Business models for treating diabetes type 1 in developing markets

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ABSTRACT,

The number of people diagnosed with diabetes increases every year. This growing market means that the market for treating diabetes will only become more attractive for both large and small businesses to dive into. The focus of this paper is to shed a light on the differences in the business models of companies operating in the market for treating diabetes type 1 in developed countries, compared to developing countries. Currently, many multinationals import their existing business models used in the western markets into these emerging markets, resulting in the difficulties these companies have had entering emerging markets. In this paper, a cross-case analysis is done between the business models of Novo Nordisk operating in a developing market (Brazil), compared to a developed market (Germany). To analyse the business model used by the firm, the framework for value creation developed by Bohnsack et al. (2013) is used. The PESTLE analysis is used for both Brazil and Germany. A cross-case analysis finds that different factors of the country influence the operations of the firm. An important factor for this difference is the economic state of the market. High unemployment and general poverty require the company to adopt a different strategy in offering its treatments. For example when the economic situation in a country improves, the focus of customers shift from purely cost, to higher service and convenience. Operating in developing countries thus does require a business model that can deal with some issues like political instability, corruption and a less developed infrastructure. There is however, a lot of potential in these markets and with the rising welfare of the population, and with the increasing focus on health, there will be increasing opportunity for companies like Novo Nordisk.

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Keywords

Business models, type 1 diabetes, value creation, developing markets, external environment

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1. INTRODUCTION

According to the World Health Organisation, the number of people diagnosed with diabetes has almost quadrupled between 1980 and 2014 from 108 million to 422 million.[i] This caused the global cost of diabetes to reach 825 billion in 2016.[ii] An estimated 490,100 children below the age of 15 are currently living with diabetes type 1.[iii] Another 77,800 are expected to develop the disease in 2011. And there is evidence that the incidence is rising rapidly.[ivvvi]

To provide a little more background on the subject, diabetes, also called Diabetes mellitus, is a disease that causes the levels of glucose in a person's blood to be too high. Someone gets this glucose from digesting food. Insulin is then needed to transport this glucose to the cells to provide them with energy.[vii] Diabetes can be separated into different groups. The two biggest ones are known as diabetes type 1, and type 2. The difference lies in the fact that patients with diabetes type 1 are not able to produce insulin, while with diabetes type 2, the body is not able to use it well.

This growing market means that the market for treating diabetes will only become more attractive for both large and small businesses to dive into. According to Kåre Schultz from Novo Nordisk, the market in Europe has matured and small growth rates are to be expected in that region. The market for diabetes treatment in developing markets on the other hand is expected to rise due to large economic growth. The focus of this paper is to shed a light on the differences in the business models of companies operating in the market for treating diabetes type 1 in developed countries, compared to developing countries.

These new opportunities also lead to new challenges in a largely new market. Therefore, a change in business models employed by the organisations is required. David J. Teece (2010) states that the essence of a business model is to define the manner in which the organisation delivers value to its customers, entices customers to pay for value and converts this to profit.[viii] Currently, many multinationals import their existing business models used in the western markets into these emerging markets, resulting in the difficulties these companies have had entering emerging markets.[ix] Therefore, business models need to adapt to this new situation.

Chen et al. (2013) remarked that the current research on business models in the medical industry is limited, although it is important for creating value for both the patient and the healthcare provider[x] This lack of sufficient research is due to the fact the most articles tend to focus on answering the questions, "Can we do this" instead of " Should we do this", according to Gamble et al. (2004). They furthermore note that when analysing business models in the medical industry, new challenges arise. Examples of this are the joint costs and that technological change can rapidly make existing ideas outdated.

This paper will examine the existing business models of medical organisations currently operating in emerging markets by analysing the operations in developing countries. This will provide an insight of the way the med-tech industry is organised. To compare the business models operating in developing countries with the business models in developed countries, the operations in developed countries are analysed and compared with the developing countries. The main research question of this paper is: *What are the differences and similarities of the business models currently used by the dominating players in the market, in the pharmaceutical industry treating diabetes type 1 by producing insulin in developing countries, compared to developing countries.*

2. THEORETICAL FRAMEWORK

To analyse the way different organisations in different markets conduct their business, the business models of the organisations will be analysed. Furthermore, different theories have been developed to analyse certain aspects of a business model.

2.1 Business Models

Many different definitions of a business model exist. [xi]Osterwalder, Pigneur & Tucci (2005) define business model as "a simplified description and representation of a complex entity of process". This definition implies that for the analysis of a business model, a conceptualization takes place with the representation of what value is provided to customers and how this is done with the respective financial consequences.[xii]

Every organisation uses a business model. This happens either implicitly or explicitly. The reason for this is that a business model crystalizes the customer needs, and the way the company creates value for this customer. It furthermore analyses the way in which customers will pay for the delivered value.[xiii] In brief, the business model is used to describe how the firm organises its activities, and its setup to compete in the market.

For an organisation to use the business models in the medical industry, they not only require a creative solution and creative thinking when developing a technology, but also when developing its business model. The reason for this is the complex structure of the sector. The medical sector is one with many stakeholders. A properly analysed business model is therefore required to reach the correct target segment.

The US medical industry for example traditionally worked with traditional business models where R&D, and innovation were important, and the target audience were physicians. The most important criteria for their commercial success were the safety of their products and the efficacy. In recent years, a switch was made from these traditional business models to a value-based healthcare system where clinical value with cost efficiency became important.

