting chemical compounds, orally or intravenously administered and dispersed to the whole body. A main topic of the current medical technology is to develop systems that efficiently deliver the drug to very local regions within the body, such as a distinct part of a target organ or a tumor. Miniaturized systems that can be controlled and directed to the target by implanted or external, e.g. through radiation, sensors are under development.[175]

Nanomaterial, commercial nanoproducts and future applications

Several commercial products and technologies purposed for medical use have already benefited from nanotechnology. Among these, nanotechnology is put into practice mainly through material applications. At the nanoscale the properties of the material can be different, mainly due to two things. First, the relatively larger surface/bulk ratio of nanostructures affects the strength and electrical properties and makes them more chemically reactive. Secondly, the quantum effects begin to show when the size is reduced to the nanoscale and affect the optical, electrical and magnetic properties of the material.[176] Quantum dots are examples of structures exploiting these effects. These are spherical crystalline nanoparticles of semiconductors with a size of a few nanometers that, due to the characteristic laws ruling the 'nanoworld', provide unique optical and electronic properties. The quantum effects appear in the particles by limiting the energies to distinct levels, in which electrons and holes (the absence of an electron) can exist. The particles can therefore be made to absorb or emit specific wavelengths by controlling the sizes of the particles. Quantum dots have found applications as fluorescent biological labels, for example to trace a biological molecule. This can be used in imaging and for devices enabling diagnostics at very local sites in the body. [177]

The material or the surface of the medical device can be improved in the interaction with biological material, by nanocoatings or other special preparations. This is done by increasing the biocompatibility, stimulating the own biological healing process or inhibiting cellular growth. There are for example nanostructured biomaterials for usage as scaffolds in the regenerative medicine and nanostructured bone replacement materials, which provide better integration of the implant in the body.[178] Stainless steel alloys or titanium has principally been the material that has been used in medical implants, such as orthopaedic implants and heart valves. The reason is primarily because they are biocompatible. The metal alloys may however wear out during the patient's life. Some nanomaterials are attractive candidates in the material of implants since they show wear and biocorrosion resistance, strength and bio-compatible properties, for example zirconium oxide (zirconia). Nanocrystalline silicon

[175] P. Driscoll, *Advanced Medical Technology, Beyond Technology: Other Medtech Market Forces*, 2007
[176] Eucomed, *Innovation in Medical Technology- Nanotechnology*, 2006 viewed on 2008-10-27 <http://www.eucomed.org/press/~/media/pdf/tl/2008/portal/press/publications/booklet01nanotechnology.ashx>.
[177] Nanowerk, *Introduction to Nanotechnology*, viewed on 2009-01-08, <http://www.nanowerk.com/nanotechnology/introduction/introduction_to_nanotechnology_1.html >
[178] Eucomed, *Innovation in Medical Technology- Nanotechnology*, 2006.

carbide is a possible alternative material for artificial heart valves mainly due to its low weight, high strength and inertness.

Different nanostructures show beneficial characteristics. A carbon nanotube is an elongated hollow single-walled molecule, of pure, hexagonally-arranged carbon atoms, resembling rolled-up chicken wire. It is typically a few nanometers in diameter and is several micrometers or even centimeters long. The nanotubes can also be multi-walled consisting of several concentric tubes. The nanotubes possess many 'extraordinary' mechanical, electronic, thermal or optical characteristics. They show a remarkable mechanical strength, flexibility and can be excellent conductors. Since the human body to a large extent consists of carbon, the nanotubes are thought of as biocompatible. Cells have been shown to grow on the carbon nanotubes, which do not appear to have toxic effects. In addition, the cells do not adhere to them, which mean that they might have possible applications as coatings of prosthetics and surgical implants. They may also have biomedical applications such as vascular stents and neuron growth and regeneration. A nanotube coupled to a single strand of DNA has been successfully inserted into a cell which means that nanotubes have potential applications in gene therapy.[179]

Within surgery, nanotechnology is used to manufacture extremely sharp surgical blades with low friction suited for optical or neurosurgery. Plasma polished diamond layers are covered with specific nanocoatings to prepare these blades. Nanomaterials such as nanotubes have been added into minimally invasive surgery catheters in order to increase their strength and flexibility.

