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IMPACTS OF THE SCHEDULED LEGISLATION CHANGE IN EUROPE FOR MEDICAL DEVICE PRODUCERS - SYSTEM DYNAMICS MODEL OF A FIRM[1]

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ABSTRACT**. **In 2021, Europe will face a fundamental change in medical device (MD) legislation with the introduction of obligatory clinical trials in lower-risk classes post-entry to the market. This change raises questions for future economic results of MD companies. We present a system dynamics (SD) model of a small company based on explicit representation of a new MD development, emphasizing the importance of the imposed legislation on otherwise intuitive management decision making. The model projections show that for small companies, the new legislation would result in almost doubling certification costs. Though the implementation of the MDR 2017/745 directive aims to increase patient safety, in the context of market development, such measures may lead to increased pressure on the horizontal integration of companies, with the exit of small firms from the market and the related decline in R&D activities at the SME level.

KEYWORDS: company, model, strategy, medical device market, legislation.

JEL classification: M14, M19, P2.

Introduction

Medical devices make an essential contribution to healthcare in the European Union (EU). They play a crucial role in diagnosing, preventing, monitoring and treating illness, and overcoming disabilities. They are also important for the economy, providing €110 billion in

sales and 675,000 jobs in Europe. The EU is a net exporter in this sector (European Commission, n.d.); its medical device (MD) industry is growing by 5% a year. There are approximately 22,500 health technology companies in Europe, 80% of which are small or medium-sized businesses with less than 250 employees. The medical technology industry includes 12% of all European patents.

In 2020, Europe will face a fundamental change in MD legislation with the introduction of obligatory clinical trials also in lower-risk classes post-entry to the market with the MDR 2017/745 regulation from May 2021 now becoming mandatory for all MD companies. Since many of them have not fully met its requirements during the transition period, there is a risk of substantial financial burden not only from the MDR conformity assessment process itself but above all from completing all necessary tests and preparing the respective technical documentation. This would certainly increase the competitiveness within the sector with some positive impact. On the other hand, many small- and medium-sized businesses are expected to cease operation. Leading managers want to know what future economic results can be expected and which strategy they should follow. Regarding the fact that the development of new medical devices generally takes place in small and medium sized companies, due to their flexibility and quick decisions compared to large companies, a question of impact of new regulation is critical (Bartlett Foote, 1991).

Both economic theory and business practice employ various methods to calculate the expected value of investments, to predict future financial flows or to estimate economic results.

In recent years, the task of evaluating investment effectiveness for MDs has been intensively solved at both the private and national level. The most common methods can be divided into three groups: 1. strategic and financial valuation of projects, (e.g., net present value (NPV), Internal rate of return (IRR), discounted cash flow (DCF)), 2. weighting and scoring of products and product criteria (e.g., analytic hierarchy process (AHP) and conjoint analysis), 3. human decision-making (fuzzy logic, actuarial models, neural networks, technology road mapping and expert systems).

Within the first group, Vernon *et al*. (2009) described the use of NPV to determine the maximum willingness to pay (WTP) using payer reimbursement signals (such as cost-effectiveness thresholds). In addition, Kiliç, Kaya (2016) claim such models are essential in order to transfer public resources to projects, having employed methods of type-2 fuzzy AHP and type-2 fuzzy Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS). Vallejo-Torres *et al*. (2011) explained how Bayesian methods can be used to incorporate all available information at the various stages of development. However, the increased complexity of this approach as the stages of development progress may pose difficulties for its practical use by MD companies.

The above described methods face additional problems due to the specifics of MD development. In case of DCF, an important business reality is ignored. Projects rarely proceed as planned and management must frequently adapt and revise former decisions as new information becomes available or as uncertainties are resolved. In case of more complex methods, people can become overly focused on model details or the numerical precision of the calculations, rather than on the quality or relevance of the input data. Some managers might feel intimidated by the complexity of the techniques, and finally, such tools require extra resources and are hence a luxury that only ‘large’ organizations may be able to afford. Moreover, MD companies use a range of other methods to decide which new products are likely to deliver good financial returns, including less tangible approaches such as ‘gut

feeling' based on experience. Quite often, such methods are used simply because 'that is the way it has been done so far'.

To answer the questions raised above, a tool is needed that not only incorporates the necessary variables and constraints, but also provides clear and understandable outputs. System dynamics (SD) modelling can provide such an instrument. Previously mentioned methods were focused solely on the evaluation of the MD development process. The strength of the SD method is in its ability to integrate this process as one of the many ongoing processes in the company, which, including feedbacks and delays, enables decision makers to instantaneously see the behavior of the whole system. It is possible to answer a question, e.g. „what is the probable outcome of deciding to fund this development by curtailing marketing expenses"? In this way, the knowledge of various company departments can be potentially incorporated into the model. The use of SD as a means to improve quality in process control automation was highlighted in (Koelling, Schwandt, 2005). This approach will reduce possible human errors. Thanks to SD, it is possible to interconnect and coordinate multiple sources of information, link the different stages of the medical device development and demonstrate them in an understandable form, and incorporate the cost of individual MDD processes. It enables displaying not only complex systems.

Therefore, our goal is to devise an SD model of a company that includes well-known and commonly used financial indicators of investment evaluation, and that could be used as a tool to facilitate intuitive management decision making. The model can be tailored to a specific company based on previous records of its activities. Subsequently, it allows projection of future macro- and microeconomic trends and examination of their impact on the company, while helping to create mitigation strategies and evaluate their expected success. The model is based on explicit representation of a new product development, emphasizing the importance of imposed legislation rules for the company's ability to successfully innovate its products.

1. Medical Device Regulatory

MDs are divided into several risk classes, and it is the manufacturer's responsibility to determine the correct classification. The following MD groups are distinguished: active, inactive, implantable, and non-implantable. This classification guides the manufacturer to select the right risk class of their MD(French-Mowat, Burnett, 2012). The risk classes are described in MDD 93/42/EEC(Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices, 1993), which specifies six classes: I, Is, Im, IIa, IIb and III, where class I represents the lowest risk and class III the highest. At present, it is relatively easy to proceed following MDD 93/42/EEC when preparing a clinical evaluation based on the essential equivalence comparison of the new MD with an equivalent device already available on the market. This may be one reason for introducing MDR 2017/745 (EU MDR 2017/745 Gap Assessment and CE Transition Strategy for Medical Device Manufacturers, 2019), which regulates essential requirements obligations, especially for preparation for the clinical evaluation. The new regulation extends the risk classes by adding the class Ir for reusable MDs and expands individual rules to determine the risk classes. The new regulation further specifies that manufacturers must carry out post-marketing clinical monitoring in order to collect clinical data and continually verify the effectiveness and, in particular, potential risks, which should prove the safety of the MD.

The new regulation brings about some changes for manufacturers. Still, it does not change much, as long as the manufacturer places the product on the market in the right way and fully under the MDD 93/42/EEC directive. However, the new regulation also determines the obligations for notified bodies, which themselves must apply for the notification to assess the conformity of the MD with essential requirements of the MDR 2017/745. This poses a risk for the manufacturer that the notified body may not succeed with its application and will be removed from the list of notified bodies for issuing new certificates according to MDR 2017/745. It gives the NB only the authorization to supervise the already issued certificates under MDD 93/42/EEC until their expiration. The manufacturer would then be prevented from making any changes to the product before finding a new notified body, which entails a significant financial burden. For many small- and medium-sized manufacturers, this could result in cessation of business.

2. Methods

2.1 Design of Study

We follow the previous work on SD modelling applied on the company level in order to devise an SD model of a company. According to Zali *et al*. (2014), mesoscale SD models (encompassing the whole firm and all its internal processes, which is a scope suitable for our model) have so far been scarce and focused almost exclusively on the question of success of a startup company (Zali *et al*., 2014).

