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REVIEW ARTICLE

PORTER´S FIVE FORCES ON MEDICAL DEVICE INDUSTRY IN EUROPE

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Summary

Healthcare is an industry that has a very strong position in economies and a relatively high share of GDP. It also includes the medical device industry. The aim of this paper is to analyse the potential of the market for medical devices in Europe. The starting point is the analysis of the external environment, describing the selected macroeconomic variables affecting aggregate demand and therefore the medical device industry in selected countries. The tool for strategic analysis of the European market is Porter's Five Forces model, where initial information is obtained from the analysis of economic indicators of the given industry, analysis of world databases data, analysis of documents dealing with studies of the medical device industry.

The European market can be described as highly competitive, with a large number of small and medium-sized companies, stable innovative activity, which is significantly defined by the regulations by the competent authorities. Globally, this industry is predicted to grow.

Key words: Medical device industry, Porter's Five Forces, Europe

INTRODUCTION

In developed countries with regard to aging population, the healthcare sector plays a large role in government spending. The share of healthcare in GDP increases. This area is, with regard to individual segments and demographic trends, paid high attention. Medical devices play an important and increasing role in the delivery of healthcare. The aim of this paper is to analyse the potential of the market for medical devices in Europe.

Medical Device is defined as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological

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process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (MedTech, 2014).

Another related concept, especially in the monitoring of expenditure in international comparison in this area, is medical technology. Medical technology is generally associated with high technology. However, it is also less sophisticated products and technologies such as operating tables, massage devices, bandages etc. These less complex sub-fields represent a large number of patent applications, and the total field is the second largest of the suggested classification with 6.3 percent of all applications in 2005 (OECD, 2014).

With increased governmental interest in value assessment of technologies, medical device manufacturers are finding it increasingly necessary to become more familiar with economic evaluation methods. Some studies sought to explore the levels of health economics knowledge within small and medium-sized enterprises (SMEs) and to scope strategies they employ to demonstrate the value of their products to purchasers (Craven et al., 2012).

Other areas which are fundamental for the medical device industry are regulatory restrictions and legal obstacles (McAllister, Jeswiet, 2003), (Matsuoka, 2012). In view of applicability of the technologies in the market there are many marketing studies (Mackert, Harrison, 2009), (Craven et al., 2012). Last but not least, the increasing limitation of resources has stimulated the discussion of the economics aspects of medical devices production (Ischinger et al., 2002).

Currently, medical technology is characterised by a constant flow of innovations, which are the result of a high level of research and development within the industry, and with the close co-operation of users. Products have a typical lifecycle of only 18-24 months before an improved product becomes available (Fig.1) (MedTech, 2014).