The diagnostic field increasingly uses nanotechnology to enable a metabolic change detection that is very local and minimally invasive. New imaging agents also enable imaging at the cellular and even down to the molecular level. The term nanosensors in a biological context refer to a nanostructure, which can detect different bio molecules that may indicate a special state of disease. For example, a specific property of the nanotube is its capacity to, under very low voltage, contract or elongate in certain electrolytes. This and other methods based on their conductor properties makes them interesting for actuate or sensor applications. Nanotubes that monitor blood glucose or CO_2-level and nanowires that detect different bio molecules such as the peptide involved in cystic fibrosis or the disease markers dopamine and ascorbic acid for diagnosis of Parkinson's disease are some examples.

As mentioned quantum dots can be used to trace biological molecules. Poly- or monoclonal antibodies labelled with a single nanoparticle e.g. of gold, silica or iron oxide, can be used for the detection of pathogenic bio molecules on bacteria or on tumour cells.[180] When the nanoparticles are illuminated, light is emitted with specific wave length. This exposes the location of the particles and thereby also the site of the pathogen.[181] A procedure like this, which targets the disease markers in combination with drugs, makes it possible to combine diagnostic with treatment interventions, called theranostics. In vitro diagnostic is also a potentially great field for nanotechnology. Attempts to minimize analysis systems that just need tiny amounts of analyte to perform laboratory tasks have resulted in nano-fluidic system, called "lab-on-a-chip". The aim is to develop these chips to perform hundreds of laboratory

[179] Nanowerk, *Introduction to Nanotechnology*.
[180] Eucomed, *Innovation in Medical Technology- Nanotechnology*.
[181] *Gold Nanoparticle Probes May Allow Earlier Cancer Detection*, ScienceDaily 2007-12-26, viewed on 2008-10-30, http://www.sciencedaily.com/releases/2007/12/071224124751.htm.

task in real time. The chips should also, in performance with other devices, be able to provide continuous monitoring of the patient's condition.[182]

Nanotechnology, with its aim to reduce the invasive incisions and to provide earlier and more accurate diagnosis methods, is giving promises of improved medical technology and increased cost-effectiveness. However, the discussion of the possible health risks of nanotechnology, might not have escaped the public's observation.[183]

Tissue engineered products on the market and development in progress

Some products that employ regenerative medicine and human tissue engineering are already on the market, e.g. human tissue engineered skin, cartilage, bones, cornea and bladder. However, the desired goal of tissue engineering is to build complete human organs on scaffolds. At this stage nerve regeneration for treatment of Parkinson's disease and Alzheimer's disease is under current research as well as regeneration of damaged heart tissue. The demand of skeletal bone is large within healthcare, e.g. for degenerative diseases and victims of accident. A lot of focus is put on biomimetic materials that are developed to act as a matrix, which interacts with the bone cells, osteocytes, and provides an adhesion site for these cells. The ageing population increasingly entails occurrences of degenerative joint conditions. The current treatment used is to partially or completely replace the joint but it could in many cases be possible and preferable to stimulate the patient's own cells in the cartilage, chondrocytes, to grow in order to replace the damaged cartilage tissue. The future may provide methods that to a larger extent avoid the need for an implant and the associated surgery.

A lot of research is also currently focusing on blood vessel engineering. The task is to develop a matrix to which both smooth muscle and vascular endothelial cells can attach in order to form tubular scaffolds similar to the native vessels. The vessels must in a suitable way sustain a pulsating pressure from the blood, which is a distinctive requirement in this type of tissue engineering. Different ways to produce the scaffolds are seen, e.g. synthetic biopolymer- or biologically derived materials are used in the matrices. Though the extended research, the prediction is that this type of very challenging medical products will need several years until marketing.

