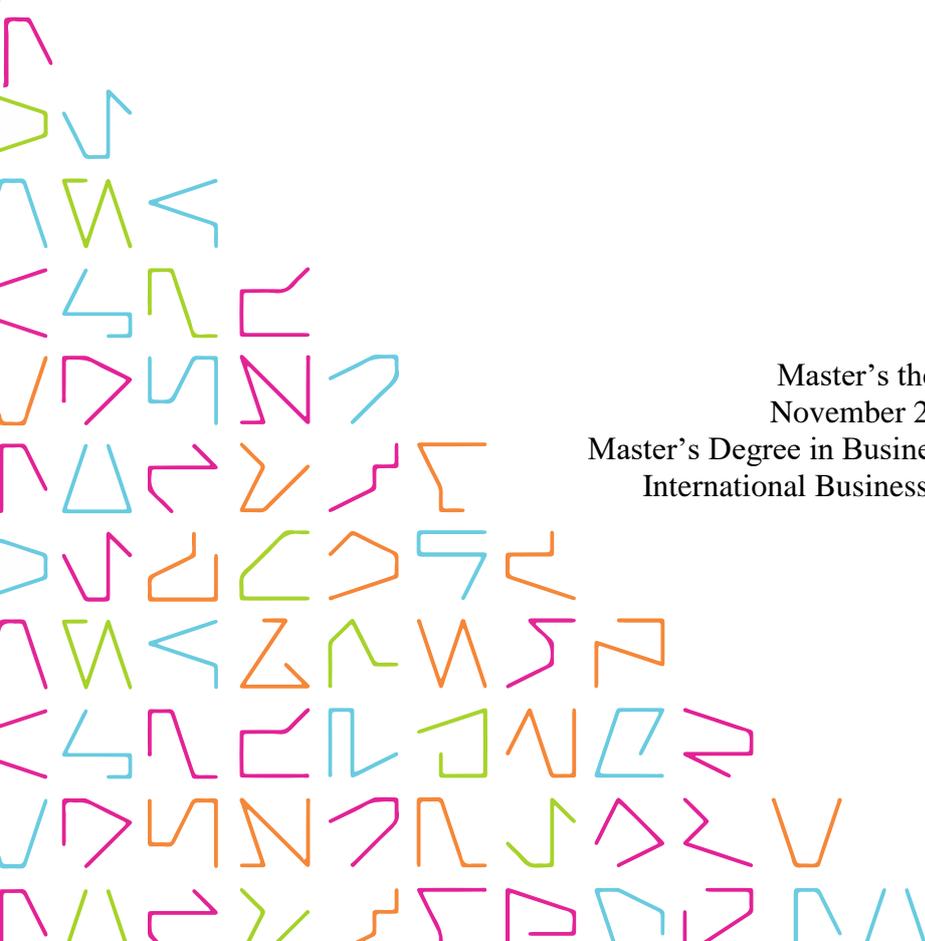


GO TO MARKET STRATEGY

Role of Medical Device Regulation in EU

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ABSTRACT

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This thesis focused on new Medical Device Regulation (MDR) in European Union. MDR became effective on May 25, 2017 with three years' transition time. Change in regulation brings a disruption to medical device companies' external environment and this regulatory landscape change has significant implications to go to market (GTM) strategy. Aim of this thesis is to study what are the significant changes in MDR affecting mostly to the GTM strategy. Methodologically this thesis followed a constructive approach aiming to develop a construction to solve a specific research problem. Thesis followed qualitative research approach with methods such as document analysis and interviews. Document analysis included 15 documents focusing on changes in MDR and the results of analysis were used to focus to the significant changes in MDR compared to previous regulations. As a result, 9 major groups of changes were identified: full life-cycle approach, new databases, product classification and approval, quality management system and related requirements, post-market surveillance system and vigilance, clinical development and surveillance, supply chain management, authorities and their roles, and implantable devices. These topics were then analyzed from GTM strategy viewpoint and linked to theoretical model of GTM strategy. Finally, practical conclusions were presented for each of the elements of GTM strategy i.e. regulatory strategy, internal analysis, external analysis, target market selection, entry mode decision, marketing plan, and tactical plan. Major recommendations included the need to rethink product portfolio because of the change in MDR and the need to start thinking GTM strategy from the very beginning of the product development in order to have all regulatory requirements implemented appropriately.

Keywords: Go to market, strategy, medical device regulation, MDR, GTM

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ABBREVIATIONS AND TERMS

C	Customer
CE	Conformité Européenne
D	Distribution
EU	European Union
Eudamed	European database on medical devices
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
GTM	Go to Market
IPO	Initial Public Offerings
IPR	Intellectual Property Rights
KPI	Key Performance Indicators
MD	Medical Device
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
MEDDEV	European guidance by European Commission
MNC	Multinational Corporation
NB	Notified Body
NGO	Non-Governmental Organization
P	Production
PMCF	Post-market Clinical Follow-up
PSM	Post-market Surveillance
QMS	Quality Management System
QP	Qualified Person
R	Research and development
R&D	Research & Development
SCM	Supply Chain Management
SME	Small and Medium-sized Enterprise
SU	Start-up
UDI	Unique Device Identification
U.S.	United States

1 INTRODUCTION

1.1 Research topic

Medical devices industry is highly regulated and medical device manufacturers must comply with national regulations in order to sell their products in the national markets¹. Scope of regulations in medical devices can be divided into several phases in the product life-cycle: pre-market, placing on-market, and post-market surveillance (WHO, 2003). Thus, regulation becomes crucial already in the development phase (pre-market) as it is required to develop and document the product according to national regulations. During placing on-market phase happens advertising and sales of products. After placed on-market, post-market surveillance must be in place meaning that products are monitored while on the use.

This thesis focuses on European medical device market and recent regulatory changes affecting the industry. In 2017, European Union (EU) updated medical devices (MD) regulative scheme and the new medical device regulation (MDR) became effective on May 25, 2017². There will be 3 years' time to comply this regulation (MD Regulation 2017/745). There are reasons for the change in the regulatory scheme. For example, when studying differences in regulatory approvals between U.S and EU, Hwang et al. (2016) found out in their study that medical devices approved first in EU market are associated with greater risk of post-marketing safety warnings and recalls with almost threefold rate. As results were based on a data set from 2005 to 2010 and contained three disease areas with most high-risk devices in medical practice (Hwang et al., 2016), it is easy to understand why EU went forward to make new medical device regulation. According to Jull (2016) the general consensus has been that it is easier to obtain CE mark than to get FDA approval for the product, and CE marking has been also a faster route (Hwang et al.,

¹ More profound description of medical device industry can be found in section 2.

² Previously EU member states were required to implement in their own legislations directives Medical Device Directive and In-Vitro Device Directive. For this reason, there was some differences between EU member countries in MD legislations. By introducing MDR all EU member states will have same rules and national legislation in this regard is not anymore needed as MDR is mandatory law. Consequently, the aim of the MDR thus is to create a real EU a real domestic market for MDs from regulation point of view.

2016). After new MDR it is possible that U.S. and EU might come closer to each other in this regard (Jull, 2016).

The change in regulation brings a disruption for medical device industry and for small companies this will be even more radical change in their operations. EY (2016) argues that this change represents one of the most disruptive changes in the whole industry in recent times. The change will affect both large companies as well as small and medium size companies. Among other changes, updated regulation explicitly for example requires that there should be a *“at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices”* (MD Regulation 2017/745). The new MDR provides an interesting topic for this thesis as EU is establishing a domestic MD market from regulation point of view as all EU member states must apply this regulation. The MDR is much more rigorous and complex than existing regulation in EU and countries following EU’s regulation scheme most probably will follow this (Elan & Chatwin, 2017).

Aim of this research is to bring light to the problem how to address in Go to Market (GTM) strategy the changes in MDR within EU. GTM strategy in general includes business planning activities such as determining costs and profits for market, understand market demand and competitive landscape, decide distribution methods and reimbursement policies, among other things (Elan & Chatwin, 2017). As different industries have different scale of regulation, for highly regulated industries regulatory strategy becomes a key aspect in GTM strategy. Even though regulatory strategy does not affect that much to actual business planning, it is a prerequisite for doing business. In medical device business, GTM planning should also scope the market requirements from regulation point of view. Regulatory bodies follow actively what is going on in the industry and require that adverse events are reported to them. If device has a safety or performance related problem, it faces a possible recall, which is a huge business risk. Regulatory audits are held by regulatory bodies as well and there could be a restriction for sales if there are no regulatory aspects in place correctly.

In this thesis, focus is more on companies that already operate in EU’s medical device market and accordingly focus is on changes of MDR and not the whole regulation as such. However, as it will be argued in this thesis, regulatory strategy is important part of GTM

strategy and cannot be dismissed. Thus, GTM strategy is not left out from this thesis but the holistic view is taken on that. Because of this, the more theoretical part of this thesis is useful also for start-ups (SU) in the medical device industry even though the changes of MDR itself, i.e. the actual empirical focus in this thesis, is not that relevant for them as they have to start from scratch regarding regulations.

1.2 Research question

At a theoretical level, the focus is on GTM strategy and especially its regulatory aspects. The aim is to understand better what are the implications from regulatory strategy to GTM strategy and what should be considered when planning to penetrate a new market. The theoretical framework gives a support for answering the research question, which at a practical level focuses on MDR content and how to cope with MDR changes in GTM strategy. The underlying assumption is that ultimately without regulatory strategy in place it is not possible to execute GTM strategy in medical device industry and release a product to the market. For example, as Elan and Chatwin (2017) argue it is important to include considerations how regulatory approvals from existing markets can be leveraged to extended markets.

Research question is developed to fulfill the research aim:

What are the significant changes in MDR affecting mostly to the GTM strategy?

Answering this question should give a light what changes MDR brings to EU. Based on the results of this study a construction³ is developed to guide how to address the changes of MDR in GTM strategy. This thesis does not try to answer what all needs to be taken into account when coming to medical device market in EU but instead what are the major changes in regulations caused by MDR. The starting point for this thesis is that there are already regulatory requirements considered in GTM strategy and now after published

³ Construction is the outcome of constructive approach methodology applied in this research. Detailed methodological approach of the research is described in section 4.1.

MDR there is a need to update the existing GTM strategy. Ultimately, the basis for successful GTM strategy is to comply with MDR and thus all changes in MDR are relevant indirectly to the GTM strategy. When answering the research question of this thesis, the significance of changes in terms of having direct impact to GTM strategy elements are analyzed in this thesis.

1.3 Structure of the thesis

Section 1 focuses on the research topic and give a general overview about this thesis. Especially research aim and research questions are described in this section.

Section 2 gives an overview of medical device industry. It begins with industry trends analyzed by U.S. Department of Commerce and continues to market cap and market segment presentations. Finally, a regulatory scheme in medical device industry as well as related product development process is described.

Section 3 continues with a theoretical framework discussion. It builds on section 2 overview and deepen the understanding of GTM strategy and its elements. Finally, a synthesis of GTM strategy elements are created.

Section 4 focuses on methodology including methodological approach, data acquisition methods, and analysis methods. In this section, especially research approach relating to empirical part of this thesis is discussed and presented.

Section 5 focuses on empirical part of the thesis addressing the research question. Subsections are organized based on results stemming from the analyzed data. Finally, a construction was developed including significant changes in MDR that were summarized from GTM strategy point of view.

Section 6 includes discussion regarding theoretical, empirical and practical results and conclusions. Finally, in this section a critical evaluation of the research design and implementation is discussed.

