

# **Market introduction implications of the artificial pancreas – a comparison between influencing market introduction factors, similarities and differences across the Netherlands, Germany and Austria**

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## **ABSTRACT**

The aim of the research is to figure out potential factors that are influencing the market introduction of a new medical device with special focus on the artificial pancreas. Those factors, which are compiled out of recent literature, are researched based on a cross-country comparison between the Netherlands, Germany and Austria to find out similarities and differences in the effect of the proposed factors regarding to each specific country. The research method is a desk research that is based on a qualitative literature review of actual and relevant articles, as well as additional information published by the European Union or the administrative healthcare bodies of each respective country. Based on this, four different factors are identified and analyzed towards their potential effect on the introduction of the artificial pancreas, which is displayed within the creation of a causal model. This is done via the close analysis of sub-categories of the factors that are based on discussions and findings within scientific literature, with the background of the differences and similarities of the country comparison. The result of the analysis gives interesting insights on possible implications of the factors for the market introduction of a new medical device, based on local rules and regulations. The paper aims to provide practical relevance in terms of providing a certain guideline and recommendation of possible factors and their implications that should be taken into account while planning and conducting the market introduction of a new medical device. Furthermore it also aims to add to current theoretical knowledge, based on providing insights of the implications of the different factors influencing the market introduction of a new medical device in different countries.

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## **Keywords**

Market introduction factors, Diffusion of Innovation, Medical Innovation, Artificial Pancreas, Netherlands, Germany, Austria,

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## 1. INTRODUCTION

During the last decades innovation in healthcare was successful in implementing new medications and medical products, which improved health care treatment for patients, for example medical devices like insulin pumps or pens (Renard, 2010).

The small company Inreda Diabetic B.V. (from now on Inreda) is currently working on the development of an artificial pancreas. This is a fairly new approach to treat diabetes with the assistance of a medical device. More background information about diabetes can be found in Appendix 9.1. Klein (2009) states that the artificial pancreas is still within the development phase, but it is a very promising approach on improving a diabetes patient's daily life. This is due to the fact that an artificial pancreas is automatically regulating the blood glucose level to an optimal standard. The regulation is achieved by an algorithm that is able to react immediately on the changes of the blood glucose level of a patient (Hovorka, 2011). This method improves the patient's life quality, due to a higher assistance with treating diabetes. Furthermore, Inreda is planning to conduct their first large clinical trial with hundred patients from the Netherlands, Germany and Austria, which are seen as potential countries for the market introduction (Inreda Diabetic, n.d.). Inreda aims to bring the artificial pancreas to the market at the end of 2015. Therefore it is crucial for them to already analyse factors, which are important for the diffusion of medical innovations, to guarantee a good market introduction.

This links to the problem within the healthcare sector that establishing the diffusion and acceptance of new innovations is difficult. Herzlinger (2006) discusses in her article the reasons why innovation within the health care sector is difficult. She divides the types of innovation in three categories, namely "consumer focused", "technology" and "business model", which are influenced by six forces, namely "players", "funding", "policy", "technology", "customers" and "accountability" that can either accelerate or decelerate innovation within the healthcare sector and may be an explanation why the diffusion of a new innovation in the healthcare sector is difficult. Berwick (2003) also underlines that diffusion in healthcare is of high concern, since even though innovations in healthcare could be accepted locally, the diffusion process takes rather long compared to other industries. Sorenson and Kanavos (2011) mention that various procurement processes of healthcare sectors, which differ throughout countries, may influence the diffusion of innovative medical devices either in a positive or negative way. In addition to that, Cappellaro, Ghislandi and Anessi-Pessina (2011) underline the interest of the government in observing and regulating diffusion of medical technology, due to a rise of health care expenditure.

Thus, the focus of the paper is lying on the elaboration of the market introduction implications for the artificial pancreas, based on influencing market introduction factors, as well as similarities and differences with regard to the effect of those factors within the Netherlands, Germany and Austria.

Therefore the main research question of the paper is

*"What factors influence the market introduction of the artificial pancreas in the Netherlands, Germany and Austria, due to specific rules and regulations?"*

To answer the main research question the following sub-questions will be answered during the thesis

*"What is the effect of Players, Funding, Policy and Accountability on the market introduction of a new medical device such as the artificial pancreas?"*

*"How do these effects differ between health systems in the Netherlands, Germany and Austria?"*

The paper will be structured as follows. Firstly, four of the six proposed factors, by Herzlinger (2006) influencing the diffusion of medical innovations in healthcare will be researched and backed up with regard to relevant academic literature. This is due to the fact that two of them cannot be researched to a satisfying extent, based on the current development stage of Inreda. The factors of observation are Players, Funding, Policy and Accountability, which are transferred into a causal model to explain the relationship between those factors, diffusion of medical innovation and the market introduction of a new medical device. Afterwards, based on the previous findings and in combination with additional literature on the different health systems in the Netherlands, Germany and Austria, the proposed factors will be analyzed regarding the similarities and differences and the actual effect on market introduction within the three observed countries. Then, a summarizing table is created, which gives a clear overview of the similarities and differences in each country. This will provide interesting insights on the effects of the proposed factors and how they differ within the country comparison. Then, the paper will give recommendations both, on the theoretical and practical level based on the findings of the analysis. Finally the possibility of future research in this field will be discussed. The contributions to the theoretical relevance of the paper are done in terms of the added knowledge within the field of factors influencing the market introduction of new and innovative medical devices. Contributions to the practical relevance are made in terms of giving recommendations based on the analysis of the effect of influencing market introduction factors. This is done with regard to a country comparison for the planned market introduction process of the small company Inreda.

## 2. IMPORTANT FACTORS FOR THE MARKET INTRODUCTION OF A NEW MEDICAL DEVICE

Based on the actual stage Inreda is in, which deals with the last clinical tests, they are already considering the market introduction of the artificial pancreas. Klein (2009) states that: "a safe and effective artificial pancreas will revolutionize the management of diabetes, when such a device is released to the general public" (p.37), which especially underlines the innovativeness of the artificial pancreas. Thus, Inreda is already in need of identifying factors and their potential effects on the market introduction of the artificial pancreas with special regard of a planned market introduction in the Netherlands, Germany and Austria.

Renard (2010) states that within Europe the usage of medical devices like insulin pumps is rather low compared to the United States. Therefore, the background of diffusion of a medical innovation is playing an important role for the market introduction of the artificial pancreas in Europe.

Diffusion of innovation within the healthcare sector is crucial at the beginning of the market introduction, since it is especially difficult in the healthcare sector to spread the usage of a new medical innovation throughout all involved stakeholders (Cain & Mittman, 2002). According to Cain and Mittman (2002) those mentioned stakeholders include policy makers and regulators, insurance funds and companies, hospitals and physicians, patients and the vendor company. On the hospital level, Greenberg, Peterburg, Vekstein and Pliskin (2005) point out that there is an upcoming need to establish criteria to evaluate the diffusion of new medical innovations.

Due to this amount of involved stakeholder parties, Berwick (2003) found that diffusion of medical innovations is likely to occur slowly. Recent academic research shows that nowadays the diffusion of medical technology is in comparison to the speed a decade ago at a higher pace (Cappellaro, Ghislandi & Anessi-Pessina, 2011). They point out that the role of financing medical technology is crucial to sustain a rapid access to the market for new medical technology, which is often hindered by policy makers in terms of reimbursement issues (Cappellaro, Ghislandi & Anessi-Pessina, 2011). Tidd and Bessant (2009) state that: “A better understanding of why and how innovations are adopted (or not) can help us to develop more realistic plans”. (p. 351).

As previously stated, Herzlinger (2006) mentions six main factors, namely “Players”, “Funding”, “Policy”, “Technology”, “Customers” and “Accountability”, which can either accelerate or decelerate innovation within the healthcare sector and therefore affect the diffusion of a medical innovation. In addition to that, the effect of the different factors on the diffusion has direct influence on the market introduction of a new medical device.

*Players* are defined as “The friends and foes lurking in the health care system that can destroy or bolster an innovation’s chance of success” (Herzlinger, 2006, p. 61).

*Funding* is defined as “The processes for generating revenue and acquiring capital, both of which differ from those in most other industries.” (Herzlinger, 2006, p. 61).

*Policy* is defined as “The regulations that pervade the industry, because incompetent or fraudulent suppliers can do irreversible human damage.” (Herzlinger, 2006, p. 61).

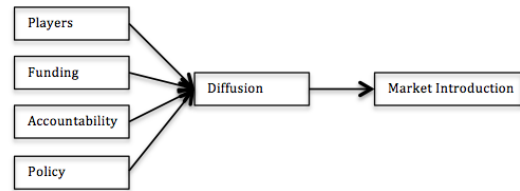
*Technology* is defined as “The foundation for advances in treatment and for innovations that can make health care delivery more efficient and convenient.” (Herzlinger, 2006, p. 61).

*Customers* are defined as “The increasingly engaged consumers of health care, for whom the passive term “patient” seems outdated.” (Herzlinger, 2006, p. 61).

*Accountability* is defined as “The demand from vigilant consumers and cost-pressured payers that innovative health care products be not only safe and effective but also cost-effective relative to competing products.” (Herzlinger, 2006, p. 61).

Although Herzlinger’s approach is mostly based on an evaluation of the American healthcare system it is still valid for use in the European market. This is due to the fact that her factors are also mentioned within academic research based on the European healthcare background in terms of influencing factors that can be categorized under her mentioned factors (Cappellaro, Ghislandi & Anessi-Pessina, 2011; Wild & Langer; Schreyögg, Bäumlér & Busse, Bartelme & Bridger, 2009).

Based on the different factors mentioned by Herzlinger (2006) a causal model is introduced to underline the relationship of her factors on the diffusion process and the market introduction of a new medical device. Thus, with the examination of the effect of the proposed factors by Herzlinger (2006) the paper will contribute to the current stream of research of factors influencing the diffusion and therefore the market introduction of a medical innovation. This will be done via a concrete analysis of the proposed factors in the context of their effect within the Netherlands, Germany and Austria.



**Figure 1. Factors influencing diffusion and market introduction**

Despite the fact that Herzlinger (2006) originally mentioned six factors, which could accelerate or hinder innovation, the model makes only use of four of them. This is based on the fact that the artificial pancreas is still within the development phase and thus the factors “Technology” and “Customers” cannot be researched to a satisfying extent. This is because the concrete implications of the artificial pancreas on those two factors are not yet known, as it is not yet finalized. (Hovorka, 2011; Klein, 2009)

Therefore, the model is based on her remaining four factors, namely Players, Funding, Accountability and Policy, which all potentially influence the diffusion of a medical innovation in a positive or negative way depending on their certain background (Herzlinger, 2006). Furthermore, it is assumed that the diffusion of a new medical innovation is directly influencing the market introduction of the medical innovation, because its success is depending on the effect of the underlying factors influencing the diffusion of a medical innovation.