The products from the regenerative medicine are often developed to meet the need for one individual patient alone. This conflicts with the aim of mass production. The benefits enclosed with such a large production cannot be gained. The situation is a challenge for the manufacturers.[184]

Digitized management of patient case books and images

Healthcare requires large and complex databases that can manage the storage of large amount of data but that also can present user-friendly and flexible systems. The breakthrough of graphic user interfaces, GUI, has demolished the barriers between the physician and the computerizing systems, enabling the clinician to easily and quickly perform his or her tasks in e.g. a Windows-based system. The emergence of the called electronic medical record, EMR,

[182] Eucomed, *Innovation in Medical Technology- Nanotechnology*.
[183] J. Wilkinson, *An Introduction to the Medical Technology Industry*, Eucomed, Cranfield, 2008 viewed on 2008-10-08, <http://www.eucomed.com/press/~/media/0C4ABA4A38E14D75BCC91C1FCA62288D.ashx>
[184] Eucomed. *Innovation in Medical Technology- Regenerative medicine and human tissue engineering,* 2007, viewed on 2008-10-29, <http://www.eucomed.org/press/~/media/pdf/tl/2008/portal/press/publications/booklet02humantissue.ashx>.

is claimed to be the largest consequence of IT applications in the healthcare so far. The change from paper chart to digitized information has brought up the handling of patient data to date.

The diagnostics outputs, e.g. laboratory data, radiology images and tissue pathology, have already partly entered the digitized record but within the next year this trend will probably be seen in a larger extent. New infrastructures are implemented in hospitals in order to meet the possibilities of handling the outcomes from the radiological examinations. The Picture Archiving Communication and Storage system, PACS, enables digital storage of radiology examinations, integrating it with the rest of the patient list. Improved networking and easier co-operation between radiologists and physicians should result in a more effective performance of the healthcare system. The large companies of radiology such as Siemens and GE try to internally consolidate this highly fragmented field and have thereby entered into the clinical software field. However, the most advanced high-technological imaging modalities are, indeed, the magnetic resonance imaging, MRI, and computerized tomography, CT, which now also face these trends of application.[185]

Additionally clinical fields of applications and integration of IT

Surgeries integrating IT in terms of medical imaging and robotics are examples of the integration of IT in medical technology. Doctors situated on one continent performing a surgery on a patient on another continent, through remote systems, is now a technical possibility. Diagnosis, consultations and information exchanges are to larger extent done without a face to face meeting between the patient and the doctor. This remote delivery of care, like telecare and telemedicine, or the transfer of information over internet might reduce the workload of the physicians on each patient and can thereby reduce the healthcare expenses. For example results from blood glucose tests or data from a pacemaker can be sent and remote monitored. [186]

The current trends of mapping individuals' different sets of genetic code and the increased use of a patient genetic makeup as guidance in treatment decisions will increase the need for digitized management and interpretation methods of the large outcome of data. Genetic information about the patient will be used to both investigate the patient's immune competence as well as the ability to metabolize drugs. The genetic variation among the population leads to different responses from treatments among individuals. Knowledge of how an individual's unique genetic code affects the ability to metabolize drugs is thought to be a key prediction to avoid adverse effects in therapy.[187]

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[185] L.R. Burns, *The Business of Healthcare Innovation*, 2007, chapter 7, Cambride University Press..
[186] J.Wilkinson, Eucomed, *An introduction to the medical technology industry*.
[187] Burns, chapter 7.

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Appendix 2 : International and European HTA organizations ψ

In order to improve the overall assessment procedures, several international committees and projects are trying to co-ordinate the assessment work and disseminate the outcomes internationally. There are organizations existing both on European and international level.