2 MEDICAL DEVICE INDUSTRY OVERVIEW

2.1 Industry trends

U.S. Department of Commerce (ITA, 2016) analyzed medical device industry trends in their report for U.S. medical device exporters. Even though these trends are presented from U.S. based companies' viewpoint, are they also applicable for internationally operating companies from other countries as well. They came up with three trends and especially regulatory convergence is highly relevant in regard of this thesis as it is one of the reasons for MDR in EU. Identified trends are:

- **Cost efficiency:** Medical device companies have understood the need to develop holistic offering to create value with efficacy for customers because of competition, developed and hybrid products, and cost control. Especially there is a trend toward value-based healthcare with all-inclusive treatment packages.
- **Export market mixture:** Developed markets like EU, Japan and Canada are big exports markets especially from US point of view but those have a relatively slow annual growth rates. Thus, developing countries are interesting new markets with double digit growth numbers.
- **Regulatory convergence:** For medical device industry, it is important that standards for regulatory approval, and risk and quality management come together and form global standards in order to facilitate growth in developing markets.

2.2 Market segments

Medical device industry can be divided into several device areas. In this section, some indications regarding different commercial aspects of the industry are presented. TABLE 1 presents fifteen biggest market segments in medical device area and related market value in 2015 as well as estimated market sizes for 2022. It is notable that all device areas are estimated to grow significantly. The IVD device area is the biggest device area but in EU for example, MDR focuses on medical devices and there is another new regulation concerning IVD devices. Thus, IVD devices and other medical devices are not competing in the exactly same market from regulatory viewpoint.

TABLE 1. Global TOP15 device areas in medical devices industry. Numbers are given in billion U.S. dollars. Source: EvaluateMedTech (2016).

	DEVICE AREA	2015	2022 (ESTIMATE)
1	In Vitro Diagnostics (IVD)	48.4	70.8
2	Cardiology	42.1	62.3
3	Diagnostic Imaging	38.9	50.3
4	Orthopedics	34.0	44.1
5	Ophthalmics	24.9	37.1
6	General & Plastic Surgery	20.2	28.1
7	Endoscopy	16.4	26.0
8	Drug Delivery	17.6	24.5
9	Dental	12.4	18.3
10	Wound Management	12.4	17.0
11	Diabetic Care	11.0	16.2
12	Nephrology	10.6	15.4
13	General Hospital & Healthcare	10.3	14.4
14	Healthcare IT	7.8	11.3
15	Neurology	6.7	11.1

Following two tables (TABLE 2 and TABLE 3) are based on source EvaluateMedTech (2016). Here it is not argued that this is an overall picture of the industry but more it gives some hints about the volumes of investments in the industry. Table 2 presents venture finance deals in medical device industry during first half of 2016. All these deals are done in U.S. which reflects the dominance of U.S. finance market in medical device industry especially in venture financing deals. IVD and cardiology device areas are well represented among all venture financing deals due to the fact that those are the biggest device areas globally as well.

TABLE 2. Global TOP10 venture finance deals in medical device industry during Q1-Q2 / 2016. Source: EvaluateMedTech (2016).

	COMPANY	FOCUS	ROUND	DEAL VALUE (\$M)
1	Flatiron Health	Healthcare IT	Series C	175

2	Guardant Health	In Vitro Diagnostics	Series D	100
3	Acutus Medical	Cardiology	Series C	75
4	Heartflow	Cardiology	Series E	64
5	Exosome Diagnostics	In Vitro Diagnostics	Series B	60
6	TransMedics	General & Plastic Surgery	Series Un- disclosed	51
7	Proteus Digital Health	Patient Monitoring	Series H	50
8	Alcresta Therapeutics	Gastroenterology	Series C	49
9	CVRx	Cardiology	Series Un- disclosed	47
10	Quanterix	In Vitro Diagnostics	Series D	46

TABLE 3 presents global IPO deals in first half of 2016. According to EvaluateMedTech (2016), amount of raised funds has dropped dramatically from previous year's first half (in numbers from \$854 million to \$164 million). Thus, the numbers here do not fully represent the overall deals in the industry. IPOs are important funding mechanism for companies allowing them to raise money from stock market. In stock market, there are companies listed also in other countries than U.S. even though from funding amount point of view in the first half of 2016 the tenth biggest venture finance deal was bigger than the biggest IPO deal, which in general is not the case in finance markets.

TABLE 3. Global TOP10 IPO deals in Q1-Q2/2016. Source: EvaluateMedTech (2016).

	COMPANY	FOCUS	COUNTRY	DEAL VA- LUE (\$M)
1	Senseonics	Diabetic Care	USA	45
2	ASIT biotech	In Vitro Diagnostics	Belgium	27
3	Valeritas	Drug Delivery	USA	25
4	Pulse Biosciences	Radiology	USA	20
5	Oncimmune	In Vitro Diagnostics	United Kingdom	16
6	Sensus Healthcare	Oncology	USA	11
7	Volpara Solutions	Diagnostic Imaging	New Zealand	10
8	PAVMED	Various	USA	5
9	SunBio	Various	South Korea	3
10	Osteonic	Orthopedics	South Korea	2

As a summary, U.S. has a strong position in financing medical device companies but among top deals in stock market IPOs there are also Belgium, United Kingdom, New Zealand and South Korea according to EvaluateMedTech (2016) analyses. Regarding venture financing deals, there are big investments to medical technology companies which is a good thing for companies rising funding. Also, global medical device market proportions are very much consistent with areas getting the biggest amount of venture financing.

2.3 Regulatory scheme

According to WHO (2003), medical device industry regulation falls to three distinctive phases: pre-market regulation, placing on-market, and post-market regulation (FIGURE 1). Pre-market controls aims to ensure that product which will be placed on-market is compliant with all regulatory requirements. Packaging and labeling (pre-market) and advertising (on-market) controls are needed to ensure correct representation of the product. Placing on-market controls ensure that medical device vendors are registered to regulator, devices are listed and after-sale obligations are in place.

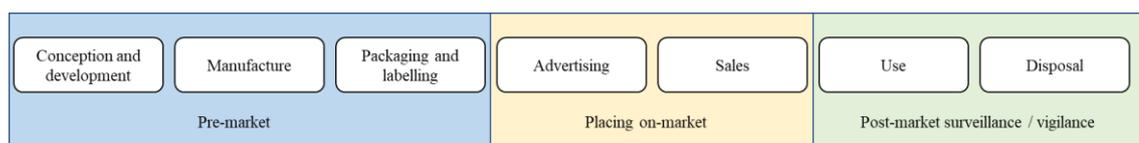


FIGURE 1. Different phases in regulation adapted from WHO (2003).

Product representation controls (labelling, packaging and advertising) aim for accurate description of the product and require instructions for use and ensure that advertisement does not use misleading claims about the product. Regarding a timing of advertisement, the general rule in regulations is that advertisement is prohibited until device is cleared for the market. (WHO, 2003).

Pre-market: Pre-market controls can include device controls for design and manufacturing including safety and performance requirements as well as quality management systems. Low-risk devices might be exempted from some regulatory requirements like quality management system. (WHO, 2003).

Placing on-market: Placing on-market controls can focus on sales of medical device. Vendor needs to register itself for governing regulatory body and list all the products that are available or in use. In this phase after-sale surveillance system needs to be on place as well in order to effectively monitor devices post-market. One of the reasons for vendor establishment controls is that it enables a pathway to get in contact with manufacturer if some adverse event happens with device. (WHO, 2003).

Post-market surveillance: Post-market controls can focus on after-sales and use of medical device. Vendors are responsible for after-sales service provision and giving users training for example. With an effective post-market surveillance system vendors are able to track with their distribution records all the devices in market and rapidly remove those in the case of problem. This requires a proper recall procedure. Adverse events are required to report as well. Post-market surveillance requires also procedures for complaint handling to analyze reported problems that relate to safety or performance. (WHO, 2003).

2.4 Product development

According to Blair & Goldenberg (2014) medical device development process includes several steps like recognizing an unmet medical need, doing fundraising or budget, concept and feasibility studies, design and its validation, clinical studies, regulatory approval, manufacturing, reimbursement, product distribution, and post-market activities. Actual phases of medical device development are presented in FIGURE 2. It is important in the new product introduction process in medical device industry to get good clinical data because many times it is the main differentiator between competitors (Blair & Goldenberg, 2014). Also, a strong team with understanding about development process and cross-functional communication is important in effective medical device development (Blair & Goldenberg, 2014).



FIGURE 2. Medical device development phases adopted from Blair & Goldenberg (2014).

Global regulatory strategy⁴ should be established already in concepting phase as it affects to many decision in later phases what should be done (Blair & Goldenberg, 2014). Especially design controls, testing of product and gathering of clinical data are affected by regulatory strategy decision. Market approval process is based on national or international regulations affecting to specific market and required data from all other phases must be planned in early phases of medical device development process. Manufacturing and distribution scalability strategy is important when market approval is getting closer or significant number of devices are needed for clinical study (Blair & Goldenberg, 2014). Manufacturing and distribution are among the very important decisions that needs to be addressed in GTM strategy. From business point of view in post-market phase it is important to continue clinical evaluation to support clinical claims and that way support market adoption, use post-market data to differentiate the technology, assess product improvements and promote the device to key opinion leaders in the industry (Blair & Goldenberg, 2014).

⁴ Regulatory strategy is discussed in section 3: theoretical framework

3 THEORETICAL FRAMEWORK

3.1 GTM market strategy overview

Ball et al. (2006) explain the normal strategy planning process in the firm. The process includes 1) analysis of external environment, 2) analysis of internal environment, 3) company's business and mission definitions, 4) strategic objectives, 5) quantitative goals, 6) actual strategy, and 7) tactical plans to achieve strategy. In this sense, GTM strategy planning process is very similar and actually it becomes part of the overall business strategy of the firm. Gould (2002) in his dissertation summarized the market selection relating literature and concluded that market screening is one of the many steps in the internationalization process. According to him, after making a decision to explore internationalization opportunities, firm screens markets to make a short list, undertake an in-depth market research focusing on the short-listed markets, selects markets to enter, and then selects the entry mode for those markets. After that there must be a decision to actually proceed with market entry and to prepare for chosen market.

Among the first steps in doing a global market strategy for medical device company it is important to understand the market and its fluctuations but also to understand regulatory, reimbursement and healthcare delivery aspects regarding market opportunities (Blair & Goldenberg, 2014). There are regulatory bodies to ensure that products placed on the market fulfill all the regulatory requirements for the product and manufacturer. Reimbursement strategies and policies, on the other hand, are important due to the fact that customers include in many countries public hospitals or private insurance providers, and there are specific requirements for products.

Situation is totally different for a multinational company operating already in several different jurisdictions than for a start-up doing its first product in some national market, because for multinational company there are already local entities established in many countries but for a start-up company or a company that begins its internationalization journey everything has to be developed from scratch. Meester (2008) developed in his master's thesis an international market entry strategy model based on systematic review from research databases (FIGURE 3). In Meester's (2008) thesis the target case was a

company which has not have any international experience beforehand. Keywords he used were relating to internationalization strategy.

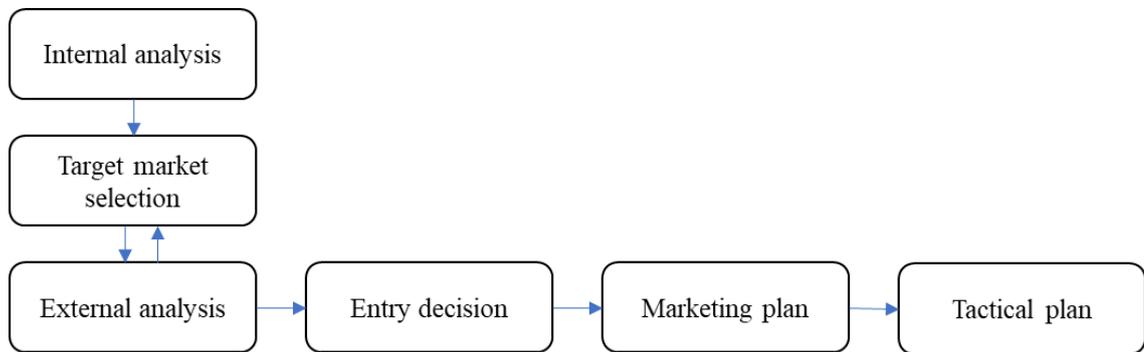


FIGURE 3. Adopted international market entry strategy model developed by Meester (2008).

