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# The Attractiveness of the European Pharmaceutical Market and its Explanatory Factors

MSc International Business and Politics

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## Executive Summary

The aim of this thesis is to assess how attractive the European market is for pharmaceutical companies. Firstly, looking into the financial crisis as an explanatory factor, as it is suspected that the crisis may have magnified changes in European governments' policies towards the industry. Secondly, looking into the EU in general to investigate which factors may affect the pharmaceutical industry's incentives to be present in the market.

I found that between January 2010 and February 2011 90 policy changes such as price reductions and changes in co-payments were carried out in 22 out of 33 European countries. Thus revealing that the financial crisis did in fact impact governmental policies towards the industry. As we are currently in an era of generics it means that potential profits are being squeezed even more, if the potential revenue a pharmaceutical company can generate while it holds its patent is being decreased.

However, it seems as if there are some general underlying difficulties within the European market, which would have been prevalent despite the crisis. One of the main challenges expressed by the interviewed industry representatives is the fact that the EU does not have one unified price and reimbursement system, which means that the companies must have 28 separate negotiations, if they wish to launch in every country within the EU. As negotiations are costly there may not be financial incentive to launch in smaller countries, as potential sales may not cover the costs of the negotiations. It has in fact already been seen that drugs are withdrawn or not even launched in the German market, which is the EU's largest pharmaceutical market. Thus potential solutions for the future may either be one unified European system or the emergence of private insurance systems.

In my study I found that despite the challenges, pharmaceutical companies will most likely still launch in the EU, because of its market size and the potential revenues it presents. However, it will not be the first place that companies will launch and some countries in the EU may not be of interest. Which may mean we will see a EU with late entries of new medication or even a lack of the newest available treatments.

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## Introduction

“A viable European pharmaceutical industry is important for European public health, economic growth, trade and science” (European Commission 2014a). The pharmaceutical industry is one of the most important industries in Europe, a world leader, as few other industries generate equally high investments in R&D, trade balance and aid to the making of skilled employment in Europe (EFPIA 2015a). However, are we currently moving down a dangerous road in which the European pharmaceutical industry may risk losing its competitiveness? And are we witnessing European governments pushing the industry to its limits? Will the future result be that Europe may lose its “historical role as a centre of worldwide investment, innovation and high-quality healthcare” (Jack 2012)?

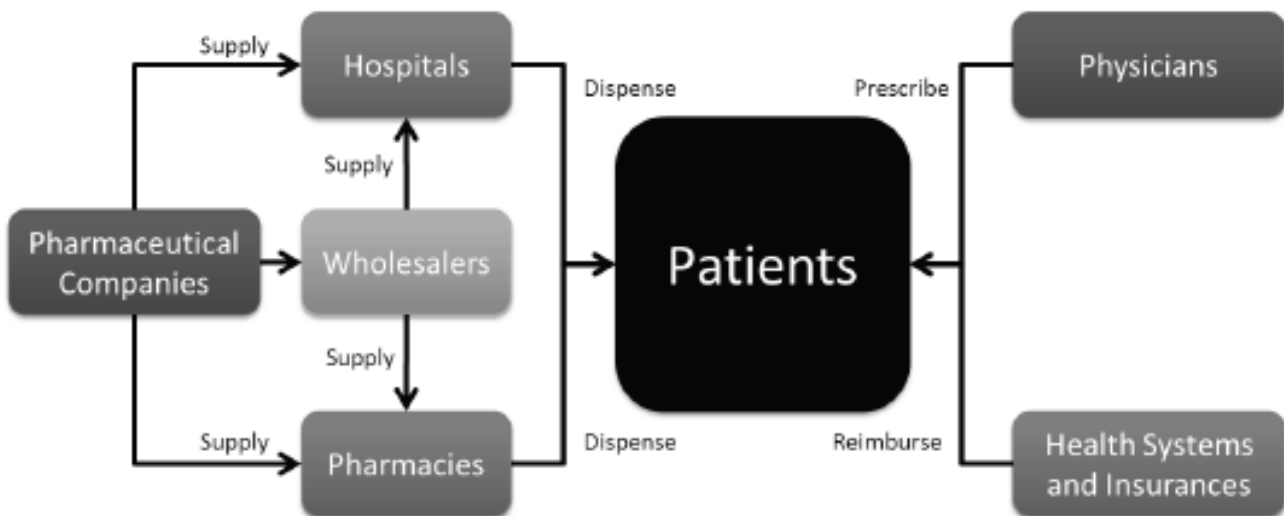
In order to fully understand the pharmaceutical industry’s current situation in Europe one has to understand that the industry’s profit margins are being squeezed from two different sides. On the one hand, there are the extraordinary and very industry specific circumstances in which the pharmaceutical companies have long been operating and operate within everywhere. On the other, there are the current challenges one finds specifically within the European Union (henceforth EU).

First of all, drug development is extremely time consuming, expensive and with high levels of risk as the path from initial research at a molecular level into a final drug being launched expands over many years. Moreover, most compounds, which enter the R&D pipeline, fail along the way. It is estimated that it in fact costs somewhere between USD 800 million and USD 1 billion to develop one single successful compound (PhRMA 2015). This expense has to cover the long route from initial drug discovery through preclinical testing to clinical trials and new drug application to approval to ensure that only safe and effective compounds reach the consumers. However, within these staggering amounts one has to remember is not only that one successful compound that made it all the way to the end user. But likewise the thousands of molecules which researchers have investigated in the early stage of drug discovery, the hundreds of potential new compounds that went into the stage of preclinical testing and the “lucky” few which made it into the clinical trials (PhRMA 2015). One single compound has to carry all these expenditures. Further, that compound has to ensure that the

company is in a financial position that enables it to continue research for the next big blockbuster.

Further, when creating a new drug you are looking at a timeline of approx. 10-12 years before the compound is launched and reaches the consumers (PhRMA 2015). Therefore, following the patent laws set out in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights it means that out of the 20 years where the company will hold the patent it will only have 8-10 years to make the needed earnings (World Trade Organization 2015). Competing drug makers are allowed, as soon as the patents expire, to sell less expensive generic drugs, which naturally cause fierce competition for the company holding the expired patent (see appendix I, figure I, page 86 for an overview of the drug timeline).

Related to the impact of competition from generic drugs is the fact that defining the pharmaceutical industry's consumers is quite difficult compared to other industries, as so many actors are involved.



"Drug flux from the pharmaceutical company to the patient" (Ades et al. 2014, p. 5)

The patient may be the end user of the compound, but the pharmaceutical company is reaching the patient through sources such as hospitals, wholesalers and pharmacies. Often a physician will be the one prescribing the compound to the patient and thus the one who decides which compound should be used. However, the one paying for the drug may be a completely other source than the patient i.e. health systems and insurance companies. Thus creating many different kinds of customers.

When focusing on the pharmaceutical industry within the EU all the general information about the industry in the above paragraphs is applicable. However, the EU also presents some different settings compared to the rest of the world, as it is a union of countries. One point is that when seeking approval for a new compound within the EU you can either seek approval for the compound in one country by submitting to the competent authority or you can follow a centralised process, which grants you approval in all Member States (Kashyap, Gupta & Raghunandan 2013).

Another important point is that some legislation towards the industry has been harmonised between Member States and some is still up to the individual Member State. Legislation, which have for example been harmonised between Member States, is transparency requirements (Vogler et al. 2011). Oppositely, pricing and reimbursement is still up to the individual Member States and hence within the EU one finds 28 different pharmaceutical pricing and reimbursement systems<sup>1</sup>.

Pharmaceutical expenditures have long been widely debated and seen as a vast issue within Member States, and since the 1990s countries have been undertaking reforms in order to limit expenses in this area (Vogler et al. 2011). This is so as health expenditures account for a high proportion of government budgets and GDPs (Vandoros, Stargardt 2013). For example health expenditures in 2010 accounted for 10.6% of GDP in Greece and 9.7% in Ireland. Further, it is found that pharmaceuticals accounts for a high proportion of the total health expenditures. Using the same examples as before for Greece in 2007 pharmaceuticals accounted for 24.8% of health expenditures whereas it for Ireland in 2009 was 17.5% (Vandoros, Stargardt 2013).

Thus the tendency already seen since the 1990s was magnified when the EU slipped into financial recession in 2009, as governments needed to find ways of creating budget savings (European Commission 2014b).

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• <sup>1</sup> In the original paper by Vogel et al. (2011) it says "27 different pharmaceutical pricing and reimbursements systems" on page 70. This I have corrected to 28 as the paper was published in December 2011 before Croatia entered the EU on July 1st 2013 (European Union 2015).

In a survey conducted from January 2010 to February 2011 by Vogler et al. (2011) it was found that 22 out of 33 Member States implemented measures to limit public medicines expenditure. In fact it was found that on average 2.7 policy changes per country were found during the research period. Some of the most commonly used measures included price reductions, changes in the co-payments and changes in the value-added tax (VAT) rates on medicines. Other examples of measures include generic substitution, INN prescribing and reference pricing systems (see appendix II, table I, page 90 for a full overview incl. descriptions of national policy measures influencing pharmaceutical sales) (Leopold et al. 2014).

### **Aims of this Study**

The aim of this study is to analyse the current European market attractiveness when it comes to the pharmaceutical industry. As Europe has recently suffered from the financial crisis this will be the first factor I will look into in order to see how the crisis may have impacted the industry. Moreover, I wish to investigate if the environment the pharmaceutical industry finds itself within in different European countries varies, and if such variations may explain different patterns of reactions. And lastly, to analyse if other factors than the financial crisis may explain the current situation. Thus I have formulated the following research question (RQ):

**“How have changes in European government’s policies towards the pharmaceutical industry been magnified by the financial crisis and to which degree do these changes account for the current European pharmaceutical market attractiveness?”**

Several approaches can be taken in answering the above RQ, and, therefore, I have formulated the following three sub questions (SQs) as guidelines for my research.

For my first SQ I want to analyse to which extent European governments responded to the financial crisis in relation to the pharmaceutical industry i.e. which potential regulatory changes took place:

**“Has the financial crisis altered European governmental policies towards the pharmaceutical industry, and if so how where they altered?”**



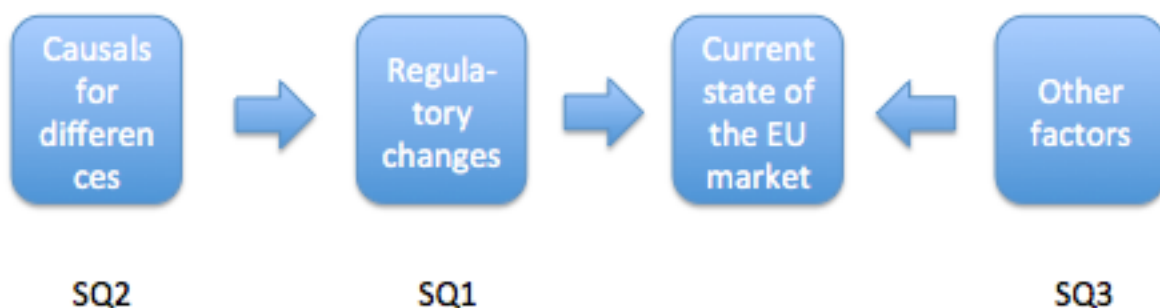
For my second SQ 2 will analyse further upon the results derived from the first SQ from which there are three plausible outcomes; 1) nothing has changed 2) changes can be seen and they are consistent across the EU and 3) changes can be seen, however, they do not follow one overall EU pattern. Therefore, if found that there in fact are changes, and that these changes do not follow one overall EU pattern I wish to analyse the different environments that the pharmaceutical finds itself within in different countries. In order to see if these differences may explain why different countries have different patterns of reactions. Hence the following SQ2:

**“What are the differences between Member States and how may these differences affect policies towards the pharmaceutical industry?”**

For the third SQ I wish to look at the current situation from not only a crisis perspective but to investigate if there may be other explanatory factors that can account for the European market attractiveness from an industry perspective:

**“How attractive is the European pharmaceutical market currently and which factors may explain the situation?”**

Thus an overview of my three SQs and how they relate is:



## Framework of Analysis

This study consists of seven chapters, which will each provide the needed information in regards to answering my RQ.

Chapter 1 is about methodology. This revolves around the methodology and methods used to conduct my research. Hence data collection, research philosophy and the like will be explained. The core of the chapter is to explain how I draw my results.

Chapter 2 revolves around the main theories that have been used i.e. Varieties of Capitalism and Global Production Networks. Content, justification and limitations of the theory will be explained in depth.

Chapter 3 looks into healthcare reforms in a historical perspective before analysing which policy measures were implemented after the EU entered the recession.

Chapter 4 focuses on how the pharmaceutical industry fits into the overall ideas set out in Varieties of Capitalism and if some causal links between chosen measurements and capitalist systems can be drawn.

Chapter 5 puts an emphasis on additional factors besides the financial crisis, which may explain the current market attractiveness of the European pharmaceutical market.

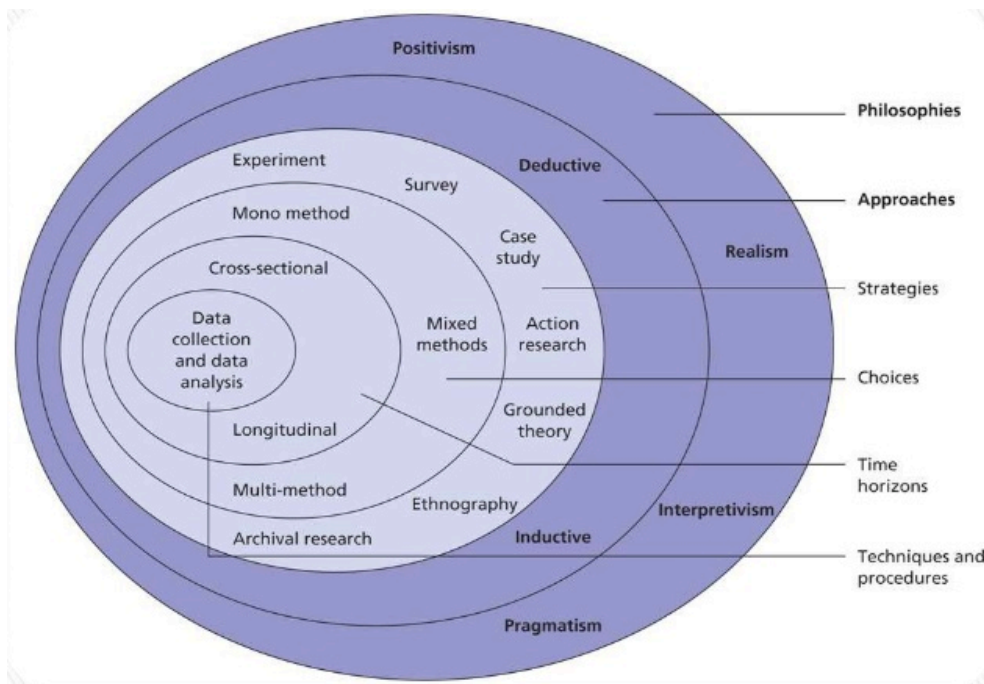
Chapter 6 will consist of a discussion, in which my findings in the previous chapters 'Analysis' will be debated.

Chapter 7 will conclude the study, sum up the main findings and provide a final answer to my RQ. Furthermore, this chapter consists of the subsection 'Other Perspectives' which will mention other directions in which I could have taken the paper.

# Chapter 1: Methodology

## 1.1 Introduction

Throughout the following chapter the different methods (i.e. techniques and procedures used to obtain and analyse data) and methodologies (i.e. theories of how research should be carried out) used to answer the RQ will be examined (Saunders, Lewis & Thornhill 2009). Thus enabling the reader to understand how and why the study has been carried in the direction it has and moreover enabling the study to be replicated by others. The outline of the chapter follows the research onion in which the analysis moves from a higher level of abstraction to the lowest possible (Saunders, Lewis & Thornhill 2009). This means that I will start out by looking into methodologies moving on to methods.



## 1.2 Research Philosophy

Research philosophy relates to how one generates new knowledge and the nature of said knowledge (Saunders, Lewis & Thornhill 2009). Acknowledging which research philosophy one is following is highly important as choice of philosophy reveals important insights into ones assumptions about how the world is seen and understood. Thus if a different research philosophy had been followed the underlying assumptions would likewise be different and hence one could have arrived at a different result for the RQ.

There are four different views one may take; positivism, realism, interpretivism and pragmatism (Saunders, Lewis & Thornhill 2009). Each philosophy has a different stand on the research studies ontology, epistemology, axiology and data collection. Ontology revolves around ones view of the nature of reality, within epistemology the attention is put on what constitutes acceptable knowledge within a certain field of study and lastly axiology focuses on how we view the role of values in research. In the following sections I will explain what my underlying assumptions and views are regarding my RQ and based on these thoughts and explanations I will deduce which research philosophy is the appropriate to follow in this study.

### **Axiology**

I will commence by looking into axiology due to the fact that I currently work for a pharmaceutical company and personal values thus are highly essential to take into consideration. I have worked for H. Lundbeck A/S in the headquarter in Valby, Denmark for more than two years from 2013. I have worked in Medical Affairs in various teams with different compounds, however, most of my efforts have revolved around the new pipeline. My work has to a high degree revolved around preparation and closure of contracts and data registration in regards to tracking of payments to Health Care Organisations and Health Care Professionals. Hence my work for H. Lundbeck A/S does not have a direct link with my RQ but I have to a high degree been inspired to take my research in this direction due to my work environment. Thus as I am a part of the environment I am studying it is very unlikely that I can conduct my research in a completely value-free way. Rather it is very likely that I will be value laden to some extent and this will impact not only what I have decided to study but also how I have decided to study it and how I will be analysing the results.

So how do I handle this situation? How do I conduct a study in which I am part of the environment being investigated and thus cannot be entirely nonbiased without sacrificing the study's validity? First of all, I need to be very transparent in all my stages of developing the study; from data collection to conducting the analysis. Further, I will be using triangulation to increase the validity and reliability of the study i.e. study the same phenomenon using different methods such as interviews, observations, secondary literature and theory (Aarhus Universitet 2014). Thus comparing different aspects, which should hopefully all support the same analysis of the phenomenon.

## **Ontology**

Moving on to ontology it is concerned with ones view of the nature of reality meaning “what assumptions do we make about the way in which the world works” (Saunders, Lewis & Thornhill 2009, p. 110). Essentially when discussing ontology it is about evaluating how you see the nature of reality. Is it socially constructed? Objective and exiting beyond human beliefs and thoughts? Or is it in fact multiple and changes according to what you are studying and what best answers what you are studying? My RQ revolves around the possible effects the financial crisis may have had on policymaking in Europe and partly on how a possible explanation of different patterns of reactions may be found embedded in different national systems. However, in my paper I am not assuming but taking it for a fact that the financial crisis has taken place. Thus an important aspect of my ontology is that I allow the reality of this crisis to exist independently of human beliefs, as I do not go into any discussions about the crisis but take it for granted that it took place. However, I do interpret the aftermath of the crisis through my own lenses when analysing the effect of the crisis on an industry. Further, I am not the only one analysing the aftermath of the crisis – politicians, industry and myself may have different views on what the reality is, as we all analyse the objective reality through our own social conditioning. However, this further adds to the validity of the study that I am not only relying on completely value-free papers solely stating facts about what may have happened, but that I use interviews with representatives from the industry and academic papers analysing the situation as well. Thereby, increasing the validity through triangulation as I allow for a whole range of opinions before concluding.

## **Epistemology**

Lastly, epistemology is what the researcher believes to be acceptable knowledge (Saunders, Lewis & Thornhill 2009). Does only observable phenomena provide adequate knowledge? Or is your knowledge derived from social phenomena and subjective meanings? Or do you in fact allow for the use of both in your study? When analysing changes in governmental policies towards the pharmaceutical industry after the financial crisis occurred I to a high degree rely on tangible observable information in regards to actual changes in policy. Meaning I rely on definable changes in law and policymaking which I would classify as indisputable facts. However, I use these incontestable facts to try to establish a link between the financial crisis and the effects on the pharmaceutical industry. Thus my social conditioning will have an effect on how I derive at this link and how I analyse its significance. Other actors such as politicians

and industry may perceive the significance of this link differently as they represent an interpreted reality, which defers from mine. Therefore, they may also take the indisputable facts of the regulatory changes, view them in a different light and create a different meaning. Because of this it is highly important in order to increase the validity of my study that I through my analysis allow for an investigation, which includes the views from different stakeholders to gain an understanding of how it could be viewed differently. Thus using these different interpretations for my discussion and finally for my conclusion.

### **Data Collection**

The last aspect, which is important to look into before summing up which research philosophy is viable considering my stance on axiology, ontology and epistemology, is which data collection techniques I will be using. As such my RQ does not dictate either qualitative or quantitative data, but considering the scope of the RQ it would be very hard to conduct the study without using both. When using both kinds of qualitative and quantitative data one uses a mixed methods approach. However, within mixed methods one analyses quantitative data quantitatively and qualitative data qualitatively (Saunders, Lewis & Thornhill 2009).

Both my epistemology and ontology revolves around an objective reality of indisputable facts of regulatory changes and a new economic setting for the pharmaceutical industry. However, at the same time they encompass this objective reality being seen and analysed through my own lenses. Thus the use of both qualitative and quantitative data is supported by my ontological and epistemological stance as I rely on quantitative data for the indisputable objective reality and qualitative data for the analysis of the quantitative data.

### **Chosen Philosophy**

When choosing a philosophy of science it is very important that this philosophy follows and allows for the underlying assumptions I have outlined in the above sections. Thus when evaluating my views on axiology, ontology, epistemology and data collection it is found that it is highly important that the research philosophy I opt for in this study allows for: 1) the researcher being part of what is researched 2) that the world exists independently and regardless of what you as an individual think of it and how you choose to analyse it. This is exactly what critical realism does. Within critical realism “the real is whatever exist, be it natural or social, regardless of whether it is an empirical object for us, and whether we

happen to have an adequate understanding of its nature” (Sayer 2000, p. 11). Meaning that observing a phenomenon may make you as a researcher more confident as to what you think exists, but the existence of the phenomenon itself is not dependant on it. Secondly, critical realism is very much related to axiology as critical realism states “science or the production of any kind of knowledge is a social practice“ (Sayer 1992, p. 6). Thus to ensure validity and reliability critical realism stresses the importance of being critical when evaluating and understanding a phenomenon (which I wish to guarantee through triangulation).

### **1.3 Research Approaches**

The chosen research strategy depends on whether you are testing or building a theory (Saunders, Lewis & Thornhill 2009). Within the deductive approach a theory and hypothesis (possibly hypotheses) are developed and the following research strategy is developed to enable the researcher to test the hypothesis. Oppositely, within the inductive approach data is collected in order to build a theory. When it comes to my chosen research approach I will follow the nature of the research cycle. The research cycle combines the two research approaches by taking point of departure in the deductive approach followed by the inductive approach (Trochim 2006). In this study I have commenced by developing my RQ and subsequent SQs, and hereafter I have chosen which theories will best support the analysis of the pharmaceutical industry in Europe. As the deductive approach subscribes, the next step is to put forward some assumptions about what my research will find. One assumption that I make is that I will find some causal relationship between the financial crisis and the changes in European national policymaking. The next step is to collect the needed data and, based on the interpretations made from the observations, either verify or reject the assumptions. Thus enabling me to answer my RQ. The following step follows the inductive approach using the collected data to formulate alternative or new causal links between the financial crisis, the pharmaceutical industry and the changes in policymaking. And in this sense form my own theory of how the links can be explained.

### **1.4 Data**

I collected both qualitative and quantitative data throughout the entire research and writing process. I collected both kinds of data as both provided valuable information in order to answer the RQ. Further, I mainly relied on secondary data, but nonetheless did collect some “raw” data on my own through interviews.

## Primary Data

The primary data I collected was mainly through interviews with employees at H. Lundbeck A/S in Valby, Denmark. However, I also conducted two interviews with industry representatives from the United Kingdom (henceforth the UK) and two representing other pharmaceutical companies in Denmark. An important purpose of the interviews was to get a first hand industry view on the potential negative impact that the regulatory changes could have had. However, the main purpose was not solely to get the industry's view on this link. It was also to see if there were some other general tendencies or settings within the EU, which caused the pharmaceutical industry to have more difficulties here than in other places. Thus to see if there were some areas' significance, which I might have overlooked. Therefore, the interviews were conducted with a range of different titles within different areas of expertise, however, concerning the interviews conducted at H. Lundbeck A/S the majority were senior directors representing the new compound pipeline. I decided to put an emphasis on getting interviews with directors and senior directors representing the new pipeline, as they will often have a very general knowledge of a compound. Thus increasing the likelihood that they may mention some positive or negative sides of the pharmaceutical industry in the EU, which I had not looked for. As I in my study focus on Denmark and the UK my interviews were solely conducted with industry representatives from these two countries. In total I conducted 11 interviews:

### H. Lundbeck A/S, Denmark

Anders Schroll, Vice President Corporate Communication and Public Affairs

Anna-Greta Nylander, Director and Head of Otsuka Alliance Team

Marija Simin Geertsen, Senior Manager, Brintellix Medical Affairs

Martin Strandberg-Larsen, Director & Head of Global Market Access, Depression Portfolio

Sam Agus, Senior Director and Head of MA Neurology

Thomas Brevig, Senior Director & Head of MA Psychiatry

Torbjörn Wærner, Senior Director Brintellix Medical & Regulatory Affairs

### Otsuka Pharma Scandinavia AB

Anonymous



Eli Lilly, Denmark

Tommy Kok Annfeldt, Customer Experience Lead Northern European Cluster

The UK:

Anne de Jong-Laird, EU Medical Manager CNS, Otsuka Pharmaceutical Companies Europe

Anonymous, working for a pharmaceutical company in the UK

I contacted an additional two industry representatives through email, but with whom I did not succeed in getting an interview. However, with a total of 11 interviews consisting of different companies in both Denmark and the UK I do not see this as an issue, as I did reach my aim of having both countries and several companies represented.

The channels used were emailing to set up the meetings and hereafter either face-to-face meetings or interviews were conducted over the phone. All the interviews with employees at H. Lundbeck A/S were conducted in person, whereas the interview with the employees at Eli Lilly, Otsuka Pharma Scandinavia AB and the interviews with the industry experts from the UK were over the phone. The conversations were set up as semi-structured interviews in which an interview guide containing some broad themes and questions were created beforehand (see appendix III page 95 for the interview guide). I chose to conduct the interviews as semi-structured, as I had some specific themes I wished to further investigate, but at the same time I wanted the interviews to be a conversation in which areas/ideas I had yet not considered could be uncovered. Therefore, I started out by asking a very general question about how the industry could be described. Followed by a question if the description would have been different, if it had been asked at the millennium in order to establish that there have been some recent developments. Hereafter, I moved towards putting an emphasis specifically on both positive and negative sides by posing a question for each. These questions serve my paper in the way that they open up for causal effects of the current situation of the industry, which I may not have put an emphasis on. Hereafter, I asked questions focusing on the future of the pharmaceutical industry, and if there are differences in between different medicine groups when it comes to regulation to see if some drugs have an “easier” time than others. Thus covering many questions that are not linked to the financial crisis directly, but are broad in their scope ensuring other factors can be accounted for. In the end I asked about the financial crisis and the regulatory changes it has brought along to see

how the industry experts evaluate these changes. The focus on the financial crisis is not until the end as I wished for the interviews to reveal potential other explanatory factors of the current state of the EU market, and hence did not want to put the focus on the crisis from the very beginning leading the mind of the interviewees in this direction.

### **Secondary Data**

As for qualitative secondary data I have mainly relied on three types of sources i.e. 1) academic articles, books and the like 2) newspaper articles and webpages of industry associations and 3) reports published by large organisations such as the World Health Organisation. The academic articles and the reports were found through tertiary literature sources i.e. search tools such as Elsevier, JSTOR, Oxford Journals and PubMed thus increasing the legitimacy of the retrieved material. Newspaper articles were mainly used to get the most up to date information of new developments in the pharmaceutical industry and some company specific information.

I have mainly relied on qualitative secondary data, however, as for quantitative secondary data I have used a study conducted by Vogler et al. (2011). The study aims at providing a country comparison of which European countries implemented what pharmaceutical policies within the timeframe of January 2010 to February 2011. The results that Vogler et al. (2011) find are put into two tables focusing on 'pharmaceutical policy pricing measures' and 'pharmaceutical reimbursement and other policy measures'. I use the findings from the tables provided by Vogler et al. and use it in a different context in which I not only explain which policy measures are found but furthermore try to explain why certain countries have or have used a policy measure and what the effects might be.

