AALTO UNIVERSITY SCHOOL OF SCIENCE AND TECHNOLOGY
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REGULATION AND COORDINATION IN EUROPEAN GENERIC MEDICINES INDUSTRY: A FUZZY SET ANALYSIS

Thesis submitted in partial fulfillment of requirements for the degree of Master of Science (Technology)

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ABSTRACT OF THE MASTER´S THESIS

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The global pharmaceutical industry is changing. A number of factors, like rising health care costs, indicate that the importance of generic medicines is growing. The European companies have particularly been affected by the harmonization of inner markets and changes in legislation. Therefore, the main research problem of the thesis is: what kind of business environment favors generic medicines industry. Secondary problems of the thesis discuss the industry dynamics at the European level in more detail through regulatory and other factors.

The thesis found that the two most important factors predicting the future success of the generic medicines industry consist of the generic promotion as well as the growing number of elderly people. The other four factors affecting the success consist of the competitiveness of domestic industry, public health care financing, income levels, and the level of coordination in the economic system. An in-depth fuzzy set qualitative comparative analysis (fsQCA) with the six factors revealed four distinct configurations of these factors lead to successful markets. None of the factors alone were found to be necessary for achieving success. The analysis suggests Europe could be divided into five regions that offer different challenges and opportunities for both companies and public policy makers. Furthermore, the analysis of company population shows that the carrying capacity of the competitive environment has been reached and the population density is declining. One reason for the declining number of companies is the escalating merger and acquisition activity.

The thesis supports an increased focus on micro- and meso-level analysis as proposed in the theory of “Varieties of Capitalism.” Combining set-theoretical research methods works well in this context and provides usable results. The thesis suggests companies operating in generic medicines industry the division of Europe should adjust their strategies specifically for these regions. In addition, public policy makers should utilize these regions and start harmonizing the promotion legislation in Europe to increase the overall effectiveness of markets.

Keywords: varieties of capitalism, fuzzy set methods, qualitative/quantitative comparisons, generic medicines	Publishing language English

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Lääketeollisuus maailmanlaajuisesti muuttuu. Monet tekijät, kuten kasvavat terveydenhuoltokulut, osoittavat, että geneeristen lääkkeiden merkitys kasvaa. Erityisesti Euroopassa yrityksille tuottaa haasteita sisämarkkinoiden yhdentyminen ja muutokset lainsäädännössä. Siksi tämän diplomityön pääongelmana on ymmärtää millainen toimintaympäristö suosii geneeristä lääketeollisuutta. Alaongelmat keskittyvät enemmän toimialadynamiikkaan Euroopassa ja siihen, mitkä ovat regulaation ohella tähän vaikuttavat tekijät.

Tämän työn perusteella kaksi merkittävintä tekijää, jotka ennustavat toimialan tulevaisuuden menestystä, ovat geneerisiä lääkkeitä tukeva lainsäädäntö ja vanhusten kasvava määrä. Neljä muuta havaittua tekijää ovat kotimaisen teollisuuden kilpailukyky, terveydenhuollon julkinen rahoitus, tulotaso ja kansantalouden koordinaatio. Syvempi analyysi fuzzy set -metodologialla osoittaa, että Euroopan geneerisessä lääketeollisuudessa on neljä eroavaa menestystekijäyhdistelmää. Analyysin ja näiden neljän yhdistelmän perusteella Eurooppa voidaan jakaa viiteen alueeseen, jotka tarjoavat erilaisia haasteita ja mahdollisuuksia niin yrityksille kuin päätöksentekijöillekin. Lisäksi yrityspopulaation analyysi osoittaa, että toimiala on saavuttanut kantokykynsä rajan ja että yritysmäärä on laskussa. Yksi syy laskevaan yritysmäärään on myös kiihtyvä yritysostojen määrä.

Teoreettisesti tämä diplomityö tukee ehdotettua suuntaa keskittyä pienempiin osiin kapitalismin eroavaisuuksien tutkinnassa. Myös joukko-opin yhdistäminen analyysimetodina sopii hyvin tähän ehdotettuun suuntaan. Geneerisen lääketeollisuuden yrityksille Euroopan jakaantuminen viiteen osaan tarkoittaa, että strategioita pitää muokata vastaamaan näitä alueita. Päätöksentekijöiden tulisi myös huomioida nämä alueet ja käyttää niitä hyväksi yhdentäessään lainsäädäntöä Euroopassa, jolloin markkinat kokonaisuudessaan tulisivat tehokkaammiksi.

Avainsanat: kapitalismin vaihtelu, fuzzy set -metodit, kvalitatiivinen/kvantitatiivinen vertailu, geneeriset lääkkeet	Julkaisukieli englanti

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1 Introduction

1.1 Background and the Objectives of the Study

Generic medicines are growing in importance in the industrialized countries simultaneously as the overall usage of medicines is increasing. In the developed countries, generic medicines industry is seen even more important than traditional innovative pharmaceutical industry. One main reason for this is the cost cutting benefits and savings generic substitution offers for the payers of the medicines. Another generally acknowledged cause for the rise of the generic medicines is that people live older in the industrialized countries and therefore the overall costs of the health care are on the rise. Generic medicines offer a way for governments to cut down their health expenses. Furthermore, the rising research and development costs in the innovative medicines industry make companies search revenue streams in other businesses including generic medicines. (DiMasi & Grabowski, 2007; European Commission, 2009; Hoffman, 2005.)

Generic medicines are also globally experiencing industry shaping forces from governments, competing industries, as well as medicine users. This puts the industry in an interesting position, which is even intensified by the benefits the industry has on the costs paid by the users and governments. Moreover, in Europe the reshaping of the continent and the unification of the markets provide even more interest for the industry-wide study. Further motivation for the study comes from the fact that the industry has substantial influence throughout Europe. A comprehensive study of the industry is needed also because an industry-wide study of the generic medicines has never been made.

From all of this the main research problem of the study is formulated: *"what kind of business environment favors generic medicines industry?"* To analyze and answer this problem thoroughly two additional sub-problems are formulated. It is previously indicated that in the generic medicines industry regulation and coordination play an important role. These additional questions address this

area as well as the chosen focus of the European countries. Also the understanding about the other factors is needed to comprehensively understand the industry dynamics. The additional sub-questions are:

1. *How does the regulation and coordination influence the dynamics of the generic medicines industry in Europe?*
2. *What other conditions are the most central for a generic medicines industry to succeed in Europe and how do they influence the dynamics of the industry?*

Two additional objectives are also set for this thesis. Reaching these objectives will help to solve previous problems and to answer the questions properly. The first objective of the thesis is to build a comprehensive understanding about the industry, its business environment, and the affecting institutional factors. This information about the dynamics of the industry should also be usable as a separate part of the thesis. The second objective is to study the differences of these factors between European countries and to understand the challenges and opportunities these differences indicate for companies and public policymakers. To be precise, this means that among others industry actors, demographic trends, and economic conditions need to be studied in addition to regulation and coordination.

However, using generic medicines industry as an empirical data for comprehensive study is rather complex. Two main reasons for this are the limited number of available cases and the above described complex environment. For studying regulation and coordination and its effect on the industry, the theory of "Varieties of Capitalism" (Hall & Soskice, 2001) will be studied profoundly. Because generic medicines industry is highly influenced by the patent and promotion legislation, the understanding about these processes at the national level is required. Varieties of Capitalism in part assesses these. Moreover, Varieties of Capitalism studies have been recently pointed in the direction of studying more specific areas and using set theoretical methods in the analysis (Jackson & Deeg, 2008).

To produce valid study and results a rather novel methodology of fuzzy set qualitative comparative analysis (fsQCA) (see generally Ragin, 2000, 2008a; Ragin & Rihoux, 2008) is implemented in the study. FsQCA is part of emerging set theoretical methodologies that have been used with success in a variety of studies of causal complexities in social and management sciences. Methodology has been especially usable in studies with a relatively low number of cases and it fits thus into the study. A general idea of fsQCA is to combine the best aspects of both qualitative and quantitative research. In order to use fsQCA and build the configurations of different factors affecting the success of the industry deep substantial and theoretical understanding is needed (Ragin, 2008a).

After building a comprehensive threefold understanding about the industry based on empirical evidence, the theory of Varieties of Capitalism, and the analysis methodology of fsQCA the analysis can be done. Concrete outcomes from the analysis will be the configurations of factors that lead to industry's success. Comparison of these against the comprehensive understanding about the coordination and regulation and other affecting factors in the industry will provide robust and usable conclusions and recommendations. The contribution of the thesis includes implications for the companies involved in generic medicines, implications for public policies, and implications for the theories of fsQCA and Varieties of Capitalism.

1.2 Scope and Limitations

The thesis focuses on the generic medicines industry in Europe. A general definition of a generic medicine is that it is a medicine that is produced without a patent protection as original medicine's patent has expired. Generic medicine is also similar to original and already authorized medicine and thus it is interchangeable in regard to the original medicine. Generic medicine contains the same quantity of active substances as original medicine. Generic medicines differ from original by name, appearance, and packaging. (EMEA, 2007.) The thesis focuses on the actors who have a marketing authorization for a generic medicine in Europe. Furthermore, particularly the focus is on the prescription

medicines. This means that among others over-the-counter (OTC) and other self-treatment medicines, and hospital medicines are excluded from the thesis. A more comprehensive industry structure will be presented in Chapter 3.1.1 Industry Structure.

Copied medicines are excluded from this thesis. Copied medicines differ from generic medicines, because copied medicines do not have a proof of bioequivalence to original medicine. Also excluded is the emerging industry of biosimilars, which are the generic versions of biomedicines.

Geographically the study focuses on the European markets meaning the European Union with Switzerland, Iceland, and Norway. From these three additional countries, the latter two operate under the rules set by European Medicines Agency (EMEA) and thus have the same basic rules governing the generic medicines industry. Switzerland is also included in the study because of the similarity to the Western-European systems even though not formally being a member of those. The final number of countries that are included in the actual analysis is 24 because of the limitations in the available data. Excluded from the study are most notably Russia and Turkey. This is a clear choice as these countries clearly have different market characteristics and regulations than the included nations.

1.3 Structure

The main areas of the thesis are firstly Varieties of Capitalism as part of the institutional theory relating to differences in operating environments, secondly the dynamics and the success factors of generic medicines industry, and thirdly the methodology of fuzzy set qualitative comparative analysis as a part of the set theoretical research approaches. Because of this chosen triple theory approach the following structure is used. Literature review of the Varieties of Capitalism will be discussed in Chapter 2. Chapter 3 discusses the theory and empirical evidence of the generic medicines industry. Chapter 4 discusses the fuzzy set qualitative comparative analysis. Chapters 2, 3 and 4 together form a

theoretical and empirical background to the thesis. In the ending part of the thesis Chapter 5 illustrates data and the analysis. This chapter also finally bridges three previously discussed parts. Chapter 6 presents the findings and the results and finally Chapter 7 presents discussion and conclusions. Simplified visualization of the structure is presented in Figure 1 below.

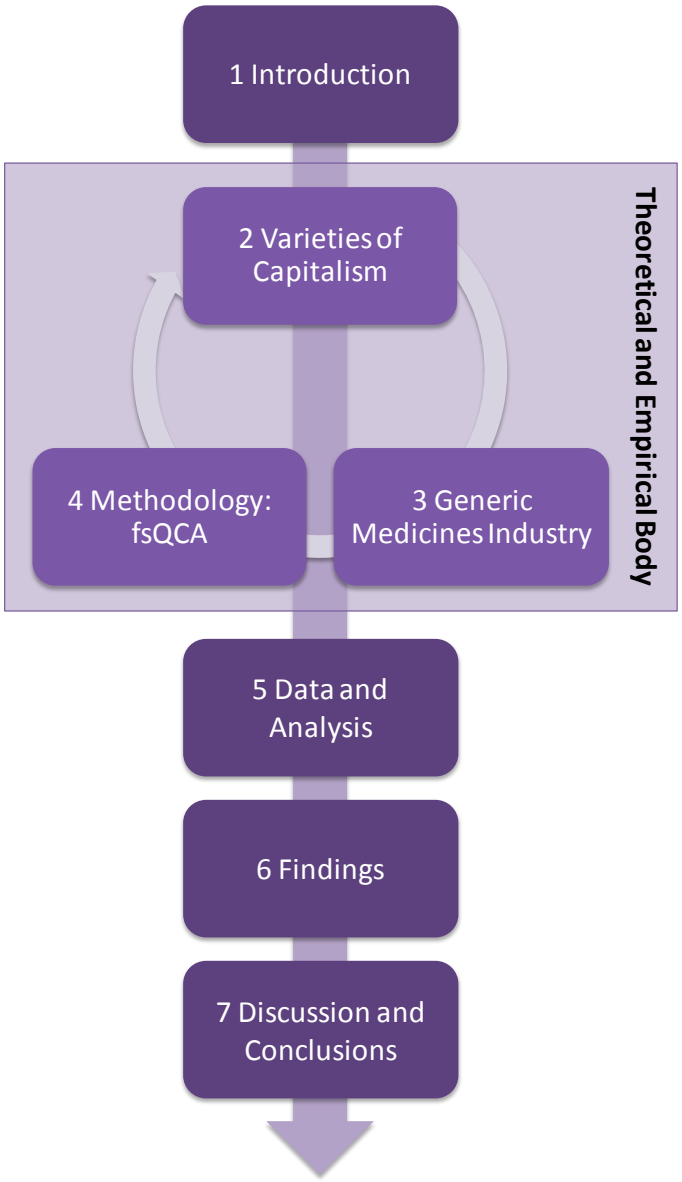


Figure 1: Simplified Structure of the Thesis

2 Literature Review: Varieties of Capitalism

This chapter enlightens the research done so far on the management theoretical topic of this thesis: Varieties of Capitalism (VoC). This field of research is relatively new and its original work is considered being a book Varieties of Capitalism by Hall and Soskice (2001). This topic will be first of three parts that form the theoretical and empirical body of this thesis.

2.1 Comparative Capitalisms

The "Varieties of Capitalism" (VoC) is a relatively new framework introduced to the greater public by Peter A. Hall and David Soskice in their book called Varieties of Capitalism (2001). Theory largely builds on their previous works and ideas (e.g. Soskice, 1999). This term has since gathered many scholars and formed a new field of research. Furthermore, the legitimization of VoC literature has tied it to be today one of the most important parts of wider and older field of literature called comparative capitalisms (CC). One of the main contributions of CC is to explain how nations respond to economic shocks from the market changing forces like globalization (see Deeg & Jackson, 2007; Jackson & Deeg, 2006). In the same context VoC focuses on market coordination. It sees firms as central actors in this analysis (Hall & Soskice, 2001).

CC and VoC, depending on the definition used in literature, can be either synonyms or more commonly, as mentioned above, VoC can be considered the most recent and prominent addition to CC. One definition of CC by Deeg and Jackson (2007) indicates that CC field refers to the diverse set of approaches and frameworks that have a common concern understanding the institutional foundations that affect the formation of diverse business organizations within different nations. On the other hand, in the original form the VoC theory by Hall and Soskice (2001) focuses on understanding the institutional similarities and differences among the developed economies. Based on these definitions, the view that considers VoC as a part of CC is adapted to the study. Moreover, this

literature review focuses on VoC literature, but because of its close relativity to CC, some aspects are also taken from CC.

To start from the beginning, the roots of VoC are, as stated by Hall and Soskice (2001, pp. 2-5), in the modernization approach (see generally Shonfield, 1965), neo-corporatism approach (see generally Schmitter & Lehmbruch, 1979), and in the social systems of production approach. Common to these approaches is that they focus on set of actors and have those as the main parts of the analysis. However, their stated level of the analysis varies. The modernization approach at one form analyzes states; neo-corporatism focuses on tri-partite bargaining that involve unions, the private sector, and government that are within one country; and social systems approach focuses on, for example, institutions like national innovation systems. As can be seen, the trend in this field has been to move the focus of the analysis from the nation level to the smaller and smaller units or sets of actors, but still keeping the focus on macro-level. VoC approach is first in this field that explicitly states that it tries to capture the firm at the center of the analysis. Firms are seen as the actors who trigger the changes in the institutional environment (Hall & Soskice, 2001). What are adapted then from the predecessors to VoC are the views on how institutions affect the economic performance.

Also on the level of constructing the framework Hall and Soskice (2001) take a lot of influence from Michel Albert (1993) although this is not much emphasized in their work. Albert was the first to argue the binary division of the main capitalist types. He described a Rhineland type and an Anglo-Saxon type very much in the same way as later VoC would describe its core models. This will be discussed later. (Crouch, 2005; Deeg & Jackson, 2007.)

From all the influence that have an effect on VoC literature emerge many high level topics, but the ones who are especially interesting for the study range from corporate strategy and legal systems to social policy. In addition to that, the actors who are analyzed in VoC approach under these topics may generally be individuals, firms, producer groups, or governments. From these, the thesis at

least partly includes all except for individuals. Furthermore, in VoC theory from all of these firms are seen as the main actors. This is because in capitalist societies firms are crucial actors and they are involved in so wide a variety of activities that they necessarily influence many levels of the economic performance. (Hall & Soskice, 2001, pp. 2-6.)

In the original form, the main VoC framework by Hall and Soskice (2001) distinguishes two main ideal types of political economies, liberal market economies (LMEs) and coordinated market economies (CMEs). This division is first and foremost based on the differences observed in the developed market economies of Western-Europe and Northern-America. Sometimes also Japan and some other Organisation for Economic Co-operation and Development (OECD) countries are included in the analysis (e.g. Amable, 2003; Hall & Gingerich, 2004; Kenworthy, 2006).

Despite the lack of analyzing all of the OECD countries, the original theory still categorizes all of these (Hall & Soskice, 2001, pp. 19-21). Hall and Soskice identify six countries to be LMEs: the USA, UK, Australia, Canada, New Zealand, and Ireland. Ten countries are identified as CMEs: Germany, Japan, Switzerland, the Netherlands, Belgium, Sweden, Norway, Denmark, Finland, and Austria. This leaves six of OECD countries in a more ambiguous position with having the elements of both of the main types. These are France, Italy, Spain, Portugal, Greece, and Turkey. Many studies simplify this division further by comparing the USA or UK as the example of ideal LME and Germany as the ideal example of CME (e.g. Hall & Soskice, 2001, chap. 10 Varieties of Corporate Governance: Comparing Germany and the UK). Generally, these countries are seen as the most ideal examples (e.g. Hall & Gingerich, 2004). However, this division and labeling can also be challenged in many various ways as will be discussed later.

According to the theory, the main basic difference between these two ideal types of economies is that, in LMEs companies coordinate their activities via hierarchies and competitive market arrangements. In LMEs market relationships are characterized by the arm's-length exchange of products or

services, which means that parties involved in exchange are independent and on an equal footing. On the other hand, in CMEs companies are more dependable on non-market relationships and they use these relationships more to conduct business and build their own competitiveness. (Hall & Soskice, 2001, pp. 8-19.)

Hall and Soskice (2001, chap. 1 An Introduction to Varieties of Capitalism) classify more detailed aspects for differentiating CMEs from LMEs. They propose classification based on five spheres in which firms must be active in order to be competitive. The spheres they propose are (i) industrial relations, (ii) vocational training and education, (iii) corporate governance and financial systems, (iv) inter-firm relations, and (v) employees and internal structure. Institutional environment inside these spheres together differentiates CMEs and LMEs.

The idea in the analysis of VoC is that the superior performance of national economy is dependent on situation rather than the system that is ruling. Hall and Soskice (2001) argue that neither of two main types of capitalisms systems, LMEs or CMEs, is better than the other creating good outcomes and good performance. To reinforce this concept, they present the idea of the institutional complementarities. The idea is that two institutions can be said to be complementary if the efficiency of one increases the efficiency of the other. This is similar to the concept of complementary goods. In practice, it is proposed that institutional practices should not be distributed randomly across nations, but there should be some clustering. This finally divides LMEs from CMEs as nations converge on complementary institutional practices. The key differences between LME and CME are presented in Table 1. The complementarities that are characteristic of the ideal types of CME and LME as proposed by Hall and Soskice are also presented in the table (2001, pp. 21-33).

Table 1: Key Differences between Ideal CME and LME in Five VoC Spheres

	CME (Coordinated Market Economy) (Germany as an ideal example)		LME (Liberal Market Economy) (The USA as an ideal example)	
	Characteristic	**Implications from complementarities**	**Characteristic**	**Implications from complementarities**
(i) industrial relations	Industry level decision making bodies, e.g. wage bargaining.	Strong unions. Longer employment contracts.	Relationships between individual worker and employer.	Highly fluid labor markets. Easier to take advantage of new opportunities.
(ii) vocational training and education	Need for labor with high industry-specific skills.	Publicly subsidized training systems for industry specific skills.	Need for labor with general skills that can be used in variety of firms.	More in-house training in companies for marketable skills.
(iii) corporate governance and financial system	Not entirely dependent on public finance.	Long run investments. Monitoring performance requires also inside information, which requires tighter networks.	Public financing.	Price of the stock important in terms of future financing and survival. Networks for information do not need to be so close.
(iv) inter-firm relations	Important role of institutions in facilitating relations.	Collaboration between firms and universities to ensure technology transfer.	Standard market relationships and enforceable contracts.	Job rotation facilitates technology exchange. Inter-firm collaboration not that important.
(v) employee relations and internal structure	Major decision need to be secured with multiple stakeholders.	Networked internal structure.	Unilateral decision making by top management.	Internal structure not needed to facilitate networking that much.

Based on this idea it is suggested that superior macroeconomic performance is a product of institutional coherence and therefore intermediate or not so institutionally coherent systems will underperform the more coherent or pure type LMEs or CMEs. Incoherence can occur either because of being in the middle in regard to coordinated and liberal market institutions or having a mix of both coordinated and liberal market institutions. According to Jackson and Deeg

(2008) this means that there is a U-shaped relationship of economic performance between the countries clustered in the bipolar line of LME and CME. (Hall & Gingerich, 2004; Hall & Soskice, 2001; Kenworthy, 2006.)

This central idea in VoC can be formulated as the first high level proposition for this thesis. A number of propositions about the issues affecting to an industry's success will be formulated in this and the next chapter. Propositions in this chapter are more general and have possibly an effect to many industries. Next chapter will introduce more detailed propositions that are mostly relevant to the generic medicines industry.

Proposition 1: Coherence and coordination in the economy affect the performance of an industry.

By looking at Table 1 some of the complementarities and their implications can be observed. Key argument by Hall and Soskice (2001) is that LMEs are more capable of having radical innovation and CMEs are more oriented in incremental innovation. Fluid decision making systems, job markets, and financing systems are a few key reasons for LMEs possessing the capability of radical innovation. For example, in LMEs rapid access to new financing makes it possible to invest faster in new key areas. In order to investments to be effective, fluid labor markets are needed to provide a quick route to access needed capabilities through job markets. On the other hand, in CMEs system supports long term investments and thus makes it possible to acquire considerable amount of industry-specific skills to provide capabilities for incremental innovation.

In practice these complementarities are also observed in some examples and empirical data that Hall and Soskice present. A key example that Hall and Soskice (2001, fig. 1.5 and 1.6) provide is about the patenting activity between Germany and the United States. It is seen that these characteristics make Germany to specialize in technological developments that are exactly opposite to those in the United States. In Germany, the innovation has been in the fields that are characterized by incremental innovation like mechanical engineering

and transport. In the United States radical innovation specific industries, such as medicines, semiconductors, and telecommunication, have been stronger. Therefore, strong US players have characterized these industries. The second high level proposition for the study can be formulated from innovation capabilities to tie the empirical context more closely to the theory of VoC.

Proposition 2: Industries needing more incremental innovation, such as generic medicines industry, should be more successful in the coordinated economies.

At the company strategy level, VoC theory suggests that there are many pathways to high performance. These pathways are based on different settings in institutional environment. There is some contradiction in this and the traditional international business studies, where usually the high performance is a result of strategy fitting to the institutional context (Jackson & Deeg, 2008). An example given here by Jackson and Deeg (2008) is from Lehrer (2000), who found out that in the airline industry two divergent paths from Lufthansa and British Airways led to equally successful performance and led to outperforming the mixed strategy of Air France.

Various contributors have explored and studied the theory with various points of view and examples. To provide more concrete reasoning for above presented division into LME and CME and to their complementary attributes one example is presented here from the group of cases in the original book. Sigurt Vitols writes about the varieties between the UK and German chemical/ pharmaceutical industries (Hall & Soskice, 2001, pp. 355-358). This example is also interesting because of its close relation to the generic medicines industry. Vitols argues that based on the theory of VoC the decline of German industry and the growth of British industry in the 1990s can be explained. British companies were characterized the ability to enter the new growth fields more rapidly because of their ability to innovate radically. In addition to that, more rapid rationalization in the production of simpler products was an important comparative advantage. The pace of change in German companies had been slower but change has also increased the importance of chemicals in compared

with pharmaceuticals. The ability to change rapidly because of the characteristics of the national institutions made German companies exit the pharmaceutical markets. Some exited totally and some continued as chemical producers. Also some transferred their key operations to US to compete in rapidly changing markets with similar capabilities as LME based companies. In general it can be said that there can be multiple paths to high performance, both for nations and companies.