In its simplest form GTM strategy has three aspects: what to sell, how to sell and who to sell (Blueapple Consulting, 2009). On the other hand, these are the bare minimum for strategy, but also it can be argued that there are many other aspects as well to think about when building a successful GTM strategy. For example, Bueno & Jeffrey (2014) include six key aspects like markets, customers, channels, product (or offering), price and positioning in GTM strategy. What makes the GTM strategy also a little difficult to address is that it has so many sides. In the model of Bueno & Jeffrey (2014) mostly marketing related aspects are took into account. There are elements in the firm itself that affect to GTM strategy as well like different resources or intellectual property rights (IPR). This little more detailed picture is painted by Elan & Chatwin (2017) who argue that an effective strategy should contain elements like:

- cost and return on investment for anticipated market
- expected market demand
- competitive landscape
- distributions methods
- reimbursement strategic and policies
- legal issues and IPR
- leveraging approvals got in primary markets to extended markets
- financial, professional and technical resources

In TABLE 4 it is presented different aspects of successful GTM strategy. There is no well-defined definition what GTM strategy should include, and thus, different authors

include different aspects of GTM strategy in their model as presented in this table. As there are several aspects that are interrelated, those are put together. Of course, not all aspects are so black and white meaning that one aspect can actually cross many others as well. For example, regulatory aspects are important part in external analysis, internal analysis and regulatory strategy itself. Another important basis for the whole GTM strategy is the product which actually affects to all boxes. Even though these different aspects are not maybe addressed straight in the GTM strategy, those can be seen important in the GTM planning and those should support each other. Thus, based on the literature, following five categories were identified:

- target market and its external analysis which includes cost and return on investment, expected market demand, competitive landscape, and customers
- entry mode decision which include distribution methods and channels
- regulatory strategy
- internal analysis including financial, professional and technical resources, legal issues, and IPR
- marketing plan including price, positioning, product, and reimbursement strategy and policies

TABLE 4. Identified elements in GTM strategy based on analyzed articles.

	Elan & Chatwin (2017)	Bueno & Jeffrey (2014)	Meester (2008)	Blueapple Consulting, 2009
cost and return on investment for anticipated market	x			
expected market demand / market	x	x	x	
competitive landscape / external analysis	x		x	
distributions methods / channels / entry mode decision	x	x	x	
reimbursement strategy and policies	x			

legal issues and IPR	x			
leveraging approvals got in primary markets to extended markets / regulation strategy	x			
financial, professional and technical resources	x			
customers		x		x
product (or offering)		x		x
internal analysis			x	
marketing plan, price, positioning		x	x	x
tactical plan			x	

In the following sections, these five identified categories of GTM strategy are presented in detailed manner. In addition to these categories, a tactical plan is needed for these in order to describe in detail how strategic goals will be achieved (Ball et al. 2006). It is not enough to have a high-level strategic plan about something but also a tactical plan how to get there. In this sense, it is important to be able to answer the question what to do, how to do it, and to who to do it.

3.2 Elements of GTM strategy

3.2.1 Internal analysis

Meester (2008) used 7S model in conducting internal analysis for his GTM strategy purposes. 7S model was developed by McKinsey consultants. It includes 7 aspects that are strategy, structure, systems, style, staff, skills, and shared values. According to McKinsey (2008) the 7S model was developed for the need to make a step forward from thinking organizations as a structure and to give more focus on the critical role of coordination in organizational effectiveness.

Another useful framework for analyzing internal and external aspects of company is SWOT analysis⁵. According to Arslan & Er (2008) SWOT analysis has its origin in 1960s and is credited to Albert Humphrey who did research in Stanford university. SWOT analysis is especially useful in strategic analysis as it combines both internal (strengths and weaknesses) and external (opportunities and threats) factors (Dyson, 2004). According to Dyson (2004) some newer approaches like resource-based view and competence-based view are based on SWOT analysis and are able to enhance the internal perspective of it. Wernerfelt (1984) lists some examples of resources including things like brand names, in-house knowledge of technology, employment of skilled personnel, trade contacts, machinery, efficient procedures, and capital among others. It is important to analyze what resources are needed in order to successfully execute GTM strategy.

Supply chain is important part of every firms' operations and should be in line with GTM strategy as well. There are few quite similar definitions what is included in supply chain. It can be seen as an integrated process wherein raw materials are manufactured into final products including 1) supply, 2) manufacturing, 3) distribution, and 4) consumer (Beamon, 1999). Li et al. (2006) very similarly presents supply chain management (SCM) to consists of upstream (strategic suppliers) and downstream (customer relationships), internal supply chain process (postponement), and information flow across a supply chain. Gunasekaran et al. (2004) define supply chain simply to include source, make / assemble, and deliver parts that is identical to Beamon (1999) if customer is not taken in account. Customer is of course part of supply chain but is it possible to manage i.e. should it be part of SCM, is another question. However, regarding GTM strategy, customers are addressed in external analysis and marketing plan. In the end, the whole company and especially SCM are targeting to serve customers which on the other hand are not possible to manage. In this sense, customer relationships (Li et al., 2006) provide a much better picture from the place of customers in the supply chain. Suppliers, on the other hand, are possible to manage and should be managed, and there the quality and extent of information plays important role especially if suppliers are seen as strategic supply chain partners (Li et al., 2006).

⁵ SWOT is an acronym and includes following words: strengths, weaknesses, opportunities, and threats.

SCM includes different functions and points of view in the firm and the need to integrate those: transportation, logistic, purchasing, supply management, operations management (including manufacturing processes), marketing, organizational theory, and management information systems (Kannan and Tan, 2005; Li et al., 2006). Thus, it is useful to have an approach presented by Beamon (1999) and not to separate different phases in supply chain too much but to focus on integrated framework to assess the performance of supply chain process. She proposed three performance measure type: resources, output, and flexibility each having a set of measurements across the supply chain.

There are some important key performance indicators (KPIs) regarding supply chain of the company. According to Gunasekaran et al. (2004) supplier delivery performance is very important in supplier part, as well as supplier lead-time, supplier pricing, efficiency of purchase order cycle time. It is also important to work closely with suppliers (Gunasekaran et al., 2004; Li et al., 2006). In production phase, Gunasekaran et al. (2004) found out that in production percentage of defects, cost per operation hour, and capacity utilization has the highest importance, but also range of products and services as well as utilization of economic order quantity are important. Beamon (1999) suggests manufacturing lead time, manufacturing cost, and inventory to be important. Beamon (1999) identified shipping errors to be one of the measures in distribution part. According to Gunasekaran et al. (2004) quality of delivered goods and on time delivery of goods both are important and related to the perceived customer value. They found out that flexibility of service systems to meet customer needs, effectiveness of enterprise distribution planning schedule and delivery invoice methods, number of faultless delivery notes invoiced, percentage of urgent deliveries, information richness in carrying out delivery, percentage of finished goods in transit, and delivery reliability performance are also important. Customers are important end-point contributing to sales. Customer satisfaction is important and partial way to measure it is by number of customer complaints (Beamon, 1999).

3.2.2 External analysis

External analysis includes market, customer, and competitor characteristics among other aspects (Meester, 2008). Analysis of expected market demand is important in order to make sure that product has a good market opportunity. This might require some kind of

market research among potential customers. Hague et al. (2013) explains how to make an affective market research in practice. Market research is needed to understand the market and unmet market needs, main delivery channels, partners, customers among other things. In the scoping part of the market research, important decisions will be made e.g. choosing geographical areas and the people to be interviewed. There are several data collection methods from which desk research (secondary data) and qualitative research (interviews as a primary data) are very useful. Market size and structure can be obtained from desk research and available secondary data sources. Qualitative research (interviews) is useful in cases where deeper exploration of phenomena is needed.

Sometimes external environment is so volatile that it is difficult to foresee the change in it, what is going to happen and act accordingly. On the other hand, sometimes external environment is reasonable stable and it is easy to plan actions there. For example, regarding the topic of this thesis, it was well known that the regulation will change but the exact timing and interpretations were not. Thus, one of the questions is how this become visible in the strategy level. Ansoff (1957) discussed interestingly how military and business are very different in their focus of strategic planning. As he says, long term business planning emphasizes trends and does not focus on contingencies that much but in military planning emphasize is on contingencies. Businesses could learn a lot from military in this regard and really considering in their short-term and long-term planning possible risks included in the changes of the external environment.

Then, how to take into account an external environment in the GTM planning? Blair & Goldenberg (2014) argue that it is important to include international and emerging markets in the very early stage of the product development in order to be successful in long-term to get to market and to bring regulatory and quality costs at lower level. As they say, it must be the rule and not an exception to think globally when creating GTM strategy in medical technology development. In general, emerging markets are associated with higher volatility in terms of external environment than established developed markets. In these considerations PESTEL analysis is very effective⁶. According to Porter (1980) there

⁶ PESTEL is an acronym for political, economic, social, technological, environmental, and legal. PESTEL analysis provides a framework to assess macro environment of the company and its situation (Yüksel, 2006).

are several factors that might affect to short-time profitability of an industry like fluctuations in economic conditions over business cycle, strikes, spurts in demand, or material shortage. As these might affect tactical decisions, competitive strategy should be based on technological and economical structure analysis (Porter, 1980).

When finally entering the new market, Porter (1980) explains how industry competition extends beyond the established players and how the forces together determine the intensity of industry competition and the total potential for profitability. For example, even though it would be very difficult to enter the industry and the company A in the industry would have a very strong market position, if there is a superior cheaper substitute it limits the potential profits for the company A. Following are the Porter's five forces explained based on his article:

1. **Threat of entry:** There are several factors to consider like cost of entry, barriers of entry, economies of scale, need for distribution channel, product differentiation, switching costs, government policy, different kind of cost advantages of established companies. As the need to invest a lot of money creates a barrier of entry into industry, MDR is such a barrier to EU wide medical device market (Ginot, 2016). It does not only make entry taking longer but because of regulatory demands also more expensive.
2. **Rivalry between existing competitors:** Tactics here are price competition, advertising battles, new products and increased customer service or warranties. Number of firms in industry affects a lot as well as slow or rapid market growth. Some other factors that matter are high fixed costs, chronic overcapacity, if product is perceived as a commodity, diversity in companies, need to achieve success, or a high exit barrier.
3. **Pressure from substitute products:** All firms in the specific industry are competing with other industry firms producing substitute products. Important substitutes are products that can basically fulfill the function of the original product and have steady price-performance tradeoff, have minimal switching cost, and are produced by high profit industry. To be effective in defending substitute products, industry firms might need to make a collective action for example in terms of advertising.

4. **Bargaining power of buyers:** There are some aspects that make buyers powerful like large volume purchases in relation to seller sales, market condition information, partial integration, impact of the supplier's product, and switching costs.
5. **Bargaining power of suppliers:** If suppliers have bargaining power they are able to rise prices or reduce the quality of their goods. Factors that raise power are small amount of dominating supplier companies that are more concentrated than the industry they are serving, supplier is selling to many industries and one industry does not represent a significant share of all sales, differentiation and switching costs, and a credible threat of forward production, while threat of substitutes lower the bargaining power. Labor can be seen as supplier as well and a high degree of organization combined with limited supply of scarce employees might affect to competition. Government has also a powerful role if it is a supplier or a buyer because there are political factors in place instead of economic circumstances.

3.2.3 Entry mode plan

Entry mode decision is one of the very important ones in GTM strategy. For a global firm this is not always such an issue as there can be international distribution channels in place but for a smaller company entry mode decision matters a lot. Buckley and Casson (1998) established a model (FIGURE 4) to explain entry mode strategy variants, and especially important in their model is how they make a distinction in the investments between production facility and distribution facility. They assume that R&D is made in home location as the location of R&D is not that relevant from entry decision point of view. They identified four main entry strategies: exporting, licensing, joint venturing and wholly owned foreign investment. In addition, firm is able to choose between greenfield investment and acquisition as well as between subcontracting and franchising (Buckley and Casson, 1998). With distribution Buckley and Casson (1998) means warehousing, transporting and in some cases retailing.