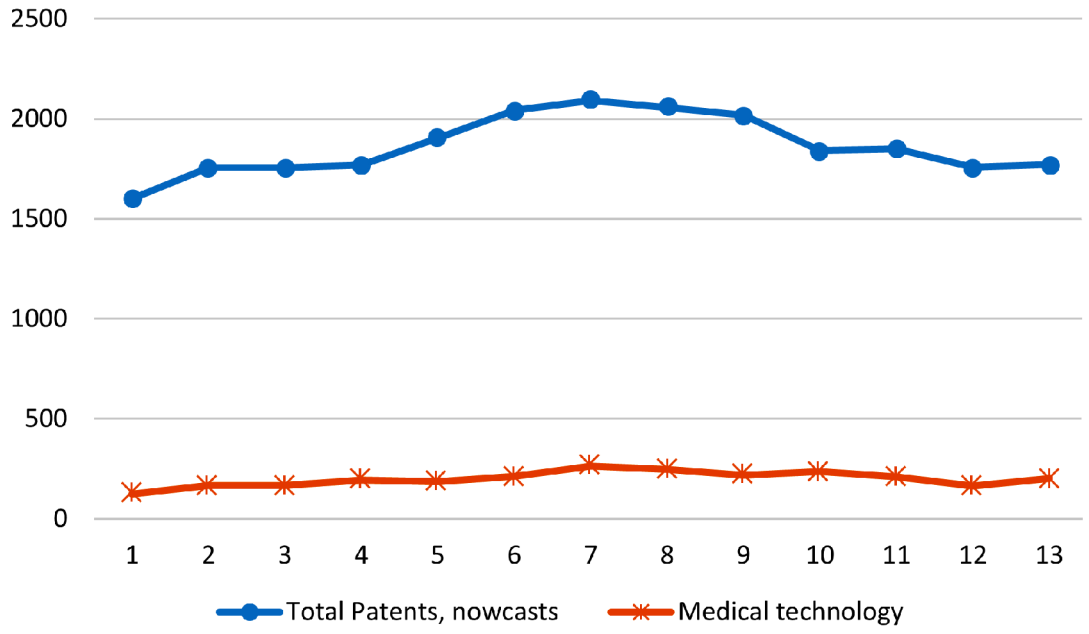

Figure 1. Medical technology innovations, source: (MedTech, 2013)

Although sophisticated medical technology is already available in health systems in developed countries, further advances are constantly being made. Societal demands for a new drug, device design and development are great. Because of advances in medical care, the mortality from cardiovascular diseases has progressively declined over the past 2 decades. The society stands on the threshold of "cures" for several of mankind's greatest afflictions, including cancer, atherosclerotic cardiovascular disease, dementia and human immunodeficiency disease (Wyke, 2004).

METHODOLOGY

The method that will be used to analyse the market for medical devices, will be an analysis of the external environment based on the factors affecting aggregate demand in the economy and leading to its potential growth. The Porter's Five Forces model will also be used. This model is one of the basic and also the one of the most important tools for analysing the competitive environment of an industry or a company and its strategic management. Its creator is Michael Eugene Porter from Harvard Business School, Institute for Strategy and Competitiveness. The model works with five elements. The essence of the method is forecasting the development of a competitive situation in the surveyed sector based on an estimate of the possible behaviour of the following entities and subjects involved in a given market and the risks for the sector from their side (Porter, 2008):

- existing competitors - their ability to influence the price and the offered quantity of the product/service,
- potential competitors - the possibility that they enter the market and affect the price and offered quantity of the product/service,
- suppliers - their ability to influence the price and offered quantity of required inputs,
- buyers - their ability to influence the price and quantity demand of the product/service,
- substitutes - price and offered quantity of the products/services at least partially capable to replace the product/service.

Porter's model is based on an analysis of the economic indicators of the industry, analysis of data from Eurostat databases, possibly the OECD, the analysis of documents dealing with studies of the medical device industry.

EXTERNAL ENVIRONMENT OF MEDICAL DEVICE INDUSTRY

The characteristics of the external environment of the medical device production market are based on a macroeconomic concept of aggregate demand. Aggregate demand reflects different amounts of goods and services (real product) that consumers, businesses, government and foreign customers want to buy at different price levels. In the event of an increase in aggregate demand, it is expected that there will be an increase in demand for all production in the economy, i.e. including the production of medical devices.

