

International Business
Master Thesis No 2002:9

MASTERING A MOVING MARKET

**-THE CASE OF MÖLNLYCKE HEALTH CARE
IN POLAND**

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ISSN 1403-851X
Printed by Elanders Novum

Abstract

Poland has been in the process of adjusting its legislation to comply with the regulatory framework for the Single European Market, ever since the application for membership to the European Union. This together with the transformation to market economy has created a dynamic and relatively unpredictable business environment for the companies active within it. This thesis examines the impact of a future EU membership on the Polish business environment and especially on the market for medical device. The uncertainties of the Polish business environment are put into the perspective of Mölnlycke Health Care, a company planning to enter the Polish market in the near future. The scenario analysis approach enables decision makers to view a strategic decision, from the perspective of various prospects of the future. Hence, within this thesis, the uncertainties of the Polish market are identified and analysed using this approach. The constructions of scenarios are used as the foundation of the analysis regarding Mölnlycke HC's future expansion in the country. A number of aspects, important to consider in the companies' future strategy development in Poland have been identified. The most important aspect is that the EC law adjustments and continued low funding to the health care system, most likely will result in market consolidation.

Key Words: EU Enlargement, Poland, Medical Devices, Mölnlycke Health Care, Scenario Analysis, and Strategy Development.

Acknowledgements

We would like to take advantage on this occasion to express our gratitude to the people who, in various ways, have helped us in the completion of this thesis.

First of all, we would like to thank Mölnlycke Health Care for giving us the opportunity to carry out this study. We would like to specially thank Anders Norén, Eric Miranda, Anders Husmark and Lina Göstasson for their assistance.

There were many people that provided us with useful information during the field study. We would especially like to send our gratitude to Iwona Wolosz at SPiDSM, Ewa Kwast and Józef Labanowski at the Swedish Trade Council, Krystof Dziółko and Iwona Gryglicka at Polfarmed as well as Barbara Patyk at PAIZ. Moreover, we are very grateful to the visited companies in Poland, which provided us with highly valuable information about the medical device industry. Furthermore, we would like to thank the Marianne Van Steen and Cornelis Brekelmans at the European Commission, as well as Marcus Siebert and Els Dedobbeleer at Eucomed.

We would also like to thank our supervisor Professor Claes Göran Alvstam for useful insights and comments during our work. Many thanks also to PhD Candidate Roger Schweizer for his assistance in the beginning of the writing process.

Finally, many thanks also to our families and friends for support and encouragement during this autumn. Special thanks to Maria Wickberg and Ausra Zaksaitė for the fruitful meetings held in Handelsrätten.

Göteborg, December 2002

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Part I



Introduction
Methodology
Theoretical Framework

1. INTRODUCTION

This chapter provides the reader with the research background, and introduces the chosen case company. It further presents the problem statements and purpose of the research, models illustrating the research as well as the outline of the thesis. Moreover, this chapter presents the delimitations of the research as well as the definitions and abbreviations used within this study.

1.1. Research Background

Central and Eastern Europe have undergone immense changes in recent history. The fall of the Berlin Wall in November 1989 led to a number of similar actions throughout the whole region. These historical events were of crucial importance for the future development in Central and Eastern Europe. The final breakdown of communism caused a shift in the trade patterns of the Central and Eastern European countries. Before these events, the trade of these countries was conducted mostly with the former Soviet Union and the communist countries in Europe. After the fall of the Berlin wall, the EU countries became increasingly important trade partners. In addition, the whole region attracted vast attention from foreign investors. The governments of the countries have actively initiated reforms in order to attract foreign investors. Multinational corporations have chosen to establish sales, production as well as research and development in the previously unexplored territory.¹

Consequently, many European Union based firms have entered these markets and invested in subsidiaries on site. This is considered to be one of the cornerstones to why Eastern European countries have, firstly worked hard to improve their relations with the EU, and secondly, applied for membership.² The expected advantages of being part of the European union are several for the candidate countries as well as for the countries already members. The enlargement will, according to advocates of the matter, extend the zone of

¹ Kozminski, Yip, 2000, p 1

² Smith, 2000, p 2

peace, stability and prosperity of Europe. The enlargement of the union will further boost economic growth and create new jobs for both old and new member states.³ The more negative debate of the enlargement has mostly been focusing on issues concerning the costs of the extension of European cooperation as well as how the future EU budget will be adjusted to the new countries.⁴

The budgetary issues are still to be solved in the negotiations between the applicant countries and the EU. The current negotiations will apart from the budgetary issues handle very sensitive matters, such as agriculture and competition.⁵ EU has together with the applicant countries put up individual plans on how each country needs to adjust to be able to cope with the membership criteria of the union.⁶ The first group of new members are said to enter the EU in January 2004. These countries are the ones that have reached the furthest in the transition towards a market economy, and the creation of new well functioning institutions to govern a market economy. The first group of applicant countries to receive an invitation to join the Union are Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia.⁷

The preparations for EU membership in the candidate countries have lead to a number of practical implications for the multinational corporations (MNCs) active in the these markets. The EU adjustments have lead to regular changes in the legislation, and in the business environment. The preparations for EU membership have meant a transformation from a centrally planned economy to a market economy. This has created a volatile business environment and consequently also an extremely unpredictable future for the companies active in the markets.

³ European Commission, 2001, p 4-5

⁴ Financial Times, 2002-07-31, p 4

⁵ Ibid

⁶ European Commission, 2001, p 4-5

⁷ Dagens Industri, 2002-10-10

1.2. The Chosen Case Company

Two courses during the International Business Program laid the ground for our interest in the chosen thesis subject. During the course *Marketing and Management in New Europe* we developed a deep interest for topics related to the European Union, particularly the enlargement issue. The course *Big Emerging Markets* created our interest for emerging markets and the strategic management that is associated with markets under development. We approached the case company Mölnlycke Health Care, with the area of interest and got positive response. Mölnlycke HC had great interest in the area since the company had expansion plans in an emerging market – Poland, which is on the brink of a EU membership. Mölnlycke HC had interest in knowing how the EU membership affected business opportunities in the Polish medical device market and consequently also future expansion plans in the country.

Mölnlycke Health Care is one of the leading manufactures of single-use surgical products in the world. The products offered include patient drapes, instrument drapes and surgical gown, caps and masks for operating staff. Moreover, the company has a strong position in the professional wound care sector.⁸ Hence, the operations are divided into two business areas - Surgical and Wound Care, where the surgical business area is sold under the brands *Klinidrape*® and *Barrier*®. The wound care business area is sold under the *Tendra*® brand name.⁹

The primary business concept of the company is to be a world-leader in the manufacturing, marketing and sales of single-use products for surgical interventions as well as wound care. The company strives for continuous improvements, and the products should always meet the requirements of the EC Medical Device Directive, FDA (USA) Medical Device Regulations and any other relevant requirements. The company furthermore strives for continuous customer satisfaction.¹⁰

⁸ Mölnlycke HealthCare, 2001, p 3

⁹ Mölnlycke HealthCare, 2001, p 8, p 12

¹⁰ <http://www.molnlyckehc.com>, 2002-11-21

Sales and marketing are the responsibility of three joint organisations, one for US, one for Europe and one for other markets. The headquarter is situated in Gothenburg, Sweden, and handles all group functions. The company has approximately 4000 employees, of which 3300 are involved in the production. Factories are situated in Belgium, Finland, Czech Republic, Mexico and Thailand.¹¹

One of the company's main objectives is to double the annual turnover from the present SEK 4,500M within a five-year period. This will be done through both generic and organic growth. The main target is to establish the company in markets where the usage rate for single-use surgical products and advanced wound care products is still relatively low. The company will therefore focus on markets like Asia, Latin America and Eastern Europe.¹²

Mölnlycke HC is at present active in Poland through a distribution agreement. The products of MHC are sold over a large part of the country. The company's strategic objective for the period 2003-2005 is to expand its operations in the Polish market. The strategic period further includes the objective of entering the Polish market, with an own sales organisation.¹³

1.3. Problem Discussion

Uncertainties of the future create a difficult but also a challenging situation for the companies active on emerging or transforming markets. A similar situation faces companies with objectives of entering these markets. These companies have the choice of entering before the country has fully adapted to market economy standards, or the option of waiting until the transition process can be considered completed, and the business climate fairly stabilised.

¹¹ <http://www.molnlycke.com>, 2002-11-21

¹² Mölnlycke HealthCare, 2001, p 4

¹³ Miranda, E., (2002-08-30)

The above-described situation can easily be related to the situation in the Eastern and Central European countries. However, another dimension of the transition must be included. These countries are not only in the transformation of becoming a market economy, they are also on the brink of EU membership. This dimension creates further opportunities and threats for companies with interests in these markets. A company planning to enter these markets must consider the current situation, as well as how the business environment is likely to change with a EU membership. The advantages and disadvantages of entering before EU accession must be evaluated in relation to the possible advantages and disadvantages of waiting until the EU membership is completed.

Ever since the collapse of the communist system, Poland has been engaged in preparations for becoming a EU member. Since the beginning of the 1990s, Poland has gone through huge economical developments, and has been one of the most dynamic economies in Europe. The economy of Poland has been characterised by steadily growth and stability. Hence, Poland has attracted a vast amount of foreign investors.¹⁴ Many Swedish companies have set up operations in Poland because of the good economic development, but also because of the geographical closeness and the large domestic market.¹⁵

The Polish medical device market, is a market where the uncertainties of the future are very obvious, hence creating a complex situation for the companies active within it. The legislation controlling medical devices is still considered to be relatively complicated and associated with a number of problems for foreign actors in Poland.¹⁶ One of the fundamentals of the EU is the Single European Market, which is based upon mutual recognition, i.e. no product legally manufactured and marketed in one member state and exported to another, is to be treated different from a domestic produced product.¹⁷ In the case of the Polish medical device market some adjustments to the Single

¹⁴ Belka, 2001, p 13

¹⁵ Godet, Golda, 2002, p 1

¹⁶ Medstat, 2001, p 24

¹⁷ Mercado, Welford and Prescott, 2001, p 92

European Market have been made, while some modifications remains to be done.

1.4. Problem Definition

The discussion above have led to the formulation of the following main question:

Main Question:

How can an MNC, active in the market for medical devices, amend to the adjustments in the direct business environment that evolves with a future Polish EU membership?

This question aims at exploring how a company could capture the opportunities that arise with a Polish EU membership. In order to better facilitate the study, the main question is divided into the following research questions:

Research Question 1:

What are the characteristics of the political and economic systems of Poland and how will these systems change with a EU membership?

This question will focus on describing the environment, from a political and economic perspective. It will furthermore explore how it is expected to change with a EU membership.

Research Question 2:

What are the characteristics of the Polish market for medical devices, and how will it change with a future Polish EU membership?

This question will explore the Polish medical device market as well as the possible changes that arise with a Polish EU membership.

Research Question 3:

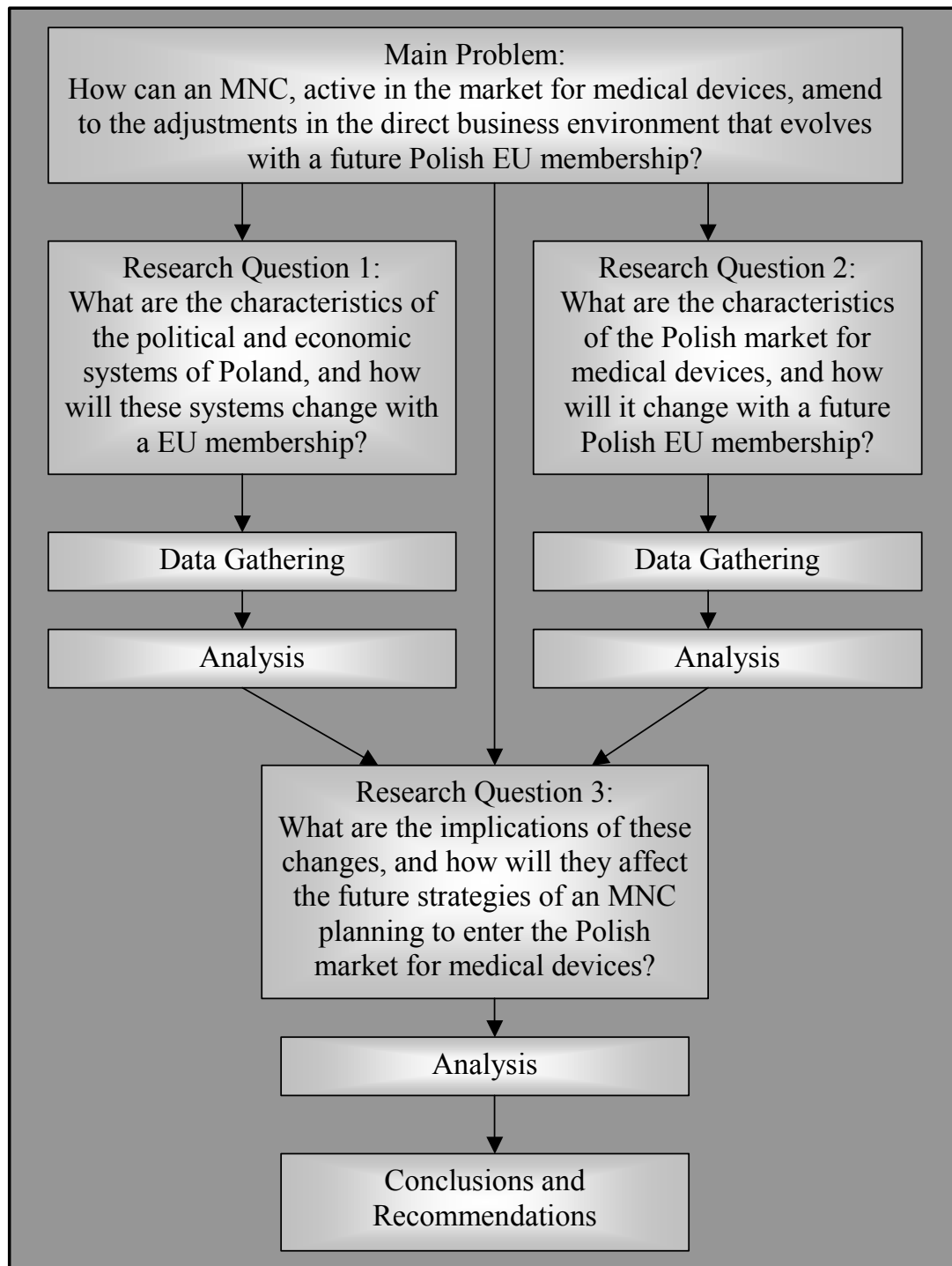
What are the practical implications of these changes, and how will they affect the future strategies of an MNC planning to enter the Polish market for medical devices?

This question aims at putting the information from the other two research questions into the perspective of the case company. The objective is to draw attention to the most essential changes that the market will face in the future, and how this should be acknowledged in the future strategies of the case company.

1.4.1. Research Model

The following model illustrates the structure of the research:

Figure 1 “The Research Model”



Source: Own Construction

1.5. Purpose

The purpose and objective of this thesis is to examine the impacts of the adjustments to EU membership on the Polish medical device market and consequently on the operations of a MNC, planning to enter the market. The purpose of the thesis is further to take a wide and broad perspective in the analysis of the most vital aspects of the Polish business environment, and how it is likely to develop in the future.

1.6. Delimitations

- This thesis focuses on the aspects of a EU membership that are considered being the most important in the medical devices industry. The excluded aspects will be foreseen since the aim of this thesis is to put the content into the perspective of our case company, together with time constraints.
- Moreover, the thesis takes an external perspective, to collect an outside view of the issue. The internal perspective, i.e. to examine our case company's view of the matter, is left out. Therefore, an extensive resource based internal analysis is not included in the thesis. However, the company is taken into consideration in the concluding part of the thesis, when future strategies are recommended.
- Further delimitations of this thesis is the fact that the subject is under constant change. Negotiations regarding the future EU enlargement are still held. At present there is still no final date for accession or the ending of the final negotiations round. This creates uncertainties regarding the exact timing of membership and consequently the implementation of the regulations.
- When examining the EU perspective, the thesis only handles Poland's accession and the following adjustments to EU, i.e. not the enlargement issue as a whole.

- Another delimitation of this research is the fact that the thesis is focusing on marketing and selling of the MNC, i.e. it does not include aspects that involve the future set up of manufacturing and research and development of medical devices. Consequently, issues regarding suppliers are left out in the industry analysis.

- Another delimitation with this study is that a specific and profound competitor analysis is left out. The rivalry among the existing competitors is described from a broad and general perspective. The detailed examination of Mölnlycke Health Care's competitors is excluded, due to time constraints

- The thesis does moreover not analyse the changes in the market for medical devices from the perspective of selecting different entry modes.

1.7. Definitions and Abbreviations

Multinational Corporation (MNC) – A company engaged in the active management of own subsidiaries in foreign countries and management integration of the operations conducted in the different countries.¹⁸

Medical Devices (MD) – The term 'medical device' covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap. The products do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.¹⁹

Direct business environment – The direct business environment is within this context, referring to the economic and political system of Poland as well as the characteristics of the Polish medical device market.

¹⁸ Gipson. C.R, 1994, 259

¹⁹ Council Directive 93/42/EEC

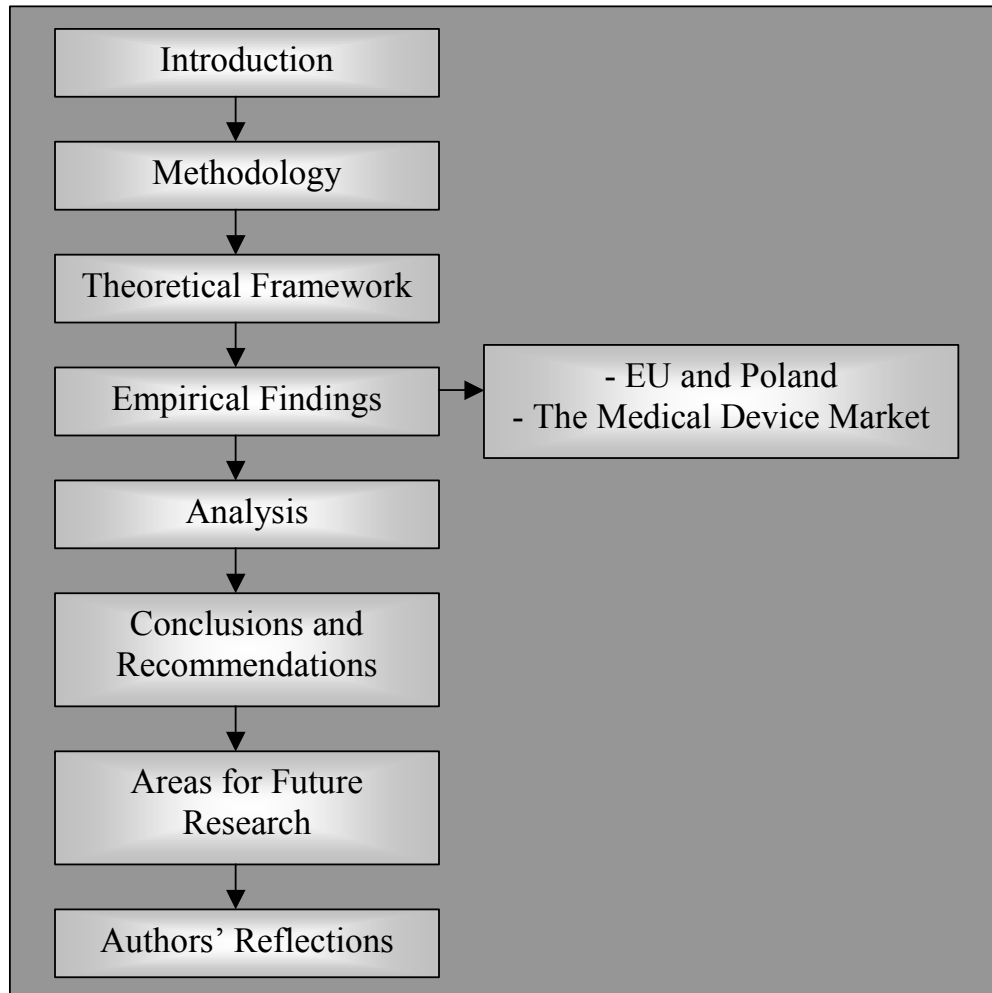
Acquis Communautaire (Acquis) – comprises the entire body of EC-law including the Treaties, regulations, directives passed by the Council of Ministers and the judgement of the European Court of Justice. The “acquis” is divided into 31 chapters (appendix 2) that are the base for the negotiations between EU and the candidate countries.²⁰

²⁰ European Commission, 2001, p 33

1.8. Thesis Outline

The following model describes the outline of the thesis:

Figure 2 “The Thesis Outline”



Source: Own Construction

2. METHODOLOGY

This chapter introduces the reader to alternative methodological approaches to research. It further motivates the choice of research strategy used when answering the problem statements of this thesis. First, the chosen research strategy and the research design are described. Hereafter, the way of collecting and analysing data is presented, before the chapter ends up with a discussion about the quality of the conducted research.

2.1. Research Strategy

A research strategy can be seen as different approaches that can be used in order to answer problem statements when conducting research. There are five main research strategies that can be used in social sciences: experiments, surveys, historical research, archival analysis and case studies. The strategy should be picked depending on the problem statement and what kind of output that is requested. Hence, each strategy has its advantages and disadvantages.²¹ According to Yin, there are three main issues to consider when choosing research strategy. Firstly, the type of research questions that are posed, secondly, the extent of control the investigator has over actual behavioural events, and thirdly the degree of focus on contemporary or historical events.²²

The research questions in this thesis are “what” and “how” questions, which can be answered with a case study. This type of questions can also be answered by other strategies. However, the effects of a EU membership, on MNCs active in the Polish market for medical devices, narrows the opportunities down. Since the Polish adjustments to EU can be seen as a contemporary set of events, over which the investigators have little or no control, we found that a case study would be the best strategy to use. Yin claims that a case study focuses on contemporary events in a real life

²¹ Merriam, 1994, pp 21-23

²² Yin, 1994, p 4

situation, which further strengthens the choice to use a case study for this research.

Furthermore, Yin divides case study research into descriptive, explanatory and exploratory cases. A descriptive case study focuses on describing the examined phenomenon in an entirely descriptive manner, without making any attempts to interpret the collected data. An explanatory case study however, uses the data to explain the examined phenomenon. An exploratory case study has the objective of exploring situations where the phenomenon can be observed and analysed in new circumstances.²³ In the case of our research, it is clear that this study is a combination of a descriptive and explanatory case study, since the objective is to describe the Polish market for medical devices and to explain the upcoming changes in the business environment.

2.1.1. Case Study Design

When designing a case study there is an option to use single or multiple designs combined with the choice between holistic or embedded designs. The multiple case design is investigating several cases, and the single design focuses on one case. There are three rationales for using a single case study: the critical case, the unique case and the revelatory case. The critical case refers to an investigation that focuses on testing, confirming or extending existing theory. The unique case investigates an exceptional or extreme case, whereas the revelatory case concerns cases that for some reasons have not been accessible to scientific research earlier.²⁴

When considering the unit of analysis, reflection upon doing a holistic or embedded study is necessary. A holistic design means that the study includes only one single unit of analysis, and that it examines the global nature of one phenomenon. The embedded case on the other hand, investigates the main problem and also related sub units of the main problem.²⁵

²³ Yin, 1994, p 15

²⁴ Yin, 1994, p 19

²⁵ Yin, 1994, p 21

Figure 3 “Basic Types of Designs for Case Studies”

	Single-Case Design	Multiple –Case Designs
Holistic (single unit of analysis)	<p>TYPE 1</p> <p>Our Choice</p>	<p>TYPE 2</p>
Embedded (Multiple units of analysis)	<p>TYPE 3</p>	<p>TYPE 4</p>

Source: Yin, 1994, p 39

This thesis follows a single case study design, based upon the revelatory rationale. The adaptation process of a EU applicant country, might not be a new phenomenon to research. However, in what way the adjustments are influencing the Polish medical device market, has to our knowledge not been investigated before.

Moreover, a holistic design is used since the research is based on one unit of analysis, i.e. the Polish business environment and the changes that arises with a EU membership. The main question and the research question are correlated, describing different aspects of the unit of analysis.

2.2. Research Method

When conducting a case study there are no limitations to what kind of scientific information can be gathered and no limitations concerning how this information shall be gathered. Therefore, both quantitative and qualitative information can be used, as well as a mixture of both.²⁶ Quantitative research

²⁶ Merriam, 1994, p 24

is of experimental, empirical and statistical nature, using for example, surveys and questionnaires as a mean to find precise and numerical results. Qualitative research uses the researcher as an instrument for the collection and analysis of the data. By conducting interviews and observations the qualitative method tries to find richly descriptive results, which create deeper understanding about the investigated area.²⁷

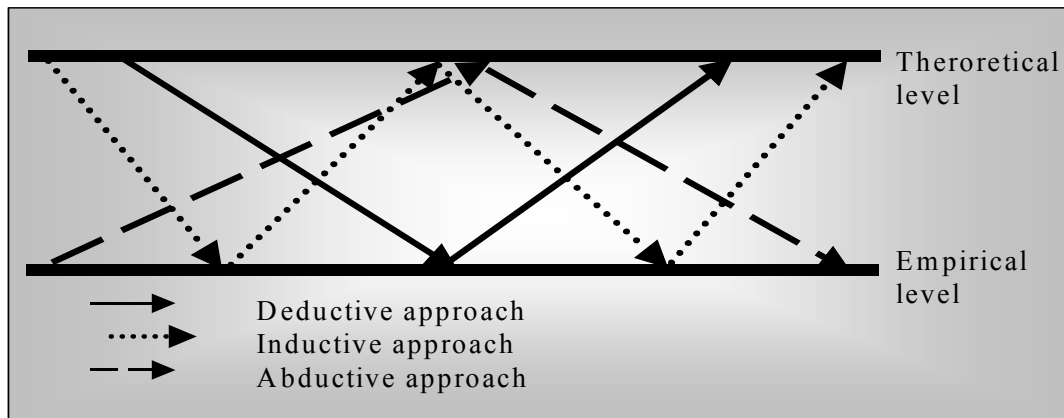
Our aim has been to describe the adjustments in the Polish business environment that arises with a future EU membership. To be able to reach our aim, we decided upon a qualitative method with an empirical focus on interviews. This method allowed discussions of the subject with the interviewees, and thereby a deeper understanding of the subject was gained.

2.3. Research Approach

The research approach describes the different possibilities an investigator has to approach the research questions starting from a theoretical or empirical level. There are three approaches possible: deductive, inductive and abductive. The deductive approach is to test already existing theory and try to see if the empirical studies support it. Using the inductive approach the researcher starts by collecting empirical data and thereafter tries to form a theory. The abductive approach combines the earlier mentioned ones. The researcher tries to use both existing theories and evidence from empirical investigations to improve or create his own theories.²⁸

²⁷ Merriam, 1998, p 6

²⁸ Merriam, 1998, p 7

Figure 4 “Research approach model”

Source: Own Construction

The research started by looking for theoretical approaches to the purpose. This resulted in the creation of a theoretical framework, which provided us with a constructive base, used during the whole thesis process.