2.2 Current Issues and Critique of the Varieties of Capitalism

Even though currently VoC theory has been legitimized and it has developed quite a dense body of knowledge, its future looks somewhat uncertain. The whole theory probably is not disappearing; it is still a valid theory and it is indicated to have many strengths that should not be abandoned (e.g. Blyth, 2003; Jackson & Deeg, 2008). However, the future should hold quite many changes to the key parts of the theory that emerge from the growing number of criticism that is experienced by the original theory. This chapter addresses the criticism of VoC theory as well as the additions and the proposed additions to the original theory.

Criticism and additions to the original theory have been divided into three slightly differing areas. Firstly, the labeling in VoC, namely the bipolar division into LME and CME, has been experiencing quite many additions (e.g. Amable, 2003; Schmidt, 2008). Secondly, coordination and institutional coherence as a measurement of success experience criticism (see generally Kenworthy, 2006). Thirdly, the analysis itself is experiencing two tiered criticism from the type of analysis, whether it should look at macro-, meso-, or micro-level, to the level of dynamism in the analysis (e.g. Deeg & Jackson, 2007; Jackson & Deeg, 2008). The main proposals for theoretical contributions emerge from the last point.

2.2.1 Labeling in the Varieties of Capitalism

Firstly, problems are seen in the bipolar division into LME and CME. One of the problems is that this division does not include even all the OECD countries, not

to mention Eastern-European economies or Asian economies. Second problem is that the studies conducted in the spirit of the original theory are mostly comparative studies between the main ideal types (see generally many of the case examples by various contributors in Hall & Soskice, 2001). In general these arguments yield the criticism that the theory is not capable of producing robust results (Jackson & Deeg, 2006; cf. Kenworthy, 2006).

To make the theory more capable of making more robust conclusions there is various additions to the original binary division between LME and CME. Instead of having these two capitalisms, at least three varieties of capitalism (Rhodes & Van Apeldoorn, 1997; Schmidt, 2007, 2008), four (Boyer, 2005; Ebbinghaus, 1999), or even five (Amable, 2003) is argued to be. In addition to these clearly labeled theories, there can be even more varieties as indicated by Schmidt (2008), for example, due to national varieties (Boyer, Crouch, & Streek, 1997) or regional and local varieties (Crouch, 2005).

Some of the main additional divisions that have been adapted for studies are firstly three tiered division where LME and CME are added with "state-influenced" market economies (Schmidt, 2007). This division works with European countries and has the states interference to the markets as the differentiator between capitalisms. This way this model tries to make a cap between it and previous three tiered models where LME and CME are added with "mixed market economies" (Hall & Gingerich, 2004) mainly to include the countries that are outliers in the original model. Similarly Europe is also categorized earlier with different labels to Anglo-Saxon, Germanic, and Latin capitalism (Rhodes & Van Apeldoorn, 1997). Also one type of division into three labels is Esping-Andersen's model where LME is as presented by Hall and Soskice, but the CME is divided into the Scandinavian type social democratic model and to the continental European model (Hopkin & Blyth, 2004).

In four tiered models, Europe is divided into Nordic, Center, Southern, and Anglo-Saxon models (Ebbinghaus, 1999) or to market-led, meso-corporatist, social democratic and state-led (Boyer, 2005). Boyer's work also gives room to

the fifth emerging form that should cover the transformation economies of the former Soviet-type economies in Eastern Europe and in China. Still in the models with four labels the same problem remains as in the three-label and original binary model: market economies outside Europe have only little importance.

Currently one of the most complex and robust theories is one Amable (2003) has presented. This theory is among a few in the group of labeling theories that can incorporate emerging market economies into the groups (see Jackson & Deeg, 2006). In a five-model theory, there is a market-based model, a social-democratic model, a continental European model, a Mediterranean model, and an Asian model (Amable, 2003).

So generally Eastern-European or emerging Asian countries can be only incorporated to the theory with five or more distinct capitalism models. For the purposes of the study possibility to incorporate Eastern-European countries to the analysis is essential as the European generic medicines markets are highly affected by them. This will be discussed later in this thesis. Therefore, it is somewhat encouraging that some efforts to study former communist countries in the context of VoC have been made (e.g. Lane, 2005; Lane & Myant, 2007).

To extend the theory to Eastern-European transition countries, Lane (2005) argues two additional models that can fit former communist countries, which have been able to adapt some form of capitalist society. He argues the models based on Amable's work (2003). First model for the former communist countries is close to Amable's continental European model, but has more state control in place. This model has the most number of former communist countries and includes all the countries that have already been accepted to the European Union. Second model Lane proposes is a hybrid state/market uncoordinated capitalism. The biggest country representing this model is Russia. Lane mentions that his model needs to be substantiated and there he sees detailed country studies as the most viable way forward.

However, binary, or any other labeling method for that matter, have other problems than finding trouble fitting all the countries to the model. Firstly, it has been argued that there are even greater varieties in capitalist models within nations (Schmidt, 2008). Secondly, it has been argued that since the creation of the theory world has changed in a way that the division by Hall and Soskice (2001) is no longer valid. Mainly due to the changes in economic environment that are caused by globalization, or Europeanization in Europe (Schmidt, 2008), the models indicated in VoC are becoming obsolete. It has been argued that in Europe the economies are converging to a common liberal model. However, there is a varying opinion saying that even though changes are there, there is no convergence to be seen (Hall, 2007).

2.2.2 Measuring Performance in the Varieties of Capitalism

The second area of the critique associated with VoC is the performance measurement. Measuring performance and efficiency in VoC have been done both with the level of coordination and institutional coherence. Both of these are somewhat relative to the critique of binary division as these measures are used as a basis for those divisions.

Hall and Soskice have chosen innovation as a representative of a success in the analysis of coordination. They chose innovation because of its importance to economic success and because they have failed to explore other areas (Hall & Soskice, 2001, p. 44). This is problematic as other areas of performance measurement might provide totally contradictory results for the sources of comparative advantage. Also the use of patent data to illustrate innovation, as Hall and Soskice propose, is questioned. Allen, Funk and Tüselmann (2006) argue that patents might not in reality translate well into comparative advantage. They, however, also note that this has not been the only measurement of success and efficiency in VoC literature since Hall and Soskice. As a whole, there is more support to coordination than there is critique.

Institutional coherence is another building block of different capitalist models that emerge from the original theory. Originally this part of the theory was argued with qualitative analysis and comparative case studies (e.g. Hall & Soskice, 2001). The problem with the comparative case studies in VoC has been that comparisons have been very limited and strictly defined. The comparisons have been made between few countries and in a particular time in history. Also many examples do not account for any other countries except ideal types. What is more, when comparing the characteristics of LME and CME with the firm specific characteristics in specific industries, there can only be a limited explanation of the success of the industry. The problem is that without being able to analyze countries outside the ideal types with all the affecting factors, theory is not capable of making sweeping statements.

There have been some studies made to test the institutional coherence in practice and with more analytical frameworks. Especially Hall and Gingerich (2004) in their study conclude that their empirical analysis supports the original hypothesis of coherent economies outperforming less coherent. However, Kenworthy (2006) quite much critiques the study by Hall and Gingerich (2004) as well as the original theory. He uses two measures of institutional coherence, one developed by Hall and Gingerich and another he has developed. By analyzing these, he finds almost no support for the notion that superior macroeconomic performance is a result of institutional coherence. In addition to that, Kenworthy critiques the research setting of Hall and Gingerich. More specifically Kenworthy argues that the forming of the institutional coherence measurement is incomplete. The factor analysis of Hall and Gingerich that is used to construct the measurement only incorporates three of five Hall and Soskice (2001) spheres and, what is more, the corporate governance sphere is represented in half of six indicators.

It seems that coherence measurement for the industry's success has more problems than a coordination measurement. Furthermore, coordination seems to address more the specific industries as the coherence addresses national

economies. For the study, a general proposition from these observations can be formulated.

Proposition 3: The value of the coherence measurement should be lower than the coordination measurement when analyzing the success of an industry.

2.2.3 Analyzing in the Varieties of Capitalism

Last part of the critique is actually more of an effort to clarify, unify, and to point a direction forward for the analysis within VoC than criticizing the previous analysis. It is first and foremost argued that more dynamism is required in the VoC analysis (Fiss, 2007), to incorporate all the current changes in the world economy. The critique addresses that weakness in many of VoC studies is the static analysis and the bias of predicting institutional stability rather than change (Deeg & Jackson, 2007; Jackson & Deeg, 2006). Especially Deeg and Jackson (2007) propose that in order to have more dynamism in the VoC theory the division of the analysis between micro-, meso-, and macro-levels needs to be clarified. A micro-level requires a stronger understanding how actors reshape the institutional environment. A meso-level requires the understanding about linkages between various institutions, which then could be used to theorize how change in one affects the other. A macro-level then moves to the level of national and international politics and, for instance, analyzes rule making processes. The main argument, about why this clarification is needed, is that current forces of globalization are much stronger in changing national institutions than the theory predicts. One clear indicator to this point that fits especially well to the pharmaceutical industry is the growing importance of multinational corporations as well as institutions that go beyond the national borders.

Furthermore, before Deeg's and Jackson's two papers Kenworthy (2006) indicated similar ideas. He indicated that analyzing at the macro-level with aggregated outcomes is extremely difficult because of the complex causal linkages. Empirical findings from macro-level analysis need to be tested thoroughly before accepting those results. This can prove to be difficult and

therefore usually macro-level analysis remains only a partial or preliminary step in the investigation of causal linkages. This is another argument that directs future research to more detailed studies in the meso- or the micro-level.

Some of the criticism to the original theory presented above have been tried to answer with some recent work. For example, proposed theory's disregard of the state influence (Jackson & Deeg, 2008) has been answered in part in Vivien A. Schmidt's work (Schmidt, 2008, 2007). In addition, the presented critique on the institutional stability has been argued against at least at macro-level: Hall and Thelen (2009) have developed the theory to cover this institutional change in more extended way than the original theory. However, the problems of setting the theory with the empirical evidence (Jackson & Deeg, 2008) are still a major concern especially at the meso-levels of the analysis (Deeg & Jackson, 2007). Deeg and Jackson also indicated that the current institutional environment is too complex for the types of theories that VoC represents. It seems that the traditional methods of analysis might not be sufficient for VoC context.

2.3 Future of the Varieties of Capitalism

The critique provides multiple viable ways for VoC theory to go forward. The problem is that on the basis of all the criticism presented above, it might not look clear that the VoC theory is viable today, for example, because of the increasingly complex environments. However, arguably only the strict labeling of capitalisms might not be relevant in today's world, but it still seems viable to construct the future of the theory based on complementarities in economies. Theory has created a standard that provides wide variety of hypotheses for understanding institutional environment as a factor effecting companies' success. However, the future contributions to this theory must be a subject to more sophisticated empirical tests. (Deeg & Jackson, 2007; Jackson & Deeg, 2006.)

As Varieties of Capitalism includes a very broad number of issues at the macro level, not all of these can be incorporated to industry specific analyses. From the previous critique things that are particularly relevant to the thesis include the categorization as a mean to simplify the complex environment, the measurement of high performance, and the combined influence of macro-, meso-, and micro-level to an industry. First the categorization or labeling, whatever it might be, could be useful in analyzing issues leading to performance differences between regions. Categorization has been effective in labeling established economies. Problems with labeling emerging economies, in this case meaning mainly the Eastern European nations, need to be assessed. For performance analysis it is important also to examine other things that might have an effect on performance, not just coordination and coherence. It is also important to understand that there can be multiple paths to high performance. To analyze complex environment as well as multiple paths to an outcome, analysis framework should also be assessed. Main issues of VoC as well as main takes for the thesis are summarized in Table 2.

Table 2: Summary of the Key Findings in Varieties of Capitalism

Critique area	Current status	General issues	Key ideas for this thesis
Labeling	1-5 or even more groups of capitalist variation.	Future of the labeling, possible convergence to a capitalist model, including emerging economies to the theory more strongly.	Categorization can be helpful in assessing performance, but there can be limitations when including Eastern Europe to analysis.
Measuring performance	Economic coherence and coordination key areas in performance measurement.	Validity of measurements used previously, providing new ways to measure coherence and coordination.	There can be multiple paths to high performance, both for nations and companies, and multiple things affect to performance and efficiency.
Analysis	Mostly qualitative comparisons between small numbers of cases. Some attempts to analyze more analytically.	Methods of analysis in different levels from macro to micro, analyzing increasingly complex environments, the analysis of change or stability in the economic systems.	The focus on the more tightly framed settings when keeping in mind also the institutional environment should provide input on the firm-level strategies. New analysis methods are needed.

Analysis methodology is a key thing when studying the generic medicines industry in the VoC context as can be seen in Table 2. Amable (2003) already showed that VoC theory is not limited to stay with the traditional variable-based approaches. He successfully introduced to the VoC discussion clustering approach. Fiss (2007) continued in another new direction and argued that set-theoretical methods are one possible way for assessing ideas and issues in this context comprehensively. Set-theoretical methods can be more complex than traditional analyses. Also the proposed advances in VoC, like moving the focus of the analysis towards micro-level, are seen to increase complexity in the analysis. As set-theoretical methods are able to address more complex settings, set-theoretical analyses are also able to produce more complex results in the context of VoC (Crouch, 2005; Jackson & Deeg, 2008). Therefore, set theoretical approaches also provide important research paths for advancing theories and testing proposed hypotheses that relate to institutions and firm performance, and causal complexity between those (e.g. Fiss, 2007; Jackson & Deeg, 2008).

In this chapter three propositions were also presented. These give a high-level view about the issues that might have some affect to industries in general. The underlying idea is that these issues affect the industry's performance in conjunction with industry and company specific factors. This is one reason that suggests that the industry dynamics need to be studied. These propositions also partly direct the research of industry dynamics. For example, like coordination in the economic environment might have something to do with the success of an industry also the industry specific coordination might influence the performance. Therefore, the next chapter will deepen this analysis to the generic medicines industry context and present more propositions relating to industry context. All the presented propositions will provide a direction for the analysis. The propositions that have been presented so far from VoC are listed in Table 3.

Table 3: Propositions Made from Varieties of Capitalism

General propositions from the VoC theory	
Proposition 1	Coherence and coordination in the economy affect the performance of an industry.
Proposition 2	Industries needing more incremental innovation, such as generic medicines industry, should be more successful in the coordinated economies.
Proposition 3	The value of the coherence measurement should be lower than the coordination measurement when analyzing the success of an industry.

These three propositions together formulate the first hypothesis addressing the key issues in the generic medicines industry.

Hypothesis 1: The performance of the industry is enhanced in coordinated market economies.

For the thesis, this means that the understanding about the institutions as a part of companies' success and therefore also for the industry's success is essential. Different types of institutions within European countries have different capabilities to provide for the companies operating within their domain. This should make industry performance vary from country to country. Especially in the generic medicines industry the public policies can be a major factor in boosting the industry within a country or restraining its progress in another.

3 European Generic Medicines Industry

The study uses generic medicines industry and its business environment as a source for empirical data. In order to find the possible success factors, a comprehensive understanding about the industry is required as proposed in the literature review. Deep understanding is also required to conduct a valid analysis using the fuzzy set methodology, which will be discussed more in Chapter 4.

To illustrate the most relevant aspects of the industry, this chapter is structured under four main topics. First the operational environment will be discussed. This includes the structure of the industry, stakeholders, and brief analysis of the company population. Second part presents the regulatory and institutional environment. This part has a partly evolutionary perspective and will introduce the patent and promotional regulation and the institutional environment. Third part discusses economic environment. Here will be presented the main market characteristics, market shares, and pharmaceutical expenditure. Fourth part is about the social environment. This part discusses the demographic factors. Technological environment is not seen that important for generic medicines that it should be discussed under its own chapter. The relevant aspects of the technological environment are included in the operational environment.

3.1 Operational Environment

3.1.1 Industry Structure

Defining generic medicines industry is not an easy task and it can be done multiple ways, as with almost any other industry today. One thing common to all definitions is that generic medicines are medicines that have lost their patent protection. Essentially the focus will be on the producers of generic prescription medicines, but the generic medicines industry can be understood also much more broadly. Within the whole generic medicines industry, there are multiple types of operators. To understand the actors and their role for the industry

more and to distinct the prescription generic medicines from the others, industry needs to be explained first in a broader picture.

Maybe in the broadest sense generic medicines industry consists of all the operations concerned with medicines which are produced and distributed without patent protection. This consists of production of general prescription medicines and over-the-counter sold medicines (OTC) that do not require a prescription and are most often used for self-care. Also included in this broad definition is the distribution network of medicines, which means wholesale companies and pharmaceutical retail outlets that in most cases are pharmacies. This is where generic medicines industry overlaps with the traditional innovative medicines industry as they both use the same distribution channels, at least to some level. Retail trade could also happen in an OTC outlet or through self-dispensing doctors in areas where this is allowed by legislation.

One part of distribution is also parallel importing (PI). This is especially characteristic of the European markets, where companies import readymade medicines from a cheaper country to more expensive country and intend to capitalize on the price difference. The free movement of goods within the EU and the price differences between old and new member states makes this kind of business possible. Parallel importing thus has an economic impact at the European level for generally lowering prices paid by the patients, which is similar to the effect of generic medicines. Parallel importing can also occur with patent protected medicines. (Enemark, Pedersen, & Sørensen, 2006.) In addition to this, there are companies that sell generics without producing them themselves. These companies can be anything from pharmacies to individual brand name holders. They usually use contract manufacturing (contract MFR) to produce their products.

On the supply side of the value chain, the production of medicines requires active pharmaceutical ingredients (API). Many companies can produce these by themselves for their medicines, but there are also companies specialized in producing only these. API companies in some cases are specialized in producing

other chemicals and thus operate with different business logic than medicines producers. API producers are business to business companies operating in the process industry setting, and require different technical capabilities than medicine producers. However, in the broad picture, these are an important part of the industry.

In parallel to generic medicines retail industry that produces products for patients operate part of the industry that works with hospitals. Hospitals use a lot of infusions and similar bulk products and all of these can be considered generic medicines in the broad definition, but obviously these are closer to consumables than prescription medicines. Consumables and other medicines that are used in hospitals are mainly bought through a tender process directly from pharmaceutical companies. In addition to that, hospitals supply a small amount of their required medicines from wholesalers. Even though not being a very visible business, it is still relatively large in size. In 2007 hospital medicines' business was approximately third of the retail business. (European Commission, 2009, p. 22.)

Furthermore, generic medicines industry has research and development (R&D) focused companies that help, among others, on the development of molecules, molecule combinations, or production processes. On the support side there are also companies categorized under service companies that serve all of the above. These companies are, for example, marketing, consulting, market research, and legal advisory companies. Especially legal advisory is important due the fact that regulatory environment is so diverse. Legal advisory ranges from patent advisory to market entry advisory.

Furthermore, biosimilars, which are the generic versions of biopharmaceutical products, are a part of the industry. In general they have similar type of supply and distribution networks than tradition medicines. However, biosimilars are still only an emerging part of the industry as the first biosimilar was accepted in the EU in April 2006 (Blackstone & Fuhr, 2008). In biosimilars the EU is overall ahead of the rest of the world, for example because of the acceptance, but

because of the emerging nature of the industry biosimilars are excluded from the study.

An illustration of generic medicines industry's value chain with the actors presented above is presented in Figure 2 below. Obviously all of these actors discussed above have an impact on the development of the industry and thus they all need to be taken into account at some level. However, the main focus of the thesis is on the actors who operate clearly in the production and selling of the generic prescription medicines. The analysis will focus on the dynamics that affect this part of the industry. The focus group is indicated in Figure 2 with a red outline. The same definition of generic prescription medicines was used as when forming a database of European generic medicines companies for GloStra database in the 2009 and 2010. This database will be used in the analysis and it is discussed in Chapter 5 in more detail.

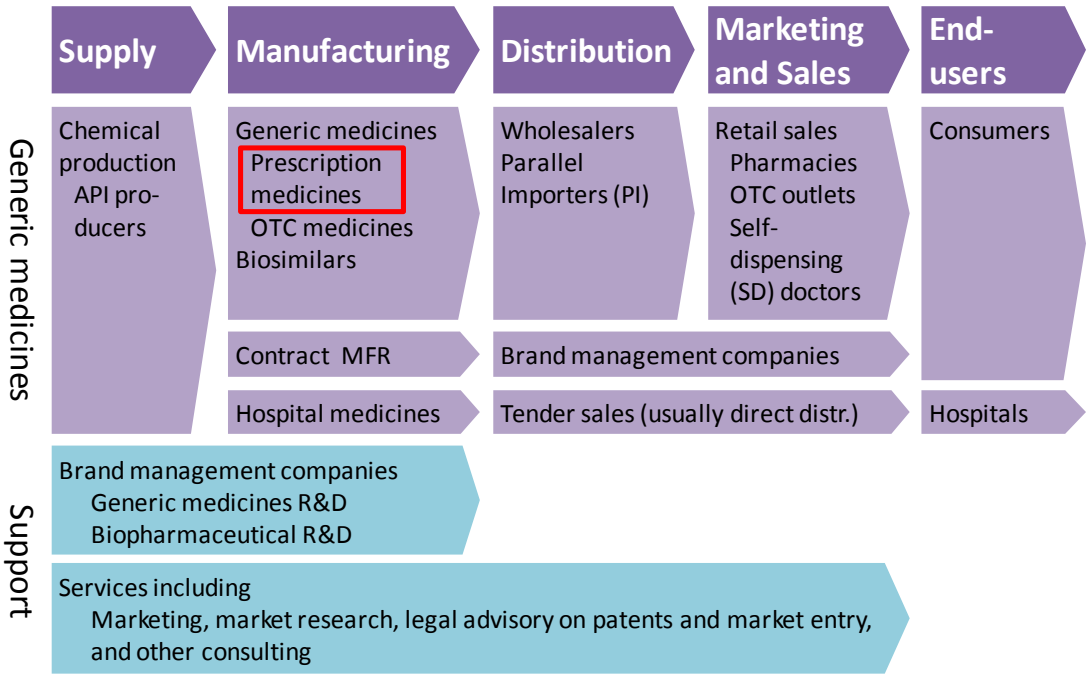


Figure 2: Simplification of the Generic Medicines Industry's Value Chain with Key Support Areas

3.1.2 Key Stakeholders

In addition to value chain, there are many stakeholders that have an influence on the industry in one way or another. Stakeholders can be divided into three categories. These three categories are government level stakeholders, industry level stakeholders, and other stakeholders. This division is presented in Figure 3 below. The division and the presented stakeholders are based on a general understanding about the industry and are presented to give a more general view of the generic medicines industry's position in the markets.

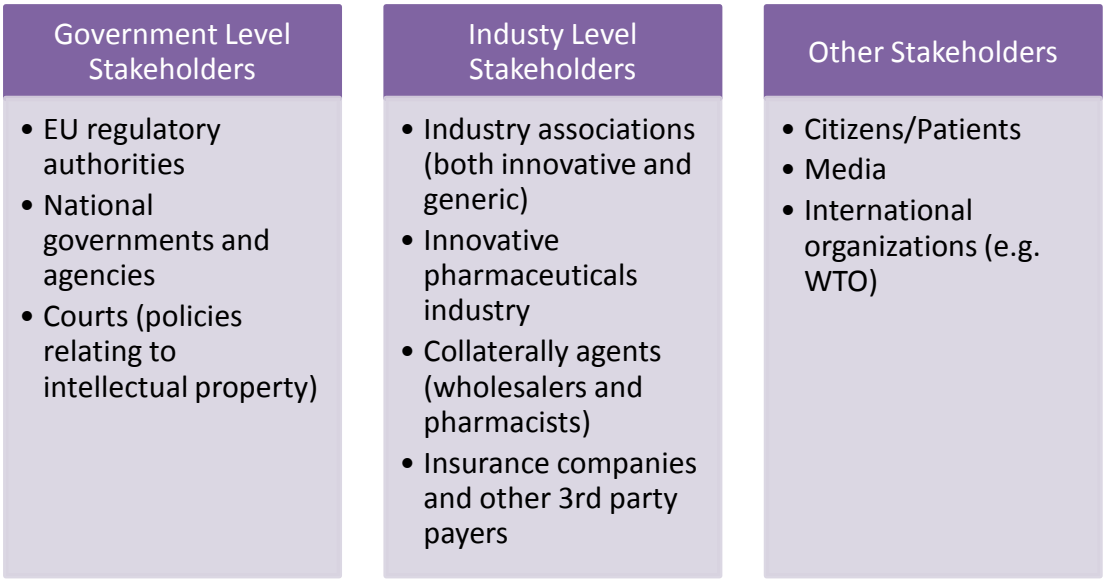


Figure 3: Stakeholders Influencing the Development of the Generic Medicines Industry

The views these stakeholders have about the generic medicines industry vary. There are groups that have a positive view about the generic medicines and they try to support them as much as possible. One of these groups is definitely the European Generic medicines Association (EGA), which among others supports various research projects to provide information about the industry. On the other hand, there are innovative pharmaceutical companies that partly see generic medicines as a competitor to their original products, but also increasingly see it as an opportunity to get additional revenue. In this landscape, governments and public agencies are in the middle and try to conduct policies

so that both industries have a possibility to thrive by keeping in mind their ultimate goal of keeping the public health expenses in minimum.

