KAUNAS UNIVERSITY OF TECHNOLOGY
SCHOOL OF ECONOMICS AND BUSINESS

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OVERCOMING THE ENTRY BARRIERS IN THE ADVANCED MEDICAL DEVICE MARKET

6211LX029 INTERNATIONAL BUSINESS

Final Degree Project

Supervisor
Assoc. Prof. Rita Jucevičienė

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Overcoming the Entry Barriers in the Advanced Medical Device Market

DECLARATION OF ACADEMIC INTEGRITY

____ _____ 2019

Kaunas

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SUMMARY

This research focus on problem when weaker economy regions like Baltic countries in Europe are in the shadow of accessing advanced medical devices. Big brands would mostly choose starting point from Germany, France, Norway or other high income/developed economy (early adopter) and finish, if they ever start, in Romania, Baltic middle income/developing economy (laggard) countries.

The aim of the master thesis is to provide solutions to overcome the entry barriers into the Lithuanian market of advanced medical devices. The research investigates distributors when they try to deliver new treatment (medical device) solution to physicians. For this reason, theoretical and empirical research to determine entry challenges for has been conducted.

The research has been done through literature review and multiple case study by collecting primary and secondary data. Secondary data of each case study was collected from official documents, industry and/or annual reports, other credible and related information. Primary data was collected by interviewing expert from one of the biggest medical equipment distribution companies in Lithuania. Each identified barrier to entry from the literature review has been evaluated by the author (using secondary data) and the expert (practical experience). Data has been collected from four different cases when medical device distributor sought to deliver new medical solution to the market.

The research findings shown match between theoretical and practical analyses. Literature analysis enabled to identify seven entry barriers in the medical device market: long reimbursement process, medical practice barrier, small market size, long purchase cycle and strong relationship bond, supplier power, competitive reaction and regulations for medical representatives.

Empirical research has shown that six of them are relevant and important when introducing new medical product to the Lithuanian market. Long reimbursement process is the strongest barrier together while the regulations for medical representatives are the weakest of the barriers. Strong evidence-based medicine, strong relationships with specialty medical societies and key opinion leaders are the best managerial solution to overcome the market entry barriers.

Rolandas Jakaitis. *Įėjimo barjerų į pažangios medicininės įrangos rinką įveikimas*. Magistro baigiamasis projektas / vadovė doc. Rita Jucevičienė; Ekonomikos ir verslo fakultetas, Kauno technologijos universitetas.
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SANTRAUKA

Magistrinio darbo problema kyla iš netolygaus inovatyvių medicininių sprendimų (prietaisų) pasiskirstymo tarp silpnesnių ekonominių regionų kaip Baltijos šalys. Didieji prekiniai ženklai daugiausia pasirinktų pradėti prekybą Vokietijoje, Prancūzijoje, Norvegije ar kitoje išsivysčiusios ekonomikos šalyje. Ir tik tada prekiauti (jei išvis pradėti) Rumunijoje ar Baltijos šalyse su vidutinėmis pajamomis.

Baigiamojo darbo tikslas - pateikti sprendimus, padedančius įveikti Lietuvos pažangių medicinos prietaisų patekimo į rinką kliūtis. Tyrimas tiria distributorius, kada jie bando gydytojams pristatyti naują medicininį sprendimą (medicininį įrenginį). Dėl šios priežasties darbe atlikti teorinė analizė ir empiriniai tyrimai, siekiant nustatyti įėjimo į rinką kliūtis.

Tyrimas atliktas apžvelgiant literatūrą ir skirtingų atvejų tyrimus, renkant pirminius ir antrinius duomenis. Antriniai kiekvieno atvejo tyrimo duomenys rinkti iš oficialių dokumentų, pramonės ir (arba) metinių ataskaitų ar kitos patikimos ir susijusios informacijos. Pirminiai duomenys rinkti apklausiant ekspertą iš vienos didžiausių medicinos įrangos platinimo įmonių Lietuvoje. Kiekviena nustatyta įėjimo į rinką kliūtis iš literatūros apžvalgos įvertinta autoriaus (pasitelkiant antrinius duomenis) ir eksperto (iš praktinės patirties). Duomenys surinkti remiantis keturiais skirtingais atvejais, kai medicinos prietaisų platintojas (distributorius) siekė pristatyti rinkai naują medicininį sprendimą (įrengimą).

Tyrimo rezultatai parodė atitikimą tarp teorinės ir praktinės analizės. Literatūros analizė leido identifikuoti septynias kliūtis medicinos prietaisų rinkoje: ilgą kompensavimo procesą, medicinos ekspertų barjerą, mažą rinkos dydį, ilgą pirkimo ciklą ir stiprius santykių saitus, tiekėjų galią, konkurencinę reakciją ir legalius reguliacinius reikalavimus medicinos atstovams.

Empiriniai tyrimai parodė, kad šeši iš minėtų barjerų yra svarbūs įvedant naują medicinos produktą į Lietuvos rinką. Ilgalaikis kompensavimo procesas yra stipriausia kliūtis, o legalius reguliacinius reikalavimus medicinos atstovams yra silpniausia kliūtys. Įrodymais pagrįsta medicina, stiprūs ryšiai su gydytojų draugijomis ir pagrindiniais nuomonės lyderiais yra geriausias valdymo sprendimas, siekiant įveikti patekimo į rinką barjerus.

CONTENT

ABBREVIATIONS

ACs	Autonomous communities
AIMDD	Active Implantable Medical Devices Directive
ASLs	Local health authorities
ATTD	Advanced Technologies & Treatments for Diabetes
BG	Blood glucose
BTE	Barrier to entry
CCGs	Clinical commissioning groups
CE	European Committee
CEPS	Economic Committee for Healthcare Products
CGM	Continuous glucose monitoring
DM	Diabetes mellitus
DRG	Diagnosis-related groups
EBM	Evidence-based medicine
EU	European Union
GBA	Federal Joint Committee
HAS	National Authority for Health
HDI	Human Development Index
IQWiG	Institute for Quality and Efficiency in Health Care
IVD	Diagnostic medical device
IVDD	In-Vitro Diagnostic Medical Devices Directive
KOL	Key opinion leader
MDD	Medical Devices Directive
NHIF	National Health Insurance Fund
NICE	National Institute for Clinical Excellence
NICE	National Institute for Health and Care Excellence
PTCA	Percutaneous transluminal coronary angioplasty
R&D	Research and development
SHCAA	The State Health Care Accreditation Agency
SMBG	Self-monitoring blood glucose
WHO	World Health Organization

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INTRODUCTION

Medical devices play essential role to healthcare in the European Union (EU). Medical technologies and healthcare innovations improve rapidly for European citizens. Medical devices constitute €110 billion in sales and provide 675,000 jobs within EU region (Medical Devices - European Commission, 2019). However, when world celebrates new medical technology introduction in to the market, weaker economy countries like Lithuania are trailing behind. Global conference Advanced Technologies & Treatments for Diabetes (ATTD) brings together leading international experts to discuss breakthroughs in diabetes treatments, a lot of attention was given for innovation of continuous glucose monitoring (CGM) technology. “Imagine if a majority of people with diabetes could get CGM reimbursed and could keep their glucose concentration within range most of the time. Time in range is the new reality, a solid clinical outcome to erudite diabetologists and, unfortunately, a mere gimmick to those firmly rooted in denial regarding the damage glucose concentrations outside the near-normal range cause to several organs.” (ATTD, 2019).

Medical equipment is saving lives and improving healthcare system. In 2017, there were 425 million adults estimated to have diabetes mellitus (DM) (“IDF Diabetes Atlas”, 2017). Without glucose meters, insulin or insulin pumps, most of these people would not last long. The reimbursement process of such a necessary device requires long path to unite multiple stakeholders to cooperate.

When companies succeed to produce breakthrough innovation, many environmental factors affect the further path of products delivery into different countries. At the request of the Netherlands government in 2007, the World Health Organization (WHO) launched project. The aim was to determine the need of medical devices in healthcare system throughout the world and gaps in availability of medical devices (WHO, 2019). Innovative biomedical technologies are driven for better health and improved quality of life, on the other hand, they are associated with higher cost of services. Because of limited resources and the need to reduce expenditure, health policy- and decision-makers must prioritize. Hereby, some technologies diffuse whereas others do not. In addition, technologies with approved clinical validity fail to fit into daily medical use, resulting prevention from benefiting from scientific progress (Lang, Wyer & Haynes, 2007).

The motive behind this paper work is to reveal barriers related to disproportional spread of advanced technologies in Lithuania’s healthcare system. Furthermore, to analyze and find out the real motive behind innovative and big companies’ decisions to cooperate with local distributors or maybe establish their office locally. For example, big brands mostly choose starting point from Germany, France, Norway or other high income/developed economy (early adopter) and finish, if they ever start, in Romania, Baltic middle income/developing economy (laggard) countries. To address these challenges literature review of classical market entry barriers has been done, moreover, market strategies and business development models are analyzed. Also, multiple case analysis and structured interviews have been used for empirical part of the thesis. Medical device business is very unique, with its specifics that are discussed further in this research project.

There are many challenges faced when companies aim to balance the demand of medical equipment in the healthcare system. It is important to look at these challenges from global to local context. Human development index (HDI) reflects citizens average life quality in terms of health, knowledge (education) and a decent standard of living. HDI is linked to the level of countries economy ("Human Development Reports", 2019). The Priority Medical Devices (PMD) project launched to analyze if medical devices on the global market meet the demand of healthcare providers. The findings where that countries in contexts with low HDI scores had the greatest gaps in availability of medical devices (WHO, 2010). Meanwhile Lithuania in 2017 has been categorized as a country that has high HDI of 0.858, raking 35th among 189 countries ("Human Development Reports", 2019). Thus, Lithuania is not even close to access all latest treatments and

technologies. There a lot to discuss about diffusion of innovative medical solutions in different markets.

Medical device business addresses unique challenges mainly because it is heavily regulated in terms of safety, efficacy, efficiency, and is strongly influenced by politics. In contrast, the business of dietary supplements has less barriers to entry (BTE). The reason is because the European Commissions' rules for food supplements are only meant to protect consumers against potential health risks, but not to be efficient and have true effect. Food supplement business is built by creating the demand artificially through special marketing strategies by shaping customers habits to buy. Hence, companies that sell food supplements would probably not emphasize products efficiency and cost effectiveness through its parameters and evidence-based medicine (EBM). The effect is not guaranteed or too low to be proved (e.g. no one knows if vitamin C will really help to avoid the flu). While companies that provide medical devices will most likely compete with strong evidence of efficacy, safety and EBM.

Weaker economy regions like Baltic countries or other small nations are in the shadow of accessing this solution. High costs for CGMs is probably one of the reasons for Lithuania to be behind. Yet, is price for reimbursement the only problem for patients to use CGMs? This raises a question which country is the first to obtain such an innovation? Does the demand vary in every country? If not, what are the other factors that influence game changers to choose selling their production to one or another country? The purpose of this paperwork is to conduct theoretical and empirical research to determine challenges associated with innovative medical devices access in Lithuania through local distributors.

Research question: What are the barriers to introduce advanced medical devices (CGMs) in developing markets (Lithuania) and what managerial tools could be used to address these barriers?

The aim of the research project is to provide solutions for overcoming the entry barriers into the Lithuanian market of advanced medical devices.

The objectives are to:

1. To discuss the nature of the advanced medical device markets and key challenges / market entry barriers faced by the new entrants in Lithuania;
2. To provide a theoretical overview of the key market entry barriers and approaches to their elimination from the new entrant perspective;
3. To design methodology for identifying key market entry barriers in advanced medical device market;
4. To identify the main entry barriers in the Lithuanian advanced medical device market and to propose the most adequate measures for overcoming the entry barriers by a new entrant company in Lithuanian market.

1. PROBLEM ANALYSIS

There are different types of barriers that occur delivering medical products to the market. Diabetes treatment case in Lithuania is a good example to illustrate key challenges that occur for patients to access advanced treatment methods. Diabetes is a group of metabolic diseases, characterized by hyperglycemia or hypoglycemia due to pancreas failure in insulin secretion, insulin action, or both. In other words, diabetes is a disorder when organism cannot control blood glucose (BG). There are two types of diabetes: Type 1 diabetes is caused by beta cell autoantibodies (dysfunctional insulin secretion) or a combination of both insulin resistance and dysfunctional insulin secretion, Type 2 diabetes has more to do with insulin resistance and is caused by poor food diet. Nevertheless, both types of DM lead to a high potential affecting nearly every organ through complications. A wide variety of complications such as cardiomyopathy, nephropathy, and neuropathy (Ndisang, Vannacci & Rastogi, 2017), long-term damage such as dysfunction and failure of the eyes, kidneys, nerves, heart, and blood vessels and many others ("Diagnosis and Classification of Diabetes Mellitus", 2013).

According to the latest 8th edition report: “diabetes is one of the largest global health problems of the 21st century”. There are more and more people each year who live with this disease. The number of adults with DM globally has increased from 108 million in 1980 to 422 million in 2014. There are few factors that made such a dramatic change: the rise in prevalence 28.5 percent, population growth and ageing 39.7 percent, interaction of these two factors 31.8 percent ("Worldwide trends in diabetes", 2016). If the numbers will continue to grow at the same pace it will reach 629 million by 2045.

Based on Bloomberg Intelligence source the key players in 2016 market of diabetes care and monitoring industry are: Johnson & Johnson, Roche, Medtronic, Abbott, Insulet and others trailing behind. These companies are highly focused on research and development (R&D) on new products and improvements on medical devices (insulin pumps, glucose meters etc.) and drugs. Currently, there are two types of glucose meters in the market. First method is the most popular categorized as self-monitoring blood glucose (SMBG) meter, this technology is 50 years old (Olczuk & Priefer, 2018). Close monitoring (measuring) of BG is difficult with most common "finger-prick" technology (SMBG), which involves puncturing the skin (usually at the tip of a finger) to obtain a drop of blood (Saptari, 2004) It is estimated that a higher rate of glucose testing (approximately 8 times/day) improves glycemic control (Miller et al., 2013), which is painful and can be difficult to maintain long-term. In addition, pharmacy records in England showed that patients who use insulin, test their blood (prick finger) 2.1 per day, meanwhile people in Europe and North America have higher rates of testing from 2.5 and 5.5 per day Dunn, Xu, Hayter & Ajjan, 2018). Thus, up to 67% of patients fail to routinely monitor BG, which is one of the major problems optimizing glycemic management. Fortunately, now the CMG method reduces the number of finger-pricks at the minimum (approximately 2 – 4 times a month). The recent evidence proves benefits of CGM technology on glycemic control and its high potential into common practice (HASHMI & MON, 2018). Moreover, CGM can help over a low socioeconomic population with limited access to current technology (Hoeks, Greven & de Valk, 2011).

Recently emerged CGM technology for is proven to be beneficial on glycemic control by monitoring it continuously. CGM reduces the number of finger-pricks and almost eliminates the pain and uncomfortable process (Saptari, 2004) (HASHMI & MON, 2018) (Hoeks, Greven & de Valk, 2011). Nevertheless, Heinemann has explained that due to high cost for CGMs, national and private health insurance (payers) in Europe are not willing to cover the expenses for patients. Payers expect manufacturers to reduce daily costs of the technology. Assuming that for one user CGM can approximately cost 5–10€ every day, in one year this could be estimated around 3000€ per patient. So, being conservative in Europe there would be 1 million potential users who have type 1 DM, collectively, this could be estimated to cost 3 billion € every year (Heinemann et al., 2012). Even though CGM coverage for countries might be costly it is proven that the rate of innovation is highly sensitive to the volume of reimbursement (Gelijns & Rosenberg, 1994). In

addition to this, the technology has strong evidence to be efficient and adding high value, however, not every patient can access it.

In the United States, private health insurance companies are responsible for CGMs reimbursement. Although CGM innovation is known to most patients, officially in Europe only strong economy countries like Germany, England, France, Norway, Sweden and others have distributors that can provide CGM products. Europe unites 28 countries and manufacturers are unsatisfied with complicated situation in region where each country has its own organizational structure and regulations (Lodwig, Kulzer, Schnell & Heinemann, 2014). Vendors can find innovative and promising products for their markets. Unfortunately, reimbursement in Lithuania is one of the barriers for firms to deliver CGMs because most patients could not afford it.

Vendors might find Lithuania's market attractive on local scale. With strong commitment distributor can get access to the manufacturer and gain its trust to sell the production (e.g. CGM innovation). However, it might not be the case for supplier (manufacturer). It is a big chance that CGM's manufacturers (e.g. DexCom, Abbott) might consider Lithuania as too small market. Therefore, market size might be one of the reasons for Baltic countries to be behind. The market in Lithuania is relatively small comparing, for example, with Germany (see **Figure *1***) having around 7.5 billion people with DM. Whereas in Lithuania the total diabetes population is around 108 000 of which Type 1 (most advanced form of disease) is 6 500 in 2017 ("Higienos institutas", 2019). Target audience for CGM technology is Type 1 diabetes. There are big global numbers of people suffering from DM, Lithuania is very small, with only 6 500 people who need this solution the most. This is one example of small market size in Lithuania for advanced product.

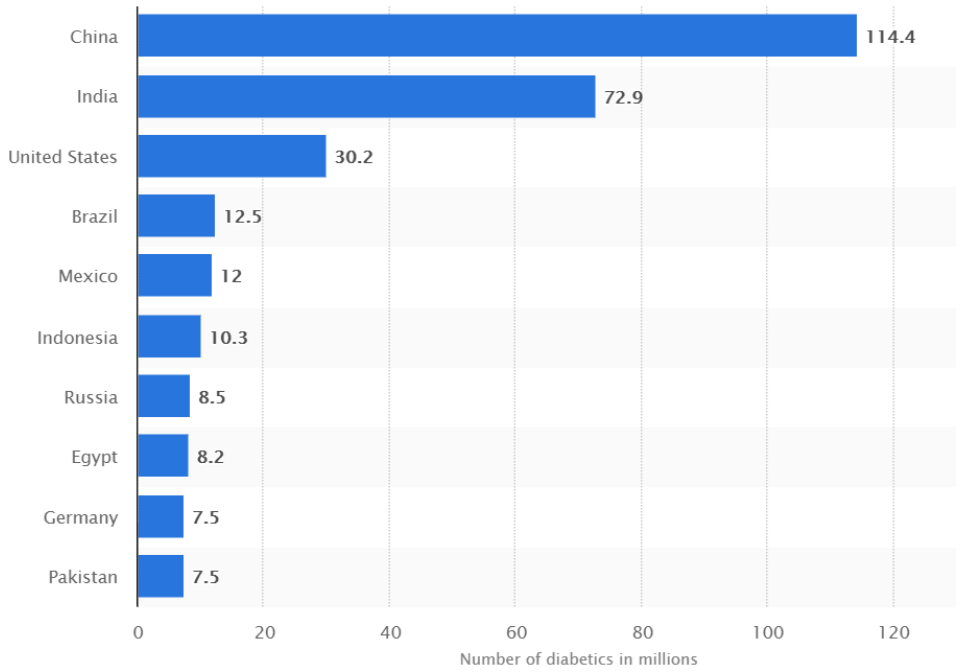


Figure 1. Countries with the highest number (in millions) of diabetics worldwide in 2017 ("Diabetics number top countries 2017 | Statistic", 2019).

Fortunately, even small market country like Lithuania could find enough resources to finance efficient treatment systems properly. An example of such in Ireland and England is the use of trastuzumab (Herceptin) - first clinically approved drug for the aggressive form of breast cancer (HER2). This type of cancer is in approximately 20-30% of human breast cancers (Nahta & Esteva, 2007). The British National Institute for Clinical Excellence (NICE) has issued guidance stating that based on clinical evidence trastuzumab has to be provided only for patients with advanced-stage of cancer by the health trusts. The drug was licensed for treating patients with advanced from of breast cancer meaning that it might spread to the other organs. Consequently, in some areas of

the UK only 10% of the early-stage cancer patients have received the drug. Even under the circumstances when doctors had strongly recommended the medication for patients, they had to refuse. This case attracted serious attention and criticism from Cancer charities and the media. After continuous pressure in 2006 NICE has issued guidance approving the compensation of trastuzumab for both early-stage and advanced-stage breast cancer patients.

Similar case recently happened in Lithuania. Here local people with Type 1 diabetes used to have a very little coverage of expenses. Although after long consistent pressure from diabetes clubs and medical specialists to the Ministry of Health (MoH). The compensation has been provided for youngsters who have Type 1 diabetes and are under 24 years old. This was first big step to Lithuania's government and for patients but still with limit to the access for age groups.

Finally, from business point of view, distribution companies must invest a lot to key opinion leaders (KOLs) education, training and provide evidence-based medicine (EBM) material. This is the only way for companies to make their business work and make latest treatment methods available to patients.

Now we have clear understanding about CGM technology and its relevance to people with DM. We also know that insulin pumps are finally covered in Lithuania and CGMs not. One of the options is to guess that no one has tried to officially distribute a such product. However, we see that stakeholders like physicians (opinion leaders or users), patients (users or buyer) and government (buyers who cover expenses) play important role in product introduction into the market. More details will be briefly discussed about barriers of innovative products implementation into Lithuania market. Further research is done by analyzing distributor's challenges of successful introduction of new medical products via barriers to entry (BTEs) in Lithuania.

2. MARKET ENTRY BARRIERS: THEORETICAL PERSPECTIVE

In this chapter critical literature analysis has been done in order to analyze relevant theories, concepts and models for BTEs of medical devices. The theory is collected to reflect and understand challenges of new medical device introduction to the market. Results of the literature analysis is grouped in different types of BTEs. In addition, theoretical literature analysis enables to identify managerial solutions that could be used to overcome each identified BTE. Finally, the theoretical results of this chapter are structured and will be used for the methodology (e.g. questionnaire) of the thesis.

Medical device distributor is a key for medical product delivery to hospitals and patients. For this reason, many BTEs are faced by distributor or manufacturer (supplier) who aims to introduce medical products for its customer. Manufacturer would face slightly different but basically the same BTEs. Manufacturer would meet other issues related to establishment of branch offices (e.g. high costs, cultural barrier, etc.), but less with the product delivery itself. Therefore, BTEs from distributor's perspective are analyzed further in the research.

RATIONALE BEHIND MARKET ENTRY BARRIERS

All BTEs are can be linked and faced at once or some may not appear depending on different situation. Porter (1980) has defined BTEs as: "factors that make it difficult for a new entrant to gain a foothold in an industry". One of the most fundamental theories regarding BTEs is developed by Leonidou (2004). He has classified export barriers (see **Figure *2)***. According to Leonidou (2004) BTEs are faced when firm decides to export in overseas markets. BTEs refer to all constraints that prevent companies from launching, developing, or sustaining the business. Shepherd (2004) and Leonidou (1995) categorized BTEs (export barriers) in two groups**:**

- Exogenous (external);
- Endogenous (internal).

Internal barriers are related with firm's resources and capabilities to start export business, and external barriers are faced in the foreign country's environment (Leonidou, 1995). Later Shepherd (2004) described BTEs by saying that external barriers are embedded in the market and cannot be controlled by the company. On the contrary, internal barriers are created artificially by the competitors (firms established some time ago) via their behavior, reaction to new entrants and implemented market strategies (Shepherd & Shepherd, 2004). It is easier to overcome internal barriers because companies have more control over them in contrast to external barriers. It is worth to mention, that Leonidou has provided more detailed classification of the barriers (see **Figure *3)***.