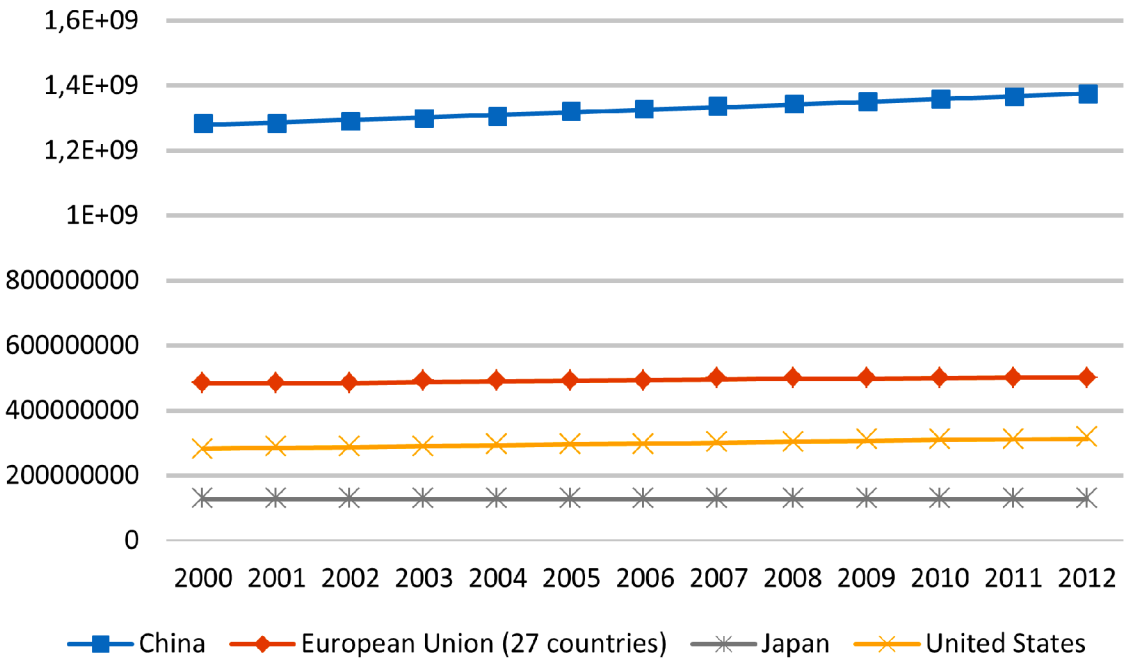

Figure 2. Development of the population in the years 2000-2012, source: according to (OECD, 2014)

The aggregate demand is the sum of household consumption expenditure (C), investment spending of companies (I), government purchases of goods and services (G) and net exports (NX), whose height depends on the price level. Anything that positively affects any of these components causes a positive demand shock, i.e. demand growth. These include the following changes (Sojka, 1999):

- optimistic expectations of the future development (consumers, companies and the state),
- increase in companies investment and the consequent development of technologies, increasing numbers of innovative products, patents,
- population growth,
- a drop in prices of imported inputs to production,
- reduction in interest rates,
- reduction in taxes,
- increase in government purchases and investments.

Due to the surveyed area, the development of the population, consumers' expectations, GDP, number of patents and patents in medical technology in selected countries will be described. The large markets that are promising for this area (also according to the existing studies) and will be compared include: Europe, USA, China and Japan (mHealthTalk.com, 2014).

Population

With a growing population it is expected that the demand for consumption goods and services will increase, including medical devices. From this perspective, the least promising countries are countries in the European Union, while China is on the other side (Fig. 2).

Gross Domestic Product (GDP)

Gross Domestic Product is one of the fundamental economic characteristics of countries; it is a key indicator of the development of the national economy, it measures the performance of the economy. It is an indicator summarising the newly created values, which are used to estimate the economic development of a country. Within the financial statement, GDP represents the value of what has been newly created in the country during the reporting period. GDP growth precedes increased demand of individual entities in the economy. Fig. 3 shows that since the economic crisis in 2008/2009 we can observe a slow growth in Japan and the USA. China has been recording a decline since 2007, however, GDP growth is still double compared to the comparator countries. In the following years, China is predicted to show still significantly higher GDP growth than Europe and USA, mainly based on innovations, new technologies and "green" energy.