The main influencers to the industry in a European context are national governments and agencies as well as the EU authorities. They have direct influence on the industry dynamics through regulatory processes. As one of the main payers, they have also incentive to use this influence. National governments work mostly on generic medicines promotion aspects and the EU authorities work more on unifying the inner markets and patent legislation. These are discussed more in Chapter 3.2 Regulatory and Institutional Environment.

Other stakeholders have mostly indirect ways of influencing the industry dynamics. Lobbying can be used to influence the legislation process. Citizens' influence is many times limited to choosing to use generic medicines instead of original medicines. This can generally be described as patient's acceptance towards generic medicines. Media can have an influence on patients' acceptance. Evidence from Portugal at least indicates that pro-generic campaigns have raised demand (Simoens & De Coster, 2006). Media's influence can also work towards legislative bodies by communicating the patient's acceptance to decision makers more effectively. From the industry structure and the stakeholder analysis, the first proposition of the industry dynamics, or fourth proposition in total, can be made. All propositions presented in this chapter will discuss to the generic medicines industry specific issues. These propositions will in combination with the previous ones direct the analysis towards the most relevant issues.

Proposition 4: The main influencers to the overall success of the generic medicines industry are the major payers of the health care costs at the government level.

3.1.3 Evolution of the Company Population

This chapter consists of two parts. First and main part is the analysis of the company population in the generic medicines industry. This part will show the

general trend in industry's structural change in Europe. Second part is a brief introduction to the major players in the generic medicines industry and will give a more detailed look of the current status.

Evolution of Density

In the discussion of organizational ecology based industry evolution, population density is a crucial framework (see generally Carroll & Hannan, 2004; Hannan & Carroll, 1992). Density dependence (Hannan, 1986) is one of the most important models relating to organizational evolution. It is used to explain the organizational entries to the organizational population. According to density-dependence model the drivers for change are legitimation and competition (Carroll & Hannan, 2004, chap. 10).

The basic theory by Carroll and Hannan (Carroll & Hannan, 2004, chap. 10) identifies legitimation and competition as opposing forces. Legitimation increases when the density increases. However, the legitimation cannot exceed a finite ceiling and competition works as opposing force when the density has increased so that the environment can no more support all the actors. Resources eventually become extremely scarce as more and more companies enter the industry.

According to the theory, the entry rate in to the population is then proportional to the level of legitimation and inversely proportional to the intensity of the competition. This means that the model implies S-shaped density curves, where density growth is first low then increases in increasing speed when legitimation effect is strong and in the end slows down again when competition effect becomes stronger and stronger and at the same time legitimation rate approaches the finite ceiling rate. This basic theory does not take directly in to account the exit rates, which occur, for example, due the consolidation of the industry.

Generic medicines industry's density with entries and exits is presented in Figure 4 below. Data for the figure is obtained from the GloStra database of

European based generic medicines companies. The database is discussed more in Chapter 5 Data and Analysis. Figure 4 presents the evolution of density from 1950 to 2008. The figure is cut at this point because of the interest in the current events and because the modern generic medicines industry did not exist at the earlier half of the 20th Century. History will be discussed more in Chapter 3.2 Regulatory and Institutional Environment, but it will be noted here that most of the companies founded even before the 1980s have their roots in other businesses and have since then transformed to the generic medicines.

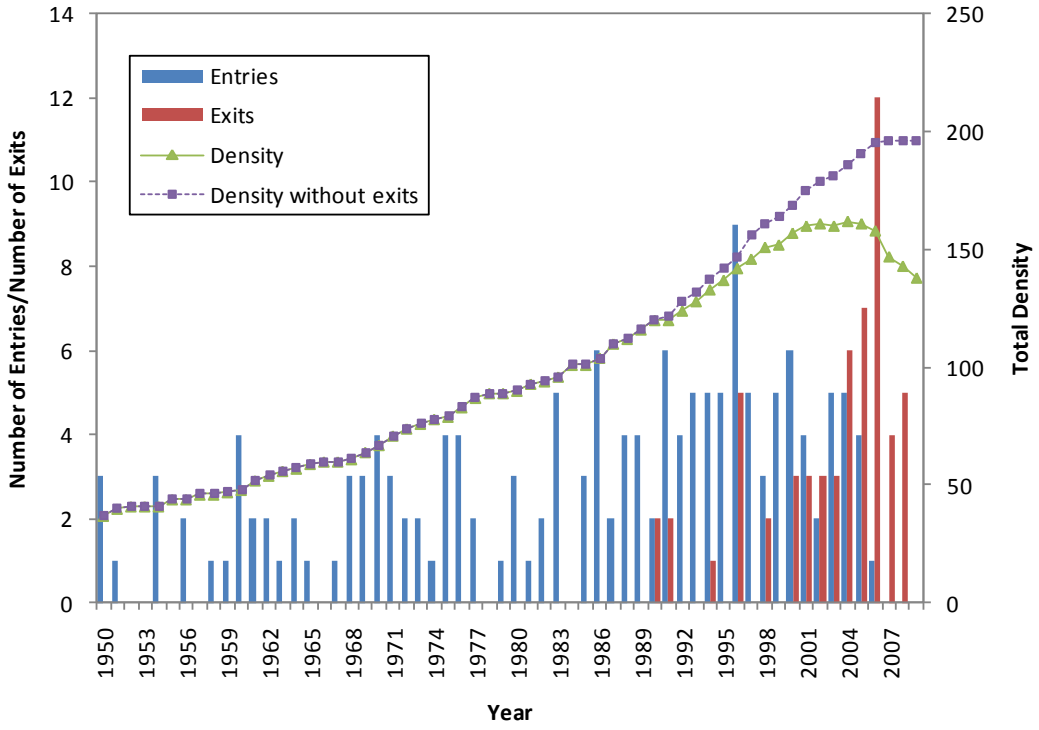


Figure 4: Density and Entries and Exits of the Generic Medicines Industry in Europe (1950-2008)

By looking at Figure 4 some conclusions about the generic medicines industry's state can be made. First of all, the S-shaped curve is seen here and the escalation in entries beginning from the late 1980s is seen. This is in line with the historical information about the rise of the modern generic medicines industry since the introduction of Hatch-Waxman Act in the United States in 1984 (see more in Chapter 3.2.1 Patent Regulation). It seems that since then the carrying capacity of the environment has been reached and entries have gone down. With the exits taken into account the density has gone down even more. Exits are mainly due the merger and acquisition (M&A) activity in the industry. In

global markets, the similar trend is also seen and M&A activity has risen substantially (Karwal, 2009). This was also seen when exit times were encoded in the database. Karwal (2009) further argues that similar trend in high M&A activity will continue. He says that since the industry is essentially highly fragmented the changing market conditions will in support this trend and further change the shape of the industry in the future. Therefore, it seems clear that industry's consolidation has started and the carrying capacity of the industry has been reached.

The Largest Companies

Information from the biggest generic medicines companies provides proof and verifies that the consolidation is one of the major industry trends. Major acquirers in the industry are the biggest companies: Teva from Israel and Sandoz a generic subsidiary of Swiss pharmaceutical company Novartis. Moreover, an industry trend seems to that smaller companies are being acquired by bigger ones rather than equally sized companies merging. This is seen also in the diminishing company density. (Karwal, 2009.)

In addition to being consolidated within the generic medicines industry, originator companies have started to acquire generic companies. For example, Zentiva was acquired by originator company Sanofi-Aventis in 2009. One reason for the consolidation and the emergence of originator companies is the faster growth of generic products in comparison to originator products. Growth projections and reasons will be discussed more in Chapter 3.3 Economic Environment. (European Commission, 2009, p. 38; Karwal, 2009.)

The largest generic companies are listed in Table 4. Due to the issues discussed here, this data is already somewhat outdated. The data of the table is from 2007 and because of the strong consolidation that is ongoing in the industry many

companies have changed their ownership since then[1] (European Commission, 2009, p. 37).

Table 4: The Largest Generic Companies in the EU 2007 by Turnover in Prescription Medicines (Reproduced from European Commission, 2009, p. 37)

Company	Rank	Turnover EU (€ thousand)	Turnover USA (€ thousand)	Turnover global (€ thousand)
Teva	1	3,388,421	1,449,732	5,763,037
Sandoz†	2	2,041,182‡	1,318,915‡	5,406,935*
Ratiopharm	3	1,021,388	n/a	1,383,599
Stada	4	900,000-1,000,000	6,519	1,570,490*
Mylan	5	800,000-900,000[1]	1,259,525	1,435,811[2]
Actavis	6	496,918	339,905	1,544,154*
Zentiva	7	341,379	0	511,646
Gedeon Richter	8	314,676	14,640	607,067
Pliva	9	282,191	104,670	564,772
Ranbaxy	10	237,432	286,579*	1,181,651*
Total		**9,940,683**	**4,780,485**	**19,969,163**

Notes:
* = global turnover for prescription medicines was not provided by the companies so the figures used refer to medicines in general.
† = these figures were originally calculated in US$. The conventional foreign exchange rate used to translate Sandoz initial US$ denominated figures into € was US$ 1 = € 0.72966.
‡ = for prescription medicine only excluding the contribution from the Anti-Infective business and/or OTC activities in some markets.
[1] = EU turnover of Merck Generics for prescription is between € 800 million and € 900 million for 2007 which includes, from the acquisition of Merck Generics Group by Mylan, the EU turnover for the fourth quarter publicly disclosed and amounting to € 272.3 million (US$ 373.1 million).
[2] =Turnover (total sales), in thousand, globally but excluding Merck Generics.

From the company population analysis, the next proposition about the industry dynamics can be made. This proposition combines two ideas. First, the survival of the company is one of the first requirements of the success and in an industry with high M&A activity companies need to be especially concerned about their survival. Second, as argued, among others in the VoC theory, there might be comparative advantages between nations that affect to industries.

Proposition 5: Nation's industry specific comparative advantages have an effect on the survival of the company population in that nation. Likewise, the survival of the company population manifests nation's industry specific comparative advantages.

[1] Teva has merged with Barr Pharmaceuticals and previously Barr acquired Pliva in 2006. Zentiva was acquired by Sanofi-Aventis and Ranbaxy by Japanese Daiichi Sankyo.

3.2 Regulatory and Institutional Environment

This chapter discusses the regulatory and institutional environment of the generic medicines industry. Regulatory environment will be discussed in two categories:

i. changes in patent and intellectual property (IP) rights legislation and
ii. changes in generic medicines promotion.

This division and the subcategories of these are presented in Figure 5.

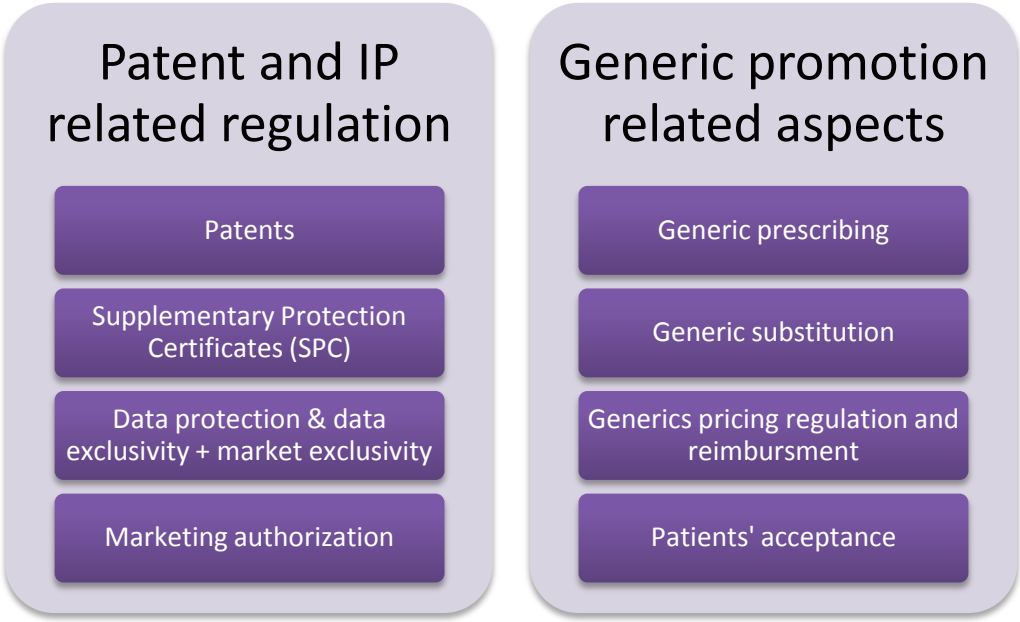


Figure 5: Two Major Regulatory Fields Affecting the Markets of Generic Medicines: IP and Promotion

The underlying idea for the division is the mechanism how these affect the industry. The mechanisms came out strongly when researching this topic. This chapter will show that patent and IP related regulation is more in the enabling role. Patent regulation decides if it is even possible to have a generic medicines industry in a given area. Promotion aspects are then decided after the generic medicines industry is established and these aspects are then more closely related to the success of the industry in a given area. In the current environment, this means that patent expiry events are occasions for generic

medicines success and causes for success are related to promotion (Redwood, 2004).

After the discussion about the regulatory environment, the institutional environment will be described. In this part, the more general level changes affecting the generic medicines industry will be discussed. This will include, among others, the EU enlargement and the overall unification of European markets.

3.2.1 Patent Regulation

Starting Point of the Modern Generics Medicines Industry

Patent and IP related legislation are in the center when thinking about the beginning of the generic medicines industry. The idea that patents are in the center is easy to point. The fact that the definition of generic medicines requires that they have lost their patent protection is a clear indication for this. Without lost patent protection medicines cannot be generic but they are, for instance, copies.

However, the exact starting point of the generic medicines industry is not easy to define. This is because industry, at least in theory, had its first possible starting point when the first ever medical patent was expired. To determine exact time is nearly impossible as patent regulations have been so varying from country to country. However, it is not even necessary to determine the entry time of the first generic medicine as the earlier business was clearly different from modern generic medicines industry. Nevertheless, in general generic medicines have been around all of the 20th Century.

To put things into perspective, Figure 6 presents change in the share of generic medicines in the markets in the 20th century. The figure shows the interesting historical development of the share of generic medicines in comparison to original medicines. Therefore, the figure illustrates the decline of the generics due the tightening IP regulation, and then the interesting rise in the share of

generics since the 1980s. This is the beginning of the modern generics industry, which started from the United States. The figure is presented as an interesting illustration of the development and should be read critically, for example, because the geography it illustrates is not explicitly mentioned. However, the information it provides correlates with the information from the literature.

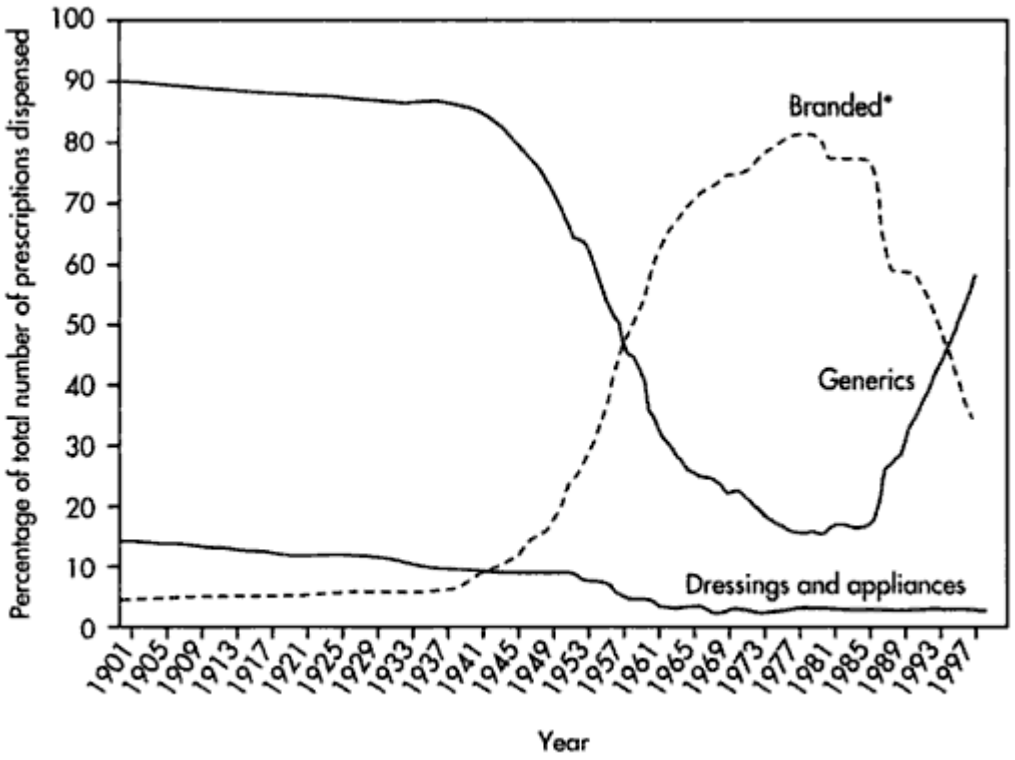


Figure 6: Proportion of Generic and Branded (Original and Branded Generics) Medicines Prescribed 1900-1997. Sources: Office of Health Economics, Department of Health, UK (1999). (Reproduced from Taylor & Harding, 2001, p. 17)

In the 1980s, the patent legislation concerning medicines was in turmoil in the United States. The United States had been showing the way in patent legislation all the way from 1790 from the introduction of the first patent law, so in that regard it is not surprising that this change also began from there (Mándi, 2003). According to many experts, one of the main triggers for the modern emergence of generic medicines, a trigger for the development that is still on-going, has been the Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the "Hatch-Waxman Act" [Public Law 98-417] (Schacht & Thomas, 2002). Hatch-Waxman Act reduced both the entry requirements and

the time to entry for generic medicines to the market and thus established the modern system for generic medicines. This act meant that generic medicines would be allowed to the market more rapidly under the Abbreviated New Drug Application (ANDA) process rather than New Drug Application (NDA) process. Also Hatch-Waxman Act made it possible for the market approval process for generic equivalents to occur before the expiration of the patent on the original brand, which is better known as the Roche-Bolar early working provision or in short Bolar provision. This provision was named after Roche Products v. Bolar Pharmaceutical court case Co., 733 F.2d 858 (Fed. Cir. 04/23/1984) that was decided shortly before enacting the Hatch-Waxman Act (Mossialos, Mrazek, & Walley, 2004, p. 252). Especially Hatch-Waxman Act gave a 180-day period of market exclusivity for the first generic medicines manufacturer to challenge the validity of the existing patent (Schacht & Thomas, 2002).

In a simplified view, as in Figure 6, there are two main groups of actors in this business: generic medicines companies and innovative medicines companies. Basically as these groups can be considered total opposites in regard to patent legislation, one decision helps other and at the same time is unbeneficial to the other. The general understanding about the beneficiary of the patent legislation follows the idea presented in Figure 6 until the 1990s. Since the legislative changes began favoring generics in the 1980s generic medicines industry continued to benefit from patent legislation changes throughout the latter half of the 1980s. It is indicated that at the beginning of the 1990s the legislation began slightly favoring patent holders again (Redwood, 2004).

Patent Regulation Development in Europe

Following the example set by the United States, similar legislation was also set in Europe, but much later. The problem in Europe was that patenting practices were different between the countries. When analyzing the patent regulation in Europe, it is important to understand the difference between basic patent being a product patent or a process patent. Basic patent, which is the first patent issued after the preparation and testing of the new active ingredient, is the basis

for the protection of the medicine, which is supplemented with various other patents. Basically, if the basic patent has been expired, the competition is open for generic products. Currently in all of the developed countries basic patent is a product patent, but this has not been the case always and process patents have provided possibilities for generic competition. (Mándi, 2003.)

American product protection dates back to 1790, but in some European countries this is a rather recent thing. Austria adopted product patent in 1987, Spain in 1992, and Finland and Portugal in 1995. Also Greece adopted product patents in the 1990s. Former Soviet Union states adopted product patents between 1990 and 1995. Even though Eastern European countries had limited patenting practices and Western European countries in general used to have at least process patents in place before adapting product patents, the development in Western Europe from process patents to product patents is more interesting. This is because the markets have been more unified in Western Europe and thus patenting differences have had more effect on the markets. (Mándi, 2003; Simoens & De Coster, 2006.)

Furthermore, in some countries those are mostly in southern Europe, patent protection as a whole is a relatively new thing. Because of the lack of the support for the international patent protection, copied medicines have been allowed in these countries and even today generic medicines markets are affected by this. For example, in Italy the patent protection was granted as late as 1978 and generic medicines as a term as late as 1996 (Ghislandi, Krulichova, & Garattini, 2005).

Differences in IP regulation, especially the process patents, between countries have been used to get the generic medicines into European markets. These differences provided possibility to enter the markets earlier than it would have been possible with unified legislation. Because within the EU products have free movement, the acceptance of medicine in one member country basically means that it can also be brought to other countries. Therefore, working around the process patent in one country allowed similar products to be marketed

throughout the EU even though in other countries these products might have violated the product patents. It was possible to use process patents this way, because changing one part in the production process is relatively simple in comparison with changing the active ingredient of the medicine. So it was possible to get a product authorized, for example, in Finland and then based on the EU market regulations rather easily seek market authorization in the other EU countries.

For the purpose of the study understanding legislation relating to basic patents is enough, as this is the main patent, which expiry enables generic competition in a large scale. However, as patenting is an important way for innovative medicines companies to protect their turnover, there are many other layers in patenting that are next presented to give an idea of the complexities involved in patent protection. As mentioned, currently basic patents in all industrial countries are product patents. Previously basic patents could have been process patents, but today process patents are one of the supplementary patent class that are used to provide additional protection for the products. Other types of supplementary patents are formulation patents, patents relating to salts and derivatives, polymorph patents, second indication inventions, metabolite patents, and dosage regimen patents. A basic idea of all of these is to extend the patent protection time of basic patent. Extension basically occurs because all of these supplementary patents are applied after the application of basic patent. This legislation on supplementary protection is generally homogeneous in Europe. (Mándi, 2003.)

Further Unification of Patent Legislation and Supplementary Protection Certificates

So currently all of the European countries have product patent systems in place and are unanimous in that sense. Also all product patents are 20-year for all pharmaceutical products except biotech. This is based on the World Trade Organization's TRIPS Agreement (Trade-Related Aspects of Intellectual

Property Rights). The TRIPS agreement has been in place for all the EU countries as part of WTO since 1994 (Redwood, 2004).

In addition to the patenting of substances and processes, in medicines the medical use of a known compound is also patentable under certain conditions. Sometimes an active ingredient can have other medical use than what it was originally developed and this type of patenting affects to this. The European Patent Convention (EPC) was held in 2000 to discuss these aspects. The decision was that only the first use is patentable. However, that decision still effectively allowed patentability of subsequent medical uses through creative patent drafting. EPC has been seen to strengthen the usage patents and increase the legal uncertainty. However, this situation was unified in 2007 when the updated version of EPC, known as EPC 2000, came into force eliminating in theory much legal uncertainty. (Roox, 2008.)

Moreover, medicines usually have a possibility to seek industry specific extensions to normal patent times due to the nature of the business. Normally, patents are granted so that the developer could have time to get profits from markets to cover the expenses that were required to make the product. In pharmaceuticals, 20 year patent protection time is shortened because of the extensive testing required before the product can have market access. Also patenting usually needs to be done for the active ingredient early in the process of developing new medicines. All this takes time from exclusive market access and thus there are additional systems in place to extend the protection time after the normal patent protection period. In regard to this, Supplementary Protection Certificates (SPC) were introduced in the EU in 1992. SPC increase 20-year patents by up to 5 years so that product would get 15 years of effective monopoly on the market. (Mándi, 2003; Redwood, 2004.)

Data and Market Exclusivities

Data protection and exclusivity as well as market exclusivity and the changes in them are another important thing affecting the position of generic medicines. Data exclusivity guarantees additional market protection for innovative

pharmaceuticals by protecting the data submitted by companies for the purposes of obtaining market approval. (Cullen, 2007.) Market exclusivity protects markets but enables the use of data and thus enables the development work on generic medicines.

Major changes in data protection in pharmaceutical industry started in 1987, when 6/10-year data exclusivity regimes were introduced to biotech products (EGA, 2004). In 1995, 10-year data exclusivity was enforced in the EU to products adapting the centralized procedure to get the marketing authorization (Redwood, 2004). Marketing authorization will be discussed more in the next chapter.

Final change to the current conditions happened in 2004 when the EU pharmaceutical legislation was amended with the directive 2004/27/EU for human medicines. This amendment included many provisions affecting the generic products and harmonization of the period of data exclusivity across the EU, which basically meant that Bolar-provision was also included in the European legislation. Accordingly the change happened 20 years after introducing Bolar-provision in the United States. Exclusivities varying between six to ten years were changed to eight years of data exclusivity plus two years of market exclusivity, adding another year for new indications authorized during the first eight years of data exclusivity. Usually, this is shortened to 8+2+(1) data exclusivity + market exclusivity. So in practice generic medicines market entry can happen in the earliest ten years after the original product but as the last two years is market exclusivity the generic entry after the end of the patent and exclusivity period is shortened (Mossialos et al., 2004, p. 247).