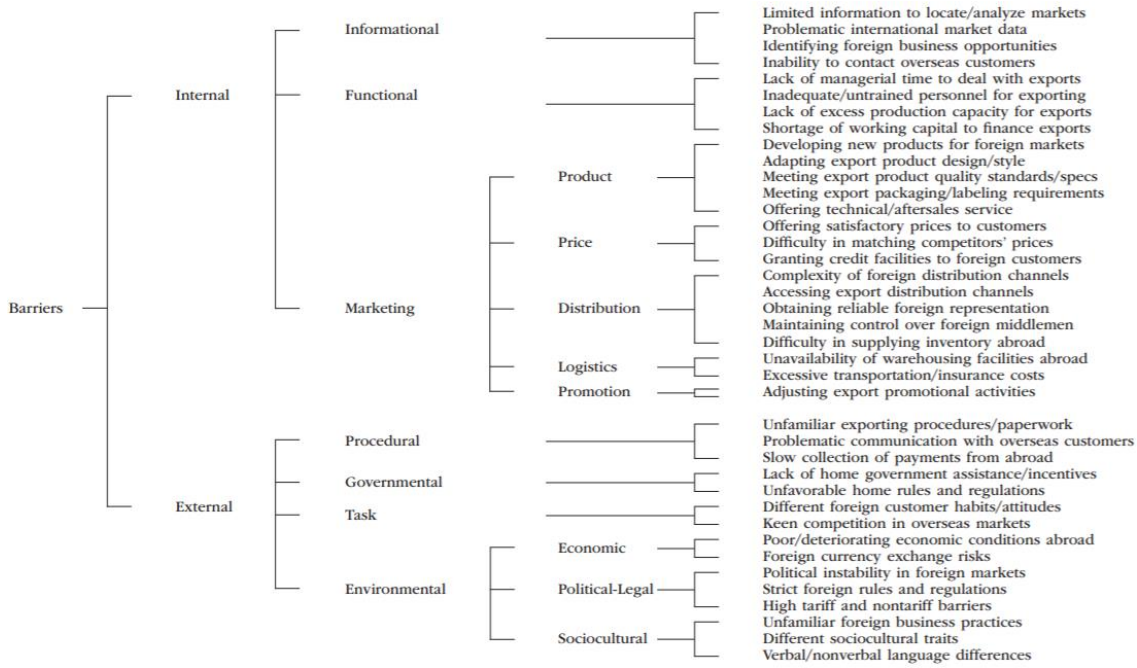


Figure 2. Classification of export barriers (adapted from Leonidou, 2004).

Internal:

1. Functional (inefficient functions like human resources, production, and finance);
2. Informational (problems in accessing foreign information and proper market research);
3. Marketing (problems dealing with tactical marketing mix decisions: product, price, promotion and place);

External:

1. Procedural (transactional problems, communication failures, slow payments collection);
2. Governmental (legal national regulations and rules);
3. Task (relate to customers and competitors like competitive reaction, different customers' habits, etc.);
4. Environmental (poor political-legal, economical, sociocultural conditions).

There are three groups of firms which identify BTEs differently from their perspective: non-exporters (companies have potential plans to export), current exporter (that have already experienced BTEs and still do), ex-exporters (that have experienced BTEs but no longer do).

For proper indication of BTEs the definition of time frame of entry is important. The theory of diffusion of innovations developed by Professor Everett Rogers (in 1962) explains the process of how, why, and at what rate new ideas and technology spread. This theory will help to explain better were further research is focused. How long BTEs are faced by new entrant or/and new medical product.

According to Everett Roger (1983) there are five innovation adoption process stages (categories of consumers) overt time: innovators (2.5%), early adopters (13.5%), early majority (34%), late majority (34%), laggards 16%.

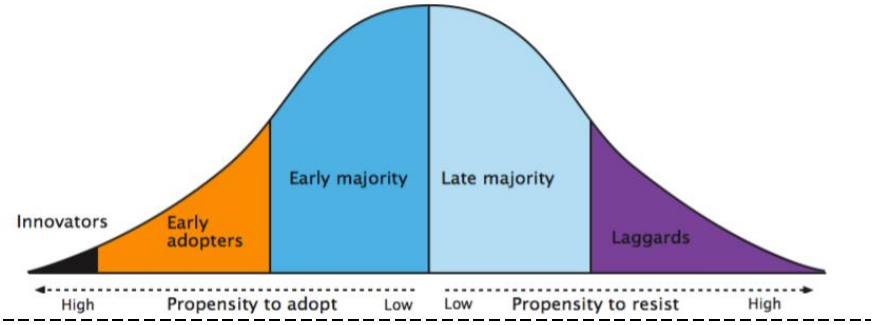


Figure 3. The order to accept the innovation (Rogers, 1983).

There might be infinite number of reasons when and where innovation starts, but there are few things in common between countries where innovative technologies have higher adoption rate and are recognized as more developed countries. In most cases successful and high added value innovation tend to spread internationally. There is always a "lead market" first country or region where the innovation is adopted. In the past, the term 'lead market' has been used to denote the country in which an innovation was invented (Yip, 1992), or in which a multinational company takes over global product responsibility, for instance, as global coordinator of marketing activities (Raffée and Kreutzer, 1989). Roger defines diffusion as a process by which an innovation is communicated through certain channels over time among the members of a social system. There are four main elements of the diffusion process (theoretical BTEs):

1) Innovation;
2) Communication;
3) Time;
4) Social system.

First the most important element is ***innovation*** itself, and past researches indicate that technology advantage, compatibility, trialability, observability, and ergonomics are the most important qualities affecting adoption rates. To have a higher adoption rate technology must have a great advantage at least at one of those qualities. Second element is the ***communication*** which is defined as the process in which we aim to share information with each other in a way to reach a mutual understanding. The information can be spread through several channels (e.g. social media, television, influencers, news etc.). Third element is ***time*** that could be measured through relationship between group of individuals in which an innovation is adopted and the other members of a system. Usually, the adoption rate is measured when a group of individuals adopt the innovation in a certain time. The final element of the diffusion process is a ***social system***. A social system is defined as a group of units that share common problems and aim to achieve same goals by solving these problems. The members or units of such a system can include individuals, groups, organizations (e.g. medical doctors in a hospital). The social system has a zone in which technology diffuses. This zone depends on other related factors like: social structure, norms, the roles of KOLs, distributors, and the efficiency or consequences of innovation.

Another theory that explains the concept of the product life cycle (PLC) can also serve as definition of time frame when BTEs are faced. William E. (1967) has defined PLC of drugs/medical products as the evolution of a product which is measured by its sales over time. The PLC is determined by two measures - catalogue life and commercial life. ***Catalogue life*** is a period when a product is in the firm's catalogue. Catalogue life begins with catalogue birth (first product's appearance in the catalogue) and ends with catalogue death (removal the product from the catalogue). ***Commercial life*** is defined as the period between the commercial birth (a product achieves a national sales volume) and commercial death (the total revenue for a product falls to 20% of the maximum monthly total revenue during the commercial life) (Cox, Jr., 1967).

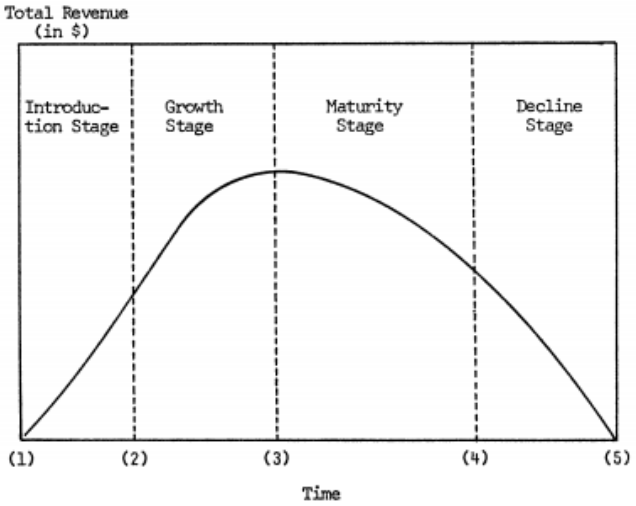


Figure 4. Stages of the product life cycle (Cox, Jr., 1967).

Phases of the PLC (from **Figure *4***): Introduction stage between catalogue birth (1) and commercial birth (2), growth stage - between commercial birth (2) and maximum monthly revenue (3), maturity stage - the time period between maximum monthly revenue (3) and commercial death (4), decline stage - the time period between commercial death (4) and catalogue death (5).

These are generic theories that are important to understand new medical product introduction in the market. The given theory has provided elements of diffusion that every innovation faces during its adoption into the market. The PLC theory has defined the introduction stage. However, time frame definition for BTEs can be described between time before catalogue birth and reasonable sales volume (adoption of as certain group like innovators or early adopters).

In this master thesis the period of PLC before ***catalogue birth*** and reasonable ***sales volume*** (from **Figure *4***) in ***social system*** of ***innovators*** and ***early adopters*** (see in ***Figure 3***) will be taken to analyze BTEs in Lithuanian in medical device market. Further research investigates most relevant BTEs to new medical equipment delivery. BTEs are extracted from theory of Everett Roger (1983), Leonidou (2004) and supported by additional literature on new medical product delivery to market. Medical device distributors can face strong external BTEs (e.g. limited market size, long reimbursement process, long sales cycle, competitive reactions, etc.).

2.1.1 BARRIER 1: COMPETITIVE REACTION

According to Leonidou (2004) keen competition (from **Figure *4***) can be faced. Following his classification this would be external BTE that is related to task barriers. Task BTEs focus on the firm's customers and competitors. Leonidou (2004) state that companies are more concerned with problems caused by competitive pressures. Therefore, deeper investigation on this BTE has been done.

Chosen market strategy can cause different types of BTEs for medical device vendors. For example, if firm does not choose to deliver innovative solutions only "mature" products that have been adopted for a long time. BTEs like competitive reactions or supplier power might be strong (because of high rivalry). Moreover, lacking competitive advantage strengthens other BTEs like long sales cycle and strong relationship bond. Chen, Smith and Grimm (1992) suggest two important factors that relate to the competitive reaction product's innovativeness and the company's reputation. Later, Waarts and Wierenga (2000) applied conceptual model for explaining competitive response (see in ***Figure 5***). Their model includes two characteristics ***action*** relating to the new product introduction itself, and ***actor***, referring to the firm behind the new product. In addition, Waarts and Wierenga (2000) found substantial effects on ***perceived threat***, which in turn was strongly related to ***competitive reaction*** probabilities. New product with high

advantage sends a signal of hostility creating strong and fast competitive reactions (Hultink & Langerak, 2002).

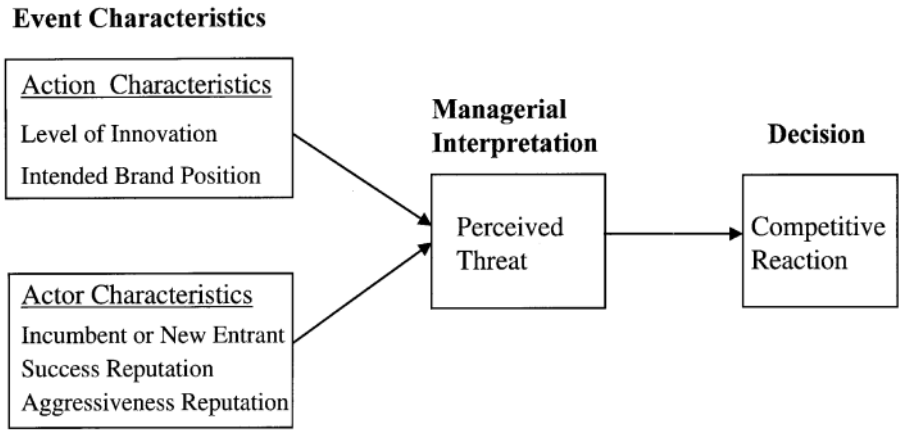


Figure 5. Conceptual model for explaining competitive response (Waarts & Wierenga, 2000).

In 1980, Porter published his book "Competitive Strategy: Techniques for Analyzing Industries and Competitors". He divided competition in three classic strategies: cost leadership, product differentiation and market segmentation. These three strategy paths lead to represent organizations target customers' needs a better price, or more effective performance than others. Essentially companies compete either with lower price (cost), perceived added value (differentiation), or by focusing on a very niche customer (market segmentation).

To estimate competitive reactions with marketing instruments Debruyne (2002) conducted a research on 509 new industrial products. Debruyne (2002) research focused on competitors' reactions when firms launch new product. The study evaluated four competitive reactions (called marketing mix): price, production, promotion, and distribution (place). The results concluded that, two thirds of the new product launches face competitive reactions. For this reason, competitive reaction is considered as a BTE.

Table 1. Percentage of different types of competitive reactions to new product (Debruyne, 2002).

Competitive reactions	Percentage of new products to which competitors reacted
Competition reacted by changing one or more of the marketing mix variables	61.1 %
Change of price	43.6 %
Change of product assortment	35.5 %
Change of promotion	23.9 %
Change of distribution	3.2 %

2.1.2 BARRIER 2: LONG PURCHASE CYCLE AND RELATIONSHIP BOND

Leonidou (2004) has distinguished slow collection of payments as BTE (from **Figure *4***). Following his classification this would be external BTE that is related to procedural barriers. Leonidou has explained this BTE from exporter's perspective. Nevertheless, this topic is very relevant to medical device distributor, because sales to the public Hospitals can take long terms. It is important to understand the purchasing process of medical equipment. This process could be described via innovation-decision process. The innovation-decision process follows five steps:

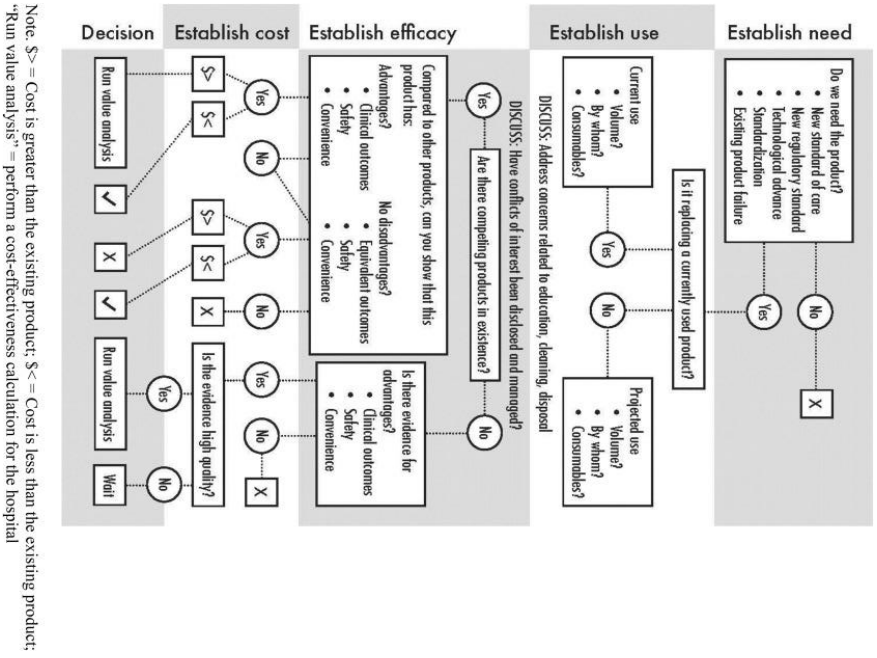
1) Knowledge;
2) Persuasion;
3) Decision;
4) Implementation;
5) Confirmation.

Knowledge is defined when an individual (e.g. physician-KOL) gains first understanding about new concept (existence of new technology) and its functions. Usually sales representatives play important role delivering this first knowledge to KOL. After KOL gain his first knowledge about innovation he shares it forming an attitude. Thereby, affecting a choice to adopt or reject possible implementation of the new concept and eventually confirmation of such concept (Rogers, 2002).

Next step is persuasion, here KOL forms a favorable or unfavorable attitude towards new technology. Then decision is being made, where KOL participates in activities that lead to a choice of adoption or rejection of innovation. If the decision is to adopt the innovation, then new technology is implemented into practice. After a try out the innovation is either confirmed or not, this is where KOL seeks for reinforcement previously made decision to adopt the innovation, however, this decision might be reversed if during a trial new conflicting technological issues about innovation occur.

Medical device distributors mostly deal with public Hospitals. Good example of innovation-decision process can be Health institutions, which implement formal decision-making processes. This process in hospitals involves clinicians and supply chain professionals to rationalize purchasing and promote cost-effective investment. There are four main phases on making decision in hospitals by establishing (find **Figure *6***):

1) The need – make physician to want new the medical device;
2) The use – give physician a tryout with your proposed product;
3) The efficacy – provide strong arguments about product's added value (its features);
4) The costs – explain the costs and given value (here good differentiation strategy from Bowman's clock can be very useful).



Note. $> = Cost is greater than the existing product; $< = Cost is less than the existing product; "Run value analysis" = perform a cost-effectiveness calculation for the hospital

Figure 6. A guiding framework for Value Analysis committee decision-making (Grundy, 2016).

When establishing the need at clinical level, clear value proposition must be made to answer the question: "Does the customer need the product?". The performance (e.g. the quality of the scan) of the equipment constitute the first level (the need) on which all other levels depend.

Next step is to establish the use at hospital, here the question is: "Is it replacing currently used product?". This concerns education where customers heavily rely on local knowledge and expertise (KOLs). Sales representative must have strong arguments and good references for the products.

Then it is very important in the purchasing decision to establish efficacy. Here the equipment differentiation (brand, price, quality, features, etc.) explains the cost effectiveness and product's advantage. This leads to final step, answering the question to customer: "What are the main advantages comparing with other products?" This is the final and most important stage where much depends not only on sales representative but also on the vendor's marketing capability (e.g. company reputation, brand, technical service, etc.).

Google and HIMSS Analytics (2013) have investigated that most purchase cycles in Hospitals take about one year and about 43% are made within six months (HIMSS Analytics, 2013). The distribution business might sound like a simple concept, but it takes time for competitors to imitate. Also, the relationships' bond is built by sales personnel with physicians that they serve. It takes time to establish these direct sales contacts thereby increasing switching costs to the doctor (build a new relationship). Moreover, if sales representative decides to switch to another company in the same business most physicians prefer to continue work with the same person. As a result, a large portion of revenues might be taken to the competitor.

One very important factor related to conservative physicians can be the cause of barrier. Leonidou (2004) has distinguished adaptation of product as BTE (from from **Figure *4***). Following his classification this would be internal BTE that is related to marketing barriers. Therefore, marketing like EBM material promotion, KOL training is important. However, sometimes clinical evidence alone is not enough. Even though new medical solution is proven to be effective, yet doctors must utilize it in their daily practice. There was a case of software system innovation for anti-coagulation applied across professional and organizational boundaries following the guidelines set out by St Vincent (1989) declaration standards which are applied in the treatment of diabetes in primary care. A directive under strong scientific evidence (EBM) but refused by many general practitioners who were not convinced of relevancy to their patients in primary care.

Doctors thought that the standards are for patients with advanced level of diabetes. Unfortunately, the adoption of the innovation was poor and declined (Fitzgerald, Ferlie, Wood & Hawkins, 2002). This concludes another strong BTE (medical expertise barrier), where conservative medical experts' reject or slow innovation adoption rate within their social structure. When company decide to introduce new product, strong sales personnel relationships with conservative doctors and long purchase cycle can recognized as BTEs.

2.1.3 BARRIER 3: LONG REIMBURSMENT PROCESS

Strict foreign rules and regulations is another BTE emphasized by Leonidou (2004). According to his classification this would be external BTE that is related to environmental (political-legal) barrier. (find in **Figure *4***). Reimbursement process is one of the most important political-legal procedures in medical device market. For this reason, deeper investigation on this topic has been done.

Limited reimbursement for sophisticated and latest advanced technologies can prevent vendors from delivering innovative solutions. Lack of reimbursement can become very strong BTE. For example, a surgery done through the skin and the femoral artery by inserting a catheter with the help of a camera, the aim of the procedure is to clear and to shunt acute pathological obstructions affecting the arteries percutaneous transluminal coronary angioplasty (PTCA). After PTCA was assigned to a Diagnosis-related groups (DRG) the compensation a was above much higher level than the procedure costs (Vozikis, Xesfingi, Moustaferi, Balbouzis & Rigatos, 2016). For this reason, back in 1994, PTCA was adopted rapidly in the United Stated, and many innovations in catheters for PTCA procedure where stimulated. However, another procedure placed in a DRG was a surgical operation of cochlear implants (an electrical transductor that transmits sound to the brain providing a sense of sound) for people with hearing loss. This has covered only a part of the implants' expenses leading to poor consumption eventually the reduction of innovations. Studies show that there is a link between the rate of healthcare innovation and its financing and integration into clinical decision making (Gelijns & Rosenberg, 1994). In addition to this, limited or no governmental coverage consequences problems for distributor to establish successful partnership with new supplier (medical device manufacturer). Supplier considers market as less attractive, or it is a crucial factor for supplier to consider new market like Lithuania.

The path to reimbursement is way more complicated and might take a lot of effort in terms of the procedure to reach and convince authorities as well as a long time till final decision will be made. For new medical technologies adoption there are three types of stakeholders (see **Figure *7***) that can be distinguished - patients, providers, and payers. Patients' role is the willingness to use the technology (create demand), providers' (manufacturers and/or distributors) role is to prescribe (fill the demand), and payers' (patients, care givers, government or national insurance) role is to pay for the products (cover the costs). If any of these stakeholders fail in their role, the adoption of innovation can be seriously threatened.

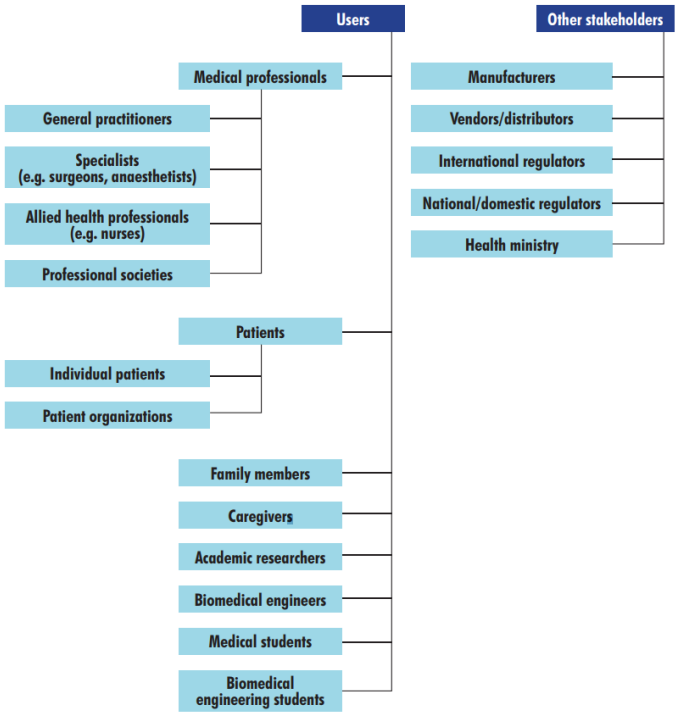


Figure 7. Stakeholders involved in the medical devices' reimbursement process (WHO, 2019).