This ground was the base for all the interview questions. During the entire writing process, we have approached both the theoretical and empirical levels at different stages. To conclude, we have used an abductive approach in our research, even though the research ends at the empirical level.

2.4. Data Collection

2.4.1. Secondary Data

Secondary data is existing information in the form of already made research.²⁹ The first step of collecting data for this thesis was to search for secondary data in the form of literature and articles in libraries as well as information from the Internet. These sources have been a base for our theoretical framework and the empirical findings.

²⁹ Widerheim Paul 1991, p 12

2.4.2. Primary Data

The secondary data together with the theoretical framework were the ground for what type of information we wanted to attain, during the primary data collection. Primary data collection is gathering data that is specific for the investigated case.³⁰ In order to understand how the Polish market for medical devices currently looks like, and how it will change in the near future, data was collected from three different categories of sources. Consequently, interviews were conducted with representatives from EU, Polish authorities as well as companies presently active in the market.

The strength with interviews as a tool for the collection of data is the direct focus on the topic of the study. On the other hand, there is a risk for bias and misunderstandings, which has to be accounted for. Interviews have been the major method in the collection of primary data. All of the conducted interviews have been taken place within a time period of one or two hours, and have been based on a mix of more or less structured questions. (See appendix 1) This is what Yin refers to as focus interviews and semi-structured questions.³¹

2.4.3. Sampling

Sampling is the selection of where to do the research, when it will take place, whom to interview, and about what.³² For this thesis interviews were conducted in Warsaw with Polish authorities and companies active on the market for medical devices. The questions were related to the shifting conditions of the Polish business environment, with a focus on the medical device market. Moreover, EU officials in Brussels were interviewed about the Polish enlargement process and how well Poland has adjusted to the *Acquis Communautaire*, in areas related to the thesis subject.

³⁰ Widerheim Paul 1991, p 12

³¹ Yin, 1994, pp 84-86

³² Merriam, 1998, p 60

The interviewed persons have been chosen because of their expertise and competence in the different fields of interest to our research. The major sampling method used is therefore the purposeful sampling. It focuses on information rich cases, from which one can learn about issues of central importance to the purpose. In the beginning of the sampling a list was created with the different competence areas that were of interest for our study. The next step was to contact persons in various organisations with knowledge in the priority areas. This is called the criterion-based sampling method and gives the investigator a possibility to make sure that the right primary data is gathered. Hereafter a combination of the convenience and the snowball sampling methods were used. The snowball strategy involves asking the contacted persons for further recommendations to other possible participants. Since we did not have a complete picture of the different subjects, we asked the contacted persons for further possible interviewees in order to get more information. This resulted in a number of new contact persons, giving us useful information. The convenience method means that the meetings were set out of accessibility.³³ We had to meet our interviewees during a limited amount of time, since our fieldtrip was conducted in a fixed period of time. Therefore, we were sometimes not able to meet the most qualified person, but someone working close to him or her.

The companies taking part in the research were chosen out of three criteria; multinational companies that have well-established operations in the Polish market and together cover the different market segments. Based on this, we have tried to find typical samples that would reflect a MNCs average situation in the Polish healthcare market.

2.5. Data Analysis

The data analysis is the procedure of making meaning of the collected data. The analysis involves different levels. The first one is the arranging of collected data after topics or chronological order to structure the case study

³³ Merriam, 1998, p 61

report. The second occurs when the data is systematically organized into categories, themes or types. The third step is to make recommendations.³⁴

After the collection of data, the empirical findings were arranged after topical order. The chosen topics were Poland's economic and political system, as well as the medical device market. The intention was to reflect the problem statements of the thesis into the structure of the analysis of the collected data.

The political and economic system of Poland was first put into the perspective of the Network Institutions Model, presented in the coming theoretical framework. To this model, an outer rectangle was added to clarify the impact of EU on Poland. Moreover, some institutions were removed, since they are not directly affected by a EU membership. Consequently these were not necessary to analyse in order to solve the problem definitions of this research.

The category containing collected data regarding the medical device industry, was firstly put into an industry analysis. The gathered information was put into a modified version of Porter's five forces of competition framework, which is presented in the coming theoretical framework.

2.5.1. Scenario Method

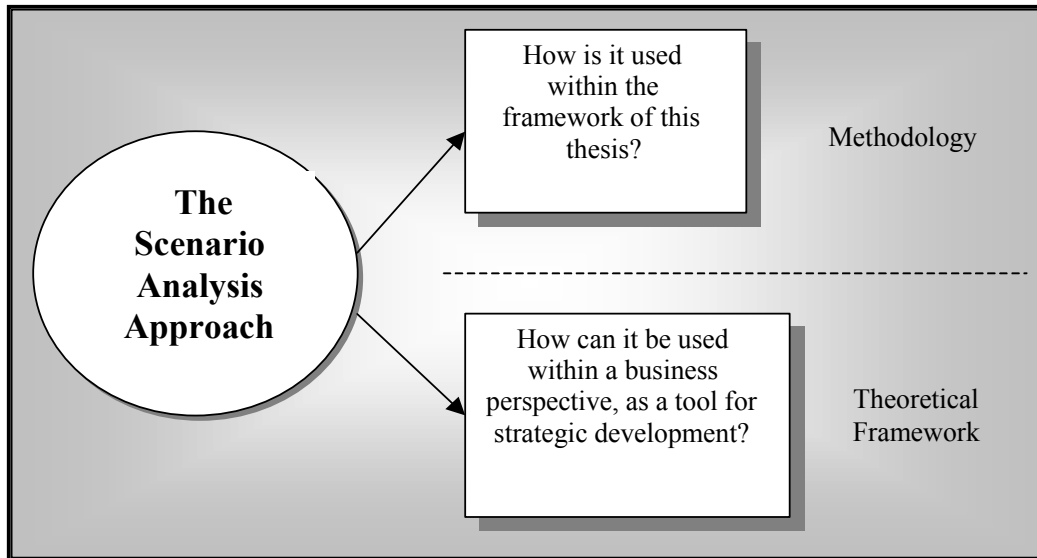
In the analysis section of the thesis we have tried to show how the Polish economic and political circumstances are influencing the medical device industry, and how this industry is likely to develop. The characteristics of the thesis required a method that allowed for a prediction of the future. The following section therefore explains the scenario planning process. We have chosen this method to create possible future scenarios of the medical device industry.

The scenario analysis approach will also be discussed in the theoretical framework, but then focusing on why the approach can be used in strategy development, and the pros and cons of the method. The following section is

³⁴ Merriam, 1998, p 180

explaining the approach as a method analysing data, rather than putting the approach into a business perspective.

Figure 5 “The Scenario Analysis Approach”



Source: Own Construction

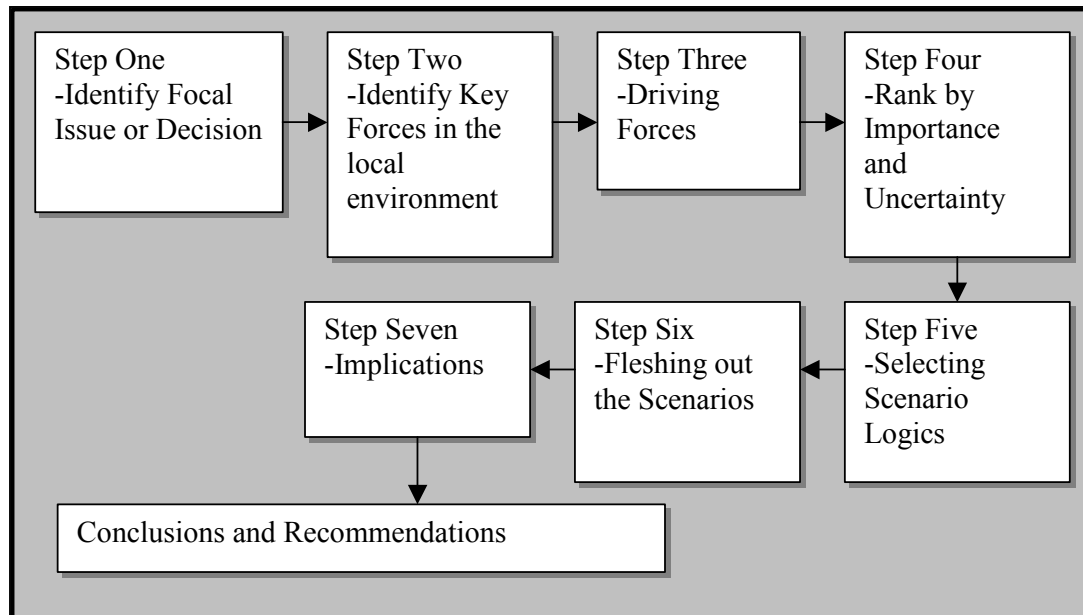
This study has developed four different scenarios for the future, and then, as a second step determined what scenarios are most realistic. Hereafter, the next step was to reflect upon possible advantages and disadvantages of entering the market within certain time perspectives, taken the conditions of the different scenarios into consideration. This has been done in the chapters of conclusions and recommendations. Hence, the scenario approach was used as a step in the process of answering the problem definitions of this thesis.

2.5.2. Scenario Planning

Schwartz has developed an eight-step model, for the creation of scenarios. Each step of the model will be briefly explained in this section. We have chosen to base the scenario planning process on this model. However, the final step of the model, which refers to the selection of leading indicators, have been left out. This step will instead be discussed in the chapter of conclusions and recommendations. Therefore, we have added this additional

step to the model. The scenario analysis will be used as the main foundation of our conclusions and recommendations.

Figure 6 “The Scenario Planning Process”



Source: Own Construction based on Schwartz 1996, pp 241-247

Identification of Focal Issue

The Scenario planning process often starts with identifying the specific issue of interest to the investigation. Within this process, it is recommended to take an inside out perspective, and thus build out toward the environment.³⁵ Shoemaker has developed a similar first step in his step-wise procedure of scenario planning. According to Shoemaker, the scenario planning process should start with defining the scope, which is to set the time frame and scope of the analysis, in terms of markets, products, geographic areas and technologies.³⁶

³⁵ Schwartz, 1996, p 241

³⁶ Dyson and O'Brien, 1998, p 189

In order to identify the focal issue, attention was given to the problem definitions and the purpose stated in chapter one. Herby the focal issue was defined as:

- How will the Polish medical device market change in the near future, put into the perspective of a company planning to enter the market?

Key Forces in the Local Environment

The following step is to list the key factors that might influence the success or failure of the focal issue. This contains information about customers, suppliers, competitors etc. This step allows for analysing the focal issue from different perspectives.³⁷ The Institutions Network Model, later described in chapter three, can be used as a tool in this step of the scenario analysis. The model can be used to illustrate changes in the external environment and the influence these changes have on the MNC. To be able to explain how other institutions in their respective external environment influence the institutions in the different fields, one can start to investigate the MNC. Hereafter it is recommended to investigate how the societal field influences the organizational field, and finally how the organizational field is affecting the MNC.³⁸

The Institutions Network Model gave us a thorough description of the external environment and EU's impact on Poland. In addition we used the findings derived from the industry analysis. These two approaches helped us in the identification of the key forces.

Driving Forces

After the listing of the key forces, the process involves an identification of driving forces in the macro environment. This includes aspects as social, economic, political, environmental and technological forces. The crucial point of this step is to consider the forces behind the micro environmental forces

³⁷ Schwartz, 1996, p 242

³⁸ Jansson, 2001, chapter 3, p 16

that were identified in step two.³⁹ Shoemaker argues that the forces mentioned by Schwartz should be complemented with legal and industry trends.⁴⁰

The identification of the driving forces, allowed us to, once again to return to the findings of the Network Institution Model. A discussion was held concerning what forces influence the identified key forces, and moreover what forces that are the most important to the focal issue.

Rank by Uncertainty and Importance

The next step in the scenario planning process is to rank and analyse the key factors in the local environment as well as the driving forces behind them, from two criteria. The first one is the degree of importance for the success on the focal issue or decision identified in step one. The second criterion is the degree of uncertainty surrounding these factors and trends.⁴¹

During this stage, the forces were listed and evaluated to the above-described criteria. Two factors were identified as being the most crucial to the focal issue, and consequently for the future turn of the market. These criteria were decided upon after long discussions, where the possible impacts of each force were taken into account.

Selecting Scenario Logics

This step relates to the selection of axes, that in a clear way indicates what factors lay the ground for future changes on the focal issues. The objective of this step is to end up with a limited amount of scenarios whose disparities would make a difference to the focal issue. The scenario drivers must be relatively few in number in order to avoid the creation of different scenarios around too many uncertainties. As soon as the essential axes of the most important uncertainties have been identified, it could be of help to present

³⁹ Schwartz, 1996, p 241

⁴⁰ Dyson and O'Brien, 1998, pp 189-190

⁴¹ Schwartz, 1996, p 243

them in a matrix, given that the uncertainties are two.⁴² According to Van Heijden, there is a danger in selecting three scenarios, since there is a tendency of choosing the middle alternative, as the most likely scenario of the future.⁴³

We chose to create a matrix by using the most uncertain and important factors in the industry that were identified in the previous step. These parameters were put on the axes of the matrix, and created four possible future scenarios of the medical device industry. The parameters were in this step thoroughly described as well as motivated. Each of the parameters was also defined and the definitions were illustrated in two figures (see chapter six).

Fleshing Out the Scenarios

This step involves a return to the previously identified key factors and trends. These factors should be taken into consideration under each of the scenarios that evolved under the previous step. The next step is to compose all the fundamentals into a narrative, analysing how the world will get from here.⁴⁴ According to Van der Heijden, the scenarios are best written as stories since this approach effectively capture the dynamics of the situation and clearly highlighting the main issues within the future setting.⁴⁵ This was acknowledged in creation of the four scenarios. The thoroughly described and defined parameters constantly assisted us in the development of the scenarios. The creation of the scenarios was an ongoing process, where each scenario was continuously discussed and supplemented.

Implications

As soon as the scenarios have been examined in detail, it is time to return to the decision identified under step one and evaluate how the decisions resemble each other in each of the enlivened scenarios. This step of the

⁴² Schwartz, 1996, p 243

⁴³ Van der Heijden, 1996, p 74

⁴⁴ Schwartz, 1996, p 245

⁴⁵ Van der Heijden, 1996, p 77

scenario planning has the objective of evaluating if the focal decision is robust across all scenarios, or if it is reasonable in only some of the scenarios.⁴⁶ In Shoemaker's scenario planning approach, this final step of the process deals with converging the scenarios towards a testing of strategies as well as new ideas.⁴⁷

This step meant a return to the focal issue, and an evaluation of the "entry decision" in each of the scenarios. The features of each scenario were put into the perspective of the case company. The outcome of this evaluation was brought to the chapter of conclusions and recommendations, for further elaboration.

2.6. Quality of the Research

In order to secure a high quality of the empirical study, the researchers need to consider different criteria for evaluating the data. The collection and analysis of the data should be approached through the key elements of validity and reliability. Validity and reliability are in a qualitative case study based on the researchers ability to plan the study and their analytical skills.⁴⁸

2.6.1. Validity

Construct validity refers to whether the researcher has the correct operational measures for the concepts being used.⁴⁹ In order to ensure construct validity, we have used multiple sources of evidence, which have laid the ground for a diverse description of the investigated areas, taking a wide range of sources into account. The construct validity was moreover enhanced by the fact that we provided the respondents with the questions in advance. The respondents could hereby prepare themselves better, which laid the ground for concise discussions during the meetings. We have furthermore used similar areas of discussion, for all interviews, in order to be able to compare the findings.

⁴⁶ Schwartz, 1996, p 241

⁴⁷ Dyson and O'Brien, 1998, p 192

⁴⁸ Merriam, 1998, p 198

⁴⁹ Yin, 1994, p 34

Internal validity concerns how truthfully the results from the investigation show the reality. Since data does not speak for itself and the researcher has to interpret it, the data is often slightly adjusted into one direction based on the researcher's previous experience. It is therefore of great importance to reflect upon means to increase internal validity when interpreting the collected data.⁵⁰

The data has been collected from multiple sources. We have hereby tried to increase the internal validity of the thesis by applying the triangulation method. By interviewing persons representing different perspectives, we have further tried to collect data from different angles of our research problem. This approach allowed for an impartial collection of data. The analysis of data has, as far as possible, been focused on actual facts derived from the interviews, rather than own interpretations. Moreover, the respondents have been asked to comment our findings derived from their interviews to avoid any misunderstandings. Finally, we have had discussions concerning the interviews, results and findings with colleagues.

External validity refers to a test of how the generalizations in the study have been made and if that is done in a reasonable way. When it comes to case studies, analytical generalization is mostly used. The researcher attempts to generalize a particular set of results, to a previously developed and more general theory.⁵¹

Since the purpose of this thesis is to examine the impacts of the adjustments to EU membership on the Polish medical device industry, the generalizations of our findings are somewhat limited. The findings related to this industry can of course be of interest for other companies active in this market. These findings could to some extent also be useful for medical device companies active in other countries going through transitions and applying for EU membership. The findings of the thesis dealing with the Polish institutional

⁵⁰ Merriam, 1998, p 203

⁵¹ Yin, 1994, p 36

setting and the impact of the future EU membership can further be generalized to other industries in Poland.

2.6.2. Reliability

Reliability handles the consistency of research results. If an investigation is repeated it is supposed to produce the same results.⁵² This creates a problem in social science, since human behaviour changes with time and sometimes also with individual. Therefore the main aim of social science should be “*to see whether the results are consistent with the data collected.*”⁵³

Yin suggests that the creation of a formal project database containing all the data will increase the reliability, by having the evidence available for other researchers.⁵⁴ We have accumulated all collected data with the objective of allowing other researchers to easily review the findings of our study. Moreover, we recorded the interviews, to reduce the risk of missing important data or misunderstanding the respondents. Finally we have been collecting data from multiple sources to make sure that the findings were not subjective.

2.6.3. Sources of Error

Throughout the research we have aimed to avoid mistakes and misunderstandings of collected data. We therefore believe that we have not made any considerable mistakes that could have decreased the credibility of our thesis. When conducting the research we have faced some difficulties. Most information from Polish authorities is only available in Polish, which to some extent has limited the collection of data. Further, we experienced some language difficulties when conducting a few of our interviews depending on the respondent’s limited knowledge in English. This was dealt with by trying to approach the question from another angle and with easier wording.

⁵² Yin, 1994, p 37

⁵³ Merriam, 1998, p 206

⁵⁴ Yin, 1994, p 95

3. THEORETICAL FRAMEWORK

The theoretical framework is divided into three sections. Firstly, the reader is introduced to the Institutions Approach as a tool for analysing the external environment. The Institutions Approach is an proficient framework for the purpose of this thesis, i.e. to analyse the external environment in an emerging market. Secondly, the chapter introduces a framework for analysing competition within an industry. Within this context, Porter's five forces of competition framework is used. As mentioned earlier, the adjustments to the EU have created a volatile business environment in the candidate countries. Therefore, the chapter finally contains theories on international strategic management with a focus on formulating strategies in an uncertain environment.

3.1. The Institutions Approach

The Institutions Approach is based on one fundamental; the external environment either indirectly or directly influences an MNC. The company is furthermore connected to its environment through different relationships and is highly dependent on the international business environment, in which it operates. A company's competitiveness is determined by three factors. The first one is the functional and technical knowledge of an enterprise. The second factor is the accumulated knowledge of the business environment that exists within the enterprise. The third factor is the company's ability to adjust to its external environment.⁵⁵ Most companies active within one market are highly similar in terms of organisational skills, and product offers. Therefore, the determinant of a company's success lies in its ability to adjust and adapt its operations towards the external environment. The company that has the best ability to design its internal organisation, in a way that it allows for optimal response to the external environment, will be the most competitive in the industry. This company will consequently also be in the best position to

⁵⁵ Jansson, 2001, chapter 4, p 1

exploit the market opportunities.⁵⁶ The Institutions Approach profoundly describes the environment, as well as putting into the perspective of the MNC.⁵⁷

3.1.1. Defining Institutions and Networks

Institutions can be defined as a group, where rules, processes and routines are shared. The behaviour of an institution is decided by the rules of the organisation itself, as well as by external institutions. How one institution is organised depends on how its environment is organised.⁵⁸

Within the Institutions Approach, an MNC is viewed as a trans-organisational network, where the MNC involves exchanges of relationships among organisational units. The network approach is seen as a departure from the traditional conception of seeing the MNC as one unit operating in highly simplified environments.⁵⁹ The network theory has moreover been used to explain and describe the internationalisation process. The evolution of internationalisation is based on the cognitive learning of managers, which increases through experience. The focal point added to this perspective is the role of the network relationships with various partners that the companies develop in order to gain increased understanding of the environment.⁶⁰ However, the network approach will in this thesis focus on how the various institutions within a country influences the MNC, and put in a perspective of identifying the most crucial factors for a company planning to enter a specific market in the country.

3.1.2. The Networks Institution Model

The *Networks Institutions Model* is a framework used for identifying institutions in emerging markets that are relevant for describing, explaining, and predicting actual organizational behaviour. The model illustrates how the

⁵⁶ Grant, 2001, p 13

⁵⁷ Jansson, 2001, chapter 3, p 1

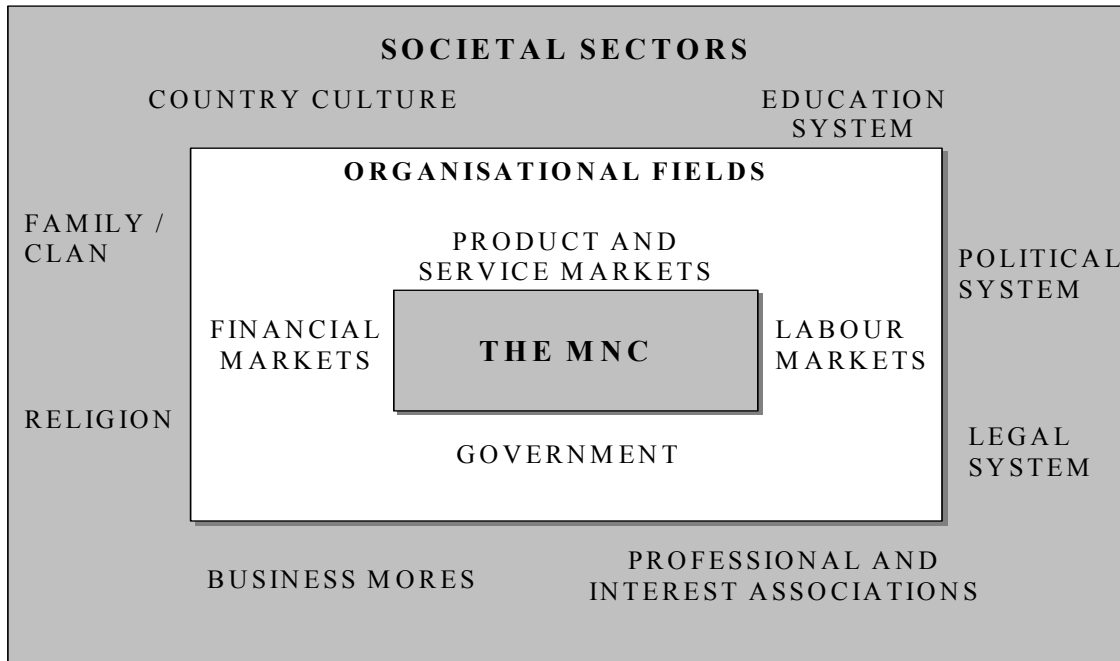
⁵⁸ www.ne.se, 2002-09-15

⁵⁹ Jansson, 2002, chapter 2, p 2

⁶⁰ International Business Review, 1997, pp 361-386

different institutions influence each other. The focal point of the institutional model is the MNC, which according to Jansson is organized by institutional principles. Consequently, the strategy and organisation of the MNC are influenced by institutional factors within the company itself, as well as by how the environment is organized.⁶¹

Figure 7 “The Networks Institutions Model”



Source: Jansson 2002, chapter 1, p 9

The institutional world is in the model divided into three levels of description: micro-, meso-, and macro institutions. The MNC, found at the micro level, is surrounded by the institutions that are the most influential to the operations of the company. The institutions within the organisational field (meso level), can have a direct influence on the MNC. Moreover, the MNC can have a direct influence on the institutions within this sector, which creates a double way interaction. On the contrary, the MNC cannot influence the institutions in the societal sector (macro level), but is indirectly influenced by them.⁶²

⁶¹ Jansson, 2002 , chapter 2, p 3

⁶² Jansson, 2002, chapter 2, p 3

There are four major organisational institutions; product/service markets, financial markets, labour markets and government. Essential societal institutions are country/culture, family/clan, religion, business mores, educational/training system, political system, legal system, and professional and interest associations. Each country has its own specific MNC environment, as a result of how the different institutions are linked to each other, forming an institutional framework.⁶³

The Model as Tool for Analysis

The environmental analysis can be conducted in an inside-out perspective as well as in an outside-in perspective. The inside-out perspective starts with the MNC, including the two rectangles in a step-wise manner, by first including the inner rectangle and then the outer. This approach helps identifying the institutions that influence the company the most. The outside-in perspective also starts with the MNC, but moves out to the outer rectangle instead of the inner as next step. This approach helps predict the environmental influence on the MNC. According to Jansson however, a combination of the two approaches is also possible. The approach chosen also depends on the topic that is studied. The approach is recommended to be different if a specific MNC is studied compared to if a specific industry is analysed. If the latter is the case, the unit put in the centre rectangle can be changed.⁶⁴

The model does not specify how the identification, description and analysis of the institutions within the model should be conducted. The analysis of the different institutions can be carried out using a number of models and tools. The chosen tools should be selected with reference to each individual case. All analysis conducted within the networks institutions approach must, however, focus on the institutions and strive towards going beyond physical facts. The analysis must include both formal and informal rules, such as norms, values, enforcement mechanisms and thought styles.⁶⁵

⁶³ Jansson, 2002, chapter 2, p 3

⁶⁴ Jansson, 2002, chapter 3, p 16

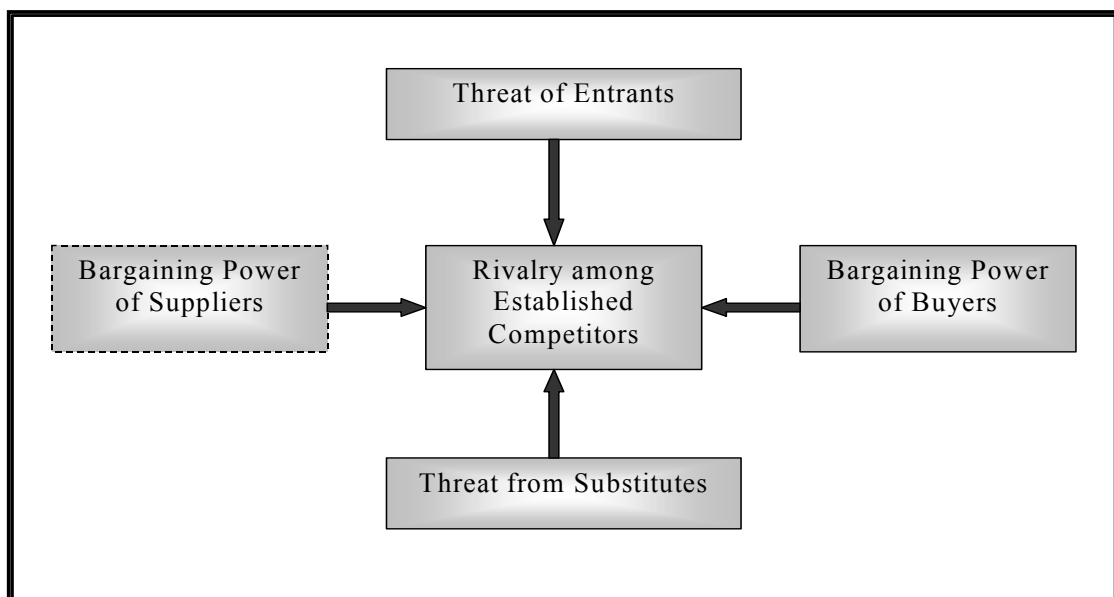
⁶⁵ Jansson, 2002, chapter, 3, p 1

3.2. Industry Analysis

A part of the networks institutions model is what Jansson refers to as product and service markets. According to Jansson, this part of the Institutional Model can be conducted by using a number of various tools. A tool for analysing the structure and competitive situation in each industry is the Porter's Five Forces of Competition Framework. Porter has identified five structural variables influencing competition as well as profitability. These variables become vital factors to consider when it comes to strategy formulation. The variables include both horizontal and vertical competition. Sources of horizontal competition are competition from substitutes, competition from entrants and competition from established rivals. The sources of vertical competition include the bargaining power of suppliers and buyers.⁶⁶

Within the context of this thesis, the industry analysis will focus on four of industry forces. The bargaining power of suppliers will be left out, since it is not necessary to analyse this factor, within the scope of the problem definitions of this thesis.