Khaledi (2015) models a firm's long-term performance through the development of internal variables, namely human resource (HR) skills, overall technological level (techno), HR motivation and product quality. These variables in turn influence the market size, market share and overall company productivity. Market size and share determine sales, while the HR variables along with techno influence productivity, and hence the production costs. Sales are then translated to firm's financial performance which is thoroughly modelled. For model calibration, the author used income statements and balance sheets for the US composite corporation. This represents the biggest limitation, as HR, techno and market size variables are modeled purely based on authors judgement. We have to acknowledge that it is indeed very hard to quantify this data in reality. Since these variables are critical for determining the long-term company performance within the model, this questions its possible use for the real-world applications and we have purposely left out variables of this type from our model.

Schwarz, Schoneburn (2002) developed a model of a small start-up firm in order to explain critical phases in its early development. A firm's growth in the model is fueled by exogenously growing market demand which raises company sales. Increased sales lead to higher liquidity allowing the firm to hire new employees, thus increasing the production capacity. Authors identified three major threats which endanger the firm in its first years of existence: declining demand, credit restrictions (lack of liquidity) and excessive entrepreneur consumption. The model is relatively simple, thus avoiding various hard to measure variables. However, its simplicity makes its use harder for medium sized companies (e.g., company produces 100 units of product per each additional employee).

Huang, Kunc (2012) went further and outlined a general model for a start-up firms with the aim of providing a template for entrepreneurs to develop an SD model of their own firm. The authors then focus on the identification of best strategies to run the start-up successfully in its first five years of existence. House, Black (2009) focused their attention on

the role of a leader in a new venture growth, using a case study of a small MD startup working on the market release of its first product. Unfortunately, the authors focused solely on the concrete managerial style and its consequences for the company's short-term and long-term performance.

Another study focused on the company strategy in relation to its long-term market success and growth. Strategies and performance of four companies producing software as an MD were analyzed. Strategies were divided according to the investment allocated to R&D, salesforce and service force expansion, customer acquisition. On the basis of the four case studies, authors developed a general growth model of a firm producing medical software with S-shaped profit evolution for all modelled strategies. Unfortunately, the description of stocks and flows is missing, along with the model calibration. The paper presents only causal loop diagrams; its application value is therefore limited (Wang, 2012).

The model developed in the current study is a combination of previous work on the same topic modified to fit the selected company, Mediatrade, and its specific business model, industry, designed also with data availability on mind. Compared to the previous studies, the model is focused on assessment of expected legislative changes to the company bottom line and to help management devise possible countermeasures, thus the result is unique compared to the previous studies.

The used approach fits well to third, „hybrid" approach of economic SD models construction as described by Radzicki (2011) with one important caveat – SD model of a company cannot be considered a well known economic model, but more as an emerging experimental approach, which is clearly visible from the previous overview of the literature.

The study describes the case of an SME company, however, it evaluates the situation from the point of view of regulation and the impact on the functioning of the company. Regardless of the size of the company, these problems will have to be solved by every company. The company is a representative of Czech manufacturers, available in the Register of Medical Devices, which is a unified system for comprehensive data management in the field of medical devices in the Czech Republic since 2015. https://eregpublicsecure.ksrzis.cz/Registr/RZPRO/). A total number of 140 companies are registered there. If we exclude in vitro diagnostic medical device (IVD) manufacturers who are not affected by new regulatory we have 53 companies. 88 % are small and medium-sized companies (*Table 1*).

Table 1. Number of MD manufacturers by size of company

Company category	Number of companies	The average number of active MDs in the registry
Micro	13	19.25
Small	18	44.75
Medium-sized	16	63,62
Large	6	57

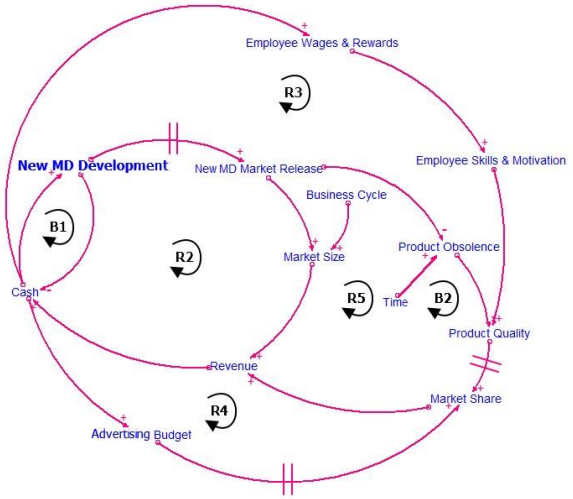
Source: own based on (Registr Zdravotnických Prostředků - RZPRO (Národní Registr Zdravotnických Prostredkù), n.d.).

These data confirm the fact which is also true at the international level; most innovative research in the field of MDs is not undertaken by big companies but by SMEs (Bernasconi, 2017; EUCOMED - Medical Technology, 2013) also in the Czech Republic (*Table 1*).

The manufacturers of medical technologies have high-level research and development capacities, and are vocal in expressing their expertise and knowledge towards the continuous

development of innovative means and accelerating this pace of development. The research, development, and production of MDs has a long tradition in the Czech Republic (*Minister Nováková: We Must Maintain and Develop the Production of Medical Devices in the Czech Republic | MPO*, n.d.). In addition to positive economic impact, the development and production of MDs also positively impacts other sectors, especially the health services sector (*Panorama of the Manufacturing Industry of the Czech Republic 2017 | MPO*, n.d.). The main change of the above mentioned regulation MDR (EU) 2017/745 is the focus on safety and risk reduction, which is to be achieved by strict processes that lead to market authorisation (Pane *et al*., 2017). This entails increased certification costs.

The model parameters were based on economic data of a sample small company operating on the MD market in Czech Republic (Mediatrade) for the years 2002–2018, where the data on research and development costs of selected MDs and financial statement items were available. The data are used to fine-tune relationships in the model.



Source: created by the authors.

Figure 1. **Causal Loop Diagram for MD Development and its Impact on Company's Cash Flow and Market Performance**

Figure 1 displays basic interactions of new MD development with company cash flow and its market performance. Maintaining high market share is crucial for long term company success. This can be done through employees' rewards which increase their motivation, which in turn leads to increased product quality. The product quality determines patients' satisfaction with the MD (or simply their medical condition), earning a higher market share after a certain delay. Higher market share brings higher revenue and ultimately higher disposable cash for the company. This is shown by the reinforcing loop marked as *R3*. Increased marketing effort (loop *R4*) can have similar effect. However, this might still be insufficient in the long term if the company fails to innovate its products. To initiate the process of new MD development (under new legislative rules and with six stages: initiation, concept, design, production, final verification, and market disposition), the company has to allocate significant funds which in turn become unavailable for other purposes. When the MD development finishes successfully, a new MD is released. That in turn decreases product obsolescence of company's MD portfolio (other market competitors also innovate) and increases product quality. The release of a new MD can also increase the market size when it addresses the needs of a new group of patients. If, on the other hand, the development process

fails in any of its stages, the company can be exposed to potentially critical failure or serious financial losses and worsened market performance.

Different scenarios were created in the model to answer the following questions:

- How do the company's economic results develop with the transition to the new legislation?
- How much would a company have to raise the product price to cover the increased costs associated with the new legislation?
- Where is the break-even point for chosen company in the MD market under the new legislation? In other words, how would a company have to increase its market share (how large the market would have to be) in order to retain its current product prices and cover the costs of the new legislation?

2.2 Company Characteristics

The main focus of the company is the development and production of external pacemakers. The company was established in 1994, and it has been delivering products for more than 20 years. It supplies customers in Turkey, Iran, Egypt, Czech Republic, Slovakia, Poland, Italy, Cuba, Georgia, Myanmar, Pakistan and other countries. The industries in which the company operates include manufacturing, installation and electric machinery repair and electronic and telecommunications equipment. The company declares that they are continuously improving their products with medical doctors. The information about company revenues for the respective product classes and services are available for years 2002-2018, alongside cost categories covering various expenditures including salaries, material costs, but also the specific costs directly connected with the MD development and its continual market approval (certification costs). Total revenues, costs and gross profit are also present. All available variables are described in *Table 2*.

