PHASES OF PRODUCT LIFE CYCLE IN THE CONTEXT OF ECONOMIC EFFECTIVENESS AND MEDICAL DEVICE DEVELOPMENT

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Abstract - A product's life cycle is tied into various economic aspects. The paper examines the role that different indicators play during such a process, along with the role played by economic effectiveness. It further looks into product life cycles in the context of medical device development. The study at hand looks to develop an understanding of the current literature that exists on the subject. It will help analyze and evaluate the role that economic indicators and economic effectiveness play during the development of a medical device. It will further expand on how other industries are different in terms of development as compared the medical industry. For the purpose of this study, various peer-reviewed research pieces were acquired and analyzed.

Index Terms - Development, Stages, Product Life Cycle, Medical Device,

I. INTRODUCTION

In the current day and age, the success of a product and its producer is hinged on how effectively they were able to infiltrate the market, command consumer attention, and maintain an edge over competition[1]. Firms need to be more innovative today than ever before[2][3]. If the product life cycle is ignored, then firms may end up investing in the wrong projects.

The product life cycle is essentially a predictor of the different stages that a product will go through in its lifetime. In its simplest form, it explains that a product is first conceived, after which it is introduced into the market, following which it experiences growth and maturity before it finally declines. During the first stage, i.e. product development, the idea behind the product will be developed. Market research will be used to gauge consumer needs with respect to expected demand. The next step is market introduction, whereby the product is released to the consumers [4]. Here, pricing and marketing are key because they help gain and hold consumer attention. After this, the product is allowed a period of growth in the market following which it peaks with the maturity stage. The product finally declines when it has lost its relevancy and is no longer able to fulfil the needs of the consumers adequately. These five stages create a curve; however, most products do not conform to a classical life cycle curve and experience market relevance differently[5]. Different methods are deployed by businesses at different points of the life cycle to ensure the success of the product at hand. [6]put forth that the introduction and growth phases require a leadership strategy, whereas the maturity stage requires a niche strategy. During decline, a harvest strategy is put into motion. In more decent times, the approach is normally coupled with efforts to allocate resources specifically to different activities during different stages. For a business to be effective, it is imperative that there be cost efficiency.

It all comes down to the competitive advantage that companies are trying to leverage in the market. The product life cycle does not just help them identity this advantage, it also helps them exploit it for their success.

The aim of this paper is to describe the phases of product life cycle as it is characterized in current literature in the context of economic effectiveness and the subsequent development of medical devices, which are understood in this paper as a specific type of product.

II. THEORETICAL BACKGROUND

Each product in the market must go through particular development phases, which differ in length according to the product. "Various research projects in marketing and management indicate that a product's life cycle is one of the main variables which have impact on the formulation of appropriate business strategy" (Anderson &Zeithaml, 1984, p. 5), which aims to maximize prospective demand for the product so that the product starts selling immediately when it is introduced in the market.

Market introduction phase

This phase involves the placement of the product in the market. Its success and its rapid rise depend on how well the company management or marketing prepared the market for the product launch. At this stage, the most important aspect is not only marketing but also increasing the frequency of repeat purchase [7]. Further development of the product already in the introduction phase is considered by some as essential as well. When the product is introduced, its popularity with customers is highly uncertain, which is why many companies produce several versions of the product and focus particularly on new innovations. The introduction phase is characterized by the fact that the costs are higher than sales or revenue, which is

understandable, since the promotion of the product should cost approximately one-third of the estimated revenue expected in the following two years.

Sales and revenue growth phase

Even while the product is in the growth phase, it is important for the company to concentrate its efforts also on improving the efficiency of the production process [8]. In order to prolong this phase, the recommended strategy is to lower the prices at the right moment, which brings new customers, for whom price is a major factor and who are ready to purchase the product for the new, lowered price, which ultimately brings revenue growth.[9]As the growth phase comes to its close, the revenue growth stops, and the product enters the maturity phase.

Product maturity phase

Once the revenue stagnates or declines, that is, the revenue is stable, the product moves into the maturity phase. The maturity phase is usually the longest phase of the product cycle. A change of region, such as move to a developing country or another locality where the product has not been offered yet and where market research shows that customers are willing to purchase the product for the given price, might be a solution to this problem, and the company can basically start anew from the revenue growth phase.

Product decline phase

Revenue decline may be caused by various factors, including the change of buyers' preferences, the rise of competition, technological innovations, or simply the inability to sell the product in the market. In response to the decline of sales, companies lower the product price, which further limits their revenue. In the product decline phase, the company stops financing marketing campaigns and other forms of promotion and usually leaves the market or its segments. Cox [10]proposed two methods to identify the phases of a product's life cycle: the catalog life and the commercial life. More specifically[11]defined percentage changes in sales which indicate the boundaries of each of the product's life cycle phases. Assuming that the distribution of percentage changes follows the normal function with mean zero, values higher than $+\sigma/2$ indicate significant growth, values ranging around $\pm\sigma/2$ indicate maturity, and values lower than $-\sigma/2$ indicate decline. While [9], confirmed the validity of the model in tracking the product performance, they pointed out that this method was not particularly helpful in forecasting trends.