Figure 8 "Porter's five forces of competition framework"



Source: Porter 1980, p 26

⁶⁶ Grant, 1998, p 56-57

The *competition from substitutes* derives from the fact that the price that customers are willing to pay for a product depends on the availability of substitute products. The substitutes that deserve attention, within this context, are products that show tendencies to improve the relation between the price and received benefit, compared to the products of the examined industry. Competition derived from substitutes might be a collective concern, which allows for unified industry actions, in order to eliminate the threat and improve the general position of the industry.⁶⁷

The *threat of entry* relates to whether an industry earns a return on capital in excess of its cost of capital. If so, that particular industry will act as a magnet to firms outside the industry. This is, in turn, related to a number of barriers to entry such as, capital requirements i.e. the capital cost of getting established in an industry. Economies of scale are required in industries that are capital, research or advertising intensive, which also can act as a threat to new entrants. Absolute cost advantages refers to the fact that many firms can have advantages over entrants because they entered earlier. Furthermore, the threat of retaliation can also act as a entry barrier. If the new entrant, risks facing powerful reprisals from financially strong competitors, it will most probably have a deterrent effect on these possible entrants. Other examples of barriers to entry are to what extent the product is differentiated, and how well known brands the competitors have been able to build. The access to channels of distribution can also be decisive for possible new entrants. By blocking the distribution channels, already established competitors could eliminate the threat of possible newcomers. Finally, possible governmental and legal hindrance within an industry is other barriers to entry.⁶⁸

The *rivalry between established competitors* is determined by a number of factors. One decisive factor is the level of industry concentration ratio, which refers to the combined market share of the leading products. Moreover, it is determined by the diversity of competitors. If the market is characterised by relatively many and somewhat equal competitors, the market structure is often

⁶⁷ Porter, 1980, p 43

⁶⁸ Porter, 1980, p 28

considered very unstable. When the growth of a market is low, the competition tends to be very fierce since the rivalry will be a battle of the existing market shares. A growing market will somehow stabilise the competition, since the growth of the market renders the existence of more firms possible. Another factor determining the rivalry is the level of strategic importance for the competing firms. If the success within a market is crucial for the company, the competitors might even sacrifice the profit of the business. Furthermore, the rivalry is determined by product differentiation, excess capacity and exit barriers, and finally, cost conditions which refer to scale economies and the ratio of fixed costs.⁶⁹

The *bargaining power of buyers and suppliers* depends to what extent buyers as well as suppliers are sensitive to the price charged by the firms of an industry. It is moreover related to the relative bargaining power of the buyer and supplier, relative to that of the seller. This refers to the size and concentration of buyers relative to suppliers, the buyers' information, i.e. the availability of information in the buying and selling process and finally, the ability to integrate vertically.⁷⁰

Even though Porter's framework for analysing the competition within an industry is comprehensive and commonly used, it has been subject to some criticism. One of the criticism that have been raised against the model is the fact that it is a static model. It views the industry structure as stable and somewhat externally determined. The competition that the model aims at analysing is, however, a dynamic process, which changes through evolution and transformation. Another area of criticism has been concentrating on the fact that business relationships are not always based on rationality. Many relationships are characterised by privilege through affection and trust, whereas others are co-dependent systems, formed by webs of companies.⁷¹ Within the context of this thesis, using a scenario analysis has solved the problem with the static nature of the model. The scenario analysis enhances the future development of an industry. Furthermore, the nature of

⁶⁹ Porter, 1980, p 37

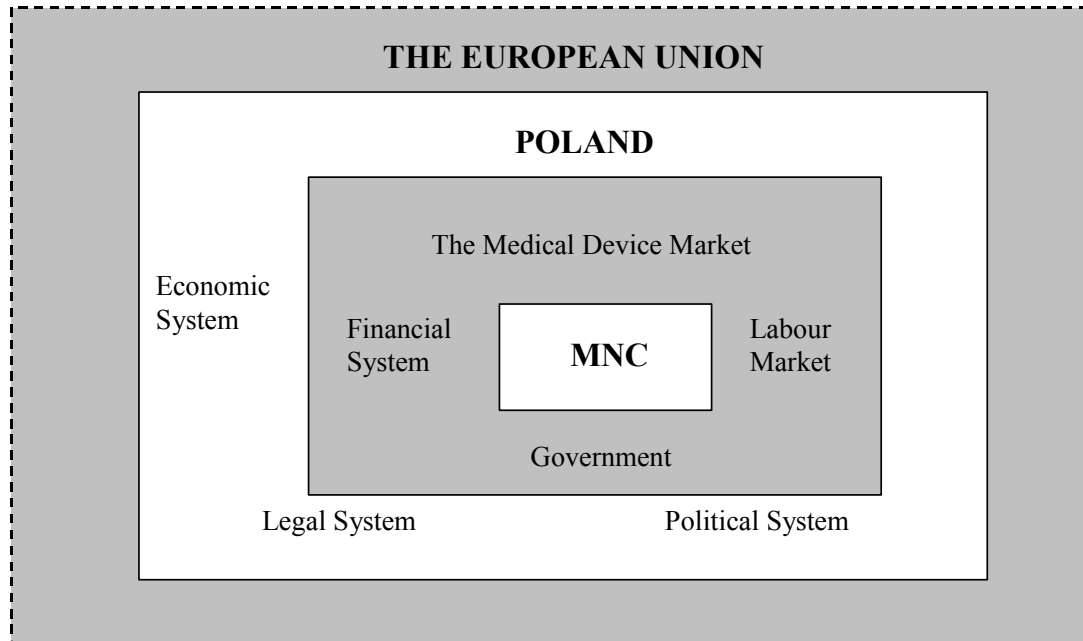
⁷⁰ Porter, 1980, p 44

⁷¹ Grant, 1998, pp 70-71

relationships is not of significant importance for the problem definitions of this thesis.

3.3. The Modified Institutional Model

The research questions of this thesis allow for a modification of the Networks Institutions Model. The focal point of this thesis is the market for medical devices and its transformation as a result of a Polish EU membership. The objective of the modification is to create a model that better grasps the fundamentals of this thesis. A supranational organisation has been added as an outer rectangle, representing the European Union. It has moreover been found necessary to exclude some of the institutions that are not likely to be affected by a Polish EU membership, in the short run. The majority of institutions in the societal sector will not change with the entrance to the European Union, and is therefore not of interest for the purpose of this thesis. Moreover, one institution, the economic system, has been added into the model. This institution refers to macro economical issues and the general economic conditions within Poland. The following model explains how the model is utilized within this research.

Figure 9 “The Modified Networks Institutions Model”

Source: Own Construction

3.4. Strategic Development

This section aims to introduce Grant’s basic framework for strategy, and put it into the perspective of this research. As explained in the methodology chapter, the Scenario Analysis Approach is here put in the perspective of strategic development and why it should be used in a business context.

3.4.1. Strategy and the external setting

Grant has developed a constructive framework for analysing and developing strategies. The strategy is within this framework seen as a link between the company and its environment. The external setting, with special focus on the stakeholders within the industry, should be put in the perspective of the company’s internal setting, such as goals and values, resources and capabilities and structure and systems. A successful strategy brings these elements together, and attains the overall objective of the business.⁷²

⁷² Grant, 1998, p 12

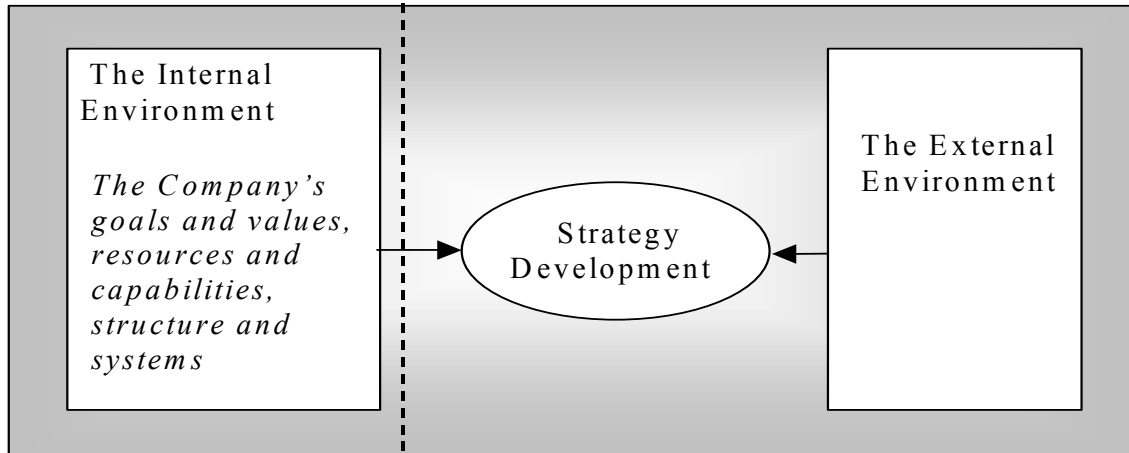
The external environment includes influences on a macro environmental level and a local or industry specific level. Within the macro environment, political, economic, social and technical forces are influencing the specific market. How these forces can influence the company, has been explained using the Institution Network Model. These factors can further determine the opportunities and threats the company will face in the future. The industry environment consists of forces that are specific to the industry and vital to the company's daily operations. It is of importance to understand the surrounding competition on the market, and how this will influence the activities of the company.⁷³ Moreover, it is important to put this into a future perspective, to gain an understanding of the future turns of the external environment.⁷⁴

As explained previously, this thesis has the objective of analysing the external environment and the changes that occur with a EU membership. The external environment includes the influences of the political and economic system of interest to the specific market. It moreover contains an industry analysis, where the market is analysed from the perspective of the various stakeholders.

The internal analysis is left out from this research. However, it is important to accentuate the relation between the internal and external environment, when it comes to strategy development. The following model aims to explain the above discussion, and to point out how strategic development is confronted within this thesis.

⁷³ Grant, 1998, p 53

⁷⁴ Grant, 1998, p 424

Figure 10 “Strategy and the External Setting”

Source: Own Construction based Grant, 1998, p 12

3.4.2. Scenario Planning

Scenario planning as an approach to strategic development first emerged following World War II as a method for military planning. The approach was pioneered in the industrial field by Royal Dutch/Shell in the early 1970s and is credited with helping Shell to brace itself for the OPEC-induced oil price hike in 1974.⁷⁵

Scenario planning is a process approach to strategy that takes the view that the future in the business world is unpredictable, even though certain events can be predetermined.⁷⁶ Scenario planning approaches the ambiguity and uncertainty aspect of the strategic questions facing the strategic management of a company. Since strategy is about planning for the future, the uncertainty aspect cannot be removed, compared to traditional strategy approach.⁷⁷

The traditional strategy approach is characterised as either rationalistic, which involves seeking to identify the optimal strategy for a company, or evolutionary, which suggests that strategy emerges, and can only be understood in retrospect. This is based on a belief that the business world is

⁷⁵ Wright, 2000, p S433

⁷⁶ Wright, 2000, p S433

⁷⁷ Van der Heijden, 1996, p 23

predictable, and that strategies that guarantee success can be developed. These strategies are irrespective of unforeseen events. This approach, to a large extent focuses on rational analysis and a huge reliance upon data and information.⁷⁸ According to Van der Heijden, this approach has attractions for managers, since it perpetuates the belief that it is possible to be in control of strategy. Unfortunately, this approach to strategy has proven to be insufficient when it is needed the most, i.e. when an unforeseen event occurs that makes the strategy obsolete.⁷⁹

Therefore, the strategic management of a company needs to plan for more than one possible outcome of the future. By using scenario planning, a company can be prepared for several different turns in the contextual environment, and might even have a good solution for a possible problem before it occurs.⁸⁰ According to Schwartz, scenarios “*can help us recognize and adapt to changing aspects of our present environment. They form a method for articulating the different pathways that might exist for you tomorrow, and finding your appropriate movements down each of those possible paths. Scenario planning is about making choices today with an understanding of how they might turn out*”.⁸¹

Scenarios should, in the end, be evaluated on how they affect management decision-making concerning the focal decision. The scenarios are to be seen as a facilitator of organizational learning through strategy development, not a completely truthful description of the future.⁸²

Bennett presents a number of critics to the scenario analysis method, to predict the future. Firstly, it is said that many scenarios may be required, that are each very time and resource demanding to investigate further. Secondly, it is stated that the people that examine the various possible scenarios, may be overloaded with complex information, involving a numerous amount of ifs and buts. Finally, although scenarios describe various possible situations, they

⁷⁸ Wright, 2000, p S433

⁷⁹ Van der Heijden, 1996, p 23

⁸⁰ Ringland, 2002, p 4

⁸¹ Schwartz, 1996, pp. 3-4

⁸² Wright, 2000, p S433

might not indicate the best possible courses of actions. However, it is also considered to be a highly practical approach to forecasting. Moreover, scenario planning is enabling the combination of an extensive range of political, economical, social and technological factors into predictions of the future.⁸³

⁸³ Bennett, 1996, p 83

Part II



Empirical Findings:
EU and Poland
The Medical Device Market

4. EU AND POLAND

This chapter contains the first section of the empirical findings. The first part contains a brief description of the EU enlargement and the Single European Market. Hereafter a short description of the Polish transition is given. This is considered of importance in order to understand Poland of today. The following part is describing the institutions presented in the Modified Network Institutions Model. The selected institutions are described from a contemporary perspective, but also taking in the effect of the coming EU membership, when relevant. Hence, this chapter will focus on the following research question:

Research Question 1:

What are the characteristics of the political and economic systems of Poland, and how will these systems change with a EU membership?

4.1. European Union

4.1.1. The Enlargement

Soon after the fall of the Berlin Wall in 1989, the European Community established relations with the former communist countries of eastern and central Europe. Moreover, the Community concluded co-operation agreements with Bulgaria, the former Czechoslovakia, Estonia, Hungary, Latvia, Lithuania, Poland, Romania and Slovenia. In 1993, at the summit in Copenhagen, the European council declared that “*all the associated countries of Central and Eastern Europe that so desire should become members of the Union.*”⁸⁴

In the 1990s, the European Community concluded the Association agreements with ten of the central and eastern European countries. These agreements provided the legal basis for bilateral relations between the

⁸⁴ European Commission, 2001, p 4

applicant countries and the countries already members of the EU. These agreements contributed to a rapidly growing trade between the EU member states and the applicant countries.

This is complemented with the European Agreements, which provides the legal basis for the relationship between the EU and the associated countries. The agreements cover areas such as trade-related issues and a platform for a political dialogue. The European Agreements monitor the overall progress made by the applicant countries, in the adoption and implementation of the *Acquis Communautaire*.⁸⁵

4.1.2. Membership Criteria

At the previously mentioned Copenhagen Summit, the Union defined the membership criteria, often referred to as the “Copenhagen criteria.” The membership criteria compel that the candidate countries must have achieved:

- Stability of institutions which guarantees democracy, the rule of law, human rights as well as respect for and protection of minorities; political criteria.
- The existence of a functioning market economy and the capacity to handle the competitive pressure and market forces within the Union; economic criteria.
- Ability to take on the obligations of membership, including devotion to the aims of a political, economic and monetary union; formal criteria.

This criterion was extended during the Madrid European Council 1995:

- A functioning administrative structure, and a transposing of EC legislation to national legislation. The legislation must moreover have been implemented effectively through appropriate and judicial structures; formal criteria.⁸⁶

⁸⁵ European Commission, 2001 p 11

⁸⁶ <http://europa.eu.int/>, 2002-12-04

4.1.3. The Negotiation Principles

In late 1997, the European Council established an overall process for all countries with the wish of joining the EU. The negotiation process is based on four principles. Firstly, the negotiations focus on the candidate country's adoption, implementation and enforcement of the *acquis*. Secondly, transitional arrangements may be agreed upon, however they are limited in scope as well as duration. Moreover, they should not have an impact on the competition, or the functioning on the internal market. In addition, they should be accompanied by a clear plan of the final adoption of the *acquis*. The third principle states that each of the negotiations of the candidate countries is conducted individually. The final principle is about the possibilities for the candidate countries to “catch up” in the enlargement process, and become one of the first tier countries. This means that every country has the right of initiating negotiations if they have made reasonable progress in their preparations of becoming EU members.

4.1.4. The Single European Market

One of the areas that is subject to negotiation in the enlargement process, is the applicant countries' adoption to the Single European Market. The creation of a Single European Market has long been one of the fundamentals of the European Cooperation. The final goal is to establish rules and policies regarding the Single European Market so that businesses can trade across national borders as well as enhancing the opportunities that arise with a large free trading area. All EU member firms have the legal right to compete on equal terms with domestic firms on other EU markets.⁸⁷ The advantages of a Single European Market is said to be derived from the wider availability of economies of scale, which will result in lower production costs for European firms. Moreover, the intensified grade of competition will lead to lower prices. The European firms will be more competitive in both international and indigenous markets. In a long-term perspective this will lead to increased

⁸⁷ Bernitz, 1992 p 60

levels of employment and investment. Another benefit is an increased level of innovation among the firms within the Single European Market.⁸⁸

Single European Act (SEA)

The legal ground for the establishment of the Single European Market is to be found within the Single European Act. The act is to a large extent based on the identification of three types of barriers, physical, fiscal and technical barriers to trade. These barriers hinder the completion of the internal market, and consequently the end goal, freedom of movement of goods, persons, services and capital.⁸⁹ *Physical* barriers encompass obstacles such as national indirect taxation and internal customs. These barriers lead to a number of practical difficulties for companies with the aim of moving goods and services across national boundaries. *Fiscal* barriers relate to different excise duties as well as indirect taxation on cross border trade. Significant differences in national legislation regarding taxes can provide major market distortions.⁹⁰ The *Technical* barriers comprise of national product registrations, national industry standards, certification processes and national testing. The technical barriers prevent many European firms to benefit from economies of scale and research and development.

The Internal Market Paper outlined strategies to handle and overcome the technical barriers. These strategies were founded on a three-tier approach based on:

- Mutual recognition
- The select approximation of standards
- The strengthening of common reporting and notification procedures.⁹¹

The first approach deals with mutual recognition. Mutual recognition means that each member state is forced to give access to goods accepted as fit for sales in another EU Member State. Furthermore, the Commission decided to

⁸⁸ Johnson and Turner 2000 p 49

⁸⁹ Wyatt, Dashwood 1993, p 353

⁹⁰ Mercado et al, 2001 p 89

⁹¹ Ibid

standardize the above-described essential requirements in areas where such approximation is beneficial. Moreover, the three-tier approach included mutual information and notification processes. This means that the Commission has to be informed by each change in the regulation and standards made on national level, through the national authorities. The community has moreover, introduced new legislation for certain industries that are considered to be especially hampered by technical barriers.⁹²

4.2. The Polish Transition

During the 1980's, the opposition against the communist rule in Poland grew stronger and the demand for reforms increased. The starting point is said to be the creation of the Solidarity movement in 1980, in association with the strike at the shipyard in Gdansk. This traders' union, and later on, mass movement, was a pro-reform movement that started the struggle against the establishment in both Warsaw and Moscow. Years of harassments from the authorities could not crush the opposition and its demand for political, social and economic reforms. More and more Poles started to question the communist regime and instead support the opposition. Towards the end of the decade, Mikhail Gorbachev had started to reform the Soviet Union. The Polish communist party felt that both the political and military support from the former USSR was incomplete. This resulted in the abandoning of the notion of one-party rule, and semi-free elections were held in 1989. The Solidarity movement was the winner of the election and the communist party agreed to give up the power in Poland.⁹³

Nearly 40 years of communism and a centrally planned economy, left Poland in a deeply unfavourable economic position after the collapse of the communism system. The economic problems were numerous, huge foreign debt, extremely high inflation together with an extreme misallocation of resources and state owned enterprises deeply lagging behind.⁹⁴ Since 1991,

⁹² Mercado et al, 2001 p 89

⁹³ Cordell, 2000, pp 2-5

⁹⁴ Belka, 2001, p 13

Poland has been engaged in an intense transition towards a market economy system. Poland has managed to make considerable progress in terms of liberalisation, privatisation, restructuring and reforming the entire economy.⁹⁵

The transformation from a centrally planned economy towards a market economy in the case of Poland can be divided into different development phases. The first stage of the transformation began in 1991, and is often referred to as the “Polish Big Bang.” At this stage, the main objective was to stabilize the, at the time, extremely unstable economic conditions in the country. Furthermore, the objective was to build and develop the institutions, necessary in a well functioning market economy. This took place through various liberalization measurements that helped the building of market economy. The restrictions of the trading of goods and foreign exchange were abolished. Moreover, the Polish currency “zloty” became internally convertible.⁹⁶

The first years of transition were a very difficult period with extremely high inflation rates, as well as steadily increasing unemployment rates. The positive outcomes of the difficult first years of transition were that the majority of price distortions were eliminated, which allowed for the market to send out correct signals to companies. The interest rates as well as the foreign exchange rates were set at realistic levels. However, the privatisation process during this time proceeded slowly.⁹⁷

To this day, small-scale privatisation has been completed successfully, but the large-scale privatisation has proceeded relatively slowly. Comparatively many enterprises are state owned and most of these companies are in poor financial shape.⁹⁸ The overall achievement of the first phase of Polish transition is that the economy became manageable together with the fact that people started behaving in a predictable manner, out of basic economical principles. Among the Central and Eastern European countries, Poland was

⁹⁵ Jolly, Kettaneh, Sljivic 2000 p 7

⁹⁶ Belka, 2001, p 14

⁹⁷ Ibid

⁹⁸ Mercado et al, 2001, p 263

the first country that fell into recession, but also the first country to achieve positive growth.⁹⁹

The positive growth started in the manufacturing industry in 1992. This growth phase also included a new tax system, with the introduction of basic personal income tax, corporate taxes as well as VAT. Between 1995 and 1998, Poland experienced an enormous GDP growth, with around 6-7% per year. During these years, the inflation rates were very low and the unemployment rate was falling. It was also during this period that the FDI started to flow into the country. Poland was perceived as a highly attractive location for foreign direct investments and was regarded as one of the most promising emerging markets in the world.¹⁰⁰

The favourable economic situation in Poland has somehow subsided during recent years. There are as mentioned before, a number of inefficient state-managed industries and in addition, Poland has a large small-scale agricultural sector that still weans on subsidies. The Polish agriculture sector will have to come to terms with more open market, especially with the prospective of the coming EU membership.¹⁰¹ According to the Commission, Poland was considered to be a well functioning market economy already in 1997. In 2001, the Commission found that *“Poland is a functioning market economy. Provided that it continues and intensifies its present reform efforts in a consistent policy environment, it should be able to cope with the competitive pressure and market forces within the Union, in the near term.”*¹⁰²

In order to be successful in the Polish market, it is vital to consider the fact that Poland has been a market economy for only twelve years. All the changes that most of the Western countries have been through during a period of decades, Poland has gone through in a ten-year period.¹⁰³

⁹⁹ Belka, 2001, p 22

¹⁰⁰ Belka, 2001, p22

¹⁰¹ <http://www.worldmarketsanalysis.com>, 2002-10-23

¹⁰² Regular Report 2002, p 33

¹⁰³ Wickman, L., (2002-10-10)

4.3. Political System

The new Polish constitution was created during the 1990s, stating that the country is a parliamentary republic.¹⁰⁴ The governmental system of Poland is based on the ideology of separation and balance between the powers. The President and the Government conduct the executive power.¹⁰⁵ The legislative power is vested in the parliament's two houses the Sejm and the Senate, where the Sejm is the most influential body in the legislative process.¹⁰⁶ The representatives in the Sejm have been elected via party lists and represent their party's opinion. The threshold for parties entering the Sejm is 5%, and 8% for coalitions.¹⁰⁷

During the whole of the 1990s, Poland's political environment has been very dynamic, where one coalition has succeeded the other. The Polish political environment is characterised by political pluralism, where a comparatively large number of parties are struggling for gaining power.¹⁰⁸ Hence, the Polish economic transformation has taken place in a very complex political environment. Even though the political history of post-Communist Poland is characterised by a number of fragile coalitions, reforms of steering the country towards a functioning market economy seem to have been the main objective for all of them.¹⁰⁹ The current political situation will be described later on in this chapter

The major effect for the Polish political system with a EU membership is that there will be new supranational institutions that also are governing the country. The decisions taken in these institutions will be compelling in Poland. The country is hereby giving up a part of its sovereignty.¹¹⁰

¹⁰⁴ www.sejm.gov.pl, 2002-10-21

¹⁰⁵ <http://www.worldmarketsanalysis.com>, 2002-11-09

¹⁰⁶ www.senat.gov.pl, 2002-10-21

¹⁰⁷ www.sejm.gov.pl, 2002-10-21

¹⁰⁸ *The Economist*, 2001-08-18, p 39-40

¹⁰⁹ *Review of Business*, Fall 2001, p 33-39,

¹¹⁰ Van Steen, M., (2002-10-16)

4.4. Government

During the 1990s, the political situation in Poland was very unstable with governments having to fight bad economy, high national debts, rising unemployment, high inflation, social unrest and political shattering. Today the situation is considered to be more stable.¹¹¹ The last election to parliament in Poland was held in September 2001, resulting in the formation of a new government. This new government is a left-central wing coalition and stands for a change in the political field. Former governments during the 1990s have mostly been right-wing coalitions.¹¹²

The largest party within the government is the Democratic Left Alliance (SLD), which is the former communist party, now transformed to a social democratic movement. The SLD party is working in direction of reforming the society and is supporting business development and a EU-membership.¹¹³ SLD has together with the Polish Peasants' Party (PSL) formed the current government, which is led by Prime Minister Leszek Miller, representing SLD.¹¹⁴ The PSL is originally a party fighting for the Polish countryside. The party stands in favour of farm subsidies, import controls and governmental intervention. However, the party has been accused by their voters for now being more concerned about what EU wants, and being to soft on defending the main issues for the Polish countryside. The hard task for the government is now to try to make the Euro-sceptic Polish countryside and the pro-EU urban elites to come closer in their opinions about Poland and EU.¹¹⁵

4.4.1. Political agenda

It is expected that the current government will push coherent reforms to narrow the hole in the public finances. The Polish budget has been characterised by rising deficits the last three years. Another big issue is to complete the last stages of the privatisation programme, which needs to be

¹¹¹ Swedish Trade Council, 2002-07-24, p 10

¹¹² <http://www.economist.com>, 2002-10-23

¹¹³ Financial Times, 2001-09-27, p 12

¹¹⁴ <http://www.economist.com>, 2002-10-23

¹¹⁵ Financial Times, 2002-06-17, p2

speeded up. A completed privatisation would ease the pressure on the public finances. Further the government has to deal with restructuring the heavy industry and agricultural sectors, reform the pension system and simplify the tax system. Painful tax rises could restore the fiscal balance and bring rates into line with the EU.¹¹⁶

Since the liberalisation, the prevailing goal of a Polish EU membership has helped to ensure policy consensus among different governments in the past. Even if the current government has ideological differences between the coalition members, this consensus is expected to remain. The new government has set a EU membership as its prime aim, and is expected to speed up the reforms to close the distance to the EU.¹¹⁷ The government states that it will be working to bring Poland into EU as promptly as possible and if Poland would not become a EU member, the country would “stumble along the periphery of civilisation”.¹¹⁸ But there is still much work and many reforms to be completed, to prepare Poland for a EU membership. Commitment from the Polish government and authorities is required, in order for the country to be ready in time.¹¹⁹

4.4.2. Local Governments

Poland is divided into 16 administrative regions, Voivodships (Województwo). Each Voivodship has an own local parliament that is led by a marshal. The marshal is responsible for the daily administration and will most probably play an increasingly important role in the development of trade and investment for the Voivodship. Further there are boroughs called Poviats (Powiat) and smaller town or parish councils called Gminas.¹²⁰

The objective of establishing market mechanism in Poland, have naturally resulted in reforms with the aim of decreasing the government's central decision making role, and hence, to decentralise the administrative structure.