Table 2. Costs and revenue specification related to the medical device development

Revenue	Costs	Variable „count“	Others
Revenue for the resale of consumable material	Purchase of material	Number of performed BTK	Cash flow
Revenue for product	Purchase of material for resale	Sales of BTK (Safety technical control)	Foreign sources („debt“)
Revenue for total sales	Purchase of material for product	Number of sold pieces (product)	Net Capital
Total revenues	Employee Wages total	Number of sales of own products and services	Profit before taxes
Subsidies	Costs of Marketing activities and international exhibition (fair) presentations	Average adjusted employee count	
Subsidy Ministry of Industry and Trade for development of cardio stimulator	Purchase of Services - Product Certification	Goods (stock of products for sale and material for resale	
Subsidy MPO for marketing	Purchase of Services - System Certification	Stock of material	
	Purchase of Services - Total	Total value of stored stocks (products and material)	
	Total costs		

Source: created by the authors.

Table 3. Certification costs for keeping the product on the market for 10 years and R&D costs, (€)

	MD class	Cost of certification for 10 years		R&D costs	
		Old	new	Inactive	Active
Certification costs for keeping the product on the market based on legislation	I	0	0	-	-
	Is	39,227	74,551	92,896	120,609
	Im	39,227	74,551	92,896	120,609
	Ir	0	0	-	-
	IIa	45,472	112,022	99,141	188,915
	IIb	45,472	114,364	34,310	195,160
	III	53,279	119,048	126,854	200,625

Source: created by the authors.

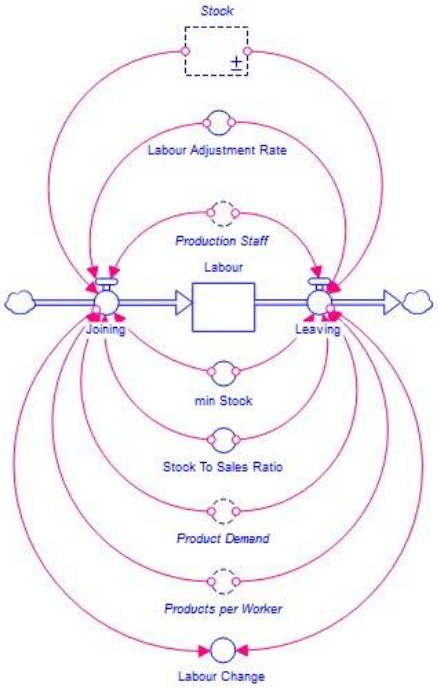
The certification costs for keeping the product on the market are shown in *Table 3*. The MD development process is assumed to last two years with the exception of class I, where it is one year.

2.3 Model Description

The model was created using the software Stella Professional, version 1.9 developed by ISEE Systems. A critical component for the model development was a detailed history of the company data, regarding its economic performance, sales, number of employees etc., as well as the communication with the company owner and domain expert. The model is divided into multiple sectors which interact with each other – labor sector, quality sector, R&D sector, market sector, production sector and financial sector. For each sector, a short description is given, followed by the list of all variables. The variable shortcut and its default value are added in parentheses for the variables used in the presented formulas. Ghost elements are defined at their first occurrence, with their parent sector given in square brackets.

2.3.1 Labor Sector

The labor sector controls the total amount of workers based on current product demand. The labor force is represented by a non-negative stock with one inflow and one outflow for hiring and dismissing employees respectively (*Figure 2*).



Source: created by the authors.

Figure 2. **Labor Sector**

The hiring/dismissing functions are set to maintain sufficient production capacity. The goal is that a given fraction of yearly product demand plus some fixed reserve are kept in stock:

$$S - d + (L + \Delta L/\alpha)p = S_{min} + \mathrm{r}\cdot\mathrm{d}, \quad (1)$$

Where:

Labor_Force (L, 1.0) – non-negative stock that permits non-integer values (part-time employees).

Labor_Adjustment_Rate (α, 1.0) - additional damping parameter to prevent oscillations in labor force in case the product demand changes rapidly.

Labor_Change (ΔL) – the actual difference between inflow and outflow of labor force.

min_Stock (S_{min}, 30) – the fixed amount of products to be kept on stock regardless of demand.

Product_Demand (d) – [Production] the yearly product demand.

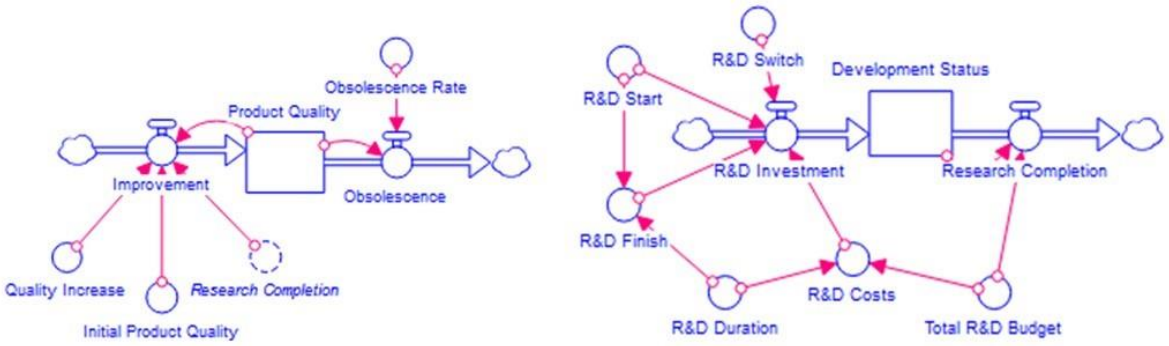
Products_per_Worker (p, 16.68) – [Production] number of products by a single worker including assembly, calibration and testing.

Stock_to_Sales_Ratio (r, 0.5) – target ratio between the amount of products on stock and the current demand.

2.3.2 Quality Sector and R&D Sector

The quality sector models the increase of a product's value as a result of a successful R&D process, as well as the natural aging of the product due to innovations introduced by competing companies. The aging is basically upscaling theR&D processes to the whole market with the obsolescence rate (about 3% of product's value per year for MDs in consideration) representing the overall pace of innovation in the field.

When a new product is put into production, the quality level is reset to the initial value and an additional quality bonus is applied. From that moment on, the quality starts to gradually decrease again (*Figure 3*).



Source: created by the authors.

Figure 3. **3 Quality Sector and R&D Sector**

Product_Quality – non-negative stocks representing the utility value of the product.

Initial_Product_Quality – initial value for the respective stock and also a value to which the quality is reset upon research completion.

Obsolescence_Rate (0.03) – relative decrease of product's value over time due to new products emerging on the market.

Quality_Increase – relative bonus applied to product quality when the research is finished.

The R&D sector models the research progress (including tests) and splits the overall costs into annual expenses. When the process is finished, the respective actions in the quality sector are triggered.

Development_Status – non-negative stock accumulating investments into research; emptied by a pulse generated on the outflow upon research completion.

R&D_Duration (3) – scheduled research duration in years.

R&D_Finish – the year when the research process is finished and the product is put into production.

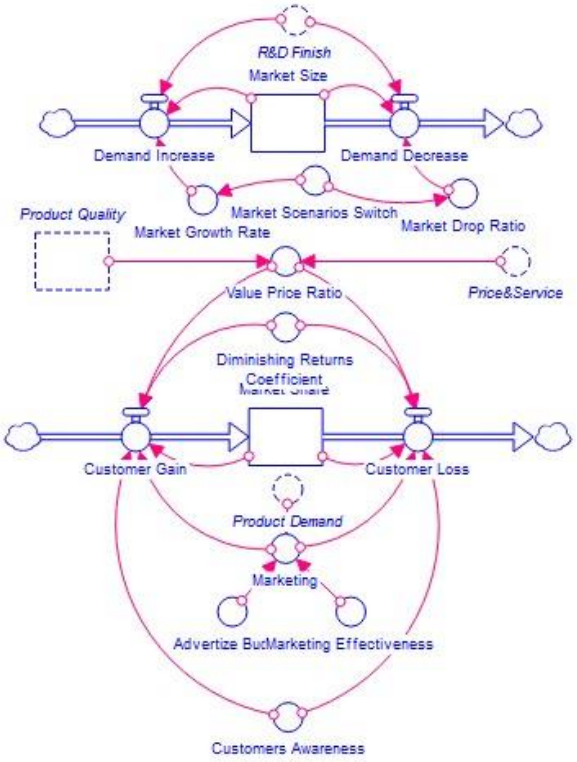
R&D_Start (5) – starting year of the research.