After performing an extensive literature research related to potential market introduction factors the results will be classified in the proposed model for the analysis. The findings of potential influencing factors will be classified as subcategories under the different proposed factors by Herzlinger (2006), namely Players, Funding, Accountability and Policy. The reviewed literature provides evidence that all of the mentioned factors are influencing the diffusion of a new medical innovation, which is elaborated on more detailed in the next sections, assuming that all of the mentioned factors of the subcategories should be considered as equally important for the market introduction of a new medical innovation.

## 2.1 Players

### 2.1.1 Approaching decision-making entities

While planning the market introduction of a medical device it is already necessary to approach groups, which are of influence of possible healthcare agenda in the potential market introduction countries, to create awareness about the medical device and convince them of its importance (Wild & Langer, 2008). Within Europe the decision-making entities are represented mostly by self-governing bodies including practitioners, insurance funds and policy makers (Schreyögg, Bäumlér & Busse, 2009). According to Schreyögg, Bäumlér and Busse (2009) those entities influence important factors for a new medical device introduction such as technological adoption or reimbursement rates. Wild and Langer (2008) discuss in their paper the importance of informing and supporting health policy within an early stage of the new medical technology to improve the decision-making and awareness of a new medical technology. This is done within the EU in terms of the European network for Health Technology Assessment, which is monitoring technologies in various stages. This includes new technologies, emerging technologies and established technologies with a new indication (Wild & Langer, 2008).

Based on the previously mentioned findings, which indicate the relationship towards stakeholders in the healthcare area, the

factor will be classified under the factor Players as **“Approaching decision-making entities”**

## 2.2 Funding

### 2.2.1 Pricing

An important factor is the initial pricing of a new medical device, which is according to Schreyögg, Bäumlner and Busse (2009) managed through the initial manufacturers of a product and, in addition to that, can also be restricted by the government depending on different countries. Those restrictions on pricing are primarily accomplished in terms of an indication of a so-called reference price, which is calculated by the comparison of prices for the product in other countries (Habl et al., 2006). Since the price of a medical device is linking to the revenue stream in terms of revenue generating for the medical device manufacturer it is important and will be added in the proposed model under the factor “Funding” as **“Pricing”**.

### 2.2.2 Reimbursement procedure

Another important aspect, which is generating revenue for a medical device manufacturer is reimbursement. Bartelme and Bridger (2009) state that reimbursement is essential for the adoption of continuous glucose monitoring (CGM) devices, since it covers the costs of the device and its related supplies. The ways Reimbursement is granted for medical products are based on differences in the reimbursement policies in different European countries (Schäfer et al., 2010; Busse & Riesberg, 2004; Hofmarcher & Quentin, 2013). This is also underlined by the conclusions of Schreyögg, Bäumlner and Busse (2009), who found that reimbursement rates within European countries vary in terms of the national or sub-national level through the decision-making on reimbursement policies on the governmental level or through self-governing bodies. Normally, according to Schreyögg, Bäumlner and Busse (2009), the reimbursement regulations are linked to the certain type of the medical device, which is grouped into three categories of medical devices. The authors, based on a classification in a certain reimbursement scheme, ranked those categories as medical aids, implants and other artificial body parts and technical equipment for professionals (Schreyögg, Bäumlner and Busse, 2009).

Based on the previous findings, which indicate the relevance of reimbursement towards the factor Funding, reimbursement will be added under “Funding” in the proposed model as **“Reimbursement procedure”**.

## 2.3 Accountability

### 2.3.1 Monitoring health system bodies

A further factor of interest is the constant surveillance of administrative health system bodies from the moment on a medical device is brought to the market. This implies several national entities, which are constantly monitoring the safety and functionality of the device (Busse & Riesberg, 2004; Hofmarcher & Quentin, 2013). Some examples of the national entities are the Federal Institute for Drugs and Medical Devices in Germany and the AGES in Austria and the Nederlandse Zorgautoriteit in the Netherlands (Busse & Riesberg, 2004; Hofmarcher & Quentin, 2013). Based on the findings, the factor will be classified under the factor “Accountability” as **“Monitoring health system bodies”**.

## 2.4 Policy

### 2.4.1 CE trademark approval

Being certified with the CE trademark is crucial in terms of the market launch in European countries, since once the medical device is certified by one notified body of a European member country, it is granted for market introduction in every single EU

member state (Altenstetter, 2003; Schreyögg, Bäumlner & Busse, 2009). Therefore, the CE trademark approval is an important factor within the diffusion of a new medical innovation, since without CE trademark approval no market admission is granted. According to Altenstetter (2003) and Schreyögg, Bäumlner and Busse (2009) the CE trademark is granted if a notified body of one single European member state is certifying the medical device as conform to the CE regulations. This mainly implies that risks have to be analyzed and out weighted in comparison to the medical benefit and the quality of the device should be conform with European standards (Altenstetter, 2003). Furthermore, the medical device has to be biological safe and compatible and the efficacy of the medical device has to be demonstrated throughout clinical studies (Altenstetter, 2003). Based on the previous findings, which clearly indicate the relevance of the factor towards policy implications, the factor will be classified under “Policy” as **“CE trademark approval”**.

### 2.4.2 Procurement decision-making process

Another important factor that influences the market introduction is the procurement decision-making process, which is closely linked to the diffusion of the medical innovation. This is because sickness funds issue tenders to procure medical goods (Kanavos, Seeley & Vadoros, 2009). Thus, winning a tender would lead to an automatically diffusion of the medical innovation due to an increase of sales. The procurement decision-making process within hospitals for instance is based on influences like human factors like user efficiency or ease of use, which contribute to the procurement decision of new medical innovations (Ginsburg, 2005). Torbica and Cappelaro (2010) point out that there is an increasing trend towards centralized procurement to increase market power and achieve cost reductions. Therefore, it is important to understand the various procurement systems throughout the countries. Based on the previous findings, the procurement decision-making process is related to policy and thus, it will be classified under the factor Policy as **“Procurement decision-making”**.

## 3. METHODOLOGY

The research of the paper is based on the approach to identify potential factors, which influence the market introduction of a new medical device, especially in the context of the artificial pancreas. The form of the research is based on a desk research including relevant and scientific literature related to the research question found via the usage of the search engine “Scopus”.

Emphasis was paid to the amount of citations of the used articles in other publications, which serves as an indication of the relevance of the used articles. A cut-off has been established at a minimum of ten citations for each article to guarantee its added value towards the literature review. Some exceptions were made in the case of a good fit towards the research topic in case of relatively new published articles. Furthermore, the year of publishing was taken into consideration, because especially in the healthcare sector rules and regulations are likely to change. Articles are limited to a year range from 2000 to 2014, however most of the articles have been published within the last ten years. A list of the used key words, which were either used independent or in combination of each other, can be found in Appendix 9.2. Based on the lack of the amount of publications within the respective field of observation also other, secondary information was gathered. This includes mostly reports published on behalf of relevant healthcare related organizations or administrative healthcare bodies. One example would be the “Health System in Transitions” series, which offered detailed insights in many of the observed topics. To ensure the integrity

of the findings, furthermore the different websites of the administrative healthcare bodies within each respective country, as well as official reports published under the European Commission were used to add to the scarce literature on influencing market introduction factors for medical devices. Examples of the websites include the websites of the Healthcare Inspectorate within the Netherlands, the Austrian Medicine and Medical Devices Agency and the Federal Institute for Drugs and Medical Devices in Germany. An example of the used reports would be the report of Kanavos et al. (2009), which elaborates on the tender systems for outpatient pharmaceuticals on the commission of the European Union.

Based on the found literature the factors were used for an inclusion in a causal model that seeks to provide an overview of four of the relevant factors mentioned by Herzlinger (2006) and their effect on the diffusion and market introduction of the artificial pancreas. The impact of those factors will be researched within the context of a comparison of the health systems in the Netherlands, Germany and Austria, to observe the similarities and differences, which may influence the factors to a different extent within different countries. A literature review on the background of the different health systems and similarities and differences is given in Appendix 9.3. Based on the findings of the country comparison, scientific literature and secondary data, the analysis will be conducted to highlight the implications of the proposed factors with regard to the differences and similarities between the countries.

## **4. ANALYSIS OF THE IMPLICATIONS OF THE INFLUENCING FACTORS WITHIN THE NETHERLANDS, GERMANY AND AUSTRIA**

### **4.1 Approaching practitioners, insurance funds and policy makers**

Whilst planning the market launch of a new medical innovation it may be beneficial to approach practitioners, insurance funds and policy makers, since those stakeholders within the healthcare system may influence important aspects like reimbursement rates and the adaption and promotion of a new technology (Schreyögg, Bäumlér & Busse, 2009). Based on the outcome of the study of the International Diabetes Federation (2013) within the Netherlands, Germany and Austria medical devices are mostly prescribed by either general practitioners or diabetes nurses, which implies that only medical devices listed in the different reimbursement lists of the different countries will be prescribed, or the patient has to pay the device completely via out-of-pocket expenses. This means that the important key actors, which should be approached before the market introduction are the different insurance funds and health policy makers, depending on the respective country. In order to do so, it is necessary to create awareness within the stakeholder group of insurance funds and policy makers. According to Wild and Langer (2008) the European network for Health Technology Assessment (EUnetHTA) has established an information newsletter, which is informing all of the European member states on emerging technologies. Thus, informing the European network for Health Technology assessment would be a good approach to create awareness about such an emerging technology like the artificial pancreas. Furthermore, there are other possibilities of creating awareness for medical innovations. For instance the German Institute of Medical Documentation and Information (DIMDI) is publishing health technology assessment reports, via its Agency of Health Technology Assessment (DAHTA), which could influence the decision-making parties to consider new medical innovations,

based on the individual outcome of the health technology assessment of a new medical innovation (DIMDI, 2014). According to Wild and Langer (2008) and Schäfer et al (2010) within the Netherlands, the Health Council of the Netherlands (Gr), which is characterized as an independent scientific advisory body, is in charge of giving advice on the potential agenda to the Ministry of Health, Welfare and Sport either on request or on its own initiative. Thus, the Health Council of the Netherlands could be approached to bring up new medical innovations like the artificial pancreas on the agenda of the Ministry of Health, Welfare and Sport in the Netherlands. Within Austria, according to Hofmarcher and Quentin (2013), the Ludwig Boltzmann Institute for Health Technology Assessment plays an advisory role for the Federal Ministry of Health in terms of the health technology assessment and the potential implications of new medical innovations for the health-care system.