The importance of medical device reimbursement may vary in different countries. For instance, in most European countries where most health services are covered by the government. By contrast, in the United States where providers (manufacturers and/or distributors) issue and submit claims to payers (private insurance) that covers the costs. In 2015, there were about 67.2 percent of U.S. citizens who received coverage from private health insurance (Seidel, Boggio Mesnil & Caruso, 2018). Here patients pay to insurance companies (privately insured patients pay themselves and then return the money from their insurer) ("United States: International Health Care System Profiles", 2019).

To explain about reimbursement, we must define payers that are two types - policy makers and budget holders. Policy makers can be government institutions like the MoH that make reimbursement decisions or recommendations by issuing them at the national level for the budget holders. While budget holders are institution like NHIF or Private Health Insurance companies that manage a budget. The budget can be collected by the budget holders through compulsory contributions (e.g. France, Germany, Lithuania) or voluntary funded (e.g. the U.S) ("Health Insurance System Home", 2019).

It is important to notice that there is distinction between countries for reimbursement decision making where reimbursement decision can be made independently by the budget holders, or by both policy makers and budget holders. The recent study was conducted to describe the different reimbursement pathways for new diabetes technologies and grouped the countries into three categories: "top-down" (policy makers are the decision maker), "bottom-up" (budget holders are the decision makers), and "mixed" (both policy makers and budget holders can be decision makers) (Seidel, Boggio Mesnil & Caruso, 2018). Since the reimbursement decision in Lithuania is made by policy maker the MoH, Lithuania in table below could be assigned to "top-down" category. The ***Table 2*** below summarizes the policy makers and budget holders and reimbursement in top largest markets for medical technologies in Europe.

Table 2. Main Policy Makers and Budget Holders and Reimbursement Pathways (Seidel, Boggio Mesnil & Caruso, 2018).

Country	Main policy maker(s)	Main budget holder(s)	Reimbursement pathway
Germany	Federal Joint Committee (GBA) Institute for Quality and Efficiency in Health Care (IQWiG)	Public health insurers Private health insurers	Mixed [a]
France	National Authority for Health (HAS) Economic Committee for Healthcare Products (CEPS)	Statutory health insurance	Top-down [b]
England	National Institute for Health and Care Excellence (NICE)	Clinical commissioning groups (CCGs)	Mixed [a]
Italy	Ministry of Health	Regions Local health authorities (ASLs)	Bottom-up [c]
Spain	Ministry of Health and Social Policy	Autonomous communities (ACs) Regional health services	Bottom-up [c]
Lithuania*	The Ministry of Health (MoH)	National Health Insurance Fund (NHIF)	Top-down [b]

[a] Reimbursement decision is be made by both policy makers and budget holders.
[b] Reimbursement decisions are only by policy makers.
[c] Reimbursement decisions are usually made by budget holders.
*Added by author of this paperwork.

It is beneficial for Lithuania to fall into a "top-down" category because in this way full potential of market access can be used (national population reach). Though, there still are high requirements for evidence so the process may take a long time and could be identified as a strong BTE.

2.1.4 BARRIER 4: STRONG SUPPLIER POWER

Maintaining control over foreign middlemen (distributor) that type of BTE has been extracted by Leonidou (2004). Under his classification this would be internal BTE that is related to marketing barrier - distribution (from **Figure *4***). If analyzed from the opposite perspective, vendor (distributor) would see this as supplier power. Good cooperation and balance between both counterparties should help to ensure smooth product's promotion and delivery to the markets. That is why, wrong relationship between manufacturer and distributor can be the cause of BTE.

According to Skinner et al. (1992), the supplier power is defined when supplier is available to influence the distributor's purchase decisions. Examples of such companies could be brands like GE Healthcare, Philips, Johnson & Johnson, and other worldwide medical companies. The elements of power (see ***Table 3***) can be distinguished as coercive and non-coercive (e.g. reward, legitimate, referent, and expert).

Table 3. Description of power over retailer elements (J. Hsiao et al, 2019).

Power	Description	Examples in industry
Coercion	The retailer's perception that the supplier can mediate punishment.	Supplier cancels business or withholds orders with retailer.
Reward	The retailer's perception that the supplier can mediate rewards of it.	Supplier offers bonus or cash discount to retailer for reaching a sales target, special offer for sales promotion allowances and better credit terms.
Expert	Supplier has information or expertise knowledge and skills desired by retailer.	Supplier has good knowledge in product and retail selling skills.
Referent	The retailer desires a sense of identification and association with the supplier.	Some suppliers pride themselves on having their brands carried in certain outlets.
Traditional legitimate	The supplier is perceived to have a legitimate right to influence the retailer and the retailer is obliged to accept this influence.	Large suppliers may be felt to legitimately influence certain marketing policies.
Legal legitimate	Based on contractual arrangement.	Supplier and retailer maintain a formal sales contract.

Power elements can make strong influence on the retailer (distributor). Jensen and Meckling (1976) raised problem when one party delegates work to another party. Agency problems come from the information asymmetry that results from this division of labor and from the conflicting goals and risk preferences of the two parties (Jensen and Meckling, 1976).

High manufacturer control relationships tend to require high investment (e.g. owned subsidiaries). In contrast, low manufacturer control over relationships (e.g. outsourced distribution) results low investment. Therefore, manufacturers choose to sell through independent distributors simply because of prohibitive expenses as well as risk to establish proprietary distribution (Anderson and Oliver, 1987; Williamson, 1975). The success of the outsourced distributor depends on the attractive products at competitive prices that are supplied by the manufacturer. Leaving both parties on the same boat and sharing the same goal of maximizing sales. The manufacturer, however, keeps the risks of distributors misrepresentation of qualifications and resources to secure the distribution contract. The distributor will pursue goals avoiding: the conflict of interests of inventory (competing products), inappropriate advertisement, price on the preferred range, improper sales train, poor after-sale service, etc. In other words, the manufacturer risks by taking moral hazard from distributors failure to put enough effort on the manufacturer's behalf.

A research conducted by Walfried M. Lassar and Jeffrey L. Kerr in 1996 has resulted a clear association between competitive (differentiation) strategy and the specific characteristics of manufacturer-distributor relationships. The investigation was to identify supplier's involvement via: distributor's behavior monitoring, contractual (legal) requirement, manufacturer coordination (e.g. obligations that constrain exit or relations with other manufacturers), dealer support (e.g. promotion materials, service standards, bonus, etc.), and distribution intensity (LASSAR & KERR, 1996).

Table 4. Summary of hypothesis results of manufacturer's involvement (LASSAR & KERR, 1996)

Constructs	Cost leader	Differentiator	Focus
Behavior orientation	Low	High	High
Contractual restrictions	Low	High	Low
Manufacturer coordination	Low	High	Low
Dealer support	High	High	Low
Distribution intensity	High	High	Low

A BTE may occur if distributors' strategy is a high-quality product (differentiation strategy) and manufacturer remains highly involved in control. Moreover, if manufacturer has all the type of power elements (see ***Table 3***) coercive and non-coercive, distributor might have difficulties to cooperate with strong brand manufacturer (e.g. Philips, GE Healthcare, etc.).

2.1.5 BARRIER 5: REGULATIONS FOR MEDICAL REPRESENTATIVES

Following Leonidou (2004) classification regulations for medical representatives would go under the same category of environmental (political-legal) barrier (find **Figure *4***). Different from reimbursement process regulations for medical representatives are more related to vendor itself, not with the specific medical product. There are different requirements and regulations from medical product development to introduction and sales to the market there are. These regulations can be divided into different stages According to WHO (2003), there are three phases in which regulations of medical device industry can be sorted: pre-market, placing on-market, and post-market regulation. Distributor takes part in placing on market phase (***Figure 8***) where regulations focus on sales.

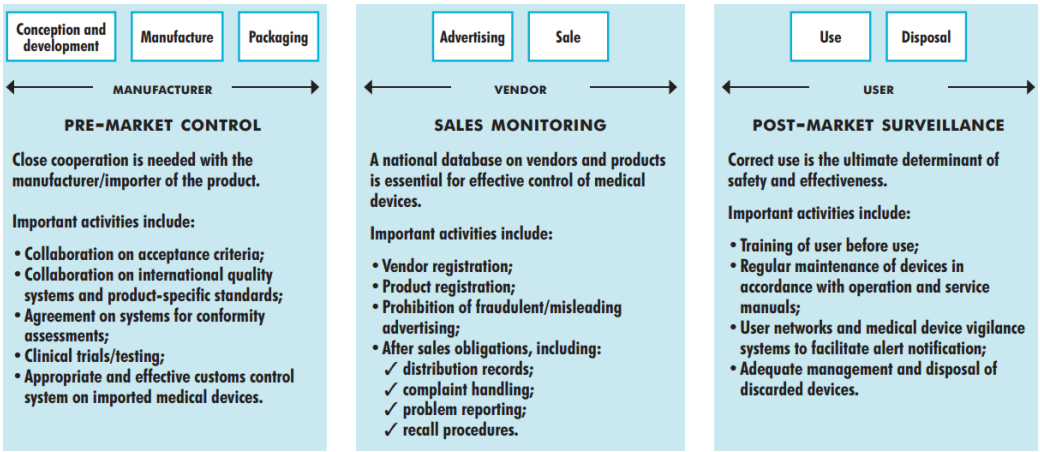


Figure 8. Life span of regulations in different phases (WHO, 2003).

As for distributor it is important to ensure that sold products (medical devices) have been manufactured and approved by European Committee (CE) mark. Medical devices must fall under any of these directives: Medical Devices Directive (93/42/EEC) (MDD), Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD), In-Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). Moreover, distributor must translate the information provided by the manufacturer on the label and in the instructions in Lithuanian language ("Medicinos priemonės (prietaisai) (pagal ES direktyvas) | VASPVT", 2019). Other responsibilities are

common sense requirements like accurate dissemination of information, warning a client about the condition of product when it is used or out of date. It is required to organize training and provide good quality service, during the operating period of medical product. Distributor should be aware of its product state in the market, respond quickly to complaints ("Regulatory framework - European Commission", 2019).

According to WHO (2003) distributor should be ready for after-sale surveillance meaning that company needs to have effective system to monitor devices post-market. Moreover, vendors are responsible for after-sales service provision, training and educating its customers. There is also requirement to report adverse events. The last important requirement from post-market surveillance is to ensure traceability by a complaint handling so that we could to analyze reported problems related to safety or performance (WHO, 2003).

It is not necessary but required by most of the manufacturers for distributor to have quality management system. Countries like China, United States, Canada, Australia and members of the EU accept ISO 13485 (Small and medium-sized enterprises, 2010). Less specific but essentially the same standard is ISO 9001 ("Differences between ISO 9001 and ISO 13485 explained", 2019) Most vendors in Lithuania have that type of quality management system (ISO 9001). Quality management system serves for two purposes - external (marketing) for export, image, prestige, customer and manufacturer trust, and internal (management) for internal system within the company, quality of real activity, clear work, division of responsibilities, reorganization of certain processes, more efficient management, lower costs.

There are many different requirement and regulations referring to different sources. Therefore, regulations for medical representatives can be one of BTEs. Lack of theoretical information has been found to overcome this type of BTE. For this reason, BTE of regulations for medical representatives will be analyzed in second (empirical) part of the research.

2.2 MANAGERIAL WAYS TO OVERCOM MARKET ENTRY BARRIERS

All BTEs that were briefly discussed referring to Leonidou (2004). Some BTEs can be linked and faced at once or some may not even appear depending on chosen market strategy, product, environment and other factors. Shepherd (2004) described external barriers as embedded in the market and cannot be controlled by the company. Whereas, internal barriers are created artificially by the competitors and tend to be weaker because companies have more control over them. Therefore, some BTEs have managerial solutions, some of them cannot be influenced.

In this section frameworks, pathways, and questions will be provided to serve as managerial solutions or guidelines to overcome identified BTEs. Further discussion will focus on what can be done to overcome each BTE.

2.2.1 OWERCOMING BARRIER 1: COMPETITIVE REACTION

The previous discussion concluded that two thirds of the new product launches face competitive reactions. The high probability to face this BTE suggest that there should be possible actions that can be implemented. Debruyne (2002) has even given precise types (see in ***Table 1***) of competitive reactions. In addition to this, two-thirds of strategic planners strongly support idea that firms would include expected competitive reactions into their strategic decisions (McKinsey & Company, 2008). Montgomery's (2005) survey shows that less than 1 in 10 managers have incorporated competitive reactions in their strategic decisions, and less than 1 in 5 expected to do so in the future (Montgomery, Moore & Urbany, 2005). Later in 2008, Kevin Coyne and John Horn have done their own research and developed a practical approach (framework) to predict competitive behavior via main questions (see **Table 5**).

Table 5. Practical approach to predict competitive behavior (Coyne & Horn, 2009).

Step	1	2	3
Questions	Will the competitor react at all?	What options will the competitor actively consider?	Which option will the competitor most likely choose?
Sub-questions	• Will your rival see your actions? • Will the competitor feel threatened? • Will mounting a response be a priority? • Can your rival overcome organizational inertia?		• How many moves ahead does your competitor look? • What metrics does the competitor use?
Action	Competitors' analyses	Making a list of competitive reactions	Pick most relevant (from 1 to 3) reactions and metrics

First step ("Step 1") is to consider the likelihood that there might be no competitive reaction at all. To determine this, following questions in "Step 1" (find in ***Table 5***) must be answered and if any of them is negative, the chances of a rival response are low. Only 23% of surveyed executives learned about upcoming competitor's new product launch early enough to respond before it hit the market. Moreover, even if competitors notice your actions, they might not consider them as a threat. It is most likely that competitors have made strategic decisions before your new product launch (e.g. their new product launches, marketing campaigns, reorganizations, major acquisitions, plant openings, and cost reduction efforts). Most of these processes must be initiated to react to your move. By understanding what it takes for your competitor to respond (in terms of expenses and effort) it is possible to sense if he will choose to ignore you.

Second step ("Step 2") is to find options that your competitor actively considers. Here a list of possible competitive reactions needs to be made. Although competitors may have a big list of response options, the serious investigation is only made on few. Daily responsibilities take a lot of time resources and can stop the competitive reaction. Moreover, it is hard to allocate time to analyze all options. The conducted survey shows that majority considered less than 4 responses to a rival's new product launch. Almost 75% of the respondents looked at 2 or 3 and less than 10% looked at 5 or more. In addition, about 55% of the participants claimed to have considered most obvious me-too reaction option (to introduce similar product or price change), and over one-third have selected only one option of competitive reaction. This gives a strong chance that competitors consider the most obvious responses.

Third step ("Step 3") is to figure out how your competitor is most likely to respond. Since in previous steps short list of competitive responses has been made. This step is most difficult to accomplish because it is not possible to be accurate 100% and avoiding predictions - is much worse. Your rivals will implement the most effective responses which require least resources (trade-off) in short-term and long-term. To guess the number of moves that rivals will implement is quite easy. Only 25% of participants considered more than 2 or 3 steps ahead. And about 25% said that they have not foreseen any steps beyond their own response. The majority of firms try to avoid complexity and keep things simple and easy to analyze (Coyne & Horn, 2009).

2.2.2 OWERCOMING BARRIER 2: LONG PURCHASE CYCLE AND RELATIONSHIP BOND

If medical equipment vendors want to succeed in long term, they must evaluate purchase cycle and build sales force structure to reflect that cycle. Well-designed and balanced salary is can drive sales force direction and motivation (Madhani, 2019). The right salary structure is attractive for competent sales representatives with the best skills, capabilities and expertise. There are multiple tools that can help to overcome long purchase cycles (e.g. economic cycle evaluation, sales force motivation and right portfolio). Moreover, even if it seems that relationship bond can become a strong barrier there are evidence that deny such an opinion. According to Matthew Dixon and Brent Adamson there are five types of sales representatives in terms of skills and behavior:

1. **Relationship builders** – develop strong personal and professional relationships. They fulfill every need and spend a lot of time with their customers.
2. **Hard workers** – start work early, finish late, and always do more than expected.
3. **Lone wolves –** have strong self-confidence, break rules and find their own way.
4. **Reactive problem solvers** – ensure good service, focus on post-market follow-ups.
5. **Challengers** – have deep understanding of their customers' business. They educate by giving their knowledge and take over control of the conversation. They can share potentially controversial views and are assertive — with both their customers and bosses.

The Sales Executive Council wanted to understand better these groups of sales people and launched a global study. There were over 6 000 volunteers from almost 100 companies from different industries in the study of sales representatives' productivity. Results showed significant differences between of Challengers and the rest of the groups. Challenger made 40% of all high-performed population. Surprisingly, the Relationship Builders accounted for only 7% of all high performers and were the least in population. Challengers had three key capabilities: to teach their customers, effectively position their sales pitch, take control of the sale. The lesson for organizations is that most of them focus on recruiting, developing, and rewarding Relationship Builders, the profile which is least likely to win (Dixon & Adamson, 2013). In addition, insights were made by Aberdeen's Research group that surveyed 67 executives from medical device industry analyzing value-based selling techniques. Leaders constituting 85% stated that they clearly translate features, advantages of solutions into economic value to customers. Moreover, those who could explain clear return-on-investment (ROI) from suggested solution make 42 % higher customer retention rate and 32 % more sales representatives achieve their annual quota (Aberdeen Group, 2012).

Recruiting right people and smart compensation models can lead to successful sales. Smart compensation models make 50 % higher impact on overall sales than changes in advertising investments (Hatami, Huber, Murthy & Lun Plotkin, 2018). Sales compensation programs are strongly related sales personnel performance. Performance can be measured in sales behaviors and outcomes (find in ***Figure 9***). Behavior performance is measured by the process of selling. Behavior control system requires high financial investments to monitor the sales process. On contrary, outcome control system focusses on short-term financial goals that conflict in achieving long-term goals. The suggested strategy is to choose compensation system that is in the middle of behavior and outcome control systems. Because one of the systems alone are too extreme and are not effective (e.g. behavior control only - poor financial performance, outcome control only – distract from creative problem solving and increase stress). Balanced system brings harmony and the reliance of sales organization.

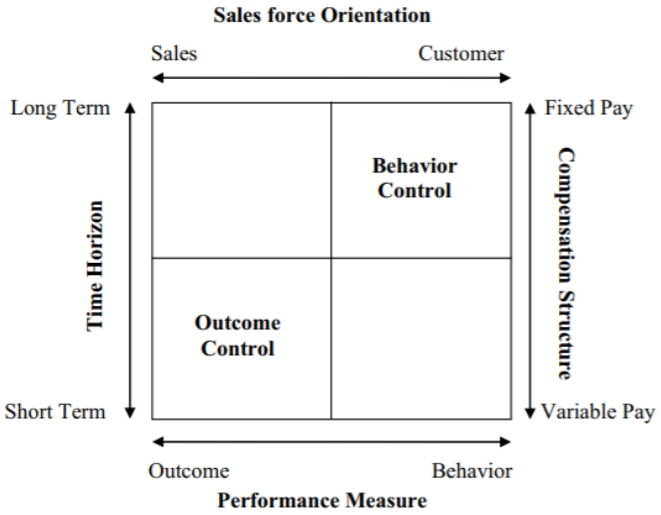


Figure 9. Salesforce control: Key dimensions (Madhani, 2015).

Right portfolio strategy can also serve as a right solution overcoming long sales cycles. Products' have different life cycles, higher or lower perceived value and demand. A research analyzing impact of product portfolio strategy on financial performance indicated that a large product portfolio helps a firm's financial performance. Portfolio strategy (see **Table *6***) is divided in product development and market entry strategy. Product development strategy can be distinguished in new (introduced within the year) and mature (adopted in the market). Also, market strategy can be leading (first to introduce products) and following (lagging in the segment).

Table 6. Product Portfolio Strategy (Kang & Montoya, 2013).

		Product development strategy	
		Mature	New
Market entry strategy	Leading	• Leading-Mature	• Leading-New
	Following	• Following-Mature	• Following-New

A study has showed that companies which introduce pioneering products (e.g. Leading-New and Leading mature) have strong impacts on short-term performances, and firms that provide non-pioneering products (e.g. Following-Mature and Following-New) do not make significant contribution. This suggest considering both product development and market entry strategies to understand the financial impacts of product portfolio. Since pioneering products require more firm resources it is necessary to keep the balance between the number of "following" and "leading" as well as "mature" and "new" products. Hence, non-pioneer (mature or/and following) products alone may not increase performance in sales or profit because pioneer (new or/and leading) products support them. However, there is a clear first-mover advantage making an immediate effect and long-term effect and only pioneering firms gained long-term financial rewards. This means that company's overall capability to be first to deliver new products in the marketplace (e.g. Pioneering Intensity) is vital for business success (Kang & Montoya, 2013).

2.2.3 OWERCOMING BARRIER 3: LONG REIMBURSEMENT PROCESS

Martin Gold is a cofounder at Technology Access Partners. Consulting firm specializes in reimbursement and economic sales strategies for biotechnology firms. Martin Gold provided steps for the companies to go through reimbursement process. These steps are given following:

1. Identify the decision makers;
2. Define the market model;
3. Identify coding gaps;
4. Determine regulatory or legislative issues;
5. Train KOLs and develop strong relationships with specialty medical societies;
6. Collect references and publish them.

The first step in the reimbursement process is to identify key payers to target right authorities (see ***Figure 7*** or ***Table 2***). For example, leaders in the MoH are the main decision makers in Lithuania.

Second step is to determine similar technologies and find their reimbursement model in country. This analysis will help to figure the value that payers (e.g. MoH) currently perceive in this particular treatment, payment methods and settings. If new medical product has no comparable product in the country, the reimbursement can be estimated by its predecessor.

After having a clear understanding of reimbursement methods and payers in the country the research of possible regulatory or legislative issues must be done. These issues can make critical impact to reimbursement process of the product. In 2000, insurance company Medicare (payer) in the US implemented the Outpatient Prospective Payment System (OPPS). OPPS changed the way how Medicare reimbursed medical devices for hospitals in the outpatient environment. OPPS funds hospitals prospectively by each Medicare's patient diagnosis, that changed old retrospective cost-based reimbursement system (Lave, 2019).

Later, very important step is to make sure that a new code for insurers will be provided and made for new medical technology. The coding system is adopted by insurers to use it in payment system. This code is used to track the types and quantities of health services delivered to patients. Missing code used as a payment mechanism could end up by no compensation at all.

Then, identify and train medical professionals (KOLs) find in (***Figure 7***). KOLs are physicians and clinicians that have authority. If possible, during the post-market phase (find **Figure *8***) distributor to continue clinical evaluation. In this way, vendor can collect references to support clinical claims and market adoption, from post-market data company can differentiate the technology by evaluating product improvements. Thus, to efficiently promote products to the KOLs in the segment or industry (Blair & Goldenberg, 2014).