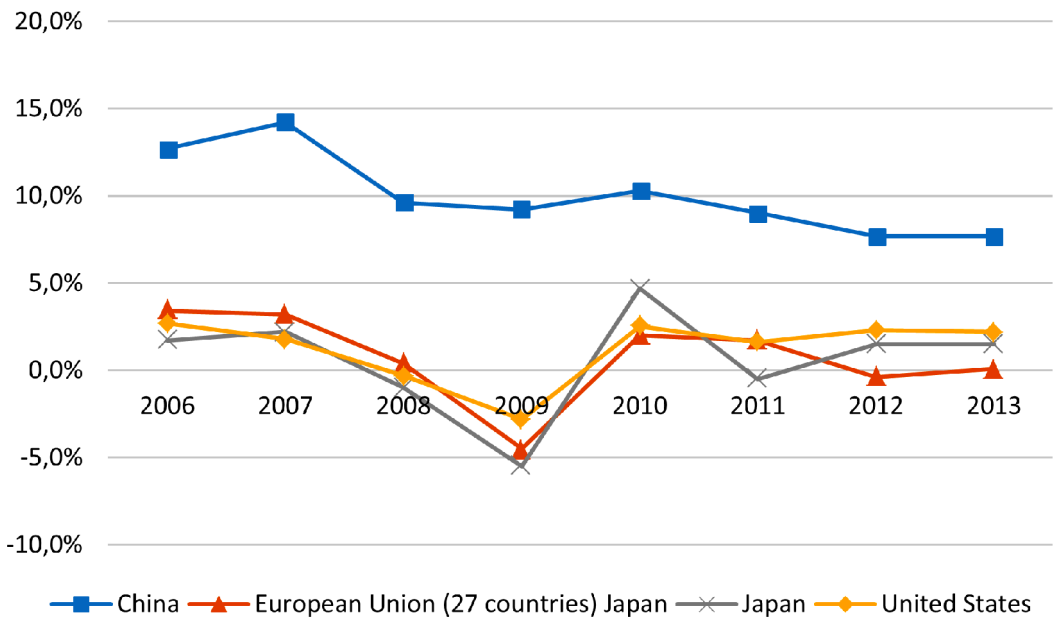

Figure 3. GDP growth in the years 2006 – 2013, source: according to (0ECD, 2014)

Patents

Investment innovative activities of firms and governments can be characterised by the number of registered patents. According to the World Intellectual Property Organisation (WIPO), China is clearly at the forefront, Japan records a decline and Europe maintains a slight increase (Figure 4). Countries with higher patent activity can be assessed as potentially economically stronger in the coming years, households in these countries will be richer and therefore their markets will be prospective.