To assess the business model of a company, Alex Osterwalder set-up the business model canvas. In their paper Business Model Generation (2010), Alexander Osterwalder and Yves Pigneur define a business model as the rationale of how an organisation creates, delivers, and captures value. They state that there is a need for a business model concept that everybody understands, which creates a shared understanding of the firm.[xiv]

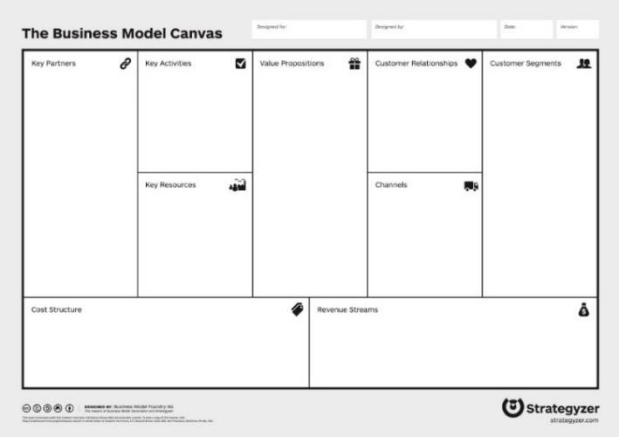


Figure 1: Business model canvas (Osterwalder & Pigneur, 2010)

They created a nine-part lay-out containing all the assumptions about the business model. These parts include: customer segments, value propositions, channels, customer relations, revenue streams, key resources, key activities, key partnerships and the cost structure of the organisation.(Ovans, 2015)(Ovans, 2015)(Ovans, 2015)(Ovans, 2015)(Ovans, 2015)(Ovans, 2015) [xv]

One of the disadvantages of using the business model canvas is the limited focus on the value proposition of the organisation. The model limits the view to the value created with revenue in return. This does not correctly grasp the extend of the value proposition of the entire organisation.[xvi]

Another model to analyse business models of organisations is through the framework set-up by David Watson (2005) in his book Business models, where he discusses investing in companies and sectors with strong competitive advantage.[xvii] In his book, David Watson analysed 129 business models trough six different components. These components are: competitors, customers, economy, management, products and suppliers.[xviii] Watson concludes that a strong competitive advantage can only be achieved by doing something different from the competition, or creating a situation where the company has low costs. The goal of this action is to add value to the customers. This will result in the opportunity to ask for a premium price.[xix]

A Third concept is made by Johnson, Christensen and Kagermann in "Reinventing your business model"[xx], where the authors analyse business models with four interconnected components. These components are the value for the company, the profit formula of the firm, the key resources that the company uses and the key activities. The authors draw the conclusion that successful companies create value for its customers, and that this leads to the company making a profit. Another necessary condition for a successful business model is that the organisation has access to the resources and is doing the proper activities. Compared with the models discussed above, the framework presented by Johnson, Christensen and Kagermann is a comprehensive concept that describes the essential components of business.

The different concepts and theories described above realize the importance of value creation as part of the business model of an organisation. Although the focus of the theories does go in-depth into this part of the business model. To properly analyse the companies in the industry, the way the companies create value has to be analysed and a comparison has to be made between the operations in the western world and the developing markets. To analyse and compare the operations, a framework has to be adopted. Bohnsack et al. (2013) proposes such a framework which will be used in this paper to assess the way the organisations create value.

2.2 Value creation

According to Teece (2010), every business uses a business model, either explicitly or implicitly. He further states that the design of the value creation is described by the business model. This leads to multiple functions of the organisation's business model. One function is that it helps the organisation understand the customer needs, and can describe the ability the organisation has to deliver value to the customer, and therefore create value.[xxi]

A framework has been designed by Bohnsack et al. (2013) to analyse the business models and to provide a clear view on the business model of an organisation capable of comparison. With the aim to let the framework remain its simplicity, the focus lays on the value creation, and capturing of the firm. This resulted in a framework made-up of three components, being value proposition, value network and the revenue & cost model.[xxii]

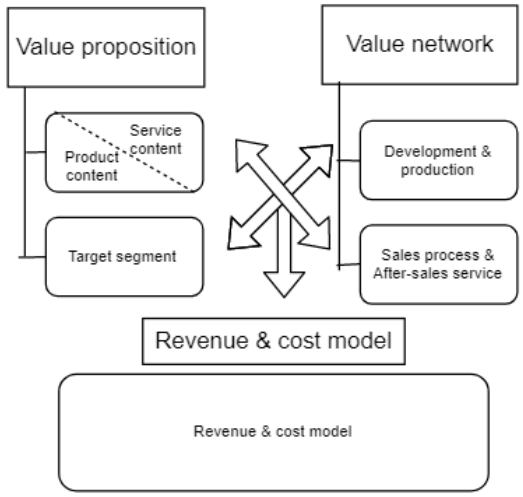


Figure 3: Framework Value creation (Bohnsack et al., 2013)

Bohnsack et al. (2013) based their framework on the work of the characteristics of value creation and value capture of organisations by Chesbrough (2007) and Teece (2010). From the work of Osterwalder et al. (2005), Morris et al. (2005), Johnson et al. (2008), Demil and Lecoq (2010) and the work of Chesbrough and Rosenbloom (2002), the three main components were derived. The reason for choosing the three components in the framework is according to Bohnsack et al. (2013) that the authors mentioned above, all see these three recurring elements as the foundation of the business model.

2.2.1 *Value Proposition*

The first component of the framework to analyse the business model is the value proposition describes the value proposition of the company as a necessary practice for a successful company to create value for the customers. In the framework designed by Bohnsack et al. (2013) the value proposition can be analysed by looking at the content of the product and/or service delivered to the customers, and with that, analysing the target segment the company aims to serve.