Insulin pumps in Lithuania were reimbursed after strong stakeholders' pressure from both physicians (KOLs) and diabetes clubs (patients). They understood and supported the product. Moreover, KOLs are like a medical advisory (early adopters) and can help in the reimbursement process. During the dialog with payers (e.g. authorities from MoH) the demonstration of cost-effectiveness and clinical value of product is needed. If payer approve the medical device for reimbursement final step is public communication. Build a publication strategy to communicate the effectiveness of the product (e.g. public journals, social media, newspapers etc.) ("Getting reimbursement for your product in the United States", 2019).

2.2.4 OWERCOMING BARRIER 4: STRONG SUPPLIER POWER

Petros Paranikas, Grace Puma Whiteford, Bob Tevelson and Dan Belz (2015) have given a guideline to deal with powerful suppliers (see below ***Figure 10***) answer the questions under each path. Start from the least-risky option that can work for medical device distributor. If both answers to the first option are negative, go to another one (riskier).

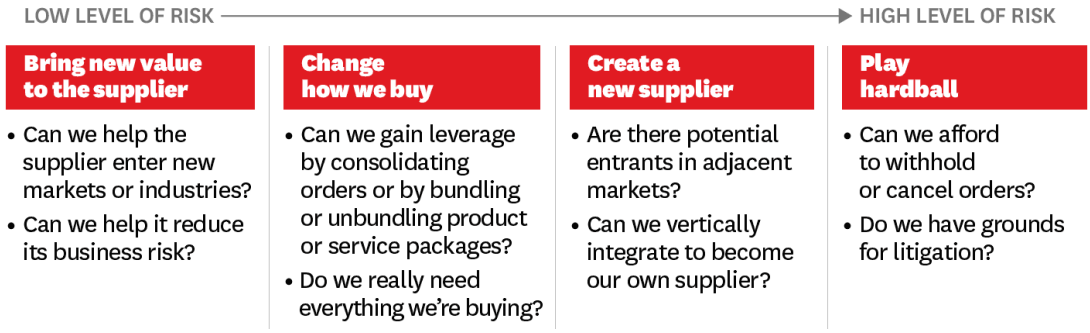


Figure 10. Negotiation path with powerful suppliers (Paranikas, Puma Whiteford, Tevelson & Belz, 2015).

First option (low risk) to consider would be to bring new value to the supplier. One way to bring value is to offer new market opportunities. If there is a chance to become a gateway to new markets. This could be the quickest and least expensive path to reduce the supplier power and gain the price reduction in return. Also, the reduction of the supplier's risks can also serve as a good tool. There could be many ways to do so, for example, buying in advance to keep more production in stocks.

Second option (neutral risk) would offer to change your purchase methods. For instance, distributor can consolidate orders by uniting business units purchase. Analyzes of companies spending can show that your company is already buying more than single business unit. Threat to suspend all purchases lead to good concession in return. In addition, different but similar case appear when distributor is buying one essential product that is vital for the business but other (surrounding) products could be bought elsewhere from another supplier. Such treat can also help to gain price concessions. In this way last strategy can be applied by decreasing the purchase volume. Shifting purchase volume from a powerful supplier to a substitute product. This case can increase the supplier's willingness to negotiate.

Third option (high risk) to create a new supplier. This would require commitment and investigation but finding a new supplier from an adjacent market could work. Simply by bringing in a new competitor from an adjacent country (geography).

If all other options have failed, the last one (highest risk) is to Play Hardball. Force your supplier to negotiate by threatening to cancel all orders, exclude the supplier from future business, or threatening litigation.

2.2.5 SUMMARY: BARRIERS TO ENTER AND MANAGERIAL SOLUTIONS

The summary of BTEs and managerial solutions is provided in this section. Michael Porter has classified market retailers as having low barriers to enter and low barriers to exit the market. On the contrary, companies in telecommunication business have strong barriers to enter and strong barriers to exit. This is because of high costs to build such an infrastructure and sell it to someone (Bpp Learning Media., 2010). However, retailers in the medical industry remain specific and have different type of BTEs. Previously discussed topics in the text are extracted in types of BTEs some of them refer to Leonidou classification (see ***Table 7***).

Moreover, there are few more BTEs that were not briefly discussed but are mentioned in a few paragraphs in the literature review. These BTES are described as "Additional BTEs" extracted in the ***Table 7***. Author of this research has personal experience in medical device distribution business and considers these "Additional BTEs" worth to analyze.

Table 7. The summary of barriers to entry and managerial solutions

No.	Type of BTE	Description	Management tool
1	Competitive reactions	Competition reacts via marketing mix variables: pricing place selective price discounts (very low margins), include substitute products, in their portfolio, etc.; or by implementing other types of competitive responses.	Market strategy selection; Practical approach to predict competitive behavior (see **Table 5**.).
2	Long purchase cycle and strong relationship bond	Decision making process and sales cycle takes up to 6-12 months or even more. Competitor's relationship with physicians can cause troubles;	Market strategy selection; Sales force motivation; Product portfolio strategy (see **Table 6**).
3	Long reimbursement process	The process of reimbursement is hard to influence and there is a big chance of failure. Normally the reimbursement process requires 1-2 years, but it could take even more.	Follow recommendations by Martin Gold;
4	Strong supplier power	Harsh conditions via monitoring or high power over distributor might cause difficulties to cooperate; Competitor's – supplier's exclusive agreements;	Negotiation path with powerful suppliers (see **Figure 10**)
5	Regulations for medical representatives	Legal requirements by the EU might cause difficulties for distributor.	No data
Additional BTEs			
6	Medical practice barrier	Conservative medical experts' rejection or slow innovation adoption rate within social structure.	Training events providing evidence-based medicine (EBM) material. Establishing relationships with key opinion leaders (KOLs).
7	Market size barrier	Lithuania has relatively small market, comparing with Germany, England or France.	No data

In general, internal forces (from **Table 7**) could be considered as moderate. Because product decision very much depends on company. For instance, switching costs for the customer very much depend on the product (e.g. if radiologist needs new ultrasound system, every company can offer it without any switching costs or new hospital are without any equipment). Moreover, product with high perceived value (good differentiation) and strong sales team can overcome competitor's sales personnel relationship bond with physicians. Promotional costs and strong competitive reaction are less dependent on the company and could be evaluated as higher BTE. To conclude theory of all internal forces they are considered weaker than external. However, important part is that product decision.

Company has almost nothing but reputation on external forces. Meaning that very little or no influence can be done (from **Table 7**) that is why external forces are evaluated as strong or very strong. If company has good network and access to all stakeholders (e.g. politicians, KOLs, patent

groups) the reimbursement process is still very long (one or more years). Additionally, long sales cycles in Hospitals is another barrier that cannot be pushed and requires long investment to sales personnel and frozen money in stored products. Also, market size is limited especially in small markets like Lithuania, this converts in very limited sale volumes making market less attractive for strong and innovative brands. Nothing can be done at this BTE, unless spreading the distribution channel in other countries. Medical practitioners can be very conservative and not accept new product even if there are strong evidence on product's effectiveness. However, focused and good promotional activities can help to overcome this type of BTE. More control company has over supplier-distributor relationships. Here good managerial skills can help on negotiation. As well as ownership of key resources (exclusivity BTE) can be bypassed via substitute products from different supplier. Overall, evaluating from analyzed theory external forces are strong BTEs.

3. METHODOLOGY FOR IDENTIFICATION OF MARKET ENTRY BARRIERS

This section will explain why and what empirical investigation method and workflow has been chosen. To approach the aim of the research project two objectives have been accomplished. The nature of BTEs has been discussed as well as theoretical overview of key BTEs and ways to eliminate them. In this section, theoretical part of the master thesis will be examined, complemented and evaluated regarding to the relevance in practice. For this reason, it is important to design methodology to identify key BTEs and ways to overcome them.

QUALITATIVE AND QUANTITATIVE RESEARCH

The research can be done through three different approaches: quantitative, quantitative and a mix of two (Jick, 1979). Qualitative research method is applied when the aim to understand some aspects of social life or human issues. In general, this method generates words, rather than numbers. While quantitative research method is usually implemented to numerical measure of something through data collection and statistical analyses (McCusker & Gunaydin, 2014). For example, the percentage of people with DM in a community. According to Yin (2009) "some experiments, such as studies of perceptions, and some survey questions, such as those seeking categorical rather than numerical responses, rely on qualitative not quantitative evidence" (Ishtiaq, 2019). Comparatively, mixed method is the strongest type of research. It is advantageous exploring complex questions and situations. Qualitative research can help to provide various strong assumptions that can be verified via qualitative data (Creswell & Creswell, 2018).

CASE STUDY

More explanation of case study is provided because theory will be used for the research. Creswell (2009) has concluded five different approaches to qualitative research:

1. Narrative research is a design when researchers provide studies (retell stories) of individuals and their lives into a narrative chronology.
2. Phenomenology is a design in which the researcher describes individuals' experiences of a phenomenon.
3. Grounded theory is a design of inquiry when the researcher uses its own experience and knowledge to compare it with theories and find differences or similarities for his hypothesis.
4. Ethnographies consists of observations and interviews selectively from cultural group analyzing patterns of behaviors, language and actions in a period of time;
5. Case study is a design of research when the researcher develops an in-depth analysis of a certain program, event, activity, process. Cases are bounded together in terms of time and activity;

Yin gives definition of a case study that is "an empirical enquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident" (Hollweck, 2016). Yin also says that case study deals with multiple variables from many sources of evidence giving theoretical proposition to guide data collection and analyses. Thera are two types of case study inquiries either a single or multiple sample cases can be used. Robson explains that single case study suits under unambiguous set of circumstances, meaning that there is a clear theoretical understanding and predicted outcomes will be found (Robson & McCartan, 2016). While multiple case study allows to create solid theory.

THE CHOSEN METHOD

Medical device industry is very niche and the number of medical companies in Lithuania is very limited. Therefore, qualitative research method has been done due to limited access to information. Primary and secondary data will be used to collect full information. Primary data will be collected by interviewing physician radiologist with Medical Doctor degree and over 15 years of experience in medical product sales (expert). This will enable to see what BTEs are faced in practice and to measure each BTE's relevance in Lithuania. The aim is to compare collected primary data and secondary data. During the interview (primary data collection) expert will evaluate each BTE. Secondary data like official documents, industry and/or annual reports, other credible and related information will be collected by the author. Each BTE from secondary data is evaluated by the author.

The goal of the empirical research is to reveal main BTEs and to propose managerial solutions while entering Lithuania market with advanced medical devices. For this reason, multiple case analysis of new innovative medical products that were introduced in Lithuania is chosen. This is the most appropriate method for such type of research. Multiple case study design is useful because:

1. Research question seeks to determine what BTEs were faced by the company in Lithuania introducing advanced medical device;
2. Research question seeks explain how BTEs could be managed and/or maybe eliminated;
3. Research is focused on BTEs of advanced medical devices that are bounded together.

First part of master project has given the theory of possible BTEs that can stop from successful introduction in the market. Leonidou (2004) theory classification of export barriers was adapted to both medical device distributor and possible new entrant (manufacturer-exporter) to Lithuania's market because they both would face basically the same challenges. Second part of this theses is meant to analyze empirical findings and compare it with conducted theory from articles, books and reports that were investigated. Inductive approach is applied to guide the case study process by giving questions from collected theory. Bernard (2002) described induction as "the use of direct observation to confirm ideas and the linking together of observed facts to form theories or explanations of how natural phenomena work".

METHODOLOGICAL LIMITATIONS

First, there were four months for the whole master theses resulting methodological limitations due to time constrains. Limitation related to time constrains cause difficulties for more extended literature review and more interviews for deeper situation analyses.

Second, because no credible theory to extract BTEs related to the nature of the advanced medical device markets has been found. BTEs were distinguished from personal author's experience as assumptions. This can limit the findings of most relevant BTEs that were not experienced by the author.

Third, qualitative multiple case study comes from only one company. This could influence all cases because of company's management policy. In addition, interview has been taken from one expert who was directly involved in all cases. This can make very subjective opinion about all BTEs.

Finally, for secondary data collection there was no data base with standardized information that could be easily picked and analyzed. Also, some BTEs that were analyzed could not be found because it is sensitive and personal firm's (vendor's) information. Consequently, this cause difficulties to objectively evaluate BTEs comparing primal and secondary data.

Overall, all these factors can make negatively influence on data and findings reliability and validity.

4. EMPIRICAL RESEARCH AND DATA COLLECTION

Few differences exist between a single and a multiple case study. A multiple case study can help to understand the differences and the similarities between the cases (Baxter & Jack, 2008; Stake, 1995), researcher can examine the data across situations (Yin, 2003). Moreover, multiple case studies can be used to find contrasting or similar results for expected reasons (Yin, 2003). By analyzing contrasts or similarities findings can be clarified to be valuable or not (Eisenhardt, 1991). Yin (2009) has given a plan to develop a case study investigation through following steps:

1. Plan – here we evaluate if case study method is appropriate for theses. If so, investigator must reveal the research question or other rationale behind choosing a case study design by understanding its advantages and limits;
2. Design – metrics and cases that will be investigated must be determined. Researchers must propose theories to set the boundaries of the study;
3. Prepare – practical skills for data collection must be developed (e.g. performing an interview without influencing the interviewees opinion);
4. Collect – systematic approach to data collection and categorization must be implemented. This is important to maintain a good chain of evidence and structure making analyses more reliable;
5. Analyze – an objective opinion is vital when analyzing patterns in the collected data. Also, researcher must ensure that continuous data revision has been done while analyzing data.
6. Share – there must be enough information in the research for further study. For this reason, main investigation audience must be defined and how the study is going to be presented (e.g. written or oral form).

To properly collect case study data Yin (2009) has offered six major sources of evidence: interviews, direct observation, participant observation, documentation, archival records, and physical artifacts. For this research investigation four different cases of new medical device introduction in Lithuania have been selected. These cases where picked from Lithuanian capital company Graina Ltd. Case company is one of the biggest medical equipment distributors in Lithuania with its branch offices in Latvia and Estonia ("Kontaktai | Graina", 2019). Firm perfectly fits profile for the research problem analyses because of continuous exploration of new products. In all four cases company had difficulties to successfully deliver products into the market. Therefore, we will be able to clearly identify where and when the innovative product failed to reach or had barely reached the market.

Based on Yin's (2009) structure, the following data collection methods has been applied:

a. Multiple sources of evidence have been used;
b. Case study database has been created;
c. A chain of evidence to ensure the credibility and reliability of the data has been maintained.

Multiple case study data were gathered and divided in two parts. First of all, secondary data were analyzed in order to evaluate each BTE (e.g. no data, weak, moderate, strong). Then interview with high position authority (e.g. directors, head of sales) or other staff that had direct experience with new product introduction will be delivered in order to supplement the data gathered in the first stage. Secondary data will be used to fulfill the missing gaps of information about BTEs and will provides us managerial solutions that were applied to overcome faced BTEs. Finally, data gathered through the first and second stage of empirical research will be analyzed, and both conclusions and recommendations will be suggested.

Three types of study interviews are available: structured, semi- structured, unstructured. The structured interview is based on a series of pre-established questions with a limited option of response. Structured interviews are strict, interviewer reads from a script and deviates from it as little as possible. The semi-structured interview has more freedom to deviate from a script. Questions are prepared to follow identified topics systematically. Interview goes through from highly scripted to relatively free form. However, the chosen guide questions provide same thematic approach during the interview (Qu & Dumay, 2011). Unstructured interviews do not reflect any theories and interviewers have no assumption in advance, this type of interview is the very time consuming. Therefore, semi-structured interview has been chosen with key questions which help to define areas and let interviewee to give more details by freewill.

To conduct better quality information, questions were coordinated and prepared before meeting interviewee. Questions where generated and classified accordingly to BTEs from theory (Blocks 1-6). The questionnaire is a tool for the interview and is built on six blocks of identified BTEs. Each case will be analyzed trying to answer all questions.

Block 1. Overcoming competitive reaction

Type of BTE	**Competitive reaction**	
Description	Competitors can react via marketing mix variables: selective price discounts (very low margins), include substitute products, in their portfolio, or by implementing other types of competitive responses.	
Question		**Example**
1A	How would you evaluate competitive reaction in terms of barrier for new product introduction?	No data; Weak; Moderate; Strong.
1B	What type of competitive reactions have you experienced during your career when introducing product: A, B, C or D?	Competitors can react: - Set selective price discounts (very low margins); - Include substitute products, in their portfolio; - Active promotion (against your product or for their product line); - Other.
1C	What methods are applied to overcome such a barrier?	Incorporate possible competitive reactions into strategic decisions by answering questions: 1. Will the competitor react at all? 2. What options will the competitor actively consider? 3. Which option will the competitor most likely choose?
1D	Is there anything else you could add on this topic?	Open question

Block 2. Overcoming long purchase cycle and strong relationship bond

Type of BTE	**Long purchase cycle and strong relationship bond**	
Description	Decision making process and sales cycle takes up to 6-12 months or even more. Competitor's relationship with physicians can also prevent from successful sales.	
Question		**Example**
2A	How would you evaluate long purchase cycle as a barrier to introduce new product?	No data; Weak; Moderate; Strong.

2B	How would you evaluate competitor's relationship bond with physicians to adopt new product?	No data; Weak; Moderate; Strong.
2C	How long does it usually take to sell medical equipment to hospitals (from first interaction with potential client and closed sale)?	Months: 0-3; 4-6; 7-12; 13-18; 24+
2D	What methods are applied to overcome long sales cycle barrier?	Product differentiation on portfolio (more pioneering products); Well-designed balanced salary;
2E	What methods are applied to overcome relationship barrier?	Hire more **challengers** that have deep understanding use of their customers' business. They educate by giving their knowledge and take over control of the conversation. They can share potentially controversial views and are assertive — with both their customers and bosses.
2F	Is there anything else you could add on this topic?	Open question

Block 3. Overcoming long reimbursement process

Type of BTE	**Long reimbursement process**	
Description	The process of reimbursement is hard to influence and there is a big chance of failure. Normally the reimbursement process requires 1-2 years, but it could take even more.	
Question		**Example**
3A	How would you evaluate long reimbursement process for new product introduction?	No data; Weak; Moderate; Strong.
3B	How long under your experience reimbursement process takes?	1-2 years, or even more?
3C	What methods are applied to overcome such a barrier?	According to Martin Gold there are steps to go through reimbursement process: 1. Identify the decision makers (leaders in the MoH); 2. Define the market model (cost-effectiveness); 3. Determine regulatory or legislative issues; 4. Train KOLs and develop strong relationships with specialty medical societies; 5. Collect references and publish them.
3D	Is there anything else you could add on this topic?	Open question

Block 4. Overcoming strong supplier power

Type of BTE	**Strong supplier power**
Description	Harsh conditions via monitoring or high power over distributor might cause difficulties to cooperate; Competitor–supplier exclusive agreements.
Question	**Example**

4A	How strong is supplier power in terms of successful new product introduction to the market?	No data; Weak; Moderate; Strong.
4B	What type of supplier power have you experienced during your career?	**Coercion** - the retailer's perception that the supplier can mediate punishment. **Reward** - the retailer's perception that the supplier can mediate rewards of it. **Expert**- supplier has information or expertise knowledge and skills desired by retailer. **Referent** - the retailer desires a sense of identification and association with the supplier. **Traditional legitimate** - the supplier is perceived to have a legitimate right to influence the retailer and the retailer is obliged to accept this influence. **Legal legitimate** - based on contractual arrangement.
4C	What methods are applied to overcome such a barrier?	Bring new value to the supplier – offer new market opportunities; Change how we buy – allocate all business units; Find a new supplier – bring competition; Play hardball - threatening to cancel all orders.
4D	Is there anything else you could add on this topic?	

Block 5. Overcoming regulations for medical representatives

Type of BTE	**Regulations for medical representatives**	
Description	Legal requirements by the EU might cause difficulties for distributor.	
Question		**Example**
5A	How would you evaluate legal regulations for medical representatives as a BTE for new product introduction?	No data; Weak; Moderate; Strong.
5B	What legal regulations are the most difficult implement?	ISO 9001 or ISO 13485, others
5C	What methods are applied to overcome such a barrier?	Open question
5D	Is there anything else you could add on this topic?	Open question

Block 6. Overcoming medical expertise barrier

Type of BTE	**Medical expertise**	
Description	Conservative medical experts' rejection or slow innovation adoption rate within social structure.	
Question		**Example**
6A	How would you evaluate conservative physicians as a BTE for new product introduction?	No data; Weak; Moderate; Strong.
6B	Could you give more details on this BTE? What were the circumstances?	Open question
6C	What methods are applied to overcome such a barrier?	Invest in KOLs' education, training, provide EBM material, etc..

6D	Is there anything else you could add on this topic?	Open question

Block 7. Overcoming small market size barrier

Type of BTE	**Small market size**	
Description	Lithuania has relatively small market, comparing other with EU countries (e.g. Germany, England or France). Problems might occur to attract innovative and big supplier (manufacturer) to cooperate.	
Question		**Example**
7A	How would you evaluate market size as a BTE for new product introduction?	No data; Weak; Moderate; Strong.
7B	What is your experience/insights on this case? How often this BTE is faced when you want to introduce product to our market to supplier?	Open question
7D	What methods are applied to overcome such a barrier?	Open question
7E	Is there anything else you could add on this topic?	Open question

4.1 SECONDARY AND DATA ANALYSES

The research question was: What are the barriers to introduce advanced medical devices (CGMs) in developing markets (Lithuania) and what managerial or other tools could be used to address these barriers? The time frame definition for BTEs has been previously discussed in the literature and is defined as time length before catalogue birth and reasonable sales volume. Secondary data is collected from officially available sources like mass media publications, institution reports, etc. Information is grouped into four different cases:

A – Cryotherapy;
B - Enhanced external counter pulsation;
C - Mindray ultrasound system;
D - Handheld ultrasound system.

All BTEs in **Table *7*** are structured from literature analyses and has been used as a tool (framework) to collect secondary data. Each case has been researched according to BTEs from **Table *7*** and evaluated by the author:

1. Competitive reactions;
2. Long purchase cycle and strong relationship bond;
3. Long reimbursement process;
4. Strong supplier power;
5. Regulations for medical representatives;
6. Medical expertise barrier;
7. Market size barrier.

Not all information was accessible via official sources. For this reason, data is not fully collected and some BTEs are skipped. Primary data collection (interview) will be implemented to fill missing gaps.

CASE A - CRYOTHERAPY

Short product description

Cryotherapy (CRYO) is scientifically proven to be effective treatment for primary prostate cancer (PC). CRYO is minimally invasive method that uses pressurized Argon gas and destroys tumoral tissue by freezing it to -40°C. It is minimally invasive method with low surgical risk and good survival rates (PC survival 98.1% and overall survival 94.4%) (Rodríguez et al., 2014). Moreover, the treatment can be used for kidney cancer (KC) (Kelbauskaitė, Dragūnaitė & Urbonavičiūtė, 2015). In 1996 American Urological Association established CRYO as an option to treat PC. Later, in 1999 the United States (Medicare and Medicaid) have approved CRYO as primary treatment of PC (HAN et al., 2003).First official knowledge about first CRYO surgery in Lithuania has been published by national media channel LRT in 2014 (Simonas Bendžius, 2014) and according to the source one surgery can cost up to for patient costs around 4 000 – 5 000 Eur (Tavoraitė, 2016). CRYO could be considered as leading-mature product (from ***Table 6***) since practice in western countries has started decades ago.