Further, I collected another type of secondary data through fieldwork for my theory chapter. One of the theories I use is global production networks and in the theory chapter I explain some of the important stakeholders that global production networks focuses on in relation to the pharmaceutical industry. This is needed, as the pharmaceutical industry is very distinctive and different from other industries. Thus in order to be able to understand the difficulties the industry may be facing one needs a basic understanding of the industry and the actors with whom it is involved. When explaining one of the actors, business associations, I have looked through the European Transparency Register (a register where the companies, organisations

etc., with which the European Parliament and the European Commission interacts are registered(European Union 2015a)) to see what kind of associations are lobbying on behalf of the industry and how much money they spend on this lobbying. I do so as these associations make available much material about the industry, key figures, the importance of the industry and so forth. Therefore, it is important to know what these associations have invested in advancing the interests of the industry in order to be able to make a correct evaluation of the sources and their validity in the context where they are used.

### **1.5 Delimitation**

First of all, due to the limitations both in time and number of pages for this study I will limit the scope of the study by not making any investigations into the financial crisis; not what caused it, the scale of it or which general worldwide effects it had. Instead I will take it for granted and as a fact that it did happen and solely be interested in the new setting that European governments and the pharmaceutical industry found themselves located within after recession times of 2009(European Commission 2014b).

A further delimitation similarly related to the time and pages constraints is the fact that whilst my focus is on countries within the EU I cannot investigate all countries. Rather I have had to make a selection of two countries allowing me to carry out a sound and in-depth investigation. One of my theoretical frameworks is Varieties of Capitalism, which divides nations into a continuum with liberal market economies and coordinated market economies at each end (Hall, Soskice 2001). Hence for my choice of countries, to use for this paper, both a country representing a liberal market economy and a coordinated market economy should be included. Due to the fact that I work for a pharmaceutical company in Denmark I have chosen Denmark as a representative for a coordinated market economy. For the liberal market economy there are two choices within the EU; Ireland and the UK. However, from my in-depth country investigation I have chosen to exclude countries such as Ireland and Spain, which were severely hit by the crisis. I have decided to do so in order to increase the validity of my study. If I had chosen one of these countries it might have been a case of ensuring I would have found what I was looking for as these countries were so severely hit by the crisis. Therefore, it would be very hard to imagine that there was a chance that the pharmaceutical industry, probably like most other industries, in these countries was not impacted. Thus as a representative of a liberal market economy I have chosen the UK. However, this does not

mean that I will completely exclude the countries hit the hardest by the crisis from my paper. They will still be included in the first analysis chapter focusing on the overall regulatory changes made in Europe after the crisis. It is only for the second analysis chapter where Varieties of Capitalism is applied that I have chosen to exclude these countries.

A further related limitation regarding Varieties of Capitalism is the fact that Hall and Soskice (2001) in their Varieties of Capitalism framework have a focus on Western Europe and the US thus leaving out Eastern Europe (Nölke, Vliegthart 2009). Analysing Eastern Europe to see how these countries fit into the overall ideas presented in Varieties of Capitalism is a story on its own and for the scope of this paper I will not make such an analysis.

In my last SQ I focus on other potential factors that could explain the current state of the industry and I have thus chosen to interview industry representatives. This means that I will not be interviewing the politicians who originally sought and approved the regulatory changes and therefore I will not get their side as to why they were needed. Nor will I get their point of view when it comes to assessing the pharmaceutical industry in Europe today. Taking the study in this direction can instead be for further studies or further perspectives in order to investigate if the politicians were fully aware of which short and long-term consequences the potential changes may have had for the industry and in general how they perceive the current market attractiveness of Europe.

Further, related to the interviews is that there are not only limitations when it comes to which stakeholder group I have decided to interview. Rather there are also limitations to the interviews I have conducted. As I work for H. Lundbeck A/S many of my interviews conducted are with Lundbeck employees. Thus to ensure that I have not only obtained one Danish company's view on my RQ I have conducted an interview with one employee from Eli Lilly and one from Otsuka Pharma Scandinavia AB. Further, as I am a Danish citizen and live in Denmark there is a majority of Danish interviews compared to UK interviews. Thus I have more primary data from the Danish industry for my analysis. However, it is important to note that I in my questions do ask the Danish industry representatives for national differences in both Denmark and the UK compared to the EU. One might wonder why representatives of the Danish pharmaceutical industry would have knowledge of the UK, but it is important to keep in mind that the UK is one of the most important pharmaceutical markets in the EU. Further,

adding to why representatives from H. Lundbeck A/S would have knowledge of the UK is the fact that there is Lundbeck Limited, which is a UK subsidiary to H. Lundbeck A/S. Hence I do try to incorporate Denmark and the UK to the same degree. However, Danish representatives may see the national differences in the UK differently from how a UK representative might see it, as a Danish representative might not follow the general societal debate in the UK as someone from the UK would.

One last limitation of the study it is important to look into is the time perspective. As I for my first SQ to a high degree use the results from the study by Vogler et al. (2011) I thus for the crisis perspective and the impact of the crisis follow the same time perspective as used in the Vogler et al. (2011) study. Hence the crisis years I focus on are January 2010 till February 2011. However, in general in my study it is necessary to go further back in time to establish whether or not healthcare reforms are a new phenomenon. Therefore, whereas I for the crisis years only focus on the same years as the Vogler et al. (2011) study I will in order to put healthcare reforms into a historical perspective look into the 1980s and 1990s.

### **1.6 Interim Conclusion**

Throughout the chapter, the methods and methodology used for this paper have been examined. Such examination carries great importance for both reader and writer. It enables the reader to understand the underlying stances on ontology/epistemology/axiology, choices made in regards to data selection and the like and thus enables the study to be replicated. It further serves the point of increasing the validity of the study by creating awareness for the writer of own assumptions.

## **Chapter 2: Theory**

### **2.1 Introduction**

The following chapter will include the theoretical framework, which will support my analysis of the pharmaceutical industry. I will be analysing the current situation from a meso level enabling me to analyse the RQ from both an industry and governmental point of view. For SQ1 I want to analyse if the financial crisis has altered European governments' policies towards the pharmaceutical industry. And additionally, if found that they have in fact made changes I wish to further examine, which changes have been made. For my SQ2 I wish to investigate if the environment the pharmaceutical industry finds itself within in different countries varies and if such variations may explain patterns of reactions.

### **2.2 Choosing a Theory for Comparing Nations**

When comparing nations and national systems one can choose between a whole range of parameters to investigate and include in ones study. History, politics, culture and institutional frameworks are all factors one could focus upon when trying to study why nations react differently to the same external force. At the core I wish to compare capitalist systems and three theories which could facilitate this should be mentioned: 1) National Business Systems, 2) Social Systems of Innovation and Production, and 3) Varieties of Capitalism (Hancké 2009). National Business Systems puts an emphasis on two dimensions when comparing capitalist systems. Firstly, it focuses on the provision of capital e.g. via banks, stock markets etc. Secondly, it focuses on the relationship between workers and management. Based on these two factors six different business systems are created (Hancké 2009). It is different within the second option, Social Systems of Innovation and Production, in which five elements of an economy is focused upon i.e. the educational system, social protection and the welfare state, product market competition, wage-setting systems and labour markets, and lastly finance and corporate governance. Based on these five elements five different capitalist models are created. The last approach, Varieties of Capitalism, takes a much more simplistic approach than the first two theories by dividing capitalist systems into two main categories. Further, stating that political institutions are the main reason why different nations have different national behaviours (Taylor 2009).

To enable the analysis I wish to carry out I need a theoretical framework that allows me to see the company (and thus the industry) as holding a key position within the political economy.

Further, I need a theoretical basis, which facilitates an analysis within the idea that institutional frameworks may condition what companies can accomplish within this certain framework. Lastly, in order to understand the difference between European countries when it comes to the pharmaceutical industry and why they may have reacted differently, I need a theoretical framework, which allows me to simplistically see how political economies operate differently from one another.

Several theories could facilitate the overall idea of comparing two capitalist systems. However, considering the above specifics of what should be enabled through the theory Varieties of Capitalism to a high degree encompasses all of the above criteria. Additionally to the strong fit of the theory, one of the reasons why I chose Varieties of Capitalism is the fact that it presents a very flexible framework (Hancké, Rhodes & Thatcher 2009).

### **2.3 Varieties of Capitalism**

In short, Varieties of Capitalism (henceforth VoC) is concerned with macro-characteristics of national political economies, and within the concept of VoC it is believed that variances in political institutions (governing labour, capital and product markets) is the main reason why nations have their own national innovative behaviours (Taylor 2009).

Looking deeper into VoC it is found that VoC sees the political economy as being actor centred i.e. the economy consists of numerous actors that all try to advance personal interests, nonetheless, this is done in strategic interaction with the other actors (Hall, Soskice 2001). Actors range from governments, unions, companies to individuals and so forth. However, VoC recognises the company as being an essential actor within a capitalist economy. Hall and Soskice (2001, p. 5) define companies as “actors seeking to develop and exploit core competencies or dynamic capabilities understood as capacities for developing, producing, and distributing goods and services”. Further, within VoC it is assumed that the behaviour of the company totals into national economic performance.

In order to be successful a company must develop relationship within five spheres: Industrial relations, vocational training and education, corporate governance, inter-firm relations and employees (Hall, Soskice 2001). The company must be able to manage the before mentioned

spheres as a company will not be able to develop and exploit core competencies without coordinating with other actors within the political economy.

***Industrial relations;*** within this sphere one finds problems that relate to overall industrial dealings such as negotiating working conditions and wages, which organisations or unions represent their workforce and more overall society based issues such as inflation or unemployment rates (Hall, Soskice 2001). All aspects, which take part in determining how productive and competitive, and therefore successful, a company may be.

***Vocational training and education;*** here companies face the problem of making sure that their workforce has the correct skills and abilities to perform well (Hall, Soskice 2001). Workers on the other hand have the problems of figuring out which skills are the most needed and where they should be placing their efforts. This synchronisation of what companies need and what workers should make available is not only a problem, which affects the success and competitiveness of a single company but likewise the national economy.

***Corporate governance;*** in general corporate governance revolves around the systems, processes and procedures, which regulate the relationship especially between managers and shareholders but covers all firm stakeholders (Kolb 2010). When putting corporate governance in relation to VoC Hall and Soskice (2001) focus on the solutions that are made to make finance available to companies and to ensure that investors will receive a return on their investment. Focus is laid here as finance available to specific projects at specific terms are part of determining company success. However, Hall and Soskice (2001) do mention other stakeholders such as other companies e.g. regarding technology transfer and industrial relations e.g. providing employee corporation and wage moderation.

***Inter-firm relations;*** covers all the relationships a company will set up with other companies, however, it in particular involves suppliers and customers (Hall, Soskice 2001). These connections are vital, as the company will need a steady and relevant supply of input, access to newest technology and demand for its outputs. Therefore, the quality of these relations depends on the economy as a whole and the company "talent pool" which is available.



**Employees;** lastly, companies have internal coordination challenges as they need to ensure that their employees cooperate with others in order to work towards the common goal of the company's objectives (Hall, Soskice 2001). Other challenges exist such as information sharing, as employees may possess unique information about a company's operations, which could be extremely valuable to management. But employees likewise have the possibility to withhold information and/or effort.

Seeing how many spheres a company has to be able to operate within and how many actors are found within each sphere the biggest issue the company faces is hence the problem of coordination (Hall, Gingerich 2009). Based on how companies are able to solve the coordination issues they may face within the five listed spheres Hall and Soskice (2001) argue that one can distinguish between two different kinds of political economies i.e. two different modes of coordination; liberal market economies and coordinated market economies. These two kinds of political economies can be placed at each their opposite pole and national political economies placed at either one or along the spectrum in between.

**Liberal market economies (LMEs);** according to Hall and Gingerich (2009, p. 137) when it comes to LMEs "relations between firms and other actors are coordinated primarily by competitive markets". Additionally, LMEs are identified by radical innovation<sup>2</sup> and new sectors of the economy (Crouch 2009). Lastly, they are characterised by neoclassical policies, hierarchies and competitive market arrangements being the main approach to which companies coordinate their activities (Hall, Soskice 2001). The LMEs are the Anglophone countries with primarily the US but further with the UK, Ireland, Canada, New Zealand and Australia.

**Coordinated market economies (CMEs);** on the contrary to LMEs within CMEs firms are more prone to engaging in more strategic interactions with actors such as suppliers of finance, trade unions and the like (Hall, Gingerich 2009). Additionally, within CMEs action is partly shaped by social and political institutions, which take on a direct involvement thus "the achievement of coordination is a political problem" (Hall, Thelen 2009, p. 256). Further, CMEs

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<sup>2</sup> Radical innovation: "entails significant shifts in product lines, the development of entirely new goods, or major changes to the production process" (Hall, Soskice 2001, pp. 38-39). Thus radical innovation is particularly important in fast-moving technology sectors.

are defined by incremental innovation<sup>3</sup>, social democracy, declining economic sectors and non-Anglophone countries (Crouch 2009). Examples of CMEs are Denmark, Germany, the Netherlands and Austria.

Summing up LMEs and CMEs represent two different kinds of institutional settings. These institutional settings within each country determine to which degree a company will be relying on market or strategic coordination (as defined within LMEs and CMEs, respectively). Hence, countries which consist of institutions which are coherent will be better at creating good macroeconomic performances. However, as long as the institutions are coherent per definition neither LMEs or CMEs are better at performing (Kenworthy 2009). By saying that the institutions are coherent it is meant that within a LME institutions should consistently be market oriented and oppositely within a CME institutions should consistently be non-market oriented. However, it is important to remember that not all countries fall neatly within the two categories of either LMEs or CMEs. Some countries such as Greece, Italy, France and Turkey are left in more of an ambiguous position not belonging to either or.

Indirectly in the above statements is that within VoC institutions are seen as resources (Hall, Thelen 2009). Further, institutions are defined as multiple often with institutions within institutions, existing in different spheres, and influential, as an institution may define acceptable behaviour from a specific cultural point of view. Hence any strategy a company may follow is most likely bound to be conditioned by several institutions. Further, VoC introduces two important notions about institutions, which are: *institutional complementarities* and *comparative institutional advantage*. Comparative institutional advantage means that a national institutional framework will be leading companies' strategies in a certain direction, as there is a limited number of ways otherwise for a company to absorb the advantages, which the institutional framework presents (Hancké 2009). Thus nations (and indirectly companies within the national setting) are specialising within either radical or incremental innovation (as explained in the sections of LMEs and CMEs, respectively). Within the notion of institutional complementarities it is argued that, "two institutions can be said to be complimentary if the presence (or efficiency) of one increases the returns from (or

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<sup>3</sup> Incremental innovation: "tends to be more important for maintaining competitiveness in the production of capital goods, such as machine tools and factory equipment, consumer durables, engines and specialised transport equipment" (Hall, Soskice 2001, p. 39).

efficiency of) the other” (Hall, Soskice 2001, p. 17). However, it is important to keep in mind that VoC does not say that e.g. a company specialised in incremental innovation cannot exist within a LME. What it does state is that the institutional features of an LME will tend to limit the company’s capacities for incremental innovation (Hall, Soskice 2001).

But what when one takes globalization into consideration? Are the differences VoC establishes still relevant when one considers the institutional changes that come with globalization? Has the concept of VoC in fact become outmoded, as national economies have become more liberalised (Hall, Thelen 2009)? When it comes to globalization there are several main reasons why it is believed that globalization will not extinguish or even diminish the institutional differences that VoC has previously identified. Firstly, within VoC it is reasoned that as companies in LMEs and CMEs develop distinctive structures and strategies for that particular national coordination mode it indirectly follows that companies across nations are not essentially similar (Hall, Soskice 2001). Secondly, when it comes to outsourcing as a consequence of globalization Hall and Soskice (2001) use the term “institutional arbitrage”, as a way of summing up that companies may move particular activities to other nations to be able to extract the advantages this particular nation’s institutional framework offers e.g. a company within a CME may move parts to a LME in order to gain support for radical innovation (as opposed to incremental innovation). However, this means that the idea of LMEs vs. CMEs is not being weakened by the concept of globalization as these corporate movements in fact are strengthening the national differences identified in VoC. As companies move seeking to exploit and gain advantage from the differences.

Further, as VoC identifies two different kinds of political economies it should hence not be seen as one political way of reaction to the pressures from globalization, but there should be two overall dynamics (Hall, Soskice 2001). Within LMEs it should be expected that as companies are facing more competition they will pressure governments for deregulation in order to stay competitive. As globalization has helped facilitate an exit for companies to other nations it puts pressure on the governments to maintain their nation’s attractiveness to the companies. Thus tilting the power balance towards the companies and ensuring deregulation. Oppositely, within CMEs not only will governments be less interested in deregulation as it weakens their institutional advantages but so will also companies. Companies will be less

interested in deregulation within CMEs than LMEs, as they draw competitive advantages from the system (as within CMEs firms are more prone to engaging in more strategic interactions with actors such as suppliers of finance, trade unions and the like) (Hall, Soskice 2001).

Thus VoC should not be perceived as a static conception of the political economy, which does not allow for nations to alter along with corporate strategies, policies, institutions etc. when challenges arise (Hall, Soskice 2001). And vice versa with corporate strategies being altered after institutional changes in order to sustain their comparative advantage. As it within VoC is argued that institutional change is a common feature of both CMEs and LMEs (Hall, Thelen 2009). Institutional change is inevitable as all actors are in a constant pursuit of self-interest and the equilibrium is bound to change due to changes in power, material situations and self-understandings of actors. Further, changes can for example be seen in the fact that developed economies have and are seeing economic activities changing into the service sector rather than focusing on the industrial sector and developments of the shared economy, digitalisation and new sectors based on e.g. biotechnology being created due to technological revolutions (Hall, Soskice 2001).

## **2.4 Academic Criticism**

Critique of VoC can be divided into three broad themes, which in key words can be summed up to: 1) do all capitalist economies not have the same institutions?, 2) VoC wrongly identifies key elements and 3) too simplistic (Hancké 2009).

The first theme of criticism revolves around the very key pillar of VoC; that there in fact are institutional divergences between different capitalist economies, and thus that the differences between capitalist systems may be found looking at differences between institutions (Hancké 2009). Critics adhering to this theme of criticism believe that one should be looking at the complete opposite of divergence i.e. convergence of institutions. It is believed that there is one world market and as more capitalist economies (at different stages of development) become included in said world economy the outcome is institutional convergence rather than divergence.

Opposite the first theme of critique the second theme does not revolve around criticising different capitalist varieties and the institutional divergence, but more as to what the key

elements of VoC are and what in fact is causing the differences between capitalist economies (Hancké 2009). Followers of this way of thinking do accept institutional divergence but look for the source of diversity between capitalist economies elsewhere e.g. in culture, history and the like. Further, it is criticised that VoC does not take the state into consideration and thus leaves politics out of the framework as well (Hancké 2009).

Another point of criticism regarding the framework of VoC is related to how companies supposedly choose their product market strategy should be varying systematically across advanced capitalist economies (Hancké 2009). Here referring to the idea of comparative institutional advantage and the distinction VoC sets up between radical and incremental innovation. Critics find that the notion of comparative institutional advantage is overstated and criticises the distinction VoC makes between LMEs being highly supportive of radical innovation and CMEs being highly supportive of incremental innovation. It is argued that one cannot make country distinctions between the two kinds of innovation as sectors can and often do contain both kinds of innovation.

The last theme of criticism revolves around the point made above of incremental vs. radical innovation and where it is found i.e. that VoC may be too simplistic. Colin Crouch (2009) highlights Amable (2003) for the work of creating a typology of capitalism, which goes beyond the dualist notion that VoC represents. Amable identifies five groups, however, additional subgroups are identified as it is found that these groups are not internally coherent. This is a very different approach from the one within VoC where two political economies are identified. It is acknowledge that there are nations that fall in between the two poles, however, the focus of VoC is on the LMEs and CMEs and much less on the nations, which do not belong to either or. Colin Crouch (2009, p. 76) points out that, “empirical cases must be studied, not to determine to which (singular) of a number of theoretical types they should each be allocated, but to determine which (plural) of these types are to be found within them, in roughly what proportions, and with what change over time”.

## **2.5 Academic Justification**

When P. A. Hall and D. Soskice (2001) originally introduced the VoC theory they thought of it as a starting point and a basis for further debates. Hence based on the criticism they received they have replied not only with further explanations and clarifications but likewise with

revisions. For example they include politics in later defences. According to B. Hancké (2009) Iversen (2005) and Iversen and Soskice (2006) provide a defence of VoC by putting explicit attention to politics and particularly “how economic arrangements influence choices of policies, electoral systems and their distributive effects” (Hancké 2009, p. 8). This criticism is thus not relevant to my study and may be disregarded, as politics are hence included.

Further, if I am to find companies based on radical innovation within a CME and companies based on incremental innovation within a LME throughout my investigations this does not mean that the theoretical framework is thus inadequate and should be discarded. As explained in the above about VoC, VoC does not say that it is impossible to find e.g. radical innovation within a CME. However, it states that the institutional features of a CME will tend to limit the company’s capacities for radical innovation. Thus VoC rationalises that it is more beneficial for companies to specialise in radical innovation in this example.

Lastly, and related to the above criticism of incremental vs. radical innovation some criticism focuses on the notion of comparative institutional advantage being overstated. One example found in B. Hancké (2009) supporting this view is a comparison of the American and German automotive and other engineering industries. Here it is found that despite the fact that the two countries represent a LME and a CME, respectively, they at the time face many of the same issues and further try many of the same organizational changes as a response to the problem. Hence if there is a distinct national institutional advantage between the two countries would the industries not be facing different problems and be trying different solutions? It may be true that the two industries are facing some of the same problems and trying the same solutions despite being located within a LME and CME, respectively. However, what the argument does not account for is the fact that the German car industry is doing very well compared to the American. Hence one may deduce that there are some institutional frameworks within Germany, could be regarding environment, petrol usage etc., which makes it easier for the industry. These institutional differences between LMEs and CMEs are accounted for within VoC and one may hence critically evaluate how valid the criticism of this aspect of VoC is. Furthermore, within my study I will look into the pharmaceutical industry in a LME and a CME in order to investigate if there could be support for the VoC framework within this industry.

## 2.6 Identifying Key Actors

Besides a theoretical framework, which allows me to compare capitalist systems, I further need a framework, which helps me identify key actors in the pharmaceutical industry. In order to recognise which actors may have an influence on policies towards the pharmaceutical industry. Several theories could allow me to carry out such an investigation. Three theories, which allow me to do so, are the value chain, global value chain and global production networks. All could disclose important actors within the pharmaceutical industry.

The value chain is defined as “the sequence of productive (i.e. value-added) activities leading to and supporting end use” (Sturgeon 2001, p. 11). Thus the value chain theory has a clear focus on the company and intra-company network, leading the value chain for the pharmaceutical industry to look like below:



Pharmaceutical Value Chain (Lane 2008, p. 249)

The global value chain adds to the value chain by not only focusing on the intra firm activities leading to the end use. Instead it allows for a value chain to be divided between several companies and spread over geographical spaces (Duke University 2014). Global production networks theory further adds to the global value chain by not only including inter-firm relationships but also extern macro tendencies (Coe, Dicken & Hess 2008).

## 2.7 Global Production Networks

“A chain maps the vertical sequence of events leading to the delivery, consumption and maintenance of goods and services - recognising that various value chains often share common economic actors and are dynamic in that they are reused and reconfigured on an ongoing basis - while a network highlights the nature and extent of the inter-firm relationships that bind sets of firms into larger economic groupings” (Sturgeon 2001, p. 10).

At the core of global production networks (henceforth GPN) are production networks, which are defined as “the nexus of interconnected functions and operations through which goods and services are produced, distributed and consumed” (Henderson et al. 2002, p. 445). Thus

GPN essentially revolves around how companies, involved in R&D, design, production and marketing of a given product, are organised into networks (both regionally and globally). In addition to taking inter-firm relationships into consideration GPN strives to include all relevant actors and relationships (Henderson et al. 2002).

However, additionally to the above Henderson et al. (2002) argue that production networks have become more complex organisational wise and more global in their scope. It is further argued that on the one hand these production networks are deeply influenced by the socio-political context in which they are embedded. On the other, that they at the same time integrate both companies and national economies into new structures.

Thus “embeddedness” is a key concept within GPN, as the very nature of GPNs is a consequence of influences from “the concrete socio-political, institutional and cultural ‘places’ within which they are embedded, produced and reproduced” (Coe, Dicken & Hess 2008, p. 279). However, GPN at the same time distinguishes between different kinds of embeddedness, as it defines both territorial and network embeddedness (with network embeddedness being defined as “connections between network members regardless of country of origin or location in specific places” (Coe, Dicken & Hess 2008, p. 289).

In the figure “A heuristic framework for analysing the global economy” by Coe et al. (2008, p. 273) an overview is provided for how GPN can be seen (see appendix I, figure II, p. 87). In the networks element (the middle element) Coe et al. (2008) focus on the relationship between actors i.e. firms, consumers, states, labour and civil society organisations. However, all of these actors are further embedded in the global economy and hence the broader structures and institutions found here (the upper element). In fact Coe et al. (2008) in this element not only focus on the global economy and macro structures, but also mention varieties of capitalism as part of this element. Thus showing the applicability of GPN to VoC. The last part of the overview is the geographical differences, which constitute the lower element.

When taking the framework developed by Coe et al. (2008) and applying it to the pharmaceutical industry one finds a long list of actors. The below overview focuses on the different steps a drug has to go through e.g. national drug policy and drug development. And further divides the actors, which may have an influence on each step, into actors found in the



public sector, private not-for-profit-sector and private-for-profit sector (Bennett, Quick & Velásquez 1997, pp. 16-18).

Function	Public sector	Private not-for-profit	Private for-profit
National drug policy	<ul style="list-style-type: none"> <li>Ministry of Health (focal point)</li> <li>Other government ministries</li> </ul>	<ul style="list-style-type: none"> <li>Professional associations</li> <li>Consumer groups</li> <li>Health care providers</li> </ul>	<ul style="list-style-type: none"> <li>Pharmaceutical companies</li> <li>Health care providers</li> </ul>
Drug development	<ul style="list-style-type: none"> <li>National research institutes</li> <li>Government research grants</li> <li>State universities</li> </ul>	<ul style="list-style-type: none"> <li>Private universities</li> <li>Private foundations</li> <li>Research institutes</li> </ul>	<ul style="list-style-type: none"> <li>Research-based pharmaceutical companies</li> </ul>
Drug registration & regulation	<ul style="list-style-type: none"> <li>National drug control authority</li> </ul>	<ul style="list-style-type: none"> <li>Consumer organizations (e.g. monitoring promotion)</li> </ul>	<ul style="list-style-type: none"> <li>Selected contract services (e.g. quality control testing)</li> </ul>
Production/importation	<ul style="list-style-type: none"> <li>State importation monopolies</li> <li>State-owned production</li> <li>Central medical stores</li> </ul>	<ul style="list-style-type: none"> <li>NFP essential drugs production</li> <li>NGO/mission essential drugs services</li> </ul>	<ul style="list-style-type: none"> <li>Local multinational factories</li> <li>Locally-owned factories</li> </ul>
Wholesale distribution	<ul style="list-style-type: none"> <li>Central medical stores</li> <li>State wholesalers</li> <li>Regional distribution</li> </ul>	<ul style="list-style-type: none"> <li>NGO/mission essential drugs services</li> </ul>	<ul style="list-style-type: none"> <li>Private large-scale wholesalers</li> <li>Private informal wholesalers</li> </ul>
Drug information	<ul style="list-style-type: none"> <li>National formulary and treatment guidelines</li> <li>Hospital and university drug information centres</li> </ul>	<ul style="list-style-type: none"> <li>Drug information centres</li> <li>Consumer groups</li> </ul>	<ul style="list-style-type: none"> <li>Media</li> <li>Industry</li> </ul>
Prescribing/advising	<ul style="list-style-type: none"> <li>Government hospitals</li> <li>Government health centres, dispensaries</li> <li>State-owned pharmacies</li> <li>Publicly-supported CHWs</li> </ul>	<ul style="list-style-type: none"> <li>Mission hospitals</li> <li>Mission clinics</li> <li>CHWs</li> </ul>	<ul style="list-style-type: none"> <li>Private hospitals</li> <li>Private clinics CHWs with user fees</li> <li>Injectionists</li> </ul>
Dispensing/retail sale			<ul style="list-style-type: none"> <li>Pharmacies</li> <li>Dispensing clinicians</li> <li>Other drug outlets</li> </ul>
Consumption by population	Households/consumers		

“Public and private actors in the pharmaceutical market” (Bennett, Quick & Velásquez 1997, pp. 16-18)

Instead of keeping it at a general level applying all of the above actors to the framework by Coe, Dickens and Hess (2008) I have selected the actors I deem the most important for my study and that I believe are the most necessary to elaborate upon in order to create a basic understanding of the industry.