In general, there are a lot of possibilities to approach especially policy makers before the market launch either on the European level or on the national level through various advisory entities. Those possibilities should be used in order to create potential awareness of the new medical innovation for the healthcare agenda of the different respective countries. Within each respective country there are different healthcare administrative related bodies, which influence health policy makers and important stakeholders like insurance funds via bringing up new medical innovations on the agenda of health technology assessment institutions or advisory councils. A practical recommendation is that the company could approach one of the mentioned administrative related bodies to either file for a health technology assessment, which would imply costs that have to be paid by the manufacturer, or to encourage a health technology assessment that is initially started by the administrative related bodies, which would imply that the costs are paid by them. Based on a positive outcome of the health technology assessment it is likely that those healthcare administrated related bodies are influencing healthcare agenda towards the new medical innovation. A brief summary of the findings of the factor can be found in Appendix 9.4.

### **4.2 Pricing**

The factor Pricing deals with the pricing procedure of new medical devices. This step is important, since new medical devices are likely to influence the national healthcare budgets and it is assumed that new innovations are cost drivers of healthcare expenditure. Nonetheless, the observed increase of total medical spending within the last decades is valuable for the patient's treatment in terms of quality improvement of the healthcare and can therefore be seen as a positive outcome of higher costs (Cutler, Rosen & Vijan, 2006). Therefore, the company should consider this factor for the pricing procedure for a new medical device. Brown, Meenan and Young (2007) discuss that especially in the early phase it is important to avoid price erosion to cover the initial development costs and other market introduction related costs for the needed market approval. Furthermore, health technology assessments are partially based on the price to determine the cost-effectiveness of a new medical innovation (Brown, Meenan & Young, 2007). In addition to that, cost reductions cannot be easily achieved, since the medical device has to fulfill certain specifications, which imply costs (Brown, Meenan & Young, 2007).

According to Habl et al. (2006), within the Netherlands manufacturers can decide on prices for their medical goods. However, the Ministry of Health may regulate those prices (Habl et al., 2006). This will be done through external reference pricing, whereas the prices for medical goods are compared

within other European countries as Belgium, France, Germany and the UK (Habl et al., 2006). Within Germany the manufacturer has a relatively free choice of pricing of the medical goods, but he is regulated via a reference price system that is set up by the different sickness funds (Habl et al., 2006). The prices are also regulated via the Ministry of Health and also the Federal Joint Committee (Busse & Riesberg, 2004). In Austria, based on the Pricing Act of 1992 the Pricing Committee of the Federal Ministry of Health is in charge of setting prices for medical goods, which is also done via external reference pricing in comparison to the European average price for medicines included in the code of reimbursement (Hofmarcher & Quentin, 2013). Thus, pricing within the three countries is mostly based on external reference pricing and involves often the sickness funds, as well as the ministries of health and furthermore decisions of the manufacturer on pricing.

Practical implications are that, based on the findings of Brown, Meenan and Young (2007), the price of the medical device should be set high enough already within the beginning to cover development and authorization costs, because the price is likely to decrease if more players introduce a medical device with the same specifications to the market. Nonetheless, due to the existence of health technology assessments the price should not be too high, because it could then be considered as a potential drawback of the new technology influencing the cost-benefit analysis performed in the health technology assessment. Thus, the medical device manufacturer should try to set up an initial market price, which is appropriate to cover the costs and already takes a potential decrease of price in to account. Based on the pricing regulation done via reference pricing it is important to notice that the price could be influenced indirectly by manufacturers that bring up the medical device on the market at the price level of their break-even point. This would lead to an automatically comparison of prices for medical devices and therefore reference pricing could be a threat, because of potentially low prices of competitors. A brief summary of the findings of the factor can be found in Appendix 9.5.

### 4.3 Reimbursement procedure

The reimbursement procedure is a critical factor concerning the introduction and diffusion of a new medical innovation, since costs of the innovation are likely to produce high additional costs in addition to the status quo (Heinemann et al., 2012). Thus, reimbursement is necessary to cope with the additional costs. Within European countries reimbursement rates differ, due to the existence of different decision-making governmental or self-governing entities on reimbursement policy (Schreyögg, Bäumler and Busse, 2009). Therefore, it is crucial to observe the reimbursement process within each respective country of comparison.

In the Netherlands the important actors concerning the reimbursement procedure are, according to Habl et al. (2006), the Ministry of Health, Welfare and Sport, which is in charge of the reimbursement status and the Health Care Insurance Board, which is playing an advisory role for the Ministry of Health, Welfare and Sport on the reimbursement of pharmaceuticals. The actual process is, according to Habl et al. (2006), structured in terms that after receiving a reimbursement application of a medical pharmaceutical manufacturer, the Ministry of Health, Welfare and Sport decides based on the input of the Pharmaceutical Care Committee, which is a part of the Health Insurance Board, to either include the pharmaceutical in the pharmaceutical reimbursement system or to not include it. If the pharmaceutical is reimbursable, it is specified on a positive list,

which is consisting of three different categories (Habl et al., 2006). The three categories are, according to Habl et al. (2006), the “Annex 1A” that consists of therapeutically interchangeable pharmaceuticals, the “Annex 1B” that consists of unique pharmaceuticals and the “Annex 2” that consists of pharmaceuticals, which are only reimbursed subject to an individual decision making process, which considers the subjective opinion of specialists, the health insurance or specialized care centers. The selection to be either included in “Annex 1A” or “Annex 1B” is based on different criteria, which is based on the therapeutically equivalent to one or more pharmaceuticals of the “Annex 1A” list and based on therapeutic value and cost-effectiveness of the pharmaceutical, which does not have a specific therapeutically equivalent (Habl et al., 2006). According to Habl et al. (2006) the exact selection criteria is based on the therapeutic, efficacy, therapeutic effectiveness, side effects, experience with the pharmaceutical, applicability of the pharmaceutical and the ease of use for the patient.

In Germany, the important actors within the reimbursement procedure are The Ministry of Health (BMG), which is involved in reimbursement decisions in cooperation with the Federal Joint Committee (G-BA) in terms of the classification of a new pharmaceutical either to be granted for reimbursement or for a classification in the listing of non-reimbursable pharmaceuticals or in the listing of inefficient pharmaceuticals (Habl et al., 2006). The Federal Joint Committee consists of Statutory Health Funds, Hospital Organizations, Physician Organizations and Patient Organizations; whereas the Patient Organizations have no voting rights and are seen as a advisory component (Busse & Riesberg, 2004). Habl et al. (2006) state in case of the approval of medical reimbursement the pharmaceuticals are classified within the Uniform Value Scale (EBM), which is published by the Ambulatory Care Committee of the Federal Joint Committee (Busse & Riesberg, 2004). They furthermore state that a listing within the Uniform Value Scale is necessary for reimbursement, since the physician may only prescribe those medical goods listed in the Uniform Value Scale. If the BMG and the G-BA decide that the pharmaceutical is reimbursable, it is transferred to the decision-making stage of the G-BA, which decides either if the new pharmaceutical is innovative or if it can be included in one of the three existing reference groups (Habl et al., 2006). Habl et al. (2006) state that those three reference groups are divided in the first group, which consists of pharmaceuticals with the same ingredient; the second group, which consist of pharmaceuticals with a pharmacological and therapeutically comparable ingredient; and the third group combining pharmaceuticals, which are used to treat the same condition. This is done according to the SGB V. Art. 35 (1) published by German law (Habl et al., 2006). In case of an innovative pharmaceutical, the G-BA requests a health technology assessment conducted by the Institute for Quality and Efficiency in Health Care (IQWiG), which determines if the pharmaceutical is seen to be innovative or not (Habl et al., 2006).

Although most of the German population is obtaining statutory health insurance (SHI), there is also the minority part of the population, which is served by private health insurers. Within the sector of private health insurers the private health insurance fee schedule (GOÄ), which is administered by the German Medical Association, is in charge of applications for reimbursement, which would be the counterpart of the SHI’s Uniform Value Scale (Busse & Riesberg, 2004). If a medical innovation is not reimbursed by either the SHI or the GOÄ, Busse and Riesberg (2004) state that there is a possibility for patients to finance the medical innovation by out-of-pocket

payments, if the medical innovation is listed on the individual health services (IGEL) list. Since there is no clear literature on the reimbursement process for medical devices within the outpatient care sector, it is assumed to be in line with the reimbursement process for pharmaceuticals.

In Austria the important actors within the reimbursement process are the Federal Ministry of Health and Women (BMGF) assisted by the Pricing Committee (PK), who are in charge for the calculation of the average EU price for the application of inclusion into the Reimbursement Code (EKO) to receive financial reimbursement (Habl et al., 2006). Based on the calculated price decision by the BMGF and the PK the Federation of Austrian Social Insurance Institutions (HVB), which the Pharmaceutical Evaluation Board (HEK) consults, is in charge of the final decision of reimbursement and the admission of pharmaceuticals within the Reimbursement Code (EKO) (Habl et al., 2006). According to them the criteria, which is used to evaluate the decision on reimbursement is based on pharmacological, medical therapeutic and pharmacoeconomic criteria (Habl et al., 2006). Hofmarcher and Quentin (2013) add also the calculation of the EU average price to the decision-making criteria of the HVB and the HEK.

Based on the decision of the HVB and the HEK the pharmaceuticals will be ordered to certain groups, called “boxes”, to regulate the usage and prescription of those medications (Hofmarcher & Quentin, 2013). First of all new pharmaceuticals remain in the so called “Red Box” for a maximum of 24 months after the price for them is set according to the EU average price or for a maximum of 36 months, if no European average price can be set (Hofmarcher & Quentin, 2013). They state that those pharmaceuticals, which are assigned to the “Red Box” may be prescribed, but an evaluation and approval of the head physician of the prescribing physician has to be obtained. Afterwards the pharmaceuticals are included within the “Green Box”, the “Light Yellow Box” or the “Yellow Box” (Hofmarcher & Quentin, 2013). Furthermore, they state that within the “Green Box” pharmaceuticals may be freely prescribed and that no head physician approval is necessary for them, since the costs for those pharmaceuticals are below the European average price (Hofmarcher & Quentin, 2013). The “Yellow Box” is divided into the “Light Yellow Box” and the “Yellow Box” whereas pharmaceuticals within the “Light Yellow Box” are only prescribed for specific symptoms accompanied by an ex-post control of prescription behavior and like in the “Green Box” the price has to be below the EU average price (Hofmarcher & Quentin, 2013). In addition to that, Hofmarcher and Quentin (2013) found that in the “Yellow Box” pharmaceuticals with essential added therapeutic value are included. The decision, if a pharmaceutical provides essential added therapeutic value, is based on the individual decision based on the patient’s need, which has to be approved by the head physician beforehand. The possibility of reimbursement for pharmaceuticals within this group is given, if the price is below the EU average price (Hofmarcher & Quentin, 2013). Furthermore, there is the possibility that a new medical innovation is not approved and therefore not listed within the reimbursement codex, which means that reimbursement may only be granted on an individual basis or no reimbursement can be granted for the specific pharmaceuticals (Hofmarcher & Quentin, 2013).

