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## THE DIGITAL TRANSFORMATION AND ITS IMPACT ON SMALL AND MEDIUM-SIZED ENTERPRISES

Anita Kyurova<sup>1</sup>

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### Abstract

*The present article examines the essence of digital transformation and the opportunities and changes associated with the application of technologies in small and medium-sized enterprises (SME's). An overview is provided to the existing digital tools and technology, like social, mobile, big data, analytics and cloud, that SMEs are adopting in the process of transforming their business operations. The paper explores the building blocks of a digital transformation journey and overlooks the planning and implantation stages of digital technology. A literature review was carried out to gain more extensive understanding of the essence of digital transformation and its impact on SMEs. In fact, the article pays special attention to the digital transformation process in SMEs.*

**Keywords:** Digital Transformation; SMEs; business; Industry 4.0; technology; digitisation

**JEL Codes:** L20, M21, O33

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### 1. Introduction

Over the past few years researchers have devoted vast attention on studying the notion of digital transformation (DT), where they have been trying to define it, evaluate its impact as well as outline the opportunities and challenges it brings for businesses and the economy. As a result of the advance of digital transformation, Sallam et al. (2020) forecasts that 75% of Fortune's top 100 global companies are going to incorporate organizational changes with the use of digital technologies by 2025. This is critical for the survival of businesses and those who fail to adapt, will vanish (Schwartz, 1999).

The rise of digital technologies, tools and experiences, etc. marks the stepping stone of the digitalisation of businesses in the modern economy and creates solid basis for building competitive advantage for businesses in the coming years. Both on European and global level, companies are appraising digital technologies as a key

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<sup>1</sup> South-West University "Neofit Rilski", Blagoevgrad, Department of Management and marketing, PhD Student, e-mail: anitka970820@gmail.com; ORCID ID: <https://orcid.org/0000-0002-9524-4045>



strategic priority (Ahmedova, 2020). Even though digital business transformation is obstructing businesses in every sector by removing the barriers between people, businesses and processes (Schwertner, 2017), it is allowing them to create new products and services and improve their processes and procedures.

As a result of the adoption of digital transformation, businesses are having the ability to reconstruct their processes and business models, increase employee's innovative capabilities and efficiency as well as improve and personalize end-customer experiences. Lucas et al. (2013) and Gregory et al. (2019) add that digital transformation affects not only the social processes in the society, but also every industry with its speed, breadth and extent to transformation and digitalisation. Digitization is already perceived as an essential determinant of success and competitiveness for all business sizes and industries (Gerasimenko & Razumova, 2020). Small businesses understand the importance of digital transformation and some have already started their digital maturity journeys. As such, a good understanding of the specifics of digital transformation is a prerequisite for the effective functioning of small business. In this context, the purpose of the present study is to reveal the essence of digital transformation and assess why businesses are now taking strategies in order to embrace it.

## **2. Digital transformation**

The notion of digital transformation is not a recent phenomenon, whereas the ideas of digital products, services and channels have been discussed by authors in the 1990s-2000s (Auriga, 2016). Prominent examples of this shift towards digital are – the use of social media for increasing awareness of fashion shops during the 1990s-2000s; followed by the usage of mobile phones and social media as mediums for customers to communicate with brands in 2000s-2015s; and later the use of PayPal as a direct payment option for businesses (Schallmo et al., 2018). The attention on digital transformation became even more prominent in 2016 during the Davos Forum, where digital technology were more constructively discussed (Min & Kim, 2021). The COVID-19 crisis also disrupted the economic activity worldwide and businesses were forced to implement digital transformation more radically (Clauss et al., 2021).

There are many definitions proposed by authors for digital transformation. Arunatillek (2015) claims that digital transformation is linked to the changes occurred as a result of technological change. Other authors believe that digital transformation refers to the process of implementing technology in process of building new business models, processes and procedures, software and tools that lead to increased income, efficiency and sustainable competitive advantage (Schwenter, 2017). Overall, digital transformation is associated with the development of new products, innovations, organizational change, new business models and strategies (Keeley et al., 2013; Fichman et al., 2014; Bharadwaj et al., 2013). In this paper, we focus on the definition provided by Vial (2019, p. 118), who believes that digital transformation is 'a process

that aims to improve an entity by triggering significant changes to its properties through combination of information, computing, communication, and connectivity technologies'. This definition doesn't only focus on the automation of businesses and implementation of new technologies, but on all improvements that an organization can undergo as part of their digital journey.

As such, businesses are now challenged to achieve digital innovation in order to maximize their business opportunities (Fichman, Santos & Zheng, 2014). According to Yoo et al. (2010), digital innovation is associated with new products, processes and business models that are enabled by the application of IT. As such, SME's critically need to adopt digital innovation in order to overcome the challenges of the external environment and improve their technical expertise (Matthews et al., 2012).

The development of digital products, services and channels have economic impact on different industries (Lau, 2019), for example – production, consumption, distribution industries as well as lead to industrial and social changes (Sallam et al., 2020; Bughin et al., 2018). Oh et al. (2022) indicate that the advance of digital transformation and the adaptation of consumers and the society to these new advances, is forcing all businesses to use of digital tools and experiences to meet the demands and requirements of their markets. Moreover, Lipton et al. (2016) claims that businesses are now restructuring their business operations, reorganizing their strategies and accelerating their digital journeys in order to keep their customer loyalty, which is the primary goal of every business.

Digital business transformation leads to a substantial change in business processes (Lundberd & Sandberd, 2020). Schwertner (2017) and Garzoni et al. (2020) claim that digital businesses are implementing digital technologies, like social, mobile, artificial intelligence (AI), analytics and the cloud in order to transform how a business operates and improve their operations. Table 1 encapsulates a summary of the most common digital technologies used that reinforce digital processes in enterprises.

*Table 1. Digital technology that enable digital transformation in SMEs*

Technology type	Characteristic
<b>Cloud Computing</b>	This is a relatively new type of technology for businesses, allowing them to have convenient network access when people need it to a shared place of customizable computing resources that can be accessed with negligible management effort and provider interaction (Schwertner, 2017). Companies are vastly relying on cloud

	technologies nowadays, whereas SMEs are increasing their investments in cloud.
<b>The Internet of things</b>	The Internet of things represent the interconnectedness of physical devices, vehicles, tools, buildings, etc. through the use of electronics, software, sensors, etc. that allows them to exchange data and communicate (Schwertner, 2017). This allows devices to be controlled remotely and reduces the human intervention in different activities. IoT also increases the efficiency, accuracy and the economic benefits for businesses by linking the external environment into the computer-based systems.
<b>Mobile Technology</b>	Mobile technology has enabled businesses to have real-time communication with their customers across the whole customer journey.
<b>Data Analytics and Big Data</b>	Businesses are facing the need to analyse their data in order to enhance their efficiency and productivity as well as the customer experiences. It is a challenge for many businesses to analyse their data, this is why they are using business intelligence tools.

*Source:* Schwertner, 2017

In addition, Oh et al. (2022) notes that these digital technologies has led to the advent of global platforms, new business models, customer experiences analysis and data-led services, forcing businesses to change the way they operate and develop new strategic models. Due to the digitization processes - machines, robots, devices and systems can respond and connect with the external environment to respond to the market changes. The introduction of new technology can predispose enterprises to satisfy customer's demands and needs, understand customer's behavior, update or create new products or services, and support the innovation processes in the organisation (Yousaf et al., 2021).

In fact, this marks the emergence of Industry 4.0, which is a new industrial scenario that marks the union of digital transformation with the socio-economic systems in the process of value creation (Muller et al., 2018). This process requires not only large investments and human experiences and knowledge, but also the

flexibility, fragmentation and smooth decision-making processes that are highly typical for SMEs rather than big organizations (Moeuf et al., 2017). Therefore, it is necessary to understand the specifics of digital processes in SMEs.

### **3. Small Businesses in digital economy**

Small and medium-sized enterprises, these are firms that are having less than 250 employees or generate up to 50 million euros annually (European Commission, 2021), are of utmost importance in the modern economy. They constitute around 90% of all business, 60-70% of employees, and about 55% of GDP worldwide (Arnold, 2019). They are not only a source of employment, but also their operations are linked to increased innovation and productivity, which are key factors for countries' economic development (Herr & Nettekoven, 2017). Drucker (2009) states that small enterprises 'represent the main catalyst of economic development', being the key pillar for social-economic development.

In the modern economy, there are two types of SMEs (Neagu, 2016):

- Traditional enterprises – Enterprises that are characterized by the lack of long-term strategy, operating in a well-defined marketplace and the operations & production are passed down from generation to generation;
- Modern enterprises – Enterprises that aim to increase the efficiency and the rate of performance of their activities by competing with other businesses and are looking for new market ventures as well as implementing cutting-edge technology.

According to Neagu (2016), only 10% of SMEs are able to survive more than 5 years on the market. Thus, it is crucial for small enterprises to constantly look for new opportunities, differentiate their products and concur new markets. They have the capacity to implement new technology and create new products at faster rates compared to larger organizations due to their limited flexibility and efforts to improve old products without the implementation rigid technologies.

On the other hand, the implementation on digital transformation is characterized with complexity in the SMEs setting, due to the ramifications of cloud computing, IoT, big data and artificial intelligence are imposing on businesses during the planning, and implementation stages. The reason for these are the limited resources and the absence of analytical and business assets that can lead the digital transformation processes (Li et al., 2018).

Nambisan (2017) believes that there are three essential elements required for the successful execution of digital transformation in SMEs:

- Digital Artifact – This is a digital item, application or media content, which is a piece of a new product or service and delivers specific purpose or value to the final user (Ekbias, 2009);

- Digital Infrastructure – This presents digital technology and systems that stimulate communication, collaboration and computing competencies (Nambisan, 2017). As part of the digital transformation journey, digital infrastructures are regarded as more than technology components. Ciborra et al. (2000) claims that digital infrastructures as cloud computing, big data, social media, etc. are supporting business processes.
- Digital Platforms – They represent shared set of services and systems that enable the hosting of different offerings, among which digital artifacts (Parker et al., 2016).

As such, SMEs can become truly digital organizations by adopting digital technologies and platforms, utilizing digital capabilities and developing digital orientation in order to achieve growth and overcome the challenges of the surrounding environment (Garcia et al., 2019; Xiaocong & Jidong, 2010). Digital orientation refers to the adoption and utilization of digital technologies, digital artifacts, digital infrastructure and digital platforms, which act as a driver for value creation and are important in the process of implementation and growth of enterprises.

#### **4. Implementation of digital technologies in SMEs**

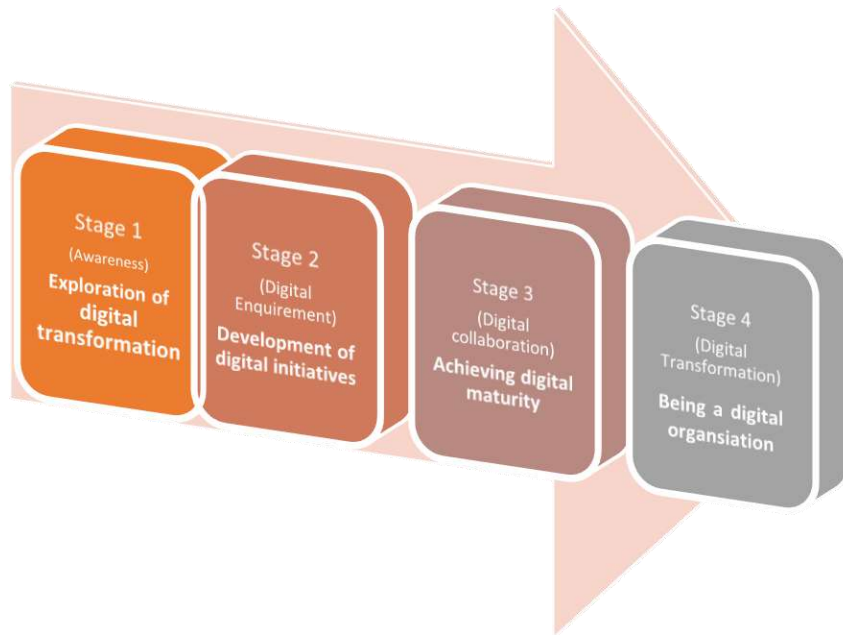
Digital technologies are affecting different sectors and industries, leading to the implementation of new business models and increased levels of innovation. Due to the need to incorporate digital transformation and improve their competitiveness on the global market, SMEs are hard-pressed to implement and use information technology (IT) as part of their operations. Pelletier and Cloutier (2019) indicate that businesses are having access to bespoke and free IT applications that can assist a variety of business functions, like:

- Marketing – ex. E-commerce platforms, Social Media Applications, Collaborations tools;
- Finance and Accounting – Secure payment solutions (PayPal);
- HR – Collaborative tools, Video conferencing (Microsoft Teams);
- Transport – navigation tools and apps (Uber).

SMEs are implementing different approaches for achieving digital transformation. Kane et al. (2019) have developed a 4-step approach for achieving a successful digital transformation journey (Figure 1).

Firstly, businesses are looking at their current strategy and aims as well as analysing the competitive environment. Stich et al. (2020) notes that this is essential in order to highlight the key needs and gaps of the organization and identify how digital tools and technologies can contribute to the digital transformation. During the first stage of the process, SMEs are facing minimal changes in the organization; rather they are exploring the different digital transformation options and processes.

*Figure 1. Digital Transformation Process in SMEs*



*Source:* Kane et al. (2019)

Secondly, the business should specify which digital maturity level they want to achieve – this can be achieved through a self-assessment, and identify what measures they want to implement (Stich et al., 2020). At this stage, the formulation of digital initiatives and processes as a result of the self-assessment is present.

In the next stage, the execution of digital initiatives is happening, resulting in businesses achieving digital maturity and the adoption of digital transformation in all business processes and goals. As a whole, at this stage, SMEs are executing the transformation roadmap in the process for becoming a fully digital organization, which is the last stage. Being a digital organization is characterized by entire digitalisation including the businesses' environment and ecosystem.

As a result, the implementation of digital technologies and tools are changing the global economic and business landscape. The success of the digital transformation is largely defined on the digital strategy developed by business leaders, who are not only promoting a culture that supports change but new inventions as well.

## 5. Conclusion

This paper indicates that digital business transformation allows small and medium-sized businesses to gain sustainable competitive advantage and adjust to the changing technology and environmental conditions (Wijayanti et al., 2021). No business can survive in isolation, thus they have to adapt to the changing environments. Digital transformation is essential for small and medium-sized businesses, allowing them to create innovative solutions, services and products through technology, with which they can communicate and attract customers as well as ease their operations and provide new working models for their employees.

The research of small business digitalisation is still limited, as researchers tend to focus on larger organizations with a few major exceptions (Chan et al., 2020). Similar to larger businesses, small and medium-sized enterprises are essential part of every economy, as they account more than half of the world's GDP. This creates an opportunity for more research in the area and understanding of: *How SMEs are engaging in the process of digital transformation and how they can successfully achieve digital maturity?*

Overall, technological changes are immensely changing the way of doing business. By understanding the different approaches to digital transformation, SMEs will be able to be more resilient, retain their loyal customers, respond more effectively to ever-changing market demands and be more competitive.