¹¹⁶ <http://www.worldmarketsanalysis.com>, 2002-11-09

¹¹⁷ Ibid

¹¹⁸ Financial Times, 2001-10-22, p12

¹¹⁹ Van Steen, M., (2002-10-16)

¹²⁰ Jolly et al, 2000, p24

The reforms have aimed to improve the effectiveness of the public administration and involved radical changes in the financial responsibility at all levels.¹²¹ However, the reforms have met with criticism, since they are said to lead to a disintegration of the country, and increase the welfare differences between the regions. Hence, some attempts to delay the decentralization process have emerged. There have been efforts to reduce the scope of responsibilities of the local governments, and to limit the financial support for them. There have also been trends towards recentralization, since there are interest groups and political parties that do not believe in the advantages of decentralization.¹²²

The local elections recently held in Poland meant a failure for the SLD to secure majority. Despite gaining victory in the majority of regional parliaments, the SLD failed in achieving absolute majorities.¹²³ However, two leaders of the opposition groupings have promised not to enter into coalition with the SLD.¹²⁴ This is the standpoint of the liberal Civic Platform (PO), a centrist party, founded in 2000 as well as Law and Justice (PiS) a party formed prior to the 2001 elections.¹²⁵

The result will mean that SLD is likely to be forced into coalition with the partner at the national level, the Polish Peasants' Party (PSL). In some cases, SLD might even be forced into coalition with the ultra-nationalists, Samoobrona (SO). This extreme right wing party gained a stable ground in the 2001 elections. The SLD has already entered into coalition with this party in the municipality of Lublin. The development of the local elections is worrying to EU observers who have previously labelled Samoobrona as a fascist party, that has radically protested against government reforms favouring the EU integration.¹²⁶

¹²¹ International Journal of Public Administration, Feb 2001, p 211

¹²² International Journal of Public Administration, Feb 2001 p143

¹²³ Poland Business News, 2002-11-06, p N/A

¹²⁴ Ibid

¹²⁵ <http://www.worldmarketsanalysis.com>, 2002-11-09

¹²⁶ Ibid

4.4.3. From Application to EU Accession

Poland submitted an application for membership to the Council in 1994, formally expressing its will to become a EU member. Hereafter the Commission investigated the possibilities for Poland to become an EU member and expressed its written opinion in 1997, “Opinion on Poland’s application for membership of the European Union – July 1997”. This was a positive report, opening up for accession negotiations between Poland and EU.¹²⁷

In 1998, accession negotiations with Poland started. The focus of the negotiations lied, and still lies, on the creation of terms deciding how Poland will adopt and implement the *Acquis Communautaire*. Furthermore discussions have been held regarding the granting of transitional agreements, their scope and duration.¹²⁸ One of the first chapters that were closed during the Polish negotiation was chapter one, free movement of goods. This chapter was agreed upon relatively smoothly and no major issues rose.¹²⁹

In October 2002, the Commission stated that Poland is likely to be able to become a EU member in 2004. The challenges for the negotiation process today are whether both parties will be able to finalise their positions in time. All chapters need to be closed by the end of this year. At the time of writing, the negotiation chapters regarding competition, agriculture, the budgetary and financing issues remain to be settled. These chapters are considered being the most difficult to reach an agreement upon, since Poland and the EU hold completely different positions.¹³⁰

The signing of the accession treaty is planned to take place in March 2003. Hereafter, Poland will have a referendum in May to accept or reject the treaty. If the vote of the Polish people is positive to a EU membership, Poland will become a member of EU in May 2004.¹³¹

¹²⁷ Jolly et al, 2000, pp 15-18

¹²⁸ <http://europa.eu.int>, 2002-10-31

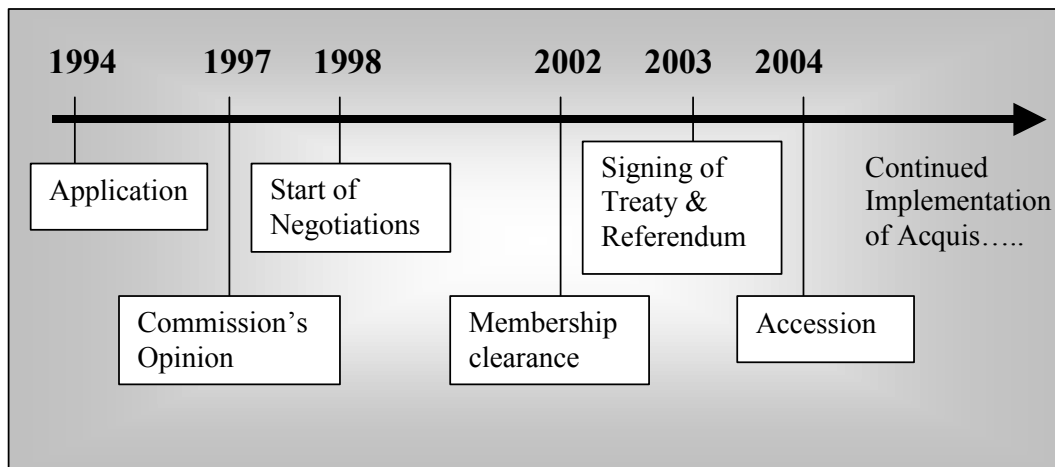
¹²⁹ Van Steen, M., (2002-10-16)

¹³⁰ Ibid

¹³¹ Ibid

The objective of the coming Copenhagen summit is to finalise the negotiations with the ten applicant countries. It will consequently determine whether Poland's effort of implementing the *Acquis Communautaire* have been enough in order to become a EU member. However, the implementation of the "acquis" is a time demanding procedure, and Poland's effort will continue after the signing of the accession treaty. The time needed for Poland to fully implement all chapters of the "acquis" completely, remains to be seen. The adjustment of the legal acts has proven to be relatively separated from the actual implementation of EC law.

Figure 11 "The accession timeline"



Source: Own construction

4.4.4. Poland and the Membership Criteria

The current situation declares that Poland will fulfil the requirements for membership set in the Copenhagen criteria, in time for the planned accession.¹³² However, the 2002 progress report has been criticised for being somewhat over-optimistic. The very positive report is said to be a result of a fear from the Commission, that a more harsh assessment might fuel EU opposition in Poland.¹³³

¹³² Regular Report, 2002, p 32

¹³³ Financial Times, 2002-10-09, p 2

Political criteria

Already in the Opinion in 1997 the Commission stated that Poland fulfils the political criteria to guarantee democracy, the rule of law, human rights and respect for and protection of minorities. Since then, Poland has made considerable progress and the country continues to fulfil the first of the Copenhagen criteria.¹³⁴

Economic criteria

Concerning these criteria, the Commission states that the Polish authorities show commitment to fulfil the economic requirements of the EU accession criteria and that Poland today is a functioning market economy. Poland has achieved macroeconomic stability and the reforms continue. Further it is stated that if the country continues to develop according to the reform path, it will be able to cope with the competitive pressure and market forces within the Single European Market. However, Poland has to this day, not been able to fulfil the criteria when it comes to competition. The competition policies are presently not fully implemented, and the negotiation chapter remains open.¹³⁵

Still, there are some areas that need to be improved. The privatisation of state owned companies has to be complete, especially in the heavy industry sector. The financial sector, agricultural sector and energy distribution are other sectors in need of reforming. Within issues related to company law, bankruptcy procedures and the registry of land there are still a need for improvements. Regarding the market economy institutions, the Commission calls for a more clearly shown independence of the Polish Central Bank. This would increase the investors' confidence in the country and ensure macroeconomic stability.¹³⁶

¹³⁴ Regular Report, 2002, p 32

¹³⁵ Regular Report, 2002, p 44

¹³⁶ Ibid

The membership criteria further require that Poland should be aiming towards a political and monetary union.¹³⁷ The EU will hereby continue to influence the development of the Polish economic system even in the longer run. Poland is presently not able to fulfil the requirements for joining EMU, but a EU membership means that the country will be striving to fulfil it.

Formal criteria

The adoption of the *Acquis Communautaire* started slowly in Poland but has later on accelerated. The vast majority of the primary legislation is now in place and most sectors are aligned with the “acquis.” However, some sectors are still lacking the necessary implementation regulations, such as medical devices. In the negotiations a detailed plan has been agreed upon to close the remaining gaps in the adoption of the “acquis.”¹³⁸

The administrative capacity of Poland to handle the *Acquis Communautaire* has advanced much since 1997, but there is a need for further development.¹³⁹ Regarding the new approach directives, explained later in this chapter, the market surveillance institutions are still not sufficiently developed.¹⁴⁰

4.4.5. The Public Opinion

The public opinion in Poland is presently 60% in favour of the EU membership and 20% to 25% against. The remaining population is uncertain about where to place their vote.¹⁴¹ Among the EU advocates are the majority of the parliament both from the government party and the opposition, the big newspapers, the big corporations, and the powerful Catholic Church. These together represent a majority of the influencing bodies in the country.¹⁴² There is a fairly small, but well organised movement opposing the EU membership. The opposition is strongest in the rural and industrial areas of Poland. The

¹³⁷ European Commission, 2001, p 4

¹³⁸ Regular Report, 2002, p 136

¹³⁹ Regular Report, 2002, p 135

¹⁴⁰ Van Steen, M., (2002-10-16)

¹⁴¹ Kwast, E., (2002-10-07)

¹⁴² Financial Times, 2002-06-12, p 1

discontent with the economic reforms in areas with high unemployment, used as an argument of the EU opposition, can become an obstacle to the Polish EU accession.¹⁴³ Today, the supporters outnumber the opponents, but the undecided voters could still trouble the results. The official opinion of the Polish government is that that the country needs a clear victory to show that the nation is united on accession. Still, the Polish people are unlikely to vote in favour for accession with eagerness. The referendum will most likely not be an easy victory for the EU advocates, since the opposition is growing.¹⁴⁴ The government does not underestimate the risk that the Poles will reject the EU accession treaty, if they find the Commission's final position not generous enough. As stated by Mr Miller: *"If they are convinced that the negotiations ended with good results for Poland, they will vote Yes. If they aren't, they will vote No."*¹⁴⁵

4.5. Legal System

The Polish legal system is based on European continental legal systems. It is based upon statutory law created by the two houses in the Parliament. The laws are hereafter complemented with regulations.¹⁴⁶ The purpose of the Regulations is to give guidelines of how to implement the Law. The Regulations have to be issued by competent organs stated in the Constitution. The most important ones of these are the President, the Council of Ministers and the Ministries. Most common is that the Minister responsible for the area, which the legal act regulates, creates the regulations.¹⁴⁷

As mentioned before, the legal bases for the Polish EU accession are in the European Agreement (EA). The agreement between Poland and EU entered into force in 1993, and contain obligations for both sides. The EA can be seen as an implementation plan of how Poland shall come as close to the *Acquis*

¹⁴³ Financial Times, 2002-04-16, p 16

¹⁴⁴ Financial Times, 2002-06-12, p 1

¹⁴⁵ Financial Times, 2002-11-23, p 2

¹⁴⁶ Jolly et al, 2000, p 24

¹⁴⁷ <http://www.llrx.com>, 2002-10-21

Communautaire as possible. The EU influence on the Polish legislation has been going on for almost a decade.¹⁴⁸

The first instance courts in Poland are the district courts, the Rejons. These courts are competent to hear criminal law cases, civil law cases and labour law cases. A verdict from the Rejons can be appealed to regional courts Okregs and thereafter to the Courts of Appeal.¹⁴⁹ There is today a major problem with accessibility to the judicial system with long court proceedings and queues before a case can be tried. In Warsaw for example, the length for court proceedings are approximately 40 months.¹⁵⁰

In the Regular Report 2002, the Commission states that progress is being made in the judiciary. There are currently reforms going on both concerning the number of courts and the administration of them. For example an increasing number of courts have been computerised in order to speed up the procedures. In addition, more judges and administrative personnel are being employed. Efforts are still to be made to ensure that the progress delivers improved efficiency in the judiciary, and to prioritise the training of judges in EC Law.¹⁵¹

Complicated legislation procedures, unclear formulated laws and regulations, and not complete practical implementation are further issues that create considerable obstacles to the business of foreign companies in Poland.¹⁵² The ongoing economic reforms, and the future EU membership are constantly requiring updating and changes of the judiciary and the laws. The legal system is still very dynamic and developing to match European standards.¹⁵³

¹⁴⁸ Van Steen, M., (2002-10-16)

¹⁴⁹ <http://www.llrx.com> 2002-10-21

¹⁵⁰ Regular Report 2002, p 22

¹⁵¹ Ibid

¹⁵² Swedish Trade Council, 2002, p 45

¹⁵³ Jolly et al, 2000, p 24

4.6. Economic System

The Polish economy is very closely connected to the world and European economy, and it furthermore closely follows the trends of the German market, since Germany is the largest Polish trade partner. About one third of the foreign trade is conducted with Germany.¹⁵⁴

The GDP growth had a steady average increase of about 4-5% between 1997 until 2000, but decreased dramatically in 2001 when the growth fell to 1%. The GDP growth for 2002 is expected to stay around 1%.¹⁵⁵ The newly elected cabinet have launched a program, with the goal of a steady increase of the GDP in a three year period. The objectives of the programme are to reach 1% during the first year, 3% the next and finally a 5% growth is expected in the final year.¹⁵⁶

The unemployment level is the highest among the Central European countries, and has steadily increased since 1997. The unemployment rate reached 17,4 % the first half of 2002. This is however, the same level as in 2001.¹⁵⁷ The unemployment is unevenly spread throughout Poland, with very high rates in the rural parts of the country, and very low in the biggest cities.¹⁵⁸

The inflation rates have steadily decreased since the middle of the 1990s, when the inflation rates reached extreme peaks. The interest rates have decreased significantly since the same period and are forecasted to stay around 12% in 2002.¹⁵⁹

The biggest obstacle for reaching the previously mentioned GDP growth programme is budget deficits. The budget deficits have increased during the recent two years. Some payments have been postponed in order to save time

¹⁵⁴ Kwast, E., (2002-10-07)

¹⁵⁵ <http://www.worldmarketsanalysis.com>, 2002-10-23

¹⁵⁶ Kwast, E., (2002-10-07)

¹⁵⁷ Emerging Europe Market Review, 2002, p N/A

¹⁵⁸ Kwast, E., (2002-10-07)

¹⁵⁹ <http://www.worldmarketsanalysis.com>, 2002-10-23

and money. One example is the cut in corporate taxes, which has been postponed. This year it is settled to be 28%, which is a disappointment for business activities.¹⁶⁰ The government consumption has decreased since 2001 and is expected to do so also in 2003.¹⁶¹ The following table summarises the development of Poland's main economic indicators.

Table 1 "Poland's main economic indicators, 1997-2003"

		1997	1998	1999	2000	2001	2002 forecast	2003 forecast
GDP	USD bn	144,0	157,7	155,4	157,5	176,2	183,9	201,2
GDP growth	Real % growth	6,8	4,8	4,1	4,0	1,0	1,0	2,5
Unemployment rate	%	10,3	10,4	13,0	15,0	17,4	19,0	19,5
Inflation	%	14,9	11,8	7,3	10,1	4,2	2,2	N/A
Interest rates	%	25	15,9	16,4	18,9	17,5	12	N/A
Budget deficiency	% of GDP	N/A	-3,2	-2,7	-2,2	-5,4	-5,1	-5,0
Government consumption	Real % growth	3,1	1,4	1,5	1,3	3,0	2,5	2,0
Investment	Real % growth	20,8	13,8	6,1	3,9	-10,2	-4,5	4,0

**Sources: Emerging Europe Market Review, 2002, p 15 and
www.worldmarketanalysis.com**

In a short-term perspective, the EU membership can have a troublesome effect on the Polish economy. The state owned enterprises, active in the heavy industry sector, will not receive any state aid, and the agricultural sector will face major reforms and restructuring. The Polish firms will face harsh competition from financially strong and more efficient foreign firms, to a larger extent than today. This will likely result in increased unemployment.¹⁶²

¹⁶⁰ Kwast, E., (2002-10-07)

¹⁶¹ Emerging Europe Market Review, 2002, p 15

¹⁶² Van Steen, M., (2002-10-16), Europe Intelligence Wire, 2002-10-14, p N/A

In a long-term perspective, a EU membership appears more positive. The access to the Single European Market will foster growth within the Polish firms, and the foreign firms, that have managed the new competitive situation. A EU accession is probable to lead to increased economic output in the long term, higher income in the private sector and higher profits for the companies. This will lead to a better situation for the Polish state since it will have larger incomes from taxes and a smaller amount of unemployed to provide for.¹⁶³

4.6.1. The Tax Environment

The tax system is becoming increasingly transparent and efficient. In 2001, new commercial and accounting regulations were introduced, Polish Accounting Regulations (PAR). These are based on the EC's seventh directive and the regulations provides for the introduction of an accrual accounting concept, requirements for tax-effect accounting, consolidation of financial accounts and requirements for computerised accounting systems.¹⁶⁴

The current government has committed itself to reduce the present tax rates.¹⁶⁵ This is a part of the previously mentioned growth programme. The current level of corporate tax is 28%, but has the target of being reduced in 2004 to 22%.¹⁶⁶ Because of the fact that the government is fighting a budget deficit the pace of this tax reform has been slowed down, but the plan is to continue even though the reductions might not be as large as first planned.¹⁶⁷

The income tax rate is presently progressive ranging from 19% to 40% depending on income. The level applicable for capital gains tax rate and branch tax rate is 28%. Dividends are taxed at the level of 15%. Indirect taxes, such as VAT are at 22% as the highest and 7% as the lowest.¹⁶⁸

¹⁶³ Patyk, B., (2002-10-09)

¹⁶⁴ World Markets Research Centre, 2002, p 36

¹⁶⁵ World Markets Research Centre, 2002, p 35

¹⁶⁶ Swedish Trade Council, 2002-10-07

¹⁶⁷ Patyk, B., (2002-10-09)

¹⁶⁸ World Markets Research Centre, 2002, p 35

In the view of EU integration, the taxation environment has been subject to some criticism. The shortcomings have been highlighted by the Commission, which has concluded that the VAT is such that it sometimes discriminates against imported products, in favour of domestic products. Moreover, the tariffs and duties have not always been as harmonised as planned, especially in the heavy industry sectors. Another shortcoming is the lack of tax inspection. Because of this, it will be very hard to establish a strong and stable tax base. However, the taxation environment has improved considerably during recent years and is expected to improve significantly during 2003.¹⁶⁹

4.6.2. Investment Incentives

The Polish governments have during the 1990s implemented several investment incentives to attract foreign direct investment. This has proven to be successful, and Poland is among the leading countries in Central and Eastern Europe when it comes to investments made by foreign companies. These incentives are currently valid as the Polish government is still trying to attract more foreign companies to invest in the country.¹⁷⁰

The government offers financial incentives in the form of grants depending on different investment criteria. These criteria are based on the size of the investment, if the investment creates new job opportunities, or result in technology transfer into the country or modernizes the domestic companies' technology. Example of grants available are investment grants providing the companies reimbursements of up to 25% of the investment, and employment and training grants, providing the company reimbursements for created jobs and training of employees up to a maximum figure.¹⁷¹

Companies that benefit from the above mentioned grants could also be eligible for further support. Of importance however, is that the maximum amount of combined applied incentives is 30% of the total investment cost in

¹⁶⁹ World Markets Research Centre, 2002, p 37

¹⁷⁰ Patyk, B., (2002-10-09)

¹⁷¹ Paiz, 2002, pp 1-10

Warsaw, and in other areas up to maximum 50% of the total investment cost.¹⁷²

Poland has also created Special Economic Zones (SEZ) where investing is especially beneficial. Investing companies are here offered preferential tax conditions both regarding company income tax, real estate tax and in some cases personal income tax as well. These offers are additional to the investment incentives that are available countrywide. To a certain extent, these incentives will be subject to a change, with the Polish EU accession, since they do not comply with the European competition laws.¹⁷³

4.7. Financial System

In late 1991, a program of bank privatisation was announced and a bank-restructuring scheme was designed.¹⁷⁴ The majority of banking stocks have been transferred into the private sector, and to a large extent, to foreign actors. The banking sector is in general considered to be sound, and there are now only two important banks left within the state sector; the main savings bank PKO and the agricultural development bank, BGZ. The domestic banking industry has been criticized for its failure to create sufficient credit services for small and medium sized enterprises. In 2000, there were 73 operating banks in the country and 46 of them, were majority owned by foreign investors.¹⁷⁵ Greater competition is now taking place, which puts pressure on earnings in the banking sector. Banks are also facing increasing competition for retail deposits from non-bank financial firms.¹⁷⁶

According to the Commission, there is no immediate threat to stability of the financial sector. Bank capitalisation has been adequate, and the regulatory and supervisory framework has been substantially upgraded in recent years.¹⁷⁷ In

¹⁷² Paiz, 2002, pp 1-10

¹⁷³ Ibid

¹⁷⁴ Belka, 2001, p 17

¹⁷⁵ <http://www.worldmarketsanalysis.com>, 2002-10-23

¹⁷⁶ Regular Report, 2001, p 32

¹⁷⁷ Ibid

light of the Polish EU membership, further consolidation will be necessary for the banking sector to become efficient by international standards.¹⁷⁸

After being inactive for more than 50 years, the Warsaw Stock Exchange reopened in 1991. More than 200 companies are now listed on the exchange and market capitalisation has reached US\$ 22 billion, which is equal to 15% of GDP. Compared to Western countries, where the market capitalisation reaches 60-80% of GDP, this is still very low in Poland.¹⁷⁹

4.8. Labour Market

During the 1990s the legislation regarding employment changed considerably. The focal issue of these changes was to shift the responsibilities of employment from the state towards the individual. This resulted in a reduction of the number of employees employed in the state-owned enterprises and the public sector. The labour management in the existing privately owned firms are due to their short experience of management, not as developed as in other market economies. Another result of the labour reforms is the emergence of unemployment, which has currently reached levels up to 17%.¹⁸⁰ The previous situation was that the people with high professional qualification, was not really threatened by unemployment. Currently, the unemployment rate for university graduates has proven to be very high as well.¹⁸¹

The regional accessibility of qualified personnel varies in different areas. The more economically advanced the region is, the easier is it to find competent labour and qualified managerial skills.¹⁸² There are usually no problems in finding people that possess the accurate education and academic skills; however, there can be great difficulties in finding people with the right personality and attitude towards the company. This can be again explained by

¹⁷⁸ Jolly et al, 2000, p 34

¹⁷⁹ World Markets Research Centre, 2002, p 22

¹⁸⁰ Jolly et al, 2000, pp 49

¹⁸¹ Labanowski, J, (2002-10-07)

¹⁸² Jolly et al, 2000, pp 49

the fact that Poland and Polish workers do not have the experience of the rules of a market economy.¹⁸³

The managerial market in Poland is characterised by a substantial shortage of executives at middle management level. Individuals with several years of experience at the middle management level, try to achieve a senior management position as quickly as possible. This lays the ground for a competence shortage, which can act as a serious hindrance for companies at an operational level. A further characteristic is job-hopping, which have become a quite frequent trend since the Western enterprises started to enter the Polish market. This happened because of the fact that the Western companies often offered the employees better salaries as well as better opportunities of advancement. However, this have stabilised during the recent years when the supply of managerial skills have increased. The job-hopping has moreover been limited due to standardised compensation levels among companies.¹⁸⁴

4.9. Summary

Poland has since the liberalisation in 1989, gradually transformed its political and legal system to meet the standards of a democratic state. Further a total reconstruction of the economic system was needed to transform into a market economy. All needed reforms have not yet been accomplished and the country is still going through an adjustment process. Currently, the needed reforms are, among others, to increase the efficiency in the judiciary, to create a more transparent tax system and to speed up the privatisation process.