Concerning the reimbursement of medical devices in Austria, the first step to be granted for reimbursement is the approval of the medical device via the CE mark in any of the European member states to get approved for market access. Hofmarcher and Quentin (2013) state that for the ambulatory care sector, which would be the market sector for Inreda’s artificial

pancreas, there is no central contract existing for medical devices. Thus, medical devices are published within the different service catalogues of the different health insurance companies for reimbursement (Hofmarcher & Quentin, 2013). They also add that reimbursement prices for around 80% of medical aids and accessories are negotiated by the Competence Centre for Medical Accessories and Therapeutic Aids, which is a part of the Austrian Miners’ and Railway Workers’ Insurance Fund (Hofmarcher & Quentin, 2013). Depending on the membership of the individual sickness fund within Austria, medical devices are fully, partially or not reimbursed based on the specific decisions of the individual sickness funds (Hofmarcher & Quentin, 2013).

In general, it can be said that the reimbursement procedures within the Netherlands, Germany and Austria all are based on an extensive decision-making process, which involves mostly the respective Federal Ministries of Health, their advisory boards and the sickness funds. However, the Austrian reimbursement procedure seems to be more complex and time consuming with the initial ranking of a new innovation in the so-called “Red Box”, which implies a restriction of widely accepted usage for a minimum of 24 months. Thus, it seems to be that the reimbursement procedures in Germany and in the Netherlands would allow the reimbursement of a new medical innovation within a shorter time period.

Given the background of the research of practical implications for the market introduction of the artificial pancreas some conclusions for the chance of reimbursement could be drawn out of the reimbursement for other diabetes related medical devices or required parts for the artificial pancreas. Heinemann et al. (2012) found that there is no general reimbursement in Germany concerning continuous glucose monitoring devices for therapeutic usage. Nonetheless, it is granted for some individuals based on the actual documentation of the urgent need for continuous glucose monitoring (Heinemann et al., 2012). They furthermore state that health insurance companies requested a cost-benefit analysis concerning continuous glucose monitoring, which would be performed by the Institute for Quality and Efficiency in Health Care on order of the Federal Joint Committee. The cost-benefit analysis could, according to Heinemann et al. (2012), take three to five years and would therefore lead to a huge delay of the reimbursement approval. In the Netherlands continuous glucose monitoring is included within the basic health insurance for three groups, which include adults with HbA1c > 64 mmol/mol, pregnant woman with either type 1 or type 2 diabetes and children (Heinemann et al., 2012). In addition to that, a study performed by the International Diabetes Federation (2013) shows that within the Netherlands, Germany and Austria reimbursement is granted for other diabetes related medical devices as insulin pens or pumps and their related supplies. However, sometimes co-payments are required, which the patients need to pay out of their pockets (International Diabetes Federation, 2013). This implies that the chance of getting reimbursed is relatively high, as parts of the artificial pancreas like the continuous glucose monitoring are already reimbursed or under assessment for reimbursement. Furthermore, as reimbursement is granted for insulin pens and insulin pumps, it is also likely that the artificial pancreas will be reimbursed, since it would provide added value to the treatment of diabetes. Also, indications about the reimbursement timeframe can just be vaguely made. The example of the reimbursement process for continuous glucose monitoring in Germany shows that in the case of health technology assessments, on which reimbursement decisions are drawn, the time till the decision will be made could take several years. This would cause a tremendous delay for the market



introduction of medical devices. Thus, a potential delay of the market introduction, caused by reimbursement procedures, should be considered while planning the market introduction.

A brief summary of the findings of the factor can be found in Appendix 9.6.

#### 4.4 Monitoring health system bodies

After the medical device is launched on the market it is constantly under supervision of administrative healthcare bodies, which are entitled to formulate sanctions in order of a malfunction of the medical device. This is especially important, since malfunctions of medical devices, like the artificial pancreas, can be crucial for the safety of the patients.

In Germany the Federal Institute for Pharmaceuticals and Medical Devices is having the monitoring role to protect the safety of patients (Habl et al., 2006). Usually, in case of a malfunction, the medical device manufacturer is in charge of informing the Federal Institute for Pharmaceuticals and Medical Devices and has to deliver concrete proposals on the further proceeding to sustain the safety of the patient (BfArM, 2013). Within the Netherlands the Healthcare Inspectorate, which acts as an advisory body of the Federal Ministry of Health, Welfare and Sport, is in charge of the supervision of the safety of medical devices before and after the market launch (Schäfer et al., 2010). In case of a malfunction of a medical device the medical device manufacturer has to inform the Healthcare Inspectorate in order to propose corrections to secure the safety of the patients (Inspectie voor de Gezondheidszorg, 2014). In Austria the Austrian Medicine and Medical Devices Agency, which is subject to the Austrian Agency for Food and Health Safety, is in charge of the monitoring of the functionality of medical devices before and after the market launch (Austrian Medicine and Medical Devices Agency, 2014).

Since all of the three countries do have monitoring administrative healthcare bodies, it would be important for the medical device manufacturer to set up preventive mechanisms against the malfunction of the medical device. Those preventive mechanisms could be done in cooperation with extensive communicational exchange between the medical device manufacturer and selected practitioners and patients. Furthermore, this monitoring principle should be established in each country where the medical device is introduced to avoid harm to the patients. It is not only important to avoid potential harm to the patients, since the implications of a potential malfunction of the medical device could lead to a tremendous decrease of the reputation of the medical device and its manufacturer. This could also have implications about potential tendering procedures, because sickness funds are not willing to pay for a medical device that could potentially harm their insured and thus, they will not consider procuring a device that had shown malfunctions. Another implication is that based on the actual extent of the malfunction, all of the mentioned administrative healthcare bodies could decide on filing sanctions against the medical device manufacturer, which could also lead to a complete removal of the medical device from the market. A brief summary of the findings of the factor can be found in Appendix 9.7.

#### 4.5 CE trademark approval

The CE trademark approval is compulsory for a new medical device to be approved for market introduction within the European Union and it is also essential for the potential reimbursement within any European Union member state (Schreyögg, Bäumler & Busse, 2009). Generally, the specifications for medical devices are compiled within the directives of the European Commission consisting of the three

directives 90/385/EEC, 93/42/EEC and 98/79/EC (European Union, 2000). Those directives were updated and amended by directive 2007/47/EC, which came to effect in March 21, 2010 (European Union, 2007; Schreyögg, Bäumler & Busse, 2009). The biggest implication of the directive 2007/47/EC for medical devices is that CE certificates are not longer issued for an unlimited timeframe and have to be reissued after a maximum of five years (European Union, 2007). Depending on the respective country there are different governmental entities in charge for the market authorization and therefore the CE trademark approval (Schreyögg, Bäumler & Busse, 2009).

In the Netherlands, the Medicines Evaluation Board (CBG) and the Dutch Health Care Inspectorate (IGZ) are in charge of the market authorization procedure and therefore also for the CE Trademark approval (Habl et al., 2006; Schäfer et al., 2010). The evaluation, if the CE Trademark is granted, is done via the notified body of the Medicines Evaluation Board, which is in case of the Netherlands the DEKRA Certification B.V. for all three types of medical devices as compiled within the directives 90/385/EEC, 93/42/EEC and 98/79/EC (European Commission, 2014).

In Austria the Federal Agency for Safety in Health Care (BASG) and its subdivision, called AGESPharmMed are in charge of the market authorization procedure. The notified bodies, which are in responsibility of giving the CE trademark approval for medical devices are the TÜV Austria Services GmbH and the Prüfstelle für Medizinprodukte Graz, whereas the TÜV Austria Services GmbH is in charge for approval of medical devices included in the directive 93/42/EEC and in vitro diagnostic medical devices included in the directive 98/79/EC (European Commission, 2014). According to the European Commission (2014) the Prüfstelle für Medizinprodukte Graz is also in charge for the approval of active implantable medical devices included in the directive 90/385/EC and also for medical devices included in the directive 93/42/EEC.

In Germany the Federal Institute for Drugs and Medical Devices (BfArM), which is under supervision of the Federal Ministry of Health (BMG) is in charge of the market authorization procedure (Habl et al., 2006). For the approval of the CE trademark, the Federal Institute for Drugs and Medical Devices is charging notified bodies, which are authorized of conducting the approval procedure for a CE trademark (DIMDI, 2013). In Germany, there are six notified bodies in charge for the approval of active implantable medical devices according to the directive 90/385/EEC (European Commission, 2014). For medical devices, which fall under the directive 93/42/ECC a total amount of fourteen notified bodies is in charge (European Commission, 2014). Concerning the in vitro diagnostic medical devices under the directive 98/79/EC there are five notified bodies in Germany in charge of the approval of the CE trademark (European Commission, 2014). A detailed overview of the exact notified bodies in Germany can be found in Appendix 9.8.

Generally, the process of the CE trademark approval has to be conducted once in any of the European member states, afterwards the medical device is granted for market introduction in any of the European member states. The basic outline of the CE Trademark approval process is that it begins with the application at the different governmental entities, which are then appointing notified bodies to test the medical devices on conformity with European law on the effectiveness and safety of medical devices. The conformity is included within the directives 90/385/EEC, 93/42/EEC, 98/79/EC and 2007/47/EC, which depend on the categorization of the medical device.



Noticeable is that within the country comparison of the Netherlands, Germany and Austria is that Germany has a far higher amount of notified bodies in comparison to the Netherlands and Austria. Another observation is that the market authorization approval procedure is based on European law under the directive 2004/27/EC about medical products for human use in terms of quality, safety and efficacy, but there are also national laws of the respective countries, which have to be fulfilled (Habl et al., 2006). Those national laws incorporate all the factors of the four EU directives and, in addition to that, they are often including laws on all kind of general medical products. Nonetheless, the European directives on medical devices can be seen as the important criteria for the approval process, because the CE trademark is mainly given on law stated in the directives. This is because they normally incorporate all necessary criteria, which is also stated in national law. Furthermore, on the specific background of diabetes and the artificial pancreas, Wenthold, Hoekstra, Zwart and DeVries (2005) argue in their article that the CE trademark approval procedure may not guarantee the long-term reliability of continuous glucose monitoring devices and should therefore be taken into for the improvement of further CE approval methods, as well as for the producing firm to guarantee the safety of the device. Practical implications for Inreda derive out of the previous analysis.