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## PROBLEMS IN THE PROMOTION OF HONEY AND BEE PRODUCTS

Savica Dimitrieska<sup>1</sup>, Tanja Efremova<sup>2</sup>

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### Abstract

*Honey and bee products are one of the most popular foods in the world which also have significant health benefits. They have been known for centuries and have been used for various purposes. However, despite their benefits, people in Macedonia do not consume honey or bee products in sufficient quantities. The biggest obstacles for not using honey and bee products is the lack of information about the advantages of this important food, the high price, the unavailability of quality honey, but also the small or no promotion of these products. The purpose of this paper is to examine the problems, especially with the promotion of honey and bee products and to propose certain solutions. To achieve this goal, the research was conducted using a questionnaire that was submitted online to a large number of consumers.*

**Keywords:** honey; bee products; promotion; price; consumers

**JEL Codes:** M31, M37, M38

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### 1. Introduction

Macedonia is mainly influenced by three climate types: continental, mountainous and Mediterranean climate. The climate implies Macedonia to be characterized with hot and dry summers and cold and wet winters. Although the climatic conditions are good, beekeeping is not very popular and developed in Macedonia. According to data from the Macedonian Food and Veterinary Agency, the number of bee families in 2020 is 308,981 and the number of beekeepers is 6,681 in 2020. For comparison, in 2016 in Hungary there were 21,565, in Romania 22,930, in Greece 24,582, in Italy 50,000 and in Germany a total of 116,000 beekeepers. (European Parliament, 2016). Consumption of honey in Macedonia is very low, only 900 grams per capita, compared to the Japanese who annually consume 16 kilograms per capita. In Europe in 2019, the highest consumption of honey per capita is recorded

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<sup>1</sup> International Balkan University, Faculty of Economics and Administrative Sciences, Republic of North Macedonia, Professor in Marketing, PhD, Savica.Dimitrieska@ibu.edu.mk; ORCID ID: <https://orcid.org/0000-0001-9808-6647>

<sup>2</sup> National Bank of the Republic of North Macedonia, Statistics Department, Advisor, Vodolija\_73@yahoo.co.uk; ORCID ID: <https://orcid.org/0000-0001-9469-0329>

in Croatia (2.59 kg per person), Greece (2.47 kg per person) and Romania (1.13 kg per person) (Index Box AI Platform, 2020).

The main reasons for the low consumption of honey in Macedonia are the following:

- People in Macedonia do not have a habit of eating honey and do not recognize honey as a healthy, nutritional, natural, even medicinal food;
- People do not have enough knowledge about the importance of honey and other bee products in the daily food consumption;
- Because of the large number of counterfeits/forgeries of honey (mixing with syrups, sugars, essential and other oils) people do not believe in the quality of honey sold;
- The State authorized institutions and agencies are not interested in proper education of people about the properties of honey;
- People do not know where and how to get quality, real and natural honey;
- There is not enough quality honey available for purchase in shops and markets;
- High price of honey (10-15 Euro/kg) compared to the low standard of people in Macedonia;
- There are no legal solutions, nor strong institutional support for protection and promotion of beekeeping in Macedonia;
- There is not enough promotion of honey and bee products, etc.

On a global scale, bee populations are also declining mainly due to various diseases, viruses that attack bees. Another reason is the use of pesticides, insecticides, but also climate change. Beekeepers must protect the bees, but the state should also be interested in greater education, legal and institutional support for beekeepers and consumers.

## **2. Literature Review**

Honey is one of nature's wonders (Kumar et. al, 2010). Honey has been a common sweetener for foods and a powerful medicinal tool for centuries. Throughout history, honey has been perceived as a nutritional food and as a healing product. Because of its antimicrobial and anti-inflammatory features, honey has also been used in cosmetics and in healing wounds and burns.

According to past historical testimonies, there is an evidence of the harvesting of wild honey, dating back 10,000 years (Arawwawala, 2017). This has been confirmed with the prehistoric drawings found in caves in Spain, 7,000 years old, that indicate some form of beekeeping. However, by 2400 BC, the art of beekeeping was well grounded in Egypt, and honey was used as a natural food and as ingredient in various food preparations. Ancient Egyptians used honey to sweeten cakes and biscuits and also for preparation of many other meals. They also used honey for embalming the dead, for mummification. Archaeologists have discovered honey comb

in Egypt that were been buried in tombs at the pharaohs and the honey was still eatable (Nayik, 2014). This is one of the most important characteristics of honey, which as a natural substance does not spoil, even after so many centuries. The ancient Greeks believed that consumption of honey could help one to live longer. Aristotle called it the “nectar of the gods”. In the Roman Empire, honey was used for paying taxes, on the same level as gold. The ancient Greeks and Romans viewed honey as a symbol of love, beauty, luxury and fertility. Indians have used honey in medicine as an antidote for plant, animal and mineral poisoning and believed that this is one of the five elixirs of immortality (Grigorova et. al, 2016). Honey is accepted as a food source and medicine by both modern and ancient generations, traditions and civilizations.

Today, the beekeeping continues to evolve. In the USA, UK, and Europe, there is a continuous rise of 'natural beekeeping', known as 'bee-friendly' or 'api-centric beekeeping'. Honey is produced in most of the countries of the world. According to Statista (2020), among the largest honey producing countries, China is in the top and followed by Turkey, Iran, Argentina, Ukraine, the USA, Russia and India. China produced 458.1 thousand metric tons of natural honey in 2020.

There are some very interesting facts about honey and bee products, such as (Rowley, 2017):

- Almost one third of the food that people eat is the result of honey bee pollination;
- A single bee can produce about 1/12 of a teaspoon of honey in its lifetime;
- Honey bees are the only insects that produce food consumed by people;
- During a single collection trip, a honey bee visits from 50 to 100 flowers;
- There are three types of bees in every hive: a queen, worker bees, and drones and only drones are male;
- Honey bees don't sleep. They spend their nights motionless, conserving energy for the next day's activities;
- Honey is the only known source of the antioxidant pinocembrin;
- Honey is the only foodstuff that contains all of the necessary nutrients to sustain life;
- The science of beekeeping is called “apiculture”.

Nevertheless, bee populations are suffering a sharp decline due to loss of their natural habitat, inadequate agricultural practices such as monocultures and pesticides, new diseases, viruses and parasites, and climate change. On the other hand, the increase in the world's population has brought with it a greater demand for food. To respond to this great demand, people are producing more food by using a lot of fertilizers, pesticides, and growth regulators that affect various living beings of the ecosystem including honeybees.

### 3. Methodology

For this paper, secondary and primary data was used. Secondary data was collected from different studies, reports, papers, expert opinions, and blogs that cover topics on apiculture. Primary data was collected through a survey that was realized with e-questionnaire. Collected data are quantitative and qualitative in nature. A comparison and historical methods were also used.

A questionnaire was made for this paper which was electronically distributed to consumers in the first half of March 2022. The questionnaire contains open and closed questions, such as multiple choice and Likert scale. Data from 89 respondents were collected. The questionnaire contains two parts, the first part refers to the demographic characteristics of the sample, and the second one contains the research questions.

### 4. Analysis and discussion

The table below presents the demographic characteristics of the sample.

*Table 1. Demographic characteristics of the sample*

Characteristics		Percentage
Gender	Male	37%
	Female	63%
Age	-18	2%
	19-30	58%
	31-50	21%
	51+	19%
Education	Primary	2%
	Secondary	34%
	High	46%
	Master degree	10%
	PhD degree	8%
Monthly income in Euro	-300 €	65%
	300-500€	21%
	500+ €	10%
	No answer	4%
Occupation	Employed	33%
	Unempolyed	10%
	Student	51%
	Retired	6%

Source: Own research

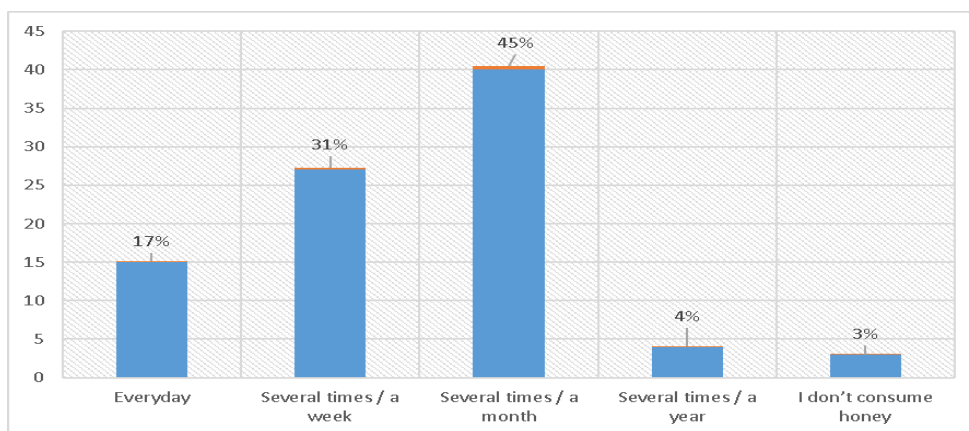
The second part of the questionnaire contains research questions on the use and promotion of honey and bee products in Macedonia.

○ **To the first question** whether they consume honey and bee products, 97% of the respondents answered positively, and only 3% answered that they are not

consumers of honey. But even though this percentage of honey consumers is high, all the answers to the following questions are worrying.

○ On the **second question** about how often consumers consume honey (Figure 1), only 17% of respondents consume honey daily. The largest percentage of respondents 45% use it several times a month, and 7% use it either several times a year or do not consume honey at all. This shows that people in Macedonia do not have a habit of consuming honey.

*Figure 1. Frequency of buying honey*

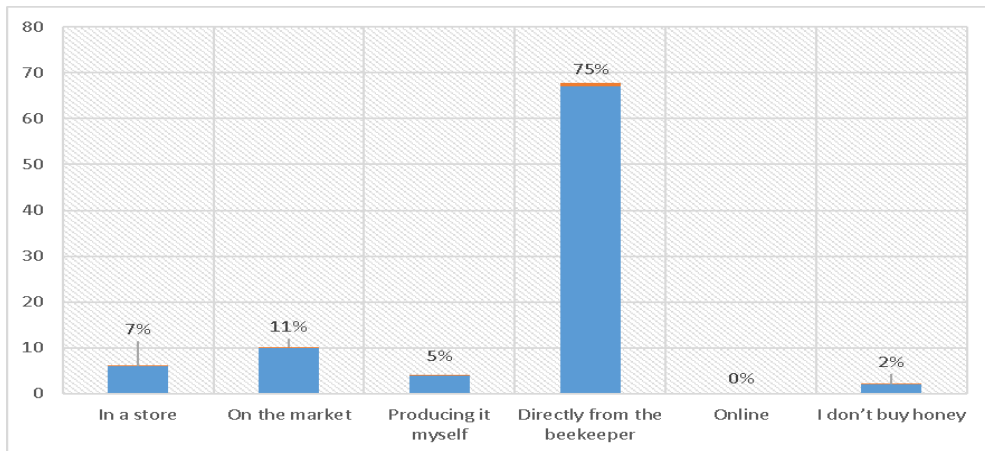


Source: Own research

○ **The third question** regarding where the respondents buy honey should be specifically analyzed (Figure 2). Namely, the largest percentage (75%) of the respondents procure honey directly from beekeepers. No respondent buys honey online, i.e. through beekeepers' websites, Internet or social platforms. A very small percentage of respondents (7%) buy honey from a store or local shop. Also, the percentage of respondents who buy honey on the market is small. Only 5% of respondents produce honey themselves. The high percentage of honey procurement directly from beekeepers should also be of concern to the state, as there is no record of honey sales. It can also be concluded that only a small part of the respondents who cannot find quality honey from beekeepers buy it in the market. Having in mind the words of Zlateva (2020) that “modern business is increasingly investing resources and efforts in the digital environment. New forms of business are emerging, the number of communication tools is growing, and all this is a result of the integration of the information and communication industry. The new generation of users has new information habits. The Internet is part of the daily life of people who actively search, communicate, and share in an online environment regularly” it is really strange and unusual that people in Macedonia do not use online sources to educate themselves and buy honey online.



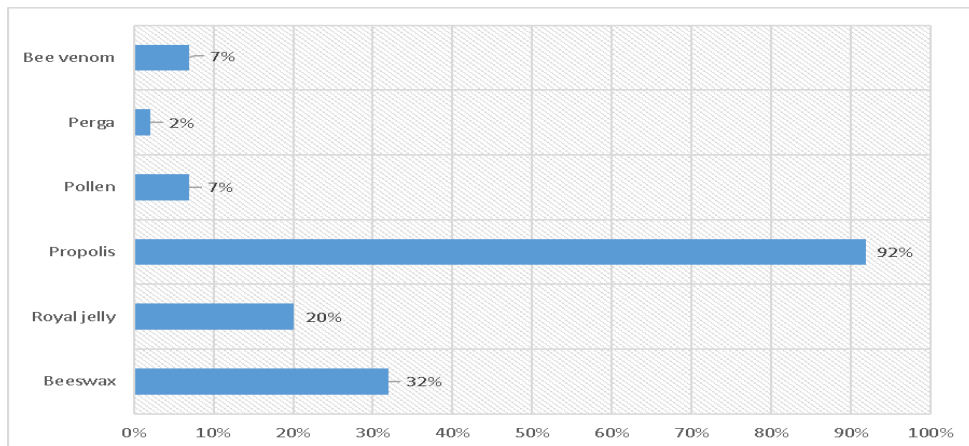
*Figure 2. Way of getting honey*



Source: Own research

○ **To the fourth question** about the type of bee product they use the most, the largest percentage of respondents (92%) answered that they use propolis (Figure 3). Least used are perga, bee venom and pollen.

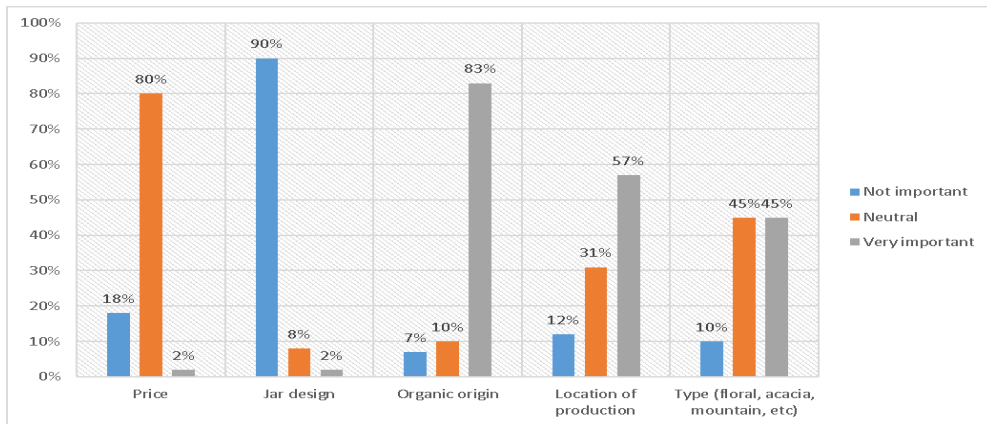
*Figure 3. Use of bee products*



Source: Own research

○ **On the fifth question** of how important the following criteria are: price, jar design, organic origin of honey, location of production, type of honey (flower, meadow, acacia, mountain, etc.) a Likert scale has been designed for consumer opinions (Figure 4). The organic origin of honey, the location of production and the type of honey are of the greatest importance for consumers. The design of the jar is the least important for consumers. Consumers are price neutral.

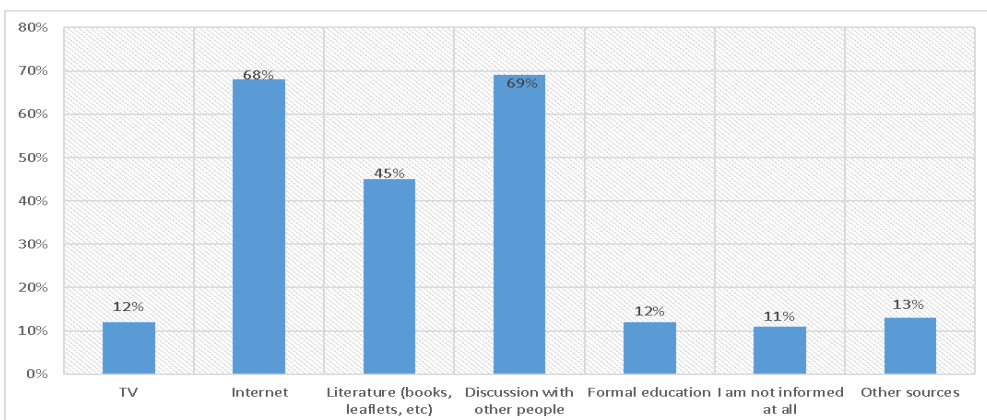
*Figure 4. Significance of certain criteria when buying honey*



Source: Own research

○ **To the sixth question** about how people are informed about the benefits and characteristics of honey (Figure 5), the largest percentage answered that they are informed from discussions with other people, but also from the Internet. Consumers are least informed by TV and formal education. The fact that 11% of respondents are not informed about honey at all is worrying. The answers to this question show that people in Macedonia are not well informed about the characteristics and benefits of using honey and bee products. Greater education and more information on this important nutritional and healing food should be provided.