2.2.2 *Value network*

As mentioned by Morris et al. (2010)[xxiii] a value network is a critical factor in the value creation of an organization. Therefore it is important to develop appropriate relationships with its customers, suppliers and its partners. When analysing the value network of an organisation, focusing on the development & production, and sales process and the after-sales service, adds additional insight on the value creation of the firm which will result in possible comparison when combined with the value proposition and the revenue & cost model of the firm.

2.2.3 *Revenue & cost model*

The third component of the framework is the revenue & cost model. The revenue model is about analysing the ability of the firm to generate revenue. The revenue model of a firm can consist of multiple revenue models which each have different pricing mechanisms according to Osterwalder & Pigneur (2002). Sources of revenue can also vary. Possible sources of revenue include government support and licensing to clients. Osterwalder & Pigneur (2002) describe the cost structure as an element which measures all the costs related to the firm by putting a price tag on all the resources, assets, activities, partners network relations and exchanges that cost the company money.

2.3 PESTLE

The Business model canvas and the framework created by Bohnsack et al. focus on the capabilities of the organisation and the value proposition that is derived from it.[xxiv] With an analysis of the value proposition, value network and the revenue & cost model, an insight in the internal capabilities of the firm in the different market can lead to new insights. This does not however, take into account quite some external factors that could be the cause of the level of succes of the different operations in their respective markets.[xxv] Different methods can be used to analyse the business environment. A widely used theory is the SWOT analysis which focusses on the strengths, weaknesses, opportunities and threats that effect the business envorinment. [xxvi] The framework however only focusses on the internal factors that influence the business environment and will therefore most likely not end up explaining differences between the analysed firms in different countries. A framework that does focus on the external factors is the PESTLE framework.

The PESTLE framework is able to analyse the external factors that have an effect on the structure, the exernal and the internal environment of the firm. It consists of six different factors: political, economical, socio-enviromental, technological, legal and environmental.

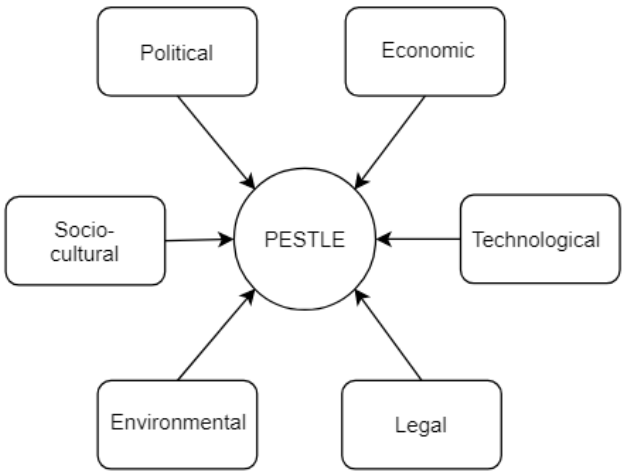


Figure 3: PESTLE Analysis (Root, 1994)

2.3.1 *Political*

The political systems of a country shape what companies can and cannot do. Government regulation can influence investment decisions by specifying conditions that must be met, and what they can charge for certain services. For the Health-tech industry, especially the health & safety regulations are of great importance to the operations. Furthermore, government expenditure and investments in the health sector can greatly influence decisions of companies to operate in a specific country. Political instability can however have a negative effect.

2.3.2 *Economic*

Economic factors include inflation, wage levels and interest rate among others. These factors analyses the state of the economy. This state is of major importance for capital investment decisions. Economic growth prospects, when negative, can lead to the postponement of new projects. Unemployment rates and the labour costs of a country on the other hand can lead to advantages of operating in this country.[xxvii]

2.3.3 *Socio-cultural*

As stated by Boddy (2014), the demographic change of an aging population clearly affects the healthcare and the pharmaceuticals businesses. Multiple socio-cultural changes can have an impact on businesses. There changes can include changes in lifestyle, levels of education and customer preferences, among others.[xxviii]

2.3.4 *Technological*

These factors refer to innovations in technology that either positively or negatively influence the market of the operations in the industry. Examples are digitalisation and automation. These

new developments can create new opportunities or reduce costs when used effectively.

2.3.5 *Legal*

The legal factors a business is influenced by are rules that are created by governments to assert their autority over their country to create and maintain a stable legal enviroment, without which ogransations would be difficult and expensive to operate. Several legal regulations companies have to adhere to are property rights (including intelectual property), employment law and business regulations.

2.3.6 *Environmental*

Environmental factors involve the natural resources available in an economy, but also the impact of climate change. This could lead to serious risk of floods, storms, droughts and heat waves, depending on the area and the industry the company operates. The limited supply of energy and water also influences the company.

3. METHODS

To analyse the business models in developing countries, Brazil is used. the focus of this paper on Diabetes in Brazil is chosen because in 2015, nearly 12 million people were affected by diabetes in Brazil. This resulted in an occurrence of diabetes of 6,3% and 15,3% is some areas. This makes Brazil the world's fourth country in terms of the amount of diabetes patients.(Coutinho & Silva Júnior, 2015)(Coutinho & Silva Júnior, 2015)(Coutinho & Silva Júnior, 2015)(Coutinho & Silva Júnior, 2015)(Coutinho & Silva Júnior, 2015)(Coutinho & Silva Júnior, 2015) [xxix]

The dominating player, as referred to in the research question, is Novo Nordisk. The decision for this company was made based on the value and volume market share of the company as a percentage of the global insulin market in 2011[xxx] With Novo Nordisk having a value market share of 44% Therefore this research will focus on analysing this company.