- **Health Technology Assessment International (HTAi)**
  HTAi is an international organization for several different stakeholders, e.g. academic institutions, healthcare providers, industry or government sector all with interests in the HTA. The aim is to provide an international forum for exchanging information.[188] The International Society for Technology Assessment in Healthcare, ISTAHC, was reorganized 2003 and resulted in the HTAi establishment.[189]

- **International Network of Agencies for Health Technology Assessment (INAHTA)**
  INAHTA was established in 1993 in order to provide an international forum for the interest common of the HTA member agencies. INAHTA contributes to the transparent approach of health technology assessments through the report of the agencies and other information that is published and available in the INAHTA database. INAHTA represents 46 agencies from 24 countries.[190]

- **International Society for Pharmacoeconomics and Outcomes Research (ISPOR)**
  ISPOR promotes the science of health economy and the scientific disciplines that evaluate the outcome of a new medical intervention. The outcome parameters that are evaluated are both clinical and economic. The society then presents the results in a useful way for the decision makers to ensure that the resources are allocated efficiently. ISPOR should also serve as a global forum where information about health economy and patient health outcome research can be exchanged. The society has more than 3600 members from 90 different countries.[191]

- **European Network for Health Technology Assessment (EUnetHTA)**
  EUnetHTA is a European Commission project which was started in 2006 as a response of the "urgent need for establishing a sustainable European network on HTA". 25 different European countries and 29 HTA institutions are represented by this project. The aim of EUnetHTA's work has since the foundations been to develop an organizatorial framework of practical tools and network for HTAs.[192]

[188] R. Banken, HTAi- Health Technology Assessment Internatinal, 2008, viewed on 2008-10-13, <http://www.htai.org/>.
[189] DIMDI, 2007, viewed on 2008-10-13, <http://www.dimdi.de/static/en/hta/koop/international.htm>.
[190] INAHTA, 2008, viewed on 2008-10-13, <http://www.inahta.org/INAHTA/>.
[191] ISPOR, viewed on2008-10-13, <http://www.ispor.org/mission.asp>.
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Appendix 3 : Toolbox

The toolbox is a timeline that describes the different activities that a medtech company need to go through. The Toolbox is an interactive instrument and is better used as an electronic document. To get access to the Toolbox contact the authors.

Appendix 4 : Questions for the screening study

- When has the company been founded?
- How many people are working in the company?
- Do you have any product that are going to be marketed soon or that has been marketed recently?
- What kind of product is it?

Product questions

- What is the value provided by this product?
  - To see what point of view he has, patient, system, technology, insurance.

- At what stage of the commercialization process are your product(s)?
  Sales:
  - Where do you market/ should market your product?
  - What is the biggest difficulty you have encountered for the acceptance?

  Technology development:
  - What phase of development is the product in?
  - When and where do you plan to market it?
  - What is the biggest difficulty you have encountered so far?

- Do you have any strategy for how to get reimbursed?

- How would you characterize your competitors?

- Would you be interested to help us with our future study?

Appendix 5 : Questions for the early stage companies

General questions about company and product

- What is your position at company XXX?
  - What kind of responsibilities do you have?
  - How long have you been working for XXX?

- How big is company XXX?
  - Turnover and employees?
  - How is the company organized?

- When did you start developing the product YYY?

- Describe the product and the technology behind it!

- What will be approximately the price of product YYY?

- What problem does your product solve for:

  - The hospitals?
  - Physicians?
  - Patients?
  - Payers?

- What are the economical benefits of your product?

Marketing strategies

- In which countries do you plan to launch the product in the future (3-5 years)?
  - Why have you chosen those markets?
  - When and how? Entrepreneurial vs. a whole country?

- What is your launching strategy in Germany?
  - In which sector will your product be used (inpatient-outpatient, hospital-ambulatory)? (% of focus (50-50?))
  - In which hospitals/offices and on what criterions have you chosen these ones?

- How do you see the German market?
  - Easy or hard to enter? Motivate!
  - Reimbursement system

Appendix 6 : Questions for the launching companies

General questions about company and product

- What is your position at company XXX?
  - What kind of responsibilities do you have?
  - How long have you been working for XXX?

- How big is company XXX?
  - Turnover and employees?
  - How is the company organized?

- When did you start developing the product YYY?

- Describe the product and the technology behind it!

- What will be approximately the price of product YYY?

- What problem does your product solve for:
  - The hospitals?
  - Physicians?
  - Patients?
  - Payers?

- What are the economical benefits of your product?