Reimbursement process as a barrier for CROY introduction in Lithuanian market. In 2015, SHCAA under the MoH (Lithuania) in collaboration with Ludwig Boltzmann Institute (Austria) have carried out a health technology assessment (HTA) on CRYO for PC and KC treatment. The committee conclusion was to recommend CRYO as a primary treatment for both PC and KC (Kelbauskaitė, Dragūnaitė & Urbonavičiūtė, 2015). However, until now the CRYO treatment is on the list of more than other 60 health technologies compiled by NHIF (Lithuania) that are still waiting for their assessment of the possibility of compensation (E-seimas.lrs.lt, 2019). CRYO is not reimbursed in Lithuania and treatment is not available for all patients with PC or KC.

Since average salary in Lithuania in 2019 is 970.30 Eur (before taxes) and minimum salary is 555 Eur (before taxes) (TRADING ECONOMICS, 2019) it is relatively expensive to afford 4 000 – 5 000 Eur surgery. Therefore, long reimbursement process can be considerate as strong BTE.

Medical expertise as a barrier CRYO introduction in Lithuanian market.

In 2014, first surgery in Lithuania has been done with colleagues from Estonia help (Ugnė Galadauskaitė, 2019). If CRYO therapy would be covered by the government, there could be 20-30 KC and around 30 PC surgery procedure a year. Unfortunately, now there are 5-6 procedures done every year and only when there are no other options (AIGUSTĖ TAVORAITĖ, 2016). Considering, that there is lack of financial and the number of surgeries is low. There might be very limited number of physicians that can actually use this technology. Lack of medical practice could also be considerate as a barrier and evaluated as moderate BTE.

Market size as a barrier for CRYO introduction in Lithuanian market. In 2012 there were 399,964 cases of PC in Europe while in 2013 Lithuania had 17,266 cases of PC. In Lithuania PC is diagnosed for 3 000 men each year (Kelbauskaitė, Dragūnaitė & Urbonavičiūtė, 2015). Moreover, in 2015 according to Eurostat Lithuania had 544 deaths caused by PC and was the 25th from 28 countries in Europe while Germany was 1st on the list with 13 919 deaths (find **Table *13***).

However, according to World Cancer Research Funds in 2018 there were over 400,000 new cases of KC and Lithuania is the 3rd from top 20 countries with the highest rate of KC (find in **Table *14***). Age-standardized rate helps to summarize the rate of disease that a population would have if it had a standard age structure. Standardization is inevitable when comparing populations. There were 338 000 new cases of KC globally in 2012. Lithuania in 2012 had 773 (per 100,000) KC diagnosis in 2012 for both sexes).

Even though, Lithuania is a small country, statistics of patients who suffer from KC and PC show that market is reasonable enough to offer new solutions. As a result, market size is considered as weak BTE.

CASE B - ENHANCED EXTERNAL COUNTERPULSATION

Short product description

In 1953, Kantrowitz demonstrated that coronary blood flow can be increased 20% to 40% by increasing diastolic blood pressure. Enhanced external counter pulsation (EECP) is a non-invasive method applying external pressure to the lower extremities in a timed, sequential manner, using pneumatic cuffs, to produce effective diastolic augmentation and increase coronary blood flow. The EECP therapy is meant to treat coronary heart disease (CHD) and angina the prime symptom of CHD (Lawson, Hui & Cohn, 2000). EECP therapy has been approved by the FDA in 1995 for the patient treatment of CHD with angina who not respond to standard procedures and pharmacotherapy (Braith, Casey & Beck, 2012). (Sharma, Ramsey & Tak, 2013). There was no data found about EECP therapy practice in Lithuania. EECP product could be considered as leading-mature product (from **Table *6***).

Reimbursement as a barrier for EECP introduction in Lithuanian market. In 2008, The National Institute for Health Research (NIHR) in England has done HTA on EECP therapy. The research findings from the HTA make direct influence on reimbursement decision-making for NICE. The aim of HTA is to determine clinical and cost-effectiveness of EECP compared with usual care and placebo. After HTA the committee of NIHR concluded to lack evidence of the clinical effectiveness of EECP in CHD as well as refractory stable angina. Moreover, the long-term effects are also uncertain on quality of life benefits (McKenna et al., 2009). Consequently, EECP therapy is not reimbursed in Europe. While treatment in United States is covered for 35 hours over 7 weeks to relief refractory angina for patients. Moreover, European Society of Cardiology state that EECP *should be considered* whereas American College of Cardiology and American Heart Association joint guidelines recommend that EECP *may be considered* for relief of refractory angina (Henrique Wolff Gowdak, 2017) (Fihn et al., 2012).

The total cost of EECP treatment per patient was estimated to be £4347 for 35-hour course, making cost per session of £124. EECP therapy is not reimbursed by Lithuania's government and is expensive for average person. Moreover, HTA results do not show strong support for that type of therapy. To conclude, reimbursement of EECP might be considered as strong BTE.

Market size barrier as a barrier for EECP introduction in Lithuanian market. According to European Heart Journal in 2012 Lithuania was ranked 7th by male (740.4) and 8th by female mortality of CHD in Europe continent (740.4 male and 450.4 female deaths per 100 000 population). In comparison, Ukraine was 1st by male and 2nd by female death rate from CHD (1077.4 male and 721.2 female deaths per 100 000 population) (Townsend, Nichols, Scarborough & Rayner, 2015). Lithuania has one of the highest CHD rates in Europe and CHD or ischemic heart disease is the most premature cause of death (Institute for Health, 2019). There is a lot of potential targeting patients who suffer from CHD in Lithuania, that is why market size is evaluated as weak BTE.

CASE C – MINDRAY ULTRASOUND SYSTEM

Short product description

Shortly after the 2nd World War various centers around the world utilized ultrasound in medical imaging. In 1942, first work applying ultrasound diagnostics on brain investigation has been published by Dr. Karl Theodore Dussik and his brother Friederich from Austria (Badiger & T. Akkasaligar, 2014). Since then, ultrasound technology evolved rapidly and now is the most powerful tool in medical imaging. Ultrasound imaging can be applied in various fields like the general abdominal and pelvis diagnostics, cardiology, ophthalmology and orthopedics and many others (Carovac, Smajlovic & Junuzovic, 2011). Major players in global ultrasound equipment market are GE Healthcare, Philips Healthcare, Toshiba Medical, Hitachi-Aloka Medical, Siemens

Heathineers and Mindray. Mindray company was founded in 1991 in Shenzen (China) by CEO Li Xiting (Forbes, 2019). Company has rapidly grown (find in **Figure *11***) and in 2001 Mindray has developed China's first digital diagnostic ultrasound imaging system ("Mindray Annual Report", 2009).

In 1980, Lithuania has first ultrasound system from Japan (Hitachi-Aloka Medical) in Kaunas and Vilnius University Hospitals. According to SHCAA in 2013 there were 664 units of ultrasound systems in Lithuania (SCHAA under the MoH, 2014). Mindray ultrasound systems were introduced in Lithuania much later could be considered as following-mature product (from **Table *6***).

Reimbursement as a barrier for Mindray ultrasound system introduction in Lithuanian market. Ultrasonography is broadly used for various purposes. Usually it is the family doctor who sends patients to radiologist or another specialist that practice ultrasound imaging. These procedures are reimbursed in Lithuania by the NHIF (www.idea.lt, 2019). NHIF also finance hospitals to buy new equipment. As reviewed in the literature (BARRIER 2: LONG PURCHASE CYCLE and relationship bond). If radiologist strongly supports the need of medical device and hospital administration is convinced to buy new solution. Hospital puts medical device in the purchase list. Therefore, reimbursement process does not play big role to prevent Hospitals from buying new ultrasound system and is evaluated as weak BTE.

Medical expertise as a barrier for Mindray ultrasound system introduction in Lithuanian market. Since Mindray product was following-mature because few decades have passed after first ultrasound system installation in Lithuania. Moreover, there were hundreds of ultrasound systems sold and used for a very long time by physicians. This can lead to very logical assumption that specialist where used to other brand names (e.g. Philips, GE Healthcare, Hitachi), their ergonomics, and had already established their opinions about each one of them. Therefore, there is a strong chance that established medical practice with other brands was a moderate BTE for Mindray ultrasound systems successful introduction into the market.

Market size as a barrier for Mindray ultrasound system introduction in Lithuanian market. In comparison of ultrasound usage in England a number of ultrasound examinations or tests has reached around 10 billion scans in 2013 (NHS England Analytical Services, 2013), while in Lithuania there were 1 691 402 exams performed using 575 ultrasound units (SCHAA under the MoH, 2014). Radiologist is specialist that deals with diagnostic images of anatomic structures and is specialized how to use medical imaging equipment. Diagnostic imaging has various types of techniques like ultrasound, X-ray, CT, PET and MRI scans. England had 3318 consultant radiologists in 2015 (The Royal College of Radiologists, 2016), whereas in Lithuania in 2018 there were 529 radiologists that can practice ultrasound diagnostics (SCHAA under the MoH, 2019). To understand better, in 2014 England had only 4.7 radiologists per 100 000 population, Germany had 9.3 per 100 000 population (SILVESTRIN, 2016). In 2018, there were 2 808 901 citizens in Lithuania (Lithuanian Department of Statistics, 2019) that is equivalent to 18.8 radiologist per 100 000 population which is relatively attractive market. As a result, market size is evaluated as weak BTE.

CASE D – CLARIUS HANDHELD ULTRASOUND SYSTEM

Short product description

The advancement of technology led ultrasound systems to evolve from stationary machines to portable (laptop size) and even handheld devices that fit into a pocket (Darby & Murugan, 2018). One of the most advanced handheld ultrasound imaging devices are manufactured by Clarius Mobile Health founded in 2014 by Laurent Pelissier. Clarius Mobile Health Inc is a startup

company that has raised $6.3 million in 2018 and now is a successfully growing company (Liu, 2018). Clarius has been introduced to European market only in 2017 when commercial sale CE mark has been approved ("Clarius Receives CE Mark Approval", 2017).This product was first handheld ultrasound system officially introduced in Lithuania and could be considered as leading-new product (from **Table *6***).

Reimbursement as a barrier for Clarius handheld ultrasound system in Lithuanian market. Clarius ultrasound systems fall under the same reimbursement process as previously discussed Mindray product. Therefore, reimbursement process does not play big role to prevent Hospitals from buying new ultrasound system and is evaluated as weak BTE.

Medical expertise as a barrier for Clarius handheld ultrasound system in Lithuanian market. According to SHCAA in 2013 there were 664 units of ultrasound systems and the share by types was: stationary (49,4 %), portable (44,3 %), and unrecognized (6,3 %) (SCHAA under the MoH, 2014). This means that physicians are used to portable and stationary equipment and its ergonomics for many years. Even if Clarius is handheld and from first look seems to be relatively small, however, its ergonomics is very different, because it requires to use mobile device as a screen which can be disturbing for some users. Moreover, Clarius whole ultrasound system is compacted into one probe making its dimensions big for a daily use ("The Clarius Portable Ultrasound Review", 2018). Therefore, medical practice is evaluated as moderate BTE.

Market size as a barrier for Clarius handheld ultrasound system in Lithuanian market. Clarius is designed for express diagnostics “point-and-shoot” (Mitchell, 2016) that require high degree portability. There a major drawback is limited image quality and its assessment of solid organ pathologies. Hence, for full examination there is still a need for stationary ultrasound machine (Tse, Luk & Lam, 2014). Handheld ultrasound devices can be accepted to a simpler application such as urology, cardiovascular and women’s health (Harris, 2017). In 2019, according SCHAA’s list of specialists with active licenses there are 92 vascular surgeons and 169 urologists (SCHAA under the MoH, 2019). This makes relatively small market in total of 261 medical practitioners for whom Clarius could be reasonable product to use in Lithuania. Therefore, market size can be considered as strong BTE.

RESULTS FROM SECONDARY DATA

Secondary data of each BTE has been evaluated by the author of the research. The evaluation of each BTE is done by the author of this research. Each case is very individual and faces different BTEs, making data difficult to generalize and compare. Measures to evaluate BTEs from product cases A, B, C and D, are following:

- No data = there has been no or very difficult to find data about BTE;
- Weak = collected data does not support BTE as a barrier, for example, market size is big enough (demand is high) and cannot be considered as a barrier;
- Moderate = collected data supports BTE as a barrier, but there are managerial solutions to overcome them;
- Strong = collected data supports BTE as a barrier and is hardly or impossible to overcome by managerial solutions;

Author’s evaluation of each BTE and summary from secondary data analyses is given in the ***Table 8***. BTE evaluation is a like measurable metric that will be later used to compare primary and secondary data and interpret results. Moreover, ***Table 8*** is painted for better visualization of the results. Missing data (gray painted) windows mean information that will be filled from interview.

Table 8. Evaluation from secondary (2) data collection

No.	Type of BTE	Product case			
		A	B	C	D
1	Competitive reactions	No data	No data	No data	No data
2	Purchase cycle and relationship bond	No data	No data	No data	No data
3	Reimbursement process	Strong	Strong	Weak	Weak
4	Supplier power	No data	No data	No data	No data
5	Regulations for medical representatives	No data	No data	No data	No data
6	Medical practice	Moderate	No data	Moderate	Moderate
7	Market size	Weak	Weak	Strong	Moderate

4.2 PRIMARY DATA ANALYSES

Primary data has been conducted through in-dept interview. The evaluation of each BTE has been done by the expert (respondent). Moreover, managerial solutions have been provided only to those BTEs that were considerate as moderate or strong. It is because only moderate and strong BTEs require managerial solutions to overcome them. There is no managerial solution to weak BTE or BTE with no data. Measures to evaluate BTEs from product cases A, B, C and D, are following:

- No data = interviewee was not aware or have not faced this type of BTE;
- Weak = interviewee does not support BTE as a barrier, for example, market size is big enough (demand is high) and cannot be considered as a barrier;
- Moderate = interviewee supports BTE as a barrier, but there are managerial solutions to overcome them;
- Strong = interviewee supports BTE as a barrier and found it hardly or impossible to overcome by managerial solutions.

The interview has been recorded and implemented in an informal environment in coffee restaurant (8th of May 2019). Interview has been recorded using Iphone 8 smartphone as a voice recorder. Semi-structured protocol has been applied following questions from blocks 1- 6. Transcript from an interview can be found in **APPENDIx 3**. Interpretation from primary data has been done by applying transcript information accordingly to BTEs and managerial solutions. Each case is analyzed individually. For easier transcript representation respondent and interviewer are marked respectively:

- Examiner – R;
- Respondent – I.

CASE A - CRYOTHERAPY

R: How would you evaluate competitive reaction in terms of barrier for new product introduction?

Respondent explained that there was no competitive reaction in cryotherapy case because there was no competition. Therefore, competitive reaction is considered weak as BTE.

I: *„A ir B atveju, pradėjus verslo modelį su šiais išorinės kontrapulsacijos ir krioabliacijos modeliais rinkoje konkurencijos nebuvo, tai konkurencinis barjeras buvo silpnas."*

R: How would you evaluate long purchase cycle as a barrier to introduce new product?

According to the respondent, sales cycle took long time. However, it was quite weak BTE because EBM material and educations events changed specialist's opinion.

I: *„Kioabliacijos (A) atveju pirkimo momentas buvo ilgas dėl to, kad reikėjo įtikinti dėl šio naujos idėjos, medotikos praktikoje. Galbūt pats pirkimas, kai klientas nusprendžia pirkti, tai jis yra įprastas bet kokiai medicininiai įrangai. Tačiau kol prieinama iki spendimo tai gali trukti labai ilgai."*

R: How would you evaluate long reimbursement process for new product introduction?

According to respondent, currently CRYO is partly covered by the NHIF, however, the process is very complicated, and the reimbursed amount is very small comparing with other EU or western countries. It is because of relatively expensive procedure for Lithuania's standards. Clinical efficacy has been proven for many years. Unfortunately, proper CRYO coverage for reasonable number of surgeries is blocked by the NHIF. NHIF does not add additional code in the list for such service (surgery). As a result, physicians must describe every cancer case individually proving that this method is the best solution. After NIHF's approval for reimbursement, hospital buys needles required for surgery and patient gets its treatment done. Physicians do not know if they can make 30, 50 or even 100 surgeries next year, because each case requires NHIF's approval. Therefore, this BTE is strong, because systematic reimbursement is not available until now.

I: *"Ligonių kasų apmokamas yra labai mažai, santykinai lyginant su Europos ir viso pasaulio, am, patirtimi, nes tai yra sąlyginai brangi procedūra Lietuvos standartais. Nors klinikinė nauda yra įrodyta daugybe metų, kur yra labai geri klinikiniai rezultatai. Tačiau apmokėjimas to didesnio kiekio procedūrų boksuoja, nes ligonių kasos nenori skirti papildomų eilučių. Barjeras buvo įveiktas, bet kompensavimas nebuvo sistemingas, nebuvo taip, kad ligoninė nežino, kad ji gali į metus atlikti 30, o kitais metais 50, o galbūt ir 100 operacijų, jiems kiekvienu atveju reikėdavo prašyti išskirtinio patvirtinimo. Tai buvo komplikuota, tai ypatingai prailgino ir dėl to šios technologijos naudojimas buvo labai apsunkintas. Tai vertinčiau kaip stiprų barjerą."*

R: What methods are applied to overcome such a barrier?

According to respondent, to overcome this BTE, manufacturer of CRYO therapy equipment provided a lot of EBM material. First, the education of KOLs has been done. Later physicians understood the importance and positive effect of the CRYO therapy. Eventually, together with Graina's support and physician's initiative in 2012 they applied for HTA done by SCHAA with Austrian institution. The conclusion of this assessment was that CRYO surgery effective and appropriate method for cancer treatment. However, further process for proper reimbursement was unsuccessful.

I: *"Pirmiausia bandėme edukuoti specialistus, kodėl tai yra taip naudinga. Tai specialistų lygmeniu pavyko tai įrodyti, pavyko atlikti keletą, keltą dešimčių taip pasakysiu. Jie matė tą naudą, matė rezultatus, tai tiesiog, mes kaip atstovas, teikėme specialų prašymą. Yra speciali metodika (HTA, atlikta Austrijos instituto) Akreditacijos tarnybai prie Sveikatos apsaugos ministerijos, kur teikėme visą eilę dokumentų, įrodančių šio, šio metodo privalumus."*

R: How strong is supplier power in terms of successful new product introduction to the market?

According to respondent, in this case manufacturer was patient and offered good conditions to operate. Supplier had good understanding that every market requires consistent marketing process and education. Therefore, this BTE was weak.

I: *"Kriobliacijos atveju gamintojas buvo labai kantrus ir siūlė geras sąlygas, nes suprato, kad kiekvienoje rinkoje reikia procesus vystyti labai nuosekliai: marketingas, klinikinė edukacija ir taip toliau. Buvo didžiulė pagalba, daug informacijos, tad šis prietaisas su šiuo barjeru nesusidūrė. Jie buvo kantrūs ir laukė kada mums pasiseks kažką parduoti."*

R: How would you evaluate legal regulations for medical representatives as a BTE for new product introduction?

According to respondent, in the European Union, we do not have any restrictions on the country of origin of the product, if the equipment is CE marked. Thus, this BTE is weak on any equipment.

I: *"Esant mums Europos sąjungoj, jokių mes apribojimų dėl produkto kilmės šalies neturėjome, įranga yra sertifikuota CE ženklinimu. Netiesiogiai reguliaciniai dalykai susiję su mūsų kompensavimo barjeru, bet visiškai netiesiogiai, tad šiuo atveju šio barjero nebuvo nei vienai įrangai."*

R: How would you evaluate conservative physicians as a BTE for new product introduction?

According to respondent, this type of BTE was faced and some of the physicians questioned: "Why to use CRYO therapy if it can be done by old surgery procedures?".

I: *"A produkto atveju, buvo grupė specialistų, kurie netikėjo kriobliacija, nes jie norėjo operuoti vėžius, kaip čia šaldyti, jeigu gali išoperuoti."*

R: What methods are applied to overcome such a barrier?

According to respondent, to overcome this BTE previously discussed education events, marketing and EBM material served well. However, there still are some surgeons that do not believe CRYO's efficacy. As a result, this BTE is evaluated as moderate.

I: *"A atveju mes barjero neįveikėme, tik jį prislopinome, sumažinome, iki šiol dar yra chirurgų, kurie netiki krioblaicija. Bet šiek tiek tų procedūrų pavyko pradėti daryti, nes mokslinė literatūra teigia, kad visas pasaulis naudoja, tai ir mes pradėjome naudoti (evidence-based)."*

R: How would you evaluate market size as a BTE for new product introduction?

According to respondent, this was a strong BTE. It is because even if there were enough patients there were only two Hospitals that could make such surgeries. The reimbursement process is very complicated and long, therefore, small market size BTE was very strong.

I: "Mažas rinkos dydis pradedant dirbti veikia, nes jis yra tik vienas centras kuris imasi ir gali daryti tokius dalykus. Tai, kad reikia keisti kompensavimo mechanizmą, jį iškovoti, kad jisai būtų, tai, kad reikia išmokti apie sistemą, reikia serviso, inžinierių pasiruošti , nes yra vienas ar du centrai, kurie gali naudotis. Tad mažas rinkos dydis yra didelis barjeras."

CASE B - ENHANCED EXTERNAL COUNTERPULSATION

R: How would you evaluate competitive reaction in terms of barrier for new product introduction?

According to respondent, there was no competitive reaction in ECCP therapy case because there was no competition. Therefore, competitive reaction is considered weak as BTE.

I: *"A ir B atveju, pradėjus verslo modelį su šiais išorinės kontrapulsacijos ir krioabliacijos modeliais rinkoje konkurencijos nebuvo, tai konkurencinis barjeras buvo silpnas."*

R: How would you evaluate long purchase cycle as a barrier to introduce new product?

According to respondent, sales process has not been even started.

I: *"B atveju, išorinės kontrapulsacijos mes nepardavėme nei vienos sistemos, net neperėjom į pardavimų etapą."*

R: How would you evaluate long reimbursement process for new product introduction?

Respondent explained that specialists from this field realized that the reimbursement by the NHIF for EECP therapy service was not available for the patients. For this reason, the equipment for EECP was too expensive for physicians to buy, because there will not be enough clients to cover the costs. In this case, specialists had not had enough commitment to move further in this complicated reimbursement process. Consequently, this BTE is evaluated as strong BTE.

I: *"Dėl to, kad specialistai galėtų naudoti tokio tipo įrangą, jie suprato, kad šiuo metu kompensuojamų paslaugų sąraše nėra tokio tipo paslaugos apmokėjimo. Jeigu jis ir būtų gretutinis, šiek tiek susijęs su mūsų įranga jis būtų labai mažas ir visiškai neatpirktų brangios kontrapulsacijos sistemos įsigijimo. Tai, o naujai kovoti už tai, kad būtų nauja „eilutė" jie nesiryžo, nes tai būtų ganėtinai sudėtingas procesas, tai čia irgi didelis barjeras, nes kompensacijos proceso nebuvo"*

R: What methods are applied to overcome such a barrier?