### **Macro Structures & Processes of Embeddedness (Upper Element)**

**The European Union;** considering my topic the most important macro structure is the EU. The EU presents a different setting for the pharmaceutical industry, as it is a union of countries. And therefore, there are characteristics here that you do not find elsewhere. First of all, it is special that you can follow a centralised process and thus be granted approval in all Member States (Kashyap, Gupta & Raghunandan 2013). Another important setting is that some legislation such as transparency directives have been harmonised between the Member States (Vogler et al. 2011).

The following point is not only applicable to the EU, but in general to the industry, as it is a unique aspect of the pharmaceutical industry that the industry is being so extensively controlled and has to have its products approved before they may reach the end-user (Ding, Eliashberg & Stremersc 2014). However, “the European drug approval processes are among the most demanding in the world” (Strandberg-Larsen 2015). The pharmaceutical industry is tightly regulated as compounds are seen as different from ordinary items of commerce. As it is impossible for the user as an individual to evaluate if a drug is safe, effective and of high quality, if no governmental approval exists (World Health Organization 2012). Hence, regulation is first and foremost put in place to protect the end-user. The directive 65/65/EEC from 1965 was the first pharmaceutical directive within the EU and has an aim of ensuring protection of the public health (Dunne et al. 2012). Much of the drive for the directive came from the thalidomide disaster from the early 1960s in which thousands of babies were born with limb deformities (Dunne et al. 2012). As their mothers had taken this drug during pregnancy without knowing what the consequences could be (see appendix I, figure III, page 88 for a timeline of pharmaceutical regulation in EU).

### **Networks (Middle Element)**

**National governments;** from the networks element one of the most important players to take into consideration is the national government. This is so as governments strongly intervene in the industry through several measures and for several reasons. First of all, the same

mechanisms are in place as within the EU that the government has to protect its citizens. However, one has to keep in mind that governments strongly intervene in the pharmaceutical industry not only to protect its population but also for economic reasons, as governments often are the largest third-party payer (Barros 2010). Thus many policy measures are in play in order for the governments to be able to limit public expenditures. One important thing to keep in mind here is that some legislation towards the industry may have been unified at a EU level, however, the pricing and reimbursement is still up to the individual governments (Vogler et al. 2011). Nevertheless, regulation in the context of the pharmaceutical industry is a double-edged sword. As at the same time as the pharmaceutical industry is subject to strict legislation, it is vastly relying on regulation to protect the industry and its interests i.e. protecting its intellectual property rights through patents (Baldwin et al. 2010).

**Insurance companies;** within many European countries the government will be the main third-party payer, however, another party which may hold this role is insurance companies (Barros 2010). The consequence of both governments and insurance companies being third-party payers is that the consumer is less price sensitive (World Health Organization 2003). This has an impact on the price that the pharmaceutical companies can charge for their product, as the pharmaceutical companies can charge higher prices than they could have done if the consumer had not been price insensitive (Baldwin et al. 2010).

**Firm alliances;** “Salient among the incentives to collaborate is the possibility of bringing together complementary assets owned by different organizations” (Stuart 2000, p. 792). Firms enter into firm alliances for many reasons, however, when focusing on the pharmaceutical industry it is found that the industry has gone through some big changes since the 1970s (Ohba, Falkner 2007). In earlier decades, the industry was driven by a more random screening in the search for a molecule, which could be turned into the next big blockbuster. Now pharmaceutical companies to a high degree enter into strategic alliances with biotech companies. The division between the two parties is that the biotech companies focus on the upstream research, whereas the pharmaceutical companies seek to obtain from them the initial drug compounds, which they can carry further by carrying out the clinical trials, launching in markets etc. (Ohba, Falkner 2007).

Another reason for a strategic alliance amongst pharmaceutical companies is to gain efforts in finding a cure against a disease and thus globally strengthen the chances of succeeding. An example of such an alliance can be found between companies such as Roche, Eli Lilly, Pfizer and H. Lundbeck A/S, which have entered into an alliance to try to develop a compound against Alzheimer's disease (Ritzau Finans 2015).

**Business associations:** Pharmaceutical companies not only organise themselves around strategic alliances with other companies within the sector, but likewise through associations. One of the biggest pharmaceutical associations within the EU is the European Federation of Pharmaceutical Industries and Associations (EFPIA). EFPIA is according to itself "the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world" (EFPIA 2015b). This EFPIA seeks to achieve by collaborating with all relevant stakeholders in order to implement policies, which "recognise the pharmaceutical industry's role in improving European public health, economic wealth, and in enhancing Europe's industrial and science base" (EFPIA 2015b).

Thus when searching the European Transparency Register<sup>4</sup> one finds EFPIA registered as an "In-house lobbyist and trade/business/professional associations" (European Union 2015b). When looking into the section of specific activities covered by the register one finds that EFPIA, "covers regularly the committee debates in the European Parliament and attends public hearings, conferences, roundtables that are important to the industry. EFPIA also meets regularly Members of the European Parliament and assistants to facilitate the dialogue with the policy makers" (European Union 2015b). When looking further, one finds in the financial data section that within the financial year of 01/2014 till 12/2014 EFPIA has put in an estimate of EUR 5,071,000 spent on the above activities.

EFPIA is but one example of an organisation lobbying on behalf of the pharmaceutical industry. When looking through the Transparency Register one finds many more such as the

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<sup>4</sup> In the European Transparency Register the companies, organisations etc., with which the European Parliament and the European Commission interacts are registered. Thus making the lobbying more transparent to the general public (European Union 2015a). In the register one can find who is pursuing what interests and with which budgets.

International Pharmaceutical Excipients Council Europe or the European Association of Euro-Pharmaceutical Companies (European Union 2015a). However, individual companies such as H. Lundbeck A/S also registers and it can be found that H. Lundbeck A/S has put in an estimate of EUR 400,000 – 499,999 spent on lobbying efforts in the financial year 01/2014 till 12/2014 (European Union 2015c). Thus illustrating not only how well interlinked the industry is, but furthermore how much money is put into lobbying for the interests of the industry.

**Patient groups;** the purpose of patient groups is to represent and advocate on behalf of the patients who are suffering from the chosen disease (Buttle, Boldrini 2001). Patient organisations thus liaise with many different stakeholders such as pharmaceuticals, governments, caring organisations and the like to the case in order to represent the interests of their patients. Their goals can be obtained through many measures such as “accumulating information for the industry, shaping healthcare policy and grouping at regional and international levels” (Buttle, Boldrini 2001, p. 205). Patient groups and pharmaceutical companies do not necessarily have to stand on each side of the fence but can mutually benefit from joint efforts. Pharmaceutical companies can for example assist patient groups by facilitating reliable and precise information about the disease in question and by supporting the patient groups in their advocacy efforts. Pharmaceutical companies, on the other hand, can benefit from patient organisations by having its corporate image strengthened through such relationship. Or it can get assistance from the patient organisation in conveying a message about a disease (as it may be the case that if a pharmaceutical is trying to convey the message itself the general public may be more sceptical as it is a corporation sending a message) (Buttle, Boldrini 2001). However, the close relationship between some pharmaceutical companies and patient groups is at the same time being criticised. It is being criticised that the relationship between patient groups and pharmaceutical companies is not more transparent, as some groups are receiving funding from the pharmaceutical companies (Sample 2013). Thus making their voice for the patients’ cause less independent from the industry’s wishes.

**Health Care Professionals;** First of all, the pharmaceutical industry is highly dependent on prescribers, as it is through these healthcare professionals that a compound is able to reach a

patient. Thus prescribers are often the targets of drug promotions in order for the pharmaceutical companies to provide inducements for the prescribers to prescribe (Komesaroff 2007). Inducements may include travel offers, gifts, drug samples, educational activities e.g. attending speaker events, and drug familiarisation.

Another key group within healthcare professionals is Key Opinion Leaders (KOLs). KOLs are influential physicians who are able to convey a message to their peers (Elliott 2010). Amongst others the pharmaceutical companies use the KOLs for consultancy reasons e.g. through advisory boards, to conduct presentations at speaker events or to conduct clinical trials. Thus KOLS are engaged by pharmaceutical companies not to influence the KOLs' prescriptions but rather to influence the prescriptions of other physicians (Sismondo 2013). However, with recent regulation, e.g. the Physician Payments Sunshine Act in the US from 2010, pharmaceutical companies are now required to make transactions between themselves and healthcare professionals (and healthcare organisations) transparent and publically available (Sismondo 2013). Thus the Act ensures that the public is aware of the relationship between certain KOLs and the pharmaceutical industry and is hence attentive of any conflict of interests.

***Distribution channels:*** In the majority of European countries most compounds are distributed through a distribution channel, which encompasses: manufacturer → (pre-wholesaler) → pharmaceutical full-line wholesaler → retail pharmacy → patient (Walter, Dragosits & Said 2012). In fact close to three-quarters of all medicines sold within Europe is distributed through wholesalers (Behner, Bünte 2007). However, this does not mean that you find an endless list of wholesalers sharing the European market. Rather the European market is becoming progressively consolidated, as you now find three players who between them control more than 60% of the distribution market, and due to their size they have become important trade partners for the pharmaceutical industry.

### **Values and Norms (Lower Element)**

The macro structures and the network actors explained in the above sections are not the only factors making up the global production networks. There is an additional element, which has an influence – the norms and values one finds within different spaces. When looking into the case of the pharmaceutical industry it is highly relevant to look into different countries' norms

and values, as these will have an impact on what kind of healthcare system the country has. And further what is expected from that healthcare system as “health care services, like other human service systems, mirror the deeply rooted social and cultural expectations of society as a whole” (Saltman, Figueras 1997, p. 5). Thus affecting the pharmaceutical industry as part of what is expected by the healthcare system is related to which drugs should be available to a patient, at what price and with what degree of self-payment. The degree of self-payment relates to whether or not society sees it as an obligation for society to ensure that all citizens can receive healthcare. Some societies in fact see it as a social or collective good that society ensures access to healthcare for all, following the line of thinking that society as a whole will benefit if an individual receives aid (Saltman, Figueras 1997). Oppositely, other societies think more of healthcare as a service, which can be bought and sold in an open market.

## 2.8 Interim Conclusion

Throughout the chapter the theoretical framework, upon which I will base my analysis, has been explained, critically examined and justifications have been provided as to why despite of the criticism it is still applicable. Thus concluding the theories used and their main concepts that I will be applying to my study are:

<b>Theory in Use</b>	<b>Main Concepts in Use</b>		
<b>Varieties of Capitalism</b>	Liberal Market Economies	Coordinated Market Economies	
<b>Global Production Networks</b>	Macro Structures	Networks	Values and Norms

## **Chapter 3: Analysis Part One**

### **3.1 Introduction**

Throughout the following chapter I will briefly look into healthcare reforms in a historical perspective to investigate when a general regulation debate towards the pharmaceutical industry originally started. Using this knowledge as a platform for analysing current trends in order to see what legislative changes have happened recently and if they are radically different from previous reforms. Lastly, to see if a link between the financial crisis and the policy changes may hence be established.

### **3.2 Healthcare Reforms in a Historical Perspective**

Within the EU health reforms are not a newly invented concept. Already in the 1980s policymakers started debating restructuring of national healthcare systems and in the late 1980s many European healthcare systems saw changes, as many countries launched reforms within this area (Hutton et al. 1994). One of the key motivational aspects for launching the reforms was cost containment.

However, before looking into the historical perspective it is necessary to define what a reform is. According to the Saltman and Figueras (1997) a reform is defined “as a process that involves sustained and profound institutional and structural change, led by government and seeking to attain a series of explicit policy objectives” (Saltman, Figueras 1997, p. 3). Thus it is important to notice that when Saltman and Figueras (1997) define reform in terms of the healthcare system they focus on fundamental structural changes, whereas they leave out normal evolutionary and incremental system changes, as these are seen as a predictable part of any system.

Thus keeping the definition of what a reform is in mind one can look into why reforms occurred. First and foremost, there were pressures related to the existing healthcare system and the health of the European population. Such pressures included an increased health spending, challenges to the health of the population and organisational and structural challenges to the systems (Saltman, Figueras 1997). Secondly, external pressures existed which had an influence on the framework of the healthcare systems. Thus “in many cases, health care reforms are not isolated phenomena, but instead form part of wider structural efforts to reform various state-supported welfare programmes and other social sectors. The reform process is influenced by political, ideological, social, historical, cultural and economic



factors, all of which need to be taken into consideration in understanding the context of pressures for reform” (Saltman, Figueras 1997, p. 5).

When focusing on the economic factor there are many sub factors to examine. It was in the late 1990s argued that in order for countries in Western Europe to stay competitive in an increasingly globalised world they had to decrease public spending (Saltman, Figueras 1997). At the time many governments were under heavy financial pressures due to issues such as increasing unemployment and social welfare costs. In addition to the general societal financial issues there were financial concerns related directly to the healthcare systems. Firstly, Europe was seeing an aging population thus creating an increased need for healthcare services. Which indirectly means that the health system saw an increase in its expenditures. Secondly, more expensive medical treatments had become available. Thirdly, the expectations of the patients and citizens were growing. With the growing expectations of the patients the patient’s rights movements were growing in Western Europe. Thus putting additional pressure on the healthcare system in terms of high-quality service, reduced waiting times etc. (Saltman, Figueras 1997).

However, additionally one has to look into some of the political movements at the time of reforms. A highly important one is the new public management development, which started in the UK under then current Prime Minister Margaret Thatcher (Groot, Budding 2008). New public management became relevant, as the 70s had seen increases in stagnation and a population that was in general having increasingly negative views on bureaucracy. Thus enabling the development of the new public management in which it “made the cost, size and operations of the British civil service policy issues” (Barzelay 2001, p. 2). Hence allowing Thatcher and her government to go through many changes within many areas of the public management.

In general a key driver of the reforms was to control healthcare costs. In the below overview “Pharmaceutical Regulatory Mechanisms In Various Nations” Hutton et al. (1994) p. 103 provides an overview of the range of measures which can be used to control costs. Arguing that all of the supply side measures found in the overview are in use somewhere in Europe, however, further arguing that the price-based control mechanism is the most common regulation form. When it comes to the demand side of regulation forms Hutton et al. (1994)

argue that the control mechanism, which used to be the most used, was the guidelines for prescribers. Nevertheless, at the time of the paper other mechanisms were being taken into use. These mechanisms include fixed budgets and positive/negative prescribing lists i.e. a positive list includes compounds which can be reimbursed through the public health system, whereas a negative list includes compounds which cannot (Hutton et al. 1994).

<b>Supply side</b>		
<b>Coverage</b>	<b>Price-based</b>	<b>Profit based</b>
Registration	Individual product cost Reference pricing Sales volume	Product rate of return Company rate of return
<b>Demand side</b>		
<b>Doctors</b>	<b>Pharmacists</b>	<b>Patients</b>
Positive and negative prescribing lists Guidelines Fixed budgets	Generic substitution Parallel importing	No reimbursement Copayment: Fixed fee Proportional

Pharmaceutical Regulatory Mechanisms In Various Nations (Hutton et al. 1994, p. 103)

Thus as seen from the above sections the idea that we need to contain health expenditures is not new. Neither is the rhetoric of generic substitution, prescribing lists, co-payments etc. In 1998 Saltman and Figueras asked the question, “What level of government regulation and/or intervention is optimal for a successful health care system?” (Saltman, Figueras 1998, p. 85). A question which to a high degree is still applicable in today’s health systems where debates are still raging.

### 3.3 Recent Healthcare Reforms

Although debates over the healthcare systems and how much money is spent on them are not new, there has been a recent wave of policy changes towards the healthcare systems and debates over how much money should be spent on pharmaceuticals. In a study conducted from January 2010 till February 2011 researchers found that 90 pharmaceutical policy measures within this time period had been carried out in 22 out of the 33 surveyed European countries (countries surveyed included 28 Member States and additionally Albania, Iceland, Norway, Switzerland and Turkey)<sup>5</sup> (Vogler et al. 2011). Furthermore, 14 countries out of the

<sup>5</sup> At the time of the survey Croatia was included as an additional country and not as Member State, as it did not become a member until 2013 (European Union 2015).

33 countries further stated that future pharmaceutical policy measures were either being discussed or currently being planned. Thus the parameters showcased below are the pharmaceutical policy measures that Vogler et al. (2011) used in their survey when investigating if European countries had responded to the financial crisis. The policy measures are divided into three sub-groups of pricing policy measures, reimbursement measures and others (policy measures that do not directly relate to either pricing or reimbursement). After describing what the policy measure is, and which countries have implemented it, I will use one country as an example to show why it may have been implemented or what the consequences are (see appendix II, table II-III pp. 91-94 for full overview of the study).

### **Pharmaceutical Pricing Policy Measures**

**Price reductions;** if price reductions are used as a policy measure by a government it simply means that it decides to reduce the set price of a compound (Leopold et al. 2014). Within the given timeframe Vogler et al. 2011 found that in total eleven countries (Czech Republic, Germany, Greece, Ireland, Lithuania, Malta, Portugal, Spain, Switzerland, Turkey and UK) implemented price reductions. In the first six months of 2010 seven countries implemented price cuts with for example the UK implementing a 1.9% price cut of branded National Health Service medicines, whereas Greece implemented quarterly price reviews followed by price cuts. In the last six months of 2010 five countries introduced (further) price reductions with e.g. Ireland implementing a second price reduction on generics. Lastly, in the first two months of 2011 three countries made price reductions. One example is Ireland introducing price reductions on on-patent medicines.

When giving Greece a more in depth look it is found that Greek health expenditures accounted for a large proportion of the governmental budget i.e. 10.6% of the GDP in 2010 (Vandoros, Stargardt 2013). Vandoros and Stargardt (2013) further explain that at the time of 2010 there were no policies encouraging generic uptake (except one which said that generic prices could not exceed 80% of the original compound). Thus leading to the fact that Greece had a very low generic uptake compared to other European countries. Greece's uptake was 26% compared to e.g. the UK's 60%. In general at the time of 2010 Greece had a very inefficient system towards pharmaceuticals which was shown in several ways: 1) prescribers mainly prescribed due to brand name, 2) there were high volumes of prescriptions leading to vast amounts of spending on compounds, and 3) high pharmacy margins leading to a large number of pharmacies (this

last point will be looked further into in the “distribution remuneration” section). Vadoros and Stargardt (2013) especially focus on two reasons as to why the Greek pharmaceutical environment has been the way it has. First of all, they note that the increases in the volumes of prescriptions took place in relatively good years, and as there were no consequences for prescribers they could continue this practice. Secondly, that corruption may be an important factor as some prescribers may have been incentivised to prescribe specific drugs. However, as stated in the 2011 study by Vogler et al. Greece in the first half of 2010 decided to use price cuts as a policy measure and Vadoros and Stargardt (2013) have calculated that on average the price cuts were 21.5%. However, introducing price cuts does have more implications for the pharmaceutical industry than just the obvious one of the prices of their products being lowered in Greece. The first issue, which is also related to the issue of generic uptakes, is that you may have cut the price on one of a pharmaceutical company’s compounds, but they still need the same revenue as before to make ends meet. “The high penetration of generic drugs is another explanation, as it means the pharmaceutical companies are losing money. So we will increase the price on the drugs we have left as we need the same revenue” (Annfeldt 2015). Another issue is the one of external price referencing (see explanation in below section), as a cut in Greek prices would affect what pharmaceutical companies would be able to charge for their products in other countries (Vadoros, Stargardt 2013). So a price cut in Greece not only can reduce a company’s earnings in Greece, but can furthermore mean reductions in price in a whole range of countries as well. And to be exact eleven countries at the time used Greece as a reference country. Which is why some companies threatened to withdraw their products from the Greek market as a consequence of the price cuts (Vadoros, Stargardt 2013).

**Discounts, rebates, clawbacks and other agreements;** In general these measurements aim at containing government expenditures. Discounts and rebates mean that producers and distributors of a compound are required to give a certain amount of discount/rebate to the purchaser (Carone, Schwierz & Xavier 2012). Additionally, clawback “policies aim at preventing budget overshooting, by claiming refunds from the industry once a target budget is exceeded” (Carone, Schwierz & Xavier 2012, p. 11). Vogler et al. (2011) found that in the first six months of 2010 Spain, Romania and Lithuania implemented measurements with for example Romania introducing clawback. Within the next six months an additional five countries, Estonia, Germany, Italy, Lithuania and Portugal, similarly implemented

measurements. Portugal decided to implement a 6% discount on reimbursable medicine. Lastly, within the two last months of the survey i.e. the beginning of 2011 Portugal made further changes.

**External price referencing (EPR);** when one uses external price referencing for a compound it means that one looks at what price the compound is sold for in other countries (Leopold et al. 2014). Thus using this information to set a benchmark/reference price for own negotiations over the price. Within the first six months of 2010 Vogler et al. (2011) found that Malta, Spain and Switzerland implemented either EPR or changes to the already existing procedures. Malta e.g. introduced EPR whereas Spain made a specification in Spanish law that countries used for the EPR scheme must be other Member States. For the rest of the timeframe of the study an additional three countries implemented policy measures related to EPR (Lithuania, Iceland and Germany). One of the effects of EPR is what we indirectly saw in the example of Greece in the “price reductions” section i.e. that countries get more interlinked and a price cut in one country can thus have an impact on other countries, as they may then want to decrease their prices as well. Thus empowering the government by providing them with a useful tool increasing their bargaining powers. A concern expressed by Martin Strandberg-Larsen, when stating that “the problem is that if a company decides to stay in a market where they get a low price that will affect prices in all other markets as countries look at each other when deciding on which price they are willing to pay” (Strandberg-Larsen 2015). However, EPR carries some other, maybe less obvious, negative impacts as well such as “lower product availability, launch delays and higher relative per capita prices in low income countries” and furthermore EPR “undermines initiatives to improve accessibility and affordability of medicines through differential pricing schemes” (EFPIA 2014, p. 1). Therefore, it may not only be the pharmaceutical companies that EPR may have a negative impact upon, as it may carry a negative impact for the patients of the country using EPR. If it means it will take longer for a new drug to be launched or if it means it will be harder to get a specific drug.

**Distribution remuneration;** when a healthcare provider, either an individual or an organisation, is paid for a service it is distribution remuneration (Leopold et al. 2014). When it comes to distribution of compounds wholesalers and pharmacies are part of the distribution line and are remunerated through mark-ups or regressive margin schemes (or

for pharmacies alone through a fee for service). A mark-up is calculated on the basis of “a defined linear or percentage amount is added to the cost of a good to ensure a profit at the wholesale or retail level” (Leopold et al. 2014, p. 632). Whereas for regressive margin scheme “the margin is expressed as a percentage of the selling price” (Leopold et al. 2014, p. 632).

Throughout the first six months of 2010 Vogler et al. (2011) found that seven countries (Belgium, Greece, Iceland, Lithuania, Portugal, Spain and Switzerland) implemented distribution remunerations changes with e.g. Greece implementing a wholesale margin cut for expensive medicines. In the following eight months an additional two countries followed with Italy implementing a wholesale margin cut and a pharmacy margin increase and Latvia implementing a wholesale margin cut. Using the example of Greece again from the “price reductions” section it was said that Greece had very high pharmacy margins leading to a large number of pharmacies (in fact Greece had the highest concentration of pharmacies within the EU) (Vandoros, Stargardt 2013). But why should a government worry about pharmacy and in general distribution margins? It should because it is in fact found that “despite recent reductions in distribution margins, the impact of distribution in different Member States can be as high as 50% of a drug’s retail price (i.e. the price payable by health insurance)” (Kanavos et al. 2011, p. 52). However, it is worth noting “the proportional impact of margins on retail prices is often higher for generics (which have lower prices) than it is for branded medicines” (Kanavos et al. 2011, p. 52). Thus overall these distribution remunerations can have a vast influence on how much the payer ends up paying for a compound, and hence are very important to bear in mind when considering policies towards pharmaceuticals cost containment.

**Value added tax (VAT) on medicines;** in general VAT is a sales tax added to most goods and services thus policy measures can either mean an introduction, elimination or adjustment of the rate of the tax (Leopold et al. 2014). Vogler et al. (2011) found that three countries, Czech Republic, Greece and the UK, between January and June 2010 changed their VAT rates on drugs. Both the Czech Republic and Greece increased their rate with 1% going from 9% to 10% whereas the UK changed its rate on over-the-counter medicines<sup>6</sup> by 2.5% increasing the

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<sup>6</sup> Over-the-counter medicines is medicine which can be bought without a prescription (National Institutes of Health 2015)

rate to 17.5%. In the last six months of 2010 Finland, Greece and Portugal changed their VAT rate by 1% each. Lastly, in the first two months of 2011 Greece, Latvia, Poland and the UK additionally implemented (further) changes. For example the UK made a further increase on over-the-counter medicines resulting in a rate of 20%. It is worth noting that in the UK medicines are exempt from VAT and only over-the-counter medicines are subject to VAT, which is with the last increase till 20% the standard VAT rate in the UK (GOV.UK 2014). Increases in VAT rates might mean that there will be a limited accessibility to medicines, as medicines will become more expensive. This could carry the impact that vulnerable groups will be hit even harder and become even more exposed (Vogler et al. 2011). Thus in the UK this potential impact may to some extent be avoided or the impact lessened, as prescription medicines are TAX exempt and only over-the-counter medicines are affected by not only increases in VAT but VAT itself.

### **Pharmaceutical Reimbursement Measures**

**Reimbursement lists;** reimbursement list includes positive/negative lists and delisting. A positive reimbursement list lists drugs, which will be reimbursed through the public health system (Hutton et al. 1994). A negative list showcases the exact opposite by being a list of drugs, which will not be reimbursed by the public health system. Furthermore, a delisting is when a drug is delisted from a reimbursement list. In Vogler et al.'s study (2011) they found that three countries (Iceland, Malta and Portugal) implemented policy measures related to reimbursements lists in the first six months of 2010. E.g. Iceland made changes related to reimbursement status for some drugs i.e. the reimbursement status being changed from a general level to an individual one. In the second focal period Iceland made further changes and Greece introduced both positive and negative lists. Lastly, during the first two months of 2011 the Czech Republic, Germany and Portugal implemented policy changes e.g. with Portugal implementing delisting of over-the-counter medicines.

**Co-payments;** a co-payment means that the patient together with the third party payer will be paying for the medicine (Kanavos et al. 2011). Vogler et al. (2011) found that four countries (Austria, Belgium, Iceland and Portugal) in the first half of 2010 made changes to their policies on co-payment. Iceland for example saw an increase in co-payments. In the second half of 2011 Belgium and Portugal made additional changes and Latvia and Lithuania initiated changes in their co-payments. Lastly, in the two first months of 2011 Austria,

Belgium, Iceland and Latvia introduced further co-payment changes with e.g. Iceland implementing yet another increase in co-payments. Furthermore, France and Denmark initiated changes in the first two months of 2011 with Denmark making increases in co-payments for fertility products.

Co-payments are usually implemented in order to generate earnings to a health system or to interfere with demands (Kanavos et al. 2011). But what are the consequences for a population when as in the above e.g. Iceland chooses to make increases in co-payments twice? Not only might it decrease the demand for drugs as already stated, but it might also decrease the demand disproportionately throughout a population. Meaning more vulnerable groups such as people with low-incomes and the elderly will have lesser access to medicines than do the “stronger” part of the population. Kanavos et al. (2011) therefore argue that when using co-payments as a policy measure it is important to ensure that the balance is kept, and the policy does not end up restricting access to medicines but rather facilitates a rational drug use. An example could be a cancer drug in Denmark, which was not reimbursed, which resulted in only people with private health insurance or people with high enough incomes could afford it. Thus creating an A and a B team within the population (Annfeldt 2015). This example may be transferable to the co-payment case of Iceland where the concern might be that an A and B population can be created when it comes to access to medication. The question thus is if the generated earnings to the government from co-payments can outbalance the negative societal impact that it may have to implement this measure.