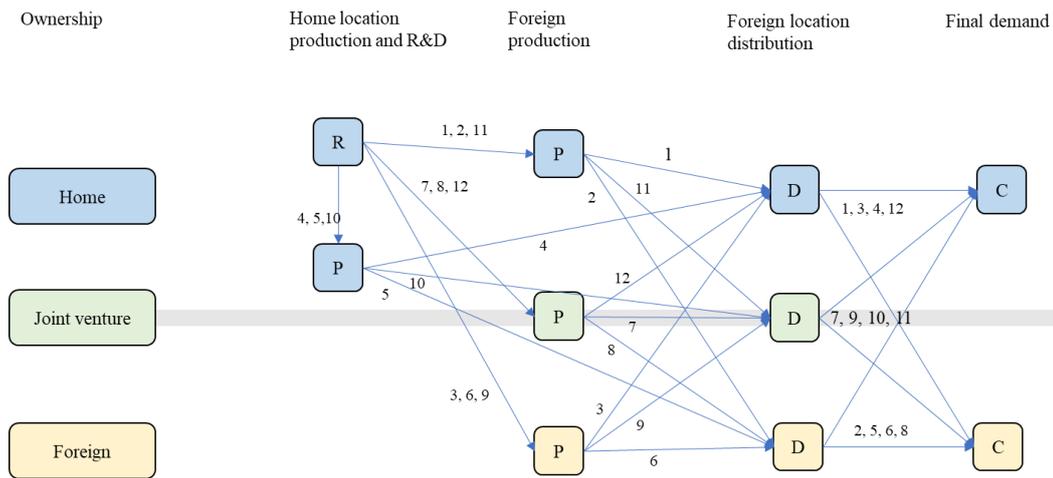


FIGURE 4. Entry mode options adopted from Buckley and Casson (1998).

Buckley and Casson (1998) acknowledge that in all those cases where entrant owns foreign production or distribution facility that ownership might be a result of greenfield investment⁷ or acquisition. In FIGURE 4 there are altogether 12 variants for a firm to enter a market. By following a specific number, it is possible to see what is the strategy variant. For example, number 1 strategy means that the firm owns foreign production and distribution facility either by greenfield investment or by acquisition.

Distribution channel is an important building block in the GTM strategy. Especially crucial it becomes if competitors have long relationships with existing channels and a newcomer must cut its profit in order to get its product accepted or in extreme case to create a totally new distribution channel for entering the industry (Porter, 1980). Also Borden (1964) sees channels of distribution very important and especially focuses on policies and procedures for used channels between manufacturer and consumer, how selective wholesalers and retailers are, and to put effort for making cooperation of the trade higher.

3.2.4 Marketing plan

According to Van Waterschoot & Van den Bulte (1992) marketing mix is part of fundamental ideas in marketing. The question behind marketing mix is what Borden (1964:8)

⁷ Greenfield investment means that firm establishes a new facility in the country without existing facility.

asks: “How can advertising, personal selling, pricing, packaging, channels, warehousing, and the other elements of a marketing program be manipulated and fitted together in a way that will give a profitable operation?”. As kind of an answer Borden (1964) gives the marketing mix⁸, which refers to combination of following marketing elements: product planning, pricing, branding, channels of distribution, personal selling, advertising, promotions, packaging, display, servicing, physical handling, and fact finding and analysis. According to him, there are four forces that govern the mixing of marketing elements: 1) consumer’s buying behavior, 2) the trader’s behavior, 3) competitors’ position and behavior, and 4) governmental behavior. As this Borden’s checklist approach is somewhat complicated, many marketing researchers started to develop simpler classification, and so 4P configuration of marketing mix emerged being pragmatically developed and widespread (Van Waterschoot & Van den Bulte, 1992). 4P classification include product, price, place, and promotion, and according to Van Waterschoot & Van den Bulte (1992) it has got some critic as well in the marketing literature. Still 4P model is one of the main contemporary conceptualization of marketing mix and it has achieved its aim to be easy to apply.

Value creation is also a one of the basic concepts of marketing. In that area, blue ocean strategy is well-known strategic tool to differentiate firm’s business. As strategy is nothing without proper execution, that was the topic in Chan Kim and Mauborgne (2015) article in which they discuss about that very concept. They provide three propositions to successful blue ocean strategy: value, profit and people. According to them, it is important to have a business which creates value for customers so that they are willing to buy the product. However, without good business model it is not possible to make profit which is essential for any business. Finally, if personnel are not willing to execute chosen strategy, it is useless to have such a strategy. Thus, people are in key role and the strategy should motivate them.

⁸ If reader wants to learn more, Borden (1964: 9-10) gives a very detailed description of each elements of marketing mix and its governing market forces. For example, Borden links consumer’s buying behavior similarly to buying power of consumer like Porter (1980) does.

3.2.5 Regulatory strategy

In the current regulatory landscape, it is important for companies to think globally but also regulators do the same. As McDermott Will & Emery (2017: 3-4) suggest that “*while the new Regulations reflect a trend toward greater harmonization of EU and US requirements, companies with global operations, distributions and products should take a holistic approach to compliance and implement regulatory and compliance processes that are appropriate, adaptable and scalable for a global marketplace.*” This is especially true and important for international or global companies but also for smaller companies willing to spread their product offerings to international marketplace.

The most important aspect in regulatory strategy is to decide if product falls into which device class. It would be good to think in strategy if it is possible to decrease product classification or get totally free from it downgrading from MD to non-MD and that way reduce the burden coming from MDR (Ginot, 2016). The intended use of the device is important in these considerations and affects to marketing strategy and down to market analysis as well. If customers will be individuals and not medical doctors for example, it might be possible to argue that product is health technology product and not a medical device at all. On the other hand, if intended users are medical doctors in hospitals and device is used in medical practice, it is very difficult to argue that it would not be a medical device.

Regulatory aspects cross many aspects in the GTM strategy and thus those must be taken in account in order to successfully operate in the market. Without complying the regulation of selected market, it is impossible to access the market and thus regulatory aspects are essential. In EU, new MDR makes the time to market period longer (Ginot, 2016) and thus regulatory strategy is especially important in order to beforehand address the possible regulatory burdens. To get an approval in the first market makes it possible to leverage it to other markets as well becoming an essential part of successful GTM strategy (Elan & Chatwin, 2017). However, this is very interrelated to internal operations of the firm and it requires that there are all the internal elements such as quality management system in place producing required artifacts for regulatory approvals in other countries.

Elan & Chatwin (2017) give few points what they think should be included and needed in an effective regulatory strategy:

- to develop a GTM strategy as early as possible
- to study the regulatory landscape in the target market in order to reduce time to market and setbacks
- to make a strong focus on quality because quality management system is a requirement in almost all regulatory approval schemes in medical device industry
- to think how to make document management system to support timely responses to inquiries from regulatory authorities
- to have experienced staff in board helping with regulatory submissions in key target markets

3.3 Synthesis of theory

Ginot (2016) argues that regulatory strategy must be a part of GTM strategy being its essential building block. At theoretical level this thesis concludes that in medical device industry regulatory strategy must be incorporated in GTM strategy in order to assure that all regulatory approvals are on place and products fulfill regulatory requirements. It is important to make a GTM strategy draft in the very beginning of the product development as there are requirements for QSM for example and if both EU and U.S. markets are in the scope of GTM strategy the applied QMS to product development and operations has to be also ISO 13485 certified and FDA 820 CFR part 21 compliant. Thus, it is possible to argue that quality management system is the basis for all the other activities in order to make sure all regulatory requirements are fulfilled in the pre-market, placing on market and post-market phases.

The framework provided by Meester (2008) is developed further in this thesis. FIGURE 5 presents the elements of GTM strategy which incorporates the regulation as an integrated framework for this thesis. It is notable that in generic GTM strategies regulatory strategy is not included but when specifically focused on medical device industry it is not possible to bypass regulatory aspects in the GTM strategy. In addition to five categories identified from literature and discussed in sections 3.2.1 – 3.2.5, there are target market selection and tactical plan included in the framework. Target market selection is not an activity as such but more a conclusion what are the decided target markets in the scope

of the GTM strategy. Tactical plan, as explained earlier, is also an essential element in the GTM strategy as it operationalizes the strategy to actions. In some sense, all the aspects of GTM strategy should be in two-way connection with each other as those are not isolated phases of strategy creation but more parts of one holistic strategy. It is very difficult to separate marketing plan to all other parts of the model. The model is not a linear in that sense.

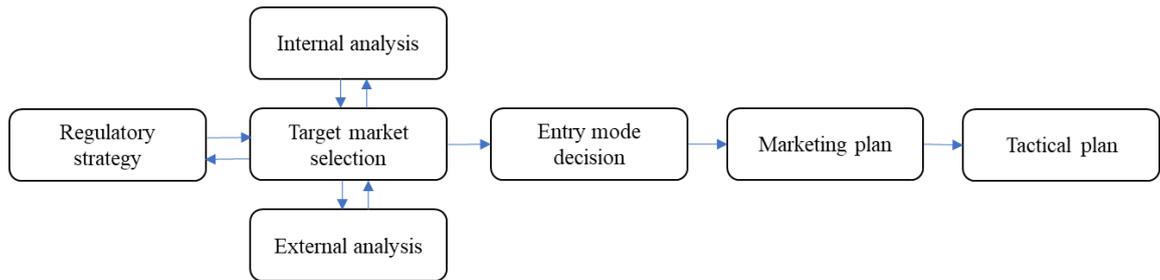


FIGURE 5. GTM strategy synthesis.

The reason why regulatory strategy is in form of strategy instead of regulatory plan, is that essentially it is a strategic decision to be made what countries' requirements are implemented in QMS and what country regulations are fulfilled with the product. Thus, this is a dialogue within the GTM strategy and at general level it might be not necessary to make a distinction between regulatory strategy and regulatory plan in relation to country regulations. Then, how to implement regulatory strategy, might be included in tactical plan if wanted, incorporating question like when to file a regulatory submission to the country. In MNC regulatory strategy is affected more by target market selection than other way around. For start-up, this is totally different case as there are no existing system in place, for example, it is important to have a quality management system (QMS). However, for both MNC and SU it is important to acknowledge the differences in markets regarding regulatory scheme applied. At general level, in TABLE 5 SU and MNC is compared to each other in order to show the differences in GTM strategy planning. Comparison is based on the assumption that for SU / SME there is no global network of channels in place for new product and QMS related aspects are not developed to be globally compliant. For MNC these aspects are assumed to work well and thus for them it is more a business type question to what markets are selected and do everything else accordingly. Because of the scale, SU and MNC cannot employ same procedures in their marketing strategy even though their product would be same kind of (Borden, 1964).

TABLE 5. Some different viewpoints between SU and MNC.

	SU / SME	MNC
Regulatory strategy	Should be decided in the beginning of the product development to what markets products are intended in order to make sure QMS and other processes are in place. Regulatory submissions focus on fewer markets.	International standards and QMS requirements are taken into account from the beginning so it is possible to decide later how to operationalize the regulatory strategy.
Internal analysis	Important to assess if there are all needed aspects of QMS, organizational arrangements that support operations, and other resources needed for operations.	Organization more probably is developed for international operations and processes are constructed accordingly.
External analysis	Focus on few market areas.	Many markets around the world. The focus is on planning the order of market entry.
Target market selection	The focus is on what markets to take in the plan.	As almost all countries are possible target markets, it is important to think what is the phasing for countries.
Entry mode decision	An important question as there is no established channels in place.	Usually there is already established channels and companies in several countries and regions to serve MNC.
Marketing plan	SU needs to focus on most important things in marketing plan.	Possibility to focus on details and to employ comprehensive procedures.

4 METHODOLOGY

4.1 Methodological approach

This thesis follows a constructive approach as guiding methodology (FIGURE 6). Kasanen et al. (1993) writes about the constructive approach in the context of management accounting but as they say it is used in technical sciences, mathematics, operation analysis, and clinical medicine. Indeed, their main point is to defend the use of constructive approach in management accounting doctoral theses because constructive approach was and is very widely used in master's theses.