III. METHODS

The research methods relied mostly on a review of current literature published on the topic of a product's life cycle in the context of medical device development. The Web of Science and Scopus databases were utilized to locate the relevant sources. The keywords used in the query were product AND life AND cycle AND (medical device development). The search was limited to the period between the years 2000 and 2018. The inclusion criteria were the relevance of the study, i.e., its focus on the given topic, and the language, extent, and quality of the study, i.e., only full-length peer-reviewed studies written in English were included. Original studies as well as review papers were included. Next, references listed in all the included studies were thoroughly checked to avoid missing a relevant source. In the end, a total of 20 studies were used and are listed in the references section. The selected sources were then analyzed by means of comparison and evaluation methods.

IV. FINDINGS AND DISCUSSION

The product life cycle may begin and end with the company that is behind the product, but it is important to understand that there are a number of different elements that can have an impact on the process at hand. Moreover, these factors can typically alter the life cycle itself.

[12]studied the impact that economic cycle can have on the product life cycle. They highlight that the life cycle has five stages, namely, the development stage where a product is conceived, introduction stage where it enters the market, growth stage where it finds a consumer base, maturity stage and decline stage where it peaks and subsequently loses market interest. The authors put forth that each phase has a different period through which it lasts, and may differentiate for different products. A typical life cycle depicts the sale and profit trends of a product. They tied in the economic cycle to the product life cycle to see how changing economies can impact products. Their work suggests that modern economics is generally atypical in terms of economic development. The impact that this has on society and consumer behavior cannot be ignored; therefore, product development must take into account macroeconomic indexes. In the longer term, if there is economic development then the product itself can experience potential growth because of technological progress and innovation.

Uramova et al. (2000) propose that each economic cycle consists of its own stages, i.e. expansion, peak, recession and trough. Many different indicators make themselves obvious during these stages. Each stage can mean something different for a product's lifecycle. In effect, when economic indicators see a downturn or experience sluggish growth, this is bound to impact businesses and in turn their product's life cycle as well.

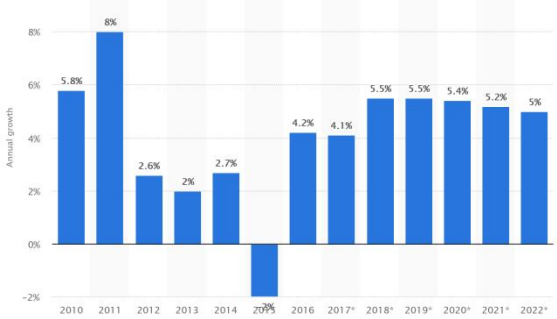
This sentiment is echoed by [13], who are of the view that improvisation is the order of the day. The situation and factors relevant and prevalent during conception phase may no longer be relevant during a product's implementation. This is the reason that the product life cycle needs to remain flexible to marketplace changes. A rigid life cycle can ultimately lead to instant failure,

or worse, dragged out failure where the collateral damage includes a waste of capital and resources.
The work of [14]focuses on new product development (NPD) and looks at the factors that are essential for a product to success. The study looks at foundational successful factors and project-specific success factors. While the study was focused on helping product managers, it simultaneously helped outline the many ways in which new products fail. The product life cycles can suffer due to organizational conflicts, weak decision making, and mishandled information.
Organizations can adapt to the evolving nature of the marketplace by adapting their products or coming up with altogether new offerings. If organizations are unable to adequately respond to changing market trends they essentially provide room to their competition [15].

Medical device development

The product life cycle takes on a different shape when it comes to medical device development. This is because the market and consumer base for such products is not the same as other goods and services.

(1) A medical device is understood as a tool, instrument, appliance, program, including programs provided by the manufacturer to be used specifically for diagnostic and treatment purposes and required for the correct application of the medical device, material, or another item provided by the manufacturer to be used with humans for the purpose of:
a) diagnosing, prevention, monitoring, treatment, or alleviation of a disease,
b) diagnosing, monitoring, treating, alleviating, or compensating an injury or a disability,
c) examining, replacing, or modifying an anatomic structure or physiological process, or
d) birth control,
and which do not achieve its main desired function in the human body or on its surface by pharmacological, immunological, or metabolic means; although their function may be supported by such means.
In other words, medical devices serve to diagnose, monitor, and treat a disease, injury, or disability. Some of the common examples of medical technology include computer tomography scanners (CT), magnetic resonance (MRI) or X-ray imaging.