R&D_Switch – boolean variable allowing to turn the research on and off for different scenarios.

Total_R&D_Budget (varies based on MD class) – the overall sum dedicated for the research.

2.3.3 Market Sector

The market sector models the increase/decrease of company's market share based on the relative value of the product with respect to its price. According to domain expert, the product reputation is built mostly through the actual experience which is shared among fellow institutions, thus only a simple marketing model is included (*Figure 4*). The market size is typically driven by legislative standards, and can be considered a fixed parameter.



Source: created by the authors.

Figure 4. **Market Sector**

The customer gain is given by:

$$\Delta M_{+} = c(1 - M)\left((q - 1) + m\delta^{(1-q)}\right), \quad (2)$$

capped so that the updated value of M does not exceed one, *where* $m = \mu a/d.$
Similarly, customer loss is given by:

$$\Delta M_{-} = cM\left(1/q - 1 - m\delta^{(1-1/q)}\right), \quad (3)$$

capped so that the updated value of M does not drop below zero.

Market_Share (M, 0.2) – non-negative stock with values between 0 and 1

Market_Size (450) – non-negative stock representing the total amount of products sold per year

Advertize_Budget (a, 0.8) – annual expenses for advertisement

Customer_Awareness (c, 0.5) – parameter that controls customer response to the difference in the relative value compared to competing products; with the default value of 0.5, the company takes all remaining market in a single year if q is three times higher compared to competing products, and half of the market when q is twice as high (with no marketing involved).

Diminishing_Returns_Coefficient ($\delta, 2$ – parameter that controls the diminishing returns of advertisment when the value to price ratio gets far from common standard (defined as 1.0)

Marketing (m) - effective money invested into one piece of product sold

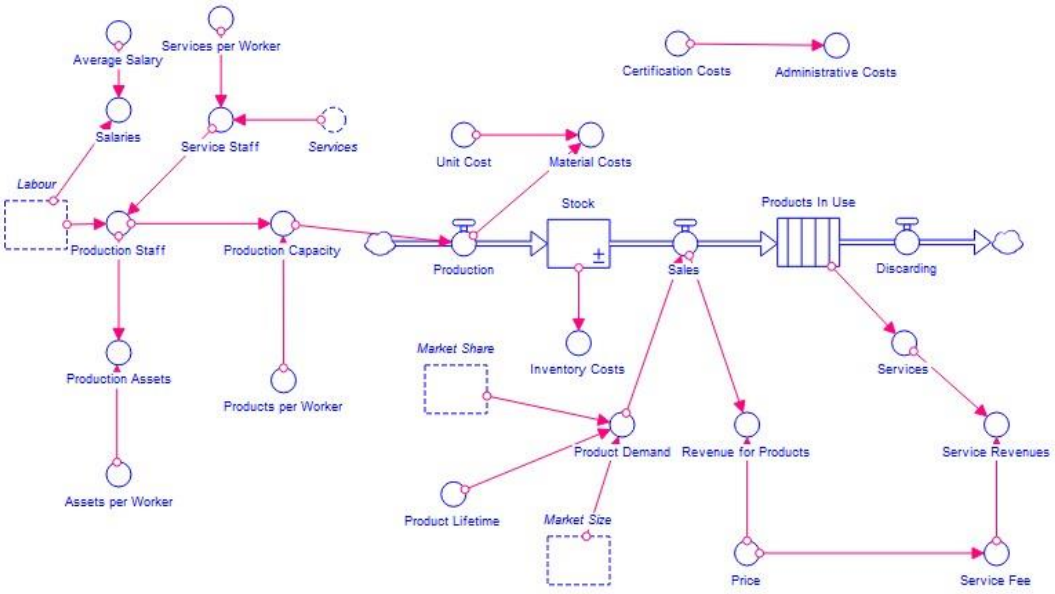
Marketing_Effectiveness (μ, 0.1) – parameter measuring the effectiveness of advertising expenses

Value_Price_Ratio (q) – product quality divided by its price

Customer awareness affects how quickly customers respond to the objective quality of the products, i.e. how quickly the company gains/loses customers if their product's quality (value-to-price ratio) starts to deviate from competitors (which have this ratio set to 1). Modelling competitors reduces to a single parameter - obsolescence rate (current value of 3% per year is a qualified guess by the domain expet).

2.3.4 Production Sector

The production sector models the company's two sources of income – product sales and services. It uses the values from both market and labor sectors as its input. The sales are given by a company's market share and the overall market size. The company gains additional profit from servicing the products during their lifetime. Both production and service staff need certain amount of assets (plant and equipment) to operate. The total amount of these assets, proportional to the number of employees, is controlled by the financial sector (*Figure 5*).



Source: created by the authors.

Figure 5. **Production Sector**

Aside from material costs and salaries, a MD vendor has additional expenses in the form of certification costs (authorization to keep the product on the market). These costs depend on the class of the device (*Table 2*), and do not depend on the amount of products sold. The expected increase of these costs as a consequence of the scheduled legislation changes becomes a crucial factor for smaller companies.

Stock (*Inventory*, 20) – non-negative stock of finished products ready for sale

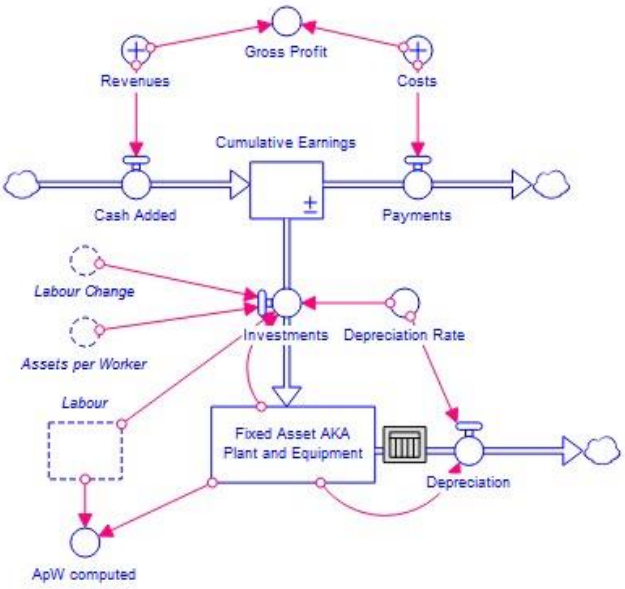
Assets_per_Worker – the value of fixed assets (plant and equipment) per worker

Average Salary (7,350) – the average yearly salary in Euros

Inventory_Costs – the storage expenses calculated as 1% of total inventory price
Material_Costs – the material costs of yearly production
Product_Price (1,171) – final product price in Euros
Production_Assets – the amount of assets used by the production staff
Products_in_Use – FIFO type conveyor; products are discarded at the end of their lifetime (7 years)
Products_per_Worker (16.68) – [Labor]
Revenue_for_Products – the total revenue for sold products per year
Service_Fee (0.05) – service price given as a fraction of product price
Service_Revenues - the total revenue for services per year
Service_Staff – the number of service workers is given by the total number of products in use
Services_per_Worker (200) – the number of services per worker and year
Unit_Cost (193.2) – the material costs of a single product in Euros

2.3.5 Financial Sector

The financial sector gathers all revenues and costs, computes the gross profit and keeps track of the overall budget. It also maintains the level of assets needed for production and servicing with respect to labor change and depreciation (*Figure 6*).