**Reference price system (PRS);** within PRS the third party payer will be looking at prices of other compounds with the same active ingredient or within a given therapeutic class (Leopold et al. 2014). Based on the prices found on these other compounds the third party payer will decide a reference price. If the price of the compound exceeds the reference price you will yourself, as the consumer, have to pay the difference between the fixed reimbursement amount and the pharmacy retail price of the compound (there may be additionally some co-payments such as prescription costs). It was found by Vogler et al. (2011) that three countries used PRS as a policy measure in the first six months of 2010. Those countries were Lithuania, Portugal and Spain. In the second half of 2010 Estonia implemented two policies and Romania one. Romania for example had a policy change implemented which meant that it changed to



therapeutic reference pricing. Thus having broader clusters to base its prices upon. Lastly, in the first two months of 2011 an additional four countries, Belgium, Latvia, Lithuania and Portugal, likewise implemented policy measures related to this system.

When assessing the impact of RPS it can be seen from the view of the industry, the patient and the government. For the government it means an instant reduction in expenditures, as there is now a set price cap as to how much can be reimbursed. For the patient it means that unless the patient is willing to pay the difference him/herself the patient will have to opt for a drug within the price cap. Overall the impact when a country introduces PRS is that it will reduce the price of all medicines within the system and thus will have a negative effect on the industry's earnings (Dylst, Vulto & Simoens 2012). However, the reference price system will naturally have a larger impact on originator products than on generics, as generics are already pressing the prices down. Leading to an overall concern for the way that government's choose to deal with pharmaceutical companies, and that it is more of a budget driven society and thus less about the quality of life (de Jong-Laird 2015). However, at the same time as it may be negative for the industry's earnings it will be positive for the governments, as expenses are reduced and thus funds are released that can be used elsewhere in the society.

### **Other Measures**

Vogler et al. (2011) besides the policy measures relating to pricing or reimbursements found a series of measures which do not directly belong to either of the before mentioned boxes. One such example is Lithuania in which INN subscribing became mandatory. The INN for a drug is the name of the active ingredient so when INN subscribing becomes mandatory it means that prescribers have to make the prescription based on the active ingredient instead of a brand name (Leopold et al. 2014). Yet another example of a measure used was seen in Spain in which a generic promotion campaign took place targeting the public.

Concluding on the results found in the Vogler et al. study from 2011 it is seen that a large range of countries are found in the study and have implemented measures, but it is also seen that there is a vast difference between how many measures a country opted for and which measures were used the most. The countries, which implemented the most measures, were the Baltic States, Greece, Spain, Portugal and Iceland (Vogler et al. 2011). The policy measure

the most used was price reductions with in total fifteen such implementations taking place. In second place one finds the reimbursement measure co-payments.

When using the VoC framework on the results found in the Vogler et al. study (2011) the countries can thus be divided into CMEs, LMEs and countries left in a bit more of an ambiguous position (in the matrix labelled mixed markets) (Hall, Soskice 2001). However, I have added an additional column titled Eastern Europe as, mentioned in the methodology, Hall and Soskice (2001) in their VoC framework leaves out Eastern Europe (Nölke, Vliegthart 2009). However, to present an accurate overview of the result presented above Eastern Europe will be included simply to show many policy measurements were implemented here.

	<b>CMEs</b>	<b>LMEs</b>	<b>Mixed Markets</b>	<b>Eastern Europe</b>
<b>Price reductions</b>	Germany Switzerland	UK Ireland	Greece, Malta Portugal, Spain Turkey	Czech Republic Lithuania
<b>Discounts, rebates etc.</b>	Germany		Italy, Portugal, Spain	Estonia, Lithuania Romania
<b>External price referencing</b>	Germany, Iceland Switzerland		Malta, Spain	Lithuania
<b>Distribution remuneration</b>	Belgium, Iceland Switzerland		Greece, Italy Portugal, Spain	Latvia, Lithuania
<b>VAT on medicines</b>	Finland	UK	Greece Portugal	Czech Republic Latvia, Poland
<b>Reimbursement lists</b>	Germany, Iceland		Greece, Malta Portugal	Czech Republic
<b>Co-payments</b>	Austria, Belgium Denmark, Iceland		France Portugal	Latvia Lithuania
<b>Reference price system</b>	Belgium		Portugal Spain	Estonia, Latvia Lithuania Romania
<b>Other measures</b>		UK	France Spain	Estonia Lithuania

In total it was found that 90 policy changes took place within the timeframe of 2010 till 2011 and when dividing the policies amongst the four categories LMEs accounted for 7 policy measurements, CMEs for 22, mixed markets for 31 and lastly Eastern Europe for 30. Solely looking at the numbers in this way would make it seem as if LMEs hardly made any changes, as one only finds 7 policy measures compared to the 31 implemented by the mixed market countries. Therefore, it should be taken into consideration how many countries, in which there were found implemented measures, are in each category. Counting the countries found in the above matrix shows that there are 2 LMEs, 7 CMEs, 7 mixed markets and 6 Eastern European countries. Thus when dividing the number of policy measures within a category with the number of countries in that category it is found that for LMEs there were 3.5 policy measures found per country for CMEs this number is 3.14, for mixed markets 4.43 and for Eastern Europe 5. Thus finding that CMEs per country implemented the least changes and Eastern European countries the most.

	<b>CMEs</b>	<b>LMEs</b>	<b>Mixed Markets</b>	<b>Eastern Europe</b>
<b>Total number of policy changes</b>	22	7	31	30
<b>Number of countries</b>	7	2	7	6
<b>Policy changes per nation</b>	3.14	3.5	4.43	5

Further it is found that the top three policy measures used within CMEs are co-payments, external price referencing and distribution remuneration. Within LMEs the top three measures are price reductions, VAT on medicines and other measures (should be noted that these were the only categories used). Lastly, for mixed markets the top three are price reductions, distribution remuneration and a tie between discounts/rebates etc. and reimbursements lists. When looking into the measures the most used it is found that LMEs and CMEs do not share any of the same top three measures. This does not indicate that there have not been CMEs that have used the same measures as LMEs, but what it does indicate is that generally the most popular implementations do go in a different direct direction from what LMEs have chosen. Leading to an idea that maybe when it comes to the pharmaceutical industry one can find distinctions in between how LMEs and CMEs decide to react. This idea is

further supported by the fact that two of the mixed markets most used measurements matched one within the CMEs top three and one within the LMEs top three. The other two mixed markets top measures were only found within the mixed markets. As VoC argues that mixed markets are somewhere in an ambiguous situation in between CMEs and LMEs it fits well that we find a top measurement from both.

### **3.4 Interim Conclusion**

In the chapter it has been discussed which policy measures governments can implement when trying to contain costs, what their effects are and which European countries have implemented such measures during the surveyed period from January 2010 till February 2011. Based on these findings the implemented measures and which countries implemented them were put in relation to VoC. Firstly, to try to establish if one market economy had implemented more measures than others. Here it was found that, within the VoC framework, mixed markets implemented the most policy measures with 4.43 measure per country and CMEs implemented the least with 3.14 per country. Secondly, when looking into the top three measures used by LMEs, CMEs and mixed markets it was found that for the measures the most used LMEs and CMEs had no measures in common. For mixed markets it was found that its top three consisted of one measure that was likewise used within LMEs and one measure that was used within CMEs. This does not give an infinite support of the VoC framework, but it does seem to support the overall idea of VoC that LMEs and CMEs have different characteristics, and that their economic markets are structured differently thus leading to different ways of reacting. For my next analysis chapter I wish to look deeper into the case by selecting two countries, representing a LME and a CME, to see if the general characteristics of the country and the characteristics of the pharmaceutical industry in each country supports the ideas put forward in VoC. And further to try to investigate if VoC can be used to explain why different countries have selected different measures.

## **Chapter 4: Analysis Part Two**

### **4.1 Introduction**

Throughout the previous analysis chapter I discovered that several changes in policy measures towards the pharmaceutical industry took place in the immediate aftermath of the financial crisis. It was also found that there were differences as to which countries took which measures. The aim of this chapter is to further analyse how the pharmaceutical industry fits into the idea of LMEs and CMEs by investigating not only if industry characteristics support what one would expect to find within a CME/LME but similarly if the overall country characteristics do. And to see if VoC can be used to make some explanations as to why different countries have implemented different policy measures. However, as explained in my methodology it would be impossible in this paper to make an in-depth investigation of all Member States. Hence the UK and Denmark have been selected as representing a LME and CME.

### **4.2 The United Kingdom**

The UK is one of the top five markets in Europe (Schroll 2015) For instance in 2013 the UK accounted for 11.4% of the European pharmaceutical market value (MarketLine 2014). Traditionally the UK has been a world leader in pharmaceutical innovation – a position which to a high degree can be contributed to the science base in the UK, which includes research institutions and the National Health Service (NHS) (House of Commons Health Committee 2005). The core objective of the NHS is to ensure that a long list of healthcare services is freely available to all citizens who should be in the need of them (Rothgang 2010). Thus meaning that the NHS is funded by general taxation (MarketLine 2014). However, at the same time you also find the National Insurance (NI) fund within the British healthcare system (Rothgang 2010). The NI fund is state managed and financed by employees and employers. An additional third source of funding of health care expenditures is private insurance, which over the last thirty years increasingly played a larger role in supporting the British healthcare system.

Besides the NHS another organisation, which is very important when considering the British healthcare system, is the National Institute for Health and Care Excellence (NICE). The main responsibilities of NICE are to “assess new drugs and treatments as they become available, provide evidence based guidelines on how particular conditions should be treated, provide guidelines on how public health and social care services can best support people and provide

information services for those managing and providing health and social care” (Cancer Research UK 2015). Hence NICE is a very important organisation not only to the NHS and the British healthcare system, but just as much to the pharmaceutical industry, as “even though a country does not have an interest in launching in the UK they might still start negotiations because of NICE. NICE is one of the most remunerated agencies in the world. So what they decide is often quoted many other places in the world” (Geertsen 2015).

When looking into general characteristics of the UK one finds a system that allows companies to easily follow changes in the industries, as they are able to quickly change their strategies if the market or technologies should see alterations (Casper, Matraves 2003). This is ensured, as short-term contracts are favoured and few long-term employment guarantees are given. For top management you find unilateral decision-making and there are few requirements to how a company’s board should be organised. This means that decisions can quickly be taken and implemented throughout the organisation. Furthermore, undesired assets can quickly be discharged and new employees hired from the outside or promoted from within (Casper, Matraves 2003).

<b>United Kingdom</b>	
<b>Labour law</b>	Liberal: decentralized wage bargaining; competition clauses struck down by courts; low barriers to employee turnover
<b>Civil law</b>	Shareholder system: minimal legal constraints on company organization
<b>Financial system</b>	Capital market system: close links to the market for corporate control; financial ownership and control of firms

Characterisation of the institutional framework in the UK (Casper, Matraves 2003, p. 1871)

Oppositely when looking into the industry in the UK one finds an industry, which has for a long time been an important part of the UK. In fact one seventh of the top hundred drugs in use today all came from the UK – a record which is only surpassed by the US (ABPI 2015a). The industries high contribution to the economy is seen when looking into gross value added<sup>7</sup>. It is found that in 2013 the manufacture of pharmaceutical products and preparations stood for GBP 13.34 billion of current price gross value added (Office for National Statistics

<sup>7</sup> Gross value added “measures the contribution to the economy of each individual producer, industry or sector in the United Kingdom” (Office for National Statistics ).

2014). Thus making up about 0.8% of the total economy. Thus as manufacturing is an important element of the UK economy the pharmaceutical industry is an important player accounting for 9% of the manufacturing economy (Office for National Statistics 2014).

Further, when assessing the industry's importance to the economy the Association of the British Pharmaceutical Industry goes as far as to call it "a jewel in the UK's scientific and industrial crown" (ABPI 2015b). Associated with the pharmaceutical industry the UK not only is a leading platform in Europe when it comes to biotechnology, it also possesses many universities carrying out biomedical research (Casper, Matraves 2003). In fact about 10% of all pharmaceutical R&D is carried out in the UK (Hammett 2014). Which actually means that the UK has the third largest share of pharmaceutical R&D in the world.

All of the above overall features are important distinctive characteristics of the British healthcare system and the British society, but how do they fit with the policy measures the UK took after the financial crisis? Recalling from the previous analysis chapter the measurements the UK implemented were a price cut of 1.9% of branded NHS medicines, two VAT increases on over-the-counter medicines firstly from 15% till 17.5% and a second increase resulting in a rate of 20% and lastly the UK had on-going implementations of a Quality, Productivity and Prevention programme (initiated in 2009) (Vogler et al. 2011). But what do these steps say about the UK's capitalist system?

In the theory chapter it was explained how Hall and Soskice (2001) debated that when looking into the five spheres of industrial relations, vocational training and education, corporate governance, inter-firm relations and employees, one could determine what kind of capitalist system the country would have. As based on how a company is capable of manoeuvring and coordinating its efforts with these five spheres one can determine if the country is either a LME or a CME. However, we already know that Hall and Soskice (2001) have classified the UK as a LME. What I wish to investigate is the pharmaceutical industry specifically to see how it fits with the idea of the UK being an LME. And based on this I want to further use VoC to see if it can be used to explain the policy measures the UK took after the crisis.

<b>Characteristics of the UK and the pharmaceutical industry</b>	<b>Implemented measures</b>	<b>Characteristics of a LME</b>
<ul style="list-style-type: none"> <li>• Anglophone</li> <li>• Globally important institutional bodies e.g. NICE</li> <li>• Strong research base</li> <li>• Historically many blockbusters</li> </ul>	<ul style="list-style-type: none"> <li>• Price reduction</li> <li>• Increases in VAT</li> <li>• Quality, productivity and Prevention programme</li> </ul>	<ul style="list-style-type: none"> <li>• Anglophone</li> <li>• Neoclassical policies</li> <li>• Hierarchies</li> <li>• Competitive market arrangements</li> <li>• Radical innovation</li> </ul>

First of all, one of the important characteristics of a LME is that radical innovation is facilitated over incremental innovation. Keeping in mind that part of the definition by Hall and Soskice (2001) of radical innovation is the development of entirely new goods this goes very well with the fact that one seventh of the top hundred drugs in use today all came from the UK (ABPI 2015a). But what in the UK may be enabling the possibility of radical innovation? In fact there are several factors mentioned in the above analysis of the UK, which combined could serve as facilitators. First of all, there is the extensive science and research base including a large biotechnology sector and universities and the fact that 10% of all pharmaceutical R&D is carried out in the UK. This does create an extensive basis for innovation hubs and potential innovation corporations across different network actors. Secondly, you find an institutional system in the UK that is geared towards rapid shifts, as companies easily can change the strategies they are following due to the widespread autonomy they have been given.

Another important characteristic of a LME is the competitive market arrangements. In general Hall and Soskice (2001) define a market as an institution that is supporting relationships through arm's-length relations and high levels of competition. Furthermore, a market contains a legal system securing formal contracting and the hierarchies firms set up themselves (Hall, Soskice 2001). Thus for a LME these are the principal institutions which a firm will need to coordinate its efforts. However, how does this go with the highly important institutions in the UK? Would it not be counter intuitive for a LME to have an organization like NICE? First of all, the pharmaceutical industry is a very unique case, as governments closely monitor it. The first European directive came in the 1960s as a consequence of a drug that had



disastrous effects on unborn babies causing them to be born with deformities (Dunne et al. 2012). So to imagine any developed country, which would not have a very strict control over the pharmaceutical products within its borders would be extremely unlikely. However, when recalling what it is that NICE in fact does, it is amongst others providing guidelines, providing quality standards and assessing new drugs. These guidelines and standards do affect the entire industry and any pharmaceutical company that wishes to launch its products in the UK as to what is expected of their products. And it is an important institution that all industry actors will have to collaborate with, but that does not necessarily mean that the mere existence of NICE will increase the collaboration in between actors in the network. Furthermore, at first sight an institution as NICE may from a liberal perspective seem as an obstacle, however, it may in fact actually function as a differentiated version of comparative institutional advantage. As explained in the theory chapter Hall and Soskice (2001) see comparative institutional advantage as the advantages a specific institutional setting will be providing and will thus be leading companies to focus on activities that will enable them to benefit from this institutional setting. However, “in the UK it is more progressive which means that challenges we face here other countries will implement further down the line. When we face the challenge earlier it means we are one step ahead of learning how to face that challenge. It means for example we are ahead when it comes to stakeholder mapping” (Anonymous<sub>A</sub> 2015). Thus NICE and the institutional structures may at first sight be a disadvantage, but as stated in the quote they prove to be an advantage further down the line.

It is possible to establish a link between the UK characteristics and the overall characteristics of a LME. But how do the policy measures implemented after the financial crisis fit into this picture? When looking into the first measure of a price cut of 1.9% on branded NHS medicines the first thing to notice is that it is only on branded medicines which means generics are not affected. Which means that we can have two possible scenarios as the originator may still hold the patent, and thus no generics are in the market yet, or generics have already entered. If the branded product still holds the patent it will simply mean a price reduction, but if generics are available on the market the price reduction on only branded products may mean that the price of the generic and the price of the branded product will get closer to each other. Thus potentially increasing competition, which is a feature of LMEs.

For the second policy measure, increases in VAT on over-the-counter medicines means that the consumer will be the one carrying the extra costs of the drug. Hence this policy measure insures more money for the government, but at the same time it does not impact the pharmaceutical industry or its competitiveness. Thus this measure has less impact on how the market operates and therefore arguably it might be seen as a measure that would be used more within a LME than a CME.

The last policy measure was on-going implementations of a Quality, Productivity and Prevention programme (a programme initiated in 2009). The purpose of the programme was to make the NHS more efficient and be able to cut costs (Alakeson 2011). One side of the programme is improving the care of the patients within several focal points, the other side is focusing on the running of NHS and how it is staffed and supplied. Thus as one side is focusing on NHS staff and how to make improvements here this could possibly be an indication of a correlation with the general characteristics of LMEs. As there within LMEs are fluid labour markets and short-term employment (Hall, Soskice 2001). Furthermore, unionisation is less prevalent than within CMEs.

#### **4.3 Denmark**

In 2013 the pharmaceutical value market in Denmark was approx. EUR 2.1 billion thus making it one of the smaller markets within the EU (Statista 2015). Nonetheless, from a Danish perspective the pharmaceutical industry is highly important, as in 2013 the total value of exported pharmaceuticals was DKK 71.3 billion (Drug Development & Delivery 2015). Thus making it one of the industries contributing the most to Danish exports as it accounted for approx. 11.4% of total exports. In fact in Denmark you find Medicon Valley, which is one of Europe's strongest life science clusters (Medicon Valley a). In Medicon Valley one finds more than 200 medtech companies and more than 100 biotech and pharmaceutical companies (Medicon Valley b).

First of all when accessing the Danish healthcare system it is important to notice that it is mainly taxes that are financing healthcare (Kristensen 2015). Taxes are used to cover expenses for general practitioners, specialists, hospital admissions, reimbursement of pharmaceutical treatment and the like. As the healthcare system is publically financed it is vital to look into Danish institutions responsible for this area. One can divide the institutions

into a national, regional and local level. At a national level the starting point is the Ministry of Health. The ministry consists of several departments, however, three that are of particular interest are the Danish Health Authority, the Danish Medicines Agency and the Danish Patient Safety Authority. These three authorities are important, as they are decision makers within the healthcare system (Kristensen 2015) (see appendix I, figure IV, p. 89 for an overview).

In connection with my study the Danish Medicines Agency is particularly interesting, as this is the agency that decides which drugs should be reimbursed. A decision which is naturally based upon many factors, however, when a company seeks to acquire reimbursement it is important that it is able to show that the drug has a clear and valuable effect on a specific symptom (Kristensen 2015). However, the agency does not take such a decision alone but relies on help from the Reimbursement Committee.

Another, important task that the agency has is that the agency is the one being notified of the price that a pharmaceutical company wants to sell its drug to the pharmacies for i.e. the pharmacy purchasing price (PPP) (however, over-the-counter products are not required to do so) (Kristensen 2015). This in fact means that Denmark has free pricing, as a pharmaceutical company does need to be granted permission for a specific price, as there are in fact no rules to comply with. However, prices are only fixed for a two-week period to ensure an intense competition. Which means that every two-weeks companies can report to the Danish Medicines Agency if prices have changed. Thus the Danish free pricing system may at a first glance seem very unrestricted. However, it does not mean that pharmaceuticals holding a patent can therefore simply let their prices be sky-high, as the Ministry of Health in fact do have an agreement with the Danish Association of the Pharmaceutical Industry. Through this agreement the Ministry of Health is thus able to control some prices (Møller Pedersen 2003).

At a regional level the Coordination Council for Placing in Service of Hospital Medicine (KRIS) and the Danish Council for the Use of Expensive Hospital Medicine (RADS) are also highly important actors from the industry's perspective (Kristensen 2015). KRIS has a focus on the hospitals as it evaluates which new drugs should be available as standard treatments there. RADS, on the other hand, especially has a focus on expensive medications or medications with high growth potentials, as it gives recommendations to the regions regarding these medications that could prove to be very costly.

When looking into the general characteristics of Denmark one finds a system that is based on the idea of the welfare state. The concept of the welfare state is also found within the Danish healthcare system, as it is based on ensuring universal access to healthcare for all citizens. In regards to pharmaceuticals the current Minister of Health, Sophie Løhde, has argued that Denmark should have a world-class healthcare system and in order to achieve it one should not shy away from the newest medications even though they may be expensive (Richardt 2015)<sup>8</sup>.

According to the Danish Ministry of Foreign Affairs key advantages of the Danish business environment include little bureaucracy, a flexicurity model and a well-educated population (Ministry of Foreign Affairs ). I will not elaborate on the last point, but the first point is also supported when looking into the pharmaceutical industry, as Denmark is very fast at approving new drugs (Brevig 2015, Agus 2015). In fact in Denmark it takes between six and twelve months where the US average of approving a new drug is 322 days and the EU's is 366 days (Drug Development & Delivery 2015). As for the second statement it goes that the Danish labour market has a flexicurity model. This model is additionally known as the "golden triangle" (Ministry of Employment ). It is known as the golden triangle as it includes three important aspect that makes the Danish labour market flexible. Firstly, it is easy to both hire and fire employees. Secondly, a security net is provided as employees are secured an income in case they should be fired. Lastly, that the government leads an active employment policy ensuring if an employee should lose a job there will be help getting a new job, offers of extra education and the like (Ministry of Employment ).

As I wish to analyse the Danish case from the same perspective as in the UK analysis I will firstly look into whether or not there may be indications that the above Danish characteristics fit the overall idea that Denmark has been classified as a CME. Secondly, use VoC to see if it may be able to explain why Denmark has opted for the policy measure it has.

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<sup>8</sup> This discussion came up with the newly launched drug Orkambi, which could be used in the treatment of cystic fibrosis. The problem with the treatment is that it would cost around DKK two million per patient per year (Richardt 2015).

Characteristics of DK and the pharmaceutical industry	Implemented measures	Characteristics of a LME
<ul style="list-style-type: none"> <li>• Life science cluster</li> <li>• Several institutions</li> <li>• Free pricing system</li> <li>• Welfare state</li> <li>• Publically financed healthcare system</li> <li>• Little bureaucracy</li> <li>• Flexicurity model</li> </ul>	<ul style="list-style-type: none"> <li>• Increases in co-payments regarding fertility products</li> </ul>	<ul style="list-style-type: none"> <li>• Non-Anglophone</li> <li>• Social democracy</li> <li>• Social/political institutions take action</li> <li>• Strategic interaction</li> <li>• Incremental innovation</li> </ul>

In the characteristics of Denmark and the pharmaceutical industry there is much that supports the general idea within CMEs that strategic interactions are preferred over competitive forces. You find a large scaled life science cluster and several institutions/agencies focused on the pharmaceutical industry. And even though one finds free pricing you still see the Ministry of Health having set up an agreement with the Danish Association of the Pharmaceutical Industry through which medicine prices can be controlled. This does to some degree testify of a society in which corporation and strategic interactions are valued.

Further related some of the main characteristics found within Denmark are the welfare state and the fact that the health care system is publically financed. This similarly supports VoC in assessing Denmark as a CME, as it speaks towards a system in which political institutions have direct involvement and take a very active role.

What may seem rather puzzling is the fact that you find free pricing of medicines and the flexicurity model within a CME. Would this not be more anticipated within a LME? The free pricing principle is market oriented and it does create a very competitive environment in which prices can be driven down. But at the same time it is not as completely unrestricted as it sounds, as there is an agreement in place which grants some control over how high prices can be. Nonetheless, this pricing principle leaves Denmark in a bit more of an ambiguous position as it is market oriented. Regarding the flexicurity model it may make it easy to fire

people, but at the same time it also means that it is easy to hire people. Additionally, individuals are insured an income while they are unemployed and many state initiatives are in place in order to make it easier to get a new job. Thus the fact that it is easy to fire people may on its own speak towards the structures of a LME, but considering the initiatives in place to help the employees that do get fired this speaks more towards a CME.

Thus overall when looking into the pharmaceutical industry and Denmark it does point towards CME characteristics rather than LME characteristics being present. However, with the pharmaceutical industry in the UK I did find indications for why radical innovation may exist. But what about Denmark? How does an innovative industry such as the pharmaceutical fit with the idea that CMEs facilitate incremental innovation? Would it not be natural to assume that an industry such as the pharmaceutical would always be generating radical innovation? Through my interviews I have found that this may not necessarily be the case. M. Geertsen (2015) when asked to describe the pharmaceutical industry in Europe in five short sentences mentioned “only low and incremental innovation” as the third point. This is further supported by T. Wærner (2015) who replied to the question of whether or not Europe is an interesting market to launch a new products that “it can be. For a company like Lundbeck it is extremely difficult as it is difficult to come with radical innovation within our area. So we are being scrutinised as we are focusing on incremental innovation” (Wærner 2015). Thus even within the pharmaceutical industry one can find incremental innovation as for example it is the case of H. Lundbeck A/S in Denmark. Hence giving support to the claim of VoC that CMEs facilitate incremental innovation.

In general, the characteristics of Denmark and the pharmaceutical industry supports the ideas set forth within VoC. However, as there is only one policy measure it is very difficult to attempt to analyse the correlation between policy measure and capitalist system. However, it can be mentioned that when it comes to Assisted Reproductive Technology (ART) treatment Denmark has been a leader within research, as it is much easier to find patients that are willing to participate if the treatment is for free (Ziebe 2010). Thus the policy measure may in fact decrease collaboration between different stakeholders. As there within CMEs is an emphasis on a collaborative environment this action may speak against the action of a CME.

#### 4.4 Interim Conclusion

Throughout the chapter I attempted to find support for the VoC framework when focusing on the pharmaceutical industry. In general, the main characteristics of Denmark and the UK found seem to indicate that when it comes to the pharmaceutical industry it supports the VoC framework. One of the academic criticism points of VoC in the theory chapter is that it puts too much emphasis on the fact that LMEs generate radical innovation and CMEs incremental innovation. Considering the pharmaceutical industry, one might expect to find an industry that would always generate radical innovation. However, one industry representative noted that one of the problems of H. Lundbeck A/S is that it focuses on incremental innovation. Thus in fact supporting the claim of Hall and Soskice (2001) that CMEs may in fact have a structure that puts an emphasis on incremental innovation. Additionally, VoC was used to try to explain if Member States' different reactions may be embedded in their capitalist systems. Overall, in the UK it was found that there might be some evidence that the policy measures implemented have traits that are more consistent with a LME than a CME. For Denmark, only one implemented policy measure was found. It is difficult to say if policy measures can be said to be more consistent with CMEs or LMEs, when there is only one policy measure to consider. However, the fact that there only was one implemented measure may on its own tell a story. Nonetheless, it would take a further in-depth analysis of Denmark to evaluate if Denmark simply has been more progressive and already has implemented measures before the crisis that other countries implemented after the crisis. Or if Denmark legislatively provides less restrictions for the industry. Before that one policy measure or the lack of policy measures can be seen as consistent with the structures of a CME or a LME.

## **Chapter 5: Analysis Part Three**

### **5.1 Introduction**

Throughout the two previous analysis chapters I have investigated how European governments' policies towards the pharmaceutical industry have changed after the financial crisis and I have used VoC on the results. Not only to extract some patterns for ways of reactions but furthermore to see if the findings could provide some support for the use of VoC on the pharmaceutical industry. Additionally, I have made an in-depth analysis of two countries representing a LME and a CME to further investigate if the characteristics of these two countries would support the overall ideas set forth in VoC. And the other way around if VoC could be used to explain the specific implementations these two countries had applied. Hence, until now the focus of my paper when trying to assess the current state of the European market attractiveness has been on the financial crisis. For my last analysis chapter, however, I wish to examine if there could be other factors within the European market that combined with the financial crisis could explain the pharmaceutical industry's situation in Europe. In doing so I will be using GPN as the overall framework i.e. use the key actors as my structure. As for the content I will mainly be relying on my interviews in order to present the challenges as the industry representatives see them.