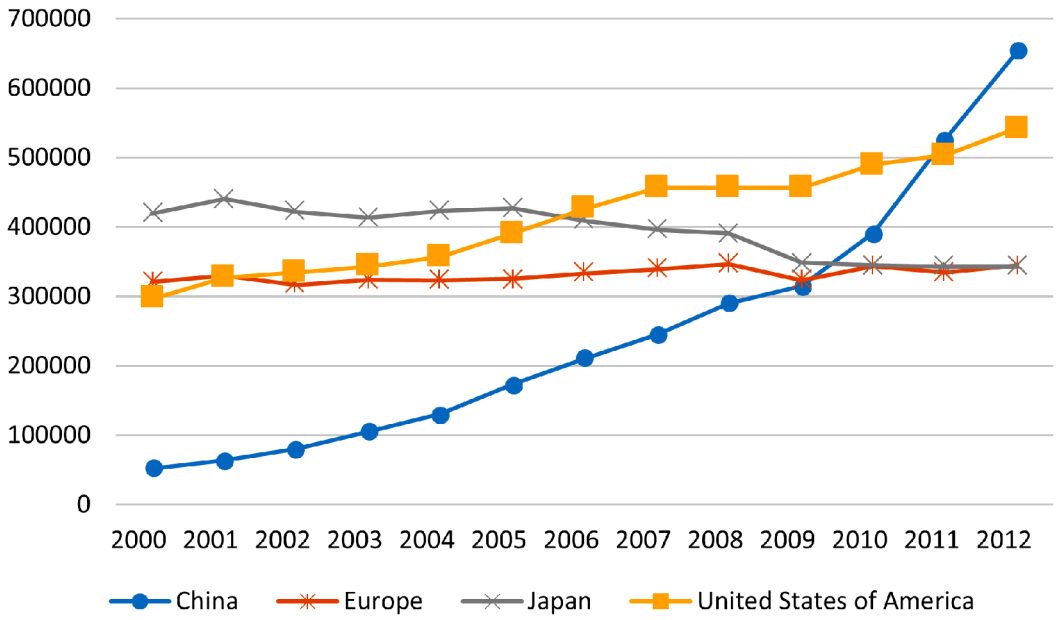

Figure 4. Development of the number of patents by WIPO in the years 2000 – 2012, source: according to (WIPO, 2014)

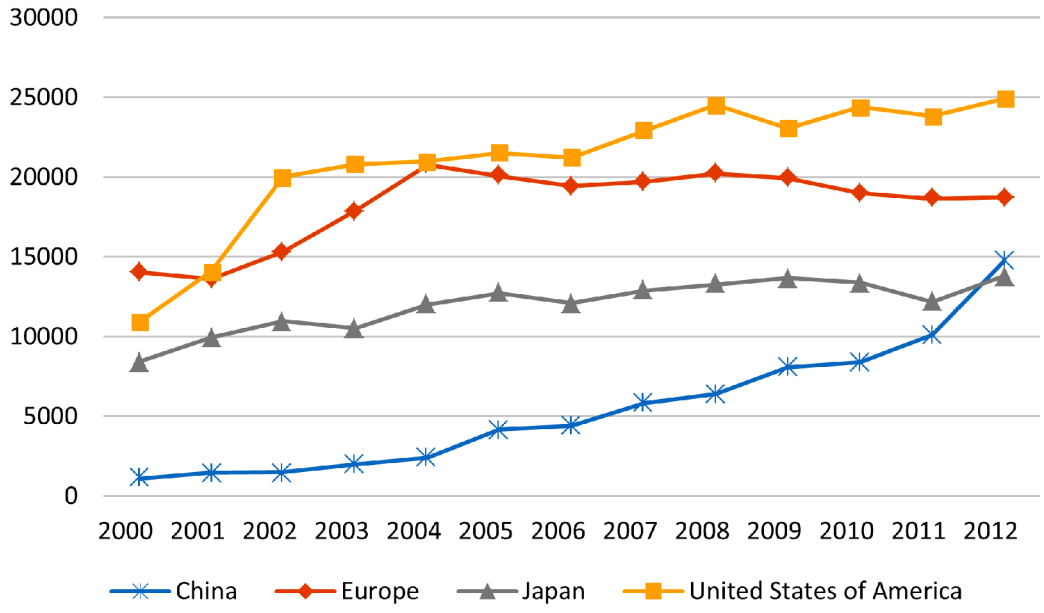

Figure 5. Development of the number of medical technology patents by WIPO in the years 2000-2012, source: according to (WIPO, 2014)

Medical Technology Patents

In the field of medical technology patents, USA has had a clear long term leading position. Europe is the only one reporting a decline, on the contrary China experiences a sharp growth (Figure 5). The development of these patents can be viewed from two sides. The first side is that the growth of this indicator is simultaneously the growth of this market in that country, on the other hand there will be a stronger competitive pressure on this market.

Expectations of future development

Expectations of future development are also among the factors affecting demand and consumers' behaviour. In the market for medical devices there is a positive expectation for the future. Available forecasts indicate growth in the market for medical devices (Happich, 2014) Fig. 6 shows the forecast for 2022, when more than a 20% increase in this market should occur.

The above development of the indicators shows that China is an interesting market, due to the growing population, GDP growth and investment in innovations. Furthermore the market in Europe will be analysed. From the existing information the market can be identified as relatively highly competitive (due to the relatively stable and relatively high number of patents in medical devices). In terms of population and GDP development, the situation is rather negative than positive.