According to respondent, to overcome this barrier, nothing much has been done. Physicians did not take initiative to move forward with this process and fight for EECP therapy coverage.

I: *"Jie nuleido rankas ir sakė, kad Lietuvai per brangu ir kad niekas čia nemokės, nors gal ir gerai yra. Procesas pasirodė, per daug stiprus, nes iš reabilitacijai skirtos įrangos yra vieni rezultatai laukiami, o iš kovos su vėžiu kiti ir kitos susidomėjimas ir kito masto."*

R: How strong is supplier power in terms of successful new product introduction to the market?

According to respondent, in this case manufacturer was patient and offered good conditions to operate. Moreover, supplier was open minded to every idea, had good pricing policy, etc. Therefore, this BTE was weak.

I: *"...gamintojas atviras bet kam ir gerą kainą ir politiką taikytų."*

R: How would you evaluate legal regulations for medical representatives as a BTE for new product introduction?

According to respondent, in the European Union, we do not have any restrictions on the country of origin of the product, if the equipment is CE marked. Thus, this BTE is weak on any equipment.

I: *"Esant mums Europos sąjungoj, jokių mes apribojimų dėl produkto kilmės šalies neturėjome, įranga yra sertifikuota CE ženklinimu. Netiesiogiai reguliaciniai dalykai susiję su mūsų kompensavimo barjeru, bet visiškai netiesiogiai, tad šiuo atveju šio barjero nebuvo nei vienai įrangai."*

R: How would you evaluate conservative physicians as a BTE for new product introduction?

According to respondent, there were few alternatives for EECP therapy, moreover, there were controversial opinions about this therapy and of its efficacy and cost effectiveness. Considering all circumstances, this BTE is was weak.

I: *"B atveju šitas barjeras buvo silpnas, nes dominavo kiti barjerai. Nors vėlgi, tam tikru atveju buvo žmonių, kurie sakė, kad yra literatūros žinių, kur kontraversiškai vertinama šio proceso nauda. Tai viską susumavus galima sakyti, kad šis barjeras buvo silpnas. "*

R: How would you evaluate market size as a BTE for new product introduction?

According to respondent, EECP therapy could have been implemented only in few centers. Therefore, market size is strong BTE.

I: *"Nedaug yra centrų, kurie imtųsi tokiais reabilitacines priemones daryti. Taip pat reikia suprasti sistemą, pasiruošti marketingo įrankius,"*

CASE C – MINDRAY ULTRASOUND SYSTEM

R: How would you evaluate competitive reaction in terms of barrier for new product introduction?

According to respondent, strong competition has been faced during the introduction of Mindray ultrasound systems because there were many other manufacturers and local representatives of these type of products. Therefore, competitive reaction is considered strong as BTE. There were few types of competitive reaction faced during the introduction like promotion against incoming new Mindray brand and a change of price. Competitors emphasized that Mindray has lack of experience and competence, is unreliable as a manufacturer. Moreover, competitors emphasized

that the country of origin is China, which also is recognized as cheap and unreliable. Distributors name was also undermined by competitors mentioning that distributor is new in its field and no appropriate service will be provided. In addition, competitors emphasized their products' reliability and strengths because they did not know much about Mindray. Later competitors had to cut their prices down to compete against one of the cheapest or maybe the cheapest product in the market.

I: *"Ultragarsinės sistemos Mindray (C) turėjo stiprų konkurentinį barjerą, nes gamintojų siūlančių panašias ultragarsines sistemas buvo nemažai. tai jų reakciją buvo sakykime marketingo srityje silpninamas gamintojo reputacija, kad tai yra naujas gamintojas, nepatyręs, taipgi, kad dar tai yra ir iš Kinijos. Taipogi, silpninama buvo mūsų kaip tiekėjo (distributoriaus) kompetencija, kad mes naujokai, neturėsim serviso. Suges, ką tada jūs darysite? Tai va, tokia buvo jų reakcija, bandoma sumenkinti produkto vertė, per gamintojo kilmę ir mūsų kaip atstovų pardavėjų ne patirtį. Taikytas anti-marketingo kompanijos prieš mus, išskiriant savo aparatų gerumą, nes jie, sakykim, nelabai ir žinojo mūsų aparatų stipriąsias ir silpnąsias vietas. Tiesiog buvo bendrai kalbama, kad bus blogai, geriau pirkit kas patikrinta ir yra žinoma"*

R: What methods are applied to overcome such a barrier?

The respondent explained, that the method to overcome this BTE was firstly to strengthen the brand name of the manufacturer. Staying in view of KOLs through all possible educating events by participating in qualifying events for physicians etc. That's how the brand name of Mindray and its representative Graina was strengthened and later not considered as unknown and new player in the market. Secondly, to gain trust and the feeling of reliability Graina applied tactics to give demonstration products for few months or even half a year. In this way, showing its customers that product has reasonable price and quality relationship and maybe even more features than previously used ultrasound systems. Moreover, Graina took well care of the customer serving personal needs, adjusting the systems individually and providing splendid delivery service.

I: *"Pirmas lygmuo tai, sutvirtinti gamintojo vardą, tai reikėjo, būti matomiems renginiuose susijusiuose su specialistų, kurie naudoja tas sistemas. Am, kvalifikacijos kėlimo renginiai, kongresai įvairūs, juose mes turėjome būti matomi ir tokiu būdu ištransliuoti žinutę, kad nuosekliai tęsiame marketingą ir įmonė, ir gamintojas jie yra galų gale žinomi, kad jau nebėra nežinomi."*

How would you evaluate long purchase cycle as a barrier to introduce new product?

According to respondent, long demonstration time and persuasion of the customer took more time because of competition. Competitors made influence on sales process term by disseminating distrust about Mindray, however, this made weak influence on sales. But overall long sales process was a moderate BTE.

I: *"Ultragarso sistemos (C) pardavimo barjeras, na, šiek tiek gal galėtų būti dėl to, kad mūsų demonstracijos turėdavo būti ilgesnės, kai sakykime, konkurentui užtekdavo pasiūlyti kainą, parodyti modelio paveiksliuką ir klientas sakydavo, gerai aš tokio tipo aparato ir noriu ir pereidavo į pirkimo procedūrą. Mums reikėdavo įtikinėti ilgiau, būdavo mėnesio, dviejų ir net šešių mėnesių demonstracija ir, kad šitas nežinomas gamintojas, jiems taptų žinomas ir mielas. Tai šiuo atveju prailgėdavo pradinėse stadijose."*

This BTE was conquered by the same method as competitor reaction BTE.

R: **How would you evaluate long reimbursement process for new product introduction?**

According to respondent, this barrier does not exist because most of the ultrasound diagnosis are reimbursed by the NHIF.

I: *"Apie ultragarsines sistemas kalbant (C ir D) šio barjero nėra, nes sistemos, jos plačiai naudojamos, neturi reikšmės kokio gamintojo jos būtų."*

R: **How strong is supplier power in terms of successful new product introduction to the market?**

According to respondent, manufacturer had set ambitious annual goals because of given low price and wide portfolio. Manufacturer (Mindray) hoped for Graina to achieve these goals quickly. There was tension between Graina and Mindray. This was a strong BTE at the beginning.

I: *"Galima sakyti, kad UG sistemos atveju, šioks toks barjeras buvo, nes gamintojas buvo labai ambicingus planus iškėlęs, ir kadangi davė gerą kainodarą ir turėjo platų asortimentą, jie žinoma norėjo gerų rezultatų ir kad mes daug parduotumėme. Tai pradžioje buvo tokios įtampos, buvo sunku pasiekti iškeltus metinius planus, nes rezultato jie norėjo labai greitai, o visur reikia laiko, prieš tai apibūdintus barjerus palaužti."*

According to respondent, to overcome this BTE Graina provided strong arguments and information of problems related to country of origin (China) and weak brand name. Mindray representatives have visited local clients together and understood the reasons of poor volume of sales. Later, manufacturer understood that poor sales were not related with lack of Graina effort and agreed to invest more into their branding by providing better quality material, making financial investment in more expensive events etc.

I: *"Padėjo tai, kad mes pradėjome komunikuoti su gamintoju, gamintojas atvykdavo į mūsų šalį, mes lankydavome klientus, kurie naudoja arba norėtų naudotis aparatu. Gamintojas išgirdo tas priežastis, dėl ko tie pardavimai pradžioje neauga, kur ta problema. Tai visų pirma, buvo identifikuota, kad gamintojui trūksta marketingo priemonių, jos nėra kokybiškos, jos nėra orientuotos į kažkokią tai vertę, pradžioje buvo nepatrauklios nepatraukus tų sistemų apipavidalinimas, kalbant konkrečiai apie brošiūras ir vaizdo prezentacijas. Ir buvo paprašyta papildomų kainos nuolaidų svarbiems projektams, taip pat jie pradėjo daugiau investuoti į savo marketingo priemonių paruošimą bei didesnį dalyvavimą tarptautiniuose kongresuose. Dar galima paminėti, kad pradėjo padėti, pradėjo skirti tam tikrus pinigus dideliems renginiams, kur mums būtų gal per didelės išlaidos jie skirdavo iš savo eilutės, kad gamintojas ir mūsų atstovas matytųsi tuose renginiuose."*

R: **How would you evaluate legal regulations for medical representatives as a BTE for new product introduction?**

According to respondent, in the European Union, we do not have any restrictions on the country of origin of the product, if the equipment is CE marked. Thus, this BTE is weak on any equipment.

I: *"Esant mums Europos sąjungoj, jokių mes apribojimų dėl produkto kilmės šalies neturėjome, įranga yra sertifikuota CE ženklinimu. Netiesiogiai reguliaciniai dalykai susiję su mūsų kompensavimo barjeru, bet visiškai netiesiogiai, tad šiuo atveju šio barjero nebuvo nei vienai įrangai."*

R: How would you evaluate conservative physicians as a BTE for new product introduction?

According to respondent, a lot of conservatism was more related to country of origin. Specialists claimed to see poor image quality, even though it was the same or even better than competitors. "Poor" image quality was an excuse for true reason the country of origin and unknown brand name. Therefore, this BTE can be considered as moderate.

I: *"Konservatyvumas nebuvo susijęs su pačia technologija, labiau buvo susijęs su kilmės šalimi. Nežinau ar čia ekspertai prieš konkrečia įrangą, ar labiau prieš kilmės šalį, ar čia tiktų aš nežinau. Bet visumoj ekspertai buvo konservatyvūs šiam naujam gamintojui. Jie nesakė tiesiogiai, kad čia kinai blogai gamina, bet jie viską suversdavo vaizdo kokybei, nors ištiktųjų tai buvo paslėpta baimė produkto kilmės šaliai ir faktui, kad tai yra nežinomas gamintojas. Šį barjerą šiam produktui vertinčiau vidutinio stiprumo."*

According to respondent, to overcome this BTE same method served as previously discussed by investing more into branding, better quality marketing material, etc. Now "word a mouth" recommendation spread among the specialist and there is no problem related to that type of BTE.

I: *"Tai yra matomumas specialistų kongresuose, mato gamintoją ir mato, kad nuosekliai dalyvaujame, vadinasi neišnykstame iš akiračio. Ir žinoma toliau įrodinėjame, kad sistema yra gera, gerai rodo, per ilgą demonstraciją yra patikima. Taip pat manau, kad tai netiesiogiai su tuo, kad žmonės buvo linkę „ai, surizikuosiu, nes labai gera kaina". O po to, vėliau, labai gerai pradėjo veikti „iš lūpų į lūpas" rekomendacijos – specialistai vienas kitam pradėjo produktą rekomenduoti."*

R: **How would you evaluate market size as a BTE for new product introduction?**

According to respondent, this BTE is weak, because market in Lithuania is big enough and application for ultrasound imaging is very broad.

I: *"Užtenka rinkos, nėra barjero, rinka Lietuvoje yra pakankama, kadangi specialistai ją plačiai naudoja."*

CASE D – HANDHELD ULTRASOUND SYSTEM

R: **How would you evaluate competitive reaction in terms of barrier for new product introduction?**

According to respondent, in this case, there were competitors in the market, who also had that type of products in their portfolio, however, there was very little or no competitive reaction and evaluated as weak BTE.

I: *"Vertinčiau kaip vidutinį, nes panašaus sistemų rinkoje buvo. Tiktais, am, aktyvumas konkurentų atžvilgiu buvo silpnas."*

R: **How would you evaluate long purchase cycle as a barrier to introduce new product?**

According to respondent, customers did not accept the product and there were no sales until now, so this BTE did not exist.

I: *"Šis barjeras nėra aktualus, nes mes neperėjome į pardavimų procesą, nors jis būtų įprastas, bet klientai iki šiol nenori tokio tipo sistemų."*

R: How would you evaluate long reimbursement process for new product introduction?

According to respondent, his barrier does not exist or is weak because most of the ultrasound diagnosis are reimbursed by the NHIF.

I: *". Apie ultragarsines sistemas kalbant (C ir D) šio barjero nėra, nes sistemos, jos plačiai naudojamos, neturi reikšmės kokio gamintojo jos būtų. A, yra mokama už atliekamus tyrimus. Asmeninės ultragarsinės sistemos, jos būtų tilpę, ko gero, po tuo pačiu ultragarsinių tyrimų atlikimu, taigi šis barjeras būtų minimalus arba jo nebūtų, tiesiog."*

R: How strong is supplier power in terms of successful new product introduction to the market?

According to respondent, manufacturer required to buy minimum amount of demonstration versions in which Graina had to invest. This amount was relatively high, but there was nothing to choose from and Graina had to agree. Hence, this BTE can be evaluated as moderate.

I: *"AUG sistemų atveju taip pat barjeras šioks toks yra, kad pradėjus su gamintoju dirbti, jis nusistatė ta tikrą įrangą demonstracinę, į kurią mes turėjome investuoti, investicija gan didelė, bet nebuvo iš ko rinktis, tad teko sutikti su jų sąlygomis. Tad vertinčiau tą barjerą tarp silpno ir vidutinio. Taip pat jie aišku reikalauja tam tikrų kiekių, kas šiuo metu, esant sunkumams įvesti šį gaminį, jaučiame vis didėjantį spaudimą, nes neparduodame tiek įrangos, kiek jie norėtų. Barjerą vertinčiau kaip vidutinį-stiprų."*

R: How would you evaluate legal regulations for medical representatives as a BTE for new product introduction?

According to respondent, in the European Union, we do not have any restrictions on the country of origin of the product, if the equipment is CE marked. Thus, this BTE is weak on any equipment.

I: *"AUG atveju – šis barjeras yra toks netiesioginis, kadangi dauguma specialistų mano, kad tipo įrangos ne visai reikia, galbūt jinai yra per brangi, kad jie ją naudotų labiau negu įprastus prietaisus. Tad konservatyvumo čia yra nemažai, jį priskirčiau prie stipraus barjero. "*

R: How would you evaluate conservative physicians as a BTE for new product introduction?

According to respondent, this BTE is indirect in this case, because most of the specialists refuse and did not understand the need of such an equipment and BTE was not managed. Clarius ultrasound system is cheaper alternative for niche purpose but less flexible in terms of applications and more expensive and for broader application. Therefore, this BTE is strong.

I: *"AUG atveju – šis barjeras yra toks netiesioginis, kadangi dauguma specialistų mano, kad tipo įrangos ne visai reikia, galbūt jinai yra per brangi, kad jie ją naudotų labiau negu įprastus prietaisus. Tad konservatyvumo čia yra nemažai, jį priskirčiau prie stipraus barjero.[…]* barjero neįveikėme."

R: How would you evaluate market size as a BTE for new product introduction?

According to respondent, this BTE is strong because market is relatively small. Ultrasound handheld can be implemented for personal use and physicians would not spend so much money (~10 000 Euro) on that type of system. Clarius is too expensive in too niche market.

I: *"Maža rinka, dar reikia daug edukuoti žmones, keisti jų įpročius, tad santykinai yra mažas rinkos dydis. Mūsų rinkos dydis, imant gydytojų specialistų skaičių, perkamoji galai yra per maža, kad gydytojai sau leistų įsigyti Asmeninę ultragarsinę sistemą. Santykinai yra per brangus daiktas, mažas kiekis specialistų."*

RESULTS FROM PRIMARY DATA

Table 9. Evaluation from primary (1) data collection

No.	Type of BTE	Product case			
		A	B	C	D
1	Competitive reactions	Weak	Weak	Strong	Weak
2	Purchase cycle and relationship bond	Weak	Weak	Strong	Weak
3	Reimbursement process	Strong	Strong	Weak	Weak
4	Supplier power	Weak	Weak	Strong	Moderate
5	Regulations for medical representatives	Weak	Weak	Weak	Weak
6	Medical practice	Moderate	Weak	Moderate	Strong
7	Market size	Strong	Strong	Weak	Strong
8	Other	No data	No data	No data	No data

4.3 PRIMARY AND SECONDARY DATA EVALUATION

Evaluation of data has been done to fit measures (weak, moderate, strong) description. More detailed investigation is provided by applying simple calculation of evaluations in different dimensions (see in **Table *10***, **Table *11***, **Table *12***). Cases are described following and summarized in this section:

A - Cryotherapy;
B - Enhanced external counter pulsation;
C - Mindray ultrasound system;
D – Clarius handheld ultrasound system.

Table 10. Authors overall evaluation from primary and secondary data.

Case	A	B	C	D
Market entry and product development strategy	Leading-mature	Leading-mature	Following-mature	Leading-new
Type of BTEs	Summary evaluation			
Competitive reactions	**Weak**	**Weak**	**Moderate**	**Weak**
Purchase cycle and relationship bond	**Weak**	**Weak**	**Moderate**	**Strong**
Reimbursement process	**Strong**	**Strong**	**Weak**	**Weak**
Supplier power	**Weak**	**Weak**	**Moderate**	**Moderate**

Regulations for medical representatives	**Weak**	**Weak**	**Weak**	**Weak**
Medical practice	**Moderate**	**Weak**	**Moderate**	**Strong**
Market size	**Moderate**	**Moderate**	**Weak**	**Moderate**

Table 11. Total number of weak, moderate and strong BTEs faced in different cases.

Case	A	B	C	D	Total
Weak	4	5	3	3	15
Moderate	2	1	4	2	9
Strong	1	1	0	2	4

Table 12. The number of overall evaluations of each BTE

Evaluation	Weak	Moderate	Strong
Type of BTE			
Competitive reactions	3	1	0
Purchase cycle and relationship bond	2	1	1
Reimbursement process	2	0	2
Supplier power	2	2	0
Regulations for medical representatives	4	0	0
Medical practice	1	2	1
Market size	1	3	0

5. DISCUSSION OF RESEARCH FINDINGS

Every case is very individual, we could start by classifying products according to applied strategy (from ***Table 6***) and comparing gathered primary (1) and secondary (2) data side by side. Detailed comparison and evaluations are provided in APPENDIX 4 (find in **Table *15***). Research findings where very interesting, because information found in literature (secondary data), matched all the conclusions made during the interview.

There were a lot of regulations for medical representatives found in the literature review. Distributors must ensure that their sold products are approved by European Committee (CE) mark and fall under regulations like Medical Devices Directive (93/42/EEC) (MDD), Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD), In-Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The assumption of BTE (regulations for medical representatives) was that this "Esurance" requirement might cause bureaucracy related problems when introducing new product in Lithuania's market. Surprisingly, during the interview, expert rejected that type of BTE as a barrier. There is no problem to sell products in Hospitals if manufacturer provides CE mark. This certificate is sent by email and it is a matter of minutes. More complications come when manuals need to be translated, however, this is BTE that can be managed simply managed by the company or special translation agency. There has been no solution to overcome legal regulations BTE in the literature review, because no specific information has been found. This also can strengthen the conclusion that regulations for medical representatives are not harsh and do not cause problems to successfully introduce new product to the Lithuania market. Further research findings follow BTEs one by one.

Competitive reactions were found to be strong BTE in one case (C) and weak in the rest of the cases (A, B, D). It is important to note that C product is following-mature meaning that

product has been introduced lately in the segment (following) and product has been in the other markets for more than one year (mature). This leads to logical conclusion that competitive reaction was strong because market was highly competitive in the first place. Even if during the interview expert evaluated BTE as strong, this was adjusted to moderate because competition had been defeated. Moreover, the theory of practical approach to predict competitive behavior (see **Table *5***) has given steps to design what could be done to overcome competitive reactions. During the interview expert did not mention any incorporated strategic decisions to predict competitive behavior and react to it. Since no preparation has been done for successful product launch this can explain reasons for strong BTE's evaluation by the expert.

Another finding is that expert emphasized two types of competitive reactions that were previously discussed in the literature (find in **Table *1***). That is, change of promotion when competitors emphasized their product's advantages and aggressively promoted against product's C country of origin (China) and unknow brand. Later rivals changed price to sustain in the market, but it was not until reasonable volume of sales made by the case company.

Case company (distributor) has beaten this BTE implementing few strategic approaches. First, to strengthen the brand name of Mindray, second to provide very professional service. First step has been done with strong cooperation with supplier (manufacturer), investment in marketing via promotion material, educating and qualifying events for physicians and, very important, customers could get demonstration products for few months or even half a year. In this way, strengthening the trust on the brand name and showing to customers that product has reasonable price and quality relationship. Moreover, Graina has provided good service which also made strong influence on customers' opinion and later leading to word a mouth recommendation.

Finally, from A and B cases are leading – mature. Leading means first to introduce product for the segment in the market. This category leads very logical conclusion that first mover avoids competitive reaction and goes around this BTE.

Long purchase cycle and strong relationship bond was evaluated as strong only in one case (C). In the rest cases according to the expert this BTE was not faced and concluded this BTE to be weak. The reason is because sales process was not reached in some cases, however, there are some adjustments that could be made. In case A, Graina went through complicated and challenging process but National Cancer Institute has rented one CRYO device and until now is used for surgeries. Therefore, this BTE should be adjusted to moderate because one product has been sold and was unsuccessful because of other BTEs. Furthermore, case B did not reach sales stage so there is no way to evaluate from both primal and secondary data. In case C, this BTE can be adjusted to moderate, because later product reached high volume of sales. Finally, in case D, vendor made marketing investments in promotion materials and sales force, but no one bought the product. For this reason, BTE can be considered as strong because it was faced, and company did not manage to overcome this barrier.

To overcome long purchase cycle and relationship bond theory has given few suggestions. Such as, investment in right sales force (challengers) who have deep understanding of their customers' business and educate customers, smart sales compensation model (salary motivation) and right portfolio (balance between non-pioneer and pioneer products). However, expert during the interview did not mention any of these methods implemented in the company. During the interview expert claimed to overcome this BTE by apply tactics that were previously discussed in competitive reaction BTE.

Long reimbursement process made strong influence on both A and B cases. This conclusion is strongly supported in primary and secondary data analyses. Moreover, same evaluation match from primary and secondary data goes to C and D cases were BTE was weak. This makes more valid conclusion about identified and analyzed BTE. The reason for this evaluation is very clear. Since products from A and B cases (leading- mature) were very specific and the market is very niche. This causes low consumption of the product making it very

expensive. Here reimbursement is vital for patients with rare diseases and from vendor's point of view important that costs would be covered. In case A, the NHIF at MoH did not make systematic financial support causing difficulties for successful product use in practice. In contrast to C and D cases, ultrasound systems can be applied to a very broad spectrum to diagnose different types of health conditions, traumas or other health related complications. Luckily, no difficult bureaucracy is faced to deliver ultrasound systems in Lithuania.