Since it is crucially important to decide in which country the CE trademark approval should be conducted, the two striking points of the analysis will be evaluated in this context.

Based on the fact that the CE trademark approval is performed with regard to the European directives and thus European law, this is no valuable factor on how to decide where to conduct the approval procedure. The number of notified bodies may however give some indications on favorable backgrounds for the approval process. Within Germany there is a high amount of notified bodies, which could all grant the CE trademark approval. However, this high amount could be either perceived as a drawback, since they all are acting independently. Thus they are acting to a certain extent to their own procedures, for example concerning the timeframe for the approval. Nonetheless, this should not be the main reason why Inreda should not aim to receive the CE trademark in Germany. The main reason to conduct the CE trademark approval not in Germany and in Austria is that although the certificate and the approval procedure is conducted in English, the correspondence between the manufacturer and the notified body can be done in the native language of Inreda. This prevents possible misunderstandings and simplifies the overall communication exchange between the notified body and the company. Therefore, they should seek to receive the CE trademark approval within their country of origin, the Netherlands. A brief summary of the findings of the factor can be found in Appendix 9.9.

#### **4.6 Procurement decision-making process**

According to Sorenson and Kanavos (2011) the German procurement policy is based on the national reference pricing and the hospital funding reforms, which would for example imply diagnosis-related group pricing. They furthermore state that the key procurement actors in Germany are the Ministry of Health (BMG), the Federal Joint Committee (G-BA), the various sickness funds, hospitals, physicians, nursing homes, manufacturers and purchasing groups. In addition to that, they point out that the procurement is mostly decentralized, but in case of the purchasing groups there are signs of centralization (Sorenson & Kanavos, 2011). Furthermore, they found that the criteria on which the procurement decisions are based involve

the price, the volume and the specific product and its quality. In Austria, according to Hofmarcher and Quentin (2013) the procurement of medical devices is influenced by the payer, which would imply that the different sickness funds are in charge of the procurement process for medical devices. Furthermore, they state that within the healthcare system there is almost no obligation by the Ministry of Finance to conduct structured purchasing methods (Hofmarcher & Quentin, 2013). Thus, it can be assumed that within Austria the procurement procedure is relatively similar to the German procurement procedure and is therefore also involving the Austrian Ministry of Health, the manufacturers and the health service providers. Whilst there is not much evidence in literature on how the countries of comparison are acting in terms of the procurement of medical devices, Kanavos, Seeley and Vadoros (2009) discuss in their study the different tendering systems for outpatient pharmaceuticals within the European Union. All of the three respective countries do have tendering systems in place for the procurement of pharmaceuticals, which are issued by the different sickness funds (Kanavos, Seeley & Vadoros, 2009). They state that within Austria those tendering procedures are issued on the basis of the actual need of procurement and the award criteria is mainly based on the best price offer. Within Germany, according to them, the tendering process is issued either on a yearly or on a two-year basis and the main emphasis of the award criteria is lying on the lowest price, the product portfolio and the supply, which is mainly similar to the award criteria found by Sorenson and Kanavos (2011). Within the Netherlands the tendering procedures are conducted on either a 6-monthly or a yearly basis and the award criteria is mainly depending on the lowest price (Kanavos, Seeley & Vadoros, 2009).

It can be assumed that based on the rising usage of medical devices within the healthcare sector the different states will also conduct tendering procedures for medical devices, which are then issued by the different sickness funds. Also it is likely that the striking criteria, namely the lowest/best price will also be used for medical devices and that the timeframe on which tendering is conducted could also be relatively similar for medical devices. This is because of the rising costs of healthcare and the initial idea of cost savings caused by tendering processes (Kanavos, Seeley & Vadoros, 2009). Thus, the procurement decision-making process would directly influence the procurement of a new medical innovation, like the artificial pancreas, in terms of a price competition within the procurement process. This is important to notice, since there are several companies working on an artificial pancreas and therefore special emphasis on the procurement should be given in each country. This could lead to consequences as price wars between the different manufacturers of medical devices within the tendering process. Therefore, it is likely that the procurement decision-making process has also implications for the proposed factor Pricing. This is based on the fact that although the medical device manufacturers are basically free to decide on their market price for their devices, they are also free to negotiate prices for their medical devices within contracts with the different sickness funds. Thus, an implication would be that the initial price stated by the medical device manufacturer is not as restricting as one could assume, since it is negotiable within tendering contracts. Another implication based on the timeframe of the actual tendering processes is that the actual timeframe differs between countries. Therefore, in the case of Germany, where tendering occurs yearly or every two years, winning a tendering procedure would result in an enormous advance compared to competitors, since sales would increase for the manufacturer winning the tendering process till a new

tendering process is issued. Within the Netherlands tendering is issued on half-yearly or yearly basis, thus the advantage would not last that long as compared with Germany. Since Austrian sickness funds are issuing tender procedures based on the actual need the actual timeframe may differ between longer and shorter periods. Therefore, no general recommendation can evolve from those insights. Generally the recommendation for practical usage would be to especially consider the award criteria of those tendering procedures, which can be seen as mainly based on the lowest price within each country. Furthermore, the timeframe till a new tendering procedure is issued has implications on a potential competitive advantage. A brief summary of the findings of the factor can be found in Appendix 9.10.

## 5. OVERVIEW OF THE FINDINGS

A summarizing table of the similarities and differences can be found in Appendix 9.11.

## 6. CONCLUSION & DISCUSSION

With regard to the main research question of the paper

*“What factors influence the market introduction of the artificial pancreas in the Netherlands, Germany and Austria, due to specific rules and regulations?”*

this paper aims to provide information about four different factors, which are influencing the market introduction, due to country specific rules and regulations within the Netherlands, Germany and Austria. All factors were especially observed on the background of medical devices, due to the planned market introduction of the artificial pancreas of the Dutch company Inreda. The basis for the factors was given by the research of Herzlinger (2006), who provided an overview of six factors that could either accelerate or slow down the diffusion within the healthcare sector depending on external influences given by the country of the market introduction. Based on four of her factors a causal model was created as a basis for the analysis. The used literature provides a clear overview of the four proposed factors, which are of relevance while planning the market introduction of a new medical innovation. Since the effects of the factors for the market introduction are researched within the context of a country comparison covering the Netherlands, Germany and Austria, a literature study on the background of the different health systems was given to indicate first similarities and differences of the respective healthcare systems, which could already affect the proposed factors. All of the observed countries do have mandatory health insurance. However, within Germany and Austria there is a two-tier health care system in place, which means that wealthier people can choose for a private insurance, which may be willing to reimburse costs for a device like the artificial pancreas sooner than statutory health insurance. In the Netherlands there is the possibility to pay for additional voluntary health insurance, which could cover costs for a device like the artificial pancreas. Therefore those differences in the organization and financing of the health systems should be closer observed by Inreda to get more detailed insights on the possibilities for market introduction. Another potential implication for the market introduction derives out of the actual amount of the population that is affected with diabetes. It may be beneficial to conduct a marketing study disseminated to potential users of the artificial pancreas in the Netherlands, Germany and Austria to receive feedback on the willingness of using the artificial pancreas to indicate potential sales volume within each country. Based on that Inreda could achieve a better planning of the potential impact of the artificial pancreas.

Afterwards the following sub-questions have been answered in terms of an analysis of the effect of each factor on the market introduction of a new medical device as the artificial pancreas:

*“What is the effect of Players, Funding, Policy and Accountability on the market introduction of a new medical device such as the artificial pancreas?”*

*and “How do these effects differ between health systems in the Netherlands, Germany and Austria?”*

This was done based on the different backgrounds of the health systems in the Netherlands, Germany and Austria.

The analysis of the different factors revealed that each factor plays a role for the market introduction of a medical device. Based on the findings a recommendation can be given to Inreda in terms that they should critically reflect on the factors.

The price of the artificial pancreas has to be set on a level that is covering their costs for the development and market introduction phase. Furthermore, it is likely that the price will decrease depending on other device manufacturers that introduce the artificial pancreas within European markets. This is key, because the price of the artificial pancreas would then be influenced by reference pricing, which takes place in all of the three observed countries.

Concerning the reimbursement, Inreda has to take into account that, in case they are one of the first companies that will bring the artificial pancreas to the market, there may be a tremendous delay in market introduction caused by health technology assessments conducted on order of sickness funds and healthcare administrative bodies. Therefore, it could already be an option within the current phase to consider ordering health technology assessments in countries that are favored for the market introduction, because there is no general timeframe for the length of the health technology assessment. According to the findings this could take several years, depending on the complexity of the medical innovation.

This is also related to the findings that in each country there is the possibility given of approaching healthcare related administrative bodies, which for instance in Germany and Austria could start a health technology assessment of the artificial pancreas themselves. This would mean that those bodies finance costs for the health technology assessment and therefore it may be a first consideration to try to influence those bodies due to the potential of cost savings for health technology assessments. Within the Netherlands the Health Council could be approached, since it gives advice to the Ministry of Health for the possible healthcare agenda.

In case of the CE trademark approval, findings showed that Inreda should consider conducting the CE trademark approval of the artificial pancreas in the Netherlands. This is mainly because of the issue of correspondence of the notified body in charge for the approval and the company, which can be done in their native language in the Netherlands.

Tenders issued by the sickness funds in the different countries are also of high concern for Inreda, because winning a tender would guarantee sales for a fixed amount of time that depends on the procedures in the different countries of observation. What is key within the procurement decision-making process is that in all three countries the award criteria is mainly based on the lowest price. Therefore those tenders are both, positive and negative for Inreda. This is because they could secure sales for an amount of time and would lead to a higher market share, but on the other hand are also leading to a decrease of the price of the medical device. Procurement is also connected to the initial pricing of the artificial pancreas, since price discounts due to

those private negotiations should also be considered while establishing the initial price for the artificial pancreas.

Concerning the accountability it is important to notice for Inreda that in every country of observation there are administrative healthcare bodies in charge of monitoring the performance of the medical device. In case of a malfunction they are able to impose sanctions against the medical device manufacturer, which could lead to a decrease of reputation and in worst case the removal of the product from the market. Therefore, the suggestion to establish monitoring principles, based on an extensive communicational exchange between the medical device manufacturer, patients and practitioners, in each country of market introduction is made.

In conclusion, the outcomes of the analysis of the different factors provide some essential points of consideration that should be further elaborated on and also be taken into account for the market introduction of a medical device. Furthermore, the paper can be seen as an initial starting point for considering those proposed factors for the market introduction and seeks to act as a guideline for the decision-making process of the market introduction of a new medical device.