For a more detailed determination of the market prospects, it is necessary to analyse the sector of healthcare, healthcare spending, also in relation to the populations of individual economies. A significant role in relation to the market of medical devices will be played by the demographic distribution of the population.

PORTER'S FIVE FORCES ON MEDICAL DEVICE INDUSTRY IN EUROPE

The Medical Industry (not only in Europe) has typical high barriers to entry in the form of high research and development expenditures, regulatory restrictions, and legal obstacles. In addition, smaller manufacturers have difficulties competing with larger healthcare supply manufacturers due to various factors such as purchasing power, sales forces, and advertising expenses (Scribd.com, 2014). Some companies have built strong brand identities around quality and innovation, resulting in the likelihood that less hospitals will choose another company's product.

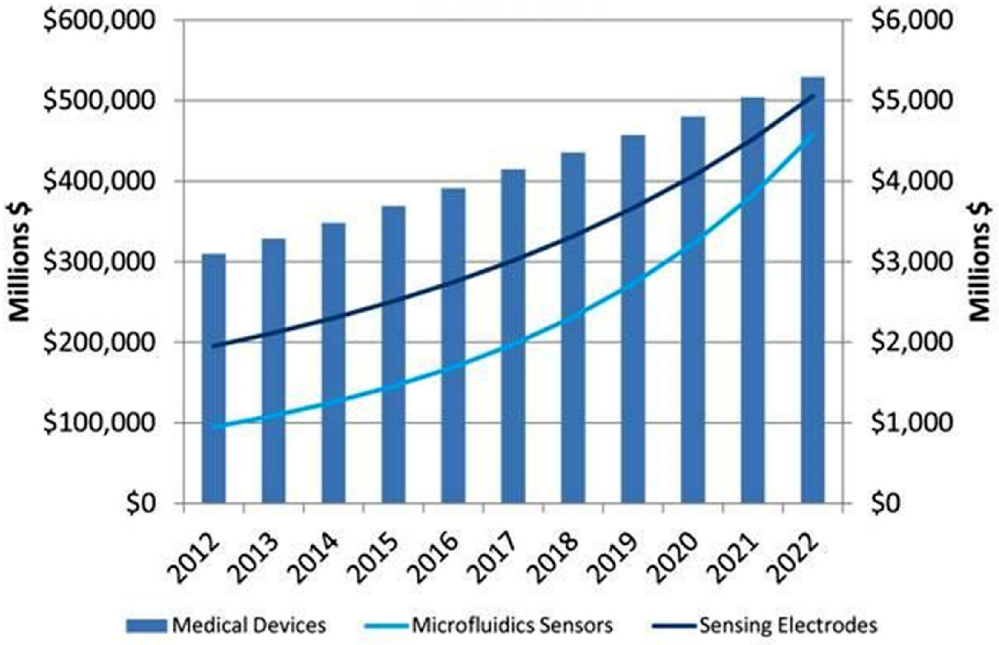

Figure 6. Expectations of future development in medical development market, source: (Happich, 2014)

Most companies have strong technology protection through patents and access to early stage capital for start-up companies in the region is often difficult to obtain (Wipperfurth et al., 2010).

Using Michael Porter's Five Forces Model, the following will examine the medical device industry in Europe.

Substitute Products

In order for a product to be a viable substitute, it must fulfil the same function as the product which it is substituting. Substitute products face the same barriers for entry that medical devices face, particularly with respect to long lead times to market and initial capital outlays (Wipperfurth et al., 2010). These barriers for entry will not stop substitute products from evolving, but will make the emergence of new substitutes more gradual than if the barriers for entry were lower.

The overall force of substitute products is medium in the medical device industry because even though there are intended tosubstitute some products, the demand for the products in general is strong and growing.

Therefore, the effect of substitute products on the market of medical devices could be described as relatively moderate.