To overcome this BTE the reimbursement pathway is provided and identified as top-down were decisions are only made by MoH and the budget holder is NHIF. Additionally, in theory six following steps were provided by consulting company

1. Identify the decision makers;
2. Define the market model;
3. Identify coding gaps;
4. Determine regulatory or legislative issues;
5. Train KOLs and develop strong relationships with specialty medical societies;
6. Collect references and publish them.

According to interviewee Graina (vendor) and supplier (manufacturer) strongly cooperate and trained KOLs as identified in theory (step six). Later, alliance between manufacturer - vendor and KOL society helped to move forward and make application for HTA proceeded by SCHAA. This is the most valid evaluation and implementation of second step. Later, KOL society wrote letters for creating new code (step three), unfortunately, this was the stage where process got stuck. CRYO surgery did not get extra code line from NHIF and stopped at this stage. Making very complicated reimbursement process and stopping from successful use in practice. A lot of shareholders are involved in this process making very difficult BTE to overcome, even if steps are clear.

Strong supplier power could not be found in the literature or other public source. As follows, no secondary data was collected in case analyses. In both cases A and B supplier power was weak, manufacturers had willingness to cooperate, share EBM material and had deep understanding of complicated product's reimbursement process. Both products A and B have very niche markets and in general have low sales volume. Therefore, it is significantly important (comparing with C and D cases) for manufacturer to find vendor that has strong commitment to deliver its product to new markets. This could lead to rational assumption that manufacturers which produce leading-mature and niche type of products are more tolerant and open minded to distributor.

The expert assessed supplier power as strong in C case and moderate in D case. There has been adjustment done to case C evaluation, because this did not stop to reach high volume of sales for the vendor. Making this type of BTE moderate in both C and D cases. In case C supplier had set ambitious annual goals while in D case requirement to buy minimum amount of demonstration versions was relatively high.

In theory, there were many types of supplier power over distributor (find in **Table *3***) but none of them where mentioned by the expert. However, in **Table *4*** were summary of hypothesis results of manufacturer's involvement accordingly to retailer's strategy (costs leader, differentiator or focus), there were some coincidences. For example, focus products are A and B and manufacturer was involved highly in behavior orientation and not in contractual restrictions, manufacturer coordination was low, but dealer support was high (opposite to the theory), also distribution intensity was low. In C case product is differentiated, so, price is moderate, targeting bigger market share and at the same time having high-quality. This matches experts experience and theoretical findings meaning that all constructs: behavior orientation, contractual restrictions, manufacturer coordination, dealer support and distribution intensity were high. In addition, interesting finding was that even if product had high quality and at the time was one of the cheapest in the market. Customers did not perceive that value, this will lead to following BTE that is discussed later.

To overcome strong suppliers power theory has given negotiation path with powerful supplier (find in ***Figure 10***), however, none of this theory was implemented according to the expert information. Vendor has provided strong arguments and information of problems related to country of origin (China) and weak brand name. Manufacturer representatives have visited local clients in Lithuania together and understood that poor sales were not related with lack of distributor's effort. Later, supplier agreed to invest more into their branding by providing better quality material, making financial investment in expensive educating events, etc. This would lead to simple conclusion feedback collection from customers (evidence), commitment and effort to communicate can change relationship between partners and grow successful business by supporting one another.

In D case, no successful sales were reached, but suppliers' requirement to invest in advance in some cases could prevent vendor for using new business opportunity and delivering product to its market.

Medical practice barrier was one of the most oppressive BTEs according to primary data (interview). Unfortunately, no secondary data has been collected to support that statement. Medical practice BTE in case A and C was assessed as moderate. Both cases had different reasons for this challenge. In case A, first CRYO surgery ever has been done in Lithuania. Before that physicians had to be convinced that this new surgery method is the best solution for patients. Cooperation between supplier and distributor helped to provide strong EBM material and change the physician's way of thinking. Whereas, case C was not something new to physicians, but product's country of origin and other conservative opinions dominated. Distributor together with vendor have put a lot of effort to change clients' beliefs with training and educations events and other previously discussed tactics in competitive reaction BTE. Not much data about this BTE has been provided from case B, but it was evaluated to be weak. Expert believed that strongest BTE in this case was long reimbursement process and that has prevented innovation from spreading. Finally, case D had other reason which is most related to this BTE but at the same time is not directly associated. Most of the specialists refuse and did not understand the need of such an equipment. Furthermore, system was more expensive for broader applications. In this case, better explanation would be that product did not find its market fit in Lithuania, because of high price and low perceived value.

Generally, to overcome this BTE same methods served as in previously discussed BTEs. Investing more into branding, better quality marketing material, EBM material, etc. Also, literature findings support instrument to educate physicians and provide EBM material.

Market size barrier was one of the strongest BTEs. Wrong assumptions have been made during secondary data analyses when this type of BTE was evaluated as weak. The reason is that wrong numbers where analyzed. The number of practitioners is as important as population of patients. In both A and B cases population of people with KC or PC and CHD is very high. However, this is not the case talking about practitioners (physicians) were only few centers could perform EECP therapy. Even worse situation in case B when there are only two hospitals in Lithuania that could make such a surgery. From vendor's point of view, renting such an equipment can make stable but very limited revenues. Therefore, market size in both cases was strong BTE.

To overcome this BTE company has made investments to open new branch offices in Latvia and Estonia. In this way market can be expanded. Moreover, good distributor's reputation and successful sales history helps to attract manufacturer to cooperate. However, these are generic solutions and could not be applied by every company. A lot of financial resources are required to open new headquarters and companies with less capital could not implement that kind of action.

6. CONCLUSIONS AND RECOMENDATIONS

After reviewing theories of the nature of the medical device markets and BTEs faced by the new entrants. The findings where useful to shape BTEs for further research investigation. The most relevant BTEs (assumptions) have been extracted according to personal author's experience in the medical device market. These assumptions of each BTE where supported by additional literature on new medical product delivery to market. Analyses have been done from distributors' perspective, because especially in small markets they are the key delivering medical products. Medical device distributors can face strong external BTEs (e.g. small market size, long reimbursement process, long sales cycle, competitive reactions, etc.).

The literature overview of each BTE has strongly supported most of the BTEs. There were some theoretical limitations for barriers like small market size and medical expertise. Therefore, less discussion has been done during theoretical overview of the theses. Besides, since no list of BTEs (classical theory) that would specially suite medical device market have been found. This might lead to other limitation of finding appropriate theoretical approaches to BTEs elimination from the new entrant perspective. It was quite difficult to find appropriate technique, method or other relevant solution to eliminate each BTE from distributor's perspective. It might be because of medical equipment sales business is very niche with specific barriers.

It was challenging to evaluate and measure each BTE in practice due to time constrains and limited access to information. That's why multiple case study design has been chosen. It was the most rational approach to analyze different cases from same business. One expert Medical Doctor with over 15 years of experience in medical device sales agreed to give an interview (provide primary data). In all four cases expert was involved personally. These four cases helped to have better quality findings from different angles.

The barriers to introduce advanced medical devices in Lithuania's market have been provided to answer to the research question. BTEs according to relevance from findings in literature review and multiple case study can be listed as follows:

1. Long reimbursement process;
2. Medical practice barrier;
3. Small market size;
4. Long purchase cycle and strong relationship bond;
5. Supplier power;
6. Competitive reaction.

Overall, to evaluate why big brands would mostly choose big markets (e.g. Germany) instead of smaller ones (e.g. Lithuania) it is simply because of huge resources required to receive governmental reimbursement approval. If the same resources to achieve reimbursement are required in both big or small markets. There is no logic to start from small ones.

To answer another part of the research about managerial or other tools that could be used to address listed BTEs. Findings according to their relevance from literature review and multiple case study can be listed as follows:

1. Provide strong EBM material and proof of product's efficacy;
2. Train KOLs and develop strong relationships with specialty medical societies;
3. Distributor's strong cooperation with supplier (manufacturer);

Since each case is very individual, one managerial solution formula will not fit all. For example, products that do not require to go through difficult reimbursement process, will not face this BTE at all. From multiple case study almost all BTEs were important. However, more attention should have been given for medical expertise BTE and market size investigation. Besides, regulation for medical representatives has proven to be not worth much of attention.

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APPENDIX 1

Questionnaire of identified BTEs for each case:

Block 1. Overcoming competitive reaction

	Question
1A	How would you evaluate competitive reaction in terms of barrier for new product introduction?
1B	What type of competitive reactions have you experienced during your career when introducing product: A, B, C or D?
1C	What methods are applied to overcome such a barrier?
1D	Is there anything else you could add on this topic?

Block 2. Long purchase cycle and strong relationship bond

	Question
2A	How would you evaluate long purchase cycle as a barrier to introduce new product?
2B	How would you evaluate competitor's relationship bond with physicians to adopt new product?
2C	How long does it usually take to sell medical equipment to hospitals (from first interaction with potential client and closed sale)?
2D	What methods are applied to overcome long sales cycle barrier?
2E	What methods are applied to overcome relationship barrier?
2F	Is there anything else you could add on this topic?

Block 3. Overcoming long reimbursement process

	Question
3A	How would you evaluate long reimbursement process for new product introduction?
3B	How long from your experience reimbursement process takes?
3C	Under what circumstances (to which products) reimbursement barrier is faced? Is it always necessary? Why?
3D	What methods are applied to overcome such a barrier?
3E	Is there anything else you could add on this topic?

Block 4. Overcoming strong supplier power

	Question
4A	How strong is supplier power in terms of successful new product introduction to the market?
4B	What type of supplier power have you experienced during your career?
4C	What methods are applied to overcome such a barrier?
4D	Is there anything else you could add on this topic?

Block 5. Overcoming regulations for medical representatives

	Question
5A	How would you evaluate legal regulations for medical representatives as a BTE for new product introduction?
5B	What legal regulations are the most difficult implement?

5C What methods are applied to overcome such a barrier?
5D Is there anything else you could add on this topic?

Block 6. Overcoming medical practice barrier

Question

6A How would you evaluate conservative physicians as a BTE for new product introduction?
6B Could you give more details on this BTE? What were the circumstances?
6C What methods are applied to overcome such a barrier?
6D Is there anything else you could add on this topic?

Block 7. Overcoming small market size barrier

Question

7A How would you evaluate market size as a BTE for new product introduction?
7B What is your experience/insights on this case? How often this BTE is faced when you want to introduce product to our market to supplier?
7C Could you give more details on this BTE? What were the circumstances?
7D What methods are applied to overcome such a barrier?
7E Is there anything else you could add on this topic?

APPENDIX 2

Primary data

Table 13. Causes of death from PC in Europe 2015 (Eurostat, 2018).

	Number of male deaths	Share of all male deaths	Standardized death rates		
			Males	Males aged < 65 years	Males aged 65 and over
	(number)	(%)	(per 100 000 inhabitants)		
EU-28	75,315	2.9	39.3	2.6	191.0
Germany	13,919	3.1	40.7	2.9	196.8
United Kingdom	11,797	4.0	49.3	3.0	240.5
France	8,937	3.0	35.1	2.1	171.2
Italy	7,200	2.4	26.4	1.6	129.0
Spain	5,747	2.7	31.1	1.8	152.1
Poland	4,877	2.4	46.2	3.4	222.8
Turkey	3,492	1.7	29.9	1.6	146.6
Netherlands	2,649	3.8	45.6	2.4	223.9
Sweden	2,358	5.3	60.3	2.2	300.5
Romania	2,197	1.6	32.9	2.9	156.9
Greece	1,761	2.9	33.4	1.9	163.4
Portugal	1,726	3.2	41.7	2.5	203.7
Belgium	1,535	2.9	37.7	2.0	185.1
Switzerland	1,355	4.2	45.4	2.1	224.3
Czech Republic	1,329	2.4	40.6	3.0	195.9
Hungary	1,256	2.0	41.7	3.7	198.3
Denmark	1,170	4.5	59.1	2.4	293.0
Austria	1,132	2.9	37.1	2.4	180.7
Serbia	1,073	2.1	39.3	3.0	189.0
Norway	1,044	5.4	62.3	2.2	310.6
Bulgaria	967	1.7	36.1	2.9	173.4
Finland	898	3.5	45.2	2.6	220.9
Croatia	824	3.1	59.4	3.1	291.7
Slovakia	681	2.5	51.1	3.9	245.9
Lithuania	544	2.7	61.0	4.5	294.6
Ireland	522	3.4	44.1	2.3	216.6
Slovenia	406	4.2	62.4	3.1	307.2
Latvia	392	3.0	69.4	5.7	332.4
Estonia	295	4.0	78.0	4.7	380.4
Cyprus	100	3.2	40.1	1.6	199.2
Luxembourg	56	2.9	33.9	1.5	167.8
Iceland	56	5.3	56.4	2.4	279.2
Malta	40	2.3	24.0	3.8	107.2
Liechtenstein	4	3.4	33.8	0.0	173.5

Table 14. Countries by age-standardized rate of KC (Bray et al., 2018).

Rank	Country	Age-standardized rate per 100,000
1	Belarus	16.8
2	Latvia	15.2
3	Lithuania	14.8
4	Czech Republic	14.7
5	Estonia	14.6
6	Slovakia	13.4
7	France (metropolitan)	12.5
8	Hungary	12.4
9	Iceland	11.9
10	Croatia	11.7
11	Uruguay	11.4
12	Ireland	11.3
13	US	10.9
14	Slovenia	10.5
15=	Canada	10.2
15=	Norway	10.2
15=	UK	10.2
18	Russia	10
19	Australia	9.8
20=	Belgium	9.4
20=	Singapore	9.4

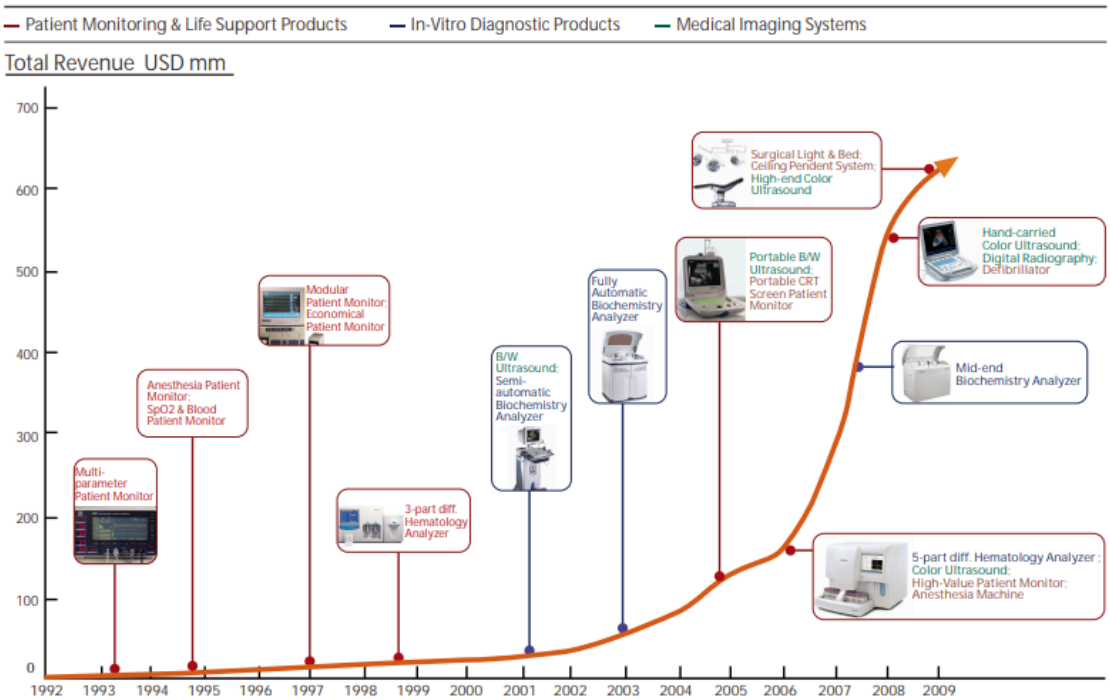

Figure 11. Product innovation and rapid growth of Mindray company ("Mindray Annual Report", 2009).

APPENDIX 3

Transcript

1. Konkurencinių reakcijų įveikimas A, B, C ir D atveju (klausiama atskirai)

1A. Kaip įvertintumėte šį įėjimo į rinką barjerą (BTE)?

A ir B atveju, pradėjus verslo modelį su šiais išorinės kontrapulsacijos ir krioabliacijos modeliais rinkoje konkurencijos nebuvo, tai konkurencinis barjeras buvo silpnas. Ultragarsinės sistemos Mindray (C) turėjo stiprų konkurentinį barjerą, nes gamintojų siūlančių panašias ultragarsines sistemas buvo nemažai. Asmenines ultragarsines sistemas (D) vertinčiau kaip vidutinį, nes panašaus sistemų rinkoje buvo. Tiktais, am, aktyvumas konkurentų atžvilgiu buvo silpnas.

1B. Su kokio tipo konkurencinėmis reakcijomis susidūrėte pristatinėjant šį produktą į rinką?

Toliau jeigu kalbant apie tą esantį stiprų konkurentinį barjerą, tai turėtume pirmiausia kalbėti apie C – ultragarsines sistemas, tai yra Mindray. Tai, tai jų reakciją buvo sakykime marketingo srityje silpninamas gamintojo reputacija, kad tai yra naujas gamintojas, nepatyręs, taipgi, kad dar tai yra ir iš Kinijos. Taipogi, silpninama buvo mūsų kaip tiekėjo (distributoriaus) kompetencija, kad mes naujokai, neturėsim serviso. Suges, ką tada jūs darysite? Tai va, tokia buvo jų reakcija, bandoma sumenkinti produkto vertė, per gamintojo kilmę ir mūsų kaip atstovų pardavėjų ne patirtį. Taikytas anti-marketingo kompanijos prieš mus, išskiriant savo aparatų gerumą, nes jie, sakykim, nelabai ir žinojo mūsų aparatų stipriąsias ir silpnąsias vietas. Tiesiog buvo bendrai kalbama, kad bus blogai, geriau pirkit kas patikrinta ir yra žinoma. Vėliau, mums peržengus ribą šių trukdžių. Konkurentam teko koreguoti savo kainą, nes mes rinkoje tapome vieni iš pigiausių jeigu ne pigiausi. Ir, be abejo, tai paveikė rinką ir konkurentai turėjo mažinti savo kainas.

1C. Kokias vadybines priemones taikėte, kad įveiktumėte šį BTE?

Pavyko pramušti ant-marketingą ir tai vyko keliais lygmenimis. Pirmas lygmuo tai, sutvirtinti gamintojo vardą, tai reikėjo, būti matomiems renginiuose susijusiuose su specialistų, kurie naudoja tas sistemas. Am, kvalifikacijos kėlimo renginiai, kongresai įvairūs, juose mes turėjome būti matomi ir tokiu būdu ištransliuoti žinutę, kad nuosekliai tęsiame marketingą ir įmonė, ir gamintojas jie yra galų gale žinomi, kad jau nebėra nežinomi. A, toliau jau tiesiogiai su kiekvienu klientu ir kiekvieną pardavimą galimybę buvo daromas pakankamai ilgos, ilgiausios rinkoje ir pradžioje buvo pakankama naujiena klientui rodyti sistemą vos ne mėnesį ar du. Tokiu būdu klientas įsitikindavo, kad aparatas turi tas pačias ar netgi ir daugiau funkcijų negu iki šiol gerai žinomi gamintojai. Jis tuo pačiu įsitikindavo jo patikimumu, nes demonstracijos metu niekas nesugesdavo. A, taipogi labai padėjo mūsų nuoseklus bendravimas, išklausimas jų norų, sistemos pareguliavimas, galų gale, pervežimas ir taip toliau, kas irgi sukėlė papildomo pasitikėjimo tiek gamintoju, tiek mūsų įmone.

1D. Ar yra dar kas nors ką norėtumėt pridėti šiuo klausimu?

Ne, aš manau, kad šia tema pakankamai aiški pozicija ir aiški situacija.

2. Ilgas prikimo ciklas ir stiprūs santykių saitai A, B, C ir D atveju (klausiama atskirai)

2A. Kaip įvertintumėte ilga pirkimo ciklą ligoninėse kaip BTE?

Bendrai pardavimas viešosioms įstaigos trunka ilgai, tai gali būti keli mėnesiai ar netgi keli metai. Viskas priklausyti nuo įvairių veiksnių. Kioabliacijos (A) atveju pirkimo momentas buvo ilgas dėl to, kad reikėjo įtikinti dėl šio naujos idėjos, medotikos praktikoje. Galbūt pats pirkimas, kai klientas nusprendžia pirkti, tai jis yra įprastas bet kokiai medicininiai įrangai. Tačiau kol prieinama iki spendimo tai gali trukti labai ilgai. B atveju, išorinės kontrapulsacijos mes nepardavėme nei vienos sistemos, net neperėjom į pardavimų etapą. Galima vadinti kaip stiprus, neįveikiamas, bet mes jo neįveikėme dėl kitų priežasčių, tai čia netiktų apie tai kalbėti. Ultragarso sistemos (C) pardavimo barjeras, na, šiek tiek gal galėtų būti dėl to, kad mūsų demonstracijos turėdavo būti ilgesnės, kai sakykime, konkurentui užtekdavo pasiūlyti kainą, parodyti modelio paveiksliuką ir klientas sakydavo, gerai aš tokio tipo aparato ir noriu ir pereidavo į pirkimo procedūrą. Mums reikėdavo įtikinėti ilgiau, būdavo mėnesio, dviejų ir net šešių mėnesių demonstracija ir, kad šitas nežinomas gamintojas, jiems taptų žinomas ir mielas. Tai šiuo atveju prailgėdavo pradinėse stadijose. Vėliau susinormalizavo sakyčiau ir tapo vienodo ilgio pats pardavimo procesas. Dėl asmeninės ultragarsinės sistemos (D) galime sakyti, kad šis barjeras nėra aktualus, nes mes neperėjome į pardavimų procesą, nors jis būtų įprastas, bet klientai iki šiol nenori tokio tipo sistemų.

2B. Kaip įvertintumėte konkurentų santykių saitus su gydytojais kaip BTE?

Konkurentai galėjo ilginti pardavimo procesą, nes jie nepasitikėjimą mūsų sistemomis, savo vizitais, savo paabejojimais: ar tikrai jūs norite pirkti šitą nežinomą, Kinietišką prekę? Galėjo, šiek tiek daryti įtaką ir ilginti prieš tai mūsų minėtą demonstracijos laikotarpį. Na, o jų norai mums visgi stabdyti pardavimą, jeigu tai būtų parvimo procesas, viešojo konkurso metu, skųsti tam tikrus reikalavimus, bet čia galbūt ne į mūsų klausimą. Kalbant apie C ultragarso sistemą atveju šis barjeras vertinamas santykinai silpnas. A atveju pardavimui mums niekas nekirsdavo, nes nebuvo konkurencinės aplinkos, tiesiog, pats pardavimas nebuvo apsunkintas. O kitų B ir D atveju mes iki pardavimo proceso nepasiekėme.