The research will be carried out over a period of 10 weeks. The market-leader in the industry, Novo Nordisk will be analysed in both Germany and Brazil. The information about the business models in the different markets will be retrieved from the company reports and articles on the internet. The research will be using secondary data, and if information is needed that cannot be found using secondary data, that information will be gathered by tying to get in contact with the companies. Other information sources include the World Health Organisation.

The business models will be analysed according to two frameworks. The first is the PESTLE analysis, which is described in the theoretical framework of the paper. The idea behind analysing the two different markets using the PESTLE analysis is to find explanations for different operations in the markets -and the reasons for superior performance of the company compared with the value creation framework of Bohnsack et al. (2013). The PESTLE analysis identifies the political, economic, social, technological, legal and environmental factors in the general environment that are relevant to the organisation.[xxxi]

The second framework by which the companies will be analysed is the framework developed by Bohnsack et al. (2013). His theory that focusses on value creation will provide further insight in the differences between the same organisations in their respective markets, because of the different value proposition, value network and revenue & cost model. When analysing organisation using this framework, the different operations of the organisations in their respective countries will be analysed and compared. Differences in cost of employment could result in different value networks in different countries within the same organisation for example.

The company analysed is the companies with the largest market share in the global insulin market.[xxxii] The company analysed is Novo Nordisk. Novo Nordisk is a Danish global medical company with approximately 42.100 employees operating in 79 countries, while selling its products in over 170.[xxxiii] The company focusses primarily on the diabetes industry with treatments for diabetes type 1 and 2, but also with a focus on preventing diabetes type 2 with for example weight and obesity management.[xxxiv]

4. ANALYSIS

4.1 Value Creation

4.1.1 *Novo Nordisk*

Novo Nordisk operates in more than 180 countries, this list includes both the richest and poorest countries in the world, with healthcare systems ranging from well-developed to non-existent.[xxxv] This statement was made by Kåre Schultz in July 2013, when he was still the chief operating officer.[xxxvi] Since the disease is deeply understood and Novo Nordisk develops protein-based treatments, the global strategy of the firm focusses primarily on the delivering of those treatments to the population.[xxxvii]

4.1.1.1 Germany

Value proposition

Product/service content

Novo Nordisk provides a range of products to deal with type 1 diabetes. Since the disease usually develops rather quickly, it is often discovered and diagnosed in childhood. This allows the patient to start treating the disease before complications develop. The different treatments all revolve around managing a balance between the levels of blood sugar and insulin in the body.[xxxviii] This balance is kept by administrating both basal insulin and mealtime insulin. The basal insulin in needed to maintain the patient's blood glucose level in between meals and overnight.[xxxix]

The Mealtime insulin which is needed in addition to the basal insulin is used to deal with the spikes of the patient's blood glucose levels shortly after mealtimes. This requires short- or rapid-acting insulin.

There are two ways to administer insulin to the body. Either by an injection beneath the skin or by using an insulin pump. The first can be performed by using a pen or a needle. The different pens offered by Novo Nordisk provide patients with many options. They can be disposable after usage of durable and pre-filled or refillable. To make them available to a wide range of users, some pens make use of a memory function and/or require

very little pressure to operate. This way, they are suited for people that struggle because of poor eyesight of memory.

Novo Nordisk furthermore focusses on more than just the injection of insulin. They state that due to the many physical factors concerning diabetes, it is also important to realise the effect that it has on the patient's emotional health. The company has a range of support initiatives to help a patient in dealing with this, and handle different situations, ranging from holidays to pregnancy.

Target segment

The end users of the products of Novo Nordisk's diabetes care products are their 27.7 million patients, with either diabetes type 1 or type 2. Since the disease leads to a lifetime of dependence on insulin injections, the demand coming from the patients is not expected to differ. There is however an upward trend in the incidence of type 1 diabetes in Germany, but further research has to be conducted to determine which factors cause this trend.[xl]

Value network

Development & production

After the development of the diabetes drug Tresiba, Novo Nordisk decided to launch its diabetes drug in Germany in May 2014 after noticing signs of the pricing model being more favourable. The previous year, the drug was already approved by the European Union. But the German authorities had been reluctant to support new and more expensive drugs, so the drug was not yet sold in Novo Nordisk's biggest market in Europe. The reason for this was that from 2011 onwards, Germany started to compare the benefits of the newly approved drugs with the currently existing treatments and provided the medical insurers with more bargaining power in the price talks with drug makers. In Germany, the drug maker is the first to set an initial price for the new products, and to get a subsidy at the same time. After a year has passed, the German authorities initiate the assessment process to find out if the price or the subsidy for the product should change.[xli]

A little over a year after deciding to launch Tresiba in Germany, the company makes the decision in July 2015 to end the sales of the drug because it failed to agree over a price during the negotiations with the German National Association of Statutory Health Insurance funds. This struggle symbolises the tensions between drug makes and healthcare providers that find themselves unhappy with the prices of modern medicines. Executive vice president Jakob Riis states that if they had accepted the offered price, it would undermine their ability to further develop medical innovations and do research on the treatment of diabetes.

Sales process & after-sales service

The sales growth in the European market has been modest in recent years according to the annual report of 2014.[xlii] In that year, the sales of insulin in Europe remained unchanged. And the sales of Novo Nordisk's diabetes care products only increased by one percent. According to the report, the company does not expect significantly higher sales growth in the coming years because the cost-cutting measures of governments is expected to continue. Other reasons explaining the modest grow are the low birth rates, the high diagnoses rates and the insulin market share of 48% which Novo Nordisk currently holds in a well-developed market.

The 2014 reports states that the key to accelerate the growth in the European market is Tresiba. They argue that when this product becomes more available to a larger number of patients, this will increase sales in the market. As mentioned before and confirmed by the annual report of 2015 of Novo Nordisk, the negative outcome of the price negotiations with the German National Association of Statutory Health Insurance ceased the Distribution of Tresiba of Germany. This strongly affected the growth of the market share in the German insulin market.