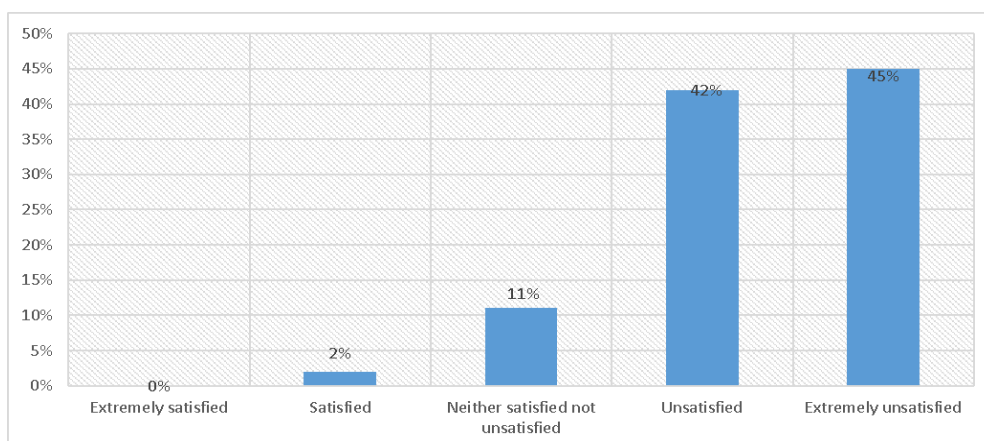
*Figure 5. Information sources about honey benefits*



Source: Own research

○ **To the last question** how satisfied the consumers are with the promotion of honey and bee products, 87% of the respondents answered that they are not satisfied with the promotion (Figure 6). This fact that there is a weak promotion of honey in Macedonia is really worrying. There is even no answer from the consumers to the question related to the “extremely satisfaction” with the promotion of honey. This issue should be an alarm for the institutions, that need to take measures for greater promotion and information of consumers about the characteristics and benefits of honey. Poor promotion leads to less knowledge and consumption of honey.

*Figure 6. Satisfaction of promotion of honey and bee products*



Source: Own research

## 5. Conclusion

Honey and bee products have been used as an everyday food that has nutritional and medical properties since ancient times. Honey is considered to be the best natural substance that has not been spoiled for centuries. Honey along with bee products should be on the table of consumers every day. But research shows that in Macedonia people do not have the habit of consuming enough honey. The reasons for the low consumption of honey, almost 1 kg / person per year, are many. But, from the aspect of this paper, the most lacking is knowledge and proper education and promotion of quality, natural and real honey. State institutions and agencies must take measures for greater protection of beekeepers, investment in beekeeping and greater education and promotion of honey and bee products for consumers.

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## GLOBAL SOCIAL RESPONSIBILITY OF BUSINESS AS A PART OF ORGANIZATION OF ITS ECONOMIC SECURITY

Yevgenia Voronyuk<sup>1</sup>

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### Abstract

*In the modern world the social responsibility of business to society becomes more and more relevant. The world trends of socio-economic development demonstrate that businesses need to implement the provisions of social responsibility at the corporate level. This article considers the general architecture of corporate social responsibility strategies (CSRS) of enterprises and their impact on the state of economic security of business. The study focuses on the development of a quality system of economic security of enterprises using CSRS.*

**Keywords:** economic security; social responsibility; organizational support its economic security; security and sustainability

**JEL Codes:** K22, L26, O11

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### 1. Introduction

The organization of an effective system of economic security of the enterprise is under the influence of risks and threats. Thus, Ukrainian enterprises in the process of building a personal system of economic security work with the following factors:

- Firstly, a market economy built on competition is a rather dynamic system that is risky.
- Secondly, in Ukraine there are still no stable rules of law to protect the interests of entrepreneurs.
- Thirdly, as the Ukrainian market is still in its infancy, there are many mechanisms that have not yet been fully developed.

The analysis of the scientific environment has shown that in the process of achieving the appropriate level of economic security, businesses must solve problems related to:

- The advantage of using a reactive approach (expectation of the negative impact of the threat and further follow-up measures to eliminate the consequences instead of premature analysis of possible ways to avoid this impact);

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<sup>1</sup> Simon Kuznets Kharkiv National Economic University, Department of international economic relations, Lecturer; e-mail: yevheniya.voronyuk@hneu.net; ORCID ID: 0000-0002-1635-7421

- The need to improve the quality of information collection not only about competitors, but also about the state of its own activities, which includes the priority of defining the goals and strategies of the enterprise;

- Insufficient application of the analysis of the costs of the enterprise for economic security;

- Neglect of the existing capabilities of the enterprise and the direction of the entire system of economic security to work with threats.

Sources of negative impact on the economic security of the enterprise can be: conscious or unconscious actions of individuals and business entities (public authorities or competitors); coincidence of objective circumstances (force majeure, innovations, etc.).

It should be noted that there are a number of reasons on which depends the economic security of the enterprise. In particular, from economic crises, emergencies, natural disasters, unforeseen changes in market conditions, social tensions, managerial incompetence, as well as failure of partners, suppliers, customers and clients to fulfill their obligations to pay contracts, supply products or change conditions.

The above demonstrates that the functioning of the enterprise directly depends on the quantitative and qualitative characteristics of economic development of the country. The country's economy is also dependent on the level of economic and social development of economic entities in its territory, as well as the environment. Each country is responsible for the future of the world, using various institutional mechanisms, formulating legislative proposals and controlling the activities of enterprises in terms of their social responsibility to society, the region, humanity.

In this context, the above issue of building an effective and harmonious system of corporate social responsibility is relevant and in need of further research.

## **2. Results and Discussion**

Ukraine's economy is at the stage of development, when the state interferes in socio-economic development even on a larger scale than defined in the first stage, while in the economic development of countries such as the United States, Japan, Britain, Germany, Sweden, France came the third stage, characterized by a decrease in state intervention in the activities of economic entities (Ukrainian Parliament, 2017).

The economic security of business processes of the enterprise is the main element and factor of its security-oriented development.

The organization and provision of economic security should be given special attention at each enterprise. The presence of a large number of threats requires the development and implementation of effective measures to ensure the economic security of business processes of the enterprise (production, financial and investment, technical and technological and innovation, marketing and personnel management).

Today, in legal terms, the economic security of entrepreneurship is organized through two levels of regulations, which are interrelated:

1) International regulations, treaties, agreements, conventions ratified in Ukraine:

- Association Agreement with the European Union - which allows for simplified trade with EU countries, thus forming new principles of economic cooperation and development (Zhykhor, Gorokhovatsky & Oleynikova, 2013);

- Membership in the World Trade Organization - provides Ukrainian companies with safe international trade and protection of their rights and resolving disputes that may arise in the process of working with other states (Parliament of Ukraine, 2008).

- Signed and ratified Free Trade Agreement between Ukraine and the states of the European Free Trade Association, the Agreement on Agriculture between Ukraine and Norway, Iceland and Switzerland (Parliament of Ukraine, 2014) and others.

2) National legislation:

- Constitution of Ukraine (1996).;

- Codes and laws of Ukraine (Code of Labor Laws, 1971), Commercial Code (2003), Tax Code (2011), Law of Ukraine "On Entrepreneurship" (2004), Law of Ukraine "On Accounting and Financial Reporting in Ukraine" (1999), the order of the Cabinet of Ministers of Ukraine On approval of the Strategy for the development of small and medium enterprises in Ukraine (2017) and others.

Thus, the study demonstrates that scientific thought in the field of economic security has served as a foundation for the formation of a legal framework for the harmonious and safe operation and development of enterprises.

On the other hand, the choice of methods to ensure the economic security of business is performed directly at the enterprise. The third element of the general organization of economic security is the ability and ability of enterprises to develop methods of adaptation to the external environment, one of the parts of which is national and international law.

In general, the organizational support of economic security of entrepreneurial activity is aimed at ensuring that each business entity has the opportunity, without creating an additional subsystem (such as a separate economic security service) directly at the enterprise, to develop safely. However, today's global competitive environment creates separate business challenges, and it is impossible to expect that the state will create the safest conditions for doing business with the help of legislation alone.

Creating conditions for the safe development of the enterprise is impossible without ensuring the preservation of the environment and other sustainable development goals.

In recent years, the concept of corporate social responsibility has become widespread in Ukraine, which is a system of public relations with stakeholders, interaction with the state in solving social problems.

The classic definition of corporate social responsibility is given by F. Kotler: "Corporate social responsibility is a free choice of a company in favor of the obligation to increase the welfare of society by introducing appropriate approaches to doing business and allocating corporate resources" (Hohulia & Kudinova, 2008).

Corporate social responsibility (CSR) extends to the following main areas: respect for human rights; compliance with legal requirements; business and corporate ethics; environmental protection; cooperation with stakeholders; compliance with international standards of conduct; transparency and accountability (Parliament of Ukraine, 2020).

According to the developed "Strategy to promote the development of corporate social responsibility in Ukraine until 2020", the need for the development of corporate social responsibility in Ukraine is due to the following factors: low level of corporate culture; legal nihilism and deformation of legal consciousness; low level of public awareness about the role of business; terminological (normative) uncertainty; closedness of Ukrainian companies to the general public; uneven consideration of the interests of stakeholders (Klymenko, 2011).

Existing models of social responsibility have a multilevel structure. Researchers on corporate social responsibility distinguish three levels for determining social responsibility.

The first (basic) level - the business pays taxes in full and legally, so the funds go to the budget, where they are distributed to the same social programs.

The second (corporate) level - socially responsible business must pay an economically reasonable salary. It's no secret that businesses now often save on salaries, seeing this as part of their costs. On the one hand, it is so. But on the other hand - business must understand that a high salary allows a person to spend money on maintaining their health, education, culture.

The third (higher) level - socially responsible business on a voluntary basis is engaged in charity. On the one hand, a potential investor has more confidence if the company can afford to implement large-scale social programs that are not directly related to production, and this is known in society. On the other hand, these programs show that the business is open, it deals not only with internal corporate programs, but also works with society.

Social responsibility not only improves the company's image, but also provides a competitive advantage in the long run, access to new markets (Rodionov, 2009).

Achieving the goals of sustainable development by enterprises is not possible to create and implement a corporate system of social responsibility, which must not only be formally documented, but be implemented at all levels of government and provided by each business process.

To build such a system, the company's management has to:

- 1) understand and analyze business models that stimulate change;
- 2) learn to inform key stakeholders about the competitive advantages of partnerships with socially responsible enterprises;



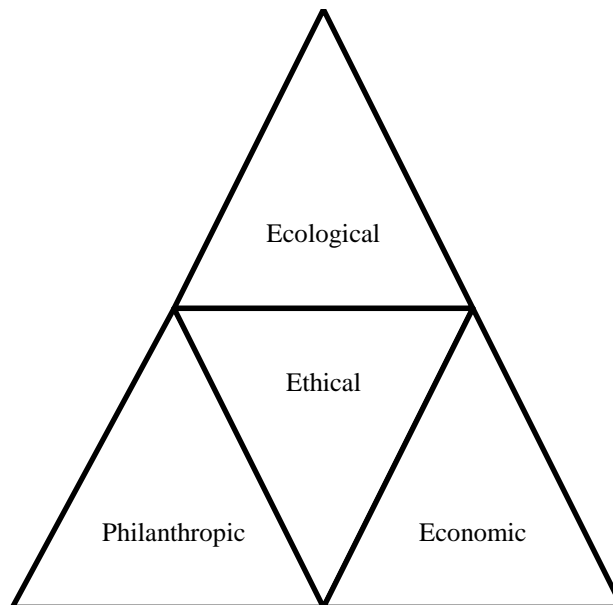
3) to explore the importance of collective efforts in achieving goals and sustainable development and how business can become a catalyst for change at the system level in the face of serious global problems, such as climate change and income inequality;

4) to study the wider ecological, political and social landscape in which the enterprise operates, including the role of government, investors and clients;

5) determine the strategic goals of achieving the goals of sustainable development

In modern conditions of global economic development, the key to the strategic safe operation of business is to achieve the goals of sustainable development through the creation of a system of corporate social responsibility, the key types of which are shown in Fig.1

*Figure 1. Types of corporate social responsibility*



*Source:* made by author

Environmental responsibility is the belief that companies must behave as environmentally safe as possible. This is one of the most common forms of corporate social responsibility. Some businesses use the term "environmental management" to refer to such initiatives.

Businesses that seek to take environmental responsibility can do so in several ways:

1) Reduction of pollution, greenhouse gas emissions, use of disposable plastic, water consumption;

2) Increasing dependence on renewable energy sources, stable resources and secondary or partially recycled materials;

3) Leveling the negative impact on the environment; for example, planting trees, funding research and making donations for appropriate activities.

Ethical responsibility is ensuring that the company operates honestly and ethically. Business entities that adhere to ethical responsibility strive to achieve fair treatment of all stakeholders, including management, investors, employees, suppliers and customers.

Businesses may perceive ethical responsibility in different ways. For example, a business may set its own, higher minimum wage if the statutory wage does not constitute the wage required to live in the region. Similarly, businesses may require that products, ingredients, materials or components be supplied in accordance with free trade standards. As a result, many businesses have procedures in place to ensure that they do not buy products created as a result of slavery or child labor.

Philanthropic responsibility is the goal of business to work actively to improve the world and society.

In addition to acting as ethically and environmentally as possible, charitable businesses often dedicate part of their earnings to measures to improve living conditions, the environment, and reduce poverty. While many companies donate to charities and nonprofits that are in line with their mission, others donate to activities that are not directly related to the specifics of their business. Some businesses go so far as to create their own charitable foundation.

Economic responsibility is a practice where the ultimate goal is not just to maximize profits, but to positively impact the environment, people and society.

Most businesses are forced to accept corporate social responsibility because of moral beliefs, and this can bring several benefits:

1) Corporate social responsibility initiatives can, for example, be a powerful marketing tool, helping the company to position itself positively in the eyes of consumers, investors and regulators.

2) Corporate social responsibility initiatives can also improve employee engagement and satisfaction;

3) Such initiatives may even attract potential employees who have strong personal beliefs that are consistent with the beliefs of the company.

4) Corporate social responsibility initiatives, by their nature, force business leaders to study practices related to how they hire and manage employees who supply products or components and provide value to customers.

Fulfillment of the above conditions can lead to innovative and revolutionary decisions that will help the company to act more socially responsible and systematically increase profits. For example, rethinking the production process in

such a way as to consume less energy and produce less waste will allow the business structure to become more environmentally friendly, while reducing energy and material costs.

Social responsibility of domestic enterprises is, first of all, payment of taxes in full, observance of labor and environmental legislation, creation of jobs, and charitable actions. All these measures are aimed at the external environment of the enterprise. Among the initiatives aimed at the internal environment are: increasing productivity, increasing competitiveness, optimizing costs, implementing a strategy for further development, improving the image, increasing turnover and the number of consumers. Most small and medium-sized businesses pay more attention to internal social programs focused on their employees. The participation of small businesses in social activities is usually informal. This phenomenon is due to the lack of management skills for social responsibility of managers of small and medium enterprises. But addressing issues such as meeting consumer needs, tackling corruption, tax compliance, certification and product quality are also relevant today (Pidubna, 2017).

The main principles of forming a long-term strategy of the enterprise in the direction of CSR are:

- 1) High quality standards of goods and services;
- 2) Fulfillment of obligations to employees, suppliers, partners;
- 3) Meeting the needs and interests of all stakeholders.

The main advantages of organizational management based on these principles include: a better understanding of the needs and expectations of society; improving the effectiveness of risk management; improving relations with stakeholders; increasing the reputation of the organization as a whole (Kozachenko, 2013).

In order to succeed in implementing the strategy, you must first study the market and conduct a qualitative analysis of external and internal factors that may to some extent affect the expected result. Since in the modern realities of market relations the analysis of four groups of factors (social, technological, economic, political) is not enough to satisfy the interests of all groups of influence, ecology and legislation are added to modern literature, the analysis of which becomes necessary for socially responsible companies. In the course of the analysis to find out the influence of factors that for a long time were not even taken into account by many companies (Kovalchuk, 2014).