Marketing Authorization

Marketing authorization is needed in the EU to put the pharmaceutical on the market. Marketing authorization can be acquired in two ways: centralized procedure or community authorization and decentralized procedure or national authorization. The centralized procedure has been in place since 1995 with the

introduction of the European Medicine Evaluation Agency (EMEA) (Mossialos et al., 2004, chap. 4). However, because the data exclusivity for centrally authorized products was ten years, generic applications did not begin until 2006 (European Commission, 2009, p. 116). Before 2006, the decentralized procedure was used to marketing authorization for the generic medicines. In this procedure, the applicant applied marketing authorization directly from one member state. If this was successful, the applicant sought to have other member states recognize the approval and grant their own marketing authorization. (Mossialos et al., 2004, chap. 4.)

The effect that centralized procedure brought to obtaining marketing authorization was predictability and clarity. The time for getting marketing authorization from the centralized procedure through EMEA is structured. Within 210 days of submitting the application the results are ready (EMEA, 2005). With the decentralized procedure, the variation was much higher. Also the procedure is now similar thorough out the EU giving equal opportunities for all the actors.

Paediatric Extensions

Paediatric Extensions or the Paediatric Regulation entered into force on January 2007. This regulation is a series of obligations, incentives, and rewards aimed at medicines for children. Opinions are varying on their effect on the generic medicines markets for children. Due to recent introduction, which means that effects are not completely seen in the industry and that this is applicable to only a portion of the industry, these extensions will not be analyzed any further in this thesis. (Howard, 2008.)

Summary of the Patent Regulation

For the success factors' analysis in generic medicines industry, it is seen that homogeneous patent protection including patenting, Supplementary Protection Certificates, data and market exclusivity as well as marketing authorization gives all the actors in the market similar environment and thus does not give

any comparative advantage. In addition to that, when thinking about the industry in the long run, the effect of extended patent protection of a single medicine is irrelevant to the overall success of the industry. Patent protection will eventually expire and enable generic competition. However, in the short term growth for the generic markets is seen to come from the patent expiries. This is indicated to be a major factor in generic medicines industry's growth, but again the effect of this is similar to all of the actors in generic medicines industry. (European Commission, 2009, p. 38; Redwood, 2004).

In other words, patent and IP regulation enables the generics medicines industry rather than decides its success. Major changes in the European legislation from the 1980s to this day have essentially simplified the process of getting generic medicines to the markets. This means that market access and market protection are predictable and thus business decision making for companies is simplified. This analysis can be formulated to another proposition about the industry dynamics. The proposition states that patent regulation is a necessary condition for the industry.

Proposition 6: Patent regulation enables the generic medicines industry, but does not substantially influence its success.

3.2.2 Promotion of Generic Medicines

In addition to the changes in patent legislation, the changes in policies regarding generic promotion have been varying from country to country. This has varied even more than patent legislation and today there is still less uniformity in these policies between the countries than there is with the patent legislation. Promotion is one of the most important aspects affecting the position of the generics from country to country.

In promotion related regulation and environment there are four main topics that will be discussed here (see Kjoenniksen, Lindbaek, & Granas, 2006; Redwood, 2004). The first area is generic prescribing, which means the possibility to prescribe using generic or International Non-proprietary Names

(INN). The second area is generic substitution, which means the possibility to change prescribed medicine to generic equivalent by the pharmacist. The third area is price regulation, under which reference price systems (RPS), reimbursements and patient co-payments are discussed. The fourth area is patient's acceptance towards generic medicines.

For the promotion of generic medicines, these points have different effects and legislative tools for governments are different for each point. Still, many times these aspects are used in parallel as they are somewhat overlapping. However, these tools do not have clear pan-European policies as will be seen next. The summary of the promotion related aspects within European countries is presented in Appendix 2. Appendix 2 is based on the data from Pharmaceutical Pricing and Reimbursement Information (PPRI) (Vogler, Espin, & Habl, 2009; Vogler et al., 2008). There have been three variations from this source: in the case of Iceland Martikainen and Rajaniemi (2002) was the source; in the case of Romania Kazakov (2007) provided data; and in the case of Switzerland Paris & Docteur (2007) provided information.

Generic Prescribing

Generic prescribing and other prescription guidelines have both varying policies between the European countries. From these two, generic prescribing is more important for generics industry's performance. Other prescription guidelines relating to economic prescribing and use of medicines also have an effect but their role for the generics can be considered being secondary and only increasing the effects of generic prescribing (Vogler et al., 2008).

Generic prescribing is a term relating to doctors' possibility to write prescriptions with generic products. When allowed in the country, generic prescribing can be indicative or obligatory. Furthermore, generic prescribing most often happens with an international non-proprietary name (INN), which basically means that prescription is written to an active ingredient. Generic prescribing can also happen with a brand name, generic name, or with a

combination of any of these. There might also be differences of allowing generic prescribing in public and private sectors. (Vogler et al., 2008, chap. 3.5.4.)

Generic Substitution

Generic substitution means that pharmacists are able to substitute a prescribed branded product with a generic equivalent product. Substitution can be either to a different proprietary name product or to a product which is marketed under the international non-proprietary name. Policies are varying for generics substitution between the countries in Europe, but usually substitution needs at least an agreement from a prescribing doctor. (Mestre-Ferrandiz, 2003.)

When country has allowed generic substitution and there is an agreement from the doctor, then the prescribing can either be indicative or obligatory. This is clearly the biggest and most significant difference between the countries allowing generic substitution. In indicative substitution, pharmacists are allowed to substitute, but in an obligatory system they are obliged. Especially in an obligatory system, doctors usually have the opportunity to deny generic substitution by indicating so in the prescription (Vogler et al., 2008). Generic substitution in most cases in Europe is related to the generic prescribing system being in place. Also substitution is in many cases combined with the reference price system, which will be discussed more in the next chapter. (Vogler et al., 2008.)

Generic Price Regulation and Reimbursement

From four points discussed here under the generics promotion, price regulation related aspects are the most complex. However, they are in a sense the most important, because they have the most direct influence on the finances of the generic medicines industry. Complexity in the pricing regulation comes from two aspects, reference price systems (RPS) and reimbursements with patient co-payments, which have slightly different effect on generics position and on generics possible success.

To understand RPS, the concept of reimbursement must be explained. Reimbursement is the fraction of the actual medicine price that is paid by a third party payer. Third party payers include governments and insurance companies and the levels on which they pay differ from country to country. In addition to that, the part that is paid by the patient after the reimbursement is called patient co-payment. (Mestre-Ferrandiz, 2003.)

In RPS, health authorities set a maximum reimbursement level for a given medicine. This level is called a reference price. Usually reference prices are not set at individual medicines directly, but medicines are categorized in groups based on similar or the same active ingredients, usage, dosage, or any combination of these. Reference prices are set for these groups. (Mestre-Ferrandiz, 2003; Vogler et al., 2008.)

When RPS is in use, a patient has possibility to choose to take a product that is under or exactly at reference price and in that case there will be no payment made by the patient. The total price of the medicine will be reimbursed. This makes RPS different from the traditional way of medicines purchase under the percentage systems, where the option for non-payment is usually not possible as patients pay the same percentage as co-payments regardless of the medicine's original price. (Mestre-Ferrandiz, 2003.)

The main objective of RPS is said to be that it increases price competition. In addition to that, it is said that RPS implicitly should increase generic penetration. Increasing generic penetration clearly indicates that the use of expensive products is cut down. This has been shown to be true at least in some cases (Aaserud et al., 2006). These are the main reasons why RPS is taken to use in an increasing number of European countries. The total number of countries in the EU that have the RPS in place is 19 after Finland adapted the system at the beginning of April 2009. This list is presented in Appendix 2. (Mestre-Ferrandiz, 2003.)

It is worth noting that RPSs vary by their principle of setting the reimbursable price between the countries. Usually a reference price is a function of the

cheapest medicine in a group, which in general is a generic medicine. As the reference price is a function of some cheaper products and as usually it is possible for a patient to get the cheapest product without paying anything, authority management for the system is needed. Products that have a price below the reference price tend to increase their price towards the reference price, which has a negative effect on the price competition. (Vogler et al., 2008.)

General differences in RPS systems between the countries, for example the medicine groups of which RPS applies or the price setting functions, are not considered that significant. The most important aspects in the analysis of price policies at the European level are between the actual implementation of RPS. In addition, reimbursement levels and co-payments that are closely related to RPS are seen to have only secondary effects on the success of the generics.

Patients' Acceptance

As mentioned patients' acceptance is one of the principal factors for how rapidly the generics opportunity can be realized in practice and how successful of the previously presented promotion related legislation is (Redwood, 2004). This can be problematic since no regulation can affect patients' acceptance directly, but patients' acceptance can have a big effect on the success since their actions can limit the use of substitution. It is also patients' decision of choosing the generic equivalent and allowing the substitution (Kjoenniksen et al., 2006). It is indicated that pharmacists and physicians are needed to provide additional information and support to increase the acceptance (Kjoenniksen et al., 2006). Media's role in distributing information could also be important.

Even though prescribing or substitution regulation has no direct way of affecting acceptance towards generic medicines, pricing regulation might have this. Kjoenniksen et al. (2006) indicates by referring to Lund-Jacobsen (1992) and to Andersson, Sonesson, Petzold, Carlsten, and Lonnroth (2005) that stronger financial incentives for patients could increase the acceptance. Even though patient's acceptance is a complex area to analyze, the indication of it

being tied to the price makes it possible to analyze its effects through the pricing regulation.

Summary of the Generic Promotion

Generic medicines promotion is still typically decided on the national level, which is clearly different from the patent legislation. There are not many policies or even guidelines that are unified in Europe. This is one reason why promotion related aspects provide opportunities for generic medicines. Also as these aspects are decided on national level and they differ throughout Europe, there is a need for unified policies in Europe. This indicates that promotion regulation should experience more changes than patent regulation. Summary of the most relevant policies in the European countries are presented in Appendix 2.

Of the aspects discussed above it is concluded that the most effect on the success of generics is achieved through price regulation. This is indicated by a few things. Patients' acceptance is pretty closely related to financial benefits they expire when substituting to generic medicines. In addition to that, reference price system is in many cases the last step in the legislative process to promote generics. It is enforced after the substitution and prescribing is allowed before. Obviously, they all work in parallel and in theory the best results for the generics should be obtained if all three are enforced simultaneously. The influence of promotion legislation on the industry dynamics can be formulated to following propositions.

Proposition 7: a) Promotion legislation affects to the success of the generic medicines industry. b) Among the promotion legislation, price regulation has single most effect on the success of the generic medicines industry.

3.2.3 The Evolution of Institutional Environment

In the European institutional environment changes that are the most interesting for the generic medicines industry are the changes regarding market

unification. Unified markets in general are more effective. On the other hand, differing policies between countries might be a source for comparative advantage and make a difference in performance. Unification of the European pharmaceutical markets started gaining respectable efforts in the late 1980s. In 1985, gradually the EU (European Economic Community at the time) started evolving more and more towards its current state and the vision of the single European market became more and more clear. At the time, the vision was to create a single European market by the end of 1992, which also escalated changes affecting pharmaceutical industry. (Orzack, Kaitin, & Lasagna, 1992.)

One obvious reason for such changes was the clear ineffectiveness of the multi-state procedures. In consequence, 1992 Maastricht Treaty on European Union was approved. It entered into force on November 1st 1993 and the EU was officially founded. This gave the EU binding authority on some health care issues (Vogel, 1998). National governments remained in control of the health policy, including pharmaceutical policy. The EU did not get authority to decide on pricing methodology and this situation remains today. (Kanavos & Mossialos, 1999.)

Soon after 1992 another set of changes were proposed and those concretized in 1993. 1993 the European Medicines Evaluation Agency (EMEA) was established and it started its work at the beginning of 1995 (Mossialos et al., 2004, p. 80; Kingham, Bogaert, & Eddy, 1994). This agency enabled the centralized approval procedure and a mutual recognition of national approval for medicines including generic ones with some exceptions (Kingham et al., 1994).

Other changes that have definitely affected the position of the generics in the European level have been the enlargements of the EU. This includes the 1995 enlargement to Finland, Sweden and Austria and the more recent enlargement to Central and Eastern European (CEE) countries and to Baltic states in 2004. The latest enlargement was in 2007 when Bulgaria and Romania joined the EU.

Maybe the most important event was the enlargement to CEE and to Baltic, because the enlargement included most countries and there the promotion

legislation affecting generic medicines has been quite different from Western Europe (e.g. Kazakov, 2007). Even though they adapted a number of collaborative initiatives already from 1997 to update their regulation to match that of the EU, the change that the accession brought was substantial. The latest addition to their regulation was the implementation of 6-year data exclusivity and 5-year supplementary protection certificates in 2000 (Mossialos et al., 2004, chap. 19). In addition to promotion, industry structures have been different due the centralized procedures in the Soviet systems (Mossialos et al., 2004, chap. 14). At the same level as the enlargement of the EU among major institutional changes affecting the position of generic medicines is definitely the change to the common currency of euro in 1999. In conclusion, changes in the institutional environment are at the higher level and thus have mostly indirect effects on the industry.

3.3 Economic Environment

This chapter will have three parts. First part discusses the overall position of generic medicines in the world. Second part is about more detailed country level data in Europe. This part discusses the generic penetration in Europe. Third part discusses the economics of the industry from the payers' perspective. It will have a focus on the expenditure on pharmaceuticals and provide information about the reasons for growing expenditure. There the rising research and development costs are an important factor. For calculation purposes currencies were exchanged to euro using the exchange rates presented in Appendix 1.

3.3.1 Generic Medicines in the World

Many reports indicate that worldwide generic medicines market will be experiencing quite a big growth in the coming years. The growth has been around 15% annually in the beginning half of the 2000s. IMS[2] estimated 17% compound annual growth rate (CAGR) between 2000 and 2004 for generic

[2] IMS Health is a private company providing proprietary data on health care

medicines sales (Hoffman, 2005). Datamonitor estimated the 14.8% CAGR for generics market value between 2003 and 2007 (Datamonitor, 2008a). This is expected to continue as both sources indicate similar numbers for the upcoming years. IMS estimates 10-15% yearly growth and Datamonitor 10.5% CAGR until 2012.

In absolute market values, generic medicines are a smaller business than original medicines. In Figure 7 the total world pharmaceutical market, which is valued around 450 billion euro, is divided into generic medicines and other medicines and to the regions of Europe and the Rest of the World (ROW). Other medicines in this case consist of original medicines and other than ethical generics, for example, meaning over-the-counter (OTC) medicines. Clearly the biggest part of the other segment is the original medicines. Furthermore, North-America consists of clearly the largest part of ROW figures in both generics and others. Data is based on reports by Datamonitor (2008a, 2008b, 2008c, 2009) and calculations.

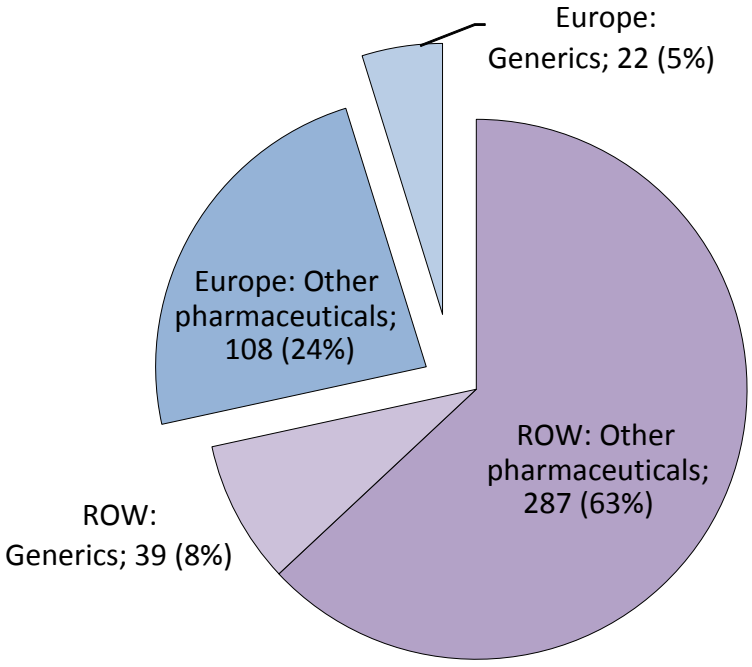


Figure 7: Market Shares and Values (€ Billion) of Generic and Other Pharmaceuticals in Europe and Rest of the World (ROW), 2008

There are many reasons for generic medicines to grow faster than original medicines. Expectations are also that this growth will continue. Many reasons are introduced in the literature. Some that are mentioned include economic growth in the regulated markets, demographic trends, and the need for cost control by payers. Moreover, the patent expiries of a large number of top-selling medicines both in the United States and Europe are one reason, why generic medicine markets are estimated to grow faster than original medicines. For example, Pfizer's Lipitor (atorvastatin), the best selling single medicine in the world with the global sales over 9.2 billion Euros, will experience patent expiry in 2011 in the United States. (European Commission, 2009, pp. 29-38; Hoffman, 2005; Pfizer, 2009.)

Because generic medicines industry looks lucrative and is experiencing higher growth than pharmaceutical industry in general, innovative pharmaceutical companies are also becoming more and more interested in generic medicines. They are struggling with their traditional business models that depend highly on research and development (R&D) being able to bring new innovative medicines to the markets. R&D costs are going up and producing new medicines is becoming also other ways more challenging. That is why traditional companies are trying increasingly to protect their turnover by switching to generic medicines with different strategies and business models. (Karwal, 2009; Sheppard, 2009.)

For the analysis of industry's success, few notions need to be made. Patent expiries are one time occasions for industry growth and as new medicines are harder and harder to develop, these occasions are becoming rarer. Long term impact of these can thus be small. Moreover, demographic trends will be discussed later and payers' influence is included in the previous Proposition 4. Therefore, the proposition from the economic environment can be formulated.

Proposition 8: Good economic situation and economic growth have a positive effect to the success of the generic medicines industry.

3.3.2 Generic Penetration in Europe

Maybe the most used measurement for overall generic medicines' success is the generic penetration, which means the market share generics capture from the original medicines. Generic penetration can be measured in value and volume. In general market share in volume is higher than market share in value because of the lower overall unit price of the generic medicines. For the purpose of the study, market shares in value will be used as these present more clearly the turnover, which is associated with generic medicines. Therefore, the industry is better comparable to other industries as well as to public health care expenses. This can be formulated as a next proposition.

Proposition 9: Penetration of the generic medicines tells about the overall success of the generic markets by comparing the industry with the traditional medicines industry.

Figure 8 below presents the market shares of generic medicines by value in selected countries by European Federation of Pharmaceutical Industries and Associations (EFPIA, 2005-2009). EFPIA data is presented here as it offered the most complete list of countries and years of data about generics penetration. Other sources for generic market shares include EGA (EGA, 2007a), European Commission (European Commission, 2009, p. 62), and various research papers (e.g. Simoens & De Coster, 2006). These have published similar data with some differences in the values. Differences in the values occur due to the fact that the definition of generic medicines is different. A report by European Commission (2009, p. 62) indicates, for example, that in Finland figures differ because big Finnish companies of Orion and Leiras are counted as innovative original medicines companies even though they are also active in generic medicines.

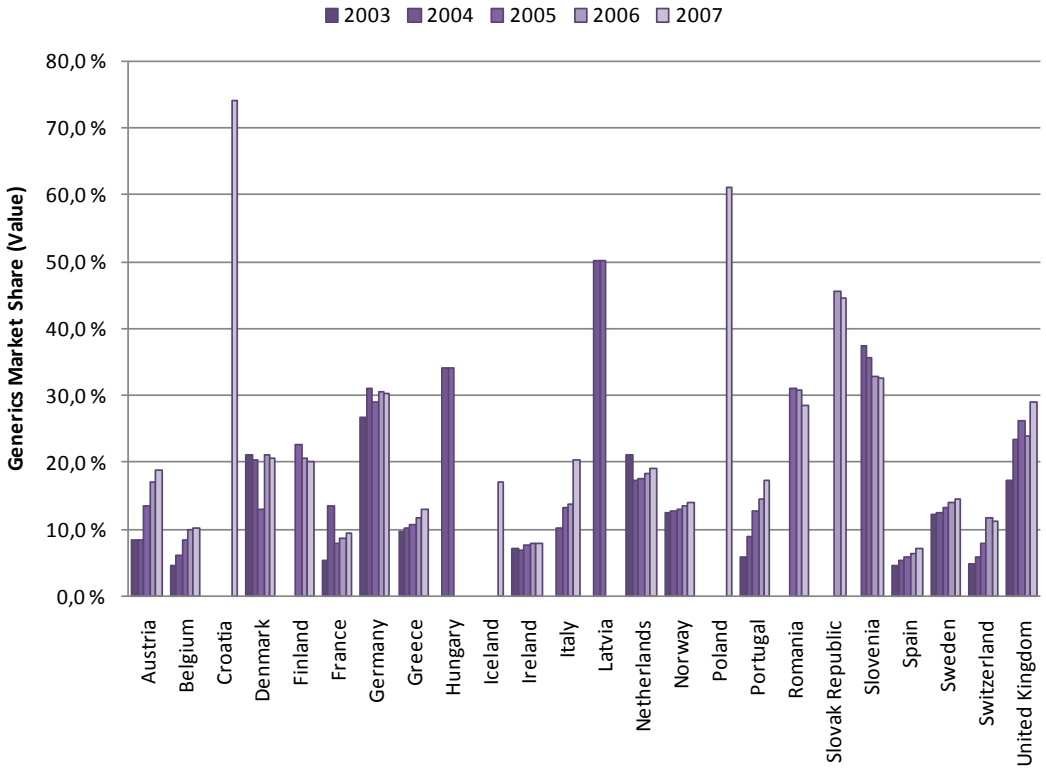


Figure 8: Generic Medicines Market Share in Pharmaceutical Market Sales by Value (At Ex-Factory Prices) in Selected European Countries 2003-2007 (EFPIA, 2005-2009)

As can be seen from Figure 8, penetration differs quite much between countries. Differences occur even though generics supporting has been on the rise for a few years already. Moreover, the EU has made efforts to unify the generic medicines markets and encourage the penetration of generics in Europe in an attempt to keep health care expenditure under control (European Commission, 2009, p. 62). Based on mainly EFPIA data and secondly on the comparative analysis done between the other reports mentioned above European countries can be divided into three groups on the basis of the penetration. This division is presented in Table 5 below.

Table 5: Grouping of European Countries Based on the Development Phase of Their Generic Medicines Markets

Group	Developed Eastern European markets	Developed Western European markets	Developing Western European markets
Generic medicines penetration by value	around 40%	20-30%	<20%
Countries	Croatia (non-EU)‡ Czech Republic* Hungary Latvia‡ Lithuania* Poland Romania Slovak Republic Slovenia	Denmark Estonia*‡ Finland Germany Netherlands† The UK	Austria Belgium France Greece Iceland Ireland Italy† Norway Portugal Spain Sweden Switzerland

Notes:
* = Classification based on EGA (2007) data rather than EFPIA data
† = Classification based on Simoens & De Coster report (2006) rather than EFPIA data
‡ = Not included in the final analysis

First group consists of countries from CEE and Balkans, which in general are the most recent members of the EU. This group is labeled as Developed Eastern European markets. They have the highest penetrations of generic medicines among the European countries. Generally their share of generic medicines from the total market exceeds 40%. The second group of countries is group that is labeled as Developed Western European countries (see Simoens & De Coster, 2006, p. 14). These countries in general have generic medicines market share of the total market in the vicinity of 20 to 30%. Even though Netherlands would not be included in this group by the very recent EFPIA figures, it is assigned here by the indication of Simoens and De Coster (2006). Last group of countries is formed from the rest of the Western European countries. This group is labeled as Developing Western European markets and those markets generally have a very low generic medicines penetration. Italy is assigned to this group on the basis of Simoens and De Coster (2006) even though the latest penetration figure is slightly above 20%.

3.3.3 Pharmaceutical Expenditure

Rising Costs as the Sources of Expenditure Rise

As has been brought up earlier, one of the main reasons why generic medicines have a big importance in Europe is the fact that expenditure on pharmaceuticals is in rise. Generics, when being cheaper alternatives to original medicines, are seen as one major way of fighting against the rising costs. Especially in Europe cutting costs is a priority because the majority of health care costs are paid by national governments.

Reasons for overall pharmaceutical expenditure rise can be seen from the expense rises in pharmaceutical companies, which at least partly are transferred to the pharmaceutical prices and thus to pharmaceutical expenditure. Pharmaceutical companies' relative expenses per new medicine rise because of two evident reasons. First the research and development (R&D) costs are on the rise and second the number of new medicines or new molecular entities (NME) being brought to the markets is on the decline. These trends can be observed from Figure 9 and Figure 10 (EFPIA, 2009).