### **5.2 National Governments**

One of the main issues seen by many of the industry representatives is the European reimbursement system (Nylander 2015, Geertsen 2015, de Jong-Laird 2015). As already discussed some policies such as the approval of a compound have been centralised within the EU, whereas others such as pricing and reimbursement policies are still up to the individual Member State (Vogler et al. 2011). Until now this has only been taken as a fact regarding the environment the pharmaceutical industry finds itself within in Europe. But how does the industry see the fact that each country is in charge of its own pricing and reimbursement policies and what might the consequences be? First of all, it is an advantage that you can get the EU marketing authorisation giving you approval in all countries. But the problem is that the true battle lies after receiving this, as you as a company do not know if the individual countries will grant you reimbursement (Nylander 2015, de Jong-Laird 2015). Thus after getting access to the EU you will have to negotiate price and reimbursement with each of the individual 28 Member States making it a complicated system (Geertsen 2015). And not only do you have to cope with different the Member States, you furthermore have to deal with the



different regions within the Member States e.g. the Basque Region in Spain (de Jong-Laird 2015). But why does it matter that pharmaceutical companies will have to negotiate with each country? First of all, you see a trend that companies are shying away from the EU, as they have to fight over the price (Agus 2015). Secondly, negotiating with a country is expensive which means that for small countries with a limited amount of potential customers the reimbursement negotiations may simply not be worth it compared to the potential earnings (Geertsen 2015). Unless the company has a headquarter in the country, as for instance H. Lundbeck A/S in Denmark, as the price you are able to get in your home market is important, as to the price you will be able to get in markets outside of the EU (Geertsen 2015, Schroll 2015). Thirdly, related to the fact that small countries may not necessarily be economically valuable to launch a new drug in is the fact that small countries may not be in a good position to negotiate over the price (Geertsen). Despite the fact that Germany is the most valued pharmaceutical market in Europe some drugs are not brought to the market or have even been removed from the market, as there simply was not a financial incentive to keep them there or launch them in the first place (MarketLine 2014, Geertsen 2015, Strandberg-Larsen 2015). As products are in fact being removed from the German market despite of its significance and size it indicates that small countries cannot afford not to pay a premium price, if even in much larger markets with many more potential users there are not enough incentives to be present with those specific drugs (Geertsen 2015).

The price that a pharmaceutical company will be able to get in a country does not only have to do with the negotiating costs mentioned above or the concept of external price referencing from the first analysis chapter. There is a whole other problem as well, which is parallel trade. Parallel trade is “the legal repackaging and reselling of genuine, non-counterfeit drugs” (Pharmaceutical Technology 2013). This means that Member States that are able to buy drugs cheaply can resell them to other Member States for higher prices due to the abolition of trade tariffs on goods (Pharmaceutical Technology 2013). However, this means that if the price that a country is willing to pay for a drug falls below the set threshold by the company, the company will not be able to sell the drug to the country. As it otherwise risks its products being sold via parallel trade to other countries that would have been willing to pay a higher price (Brevig 2015).

From the governments perspective they, however, have to balance their budgets. Thus it is an important issue that the budgets available for pharmaceuticals are not isolated from the other budgets that a government has to balance. Governments have to balance their budgets even between pharmaceuticals deciding which drugs to spend their money on (Agus 2015). Hence when it comes to the current environment that the pharmaceutical companies find themselves within in Europe there are many challenges according to the industry representatives. However, a problem such as the fact that governments will have to balance their budgets will never change. However, the way pricing and reimbursement work within the EU currently may change in the future.

### **5.3 European Union vs. Insurance Companies**

In the GPN theory the EU and insurance companies would represent each their element with the EU being part of macro structures and insurance companies being part of the pharmaceutical companies' network. The reason why they have been put together is that they represent two different scenarios, as to how the pricing and reimbursement challenges associated with individual governments may be addressed in the future. When asked of the future of the pharmaceutical industry in Europe in general three different outcomes were identified: 1) Even stricter regulation, 2) one unified European reimbursement system or 3) an individual insurance system (Brevig 2015, Geertsen 2015, Strandberg-Larsen 2015). Firstly, one potential future for the pharmaceutical industry in the EU is an industry, which will be subject to even more strict regulation. Potentially leading to a Europe which will see few and even late entries of new drugs (Brevig 2015). The second option is that a centralised pricing and reimbursement system will appear in the EU (Geertsen 2015). Thus meaning, as companies will not have to negotiate with 28 Member States, costs will be reduced vastly and that being a small country will not be an issue, as the potential number of users would not be counted per country but combined within the EU. Not everyone, believes it will go as far as to be one completely centralised pricing and reimbursement system, but suggests in hypothetical terms, that possibly some overall agreements will be made at a European level (Strandberg-Larsen 2015). Thus allowing for adjustments on a national level. This could potentially mean that countries that would be similar or have similar economic settings would cluster together. The third potential scenario we might see is the appearance of an individual insurance system (Brevig 2015). This might happen if more and more patients within the EU

do not have access to the newest medication (Strandberg-Larsen 2015). Regarding this scenario there are still two uncertainties to keep in mind. First of all, with the norms and values vested in how Member States see their healthcare systems will they allow for an insurance based system to emerge in which the state does not play an active role (Schroll 2015)? Secondly, it is uncertain if pharmaceutical companies would see the emergence of a private insurance system as an incentive to launch (Geertsen 2015). That may depend on the size of said private insurance market.

#### **5.4 Patient Groups & Political Pressures from Society**

A completely different obstacle that the industry representatives put an emphasis on is the fact that different kinds of medications have different levels of difficulties in getting reimbursed. When it comes to medication, which focuses on areas with a high mortality for the country sensitive population ie. the working and/or young population one finds that these types of medication has a less of a challenge (Wærner 2015). However, the degree as to how hard it is for a drug to get reimbursed does not always come from what is economically best for a country (Brevig 2015). Rather it can stem from push from patient groups. If looking into oncology in the UK one finds that many cancer patient groups and funds exist which means that medication within oncology has extra opportunities of getting to the market (Schroll 2015). In fact one finds that if the public decides that it will not reimburse a compound these cancer funds might step in and reimburse it regardless (Strandberg-Larsen 2015). Thus enabling medication within this disease area to have an alternative route to the market. However, the problem with this is that you have other disease areas where patients and their relatives are less capable of creating political pressure, which means that it for the politicians is easier to say no to drugs within these disease areas (Nylander 2015). Meaning that you have disease areas where the specialised medication is just as expensive to develop, as the oncology treatments, however, they may be much harder to get reimbursed (Anonymous<sub>B</sub> 2015). A potential consequence could be that some disease areas will lose research (de Jong-Laird 2015). Furthermore, areas where medications already exist similarly have a higher challenge (Wærner 2015). However, the fact that medications already exist does not necessarily mean that these treatments are particularly good.

## 5.5 Pharmaceutical Industry

Besides the already mentioned points the industry representatives mentioned several other arguments related to the companies themselves and the industry in general. This has the impact that not only criticism towards the surrounding environment is given but likewise criticism and ideas for the industry itself to improve. The first point is in relation to pharmaceutical companies and value proposition. If we go ten years back in time it started being considered that value proposition should be defined already in R&D i.e. very early in the process of the drug development (Geertsen 2015). However, not a lot has changed in this area since then, as the pharmaceutical industry is a slow moving industry. To people in the industry this can be perceived as disappointing compared to other industries that are moving faster (Geertsen 2015). Related to the value proposition of a compound is what kind of innovation it represents. H. Lundbeck A/S focuses on diseases in the central nerve system, which is an area in which it is difficult to create radical innovation (Wærner 2015). However, it may be a general trait of the pharmaceutical industry in Europe that it focuses on only low and incremental innovation and thus has no breakthrough innovation (Geertsen 2015). As already stated governments have to weight their budgets, meaning that if they have a choice between a radically new treatment that may either completely cure a disease or even make extinct a disease or a new drug with incremental value meaning it might cure some symptoms for a disease in which you already have treatment governments will choose the former (Agus 2015). In fact governments are afraid of disease mongering due to their limited budgets. But the fact is that pharmaceutical companies are aware of the fact that governments have limited budgets and cannot spend endless of amounts of funds on pharmaceuticals. Hence it is the responsibility of the companies to bring to the market drugs of radical innovation instead of simply relying on creating incremental innovation.

Furthermore, and not just related to what kind of innovation the industry is focusing on is what kind of business model it is based upon. The current is based on developing a drug, obtaining market access, getting the right price and then take it from there (Anonymous<sub>A</sub> 2015). However, the pharmaceutical industry currently finds itself within a limbo in which it needs to reinvent itself, as the current business model cannot go on (Annfeldt 2015). The industry needs an optimised business model in which costs can be brought down but where the industry can still create profits even though the revenues may be smaller (Schroll 2015).

In general the industry needs a more creative approach, which allows it to move beyond the pill (Anonymous<sub>A</sub> 2015, Agus 2015).

The last point has to do with competition in between companies in general, as it is very much an era of generics (Anonymous<sub>A</sub> 2015). Generics are much cheaper than the original compound and hence mean that governments are able to save much money by using these. However, one has to remember that generics do not bring new medicines and hence new treatments to the market (Annfeldt 2015). This combined with the fact that Europe is no longer focused on getting the best treatment but rather the cheapest makes it additionally difficult for the pharmaceutical industry (Schroll 2015). As Europe is willing to pay much less than the US for the same medication this means that the incentives for pharmaceutical companies to bring drugs to the European market have decreased. This trend of trying to limit public expenditures by focusing on the medicines expenditures is worrisome to some industry representatives, as it is seen as governments taking the easiest way without assessing what may be the best for the treatment of the patient (de Jong-Laird 2015). Nonetheless, it is much easier to limit public expenditures when it comes to medicines compared to services, as it only requires the stroke of a pen (Anonymous<sub>A</sub> 2015).

## 5.6 Interim Conclusion

Throughout the chapter it was found that there are several areas within both the environment of the EU and within the industry itself that the industry representatives found challenging and troublesome or in need of improvements. The main difficulty mentioned was the fact that pharmaceutical companies have to negotiate price and reimbursement with each Member State as it is a very costly process and may not necessarily be worth it, if either the price they can get is too low or if the potential amount of users is too small. Potential solutions may be the emergence of a centralised price and reimbursement system or an individual insurance system. Another issue found is that some diseases are more “popular” when it comes to gaining support, and thus companies focusing on these disease areas will have an easier time making a return on their investment. Lastly, it is problematic for the industry that it is an era of generics and that Europe is not seeking the best possible treatments but the cheapest. However, the industry itself carries a responsibility when it comes to generating radical rather than incremental innovation, as governments must be expected to wish to spend their

limited funds on medication that does not simply carry incremental value, if the choice is between radically new medicines and medicines with a incremental value proposition

## Chapter 6: Discussion

It has been found that not only a few but several policy measures to contain governments' medicines health expenditures were implemented during the period of 2010 till 2011. And furthermore, that in fact 22 out of 33 European countries have implemented one or more measures. The idea that governments should try to control its expenditures when it comes to pharmaceuticals is not new and neither are the concepts of how it can be done. However, a new wave of reforms hit Europe as vast amounts of countries decided to control and limit their expenditures in the immediate aftermath of the crisis. In total 90 policy changes took place within the 14 months Vogler et al. (2011) analysed and several policy measures were used. The policy measures used included price reductions, changes in the VAT on medicines, changes in co-payments and external price referencing. Thus governments have a long list of parameters available when trying to limit their expenditures either by simply decreasing the price they are willing to pay for a drug, trying to ensure a higher penetration of generics, increasing the amount that patients will have to pay themselves and so forth. Thus from the amount of policy changes that occurred after Europe fell into recession in 2009 it can quite clearly be seen that the financial crisis did have an affect on European governments' policies towards the pharmaceutical industry.

When applying the VoC framework to the 90 policies that were implemented from 2010 till February 2011 it was found that LMEs accounted for 7 policy measurements, CMEs for 22 and mixed markets for 31 (Eastern Europe accounted for 30 implemented measures). However, when taking into consideration how many countries are within each category it was found that for LMEs there were 3.5 policy measures found per country, for CMEs this number was 3.14 and for mixed markets 4.43. Thus revealing that CMEs in general implemented the least policy measures within the analysed period. However, additionally it was found that when comparing the three most used measures by CMEs and LMEs they had not used the same measures. Furthermore, mixed market shared one of the measures the most used with CMEs and one with LMEs. Looking at the result in this way does give an indication of support for the ideas presented within VoC that CMEs and LMEs would have different characteristics and different structures leading to different ways of reaction. However, what one would additionally have to consider is the fact that there could be other factors playing an important part, as to why some countries have implemented more measures than others. First of all, it

should be considered that some countries simply are more progressive when it comes to legislation aimed at the pharmaceutical industry. Meaning that some of the measures that other countries have been implementing after the recession others may have implemented even before the crisis started. Secondly, some countries may have a strong pharmaceutical industry in place, which may be influential enough and may have spent high amounts of money on lobbying efforts attempting to favour the industry. Thus meaning that if we do not see that many policy measures in a country could it be because the country has a powerful pharmaceutical industry itself? Or could there be other powerful stakeholders trying to further their interests? Lastly, one might also want to consider corruption as an explanatory factor in some countries. Especially with the Greek example in the first analysis chapter there was a focus on how corruption may for example have favoured some products. All of these examples of additional factors could play an important part as to why we see the policy measures being implemented within the timeframe that we do. Therefore, it could be beneficial to look into each country over a much longer period of e.g. 10 years to see, based on this larger timeframe, if the same trends of LMEs and CMEs preferring different policies when it comes to the pharmaceutical industry seen within the Vogel et al. (2011) study are seen here as well.

In my study I conducted an in-depth analysis of Denmark and the UK as they represent a CME and a LME, respectively. There were two main reasons for this. First of all, VoC has been criticised for the fact that it says that within LMEs there will be a focus on radical innovation and within CMEs there will oppositely be a focus on incremental innovation. As it is seen by some as being too simplistic a version of the reality. However, as the pharmaceutical industry lives off innovation and creating new drugs I thought it would be interesting to see if one within an industry in which it should be expected that one would find radical innovation rather than incremental innovation, still would be able to see some distinctions of more radical innovation within LMEs and incremental within CMEs. In general, the overall characteristics of the UK and Denmark and the characteristics I identified when it came to the pharmaceutical industry did fit with what one might expect to find within a LME and a CME. Furthermore, what is quite interesting is that some industry representatives did mention incremental innovation when interviewed and describing the current state of the pharmaceutical industry in Europe. Furthermore, one pointed out that for H. Lundbeck A/S it



is difficult to create radical innovation within their area. This does give some support to the claim of VoC that one can expect to find incremental innovation even within the pharmaceutical industry and very likely within CMEs, as both industry representatives mentioning this problem come from the Denmark. However, the fact that they come from the same country and in fact the same disease area causes one to suspect that there is a chance that it is either this company, within this disease area or within this country that incremental innovation is found. Therefore, in order to fully be able to support the claim of VoC one should firstly analyse other companies in Denmark focusing on other disease areas to see if they in fact similarly generate incremental innovation. Furthermore, analysing other CME countries within Europe to see if the same result is found.

Secondly, VoC was used in the context of an analysis of two countries in order to see if it would be possible on the basis of their capitalist systems to make some explanations, as to why the two different countries have implemented different measures. Thus to try to find if explanations to different reactions could be embedded in differences in their capitalist systems. When looking into the UK first there were some overall ideas that the UK's choice of price reductions, increases in VAT on over-the-counter medicines and implementations of a Quality, Productivity and Prevention programme might fit more with a LME than a CME. However, when it came to Denmark only one policy measure was implemented i.e. increases in co-payments regarding fertility products. However, the fact that Denmark only made one policy change within the analysed period may in fact say something on its own. Possible reasons as to why Denmark only implemented one measure could either be that Denmark has been very progressive and thus had strict regulation towards the industry in place before the crisis, or simply that Denmark has a freer environment when it comes to this particular industry. Nonetheless, it would take a larger analysis of Denmark in order to establish which stories the lack of measurements may reveal about its capitalistic system.

However, besides seeing the implemented measures in regards to VoC it is important to evaluate how critical these changes are seen in the industry, and if there are other factors, which could help explain the current situation of the European market attractiveness when it comes to pharmaceuticals.

In general when the industry representatives were asked if they could name some advantages of selling drugs to European nations they struggled. They would mention the size of the market, the knowledge base, overall wealth of Europe and so forth, but overall they had a much easier time listing challenges to the European market. One of the main challenges that was listed is the fact that price and reimbursement has not been harmonised between Member States, which means that pharmaceutical companies are faced with 28 different systems and 28 different negotiations. A negotiation can be a costly process and if the market is too small within that country i.e. the number of potential patients that would be able to benefit from the drug is too small revenues may not be high enough to consider launching the drug in that country. Furthermore, it puts pressures on smaller countries to pay a premium price, as it has already been seen that products are being pulled out of or not even launch in Germany, which is considered Europe's biggest market. If there is not enough financial incentive to launch in Germany how should small countries be able to attract the newest drugs without being willing to pay the premium price? The consequence may be that we will see a distortion within Europe with some populations having access to several choices and to the newest available medication, whereas we will see others with a much more limited offer.

When it comes to the price that a country is willing to pay for a compound there is more to consider than solely the size of the country. Two other key terms that are highly important are external price referencing and parallel trade. External price referencing meant looking at other countries seeing what they would be willing to pay and then deciding a price yourself. Parallel trade focuses on the fact that Member State can resell compounds to other Member States, carrying the problem that if a company sells its drug cheaply to one country other countries can buy the drug from this country at a cheaper price. This means that as the countries are so interlinked the price that a company sells its drugs for in one country can have an enormous impact on what it will be able to generate of earnings in another. Therefore, if a company should compromise on its price in one country it could mean it would have to do so in many others as well.

A further problem with the price reductions is the fact that a company may hold a patent for 20 years, but it is only able to generate revenue during the last 8-10 years after it has been launched. As soon as the generics hit the market after the patent has been lost the company

faces an extremely severe level of competition. Thus it can be challenging if governments try to reduce the potential revenue that a company can earn within the years before the generics enter the market (Anonymous<sub>B</sub> 2015).

The distortion previously mentioned between Member States may not only be seen in between countries but also within countries. Such a distortion could be seen if medication is not made available through the healthcare system, but if patients have to rely on own income or private insurances. This could potentially create A and B teams with the more vulnerable groups in society being affected the most by governmental cost containments. Potentially further increasing the span between population groups.

A third distortion that may be seen is not solely between countries or between population groups but between disease areas. Some disease areas such as cancer are fortunate to enjoy the backing of strong patient groups and funds and overall have a strong network that aids in generating powerful public pressures. Making it much harder for politicians to say that they will not reimburse a new compound within oncology. Whereas other disease areas may be lacking this ability to generate such pressures, which means that it will be more likely that politicians will have an easier time to say no to new medication within these disease areas. Meaning not only that some patient groups will have access to less medications, but furthermore that some disease area may lose research if companies decides to use their efforts where reimbursement is easier.

The overall impression from the industry representatives was that we are currently seeing a Europe that is trying to get medications as cheaply as possible. But might the industry be over exaggerating? Is the industry in fact just whining trying to look out for its own revenues and interests? When assessing the above there is no doubt that the industry is facing a difficult time in Europe with many barriers and challenges. And that European governments cannot expect to be able to buy the newest drugs cheaply considering how expensive it is to develop a new compound. However, at the same time the industry knows that governments have limited budgets. There is nothing new or ground breaking about this fact. Furthermore, this will not all of a sudden change in the future, as governments will continue to balance expenditures within several sectors, as they are currently. The question then is if knowing this you can still expect a government to pay a premium price for incremental innovation? Rather

would it not be very plausible that if a government has access to a good drug that for many patients can be very helpful and that it can get cheaply compared to your new drug that it would go for the former? There is no doubt that the pharmaceutical industry has a difficult time foreseeing the future landscape considering how many years out in the future it can be before initial drug processes started today will reach the market. However, they do have a responsibility to bring to the market drugs representing radical innovation and a big difference, if they should expect governments to pay a vast amount of tax money on this drug. The problem can be that after you have launched a blockbuster it means ages of good life for you as a company, which may mean that some companies start relaxing or they may put all their efforts into finding a new drug related to the blockbuster they have just launched trying to replicate the success; the sleeping bear syndrome (Geertsen 2015). However, if a company puts all its efforts into developing a drug which is similar to an already existing blockbuster, it means that they are focusing on incremental innovation instead of using their resources focusing on satisfying new unmet needs. Thus meaning that the industry cannot simply blame governments for the current situation, as it is an expected requirement that the industry should be developing drugs that the governments and the patients in fact have a strong and unmet need for.

Summing up the industry representatives see many challenges of different characters within the EU. Some are solely related to the environment set up by the European governments and the EU such as the national pricing and reimbursement systems. Others are more targeted at the industry itself focusing on the responsibility it has for ensuring that value proposition is part of the early stages of the development of a drug and that the industry does simply not just rely on incremental innovation. When it comes to the policy measures implemented from January 2010 till 2011 there is a general consensus among the industry representatives that these policy changes by no means are making it any easier for the industry. But that there are other problem areas such as the reimbursement system which may be even more prevalent, when it comes to accessing the market attractiveness of the European market.

## Chapter 7: Conclusion

The aim of this study was to analyse how European governments' policies towards the pharmaceutical industry might have been affected by the recent financial crisis and furthermore to analyse if the financial crisis might be the main explanatory factor as to the current European pharmaceutical market attractiveness or if there may be other reasons.

I have found that the financial crisis did have a vast impact on governmental policies, as in fact 22 out of 33 European countries in between January 2010 and February 2011 implemented 90 measures in total. Measures used to contain pharmaceutical expenditures included price reductions, external price referencing, co-payments, reference price systems and the like. When using the VoC to analyse whether or not a pattern could be attracted from the many countries that implemented policy measures it was found that mixed markets such as Greece and Spain on average implemented the most policy measures with an average of 4.43 per country whereas CMEs implemented the least with an average of 3.14 per country. When looking further into Denmark and the UK to look into the different settings that the pharmaceutical industry finds itself within in different European countries it was found that even though I was analysing a highly innovative industry the general characteristics found within each country and the characteristics of the pharmaceutical industry did align with the general definitions of LMEs and CMEs, respectively. Thus giving support to the fact that even within an industry such as the pharmaceutical VoC is applicable. Furthermore, I looked into the policy measures Denmark and the UK applied within the timeframe of January 2010 till 2011 attempting to analyse the policy measures on the basis of VoC. When analysing the measures from a UK perspective there may be some indications that the policy measures could be more in line with how one might expect a LME to react. When assessing the policy measures implemented in Denmark there was in fact only one measure that was implemented within the given period. Therefore, it is very difficult to say if the action may speak towards what one might expect of a CME. However, the fact that Denmark only implemented one policy measure could tell a story on its own, as it could potentially mean that Denmark has a more progressive environment and had implemented stricter regulation long before Europe fell into recession. On the other hand, Denmark does have a free pricing system thus one might expect an opposite scenario in which Denmark simply represents a less restrictive environment. Thus if one were to make further investigations it may be found that the lack of

measurements may thus mean that an alignment within the characteristics of a CME or a LME might be found.

When considering the fact that it takes 10-12 years to develop a new drug, the company can only hold the patent for 20 years and that we have an era of generics which means that as soon as the patent is lost revenues will drop immediate it means that the companies are very dependent on the 8-10 years where the company has the possibility to make a return on its investments on this new drug. When thrown into the picture the fact that governments wish to contain their expenditures and do so through various measures it means that the pharmaceutical companies are being squeezed even more within the timeframe where they have to ensure they can make a return on their investment and secure funds for new developments in R&D.

However, there are more challenges to the European market than the pharmaceutical policies after the crisis. A main problem is the fact that Europe does not have one unified pricing and reimbursement system, which means that companies will have to negotiate with 28 Member States. As this can be a very costly process and if countries are then not willing to pay a premium price for the compounds it may mean that some countries, especially smaller countries with a smaller potential market, will not gain access to the newest medication. Further challenges within the EU are the fact that as the EU is a union of countries it means that countries have become more integrated and linked. Thus if a country wishes to pay a price that falls beneath their threshold the company cannot sell its compound for reasons such as parallel trade. Lastly, some disease areas are better at generating public support and backing from funds, which means that some disease areas may lose research if they have a harder time than others in getting reimbursed.

In general, we are witnessing a EU that seeks to get medication as cheaply as possible and with many challenges to entering the market. This has the consequence that many pharmaceutical companies no longer prioritise Europe. They might still launch in Europe due to its size but it will not be the first place they launch. Thus we may see a Europe with either few or very late entries, which could mean we might see a private insurance system as a solution if the European population wishes to be secured access to the newest treatments. Furthermore, we might see changes in the European structure with the emergence of a

unified pricing and reimbursement system, which would make it easier to launch a new compound in Europe.

Overall, the pharmaceutical policy changes that came along after the recession have made it harder for pharmaceutical companies in Europe, however, there are many other factors which means that the European market is not very attractive in the eyes of the pharmaceutical industry. The main problem seems to be the fact that Europe has 28 different price and reimbursement systems. However, one has to keep in mind that the industry does carry a responsibility of generating drugs of radical innovation rather than simply relying on making incremental innovation to already existing products. As governments with limited budgets cannot be expected to spend vast amount of money on a new drug of incremental value if they have an effective generic at a much lower price. It will be interesting to see the future pharmaceutical landscape in Europe and see if Europe may move down the path of one unified price and reimbursement system or if we will see something closer to the American model of private insurance.

### **Other Perspectives**

First of all, I could have looked further into the theoretical framework of VoC and the fact that VoC excludes Eastern Europe from its studies (Nölke, Vliegenthart 2009). Thus an interesting point could be to analyse Eastern European countries in order to understand how they fit into the overall ideas of LMEs or CMEs. Moreover, considering theoretical apparatuses it furthermore could be interesting to look into theories classifying healthcare systems in order to analyse whether or not one could use set identified types of healthcare systems when analysing which pharmaceutical policies have been implemented in the different countries (Wendt, Frisina & Rothgang 2009). Wendt, Frisina and Rothgang (2009) establish 27 different kinds of healthcare systems on the basis of the dimensions financing, provision and regulation of healthcare.

Further, it could have been interesting to analyse several trends within the pharmaceutical industry. First of all, there is this consensus that the current business model within the pharmaceutical industry cannot continue and that the industry needs to reinvent itself. Thus it could have been very interesting to analyse which potential business models that the

industry could be opting for and how it may change the way we do healthcare. This could be areas such as the idea of beyond the pill or e-health.

Secondly, we are currently seeing a trend in which pharmaceutical companies are moving towards developing drugs that are more specialised and effective. This means that a smaller group of patients will be targeted and be able to benefit from the treatment. However, this further means that the treatments will be extremely expensive, as you will only have a small patient group that should pay for the development of the drug (Werth 2013). What is extremely interesting about this trend is how we as a society view it. When should a society say that we have to draw the line? Governments have limited budgets and they will not change unless we increase taxes so the whole idea is how we utilise the funds within society the best. But how do we define what you as a citizen should have the right to expect treatment for and how do we define the value of life and life quality?