The most common approach for most companies is that the sequence of stages of strategy formation is as follows: definition of mission and goals, analysis of internal opportunities, analysis of the external environment, analysis of alternatives and choice of strategies, implementation and evaluation of the chosen strategy. Each stage of forming the strategy of the enterprise must be consistent with the principles of social responsibility, which are the basis of the basic concept of CSR. The basic concept of CSR of the enterprise is the complex model which is directed on satisfaction of

interests of all participants of business process. According to this approach, we will identify the main stages of forming a strategy of corporate social responsibility for Ukrainian enterprises (Saprykina, Lyashenko & Saensus, 2011).

Defining the mission of CSR (Thompson & Strickland, 2006):

1) The mission of social responsibility is to improve the quality of life of employees, the local community and society.

2) Formation of the system of goals (goal trees) of CSR.

3) The goals of a socially-oriented enterprise include:

3.1) Ensuring the socio-economic development of staff.

3.2) Ensuring the production of quality products.

3.3) Ensuring activities aimed at saving resources.

Analysis of the internal environment. The analysis is conducted to identify strengths and weaknesses and should focus on analyzing the company's social initiatives focused on employees, organizational culture, production and sales. Examples of internal responsibility can be actions focused on compliance with working and leisure conditions, timely payment of wages, benefits (Yermoshenko & Goryacheva, 2010).

Analysis of the external environment. The analysis should focus on external projects that are related to the activities of the enterprise, as well as on the nature of relations with external stakeholders. Assessment of the level of social responsibility. For small and medium-sized businesses, the third (higher) level is not always possible. Small and medium-sized businesses can be more active in implementing issues related to fair payment of taxes (first level) and decent wages (second level of social responsibility) (Martyniuk, 2013).

Choice of strategy. Based on the analysis of the internal and external environment and the assessment of the level of social responsibility of the enterprise, the appropriate strategy and directions of CSR are selected.

Implementation of CSR strategy. The next stage is the development of social programs and projects, action plans aimed at implementing the strategy. The implementation of the strategy should be aimed at establishing a correspondence between the chosen strategy and internal organizational processes in order to focus the activities of the organization on its implementation (Zhykhor, Gorokhovatsky & Oleynikova, 2013).

Evaluation of the implementation of the CSR strategy. There are four criteria for assessing social responsibility: economic (profit), legal (compliance), ethical (ethical behavior), acceptance of responsibility (improving the welfare of society and quality of life) (Krakos & Razgon, 2008).

Thus, we can conclude that the content of the strategy is to ensure a high level of corporate social responsibility, which may include the following main components:

1) Development of a concept of staff training, which should include various forms and methods of training. Staff training in special courses conducted by higher

education institutions (MBA programs); courses and trainings focused on acquiring specific knowledge and skills.

2) Strengthening social protection of workers. In this section of the basic strategy of corporate social responsibility, a social package is formed, components of social infrastructure are improved, and so on. At the expense of profit additional compensation can be established for workers, pensioners, mothers, decrease in prime cost of the goods and services sold within the limits of a social infrastructure of the enterprise.

3) Health of the population (community), development of local and regional infrastructure. This section provides for the establishment of relations and cooperation with local authorities for sports, charity, sponsorship events involving the resources of the enterprise: human, informational, financial, etc.

4) Business ethics. Based on the developed Code of Ethics, the principles of conduct with business partners are established.

5) Environmental friendliness and environmental activities include not only compliance with the law, but also voluntary actions aimed at cleaning the surrounding areas from dirt; actions aimed at saving energy and resources, etc.

6) Meeting the needs of consumers primarily in the production of quality products that meet all international standards, using environmentally friendly raw materials (Lyashenko, 2012).

### **3. Conclusions and Recommendations**

The study showed that the implementation of corporate social responsibility system is one of the elements of the organization of an effective system of business's economic security.

For any business it is very important to form its own strategy of corporate social responsibility and choose effective tools and methods to ensure it. Only in this case, CSRS becomes an effective element of the economic security of business.

The use of corporate social responsibility strategies demonstrates the assessment and understanding by business of its responsibility to society and the world.

Analysis of international trends in corporate social responsibility showed that now the whole business community is trying to reduce its impact on the environment. Such position of business has found support and reflection in the legislation of different countries of the world. For this purpose new laws, institutional mechanisms and forms of strategic partnerships are being introduced all over the world. The attention of state authorities to the issues of social responsibility of business creates additional competitive advantages for companies which adhere to the established framework of corporate social responsibility, which also increases the level of their economic security.

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## LEADERSHIP THEORIES REVIEW

Victoria Gentsoudi<sup>1</sup>

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### Abstract

*Through years many theories, definitions and classifications about leadership have been developed and can be found in the contemporary literature. Despite the fact that volumes of writings about leadership exist in global literature still it is considered a debated subject since the leadership content remain inconsistent and unclear. In addition, researchers in an effort to define and classify leadership have concluded that it is a complex, flexible and multidimensional phenomenon which requires plenty light to be shed on it. The most prominent theories that emerged during 20<sup>th</sup> century and will be analysed in chronological order constitute of the Great Man theory, Trait theory, Contingency and Behavioral theory. The purpose of the present paper is to examine the wider context of leadership and its effectiveness towards improving, through organizational changes, the public sector in times of crisis. It can be considered as an additional conceptual approach to the existing literature.*

**Keywords:** Leadership; Decision Making; Public Sector; Financial Crisis; Humanitarian Crisis

**JEL Codes:** M10, M12, J24

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### 1. Introduction

In recent years many factors such as political, economic, social and cultural standards, technological changes, international competition, and deregulation of markets play an important role in shaping new conditions in work place which requires the implementation of new leadership approaches and techniques (Daft, 2015). Especially in times of humanitarian and financial crisis, immediate response is imperative in order to cope with the fast changing economic environment and increasingly globalised world. In order for any sector to adjust to the new conditions, change must be implemented and this can be achieved through the implementation of the most suitable leadership style according to the environment in which it is practiced. It goes without saying that proper leadership is considered to be the driving force for this change. This is why it is crucial for leaders to be able to adapt to the new requirements and react with immediate organizational changes in order to provide the organization with the most effective and productive leadership implementation. But

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<sup>1</sup> SWU “Neofit Rilski”, Blagoevgrad, Bulgaria, Faculty of Economics, PhD student, e-mail: giotisveta@gmail.com; ORCID number: 0000-0002-2883-1311



what are those qualifications that may give prominence to the most capable leader. Are the leadership skills acquired or inherited traits?

It is commonly believed that a good leader must be well educated, skilled, experienced, committed, patient, and most importantly be capable to set the goals and cooperate accordingly with his subordinates in order to achieve their purpose. In order for a leader to be considered capable is to gather all those traits and behaviours that are required so as to increase his leadership capabilities. Although, many researchers have defined different leadership theories that have been refined and modified with passage of time. As Warren Bennis and Stogdill (1948) have mentioned the leadership sector has been examined and defined in great extent by many authors but still little knowledge we have on it. This is why leadership is considered as complex subject and still generates captivating and confusing debate. Even though we cannot define accurately and restrict the term and concept of leadership, we can provide a general perception of the term. This perception of leadership can be described as the ability of an individual (leader) to build a relationship of trust and commitment between him and other individuals or group of individuals (followers) influencing and empowering them in order to pursue and achieve the goals of a vision.

The information mining through the followed methodology and the literature review allows a wide applicable range of scientifically supported views while conducting a systematic review of the current scientific literature.

## **2. The Conceptual Framework of Leadership**

Much research has been devoted in order to find and describe the features of the most capable leaders whose leadership style may find application in the most effective and productive way.

Despite the prevailing belief that that public sector's organizational effectiveness depends primarily on factors beyond the control of the leader, such as social, economic or market conditions, government policies and technological changes, there are authors who suggest that there is an innate need for people to find someone in the face of whom to see the leader that is capable to lead, guide, organize and inspire them (Golensky & Hager, 2020).

The portrait of this leader is constituted by a self-composed leader with capacity building and acquisition of expertise, capable to lead and whose actions can be predicted and understood and not the result of random events (Pfeffer, 1977). A leader is the person who can accept, adjust and cope with the change. He is the one to take on the change process of an organization by creating and defining the vision of the future through specific directions, strategies and innovations. In other words, the leader is capable to provide the right direction to their followers by inspiring, motivating, influencing and empowering them to overcome any obstacle through the provision of the right incentives to achieve the vision they share (Kotter, 1990). Fiedler (1971) pointed out that there is a wide range of definitions of the conceptual

framework of leadership as well as corresponding theories. Taking that view into consideration, the different meaning of the term "leadership" and according to W. Bennis and B. Nanus (1986), who believe that leadership is the most visible phenomenon but little understood we will adduce the theoretical approaches of leadership that have been developed through years so as to provide readers with deeper and more complete knowledge on the subject. According to Bourandas (2005), leadership is a process of "Influencing the thinking, feelings, attitudes and behaviors of a small or large, formal or informal group of people by one person (leader), in a way so that voluntarily and willingly and with the appropriate cooperation to give their best itself to effectively implement the goals arising from its mission team and its ambition for progress or a better future". In other words, leadership reflects the interactive relationship between leader and followers who share a common vision which is to join forces within democratic decision-making processes in order to achieve an aim common for all so that everyone can enjoy its benefits (Daft & Lane, 2018). Additionally, leadership can be described as an interactive activity or a procedure during of which a leader sets a vision, influences the behaviour and actions of the followers, empowers them and cooperate with them in order to shape the culture of the organism and achieve the purposes. It is not clear if the ability to lead is product of innate factors or something that is acquired due to the fact that there are factors and situations that prevent from shaping a clear perception of it. For instance, few decades ago researchers using as tool the development of psychology proceeded to adding few more traits such as the age, social characteristics such as popularity as well as skills such as fluency, personal integrity, responsibility, intelligence, interpersonal skills and independence (Daft & Lane, 2018). The environment, the culture and the situation in which a leader acts plays crucial role too. Particular situations demand particular forms of leadership. Evans and Lindsay (1999) refer to leadership as an individual's effectiveness to gain control over systems and people converting them into followers so as to implement his aspirations with the ultimate purpose the pursuit of specific positive results. Goleman (2002) defines leadership as the ability of an individual to inspire and guide other individuals and groups towards a common goal, promoting or managing change properly. According to Yukl (1994, 1999) "The term leadership includes processes of influence, which imply the definition of the objective goals of the team or organization, the creation of incentives for the manifestation of project behaviour that is aimed at the pursuit of these objectives as well as the contribution to the preservation of the team and the culture". Another definition given by Stogdill (1950) "Leadership is the process of influencing the actions of an organized group of individuals so that they work willingly to achieve group goals".

Taking into consideration all the above definitions and in an attempt to provide a more generalized definition attribution, leadership can be described as "A process where an individual exerts influence over a group of individuals in order to achieve a common goal" (Northouse, 2016). We can understand that leadership constitutes by

five fundamental elements; the leader, the followers, the vision, the source of power and the situation or the environment within all of the aforementioned coexist. No leader occurs if there is no team to lead and no vision to realize. The most basic definition of leadership was formulated many decades ago by Hersey and Blanchard (1969), who define leadership as the process that aims to influence the actions of an individual or an organized unit trying to achieve the goals that have been set under granted and stable conditions.

### **3. Leadership Approaches**

In 1950, a new approach had been developed known as the ‘Great Man Theory’ according to which genes are responsible for prominence of certain individuals to leadership positions and being passed down from generation to generation. Thereafter, early trait researchers studied the personality attributes that they believed were related to leadership effectiveness and many of them considered them as innate (Kanji & Moura, 2001). Trait approach focuses on the investigation of personal qualities, talents and skills of leaders as well as the determinants that differentiate leaders from non-leaders/followers (Mann, 1959).

Another classification of leadership styles derives from the trait theory according to which leadership characteristics and skills are not innate but can be gained, learned and developed. Yukl (2013) says the term refers “to a variety of individual attributes, including aspects of personality, temperament, needs, motives, and values”. Daft (2015) refers to traits as “the distinguishing personal characteristics of a leader, such as intelligence, honesty, self-confidence, and appearance.” Antonakis et. al (2004) describe the trait term as “relatively stable and coherent integrations of personal characteristics that foster a consistent pattern of leadership performance across a variety of group or organizational situations”. Stodgill (1904 - 1974) having examined many trait studies of the previous literature concluded that the concept of a leader was framed around an individual who exhibits the ability to work with a group in attaining mutual goals. The traits that this individual was displaying included “intelligence, self-confidence, alertness to others’ needs, understanding of tasks, initiative and persistence in addressing problems, and desire to take responsibility and hold positions of dominance and control”. He also suggests that leadership is not only about featuring specific traits but also cooperating actively with the members of a team in which the leader has active participation setting the vision and exhibits the ability to take on and handle any issue may arise until the goals are achieved (Yukl, 2013). Warren Bennis have stated that “leaders are people, who are able to express themselves fully”. “They also know what they want”, he continues, ‘why they want it, and how to communicate what they want to others, in order to gain their co-operation and support.’ Concluding, “they know how to achieve their goals” (Bennis, 1998, p. 3).

In 2016, Northouse having conducted his own review added three more leadership traits: determination, integrity, and sociability (Northouse, 2016). Despite the fact that many authors consider leadership traits as innate, Kirkpatrick and Locke (1991) stated that can be also learned including more traits in the list such as motivation and integrity. When it comes to the personality determinants that differentiate leaders and non-leaders, Fleenor (2011) stated that many early trait researches tried to identify features associated with successful and effective leadership. They had assumed that between leaders and non-leaders there was a status and position difference. Leaders appeared higher leadership qualities such as higher intelligence, extraversion, adjustment, dominance, and self-confidence, fact that promoted them hierarchically higher in contrast to non-leaders who were hierarchically lower due to their lower traits (Fleenor, 2011).

In terms of behavioral theory, the effectiveness of the leader depends on his behaviour. Leadership attributes are not innate but can be taught, developed through leader's own efforts, desire, experiences and practice and lastly can be enriched (Dalakoura, 2012). In general, behavioral leadership theory involves observing and evaluating a leader's actions and behaviors when they are responding to a specific situation. Their ability to lead in an effective way stems from the cultivation and implementation of specific behaviors. "The behavioral approach is quite different from their approaches characteristics and skills, because it focuses on what leaders do and not on who is. The behavioral approach argues that leaders mainly present two types of behaviours: work behaviours and relational behaviours. For the Behavioral approach, the central focus, is to examine how leaders combine these two types of behaviours in order to influence the others" (Northouse, 2019). In an effort to enrich the above statement we will adduce different patterns of behavior known as leadership styles. According to Blake and Mouton's Managerial Grid (1964; 1978) the most prominent styles that were developed are firstly about leader's concern for the task, focusing on organizing his team and procedures that must be followed in order to pursuit more effective and achieve specific goals. Second style refers to leader's sense of responsibility in meeting his followers' needs, showing interest about their concerns, interests, problems and development. They also promote interaction, views, ideas and suggestions exchange through the process of empowerment and they cultivate an environment of trust and commitment in order to increase productivity.

Much research has been conducted in order to define the correlation between the kinds of behavioral features of a leader that lead to achievement of the purposes that have been set and the satisfaction among his subordinates. The most prominent research studies have been conducted in the field of leadership behaviours includes McGregor's 'Theory X' and 'Theory Y', the research of Ohio State Study and Michigan Study and Blake and Mouton's Managerial Grid. When it comes to Douglas McGregor's 'Theory X' and 'Theory Y' (1960), he identifies two styles of leader's behavior in the workplace that are diametrically opposed. The democratic (Theory Y)

and the authoritarian (Theory X). McGregor in his theory address a series of hypotheses regarding the nature of leaders and subordinates relation and the human nature in general, providing an integrated perception about the philosophies of administrative practice and leadership model that should be avoided (Theory X) and the leadership model that is reasonable to be implemented (Theory Y) in order for effectiveness and satisfaction for people in the working environment to be achieved (Bourandas, 2002). D. McGregor embraced in his theory Maslow's theory according of which employees and individuals in general are motivated according to the satisfaction or not of their needs (Maslow, 1943).