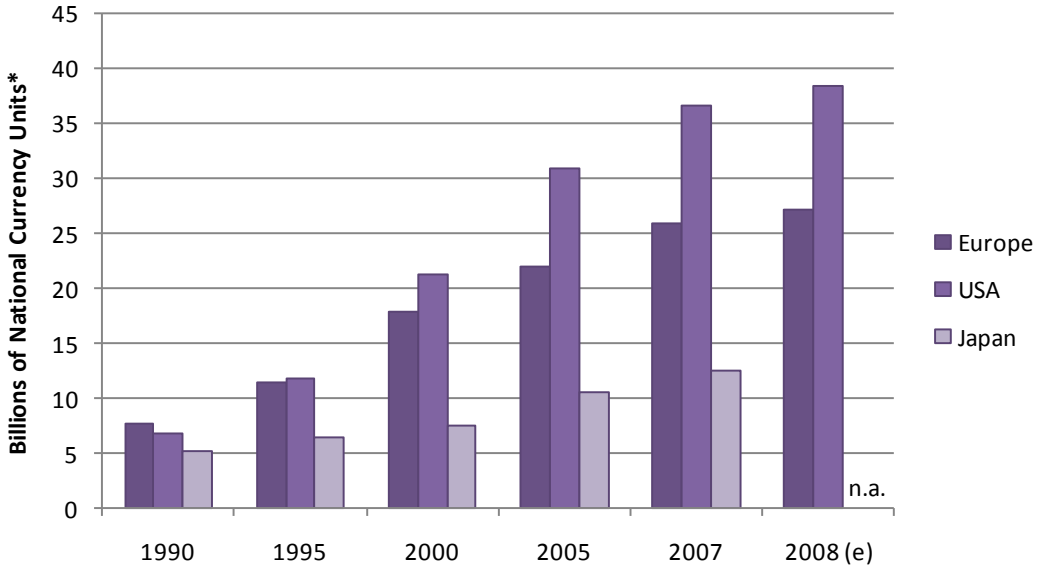


Figure 9: Pharmaceutical R&D Expenditure in Europe (Billion of National Currency Units), 1990-2007 (Reproduced from EFPIA, 2009)

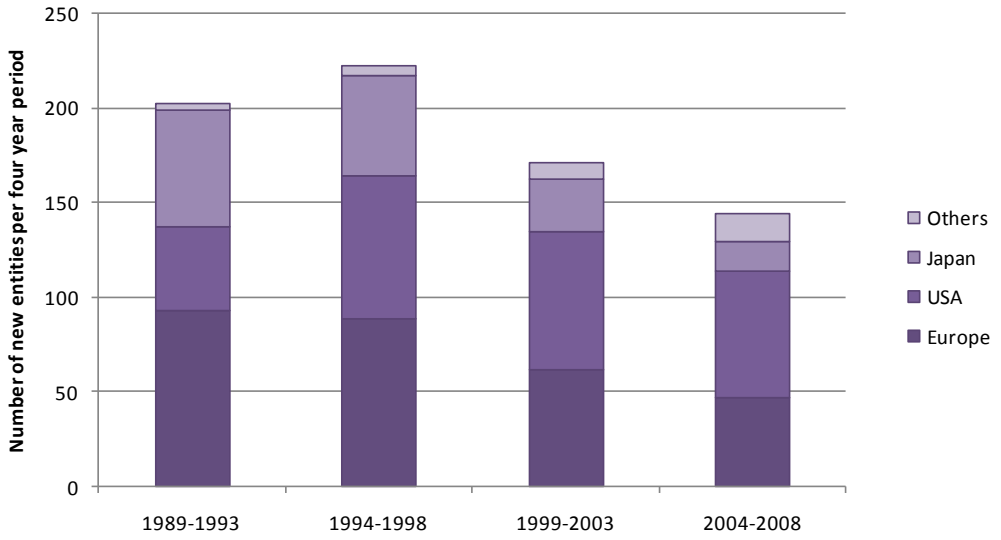


Figure 10: New Chemical or Biological Entities (1989-2008) (Reproduced from EFPIA, 2009)

Together these trends mean that the cost per new molecule has risen substantially. Comprehensive analysis on the subject shows that the total costs of developing a new molecule have increased at an annual rate of 7.4% above general price inflation from 1987 to 2001 (DiMasi, Hansen, & Grabowski, 2003). In 2001, the total cost estimate is US$ 802 million. More recent analysis shows that this has risen to 1 318 US$ million in 2006 (DiMasi & Grabowski, 2007). There the annual growth rate is even over 10%. Clearly original medicines are becoming more and more expensive due to these cost increases.

The unit price rise was discussed above as one reason for rising expenditure on pharmaceuticals in health care. Another reason is the rising use of pharmaceuticals. There the increasing number of elderly people is one important reason and this will be discussed more in Chapter 3.4.1 Demographic Factors.

Pharmaceutical Expenditure Trends

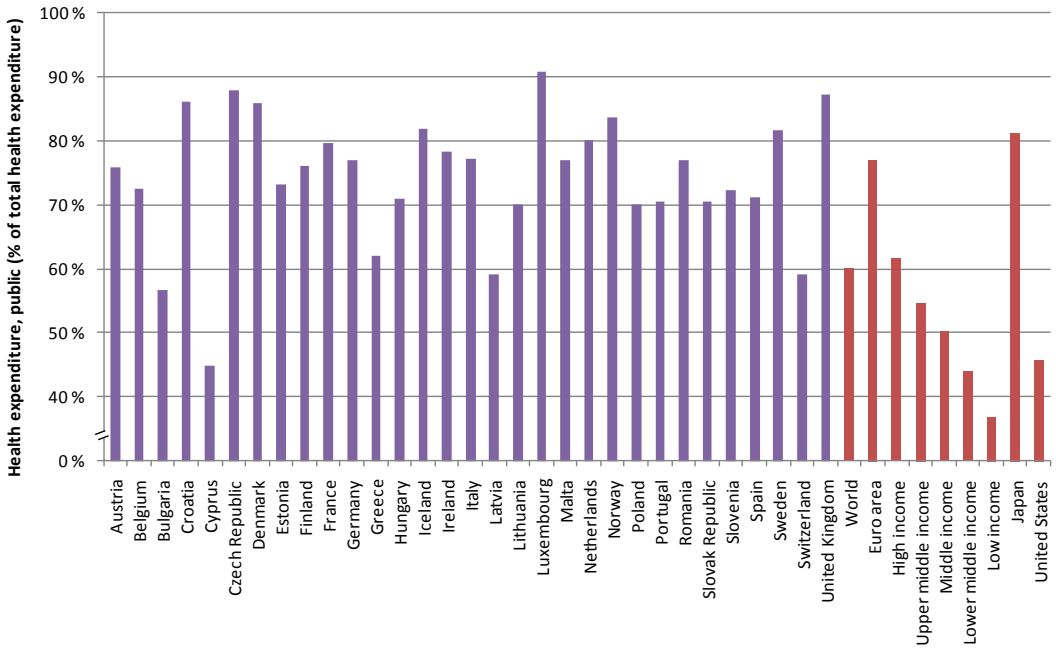
Because of the various policies in place and other measures that national governments have the radical change in costs is not so clearly seen in public expenditure. The trend is that costs are rising, but not as steeply as in R&D of medicines. According to World Bank Health, Nutrition and Population (HNP)

statistics[3] in the euro area the public health expenditure as a share of total health expenditure rose from 75.7% in 2002 to 76.9% in 2006. Similarly the share of public health expenditure as a share of GDP rose slightly from 7.2% to 7.5% from 2002 to 2006. This leads to the next proposition about the industry dynamics.

Proposition 10: Rising pharmaceutical R&D costs increase the pharmaceutical prices and thus health care expenditures.

Public health expenditure as a share of total health expenditure in 2006 for European countries as well as other selected regions is presented in Figure 11. The figure shows differences in Europe and even more in the World. Euro area has a clearly higher public expenditure share of the total health care expenditure than, for example, the World. This supports the fact that national governments have a reason to fight the rising costs in pharmaceuticals and therefore the rising public expenditure.

[3] World Bank's HNPStats. URL: http://go.worldbank.org/N2N84RDV00



Notes:
Income group classifications:
Low income: $975 or less
Lower middle income: $976 - $3,855
Upper middle income: $3,856 - $11,905
High income: $11,906 or more
Divided according to 2008 GNI per capita, calculated using the World Bank Atlas method.

Figure 11: Public Health Expenditure as a Share of Total Health Expenditure in 2006 in European Countries and Various Other Regions (World Bank's HNPStats)

3.4 Social Environment

3.4.1 Demographic Factors

This chapter of the social environment will discuss only the effects of changing demographic factors on the generic medicines industry. According to Hoffman (2005) demographic trends affect the generics demand. The main demographic factor that is seen to have an impact on the success of the generic medicines is the aging population. This is because of two facts. Firstly the population in Europe, as well as in any other industrialized country in the world, is aging rapidly. Secondly older population consumes much more health care resources than any other younger age groups. For the aging population it has been estimated that the number of elderly citizens, meaning citizens aged 65 and over, will rise in the EU from 85 million in 2008 to 132 million in 2035 and to over 150 million in 2060. As a share of the total population, this means that the group of citizens over 65 in 2008 is approximately 17%, in 2035 it is 25%, and

in 2060 it is already 30%. Average estimated share of the elderly people in the EU and in selected member states are presented in Figure 12 below. The figure presents the cumulative share of the elderly people until indicated year. This means that, for example, the total share in 2035 is the sum of the bars of 2008 and 2035. (Eurostat, 2008.)

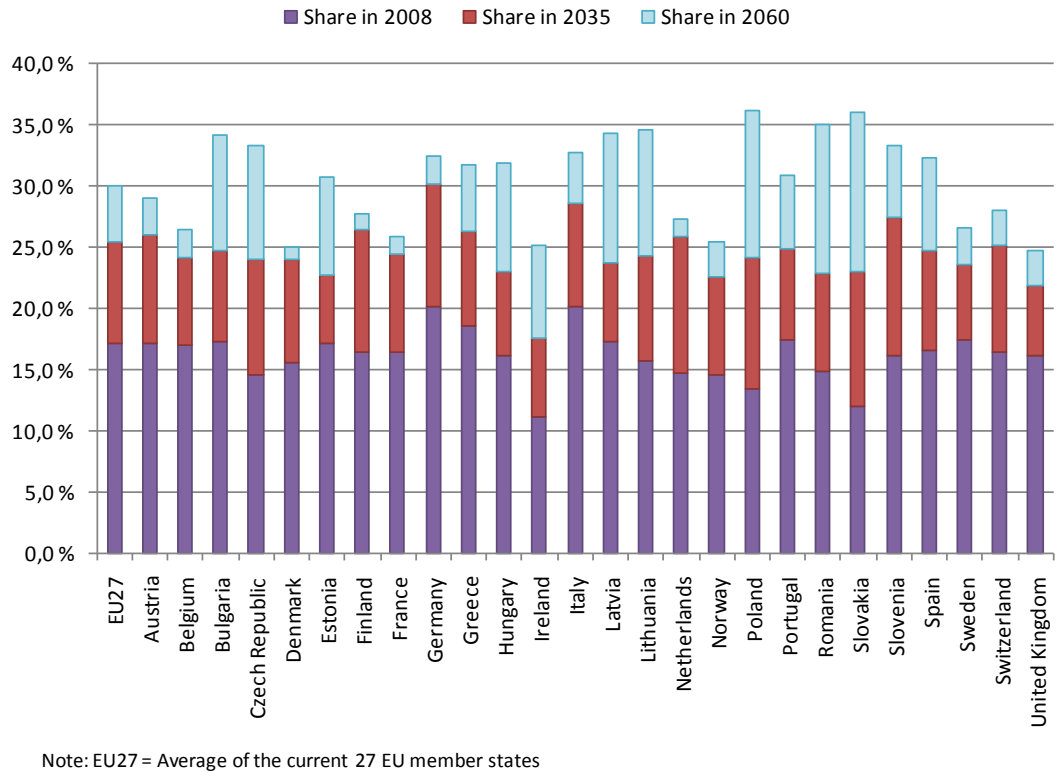


Figure 12: Estimated Cumulative Share of the People Aged over 65 in the EU and Selected European States, 2008-2060 (Eurostat, 2008)

There is substantial rise in the share of elderly people throughout the EU. Especially it seems that Eastern European countries are affected most by this demographic change. The whole change is made even more important because in health care the expenditure the EU member states currently spend on the citizens aged over 65 is between 30-40% of total health expenditure. The health care expenditure share is clearly higher than the share of the population. Part of this expenditure is obviously hospital expenses, treatments, and others, but also medicine expenditure is big. Radical rise in public health care expenditure as

population gets older is presented in Figure 13. (Economic Policy Committee, 2001.)

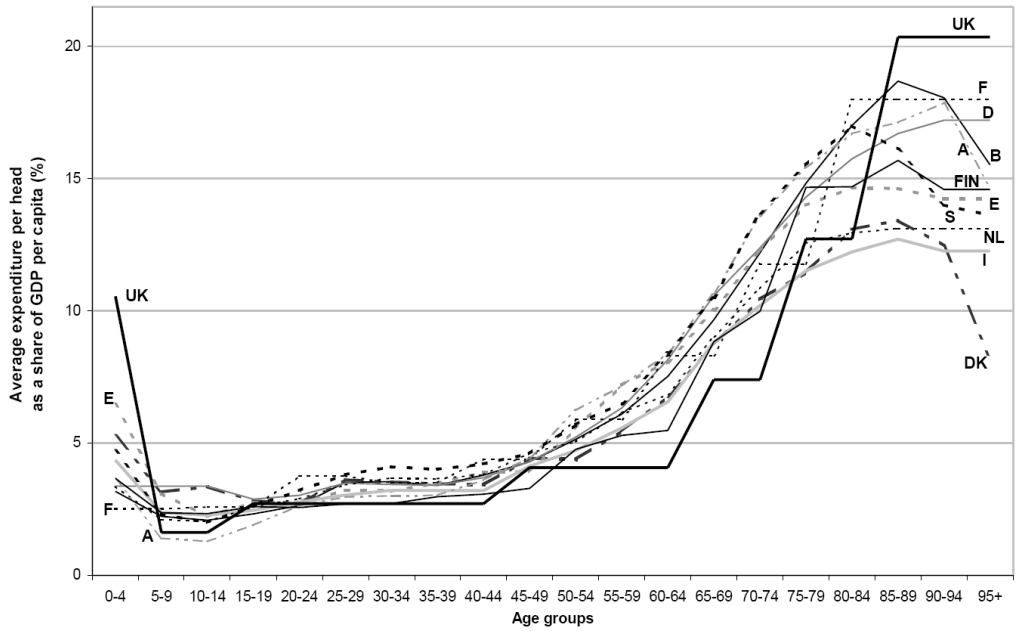


Figure 13: Age Profiles for Public Expenditure per Head on Health Care (Reproduced from Economic Policy Committee, 2001, p. 9)

In addition to these, aging population also has other implications for the EU, for example, rising pension costs and lowering share of working age, which means lower production in case of every other factor remains at the status quo. However, in the context of pharmaceutical industry and generic medicines these do not have direct effect and are thus not that important for the overall performance. Demographic trends influencing the dynamics of the industry can be formulated to the next proposition.

Proposition 11: The rising share of the elderly people increases the health care expenditures.

3.5 Summary of the Generic Medicines Industry

Above the industry was discussed under four broad topics. First area that was discussed was the operational environment. This analysis revealed the diverse playground surrounding this thesis' core group of actors, the companies that have a marketing authorization for their generic prescription medicines in the

EU. Also the industry consolidation that has started was discussed and the effects this has had on the company population.

After that the regulatory and institutional environment was discussed. To summarize major evolutionary changes in regulatory and institutional environment a timeline is presented in Figure 14. The figure is loosely adapted from EGA (2007b) and is filled with additional information that has been discussed above. The overall idea that Figure 14 shows is that institutional environment as well as patent legislation has unified in Europe in the last two decades.

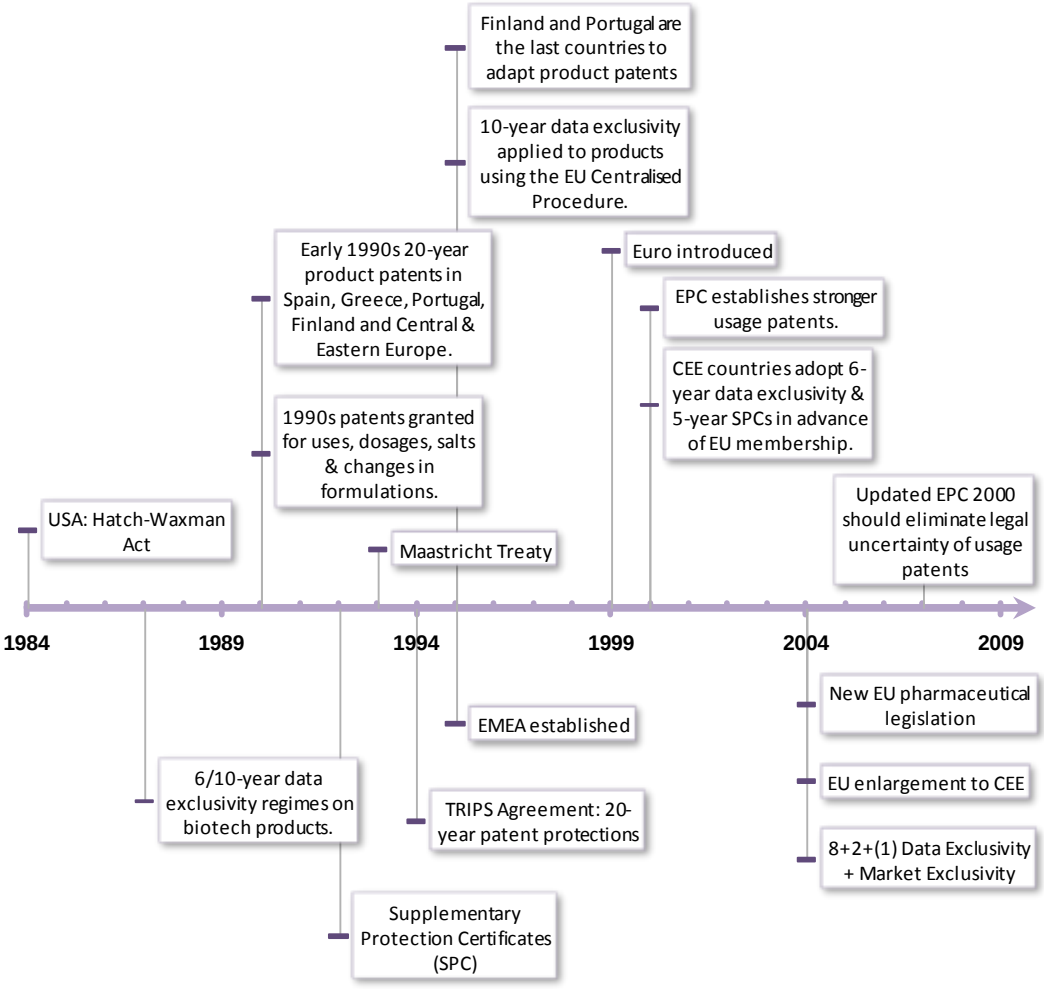


Figure 14: Timeline of the Major Changes in the European Regulatory and Institutional Environment Affecting Generic Medicines

If looking at the regulatory environment, more closely one important difference can be seen that should have an effect on the success of the industry. The

difference is between patent and promotion regulation. In general, patent regulation is more homogenous in the EU and it is more clearly decided on the EU level. On the other hand, generic medicines promotion related aspects are still under the development to become unified in the EU. Currently these policies vary within the EU members quite much and are decided on the national level. So it seems that patent legislation has provided a lot of opportunities for generic medicines in the history. However, today promotion legislation provides most opportunities. Furthermore, these opportunities differ from country to country.

Economic environment was discussed in the third part. This part showed that generic penetration, maybe the single most comprehensive indicator of the generic medicines overall success, varied between European countries. Eastern European countries had the highest penetration and Western European countries clearly had a group of countries with developed generic medicines markets and another group with developing markets.

In the economic environment, the generic medicines position in the world was also discussed. Clearly, it is seen with generic medicines as well as with original medicines that the main markets are in the industrialized and wealthier countries. Also it was shown that due to the number of factors generic medicines had grown much faster than original medicines. This growth is also estimated to continue, which will introduce new companies to the markets. Moreover, the bulk of companies entering the markets are seen to be original medicine companies, which is seen as a major factor for accelerated mergers and acquisitions activity in the industry.

Final issue that was discussed as a part of economic environment was the pharmaceutical expenditure. National governments in Europe are facing the problem of growth in health budgets and one reason for this is the growth in R&D costs. The number of new molecules is going down in original medicines industry at the same time as overall R&D expenses are going up. This substantially increases the unit price for a single new molecule, which obviously

raises the prices of medicines. In fighting the rising pharmaceutical expenditure public policies are in a key role in Europe.

Under the social environment another reason for rising public health expenditure was discussed. This was the growing share of elderly people in Europe as well as in any other industrialized country. The current share of 17% of the population being older than 65 years of age is estimated to almost double to 30% in 2060. This is even more important for the health care than other industries, because at the age of 65 the public health expenditure rises considerably.

All in all, multiple factors are seen affecting the industry. Relevant factors were formulated as propositions about the industry dynamics and are presented in Table 6. These propositions formulate one part of the overall industry dynamics. From these propositions total of six hypotheses can be formulated in addition to the first hypothesis formulated from the VoC theory. These will be presented below.

Table 6: Propositions Made from the Generic Medicines Industry

More specific propositions from the generic medicines context	
Proposition 4	The main influencers to the overall success of the generic medicines industry are the major payers of the health care costs at the government level.
Proposition 5	Nation's industry specific comparative advantages have an effect on the survival of the company population in that nation. Likewise, the survival of the company population manifests nation's industry specific comparative advantages.
Proposition 6	Patent regulation enables the generic medicines industry, but does not substantially influence its success.
Proposition 7	a) Promotion legislation affects to the success of the generic medicines industry. b) Among the promotion legislation, price regulation has single most effect on the success of the generic medicines industry.
Proposition 8	Good economic situation and economic growth have a positive effect to the success of the generic medicines industry.
Proposition 9	Penetration of the generic medicines tells about the overall success of the generic markets by comparing the industry with the traditional medicines industry.
Proposition 10	Rising pharmaceutical R&D costs increase the pharmaceutical prices and thus health care expenditures.
Proposition 11	The rising share of the elderly people increases the health care expenditures.

Propositions 4 and 10 formulate a hypothesis addressing the role of public financing in health care. Due to the role of governments as payers and the rising pharmaceutical costs this hypothesis is formulated.

Hypothesis 2: The high public share of the health care expenditure enhances the success of the industry.

Proposition 5 formulates the next hypothesis that addresses the company population. The central role of the companies as actors in any economic system was also stressed in VoC.

Hypothesis 3: The survival of the domestic generic medicines companies indicates suitable conditions for the whole industry.

Propositions 6 and 7 formulate a hypothesis about the legislation of the industry. The importance of regulation and legislation for the industry is shown in the study. This hypothesis shifts the focus to the most relevant part of the regulation.

Hypothesis 4: The enforcement of generic promotion by price regulation enhances the success of the industry.

Proposition 8 formulates a hypothesis about the role of national income. In Europe with high income developed nations this hypothesis is especially relevant.

Hypothesis 5: High national income enhances the success of the industry.

Proposition 9 formulates a hypothesis about measuring success in the industry. Penetration by value as a measurement is useful as the figures are comparable to, for instance, other industries and national budgets.

Hypothesis 6: The performance of the generic medicines industry can be measured by penetration. (High penetration is a sign of success of the industry).

Finally, Proposition 11 formulates a hypothesis about the role of demographics. Especially in Europe and other industrialized nations the importance of demographics for the development of the industry is substantial.

Hypothesis 7: The high share of elderly people enhances the success of the industry.

All of these hypotheses, the one presented previously and the six more closely industry related, are summarized in Figure 15. In Figure 15, the reasoning from the propositions to the hypotheses is also visualized. The hypotheses together build a framework for the analysis, which will be discussed more in Chapter 5 Data and Analysis.