Based on the findings of the desk research the conclusion can be made that the implications of the factors proposed within the theory are also existing within the surrounding of the healthcare systems of the Netherlands, Germany and Austria. Thus, all of the mentioned factors are of practical relevance within the context of the market introduction of the artificial pancreas. However, the observed theoretical background of the factors dealt mostly with finished products ready for the market introduction, thus there may be the need of adding some insights about factors influencing products that are in the development phase, like the artificial pancreas.

As being the starting point for future research, the paper is limited in terms of its theoretical background. The findings could be of higher relevance and practical usage if the study would also include opinions gathered by qualitative interviews. Those qualitative interviews could gather the opinions of both medical device manufacturers within the development phase of their medical device and medical device manufacturers, which have recently introduced a medical device on the market. This could lead to a better indication or a potential ranking of relevant factors, since the experience of the medical device manufacturers could be used to provide more detailed insights of practical relevance. Therefore, the approach of gathering evidence of important factors, at the basis of qualitative interviews with the medical device manufacturer, is assumed to be of high relevance for collecting and testifying further factors that could have an effect for the market introduction of new medical devices.

## 6.1 Practical relevance

The paper provides an overview and analysis of factors, which should be considered for the market introduction of a new medical device and especially the artificial pancreas. This is of use to organizations that are currently within the development and testing phase like Inreda. The different factors could provide a kind of guideline for companies to prepare themselves for their planned market introduction. Furthermore, the comparison between the effect of the different market introduction factors within the Netherlands, Germany and Austria provides detailed information about local rules and regulations that have to be fulfilled and minded while considering the market introduction of a new medical device. Also, practical recommendations deriving from the analysis are mentioned to further elaborate on the analysis.

## 6.2 Scientific relevance

This paper has scientific relevance, because it aims to contribute to the existing literature on the possible implications of market introduction factors for the initial market introduction of a new medical device. Furthermore, special regard was paid to the factors, which could influence the market introduction of the artificial pancreas. So far, not much was known about the influence of different factors for the market introduction, with regard to the context of medical devices based on local rules and regulations within different countries. Thus, the paper provides a possible starting point to the field of research of factors influencing the market introduction of medical devices.

## 6.3 Limitations

Based on the theoretical setting of the literature study a limitation of the research is that findings and the outcomes are not evaluated via empirical tests, which could prove the results found in existing literature. In addition to that, not much literature exists about medical devices and thus the analysis of the factors is sometimes based on country specific procedures dealing with pharmaceuticals. Thus, some conclusions are based on the assumptions that the procedure for medical devices is relatively similar to the procedure for pharmaceuticals in the different countries. In addition to that, rules and regulations within the healthcare sector are likely to change. Therefore, one has to consider further changes due to rules and regulation in this field. Furthermore, the proposed factors influencing the market introduction may not be the only factors that could play a role for the market introduction of a medical device and are also influenced by the authors personal evaluation and assumptions.

## 6.4 Indications for future research

Further research could be conducted to empirically test the proposed factors to generate evidence if the factors play a role for the market introduction and, if they do, to what extend. Another potential field of further research would be to consider additional factors that may influence the market introduction of a new medical device in order to complete the overview of market introduction factors. Furthermore, two of the initial proposed factors by Herzlinger (2006), namely Technology and Customers were not taken into account for the consideration, because of the current phase of the artificial pancreas. Thus, those two factors could also be taken into consideration after the artificial pancreas is ready for the market introduction or introduced on the market. Within the analysis the relevance of health technology assessments is displayed. Those health technology assessments also include human factors and the improvement in life quality for the patients in their evaluation, which would also be an interesting factor to base further empiric research on. Also, the analysis of the factors revealed that there is some interdependency between the factors, for instance pricing and the procurement decision-making process are closely related to each other. This might also be an interesting starting point to research those interdependencies of the mentioned factors.

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## 9. APPENDIX

### 9.1 General information about diabetes

Diabetes is described as a chronic disease, which leads to an increase of blood sugar and can be divided into two different types of diabetes. Those two types are called type 1 and type 2 diabetes. Type 1 diabetes is caused by a lack of insulin production due to the destruction of insulin producing cells, which is therefore leading to high blood sugar, due to the lack of regulation through insulin (Atkinson, Eisenbarth and Michels, 2013). A resistance to insulin, which seems to be often caused by a volatile lifestyle including physical inactivity or overweight, causes type 2 diabetes (Stumvoll, Goldstein and van Haefen, 2005). The distribution of people affected with type 2 diabetes is roughly around 90% in comparison to around 10% of people affected by type 1 diabetes (Stumvoll et. al, 2005).

During the last decades the amount of people who are suffering from diabetes grew from 153 million affected people in 1980 to 347 million affected people in 2008 (Danaei et al., 2011). In addition to that, the International Diabetes Federation concludes that in 2013 there were 382 million people affected by diabetes and till 2035 this number will rise to more than 471 million people living with diabetes (International Diabetes Federation, 2013). Furthermore, the International Diabetes Federation (2013) states in their 6<sup>th</sup> edition of their Diabetes Atlas that: “By the end of 2013, diabetes will have caused 5.1 million deaths and cost USD 548 billion in healthcare spending.” (p. 7).

Due to this rapidly increasing amount of patients many companies have seen the necessity to deal with improving diabetes care and therefore developed various treatment methods that are used among countries to approach diabetes. Those treatment methods concern medical devices as insulin pens or insulin pumps (Renard, 2010). Besides the improvement of patients suffering from diabetes the financial context of diabetes care is also important for companies offering medical devices.

### 9.2 Used keywords for the literature search

Table 1. Summary of the key words used

Keywords
Diabetes, artificial pancreas, healthcare, health, policy, reimbursement, market introduction, medical device, financing, procurement, monitoring, diffusion, health technology assessment, continuous glucose monitoring, Europe, Decision making, economics, healthcare systems, country comparison, Germany, Netherlands, Austria, social health insurance, costs, accountability, co-payments, health insurance, adaption, regulation, marketing authorization, innovation, medical technology, notified bodies, assessment, health expenditure, pharmaceutical, licensing, marketing theory

### 9.3 Health systems in the Netherlands, Germany and Austria

Within the European Union, especially in the northwest of the EU, the health care systems are mostly of high quality and assure good health care to the different populations. The focus of the paper is lying especially on the three different health systems of the Netherlands, Germany and Austria, since Inreda B.V. is planning to conduct a large clinical trial with voluntary diabetes patients from the above-mentioned countries. Therefore, this section deals with the characteristics and differences between the three health care systems.

#### 9.3.1 The Netherlands

The Netherlands is a state that is located within the northwestern part of Europe. Currently there are around 16,850,000 inhabitants living within the Netherlands (Centraal Bureau voor de Statistiek, 2014). According to the IDF Diabetes Atlas 6<sup>th</sup> edition (2013) among 7,5% of the adult population (20-79 years) suffer from diabetes. In 2012 the per capita total expenditure on health was reaching 5.384,6\$. The total expenditure on health as a percentage of the gross domestic product resulted in 12,4% of the GDP (WHO: Netherlands statistics summary, 2014).

In general, the Dutch health care system can be characterized as a Bismarck model of health care (Bevan, Helderma and Wilsford, 2010). The characteristic of a Bismarck health care system care is that it is mainly financed through private insurance plans, which are based on contributions by the employers and employees (Busse and Riesberg, 2004; Bevan et. al, 2010). Further characteristics of the Bismarckian health system are according to Bevan et al. (2010) and Busse and Riesberg (2004) that there are various insurers within the insurance market, privately owned providers, the choice of freedom to select the primary health care supplier and direct access to specialists.

The Dutch health care system has been reformed in 2006. The outcome of the reform has changed the role of the government from a directing one towards a supervisory role. Throughout this change “Responsibilities have been transferred to insurers, providers and patients.” (Schäfer et al., 2010, p.24).



Further impacts of the health care system reform deal with the new possibility for insurance companies to negotiate with health care providers on the certain extent of their services as well as financial benefits of the health care insurers implying the possibility to give out dividends to shareholders (Schäfer et al., 2010). Also, health insurance was made compulsory for every citizen in the Netherlands after the health care reform (Hassenteufel and Palier, 2007). Bevan and van de Ven (2010) also mention that the freedom of choice for a specific insurance package offered by a specific insurance company is enhancing the competition between the insurance companies, which automatically implies an incentive for efficiency. Furthermore, they conclude that the competition between health care providers leads to tremendous discounts between forty and ninety percent of the original value of, for example, generics, due to a more efficient purchasing process and the pressure of competition.

Despite of the various improvements of the Dutch health care reform, Bevan and van de Ven (2010) also mention drawbacks of the reform that are including negative implications like substantial incentives for risk selection, the problematic definition of 'legal care duty' and complications while switching the insurance company, because of the barriers of acceptance of an additional voluntary health insurance, which is included in the third block of the Dutch health care system.

According to Schäfer et al. (2010) the Dutch health care system is financed through three various blocks.

- The first block deals with a long-term care social health insurance plan, which is covering financial consequences due to the necessity of continuous care. The costs of the continuous care are covered by income-related payments to the Algemene Wet Bijzondere Ziektekosten (AWBZ). They state that the patients are able to receive care after an evaluation of their sickness status, which is done by certain care offices, named *Zorgkantoren*, which: "operate independently, but are closely allied to health insurers" (Schäfer et al., 2010, p. 25).
- The second block consists of the Health Insurance Act, called *Zorgverzekeringswet*. Contributions to the *Zorgverzekeringswet* are made first, in terms of a general payment of a Dutch citizen to the health insurer that is in his favor and second, an income-based contribution to the Dutch health insurance fund, which is calculated from the citizens income (Schäfer et al., 2010).
- The third and last block is about an additional voluntary health insurance that aims to cover costs that are not covered by the two blocks mentioned before (Schäfer et al., 2010).

As stated before, the Dutch health care system can be mainly characterized as a Bismarckian health care system. Nonetheless, there are various opinions about the common understanding that the Dutch health care system is strictly following a Bismarckian approach. Hassenteufel and Palier (2007) argue that due to the fact that the first building block of the Dutch health care system, which consists of the Algemene Wet Bijzondere Ziektekosten (AWBZ), is financed partly by taxes to cover long-term and mental care, the Dutch health care system is not strictly following a Bismarckian health care approach. Another remark, that the Dutch health care system is not strictly following the Bismarckian style of health care, given by Bevan et al. (2010) is that a Bismarckian health care approach usually provides guidelines by rules and regulations, which are assigning certain citizens to certain insurance schemes, which is preventing competition between different insurance companies. Despite this remark they also state that the second block, consisting of the *Zorgverzekeringswet*, clearly has Bismarckian attributes, since it is financed by a deduction of payroll of the Dutch citizen to the Dutch health insurance fund and the individual payment to a health insurer of the citizen's favor (Schäfer et al., 2010).