Buyer Power

Purchasers of healthcare facilities are physicians, hospitals, nursing homes for the long-term sick and households. In relation to the whole field of healthcare, buyer power could be described as moderate (Wipperfurth et al., 2010). In benefit for buyer power there are two key reasons - buying power is becoming more and more consolidated in the industry, and medical reimbursement policies are evolving. On the other hand, they are specific products that are related to the health status of the population and demographic development with more than their current purchasing power.

Table 1. Top Medical Device Manufacturers (in 2013, $ billion)

The Company	Revenue 2012	Revenue 2013
Johnson & Johnson	27.4	28.5
Siemens	17.7	17.87
Medtronic	16.6	17
Roche	10.95	11.3
Cividien	9.85	10.2
Abbott Laboratories	9.6	9.86
General Electric	9.83	9.78
Philips	9.63	9.4
Stryker	8.66	9
Boston Scientific	7.25	7.14

Source: (Hollmer, 2013)

Supplier Power

The suppliers to the medical device industry include manufacturing companies included in many CZ NACE sectors. Global markets also allow access to entities on various continents and in differently industrialised economies. It is a large and diverse group of entities. From this perspective of their large selection and ease of substitutability, their bargaining power is weak.

On the other hand, there are factors that limit the producers of medical devices in changing suppliers. These include (UK Essays, 2013): switching costs and forward integration. Switching costs are costs to a medical device producer that are incurred when it switches from one supplier to another. Forward integration occurs when a supplier decides

to become a direct competitor in the market that it serves. It applies only to those suppliers, who provide complex components that are critical to the manufacture of medical devices.

Existing Rivalry

There are many firms in the medical device industry competing with each other for the same market. There are almost 25,000 medical technology companies in Europe. Most of them are based in Germany, followed by the UK, Italy, Switzerland, Spain and France. Small and medium-sized companies (SMEs) make up almost 95% of the medical technology industry, the majority of which employ less than 50 people (small and micro-sized companies) (MedTech, 2013).

The existing competition is very strong due to (Wipperfurth et al., 2010):

- low product differentiation in some key markets,
- low switching costs by hospitals,
- changes connected with reimbursement, regulatory,
- biologic challenges.

The current ranking of the most powerful companies in the medical device industry is given in Table. 1.

Confirming the existence of strong competition in this market may also include the declining venture capital investment (Fig. 7).

Despite this strong competition, this sector is predicted to grow.

External Forces

Several external forces exert a significant effect on this industry, such as government involvement regulatory agencies and reimbursement policies. Medical device regulation in the EU is governed by three EU directives and their subsequent amendments:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990).
- Council Directive 93/42/EEC on Medical Devices (MDD) (1992).
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998).

Figure 8 gives an overview of the EU regulatory framework for medical devices.

The influence of these factors and the market for medical devices is very strong.