In terms of Ohio State Study, Fleishman, Shartle and Stodgill, conducted a series of researches in order to identify the dimensions of two new types of leadership behavior and study the effectiveness of their implementation on people. For this reason, researchers developed an instrument known as the Leader Behavior Description Questionnaire (LBDQ) setting as pillars of research two key characteristics of leadership behavioral, the initiating structure behavior and the consideration behavior.

The second best-known behavioral leadership studies involving the use of questionnaire conducted by the University of Michigan which intended to identify the principles and types of leadership styles that were job-oriented fact that led to greater productivity and another one which was more anthropocentric which emphasizes on human relations and is concerned on enhancing job satisfaction among workers (Likert, 1961).

Referring to Blake and Mouton's Managerial Grid, in 1960, Robert Blake και Jane Mouton developed their theory based on two behavioral dimensions; concern for production and concern for people. "Managerial Grid" is an example of a practical model leadership, which is based on two dominant leadership behaviors: work and relationships" (Northouse, 2019). The content of behavioral theories exhibits a distinction between the leaders that are task-oriented and those leaders who are person-oriented (House & Aditya, 1997). When it comes to people-oriented leadership, leaders build interpersonal connections with subordinates, supervisors, employees or even clients while attaches great importance in understanding people's needs and views in order to create an interaction working environment in which motivation, empowerment, mentoring and reward prevails. On the other hand, when it comes to task-orientated leadership, leaders are more oriented to the final result which can be achieved through the implementation of organized processes and instructions.

In 1990, Rensis Likert, director of the University's Institute for Social Research of Michigan and his partners researched and developed a theory based on four leadership styles consisted of exploitative authoritative, benevolent authoritative, consultative and participative (Bourandas, 2005). In the exploitative authoritative system, the leader gathers the ultimate power in his hands, setting the goals of the

organization while the policies, rules and decision-making process is determined by the top leadership and are transmitted in the form of orders to the subordinates. In the Benevolent Authoritative System the superiors are not in control of their employees implementing a bottom-up communication (Bourandas, 2002). In the Consultative System responsibility and authority are spread widely throughout the organization, while communication and team work are promoted between the employees and the superiors. In the Participative System which according to Likert is considered the most effective is based on the leader's complete trust in the members of the organization. Decisions are made through democratic procedures, with the participation of the members whom these decisions concern (Bourandas, 2002).

Contingency theories refer to the concept that leaders are approached through contingencies, focusing on the behavior of leaders, citing the conditions and situations that prevail in the environment inside and outside the organization, while great emphasis is placed on the issue of the effectiveness of the leadership model in the workplace. Some of the most well-known contingency theories are Fiedler's (1967) contingency model and the Vroom-Yetton (1973) leadership models. In 1967, Fred Fiedler developed a leadership model which exhibited a correlation between the effectiveness of the Leader and the leadership style he chooses to adapt regarding specific circumstances. Leadership can be defined as effective according to the presence of four parameters the leadership style, the relation between the leader and his subordinates, task's construction and the power that the leader draws from his position. Although only the last three are indicative factors that can be used in order to describe and evaluate which leadership style (work-oriented/relationship-oriented) is appropriate to be implemented for the specific occasion. Specifically, when leader obtains strong leadership position and structures a strong relationship that contains effective and constructive cooperation between the leader and his subordinates can be considered as favorable while clear task structure is provided by the leader in order for team to function under coordination. Based on this theory the leadership style that can be applied will be focused on either tasks (authoritarian) or human resources (participatory procedures). According to Fiedler (1967) the effectiveness of leadership is not completely influenced by either the leader who focuses on human resources or the one who focuses on the functioning of the organization. The contingency theory organization does not obligate leader to adapt his leadership style on an occasion that requires an indifferent management from his leadership orientation but to choose the right leading member with the qualifications that are required in order to address the certain occasion.

This model focuses on the interaction of the leader's behavior and follower readiness to determine leader effectiveness. Leader's effectiveness can be translated into their team's readiness and maturity to address issues and complete their duties under specific situations. Moreover according to the theory the assigned task must be in proportional to relationship behavior and follower's maturity and readiness in order

to achieve organization's desired results. As follower's maturity increases the leader focuses less to supervision of the process and focuses more on creating and building a constructive working environment in which interactiveness, satisfaction and team's evolution have a primary role. By focusing on them between relationship the leader achieves to enhance followers' performance, meet their needs, highlight human's element value, cultivate and develop followers' working and social capacity (Golensky & Hager, 2020). Hersey and Blanchard developed four types of leadership styles based on the task and relationships that leaders experience in the workplace. The first type refers to delegating style in which the maturity of followers seems to be high and thus the leader assigns his subordinates with tasks, duties and full responsibility on decision making process. The second style is the participating style in which the leader follows a leadership approach based on shared ideas, cooperation and both parts participation in decision making process enhancing. The Selling style which constitutes the third style is a high task and relationship behavior approach in which the leader by implementing the technique of persuasion "sells"/shares his ideas with his inexperienced followers explaining them the concept of the assigned task providing them with directions and motivation so as to develop their skills. Lastly, the fourth style refers to telling style in which followers are inexperienced and requires leader's direct instructions, supervision, motivation and empowerment. Leader is more oriented in tasks accomplishment rather than relationship with the followers due to followers' low confidence and experience.

Robert House in 1971 introduced his version of a contingent theory of leadership known as path-goal theory which emphasizes on the relationship between leadership style and the ability to motivate subordinates in a positive way in order to achieve the set goals. Driven by follower characteristics and workplace characteristics leaders' main responsibility is to adapt and implement the most effective leadership style at a given situation, provide his followers with instructions, motivation, empowerment, support and all the required information they need in order to clear a path and subserve their efforts to accomplish the assigned task. Specifically, the conceptual perception of the path-goal theory refers to leader's effectiveness to adapt his leadership style according to his followers' needs, set organization's goals, identify the methods that must be applied, intervene when is needed, clarify and clear the path that has to be followed so as to eliminate the obstacles his followers may face to the goal (Robbins & Judge, 2019; Northouse, 1997).

The Vroom-Yetton contingency model, developed in 1973 by Victor Vroom and Phillip Yetton (with additional collaboration by Arthur Jago, in 1998) focuses on the correlation between leader's behaviour and the conditions under of which he is called to adopt the most effective leadership style (Vroom & Yetton, 1973). They developed five different leadership styles, fact that indicates there is not only one leadership style suitable for any situation but pointed out the need for leader to adopt new leadership styles and adapt his own leadership style each time is needed to the

current situation. First leadership model is the autocratic in which the autocratic leader makes his own decisions using information that is readily available to him or her at the time counting only on his own. The second leadership model refers to leader's ability to collect the required information from his followers and then proceed to decision making on his own. The third leadership style is the consultative type in which the leader shares the problem and asks for ideas and suggestions from each subordinate individually. Then he makes own decision. The fourth style is all about the leader sharing the problem with the whole team as a group and asks for their ideas and suggestions. Then he makes his own decision. The last type refers to the Group-based type where the leader discusses the problem and the concerning situation with his team as a group and asks for their ideas and suggestions through brainstorming. Every opinion and decision is accepted and the decision making process involves both parties. The Vroom and Yetton model is simple and has practical utility. Nevertheless requires proper assessment of the answers to the critical questions it contains.

#### **4. Conclusion**

Concluding, having examined and adduced the existing literature of the most prominent leadership theories this paper aims to present a deeper insight into leadership theories. The paper attempted to explain the content differences between trait, behavioural and contingency theories. The study can contribute to providing readers with a deeper and more insightful understanding about the leadership styles and leaders' skills that are required in order for a leader to be proved capable to achieve an organization's goals. Specifically, Great men theory claims that the leader characteristics are innate (Kirkpatrick & Locke, 1991). On the other hand, trait theory states that the leader characteristics can be both innate and acquired as well (Pierce & Dunham, 1990). Behavioral leadership theory suggests that the success of a leader stems from his behavior, personal willing for evolution and capability to learn and develop his leadership skills through adopting beneficial behaviors and performing them in order to achieve the goals his set. In other words leaders are made owing to their learnable behaviours rather than their natural attributes. When it comes to Managerial Grid formed by Blake and Mouton the most prominent leadership style is the Team Leadership which is largely in line with McGregor's Theory X which is oriented to keep a balance between production and team's satisfaction. In contingency theory of leadership the determining factor of this theory is the situation a leader acts in, which affects directly his performance, effectiveness and his ability to adapt accordingly.

It is generally accepted that efficient leadership is developed through a never-ending process of self-study, education, training, and the accumulation of relevant experience (Bass & Bass, 2008).



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## A REVIEW OF TRADITIONAL APPROACHES OF STUDYING LEADERSHIP STYLES

**Konstantinos Goulas<sup>1</sup>**

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### ***Abstract***

*This article is going to present a review of the most influential and mainstream theories about leadership, which are of significant meaning for a successful manager. The author will focus on some leadership theories by giving a more detailed image of the characteristics and attributes that an effective manager should have. The principal message of this article is that it is important to reflect the type of leader that a manager wants to be so that he remains loyal to his principles. In conclusion, the author leads to the fact that the traditional theories of leadership have not provided a completely satisfactory framework for leadership effectiveness. The modern theory emphasizes the image of an effective manager as an organizational reality.*

**Keywords:** *leadership theory; entrepreneurship; leader behaviour; relational leadership; transactional*

**JEL Codes:** *O15, L26, M12*

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### **1. Introduction**

There has been a great controversy amongst academics regarding the concept of the leader. Discussions about leadership have existed since the first scientific studies of economics. However, leadership is hardly a topic that originates with the advent of the academic study of businesses. The first and oldest text about leadership that has been translated by Battiscombe (1909) was the Teachings of Ptah-Hotep which was written for Pharaoh Isesi's son of the fifth dynasty. This text was a treatise that depicts the ways of being an effective Pharaoh or a nation's leader. Although it's relatively easy to look at how effective an organizational leader was based on her or his accomplishments, the fact of determining whether or not someone will be an effective leader before his ascension is a difficult task. Numerous scholars have developed a variety of methods and theories in order to describe and explain leadership which was an auxiliary tool for businesses to select the most capable leader.

Michael Hackman and Craig Johnson have developed five primary approaches to understanding and explaining leadership (Hackman & Johnson, 2009). These are a) the Traits approach b) the Situational approach c) the Functional approach d) the

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<sup>1</sup> South-West University "Neofit Rilski", Blagoevgrad, Department of Management and marketing, PhD Student, e-mail: k\_goulas2005@yahoo.com; ORCID ID: 0000-0002-3309-4918

Relational approach and e) the Transformational approach. These approaches are going to be analyzed in the following sub-sections.

## 2. Literature Review of the traditional approaches to studying Leadership styles

### 2.1. Trait Approach

The most basic approach is most well known as the trait approach. According to this approach, effective leaders should exhibit a variety of physical, mental, or personality traits, while non-leaders, or even ineffective leaders, do not. It's the oldest of all the approaches that researchers have analyzed. According to the predominant literature review that has been published till the previous year and is presented as a summarized table in the section of the appendix (Table 1: Traits associated with the leadership), there are basic traits that are associated with leadership. In Stodgill's handbook (1970), the traits are divided into six sub-categories that are closely related to the personal characteristics of the leader which are physical, social background, intelligence, personality, task-related and social.

Secondly, according to Mann (1959), which is presented in Table 1 the main idea of his text is that a strong relationship is being displayed between the personality of the individual employee and his or her performance. This also strengthens the trait theory. Furthermore, Kirkpatrick (1991) analyzes the appropriate characteristics that an executive should have and these are also presented in Table 1.

Finally, Lussier and Achua (2007) refer in their analysis to the traits that a successful leader should have to develop his skills and make the right decisions about the welfare of his firm (presented in Table 1).

*Table 1. Traits Associated with Leadership*

<i>Stodgill (1990)</i>	Adaptability Adjustment Assertiveness Alertness Creativity, Originality Diplomacy Dominance Emotional Balance Enthusiasm Extraversion Independence, Nonconformity Objective, Tough-mindedness Resourcefulness Self-confidence Sociability, Interpersonal Skills Strength of Conviction
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	Tolerance of Stress
<i>Mann (1959)</i>	Adjustment Conservatism Dominance Extroversion Intelligence Masculinity
<i>Kirkpatrick and Locke (1991)</i>	Cognitive ability Integrity Motivation Task knowledge
<i>Lussier and Achua (2007)</i>	Dominance Emotional Intelligence Flexibility High energy Integrity Intelligence Confidence Drive Internal Locus-of-control Self-confidence Sensitivity to others Stability

*Source:* Bass & Stodgill, 1990

These studies have come to a variety of different traits over the years. Although there is some overlap, each list is unique. One of the most fundamental problems with the trait approach is that recent scientific research has provided an ever-ending list of personality traits that are closely connected to leadership. In conclusion, no clear or replicable list of traits exists.

The authentic perception that leaders were created through a magic checklist of personality traits has fallen out of favor in the leadership community (Dinh & Lord, 2012). However, in modern leadership theory personal traits have been reintegrated as important aspects of the process of leadership. In Scott Shane's book *Born Entrepreneurs* (2010), the writer argues that even the genetic characteristics may not cause people to become leaders or entrepreneurs, the personal genetic makeup of each individual probably strengthens the likelihood that he would succeed in becoming a leader or entrepreneur. In this respect, Zaccaro (2007) have argued that personality traits of leaders should be assessed within the framework of specific leadership events and not by taking as considered fundamental aspects of a concrete phenomenon called 'leadership'. More effectively, Dinh and Lord (2012) argue that an individual's traits

may impact how they behave within a specific leadership situation but those specific personality traits may not be seen across all leaders in all leadership contexts.

## *2.2. Situational Approach*

As trait approaches became out of date, recent approaches to leadership began emerging in which leadership depended on a variety of situational factors such as a task to be completed, leader-follower relationships or interactions, follower motivation, and commitment. These modern leadership theories are commonly known as situational approaches. While many leadership theorists fall into the situational approach, two of them are most widely known and are going to be described here: a) the Contingency theory of Fiedler (1967) and b) the situational leadership theory of Paul Hersey and Kenneth Blanchard (1969).

Fiedler started analyzing his theory to explain the concept of leadership in the 1950s and '60s. Through his presentation, Fiedler (1967) resulted in his theory which is recorded as the "Contingency Theory of Leader Effectiveness". Based on this particular theory, Fiedler (1967) asserted that leadership is a detailed reflection of both a leader's personality and behavior. Fiedler argued that leaders are stable in their leading way, but as the circumstances change, leaders need to adjust their strategies. The fundamental starting point of Fiedler's Contingency theory was the concept that leaders are often task or relationship-oriented (Fiedler, 1967). The organizational leaders were interested more in tasks and thus, organizational goals getting achieved. On the other hand, relationship-oriented leaders focused on building positive relationships based on mutual trust and respect. In order to determine a leader's preference for tasks or relationships, leaders are asked to evaluate all employees with whom they have cooperated and select the employee that they have had the opportunity to confront difficult circumstances (Fiedler, 1967). When you think of the follower that the leader had the most trouble with, it's usually very easy to determine whether the leader is more task or relationship-oriented because that follower is generally the opposite (Fiedler, 1967). Fiedler termed this follower in his Contingency Theory the leader's least preferred co-worker (LPC) (Fiedler, 1967).

The basic model proposed by Paul Hersey and Kenneth Blanchard (1969) is also divided into the task (leader directive behavior) and relational (leader supportive behavior) dimensions. However, Hersey and Blanchard's theory of leadership starts with the basic notion that all the followers don't need the same task or relationship-based leadership. This means that the type of leadership a leader should utilize with a follower depends on the follower's readiness.

## *2.3. Functional Approach*

With respect to the trait and situational approaches to leadership, the basic outcome called "leadership" is a chain of traits that are going to fabricate the concept. According to the theory of the functional approach, on the other hand, the researchers

admit that a leader is someone who looks, acts as a leader, and communicates like a leader. To understand the functional approach to leadership, there have been briefly analyzed two different sets of researchers commonly associated with this approach: Chester Barnard's Functions of the Executive (Barnard, 1938) and Kenneth Benne and Paul Sheats' Classification of Functional Roles in Groups (Benne & Sheats, 2007).