Source: created by the authors.

Figure 6. **Financial Sector**

As macroeconomic aspects are not the concern of this study, the model is very simplified, not including taxes, debt, interests and other factors.
Cummulative_Earnings – stock representing company‘s total earnings or losses
Depreciation_Rate (0.2) – represents the relative depreciation of existing assets
Fixed_Assets – non-negative stock representing the total value of all plants and equipment; proportional to the total number of employees with the initial bonus of 800 €

Gross_Profit – revenues minus costs in Euros for current year

3. Results

3.1 Selected Economic Indicators of the Company

The authors prepared a model that examines three main aspects related to the transition to the new legislation, the strategy of price change in the context of the new legislation and market size. The economic result, break-even point, profitability and costs and revenues were considered (*Table 4*).

Table 4. Selected economic indicators for different scenarios; developed MD class IIb

Scenario no.	Legislation/R&D	Economic result [thousands €]	Break-even point	Profitability	Total number of products sold	Cumulative sales [thousands €]	Relative market share at the end of simulation
1	old/no	92.9	11.7	0	552	871	0.157
2	new/no	33.2	16.7	0	552	871	0.157
3	new/yes	-77.9	34.7	0.409	843	1,271	0.86
4	new/yes (foreign market entry)	14.8	60	0.964	1,260	1,820	0.841
5	new/yes (demand reduction)	-162	26.6	0.0954	596	920	0.894

Source: own calculations.

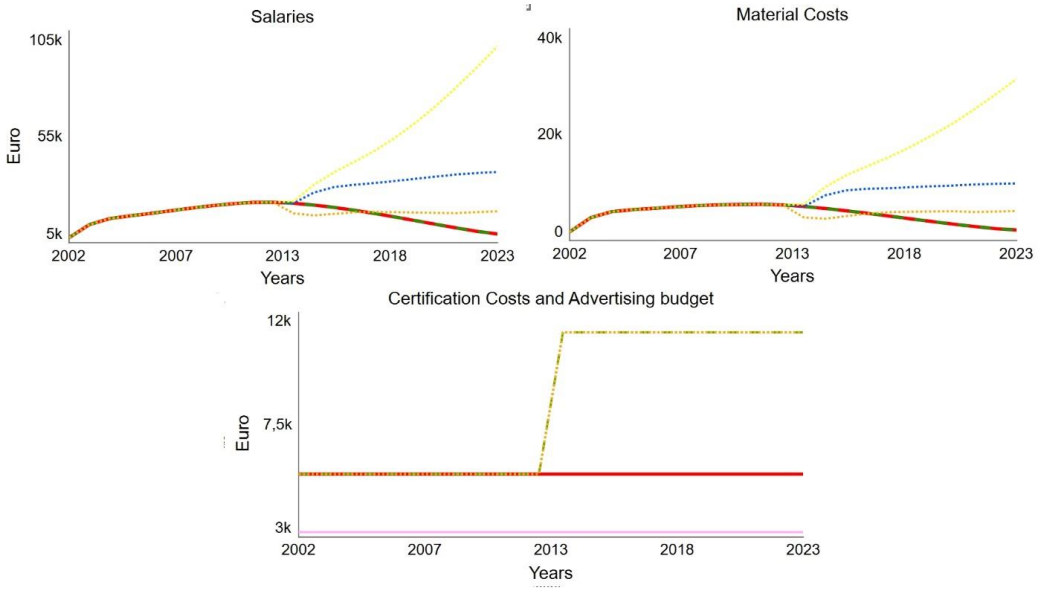
The analysis focused on five scenarios, compiled with the help of a domain expert, reflecting the main challenges that the company will face in the upcoming years. In the first scenario, the company does not develop new MD and the life cycle of the existing product only takes place under the current legislation. In the second scenario, the new legislation is introduced in 2013, and the company still does not develop new MD. The third scenario also switches to the new legislation, but the company is already investing in the development of a new MD starting from 2010 which is launched in 2013, inspired by the EPG10P pacemaker by Mediatrade. The fourth and fifth scenarios represent the biggest opportunity/threat for the company as identified by the domain expert, namely, the expansion to foreign markets (scenario 4). Having gained the majority of the Czech market, the next step could be registering and certifying the company's external pacemaker abroad, whereas the threat concerns the possible legislative changes for hospitals where Czech cardiologists and cardiac surgeons currently prefer an alternative rapid treatment in the form of medication and subsequent immediate implantation of a pacemaker, and they oppose the requirement to have at least one external pacemaker for each department. This would mean a rapid reduction of the market in terms of demand for new devices in the Czech Republic.

With the transition to the new legislation, the economic result is expected to decline (up to -77,900 €). In order to cover the increased costs, the company would have to raise the price by 115.3 € per product (10.15% increase). Another source of financing MD development under the new legislation could be entering foreign markets. This scenario shows a positive cumulative economic result of 14,800 €. The break-even point for the

company shifts from 11.7 to 16.7 between scenarios 1 and 2. The highest value is achieved for the new market entry scenario where the company gains profit by selling more products, but at the same time, the absolute variable costs increase with the number of products sold (this causes a shift of the break-even point). This confirms that the legislative change and the associated cost increase can only be overcome by expanding the company.

3.2 Cost Development Analysis

There is no difference in the development of labor force and material costs between the first two scenarios; the company's sales decline as the MD becomes obsolete without development (*Figure 7*). The market share decreases significantly in the last years of the simulation (*Table 3*), and along with it, the number of employees and material costs. Only the certification costs increase from 5,520 € to 11,200 €.



Notes: legend: Scenario 1 Old legislative rules without development of new medical device; Scenario 2 New legislative rules without development of new medical device; Scenario 3 New legislative rules with development of new medical device; Scenario 4 New legislative rules with development of new medical device and entry on a new foreign market; Scenario 5 New legislative rules with development of new medical device and reduced demand; Advertising Budget.

Source: created by the authors.

Figure 7. **Development of Selected Company Cost Indicators in Simulated Scenarios, (thousand €)**

Table 5. Relative share of certification costs in total costs depending on legislation

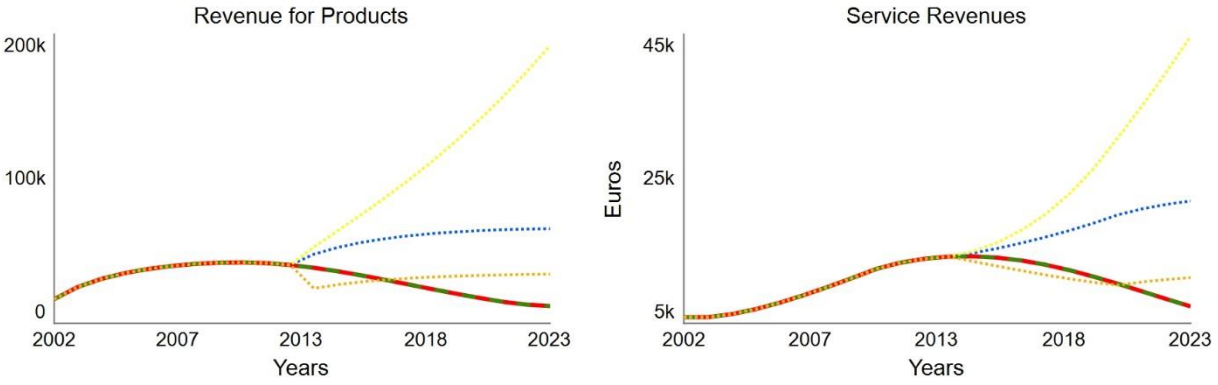
Is	Is	Im	Im	IIa	IIa	IIb	IIb	III	III
Old	New	Old	New	Old	New	Old	New	Old	New
6.9%	12.4%	6.9%	12.4%	9.46%	17.5%	9.46%	17.5%	9.16%	18.4%

Source: own calculations.