## Bibliography

- Aarhus Universitet 2014, 11/21/2014-last update, *Triangulering*. Available: <http://metodeguide.au.dk/metodeguiden-i-religion/generelle-metodiske-overvejelser-og-problemstilinger/triangulering/> [2015, 11/21].
- ABPI 2015a, , *Industry achievements*. Available: <http://www.abpi.org.uk/industry-info/achievements/Pages/default.aspx> [2015, 12/25].
- ABPI 2015b, , *Value of the pharmaceutical industry in the UK*. Available: <http://www.abpi.org.uk/industry-info/knowledge-hub/uk-economy/Pages/voi.aspx> [2015, 12/25].
- Ades, F., Zardavas, D., Senterre, C., de Azambuja, E., Eniu, A., Popescu, R., Piccart, M. & Parent, F. 2014, "Hurdles and delays in access to anti-cancer drugs in Europe", *ecancermedicalscience*, vol. 8, pp. 482.
- Alakeson, V. 2011, [Homepage of In Control], [Online]. Available: <http://www.in-control.org.uk/media/6115/qipp%20and%20personal%20health%20budgets.pdf> [2015, 12/28].
- Baldwin, R., Cave, M., Lodge, M., Towse, A. & Danzon, P.M. 2010, *The Regulation of the Pharmaceutical Industry*, Oxford University Press.
- Barros, P.P. 2010, "Pharmaceutical policies in European countries" in *Volume 22 - Pharmaceutical Markets and Insurance Worldwide*, ed. A. Dor, Emerald Insight, .
- Barzelay, M. 2001, *The new public management: improving research and policy dialogue*, ebrary, Inc, Berkeley New York; Berkeley, Calif.
- Behner, P. & Bünte, M. 2007, *Getting to Grips with The Supply Chain: How Pharmaceutical Companies can Enhance Patient Safety and Protect Revenues by Increasing Their Control Of Drug Distribution*, Bootz & Company.
- Bennett, S., Quick, J. & Velásquez, G. 1997, *PUBLIC-PRIVATE ROLES IN THE PHARMACEUTICAL SECTOR: Implications for equitable access and rational drug use*, <http://apps.who.int/medicinedocs/pdf/whozip27e/whozip27e.pdf> edn, World Health Organization.
- Buttle, F. & Boldrini, J. 2001, "Customer relationship management in the pharmaceutical industry: The role of the patient advocacy group", *Journal of Medical Marketing*, vol. 1, no. 3, pp. 203-214.
- Cancer Research UK 2015, 02/23-last update, *What is NICE and how does it work?*. Available: <http://www.cancerresearchuk.org/about-cancer/cancers-in-general/cancer-questions/what-is-nice-and-how-does-it-work> [2015, 12/23].
- Carone, G., Schwierz, C. & Xavier, A. 2012, *Cost-containment policies in public pharmaceutical spending in the EU*, European Commission.
- Casper, S. & Matraves, C. 2003, "Institutional frameworks and innovation in the German and UK pharmaceutical industry", *Research Policy*, vol. 32, no. 10, pp. 1865-1879.
- Coe, N.M., Dicken, P. & Hess, M. 2008, "Global production networks: realizing the potential", *Journal of Economic Geography*, vol. 8, no. 3, pp. 271-295.

- Crouch, C. 2009, "Typologies of Capitalism" in *Debating varieties of capitalism, A reader*, ed. B. Hancké, Oxford, , pp. 75-94.
- Ding, M., Eliashberg, J. & Stremers, S. 2014, *Innovation and Marketing in the Pharmaceutical Industry - Emerging Practices, Research, and Policies*. Springer.
- Drug Development & Delivery 2015, , *Denmark's Pharmaceutical Market Value to Decline to \$3 Billion by 2020*. Available: <http://www.drug-dev.com/Main/Back-Issues/Denmarks-Pharmaceutical-Market-Value-to-Decline-to-840.aspx> [2015, 12/30].
- Duke University 2014, , *Tools and Concepts*. Available: <https://globalvaluechains.org/concept-tools> [2015, 12/13].
- Dunne, S., Shannon, B., Dunne, C. & Cullen, W. 2012, "A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study", *BMC Pharmacology & Toxicology*, vol. 14, pp. 1-19.
- Dylst, P., Vulto, A. & Simoens, S. 2012, "Reference pricing systems in Europe: characteristics and consequences", *Generics and Biosimilars Initiative Journal (GaBI Journal)*, vol. 1, no. 3-4, pp. 127-131.
- EFPIA 2015a, , *The European Pharmaceutical sector is a world leader*. Available: <http://www.efpia.eu/topics/industry-economy/trade2015>, 11/20].
- EFPIA 2015b, , *Who we are*. Available: <http://www.efpia.eu/about-us/who-we-are> [2015, 12/01].
- EFPIA 2014, *Principles for application of international reference pricing systems*, The European Federation of Pharmaceutical Industries and Associations.
- Elliott, C. 2010, "The Secret Lives of Big Pharma's 'Thought Leaders'", *The Chronicle of Higher Education*, [Online], , pp. 12/01/2015. Available from: <http://chronicle.com/article/The-Secret-Lives-of-Big/124335/>.
- European Commission 2014a, *Commission staff working document: Pharmaceutical industry: a strategic sector for the European economy (SWD(2014)216/F1)*, European Commission.
- European Commission 2014b, 04/09-last update, *Why did the crisis happen?*. Available: [http://ec.europa.eu/economy\\_finance/explained/the\\_financial\\_and\\_economic\\_crisis/why\\_did\\_the\\_crisis\\_happen/index\\_en.htm](http://ec.europa.eu/economy_finance/explained/the_financial_and_economic_crisis/why_did_the_crisis_happen/index_en.htm) [2015, 11/21].
- European Union 2015a, 11/25-last update, *Transparency and the EU*. Available: <http://ec.europa.eu/transparencyregister/public/homePage.do> [2015, 12/01].
- European Union 2015b, 04/27-last update, *Transparency Register - European Federation of Pharmaceutical Industries and Associations*. Available: <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=38526121292-88> [2015, 12/01].
- European Union 2015c, 04/27-last update, *Transparency Register - H. Lundbeck A/S*. Available: <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=118500617129-29> [2015, 12/01].

- GOV.UK 2014, 12/24-last update, *VAT rates*. Available: <https://www.gov.uk/vat-rates> [2015, 12/15].
- Groot, T. & Budding, T. 2008, "NEW PUBLIC MANAGEMENT'S CURRENT ISSUES AND FUTURE PROSPECTS", *Financial Accountability & Management*, vol. 24, no. 1, pp. 1-13.
- Hall, P. & Gingerich, D.W. 2009, "Varieties of Capitalism and Institutional Complementarities in the Political Economy: An Empirical Analysis" in *Debating varieties of capitalism, A reader*, ed. B. Hancké, Oxford, , pp. 135-179.
- Hall, P. & Thelen, K. 2009, "Institutional Change in Varieties of Capitalism" in *Debating varieties of capitalism, A reader*, ed. B. Hancké, Oxford, , pp. 251-272.
- Hall, P.A. & Soskice, D.(.). 2001, *Varieties of capitalism, The institutional foundations of comparative advantage*, , Oxford.
- Hammett, S. 2014, , *2015 life sciences outlook United Kingdom* [Homepage of Deloitte], [Online]. Available: <http://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-life-sciences-report-united-kingdom.pdf> [2015, 12/28].
- Hancké, B. 2009, "Introducing the Debate" in *Debating varieties of capitalism, A reader* Oxford, pp. 1-17.
- Hancké, B., Rhodes, M. & Thatcher, M. 2009, "Beyond Varieties of Capitalism" in *Debating varieties of capitalism, A reader*, ed. B. Hancké, Oxford, , pp. 273-300.
- Henderson, J., Dicken, P., Hess, M., Coe, N. & Yeung, H.W. 2002, "Global Production Networks and the Analysis of Economic Development", *Review of International Political Economy*, vol. 9, no. 3, pp. 436-464.
- House of Commons Health Committee 2005, *The Influence of the Pharmaceutical Industry*, Volume II edn, House of Commons.
- Hutton, J., Borowitz, M., Oleksy, I. & Luce, B.R. 1994, "The pharmaceutical industry and health reform: lessons from Europe", *Health Affairs*, vol. 13, no. no.3, pp. 98-111.
- Jack, A. 2012, *European healthcare: Ailments encapsulated*, 15 February edn, The Financial Times Limited.
- Kanavos, P., Vandonos, S., Irwin, R., Nicod, E., Casson, M. & Medical Technology Research Group - LSE Health London School of Economics and Political Science 2011, *DIFFERENCES IN COSTS OF AND ACCESS TO PHARMACEUTICAL PRODUCTS IN THE EU*, European Parliament.
- Kashyap, U.N., Gupta, V. & Raghunandan, H.V. 2013, "Comparison of Drug Approval Process in United States & Europe", *Journal of Pharmaceutical Sciences and Research*, vol. 5(6), pp. 131-136.
- Kenworthy, L. 2009, "Institutional Coherence and Macroeconomic Performance" in *Debating varieties of capitalism, A reader*, ed. B. Hancké, Oxford, , pp. 180-199.
- Kolb, R.W. 2010, *Robert W. Kolb : Corporate Governance : A Synthesis of Theory, Research, and Practice*, John Wiley & Sons, Hoboken, NJ, USA.

- Komesaroff, P.A. 2007, "Relationships between health professionals and industry: maintaining a delicate balance", *Australian Prescriber*, [Online], vol. 30, no. 6, pp. 2015. Available from: <http://www.australianprescriber.com/magazine/30/6/article/920.pdf>.
- Kristensen, F.B. 2015, December-last update, *Denmark – Pharmaceuticals* [Homepage of International Society for Pharmacoeconomics and Outcomes Research], [Online]. Available: <https://www.ispor.org/HTARoadMaps/Denmark.asp> [2015, 12/30].
- Lane, C. 2008, "National capitalisms and global production networks: an analysis of their interaction in two global industries 1", *Socio-Economic Review*, vol. 6, no. 2, pp. 227-260.
- Leopold, C., Aukje, K.M., Vogler, S., Valkova, S., Kees, d.J., Leufkens, H.G., Anita, K.W., Dennis Ross-Degnan & Laing, R. 2014, "Effect of the economic recession on pharmaceutical policy and medicine sales in eight European countries", *Bulletin of the World Health Organization*, vol. 92, no. 9, pp. 630-640.
- MarketLine 2014, "Pharmaceuticals in the United Kingdom", *Pharmaceuticals Industry Profile: United Kingdom*, .
- Medicon Valley a, , *MEDICON VALLEY FACTS*. Available: <http://www.mediconvalley.com/sitecore/content/MediconValley/Home/Facts/Medicon%20Valley%20Facts> [2015, 12/30].
- Medicon Valley b, , *YOUR BUSINESS OPPORTUNITIES IN MEDICON VALLEY*. Available: <http://www.mediconvalley.com/Business%20Opportunities> [2015, 12/30].
- Ministry of Employment , *Flexicurity i Danmark*. Available: <http://bm.dk/da/Beskaeftigelsesomraadet/Arbejdsret/Det%20arbejdsretlige%20omraade/Flexicurity/Flexicurity%20i%20Danmark.aspx#> [2015, 12/30].
- Ministry of Foreign Affairs , *The World's Best Business Environment* . Available: <http://www.investindk.com/Why-Denmark> [2015, 12/30].
- Møller Pedersen, K. 2003, "Pricing and reimbursement of drugs in Denmark", *The European Journal of Health Economics*, vol. 4, no. 1, pp. 60-65.
- Nölke, A. & Vliegenthart, A. 2009, "Enlarging the Varieties of Capitalism: The Emergence of Dependent Market Economies in East Central Europe", *World Politics*, vol. 61, no. 4, pp. 670-702.
- Office for National Statistics 2014, 07/04-last update, *What does the UK pharmaceutical industry look like today?*. Available: <http://www.ons.gov.uk/ons/rel/iop/index-of-production/april-2014/sty-pharmaceuticals.html> [2015, 12/25].
- Ohba, M. & Falkner, R. 2007, "Innovative capabilities and strategic alliances: Who is gaining what in the pharmaceutical industry?", *Journal of Commercial Biotechnology*, vol. 13, no. 4, pp. 273-282.
- Pharmaceutical Technology 2013, 02/21-last update, *Unravelling the EU's parallel drug trade dilemma*. Available: <http://www.pharmaceutical-technology.com/features/featureunravelling-eu-parallel-drug-trade-dilemma/> [2016, 01/01].

- PhRMA 2015, "Biopharmaceutical Research & Development: The Process Behind New Medicines", *PhRMA.org*, [Online], , pp. 20-11 2015. Available from: [http://www.phrma.org/sites/default/files/pdf/rd\\_brochure\\_022307.pdf](http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf).
- Richardt, M. 2015, 09/01-last update, *Sundhedsminister: Sundhedsvæsen i verdensklasse kræver ny og dyr medicin* [Homepage of DR], [Online]. Available: <http://www.dr.dk/nyheder/indland/sundhedsminister-sundhedsvaesen-i-verdensklasse-kræver-ny-og-dyr-medicin> [2015, 12/30].
- Ritzau Finans 2015, *Lundbeck i milliardssamarbejde om kur mod Alzheimers*, Børsen.
- Rothgang, H. 2010, *The State and Healthcare: Comparing OECD Countries*, , Basingstoke.
- Saltman, R.B. & Figueras, J. 1997, "European Health Care Reform - Analysis of Current Strategies", *WHO Regional Publications*, , no. European Series, No. 72.
- Saltman, R. & Figueras, J. 1998, "Analyzing the evidence on European health care reforms", *Health Affairs: Health Aff.*, vol. 17, no. 2, pp. 85-108.
- Sample, I. 2013, , *Big pharma mobilising patients in battle over drugs trials data* [Homepage of The Guardian], [Online]. Available: <http://www.theguardian.com/business/2013/jul/21/big-pharma-secret-drugs-trials> [2015, 11/29].
- Saunders, M., Lewis, P. & Thornhill, A. 2009, *Research methods for business students*, 5. ed. edn, Pearson Education Limited, Harlow.
- Sayer, A. 2000, *Realism and social science*, , London.
- Sayer, A. 1992, *Method in social science: a realist approach*, 2. ed. edn, , London.
- Sismondo, S. 2013, "Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won't Cast Light On", *Journal of Law, Medicine & Ethics*, vol. 41, no. 3, pp. 635-643.
- Statista 2015, , *Pharmaceutical market value in selected European countries in 2013 (in million euros)*. Available: <http://www.statista.com/statistics/316076/european-pharmaceutical-market-value-by-country/> [2015, 12/30].
- Stuart, T.E. 2000, "Interorganizational alliances and the performance of firms: a study of growth and innovation rates in a high-technology industry", *Strategic Management Journal*, vol. 21, no. 8, pp. 791-811.
- Sturgeon, T.J. 2001, "How Do We Define Value Chains and Production Networks? \*", *IDS Bulletin*, vol. 32, no. 3, pp. 9-18.
- Taylor, M.Z. 2009, "Empirical Evidence Against Varieties of Capitalism's Theory of Technological Innovation" in *Debating varieties of capitalism, A reader* Oxford, , pp. 221-247.
- Trochim, W. 2006, , *Deduction and induction* [Homepage of Web Center for Social Research Methods], [Online]. Available: <http://www.socialresearchmethods.net/kb/dedind.php> [2015, 11/23].
- Vandoros, S. & Stargardt, T. 2013, "Reforms in the Greek pharmaceutical market during the financial crisis", *Health policy*, vol. 109, no. 1, pp. 1-6.

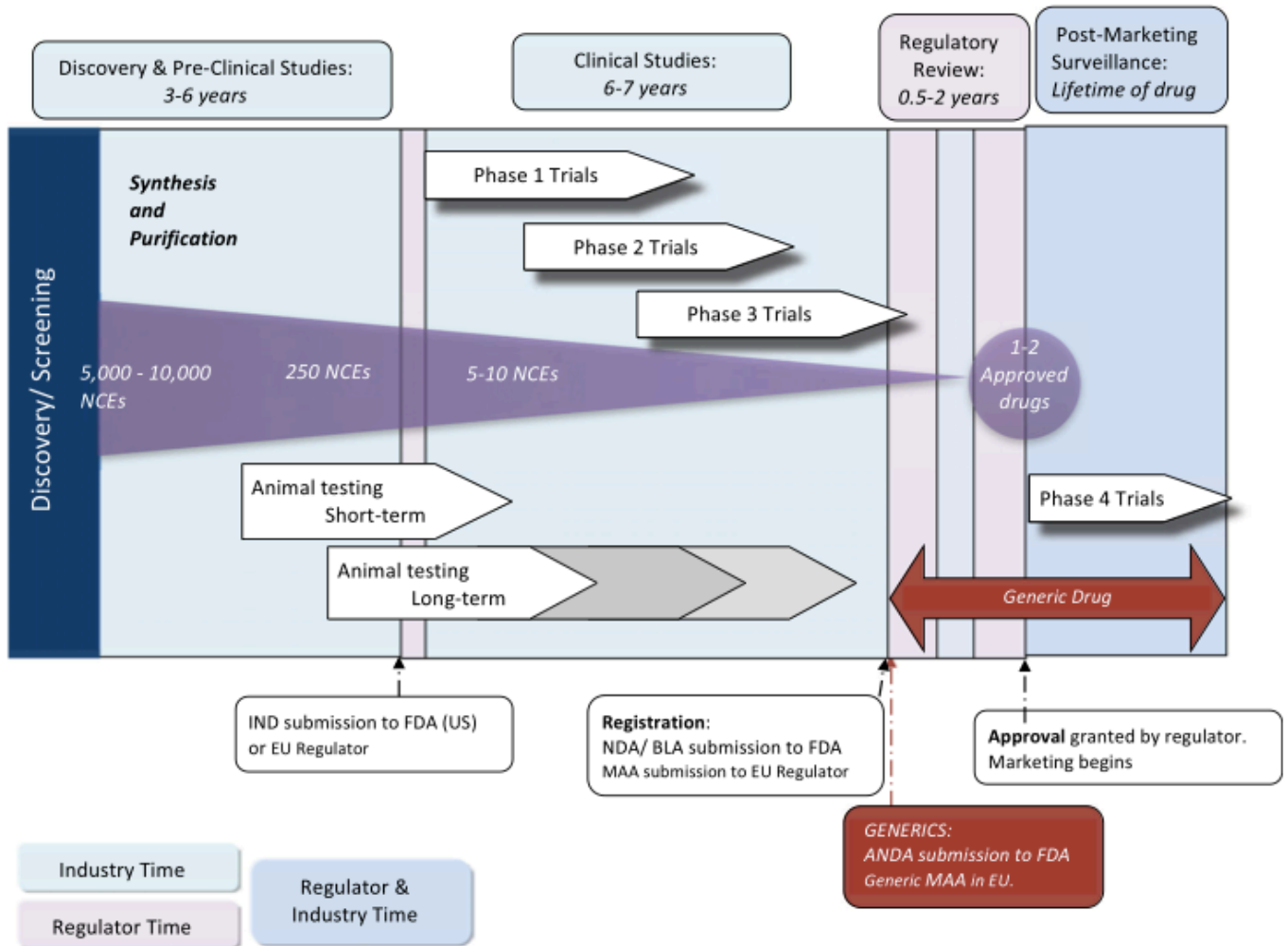
- Vogler, S., Zimmermann, N., Leopold, C. & de Joncheere, K. 2011, "Pharmaceutical policies in European countries in response to the global financial crisis", *Southern Med Review*, vol. 4, no. 2, pp. 69-79.
- Walter, E., Dragosits, A. & Said, M. 2012, "Access to pharmaceutical products in six European countries – analysis of different pharmaceutical distribution systems", *Farmeconomia : Health Economics and Therapeutic Pathways*, vol. 13, no. 1, pp. 33-41.
- Wendt, C., Frisina, L. & Rothgang, H. 2009, "Healthcare System Types: A Conceptual Framework for Comparison", *Social Policy & Administration*, vol. 43, no. 1, pp. 70-90.
- Werth, B. 2013, "A Tale of Two drugs", *MIT Technology Review*, .
- World Health Organization 2012, , *Pharmaceutical Legislation and Regulation. (MDS-3: Managing Access to Medicines and Health Technologies, Chapter 6)*. Available: <http://apps.who.int/medicinedocs/documents/s19583en/s19583en.pdf> [2015, 11/29].
- World Health Organization 2003, , *Drugs and Money - Prices, Affordability and Cost Containment*. Available: <http://apps.who.int/medicinedocs/pdf/s4912e/s4912e.pdf> [2015, 11/29].
- World Trade Organization 2015, , *URUGUAY ROUND AGREEMENT: TRIPS <br />Part II – Standards concerning the availability, scope and use of Intellectual Property Rights<br />Sections 5 and 6*. Available: [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04c\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm) [2015, 2015, 11/20].
- Ziebe, S. 2010, 06/28-last update, *The death of Denmark's public ART funding* [Homepage of BioNews], [Online]. Available: [http://www.bionews.org.uk/page\\_65111.asp](http://www.bionews.org.uk/page_65111.asp) [2016, 01/02].

# Appendices

## Appendix I

Figure I

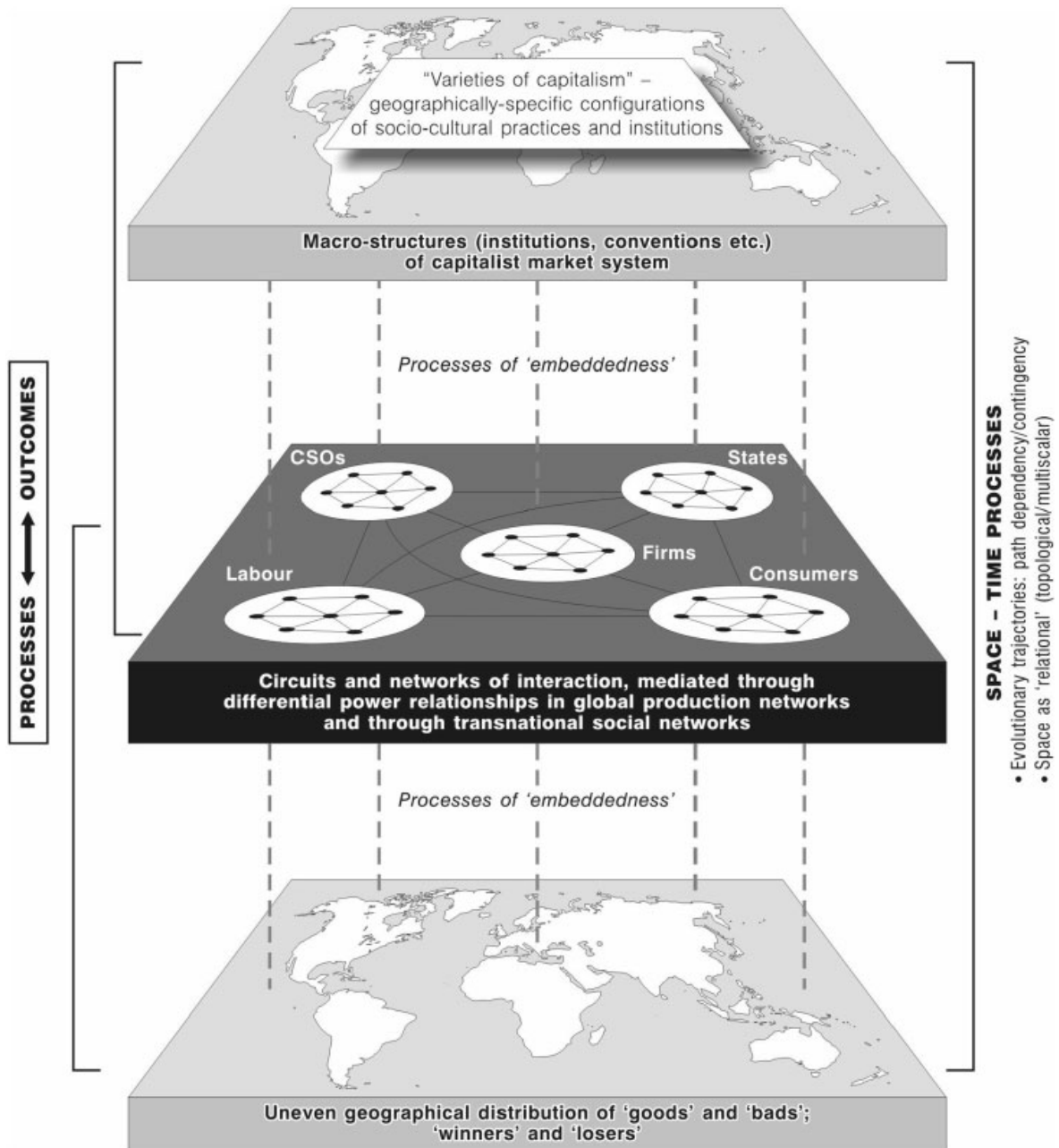
Schematic of Drug Development Process (Dunne et al. 2012, p. 8)





**Figure II**

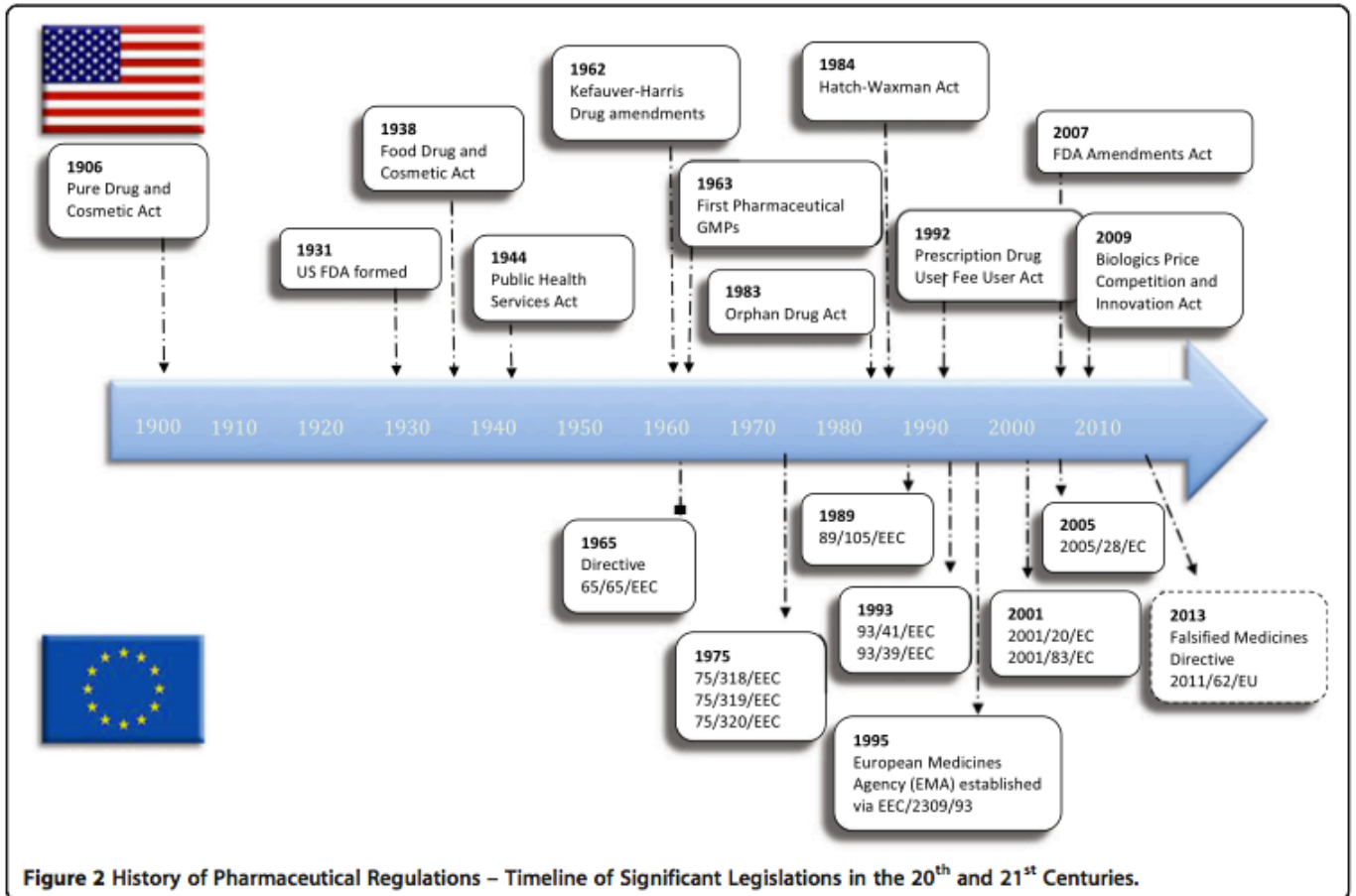
A heuristic framework for analysing the global economy (Coe, Dicken & Hess 2008, p. 273)





**Figure III**

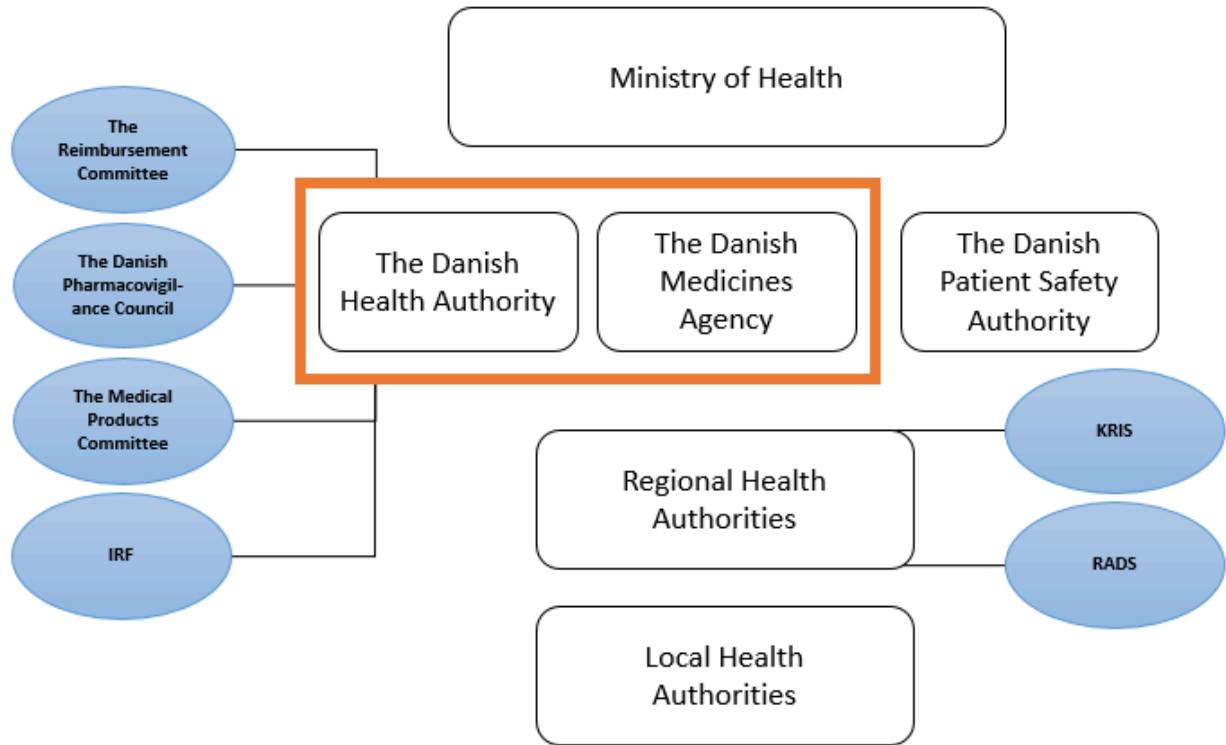
History of Pharmaceutical Regulations – Timeline of Significant Legislation in the 20<sup>th</sup> and 21<sup>st</sup> Centuries (Dunne et al. 2012, p. 6)



**Figure 2** History of Pharmaceutical Regulations – Timeline of Significant Legislations in the 20<sup>th</sup> and 21<sup>st</sup> Centuries.