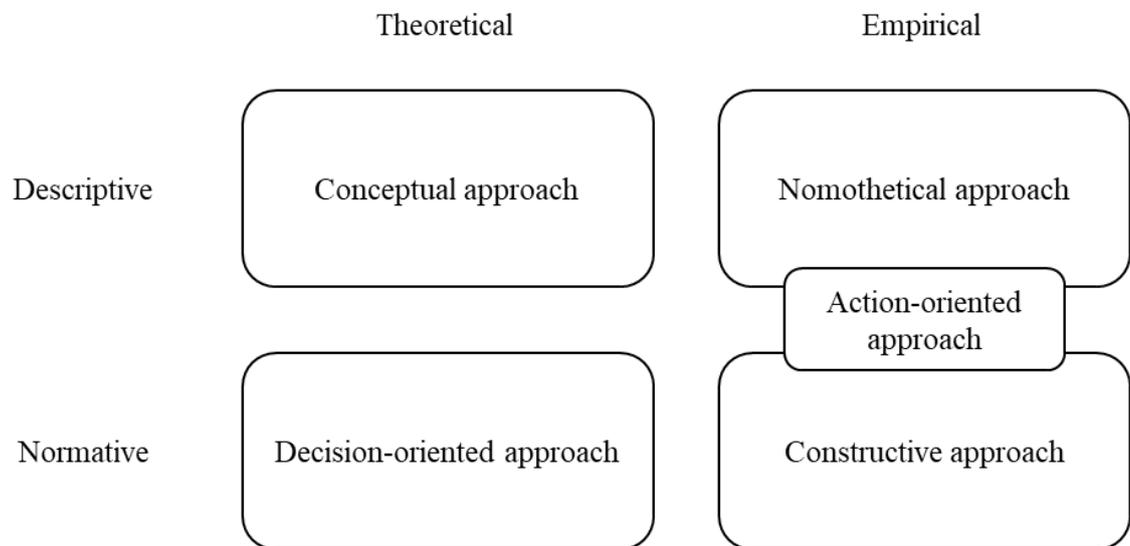


FIGURE 6. Methodological choices for management research (Kasanen et al., 1991, 1993).

Constructive research aims to produce a construction, which aims to solve a practical managerial problem (FIGURE 7). Construction can be a model, diagram, plan, organization or some other clearly defined artefact (Kasanen et al., 1993). Construction should be relevant in both practice and theory in order to fulfill the needs for both academic community and business community. Also construction should be functional in practice as well, otherwise it would make no sense to use it. These two attributes, i.e. functional and relevant, are important as without functionality it does not matter how relevant the construction is if it does not make any sense to apply in practice. On the other hand, even though the solution would be very functional in practice but if it does not solve the right

problem it just is not relevant. Beside connection to theory also theoretical contribution is important in constructive research as it justifies very practice oriented research.

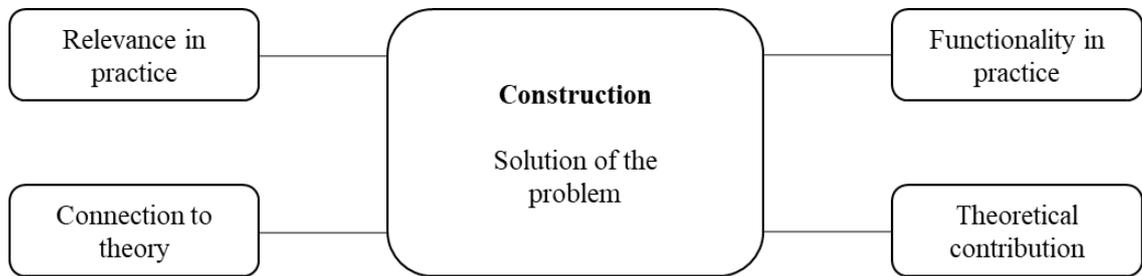


FIGURE 7. Content of construction produced in constructive approach (Kasanen et al., 1993).

According to Kasanen et al. (1993) the constructive research process consists of several phases:

1. Finding a practical problem with a research potential
2. Developing a deep enough understanding about the topic
3. Constructing a solution
4. Demonstrating that the solutions works
5. Showing theoretical connections and contribution
6. Examining the scope of applicability of the solution

These phases are adopted for the need of this thesis. Phase 1 requires to find a practical problem with research potential as is discussed in section 1.1. The new MDR provides a practical and relevant problem for this thesis. It is very contemporary challenge every medical device company needs to face in near future. Phase 2 requires developing a deep enough understanding about the topic that is done by reading a lot of material that is used also as a data for this thesis. Phase 3 requires to construct a solution, which has presented in section 5. In phase 4, it is demonstrated that the solution works that is discussed in section 6.1 and 6.2. In phase 5, it is discussed how research is connected and contributing to theory. This is discussed in section 6.1. In phase 6 the scope of applicability of the solution is examined. This will be documented in the section 6.3 in this thesis together with the evaluation of the research design and implementation in general.

4.2 Data acquisition methods

Due to the nature of the research problem addressed in this thesis it is decided to rely mostly on written material as an empirical data. Primary data for the analysis is the new MDR published by EU (MD Regulation 2017/745) and the reports from international consultancies and notified bodies (NB) operating in medical device industry. As the new MDR is a significant change in the industry, many of the international consulting companies have developed white papers to sell their expertise in the area and to help their customers to get a high-level understanding what is going to happen. Even though these white papers as such are not the whole truth, those give anyway a good supplementary information how the changes in MDR are interpreted. In addition, as MDR is altogether 177 pages long, it is not practical to compare the whole document to old directives. These white papers are especially useful when answering the research question as the consulting companies have done their high-level analysis regarding MDR with multiple researchers.

Research process was as following in this thesis. First Google search service was used to identify articles⁹. Keywords “medical device regulation EU changes”, “medical device regulation”, “medical device regulation changes”, and “medical device regulation EU” were used. Searching was conducted on 1.9.2017. With each keyword 100 first search results were reviewed and out of these 400 search results altogether 18 relevant articles, white papers, blog posts, news articles, facts sheets etc. were found. In addition, 4 white papers were found when checking webpages of relevant organizations and going forward with internal references in the found documents. Out of these 22 items 15 were selected for closer scrutiny based on following criteria: 1) publisher of the item is an international actor in medical device industry (law firms, NBs, consultancy agencies, NGO), 2) item focuses on changed aspects in MDR generally or clearly to specific sub-section of MDR, and 3) item contains analysis regarding changed aspects of MDR and not only a list of topics subject to change.

⁹ Even though the Google search service is not the professional tool to find scientific articles, in this thesis it does not matter as that was not the purpose of the search. Instead, more popularized content of MDR topic was subject for the search and in this kind of quest Google search service is very useful.

TABLE 6. Selected items for document analysis.

Author	Title	Date	Type	Firm type	Pages
BSI	Medical Devices Regulation What you need to know	May, 2017	Fact sheet	NB	42
BSI	The proposed EU regulations for medical and in vitro diagnostic devices - An over- view of the likely outcomes and the consequences for the market	Oct, 2015	White paper	NB	15
Cromsource	Changes to EU Medical Device Legislation – What you need to know	Jun, 2016	White paper	Consul- tancy	9
Deloitte	Preparing for the future: The new European Union medical devices regula- tion	2016	White paper	Consul- tancy	21
Emergo	Understanding Europe’s New Medical Devices Regulation (MDR 2017/745) – Key changes contained in the pro- posed MDR and their impact on manufacturers	May, 2017	White paper	NB	15
EY	How the new EU Medical Device Regulation will disrupt and transform the industry	2016	White paper	Consul- tancy	20
Hope	Analysis of the new Medical Devices Regulation (MDR) and In vitro diagnostic Medi- cal Devices Regulation (IVDR) draft texts	2017	White paper	NGO	10

Jones Day	EU Medical Device Regulation 2017/745 and In Vitro Diagnostic Regulation 2017/746	Jun, 2017	Article	Law	3
K&L Gates	Medical Device Regulation Update	May, 2017	White paper	Law	4
LNEGMED	The medical device and in vitro diagnostic regulations (MDR and IVDR): Changes and impacts	Apr, 2017	Blog	NB	5
McDermott Will & Emery	The New EU Regulation on Medical Devices Aims at Enhanced Product Safety and Further Harmonization	May, 2017	White paper	Law	4
NAMSA	EU Medical Device Regulatory Framework: Practical Impact of New Regulations	Jul, 2013	White paper	Consultancy	8
NAMSA	EU MDR Poses Significant Changes for Importers and Distributors	Jul, 2017	Blog	Consultancy	11
Squire Patton Boggs	EU Medical Device and IVD Regulations Overview Series Parts 1-2	Jan – Feb, 2017	White papers	Law	8
TÜV SÜD	The EU's Medical Device Regulation – Staying up to date with requirements	2016	Fact sheet	NB	4

As MDR was published in May 2017, there are not yet defined practices how to apply that in practice in companies. Thus, instead of doing interviews, in this thesis white papers published by international organizations were used as sources of data supporting the analysis of the new MDR content. However, few expert interviews were conducted as well focusing on developing the construction during the development phase of it and on changes in MDR in order to make sure that the construction development stays on the right track. These unstructured interviews gave support also in the interpretation of

changes in the MDR content. Altogether 3 peoples were interviewed. In addition, several discussion were conducted within the topic regarding changes in MDR in order to understand better the impact of new MDR.

TABLE 7. Conducted interviews.

Role of interviewee(s)	Number of interviewee(s)	Timing	Topics
Consultants in quality, regulation and technology	2 (group interview)	August, 2017	Requirements of MDR, effects to companies, significant changes.
Regulatory affairs program manager	1	October, 2017	Focus on post-market surveillance and clinical evaluation and investigation.

4.3 Analysis methods

As already published documents were primary data source for this thesis, document analysis is used as an analysis method. Document analysis is an affordable way to get empirical data but it is still often combined with interviews to ensure credibility of results and reduce potential bias for results¹⁰ (Bowen, 2009). This practice is applied also in this thesis as document analysis is complemented with interviews.

Protocol in document analysis includes phases of finding, selecting, making sense of, and synthesizing data contained in documents under analysis (Bowen, 2009). First two phases were discussed already in section 4.2. Based on the selection process altogether 15 items were chosen for analysis. Making sense of data contained in documents is a challenging task due to great amount of pages. Analysis started with reading through all the documents and to identify changes in MDR described in documents. These identified changes were

¹⁰ There are several ways to do triangulation: data, methods, theories, and researchers (Laine et al., 2007). Idea of triangulation is to reduce bias as mentioned e.g. by Bowen (2009) but also to deepen the understanding of the understanding of the case (Laine et al., 2007). This deeper understanding of the studied phenomenon is the main reason in this thesis for conducting few interviews in addition to document analysis.

put to matrix in order to see what were the most common changes. Altogether 57 changes were identified. This phase already was based on researcher's judgement and interpretation as identified changes were grouped and counted. Then these 57 changes were grouped forward resulting 10 distinct groups. The first of the groups contained general introductory topics and 9 others more specifically changes in MDR compared to earlier directives. Each of these groups are discussed in section 5. These identified themes were also studied against MDR in order to get more insight regarding the changes and to confirm the interpretations made in studied documents. As there were many sources implying specific changes and MDR supported the notions, it was decided not to reference to specific sources in the section 5 but write about changes based on analyses. In the case of original ideas presented in data source, references are given.

Alongside with the document analysis also few interviews and group discussions were conducted. The first interviews were done mainly to confirm the importance of topic, to study the changes in new MDR and to get a general feeling about it among the practitioners in the field. Following interview focused on the major changes identified in the data analysis. The aim of the interviews was to both validate the construct made out from significant changes in the MDR but also to get more insight regarding new requirements and the implication for the firms entering the EU medical device market.