The many governments of the 1990s have struggled with the country's bad economy and rising unemployment. Another problem in the political field has been the unstable political situation with the relatively frequent changes of government. The current political agenda focuses on decreasing the budget deficits. The current macroeconomic situation is characterised by a stagnation

¹⁸³ Wickman, L, (2002-10-10)

¹⁸⁴ Jolly et al, 2000, pp 49

in GDP growth, rising unemployment, and increasing budget deficits. The prime aim of the government is at present to speed up the reforms to close the distance between Poland and EU.

Poland submitted an application for EU membership in 1994, and has ever since, adjusted its regulatory environment to comply with EC legislation. The official aim of both parties is to sign the accession treaty in March 2003, followed by accession in 2004. The signing of the accession treaty will be followed by a Polish Referendum in May 2003. At present, the public opinion is 60% in favour of a EU membership. In a short-term perspective a EU membership is expected to create very difficult conditions for the Polish economy. However, in a long-term perspective the membership is expected to foster economic growth and lead to increased economic output.

This chapter has been discussing the external business environment that companies are facing in Poland. The next section of empirical findings will discuss the special conditions of the dynamic Polish medical device market.

5. THE MEDICAL DEVICE MARKET

This chapter starts by explaining the EC Medical Device Directive and the Polish adjustments made to this Directive. Moreover, the current Polish health care system is explained as well as the future reforms, expected to take place in 2003. The chapter ends up with an industry analysis, based on the framework explained in the theoretical chapter. This chapter will focus on the following research question:

Research Question 2:

What are the characteristics of the Polish market for medical devices, and how will it change with a future Polish EU membership?

5.1. The EC Medical Device Directive

Three Directives, covering an extensive scope of products, regulate the Medical Device sector. The first Directive, adopted in 1990 deals with implantable medical devices. In 1993, the second Directive was adopted, dealing with medical devices in general. The third directive, adopted in 1998, deals with “in vitro diagnostic medical devices.”¹⁸⁵ This description will however focus on the second Directive, e.g. the Directive dealing with medical devices in general, the Council Directive 93/42/EEC. This is the Directive that regulates most of the medical device products, and the products of Mölnlycke Health Care.

5.1.1. The New Approach

The directives concerning medical devices are based on the “new approach” principles. The Directive explains the essential requirements that devices have to meet, when they are put on the market or into service.¹⁸⁶

¹⁸⁵ Eucomed, 2000, p 36

¹⁸⁶ Ibid

The requirements relate to issues such as risk assessment and risk management. Products can only be placed on the market if they have been subject to a risk assessment, a risk management's process as well as a risk/benefit analysis. Hence, *“devices can only be placed on the market provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety”*.¹⁸⁷

The new approach means that the manufacturer takes full responsibility of the safety of the products, as described above. After the products have been placed on the market, market surveillance authorities can control that the product is safe. If the product does not fulfil the requirements, the authorities have the right to withdraw the product from the market.

The new approach consequently shifts the responsibility towards the manufacturer. The main objective with this approach has been to secure innovation, since the manufacturer is not constrained by regulations regarding technical solutions, because of the focus on risk management.

5.1.2. Essential Requirements

Moreover, the Directive states that the solutions adopted by the manufacturer for the production of the device, should be in conformity with safety principles. In selecting the best suitable production solutions, the manufacturer should apply principles that eliminate risk, as far as it is possible. The manufacturer should moreover take adequate protection measures, and inform users of the residual risks due to any shortcomings of the production measures adopted.¹⁸⁸

In order to ease compliance with essential requirements, the Directives should facilitate the harmonisation of European Standards. Compliance with

¹⁸⁷ Medical Devices Expert Group, 2002-06-05, p 26

¹⁸⁸ Council Directive 93/42/EEC, article 3

harmonised standards will provide a presumption of conformity with the essential requirements. The standards however, remain voluntary.¹⁸⁹

5.1.3. Classification and Conformity Assessment

The classification of medical devices is divided into four categories, Class I, Class IIa, Class IIb and Class III. Class I represents low risk products Class IIa low to medium risk, Class IIb medium risk and Class III represents high risk.¹⁹⁰

The Directive contains some conformity assessment procedures, depending on the type of products and the risk involved. These procedures always involve independent bodies, Notified Bodies, which are designated and monitored by some of the EU member states.¹⁹¹

The various classifications of devices are exposed to different conformity assessment regimes. Class I devices are not subject to conformity assessment, except from sterile products and measuring devices, which are subject to a limited extent of conformity assessment. In general, all of the products in the other classes require the procedure of conformity assessment.¹⁹²

5.1.4. CE Marking

Devices that meet the essential requirements and have undergone a correct conformity assessment procedure will be CE-marked. This mark represents a formal statement of the manufacturer that the product is in compliance with the requirements of the Directive.¹⁹³

The CE mark is considered to be beneficial for all involved actors. The manufacturers are ensured that the CE-marked products can be sold all over EU in all European Economic Agreement countries, without undertaking

¹⁸⁹ Brekelmans, C., (2002-10-16)

¹⁹⁰ Council Directive 93/42/EEC, article 9

¹⁹¹ Medical Device Expert Group, 2002-06-05, p 26

¹⁹² Eucomed, 2000 p 39

¹⁹³ Brekelmans, C., (2002-10-16)

expensive compliance procedure in each of the countries. The CE marking is furthermore considered beneficial to patients and hospital staff, since they can be sure that the products concerned have been designed and manufactured to meet high standards.¹⁹⁴

5.1.5. Additional Provisions

Moreover, the Directive represent a number of provisions that indicate the specific nature of medical devices for public health, in comparison with other products covered by the New Approach legislation. These provisions concerns, post market surveillance and vigilance procedures, procedures for system and procedure packs, registration of persons responsible for placing devices on the market, and clinical investigation. Moreover, the provisions concern reclassification of medical devices and precautionary principle.¹⁹⁵

5.2. Polish Medical Device Legislation

For companies, active on the medical device market, Poland has long been considered one of the most difficult countries for registration of products, together with USA, Japan and Taiwan.¹⁹⁶

5.2.1. The Former Legislation

In 1989, preparations began to develop legislation regarding drugs and medical devices. Poland did by that time not have any regulations concerning these kinds of products. The result was a new law regarding drugs and medical devices, which came into force in 1991. This legislation was very similar to the one regulating pharmaceuticals, and did not really consider the special features of medical devices. The 1991 law lead to a very complicated, centralised and bureaucratic system, for registration of products.¹⁹⁷

¹⁹⁴ Eucomed, 2000, p 36

¹⁹⁵ Medical Devices Expert Group, 2002-06-05, p 32

¹⁹⁶ Urbanowska-Bak, Z., (2002-10-07)

¹⁹⁷ Ibid

Under the 1991 legislation, the registration process could take up to 8 months, for one device, or even longer. Some products could take 2 years to get registered. In order to avoid a prolonged registration process, the company had to actively push the process forward, by being in constant contact with the registration office.¹⁹⁸ A very extensive amount of various documents was needed in the registration process. Example of these are: list of suppliers, sterilisation process, product specification, raw material specification, detailed description of facility, stability data, bio compatibility, test methods and test results for all parameters, clinical trials, as well as all labels and leaflets, describing the features and characteristics of the product. Already before the manufacturer applied for marketing permission, it had conducted several tests on the products. Therefore all testing were repeated two times.¹⁹⁹

Under this law, there were two separate authorities responsible for registration for medical materials. There was one agency responsible for registration of smaller medical materials and one agency responsible for larger and more technologically advanced machinery.²⁰⁰

5.2.2. The Adjustments to EC Law

The above-explained law expired the 1st of October in 2002, and a new law came into force. The law is voted by parliament, but there are still no regulations.²⁰¹

The new Polish legislation regarding medical devices is regarded as fully compatible to the European Medical Device Directive 93/42/EEC.²⁰² The classification of medical devices is exactly the same as in the Council Directive 93/42/EEC. The declaration of conformity, essential requirements, issues related to custom made devices, as well as CE marking are all in compliance with the EC Directive.²⁰³

¹⁹⁸ Olejnik, A., (2002-10-11)

¹⁹⁹ Urbanowska-Bak, Z., (2002-10-07)

²⁰⁰ Bartosik, A., (2002-10-09)

²⁰¹ Woloz, I., (2002-10-14)

²⁰² Bartosik, A., (2002-10-09), Roa-Cremeno, M., (2002-10-16)

²⁰³ Bartosik, A., (2002-10-09)

The authorised representative is defined as the person living in the territory of the Polish Republic, or a legal entity located in the Polish Republic, carrying out operations on the behalf of a foreign manufacturer. The authorised representative must, before selling any products, make a notification to the Polish authority.²⁰⁴

All CE marked products will directly meet the Polish requirements of medical devices. Before market authorisation, the authorised representative must register each product, based on the CE mark, declaration of conformity, and labels and leaflets of the product. In comparison with the previous legislation, the registration process has been simplified enormously.²⁰⁵

Hence, in order to be able to sell medical devices in the Polish market, all products must have the CE mark. This issue is however subject to a transitional arrangement, which means that the products that are sold in Poland at the moment, can be sold within the country without the CE mark until the 1st of January 2006.²⁰⁶

In general, foreign companies are pleased with the changes. However, many of the domestic companies, do not have CE mark on their products. To them, this can create huge obstacles in the future, since receiving the CE mark can be a very resource demanding procedure.²⁰⁷

5.2.3. Implementation

As previously mentioned, the law has passed through the parliament and came into force from the 1st of October in 2002, but there are at present no detailed regulations regarding the content of the law.

²⁰⁴ Urbanowska-Bak, Z., (2002-10-07)

²⁰⁵ Urbanowska-Bak, Z., (2002-10-07), Dziolko, K., (2002-10-11), Olejnik, A., (2002-10-11)

²⁰⁶ Roa-Cremeno, M., (2002-10-16)

²⁰⁷ Urbanowska-Bak, Z., (2002-10-07, Dziolko, K., (2002-10-11), Bartosik, A., (2002-10-09)

The opinions vary substantially on when the regulations will be ready. It can take from one up to three quarters to fully implement the law.²⁰⁸ However more optimistic sources argue that only a shorter period will be needed for the Ministry of Health to prepare the regulations of the law.²⁰⁹ A few of them have already been published on Ministry of Health's web page. The law regarding pharmaceuticals has also changed and since there is more money involved in this industry, the pharmaceutical regulations are prioritised, in comparison with medical devices.²¹⁰

One of the implementation aspects of the new act is the merger between the Drug Institute and the Bureau of Medical Device Registration into one certification office for medical products and medical devices. Consequently, the authority that previously registered the medical device products is changing and the specific tasks of this new agency are at the time of writing, not specified.²¹¹ The new registration authority is called Office for Medicinal Products, Medical Devices, and Biocide Products' Registration.²¹² The Ministry of Health has not yet announced the future notified bodies that in the near future will be authorised to give CE certificates.²¹³

The current situation is that the companies active in the market for medical devices do not know under what law their products and activities are regulated. The relatively indeterminate situation is uncomfortable for all involved parties.²¹⁴

The Role of the Interest Associations

There are two major interest organisations working with the medical device industry in Poland, Polfarmed and SPiDSM. Both organizations are taking part in the current creation of regulations for the new medical devices law, as

²⁰⁸ Urbanowska-Bak, Z., (2002-10-07)

²⁰⁹ Dziolko, K., (2002-10-11)

²¹⁰ Olejnik, A., (2002-10-11)

²¹¹ Juszcyk, G., (2002-10-09)

²¹² Gryglicka, I., (2002-11-04)

²¹³ Bartosik, A., (2002-10-09)

²¹⁴ Bartosik, A., (2002-10-09), Urbanowska-Bak, Z., (2002-10-07), Woloz, I., (2002-10-14)

consulting bodies. The interest groups influence on the Ministry of Health is strictly advisory and the Ministry of Health will take the final decision on which regulations to introduce.²¹⁵

Presently there is no extensive cooperation between these organizations in order to influence the Ministry of Health. Lobbying in the medical device market is according to Boston Scientific not existing, “*there is no fighting at all.*”²¹⁶ This is a result of the fact that there are two industry associations, where one is covering pharmaceutical companies and Polish medical device manufacturers, Polfarmed. The other organisation, SPiDSM, mostly has foreign medical device companies as members. The interests of these two organisations are not always the same, for example the issue of the CE mark. Basically all foreign companies have their products CE marked, whereas some of the Polish manufacturers have not. This is further complicated by the fact that Polfarmed is representing both pharmaceutical companies and medical device companies.²¹⁷

Future Challenges

Some critics have been raised about the fact that the new registration office for medical devices will be in a directly subordinated position to the government. It will not be an independent body. Consequently, a company cannot object to anyone if it is not satisfied with a decision of the registration office. According to the law a company has the possibility to protest to Ministry of Health, but this creates a complicated situation, since the Ministry of Health is the head of the registration authority.²¹⁸

Another challenge within this context is the high level of bureaucracy that characterises the Polish authorities. History-wise, the Polish authorities have been working in an inefficient and bureaucratic way and the transparency have been low. In spite of the current reforms of the Polish society, contacts

²¹⁵ Dzielko, K., (2002-10-11), Wolosz I., (2002-10-14)

²¹⁶ Olejnik, A., (2002-10-11)

²¹⁷ Wolosz, I., (2002-10-14)

²¹⁸ Olejnik, A., (2002-10-11)

with public authorities have not become less complicated.²¹⁹ The bureaucracy is deeply rooted in the Polish society and is more visible than in other countries. In many cases, people within the authorities have worked there for a very long time. This creates a hindrance for improvements, since a higher level of efficiency and transparency would increase their power.²²⁰

Further criticism has been raised towards the fact that a company wanting to register a product has to pay for it. This is not the case in the rest of Europe, where you pay a notified body, for receiving the CE mark. However, even if the company has the CE mark on all of the products it is still forced to pay the Polish authorities a registration fee. This is considered to be against the spirit of a free market and creating unnecessary obstacles for companies, active on the market for medical devices.²²¹

Another challenge for the future is the problems that have been raised in the report on the functioning of medical devices among the current EU member states. The report raised the issue concerning lack of expertise among notified bodies. It was concluded that the sometimes very sophisticated medical device products could be very hard to evaluate by the authorities. According to the Commission, this might be a challenge also for the candidate countries, since they have no experience in the monitoring the new approach legislation. If the current member states, with nearly ten years of experience have problems with the legislation, it is not hard to imagine the difficulties the candidate countries might face. The new approach means a completely new way of working for the Polish authorities, which can be quite a challenge in the beginning.²²²

²¹⁹ Swedish Trade Council, 2002

²²⁰ Wickman, L., (2002-10-10)

²²¹ Olejnik, A., (2002-10-11)

²²² Brekelmans, C., (2002-10-16)

5.3. Public Procurement

The current legal base for Poland's public regime is the Public Procurement Act (PPA) of the 10th of July 1994.²²³

In May 2001, new public procurement legislation that aligns Polish regulations with EU regulations came into force. These provisions had the objective of reducing the potential for corruption and price-fixing in tenders, as well as instituting a better appeals process.²²⁴ The law furthermore widens the categories of procurement for which public announcements must be made. It also requires that institutions must publish information about their annual plans for public procurement, thus increasing the opportunity for potential bidders to find out about them and to be able to plan ahead.²²⁵ Tenders are published in the public procurement bulletin "Zamowienia Publiczne."²²⁶ Everything that a hospital buys that exceeds 3000 Euros must be bought through an open tender.²²⁷ The criteria for the selection of the winning bidder have gone through considerable change, and are at present in line with the criteria laid down by the EU. The new legislation encompasses better differentiation between the evaluation of the bidding offer and the evaluation of the bidding company itself in terms of reliability and qualifications.²²⁸

The law also contains procedures to prohibit unfair cartels in tender biddings, even though it will be possible for a group of companies to enter a tender as a group. Still, it preserves a 20% price advantage for domestic bidders in tenders.²²⁹ The legal base for these domestic preferences is the regulation of Council of Ministers of the 28th of December 1994. Domestic preferences are allowed in relation to the EU Member States, but this clause will expire in 2004.²³⁰

²²³ <http://www.euroinfo.org.pl>, 2002-11-11

²²⁴ <http://www.worldmarketsanalysis.com>, 2002-11-09

²²⁵ Olejnik, A., (2002-10-11)

²²⁶ Medistat, 2001, p 25

²²⁷ Olejnik, A., (2002-10-11)

²²⁸ <http://www.worldmarketsanalysis.com>, 2002-11-09

²²⁹ Wolosz, I., (2002-10-14)

²³⁰ <http://www.euroinfo.org.pl>, 2002-11-11

The country clause has acted as a huge obstacle for the foreign companies, active in the Polish market for medical devices. The domestic companies have, to a large extent, been unjustly favoured during tenders. Many of the foreign companies have occasionally been discriminated during the hospitals' purchasing process, which have led to limited sales opportunities.²³¹

5.4. The Polish Health Care Sector

The national health plan in Poland states that the citizens are responsible for their own health. The state shall be devoted to create good conditions for the provision of care, and good accessibility, when needed by the citizens.²³²

The Current system

The health care system had until 1999 been entirely state-owned and centrally controlled. In 1999, extensive reforms took place with the objective of decentralising and restructuring the system. The responsibility for both the operational and financial administration of health care was decentralized from the Ministry of Health to the 16 Voivodships. In each Voivodship a Regional Health Insurance Fund was created. A mandatory health insurance premium of currently 7,5% is derived from the individual's income tax to the funds. There have been discussions about raising this rate gradually, because of the under funding of the Polish health care. It was though decided in December 2001 to keep the current amount.²³³ These Regional Insurance Funds are responsible for the collection of the financial contributes, administering collected funds, and distributing the means after instructions from the local governments and the Ministry of Health.²³⁴

The health care providers (hospitals, clinics, and doctors) are no longer budget units under the state budget, but considered independent public health care units. The hospitals are responsible for their own financial and operational management, and hereby also the purchases of products and

²³¹ Miranda, E., (2002-10-31), Norén, A., (2002-11-26)

²³² <http://www.worldmarketsanalysis.com>, 2002-11-07

²³³ Sobczak, A., (2002-10-08)

²³⁴ <http://www.worldmarketsanalysis.com>, 2002-11-07

material for use in patient care. The Regional Health Insurance Funds and the health care providers are drawing up contracts between them. The Funds are free to place the contracts with the health care provider found most suitable.²³⁵

Criticism against the current system

There has been criticism against this reform. The main argument has been that the different regions in the country have developed their own health care policies and that the level of health care is uneven throughout the country. Wealthier and more populated regions with large hospitals have received more funding from their taxpayers than the poorer regions with smaller population. With different sums of funding in different regions, the system has not been able to supply a health care, with an even level of quality throughout the country. The current government claimed substantial changes in the health sector in the election campaign 2001. The main goal was to increase the overall funding and centralising the health care system to provide a national health care policy with better national care without differences between the regions.²³⁶

The new system of 2003

The planned changes are designed as improvement of the current system rather than implementation of a new system. From January 2003, one National Health Care Fund is to be created with 16 local branches. The National Fund shall implement a programme of standardisation of hospitals contracting methods. Moreover, an equalisation of access to standardised health care services over the country is to be obtained. To be able to achieve this, a National Health Information System will be created to monitor the new system with information from the regions. The Information System will be the base for analysing the needs of the population and monitoring the equality level of the provided health care.²³⁷

²³⁵ Sobczak, A., (2002-10-08)

²³⁶ Sobczak, A., (2002-10-08)

²³⁷ Sobczak, 2001, 2002

The premiums from the income tax will keep the level of today, but the premiums are to be collected by the National Health Care Fund. The fund shall distribute its income to the local 16 branches that thereafter is responsible for the funding of the hospitals as described above. Hereby the regional differences in funding are to be equalised.²³⁸ This system is furthermore said to create increased efficiency and cost-effectiveness in the Polish health care.²³⁹

To summarise, the goal of the new health care system is to shift the work with the health policy to a central body, the Ministry of Health, to be able to provide more equal health care all over the country. At the same time it is claimed to be of importance to keep the active self-governing roles of the hospitals.²⁴⁰

5.5. Overview of the European Market

The European medical device market was valued at more than US \$ 38 billion in total in 2000. The market is divided into a numerous amount of various segments that are devoted to the diagnosis as well as treatment of the majority of existing diseases and disorders that can affect the human body. The products span over a broad platform, from high technological machinery to disposable products. In general, the markets for all medical products are growing and offer immense opportunities for manufacturers globally. The ageing of the global population will have a drastical impact on the future need for medical technologies and devices.²⁴¹

²³⁸ Sobczak, 2002

²³⁹ <http://www.worldmarketsanalysis.com>, 2002-11-07

²⁴⁰ Sobczak, 2002

²⁴¹ Eucomed, 2000, p 8

Table 2 “The Global Medical Device Market 2000”

Country/ Area	Market Size 2000 billion US \$	% Of World Market 2000	Health Expenditure % GDP	Medical Devices per capita US \$
EU	38*	25,6 %	5,7 %	61
USA	55*	41,5 %	13,9 %	115
Japan	23*	15%	7,1%	107
Rest of the World	32*	18%	N/A	N/A
World	148*	100%	N/A	N/A

Source: Eucomed, 2000 (*In-vitro Diagnostics devices excluded)

The medical device industry in the EU is significantly fragmented with 7000 companies, employing 300 000 people. The sector is dominated by small enterprises, of which 70% having fewer than 50 employees. Of the active European companies, 24% employs between 50 and 250 people. The majority of companies have an annual turnover of less than US \$ 6,5 million and only a small number of companies are having a turnover that is exceeding US \$ 35 million.²⁴²

The European Industry is regulated under the same Directive. However, the market is very diverse when it comes to funding and reimbursement, which is based on the fact that each of the member states has their own individual health care system. The regulation provides companies with market access, but strategies have to be adjusted to each of the individual health care systems.²⁴³

²⁴² European Business Journal, 2002

²⁴³ Siebert, M., (2002-10-17)

Table 3 “Key Facts of the EU Medical Device Market 2000”

Country	Population Million	GDP Billion US \$	Health Expenditure Billion US \$	Health Expenditure as % GDP
Austria	8,1	175,5	14,0	8%
Belgium	10,24	205,1	15,4	7,5%
Denmark	5,4	114,5	8,4	6,4%
Finland	5,2	95,4	6,4	7,5%
France	60	1215	89,8	9,7%
Germany	82	1781	151,1	10,7%
Greece	10,7	131,6	8,8	5,9%
Ireland	3,7	70,0	3,9	5,5%
Italy	57,5	978,6	75,6	7,7%
Luxembourg	0,43	12,8	0,8	7%
Netherlands	15,8	320,9	24,5	9,6%
Portugal	9,9	133,3	9,7	6%
Spain	39,7	594,5	30,1	8,1%
Sweden	8,9	161,1	13,2	9,8%
Switzerland	7,3	176,6	15,7	9,8%
United Kingdom	58	1014	68,0	6,7%

Source: Eucomed, 2000 * Switzerland included

The European medical device industry is currently facing an annual growth rate of 5%. The EU enlargement is forecasted to increase the medical device market within the candidate countries gradually to about 30%, in 2010.²⁴⁴ The five largest candidate countries are today spending an amount that is comparable with the market size of Switzerland, regarding medical devices. In 2010, these countries will have a combined market comparable with the size of the UK.²⁴⁵

The European market will continue to be discussed in the coming section, where it is put in relation to the Polish market. However, the focus will be on the features of the Polish medical device market.

²⁴⁴ Roland Berger Strategy Consultants, p 8

²⁴⁵ Siebert, M., (2002-10-17)

5.6. The Polish Market

In 2000, the Polish market for medical devices was valued at US\$ 675 million. The healthcare expenditure counted for US\$ 8,9 billion in 2000, which is equivalent to 5,5% of GDP. Complementary key facts concerning the Polish market for medical devices are summarised in the table below:

Table 4 “Key Facts of the Polish Medical Device Market 2000”

KEY FACTS Poland 2000	
Population	38,7 million
Health Care Expenditure	US\$ 8,9 billion
Health Expenditure per capita	US\$ 230
Health Expenditure as % of GDP	5,5%
Medical Device Market	US\$ 675 million
Medical Device Expenditure per capita	US\$ 18

Source: Medistat, 2001

Compared to the EU member states, it is clear that Poland’s total health care expenditure is very small, taken the population of 38,7 million, into consideration. Poland’s total expenditure nearly equals the total expenditure of Denmark with a population of 5,4 million. Comparing the health expenditure as percentage of GDP, Poland is on the same level as countries like Ireland and Greece.

Since the early 1990s, the World Bank has been involved in various health care initiatives in Poland. Projects are aimed at improving primary care provision, regional restructuring, strengthening of the National Health Service and health promotion.²⁴⁶

In 1999, Poland imported medical supplies (including among others medical dressings, sterile and surgical goods) for US\$ 51 million and exported

²⁴⁶<http://www.worldmarketsanalysis.com>, 2002-11-17

products worth US\$ 10 million. The trade balance regarding Medical Supplies was consequently negative in 1999, US\$ -41 million. The only products, within this category, that did not meet negative trade balance were non-adhesive medical dressings, which had a positive trade balance of US\$ 7 millions. The leading importer to Poland is the EU, which accounted for 57,5% of imports in 1999. US accounted for 22,8 %, Japan for 7,3%, Other Asia, 5,1% and other countries 7,3% of the Polish imports. (See appendix 3 for further details.)

The custom tariffs for wound dressings and surgical drapes are currently subject to a 0% rate for import from the EU and other EEA countries. Put in the perspective of the case company, the import tariffs regarding Thailand are currently at the level of 5-6%. Moreover, imports from Mexico are subject to a 7% custom tariff. With a EU accession this will be adjusted to common EU levels.²⁴⁷

5.6.1. Threat from Substitutes

The medical device market is, as stated before, a very fragmented market, comprising of a numerous amount of segments. The threat from substitutes therefore varies substantially, depending on the different segments. Pharmaceuticals can be substitutes in different areas, since both medical devices and pharmaceuticals can be used to treat the same illness, but in different ways.²⁴⁸ The main reason why pharmaceuticals can be seen as substitutes in Poland is that these two fields of products sometimes are competing about money from the same funding sources.²⁴⁹

The largest substitutes to the surgical drapes and dressings are the products made in washable materials. These can be perceived as cheaper, since the price will be divided on several using occasions.²⁵⁰ The wound care segment consist of a broad variety of different wound dressings, where some are based

²⁴⁷ Patyk, B., (2002-11-18)

²⁴⁸ Siebert, M., (2002-10-17)

²⁴⁹ Wolosz, I., (2002-10-14)

²⁵⁰ Mölnlycke Health Care, 2001, p 8

on more advanced principles than others. Within this segment, the less advanced wound dressings could be seen as substitutes to the more advanced, and vice versa.