The first great functional theorist was an organizational scientist named Chester Barnard who published a seminal book in 1938 entitled "The Functions of the Executive" (Barnard, 1938). The title of this particular book resulted in giving the name in the concept of Functional Approach to Leadership. Barnard argues in his book that executives have three basic functional roles (Barnard, 1938). The first function that a leader should have is the formulation of the organization's basic purpose and objectives. The second function of a leader according to this framework was securing essential services from other members. According to Barnard's framework, the primary function of an executive should be to establish and maintain a system of communication. In this respect, leaders have a fundamental task in creating and controlling the formal and informal communication systems within the organization (Barnard, 1938). Barnard was one of the first researchers to extol the importance of understanding both formal and informal communication within an organization.

Kenneth Benne and Paul Sheats' set out to develop a helpful tool for analyzing and understanding the functional aspects of leadership. Their article titled "Functional Roles of Group Members" (Benne & Sheats, 2007) was designed to analyze how people interact and behave within a small group or team. The basic premise of Benne and Sheats' (2007) theory was that different people in different group situations will assume a variety of roles within a group. Some of these roles will be prosocial and will help the group achieve its basic goals, while other roles are antisocial and can negatively impact a group's ability to achieve its basic goals.

#### *2.4. Relational Approach*

The next approach is called the relational approach because it doesn't focus on traits, characteristics, or functions of leaders and followers, but instead, this approach focuses on the types of relationships that are being developed between leaders and followers. The author of this article gives a brief image about the Relational Approach by describing two different perspectives on this approach which are a) Robert Blake and Jane Mouton's Managerial Grid (Blake & Mouton, 1964) and b) George Graen's Leader-Member Exchange Theory (Graen & Uhl-Bien, 1995).

The first major relational approach to be discussed is Blake and Mouton's Managerial Grid. (Blake & Mouton, 1964). The title of the concept Management Grid (Blake & Mouton, 1964) indicates that it is a suitable tool for effective leadership.

The original grid which was created in 1965 caused the two researchers to worry about whether or not a leader was genuinely concerned about his followers or his production. How an individual leader approaches both relationships and tasks will determine where he or she sits as a leader on the management grid. As a consequence of the above, we conclude that there are five basic leadership styles: impoverished, authority-loving, country club, team, and straight on the road

In the mid-1970s, George Graen started suggesting a different classification of theory for understanding leadership. Graen's theory of leadership proposed that leadership should be understood as existing in three distinct realms: a) follower b) leader and c) relationship (Graen & Uhl-Bien, 1995). The main concept of the Leader-member exchange theory is that leaders and followers exist in a bilateral relationship. From this perspective, the concept of leadership should be examined in combination with the nature of that relationship.

### *2.5. Transformational Approach*

The ultimate leadership approach is popular amongst organizational theorists. The term "transformational approach" of leadership was firstly mentioned by James Downton in his text about the concept of Rebel Leadership (Downton, 1973). Furthermore, the concept of Transformational leadership was analyzed in a more detailed view by the political sociologist James MacGregor (James MacGregor, 1978).

According to this approach, the whole meaning of leadership can be entirely understood by describing the two sides of the coin of leadership which are transactional and transformational leadership. Transactional is the type of leadership which focuses on a series of exchanges that can occur between a leader and followers. Promotions and pay raises have been the most predominant strategies for transactional leadership throughout the corporate USA. Promotions or pay raises are offered to the followers that meet the leaders' demands and succeed in their goals by transactional leaders. Rewards have also been used as a tool utilized to get the best outcome in terms of the followers reaching goals or even exceeding them. Rewards are also the external motivation for followers and if they cease to exist, followers will lack their motivation to be successful.

On the other hand, we could easily deduce that transformation leadership could be defined as the procedure of interaction and engagement among people that creates a higher level of motivation and morality to both sides, the side of the leader and the side of the follower.

More essentially, transformational leadership is most simply understood as leading followers to meet or exceed goals because the leader provides rewards to followers. Charismatic and inspirational leadership, intellectual stimulation, and individualized consideration are the three factors of transformational leadership proposed by Bernie Bass as a more in-depth understanding of its nature (Bass, 1985).



Charismatic leadership is considered to be the ability of the leader to influence and inspire his team to achieve targeted goals or tasks. Undoubtedly, the ability of influencing is unique and not everyone possesses it. The different characteristic of this type of leadership is that while in any other case the leader rewards his followers for executing their tasks, the transformational leader inspires his team without promising any rewards (Bass, 1998). The followers are motivated by their leader's vision. Another important factor of transformational leadership is the intellectual stimulation (Northouse, 2007). More explicitly, transformational leaders encourage their team to be more creative, innovative and to challenge both their own and leader's and indirectly the organization's values and beliefs (Northouse, 2007). According to Northouse (2007), both transactional and transformational leaders engage in intellectual stimulation themselves, the purpose of that intellectual stimulation differs. In this respect, transactional leaders tend to focus on how best to keep their organizations and the systems within their organizations running. The final factor of transformative leadership is individual consideration. The main point of this factor is that the leader evaluates the potential of his followers and by providing them directions, he individually assigns tasks to his followers in order at first to significantly alter their skills and motivations and secondly to meet immediate organizational needs. The concept of this factor is that the leader achieves the maximized potential of his followers which in turn leads to the maximization of his resources.

### **3. Conclusion**

In conclusion, there are many models and approaches that have been analyzed through the years. However, historically the most widely known and accepted models/approaches are the following, summarized as key points:

- Trait Approach: it's the oldest approach and is based on the assumption that some people are born with specific characteristics related to their personality or with special communication skills that make them suitable for leaders.
- Situational Approach: this approach is considered to focus on specific organizational contexts or situations that enable leadership.
- Functional approach: According to this approach, the prominent leader is someone who looks like, acts like, and communicates like a leader.
- Relational approach: leadership is a matter of building and maintaining relationships with one's followers.
- Transformational approach: a leader is a person who utilizes communication to increase followers his morale and ideas, motivation, and performance to accomplish organizational goals.

In this respect, these approaches have each contributed to the understanding of leadership, none of the approaches has provided an entirely satisfactory explanation of leadership and leadership effectiveness. After the '70s, there have been various

alternative approaches put forward. Researchers have drawn a line between the old versus the newer paradigm models of leadership (visionary, charismatic, transformational). Those new models are not irrelevant to the concepts of 'charismatic leadership', 'visionary leadership, and 'transformational leadership. The conclusion is that traditional approaches as they have already referred consider leadership as a process, that involves influencing others, occurs within a group context and involves goal attainment while more recent definitions of leadership have stressed the importance of the role of leader and focus more on the character of a leader as 'defining organizational reality'. Undoubtedly, all these approaches resulted in the fact that the role of the leader is considered to be of first and primary importance for the welfare of every firm.

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## ASSESSMENT OF PHARMACEUTICAL MANUFACTURERS' COMPETITIVENESS

Milena Filipova<sup>1</sup> Yulia Nedelcheva<sup>2</sup>

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### Abstract

*The aim of the article is to assess the competitiveness of pharmaceutical manufacturers. The assessment was carried out for six producers in Bulgaria with largest volume of production. The assessment is based on a model, which is a combination of quantitative and qualitative indicators of manufacturers. The answers of 52 respondents from a survey were used to determine the quality indicators of the model. The results of assessment identify quality indicators as leading to manufacturer competitiveness. The competitiveness of the product (ratio of product quality to price) has the greatest weight in assessment the manufacturer competitiveness. The quantitative indicators of the individual producers have similar values and therefore have little effect on the assessment of their competitiveness. The state participates in the assessment of the competitiveness of pharmaceutical manufacturers by determining of pharmaceutical products that price is paid partially by a competent authority.*

**Keywords:** Bulgaria; survey; pharmaceutical products

**JEL Codes:** D22; I11; L11

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### 1. Introduction

Manufacturers of pharmaceutical products achieve their own economic goal of increasing production while at the same time fulfilling a social goal of improving healthcare. These two roles of producers are balanced and have a synergistic effect in increasing their competitiveness. Unlike other manufacturers, competitiveness for the pharmaceutical manufacturers leads to the supply of innovative, efficient and affordable pharmaceutical products.

The environment of COVID-19 pandemic (2020-2022) further drew attention to the importance of pharmaceutical manufacturers for the development of the economy and the well-being of the society. Their competitiveness already exceeds the micro level of influence and is the subject of national and international research. The

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<sup>1</sup> South-West University "Neofit Rilski", Blagoevgrad, Department of Management and marketing, Professor, PhD, e-mail: emili2000@abv.bg; ORCID ID: <https://orcid.org/0000-0002-5003-006X>

<sup>2</sup> South-West University "Neofit Rilski", Blagoevgrad, Department of Management and marketing, PhD Student, e-mail: yulia.nedelcheva@abv.bg; ORCID ID: <https://orcid.org/0000-0002-0252-1825>

new reality has set a new framework for the development of pharmaceutical manufacturers, including their competitiveness. As an added value of increasing the competitiveness of pharmaceutical manufacturers are the corrective measures at the macro level for the competitiveness of the national economy and for the development of society.

## 2. Assessment method

In assessing the competitiveness of pharmaceutical manufacturers we will use a model proposed by M. Velev (Velev, 2004). The model is a combination of quantitative and qualitative indicators. Each indicator is adjusted by a weighting factor, which is determined empirically based on expert opinions. For a specific sector of the economy, the model of R. Dimitrova is applied, which is a modification of the model of Velev (Dimitrova, 2014):

$$C = 0.22Cp + 0.13Im + 0.13Fm + 0.4Am + 0.13Lp + 0.13Fp + 0.12Gm$$

where:

*C* – competitiveness of the manufacturer;

*Cp* – competitiveness of the product;

*Im* – innovation of the manufacturer;

*Fm* – flexibility of the manufacturer;

*Am* – adaptability of the manufacturer to the market;

*Lp* – labor productivity;

*Fp* – financial performance;

*Gm* – growth of the manufacturer.

The higher the value of the assessment, the higher the current competitiveness of the enterprise.

From all manufacturers of pharmaceutical products in Bulgaria, we select those with the largest production volume (Borisova, 2017). The sample covers six producers – Balkanpharma-Dupnitsa, Balkanpharma-Razgrad, Balkanpharma-Troyan, Bul Bio, Sopharma and Tchaikapharma. From their annual financial statements, certified by an independent auditor, we calculate the quantitative indicators of the Velev-Dimitrova model (labor productivity, financial performance, growth of the manufacturer).

To determine the quality indicators of the Velev-Dimitrova model (competitiveness of the product, innovation of the manufacturer, production and marketing flexibility of the manufacturer, adaptability of the manufacturer to the market) a survey was conducted during 13.10-12.11.2021. The survey was sent to the respondents via social networks, which explains the large percentage of middle-aged respondents (Gergova, Stoimenova & Sidjimova, 2019). The respondents are 52 people with diverse socio-demographic characteristics, i.e. respondents cover a wide range of consumers of pharmaceutical products (Ilieva-Tonova, Stoimenova, &

Pencheva, 2016). The highest share of participation in the survey are persons with a master's degree (61%), aged 36-45 (44%), ultimate consumer of a pharmaceutical product (75%), woman (63%).

### 3. Results

The assessment of competitiveness is presented in Table 1. For comparison to assessment, respondents' preferences for a specific pharmaceutical manufacturer are presented (Ilieva-Tonova, Pencheva & Serbezova, 2022). For example, Sopharma is the most preferred manufacturer while its competitiveness assessment ranks it third. Another example of the assessment of the competitiveness and preferences of the respondents is Balkanpharma-Troyan – the least preferred producer by the respondents and with the highest assessment of competitiveness. The difference between assessment and preference is due to the fact that respondents' opinions do not take into account financial performance (Nedeltchev, 2005).

*Table 1. Basic data of the assessment and the survey*

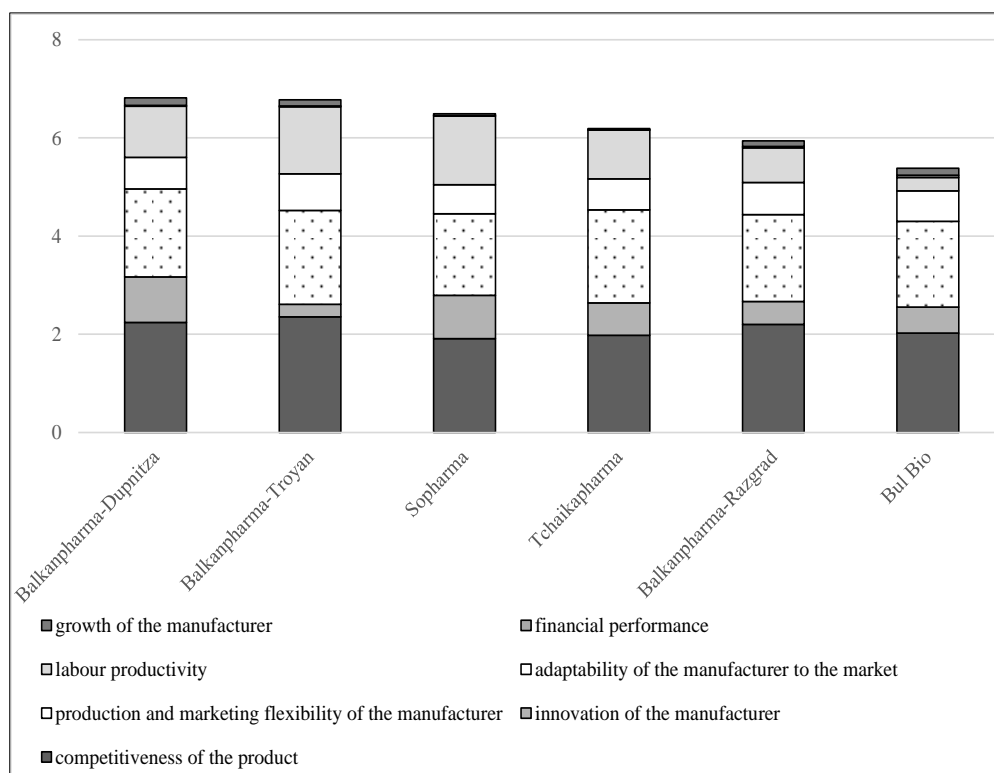
	Assessment of competitiveness	Preferred manufacturer, %
Balkanpharma-Dupnitza	6.81	9.6%
Balkanpharma-Troyan	6.77	5.8%
Sopharma	6.49	51.9%
Tchaikapharma	6.19	13.5%
Balkanpharma-Razgrad	5.94	9.6%
Bul Bio	5.38	9.6%

*Source:* authors' data

### 4. Discussions

The components of competitiveness assessment are presented in Figure 1. The high assessment is influenced by the quality indicators of the Velev-Dimitrova model.

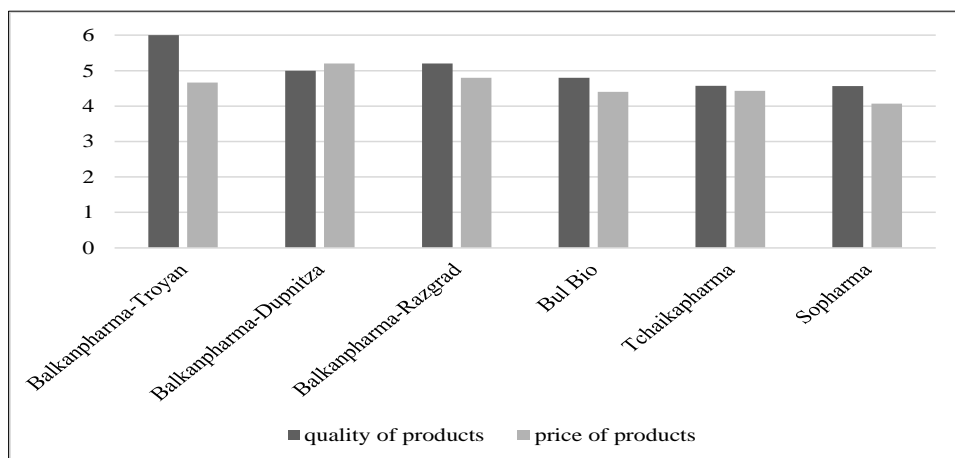
Figure 1. Assessment of the manufacturers' competitiveness by components



Source: authors' data

*Competitiveness of the product.* In the first places are manufacturers with high quality indicators. The competitiveness of the product has the greatest weight in assessment of the manufacturers' competitiveness (Keremidchiev & Nedelchev, 2022). This indicator is defined as the ratio of product quality to price. Balkanpharma-Dupnitza has the highest value of this indicator (2.24), which determines its highest assessment of the manufacturers' competitiveness. The lowest value of this indicator has Sopharma (1.91). As per respondents, the quality of the products is more important for the respondents than the price of the products (Figure 2).