5 RESEARCH RESULTS

5.1 Introduction to medical device regulation

Articles are quite in agreement that MDR increases transparency, traceability and patient safety as well as quality and reliability of medical devices. Some of the weaknesses in existing directives were according to EY (2016) that existing rules were not able to follow technical and scientific progress, patients and care providers did not have access to sufficient information regarding safety and clinical performance of device, devices were not always possible to track back to original suppliers, and different EU countries interpreted requirements differently. These weaknesses are tried to solve now in MDR. However, several patients have been suffered from these weaknesses already. According to EY (2016) there were several this kind of events that triggered the need for regulatory reform in Europe:

- August 2010 there was a recall of ASR™ metal-on-metal hip replacement system because there was a five-year failure rate for the product about 13%.
- July 2011 U.S. FDA gave a warning regarding serious complications associated with surgical mesh for transvaginal repair.
- June 2012 became known that Poly Implant Prothese sold breast implants made with industrial-grade silicone instead of medical-grade silicone affecting about 300 000 women.

The reform in medical device industry regulation do not come without cost. As EU used to be an attractive first market, under MDR that might be not the case anymore as market authorization timeline will be longer and with more cost. Regarding existing devices on the EU market, evidence for those might need to be updated to be compliant with MDR. Thus, from business perspective, there is a good opportunity to go through the product portfolio in order to determinate MDR's impact on profits or as EY (2016 :7) put it out: *"Market access will require companies to conduct deep portfolio audits to determine impact on margin"*. Even though many firms do regular reviews to their product portfolio, now as new requirements appeared for existing products as well, the cost to comply MDR might get so big that from business point of view the decision in some cases can be that it is more profitable to stop selling the product. As Deloitte (2016: 1) argue: *"Cost of*

compliance will most likely be significant". A one consequence is that to be effective in complying MDR a cross-functional approach is needed. Here regulatory affairs function has a great opportunity to bridge the knowledge gap to C-level people in company in order to help companywide approach to understand the MDR's impact to product portfolio.

FIGURE 8 presents those identified changes from analyzed articles that were mentioned at least in three articles. Altogether over 50 unique changes were identified. This section 5 is organized based on results stemming from empirical part of this thesis. For example, Deloitte (2016) explains how supply chain, product safety and PMS, overhaul of QMS and its certification, and clinical evidence requirements all are impacted and where new requirements are mostly felt. These all are identified here also as major categories of changes. Even though findings are categorized within following 9 sections, many of those are very connected in practice.

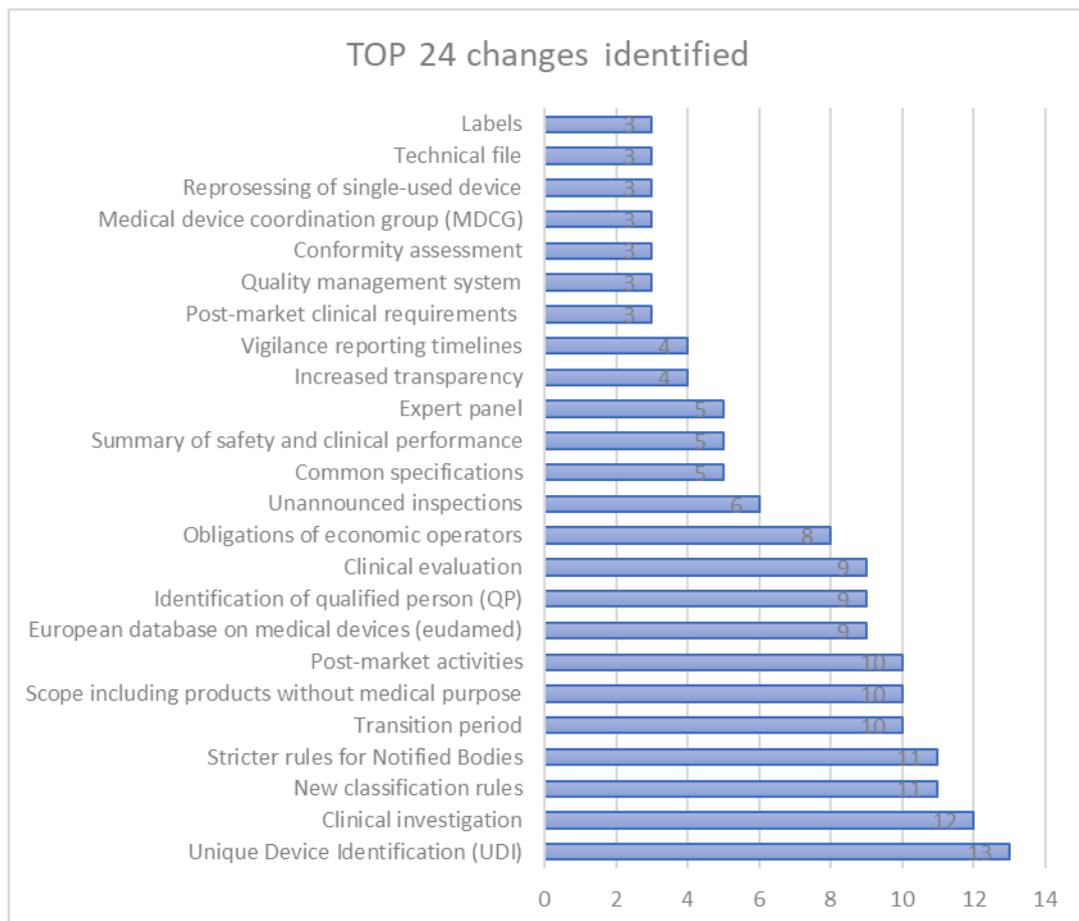


FIGURE 8. Top 24 changes identified from analyzed articles.

Transition period for MDR is explained in Article 120 of MD Regulation (2017). In general, the transition timeline is three years for manufacturers to get their certificates updated in accordance with MDR. FIGURE 9 summarizes the main dates that are listed below:

- 24 May 2017: Certificates prior MDR are valid until the end of period indicated in certification
- 25 May 2017: MDR comes into force
- 26 May 2020: No registrations based on MDD are allowed
- 26 May 2020: No significant changes in design or intended use are allowed (for MDD devices) and post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply instead of the corresponding requirements in those Directives
- 27 May 2022: Certificates based on Annex IV prior MDR become void at the latest
- 27 May 2024: Certificates after MDR become void (or after 5 years from issuance)
- 27 May 2025: No more making available on the market or put into service based on MDD

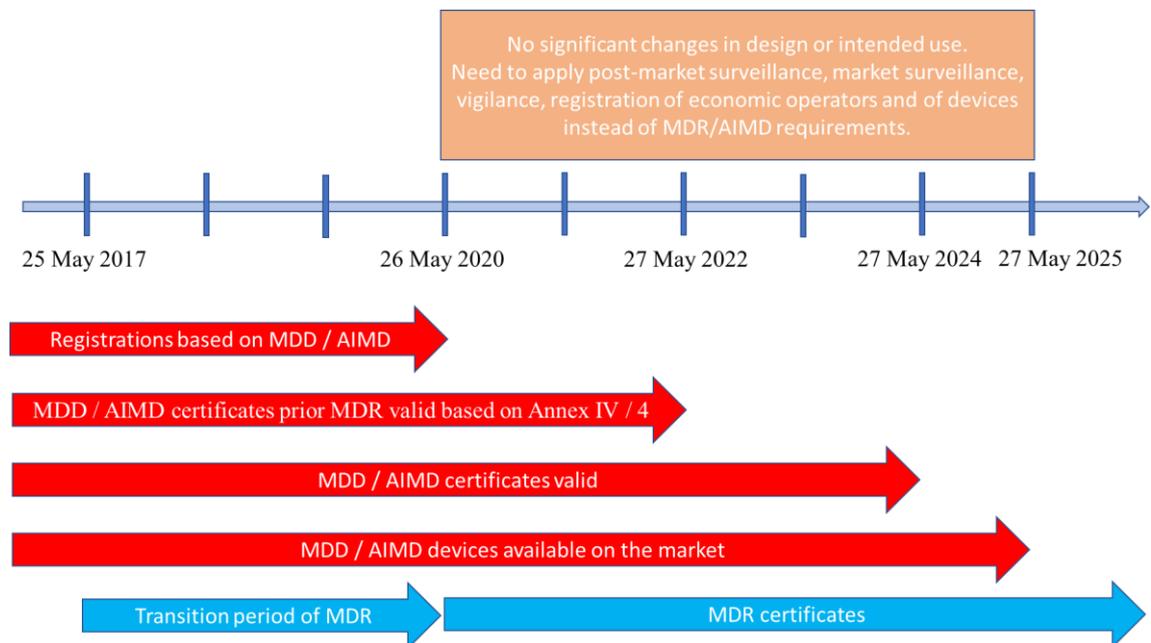


FIGURE 9. Transition timelines based on MD Regulation (2017).

5.2 Full life-cycle approach

MDR does not only focus on pre-approval part of product life-cycle meaning the path to CE-marking but the viewpoint comes from the full product life-cycle approach. In this sense, the MDR comes closer to U.S. FDA regulations and many international standards. Concretely this can be seen as many European guidance documents' (MEDDEVs) content is incorporated into practice in MDR including guidance on authorized representation, clinical evaluation, vigilance, and post-market clinical follow-up. Therefore, there is less space for interpretation because these are mandatory requirements in MDR. Because of this, current processes in the firms need to be evaluated and it might be possible that some re-engineering will be needed to bring the processes up-to-date with MDR requirements.

5.3 New databases

It is the responsibility of the Commission after consulting Medical device coordination group¹¹ (MDCG) to set up, maintain and manage European database on medical devices (Eudamed) consisting of several databases summarized in Article 33 (MD regulation, 2017). As these databases are all under Eudamed, BSI (2017) presents the databases included in MDR as a building where Eudamed is a roof and UDI database and electronic system on registration of economic operators as a second and first floor. In the middle as pillars are the rest five databases. Eudamed includes the summary of safety and clinical performance in addition to these following databases:

The electronic system for registration of devices: This is part of Eudamed database and includes information described in Section 2 of Part A of Annex VI. This database contains information relating to the device.

The UDI-database: UDI is developed to get a better traceability of a product throughout the supply chain. The UDI number include a device and a production identifier and is

¹¹ Role of MDCG is presented in section 5.9 concerning authorities and their role.

labeled in the product and in its packaging. The UDI database is accessible to the public with no charges.

The electronic system on registration of economic operators: This is a database including information described Section 1 of Part A of Annex VI. This includes type of economic operator whether it is manufacturer, authorized representative, or importer; its name, address, and contact details; and name and contact details of anyone who has carried out the registration on behalf of economic operator. In addition, contact details of person in responsible for regulatory compliance must be registered as well.

The electronic system on notified bodies and on certificates: This database includes information about notified bodies and their operation. It also includes information concerning certificates of conformity issued as well as suspended, reinstated, withdrawn or refused certificates, and any restriction put onto certificates.

The electronic system on clinical investigations: This database is used to create identification numbers for clinical investigations and as an entry point for the submissions for clinical investigations and report as an endpoint. The database is also used to report adverse events occurred during the clinical investigation.

The electronic system on vigilance and post-market surveillance: The Commission sets up and manages this database in collaboration with Member States in order to process and collate information regarding reports on serious incidents and field safety corrective actions and periodic summary reports if applicable. It also includes periodic safety update reports and field safety notices. Statistically significant increase in the frequency or severity of incidents is also something that might be needed to report as well.

The electronic system on market surveillance: This database includes information regarding conducted surveillance activities and inspection reports. It also include information regarding devices that have an unacceptable risk to health and safety or is non-compliant. Also, any preventive health protection measures, e.g. such as device withdrawal from market or recall, can be found from this database.