Revenue & Cost model

The pricing and the reimbursement of medicines and treatments varies quite a lot between different countries. This influences the price of the treatments Novo Nordisk offers in a market. The company states that the price is dependent on a couple of factors, including a comparison with other treatments for the same condition, the level of development of the local economy and the pricing and reimbursement systems in the respective country.[xliii]

As stated before in the case of implementing Tresiba in the German market, after setting an initial price for the treatment, a process of negotiation with GKV-Spitzenverband, association that represents healthcare insurers, started. An important reason for the price negotiation failing was that when determining their position in the negotiations, Novo Nordisk did not only base their price on the costs of producing the treatment. It also planned on using the income of the sales to fund further research to create new and improved treatments.[xliv]

4.1.1.2 Brazil

Value proposition

Product/service content

In addition to the regularly offered diabetes treatments, Novo Nordisk also has a special program called Changing Diabetes. It is setup for developing countries which includes developing markets in Latin America. The idea behind this program is that the company aims to reach even more people with serious chronic diseases. Since the regions all have different characteristics, the program requires a market-fit business model. Maziar Mike Doustdar, executive vice president of Novo Nordisk's International Operations states that this market-fit approach is the right way to operate in different types of countries. According to him, they can provide high-quality insulin at very low prices in less developed countries and modern insulin with additional properties in developing countries.[xlv]

Target segment

Currently mature markets such as Europe and Japan experience the pressure of their aging population leading to increasing health care expenditure and a rapidly rising number of patients diagnosed with chronic diseases. This situation is now occurring in developing countries and the increasing number of biosimilar

products available on the market provide lower-priced treatment options across the world. [xlvi]

Value network

Development & production

In 2008 Novo Nordisk made a major expansion to its operations by investing 146.5 million euros in the expansion of its insulin production facilities in Montes Claros, Brazil. This investment made this facility the largest manufacturing facility of the firm outside of Denmark and was the largest investment in the pharmaceutical industry of Brazil in the history of the country. The produced insulin will be use to fill 3 ml Penfill cartridges which can be used in the NovoPen and the FlexPen, made by the company. Novo Nordisk also made an additional investment of approximately 40 million euros by constructing a FlexPen manufacturing facility in Montes Claros. The two investments match the global production strategy of the firm, with around 95 per cent of the total volume being exported to countries such as the UK, Canada and Germany and also to developing countries. [xlvii]

One of the core capabilities of Novo Nordisk which is partly contributed to the operations in Brazil is the ability to make treatments available at very low prices in developing countries while maintaining quality. Although the production of the active pharmaceutical ingredients takes place, mainly in Denmark, the production of diabetes finished products in Brazil enables transport to other markets.[xlviii]

According to Professor Jacob Sten Petersen, corporate vice president of Global Research at Novo Nordisk, the company has come several steps closer to developing beta cells that can be transplanted into patients with diabetes type 1. This would ultimately be part of a cure of the disease. If it is not only possible to transplant new beta cells, but also keep them alive, this could be a permanent cure for the disease. [xlix]

Sales process & after-sales service

In 2017, Novo Nordisk reached a new status in Brazil. Both in July 2016 and in January 2017, it was the market leader in the country's diabetes market, with a share of over 13%, thus outperforming competitors like Eli Lilly and Merck Serono. The firm recently renewed a contract with the Brazilian government to ensure the supply of human insulin. The total value of the contract is estimated to be 65 million USD.[l]

Although this result is partly due to the sales growth of type 2 diabetes treatments like Victoza, one of the methods to consolidate this position as market leader in the diabetes type 1 market is Tresiba. After being approved in 2016, the long-lasting duration of the treatment is expected to boost sales, because the duration of up to 42 hours also decreases the number of doses require, which results in reduced spending for patients.[li]

Revenue & Cost model

The new contract with the federal government of Brazil to supply insulin ensures Novo Nordisk of a revenue of around 65 million USD, which is around 10% of the estimated worth of the Brazilian diabetes market of around 640 million USD, according to IMS Health in 2015.[lii] In addition to supplying insulin, the company intends to bring more of its clinical research to the country. The price of the medicines offered by Novo Nordisk depends on a number of factors. It is among others influenced by the prices of the medicines offered by competitors. Another influential factor is the state of the local economy, so the treatments remain affordable.

4.2 PESTLE:

4.2.1 *Germany*

4.2.1.1 Political

According to Hamilton & Webster (2015), the legislative branch of Germany is the parliament with an important role for the Chancellor, along with cabinet members and ministers.[liii]

The healthcare system in Germany consists of four basic principles. The first is that there is a basic insurance that is compulsory for everyone. If you earn more than the set fixed amount, you can choose to have private insurance. The second principal is that health care in Germany is mainly financed by the premium that are paid by insured employees and their employers. Another contribution is made by tax revenue surpluses. The third principle is the principle of solidarity. This results in all the insured members carrying the joint risks of medical costs in case of illness. This way, the rich help the poor and the healthy help the ill. The premium paid depends on income, with a set maximum percentage for high incomes. The last principle is the principle of self-governance. This means that although the German government sets the conditions for the medical care, the financing in and the organising of the individual medical services remains that responsibility of self-governing entities like doctors, dentists, insurers, etc. The Federal Joint Committee (G-BA) is the highest entity in the health insurance system.('Health care in Germany: The German health care system', 2018)[liv]

The CPI (Corruption Perceptions Index) ranked Germany 12th out of 180 analysed countries, in terms of corruption. With a score of 81 out of 100, Germany is relatively clean.