The percentage of certification costs varies relative to the risk class, but these costs remained relatively stable and the manufacturers were able to integrate them in their business plans. With the implementation of MDR 2017/745, these costs will nearly double (*Table 5*; the price increase includes legislative requirements but not the costs for PMCF or clinical trials, which may exceed the company's total budget many times). The manufacturers now face a decision as to how to set their business plan before the legislative change takes place; more reserves need to be created to cover the price increase.

3.3 Revenue Analysis

In scenario 3, the cumulative sales increase by 53% (*Table 4*), which results in doubling the labor and material costs in the last year of the simulation. In case of a successful expansion to foreign markets (scenario 4), the number of products sold is more than double when compared with scenarios 1 and 2, with a significant increase in labor and material costs. The last, fifth, scenario shows a sharp decline in sales, which cannot be overcome even when launching a new product and gaining a greater market share. The sales return to the pre-2013 level only after 10 years (and taking almost the entire market), as shown in *Figure 8* below.



Notes: legend: Scenario 1 Old legislative rules without development of new medical device; Scenario 2 New legislative rules without development of new medical device; Scenario 3 New legislative rules with development of new medical device; Scenario 4 New legislative rules with development of new medical device and entry on a new foreign market; Scenario 5 New legislative rules with development of new medical device and reduced demand.

Source: created by the authors.

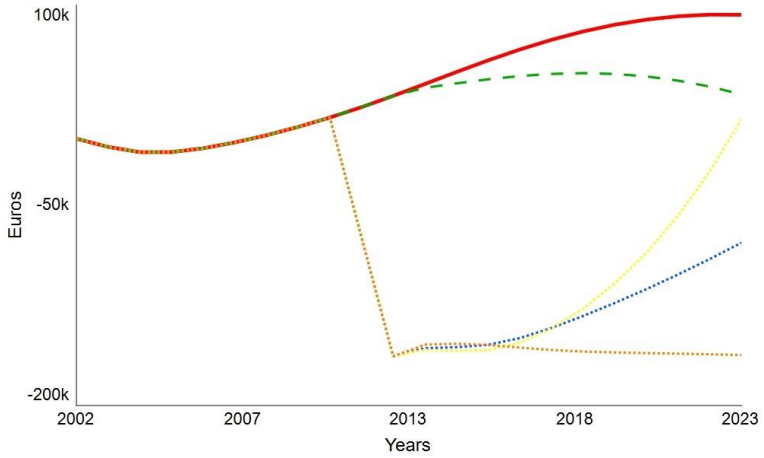
Figure 8. **Development of Selected Company Revenue Indicators in Simulated Scenarios, (thousand €)**

Product revenue corresponds to the defined scenarios, and to the number of products sold (*Table 3*). The development of product's post-sale service revenue is related to the current number of products in use. Each device sold has a lifespan of 7 years, and each year, a security check must be performed to verify its functionality. Service revenues therefore respond to changes in sales with certain delay. E.g., in scenario 3, there is a gradual increase in sales following the launch of a new MD, and while the growth stops after approximately 3–4 years, the service revenues are growing until the end of the simulation. The increase in both product and service revenues is 54%, but the latter does not reach this value until five years later. The charts show that the revenues tend to zero for scenarios 1 and 2, and that scenario 5

also poses a serious threat to the company. What is crucial, of course, is the overall economic result, as shown in the following chart.

3.4 Development of Economic Results and Market Share

The economic results in case of new MD development show a significant decline at the time of the investment (2011–2012), with scenario 4 being the only one, where the company retains positive cumulative earnings; just in the last year of the simulation, as shown in *Figure 9*. The impact of the legislative changes on the cumulative economic result is captured between scenarios 1 and 2, indicating approximately 50% reduction in profit.

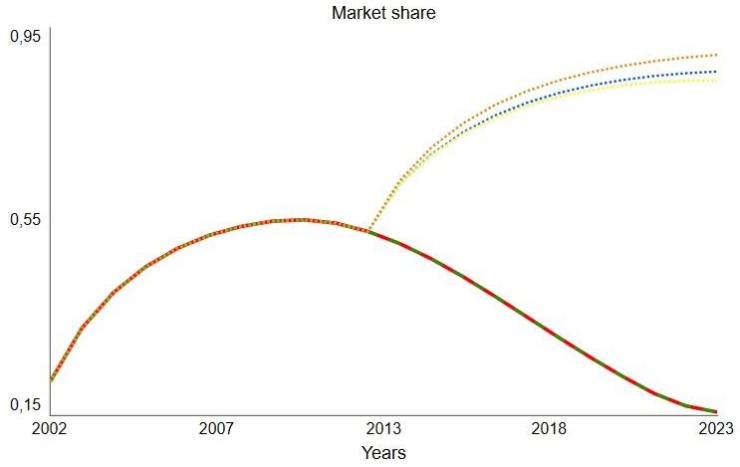


Notes: legend: Scenario 1 Old legislative rules without development of new medical device; Scenario 2 New legislative rules without development of new medical device; Scenario 3 New legislative rules with development of new medical device; Scenario 4 New legislative rules with development of new medical device and entry on a new foreign market; Scenario 5 New legislative rules with development of new medical device and reduced demand.

Source: created by the authors.

Figure 9. **Development of Cumulative Earnings in Simulated Scenarios, (thousand €)**

When considering other possible development scenarios, it is clear that entering new markets would greatly improve company's performance, allowing it to reach positive economic results starting with the year 2022. The least favorable is the last scenario, where the number of required MDs in health facilities is reduced to half of the current value. This scenario documents that it is essential for the company to operate across different markets and business models. The lack of an alternative would in this case bring significant losses that would not be sustainable in the long term. The first scenario is presented for comparison only, as it will not be possible to operate under the old legislation from 2022 onwards.



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Source: created by the authors.

Figure 10. **Development of Company's Market Share, (thousand €)**

Scenarios 1 and 2 end up with minimal market share for the company (*Figure 10*). In contrast, the development of a new MD leads to gaining the majority of the market, which is in line with the historical record for Mediatrade. The exact values of market share in 2023, i.e. ten years after introducing the MD in the market, are presented in *Table 3*, last column.

4. Discussion

The example of a selected European company developing new products on the MD market has shown what the transition to the new European legislative conditions could mean for small companies. The present study is a unique transformation of the actual situation of a real-life company Mediatrade into a numerical simulation based on the data obtained from company's financial statements and consultations with its management. The company currently holds a certificate for their products - single-chamber external pacemakers. In the Czech Republic, the company covers almost 95% of the market. The certificate is valid until 2021, and after 2020, no changes can be made provided the company stays with their current notified body which provides its services under MDD 93/42 / EEC for significantly lower price than other European notified bodies (NBs). In this way, Czech manufacturers are supported by the country in entering the market. With the adoption of MDR 2017/745, this NB will likely lose its status, and the manufacturers will be forced to look for another European NB where the price for the conformity assessment is higher in the order of thousands of euros, which will affect the whole model and business plan settings.

While searching for new NB, the certification was priced 3 times more than the current price, still under the conditions of MDD 93/42/EEC, while the expected price under MDR is even higher. With the current level of sales, the company will not be able to cover the certification costs, hence it must expand in foreign markets (see scenario 4 in the results section). The company already tried selling to India, Pakistan and other Asian countries,

where its sales are gradually increasing, but the price in these markets is lower by almost two thirds in comparison with the European market. To successfully establish itself on the foreign market, the company needs another model of external pacemaker, which could be used in tenders for the acquisition of new MDs in medical facilities. The company developed such a model, and only in 2019, they applied for conformity assessment and the issuance of a certificate with their current NB, which set the price of the certification and the certification timeline. The schedule, however, extends past May 2020, so the certificate will not be issued. The company is left with only two options if they want to market the product: to keep on selling the existing product until 2021 and increase the budget for subsequent certification, but without technological upgrades, thus losing the competitive advantage, or to apply for conformity assessment and certificate issuance with another NB, where the price would be several times higher. Since the company does not have sufficient budget to do that, it must try to increase the sales of the existing product in foreign markets. Once the company has reached sufficient budget, it must apply for conformity assessment under MDR 2017/745. However, this involves submitting clinical data for a new product, which should ideally be obtained by a clinical trial, raising the costs even further. The company nevertheless has the option to set up a quality PMCF to obtain clinical data from its existing resources, which can then be used to perform a clinical evaluation. Although the situation may seem hopeless, should the company fail to set the right PMCF plan, in 2020, it can apply for a conformity assessment for both the existing and newly developed MDs, possibly obtaining the certificate in 2021. This will depend on the strategy and the business plan which must be conceived to gain the resources needed for the certification with the new NB, either by increasing both product and service prices, or by expanding the portfolio as a distributor and seller of medical consumables.