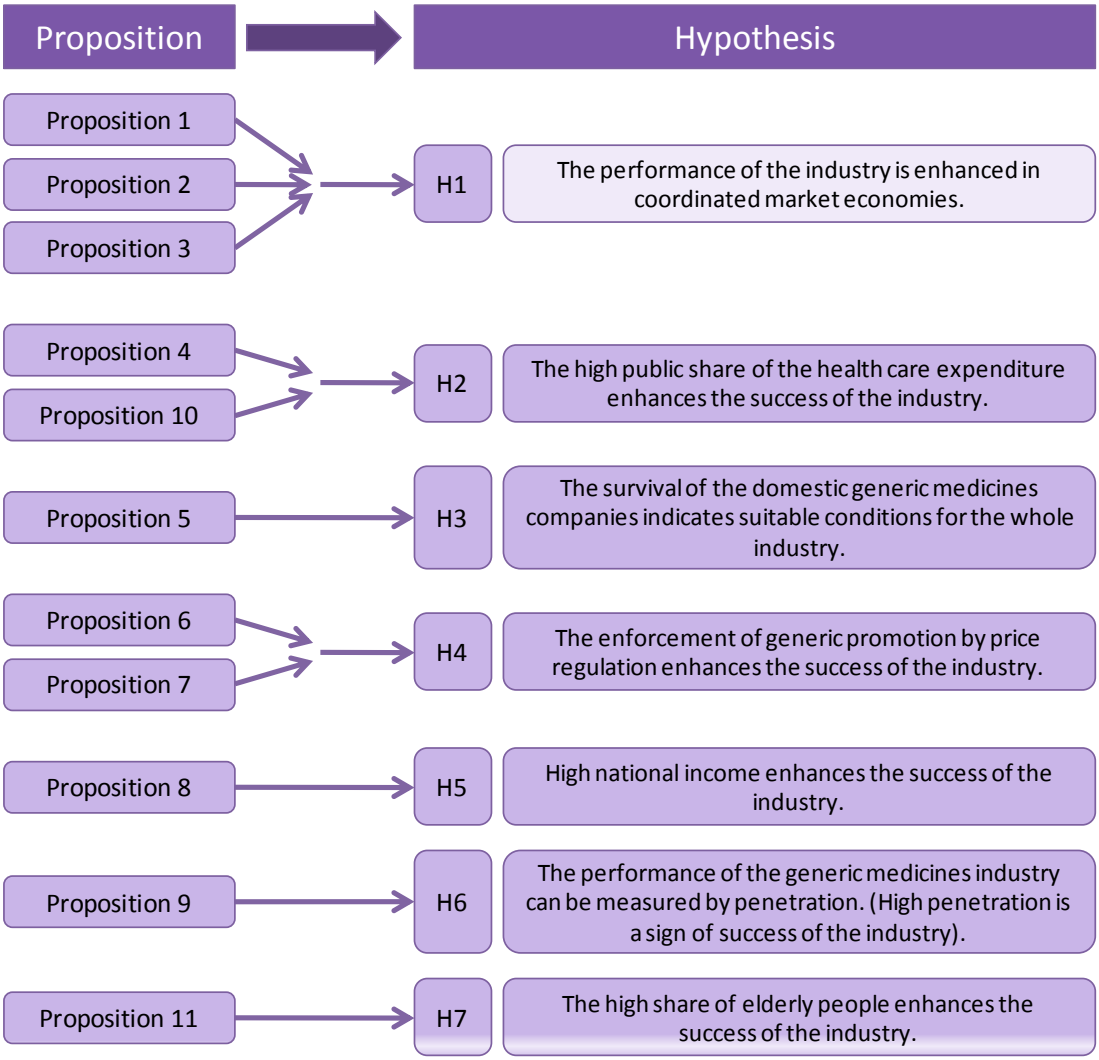


Figure 15: Summary of the Hypotheses and the Reasoning from the Propositions to the Hypotheses

4 Methodology: Fuzzy Set Qualitative Comparative Analysis

The study seeks to utilize fuzzy set qualitative comparative analysis (fsQCA) (Ragin, 2008a, 2000) as the methodology for analyzing causal conditions and their dependencies among generic medicines companies' performance in Europe. In the Varieties of Capitalism approach the use of set-theoretical methods was proposed. This was because of the problems with the traditional analysis methods and increased complexity in the research settings.

FsQCA, which is also sometimes only referred to as fuzzy set analysis, is a rather new set-theoretic methodology to be used in social sciences. It is said that fsQCA is a middle path between quantitative and qualitative methods. These in this context are usually referred to as a case-oriented approach and as a variable-oriented approach respectively. In addition to that, it is also said that fsQCA is not only a compromise between these two but it can actually go beyond the limitations of both (Ragin, 2008b). Limitations in the more traditional methods might include the shortage of data to make statistically significant analysis or the limitations to make a generalized conclusion from too detailed studies.

Ragin's work introduced fsQCA to social sciences at the beginning of the 2000s. However, even though fsQCA in social sciences has only been used for less than a decade the foundations for Ragin's work and thus more generally for this type of analysis are much longer in the past. Fuzzy sets were first introduced in 1965 by Lotfi A. Zadeh (1965) as an extension to classical sets. In classical sets, binary coding is used to formulate sets. Fuzzy sets introduced a continuous real unit interval of [0, 1] and thus allowed elements to have a membership of varying degree in a given set.

The actual analysis of the relations between the sets has its foundation in an earlier work by Ragin. Ragin introduced qualitative comparative analysis (QCA) already in 1987 (Ragin, 1987). From QCA, the logical operations follow to the fsQCA. Original QCA was also based on the set theoretical framework, but with classical sets with the binary values. That is why in some of the resent studies it

is referred to as a crisp set qualitative comparative analysis (csQCA) to distinguish it from other types of QCA such as fsQCA (see generally Wagemann, 2009). FsQCA is a part of set-theoretical methodology that allows as well as requires different approach from some of the more conventional data analysis methods (Fiss, 2007; Pajunen, 2008; cf. Järvinen, Lamberg, Murmann, & Ojala, 2009). In fsQCA Boolean algebra is used to analyze combinations of sets. Traditional statistical methods, procedures, tests, and scores cannot be directly utilized in fsQCA.

After this brief introduction, fuzzy sets, QCA, and the combination of them, fsQCA, will be discussed more closely. Detailed description is in place since this methodology has not been used in that many studies yet. The fsQCA will be the third and final part of the theoretical and empirical body of this thesis.

4.1 Fuzzy Sets

The idea of fuzzy sets is pretty simple and is well documented in various books and papers after Zadeh's introduction (Zadeh, 1965). Fuzzy sets allow elements in a set to have the degrees of membership in a given set. In fuzzy sets the membership of an element in a set is valued to the real unit interval from zero to one or with the mathematical notion [0, 1]. The score of one means that an element is fully-in a set and value zero means that an element is fully-out of a set. In crisp sets, the way in which classical bivalent sets are called in social science (e.g. Wagemann, 2009), the only available values are zero and one. This opens up much more possibilities to analyze membership in a particular set than crisp sets offer.

Another important in fuzzy sets is the score of 0.5. This indicates the crossover point with the maximum ambiguity of the membership in the set. In general, scores in the open ended interval of (0, 0.5) are said to be more out of the set than in the set and scores in the open ended interval of (0.5, 1) are said to be more in the set than out of the set. All of the variables that are used to construct the sets are needed to transform into this total interval of [0, 1].

The process of transforming variables to sets is called calibration. The calibration process presents one superiority quality of fuzzy sets in illustrating things: irrelevant variation can be eliminated from the sets. In simple terms, this means that zero value in the ordinal scheme does not need to mean zero membership. Other membership scores are also set according to the definitions of the researcher by focusing most on the specifications of full membership and full non-membership, as well as the specification of fuzzy set score of 0.5. This implies that in certain analyses fuzzy sets can be more efficient than crisp sets. Calibration will be discussed later as a part of illustration of fsQCA itself.

Zadeh's work was at first used mainly in technical sciences such as in the control theory. It was not until the 80s when fuzzy sets were introduced to social sciences by Smithson (1987). However, Smithson introduced only the construction of the sets. The in-depth analysis of fuzzy sets as it is used today was not introduced in this context. However, in the same year Ragin (1987) introduced the predecessor methodology for analyzing fuzzy sets known as the qualitative comparative analysis (QCA). The next chapter will discuss this.

4.2 Qualitative Comparative Analysis (QCA)

Second part constructing fsQCA is qualitative comparative analysis (QCA) (Ragin, 1987). Building on this Ragin's seminal work different comparative case analysis techniques have been developed. Today fsQCA is one of the most well known of these techniques. Some of the other better-known techniques in this field include multi-value QCA (mvQCA) (e.g. Cronqvist & Berg-Schlosser, 2009) and temporal QCA (TQCA) (e.g. Caren & Panofsky, 2005). (Rihoux, 2006.) This chapter will discuss the basics of QCA and then build on that and the traditional fuzzy set theory the combination of these called fsQCA.

QCA was first introduced as a method of formalizing and extending traditional comparative case-study methodology (Ragin, 2000, p. 120). In case studies, the problem is that there are very few data points that usually are not enough to do statistically valid analysis. QCA is designed to overcome this problem by

introducing tools for comparing cases as the configurations of set memberships (Ragin, 2000). Because QCA operates in sets, operations are based on the variations of Boolean algebra, rather than linear algebra (Ragin, 2000, p. 121). In fsQCA, the algebra is called fuzzy algebra but it is analogous to Boolean algebra in its operations (Wagemann, 2009). This means that operations that can be used in QCA of any kind are especially negation, logical and, and logical or (e.g. Pajunen, 2008).

Negation is basically the opposite of the original value and in QCA it can be presented with the formula

$$\sim A_i = 1 - A_i$$

Here A is the membership in the original set and the tilde sign "∼" is used to present the negation. Subscript "i" indicates the "ith" case.

Logical and is used in combining two or more sets. It is more commonly known as set intersection. In fuzzy sets logical and is obtained by getting the minimum membership score of each case in sets that are combined. Logical or is also used in combining two or more sets. This is more commonly known as the union. Logical or uses the maximum membership score of each case in sets that are combined.

The idea of QCA is to make comparisons between causal conditions in included cases to see if their presence or absence has analytical interest for the presence of the outcome. This means that constructing a data set for the QCA requires a construction of the selected number of causal conditions or factors and the construction of one outcome. Analogy to the statistical analysis, if it is necessary to make, is that causal conditions are independent variables and an outcome is a dependent variable.

In social sciences, the research usually begins with an outcome and its explanation (Ragin, 2000, p. 130). That is why the outcome for the analysis should be set early on. Then to explain this outcome researcher should identify

a proper number of causal conditions. The question is what the proper number of causal conditions is. Obviously restricting for identifying these conditions is the amount of data from which causal conditions can be constructed. This is similar to any statistical analysis. Also there should be no causal conditions identified that are similar to all cases in the analysis. If the condition identified is the same in all of the cases, it will obviously be present in the solution as it is a necessary condition for a case to exit.

Moreover, Marx (2006) has studied the QCA setting with random data matrixes. He finds out in his analysis a benchmark table that assesses the probability to find a model with a given number of cases and causal conditions. He, for example, has found out that at least 16 cases should be used when using six causal conditions. This is because, with six factors when cases fall below 16 there is a high change that random data will generate results, which means that there is a change that results are not valid. In his analysis five conditions would need 13 cases and seven conditions would need 27 cases. This analysis points some direction to the maximum number of causal conditions for a given number of cases.

Tradition in the field has been that the number of causal conditions ranges from six to eight. Some practical reasons for this are that a smaller number of conditions would provide too simple solutions. This means that essential information might be required to generalize too much. On the other hand, more than eight conditions would generate too complex solutions and it would be hard to draw any conclusions from those. (Ragin & Rihoux, 2008, p. 28.) In the end, identified causal conditions give different combinations for causal conditions according to formula 2^k, where k is the number of identified causal conditions. Formula comes from the fact that each condition can either be present or absent in the actual solution.

The ultimate objective in QCA is to identify different causal combinations leading to similar outcomes. This is called causal complexity (see Ragin, 1987; Ragin & Sonnett, 2004). As a more developed version of QCA, fsQCA is especially

suitable for analyzing causal complexity as it provides means to analyze even more complex situations. However, it also creates more restrictions for identifying causal combinations or results. FsQCA will be discussed in the next chapter.

4.3 Fuzzy Set Qualitative Comparative Analysis (fsQCA)

4.3.1 Set Theoretical Properties of fsQCA

In combination of previously discussed fuzzy sets and QCA, Ragin formulated the fsQCA methodology (Ragin, 2000, 2008a). It was introduced as a methodology for social science. Since its introduction, it has been gaining more and more interest among researchers from various fields. At first fsQCA was especially adapted to politics research (e.g. Epstein, Duerr, Kenworthy, & Ragin, 2008; Stokke, 2004). Very recently methodology has been also adapted to management and business research and it is gaining more and more interest in this field also (e.g. Järvinen et al., 2009; Pajunen, 2008; Fiss, 2008).

The reason why fsQCA is adapted to research is that there are clear benefits of using fsQCA. First benefit is that there is the possibility to conduct data analysis with fewer data points than with more traditional methods such as regression analysis. Second benefit is the possibility to conduct more complex analysis and thus obtain results from more complex phenomena.

The idea in fsQCA is to explain a certain outcome with different causal conditions with QCA methodology, but replacing binary sets with fuzzy sets. However, it should be noted that crisp sets can also be used in parallel to fuzzy set as they can be considered a special case of a fuzzy set. All the values are calibrated to the closed real interval of [0, 1] to form fuzzy sets. As stated before, important values in setting or calibrating fuzzy sets are full non-membership with the score of 0, full membership with the score of 1, and maximum ambiguity (fuzziness) of the membership with the score of 0.5. When calibrating these three points, they need to be qualitatively anchored. It is required for the researcher to present a rationale for these points. Other values are

quantitatively assigned and thus fsQCA actually is able to combine qualitative and quantitative assessment (Ragin, 2008a).

In calibrating fuzzy sets scores for fsQCA the interval [0,1] can be either set as continuous or it can be divided equally into a number of classes. For example, a three-value fuzzy set adds crisp set with one class that is of value 0.5. The idea of using these classifications is that they give qualitative anchor points for quantitative codings. Some of these are presented among others by Ragin (2008a, 2008c). Even though the fuzzy sets that are not continuous might seem similar to ordinal scales it is not in the context of fuzzy sets. In ordinal scheme, values are set into the set by simply based on their rank order. In fsQCA, this ordinal ranking is only first part of calibration. In second phase fuzzy sets are made distinct by the researcher's conceptualization of the set. This was discussed above. (Ragin, 2008a.)

Subset relation is the key set theoretic relation when studying causal complexity. Ragin states that if cases that share several causally relevant conditions uniformly exhibit the same outcome, means this that these cases constitute a subset of instances of the outcome (Ragin, 2000, 2008a). This subset relation means that a specific combination of causally relevant conditions may be interpreted as sufficient for the outcome. There are two key set-theoretical definitions that are important for causal conclusions in the fsQCA and sufficiency is the first of these. There could be different combinations that display the outcome. These all may be interpreted as sufficient for the outcome. Like in the real world there is possibility for having different combinations that result in the same outcome.

By definition, sufficiency implies that the causal condition X is a subset of the outcome Y. This means that for all cases outcome Y gets membership scores greater than or equal to causal condition X:

$$X_i \leq Y_i$$

Another set-theoretical definition for fsQCA is necessity. In general necessary conditions are important to both social theory in general and therefore also to the fsQCA. By definition, theoretically relevant causal condition is necessary if it is present in all instances of an outcome. In fsQCA, the causal factor X is necessary if the outcome Y can be considered a subset of the causal condition X. The outcome Y can be considered a subset of the causal condition X if fuzzy membership scores of the causal condition X are greater than or equal to the scores of the outcome Y for all cases:

$$X_i \geq Y_i$$

Because of the fundamentally bivariate nature of the hypotheses about necessary and sufficient causation, the whole analysis is bivariate. This means that fsQCA does not suffer from a small-N or degrees of freedom problems, which are common to multivariate regression methods and therefore with fsQCA the statistical significance can be reached with a modest number of cases (Katz, Vom Hau, & Mahoney, 2005). The actual analysis of fsQCA closely follows the procedures described already in the original QCA (Ragin, 1987). The next chapter will discuss these practicalities in more detail.

4.3.2 Conducting fsQCA

Presently fsQCA should be conducted using the truth table algorithm that was introduced by Ragin (2008a). Previously there has been another algorithm for conducting fsQCA. The inclusion algorithm is the older one and it was presented at the same time as fsQCA by Ragin (2000). This has been applied in several studies (see Katz et al., 2005; Pajunen, 2008), but currently inclusion algorithm is under further development and it is seen that at the moment the truth table algorithm is superior to the inclusion algorithm. The inclusion algorithm is being developed to be more robust and to make it more consistent with the truth table analysis, but until the new release inclusion algorithm should not be used for fsQCA. The thesis will also employ the truth table algorithm meaning that the study is mainly of sufficient causation. (Ragin, 2008c.)

The actual analysis when using the truth table algorithm will be explained next (for more detailed discussion, see Ragin, 2008a). The analysis begins with selecting k number of causal conditions to explain one outcome. These causal conditions together construct a multidimensional vector space with 2^k corners. Each of these corners represents one line in the truth table. In addition to that, a case is regarded as a member of the corner when it has a fuzzy set membership score of more than 0.5 in that corner.

After the table is constructed the researcher should assess each configuration, meaning each the row, on two aspects. First researcher assesses if the configuration is relevant. If it indeed is, then the configuration needs to be assessed on its sufficiency for the outcome in question. In practice, relevant configurations are distinguished with the empirical evidence. For a small number of cases, adequate empirical evidence to support the idea that a configuration is relevant can be considered one case. Those configurations that have membership frequencies below the threshold are called logical remainders and are removed from the table, because they lack adequate empirical evidence.

On the remaining configurations, the evaluation whether the configuration is sufficient or not for the specific outcome needs to be done. This is evaluated with the consistency measurement. Consistency is defined as follows (Ragin, 2008a, 2006).

$$\text{Consistency } (X_i \leq Y_i) = \frac{\sum_{i=1}^{N} \min (X_i, Y_i)}{\sum_{i=1}^{N} X_i}$$

where X_i represents membership scores in a combination of causal conditions, and Y_i represents membership scores in the outcome. “Min” means the selection of the lower of two values. Consistency score can be from zero to one, where one indicates full consistency. Full consistency means that all cases are subsets of the outcome. For consistency scores Ragin (2008a) recommends that a cut-off value of 0.85 or higher is used. In addition to that, he states that it should not be less than 0.75 in any case, since scores between 0 and 0.75 indicate substantial inconsistency. Based on the scores and their analysis the column termed as

"outcome" at the analysis software is encoded in consistent and inconsistent cases. Software will be discussed more in the next chapter.

After all this data is imputed to the software, the Quine-McCluskey algorithm of QCA, which included in the software, is used to find the final solution. This gives three solutions. In the language of Ragin and Sonnett (2004) two original solutions are called the "complex" and "parsimonious" solutions. Complex solution is more detailed and includes more rows than parsimonious. Parsimonious solution is generated by re-analyzing the truth table with the remainder rows, or rows with combinations lacking good instances, set to "don't care" (Ragin, 2008a).

The third solution is called "intermediate" solution. Intermediate solution can be obtained by providing additional simplifying assumptions in the course of analysis. A researched might have a reason to provide these assumptions if complex solutions have a change to be too complex. (Fiss, 2008.) However, by providing simplifying assumptions, the generalization of the results becomes harder and thus the use of intermediate solutions should be assessed separately for each study.

When the solutions are obtained, they still need to be analyzed more closely. To help this two description measures exists. These are consistency and coverage. Consistency measures the accuracy of a solution and is analogous to the configuration consistency presented above. In analyzing results, consistency score should be assessed before assessing the coverage. There is no reason in analyzing the coverage of the solution that is not a consistent subset of the outcome (Ragin, 2006).

After establishing the consistency, coverage, which measures the generality of the solution, needs to be assessed. Coverage describes the amount to which solution covers the outcome or in other words the importance of a causal combination in achieving the outcome (Fiss, 2008). It is calculated using the formula:

$$\text{Coverage } (X_i \leq Y_i) = \frac{\sum_{i=1}^{N} \min (X_i, Y_i)}{\sum_{i=1}^{N} Y_i}$$

Values are between zero and one and the values close to one imply high coverage.

There is often a trade-off between consistency and coverage. High consistency could lead to low coverage and vice versa. That is why it is important to understand the differences between these two when analyzing the results. More interesting results therefore have high consistency scores. Their coverage scores only imply the empirical importance. In practice this means that in studies where there are a small number of cases and a lot of causal combinations found the coverage of a single combination is usually low. (Ragin, 2006.)

4.4 Software

The actual analysis is conducted using the software package intended for fsQCA (Ragin, Drass, & Davey, 2009)[4]. This software has the truth table algorithm implemented in it with all the above described features. More detailed discussion about the practicalities in the use of the software is presented by Ragin (2008c).

One thing that is notable for using software is the fact that it has a limitation of analyzing cases with memberships of exactly 0.5. This is because these membership scores actually have membership in the multiple corners of the constructed vector space. Ragin (2008d) recommends avoiding the use of 0.5 membership score for causal conditions. Fiss (2008) proposes another solution to overcome this problem. He proposes that adding a constant of 0.001 to all

[4] fs/QCA 2.5 software Ragin, C. C., Drass, K. A., & Davey, S. (2009). Tucson, Arizona: Department of Sociology, University of Arizona. The program can be downloaded from the website www.fsqca.com (Accessed 19.2.2010).

membership scores below 1 eliminates the problem, but does not change the results significantly.

4.5 Applicability to the Study

As a methodology fsQCA is nowhere near finished and criticism on its usage in social sciences is also available (e.g. Lee, 2008). Regardless of that, this methodology is adapted here as it is seen that it provides the most comprehensive analysis on the causal dependencies in generic medicines industry in Europe. Therefore, the results should also be the most usable.

Few clear reasons for choosing fsQCA can be found. First of all the methodology supports the future research proposals for the Varieties of Capitalism theory as discussed earlier. Secondly, the study has the limitation with the number of cases available for analysis, which makes standard statistical analysis a difficult task. On the other hand, analyzing every country qualitatively as separate cases would be a too difficult and complex task.. In addition, as fsQCA is a relatively new methodology studying its applicability to this context provides important information about its usability.

In comparison to other mentioned QCA variations such as crisp set QCA and multi-value QCA, fsQCA stands out by being able to handle the most complex situations (Rihoux, 2006). The chosen empirical data of generic medicines industry is very complex and therefore requires a complex methodology to produce robust results. FsQCA is seen to fit this setting best and thus it builds the third part of the theoretical and empirical body of this thesis. In the next chapter, all of these parts will be combined and the analysis setting will be discussed.

5 Data and Analysis

This chapter elaborates the used data and the analysis of the generic medicines industry's success factors in Europe. First the overview of the analysis setting with data and calibration methods is presented. Then used fuzzy sets are presented case by case. Reliability and validity will also be assessed case by case.

5.1 Overview of the Factors

In the study, the assessment of reliability and validity follows the positivist tradition (e.g. Behling, 1980; Cook & Campbell, 1979) in the way explained by Gibbert, Ruigrok and Wicki (2008). In this setting, the assessment is divided into internal validity, construct validity, external validity, and reliability. Internal validity addresses the causal relationships between factors and results and therefore in the study is mostly associated with choosing the factors. Construct validity addresses operationalization of relevant concepts. In the study, this mostly refers to the conceptualization of chosen factors and that those represent what they are said to represent. External validity refers to generalizability to other context. Finally, reliability refers to the absence of random error in sources and methods and enabling the research to be conducted again using the same path. All of these aspects will be assessed in parallel of explaining the analysis.

The analysis will be conducted with six causal conditions. There are two reasons for this. First, the more theoretical reasons are that it is in line with the practicalities proposed for QCA (Marx, 2006). Marx's analysis proposes the maximum number of causal conditions for the thesis to be six with available 24 cases. Second reason for choosing six conditions is the more practical. Seven hypotheses were formulated from the propositions addressing the industry dynamics (see Chapters 2 and 3 and Figure 15 at p. 65). From these one transfers to outcome and six to the causal conditions. It is seen that with six conditions explaining the outcome it is possible to include the most relevant

aspects of the industry and, furthermore, nothing irrelevant needs to be included. Six causal conditions are also in line with the practicalities in the recent fsQCA studies (Ragin & Rihoux, 2008, p. 28). In practice, fuzzy sets are used in operationalizing the hypotheses. All the fuzzy sets with the hypotheses and the measurements used to construct the fuzzy sets are presented in Table 7. The reasoning for operationalization and measurement will be further elaborated under the chapters of each fuzzy set.

Table 7: Summary of the Constructed Fuzzy Sets

Category	Hypothesis	Measurement	Abbr.	Fuzzy Set (of countries with)
Outcome	H6: The performance of the generic medicines industry can be measured by penetration. (High penetration is a sign of success of the industry).	Penetration of the generic medicines in value	PEN	Successful generic medicines industry
Causal Conditions	H3: The survival of the domestic generic medicines companies indicates suitable conditions for the whole industry.	Survival rate of the domestic companies	SUR	Competitive domestic generic medicines industry
	H2: The high public share of the health care expenditure enhances the success of the industry.	Share of public health expenditure of total health expenditure	PHE	Publicly financed health system
	H5: High national income enhances the success of the industry.	GNI per capita	GNI	High national income
	H7: The high share of elderly people enhances the success of the industry.	Share of the population over 65 years	O65	High share of elderly people
	H1: The performance of the industry is enhanced in coordinated market economies.	Level of coordination in the capitalist system according to VoC	COO	Coordinated market economy
	H4: The enforcement of generic promotion by price regulation enhances the success of the industry.	Presence of the reference price system	RPS	Established generic medicines promotion

As mentioned, the thesis is able to use 24 European countries as cases for the analysis. Case countries are presented in Appendix 3. Furthermore, the analysis is based on current conditions, which means that data is from the years 2007 and 2008 in most of the cases. These were the most recent years of which comprehensive data was available.

When looking at calibration procedures in the recent studies that have employed fsQCA (e.g. Fiss, 2008; Järvinen et al., 2009; Pajunen, 2008), it can be seen that there are no standards for calibration. The number of categories for fuzzy set calibration as well as the method of calibration to continuous fuzzy sets differs. However, Ragin (2008b) recently presented two distinct methods for calibration: the direct and the indirect method of calibration. The thesis will apply both of these methods for calibration of different fuzzy sets.