5.6.2. Threat of Entrants

In general, the threat of entrants in the European market can be considered moderate. This is a result of the previously explained diversity of the market. There is, in a short-term perspective, not much space for growth, which can have a deterrent effect on possible entrants. However, the segments that are driven by relatively new technology might have space for growth and this fact can act as an incentive for new players.²⁵¹

The capital requirements are very high in the high technology segments, and in other research and development intense segments of the diverse market. This creates an entry barrier for new players.²⁵² Among segments dominated by disposable products, the active companies can be dependent on economies of scale, which in turn can create a barrier of entry.²⁵³ Moreover, the market for medical devices is a highly regulated environment, forced under relatively intricate legislation. This might also create a barrier to entry, especially with the current confusion regarding the Polish legislation.²⁵⁴

Put into the perspective of the future Polish EU membership, the barriers of entry will be lowered considerably with the Polish adjustments to EC law. The regulative environment has before these amendments been very complicated.²⁵⁵ This might have had a deterrent effect on possible entrants, since the regulation forced companies to act in a totally different manner compared to the EU market. The changes in the regulatory framework might attract companies not yet active in the market, since the environment becomes more similar to the common European market.

²⁵¹ European Business Journal, 2002,

²⁵² Wolosz, I., (2002-10-14)

²⁵³ <http://www.kimberly-clark.com>, 2002-11-11

²⁵⁴ Siebert, M., (2002-10-17)

²⁵⁵ Ibid

Another repellent effect for companies planning to enter the Polish market is the lack of financial resources that exists among the Polish hospitals. This will be further explained in coming sections.²⁵⁶

5.6.3. Rivalry among Established Competitors

This section contains a description of the level of competition and market structure within the medical device market. The European industry is briefly explained, followed by more extensive description of the Polish market. Moreover, this section includes the impacts of the EU membership as well as the prospect of consolidation.

Market Structure

On the European level, the competition is divided among three types of firms. The first group consist of international multi-products companies, such as General Electric Medical, Siemens, Philips, Johnson & Johnson, Baxter, 3M, Smiths PLC. This group also contains expanding companies like Mölnlycke Health Care. Common for these companies are that they carry out research and development and develop new technology. The second group contains firms with strong regional presence and R&D technology, however within a narrower product area. Examples of these firms are Smiths Groups plc, Braun, Bausch and Lomb, and Boston Scientific etc. The third group include newcomers with the objective of becoming niche players based on new technology. This segment includes small, often family owned firms operating on a national base.²⁵⁷

The same type of structure can be used in explaining the Polish medical device market. The competition is at present very tough, since all kinds of companies are represented on the market. There are many foreign actors, and additionally, many medium small size players.²⁵⁸ In Poland, there are approximately 400-500 small local companies, involved in manufacturing of

²⁵⁶ Gryglicka, I., (2002-10-11)

²⁵⁷ European Business Journal, 2002

²⁵⁸ Roszkowski. L., (2002-10-11)

medical devices.²⁵⁹ The small local producers and the domestic manufacturing are limited to basic diagnostic equipment, hospital furnishing and equipment, surgical instruments, and disposable products. Polish manufacturers are within some segments not considered competitive because of high production costs, lack of modern technology, low quality products and lack of marketing skills and resources, even though this is gradually improving.²⁶⁰

A segment where the above-described situation, is gradually improving are segments comprising of products such as disposables. Within the majority of world markets, the international companies (first group) are dominating. This is however not the case in Poland, where a number of domestic producers are market leaders.²⁶¹ These market-leading companies are very competitive in terms of price as well as quality.²⁶²

However, regarding the segments comprising of the high technological machinery, the market structure is completely different. This segment is in Poland, completely dominated by foreign actors. There are basically no domestic producers in this segment. Many of the high technology machinery segments are totally dominated by Philips, Siemens, and General Electric.²⁶³

Impacts of the Polish EU membership

In general, the future EU membership is considered to attract more foreign companies to establish themselves in Poland.²⁶⁴ Many companies want to “wait and see” what the EU membership will bring, and therefore an increasing amount of FDI is expected after the Polish EU membership.²⁶⁵

Regarding medical devices, the outlook for increased competition with the EU membership is depending on the various segments of the market. In

²⁵⁹ Worldmarketanalysis.com, downloaded: 2002-11-07

²⁶⁰ <http://www.ita.doc.gov/> 2002-11-03

²⁶¹ Miranda, E., (2002-10-31)

²⁶² Norén, A., (2002-11-26)

²⁶³ Bielecki, K., (2002-10-08)

²⁶⁴ Patyk, B., (2002-10-09)

²⁶⁵ Kwast, E., (2002-10-07)

general, the companies selling high technology machinery consider the Polish market to be saturated, due to the fact that basically all the global actors are already present in the Polish market.²⁶⁶ Within this segment there is also a complete lack of domestic producers.

The competition within the less sophisticated segments of the medical device market is expected to change with a Polish EU membership. There might be more companies entering the Polish market, which will increase the competition. The change in the competition will be more difficult for the Polish companies, because of their lack of financial capital.²⁶⁷ Within the segments that include a number of Polish players manufacturing; basic diagnostic equipment, hospital furnishing and equipment, surgical instruments, and disposable products, there is room for acquisitions. Acquisitions might be appealing to the foreign actors, active or not yet active in the Polish market, managing a stronger capital base than the Polish players.²⁶⁸

However, the Polish market for medical devices has already, due to the large domestic marketplace, attracted many of the international companies. According to the interest association for medical devices and pharmaceuticals, the majority of the important foreign medical device companies are already established in the Poland.²⁶⁹

Consolidation

The European Industry has, during recent years been subject to a consolidation process. Typical for the industry is that new technologies that originated from smaller innovative companies are acquired by the larger international ones. Hereby, the technology can reach a larger market.²⁷⁰

²⁶⁶ Bielecki, K., (2002-10-08), Olejnik, A., (2002-10-11), Roszkowski, L., (2002-10-11)

²⁶⁷ Tunikowska, B., (2002-10-14)

²⁶⁸ Burczynska, B., (2002-10-09)

²⁶⁹ Gryglicka, I., (2002-10-11)

²⁷⁰ Dedobbeleer, E., (2002-10-17)

A prospect for the future is that consolidation will take place in Poland as well. The Polish market is in the same way diverse like the European one, which might lay the ground for future mergers and acquisitions. Another contributing factor, linked to the Polish EU membership, is the issue of CE marking. With the Polish EU membership, all manufacturers will be forced to have their products CE marked, which sometimes can be a very expensive procedure. The lack of financial resources among the domestic actors might be another causative reason for further consolidation of the Polish industry.²⁷¹

5.6.4. Bargaining Power of Buyers

Within this section, the financial situation in the European and Polish health care systems is discussed. This is followed by a discussion of the customers in the Polish market for medical devices. This section ends up with a description of the customers' buying process.

Financial Constraints

In most countries in Europe there is a political debate about the financing constraints in the health care sector. All healthcare systems are facing the problem with limited sources of funding, but almost unlimited demand.²⁷² This is mirrored down to the hospitals and clinics doing the actual purchasing, in order to provide health care. With scarce funding the buyer becomes more price aware and more willing to negotiate about the price.

The main difference between the Polish and the European markets of today is the fact that the European markets are wealthier. The financial problems within Poland are larger compared to many of the European countries.²⁷³ As mentioned before, the total health care expenditure per capita in Poland is low, 230 US Dollars. In percentage, the total expenditure on health of the GDP in Poland is 5,5%, which is among the lowest in Europe.²⁷⁴ Most

²⁷¹ Burczynska, B., (2002-10-09), Roszkowski, L., (2002-10-11), Tunikowska, B., (2002-10-14)

²⁷² Siebert, M., (2002-10-17)

²⁷³ Tunikowska, B., (2002-10-14)

²⁷⁴ Medistat, 2001, p 1

probably an increase in the expenditure will not be an immediate result of joining the EU, but maybe in a longer time perspective.²⁷⁵

The Customers

The majority of the Polish hospitals are publicly owned. The state owns a number of national hospitals, and university hospitals. The Voivodships, Poviats, and Gminas are also owners to some hospitals and public units. There are around 800 hospitals in total, of which 40-50 are privately owned. The private hospitals are often small and specialised.²⁷⁶ The private sector has the ability to provide superior facilities compared to the under-funded public sector. However, these hospitals are at present very expensive and consequently have a very limited clientele.²⁷⁷ The number of privately owned hospitals has increased during recent years, and is expected to do so in the nearest future.²⁷⁸

Since the reform in 1999, the hospitals have been responsible for their own financial management and thereby also purchasing. Some hospitals have been managing well, but many hospitals have been having problems adjusting to market economy and self-management. Limited funding and lack of experience in financial management are two factors that have contributed to the fact that many hospitals today are having large debts. The total debt of the Polish hospitals to different stakeholders is currently between 5 – 7 Billion Zlotys.²⁷⁹ Hospitals battling with scarce resources and debts have made the price the one and only criteria in the purchasing process. The crucial issue of the future is whether the hospitals will have enough money to buy high quality products. If they are not in the position of buying high quality products, they will continue to buy the cheapest alternative only. Price is currently the most important factor on the Polish market, followed by time to deliver and quality.²⁸⁰

²⁷⁵ Tunikowska, B., 2002-10-14

²⁷⁶ Sobczak, A., (2002-10-08)

²⁷⁷ Medistat, 2001 p 16

²⁷⁸ Burczynska, B., (2002-10-09)

²⁷⁹ Wolosz, I., (2002-10-14)

²⁸⁰ Tunikowska, B., (2002-10-14)

There are many companies active in the Polish market for medical devices. Most of the big global players are present together with some local companies. Therefore, the hospitals often have many offers to choose from when purchasing, which further increases their bargaining power.

Large global actors, and well-equipped domestic companies are competing in the segments of surgical dressings and wound care. The many offers to choose from, and the price sensitivity, again give the hospitals fairly strong bargaining power. This bargaining power is further strengthened by the fact that some of the products within this segment are relatively less differentiated. This makes it easier for the hospitals to switch to a product from another producer.

One field where the power of the hospitals is clearly shown is regarding payment. The unhealthy financial situation of the hospitals has led to substantial delays in payment for delivered goods. The term for payment in Poland is long, normally 180 days, and sometimes even 240 days. Even after this period the companies often have to wait for payment. It is common with payment negotiations between the selling company and the hospitals. Some companies try to hold new deliveries to the hospitals in debt, until they have received at least a part of the liability. When companies have stopped deliveries to the indebted hospitals, it has resulted in a bad reputation for the company concerned, and consequently reduced good will.²⁸¹

The Buying Process

Nearly all of the public hospitals' buying is conducted through open tenders, without interference from the state. However, the privately owned hospitals are not bound to open tenders. The public hospitals buy individually and separately, apart from some of the more advanced and expensive products, which are purchased through a "bank", e.g. a joint buying cooperation. This is done in order to press down the prices.²⁸²

²⁸¹ Wolosz, I., (2002-10-14)

²⁸² Urbanowska-Bak, Z., (2002-10-07)

Everything that the public hospitals buy, that exceeds 3000 Euros, must be bought according to the principles of the act on public procurement. This act includes specific regulations regarding when the hospitals must organise open tender, limited tender, negotiations etc. This is applicable for all types of products and services.²⁸³

This act also contains a clause that the ordering party may use country preferences in the decision process. In practice, this means that the ordering party may prioritise Polish suppliers over foreign ones. If the hospital intends to do so, this must be announced in advance. This regulation will be in force until June 2004.²⁸⁴

In general, Polish doctors are very well educated and up to date with new innovations. They are very aware of the product development. Many hospitals are managed by professors, with great knowledge about product developments. Therefore they want to have exactly the same, or if possible, even better products.²⁸⁵ There is a preference for foreign brands when it comes to medical devices. These products are considered to be of higher quality, in comparison with the domestic brands, even if this is not always the case.²⁸⁶

²⁸³ Olejnik, A., (2002-10-11)

²⁸⁴ Ibid

²⁸⁵ Burczynska, B., (2002-10-09), Tunikowska. B., (2002-10-14)

²⁸⁶ Dziolko. K., (2002-10-11), Tunikowska. B., (2002-10-14)

5.6.5. A Future Perspective

This section will present the future prospects of the medical device market, divided into the threats and opportunities of the future.

Opportunities

A benefit of the EU membership is the fact that the custom clearance will be taken away. This means that the products will reach the customers much quicker than before, which will lead to better service for the customers. This is of course an opportunity for companies with no manufacturing in Poland.²⁸⁷

Further benefits of the coming EU membership are the adjustments in the legal framework, which was explained in the beginning of this chapter. The changes in the regulatory framework means an opportunity for the foreign companies but an obstacle for many of the domestic producers, because of the future requirements of the CE mark. This might, to some extent have an effect of the market structure, since it lays the ground for acquisitions.²⁸⁸

The well-educated workforce in the health care sector is considered to be an opportunity for companies with the aim of selling medical devices.²⁸⁹ As mentioned before, the hospital staffs are often very well aware of product developments in the market for medical devices.²⁹⁰

The present opportunities for companies active in the Polish medical device market are the size of the market, and the future growth potential of the market. The health care system is expected to receive more money in the future.²⁹¹ The EU accession is expected to foster medical device sales in the candidate countries. The membership in the EU will lead to increased economic output, and consequently higher income of the private and public sectors. Moreover, it will lead to a higher price transparency between the national markets of the EU, which in turn will lead to a broader

²⁸⁷ Olejnik, A., (2002-10-11)

²⁸⁸ Tunikowska, B., (2002-10-14)

²⁸⁹ Olejnik, A., (2002-10-11)

²⁹⁰ Tunikowska, B., (2002-10-14)

²⁹¹ Olejnik, A., (2002-10-11), Roszkowski, L., (2002-10-11), Burczynska, B., (2002-10-09)

standardization of registration guidelines throughout EU, but also EU laws against price discrimination. These factors will combine lead to a boost in the medical device sales.²⁹²

Threats

At the same time as the adjustments to EC law creates opportunities, it also creates some threats for the companies active in the Polish market. The adjustments create a huge number of changes at the same time as well as a very unsure outcome of them. The Polish healthcare system has gone through some revolutionary changes since 1999, when a new system was introduced. The current government has initiated further reforms within this area. This further complicates the regulatory environment that the companies operate within.²⁹³

Bureaucracy is furthermore considered a threat to the players in the Polish medical device market. The industry is relatively centralised and the Ministry of Health governs much of the legislation and future changes.²⁹⁴ History-wise, the Polish authorities have been working in an inefficient and bureaucratic way and the transparency has been low. In spite of the current reforms of the Polish society, contacts with public authorities have not become less complicated.²⁹⁵ The bureaucracy is deeply rooted in the Polish society and is definitely more visible than in many EU countries. The bureaucracy can create major difficulties for companies wanting to establish themselves in the Polish market.²⁹⁶

Moreover, Poland is still not a very wealthy country. Some of the medical devices that should be reimbursed by the hospitals are not, because of lack of money. The reimbursement system and the cash flow within the health care system in Poland are not good, and this creates limitations.²⁹⁷

²⁹² Roland Berger Strategy Consultants, 2002, p 18

²⁹³ Tunikowska. B., (2002-10-14)

²⁹⁴ Olejnik, A., (2002-10-11), Urbanowska-Bak, Z., (2002-10-07)

²⁹⁵ Swedish Trade Council, 2002

²⁹⁶ Wickman. L., 2002-10-10

²⁹⁷ Olejnik, A., (2002-10-11), Roszkowski. L., (2002-10-11)

5.7. Summary

The EC Directive, covering medical devices, is based on the New Approach. The directive sets the essential requirements that the products should meet to be CE marked, and thereby be allowed to be put in the market. The previous complicated Polish legislation on medical devices has, since October 2002, been replaced by a new legislation. This new act is in compliance with the EC Directive. All products sold in Poland have to be CE marked. However, domestically produced products can be sold in Poland without CE mark until January 2006. The current problem is that there are no regulations, which means that the new act cannot be fully implemented.

The Polish health care system is going through reforms. The system has been decentralised and the Voivodships are operationally and financially responsible for providing health care. The main problem within the health care sector is the lack of sufficient funding. Poland's health care expenditure is comparatively low. The vast majority of the Polish hospitals are publicly owned, but are themselves responsible for their purchasing. Because of the financial shape of the hospitals, the price is the most important factor in the purchasing process.

The Polish medical device market is very diverse, comprising of both foreign and domestic companies. The domestic companies are present within the less sophisticated segments. The financial limitations of the customers have led to a hard competitive situation. The EU membership is expected to increase the competition further, by the entry of more companies, and the new demands that are put on the companies active in the market.

Knowing the general conditions of the Polish business environment and the specific environment for the medical device market, the next section will deal with scenario planning. The main forces in the industry are analysed and how they might influence the industry in the future.

Part III



Analysis
Conclusions & Recommendations
Areas for Future Research
Authors' Reflections

6. ANALYSIS

In this chapter the empirical findings are put into the perspective of the theoretical framework presented in chapter three. The chapter is based on Schwartz's Scenario Planning Process, and the various steps that were presented in chapter two. The chapter ends up with a scenario discussion. This chapter focus on the following research question.

Research Question 3:

What are the implications of these changes, and how will they affect the future strategies of an MNC planning to enter the Polish market for medical devices?

6.1. Scenario Analysis

Within this context, the scenario planning process is first and foremost used as a tool in analysing the possible future positions of the Polish medical device market. The aim is to put focus on issues with a direct effect on the industry, and consequently also for a company planning to enter the market. The competitiveness of a company is dependant upon the functional knowledge of an enterprise and how much accumulated knowledge it possesses about the business environment. Most competing companies have similar organisational skills and product offers. Therefore, the company's ability to adapt its operations to the external environment becomes crucial. The company that best designs its internal organization to the demands of the external environment will become most competitive in the industry. A successful strategy brings the company's goals, values, resources and capabilities together to create a link towards the external environment. For a company planning to enter a market, it is crucial to gain a good understanding of the external environment, and how it could change in the future. The scenario analysis facilitates the identification of the most essential aspects of the future.

6.1.1. Identification of Focal Issue

The scenario planning process starts by evaluating what issue should be answered with the scenario analysis process. The identification of the focal issue meant a return to the purpose of this thesis. The focal issue of the scenario planning process is:

- How will the Polish medical device market change in the near future, put in the perspective of an MNC planning to enter the market?

The time perspective used within the scenario planning process, and the term “near future” are within this process set to five years. Hence, the scenarios will describe the situation of the Polish market in the year of 2007.

6.1.2. Key Forces in the Local Environment

A useful tool in the identification of the relevant forces with impact on the focal issue was the Modified Institutional Model. This model has contributed to a constructive description of the external environment. By adding the EU field, the supranational organisation’s impact on Poland, as well as on the examined market has been made apparent. The key forces are the main influences in the local environment and consequently the most crucial for a successful market entry to the Polish medical device market. The identified key forces are described and motivated below. Most of the found key forces are connected to the institutions within the organisational field in the Network Institution model. According to this model, an MNC could to some extent influence these institutions, at the same time as it is directly influenced by different actions of these institutions or forces.

Legislation

The medical device industry is a relatively regulated industry, since the products are used in health care, affecting the health of the patient. The operations of a company active within this industry, consequently depends on the legislation and the regulatory demands that exist to ensure the safety and health of the patients. Hereby, the regulatory environment concerning medical

devices is more extensive, in comparison with other industries. The previous Polish legislation contained a number of provisions that in practice created technical barriers to trade for the companies active in the Polish market. These provisions were for example extremely complicated national product registrations and specific industry standards. In order to receive marketing permission in the Polish market, additional clinical tests had to be conducted in the country. These technical barriers to trade have to be abolished before the Polish medical device market can become a part of the Single European Market.

A substantial part of the Polish legislation has for several years been adjusted according to EC law. As became apparent in chapter five, the framework regulating the Polish medical device market is currently changing, to adapt to EC law. The Polish legislation has been adjusted to the Council Directive 93/42/EEC, through an act that came into force in October 2002.

Another part of the regulatory framework with direct consequences for the actors within this market, is the law, regarding public procurement, since the majority of hospitals are publicly owned. As presented in chapter five, this act regulates the hospitals' buying procedures. The law presently includes a clause allowing for domestic preferences within open tenders. This will change in 2004, when the advantage will be withdrawn, for compliance with EC law, and the functioning of the Single European Market.

Implementation

This force relates to the practical functioning of the previously described legislative aspects. The implementation of a law is determined by the administrative capacity and the competence that exist within the legal system. Hence, this force relates to how well the legislation is functioning on the operational level, which consequently influences the concerned companies.

The EC legislation regarding medical devices is based on the new approach. The main fundamental of the new approach is that it shifts the safety

responsibility from the authorities towards the manufacturer. The main objective with this approach has been to secure innovation, since the manufacturer is not constrained by regulations regarding technical solutions. The directive is instead based on risk management.

The sophistication of the products put high demands on the competence of the authorities. In order to make the new approach work satisfactory, the related authorities must have adequate knowledge about the products, manufacturing procedures and their possible impact on the patient's health. According to the Commission, several member states today face difficulties in implementing the new approach legislation completely, due to the complexity of the products. The authorities responsible for procedures such as market surveillance, as well as the notified bodies sometimes lack the knowledge to carry out these procedures adequately.

The Council Directive 93/42/EEC on medical devices has not yet been implemented in Poland. There are still no regulations regarding the law. One of the reasons behind this delay might be that the Polish authorities face a completely new type of legislation. The old legislation was based on pre market testing, done by the authorities, before the product was given marketing permission. This system meant a very intricate and often time-consuming registration process for the concerned companies. The EC legislation, based on the new approach, forces the authorities to act in a completely new manner. The Polish authorities lack the experience of handling the new approach directive, which might create problems in the near future.

Bureaucracy

Because of the central role of legislation within this industry, contacts with authorities can be of crucial importance for successful business operations. As a consequence, the level of bureaucracy within state authorities can play a decisive role for the companies concerned.

The Ministry of Health, and related authorities have long played a central role in the medical device industry. The Polish authorities are characterised by a high level of bureaucracy. For companies, contacts with authorities have meant complicated and time-consuming processes. The high level of bureaucracy can be interpreted as a legacy from the communist period. The transition to democracy and market economy, have had considerable effects on the Polish society. Still, the bureaucracy is somewhat regarded as an obstacle for business operations in Poland. The bureaucracy is deeply rooted in the Polish society and this will most probably not change in the near future. Within an industry that presupposes contacts with state authorities, great importance is attached to personal contacts and personal networking.

Health Care System

The health care system creates the foundation to how the customers behave. The degree of independency of the hospitals is related to the health care system of the country. Health care reforms are another key force that can determine future turns of the market. The health care reforms are of huge importance to the actual selling process, and how the medical devices are bought and reimbursed.

Until 1999, the Polish health care system had been entirely state-owned and centrally controlled. After 1999, the responsibility for health care was decentralized from the Ministry of Health to the 16 Voivodships. In each Voivodship a Regional Health Insurance Fund became responsible for the operational and financial administration of health care.

The decentralisation of the system, have faced severe criticism from the public. The system created an uneven allocation of funding, and the differences among the wealthier parts of Poland, compared to the rural regions, have become a major problem. The current government has therefore decided to initiate new health care reforms in 2003. The objectives of these are first and foremost to eliminate the regional differences that exist in the quality of health care. This means that the funding will be centralised under one National Health Care Fund, instead of the current 16 regional ones. Moreover, the government will initiate one national health care policy, to further create equality throughout the country.

The Customers

The financial position of the customers is related to the health care system of the country. The financial status of the hospitals is a result of how the money is distributed within this system. The customers and their financial position as well as the actual buying process are obviously a key force, when considering future strategies.

The health care providers used to be budget units under the state budget, but are now considered independent public health care organizations. The hospitals are responsible for their own financial and operational management, and hereby also the purchases of products used in patient care. The majority of the Polish hospitals are publicly owned. Hence, the hospitals are totally dependent on public funding. As presented in chapter five, the health care expenditure in Poland is very low, compared to many other European countries. This has left the hospitals in a financially bad situation, with very limited funds for purchasing.

The private hospitals in Poland have increased substantially in recent years. They are often in a better financial position than their public counterparts, and can consequently often provide care of a higher quality. They are moreover not obliged to use open tenders when purchasing medical devices.

Competitive Situation

This force is determined by the amount of companies active in the market, their resources, but also the financial position of the customers within the market. This will determine the level of competition that exists within the market.

At present, the competition is very tough, due to a significant diversity of the companies, represented on the market. There are many foreign actors, and additionally, many medium small size players. In Poland, there are around 400-500 small local companies, involved in the manufacturing and selling of medical devices. Some of the segments that are globally dominated by a number of large multinational companies are in Poland lead by a number of Polish manufacturers.

In the European market, there are clear signs of a consolidation process. There are many factors that lay the foundation for a similar development in the Polish market. The majority of the large multinational companies within the industry are already present in the Polish market. The companies not yet active in the market might enter in the near future, because of the future market potential. The regulatory environment in Poland will moreover be fully adjusted to the European one, and possible barriers will be removed. It is therefore highly likely that the consolidation process that has started on European level will be brought to the Polish market as well.

Another contributing factor, linked to the Polish EU membership, is the issue of CE marking. With the Polish EU membership, all manufacturers will be forced to have their products CE marked, which sometimes can be a very expensive procedure. The lack of financial resources among some of the domestic actors might be another causative reason for further consolidation of the Polish industry. Moreover, the fact that these companies are in an inferior financial position, compared to their multinational counterparts will most probably mean that they will face problems with the increased future competition. In extreme cases, they will be driven out of competition because of their lack of financial means. Finally, there will be no legal ground for

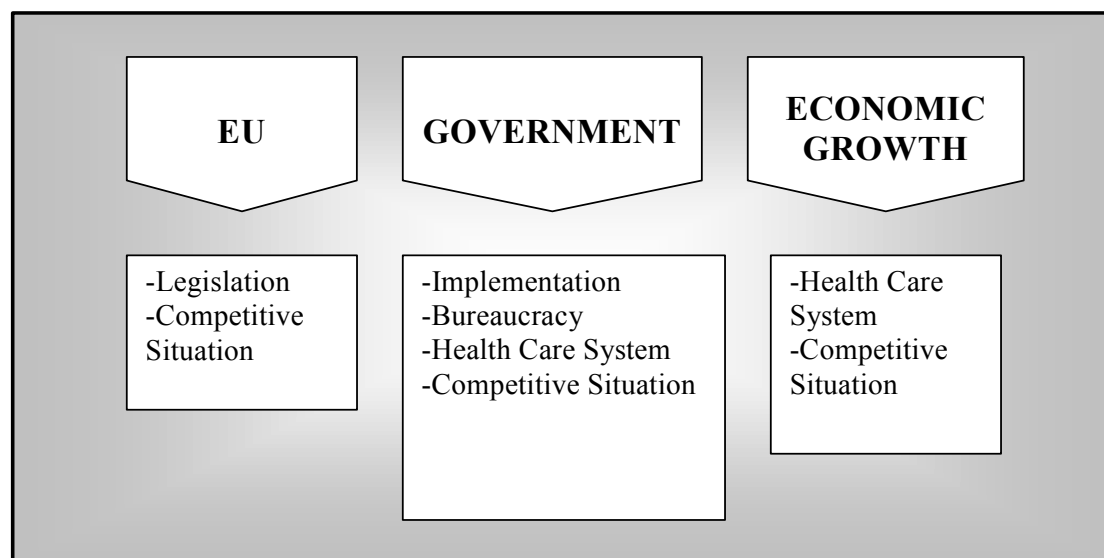
using domestic preferences in the open tenders, which can hit hard on some of the less efficient domestic companies.