The short-term political risk in Germany increased somewhat in the wake of the Bavarian state election. The Christian Social Union (CSU) saw their absolute majority in the parliament disappear, and also the Social Democrats (SPD) experienced the lowest support in the history of their party. This result could break the alliance between the SPD and the CDU.[lv] Although Germany will probably remain Europe's top economy, the political uncertainty could have an effect on the long-term investments. Far-right partisans increased their representation in the Congress and the criticism of the way Angela Merkel is dealing with the refugee crisis remains.

4.2.1.2 Economical

Germany is the top economic power in Europe and the fourth globally. The GDP of Germany increased with 2.1% in 2017, which was the highest growth rate since 2011. This increase is partly due to the export revenues, but also due to the surge in consumer spending. This is caused by the low borrowing costs, the strength of the labour market and the rising income of the German population. The unemployment also decreased since 2015, and fell to 3.7%. This low rate does not represent the social

and geographical disparities. Unemployment is still a significant issue in former East Germany and the many rural areas in the country.[lvi]

The German economy faces many challenges. It will have to deal with the aging population, a lack of engineers and researchers, the transition to sustainable energy from 25% to 80% before 2050, which also involves the exit from the use of nuclear energy by 2022 and the modernisation of coal plants.

4.2.1.3 Socio-cultural

According to Tamayo et al. (2016)[lvii] in their research about the prevalence and the incidence of diabetes in Germany, out of the 65.6 million policyholders, 6.4 million were diagnosed with diabetes in 2009. This means a 9.8% prevalence in 2009. In 2010, 6.7 million out of 64.9 million policyholders were affected by diabetes, representing 10.1% of the policy holders. Type 1 diabetes accounted for 0.3% in both 2009 and 2010.

Another trend in society is the eroding public opinion, trust and reputation of the pharmaceutical companies, according to a recent analysis. Together with a decline in reputation score, there was also a significant decline in the public's perception of the transparency, authenticity and openness of the pharmaceutical companies.[lviii]

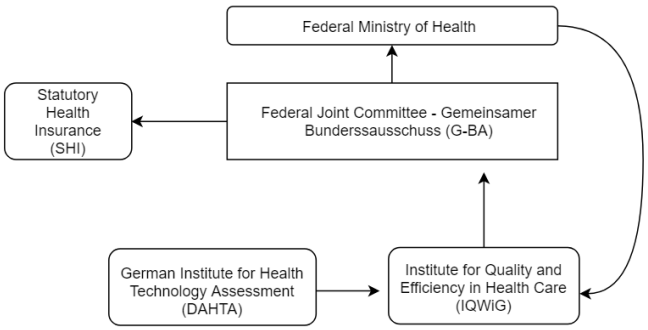
4.2.1.4 Technological

The World Bank ranked Germany first in their worldwide assessment of both the quality of its infrastructure and its logistics performance in 2018[lix] With the port of Hamburg, Bremerhaven and 250 additional inland ports, the port infrastructure of Germany facilitates an efficient delivery of good to the largest market in Europe.

4.2.1.5 Legal

The Professional Society for Health Economics and Outcomes Research (ISPOR) was founded to promote the excellence of health economics and outcomes research to improve the decision making for health around the globe. They created the "Global Health Technology Assessment Road Map (2009) which consists of elaborate explanations of the rules, regulations and structures of the Healthcare system in Germany.

The framework of the German health care system is based on central decision making. This is structured in the following way. Legislation is established by the parliament, decrees are issued by the Ministry of Health, directives issued by the Gemeinsamer Bundesausschuss (B-BA) under the supervision of the ministry, and the contracts between the self-governing organisations are under supervision of the ministry.



The Ministry of Health is responsible for setting the framework for health care interventions, proving the measures taken within this framework, monitoring the outcomes of the chosen reforms, and controlling the work of the Statutory Sickness Funds.

The G-BA consists of doctors, dentists, and representatives of hospitals, statutory health insurers and patients. The G-BA is the central decision making body concerning drug provision for those with statutory health insurance, which is around 90% of the German population.

4.2.1.6 Environmental

The OECD environment programme reviewed the environmental performance of Germany. They found that the protection of the environment continues to be of major public concern which is of high priority to policymakers. This is partly due to the high level on industrialisation, the high density of the German population and the strong dependence on fossil fuels. The report concludes that Germany has met most of both its national objectives and its international objectives. They have shown significant progress in dealing with the emissions, water pollution, the use of resources and their waste management. [lx]

4.2.2 *Brazil*

4.2.2.1 Political

Brazil is a federal state and consists of 26 states and a Federal District, with a Presidential political system. The institutions in Brazil that have the legal power to make decisions for the area and over the population living there, which is backed by the power to coercion, have their own characteristics. The legislative branch of Brazil is the congress[lxi]. The national congress of Brazil is bicameral and composed of the Senate and the Chamber of Deputies.[lxii] Both chambers are directly elected every four years. The Senate consists of three representatives from each unit of the Federation, thus having a total of 81 senators. The Chamber of Deputies consists of a total of 513 representatives from all the districts. The number of representatives differs per district, ranging from 8 to 70, depending on the size of the district. The result of this distribution is that the rural areas are relatively over-represented compared to the large urban areas. [lxiii]

The executive branch of the Brazilian government is the entity that puts the laws into effect and makes sure that the desired outcomes are achieved. This branch is headed by the President and the cabinet.