**Figure IV**

Decision Makers in the Danish Health Care System (Kristensen 2015).



## Appendix II

### Table I

National policy measures influencing pharmaceutical sales (Leopold et al. 2014, p. 632).

Table 1. National policy measures influencing pharmaceutical sales<sup>19</sup>

Policy measure	Definition
<b>Pricing</b>	
Price cut	A cost-containment measure whereby the set price of a medicine is reduced by the authorities.
External price referencing	External price referencing is the practice whereby the price of a medicine in one or several other countries is used to derive a benchmark or reference price for the purpose of setting or negotiating the medicine's price in a given country. Policy changes in external price referencing include the introduction or abolition of this pricing policy and altering the methodology (e.g. changing the basket of reference countries or the way of calculating the benchmark price).
Distribution remuneration (i.e. mark-ups, margins and fees for service)	Distribution remuneration is the payment of a health-care provider, whether an individual or an organization, for the services provided. In the distribution of pharmaceuticals, wholesalers and pharmacies are remunerated using mark-ups or regressive margin schemes or, for pharmacies alone, by paying a "fee for service". With mark-ups, a defined linear or percentage amount is added to the cost of a good to ensure a profit at the wholesale or retail level or both. With regressive margin schemes, the margin is expressed as a percentage of the selling price. Policy changes in distribution remuneration include adjusting the mark-ups or margins used for wholesalers or pharmacies or changing the type of distribution remuneration for a defined actor. Changes may also be made to the types of medicines (e.g. reimbursable medicines or prescription-only medicines) to which distribution remuneration applies.
VAT on medicine	VAT is a sales tax on products that is collected in stages. It is a wide-ranging tax that is usually designed to cover most or all goods and services, including medicines. Policy changes in VAT include the introduction or abolition of VAT on medicines and altering the VAT rate on medicines.
Extraordinary price review	Price reviews involve reviewing the process by which the set price of a medicine was established. Reviews may or may not be performed in combination with reimbursement reviews. Reviews can be performed systematically (e.g. once a year) for all reimbursed medicines or for a group of medicines (e.g. for a specific indication) or at any time.
<b>Reimbursement</b>	
Reference price system	With a reference price system, which is also referred to as internal or therapeutic reference pricing, the third party payer determines a reference price for the reimbursement of medicines with a particular active ingredient or in a given therapeutic class. If the price of the medicine exceeds the reference price, the health-care consumer must pay the difference between the fixed reimbursed amount (i.e. the reference price) and the actual pharmacy retail price in addition to any copayments (e.g. prescription costs and percentage copayment rates). Policy changes in the reference price system include the introduction or abolition of a reference price system and changing the methodology by which clusters of medicines are established for determining a reference price (e.g. by grouping identical or similar medicines).
Out-of-pocket payments	Out-of-pocket payments are payments made by health-care consumers that are not reimbursed by a third-party payer. They include cost-sharing, fixed or percentage copayments and informal payments to health-care providers.
Delisting	Delisting is the exclusion of a medicine from a reimbursement list (e.g. a positive list), which often results in exclusion from reimbursement.
<b>Generic drugs</b>	
INN prescribing	With INN prescribing, prescribers (e.g. physicians) are required to prescribe medicines using the INN for the pharmaceutical (i.e. the name of the active ingredient) instead of a brand name. Policy changes in INN prescribing include its introduction or abolition, changing the way INN prescribing is organized (e.g. by imposing or eliminating financial incentives) and changing from indicative to obligatory INN prescribing.
Generic substitution	Generic substitution is the practice of substituting a medicine, whether marketed under a trade name or generic name (i.e. a branded or unbranded drug), by a less expensive medicine (e.g. a branded or unbranded generic drug), which often contains the same active ingredients. Generic substitution may be encouraged (i.e. indicative generic substitution) or required (i.e. mandatory generic substitution). Policy changes in generic substitution include its introduction or abolition, changing the way generic substitution is organized (i.e. imposing or eliminating financial incentives) and moving from indicative to obligatory generic substitution.
Public campaigns	Policies, regulations, measures and initiatives promoting the use of generic drugs or licensed, off-patent medicines are typically undertaken by government authorities. Policy on generic drugs may be targeted at prescribers, pharmacists, patients or consumers, or other stakeholders.

INN: international nonproprietary name; VAT: value-added tax.

**Table II**

Pharmaceutical pricing policies measures in 33 European countries in 2010 and 2011 (Vogler et al. 2011, pp. 73-74).

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
<b>Price reductions</b>	<p><b>Czech Republic:</b> price cut of 7% on reimbursable medicines</p> <p><b>UK:</b> price cut of 1.9% on branded NHS medicines as part of 2009 PPRS</p> <p><b>Spain:</b> price cut of 30% on generics</p> <p><b>Greece:</b> quarterly price reviews followed by price cuts</p> <p><b>Ireland:</b> price reductions on generics</p> <p><b>Lithuania:</b> price cuts of 11% on non-reimbursable medicines</p> <p><b>Turkey:</b> price cut under reference price on 20 years old medicines</p>	<p><b>Lithuania:</b> price cut of 10% on reimbursable medicines</p> <p><b>Switzerland:</b> implementation of price review into practice</p> <p><b>Portugal:</b> price reduction for original medicines and for generics following annual price review</p> <p><b>Ireland:</b> another price reduction on generics</p> <p><b>Germany:</b> price freeze of reimbursable medicines</p>	<p><b>Czech Republic:</b> price cut of 7% on non-revised medicines</p> <p><b>Ireland:</b> price reductions on on-patent medicines</p> <p><b>Malta:</b> price cuts in the private market</p>	<p><b>Iceland:</b> price review of all medicines with predicted price cuts of 3%-5%</p> <p><b>Turkey:</b> price cut on off-patent medicines under discussion</p>
<b>Discounts, rebates, claw-backs/pack-back &amp; other agreements</b>	<p><b>Spain:</b> 7.5% discounts on original medicines and 4% on orphans</p> <p><b>Romania:</b> introduction of claw-back</p> <p><b>Lithuania:</b> introduction of price notification for non-reimbursable medicines (before not regulated)</p>	<p><b>Estonia:</b> introduction of price agreement also for 50% reimbursable medicines (before not regulated)</p> <p><b>Germany:</b> increase in mandatory manufacturer's rebate to social health insurance (6% → 16%)</p> <p><b>Portugal:</b> discount of 6% for reimbursable medicines</p> <p><b>Italy:</b> choice between pay-back and price cuts</p> <p><b>Lithuania:</b> extension of price-volume agreement to high-cost medicines</p>	<p><b>Portugal:</b> 7.5% lower price than 2010 needs to be granted to NHS institutions for specific biologicals</p>	<p><b>Poland:</b> new reimbursement law valid from 2012 on – several changes, e.g. obligatory pay-back in case of budget excess, voluntary in risk-sharing schemes; tax on manufacturers' income to publicly fund clinical trials</p>
<b>External price referencing (EPR)</b>	<p><b>Malta:</b> introduction of EPR</p> <p><b>Switzerland:</b> extension of basket (4 → 6 countries)</p> <p><b>Spain:</b> specification in law to have EU Member States as reference countries</p>	<p><b>Lithuania:</b> extension of basket (6 → 8)</p> <p><b>Iceland:</b> change in calculation methodology for hospital medicines (lowest price)</p>	<p><b>Germany:</b> EPR-like procedures provided for in law (implementation from 2012 on)</p>	<p><b>Slovakia:</b> change in calculation methodology (6 lowest prices → 2 lowest prices of EU-26; in Parliament)</p>
<b>Distribution remuneration (margin*)</b>	<p><b>Iceland:</b> pharmacy margin increase</p> <p><b>Switzerland:</b> pharmacy margin cut</p> <p><b>Spain:</b> increase of a part of pharmacy margin for expensive medicines</p> <p><b>Greece:</b> wholesale margin cut for expensive medicines</p> <p><b>Lithuania:</b> introduction of wholesale and pharmacy margin regulation for non-reimbursable medicines</p> <p><b>Portugal:</b> pharmacy margin increase for non-reimbursable medicines</p> <p><b>Belgium:</b> new pharmacy margin</p>	<p><b>Italy:</b> wholesale margin cut &amp; pharmacy margin increase</p>	<p><b>Latvia:</b> wholesale margin cut</p>	<p><b>Portugal:</b> discussion about pharmacy margin cut</p> <p><b>Germany:</b> change in structure of wholesale margin from 2012 on</p> <p><b>Poland:</b> new reimbursement law valid from 2012: pharmacy margin change</p>

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
<b>Value added tax (VAT) on medicines</b>	<p><b>Czech Republic:</b> increase (9 → 10%)</p> <p><b>UK:</b> increase on OTC/standard rate (had been temporarily reduced in 2008: 15 → 17.5%)</p> <p><b>Greece:</b> increase (9 → 10%)</p>	<p><b>Finland:</b> increase (8 → 9%)</p> <p><b>Portugal:</b> increase (5 → 6%)</p> <p><b>Greece:</b> increase (10 → 11%)</p>	<p><b>Greece:</b> decrease (10 → 6.5%)</p> <p><b>Latvia:</b> increase (10 → 12%)</p> <p><b>UK:</b> increase on OTC (17.5 → 20%)</p> <p><b>Poland:</b> increase (7 → 8%)</p>	

**Table III**

Pharmaceutical reimbursement and other policy measures in 33 European countries in 2010 and 2011 (Vogler et al. 2011, pp. 74-75).

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
<b>Reimbursement lists / (de)listing/ reimbursement procedure</b>	<p><b>Malta:</b> listing of new medicines (on-going 2010/2011)</p> <p><b>Iceland:</b> changes in reimbursement status (from general to individual) for some medicines (e.g. respiratory)</p> <p><b>Portugal:</b> procedural changes (shorter reimbursement decision time for generics)</p>	<p><b>Greece:</b> re-introduction of positive list and negative list</p> <p><b>Iceland:</b> changes in reimbursement status (from general to individual) for some medicines (e.g. antidepressants)</p>	<p><b>Czech Republic:</b> ongoing review of all medicines (started already in 2008)</p> <p><b>Germany:</b> new reimbursement law – value assessments</p> <p><b>Portugal:</b> Delisting of OTC medicines</p>	<p><b>Poland:</b> new reimbursement law valid from 2012 – several changes, e.g. quicker reimbursement decision, but granted for limited time (2-5 years)</p> <p><b>Czech Republic:</b> discussion about introduction of negative list</p> <p><b>France:</b> change of reimbursement system under discussion</p> <p><b>Netherlands:</b> change in funding of TNF-inhibitors (2012)</p>
<b>Co-payments</b>	<p><b>Austria:</b> annual increase of prescription fee</p> <p><b>Belgium:</b> annual indexation of co-pay.</p> <p><b>Iceland:</b> increase in co-pay.</p> <p><b>Portugal:</b> temporary exemption (6/2009 – 5/2010) from co-pay. for low-income pensioners for generics was changed (from generics to 5 lowest priced medicines in a cluster)</p>	<p><b>Belgium:</b> increase of percentage co-pay. for some medicines (at different times during 2010)</p> <p><b>Lithuania:</b> change in minimum co-pay.</p> <p><b>Latvia:</b> increase of reimbursement rate for cardiovascular medicines (50% → 75%)</p> <p><b>Portugal:</b> introduction of co-pay. on medicines which low-income pensioners had been exempted from before</p>	<p><b>Denmark:</b> increase in co-pay. for fertility products</p> <p><b>France:</b> decrease of reimbursement rate (35 → 30%)</p> <p><b>Austria:</b> annual increase of prescription fee</p> <p><b>Belgium:</b> annual indexation of co-pay.</p> <p><b>Iceland:</b> increase in co-pay.</p> <p><b>Latvia:</b> change in new co-pay.</p>	<p><b>Poland:</b> changes in co-pay. following new reimbursement law</p> <p>Under discussion in Czech Republic, France, Iceland, Latvia, Portugal</p>
<b>Reference price system (RPS)</b>	<p><b>Portugal:</b> higher RP for more patients</p> <p><b>Spain:</b> change in methodology allowing lower RP (average of 3 lowest prices → lowest priced product in a cluster)</p> <p><b>Lithuania:</b> new rules of price of generics compared to equivalents</p>	<p><b>Estonia:</b> inclusion of 50% reimbursable medicines in RPS (before not) (7/2010)</p> <p><b>Romania:</b> change to therapeutic reference pricing (broader clusters)</p> <p><b>Estonia:</b> new rules for price of generics and biologicals in the RPS (10/2010)</p>	<p><b>Latvia:</b> new rules for price of generics in a cluster (lower prices)</p> <p><b>Portugal:</b> change in methodology of RP (lower RP)</p> <p><b>Belgium:</b> new rules for price of generics in a cluster (lower RP)</p> <p><b>Lithuania:</b> change in methodology of price of most expensive medicines in a cluster (lower prices)</p>	<p><b>Czech Republic:</b> discussion about tendering for generics</p> <p><b>Lithuania:</b> discussion about change to therapeutic reference pricing (broader clusters)</p> <p><b>Ireland:</b> introduction of RPS planned</p> <p><b>Poland:</b> changes in generic price links due to new reimbursement law (2012)</p> <p><b>Romania:</b> discussion about extending RPS</p>

Policy measure	Implemented			Planned / discussed
	1-6/2010	7-12/2010	1-2/2011	
<b>Other measures (not directly linked to pricing &amp; reimbursement)</b>	<p><b>Lithuania:</b> obligation for pharmacies to offer least expensive medicine to patients and to have it on stock (1/2010)</p> <p><b>Estonia:</b> introduction of e-prescribing (1/2010)</p> <p><b>Estonia:</b> obligation for pharmacies to offer least expensive medicines to patients and to have it on stock (4/2010)</p> <p><b>Lithuania:</b> obligation for pharmacies to install price monitoring systems (5/2010)</p> <p><b>Lithuania:</b> INN prescribing becomes mandatory (6/2010)</p>	<p><b>Estonia:</b> generics promotion campaign addressed to the public</p> <p><b>Spain:</b> generics promotion campaign addressed to the public</p>	<p><b>France:</b> definition for "quasi-generic"</p> <p><b>UK:</b> Quality, Productivity and Prevention programme on-going (introduced 2009)</p>	<p><b>Czech Republic:</b> enforcement of INN prescribing</p> <p><b>Portugal:</b> e-prescribing as prerequisite for reimbursement (originally planned from 3/2011 on, postponed for 8/2011)</p> <p><b>Portugal:</b> continued generics promotion</p> <p><b>Slovakia:</b> draft law about INN prescribing becoming mandatory</p> <p><b>Poland:</b> new reimbursement law valid from 2012 on: information duties of pharmacies about least expensive equivalent medicines and having them on stock</p> <p><b>UK:</b> discussion about introduction of value-based pricing in 2013 (after PPRS ending)</p>

## Appendix III

### Interview Guide

I am writing my thesis in international business and politics, so I am focusing on the pharmaceutical industry in Europe after the financial crisis to see if governments may have changed their policies towards the industry as a consequence of the crisis.

First two practical things. I will have to make a transcript of the conversation and include with my thesis, so I wanted to ask if I might mention you by name or if you would prefer to be anonymous. And then normally the thesis will be published online at the university's homepage and I do not think it will be an issue as all my questions are very general and about the industry as such. But just so you know that I can make the thesis confidential so that it won't be published anywhere. But we can just come back to that after you have heard the questions.

Name and title

For how long have you worked for company X?

In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?

Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?

In short what are the five biggest advantages of selling to European nations?

In short what are the five biggest challenges of selling to European nations?

In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?

Are there any particular barriers, which appear to be due to new price regulations?

Is there any difference due to different medicine groups?



How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?

How do you see the future of the pharmaceutical industry in Europe?

I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?

In August 2015 H. Lundbeck A/S went through a large scaled firing round. Part of the explanation was losing patents on compounds and the newly launched compounds having to pick up. Do you think this firing round may be related to the changed regulation towards the pharmaceutical industry in Europe?

Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?

## Appendix IV

Interview I, conducted in person 08-12-2015. The views expressed here are those of the interviewee and not of the company.

### **Name and title**

Sam Agus, Senior Director and Head of MA Neurology.

### **For how long have you worked for H. Lundbeck A/S?**

I have been at Lundbeck since September 2014 but I have been in the industry since 2001 working with clinical studies. In 2003 I began doing consultancy work for small pharma companies and since 2006 I have worked with big pharma.

### **In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

High pressure to make sure payer are paying for effects. But effect does not mean individual effect more effect on the healthcare system or society. Paying structure in Europe is central, state based. The financial crisis is not over in Europe. It is all about priorities, about other budgets than pharma and within pharma. For example there is the refugees crisis, paying for security systems, pay debts etc.

### **Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

Overall the industry was not impacted by the crisis, during the past 15 years the industry moved quite a lot from civil markets. According to Ernst & Young pharma has moved from 1-0 model to a 2-0 blockbuster model, which dominates pharma. But it now has to move into 3-0 in which it develops full services, beyond the pill. That was the talk of 2009. Margins on pharma are quite good, but R&D changes the whole thing. The pharmaceutical industry has changed from own pipeline to buying small companies but only big pharma can do that. When looking into top blockbusters they were sold by big pharma. But not only small pharma

companies are being bought, also big ones. It has changed for more specialised diseases, there is a trend that pharma goes for high price low volume.

The big companies are still the same that were in 2008. Novartis formed in 2001, but it is the same big players, just more condensed through mergers. Alagma is new but is gone next year. Valeant, their days may be numbered.

We have also seen an increased scrutiny towards the industry, a big scrutiny from the public. In 2008/2009 transparency became the word, how much we pay doctors etc. It meant significant limitations. Today it is even worse. EU governments jumped on that, as it is another way of making sure that somehow things are done the right way. EU is a central reimbursement continent, which means that the prices for new medications are much lower. They would be much higher in the US. In EU they want to know how is this better and why is that better is worth something. Pharma tends to think it is a hassle, but it is a priority issue. They have to weight their budgets for example with the refugees crisis. Even within pharma they have to prioritise. If you have the choice between a medication, which may completely cure and make extinct a disease and another medication, which will cure some symptoms for a disease in which you already have existing medication, you will use the medication doing the former. Governments are afraid of disease mongering, as they have limited budgets. Otherwise people will have to pay more in taxes. But they also have to balance with other industries. For example look at Denmark where the pig industry is an important part of the economy, is it not just as important to use budget for such an industry? So that is why they have to scrutinise, and they should.

Now there are apps and tools out there to help the patients. Those should now be seen as medical devices, as they are beyond the pills options. But pharma is still stuck to this old model. Sovaldi, a drug against hepatitis C, will cost maybe 200.000 a year for a patient, so it is a very expensive product. But it is still a drug, which is not so specialised disease wise. Interesting to see how will they take it in the EU.

### **In short what are the five biggest advantages of selling to European nations?**

Once you get an approval and you agree on a price it is much easier. After all the approvals and negotiations there is a clear model of what should be done. In the US even when you

agree with an insurance company to sell your medication they put in many steps to make it more difficult for you.

In the EU after you have gotten approved and agreed on a price it is much up to the physician so you can talk to the physician to try and get them on board and convince them why your product is good and worth it. Some countries in Europe are trying to put in systems of “adopted licensing“. The EU wants to be a spearhead. Some countries are even trying to look into adopted pricing and reimbursing, Italy for instance. David Cameron has committed that Britain should be a spearhead and the Dutch authorities are also interested.

**In short what are the five biggest challenges of selling to European nations?**

Despite of the EU it is still very fragmented. Most approvals are either centralised or decentralised. If centralised all countries should be aboard but for example when it comes to pricing and reimbursement the whole thing changes. Germany is very much about processes, France is about defining what is valuable and some countries work very slowly.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

Denmark is one of the easiest countries to approve new drugs. Denmark and Sweden are very fast, the UK is reasonable. The UK has a different model where you have to go to a specialist.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

I think it is. They ask the right questions, as they need to see the advantages. It is a big market, however, it is frustrating. In the EU you have to fight the price, so people are going away from the EU. But I still think the EU is a good opportunity. It has the patients, the systems, the methodology and it has the scrutiny so why not?

**How do you see the future of the pharmaceutical industry in Europe?**

Indeed, with the current environment, companies may find Europe as less attractive, due to the processes that are in place for HTA and P&R. Having said that, Europe continues to be a big market, in which medical practice is well developed and where doctors and patients are

very interested in new, high-impact, treatments. It is likely that, the growing pressure from the medical community and patient organization, in most countries, a revision of processes will take place. It does not necessarily mean a favourable pricing situation, it probably means more robust and clear processes, that will allow a better development and introduction of new products. Adaptive licensing and adaptive pricing may become novel processes that will be incorporated to support these interactions, especially in areas of high unmet need.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

We already see a negative attitude in companies towards this scrutiny. It is even more difficult, when the processes which are in place are very diverse, and even within each country, it is not always clear, at least not in advance, to predict, what will be the data that will facilitate a successful HTA and P&R process. Having said that, it is clear, that government will face an increasing public pressure, to implement an environment, which will not be influenced only by price and expenditure and will take into account broader and more patient-centric methods to assess value proposition, and not only in terms of cost-effectiveness. At least in disease areas with a high unmet need.

**In August 2015 H. Lundbeck A/S went through a large scaled firing round. Part of the explanation was losing patents on compounds and the newly launched compounds having to pick up. Do you think this firing round may be related to the changed regulation towards the pharmaceutical industry in Europe?**

I suspect this had some influence on the process. It is clear that Lundbeck, like many companies, is seeking to expand into markets, which in the past, were not primarily targeted for example Asia and Latin America. The goal is to create higher diversity and less dependence on the established markets, especially in Europe.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

As mentioned, pharma has gone through several changes during the past decade. Some of these are driven by the financial situation in Europe, others relate to reduced profitability. Again, in part, relating to a high scrutiny on medication cost in Europe, but probably more on reduced R&D success and profitability. Increased regulations on conduct of development and promotion of medicinal products. Moving forwards, pharma will have to adapt to more scrutiny, increasing demand for real-world data, post approval and a changing methods to assess value and benefit, focusing more on long-term and patient-centric outcomes. This can possibly lead to further structural changes as well as development and commercialization process changes.

Interview II, conducted over the phone 10-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Tommy Kok Annfeldt, Customer Experience Lead Northern European Cluster, Eli Lilly.

**For how long have you worked for in the pharmaceutical industry?**

I have worked at Eli Lilly since Jan 2010. However, I did also finish my master's at Lundbeck but went straight to Eli Lilly after.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

We are currently in a limbo where we need to reinvent ourselves and find a new business model for the future as the current one cannot go on.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

No, not much.

**In short what are the five biggest advantages of selling to European nations?**

No, but I can think of some disadvantages.

**In short what are the five biggest challenges of selling to European nations?**

As I see it there are two main disadvantages. The first one is the payer environment in which the payers are not directly liable towards the patient. For example in the US they are, as the insurance companies have an interest in optimising their offers, as customers can otherwise find another insurance company. The payers in Europe do not need to hold up to expectations.

The other one is that the industry is not allowed to address patients directly. In the US for example you can have direct customer advertising. And I am not saying that we should have direct advertising but I think we should be able to educate the patients. We should do this, as

patients cannot rely on nurses or physicians to know all the different treatments. They cannot rely on their physician to know what medication would be the best, as they may rely on the one they already know. In their defence it is difficult to be up to speed but that is why it is important for patients to have access to information. Not many have an interest in providing this besides the pharmaceutical companies.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

NICE which they have in the UK we do not have in Denmark. Other than that much is the same for example with advertising. Nothing that would force us to change strategy.

**Are there any particular barriers, which appear to be due to new price regulations?**

Especially in DK and increasing barriers. Access for new medication is done in a rigorous way. Doesn't take the patients into consideration. However, it does matter to patients. If you as a company can probably only get a low share of the market you might just say you will take your money and spend it elsewhere. A shame for Danish patients.

**Is there any difference due to different medicine groups?**

Do not know. Do not think that some have it easier than others. If you take cancer medication for example there is still much debate over it. I do not think it is unfair, as we need to have the debate. There is the debate that medicine should be for free so you need to have the debate to explain why it is the way it is. Generics are not bringing any new medicines, new treatments to the market.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

The short answer is no. If you look at the US you find a much more interesting market. They will pay a higher price in the US, they are more willing to pay for it. I do not know how long this will go on but for now that is the current state. When you talk to people in the US you get the sense that EU is just too big a problem. It is a big market so they will still launch but it is not the first place they do it.



### **How do you see the future of the pharmaceutical industry in Europe?**

As I said in the beginning we will have to change the business model. So we will see that. Beforehand, we would just launch a product and patients and physicians would then have to figure out themselves how to use it themselves.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

It is very much an impact. Take a look at Norway for example, they take an average the three lowest purchasing prices and base their prices on that. Why would you launch where you get a low price? It has real impact on people and the patients. We have seen examples of a cancer treatment that was not reimbursed in Denmark. Which meant that only people with private insurance or people who are lucky enough to be able to afford it themselves could get it. Unfortunately, it also meant that an A and a B team were created. And we have that right now.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

The high penetration of generic drugs is another explanation, as it means the pharmaceutical companies are losing money. So we will increase the price on the drugs we have left as we need the same revenue. Which is also why you can argue against generics. Related to the crisis is also the fact that the amount of people who can afford the expensive medicine on their own has decreased. People have lost their jobs etc. And generally pharma does not stick its neck out and say "this is what we do". We are afraid to damage our reputation even when it could do us good.

Interview III, conducted over the phone 10-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Anonymous<sub>A</sub>, representing a United Kingdom pharmaceutical company.

**For how long have you worked for the company?**

I have been working for my current company since October 2010.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

I cannot say for Europe but for the United Kingdom it would be change, cost pressure, uncertainty, challenge and limited opportunities. The uncertainty comes from cuts in budgets and then sometimes receiving extra funding, but in the larger it is cuts in budgets.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

Definitely. The changes in the UK have come about since 2013, but they have been planned since 2010. The crisis that occurred is not just going away, so we do face a challenge. Which most people could foresee, and should have foreseen unless you were living in their own world. But the extend of the changes people could not have known of.

**In short what are the five biggest advantages of selling to the UK?**

In the UK it is more progressive which means that challenges we face here other countries will implement further down the line. When we face the challenge earlier it means we are one step ahead of learning how to face that challenge. It means for example we are ahead when it comes to stakeholder mapping.

**In short what are the five biggest challenges of selling to the UK?**

The healthcare reimbursement system.

**Are there any particular barriers, which appear to be due to new price regulations?**

We have something here called value-based pricing and it does bring challenges. It has been in use for a year.