Source: [2]

Medical innovations are necessitated in an entirely different manner. Apart from financial returns and product effectiveness and safety, clinical improvement in care and the "do no harm" element has been highlighted by Fiedler and [16] are significant concerns. The addition of regulatory processes sets such products apart from other industries. The authors go on to elaborate on a different form of lifecycle for medical devices altogether.
When studying the US (or many other markets) we find that the first stage is conception. The innovation finds its way to becoming a product if its use has been identified already[17]. After this, a prototype is developed, subsequent to which the medical device is subjected to preclinical investigation, and then advanced clinical or post marketing studies. The final stage is the end of life stage where a product is finally discontinued based on the advice of a body such as the FDA [16]. [18]also elaborates on the EU product life cycle in the context of medical device development. Herein, the Medical Device Directives outline the procedure to get a product approved.
In terms of failure of product, the typical decline period does not seem to apply in this context. For instance, while a typical life cycle puts forth only five stages, in the context of medical innovation, [19]even highlight that there may be seven stages and not the typical five. The seven-stage model was originally introduced in 1981 by McKinlay. According to this model, the following stages are applicable to surgical devices:
- Stage 1 – Promising reports

This is where new innovation or medical advancement may find media attention.
- Stage 2 – Professional and organization adoption

The innovation is picked up by institutions and professionals
- Stage 3 – Acceptance and endorsements

The public acknowledges the innovation, and the healthcare professionals help mainstream it in their own capacity, i.e. doctors may adapt it, insurers may provide funding, etc.
- Stage 4 – Standard procedure and observational reports

Studies are conducted around the innovation in question as it becomes a part of usual clinical care. Research looks into how efficient a solution it is to whatever health issue it is relevant for.
- Stage 5 – RCTs

Randomised controlled trials are held which may or may not show that the innovation is not as effective as was originally thought.

The total product life cycle (TPLC) determined by the Food and Drug Administration (FDA) relies on an industry-acceptable model compliant with the directives of the International Organization for Standardization (ISO). Specifically, ISO 9001:2008 (International Organization for Standardization, n.d.a) sets out standards for quality management and

provides tools for companies to consistently deliver high-quality products and services.

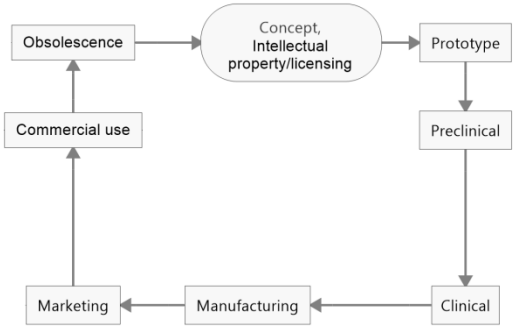


Fig. Visualization of the individual phases and their relationships in the total product life cycle of medical devices

The process is not as elongated for other consumer goods, which rely solely on the average consumer and not on professionals who will eventually provide a final verdict on their effectiveness. [19]pointed out the limitation of this process by highlighting that evidence and testing of the efficiency and effectiveness of a medical innovation should take place before it is launched. Here, it is the surgeons that must act as ethical gatekeepers.

The critical nature of the products that fall under medical device development influences the product lifecycle heavily. The producers must think of regulations and safety in a more concrete manner, as opposed to goods from other industries.

Table 2 Types of analysis and indicators used in a product's life cycle

Analysis types and indicators[13]	
Type of analysis	Indicators
Opportunity analysis	Organizational effectiveness
Testing (customers expectations)	Life-cycle flexibility
Commercialization	
Monitored areas containing other indicators for measurement[20]	
• Engineering subsystem issuing the change • Subsystem interface complexity • Designer experience/knowledge • Frequency of change	
Examples of metric in a product's life cycle[3]	
• total number of potential customers • overall cumulated customers up to time • the cash flow per unit sold • total expected potential cash flows • overall revenue received from product sales up to time • the cash flow from products	

Source: based on

CONCLUSION

The concept of a product's life cycle was formulated around the 1950s, and since then, the model has not undergone any major modifications. The environment and circumstances of production have however changed significantly over the past half a century. Given the fast pace of market and business development today, companies have to devise strategies if they are to become or remain competitive. Different enterprises start collaborating, e.g., in the form of extended or virtual enterprises, with the aim to build upon simple products and create extended products to grow their business. The rapid growth in the area of product innovation means that companies are forced to modify their former views and approaches regarding the product conception.

Innovation in any area is essential for all companies. Innovation is the competitive advantage that helps the company move forward faster than competing companies. Innovation consists in consistently offering better and more advanced products, which is achieved by improving technological production processes, enhancing the products themselves, improving customer service, and optimizing work organization and workflow. In this respect, innovation is the result of a long-term process, which starts with a new idea and goes on through applied phrases when the product is utilized for practical use.

The goal of this paper was to provide a brief overview of current approaches to the product life cycle phases in the context of medical devices. The research has shown that the structure of phases, even with respect to the ongoing fast business and market changes, remains practically unchanged in its main aspects. However, a change is apparent when focusing on medical devices because here, the individual phases need to take into account legislative limitations and criteria and risk analysis. The next step in this field of research is to focus on relevant legislation in different states in order to describe the current situation in the market in detail.

ACKNOWLEDGEMENTS

The paper is supported by the project GAČR 2017 No. 15330/16/AGR Investment evaluation of medical device development run at the Faculty of Informatics and Management of the University of Hradec Kralove, Czech Republic.

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