According the CPI (Corruption Perceptions Index) 2017, Brazil is ranked 96th out of 180 analysed countries.[lxiv] Focussing on the political front, corruption limits the democracy and the rule of law. Corruption in Brazil can therefore lead to offices and institutions being used for private advantage. This can be especially harmful for emerging countries like Brazil, because accountable political leadership is extremely difficult in a corrupt climate.[lxv]

4.2.2.2 Economical

Since the new millennium, strong growth and the social progress of the country turned Brazil into one of the world's leading

economies. A long and hard recession started in 2014 of which Brazil is now slowly emerging. One of the problems Brazil is struggling with is the inequality. Difficult choices have to be made on a political level to reform the social expenditure of the country. Accountability also has to be improved to tackle the ever present fight against corruption.[lxvi]

In September 2017, Brazil reached a new 18-year low in terms of inflation. Due to multiple reasons like an abundant harvest, the central bank had enough opportunity to cut interest rates. The IPCA consumer price index rose 2.46 percent, the 12 months leading up to August 2017, according to IBGE a statistics agency. This statement suggest that the labour market and consumer spending have yet to generate substantial price pressures although they have improved recently. Due to this inflation rate falling well below the expectations made by the central bank's target range, the central bank was allowed to cut the interest rate to the lowest levels since 2013.[lxvii]

Almost a year later in May 2018, Brazil's inflation held below the official target range. This hampered the efforts of the central bank that wishes to reignite price hikes. The reason for this is the slow economic recovery of the country's economy. This inflation rate again has held below the 4.5 percent plus or minus 1.5 percentage points for almost all of the year. Since the expectations for an increasing inflation rate in 2018 are low, the central bank is likely to focus on a lower set inflation rate of 4.25 percent in 2019.[lxviii]

The Unemployment rate of Brazil is currently 12.1%.[lxix] If looked at from a five year perspective, the conclusion can be drawn that from 2015 onwards, the unemployment rate has risen significantly. After 2015 the unemployment rate remains higher than 8% with at the highest point, almost reaching 13.7% in 2017.

Looking at the economic consequences of the relatively high level of corruption in Brazil, corruption has a negative influence on the market because it hinders the development of fair market structures and effects fair competition, which as a result deters investment. Corrupt politicians also tend to focus public investments on high-profile projects such as power pants and dams, instead of hospital, schools and other urgent infrastructure projects.[lxx]

4.2.2.3 Socio-cultural

According to Coutinho & Silva (2015), the majority of patients diagnosed with diabetes do not meet the metabolic control goals. This results in an extremely high economic burden. The current situation also creates an opportunity for more effective approaches in both the prevention and the management of diabetes.[lxxi] In 2017, the number of people below the age of 19 that were diagnosed with diabetes type 1 was 88.300.[lxxii] Since type 1 diabetes is a chronic disease which is usually diagnosed during childhood, it requires strict treatment for the entire life of the patients. According to Cobas et al. (2013), The overall direct medical cost per capita for the analysed patients with type 1 diabetes was 1319,15 US$ per year, where direct expenditure on diabetes treatment was 1216.33 US$ per year.[lxxiii]

The diagnosis of diabetes type 1 requires a patient to make several significant changes to his/her lifestyle. The main issue is carefully monitoring their glucose level. Four key aspects in the patient's lifestyle are frequently testing their blood sugar level, careful meal planning, daily exercise and taking insulin and other medication.[lxxiv] As can be concluded from the research of Scain, Friendman and Gross (2009), there is a direct link between the schooling of patients about diabetes 2 and the changes they should make to their lifestyle, and how their self-management improved their glycemic control[lxxv] The growing middle class and the increasing education in Brazil could therefore lead to more awareness on how to deal with diabetes type 1 as well.

4.2.2.4 Technological

According to Amann et al. (2016), the Brazilian infrastructure continues to characterise the Brazilian economy. Although the problems are clear, proper investments have not been made in areas including highways, urban transportation, ports and electricity generation and transmission, among others. Amann et al. (2016) argue that the main reason for the issue lies in the regulatory systems of Brazil. Brazil's regulatory governance proved deficient and this in turn deterred investment. At the same time, the domestic financing for infrastructural invest has been squeezed by the fiscal constraints of the public sector.

4.2.2.5 Legal

The Ministry of Health is a body of the Executive Power responsible for outlining the policies and public plans oriented to prevent, promote and assist the Brazilians' health, aimed at improving the quality of life and exercising their citizenship. When manufacturing or importing medical devices or products to Brazil, they have to be registered properly. For this they have to adhere to the rules of the Brazilian National Health Surveillance Agency (ANVISA).[lxxvi] ANVISA is a government-owned entity, which safeguards the quality and legitimacy of the medical products.[lxxvii]

In addition to correct registration, pharmaceutical products can be marketed and distributed in Brazil if their price is approved by the Chamber of Drug Market Regulation (CMED), and if the products are manufactured or imported by establishments duly licensed by the local authorities. This can be the municipal of state government. To obtain approval, the applicant has to submit all the required information to the ANVISA. This information includes details of the manufacturing process, results of the clinical trials and safety and efficacy data.

The regulations described previously are designated for pharmaceutical products that are intended to be marketed. An important difference in these regulations however is made between products that intend to be marketed and products that are exclusively used for a clinical trial or used to meet the prescription of a specific patients.

4.2.2.6 Environmental

The work of Siche et al. (2006)[lxxviii] made a comparative analysis of the two most used environmental sustainability indices of nations, the "ecological footprint" and the "environmental sustainability index". They thus analysed the ecological footprint per capita of Brazil, but also the capacity and consumption per capita of the country. After subtracting the latter from the former, they created the "ecological deficit". They then compared it with 11 other countries, ranging from Nicaragua to Denmark. They scored Brazil as the country with the largest ecological deficit per capita, locating it between the more sustainable countries on the planet.