6.1.3. Driving Forces

This step involves an identification of the driving forces on a macro level. These are the driving forces behind the issues identified in the local environment. The driving forces are mostly found within the societal sector in the Network Institution Model. The societal sector institutions indirectly influence the MNC, whereas the company has no ability to conduct any influence on them. One of the driving forces is the government. However, this driving force is to be found in the organisational field within this model. This implies that a company could influence the government to some extent, for example by lobbying.

The relation between the key forces in the local environment and the driving forces will be explained in the coming sections. The link between these forces is summarised in the following model.

Figure 12 “The driving - and key forces”



Source: Own Construction

EU

The EU acts as the major driving force when it comes to legislation regarding the medical device industry and also regarding public procurement. The EU can moreover act as a driving force of the competitive situation within the market, since it helps creating transparency between the member states, and can therefore attract more companies to enter the Polish market.

One of the major foundations for the European co-operation is the creation of a Single European Market, with an elimination of all physical, fiscal and technical trade barriers. This is to create a more efficient business environment, since products can be moved and sold throughout EU, without interference from authorities of each member state. This will in turn have a positive impact on European business and consequently create job opportunities and economic growth. As a member state of the EU, each country must fully comply with the strategy founded for the elimination of trade barriers.

Poland has, with the application for membership, agreed to this foundation and issues related to the creation of a common market. The adjustments to EC law have been an ongoing process since 1993, when the European Agreements came into force. Since 1997, EU has, through regular evaluations, published its opinion of how far Poland has come in the adjustment process. These evaluations are based on the *Acquis Communautaire*, divided into 31 chapters. The first chapter concerns issues related to the free movement of goods. This chapter is provisionally closed, but includes transitional arrangements for medical devices.

Government

The government act as a driving force behind several of the key forces in the local environment, since they have the power to influence the business environment. Some of these decisions will have a direct impact on the Polish medical device industry.

Being the principal body of the executive branch, the government endure full responsibility of implementation of the legislation. The government can consequently effect the creation of regulations and how an act works on the operational level. The responsible ministry depends on the scope of the act. Issues that relates to health care and consequently medical devices come under the responsibility of the Ministry of Health. The act on medical devices was planned to enter into force in 2001, but has ever since been postponed. The Ministry has not yet issued the regulations, which creates a legal vacuum. Hence, even if the legal base of the new act has entered into force, the lack of regulations makes the law inadequate.

The government can furthermore, to a limited extent, be seen as a driving force for the bureaucracy that exists among the state authorities. Even though the level of bureaucracy is determined by the attitude of people, the government can to a certain extent influence it, by reforming and reorganising the authorities.

Naturally, the government also act as a driving force behind the health care system and the health care reforms that take place within the country. Consequently the government is in total power of the allocation of financial resources in the health care system.

Finally, due to the above-mentioned issues, the government should be seen as a driving force of the competitive situation. In addition to their influence of the health care system, they are also in power to influence the business environment by various reforms. The government has been able to attract foreign direct investments, by various investment incentives. This possibility will however be restricted when Poland becomes a EU member. The government then has to ensure that the incentives are not in conflict with the competition policies of the EU.

Economic Growth

The economic situation of Poland is of course linked to the above-mentioned driving force, the government. However, within this context, the economic growth is considered as a somewhat independent force, that is a result of the global economy rather than the actions of the Polish government. The EU membership is within this force considered to be a factor that will have a positive effect of the economic growth in a long-term perspective. The economic growth is the driving force behind the public spending on health care, but also on the competitive situation within the medical device market.

The Polish economy is influenced by the world and European economies. Furthermore, it closely follows the trends of the German market, since Germany is the largest Polish trade partner. Most countries in Europe face financial struggles with the funding of the health care systems, and hence the ability of being able to provide high quality care for the citizens. The funding of a public health care sector is of course directly connected to the economic conditions of the country.

As mentioned before, Poland's health care spending is very low, in comparison with other European countries. In order to be able to provide high quality care for the large population, this must increase in the future. If Poland will be able to provide high quality care in the future depends on how much money the state can appoint for this purpose. This is in turn a result of the overall status of Poland's economy.

As became apparent in chapter four, the access to the Single European Market is, in the long term, expected to foster economic growth within Poland. A EU accession is probable to lead to increased economic output in the long term and a higher income in the private sector. This will lead to a better situation for the Polish state since it will have larger incomes from taxes and smaller amount of unemployed to provide for.

With an increased amount of money spent on healthcare, the market for medical devices will grow. This will have a direct impact on the competitive

situation within the industry. A market growth will most likely attract an increased amount of companies fighting for market shares.

6.1.4. Ranking and Selecting Scenario Logics

The exact date for the Polish EU membership is not yet determined. When constructing these scenarios, the assumption is that the EU membership will occur in the very near future. However, it is important to construct a matrix with the ability to illustrate the future with or without Polish EU membership. By analysing the key forces and the driving forces behind them, the two most uncertain and important are considered to be, **the financial means to the Polish health care system** and **the implementation of the EC regulations in Poland**. The level of EC law implementation is a factor that can be evaluated even if a membership is postponed. Moreover, the financial situation of the health care system, is not directly influenced by the EU. These parameters, and what characterises them, will be described in the following section.

Low EC Law Implementation

Within this parameter, the legislation is adjusted, but the government has not been able to implement the changes in the regulatory framework. The situation is still somewhat an “in-between solution” of the old and new system. There is a lack of competence within the authorities on how to facilitate the new approach legislation. The CE mark is valid, but there are still a few complicated national procedures that have to be dealt with in order to receive market authorisation in Poland. The Polish authorities have problems in adjusting to the new approach, and are therefore still handling the registration of products, according to the old standards. The behaviour of the Polish authorities is still characterised by the philosophy of the old system. Consequently, this creates major obstacles for the companies active within the Polish healthcare market, since there are no apparent guidelines on how to act.

Moreover, the players on the market are still not equally treated within the tender processes. The country preference clause within the public procurement legislation has been abandoned, but the customers still tend to unjustly favour the domestic producers. Even though there is no legal ground for a favouring of the domestic producers, the hospitals still find ways to overcome this.

High EC Law Implementation

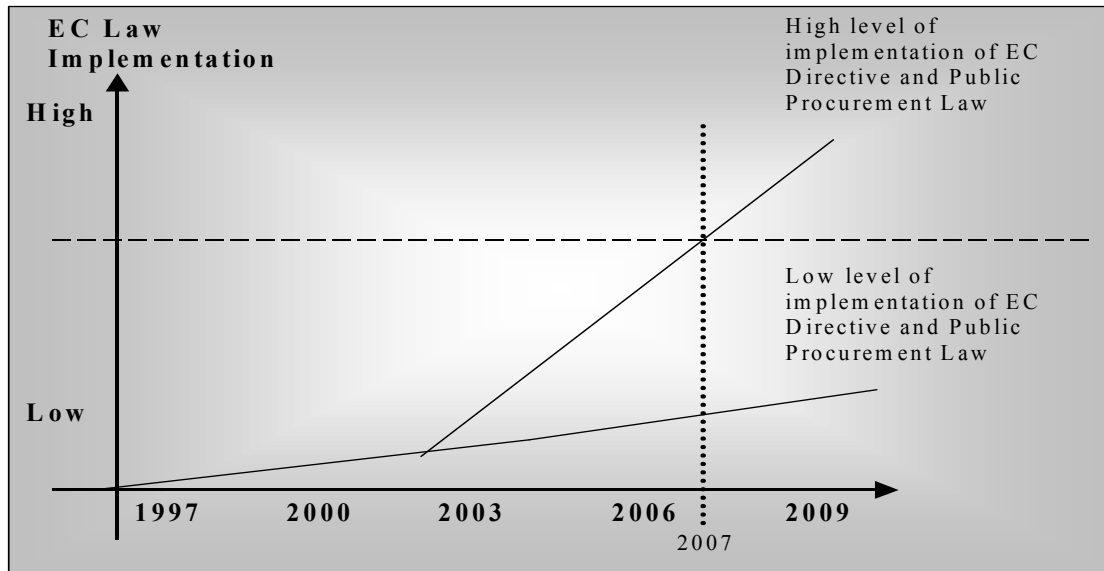
According to this parameter, the medical device directives of the European Union have successfully been implemented. The European “rules of the game” are valid in Poland and all companies, domestic and foreign, are treated equally. The new medical device act is implemented with regulations, which are fully followed by the actors on the market. The previous complicated registration process is replaced with the CE mark.

The Polish authorities managed to adapt to the new approach, and the required administration is sufficient. This well working implementation of the European rules means that the companies do not need to have contacts with the Polish authorities to the same extent as before. The registration process is simplified, and the implementation of the CE mark means that only a notification of the manufacturer is needed, not additional registrations of the products.

In the field of public procurement, the discrimination of foreign companies has no legal ground anymore, since the clause regarding country preferences has been removed. This is fully adopted by the buyers, treating the domestic and foreign companies equally in the tender process. The hospitals are now focusing on the content of the bid instead of the origin of the company bidding.

The following model illustrates the gradual adoption of EC legislation. The model visualises the until now reached level of EC law implementation, and how it could develop in the future.

Figure 13 “The implementation parameter”



Source: Own Construction

Continued Low Funding of the Health Care System

The reforms and improvements of the health care sector will within this parameter be limited to reallocations of the existing financial resources. The government has not been able to increase the amount of funding intended for health care. The bad financial situation in the health care sector is partly a result of the country’s economic situation.

As mentioned before in this analysis, the driving forces behind this key force are the government and the economic growth. The government is the head of all health care reforms, and consequently also in charge of the funding. Continued low funding to the health care system means that the government has not been able to allocate increased resources for health care. The economic growth is low, and even if the government increases the amount of funding the total health care expenditure remains low.

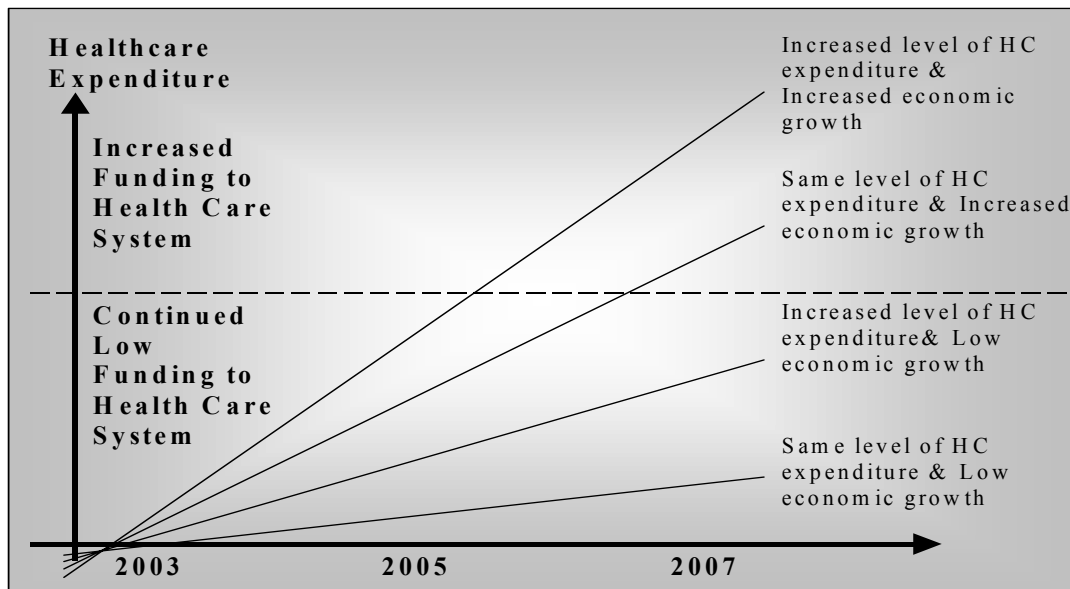
Increased Funding of the Health Care System

The government has within this parameter been able to increase the health care spending. The health care reforms will therefore focus on improving the public provided care. The improved financial situation in the health care sector is a result of Poland's economic situation.

Increased funding of the health care system can have its base in a substantial economic growth, without interference from the government. The percentage of funding remains on the level of today, and the amount of money increases, as a result of the economic growth.

Another aspect could be that the economic growth has contributed to improve state finances, which gives the government the opportunity to earmark a higher percentage of the income tax to the health care sector. This would allow for an even higher increase of the health care funding. The following model illustrates the discussion held above.

Figure 14 “The funding parameter”

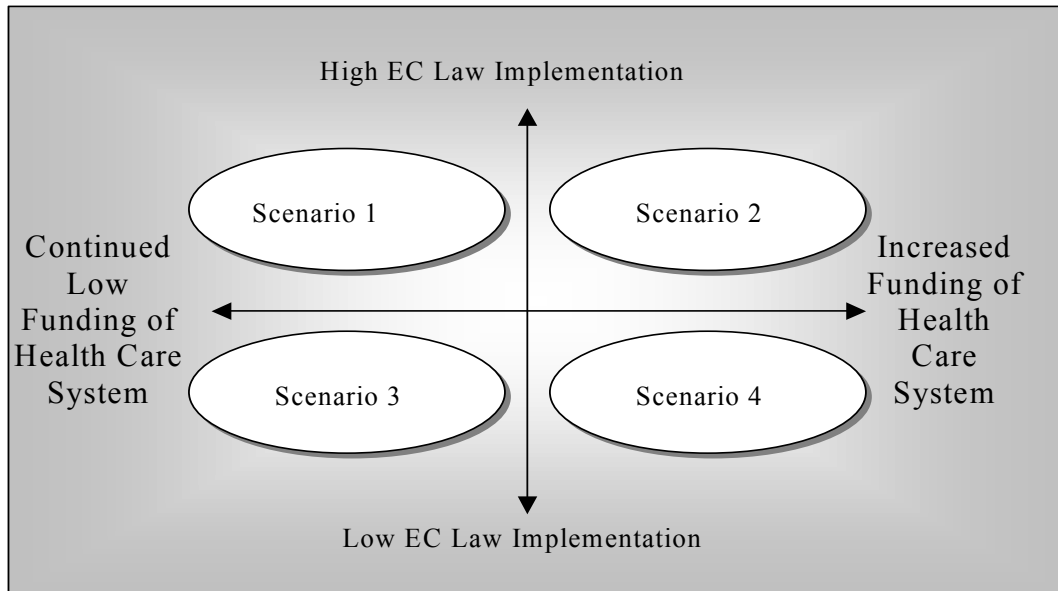


Source: Own Construction

6.1.5. Fleshing out the Scenarios and their Strategic Implications

Based on the discussion in the previous section, a matrix has been constructed. The matrix below creates the base of the four various scenarios.

Figure 15 “The Four Scenarios”



Source: Own Construction

As mentioned before, the time perspective used within the scenario planning process is set to five years. Hence, the scenarios will describe the situation of the Polish market in the year of 2007.

Scenario one -“Surviving Consolidation?”

According to this scenario the future is mostly influenced by legal compliance with the EC-directives and a financial situation similar to the one of today e.g. a low public health care spending.

The aim of achieving higher quality care cannot be reached, and the hospitals are in a financially bad position, with high debts. In order to provide the best possible care, the physicians of course require the best possible equipment and materials. Due to financial constraints this can however not be achieved, and the hospitals have to make certain concessions in their purchasing. Within

this context, the hospital's one and only criteria when evaluating a bid is the price. The price is therefore the overall competition tool and the price of the product undoubtedly the most important factor in the buying process.

The situation with continued bad financing of the hospitals is not likely to attract new companies to the market. However, the future potential of the market is seen as an incentive for entering the market. In addition, the previous complicated legislation which acted as a legal barrier, has been removed. There are therefore many companies competing in the market and several financially strong international players have subsidiaries in Poland.

The companies that have not been able to adjust and compete with the new rules of the market are facing major difficulties. One difficulty is the new legal requirements that are put on the domestic manufacturers, in terms of CE marking. The second difficulty is that the preferential treatment given to them during tenders has been abolished. Some of these companies are moreover operated less efficiently than their foreign competitors, which further reduces their ability to compete with the financially strong players.

The companies that have not been able to adapt to the changing environment have faced bankruptcy or been subject to acquisitions from larger firms, with more capital. The changes in the regulatory environment have facilitated the possibilities as well as the opportunities for acquisitions.

The limited financial means of the healthcare sector act as an obstacle for the profit potential of the medical devices companies. There is a structural overcapacity within the Polish market for medical devices, and the market has somewhat stagnated. Even though the demand for products is large, the financial constraints hinder the hospitals from buying the demanded amount. The overcapacity further strengthens the price competition among the competitors within the industry. The availability of products exceeds the possibilities for sales and to be able to sell the companies will have to cut prices.

All companies are fighting for very limited sales possibilities, and some also for survival. The only possibilities for increased sales are either to take market shares from your competitors, or to acquire the companies that hold a certain market share.

A further objective of acquisitions is a broadening of the product portfolio. The acquiring companies are now able to compete in low price segments as well as high quality segments. Moreover, the acquiring companies will get access to the acquired companies sales force, as well as the highly valuable customer contacts. An extensive consolidation process of the market is taking place.

Strategic Implications:

- The previously complicated registration process is abandoned.
- The CE mark is the only certificate required to sell products on the Polish market.
- Transparency in legislation has been increased and the “rules of the game” are the same as on the Single European Market.
- Fewer contacts with authorities needed in business operations within the medical device market.
- Hard competitive situation where price is the most important factor for the customer.
- Competitive situation is characterised by consolidation.
- Competition is mainly composed of several financially strong companies that cannot easily be outmanoeuvred.

Scenario two – “Survival of the fittest”

This scenario is characterised by high EC law implementation and increased funding to the health care system.

The demand for medical devices increases with the improved financial situation of the customers. The hospitals have the possibility to buy larger quantities of the products. Moreover, price is not the only factor of

significance in the buying process. The hospitals now have the possibility to consider the companies' whole offer, including quality as well as delivery time. The price sensitivity among the hospitals has decreased with the increased funding to the health care sector. This provides companies selling high quality products, with enhanced opportunities to increase sales.

The possibilities of selling larger volumes in a growing market, has attracted many foreign companies with strong capital base. This is further reinforced with the growing demand for high quality products. The adoption of European law has further strengthened the incentives to enter the Polish medical device market, by making the legal environment more transparent and familiar to the actors. However, the companies entering during this phase might face hard retaliation from the financially strong companies, already present on the market. A new entrant must be prepared to face strong and aggressive marketing campaigns with increased sales promotion, increased advertising and maybe also some "dirty tricks."

With the high amount of companies present in the market, the availability of partners for entering the market via a distributor, are limited. Therefore, a company might be forced to set up its own organisation. Many companies are present in the market and the competitive environment has become extremely hard.

There is a fighting among all companies about achieving larger market shares and increasing profit. The more financially powerful companies are using their resources to drive the smaller actors out of competition from the more profitable market segments. As a consequence of this, the dominating companies can to some extent divide the market shares among them. The competition is very harsh, since there is so much at stake, in terms of profit.

Since the market is growing and more funding is allocated to the health care sector, there is also room for some smaller players in the market. These companies are holding smaller market shares, but are also operated with profit. This segment consists of the firms that have managed to cope with the

demands of the new competitive environment. The resources of these companies are however very limited and consequently also their ability to compete on the same level as their multinational competitors. Domestic companies that are not able to handle the new competitive situation will either go bankrupt or be acquired. Thus, a consolidation process takes place.

Strategic Implications:

- The previously complicated registration process is abandoned.
- The CE mark is the only certificate required to sell products on the Polish market.
- The adjustments in legislation create more transparency and a more familiar legal environment for the foreign actors.
- Fewer contacts with authorities needed in business operations within the medical device market.
- All actors in the market are treated equally during the tender process.
- Possibilities for increased sales, since the market is growing.
- Price is not the only factor considered in the purchasing process.
- Very harsh competitive situation, focused on increasing market shares.
- Competition mainly carried out between the financially most powerful companies.

Scenario three -“Status Quo”

This scenario is characterised by low implementation of the EC Law as well as a continued low funding of the health care system.

As a result of the bad financial situation of the hospitals, the one and only criteria in the evaluation of bids is the price. The buyers have to make concessions regarding the quality of products. The companies' ability to offer a whole solution, from production to delivery, is consequently not acknowledged by the buyers.

The competitive situation is to a large extent characterised of diversity, where large multinational firms and a number of small and medium sized domestic firms are present in the market. The Polish medical device market has stagnated and there are too many companies present on the market, in relation to the possibilities for profit. There is a huge demand for new equipment from the hospitals, but the financial constraints hinder them from purchasing. The over capacity that exist within the industry, force companies to lower the price to be able to sell. The rivalry among the existing firms is very intense.

Because of the continued low level of EC law implementation, the firms with a relatively bad financial situation have survived. These firms are still given preferential treatment during the tender process. They have also captured the opportunity of the loopholes that exist within the implementation of EC law, to create benefits for their business operations. This situation fuels legal actions, which tend to be resource demanding and long-lasting judicial processes for all involved actors.

The environment for investments into the medical device market, is associated by a high level of risk, since the growth of the health care sector has somewhat stagnated. Moreover, there is a lack of transparency of the regulatory environment, which further increases the risk. The legal barriers to entry have not been lowered.

Within this scenario, the ability to increase sales and market shares is limited, because of the stagnation of the market. One way to increase sales is to gain market shares through acquisitions. However, the low implementation of EC law is to some extent preventing this development. There are no inducements for consolidation, since the smaller domestic firms manage to stay in business. These companies are well acquainted with this business environment and receive preferential treatment in the selling process.

Strategic Implications:

- The regulatory environment is an “in between system,” characterised by a low level of transparency.
- The CE mark has to be complemented by an additional bureaucratic Polish registration process.
- Regular contacts with Polish authorities are needed.
- Domestic companies are unjustly favoured in the tender processes.
- Legal actions might be necessary.
- Hard competitive situation where price is the most important factor when the customer is evaluating the bids.
- Competitive situation is characterised by diversity. Market is divided among large multinational players and small and medium sized firms.
- The possibilities for increased sales are very limited.

Scenario four –“Survival of the not-so fit”

This scenario is characterised by a low level of EC Law implementation as well as an increased funding of the health care system.

The growth of the overall economy has resulted in increased health care expenditure, and consequently more money for the customers to spend. The hospitals have the ability to evaluate features beyond price, when comparing the bids from medical device companies. There is a shift from price focus only, to an evaluation of the whole solution, taking in aspects such as delivery time, quality, and ability to deliver huge quantities etc.

The low level of EC law implementation, and the loopholes that exist within this context, can lead to legal actions. This tends to be a very resource-demanding and long-lasting judicial processes for all involved actors.

The fact that there is a substantial growth within the health care market boosts the sales of medical devices. This is of course recognised by all medical device companies, and therefore, companies not yet active in Poland enter the market. As a result of the market growth, the industry structure continues to

consist of a large number of capital-wise very different companies, both foreign and domestic.

There are some barriers that hinder companies from entering the market. One of these is the legal barrier, referring to the prevailing legal confusion. The fact that there is an act in compliance with the EC-directive that has not been implemented leaves the entering firms puzzled about which rules to follow. The companies already active in the market have created a larger understanding of how to behave. By being present in the market, they have gradually been able to learn how to act.

The low level of EC law implementation acts as a hindrance to consolidation. The loopholes in the implementation together with the growth of the market create opportunities even for the less effective companies to get a share of the market. The competition is therefore, within this scenario, characterised by a large number of very diverse actors.

Strategic Implications:

- The regulatory environment is an “in between system”, characterised by a low level of transparency.
- The CE mark has to be complemented by an additional bureaucratic Polish registration process.
- Regular contacts with Polish authorities are needed.
- Domestic companies are still unjustly favoured in the tender processes.
- Legal actions might be necessary.
- Possibilities for increased sales.
- Price is not the only factor considered in the purchasing process.
- Competitive situation is characterised by extreme diversity. Market is divided among several large multinational players and several small and medium sized firms.

Scenario Discussion

The construction of the scenarios has shown that the two parameters used on the axes, create four different competitive situations, to be acknowledged when formulating future strategies. These four future scenarios will consequently have different implications for a company planning to enter the Polish market for medical devices. During the evaluation of the scenarios we have found that three of the scenarios can be seen in a sequential order, starting with scenario three.

To a large extent, scenario three describes the present situation on the Polish market. The low grade of implementation of legislation regarding medical devices will most likely accelerate with the official goal of becoming a EU member in 2004. The implementation of the EC directives can however take a long time, and it can take several years before the administration is sufficient. The new approach legislation means a totally new way of working for the Polish authorities, which might delay the process further. At present, the Ministry of Health is restructuring the authorities dealing with medical devices, and the delegation of the tasks is not yet completed. Even if the implementation of EC law might take a long time, this will most probably happen before there will be an increased funding to the health care sector. The funding to the health care sector is related to the overall economic performance of Poland. Poland's economy is currently characterised by increased budget deficit, stagnation in GDP growth and increasing unemployment. This will most likely have a negative effect on the health care spending in the near future.

Therefore, the next phase that the medical device market will go through is most likely the consolidation process in scenario one. All companies are, within this scenario, fighting to increase sales in a stagnated market. The continued low funding to the health care sector, together with the high level of EC law implementation, will lead to a consolidation process, where the financially strong companies acquire the smaller competitors, to gain market shares. This is possible since the smaller companies will most likely not be

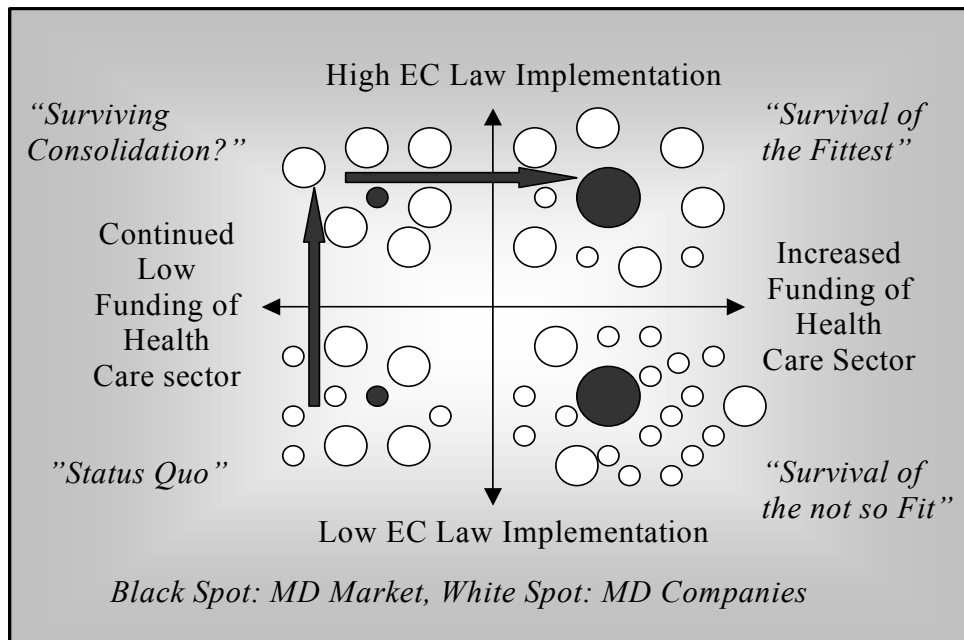
able to cope with the new competitive situation of the Single European Market.