The model developed in this study is a tool which gives management information about what will happen if they do anything and can also crudely forecast the impacts of their current decisions.

To apply the model outcomes correctly, one needs to be aware of its limitations, which are of two types. One is due to the lack of relevant data for some of the model parameters, the second one stems from the simplified assumptions the model uses. In the labor sector, we assume that we can always hire a sufficient number of employees at each timestep to achieve the desired production and service capacity in the next timestep. This is an issue for smaller companies where especially the R&D (including testing) depends on a few individuals with crucial knowledge. In our model, the researchers are not considered part of the labor sector and their salaries are contained in the total R&D budget. Some values or formulae are at best a wild guess or an application of general rules and common sense which may be inaccurate in the given context.

The total R&D budget is known with reasonable accuracy for each MD class (*Table 2*), yet, a large amount of data from multiple vendors would be needed to properly model the research failure. The actual numbers of production and service staff (and potentially other employees) had to be second-guessed from the above, as no detailed list was available. All these data would differ for each company and for each individual product. While the overall advertising budget is known, we have no data or even estimates on the real impact of advertisement. In MD business, especially in small local markets, the general principles may not be applicable. The entire market sector is thus very simplified and the respective formulas for gaining or losing market share cannot be calibrated properly. The competition is represented by historical data which corresponds to Mediatrade's experience on the Czech market with pacemakers. This is one of the main uncertainties, given the large variety of

possible competitor reactions which are unknowable in advance. The company can react after the initial observation with some delay. The increased costs associated with the new legislation would fuel the competition to some degree, as one of the solutions is simply to increase the company's market share (and thus the total income). This should increase the overall pace of innovations (represented by *Obsolescence Rate*), but by how much is hard to predict.

Given the purpose of the model and the above mentioned limitations, the chosen simulation period is sufficient to evaluate the impacts of the legislative change - increased R&D and certification costs clearly manifest due to the short intervals of both processes, giving managers the option to respond by changing the company structure or strategy based on current market conditions.

Looking at other studies (Bandyopadhyay, 2013; Banerjee, Soberman, 2013; Cellini *et al*., 2018; Ding, Niu, 2019; Mazzola *et al*., 2015), we see that a wide spectrum of topics associated with corporate business was addressed; such as (a) issues concerned with the market landscape; (b) topics dealing with quality; (c) discussions exploring PD and innovation; (d) issues with productivity and profitability; and (e) topics dealing with customer utility. All of the issues concerning demand and corporate sales, market share, market strategies, and internal decisions, as well as all topics related to market size, competition in market, market openness and liberalization, export and import, governmental laws, and other macro-level subject matters all fall under the market landscape category (Arafa, ElMaraghy, 2012; Chenavaz, Jasimuddin, 2017; Edison *et al*., 2018; Narayana *et al*., 2019; Olper *et al*., 2013; Zhang *et al*., 2018). Nevertheless, only a few papers provide complete setting and build the model based on real-life data of one or more companies. The firm's capability to balance exploration and exploitation determines its growth and sustainability over time (AbdelShafy *et al*., 2015). Exploitation consists of minimizing unit costs of established products and maximizing the sales of these products. Exploration includes R&D leading to a new product which can enter new markets, or considerably improving existing product design. The findings of (AbdelShafy *et al*., 2015) suggest that company growth is based on balancing capacity acquisition and sales volumes, highlighting the importance of innovativeness for company's long-term market survival. This is especially true in companies developing MDs as the development of MD is a specific process, subject to various legislative restrictions. However, there are no specific values in comparison to our study.

From the point of view of future development and research, a deeper analysis and description of partial parts of the model is expected, from development research through the production and financial sectors. All this will be based on a more robust database based on data from a larger number of companies in the industry.

Conclusions

The manufacturer's entry in the regulated MD market involves the obligation to comply with many regulations, directives and laws in order to ensure a high level of safety for patients. Emphasis is placed on preclinical and clinical evaluations of MDs, so that the manufacturer must prove not only the effectiveness but also the safety of the device. All testing is very expensive, the manufacturer is required to perform many tests in certified laboratories, yet, it is ultimately up to the manufacturer to decide whether the test results are acceptable and compliant. Furthermore, there is the requirement to create technical documentation and to set up a product quality management system. All activities pertaining to

regulatory affairs of MDs are associated with high costs. With the upcoming legislation change, it is important especially for small- and medium-sized companies to properly set up all the parameters of the company's functioning so that they can compete in the European market. Concerning the MD industry in the Czech Republic, switching from MDD to MDR may not pose a significant risk to businesses (aside from increasing the cost of the entire process), provided all MDD requirements were fulfilled without exception. Unfortunately, many companies considered some MDD requirements only as recommendations, thus the cost increase will also apply to the completion of tests and documentation, and in some cases to the creation of complete documentation. Full MDR compliance can be perceived by the company as a kind of protection that warrants the product's safety, both clinical and general. Understanding the importance of MDR can make a company more competitive, can be costly to some extent, as a post-market continuous process, but on the other hand allows for continuous monitoring of technical trends and enhancing the safety of its MD.

The model projections show that the adoption of the new legislation is a serious threat to the selected company, Mediatrade, as its survival requires major changes in its operation. In order to maintain profitability, it must either expand massively in new markets (more than doubling the number of pacemakers sold in scenario 4) or halt the development and sale of the non-upgraded pacemaker with a gradual loss of its market share, in the long term forcing the company to leave the market or close its business (scenarios 1 and 2). Another option is to project the increased costs into the product price (10.5% increase for zero profit). Maintaining a moderate profitability would require much higher value.

For similar micro and small companies, we expect almost doubling the share of certification costs in the total costs for most of the MD security classes. The relative increase for mid- and large-cap companies would be much lower, and therefore does not pose the same level of threat. This could in turn lead to increased merger and acquisition activity on this market, or alternatively lead some companies to exit causing decline in R&D activities at the SME level.

The implementation of the MDR 2017/745 directive is in the interest of protecting and increasing patient safety. Its benefits therefore cannot be underestimated. At the same time, higher prices of MDs and a greater burden on public health budgets can be expected.

References

AbdelShafy, A., Romme, A.G.L., Walrave, B. (2015), *Why some small and medium enterprises grow and others do not?*, Proceedings of the 33rd International Conference of the System Dynamics Society, 19-23 July 2015, Cambridge, *Massachusetts*, conference, available at, https://research.tue.nl/en/publications/why-some-small-and-medium-enterprises-grow-and-others-do-not, referred on 18/03/2020.

Arafa, A., ElMaraghy, W.H. (2012), „Enterprise Strategic Flexibility", *Procedia CIRP*, *3*, pp.537-542, doi.org/10.1016/j.procir.2012.07.092.

Bandyopadhyay, S. (2013), „Market thickness, prices and honesty: A quality demand trap", *Mathematical Social Sciences*, Vol. 65, No 1, pp.52-59, doi.org/10.1016/j.mathsocsci.2012.07.001.

Banerjee, S., Soberman, D.A. (2013), „Product development capability and marketing strategy for new durable products", *International Journal of Research in Marketing*, Vol. 30, No 3, pp.276-291, doi.org/10.1016/j.ijresmar.2013.01.003.