Marketing strategies

- In which countries do you plan to launch the product in the near future (3-5 years)?
  - Why have you chosen those markets?
  - When and how? Entrepreneurial vs. a whole country?

- What is your launching strategy in Germany in term of time and where (geographic)?
  - In which sector will your product be used (inpatient-outpatient, hospital-ambulatory)? (% of focus (50-50?))
  - In which hospitals/offices and on what criterions have you chosen these ones?

- How do you see the German market?
  - Easy or hard to enter? Motivate!
  - Reimbursement system

- When do you expect to have established reimbursement for your product in Germany?

German market

- When did you start considering the reimbursement issue?
  - In what year?

    - In what phase were you at the time?

- Have you acquired any knowledge about the German reimbursement system?
    - What kind of knowledge?
    - How did you acquire it?

<u>In the hospital sector</u>

- Is your product represented within a DRG today?

- Does your product have an OPS/ICD code?

- What is your plan for getting your product represented within the G-DRG system?
    - Are you aiming at getting a NUB?

<u>In the ambulatory sector</u>

- What is your plan for getting your product represented within the EBM catalogue?

<u>General</u>

- Who are the key actors that you need to convince in order to be successful in the reimbursement issue?
    - How do you plan to convince them?
    - Will you hire specialists for this?

- How were the clinical trials for product XXX designed?
    - What kind of data have you collected?
    - What kind of evidence have you collected that actually prove that the product solve the problems?
        - How does it prove it?
    - What is your aim with the clinical trials? (Proving that the technology is working, getting a CE-mark?)

- What organizations in Germany do you have contact with?
    - How do you think they can help you to get reimbursement in Germany?

- What is your company's part in the reimbursement process?
    - Involvement in the different steps?

- How much time do you think it will take from the first usage in Germany until your product is included in the reimbursement system?

- How much resources have you allocated to the reimbursement issue?
    - Compared to regulatory and R&D

Appendix 7 : Questions for the backtracking company

- Description of the product

- If we focus on the product, can you say when:
  - The idea emerged
  - The company started with the development
  - You started the marketing phase
  - You launched the product in Germany
  - You started dealing with the German reimbursement

- Did it go as you expected? Did one of these phases take longer/less time than planed?

How did you do it? Reimbursement procedure

- How did you manage to get the first products into the market?
  - What hospitals did you turn to?

- Is your product XXX represented within the G-DRG system today?
  - If no, how do you manage to sell it?

- How did the procedure for getting into the G-DRG system look like?
  - Describe the procedure for entering the G-DRG for product XXX.
  - How is it represented in the system? (supplementary or DRG)

- How did the company acquire the knowledge about the reimbursement system in Germany?
  - What kind of knowledge was important to launch the product?
  - How did you acquire it (external/internal)?
  - What was the strategy for acquire and keep the knowledge within the company?

- What was approximately the amount of money and time you spent on the reimbursement issue for this product in Germany?
  - Compared to regulatory and R&D?
  - Compared to what you expected?

- How was the company involved in the whole process?
  - How involved were you in the different steps?
  - How many people were involved in the reimbursement process? Compared to the regulatory step?
  - Who were the key actors that you needed to convince in order to be successful in the reimbursement issue?
  - How did you convince them?
  - Did you hire specialists for this?

- What kind of data from the clinical trials did you use later on to get reimbursement?

Good and bad things (Considerations about the reimbursement procedure)

- What were the main obstacles during the whole process of getting product XXX represented within the G-DRG system?
  - What were the expected biggest difficulties?
  - What were the biggest difficulties you actually faced?

- What were the biggest issues for entering the reimbursement system in Germany compared to other countries?

- Did any organizations (German or Swedish) help you in the process? (DIMDI, InEK, physicians, others)
  - How did they help you?
  - Were you able to affect the situation by negotiations with them?

- Is the reimbursement level in Germany enough to cover all the expenses for the hospitals?
  - How high is the level of payment compared to other countries?

- What would you have done differently?

- What would be your advice for a small company that is right now facing the German reimbursement system?