5.4 Product classification and approval

All currently approved devices need to be recertified according to new MDR requirements. Also the scope of products that are included in MDR is broader than it was in previous regulation. In MDR, there are several products in the scope still not being medical devices. These devices are listed in Annex XVI and are as followed: contact lenses, surgically invasive products intended to modify anatomy or fix body parts, substances to be injected to human, equipment used for fat tissue removal, light emitting equipment including lasers and other intense pulse light equipment, and brain stimulators. These are subjected to common specifications that are considered to be state of art technical and clinical set of requirements and exists in parallel to the harmonized standards. Manufacturers needs to comply with common specification but it is also possible to apply solutions that ensure an equivalent level of safety and performance.

In MDR there are 22 rules how to classify different devices. The classes of devices are I, IIa, IIb and III. The lowest class is I and it is the default class. Generally regarding classification rules, there are not very big differences. However, existing devices must be assessed according to new classification rules to make sure that classification will be correct. Accessories for a medical device are classified independently from the medical device. In MDR, all medical devices, accessories and devices with non-medical purposes listed in Annex XVI of MDR are referred as devices and thus there is no separate rules for those except if specifically mentioned. Assessment of the conformity is done according to applicable conformity assessment route described in annexes IX, X and XI (MD Regulation, 2017). For Class I products EU declaration of conformity is enough and there is no a separate route to conformity assessment. Article 52 in MDR describes conformity assessment routes for each device class.

One of the biggest changes in definitions is that software is an active device according to MDR. This has straight implications to device classification and also it means that unlike in the previous regulation, in MDR it is directly stated that software is a medical device as any other even though there is no hardware component associated with it. Because of the classification rule, most software products fall into the class IIa and in some cases IIb unless it is possible to argue that software is not used for making decisions with diagnosis or therapeutic purposes then being class I. Mentioned explicit inclusion of software in

classification however has significant consequences for software industry and especially mobile health sector. There is no more possibilities to exclude software or mobile application from fulfillment of regulatory requirements if the application fall to definition of medical device. Lifestyle or wellbeing software is however out of MDR's scope.

Reprocessing of single-use device is only acceptable if national law allows that and even in that case, requirements of MDR need to be followed and anyone who reprocesses single-use device is considered to be a manufacturer. The consequence is that the one who reprocesses the device needs to fulfill requirements required from manufacturer. In some cases, it is possible that Member States decide not to apply all rules if requirements announced in Article 17 are fulfilled. It is also possible that Member State introduce a stricter law than the MDR regarding reprocessing of single-use devices.

Essential requirements of previous regulations are replaced in Annex I by safety and performance requirements. Even though these are similar, the level of detail is increased in MDR regarding these as well as the number of requirements. Annex II in MDR describes what technical documentation needs to be provided. There are new implications on information included on labels in MDR and those has to be taken into account. For example, there should be an indication that device is medical device. Annex III describes technical documentation on post-market surveillance including PMS plan, periodic safety update reports and PMS report. Regarding instructions for use, class I/IIa devices are exempted if those devices can be used safely without any instructions. MDR provides a detailed list of content what should be included in the instructions for use.

5.5 Quality management system and related requirements

Manufacturer needs to establish, document, implement and maintain a risk management system, which needs to be applicable to the whole life-cycle of the product. In addition to that, also quality management system (QMS) is obligatory for manufacturer. QMS needs to be established, documented, implemented, kept up-to-date and continually improved and it should be compliant to the MDR *“in the most effective manner and in a manner that is proportionate to the risk class and the type of device”* (MD Regulation,

2017: 26). QMS incorporates the regulatory requirements and ensure systematic implementation of those throughout the device life-cycle. According to Deloitte (2016), the implementation of EN ISO 13485:2016 QMS is in the critical path for CE-mark approval and must be taken into account. Transition period for that is until March 2019. Especially important this in the in the cases, due to the mergers or acquisitions for example, where manufacturer has several QMS incorporated globally. In addition to QMS requirements, products and suppliers are faced increased scrutiny by regulatory authorities in forms of inspections and audits in order to ensure compliance to the requirements. This has an implication for manufacturers as well to emphasize more the product testing.

Every firm in medical device industry needs a qualified person (QP) who is responsible for regulatory compliance. The qualification person should have, is either a university degree in law, medicine, pharmacy, engineering or another relevant scientific discipline combined with at least one year of professional experience in quality management systems or in regulatory affairs working with medical devices, or without the university degree four years of professional experience instead of one year. Micro and small enterprises do not need to hire a QP but needs to have one available. For others, the person needs to be hired to the company including authorized representative. The responsibility QP has is quite extensive including check of conformity of the devices, up-to-date technical documentation and EU declaration of conformity, the PMS obligations, the reporting obligations, and the statement regarding investigational devices. QP must have a full authority in manufacturer's organization to fulfill his duties.

5.6 Post-market surveillance system and vigilance

Manufacturer needs to establish a post-market surveillance (PMS) system, described in PMS plan, which gathers data on quality, performance and safety, and on handling of preventive and corrective actions. There are several activities to which data gathered by PMS system must be used to. The electronic system on vigilance and post-market surveillance is used for PMS system reporting purposes. The major change in PMS system is the need to gather real-life data for the post-market clinical performance evaluation feeding clinical evaluation and risk management process. Thus, PMS plan includes also PMCF plan as well.

MDR makes a difference between serious and non-serious incidents regarding reporting guidelines and timelines. Manufacturer needs to track incidents and to report if there is any statistically significant increase in the frequency or severity of incidents that are non-serious or that are expected to have undesired side-effects that 1) could have impact on the risk-benefit analysis and 2) could lead to risks to health of safety of patients, users or other persons and 3) are unacceptable when weighted against the desired benefits. Manufacturer needs to estimate the foreseeable frequency and severity of such incidents and assess the increase based on that.

Regarding serious incidents, manufacturers need to report to relevant competent authorities those as well as field safety corrective actions conducted for the product or involving the product. Even though timeline for reporting is dependent on the severity of the serious incident, manufacturer needs to report serious incidents immediately when they know the causal relationship between their device and the incident. The maximum delay for reporting is 15 days after manufacturer became aware of the serious incident that means that manufacturer needs to put effort to the investigation. In the case of death of patient or dramatic deterioration of patient's health, this is only 10 days maximum or as soon as there is a suspect regarding causal relationship between serious incident and the device. If manufacturer becomes aware of event of a serious public health threat it has to report that immediately or in two days. In all these cases, it is possible to submit first an initial report in order to make sure that timely reporting is achieved and then update it later. Also, if manufacturer is unsure whether to report an incident or not, this kind of potentially reportable incident needs to be reported as well within the timeframe required.

Class IIa device manufacturers need to update periodic safety update reports every two years and class IIb / III device manufacturers need to update it annually. Throughout the life-cycle of the product following aspects needs to be set out: the conclusions of the benefit-risk determination, the main findings of the post-market clinical follow-up (PMCF), the volume of sales, an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device (MD Regulation, 2017: 74).

5.7 Clinical development and surveillance

Clinical aspects of medical device requirements include possible clinical investigations providing clinical data, clinical evaluation and post-market clinical follow up. To conduct clinical evaluation, manufacturer needs to establish and to keep up-to-date a clinical development plan, which first of all identifies relevant safety and performance requirements needing support from clinical data and is applicable to the whole lifecycle of the product from the very first first-in-man studies to PMCF, which is a part of PMS system and its purpose is to continuously keep clinical evaluation up-to-date. Clinical evaluation plan includes also a clinical development plan, which describes the progression from exploratory investigations and ends to confirmatory investigations and includes milestones and acceptance criteria.

Manufacturer needs to plan, conduct and document clinical evaluation, which needs to be in line with the characteristics of the device and its intended purpose. Clinical evaluation should be conducted in line with MEDDEV 2.7/1 rev 4 (being the newest) guidance and it needs to be a systematic process focusing on device's performance and safety aspects. Clinical evaluation process evaluates the clinical data that can be gathered from manufacturer's own clinical investigation with the medical device itself or it is possible to use data produced with similar device reported in scientific literature.

Clinical data is the basis for confirmation of conformity with safety and performance requirements as well as for the evaluation of undesirable side-effects and acceptability of risks and benefits analysis of the device. Thus, clinical data needs to provide sufficient clinical evidence, which is subjected to clinical evaluation and wrapped-up in clinical evaluation report. In general, MDR includes stricter requirements for clinical investigations and clinical evaluation. Thus, already conducted clinical investigations for existing products might be needed to update. The electronic system on clinical investigations should be interoperable with the EU database used for clinical trials on medicinal products for human use. There are similarities between MDR and the regulation on clinical trials which means that current clinical trial systems developed for human medicinal products can be used as a basis for medical device investigations.

Regarding summary of safety and clinical performance, MDR defines in Article 32 what should be included in it. This includes a lot of information regarding device for example intended purpose, summary of clinical evaluation, and information on PMCF. Post-market system should provide input to clinical evaluation and for implantable and for class III devices PMCF should include also “*post-market studies to demonstrate the safety and performance of device*” (MD Regulation, 2017: 58).

5.8 Supply chain management

Supply chain of medical device is much more regulated than it used to be in previous directives (FIGURE 10). Economic operators, including manufacturer, authorized representative, importer and distributor, are facing a higher level of responsibility regarding medical device. In MDR the requirements for cooperation between economic operators has increased significantly as well as responsibility for each economic operator. Thus, it should impact on supplier agreements between economic operators. Throughout the whole supply chain a level of scrutiny has increased as well. MDR applies also to cases where distribution is organized through Internet.

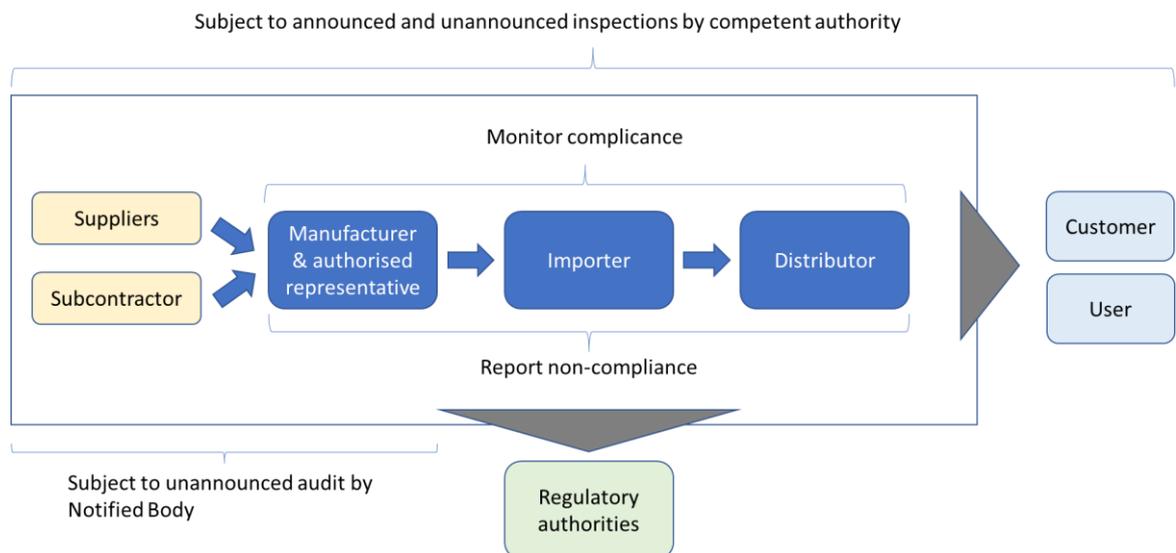


FIGURE 10. Economic operators in the supply chain. Adapted from Deloitte (2016) and BSI (2015).

Identification requirements within the supply chain are strict and all economic operators must collaborate in order to be able to achieve traceability of devices. All economic operators must be able to identify from which economic operator they have received a device and to whom they have directly supplied the device being it either other economic operator or any health institution or healthcare professional. In addition, each economic operator needs to make sure that previous economic operator has fulfilled MDR requirements. It means that both importer and distributor needs to ensure independently that manufacturer has fulfilled its responsibilities and the device meets all MDR requirements. However, there are many questions related to these responsibility questions and it might take some time until there are correct interpretations about that.