Cellini, R., Siciliani, L., Straume, O.R. (2018), „A dynamic model of quality competition with endogenous prices", *Journal of Economic Dynamics and Control*, Vol. 94, No C, pp.190-206.

Chenavaz, R.Y., Jasimuddin, S.M. (2017), „An analytical model of the relationship between product quality and advertising", *European Journal of Operational Research*, Vol. 263, No 1, pp.295-307, doi.org/10.1016/j.ejor.2017.05.016.

Council Directive 93/42/EEC (1993), Concerning medical devices, 31993L0042, CONSIL, OJ L 169, available

at, http://data.europa.eu/eli/dir/1993/42/oj/eng, referred on 18/03/2020..

Ding, C., Niu, Y. (2019), „Market size, competition, and firm productivity for manufacturing in China", *Regional Science and Urban Economics*, Vol. 74, No C, pp.81-98.

Edison, H., Smørsgård, N.M., Wang, X., Abrahamsson, P. (2018), „Lean Internal Startups for Software Product Innovation in Large Companies: Enablers and Inhibitors", *Journal of Systems and Software*, Vol. 135, pp.69-87, doi.org/10.1016/j.jss.2017.09.034.

EU MDR 2017/745 (2019), *Gap assessment and CE transition strategy for medical device manufacturers*. Emergo, available at, https://www.emergobyul.com/mdr, referred on 10/01/2019.

European Commission. (n.d.), *Medical Devices | Vnitřní trh, průmysl, podnikání a malé a střední podniky*, available at, https://ec.europa.eu/growth/sectors/medical-devices_cs, referred on 23/09/2019.

French-Mowat, E., Burnett, J. (2012), „How are medical devices regulated in the European Union?", *Journal of the Royal Society of Medicine*, Vol. 105, Supplement 1, S22-S28, doi.org/10.1258/jrsm.2012.120036.

House, J.L., Black, L.J. (2009), „The Hero and the Warrior in New Venture Growth", presented at *the The 27th International Conference of the System Dynamics Society*, Albuquerque, New Mexico, USA, on July 26 2009, pp.1425-1421.

Huang, X., Kunc, M. (2012), „Modeling Start-ups using System Dynamics: Towards a generic model", Paper to be presented at the *The 30th International Conference of the System Dynamics Society*, St. Gallen, Switzerland July 22 - July 26, 2012.

Khaledi, H. (2015), „A Generic System Dynamics Model of Firm Internal Processes", in: *33rd International Conference of the System Dynamics Society*, Boston MA.

Kiliç, M., Kaya, İ. (2016), „The prioritisation of provinces for public grants allocation by a decision-making methodology based on type-2 fuzzy sets", *Urban Studies*, Vol. 53, No 4, pp.755-774, doi.org/10.1177/0042098014566370.

Koelling, P., Schwandt, M.J. (2005), „Health Systems: A Dynamic System~benefits From System Dynamics", *Proceedings of the Winter Simulation Conference*, pp.1321-1327, doi.org/10.1109/WSC.2005.1574393.

Mazzola, E., Perrone, G., Kamuriwo, D.S. (2015), „Network embeddedness and new product development in the biopharmaceutical industry: The moderating role of open innovation flow", *International Journal of Production Economics*, Vol. 160, pp.106-119, doi.org/10.1016/j.ijpe.2014.10.002.

Bartlett Foote, S.(1991), „The Impact of Public Policy on Medical Device Innovation: A Case of Polyintervention", in: A.C. Gelijns, E.A. Halm (eds.), *The Changing Economics of Medical Technology*, National Academies Press, pp.89-95.

Narayana, S.A., Pati, R.K., Padhi, S.S. (2019), „Market dynamics and reverse logistics for sustainability in the Indian Pharmaceuticals industry", *Journal of Cleaner Production*, Vol. 208, pp.968-987, doi.org/10.1016/j.jclepro.2018.10.171.

Olper, A., Curzi, D., Pacca, L. (2013), *Trade, Import Competition and Productivity Growth in the Food Industry* (No. 33713; LICOS Discussion Papers). LICOS - Centre for Institutions and Economic Performance, KU Leuven.

Radzicki, M.J. (2011), „System Dynamics and Its Contribution to Economics and Economic Modeling", in R.A. Meyers (Ed.), *Complex Systems in Finance and Econometrics*, Springer, pp.727-737, doi.org/10.1007/978-1-4419-7701-4_39.

Schwarz, R., Schöneborn, F. (2002), *An elementary dynamic model of a small start-up firm*, 20th International Conference on the System Dynamics Society, July 28 – August 1, available at, http://oeconomia.com/Controlling/forschung/sd/beitrag_palermo.pdf, referred on 18/03/2020.

Vallejo-Torres, L., Steuten, L., Parkinson, B., Girling, A.J., Buxton, M.J. (2011), „Integrating Health Economics Into the Product Development Cycle: A Case Study of Absorbable Pins for Treating Hallux Valgus", *Medical Decision Making*, Vol. 31, No 4, pp.596-610, doi.org/10.1177/0272989X10388041.

Vernon, J.A., Goldberg, R., Golec, J. (2009), „Economic Evaluation and Cost-Effectiveness Thresholds: Signals to Firms and Implications for R&D Investment and Innovation", *PharmacoEconomics*, Vol. 27, No 10, pp.797-806, doi.org/10.2165/11313750-000000000-00000.

Wang, W. (2012), *To Grow or Not to Grow? A Multiple-Cases Study on the Growth Dynamics in Medical Care Software Firms*, The 30th International Conference of the System Dynamics Society St. Gallen, Switzerland -- July 22-26, available at, https://archives.albany.edu/downloads/xd07hb40b?locale=it, reffered on 23/04/2020.

WHO | Regulations. (n.d.). WHO, available at, http://www.who.int/medical_devices/safety/en/, referred on 23/09/2019

Zali, M., Najafian, M., Colabi, A.M. (2014), „System Dynamics Modeling in Entrepreneurship Research: A Review of the Literature", *International Journal of Supply and Operations Management*, Vol. 1, No 3,

pp.347-370, doi.org/10.22034/2014.3.06.
Zhang, X., Zhang, L., Fung, K. Y., Rangaiah, G.P., Ng, K.M. (2018), „Product design: Impact of government policy and consumer preference on company profit and corporate social responsibility“, *Computers & Chemical Engineering*, Vol. 118, p.118-131, doi.org/10.1016/j.compchemeng.2018.06.026.

SUPLANUOTŲ TEISĖS AKTŲ PAKEITIMŲ EUROPOJE POVEIKIS MEDICINOS PRIETAISŲ GAMINTOJAMS – ĮMONĖS SISTEMOS DINAMIKOS MODELIS

Petra Marešová, Lukáš Režný, Petr Bauer, Lukas Peter

SANTRAUKA

2021 m. Europa patirs esminį medicinos prietaisų įstatymų pakeitimą, kai bus įvesti privalomi klinikiniai tyrimai mažesnės rizikos grupėms po patekimo į rinką. Šis pakeitimas kelia klausimų dėl būsimų medicinos prietaisų bendrovių ekonominių rezultatų. Pateikiamas mažos įmonės sistemos dinamikos (SD) modelis, pagrįstas aiškiu naujos medicinos prietaisų plėtros vaizdavimu, pabrėžiant įvestų teisės aktų svarbą intuityviajam valdymo sprendimų priėmimui. Modelio prognozės rodo, kad mažoms įmonėms nauji teisės aktai beveik padvigubintų sertifikavimo išlaidas. Nors įgyvendinant MDR 2017/745 direktyvą siekiama padidinti pacientų saugą, rinkos plėtros kontekste tokios priemonės gali sukelti didesnį spaudimą horizontaliai įmonių integracijai, mažoms įmonėms pasitraukiant iš rinkos, ir su tuo susijusiam nuosmukiui mokslinių tyrimų ir plėtros veiklose SME lygiu.

REIKŠMINIAI ŽODŽIAI: įmonė, modelis, strategija, medicinos prietaisų rinka, teisės aktai.