The second index analysed is the environmental sustainability index (ESI). This widely used index is based on the ability to maintain valued environmental assets over the next several decades and to manage the problems that arise from environmental change. The ESI consists of 5 dimensions:

environmental systems (air, water, land, biodiversity), stresses (situations very critical of pollution or any excessive level of exploration of natural resources), human vulnerability (national situation and the illnesses related to environment), social and institutional capacity (capacities that allows the dealing with of problems and environmental challenges) and global stewardship (efforts and representative projects of international cooperation of the global responsibility). The ESI-value of a country can range between 0 and 100, where 0 indicates "most unsustainable" and 100 indicates "most sustainable". From the twelve analysed countries, Brazil is ranked third and is ranked as a sustainable country.

5. CROSS-MODEL ANALYSIS

Since insulin was developed quite some years ago, one of the current organisations dominating the industry is constantly developing new way to incrementally improve the quality of the treatment but also improving the treatments to make the life of the patients more convenient and improve the quality of life for diabetes patients. The products sold are primarily the same in the different analysed market. The main difference is in the service and the price. The set price for Novo Nordisk products is based on a market analysis, which means that in a less developed market with lower consumer power, the price of the products is lower. In a developed market like Germany, there is more focus on the service and higher demand for the products that are more consumer friendly. This way the business model adapts to the market. The most important reason for this is the difference in economic strength between a developing country like Brazil and a developed country like Germany. The initiative of Novo Nordisk which aims to provide treatment in the poorest areas in the world does require a largely different business model, and is focussed on delivering treatment for the lowest possible price, since this is required to reach their goal to make their treatments available for as many people as possible.

Analysing the targets segments of the company in both markets did not lead to significant differences, since the demand for treatment is fixed. The difference in the expenditure of the different treatments and their respective quality levels is again based on the state of the economy.

The development of new products and the research is mainly done in Denmark and developed countries. An important reason for this is the great infrastructure of the country and the available resources. Switching this part of the operations would require great investment in the Brazilian infrastructure. The large investments related to the new factory in Brazil are directed at capitalising on the state of the economy and therefore the low labour costs. The troubles accompanying the negotiations with the German government regarding introducing and selling the Tresiba drug in Germany can be partly explained by the societal trend of decreasing public opinion of pharmaceutical companies, which is adopted by politics.

Furthermore, the companies in the pharmaceutical industry have realised that the market in a well-developed country like Germany has matured. As an effect, large increases in market share can only be achieved if new treatments are developed that outperform the current ones. An example of this is the development of Tresiba by Novo Nordisk, with which they expect to consolidate their position as market leader. On the other hand, in developing market, with an improved business model, a larger market share can be attained by making the existing products better available for the majority of the population.

An important part of this is the way the products are priced in the pharmaceutical industry. Besides the need to meet the costs that are made during the production of the treatment, the company also needs to create a profit which is then reinvested in the research and development of new treatments. This is an important area on which the negotiations of Novo Nordisk with the German government failed. The relative flexible pricing does enable the company to provide poorer areas with low-priced treatments which meets the state of the economy and the income of the population.

6. CONCLUSION

There are definitely differences between the business models of insulin producers operating in developing markets and insulin producers in developed countries. An important factor for this difference is the economic state of the market. High unemployment and general poverty require the company to adopt a different strategy in offering its treatments. The state of the Brazilian economy switches the focus of its people to cheaper treatments than for example Germany. In more stable and prosperous economies, patients can afford extra options besides the minimum requirements to deal with their disease, and are more convenient and improve their quality of life. The pricing model of the firm also enables them to offer their treatments to the poorest areas in the world.

Analysing the value creation of the firm in both markets revealed quite some differences that can be explained by the PESTLE analysis conducted about the characteristics of the Brazilian and German external environment in which Novo Nordisk is operating. Brazil and Germany are chosen as a symbolisation of developing markets and developed markets. This made it possible to conduct a comparison. Further research has to be done on this subject to provide an overview of all the consequences of operating in the different markets and a larger number of markets have to be analysed to conclude if Brazil and Germany accurately represent the developing market and the developed market.

Operating in developing countries does require a business model that can deal with some issues like political instability, corruption and a less developed infrastructure. There is however, a lot of potential in these markets and with the rising welfare of the population, and the increasing focus on health, there will be opportunity for companies like Novo Nordisk to capitalise upon.

7. LIMITATIONS

A limitation of this paper is the timespan in which the thesis should be written. Another issue is the number of pages and the extend of the research. Without the limitations described above, a broader sample of companies could have been studied that could have led to better, more meaningful conclusions on the subject. The sample of this paper does not necessary represent the market accurately. Furthermore, analysing more countries and their markets would have provided a better insight in the 'developing markets' and 'developed markets'.

A problem encountered when analysing Brazil was that much of the literature and papers are in Portuguese. As a result, not all the information was usable.

Furthermore, there do not currently exist a lot of statistics about patients diagnosed with diabetes type 1 compared with diabetes type 2. Combining this with the language barrier in the Brazilian market resulted in a scarce amount of information.

To get the results that are required in order to make a meaningful analysis of the entire pharmaceutical market which focusses on the treatment of diabetes type 1, in further research more companies should be analysed when comparing the two countries. The companies should operate in both Brazil and Germany.

To draw proper conclusions about the industry in developing countries and developed countries, further research should include a greater sample of countries both part of the developed world and the developing world. This way the conclusions that will be draw are more representative, compared to just analysing two countries.

The reason for the scope of this paper only including the analysis of Novo Nordisk is the limited time, and the lack of secondary information of its competitors in the diabetes type 1 industry in both markets.

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