**Is there any difference due to different medicine groups?**

Lifesaving medicines will have an easier route and maybe medicines where there are fewer options will also have an easier route.

In the UK we have patients' voice. It is not at its full potential. The patient's voice is there to aid the patient, there is always a need for another choice. But there is a good focus on mental health in the UK, as there are great financial costs of mental health for society.

**How do you currently see the state of the pharmaceutical industry in the UK? Is the UK an interesting market to launch new products?**

It is very much an era of generics. That says a lot. But the UK does provide a nice launch test bed to test new drugs. Much is based on cost-benefit rather than the therapeutic benefit. Of course they are interlinked but it is very much about cost-benefit. So pharma needs more creative approaches. There is the old model of having a drug, getting market access, getting the price and then going from there, but because of cost pressures we need more of a value-based proposition. We need a new model but it of course depends on the drug and the therapeutic area.

**How do you see the future of the pharmaceutical industry in the UK?**

The same as it has been since 2010. It is a state of flux, change and responding to changes. One word I can think of is challenging. It is a case of having a strong industry in place to help overcome the challenges. Research does shy away from the UK at the moment, as it is a challenging environment. But they are also trying to change this to make the UK more attractive.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the**

**co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

It is one of the big factors. Medicines account for only 1% of NHS budget, but it is the easiest to cut with only the stroke of a pen. It is easier to cut than services, which takes much longer. Which is why there is only going to be more cuts in the future.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

First of all, when you look into the number of treatments available there are many for example within mental illnesses, whereas you have a very limited choice within Alzheimer's. So regardless of the crisis when you have many compounds within the same area, you will have to differentiate your drug. It was bound to happen within some therapy areas. And now there are new innovative treatments coming, so it is only going to be more challenging. The more drugs the more challenges.

Interview IV, conducted over the phone 18-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Anonymous<sub>B</sub>, Otsuka Pharma Scandinavia.

**For how long have you worked for Otsuka Pharma Scandinavia?**

I have worked for Otsuka for 3.5 years and been in the industry for 11 years.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

Restrictive, the attitude towards the industry is not that good, it is hard to get access to doctors and healthcare, and lots of generics.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

Yes. Openness towards the industry was better, there was a higher interest in collaboration, doctors had more to say and it was less restrictive.

**In short what are the five biggest advantages of selling a drug to European nations?**

I think it is very structured so once you get access from EMA you are in. There is also a higher interest in getting new drugs rather than only having the old ones.

**In short what are the five biggest challenges of selling a drug to European nations?**

I would say almost the same if that is possible. It is restrictive, top driven and you have to make a big difference to get in, which is also the way it should be.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

I am sure there are some. In the UK they are driven by NICE guidelines. In Denmark you have the same kind of guidelines driving the market.

**Are there any particular barriers, which appear to be due to new price regulations?**

Definitely, if you look at very specialised drugs for example oncology, cancer, there is a high focus here and higher prices are accepted. On the other hand, you can have some specialised drugs that are just as costly to develop but it can get very hard to get it reimbursed.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

Compared to the US? The US is easier to get in and it might be more restrictive in the EU but if you get in it can still be worth it. You also need to have more of a political view now. In Denmark you for example have Sundhedsstyrelsen and RADS you have to get approval from. So there is a long way to go before it pays off.

**How do you see the future of the pharmaceutical industry in Europe?**

Changing if you look from the inside. I think we will have different roles but I think health economy, market access and medical will be big. I think we will also work on projects. When comparing to the US I think Europe will still continue to be an interesting market, as I do not think Europe will just accept the industry's focus only being on the US and Europe just having old drugs. And therefore it will continue to be interesting.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

It is a result of generics and PI. So you have to have special needs to get new drugs rather than just using generics. So we have to be very efficient when we can get the full price before the generics enter the market. If they want to reduce prices at the same time that can be tough. This also means that there is a focus on cancer for example where you can get a higher return on your investment. But this also has the effect that there will be less research on other disease areas.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

Before the millennium there have been relations between doctors and the industry, which have not been as good as one could have wished. But I think for the guidelines for the drugs they are very much driven by the economy.

Interview X, conducted in person 21-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Thomas Brevig, Senior Director & Head of MA Psychiatry.

**For how long have you worked for H. Lundbeck A/S?**

Since 2011, January 1<sup>st</sup>.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

Willingness to pay for new medicine, differences in what is available, what is offered. There is a huge span from very few drugs to many drugs offered in different countries. Time and processes to get final access also varies from country to country.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

Yes, would have been quite different. There has been a development over 10-15 years, so it would have been different at that time.

**In short what are the five biggest advantages of selling to European nations?**

To help patients with a new drug instead of having limited access to patients must be the biggest advantage, additional business in a country and it is always in our interest to have our products on the home market. Can also be a reference for other countries with those countries looking at the home market.

**In short what are the five biggest challenges of selling to European nations?**

The market access situation, price pressures and that different strategies are needed compared to other regions. Also different information packages might be needed for different countries, which is an extra burden.



**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

Definitely. They are both fast to accept new medicines, but they also have a very rigorous process in the UK from a health technology perspective. For both goes that they have a lot of medicines available to people. And they are very different from France and Germany for example, particularly from Germany.

**Is there any difference due to different medicine groups?**

Yes, absolutely. Not only based on what is economically best for the country, but also based on the push from patient organisations. Disease understanding and awareness is important.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

Like all other countries it is interesting, but it is not as easy as it used to be. So it is less interesting compared to the US and Japan and other markets as it takes more work.

**How do you see the future of the pharmaceutical industry in Europe?**

It can go to ways in principle. The first one is even more strict evaluation of medicines and a Europe with few and even late entries of new drugs. Or it can go to a more insurance-based system like in the US. But that is also quite costly. The US will have problems with their model also. But if that is the future it looks brighter for the pharma industry.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

It has affected tremendously. Price reductions are not only reducing prices, it has further impacts. If the price goes below the threshold companies cannot make their drugs available in that country for obvious reasons such as to parallel trade. In the country and for specific patients groups it is all or nothing.

**In August 2015 H. Lundbeck A/S went through a large scaled firing round. Part of the explanation was losing patents on compounds and the newly launched compounds having to pick up. Do you think this firing round may be related to the changed regulation towards the pharmaceutical industry in Europe?**

Not necessarily the financial crisis, maybe indirectly. For Lundbeck it is about timing and revenue loss due to losing patents especially Cipralext and with the timing and revenue from new products being less than anticipated. Its about willingness for having negative numbers and for how long would that be tolerated. So it is a few factors together. But I do not think it is closely linked to the crisis. And I do not think the development in Europe has been due to the crisis. I think it would have happened anyways.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

Countries have to priorities between drug budgets and other budgets. So when they see larger increases in drug budgets they have to cope. So some drugs are just not available, just to handle the healthcare system and cover all costs.

[Interview XI, conducted over the phone 07-12-2015. The views expressed here are those of the interviewee and not of the company.](#)

**Name and title:**

Anne de Jong-Laird, EU Medical Manager CNS, Otsuka Pharmaceutical Companies Europe.

**For how long have you worked for Otsuka?**

20 months for Otsuka, but I have been in the industry since 2009.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

Challenging, budget driven society, less health driven, less about the quality of life but more about the budgets.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

There has happened a shift towards a “payer driven insurance company perspective” approach. It is less about the patient.

**In short what are the five biggest advantages of selling to European nations?**

Even though it is budget driven the EU has a different culture than for example the US, as they have a different healthcare system in the US. And a different way the patients move through the system. We have more of a social system in Europe in which the added value of a person to a society drives the system.

**In short what are the five biggest challenges of selling to European nations?**

There are big differences within the EU. It is very budget driven, an approach the US is moving towards. The true battle begins after you have received the EU marketing authorisation, as you do not know if you will get reimbursed in the individual countries. And not only do you have to deal with different countries but also different regions as for example the Basque

region in Spain. Another example is Germany where they have a very strong body in which you find a cost-benefit view on drugs and have to be able to demonstrate the effectiveness of a drug.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries in terms of challenges or advantages?**

In the UK you have to be accepted by NICE, but hereafter you still have to go to a regional level getting acceptance here. Making it a very complicated system.

**Do you think there any particular barriers, which appear to be due to new price regulations?**

Probably, but I am not sure. That would be a question for a market access person.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

I am biased as I work in CNS, which is a particularly difficult area. It takes longer for a drug to reach the market, it is less evidence based and failure rate is higher. It is frustrating to see drugs fail. It also has to do with finance as companies pull out when it is so difficult. Take Alzheimer's as an example, no drug against Alzheimer's has reached the market in the last 15 years.

**How do you see the future of the pharmaceutical industry in Europe?**

A challenge. The trend of the finance driven society will continue and it will become increasingly difficult to bring novel drugs to the market. It will also be a generic driven market, as it is so much cheaper. I find that worrisome as this will also mean a lot of areas will lose research. In general there is a negative view on the industry, as people think drugs are too expensive and should be cheaper.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the**

**co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

I worry that there is this trend to limit expenditures in health. It is necessary but they take the easiest way by limiting medicines expenditures. It is a short sighted way to look at the treatment of a patient and not in the interest of the patient.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

It is difficult to answer due to the huge recession. People have become much more conscious, which is not necessarily a bad thing. However, it is very difficult to answer, if we would still see the changes we have seen now, if we had not gone through the recession.

Interview XII, conducted in person the 08-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Marija Simin Geertsen, Senior Manager, Brintellix Medical Affairs

**For how long have you worked for H. Lundbeck A/S?**

Since March 2013, but I have been in the industry for nearly 10 years in total.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

High price focus, budget restrictions, only low and incremental innovation and no breakthrough innovation. On the positive side stakeholders tend to be more communicating, amongst themselves and with pharmaceutical companies. Also there seems to be some alignment between the pure approval of product and the reimbursement of the products. There is also a focus on digital technologies. The buzzword right now is patient centricity, it is related to the digital technology. But there is still a long way to go for EU compared to the US.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

Somewhat differently. When I started working in the pharma industry people started to talk about value proposition needing to be defined already in the R&D, so much earlier in the development of a compound. But not a lot has moved. The trends were already there, but the usage in pharma is very slow. Disappointing as other industries are moving faster.

**In short what are the five biggest advantages of selling to European nations?**

It is hard to say, not sure if I can currently see any benefits compared to the US. One benefit may be that the EU has a long history of regulation and transparency compared to some emerging markets.

**In short what are the five biggest challenges of selling to European nations?**

Reimbursement of products is linked to governmental budgets and they are more heavily linked to recession than private budgets. That is why the industry was more impacted by the crisis. There has also been a decline of financial attractiveness. And marketing authorisation is centralised and get your product approved in all countries, but that does not mean you will get it reimbursed in all countries. It is a complicated system. And it is a problem with small countries, as what you can earn in a small country like Denmark may not make the reimbursement negotiations worth it.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

I would say Denmark is more in danger, as it is a small market and less attractive. There is less incentive for a pharmaceutical company to launch unless you have a headquarter there, like Lundbeck. I am less worried as the UK is a top EU country. Even though a country does not have an interest in launching in the UK they might still start negotiations because of NICE. NICE is one of the most remunerated agencies in the world, so what they decide is often quoted many other places in the world.

Some products have been removed from Germany despite its size because there were not enough financial incentives. So difficult for Denmark not to pay a premium price, when drugs are even being removed from the German markets, which consists of so many more people.

**Are there any particular barriers, which appear to be due to new price regulations?**

I am not sure. If you look recently at how the Danes voted regarding the EU voting, I would hope that countries would vote for more centralised procedures. Especially very important for the pharma industry, but could be the same for many more industries. It is not attractive to negotiate the price with every single country. It would make it simpler if there was a unified reimbursement policy in the EU.

**Is there any difference due to different medicine groups?**

If I were the budget holder I would have a hard privatisation mindset. All pharmaceutical companies will say that the product they are launching is important for the patient. For

example depression is a big disease and it will be more and more prevalent. And it is very important but compared to cancer and the high number of patients who die from this disease that will be a bigger priority at the agenda of the payer.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

No, I would not think so. Financially it is much more interesting in the US, at least within the areas of depression area and allergy where I have worked. You find a much bigger financial potential in the US, it is more centralised in the US but also more regulated for example when it comes to promotion. But you still know as a pharma company what you can do and what you cannot do. Digital platforms are much more possible in the US, they are non-existent in the EU but emerging in the US. So there are clear advantages in the US compared to the EU.

**How do you see the future of the pharmaceutical industry in Europe?**

Some not so good developments will happen and they will probably push for solutions. In the short term companies may be withdrawing new products or will not be willing to launch them in the first place. Especially in the small countries but also in the bigger ones as Germany for example. That will create a pressure in the population against the governments to get new mechanisms in place to ensure new medicines will reach the market. It could lead to options for private insurance, but it could also be that a centralised reimbursement system will emerge in the EU. If they want to keep it the way it is an emergence of private health insurance companies may appear. So private access to medication might be a scenario. But I do not know if pharmaceutical companies will see this as an incentive to launch, depends on the size of the private insurance market.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

It becomes less and less attractive to launch in these countries. Simply the price the countries can offer does not cover the costs.



**In August 2015 H. Lundbeck A/S went through a large scaled firing round. Part of the explanation was losing patents on compounds and the newly launched compounds having to pick up. Do you think this firing round may be related to the changed regulation towards the pharmaceutical industry in Europe?**

Partly related. This is just my personal opinion but Lundbeck should have been more focused in their clinical research. I would call it a sleeping bear syndrome. Once a blockbuster has been launched it means ages of good life. Lundbeck should have invested in new products as they had already satisfied a need. Should have been much stronger at pushing to find something new. You can find similar sleeping bear syndromes in other companies where larger companies have been bought by smaller, as they have been trying to find something similar to their blockbuster.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

Two things: 1) budget restrictions and crisis 2) pharma are growing their expenditures whereas the innovation is incremental. If you are on the other side you need to tell them that you cannot expect a premium price, if you're just giving a new compound that is just a little bit better than what is already out there. You need to adapt to the world of cost savings.

Interview XIII, conducted in person 21-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Anna-Greta Nylander, Director and Head of Otsuka Alliance Team.

**For how long have you worked for H. Lundbeck A/S?**

I started in 1997 and come here straight from university. But I have worked in different positions here. I was 9 years in marketing and am now in R&D.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

Definitely a very competitive market, very high price and reimbursement entry barriers, different rules and regulation in each country, which makes it very complicated.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

I think already around the millennium there were many changes moving in this direction. Maybe it was not anticipated that it would move this much in this direction.

**In short what are the five biggest advantages of selling to European nations?**

That is a difficult one. There is the marketing authorisation with the MEA providing the marketing authorisation, which is an advantage that was not the case in the beginning of 2000.

**In short what are the five biggest challenges of selling to European nations?**

The price and reimbursement environment is the main one. Also from a pharma perspective it is much much more challenging to meet the physicians and to promote to our drugs.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

There is. Even within a country you have different reimbursement and pricing systems.

**Are there any particular barriers, which appear to be due to new price regulations?**

Price pressures from any society make it harder and harder. If you were sitting on a committee it is of course about making the budgets balanced. So they have to take tough decisions. This also means they have a financial focus and less of a focus on the patients.

**Is there any difference due to different medicine groups?**

For sure. If you look at health assessment for example in Italy there is a lot of political pressure for example to provide medication within oncology. On the other hand, it is easier to say no to medication within mental health, as there is less of a political pressure. Patients suffering from mental illnesses and their families are less strong in placing political pressure.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

I think on this one we should listen to our CEO, so it is probably not that interesting.

**How do you see the future of the pharmaceutical industry in Europe?**

Might be a scary perspective. If many pharma companies do not think it is worth it we will be seeing areas that do not have the access to the latest medication.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

It is linked to the fact that it is difficult to get med reimbursed. We are in the business of prescription medicines and it may be different for over-the-counter medicines, but all of this pressure is putting up extra barriers.

**In August 2015 H. Lundbeck A/S went through a large scaled firing round. Part of the explanation was losing patents on compounds and the newly launched compounds having to pick up. Do you think this firing round may be related to the changed regulation towards the pharmaceutical industry in Europe?**

We were mostly affected by losing the patents and being in a launch period. It takes some time before they can accelerate. To what degree the firing round was related to the financial crisis is difficult to say. The entry barriers might be higher.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

It is all purely financial and about governments using the financial measures they have available.

[Interview IX, conducted in person 22-12-2015. The views expressed here are those of the interviewee and not of the company.](#)

**Name and title**

Anders Schroll, Vice President Corporate Communication and Public Affairs.

**For how long have you worked for H. Lundbeck A/S?**

Since 1999, which is when I had just graduated from university.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

Period of change, still figuring out how you can have a business model that will have success in today's environment, certainly an environment where the payer and the price are dominating the market, makes it challenging to bring new innovative treatments to patient.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

Sure, back then we saw a clear focus on securing the best treatment for citizens. For Lundbeck it was our most important market, where we would bring treatments first.

**In short what are the five biggest advantages of selling to European nations?**

I do not necessarily see an advantage of selling to European countries. But when you invest billions of Kroner in treatments the more patients you can treat the bigger the chance is to get a return on your investment. And the EU covers 20 per cent of the world market.

**In short what are the five biggest challenges of selling to European nations?**

There are many challenges because Europe is not anymore focusing on getting the best treatment. Europe is more focused on how they can get the cheapest treatment, therefore, the incentives for us to bring medicines to patients have been lowered. I will give you an example. In the US they may be willing to pay 10 dollars for one treatment whereas in Europe they would want us to sell it for less than a euro.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries**

Every market in the EU have their own system, healthcare system, therefore every market includes different opportunities and challenges. Denmark from a Lundbeck perspective is very important due to the fact that it is our country of origin. What we get on the Danish market is important to what we can get outside of Europe. The UK has in the past been a very important market as well and it is still in the top 5 markets in Europe.

**Are there any particular barriers, which appear to be due to new price regulations?**

A lot of it is in relation to price regulation or all it. It could also be called regulation that tries to restrict government expenditures.

**Is there any difference due to different medicine groups?**

Today compared to 15 years ago there has been a change. There is a second order of competition between disease areas. Looking at oncology the UK for example has cancer funds that give them extra opportunities of getting to the market.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

Not anymore. It is still relevant as it covers 20 per cent as I already mentioned. But Europe would not be where we would launch first. Now we will launch in the US first, then look for opportunities in the international markets and then consider the EU.

**How do you see the future of the pharmaceutical industry in Europe?**

In the mid-term I think we will see a more optimised business model. A pharma model on how can you bring down costs and still have a profitable model but with less revenue, in the past the focus was on how you could grow. I hope that in the long-term policy makers will understand and change their current policies. Everyone agrees that we have an issue with antibiotics, as policy makers in the 90s would not pay for new antibiotics. We now have that issue in other disease areas, so policy makers will have to change their policies. I am always an optimist and hope that sometime in time they will understand this. Otherwise it may move

towards a private insurance market if the public cannot fund it. But I do not think the policy makers want a system in which the public healthcare does not play an important role.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

It has certainly impacted the industry. We have now products that are only on certain markets in Europe. In others we have had to reduce our efforts in educating doctors.

**In August 2015 H. Lundbeck A/S went through a large scaled firing round. Part of the explanation was losing patents on compounds and the newly launched compounds having to pick up. Do you think this firing round may be related to the changed regulation towards the pharmaceutical industry in Europe?**

There is certainly a link. When looking at the restructuring it was mainly in Europe. We are looking at how we can make a profitable business model in Europe.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

15 years ago the US also back then was the most important market. Americans have a will to get access to the newest medicines and are therefore willing to pay for it. But the financial crisis may have made this span bigger.

Interview X, conducted in person 10-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Martin Strandberg-Larsen, Director & Head of Global Market Access, Depression Portfolio

**For how long have you worked for H. Lundbeck A/S?**

Since June 1<sup>st</sup> 2014, but I have been in the industry since 2008.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

Innovation, patient centricity, changing policy environment, long term investments. It takes 10-15 year from the initial molecule to reach the patient, so it is a real challenge to predict the future landscape. All the products you are introducing today were started prior to the crisis. Today there is a pressure on price levels and the way we need to demonstrate value.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

One of the ways it has changed is that before the key customer segment was prescribers. Increasingly patients have been empowered, but also the payer as a key customer has come in. Before we only had to prove that a drug was safe, of high quality and effective. Today we need to talk about it being affective in real life, outside of clinical trials, and we need to show the budget impacts.

**In short what are the five biggest advantages of selling to European nations?**

Very few, but population size, overall wealth perspective, there are still a lot of patients and unmet needs. Also there are a lot of skilled people in the industry. The knowledge base is in Europe and has been built up by the pharmaceutical industries in many years being present and strong here. Big advantage when it comes to recruitment of patients in the EU, as it is easy to follow patients due to for example CPR numbers and the fact that there is a stable structure. In the EU there is also a high level of HCP education.



**In short what are the five biggest challenges of selling to European nations?**

There is a pressure on pharma budgets. More and more countries are starting to disinvest in Europe. Not possible to make a business case as the European drug approval processes are among the most demanding in the world, but will pay less compared to the US. The EU is letting the US pay for new innovations. Another challenge is that Europe has so many different markets with different requirements.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

Denmark and the UK's healthcare systems are very similar. But in the UK they take the payer customer very seriously. You have to prove economic value and quality of life. There is a free pricing system in Denmark, but there is often talk in Denmark that we should do the same as in the UK. It has not happened yet, as there in Denmark is a focus on the clinical information and less focus on patients' needs.

**Are there any particular barriers, which appear to be due to new price regulations?**

More and more countries are introducing health economic evidence based requirements, which we have recently seen in France. The UK has had this system before the crisis whereas Germany also introduced it after the crisis. The effects seen is that drugs are no longer brought to the market in Germany or they are even being pulled out. This has caused many health policy debates in Germany, as it starts being a problem that other Europeans have access to medication that they do not have in Germany. Which is a paradox as Germany is one of the countries in Europe doing most economically well.

**Is there any difference due to different medicine groups?**

Varies country by country. Oncology, cancer, has the same assessment requirements but in the UK you have cancer funds that step in if the public decides that it will not reimbursement the drug. So you have this alternative funding that will pay for it anyway. When it comes to orphan drugs, drugs for rarer diseases, they in practice have quicker regulatory approval sometimes and there is a higher willingness to pay for these drugs.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

There are still many unmet need if you look at public health needs for new medicines, but there is the challenge in the EU that many countries de-prioritise to pay for the new options, and that they have a high bar for how to accept value.

**How do you see the future of the pharmaceutical industry in Europe?**

Not sustainable that the EU is not investing in medicines and that the US is paying for the innovation. You already see this discussion in Germany. But the problem is that if a company decides to stay in a market where they get a low price that will affect prices in all other markets as countries look at each other when deciding on which price they are willing to pay. So natural that pharma will focus on the US.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

I believe it will continue to impact but clearly the trend is not sustainable in the long run. Our CEO of Lundbeck compared it to the case of a 40 years old telephone landline vs. a smartphone. The customer can clearly see in the smartphone arena that it would not work to expect to pay the same for the new smartphone and the old landline. But we still need the customer in the pharmaceutical industry to understand that. More and more patients will not have access to the newest medication and as a potential consequence we might see an individual insurance system in the EU. That will change the way we do healthcare.

**Do you think we might see one unified reimbursement system in the EU?**

There is a lot of effort, for example EUnetHTA, that aims to work in that direction. Do not think it is something we will see, as there are still so many differences in between the countries. But what we might see is that we will agree on something on a European level and then there will be some sort of adjustment of that on the national level. So that we may see are

countries that are similar or with similar economic setting will cluster together. But this is in very hypothetical terms.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

For a long time there were few new pharmaceuticals being sent for approval, the industry had gotten used to the blockbusters and the good life after. After the crisis many more applications for new drugs were seen, but at that time we were also seeing limited budgets to pay for all these new drugs. Another thing is that pharma prices are seen as unreasonably high by the general public and many other parties. This is not fully true, though it might be true for some products within oncology. A lot of funding has been released due to generics and policy makers now have to decide to reinvest that released funding with another area or spend it elsewhere. A consequence of drugs not being launched in Europe or being prioritised being launched other places is that research and clinical trials will also move to where the products are being launched. Which may mean Europe will lose its knowledgebase.

Interview XI, conducted in person 11-12-2015. The views expressed here are those of the interviewee and not of the company.

**Name and title**

Torbjörn Wærner, Senior Director Brintellix Medical & Regulatory Affairs

**For how long have you worked for H. Lundbeck A/S?**

Since February 2003, which is when I started in the industry.

**In my study I am focusing on the pharmaceutical industry in Europe so if you could use only 5 words or 5 short sentences to describe the current state of the pharmaceutical industry what would they be?**

I can say more about CNS, but in general the industry is facing big challenges, problems with innovation, something related in general to medications and something you see in many disease areas but also clearly in CNS is that new drugs are just versions of old drugs. We also see a global issue, but also in the EU, that what is the fundamental business idea? Is it to generate and sell medicines or could it be something else for example to develop treatment? Based on all of this authorities in the EU have extreme market access issues. It is more pronounced in the EU and that makes it very difficult for the industry.

**Do you think your key words describing the industry would have been different if you had been asked for example at the start of the millennium?**

I would have described it in very similar ways, but would have expected the EU to bring more opportunities.

**In short what are the five biggest advantages of selling to European nations?**

Do not know if I see any advantages. There is an academic knowledge around medicine, biology and CNS knowledge, which is heavily weighed to the EU. And there is an academic network in Europe.

**In short what are the five biggest challenges of selling to European nations?**

It is easy to export and import drugs, but you also see this parallel between countries, as they are independent but still subject to the lowest pricing country.

**In my study I am focusing on DK and the UK - are there regional/national differences for these two countries?**

What I think of immediately is the evaluation of a new drug. In the UK they have the NICE evaluation, which is a heavy authority with a huge impact. To me it is the size that has the impact. Denmark has less academic weight, it is a smaller country and so forth.

**Are there any particular barriers, which appear to be due to new price regulations?**

Yes, this is evolving all the time. We have a situation where the German market access authorities now have regulations that make it very hard to launch new drugs, almost impossible. This was not the case 10-15 years ago. You have a similar case in France. Turkey, as another example, has become a much lower value market. Almost year-by-year it is getting harder.

**Is there any difference due to different medicine groups?**

Yes, I am sure. There are differences between disease areas. How should I phrase it, disease areas that have high mortality, for example cancer, for the country sensitive population meaning the working population or the young population have lesser of a challenge. Areas where there do already exist treatments have a higher challenge. Not saying that these existing treatments are necessarily good.

**How do you currently see the state of the pharmaceutical industry in Europe? Is Europe an interesting market to launch new products?**

It can be. For a company like Lundbeck it is extremely difficult, as it is difficult to come with radical innovation within our area. So we are being scrutinised, as we are focusing on incremental innovation.

**How do you see the future of the pharmaceutical industry in Europe?**

There will always be a future as there always will be scientific development in the EU, but it will be increasingly difficult for big pharma to exist in EU. All in all I think that there is a risk that pharma will pull out of the EU.

**I found a study, which was conducted, from January 2010 to February 2011 in which it was found that 22 out of 33 European Member States implemented measures to limit public medicines expenditure. Measures such as price reductions and changes in the co-payments for example. How do you believe this has and will impact the pharmaceutical industry?**

That is obvious that revenues are going down. This is the immediate impact. The secondary impact is that it is more and more costly to develop new drugs, which will lead to some companies pulling out from some disease areas, and eventually even pull out from the EU.

**In August 2015 H. Lundbeck A/S went through a large scaled firing round. Part of the explanation was losing patents on compounds and the newly launched compounds having to pick up. Do you think this firing round may be related to the changed regulation towards the pharmaceutical industry in Europe?**

That is a difficult question. The gap between the old blockbusters and new drugs would have been the same regardless of the crisis. In addition Lundbeck is preparing itself for not having blockbusters in the way it used to. It used to be a one compound company, now the aim is to broaden the portfolio. This is not only because of the crisis in the EU and it is not only happening in the EU.

**Considering the topic of changed regulation towards the pharmaceutical industry in recent years my focus point has been the financial crisis. Do you think that there could be some other explanations or areas I might have overlooked?**

Well yes. There was an economic crisis in the US as well but we do not see the same effect on the industry over there. In Europe there had been a focus on cost containment before the crisis started but that was intensified during the crisis. But I think we would have seen the same development anyways. It would in the future, I am of course not a fortune teller, but what I am getting at is why have we not seen it in the US? It would be surprising if we do not

see it in the US as well. As it is unsustainable with the huge drug expenditures they have. This is not a consequence of the crisis but it of course gets more obvious during a crisis.