2C. Kiek laiko įprastai trunka parduoti medicininę įrangą ligoninėms (nuo pirmojo pokalbio iki parduoto produkto)?

2D. Kokias vadybines priemones taikėte, kad įveiktumėte ilgą pirkimo ciklą ligoninėse?

2E. Kokias vadybines priemones taikėte, kad įveiktumėte stiprius santykių saitus su gydytojais?

Abiem klausimais 2D ir 2E, mes kartotumėmės. Nes, atsakymai buvo pateikti pirmo barjero diskusijoje.

3. Ilgas kompensavimo procesas A, B, C ir D atveju (klausiama atskirai)

3A. Kaip įvertintumėte ilga naujo produkto kompensavimo procesą kaip BTE?

Aš gal apibūdinsiu šį kompensacijos procesą, tai įsigyti bet kokio tipo įrangą, ligoninės perka iš savo biudžeto, bet paslaugos, kurios jos teikia pacientam su turima įranga, yra kompensuojamos skirtingai. Čia reikėtų paminėti kiekvieną tą išskirtinumą per kiekvieną mūsų atveji. Tai A atveju, kompensavimas už krioabliacines operacijas, tai yra navikinių susirgimų naikinimas šalčiu, naudojant specialią sistemą ir specialias adatas. Ligonių kasų apmokamas yra labai mažai, santykinai lyginant su Europos ir viso pasaulio, am, patirtimi, nes tai yra sąlyginai brangi procedūra Lietuvos standartais. Nors klinikinė nauda yra įrodyta daugybe metų, kur yra labai geri klinikiniai rezultatai. Tačiau apmokėjimas to didesnio kiekio procedūrų boksuoja, nes ligonių kasos nenori skirti papildomų eilučių, taip vadinkime. A, daugiau, apmokėti tokio tipo operacijų ir kompensavimas už šitas operacijas gydymo įstaigai yra labai sudėtinga, nes kiekvieną atvejį, kiekvieną susirgimą, jos turi aprašinėti individualiai, sakydami, kad toks gydymo metodas yra geriausias ir ligonių kasos turi patvirtinti, kad apmokės tokio tipo procedūrą. Tokių būdu gydymo įstaiga gali pirkti adatas, užsisakyti, ir atlikti tą operaciją. Tai šiuo atveju, čia buvo ganėtinai stiprus barjeras, kad tos operacijos ir tų priemonių kiekis būtų didesnis. Barjeras buvo įveiktas, bet kompensavimas nebuvo sistemingas, nebuvo taip, kad ligoninė nežino, kad ji gali į

metus atlikti 30, o kitais metais 50, o galbūt ir 100 operacijų, jiems kiekvienu atveju reikėdavo prašyti išskirtinio patvirtinimo. Tai buvo komplikuota, tai ypatingai prailgino ir dėl to šios technologijos naudojimas buvo labai apsunkintas. Tai vertinčiau kaip stiprų barjerą. Dabar jeigu kalbant apie išorinę kontrapulsaciją (B), vėlgi, nei pardavimo proceso mes nepasiekėme, bet priežastys dėl ko mes nepasiekėme čia susiję yra. Dėl to, kad specialistai galėtų naudoti tokio tipo įrangą, jie suprato, kad šiuo metu kompensuojamų paslaugų sąraše nėra tokio tipo paslaugos apmokėjimo. Jeigu jis ir būtų gretutinis, šiek tiek susijęs su mūsų įranga jis būtų labai mažas ir visiškai neatpirktų brangios kontrapulsacijos sistemos įsigijimo. Tai, o naujai kovoti už tai, kad būtų nauja „eilutė“ jie nesiryžo, nes tai būtų ganėtinai sudėtingas procesas, tai čia irgi didelis barjeras, nes kompensacijos proceso nebuvo. Apie ultragarsines sistemas kalbant (C ir D) šio barjero nėra, nes sistemos, jos plačiai naudojamos, neturi reikšmės kokio gamintojo jos būtų. A, yra mokama už atliekamus tyrimus. Asmeninės ultragarsinės sistemos, jos būtų tilpę, ko gero, po tuo pačiu ultragarsinių tyrimų atlikimu, taigi šis barjeras būtų minimalus arba jo nebūtų, tiesiog.

3B. Kiek laiko iš Jūsų patirties trunka kompensavimo procesas?
Šiuo atveju, jeigu kalbant apie procesą, kaip įvesti naują produktą, naujo tipo paslaugą. Kaip padėti gydymo įstaigai motyvuoti ligonių kasas, kad tokio tipo įrangos reikia. Kad tokio tipo gydymo metodai taikomi pasaulyje, vakarų pasaulyje yra labai sėkmingi, turi labai ryškią klinikinę naudą lyginant su kitais metodais. Kaip pasiekti, kad ligonių kasa skirtų tokio tipo procedūrom naują įkainį, naują „eilutę“ ir tuos pradžioje bent mažą kiekį procedūrų ir po to jau didintų. Šitas procesas gali užimti metų metus, šiuo atveju mes dirbame nuo 2012 metų ir sisteminio kompensavimo nepasiekėm.

3C. Kokias vadybines priemones taikėte, kad ilgas kompensavimo procesą?
Šis barjeras, kalbant apie atvejį A, gamintojo pagalba mes turėjome daug klinikinių duomenų, nepriklausomų tyrimų. Pirmiausia bandėme edukuoti specialistus, kodėl tai yra taip naudinga. Tai specialistų lygmeniu pavyko tai įrodyti, pavyko atlikti keletą, keltą dešimčių taip pasakysiu. Jie matė tą naudą, matė rezultatus, tai tiesiog, mes kaip atstovas, teikėme specialų prašymą. Yra speciali metodika (HTA, atlikta Austrijos instituto) Akreditacijos tarnybai prie Sveikatos apsaugos ministerijos, kur teikėme visą eilę dokumentų, įrodančių šio, šio metodo privalumus. Teikėme ir jie buvo svarstomi ir išvados agentūros buvo, kad kaip ir gal ir galima būtų naudoti, bet apribojant indikacijas. Tai šis vienas iš procesų buvo, bet sakykime, visas procesas vis tiek užstrigo, nes laikotarpyje tarp institucijų bendradarbiavimo, netgi Akreditacijos tarnybai nusprendus, kad tai galima naudoti ir yra tinkantis metodas. Sekantys etapai susiję su pačiu apmokėjimu ir pačiu pinigų skyrimu pradėjo strigti, nes ten yra jau kiti žmonės ir jiems vėl tarsi, jie nesupranta, kokia čia ta nauda ir kodėl čia reikėtų skirti, ir kam to reikia. Tai šiuo atveju, mes kaip atstovas užsiėmėme edukacija ir reikiamų dokumentų surinkimu ir, be abejo, tai buvo jungtinė veikla su vartotoju, kuri norėjo, tą technologiją naudoti. Tai buvo bendras darbas, jiems padedant tuo tinkamus dokumentus surinkti, taipogi, jie patys įdėjo nemažai darbo ir iniciatyvos susirašinėjant su institucijomis. Išorinės kontrapulsacijos atveju, šio proceso mes nesugebėjome įveikti, nes vartotojų buvo visiškai kitas segmentas, kiti gydytojai. Sakykime, kardiorebilitacija vadinama, jie tokio proceso neįsivaizdavo, kad gali būti. Ir tiesiog neparodė iniciatyvos, kad reiktų pradėti domėtis, inicijuoti tam tikrus raštus, sakykime. Ir tokį kompensacinį variantą „išsimušti“. Jie nuleido rankas ir sakė, kad Lietuvai per brangu ir kad niekas čia nemokės, nors gal ir gerai yra. Procesas pasirodė, per daug stiprus, nes iš reabilitacijai skirtos įrangos yra vieni rezultatai laukiami, o iš kovos su vėžiu kiti ir kitos susidomėjimas ir kito masto.

3E. Ar yra dar kas nors ką norėtumėt pridėti šiuo klausimu?
Ne, neturiu ką daugiau pridurti šia tema.

4. Stipri tiekėjo galia A, B, C ir D atveju (klausiama atskirai)

4A. Kaip įvertintumėte stiprią tiekėjo galią kaip BTE norint pristatyti/pristatant naują produktą rinkai?

4B. Su kokio tipo tiekėjo galiomis teko susidurti šio produkto atveju? Apskritai per savo karjerą? Pakomentuokite plačiau.

Jeigu vertinti šį barjerą kaip gamintojo papildomi reikalavimai arba labai aukšti tikslai keliami, kuriuos sunku pasiekti mažoje rinkoje – ar tai galėtų būti mums barjeras? Tiesiog nebetęsti šių išvardintų įrangos A B C D įrangos įvedimo į rinką, nei su vienu mes nesusidūrėme ryškiai. Apie kiekvieną atvejį atskirai:

Kriobliacijos atveju gamintojas buvo labai kantrus ir siūlė geras sąlygas, nes suprato, kad kiekvienoje rinkoje reikia procesus vystyti labai nuosekliai: marketingas, klinikinė edukacija ir taip toliau. Buvo didžiulė pagalba, daug informacijos, tad šis prietaisas su šiuo barjeru nesusidūrė. Jie buvo kantrūs ir laukė kada mums pasiseks kažką parduoti.

Išorinė kontrapulsacija – taipogi mes niekur nenuėjome, bet gamintojas atviras bet kam ir gerą kainą ir politiką taikytų.

UG sistemų atveju – kadangi gamintojui rinkoje pradžioje buvo sunku, bet vėliau jis tapo žinomu visame pasaulyje, baigėme ties tuo, kad gamintojo barjeras. Baigėme ties tuo, kad gamintojas, gamintojo barjeras. Galima sakyti, kad UG sistemos atveju, šioks toks barjeras buvo, nes gamintojas buvo labai ambicingus planus iškėlęs, ir kadangi davė gerą kainodarą ir turėjo platų asortimentą, jie žinoma norėjo gerų rezultatų ir kad mes daug parduotumėme. Tai pradžioje buvo tokios įtampos, buvo sunku pasiekti iškeltus metinius planus, nes rezultato jie norėjo labai greitai, o visur reikia laiko, prieš tai apibūdintus barjerus palaužti.

Gamintojo reikalavimai buvo gan didoki, buvo metų, kai buvo sudėtinga planus pasiekti, bet šiuo metu šis barjeras nėra labai svarbus, nes mums gerai sekasi. Tačiau pradžioje tai buvo barjeras.

AUG sistemų atveju taip pat barjeras šioks toks yra, kad pradėjus su gamintoju dirbti, jis nusistatė ta tikrą įrangą demonstracinę, į kurią mes turėjome investuoti, investicija gan didelė, bet nebuvo iš ko rinktis, tad teko sutikti su jų sąlygomis. Tad vertinčiau tą barjerą tarp silpno ir vidutinio. Taip pat jie aišku reikalauja tam tikrų kiekių, kas šiuo metu, esant sunkumams įvesti šį gaminį, jaučiame vis didėjantį spaudimą, nes neparduodame tiek įrangos, kiek jie norėtų. Barjerą vertinčiau kaip vidutinį-stiprų.

4C.Kokias vadybines priemones taikėte, kad įveiktumėte stiprią tiekėjo galią?

Padėjo tai, kad mes pradėjome komunikuoti su gamintoju, gamintojas atvykdavo į mūsų šalį, mes lankydavome klientus, kurie naudoja arba norėtų naudotis aparatu. Gamintojas išgirdo tas priežastis, dėl ko tie pardavimai pradžioje neauga, kur ta problema. Tai visų pirma, buvo identifikuota, kad gamintojui trūksta marketingo priemonių, jos nėra kokybiškos, jos nėra orientuotos į kažkokią tai vertę, pradžioje buvo nepatrauklios nepatraukus tų sistemų apipavidalinimas, kalbant konkrečiai apie brošiūras ir vaizdo prezentacijas. Vėliau jie suprato, kad ta kilmės šalis Kinija yra irgi svarbus dalykas, kad jie turi investuoti patys į tai, kad jie turi būti labiau matomi didžiuosiuose tarptautiniuose kongresuose tam, kad mūsų gydytojai išvykę į tarptautinius kongresus sugrįžtų su didesniu pasitikėjimu, kad šis gamintojas nėra kažkoks atsarginis žaidėjas, sėdintis paskutinėje vietoje. Tad su jais komunikuojant, pavyko įrodyti, kad sunkumai ir neaugantys pardavimai yra susijęs ne su mūsų veiklos stoka, bet susiję su tam tikrais dalykais, kur mes vieni nenugalėsime. Ir buvo paprašyta papildomų kainos nuolaidų svarbiems projektams, taip pat jie pradėjo daugiau investuoti į savo marketingo priemonių paruošimą bei didesnį dalyvavimą tarptautiniuose kongresuose. Dar galima paminėti, kad pradėjo padėti, pradėjo skirti tam tikrus pinigus dideliems renginiams, kur mums būtų gal per didelės išlaidos jie skirdavo iš savo eilutės, kad gamintojas ir mūsų atstovas matytųsi tuose renginiuose.

4D. Ar yra dar kas nors ką norėtumėt pridėti šiuo klausimu?

Ne, neturiu ką daugiau pridurti šia tema.

5. Legalūs reguliaciniai reikalavimai A, B, C ir D atveju (klausiama atskirai)

Esant mums Europos sąjungoj, jokių mes apribojimų dėl produkto kilmės šalies neturėjome, įranga yra sertifikuota CE ženklinimu. Netiesiogiai reguliaciniai dalykai susiję su mūsų reimbursement barjeru, bet visiškai netiesiogiai, tad šiuo atveju šio barjero nebuvo nei vienai įrangai.

6. Konservatyvūs medicinos ekspertai A, B, C ir D atveju (klausiama atskirai)

6A. Kaip įvertintumėte konservatyvius medicinos ekspertus kaip BTE norint pristatyti/pristatant naują produktą rinkai?

6B. Kokiomis aplinkybėmis susiduriate su šiuo BTE?

Konservatyvūs medicinos ekspertai yra susiję su galbūt kitu barjeru, šiek tiek persidengia su mūsų kalbėtu ilgo įvedimo į rinką barjeru, bet konservatyvūs gal apibūdinčiau tuo kad, A produkto atveju, buvo grupė specialistų, kurie netikėjo kriobliacija, nes jie norėjo operuoti vėžius, kaip čia šaldyti, jeigu gali išoperuoti. Tai šitas barjeras šioks toks buvo, kitų sričių, nes gydymo metodai turi alternatyvias įvairias, tai vienas metodas norėjo neįsileisti kito metodo, tai, sakykim,

B atveju šitas barjeras buvo silpnas, nes dominavo kiti barjerai. Nors vėlgi, tam tikru atveju buvo žmonių, kurie sakė, kad yra literatūros žinių, kur kontraversiškai vertinama šio proceso nauda. Tai viską susumavus galima sakyti, kad šis barjeras buvo silpnas.

UG sistemos – konservatyvumas nebuvo susijęs su pačia technologija, labiau buvo susijęs su kilmės šalimi. Nežinau ar čia ekspertai prieš konkrečia įrangą, ar labiau prieš kilmės šalį, ar čia tiktų aš nežinau. Bet visumoj ekspertai buvo konservatyvūs šiam naujam gamintojui. Jie nesakė tiesiogiai, kad čia kinai blogai gamina, bet jie viską suversdavo vaizdo kokybei, nors ištiktųjų tai buvo paslėpta baimė produkto kilmės šaliai ir faktui, kad tai yra nežinomas gamintojas. Šį barjerą šiam produktui vertinčiau vidutinio stiprumo.

AUG atveju – šis barjeras yra toks netiesioginis, kadangi dauguma specialistų mano, kad tipo įrangos ne visai reikia, galbūt jinai yra per brangi, kad jie ją naudotų labiau negu įprastus prietaisus. Tad konservatyvumo čia yra nemažai, jį priskirčiau prie stipraus barjero.

6C. Kokias vadybines priemones taikėte, kad įveiktumėte konservatyvių medicinos ekspertų nuomonę?

Galima sakyti, kad šį barjerą įveikėme tomis pačiomis priemonėmis, kaip ir anksčiau minėtus barjerus – tai yra edukacija per marketingą. A atveju mes barjero neįveikėme, tik jį prislopinome, sumažinome, iki šiol dar yra chirurgų, kurie netiki krioblaicija. Bet šiek tiek tų procedūrų pavyko pradėti daryti, nes mokslinė literatūra teigia, kad visas pasaulis naudoja, tai ir mes pradėjome naudoti (evidence-based).

B atveju – barjerą įveikėme.

O ties C atveju, barjerą mes įveikėme tomis pačiomis priemonėmis, apibūdintomis pirmoje klausimų grupėje – tai yra matomumas specialistų kongresuose, mato gamintoją ir mato, kad nuosekliai dalyvaujame, vadinasi neišnykstame iš akiračio. Ir žinoma toliau įrodinėjame, kad sistema yra gera, gerai rodo, per ilgą demonstraciją yra patikima. Taip pat manau, kad tai netiesiogiai su tuo, kad žmonės buvo linkę „ai, surizikuosiu, nes labai gera kaina“. O po to, vėliau, labai gerai pradėjo veikti „iš lūpų į lūpas“ rekomendacijos – specialistai vienas kitam pradėjo produktą rekomenduoti.

D atveju – barjero neįveikėme.

6D. Ar yra dar kas nors ką norėtumėt pridėti šiuo klausimu?

Ne, neturiu ką daugiau pridurti šia tema.

7. Mažas rinkos dydis A, B, C ir D atveju (klausiama atskirai)

7A. Kaip įvertintumėte mažą Lietuvos rinką kaip BTE norint pristatyti/pristatant naują produktą rinkai?

7B. Kokia Jūsų patirtis/įžvalgos šiuo atveju? Ar galėtumėte detalizuoti aplinkybes šio BTE atveju?

A – Krioabliacija. Kalbant apie apsisprendimą ar dirbti ar ne, tai mažas rinkos dydis pradedant dirbti veikia, nes jis yra tik vienas centras kuris imasi ir gali daryti tokius dalykus. Tai, kad reikia

keisti kompensavimo mechanizmą, jį iškovoti, kad jisai būtų, tai, kad reikia išmokti apie sistemą, reikia serviso, inžinierių pasiruošti , nes yra vienas ar du centrai, kurie gali naudotis. Tad mažas rinkos dydis yra didelis barjeras.
B - Išorinė kontrapulsacija. Nedaug yra centrų, kurie imtųsi tokiais reabilitacines priemones daryti. Taip pat reikia suprasti sistemą, pasiruošti marketingo įrankius,
C – Ultragarso sistemos Mindray. Užtenka rinkos, nėra barjero, rinka Lietuvoje yra pakankama, kadangi specialistai ją plačiai naudoja.
D – Asmeniniai UG (Handheld ultrasound system). Maža rinka, dar reikia daug edukuoti žmones, keisti jų įpročius, tad santykinai yra mažas rinkos dydis. Mūsų rinkos dydis, imant gydytojų specialistų skaičių, perkamoji galai yra per maža, kad gydytojai sau leistų įsigyti Asmeninę ultragarsinę sistemą. Santykinai yra per brangus daiktas, mažas kiekis specialistų.

7D. Kokias vadybines priemones taikėte, kad įveiktumėte mažos rinkos BTE?
Iš esmės nieko daug šiuo klausimu negalime padaryti. Tačiau yra keletą strateginių sprendimų, kuriuos mes kaip atstovas (distributorius) atlikome. Tai yra, įsteigėme, am, „praplėtėme“ savo rinką kitose Pabalčio valstybėse, tai yra Estija, Latvija. Taipogi, bandome diversifikuoti produktus ir pristatyti gamintojui save, kaip plataus asortimento distributorių, tokiu būdų sakydami, jog galime į savo portfely įsitraukti ir kitus gamintojo produktus. Įmonės geras vardas ir patirtis rinkoje, taip pat daro įtaką gamintojo apsisprendimui.

9. Apibendrintai kiekvienu atveju: Kaip įvertintumėte kiekvieną BTE, bendrai norint pristatyti/pristatant naują produktą rinkai?

9A. Konkurentų reakcija atveju:
A – nebuvo;
B – nebuvo;
C – buvo;
D – buvo minimali.

9B. Ilgas pirkimo ciklas ir stiprūs santykių saitai atveju:
A – nebuvo;
B – nebuvo;
C – buvo, stiprus;
D – nebuvo.

9C. Ilgas kompensavimo procesas atveju:
A – stiprus;
B – nebuvo;
C – nebuvo;
D – nebuvo.

9D. Stipri tiekėjo galia atveju:
A – silpna;
B – silpna;
C – vidutinė (taip pat buvo įmonių, kurios taipogi norėjo atstovauti šį gamintoją, tad reikėjo šiek tiek pakovoti);
D – vidutinė.

9E. Konservatyvūs medicinos ekspertai atveju:
A – vidutinis;
B – vidutinis;
C – vidutinis;
D - stiprus, neįveikiamas.

9F. Mažas rinkos dydis atveju:
A – stiprus;
B – stiprus;
C - nėra barjero;
D – stiprus.

9. Kuo skiriasi medicinos verslas nuo kitų verslų, kokie specifiniai momentai?

Medicinos įrangos pardavimų sritis yra labai siaura, ji žinoma nėra pati siauriausia, kaip antais atominė energetika, bet yra labai siaura. Konkurencinė aplinka yra labai specifiška. Susijusi labai ne kiek su pačiu daiktu ar gamintoju, bet su vietiniu atstovu gamintojo, jo įdirbiu, jo žinomumu rinkoje. Gamintojo atstovo darbo kokybė, žinomumas, istorija rinkoje yra labai svarbus momentas. Geram produktui gali labai nesisekti parduoti, jeigu yra blogas jo atstovas. Ir atvirkščiai – prastesnis produktas gali būti parduodamas pakankamai gerai vien dėl gero atstovo įdirbio ir didelio jo žinomumo.

Geri santykiai su klientu ir žinomas atstovas, patikimas atstovas yra raktas naujam produktui sėkmingai įeiti į rinką. Bet yra ir išimčių – didelei inovacijai įprasto tipo tiekėjas, dirbantis įprastais metodais, neįves didelės naujovės.

APPENDIX 4

Table 15. Secondary (2) and primary (1) data collection

Product type	Cryotherapy (A)		Enhanced external counter pulsation (B)		Mindray ultrasound system (C)		Handheld ultrasound system (D)	
Market entry and product development	Leading-mature		Leading-mature		Following-mature		Leading-new	
Data collection	(1)	(2)	(1)	(2)	(1)	(2)	(1)	(2)
Type of BTEs								
Competitive reactions	Weak	No data	Weak	No data	Weak	No data	Weak	No data
Purchase cycle and relationship bond	Weak	No data	No data	No data	Weak	No data	Weak	No data
Reimbursement process	Strong	Strong	Strong	Strong	Weak	Weak	Weak	Weak
Supplier power	Weak	No data	Weak	No data	Strong	No data	Moderate	No data
Regulations for medical representatives	Weak	No data	Weak	No data	Weak	No data	Weak	No data
Medical practice	Moderate	No data	Weak	No data	Moderate	No data	Strong	No data
Market size	Strong	Weak	Strong	Weak	Weak	Strong	Strong	Moderate
Other	No data	No data	No data	No data	No data	No data	No data	No data