In a longer perspective, the health care system will receive an increased amount of money. A EU accession is probable to lead to increased economic output in the long term, higher income in the private sector and higher profits for the companies. This will lead to a better situation for the Polish state, since it will have larger incomes from taxes and smaller amount of unemployed to provide for. This will lead to a competitive situation similar to the one described in scenario two. The financially strongest companies will increase their market shares, and dominate the largest part of the market.

To conclude this discussion, scenario three describes the situation of today. It is also reasonable to believe that the next phase that the market will go through is the situation illustrated in scenario one, followed by scenario two. However, when these developments will take place is very hard to predict.

Within this context, it is further highly important to point out that the scenarios should be seen as a facilitator of learning, not a completely truthful description of the future. The objective of the scenario planning process has been to analyse possible future turns of the market. Nevertheless, the future might show that the market will develop in another direction than the findings of the analysis have shown. However, referring to the findings of the conducted research, it is our belief that the scenarios give a constructive description of how the future might develop. The following model illustrates the competitive situation of the different scenarios, as well as the sequential order, presented in the discussion above.

Figure 16 “The Competitive Situation of the Scenarios”



Source: Own Construction

The implications of the constructed scenarios, put into the perspective of a company planning to enter the market, will be discussed in the coming chapter. The following model explains the sequences of the constructed scenarios.

7. CONCLUSIONS & RECOMMENDATIONS

This chapter present the conclusions of the empirical findings and the analysis. The three research questions used in various sections of this thesis, constitutes the basis of the conclusions drawn in this chapter. The findings of the three research questions enables for conclusions of the main question. Given the conclusions of the research, the chapter ends up with presenting recommendations on how to manage the presented changes.

7.1. General Conclusions

This chapter herewith allows for a return to the main question of the thesis:

Main Question:

How can an MNC, active in the market for medical devices, amend to the adjustments in the direct business environment that evolves with a future Polish EU membership?

7.1.1. EU and Poland's Political and Economic System

The political and economic system of Poland will not change considerably at the day of accession. Instead, the political and economic environment has been subject to change ever since the liberalisation in 1989. EU has had a supportive influence in the second half of the Polish transition. Ever since the European Agreements, Poland has adjusted its regulatory environment to comply with the EU legislation. The success of these adjustments has been evaluated regularly in progress reports, conducted by the Commission.

In the Regular Reports the Commission has given both positive and negative feedback on how well the market economy in Poland has developed, and what areas are in need of improvements. The role of EU can furthermore be described as having a somewhat stabilising influence in the dynamic transition process. EU will continue to have a huge impact on Poland and its economic and political system, since the country after accession must steer its

policies to be in line with the objectives of the EMU. Hopefully, this will further stabilise the future business environment.

The current political situation in Poland is today to a large extent divided into EU advocates and EU opponents. In general, the EU opponents are to be found among the more nationalistic, protectionist movements within the country. If these movements would gain increased power, the EU integration and market economy reforms would most likely stagnate. This could mean less transparent environment for foreign investors to operate in. However, this kind of future development is not seen as very likely, since the EU advocates outnumber the EU opponents in terms of power. The majority of influential bodies in Poland are pro a rapid adjustment to market economy, as well as to a EU membership.

The present government in Poland is in favour of a EU membership and the referendum is preliminary set to May 2003. The referendum will determine if the Polish people want to join the EU or not. Presently the public opinion is in favour of a membership and Poland will most likely vote in favour of joining the EU. However, the outcome of the final negotiation round can be the determining factor of where the Poles will place their vote. Another factor will be the influence of the opponents in the public debate.

Poland has managed to transform its former centrally planned economy to a functioning market economy. Still, there are improvements that need to be done before the Polish economy is completely comparable to the market economies of the European Union. These changes will occur gradually, and accumulate with gained experience.

The Polish economy is today, to a large extent influenced by the EU economies, especially Germany. The EU membership will most likely interlink the economies further. When Poland becomes a part of the Single European market, the trade between Poland and other EU member states is expected to increase. This would further increase the involvement between the economies.

However, the EU membership will most likely not have a substantial positive impact on the Polish economic situation in the short term. On the contrary, it is to some extent, expected to put Poland in an unfavourable economic position in coming years. However, in the long run, the EU membership is supposed to boost the economic growth as well as having a considerable positive impact on the Polish economy.

Poland has since several years been one of the most popular locations for foreign investments in Central and Eastern Europe. The favourable geographic location and the huge domestic market are considered to be some of the reasons behind this development. The government have offered a number of favourable investment incentives for attracting foreign direct investments. Some of these incentives will be changed from the day of accession, since they are considered to be in conflict with EU competition policies.

Another aspect of the economic system is the taxation environment, which according to the Commission is not working satisfyingly. It is however expected to improve considerable in 2003, when the EU accession is coming closer. In general the financial system of Poland is considered sound. Still, compared to the majority of the present EU member states, there are inefficiencies among the existing banks.

The Polish labour market is not expected to change with a Polish EU membership. There are however several characteristics that are important to highlight within this context. There is considered to be a lack of middle managers within the Polish labour force. It is furthermore considered to be rather difficult to find employees with experience and an understanding for the western way of doing business. The special features of the Polish business environment, nevertheless increases the importance for recruiting the right people with adequate experience as well as a proper attitude.

Poland is still in the adjustment period of transposing EC law to national law. New demands are put on the authorities, which might not have the accurate

knowledge, nor the competence in how to monitor these new demands. This is probable to lead to a lack of transparency in the near future.

Currently, one of the main problems for Poland is that the judicial administration is not in a position to handle legal and judicial processes in an efficient way. It has today proven to be a very time and resource demanding procedure to be involved in legal processes in Poland. However, reforms have been initiated to improve the situation of the Polish judicial system.

The above-described situation points out that the economic and political system of Poland is characterised by very dynamic conditions. This is something that has to be acknowledged in the formulation of future strategies for business operations in the country. The uncertainty aspects must be the underlying fundamental in all strategic development. It is highly important to get rid of certain assumptions that are made about other markets, since Poland is still in a transition process, with only ten years of experience of how to monitor a market economy.

7.1.2. EU and the Polish Medical Device Market

As a result of the future EU accession, the medical device market has faced considerable changes, in terms of the regulatory environment. The legislation regarding medical devices and the legislation regarding public procurement have been adjusted to comply with the EC law. There will be new requirements set on the domestic producers. The CE mark will become obligatory for market authorisation in Poland. Moreover, there will in 2004, be no legal ground for the domestic favouring in the open tenders. The adjusted legislation will create transparency for the pan European firms that have already adapted to the EU standards and are well acquainted with the regulatory environment. Increased contacts with state authorities might be needed in the immediate future, when the system will be characterised by an “in between system” and lack of clear guidelines.

The new regulatory environment is therefore connected to a certain risk, since there is a lack of guidelines for the involved actors. The current situation

causes great confusion for the companies, since the Ministry of Health cannot provide accurate information.

The Public Procurement act includes a clause which allows for domestic preferences in the evaluation of bids during tender processes. The domestic companies have sometimes been groundlessly favoured during the tenders, despite the fact that foreign products in general are considered to be of better quality among the hospital staff. As discussed in the analysis, there might be a shift within the purchasing process, towards an evaluation of the whole solution instead of the price merely. This will likely happen as soon as the health care sector receive increased funding.

The application for EU membership has not had any effect on the health care system in Poland. The system has since 1999 gone through considerable changes, and meet a robust public discontent. Due to the reforms in 1999, the health care system went from centralisation to decentralisation. The reforms of 2003 will to a certain extent again somewhat centralise the system. The health care sector is under development and characterised by a strive for finding the best suitable form for it.

Poland's health care expenditure is in comparison with the EU member states very low, and many of the hospitals are in a bad financial shape. This will most likely stay at the same level in the following years. In the long run however, the EU membership is expected to increase the sales for medical devices. The future growth potential of the market is seen as the most important incentive for all interviewed companies, active with own sales organisations in Poland. There is a general assumption that Poland sooner or later will have to increase its health care expenditure. All companies want to be established in the market and have well-established operations before this growth will take off.

With the Polish EU membership, the custom clearance will be removed. This has been regarded as an obstacle for the companies without manufacturing in Poland. The custom tariffs for imported medical devices will be adjusted to the EU level when Poland joins the EU.

To summarise, the main opportunity that arises with the Polish EU membership is the adoption of EC-law, which will result in a more transparent legal environment for the companies, with experience from the Single European market. Further benefits from the EU membership are the removal of the time consuming and resource demanding custom clearance procedure. Another future opportunity, not directly connected to the EU membership, is the future market growth. The clearest threat within the Polish medical device market is the currently limited funding of the health care system. There are many companies present on the market, all fighting for limited sales possibilities. The analysis chapter evaluated the future market structure and the competition that Mölnlycke HC is likely to face in coming years. The future will most likely be characterised of consolidation in most of the market segments. Mölnlycke HC will in future years face a strong competition from the financially strong multinational competitors, as well as the current domestic market leaders.

7.1.3. The Implications of the Changes

The implication of the above-presented changes, allows for a return to the analysis of the competitive situation made in chapter six. As presented in this chapter, the future turns of the market will to a large extent be influenced by the level of EC law implementation together with the degree of funding that the Polish health care system will receive in the future. The scenarios constructed in the analysis chapter presented four various alternative of a future market structure, visualised in figure 16. In the scenario discussion it was found that the market most probably will go through a consolidation process, before there will be increased funding to the health care system.

The current market is characterised by low health care spending and low implementation of EC legislation. This might not be very appealing for Mölnlycke HC to enter into. Many of the international competitors are however, already present on the market. These competitors are established with subsidiaries in Poland and own sales forces. The companies have since many years been able to build a brand awareness and an increasing demand for their products. Moreover, the companies have since several years gained experience of the market and the changing business environment. Several years of experience of the Polish market has further enabled them to develop a well functioning contact net. Some of the domestic competitors have long had a very strong position within their market segments. The domestic companies that will cope with the new demands of the market are expected to further strengthen their positions.

When the consolidation process starts and the market is more or less divided among the financially strong players, it would be extremely hard for Mölnlycke HC to enter the market. The companies that have managed to gain substantial market shares through mergers and acquisitions will be in a highly favourable position when the market growth sets off. When a few financially strong players dominate the market, Mölnlycke HC will have to struggle very hard to gain market shares.

It might be considered more appealing for Mölnlycke HC to enter the market, when the regulatory environment has somewhat stabilised and the necessary administration to handle the new legislation is sufficient. Furthermore, another factor strengthening this decision would be the bad financial situation of the Polish hospitals, and the current unhealthy conditions of the Polish economy. However, even if the environment is somewhat chaotic at the moment, the company could lose very much by waiting, since the majority of competitors will, with their experience, be better equipped to drive possible new entrants out of competition.

The establishing of Mölnlycke HC's future sales organisation in Poland will most likely be a very time consuming process. As mentioned earlier in this chapter the company's success is to a large extent determined by the qualities of the workforce. Mölnlycke HC needs to find people with a combination of the right education, experience and an attitude in line with the company culture. Moreover, to build the accurate competence once the labour force is established could take several years. This must be acknowledged in the strategic planning. Once the company is established in Poland, it would take an additional number of years before the company can compete on the same level as its competitors.

Taken the above aspects into consideration, Mölnlycke HC should consider entering the Polish medical device market before the market will be characterised by the features outlined in scenario one.

7.2. Recommendations

The section above described and motivated the best timing for a market entry. The following section will focus on recommendations on how to best manage the future changes within the business environment.

The business environment as well as the market is going through a period characterised by *dynamism*. Moreover, the health care system has also gone through considerable changes in recent years. The health care sector is under development and characterised by a strive for finding the best suitable form for it. The dynamic conditions of the market must be acknowledged in the future strategy formulation. Since the environment is under constant change, Mölnlycke HC needs to *constantly update information* regarding changes in the legislation, changes in the health care system, as well as other areas of importance. This allows for a *well-developed contact net* that can provide accurate information. Moreover, it could be of importance with a *well functioning information system*. Mölnlycke HC should moreover strive to secure a *good information flow* from the Polish subsidiary to the concerned parties in the organisation.

This situation calls out for a need of a ***certain division*** within the future Polish subsidiary, that handles all the legal issues related to the operation of the company. The dynamic regulatory environment creates a need for a constant updating and reflecting on the legal changes and what implications it might have for the business operations.

Furthermore, the above-described circumstances create a need for, as far as it is possible, ***efforts to influence the decision makers***. The interest associations act as a tool for this type of influence. However, according to many of the members of these associations, there have not been much lobbying or attempts to influence the Ministry of Health. Therefore, Mölnlycke HC should be prepared to take an ***active role*** in these interest associations, to strengthen the overall influence of them.

The current Polish medical device market is considered a very ***centralised industry***, due to the importance and influence of the Ministry of Health. Many of the multinational companies are established in Warsaw whereas the domestic producers seem to be more evenly spread throughout the whole country. The interest associations are also located in the capital city. In the case of Mölnlycke HC, it is our belief that the business is best set up in or around the Warsaw area. Among the global players there seem to be a general belief that the ***closeness to the centre of power*** is a crucial factor when choosing the right location. Mölnlycke HC should therefore seek to establish the sales organisation in ***Warsaw***. However, in a long-term perspective, and with the gradual implementation of EC law, the company might be less dependent on a centralised location.

Many of the companies in the medical device market have a sales force that enables them to reach hospitals ***all over the country***. Even though this might be hard to obtain in a short-term perspective, the objective must be to, as soon as possible, cover the whole country. To be able to increase sales and acquire larger market shares, the company should compete on the same geographical areas as its competitors.

As mentioned before, the foreign companies have sometimes been subject to discrimination during tenders. This has happen despite of the fact that the hospital staffs in general are considered to have a preference for foreign brands. In general, the foreign produced brands are often considered to be of higher quality compared to domestic brands. Future marketing strategies should therefore ***focus on the hospital staff***, i.e. doctors and nurses and get them to take a more active role in the purchasing process.

This study has furthermore shown that the future might involve a shift of focus in the purchasing process. Once the health care system receives more money, the purchasers will be able to evaluate more than price related factors, such as quality. Mölnlycke HC could therefore create huge advantages by strongly ***positioning*** themselves as a ***high quality*** company.

As pointed out before in this chapter, the ***human resources*** are of crucial importance for companies active in the medical device industry. Mölnlycke HC must carefully recruit the future employees. Apart from the accurate education, the managers should preferably have experience from the health care industry and practical management skills from the western way of conducting business, or at least an understanding of how to best do so. Establishing an adequate workforce in Poland, could take several years and ***careful recruitment*** must be complemented by ***internal training***. Through this, the company can secure that the company values and the organisational culture are transferred to the future Polish subsidiary.

8. AREAS FOR FUTURE RESEARCH

This study enables a number of opportunities for further research. This section will present the areas that we have come across during our study, which could request further investigations.

EU has adjusted the regulatory environment and created common legislation regarding medical devices, which creates transparency for the companies active within the European industry. However, the health care systems of the EU member states are very diverse, in terms of funding, as well as the formal structure of the different health care systems. It would in this context be very interesting to study how the companies adjust their strategies to the health care system of each member state.

The health care expenditure is in Poland very low, compared to other European countries. The hospitals are in a bad financial shape and are forced to make considerable concessions in the purchasing process. The Polish hospital's buying process would be interesting to investigate further. In order to develop successful marketing strategies, it is important to analyse the hospital's preferences in detail. This issue could be an interesting subject to enter more deeply into.

This research has taken an external approach, focusing on the Polish business environment. As stated several times in the thesis, the external view must be complemented with an internal analysis, in order to develop successful strategies. Hence, an area for further research could be a profound analysis of the resources and capabilities of a company, active on the Polish market for medical devices, and consequently confirm the suitability of the companies' strategies.

As pointed out on several occasions within this thesis, the Polish medical device legislation has entered into force, but has not yet been implemented. The adjusted legislation is based on the new approach, which put new demands on the Polish authorities. It could therefore be interesting to, in a

couple of years, investigate how the Polish authorities have been able to adjust to these new demands and how well the legislation is functioning in practice, for all involved actors.

One of our main conclusions has been that a consolidation process most likely will take place in the Polish market for medical devices in the future. This conclusion allows for a future follow-up, in order to analyse the market structure, and the effect that the EU membership actually had on the market, and consequently the level of competition taking place within it.

9. AUTHORS' REFLECTIONS

The objective of the summit that will be held in Copenhagen 12-13 December 2002 is to complete the first part of the eastward EU enlargement. During the autumn, and consequently during the writing process of this thesis, the final negotiations between the EU and the candidate countries, have taken place. The Copenhagen summit will determine whether the negotiations have been successful enough, and if Poland and EU can agree on the content of the accession treaty.

Poland is by many considered the key country in the enlargement process, and it is considered of great importance that the country is among the first tier Eastern European states joining the EU. When the EU enlargement negotiations started, Poland was considered to be the country that was closest to a EU membership among the Central and Eastern European countries. The country was adjusting fast to close the gap between itself and the EU, and the negotiations moved forward relatively rapidly. During the latest years, the negotiations have not proceeded as smoothly. At the same time as the Polish negotiations have somewhat stagnated, the other candidate countries have been able to speed up their negotiations with the Commission. Poland is now considered to be the country with most work ahead, in the preparations of becoming a EU member in 2004.

The result of the Copenhagen summit can either result in the creation of an accession treaty, or that both parties have not been able to reach an agreement. This will then result in a delayed Polish EU membership, and that the negotiations are put on hold for an uncertain period of time. This would be a setback, not only for the enlargement advocates of the EU, but also for Poland, and its future development. The EU membership has long been the main objective for Poland and it is very uncertain how the future will develop, if the country will not be among the first tier countries.

Even if the Commission and Poland manage to finalise their positions at the Copenhagen Summit, the Poles have the power to neglect the accession treaty in the referendum in May. This is expected to happen if the outcome of the negotiations is not considered acceptable to the Polish voters.

It is our belief that the future turns of the examined market and the following implications will take place irrespectively of a Polish EU membership in 2004. However, the development could be somewhat delayed with a postponed accession to the EU. Most likely, a postponed EU membership will lead to stagnation in the implementation of the EC law. The current legal confusion will continue for an undetermined period of time.

The outcome of the Copenhagen Summit will be a yet historical event in the Polish transition. It will then be decided whether Poland will continue to be a part of "Eastern Europe," or becoming a member state of the European Union.

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Ms. Gryglicka, I., (2002-11-04), Administrator, Polfarmed, Warsaw

Ms. Patyk, B., (2002-11-18), Consultant, PAIZ, Warsaw

Mr. Lagerstedt, L., (2002-11-13), Consultant, Kommerskollegium / National Board of Trade, Stockholm

Appendix 1

Areas for discussion during the Interviews:

Medical Device legislation

- The previous medical device legislation and enclosed registration process
- The new EU adjusted legislation and the enclosed registration process
- The competence of the related authorities
- Challenges for the future

Public Tenders

- The legislation regarding Public Procurement
- The adjustments to EU
- The buying process of public hospitals

Competition and Market Structure

- The competition and market structure of the Polish medical device market
- The effect of EU membership
- The domestic vs. foreign players
- Future opportunities
- Future threats
- The future turns of the market
- Differences and similarities of the Polish and the EU MD market
- The market potential

The business environment

- The Polish business culture
- Swedish vs. Polish business culture
- Lobbying
- The role of the Interest Associations
- Financial Markets
- The transition process and the practical implications

- The market potential
- The labour market
- The tax environment

The coming EU membership

- The public opinion
- The main benefits
- The main costs
- The impacts on competition
- Sensitive issues in the negotiation process
- The time for entry
- The positive aspects of an enlarged SEM
- The negative aspects of an enlarged SEM

The Medical Device Market

- The health care system
- Future reforms
- Private and public hospitals
- Independency of the hospitals
- Product preferences (country of origin, brand, price etc)
- Market potential
- Key success factors
- Possible barriers to trade
- The EU impact on the MD market
- Location aspects
- The importance of personal contacts in business operations

Investment Climate

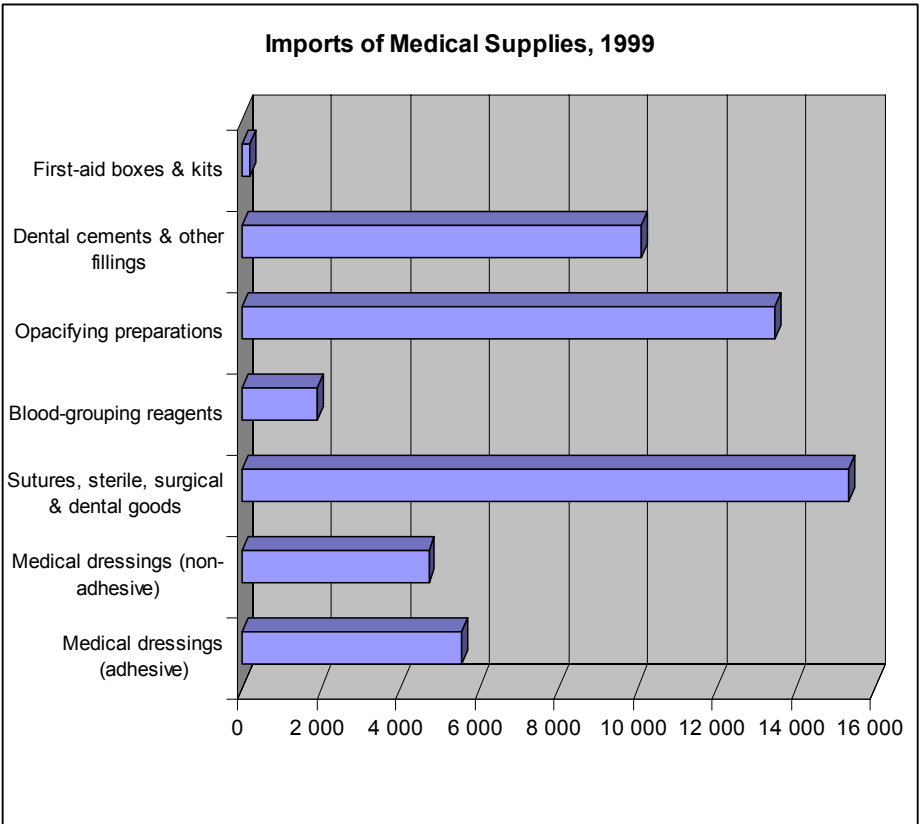
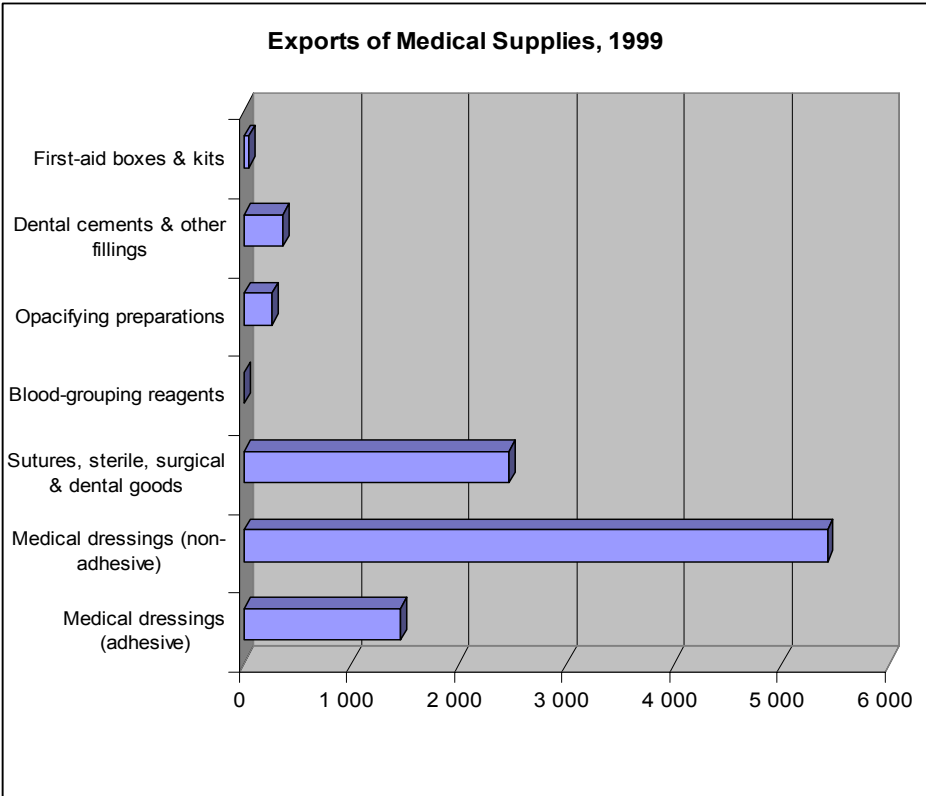
- FDI policies and the general investment climate in Poland
- The effect of a EU membership
- Investment climate for medical devices
- Main shortcoming and main advantage of investing in Poland

Appendix 2

The chapters of the *Acquis Communautaire*:

- CHAPTER 1 Free movement of goods
- CHAPTER 2 Freedom of movement for persons
- CHAPTER 3 Freedom to provide services
- CHAPTER 4 Free movement of capital
- CHAPTER 5 Company law
- CHAPTER 6 Competition policy
- CHAPTER 7 Agriculture
- CHAPTER 8 Fisheries
- CHAPTER 9 Transport policy
- CHAPTER 10 Taxation
- CHAPTER 11 Economic and monetary union
- CHAPTER 12 Statistics
- CHAPTER 13 Social policy and employment
- CHAPTER 14 Energy
- CHAPTER 15 Industrial policy
- CHAPTER 16 Small and medium-sized enterprises
- CHAPTER 17 Science and research
- CHAPTER 18 Education and training
- CHAPTER 19 Telecommunications and information technologies
- CHAPTER 20 Culture and audio-visual policy
- CHAPTER 21 Regional policy and co-ordination of structural instruments
- CHAPTER 22 Environment
- CHAPTER 23 Consumers and health protection
- CHAPTER 24 Co-operation in the fields of justice and home affairs
- CHAPTER 25 Customs union
- CHAPTER 26 External relations
- CHAPTER 27 Common foreign and security policy
- CHAPTER 28 Financial control
- CHAPTER 29 Financial and budgetary provisions
- CHAPTER 30 Institutions
- CHAPTER 31 Other

Appendix 3



Imports by Category, 1999 (%)