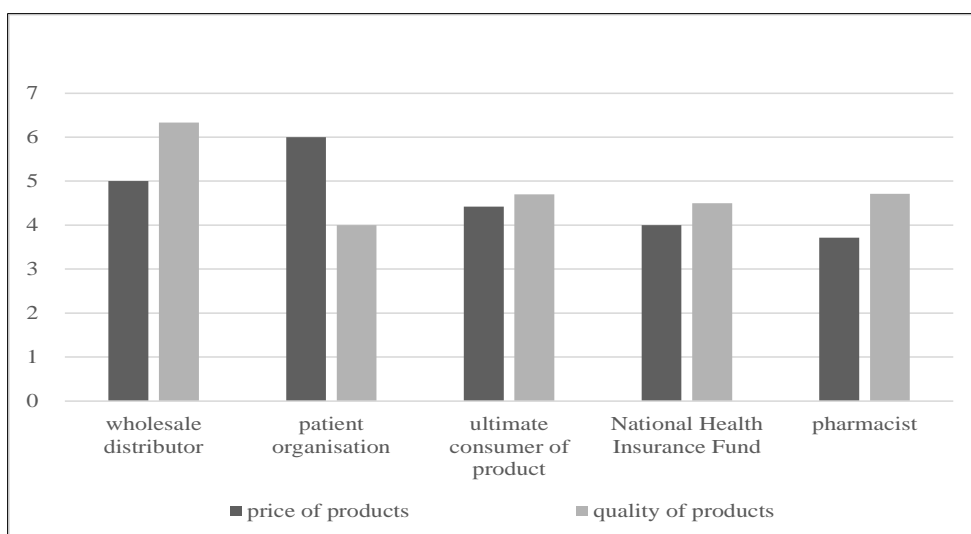
*Figure 2. Survey data for quality and price of pharmaceutical products by manufacturers*



*Source:* authors' data

Individual groups of respondents have a characteristic opinion about the price and quality of products when assessing the competitiveness of manufacturers (Madgerova & Kyurova, 2014). Only in the case of patient organisations the price is more significant than the quality of the pharmaceutical products (Figure 3).

*Figure 3. Survey data for quality and price of pharmaceutical products by respondents*



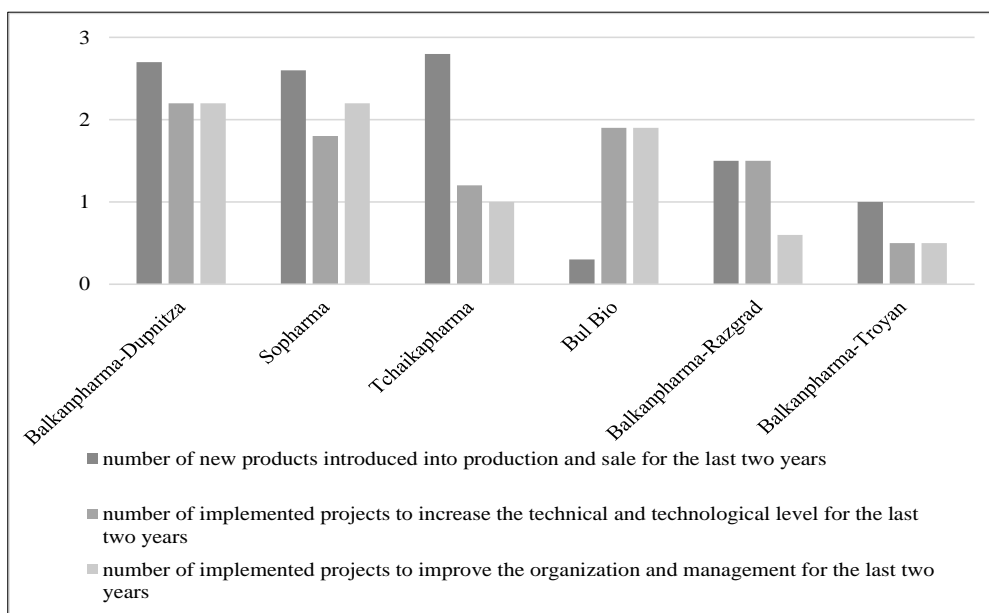
*Source:* authors' data



Respondents' opinion on the price of pharmaceutical products largely depends on state intervention in pricing (Nedelchev, 2019). The National Council on Prices and Reimbursement of Medicinal Products every six months includes certain pharmaceutical products in a list on which the state pays part of the price of the product (Yuleva, 2019). For the period of our competitiveness assessment, four of the producers are on the list for paying part of the price by the state: the state pays 67% of the price for 74 products of Balkanpharma-Dupnitsa and Balkanpharma-Troyan, 60% for 84 products of Sopharma and 62% for 117 Tchaikapharma's products. State participation in the formation of selling prices is depend of the age and health status of citizens.

*Innovation of the manufacturer.* Innovation of the manufacturer is determined by the number of new products introduced into production and sale in the last 2 years, the number of projects implemented in the last 2 years to increase the technical and technological level, and the number of projects implemented in the last 2 years for improving the organization and management of the manufacturer. Balkanpharma-Dupnitsa has the most innovations (0.92) and the least – Balkanpharma-Troyan (0.26). The values of this indicator are in line with the nature of pharmaceutical products as part of the healthcare system (Petrova, 2018).

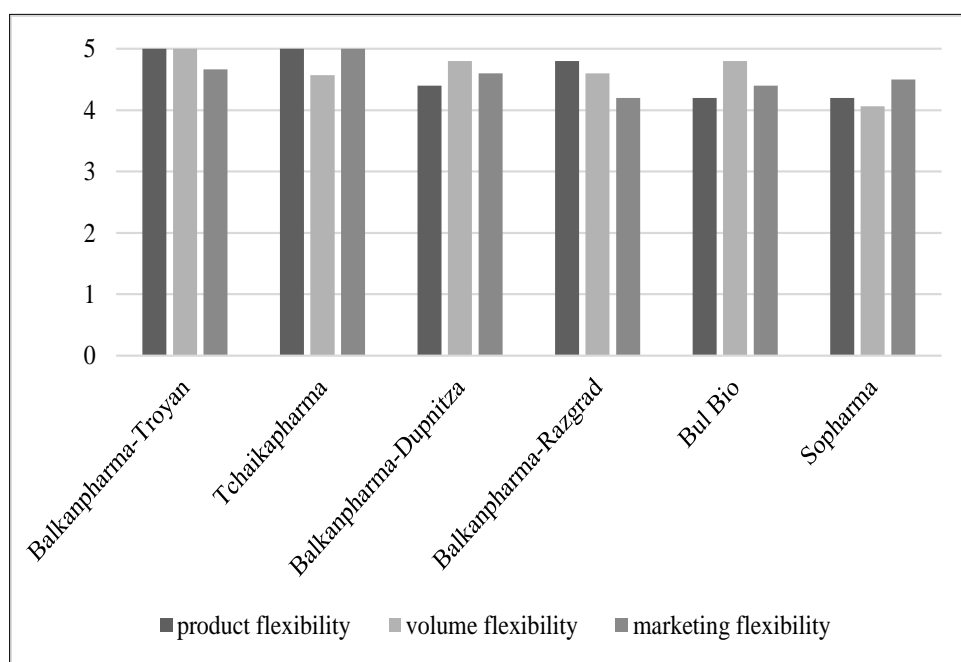
Figure4. Survey data for innovation of manufacturers



Source: authors' data

*Flexibility of the manufacturer.* This component has little weight in the model and second place in importance for the final assessment of competitiveness. The indicator is determined by three components: product flexibility, volume flexibility, and marketing flexibility (Figure 5). The values of this indicator are very close for all producers. For the total assessment of competitiveness, the volume flexibility (4.64) is of a little big importance over product flexibility (4.60) and marketing flexibility (4.56) (Figure 5). Leading position of flexibility is for Balkanpharma-Troyan (4.89) and lowest assessment level for Sopharma (4.26).

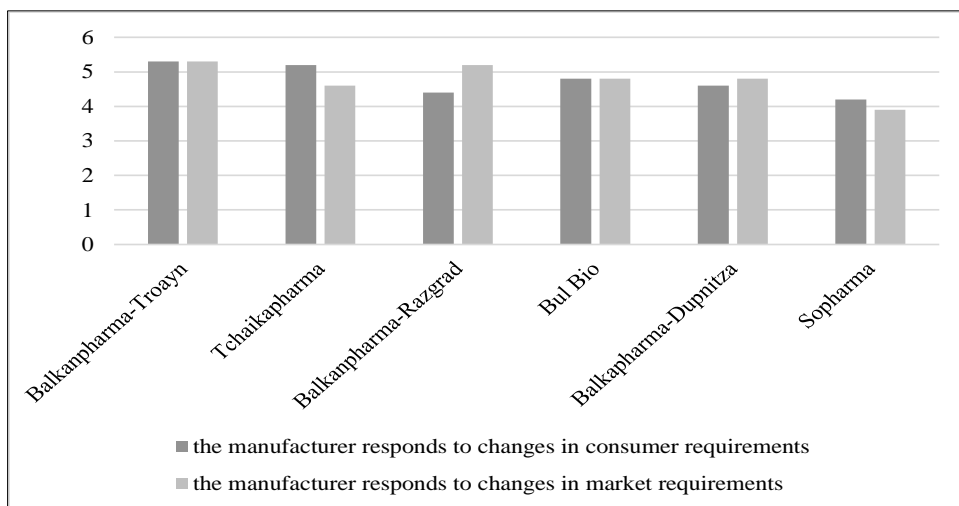
*Figure 5. Survey data for flexibility of manufacturers*



*Source:* authors' data

*Adaptability of the manufacturer to the market.* The adaptability of the manufacturer to the market includes responds to changes in consumer requirements and in market requirements (Figure 6). Balkanpharma-Troyan has highest assessment for adaptability to the market (5.3) and Sopharma – the lowest one (4.1).

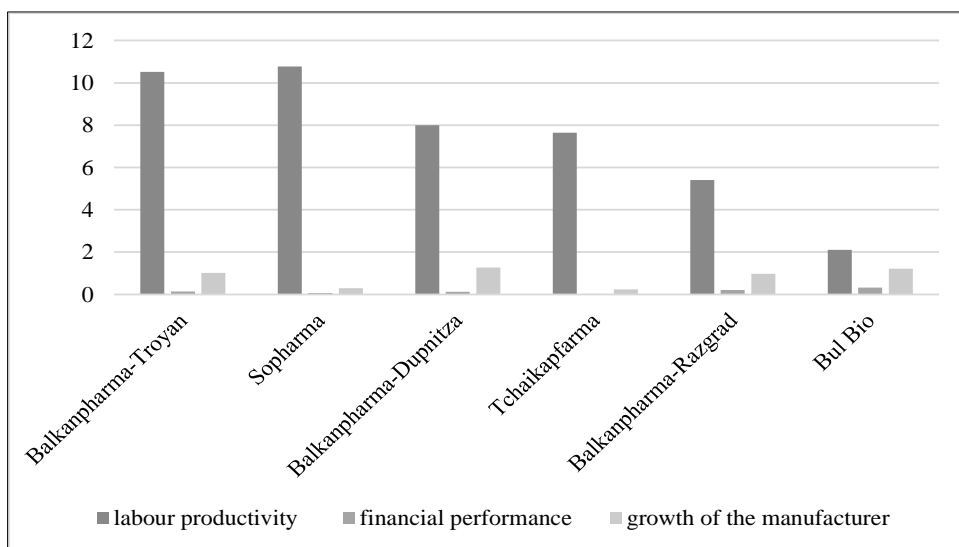
Figure 6. Survey data for adaptability of manufacturer to the market



Source: authors' data

Quantitative components of the model (labor productivity, financial performance, and growth of the manufacturer) have low weights for the competitiveness of manufacturers. Balkanpharma-Troyan has the best economic indicators again (Figure 7).

Figure 7. Economic indicators of manufacturers



Source: authors' data

## 5. Conclusion

Our assessment identify quality indicators as leading for manufacturers' competitiveness. The quantitative indicators of the individual manufacturers have similar values and therefore have little effect on the assessment of their competitiveness. The best competitiveness belongs to Balkanpharma-Dupnitsa due to highest values of innovation of the manufacturer and growth of the manufacturer. The second rank is for Balkanpharma-Troyan – this manufacturer has best values for competitiveness of the product, flexibility of the manufacturer, and adaptability of the manufacturer to the market. At the other pole is Bul Bio – good economic indicators that have low weights in the competitiveness model.

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## TECHNOLOGICAL FUTURE OF PHARMACEUTICAL INDUSTRY– DEVELOPMENT PERSPECTIVES

**Vladimir Boychev<sup>1</sup>**

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### **Abstract**

*Digital revolution and innovations are the modern phenomena pharmaceutical industry should take advantage of. The prevention of diseases will also facilitate the progress of the sector. This publication examines the key factors influencing pharmaceutical industry behavior and bears the potential to drastically change the sector in the upcoming years. The forthcoming challenges and changes appearing on the horizon require careful and precise consideration of new kinds of markets, alternative business models or even a complete change in the way pharmaceutical companies operate. The future of the industry is defined by the introduction of various technologies that are currently changing and will continue to change all aspects of the industry – production of pharmaceuticals, supply chain, clinical trials, etc. The leading tendencies in the advancement of the pharmaceutical sector in 2019-2021 are also analyzed with a focus on new technologies and digitalization. Different trends have changed the sector inevitably having both short-term and long-term impact.*

**Keywords:** pharmaceutical industry; transformation; digital future; perspectives; artificial intelligence; drug development process; robotics

**JEL Codes:** I15; O14

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### **1. Introduction**

The global pharmaceutical industry continued to invest efforts and dedicating resources in its development, despite the inevitable COVID-19-related transformation and the challenges it had to overcome in the last two years. Despite the global slowdown, the ambition to demonstrate innovative potential to launch new products and improve patients' lives in the rapidly evolving worldwide remains unchanged.

The leading role of technologies required a transition to innovative solutions such as artificial intelligence and software learning so as to ensure better processing and use of big data in the sector.

The major long-term developing tendency in the pharmaceutical sector in the last decade defined the shift from the production of traditional drugs with small molecules to biotechnologically centered strategies.

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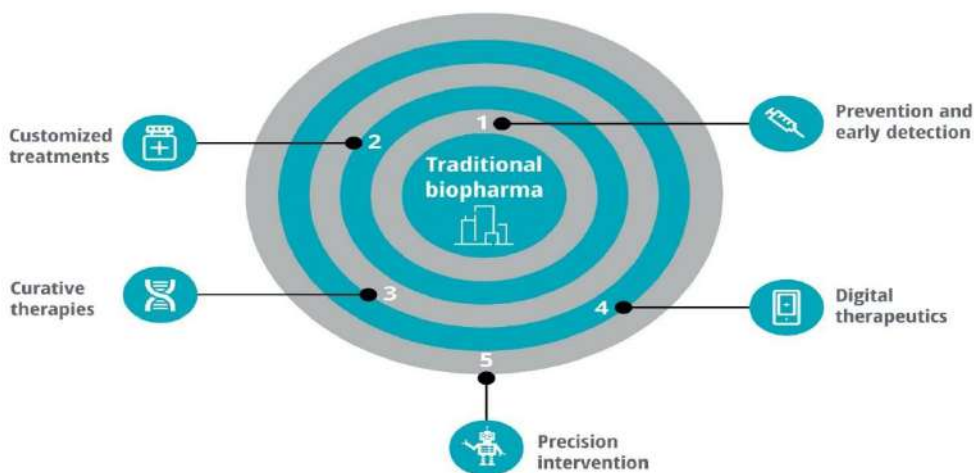
<sup>1</sup> UNWE, Sofia, Department of Tourism, PhD student, e-mail: vlboychev@gmail.com; ORCID ID: <https://orcid.org/0000-0002-9317-7360>

The growing investments in research and advanced activities for the production of new pharmaceuticals, biological products, cell and gene therapy, etc. require solid expertise, experience and reliable infrastructure in the entire process of launching new pharmaceuticals, from their clinical creation to legitimate approval for market release.