Ragin (2008b) describes the procedure of both of the calibration methods in detail. In the direct method the transforming of variables needs three anchor points of full membership, full non-membership, and the crossover point of 0.5. After deciding on these the first step is to convert variables in to metric of log odds. For example, in this method the full membership with set membership scores ≥0.95 get the log odds of membership ≥3.0 and full non-membership with set membership scores ≤0.05 get the log odds of membership ≤-3.0.

After the log odds transformation the membership scores are calculated using the formula

$$Degree\ of\ Membership = \frac{e^{(\log\left(\frac{p}{1-p}\right))}}{1 + e^{(\log\left(\frac{p}{1-p}\right))}}$$

In the formula, exponentiated log odds are divided by the unity plus the exponentiated log odds to obtain the degree of membership (Fiss, 2008). Ragin (2008b) notes that his procedures are mathematically incapable of producing set membership scores of exactly 1.0 or 0.0. That is why above, for instance, full membership score is already indicated with the value 0.95. According to Ragin,

the membership scores of 1.0 and 0.0 would correspond to infinites for the log odds.

Even though the direct method has some limitations, it is indicated to be a superior method (Fiss, 2008; Ragin, 2008b). Fiss (2008) states the advantage being that it converts any interval variable into a set by using a metric that is symmetric around zero and has no floor or ceiling. In addition to that, fuzzy sets range from 0 to 1 as well as are tied to the thresholds of full membership, full non-membership, and the crossover point. Ragin (2008b) also estimates this procedure to produce results that are consistent with the conceptualization of degree of set membership.

Due the limitation in data not all the set can be constructed in the thesis by the direct method. The indirect method proposed by Ragin (2008b) is therefore also applied. This method relies on the broad grouping of the cases. Ragin uses the grouping to six categories. Those categories and qualitative anchors are: 1 fully in, 0.8 mostly but not fully in, 0.6 more or less in, 0.4 more or less out, 0.2 mostly but not fully out, and 0 fully out. Notable here is that three important thresholds do not need to be directly defined with external criteria. Especially the score 0.5 is missing. So if finding qualitative anchors is problematic, the indirect method should be used.

After the grouping of the cases, the indirect method uses the original data as the independent variable and the qualitative codings as the dependent variable to estimate the predicted set memberships. Ragin points out that this procedure should be conducted with a fractional logit model. This is implemented in STATA[5] in the FRACPOLY procedure (see more detailed discussion in Ragin, 2008b), which is indicated to be the simplest way to construct this transformation. Therefore, this procedure will be employed here, where applicable.

[5] STATA is a data analysis and statistical software from StataCorp LP, College Station, Texas

There are three reasons why methods proposed by Ragin (2008b) are adapted in this thesis. First, these are the most recent proposals for calibration. Second, they have already been employed in studies and thus at least partly validated. Fiss (2008) has recently used the direct method of calibration in his study. Third, the direct method is included in the latest version of fs/QCA (2.5) to automate the calibration after setting three threshold values[6].

The above presented reasoning addresses the reliability in the study. The use of methods that have been studied and validated previously reduces the random error that emerges from them. In that regard, the study reaches the required reliability for the methods. Next the chosen method of calibration as well as the used data will be explained for each constructed fuzzy set.

5.2 Outcome Factor

5.2.1 Successful Generic Medicines Industry (PEN)

The chosen outcome factor is the fuzzy set of countries with successful generic medicines industry. It is abbreviated as PEN based on the generic medicines penetration, which is the data it was constructed from. PEN is chosen as the outcome factor because it is seen to describe the overall success of the industry in the country comprehensively. The value of the penetration measurement is indicated by the industry analysis and expressed in Proposition 9.

For the analysis PEN uses European Federation of Pharmaceutical Industries and Associations (EFPIA) data set for generic medicines market share by the value in a case country in 2007. This data can be extracted from their yearly publication of The Pharmaceutical Industry in Figures[7] (EFPIA, 2009). This data set covers 21 cases. Due the data set limitation, Czech Republic and Lithuania are added from European Generic medicines Association (EGA) data set from

[6] Method can be found from the "Compute" -menu under the "Calibrate" -procedure
[7] Available at EFPIA website. URL: www.efpia.eu

2004[8]. In addition, Hungary is added from EFPIA (2007) data set that covers the year 2005, because it has not been present in the more recent data sets.

There are differences in the penetration data from various data providers. Relevant penetration data is provided among others EFPIA, EGA, and European commission. Many are based on some form of IMS data, which is not publicly available. Differences in the data sets come from definitions that they use. Nonetheless, EFPIA is chosen as the main data set because it covers the most case countries and has also published accurate numbers rather than just bar charts, from where only data estimates could have been extracted. Based on this reasoning PEN reaches the construct validity as well as the reliability required for the study. For the construct validity, the theory indicates that penetration is reasonable measurement for success and based on that PEN is able to conceptualize that. For the reliability assessment it can be argued that the random error is minimized by using the EFPIA data in a way explained above.

This data is encoded in fuzzy sets using the indirect method. A case is coded to be fully out of the set if the penetration is below 10%. This classification is used by EGA in one of their reports to classify the countries with the worst generics markets (EGA, 2005). Same report classifies the best markets to above 40%. Here to get the score is lowered to 30% because in general EGA has slightly higher penetration figures and also 30% penetration is still well above the median penetration of about 20%. Therefore, with 30% penetration a case can be considered to be fully in the set of successful generic medicines industry. As a result qualitative coding uses the following six categories: Over 30%-penetration scores 1; over 25% scores 0.8; over 20% scores 0.6; over 15% scores 0.4; over 10% scores 0.2; and 10% and below scores 0. After that, in the way described above, the interval-scale penetration data and qualitatively coded groupings are processed in STATA, which gives the predicted set membership scores that will be used in the analysis.

[8] Available at EGA website. URL: www.egagenerics.com

5.3 Causal Conditions

5.3.1 Competitive Domestic Generic Medicines Industry (SUR)

First causal condition is a fuzzy set of countries with competitive domestic generic medicines industry. It is abbreviated as SUR, because of the used raw data of survival rate of the companies in a given country. This causal condition reflects the effects that domestic companies' performance has on the success of the industry. The density analysis of the company population and Proposition 5 support the use of this causal condition.

SUR data is based on GloStra generic medicines companies' database[9]. This database is conducted as part of GloStra research on generic medicines industry in Europe. Company data for this database was originally extracted from a number of sources. Main sources were the member organizations of EGA, which were able to track down on the yearly basis from the Internet Archive Wayback Machine[10]. Other major source for company information was the Lexis-Nexis newsfeed, which was partly processed with custom made software. This information was supplemented from the company websites. After the companies were identified, the database was added with the incorporation dates as well as the exit dates of applicable companies. Major source for this data was AMADEUS database[11], which is not publicly available. In addition, at this stage company websites were used to fill the data gaps. The GloStra database is not publicly available. The reliability of sources and methods can be challenged, but overall with the research setting limitation these sources and methods were the most usable. Concerns for reliability raise the use of multiple sources, the limitation in which sources are documented, as well as the manual work required to build this database.

[9] Database constructed with a joint work by Ville Airo, Heikki Arbelius, and Mikael Bruun. (2009). Espoo: Institute of Strategy, Helsinki University of Technology (currently Aalto University School of Science and Technology).
[10] The Wayback Machine. URL: www.archive.org
[11] AMADEUS database. URL: http://amadeus.bvdep.com

The survival rate was chosen as a measurement of industry's overall competitiveness because of a few reasons. It as a measurement is actually able to capture the long term success of the industry as it calculates all the entries and exits. In addition, firm survival is one of the most used measurements of firm performance, which is indicated among others by Klepper (2002). This comment also addresses the construct validity of SUR. On the other hand, the survival rate was chosen partly because of the necessity, because other data of the performance was not available. For example, growth rates of any kind were not available, and any other meter that could be conducted from the company database with entries and exits was not seen as good as a meter as the survival rate. For example, an entry rate would be largely biased because many of the companies have origins long before the start of modern generic medicines industry. They are in a sense de alio or diversifying entrants. Also entries have diminished in the recent years and thus entry rate based meters would not describe the current situation that well. Also the density measurement in this kind of industry would not be easily divided into countries. It is a valid measurement at the European level, but when certain countries (like Finland) have only one entrant, density measurement at a country level was not seen justified. Based on this reasoning the highest construct validity can be reached with the chosen conceptualization.

To conduct the survival rate for the companies in the country the following formula was used

$$Survival\ rate\ (\%) = (1 - \frac{exits}{entries}) \times 100\%$$

The highest score is 100%, which is obtained with at least one entry and not exits. The lowest score is 0%, which is obtained if exits are equal to entries. If there are no entries, this formula cannot be used. However zero entry basically means that there has not been a generic medicines industry and thus a country is fully out of the set SUR, which represents a successful industry.

This data is encoded in fuzzy sets using the indirect method. A case can be considered being fully in a set if the survival rate is 100%. This is because only then there is proof that industry has been competitive all the time. A case is fully out of the set if the survival rate is 20% or below or there has been no entries. In these cases majority of the companies have exited or there has not even been an industry. Therefore, qualitative coding uses the following six categories: 100% survival rate scores 1; 80% and above scores 0.8; 60% and above scores 0.6; 40% and above scores 0.4; 20% and above scores 0.2; and below 20% as well as countries with no entries scores 0. For STATA analysis countries with no entries will be encoded in 0% survival rate. After that, in the above described way, the interval-scale survival data and qualitatively coded groupings are processed in STATA, which gives the predicted set membership scores that will be used in the analysis.

5.3.2 Publicly Financed Health System (PHE)

Second causal condition is the fuzzy set of countries with a publicly financed health system. It is abbreviated as PHE, because of the used data set of public health expenditure as a percentage of the total health expenditure. This causal condition reflects the effect public expenditure has on the performance of the industry. The use of this causal condition is based on two propositions. Public health expenditure experiences a lot of growth pressure (Proposition 10) and public policies are considered being in the key position for supporting generic medicines (Proposition 4).

PHE is based on the data set of public health expenditure (the % of total health expenditure) in 2006 by World Bank. Data is available at the HNPStats – the World Bank's comprehensive database of Health, Nutrition and Population (HNP) statistics[12]. All the cases have the data from 2006. HNP database was also chosen as the source for other statistical information, because it had the most

[12] World Bank HNPStats Home. URL: http://go.worldbank.org/N2N84RDV00

comprehensive list of indicators and the reliability of data from World Bank is rather high. PHE, GNI, and O65 are constructed from the same database. Comprehensive data is publicly available at their website.

Specifically, the data for PHE was chosen because it describes the share of the public expenditure in more detail than, for example, the coarser measurement of public health expenditure as a share of total GDP. Also there was no data available that would give even more detailed information about all the case countries. One of such data sets could have been the data for public expenditure as a share of total expenditure on prescription medicines. However, this data was available only for a few case countries and the decision was made to rather include more cases than get the more detailed data. Overall it can be argued that the construct validity of this chosen conceptualization was the highest.

PHE is configured using the direct method in the spirit of Fiss (2008). The threshold for being completely out of the set is set to 61.6%. This is the average share of expenditure in the reference group of high income countries. Below the average there cannot be a high share of public health expenditure. A case is encoded to be fully in the set if the share is above 81.3%. This share is the share which Japan has and can be considered as an example of the country with a high share of public expenditure in health care. Also the share of 81.3% is close to the 75th percentile of the case countries. 75th percentile is between the values of 80% and 81.7%. The crossover point is set to about 76%, which is the 50th percentile of case countries.

5.3.3 High National Income (GNI)

Third causal condition is the fuzzy set of countries with high national income. It is abbreviated as GNI, because of the used data set of Gross National Income per capita. This causal condition reflects the effect level of the income has on the performance of the industry. The use of this condition is supported by the fact that wealthier countries use in general more on the health care and on pharmaceuticals, which can be seen from looking at the world medicine markets

(Proposition 8). Also economic growth has been in theory indicated as one of the reasons for the future success of the industry. This factor assesses if these are true for generic medicines.

GNI fuzzy set is based on the data set of Gross National Income per capita in current US dollars measured using World Bank's Atlas method from the same World Bank database as fuzzy set PHE. Data is from the year 2007 except in the case of the UK, which is from 2006. These were the latest available years. The construct validity of GNI does not raise many problems, but the internal validity of it possibly raises some. The use of GNI as a factor is maybe the least supported by the theory.

GNI is configured using the direct method similarly as in the PHE case. Here the case is considered being completely out of the set if the GNI per capita is below $ 11,906. This is the threshold World Bank uses for high income countries. A case is considered being fully in the set if the GNI per capita exceeds $ 46,040, which was the GNI per capita in the United States in 2007. This value is close to the 75th percentile of the case countries. The crossover point is set to $ 37,572, which was the average GNI per capita for high income countries in 2007.

5.3.4 High Share of Elderly People (O65)

Fourth causal condition is the fuzzy set of countries with a high share of elderly people. It is abbreviated as O65, because of the used data set of the share of the population aged 65 years and over. This causal condition reflects the effect elderly people have on the performance of the industry (Proposition 11). Statistics and theory indicate that from the age of 65 onwards the health care expenditure of a citizen dramatically increases. To capture this change in expenditure and see its effect on the overall success of the industry, the use of this data is justified.

O65 is based on the data set Population ages 65 and above as a share of total population in 2007 by World Bank. Data comes from the same database as PHE and GNI and all the countries have the 2007 data, which is the latest available.

The conceptualization of O65 raises close to none validity and reliability issues. The use of O65 as well as its conceptualization is well supported by the theory.

O65 is configured using the direct method similarly as in the cases of PHE and GNI. The case is considered being fully in the set if the share of elderly people exceeds 17.7%, which was the average value in the euro area in 2007. This value sets in the case countries to about 90th percentile. The case is considered being fully out of the set if it falls below 12.3%. This is the value the United States has and it is really low for industrialized countries. The crossover point is set to 14.9%, which was the average of the high income countries in the world in 2007.

5.3.5 Coordinated Market Economy (COO)

Fifth causal condition is the fuzzy set of countries with coordinated market economy. It is abbreviated as COO, because of the used data set of Coordination index (Hall & Gingerich, 2004). This causal condition reflects the effect level of the coordination in the national economy level has the performance of the industry.

COO was chosen as causal condition, because according to Varieties of Capitalism theory it should indicate something about the performance of the industry in a given country (Proposition 1). According to theory the level of coordination, from liberal to fully coordinated, affects the performance of industries in that country. Both of them have certain industries that they support more than the others. In the most simplistic view, this is based on the idea that liberal system supports radical innovation and coordinated system is for incremental innovation. For this analysis it is understood that according to theory generic medicines should perform better in coordinated environment regardless of the fact that innovative medicines are one of the primary examples of the industries that perform better in liberal environments (Proposition 2).

Another measurement of the economic systems performance in the Varieties of Capitalism theory is coherence, which was discussed in the literature review

chapter. This was thought as possible causal condition, but it was seen that actually coherence of a system affect more on the higher level national economy issues. Theory says that coherent economies outperform the incoherent ones. This says only a little about the specific industries and therefore implications for generic medicines industry are far harder to get from the coherence index than from coordination (Proposition 3).

Majority of the COO scores come from Coordination index by Hall and Gingerich (2004) from 1990-1995. They have calculated the scores for each of the OECD nations, which they had data, based on factor analysis. They give coordination scores for these countries in the closed interval from 0 to 1, where 1 is totally coordinated and 0 is totally uncoordinated or liberal. Countries are set at this interval indicating the level of the coordination they have in their economic system.

The fuzzy set calibration of the COO was done using the indirect method, but with certain modifications. First countries that are presented in the Coordination index were transformed to six fuzzy set classes. In this division 1 is for coordinated market economy with Germany and Austria with full scores. 0 is for uncoordinated or liberal market economy, where the UK scores only 0 in Europe. Other scores were linearly transformed. At this point, the indirect method is terminated and these scores will be used as the fuzzy set scores. Termination was done because there was not enough statistical data to construct the final scores. However, these types of scores without any transfer procedure have been used previously in fsQCA studies (e.g. Katz et al., 2005). Therefore, this is not seen as a problem or a major limitation.

Hall and Gingerich analysis excludes nine case countries: Czech Republic, Greece, Hungary, Iceland, Poland, Slovak Republic, Lithuania, Slovenia, and Romania. Of the unanalyzed countries, Central and Eastern European (CEE) countries are set to 0.6 based on the idea that is presented by Lane (2005) that indicates these countries having relatively high state coordination. CEE countries are said to represent continental European models in many ways. So

they are seen to be closer to coordinated market economy than liberal and they are also not in the ambiguous position. 0.8 is seen as too big score for these countries' coordination index. Moreover, Iceland is set to 0.8 to correspond with the majority of the Nordic countries. Furthermore, Greece is set to 0.8 based on the analysis by Knell & Srholec (2005). Their analysis indicates Greece to have the highest level of coordination of all European countries. When comparing this with the original theory and Germany and Austria, which score relatively low on coordination in Knell and Srholec analysis, it is understood that this analysis has different underlying assumptions. Therefore, the full score of 1 to Greece is discarded, but it is understood that Greece has a high level of coordination and thus has the score of 0.8. In conclusion, the main reliability issue in the use of COO is that the data possesses sources for random error that emerge from the use of multiple sources. On the other hand, the conceptualization of COO is in line with the theory.

5.3.6 Established Generic Medicines Promotion System (RPS)

Sixth and final causal condition is the fuzzy set of the countries with an established generic medicines promotion system. It is abbreviated as RPS, because of the used data of having reference price systems in place. This causal condition reflects the effect promotion of the generic medicines has on the performance of the industry. Mrazek and Frank (Mossialos et al., 2004, p. 247) argue that in general countries that have greater generic medicines penetration into their markets have implemented policies that favor their use.

Reference price system specifically was chosen as a causal condition, because in theory patent legislation is enabler for the generic medicines industry (Proposition 6), but the promotion legislation decides its success in a given country. According to the analysis, reference price system is one of the most important parts of the generic medicines promotion (Proposition 7). Other parts of the promotion include generic prescribing and substitution. From these different types of promotions reference price system was chosen because is seen to have the most effect on the level of promotion. This is because of three

reasons. Firstly, it cannot be overturned by any indication of the prescribing physician. Secondly, it has only two states of being available or not being available, in comparison to prescribing or substitution, which can be indicative or obligatory when they are available. Thirdly, it has the most direct effect on the economy of the health care. It was also researched whether these three forms of promotion could be combined with a function. However, it was seen that combination of these would make the scoring extremely complex and therefore the idea was discarded.

RPS is based on the data whether the reference price system is in place or not. Data is mainly from Pharmaceutical Pricing and Reimbursement Information (PPRI) (Vogler et al., 2009; Vogler et al., 2008). However, this data is available from many sources. Data is from the year 2007, because that is the year majority of the other data is also from. Therefore Finland has not yet implemented the reference price system, which was enforced in 2009. RPS is calibrated to fuzzy set as a crisp set, where 1 is if the reference price system is in place and 0 is if not. Reliability of the data source is high as it can be verified from multiple other sources. Validity, especially construct validity, issues in RPS is raised by the fact that other areas of promotion legislation are not included in it. However, as discussed it is seen that the combination of all the areas of the promotion might have been an even bigger source of validity problems.

6 Findings

After procedures described in Chapter 5, fuzzy sets are obtained. The fuzzy sets are presented in Table 8. The full data table and the qualitative codings for the applicable fuzzy sets are presented in Appendix 4. Finally before the analysis all the values below the full membership score of 1 in these fuzzy sets were added a constant of 0.001 following the proposition by Fiss (2008). This can be observed from the table and was discussed in Chapter 4.4 Software.

Table 8: Fuzzy Set Scores

Case	PEN	SUR	PHE	GNI	O65	COO	RPS
AT	0.457	0.001	0.471	0.831	0.871	1	0.001
BE	0.087	0.202	0.311	0.781	0.941	0.801	1
CH	0.130	0.307	0.031	1	0.761	0.601	1
CZ	0.977	0.975	1	0.061	0.411	0.601	1
DE	0.939	0.817	0.561	0.621	0.991	1	1
DK	0.544	0.202	1	1	0.681	0.801	1
ES	0.010	0.618	0.261	0.281	0.901	0.601	1
FI	0.530	0.975	0.471	0.921	0.821	0.801	0.001
FR	0.063	0.975	0.881	0.611	0.821	0.601	1
GR	0.201	0.975	0.051	0.201	0.981	0.801	1
HU	0.986	0.602	0.241	0.051	0.661	0.601	1
IE	0.023	0.307	0.751	0.971	0.011	0.201	0.001
IS	0.377	0.975	0.971	1	0.031	0.801	1
IT	0.534	0.899	0.611	0.381	1	0.801	1
LT	1	0.001	0.211	0.041	0.701	0.601	1
NL	0.481	0.389	0.901	0.951	0.411	0.601	1
NO	0.240	0.001	0.991	1	0.471	0.801	0.001
PL	1	0.602	0.211	0.041	0.141	0.601	1
PT	0.396	0.917	0.231	0.101	0.911	0.801	1
RO	0.895	0.260	0.561	0.031	0.501	0.601	1
SE	0.266	0.975	0.961	0.971	0.951	0.601	0.001
SI	0.973	0.260	0.301	0.131	0.761	0.601	1
SK	1	0.001	0.231	0.051	0.031	0.601	1
UK	0.911	0.389	1	0.751	0.801	0.001	0.001

Fuzzy set values should differ across cases. Differences between cases apply here as can be observed from the table. Different conditions across countries were evident after the industry analysis, but also the differing sets are required to obtain any interesting and usable results at all from the fuzzy set analysis.

This is important also for the internal validity. Internal validity also requires that overall relationships between the factors are non-trivial. Based on the theoretical and empirical analysis presented previously in the thesis as well as building the fsQCA setting the internal validity of the factors is reached.

After pointing out the necessary variation between cases the fs/QCA software was used to obtain results. Based on the normal procedure for studies with a small number of cases (Ragin, 2008c) frequency cutoff was set to 1. If frequency cutoff were set any higher, the selected cases would have captured less than 50% of the cases, which would have been significantly lower than the indicated minimum level of 75-80%. Similarly the consistency cutoff is set to 0.85, which is in line with the theory. Preliminary analysis did not indicate a reason for setting consistency cutoff value any lower. Neither was there enough evidence to set it any higher.

To present the results in more readable format Ragin and Fiss (2008) have recently introduced a notation to illustrate results. In this notation, there are full circles, which indicate the presence of a condition, and crossed circles, which indicate the absence of a condition from the obtained causal combination. In addition to that, large circles indicate core conditions that are part of the both parsimonious and complex solutions, while small circles indicate peripheral conditions that are present only in complex solutions.

Table 9 shows the results for fsQCA of successful generic medicines markets. Solutions are divided into numbers based on the parsimonious solution they represent. In other words, there are total of four obtained parsimonious solutions. All the complex solutions that have the same parsimonious solutions included in the configuration are categorized under the same number. In those cases, letters after a solution number indicate differences in the complex solutions. The descriptive statistics are obtained from the complex solution.

Table 9: Configurations for Achieving Successful Generics Markets

	Solution				
	1a	**1b**	**2**	**3**	**4**
Competitive domestic generic medicines industry		●		⊗	⊗
Publicly financed health system	⊗		⊗	●	●
High national income	⊗	⊗	●	●	●
High share of elderly people	⊗	⊗	●	●	⊗
Coordinated market economy	●	●	●	⊗	●
Established generic medicines promotion system	●	●	⊗	⊗	●
Consistency	0.95	0.92	0.94	1.00	0.88
Raw Coverage	0.22	0.18	0.08	0.07	0.11
Unique Coverage	0.08	0.04	0.07	0.06	0.06
Overall Solution Consistency	**0.94**				
Overall Solution Coverage	**0.47**				

Notes:
● Precense of the condition in the complex and parsimonious solutions
● Precense of the condition in the complex solution
⊗ Absence of the condition from the complex and parsimonious solutions
⊗ Absence of the condition from the complex solution

Results show relatively high consistency throughout. All four solutions are within the limits of acceptable consistency, which is above 0.80. They actually have even higher consistency than 0.85, which was the limit for individual lines at the truth table. In addition, similar consistency in all the solutions indicates that these different configurations similarly lead to the same result of successful generics markets. In other words, there are possibly at least four distinctive paths to successful generic medicines markets in Europe.

Solutions 1a and 1b indicate similar paths to successful markets. In this solution, the country has for the core conditions a relatively low share of elderly people and low income levels. For the peripheral conditions coordination in the economy is similarly high as well as countries have established systems for

promoting generic medicines. Financing in the health care and domestic industry's competitiveness differ for these solutions. The core conditions in the solutions 1a and 1b refer clearly to Eastern European countries. Therefore, partial empirical evidence can be found in number of Eastern countries. Many countries are close to at least some of the conditions. Especially, Poland and Slovak Republic offer close empirical evidence for the solution 1a and Czech Republic for the solution 1b. In addition, Poland has some empirical evidence for the solution 1b. For 1b the evidence from Poland differs to some extent from the solution because the domestic industry has not been very competitive.