Since 2005 reimbursement is done in the Netherlands by a Diagnosis Related Group system, which is monitored and regulated by the Dutch Healthcare Authority (NZA) with the classification of diagnosis related groups in two different groups (Schäfer et al., 2010). The main difference is that the first group has a fixed and regulated reimbursement amount set by the Dutch Healthcare Authority, whereas the second group negotiates the exact reimbursement amounts directly between the healthcare insurers and healthcare providers within renewable contracts (Schäfer et al., 2010).

**Table 2. Summary of the Dutch key health system figures**

<b>Dutch key health system figures</b>	
Inhabitants (approx.)	16.850.000
% of adult population suffering from diabetes	7,5%
Per capita total expenditure on health	5.384,6\$
Total health expenditure as a percentage of GDP	12,4%

Source: Centraal Bureau voor de Statistiek (2014); WHO (2014); International Diabetes Federation (2013)

### 9.3.2 Germany

Germany is located in the central part of Europe and is, in addition to that, a direct neighbor state to the Netherlands. With around 80.511.000 million inhabitants according to the Statistisches Bundesamt (2013) it is the country with the second highest population within Europe. Currently around 12% of the adult population is suffering from diabetes according to the IDF Atlas 6<sup>th</sup> ed. (International Diabetes Federation, 2013). Furthermore the per capita total expenditure on health equals 4617\$ in 2012 and the total expenditure on health as a percentage of the gross domestic product resulted in 11,3% within 2012 (WHO: Germany statistics summary, 2014).

The German health system has a long tradition and it can be seen to be the first social security system. It was introduced by Otto von Bismarck in 1883 and accepted by the parliament, which was leading to the first mandatory health security insurance system (Busse and Riesberg, 2004). Within those times it was a radical novelty to the existing rules and regulations, because it introduced a new way of collecting funds to serve the society's well being (Bärnighausen and Sauerborn, 2002). Therefore German citizens benefit from the Bismarckian health insurance system in the way that it offers them various benefits like the choice of determining the responsible for primary health care delivery and immediate access to specialists (Busse and Riesberg 2004; Bevan et al., 2010).

In Germany statutory health insurance is the biggest source of financing health care, in which about 88% of the population are included (Busse and Riesberg, 2004). There are around 160 health insurance funds that are competing as not-for-profit, non-governmental organizations and they are funded by equal contributions of the employer and the employee (Smith et al., 2012). Smith et al. (2012) further mention that the part of the German citizens that is not covered by the statutory health insurance is, according to them, covered by private health insurance, for example civil servants with complementary private insurance or wealthy citizens who chose to entry the private health insurance. During a health care system reform in 2009 it is mandatory since then to be either covered by the statutory or the private health insurance (Thomson, Osborn, Squires and Reed, 2011).

Nonetheless, there is still kind of a two-tier classification of health insurance in Germany after the reform, because according to Flood and Haugan (2010) German citizens that are earning above 48,000€ per year can either choose between the social health insurance and a private insurance plan.

In addition to that, the two-tier classification of the possibility of a private health insurance for the wealthier citizens in Germany should be considered as an alternative to cover all possible core costs and is not used by everyone (Flood and Haugan, 2010; Busse and Riesberg, 2004). Furthermore, as in the Netherlands, there is the possibility of a voluntary complementary insurance plan, which covers additional costs for medical treatments like dentist surgery.

Resulting there are also three blocks on which the financing of the German health care system is based:

- The statutory health insurance, which covers around 88% of the German citizens and is financed by equally contributions of the employer and the employee to sickness funds
- The private health insurance, which covers around 12% of the German population and is either financed by the wealthy part of the population to cover all possible core costs, or people which are forced to have a private health insurance because of their current job as civil servants
- The voluntary complementary insurance plan, which aims to provide a better reimbursement mostly for citizens that are covered by the statutory health insurance plan.

Another main characteristic of the German health system is according to Smith et al. (2012) the separation of power between the federal level, the state level and corporatist institutions, which is improving the decision making process through the separation of power from the government to other entities like the parliament or the states.

Especially interesting in the context of the foundation of the Federal Joint Committee (G-BA) in 2004, is that the collaboration of the health insurance funds, hospitals and physicians and the national associations of statutory health insurance is discussing about the benefits and drawbacks of health services, while taking the advisory opinion of patients into account within their decision making process to improve health services (Loh et al. 2007; Smith et al., 2012). Regarding to the reimbursement scheme within Germany one can observe that the G-BA is working as the main body in charge for the reimbursement process of medical devices in Germany (Busse and Riesberg, 2004). To assure that the reimbursement process is initiated for medical devices, the CE trademark has to be granted by a notified body within any of the European member states (Schreyögg, Bäumlner and Busse, 2009).

**Table 3. Summary of the German key health system figures**

German key health system figures	
Inhabitants (approx.)	80.511.000
% of adult population suffering from diabetes	12%
Per capita total expenditure on health	4.617\$
Total health expenditure as a percentage of GDP	11,3%

Source: Statistisches Bundesamt (2013); International Diabetes Federation (2013); WHO (2014)

### 9.3.3 Austria

Austria is a European state, which is located in central Europe and is a direct neighbor to Germany in the northern part. It consists of nine provinces. Austria is the state with the smallest amount of inhabitants compared to Germany and the Netherlands, with only 8.453.191 inhabitants in 2012 (Bundesanstalt Statistik Österreich, 2014). According to the IDF Atlas 6<sup>th</sup> ed. (International Diabetes Federation, 2013) currently around 9,3% of the adult population of Austria (20-79 years) is suffering from diabetes. The WHO states that in 2012 the per capita total expenditure on health was 5065,1\$ and the total expenditure on health as a percentage of gross domestic product was 11,5% (WHO: Austria statistics summary, 2014).

In general the Austrian health system is seen as highly decentralized and consisting of multiple actors (Hofmarcher and Quentin, 2013). In addition to that it can be seen as a self-governed health system (Zechmeister, Österle, Denk and Katschnig (2002). Furthermore it is also seen as a health care system that is based on the Bismarckian approach (Franken, le Polain, Cleemput, Koopmanschap, 2012). According to Hofmarcher and Quentin (2013) multiple actors include decision-making entities on the regional and federal level, which implies the involvement of the provinces and the general government within the decision making process on health care affairs in Austria. The Austrian health care system is mostly financed by social insurance funds that are contributing for around 50% of the health expenditure, which is financed by equally distributions from the employer and the employee (Zechmeister et al., 2002; Hofmarcher and Quentin, 2013). According to Zechmeister et al. (2002) around 25% of health expenditure is financed by contributions of tax income of the state and the different provinces. They also state that the rest of the health system financing is covered by out-of-pocket payments, which include payments for hospital services, private insurance or other health related services. Furthermore citizens of Austria can basically choose between a health insurance funded by payments to a public fund or additionally privately paid health insurance, which grants certain bonuses like preferred treatment or single rooms at hospitals (Hofmarcher and Quentin, 2013).

Thus, in order to achieve a better overview for comparison the three main blocks of health care financing in Austria are:

- Half of the health care system is served by sickness funds, which are financed by contributions of employers and employees
- Around 25% is tax-financed via contributions of the state and the nine provinces
- The remaining 25% are financed by out-of-the pocket payments, which includes co-financing of medications or payments for additional health related services

Based on the Bismarckian health care approach Austrian citizens are also members of one of the 19 insurance funds existing in Austria, whereas most of the population is a member of one of the nine sickness funds of the nine provinces (Winkelmayer et al. 2010; Hofmarcher and Quentin, 2013). Winkelmayer et al. (2010) also state that those sickness funds cover most of the health care services and all medications, which are reviewed by a council and, in case of effectiveness in improving the health care standard of patients, approved for reimbursement. Since not all reimbursement costs are covered by the sickness funds, for example for the prescription of medication, patients have to cover a certain extent in form of co-payments of €5,15 in 2012 with a maximum cap of 2% of the citizens annual net income (Hofmarcher and Quentin, 2013). According to them to receive financial reimbursement medications and medical devices have to be approved by the AGES Medicines and Medical Devices Agency, which is in charge of the evaluation, monitoring and the licensing process of medicines and medical devices. After the approval of the AGES the regional health insurance funds are in charge for the payment and reimbursement of a medical device, which is part of the insurers service catalogue, since there are no general contracts existing on the reimbursement process for medical devices (Hofmarcher and Quentin, 2013). In addition to that, Hofmarcher and Quentin (2013) state that pricing of medical products is done by the Pricing Committee taking the average price for the medical product in Europe into account, which is then referring to the reimbursement decision making process on reimbursement rates fulfilled by the Association of Austrian Social Security Institutions (HVB). According to them reimbursement rates vary and may either be fully, partially or not covered by the health insurance companies, depending on the reimbursement decision-making process.

**Table 4. Summary of the Austrian key health system figures**

<b>Austrian key health system figures</b>	
Inhabitants (approx.)	8.453.191
% of adult population suffering from diabetes	9,3%
Per capita total expenditure on health	5.065,1\$
Total health expenditure as a percentage of GDP	11,5%

Source: Bundesanstalt Statistik Österreich (2014); International Diabetes Federation (2013); WHO (2014)

### 9.3.4 Similarities and differences within the health care systems of the Netherlands, Germany and Austria

After discussing main figures of the three health systems in the Netherlands, Germany and Austria, the main similarities and differences will be discussed within this section.

Starting with the similarities, all of the nations base their health care system on the Bismarck model, which was introduced within 1883 (Bevan et al., 2010; Busse and Riesberg, 2004; Franken et al., 2012). Thus, all the implications of the social health care model apply in the Netherlands, Germany and Austria, including characteristics as the choice of freedom to select the provider of primary health care, direct access to specialists and a variety of insurers on the insurance market (Bevan et al., 2010; Busse and Riesberg, 2004). Based on the Bismarckian approach of a social health care system all of the three health systems are mainly financed by contributions to sickness funds, which are mainly paid by equal contributions of the employer and the employees (Schäfer et al., 2010; Busse and Riesberg, 2004; Zechmeister et al., 2002; Hofmarcher and Quentin, 2013). Another similarity of the three health care systems is that nowadays it is mandatory to have health care insurance, which was established after health care reforms in the three countries (Thomson et al., 2011; Schäfer et al., 2010; Hofmarcher and Quentin, 2013). Wild and Gibis (2003) mention that the biggest similarity of the health care systems in the Netherlands, Germany and Austria is the distinction between the different sectors within the health care systems and the distinction between the reviewing procedure of medicine and medical devices. Due to the various health care reformations within the different countries this statement is not valid nowadays, since various reforms and technological progress on the EU and state level enhanced the importance of the evaluation of medical devices (European Commission, 2000; Schäfer et al., 2010). Franken et al. (2012) also state that within countries in the European Union drugs are assessed and enlisted for authorization for reimbursement. The authorization for reimbursement initiated by certain councils like the AGES Medicines and Medical Devices Agency (Hofmarcher and Quentin, 2013).