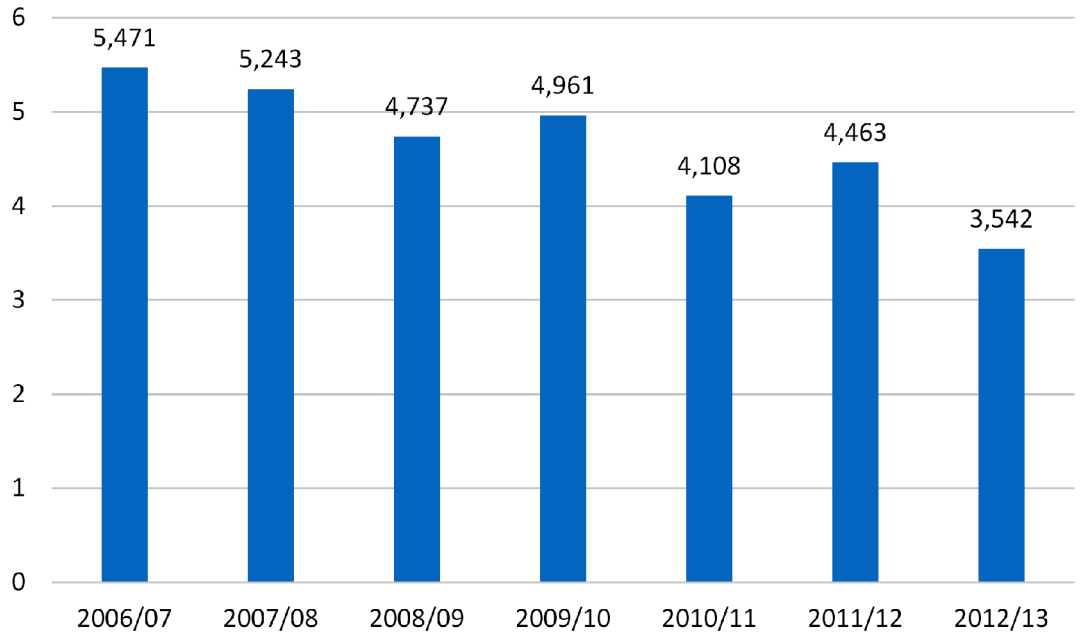

Figure 7. 7 Med-tech venture capital investment - U.S. and Europe 2006-2013 (fee-based), source: (The Statistical Portal, 2014)

<table>
<tr><td rowspan="5">PRE - market</td><td rowspan="4">Conformity assessment procedure</td><td colspan="4">Classification of medical devices</td></tr>
<tr><td>Class I (low risk)</td><td>Class IIa</td><td>Class IIb</td><td>Class III (high risk)</td></tr>
<tr><td colspan="4">Technical documentation
Quality Assurance System
Notified Body Audit</td></tr>
<tr><td>Manufacture’s self-assessment of his device</td><td colspan="2"></td><td>Pre-market approval for class III</td></tr>
<tr><td>Declaration of conformity and CE marking</td><td colspan="4">Manufacturer issues a declaration of conformity stating that each device is in compliance with the all applicable Directives and affixes the CE manufacturing</td></tr>
<tr><td rowspan="3">POST - market</td><td rowspan="2">Surveillance system</td><td colspan="4">Manufacturer must keep TD and QAS updated and adapt according to all gained post-market experience. NB regularly audits both, typically once per year</td></tr>
<tr><td colspan="4">Market Surveillance system (PMS) – integrated part of the quality assurance system</td></tr>
<tr><td>Vigilance system</td><td colspan="4">a) Manufacturer is obligated to report any incident related to his devices to the Competent Authority
b) A Member State may decide to withdraw, restrict or prohibit the marketing of the device</td></tr>
</table>

Figure 8. EU regulatory framework for medical devices , source: (Eucomed, 2013)

CONCLUSION

The aim of this paper was to analyse the potential of the market for medical devices in Europe. The starting point was an analysis of the external environment, describing the selected macroeconomic variables. The attention was focused on the development of population, GDP, consumers' expectations and innovative activity in general as well as in medical technologies. Europe was in this respect compared with the USA, Japan and China. An interesting market is China due to the growing population, GDP growth and investment in innovations. The European market is very competitive due to the number of firms and the number of patents in the field of medical technologies. In terms of population and GDP development, the given situation is somewhat negative rather than positive.

Furthermore, the attention was specifically focused on the European market, using Porter's Five Forces model. The given market contains relatively strong barriers to the entry in the form of the need of capital input, high research and development expenditures, regulatory restrictions, and legal obstacles.

The market includes a large number of small and medium-sized companies (about 95%) and stable innovative activity. In recent years, there has also been a reduction in risk capital in this area, which corresponds with the difficult situation of start-ups companies. In terms of Porter's model, the power of suppliers, customers and substitutes can be described as moderate or weak. Companies have the opportunity to choose from a number of suppliers, including global markets, on the other hand, a change of supplier may be associated with costs.

External forces have a significant effect on this industry, such as government involvement regulatory agencies and reimbursement policies.

On a global level we can expect growth in this market, especially in the emerging economies. The impetus for the development of medical devices in developed economies includes the demographic changes in the population structure.

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