Solution 2 offers the second path to successful markets. In core conditions, solution 2 shows that having low public financing in health care combined with not having promotion to generics will lead to successful markets. This solution has only little empirical evidence. Two countries that are the closest in these aspects are Austria and Finland. However, the factor about the low public health care financing is not that evident in these countries. The share of public financing is about average in Europe. However, the peripheral conditions fit these countries. In addition, these countries do not have very successful markets either. Furthermore, in 2009 Finland adapted the RPS, which indicates that this combination was at least not that viable in reality.

Solution 3 indicates the third path to successful generics markets. Here the core conditions indicate the absence of competitive domestic industry, a high share of elderly people and the absence of the promotion systems. For the peripheral conditions this solution indicates publicly financed health systems, high national income and the absence of state coordination in the market economy. For the solution 3, the UK provides empirical evidence. Another liberal market economy in Europe, Ireland, differs from this solution by having a low share of elderly people and interestingly also having unsuccessful generics markets.

Solution 4 has for the core conditions poorly competitive domestic industry, a low share of elderly people, and established promotions systems. In addition, peripheral conditions indicate publicly financed health care systems, high

income levels, and coordination in the market economy. For the solution 4, the Netherlands offers empirical evidence.

The coverage of the solutions remains relatively low: all raw coverage scores stay under 0.25. This can be seen also from the partial lack of empirical evidence. However, this does not raise much concern as in many cases high consistency has a tendency to indicate low coverage. Furthermore, consistency is more important from two figures and therefore results can be accepted.

The overall coverage of the solution is higher than the coverage of the specific solutions. Overall coverage is about 47%. This indicates that almost half of the configurations that lead to the successful generic medicines markets are present within these solutions. On the other hand, there are still a number of configurations leading to the successful markets that are not presented in these solutions. These solutions do not meet the imposed consistency and frequency thresholds and are therefore excluded.

Moreover, there is not one condition that is present in all of the solutions. This is even though, for example, at the level of coordination there are only two countries that can be categorized as liberal. Solution 3 provides a configuration for achieving successful markets in liberal market economies. The absence of such condition that is present in all the solutions possibly indicates that no necessary conditions can be found for achieving successful generic medicines markets. For the hypotheses presented in setting the fuzzy sets, this means that there can be an environment, where some of the hypotheses might not be applicable. For example, it is doubtful if the industry's performance is enhanced in the liberal market economies, by increasing the coordination. It was neither intended nor possible with the chosen methodology to analyze the separate effect of the causal conditions on the industry's performance.

Furthermore, clearly all of the solutions have at least some conditions absent in their configuration. According to theories and the hypotheses of conditions, the best market conditions should be achieved with all the conditions being present in the configuration. Currently a country with all the conditions present is not

reality and a possibility to analyze the real effect of having all conditions present is limited. However, from the obtained solutions it can be seen that each absent condition can be fought back with a configuration of others. This shows that actually all the conditions do not need to be present to achieve successful generic medicines markets.

7 Discussion and Conclusions

7.1 Conditions for Successful Generic Medicines Markets

Analyzing the industry as complex as generic medicines called for new types of methods. A partly iterative process of studying the industry with the proposed frameworks from Varieties of Capitalism and fsQCA proved to be successful in this context by producing concrete findings. Eventually each part of the analysis complemented every other and the study was capable of providing reasonable and interesting results and implications. In that respect, the study confirmed current views, brought new ideas to the field, as well as opened new research avenues. However, there is still work in building the validity of the methods further and in bringing these results to practice.

The understanding about the industry dynamics suggests that there cannot be simple and straightforward answers to research questions, which is also usually the case with this kind of research setting. For the first sub-problem, based on the previous discussions in the thesis it is clear that the patent and intellectual property rights legislation is something that is needed for the industry to exist, but it does not decide the success of the industry. The success is largely decided by the promotion legislation. The question about how regulation influences the overall dynamics has a more complex answer. Regulation is only one part of the affecting factors and its effect depends on the other factors as well as the inner relations of all the factors. For example, other conditions affect the role regulation has in setting industry dynamics in certain environments. Other central factors that were identified from the propositions provide a partial answer to the sub-question two about the other affecting conditions. Together with these conditions regulation and coordination influence the industry dynamics. Therefore, in this complex environment the main research question about the favorable conditions does not have an answer that finds the one single most suitable set of conditions for generic medicines industry in Europe. However, it can be argued that there are conditions that promote success more in certain regions than others. These were illustrated in Chapter 6.

To deepen the understanding about the favorable business environments the analysis of industry dynamics and fsQCA suggests that European countries can be categorized into five groups. The basis for division comes from the previously found configurations for successful markets. However, since currently in all regions there possibly cannot be found a successful configuration, division is also done based the overall characteristics of the countries as identified already for the purposes of fsQCA. Five groups that are found are: Eastern European countries, Liberal market economies, Nordic countries, Mediterranean countries, and Central European countries. These groups are presented in Table 10.

Table 10: Categories of the European Generic Medicines Markets

	Eastern European countries	**Liberal market economies**	**Nordic countries**	**Mediterranean countries**	**Central European countries**
Characteristic	Low income Low share of elderly Coordinated Established promotion	Liberal High income	Public health care High income Similar coordination ("Nordic") Relatively low penetration	Successful domestic companies Low generics penetration High share of elderly Similar coordination ("Mediterranean") Established promotion Non-public health care	High income
Corresponds fsQCA solution no.	1	3	-	-	4 (partly)
Example countries	Czech Republic Hungary Lithuania Poland Romania Slovak Republic Slovenia	Ireland The UK	Denmark Finland Iceland Norway Sweden	France Greece Italy Portugal Spain	Austria Belgium Germany The Netherlands Switzerland
Problems	Overall low health expenditure	Non-successful generic medicines companies	Varying promotion and success of companies	Poor performance (medicines) despite the supporting aspects Copied medicines	Varying policies and overall success of the generics

In the table, first the characteristics of the group are presented. These are the main differentiating factors between the regions. In addition, the corresponding

solution number from fsQCA is presented for those regions where successful configurations are found. In the “example countries” -line all the case countries are divided into the region they fit the best. Finally, key problems for each region are presented. Problems can be related to market conditions, to companies, or to public policy.

The solution number from fsQCA that corresponds to some countries of the region offers a clear answer to the most suitable conditions in that region. The regions that currently do not possess the combinations of conditions leading to successful markets can also develop such conditions but has not yet done so. In these regions, a model for successful markets can come from other regions or from a successful country. However, maybe the most important thing for all the regions to achieve successful markets is to achieve the unification of the promotion legislation. The effect of promotion legislation on market conditions is maybe the biggest from all the identified factors and if it is not unified it lowers the efficiency of total markets.

In comparison to previously presented studies, the findings of the study are in most aspects similar. First of all, Varieties of Capitalism (VoC) argues that coordination in market economy should be more suitable for generic medicines. This is because generic medicines are closer to industries needing incremental innovation than radical innovation. From the complex solutions in fsQCA (Table 9) four out of five support this idea and have coordinated market economy present in the configuration. As innovation is one of the main ideas in VoC, solution 4 is a little bit disturbing as it shows some contradiction of having coordinated market economy with the absence of competitive domestic industry. In coordinated economies, industry should also be competitive. Then again, for competitive domestic industry and coordination other solutions are more or less in line with the previous studies.

Moreover, in comparison to fsQCA studies in general these findings seem to be in line. The reasoning from the theory and previous studies for choosing six causal conditions appears to have been relatively successful. Results give

solutions that are able to explain the complexities in the business environment. The solutions are not too complex. Also there is no reason to regard these results as totally random. What is more, combining VoC with the set theoretical analysis methods, as has been suggested, seems to have been working relatively well. The micro- and meso-level analysis gives usable results for generic medicines industry, but also contributes to the macro-level.

7.2 Implications to the Theory of Capitalist Variety

Theoretical implications in the study also relate to Varieties of Capitalism (VoC) and fsQCA. In neither of the fields nothing groundbreaking was achieved, but some of the presented critique in these fields could be addressed. Especially in VoC the study is able to validate the proposed future orientation of the studies by conducting a study well in that spirit. Based on the study it can be said that fsQCA in this kind of context is definitely a possible way ahead for the analysis in VoC.

Another clear implication for fsQCA is seen from the analysis setting. As was presented, the study used multiple data sets with multiple calibration methods. In general studies utilizing fuzzy sets when studying comparative advantages between nations have used one dataset or otherwise comparable data. Previous studies have also used similar calibration methods for all of the factors. (E.g. Pajunen, 2008; Schneider, Schulze-Bentrop, & Paunescu, 2009.) After getting realistic results with the chosen method in the study, a conclusion is that it is possible to use a variety of sources and calibration methods in these kinds of studies regardless of the current practices. Based on the study it could even be concluded that in the spirit of proposed VoC future orientation the use of multiple datasets is encouraged. The setting in the study does not influence the results significantly, but deepens the analysis substantially. The study provides an argument for using multiple datasets even though this has not been a practice in the recent fsQCA studies.

The above presented categorization of the European generic medicines markets (Table 10) offer empirical evidence to support VoC theory. The grouping resembles some of the labels presented under VoC earlier. The resemblance itself is quite remarkable and gives support to the VoC theory. In general the idea that European countries can be classified to seemingly homogeneous groups supports the labeling approach in VoC. The labeling approach has been experiencing a lot of critique, but these results argue against those. However, these results are likely to only be applicable in specific context as the analysis has focused on generic medicines. Nevertheless, as moving to micro-level analysis has been the pointed direction for VoC studies, overall these results support the original theory as well as the future orientation of VoC. In other words, it seems that the pointed direction is right and under these assumptions the presented VoC theories are valid.

Furthermore, in the VoC field there have been two groups: one arguing convergence and one arguing against it. Currently maybe more support is on the side of not converging market economies, but the convergence ideas are not totally gone. In the study, the possibility to label countries to distinct groups argues clearly against the convergence of CMEs to LMEs, or against any convergence to one type of market economy. So the study takes a similar route than the majority of scholars in VoC and offers micro-level evidence against the convergence. Notable at this and at the above labeling idea is that underlying assumptions for the analysis partly come from the original theory, which supports labeling. In this sense, these arguments can be biased. However, because labeling is only reinforced by the other factors in this analysis, the presented arguments supporting the labeling approach can be considered valid. If there were convergence and the labeling approach was groundless, other factors in the analysis would make the categorization much harder than what is presented in Table 10 above.

7.3 Managerial Implications

For companies operating in the generic medicines industry the future looks interesting. As has been brought up, there are a lot of changes in the horizon that affect the industry and its dynamics: patent expiries, the blurring of the industry borders with innovative medicines giants that are emerging to the generic medicines markets as well as the emergence of biosimilars, and the changing demography to name a few. Many of these points have already been analyzed here and in different other contexts. Therefore those are relatively well known for the companies. The implications that rise from the study therefore do not focus on these, but instead try to present maybe more general implications that affect the whole industry.

The first clear implication comes from the analysis of industry population: it seems that there is only a little room for new companies. Especially difficult this environment seems for small companies. Currently, it seems that bigger companies are the market winners. The industry is characterized by the mergers and acquisitions (M&A) activity where bigger companies acquire the smaller ones. Companies, at all levels of the generic medicines industry, need to be ready for escalating M&A activity. One big reason for M&A activity seems to be the idea of capturing scale advantages. However, on the basis of the study even more important seems to be the market access to different regions and, furthermore the ability to obtain capabilities from these different regions. The best performing companies in the industry are widely diversified global giants.

Looking at Table 10 above some more detailed implications for companies can be seen. First of all, five categories of diversified markets imply that companies need to tailor their strategies for each of these regions where they are active if they want to be competitive in these regions. Policies as well as the market characteristics differ between the regions and this definitely has an effect on the companies operating in these regions. For example, a country group called Liberal market economies has a good basis for having markets for generic medicines and there is also evidence for this. In Ireland, there is also potential

for substantial growth in the market value. However, noticeable for the companies operating in this environment is that the domestic companies have not been that competitive. This clearly needs to be assessed in the strategies.

In the Eastern Europe growth potential from getting more penetration is small, but the rise in income levels might cause the prices go up and therefore there might be market potential. In Nordic countries, the varying promotion and the varying success of the domestic companies provide challenges. Varying promotion legislation might be a reason for some countries having successful domestic companies. This is because market sizes are relatively small and the challenge of understanding legislation might work as an entry barrier.

In Mediterranean countries, the biggest problem still seems to be the copied medicines. The basic requirements for markets seem to be in order, but still markets are small. There are really high shares of elderly people as well as established promotion systems in the Mediterranean countries. The only thing that is missing is the substantial public financing in health care, which could also be a source for not having high penetration rates.

In Central European countries policies and other market characteristics are different from country to country. Germany offers successful markets with all the identified factors supporting the markets. On the other hand, there are also countries like Belgium where penetration rates are very low as well as the survival of domestic industry is bad. It seems that for Central Europe there needs to be the most individualized strategies for each country.

7.4 Public Policy Implications

Similarly, as for companies in generic medicines industry, the future is interesting for public policy makers. As presented, the rising health care costs need to be contained. However, the full support for generic medicines is not possible, because the innovative medicines industry is also needed to find new molecules. For public policy the implications from the study are in consequence focused on making the markets more effective overall.

As has been argued, the inner markets of generic medicines in Europe are not reality. The biggest problem preventing similar markets is the differences in promotion legislation. Every country has its own policies, which make the market heterogeneous. The first implication from this would be that EU would set the promotion legislation like they now do with the patent legislation. This should in theory greatly increase the overall effectiveness of the markets. Still since this requires big institutional changes, in the current EU this kind of arrangement does not seem possible. Therefore, to take the first step towards pan-European policies, countries within certain regions should together formulate similar policies. This would be in line with the proposition of companies forming strategies for regions above presented regions. Having more transparency in policy setting allows companies to formulate their strategies better, which increases competition. In market economies, this should have the effect of making the overall markets more effective.

When setting the public policies within regions, the results of the study could be utilized. As the categories presented earlier in Table 10 are a result of in-depth analysis of the industry, there are similarities already between the countries within each category. These could be utilized as the starting point of unified public policy setting. For example, in Mediterranean countries the increases in public health care support could be decided together. The setting of policies within regions is supported by the fact that only four distinct ways to achieve successful generic medicines markets have been identified as was presented in Chapter 6 Findings.

In public policy setting the fact that some factors do not change instantaneously needs to be taken into account. Especially the income levels of the country and the share of elderly people cannot be changed radically but their change is inevitable. This means, for example, to Eastern European countries that the markets that are now functioning need to change together with the changing demographics and income levels. If Eastern European countries catch Western European countries in these aspects, it could well be that the best market conditions for these markets are closer to successful market conditions in

today's Western Europe than today's Eastern Europe. As policy changes are neither fast, these aspects need to be taken into account already. The homogenization of European generic medicines markets can partly happen because of the inevitable convergence towards the same economic levels in the EU.

7.5 Limitations and Directions for Future Research

The main limitations of the study are associated with data. The study combined a few datasets and used different calibration methods to those and tried to capture more aspects of the industry that way. Depending on the point of view this either could be a strength or weakness in the study. The method proved to be successful here, but also this might have reduced the validity. Practical problems when taking the study towards micro-level analysis inhibit possibility to follow closer the current practices in the field. At micro-level, it is almost impossible to get the data from a single source.

Also the data for single fuzzy sets, for PEN and COO especially, can be argued not to be coherent. In those cases data for a single fuzzy set comes from a few sources and at some level those sources are not comparable. For the generic penetration, the problem might not be that big since overall the numbers are similar across different data set. However, especially Greece having a very high coordination in the economic system can be misinterpreted. In this case the definitions of coordinated and liberal systems can be quite different between two used sources. Furthermore, the majority of COO data from Hall and Gingerich (2004) is rather old and has also experienced an indirect critique. The same critique that addresses the whole VoC theory addresses the coordination index created from it.

Another source of errors in the study is the whole research setting. Even though the theories as well as the industry have been studied intensively and profoundly, in complex environments there are some aspects that could have been missed. When combining this to the novel analysis method, which is

largely dependent on the researcher's conceptualization of the problem, it can raise questions about the repeatability of the study. It can be argued that this kind of study can be done in multiple ways. In other studies there could be other factors and therefore results could differ. These limitations offer fruitful avenues for the future research in all three areas discussed. The chosen approach and the level of the analysis mainly determine which limitation causes most problems and then which part of the data needs to be re-examined.

The proposals for meso-level present maybe the clearest continuum for the study. In this path, the theoretical contribution to all the theoretical fields of the study could be deepened the most. Especially this is true for fsQCA, where in the study the analysis has been only at one level. In other words, secondary factors affecting the chosen factors have not been studied. To deepen this analysis, the second level factors could be analyzed more. Analysis could be conducted in multiple ways and methods but if wanting to remain in fsQCA setting Goertz and Mahoney (2005) present the idea of analyzing at multiple levels with fuzzy sets. This analysis incorporates even more of the inner relations between factors. Moreover, this setting could include more factors affecting the industry. For example, examination of how the legislation for promotion evolves could be fruitful. In deepening this analysis all the other legislation for promotion as well as the incentives for professionals, and the media campaigns for patients and professionals could be evaluated more. These could be incorporated together to form a new factor to replace RPS factor in the study. Acquiring considerable amount of new data as well as unifying current data will be required in this path.

The study could also be moved in the direction of macro-analysis. In the study, the capitalist variety has been used as a source of comparative advantage. It could be interesting to analyze also in other direction and see the effect generic medicines industry and all the other factors have on the coordination changes. In this analysis more understanding needs to be built on the institutional environment. The understanding about the policy setting procedures as well as other national and international systems needs to be strengthened. In particular

the limitations in the coordination data need to be dealt in this approach. This approach should contribute most to the Varieties of Capitalism.

At a micro-level, the success of the companies could be analyzed more. Even if not doing this in the fsQCA setting, the analysis of other factors in company performance could provide even more practical implications for companies in generic medicines industry. For fsQCA, as was discussed briefly in the explanation of the SUR factor, company success could be further analyzed by obtaining various other indicators about their performance. In addition, controlling the performance indicators with descriptive factors, like structure, operational environment, and strategy, could provide more practical implications for companies. Also one possible way of analyzing performance could be the analysis of the factors leading to poor performance. At micro-level it is also vital to understand that the changes are the most rapid. This presents constant challenges for managers and they thus need constant updates on the status of the industry.

At all levels, the turmoil in the world economy affects the results somewhat. The study is largely based on the data before credit crisis. In the data, the growth in the generic medicines industry was argued to continue without disruption to the future. However, it seems that the decline in the growth rates is almost certain also in the pharmaceutical industry (Gorka, 2009). However, maybe the constant need for health care makes this decline smaller than in some other industries. Nonetheless, this effect should be analyzed more to adjust the proposed implications to match the current situation.

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Appendices

Appendix 1: Exchange Rates

	US dollars	British pounds	Japan yens
One euro equals	1.50	0.90	133

Source: Kauppalehti 23.11.2009

Appendix 2: Summary of the Generics Promotion in European Countries

Country	Generic Prescribing [a]	Generic Substitution [a]	Reference Price System [b]
Austria	Not allowed	Not allowed	No
Belgium	Indicative INN prescribing	Not allowed	Yes, since 2001
Bulgaria	N.a.	Not allowed	Yes
Cyprus	Not allowed in the private sector (only in the public sector)	Not allowed in the private sector (obligatory in the public sector)	No
Czech Republic	Indicative INN prescribing	Indicative generic substitution	Yes, since 1995
Denmark	Not allowed	Obligatory generic substitution (also for non-reimbursable pharmaceuticals)	Yes, since 1993
Estonia	Obligatory INN prescription	Indicative generic substitution	Yes, since 2003
Finland	Indicative INN prescribing	Obligatory generic substitution	Yes, since 2009[c]
France	Indicative INN prescribing	Indicative generic substitution	Yes, since 2003
Germany	Indicative INN prescribing	Obligatory generic substitution	Yes, since 1989
Greece	Not allowed	Not allowed	Yes, since 2006
Hungary	Indicative INN prescribing	Indicative generic substitution	Yes, since 1991
Iceland	Allowed	Not allowed	Yes, since 1995
Ireland	Indicative generic prescribing (INN or brand name)	Not allowed	No
Italy	Indicative INN prescribing (INN, brand name and generic name)	Indicative generic substitution	Yes, since 2001
Latvia	Indicative INN prescribing	Obligatory generic substitution	Yes, since 2005

Country	Generic Prescribing [a]	Generic Substitution [a]	Reference Price System [b]
Lithuania	Obligatory generic prescribing (writing of brand name only with justified reason)	Indicative generic substitution	Yes, since 2003
Luxembourg	N.a.	Not allowed	No
Malta	N.a.	Indicative generic substitution	No
Netherlands	Indicative INN prescribing	Indicative generic substitution	Yes, since 1991
Norway	Indicative generic prescribing	Indicative generic substitution	No
Poland	Indicative generic prescribing (INN, brand name or generic name)	Indicative generic substitution	Yes, since 1998
Portugal	Obligatory INN prescribing	Indicative generic substitution	Yes, since 2003
Romania	Allowed	Allowed	Yes
Slovak Republic	Indicative INN prescribing	Obligatory generic substitution	Yes, since 1995
Slovenia	Indicative INN prescribing	Indicative generic substitution	Yes, since 2003
Spain	Indicative INN prescribing	Allowed	Yes, since 2000
Sweden	Not allowed	Obligatory generic substitution	N (existed from 1993 to 2002)
Switzerland	Not allowed	Allowed	Yes, updated 2002 (works slightly differently)
United Kingdom	Indicative generic prescribing	Not allowed	No

Notes:
[a] = PPRI Report (Vogler et al., 2008)
[b] = New PPRI analysis including Spain (Vogler et al., 2009)
[c] = Esitteitä 2009:3 (Finnish Ministry of Social Affairs and Health, 2009)
N.a. = Information not available

Appendix 3: Basic Data on the Case Countries

Case No.	Abbreviation	Country	EU Accession
1	AT	Austria	1995
2	BE	Belgium	1957
3	CH	Switzerland	N/A
4	CZ	Czech Republic	2004
5	DE	Germany	1957
6	DK	Denmark	1973
7	ES	Spain	1986
8	FI	Finland	1995
9	FR	France	1957
10	GR	Greece	1981
11	HU	Hungary	2004
12	IE	Ireland	1973
13	IS	Iceland	N/A
14	IT	Italy	1957
15	LT	Lithuania	2004
16	NL	Netherlands	1957
17	NO	Norway	N/A
18	PL	Poland	2004
19	PT	Portugal	1986
20	RO	Romania	2007
21	SE	Sweden	1995
22	SI	Slovenia	2004
23	SK	Slovak Republic	2004
24	UK	United Kingdom	1973

Notes:
N/A = Not an EU member state

Appendix 4: Raw Data and Qualitative Codings for Fuzzy Sets

	PEN		SUR		PHE	GNI	O65	COO	RPS
Case	Penetration 2007 or latest (%)	Qualitative Coding	Survival rate until 2008 (%)	Qualitative Coding	Public health expenditure (% of total health expenditure) 2006	GNI per capita (current US$) 2007 or latest	Population ages 65 and above (%) 2007	Coordination index or other source (see text)	RPS since
AT	18.7	0.4	N/A	0	75.9	41960	16.7	1	NA
BE	10.2	0.2	25	0.2	72.5	41110	17.4	0.74	2001
CH	11.3	0.2	40	0.4	59.1	60820	16.0	0.51	2002
CZ	33.0	1	100	1	88.0	14580	14.6	CEE	1995
DE	30.3	1	81	0.8	76.9	38990	19.6	0.95	1989
DK	20.5	0.6	25	0.2	85.9	55440	15.6	0.7	1993
ES	7.2	0	68	0.6	71.2	29290	17.0	0.57	2000
FI	20.2	0.6	100	1	76.0	44300	16.3	0.72	2009
FR	9.5	0	100	1	79.7	38810	16.3	0.69	2003
GR	13.0	0.2	100	1	62.0	25740	18.5	Greece	2006
HU	34.2	1	67	0.6	70.9	11680	15.5	CEE	1991
IE	8.0	0	40	0.4	78.3	47610	11.1	0.29	NA
IS	17.0	0.4	100	1	82.0	57750	12.0	Nordic	1995
IT	20.3	0.6	88	0.8	77.2	33490	20.1	0.87	2001
LT	41.6	1	N/A	0	70.0	9770	15.7	CEE	2003
NL	19.2	0.4	50	0.4	80.0	45650	14.6	0.66	1991
NO	13.9	0.2	N/A	0	83.6	77370	14.8	0.76	NA
PL	61.0	1	67	0.6	70.0	9850	13.3	CEE	1998
PT	17.4	0.4	90	0.8	70.5	18950	17.1	0.72	2003
RO	28.5	0.8	33	0.2	76.9	6390	14.9	CEE	Yes
SE	14.5	0.2	100	1	81.7	47870	17.6	0.69	NA
SI	32.6	1	33	0.2	72.2	21510	16.0	CEE	2003
SK	44.6	1	N/A	0	70.6	11720	11.9	CEE	1995
UK	29.1	0.8	50	0.4	87.3	40660	16.2	0.07	NA