Manufacturer needs to cooperate with other economic operators regarding post-market surveillance as well. Importers and distributors must forward to the manufacturer or to the authorized representative all complaints and reports about suspected incidents from end users. If incident is serious importer and/or distributor must report it also to relevant regulatory authorities.

Distributor or importer gets the obligations of manufacturer if it 1) makes the device available on market under its name, registered trade name or registered trade market, 2) changes the intended purpose of device placed on the market, or 3) modifies the device placed on the market. Exception to the point 1 is if there is an agreement between manufacturer and distributor or importer that manufacturer is identified in the label and is responsible to fulfill the requirements of the MDR. In that case distributor or importer does not get the obligations of the manufacturer.

5.9 Authorities and their roles

There are several authorities and actors governing medical devices. First of all, Member States of EU have a lot of authority to the MDR as they constitute Commission and MDCG. Commission has a lot of responsibility although they must consult often MDCG first. Commission is able to make a decision for example whether or not some product or category of products falls within the definition of medical device. Member states designate competent authorities that are responsible for implementing MDR. Also Member

States appoint persons to MDCG, which has several tasks in advising the Commission, contributing to several activities established in MDR and implementing MDR, and to assist competent authorities of the Member States in their coordination activities. Commission may designate expert panels for making assessments of clinical evaluation evidence and expert laboratories having expertise in physico-chemical characterization or different kind of biological, mechanical, electronic and toxicological testing. According to MDR members of MDCG, expert panels and laboratories must be independent and should have not any financial or other interest in medical device industry affecting their impartiality.

Member States designate NBs and in such cases Member States also need to appoint an authority to conduct activities to establish a NB and monitoring it later. In MDR, the role of notified bodies changes from an industry partners to “policing bodies” as they have both right and duty to conduct unannounced factory audits for example (Hope, 2017). These unannounced audits and product sample checks NBs are expected to do also means they have more authority than previously. However, it is also expected much more from NBs as they need to follow stricter rules in their operations. In addition, there is for example a special procedure for some class IIb/III devices which requires NB to conduct a clinical evaluation assessment report and forward it to Commission, which forwards it to the relevant expert panel giving or not to give a scientific opinion about clinical evidence that might affect to the certification process.

One important clarification in MDR relates to liability of manufacturer regarding a defective device. Natural or legal person is able to claim compensation in a manner that is in proportion to the device risk class and type as well as the size of the enterprise in question. Manufacturer needs to have measures in place to provide sufficient financial compensation based on their potential liability.

5.10 Implantable devices

At general level, implantable devices are incorporated to MDR alongside with other medical devices. Implant card is introduced in Article 18 in MDR. Manufacturer needs to

provide following information with the implantable device: information allowing identification of the device; any warnings, precautions or measures relevant for patient or healthcare professional regarding how the device interferences with different situations; information regarding expected lifetime and necessary follow-ups; and all other information that is needed for the safe use of the device. All this information needs to be so easily understandable that a layman is able to understand the content of the information. This information needs to be available for patients in a Member State's language and via website of the manufacturer. Also health institutions need to make information about implants available for patients. There are some implants that are not in the scope of the implant card such as sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. Regarding materials used in the devices and implants, there are strict rules how much carcinogenic, mutagenic or toxic, or endocrine-disrupting substances can be found from materials used in invasive materials, or from those materials that are used in administer medicines, body liquids or other substances, or transport or store such medicines, body fluids or substances.

5.11 Synthesis of results

Based on these analyzed changes a construction can be developed summarizing most relevant aspects of changes for GTM strategy development. The construction includes following elements:

- **Full life-cycle approach:** MDR takes into account the whole life-cycle of medical device. Thus, there are more requirements focusing on after-market processes and those processes need to be incorporated into the quality management system.
- **New databases:** New databases require manufacturers to share some information about medical devices that was not necessary earlier. In addition, activities around the databases affects to the company and its supply chain network as well.
- **Product classification and approval:** In previous regulation registration of software applications was easier and could cost less generally speaking, but MDR requires in many cases to register medical apps. Similar kind of up-classification has happened for other products as well. As existing products need to comply with

regulation, in some cases this means that more documentation needs to be provided. Thus, it is an important place to think if all products really are needed in the market or if their business cases are good enough.

- **Quality management system and related requirements:** Regarding qualified person, micro and small companies need to make sure that they have a one either permanently or from consultancy. For other companies QP needs to be hired.
- **Post-market surveillance system and vigilance:** PMS system needs to be in place for gathering data from the field regarding medical devices.
- **Clinical development and surveillance:** There are new requirements in MDR regarding clinical data and clinical evaluation and those need to be taken into account when implementing requirements of MDR. As there is a possibility that clinical evidence of existing devices must be updated as well, there is associated an extra cost in obtaining clinical evidence.
- **Supply chain management:** These changes affect significantly to manufacturer's supply chain and the requirements importers and distributors need to comply with. Because the aim of transparency, importers and distributors need to verify that all requirements are fulfilled.
- **Authorities and their roles:** There are several active authorities in the medical device industry that have their own purpose. The role of NBs is even more strictly to make sure that manufacturer fulfills all the applicable requirements.
- **Implantable devices:** Information needed to accompany with the device is regulated and needs to be understandable for layman. This might affect to marketing plan of the GTM strategy.

6 DISCUSSION

6.1 Discussion of results and contribution to previous research

This thesis aimed to answer the research question which asked what are the significant changes in MDR affecting mostly to the GTM strategy. In order to answer this question, first changes in MDR were studied and results were presented in sections 5.1. – 5.10. Then in the synthesis section 5.11 there was introduced the developed construction focusing on those aspects of MDR changes that impact GMT strategy. The construction should give a good baseline for medical device companies to get ready for EU market. Regarding GTM strategy, it is an important question for medical device manufacturer if the medical device is regulated based on MDR. It is clear that the easiest for medical device companies would be that their product is not regulated within the scope of MDR at all. In this case, it is not possible to talk about medical device anymore but it is health or lifestyle device for example.

At theoretical level this thesis focused on the role of regulation in the GTM strategy planning. Traditionally regulation has not been essential part of the GTM planning which has focused on commercial planning of product introduction to new market (e.g. Bueno & Jeffrey, 2014). Thus, regulatory strategy is somewhat separate from GTM strategy but interrelated. However, as Elan & Chatwin (2017) put it out, the first market approval and its leveraging in other markets is an important strategic decision for a firm and should be a part of GTM strategy planning. Thus, to really being able to do GTM planning, many aspects of regulatory strategy has to be taken into account. In addition, there are several aspects stemming from regulation that are not part of regulatory strategy as such. For example, a decision of which quality management system or systems will be followed has a significant consequence for target market selection. If correct quality management system requirements are not followed and fulfilled, there are perhaps no possibilities to release a product in a desired market. For established companies operating in medical device industry this is not a problem as many of those doing international business have implemented their target country regulations already in the quality management system. However, in case of a start-up aiming to international markets, the target markets have a

huge impact and this decision has to be done in the very beginning of the product development. Thus, for a start-up it is important to take into account regulations in the very beginning of the product.

The main theoretical contribution of this thesis was to argue that a regulatory landscape change might have a significant implication to the GTM strategy which has been understood to be a commercial strategy focusing on how to enter to which countries and with which products. Thus, the regulatory strategy should be an integral step in the GTM strategy as is the marketing plan. In this thesis, a two-way communication between target market selection, internal analysis, external analysis and regulatory strategy was summarized in the theoretical framework discussion (FIGURE 5). Target market selection can be a result of other analysis but also there can be a decision regarding desired target market and then it is an input to analyses to see what needs to be done in order to enter desired market. In section 6.2 is presented more thoroughly practical implications for GTM strategy based on the results of this thesis.

6.2 Practical conclusions

There are a lot of things to consider for a company in medical device industry regarding GTM strategy. As MDR gives new requirements for the company and for a product to comply, it is a good moment to rethink the whole product portfolio in order to make sure that the right products are in place. For new products, GTM strategy planning should be started very early in product development in order to decide what are the markets in the scope of the product and to do product development accordingly. There are many important aspects coming from MDR that might have an impact to GTM strategy content. The major implications for the elements of GTM strategy stemming from the changes in MDR are described below based on analysis presented in sections 5.1 – 5.10:

Regulatory strategy: MDR has a full life-cycle approach and implies a significant impact to regulatory strategy. Especially product classification and approval process has changed and regulatory strategy needs to be updated accordingly. Regarding quality management system and related processes, there are new requirements that needs to be implemented. In addition, every firm need a person who is responsible for regulatory affairs in the firm.

Internal analysis: Regarding suppliers and sub-contractors, MDR has some implications including unannounced audits by Notified Bodies. Quality management system and other systems like PMS system and clinical evaluations have many implications to internal aspects what needs to be taken into account in internal analysis.

External analysis: MDR introduced new databases to which manufacturers need to put data and that way to make public some information. The consequence is that there is much more information to be found from the companies in the medical device industry because of these databases. There are new authorities in medical device industry that need to be considered. For some, like NBs, MDR gives much more responsibility but also authority that might affect manufacturers and other economic operators.

Target market selection: MDR brings a significant difference regarding target market selections as regulation in all EU countries is harmonized after MDR comes into the force. Thus, national regulations do not restrict target market selection that much anymore.

Entry mode decision: Entry mode decision should include a consideration regarding supply chain structure. Responsibility of importers and distributors has increased significance in MDR and every economic operator needs to ensure that products they distribute are compliant with the regulation and in some cases, they must report non-compliances to regulatory authorities. They are subjected to unannounced and announced inspections as well. Thus, MDR has a significant impact to entry mode decision and especially for economic operators within the supply chain.

Marketing plan: There are no changes identified to affect to marketing plan as such except the requirements given for implant manufacturers regarding the information associated with the use of implants. Article 7 in MDR says that it is prohibited to use in advertising of device anything misleading for the user or the patient with regard to the intended purpose, safety and performance. But that was not identified as a major change nevertheless.

Tactical plan: Major tactical decisions relate to the transition period timeline of MDR. First strategic level decisions are needed in order to streamline product portfolio or to

ensure that the current portfolio something to go forward with. After that it is important to make tactical decisions when and how to transit old products to new regulation. Similar tactical planning in resource allocation for example is needed when making company processes compliant with the MDR.

6.3 Critical evaluation of the research design and implementation

In methodological sense, in this thesis the constructive approach was applied. Validity of the construction is studied based on weak and strong market test (Kasanen et al., 1991). In this research developed construction cannot pass the weak nor strong market tests yet for two reasons. The more prevalent one is that construction was not developed for actual company but for a generic company in medical device industry. Even though the construction is relevant for each medical device company in the field, it has to be adapted to actual operations of the firm. Regarding this, however, there is another reason why market tests are not possible to pass yet. Based on interviews and for example information found from National Supervisory Authority for Welfare and Health there are no possibilities to register a medical device per MDR yet even though it is already applied legislation. Nevertheless, the weakness of this thesis is that there is no case company involved in the research process making it more practical.

Research results can be evaluated based on reliability and validity (Fidel, 1984). Validity means how well the research hits its target (Fidel, 1984). Validity of research results is enhanced by comparing white papers with actual MDR and that way see if those are in line. These findings are discussed in interviews as well in order to make sure results are applicable in the reality. Reliability, on the other hand, is more difficult to ensure in qualitative research studies. Reliability means the possibilities to produce the same results in environment where conditions are constant and research design is same (Fidel, 1984). One of the important means to ensure reliability is to make research process visible (Stenbacka, 2001). Analysis of data and selection criteria is based on researcher's reasoning and thus the reasoning needs to be brought visible to reader. It is very essential that the process of analysis is rigorous and transparent (Bowen, 2009).

Scope of applicability is wide in this thesis. Most of the companies operating in the medical device industry need the results developed in this thesis. Even though this thesis is not developed for any company alone, there are many companies that in practice benefit from the results of the thesis. What is out of scope is operational aspects of the GTM strategy and MDR changes. Changes as such are important for a company that is already operating in the industry. For a company that is a new in the industry it is more important to develop right practices from the scratch.

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