Although the health care systems in the Netherlands, Germany and Austria are based on the Bismarckian approach of social health care, there are also differences due to specific rules and regulations within the countries. One main difference is lying in the way of the distinction between statutory health care and private health care insurance. In Germany and Austria, it is possible to decide for private health care insurance from a certain point of income level onwards (Flood and Haugan, 2010; Hofmarcher and Quentin, 2013). This can be described as a two-tier health care system, since it offers benefits to those, who are wealthier and obtain private insurance in terms of higher quality of treatment, reduction of waiting times, or preferred room selection in hospitals (Hofmarcher and Quentin, 2013). The Netherlands can therefore be defined as a one-tier health system, which aims to serve its patients in an equally and fair manner, because it is only possible to buy complementary private insurance to cover costs that are not reimbursed by the sickness fund (Schäfer et al., 2010). Traditionally the manufacturer of a new medicine or medical device initiates the reimbursement process, but two exceptions of this common way of handling reimbursement are expensive inpatient drugs in the Netherlands and ad-hoc procedures performed by the Austrian Medicines and Medical Devices Agency (Franken et al., 2012).

In terms of financing expenditure within the different health systems the per capita total expenditure on health in 2012 differs slightly between the three countries, with the Netherlands spending the highest amount, namely 5.384,6\$, Austria spending 5.065,1\$ and Germany spending the lowest amount, which results in 4.617\$ (WHO: Austria statistics summary, 2014; WHO: Germany statistics summary, 2014; WHO: Netherlands statistics summary, 2014). Also the WHO statistics summary (2014) states that there are slightly differences within total health expenditure as a percentage of GDP, resulting in the same ranking as for the per capita total expenditure on health with the Netherlands spending 12,4% of their GDP on health, Austria spending 11,5% on health and Germany spending 11,3% of their GDP on health.

Concluding one could observe that although all three health care systems are based on a Bismarckian approach, through the reforms of the health systems and new European wide regulations the health care systems differ to some extent in terms of the exact way of financing and organizational structure.

## 9.4 Overview of findings of the factor “Approaching decision-making entities”

Table 5. Summary of the findings of the factors “Approaching decision-making entities”

Factor	Netherlands	Germany	Austria
Approaching decision-making entities	- Health Council of the Netherlands gives advice on possible healthcare agenda	- German Institute for Medical Documentation and Information in charge of HTA reports	-Ludwig Boltzmann Institute for Health Technology Assessment gives advice to the Ministry of Health based on HTA's

Source: Dimdi (2014); Wild & Langer (2008); Schäfer et al. (2010); Hofmarcher and Quentin (2013)

## 9.5 Overview of findings of the factor “Pricing”

Table 6. Summary of the findings of the factors “Pricing”

Factor	Netherlands	Germany	Austria
Pricing	<ul style="list-style-type: none"> <li>- Manufacturers can decide on prices</li> <li>- Possible regulation by the Ministry of Health on price regulation (reference pricing)</li> </ul>	<ul style="list-style-type: none"> <li>- Manufacturers can decide on prices</li> <li>- Possible regulation by the Ministry of Health, Federal Joint Committee and sickness funds on price regulation (reference pricing)</li> </ul>	<ul style="list-style-type: none"> <li>- Manufacturers can decide on prices</li> <li>- Possible regulation by the Ministry of Health on price regulation (reference pricing)</li> </ul>

Source: Habl et al. (2006); Busse & Riesberg (2004); Hofmarcher & Quentin (2013)

## 9.6 Overview of findings of the factor “Reimbursement procedure”

Table 7. Summary of the findings of the factors “Reimbursement procedure”

Factor	Netherlands	Germany	Austria
Reimbursement procedure	<ul style="list-style-type: none"> <li>- Key actors: Ministry of Health, Welfare and Sport, Health Insurance Board</li> <li>- Decision is made on the inclusion in the reimbursement system</li> <li>- Categorization is based on a positive list depending on if it can be compared to other products or if it is seen as unique</li> </ul>	<ul style="list-style-type: none"> <li>- Key actors: Ministry of Health, the Federal Joint Committee and sickness funds</li> <li>- Procedure depends on whether innovativeness is given</li> <li>- If it is seen as innovative: HTA performed by IQWiG</li> <li>- If not: Categorization in similar groups of existing products</li> <li>- If reimbursement is granted → listing in the Uniform Value Scale</li> </ul>	<ul style="list-style-type: none"> <li>- Key actors: Federal Ministry of Health and Woman, Pricing Committee, Federation of Austrian Social Insurance Institutions</li> <li>- Decision is made for inclusion in the Reimbursement Code</li> <li>- If reimbursement is granted → Ranking in a “Box” system</li> </ul>

Source: Habl et al. (2006); Busse & Riesberg (2004); Hofmarcher & Quentin (2013)

## 9.7 Overview of findings of the factor “Monitoring health system bodies”

Table 8. Summary of the findings of the factors “Monitoring health system bodies”

Factor	Netherlands	Germany	Austria
Monitoring health system bodies	<ul style="list-style-type: none"> <li>- Healthcare Inspectorate</li> </ul>	<ul style="list-style-type: none"> <li>- Federal Institute for Pharmaceuticals and Medical Devices</li> </ul>	<ul style="list-style-type: none"> <li>- Austrian Medicine and Medical Device Agency</li> </ul>

Source: Habl et al. (2006); BfArM (2013); Schäfer et al. (2010); Austrian Medicine and Medical Devices Agency (2014)

## 9.8 Overview of the notified bodies in Germany

Table 9. List of the notified bodies within Germany

Directive	Notified bodies
90/385/EEC	TÜV NORD CERT GmbH, TÜV SÜD Product Service GmbH Zertifizierstellen, TÜV Rheinland LGA Products GmbH, MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH, BSI Group Deutschland GmbH, LGA Intercert Zertifizierungsgesellschaft mbH

<b>93/42/EEC</b>	TÜV NORD CERT GmbH, TÜV SÜD Product Service GmbH Zertifizierstellen, TÜV Rheinland LGA Products GmbH, MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH, BSI Group Deutschland GmbH, LGA Intercert Zertifizierungsgesellschaft mbH, DEKRA Certification GmbH, DQS Medizinprodukte GmbH, VDE-Prüf- und Zertifizierungsinstitut GmbH, Materialprüfungsamt Nordrhein-Westfalen, ECM- Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, MDC Medical Device Certification GmbH, SLG Prüf- und Zertifizierungs GmbH, Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH
<b>98/79/EC</b>	TÜV SÜD Product Service GmbH Zertifizierstellen, DEKRA Certification GmbH, TÜV Rheinland LGA Products GmbH, MDC Medical Device Certification GmbH and the BSI Group Deutschland GmbH

Source: European Commission (2014).

## 9.9 Overview of findings of the factor “CE trademark approval”

**Table 10. Summary of the findings of the factors “CE trademark approval”**

<b>Factor</b>	<b>Netherlands</b>	<b>Germany</b>	<b>Austria</b>
CE trademark approval	- Based on EU and national law - 1 notified body (DEKRA)	- Based on EU and national law - More than 10 notified bodies	- Based on EU and national law - 2 notified bodies

Source: Schreyögg, Bäumlér & Busse (2009); Habl et al. (2006); European Commission (2014);

## 9.10 Overview of findings of the factor “Procurement decision-making process”

**Table 11. Summary of the findings of the factors “Procurement decision-making process”**

<b>Factor</b>	<b>Netherlands</b>	<b>Germany</b>	<b>Austria</b>
Procurement decision-making process	- Tendering procedure issued by sickness funds every 6 months or yearly - Criteria is based on the lowest price	- Tendering procedure issued by sickness funds yearly or every 2 years - Criteria is based on the lowest price, product, quality & volume	- Tendering procedure issued by sickness funds depending on the actual need - Criteria is based on best price offer

Source: Kanavos, Seeley & Vadoros (2009); Sorenson & Kanavos (2011)

## 9.11 Similarities and differences of the analysis within the three countries

Table 12. Combined summary of the findings of the factors

Factors	Subcategories	Netherlands	Germany	Austria
Players	Approaching decision-making entities	- Health Council of the Netherlands gives advice on possible healthcare agenda	- German Institute for Medical Documentation and Information in charge of HTA reports	-Ludwig Boltzmann Institute for Health Technology Assessment gives advice to the Ministry of Health based on HTA's
	Pricing	- Manufacturers can decide on prices - Possible regulation by the Ministry of Health on price regulation (reference pricing)	- Manufacturers can decide on prices - Possible regulation by the Ministry of Health, Federal Joint Committee and sickness funds on price regulation (reference pricing)	- Manufacturers can decide on prices - Possible regulation by the Ministry of Health on price regulation (reference pricing)
Funding	Reimbursement procedure	- Key actors: Ministry of Health, Welfare and Sport, Health Insurance Board - Decision is made on the inclusion in the reimbursement system - Categorization is based on a positive list depending on if it can be compared to other products or if it is seen as unique	- Key actors: Ministry of Health, the Federal Joint Committee and sickness funds - Procedure depends on whether innovativeness is given - If it is seen as innovative: HTA performed by IQWiG - If not: Categorization in similar groups of existing products - If reimbursement is granted → listing in the Uniform Value Scale	- Key actors: Federal Ministry of Health and Woman, Pricing Committee, Federation of Austrian Social Insurance Institutions - Decision is made for inclusion in the Reimbursement Code - If reimbursement is granted → Ranking in a "Box" system
	Monitoring health system bodies	- Healthcare Inspectorate	- Federal Institute for Pharmaceuticals and Medical Devices	- Austrian Medicine and Medical Device Agency
Policy	CE trademark approval	- Based on EU and national law - 1 notified body (DEKRA)	- Based on EU and national law - More than 10 notified bodies	- Based on EU and national law - 2 notified bodies
	Procurement decision-making process	- Tendering procedure issued by sickness funds every 6 months or yearly - Criteria is based on the lowest price	- Tendering procedure issued by sickness funds yearly or every 2 years - Criteria is based on the lowest price, product, quality & volume	- Tendering procedure issued by sickness funds depending on the actual need - Criteria is based on best price offer

Source: Dimdi (2014); Wild & Langer (2008); Schäfer et al. (2010); Hofmarcher and Quentin (2013); Habl et al. (2006); Busse & Riesberg (2004); BfArM (2013); Austrian Medicine and Medical Devices Agency (2014); Kanavos, Seeley & Vadoros (2009); Sorenson & Kanavos (2011); Schreyögg, Bäumlér & Busse (2009); European Commission (2014)