Experienced and reputable experts, equipped with innovative development and production laboratories, will be permanently assigned the creation of drugs by pharmaceutical companies in the future. The industry will invest significantly in an organic and non-organic portfolio, including the production of small molecules and biological products, development of drugs, production of viral vectors, cell and gene therapy.

Nowadays, the development of pharmaceutical companies has been influenced by a number of factors, factors that can seriously remodel the sector in the upcoming years - Figure 1 (Yang et. al, 2020).

*Figure 1. Five forces of potential disruption to the biopharma industry*



Source: Deloitte Insights

Prevention and early diagnosis of illnesses, personalized treatment, innovative medical therapies, digital therapy and a precise use of sophisticated treatment technologies and medical products require careful attention. These factors can have significant impact on pharma companies and their patients (Yang et. al, 2020).

Establishing the future of healthcare, pharmaceutical companies need to consider new strategic investments to ensure success. Analysis of new markets, alternative business models or a total change in the operating methods will be highly

recommended for the drug sector to deal with the forthcoming changes appearing on the horizon.

## **2. Impact on pharmaceutical industry**

### *Factor 1: Prediction and early detection*

Prevention of disease and a shift to wellness is a core pillar of Deloitte's perspective on the future of health. We expect that over the next 20 years, we will be able to detect some diseases and prevent them from advancing possibly even before symptoms arise. Today, for example, clinicians can detect the early stages of melanoma much earlier than in the past, and early treatment can eliminate the disease completely (Yang et. al, 2020).

### *Factor 2: Personalized treatment*

People suffer from diseases and respond to treatments in various ways. The vast majority of patients may not receive the full potential benefit of drugs that they are treated with, because we don't yet know how to effectively stratify patient populations. A therapy that is effective for one patient, might be different for another patient and never reach the optimal active concentration. Giving each patient a personalized dosage or the optimal combination of drugs, could lead to better outcomes.

### *Factor 3: Treatment therapies*

The therapies can potentially reduce the frequency and spread of many diseases. Therapies of this kind are typically temporary and tend to reduce the symptoms of a disease by targeting the main condition in a permanent or semipermanent way. It is predicted that the single-genetic mutation can trigger diseases that will be among the first ones treated by this kind of therapy (for example different types of cancer, sickle cell anemia, and some rare diseases). More than 1000 clinical trials for cell and gene therapies were performed worldwide at the end of 2019. A variety of diseases (such as cancer, musculoskeletal disorders and neurogenerative diseases for example) became the focus of these trials.

### *Factor 4: Digital therapy*

Patients are equipped with software programmes that help prevent, manage or cure medical disorder or disease based on collected data. Technologies of this kind are a potential viable alternative to traditional pharmacologic treatments or can be used together with drugs, devices or other therapies, optimizing patients' caretaking and improving health results.

### *Factor 5: Precision intervention*

The more sophisticated medical technology allows for earlier interventions and raises the effectiveness of procedures that reduce or even eliminate the need for pharmaceutical products. The advances in robotic surgery, nanotechnologies and tissue engineering are also included. Improvement of this technology can lead to

substantial progress in cancer treatment, treatment of infectious diseases, chronic pain and inflammatory conditions.

All of the above-mentioned factors raise serious questions for pharmaceutical companies about the markets they operate in and how the threat of disruption could impact them. The contemporary model of drugs sale treating symptoms or mitigating the progression of chronic diseases is no longer viable. The volume of sales of medicine in all variations of a disease could possibly be reduced due to more effective prevention, higher stratification of diseases, better tailoring of treatment regimens, an increase in curative therapies, behavioral intervention and advanced medical procedures. Considering the challenges arising, biopharma companies should ask themselves the following questions: How could each of these five factors affect their current business model? Where to find new opportunities? What are the potential threats for their current business? How can they unfold with time? How willing are they to participate in the emerging areas? How can they address the emerging challenges? How to react without regret (potential partnerships for example)? (Yang et. al, 2020).

Some diseases will be prevented, cured or controlled with non-pharmacological interventions by 2040. If this suggestion turns out to be true, less people will suffer from chronic diseases and less therapies will be needed. As a result, what has traditionally been managed by pharma sector, treatment of chronic diseases for example, is likely to erode. Consequently, if pharmaceutical companies wish to survive, a drastic change and significant expansion are essential. Furthermore, only pharma companies, who are able to transform their business models, could enjoy future success based on prevention, early detection and personalized therapies.

Pharmaceutical industry key tendency in development is the opportunity to use artificial intelligence algorithms that will ensure timely creation of innovative drugs and their successful launch, algorithms that facilitate the decision-making process of licensing, business strategy, merging and acquisition.

The variety of technologies introduced in pharma companies together with modalities represent another key trend in the pharmaceutical business development that will be further observed. Cell and gene therapies (CGT) will probably continue to be under the focus in the forthcoming years.

Pharma companies are now aware that the introduction of patient-oriented solutions depends on solid clinical evidence. Additionally, in terms of the highly regulated healthcare system, it becomes extremely hard to compete. Some novelties in the use of digital technologies in pharma industry are worth to be mentioned – the focus on the digital product effectiveness to generate solid evidence and the merge of generic drug manufacturers with technologically innovative companies in order to achieve higher productivity. Healthcare systems worldwide become more and more flexible and experiment with the current workflows, especially when aiming to improve effectiveness. Owing to a training and educational software for radiologists,



radiology can be given as a good example of improved working methods. IT products bear the potential to facilitate the functioning of a number of clinics in future.

The future of pharmaceutical industry will be continually marked by consolidation of development and manufacturing companies (CDMO) – a type of companies that provide both development and production of drugs. Companies offering a wide range of services with diverse customers' groups prove to be more viable.

The pharma industry now faces the challenge to create various drug delivery devices providing a personalized dose of medicine. The aim of achieving higher efficiency has led to more and more efforts being invested in the development of nasal forms of drugs. Companies have been recently working on the creation of electronic conceptual devices that will notify patients with a special application. These devices monitor the timely intake of medicines and inform the patient of the achieved dose effectiveness.

A few tendencies marked the development of pharma industry in 2020:

- increased use of marihuana for medical purposes;
- development (although slow-paced) of “precision medicine” that guarantees production of drugs in doses and intake forms tailored to patients' needs;
- integration of block chain technology;
- digital solutions installation;
- reduction of industrial capacity;
- use of cloud technologies;
- periodical pricing and strict continuous control on price speculation;
- digital training of professionals and a greater focus on R&D to ensure quality clinical trials, and tests that will allow to identify drugs and to improve business expertise and patients' lives.

### **3. Pharmaceutical industry trends in 2021**

The main problems of 2021 were closely related to the pandemic and its outcomes. The leading industrial problems and trends of 2021 are connected with cybersecurity development, antimicrobial resistance, environment, supply chain challenges, shift from animal testing, digital transformation and digital clinical trials (Sokolova, 2021).

The continuous digital transformation of pharma industry allows big data collection and management online, but at the same time creates a risk of cyberattacks. Some of the problems the pharma industry has to handle are intellectual property theft, cyber espionage, cyberattacks, such as Ramson ware and Phishing attacks. Moreover, serious risks concerning COVID-19 vaccine emerge – cyber espionage to steal vaccine data, cyberattacks on online platforms for vaccine appointments and use of stolen data to misinform the population.

The excessive and uncontrollable use of antibiotics has not only led to antimicrobial resistance, but appears to be one of the greatest challenges for pharma industry that affects healthcare systems worldwide and in particular pharmaceuticals. WHO defines antimicrobial resistance as one of the ten great global health threats in 2019 just before the pandemic outbreak, that can be explained with the unlimited access to antimicrobial drugs, inappropriate prescription and the restricted knowledge patients have (WHO, 2019). The appearance of COVID-19 pandemic worsened the situation.

The development of new antibiotics is extremely necessary, but antimicrobial resistance develops much faster than their respective research and experiments. In addition, according to WHO analysis almost all new antibiotics entering the pharma market in the last decades are simply variations of drugs, developed before the 80s of 20th century and cannot be as effective as expected (WHO, 2021). Consequently, these new drugs are incapable to handle the challenge of antimicrobial resistance spread. Pharma industry has the important task to develop innovative drugs providing sustainable funding for research.

A substantial negative impact on surrounding living organisms is caused by pharma manufacturer's waste, with chemicals being disposed in water and soil. Furthermore, pharmaceutical waste is also generated by chemists and hospitals and a certain number of medicines traditionally used by households are disposed as garbage.

A few more factors contributing to the environmental pollution by the industry appeared with the coronavirus pandemic: the number of plastic personal protective equipment (PPE; gloves, surgical and non-surgical masks, gowns, face shields, etc.) produced and used worldwide has significantly risen. In addition to the previous efforts to reduce negative ecological impact, driven by the COVID-19 pandemic, the pharma industry is forced to take additional measures to combat environmental pollution.

The continuing COVID-19 crisis has resulted in disrupted pharmaceutical supply chains. Just like in any other industry, pharma industry faces the problems of reduced workforce due to illnesses or even deaths, travel restrictions, technological hardships, change in specific drugs demands and great insecurity. The key challenges pharma supply chains have to deal with are the scarcity of raw materials and vaccine distribution.

The shortage of raw materials and active pharma ingredients (API) is caused by the great impact of coronavirus pandemic on their two world leading producers – China and India. In February 2020, the Food and Drug Administration (FDA) in the USA announced the first case of drug shortage in China after the coronavirus outbreak (U.S. FDA, 2020). The situation has not improved much since then. Indian pharmaceutical industry is highly dependent on the raw materials imported from China with 70% of Chinese API being exported to India. Export restriction of more than 20 APIs in March 2021 was imposed by the Ministry of Trade and Industry of

India due to the rising number of COVID-19 cases. Moreover, the last mass pandemic in India triggered a drastic price rise of raw materials with up to 200% (Chandna, 2021). All these factors globally impacted all pharma industries around the world, since they can lead to a shortage of basic drugs used for active treatment of acute conditions or chronic diseases.

The latest vaccination campaign proved to be not only the biggest and fastest in human history, but it also faced a number of challenges. Some of the challenges was associated with the distribution logistics, because the vaccine is highly dependent on the cold delivery specific requirements (for example, use of dry ice or refrigerators storage during transportation, Bluetooth to monitor and control temperatures, etc.). Reaching the final destination brought additional challenges such as ensuring security (video recording of vaccines storage area, application of GPS sensors to define location during transportation, etc.) and the most suitable storage device (refrigerator, freezer, ultra-freezer with low temperature, etc.). Countries with low and medium living standards and income found it extremely hard to meet these requirements, because most of them do not have proper infrastructure for effective storage, transportation and delivery of vaccines.

The traditional biomedical testing on animals is typical for the pharma industry. Despite the fact that the latest statistical data proves that 92% of animal-tested medicines are ineffective for humans, only 0,02% of animal-tested medicines are available to the public (Hanson, 2021). In spite of the idea that the shift from animal testing is a process that requires a lot of time, a few alternative testing methods are already in use: in vitro testing, computer modelling, participation of volunteers, and human-patient simulation. In general, the pharmaceutical industry has now been paving the way for standards that exclude animal testing.

One of the major trends in the development of pharmaceutical industry in 2021 is the industrial digitalization that started just before the COVID-19 outbreak. Some technology achievements allow for increased production and better quality of drugs thus improving the competitiveness of pharma companies – the artificial intelligence. Concerning the artificial intelligence, COVID-19 pandemics turned out to be a necessary evil that accelerated the introduction of technologies in the pharmaceutical industry: according to the IT company Global Data report artificial intelligence is likely to transform the pharmaceutical industry in the forthcoming years (Global Data report, 2021). The urgent need for vaccines and drugs for COVID-19 prevention and treatment has triggered innovations and represent a turning point for the introduction of such technology in the industry.

The contribution of artificial intelligence for the acceleration of the drug development process was also outlined in some online articles of “The Guardian” (Kollewe, 2021). Pharma companies have been always criticized for the slow technological progress. Special attention must be paid to the fact that the process of drug development is a slow, expensive and relatively successful process without

artificial intelligence: research and testing, acquiring legitimate approval of every new drug require approximately a decade and more than \$ 2 billion investment. Artificial intelligence contributes to the reduction of time needed for big scientific data analysis in order to better understand the specifics of a certain disease and to find potential candidates for treatment. The technological ability to compare thousands of data pages published online within seconds is the greatest advantage. What is more, artificial intelligence allowed for a quick and successful COVID-19 vaccine development. In addition to elaboration of drugs, innovations can be applied in a wide range of other activities that will allow for better design and recruitment of participants for clinical trials, more intelligent and effective supply chains, targeted sales and marketing.

According to a recent report on the use of robotics in industry, the need of automation in pharmaceutical production units is growing (Market Analysis Report, 2021). The solution to the problem can be found in the introduction of robotics to pharma manufacturing. Coronavirus pandemic additionally accelerated this process as pharmaceutical companies had to overcome the workforce shortage and increase domestic production through automation, rather than outsourcing. The report also demonstrated the various benefits of using robotics in drug manufacturing: improved productivity and quality of drugs, space utilization, less workforce turnover, increased safety, reduced downtime, better waste management. As for the production itself, automation reduces the error rate and frees people from monotonous and time-consuming work, raising the productivity of a plant. In the USA, for example, the partnership between Clemson College of Engineering, Computing and Applied Sciences (Clemson College) and the company Nephron Pharmaceuticals led to the invention of a syringe filling robot (Clemson University, 2021). The process of filling syringes with drugs is traditionally carried out by technicians and requires up to five professionals daily. The robot can fill, close and seal syringes without any human intervention.

Using robotics has proved to be effective, the tendency will continue after the COVID-19 crisis as well: the long-term benefits of robots make them a cost-effective tool in the production process. The digital clinical trials suggest limited or no personal interaction between the patients and the researchers. Connected devices, telemedicine and mobile providers of healthcare services allow distant data collection. All activities from A to Z can be distantly implemented in patients' homes. Among other benefits, clinical trials of this type provide patients with a more streamlined experience, reduce the time-consuming personal visits and better access to patients in rural areas or remote communities. However, there are certain risks such as unknown side effects or wrongful use of data.

COVID-19 catalysed the adoption of decentralized clinical trials and they immediately turned into strategic priorities for many pharmaceutical organizations. This trend is expected to last long after the coronavirus crisis since these trials bear the potential to change fundamentally the clinical trial procedure.

#### 4. Conclusion

Having both short-term and long-term impact on all of the above-mentioned tendencies in the development of pharma industry in the last two years, will undoubtedly change it. It is worth mentioning that a growth of \$1.5 trillion in pharma sector in 2023 is forecasted. It is also expected that pharma industry will be significantly affected by innovative technological breakthroughs in the next two to five years. More than 450 drugs were withdrawn from the pharma market in the last 25 years. That is one of the reasons why precision medicine will be an inseparable part of the pharma industry transformation. Considering the perspectives on the technological future of the pharmaceutical industry presented in this article, we can conclude that the sector is ready for the adoption of Industry 4.0. The pharmaceutical model is definitely transitioning to digital solutions, key research innovations and new emerging markets. The role of artificial intelligence, robotics and research and development (R&D) of pharmaceuticals, is evident. Probably, mobile health applications will even transform healthcare and diagnostics. Big data and digitalization processes will also impact the manufacturing and distribution of pharmaceuticals. The exact changes are yet to be seen.

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## COMPETITIVENESS FACTORS OF PHARMACEUTICAL MANUFACTURER

Milena Filipova<sup>1</sup> Yulia Nedelcheva<sup>2</sup>

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### Abstract

*The purpose of the study is to determine the competitiveness of pharmaceutical manufacturers in Bulgaria in unique environment of COVID-19 pandemic. The focus of the study is to fix the main factors that determine competitiveness. Achieving this purpose will form a better understanding of functioning of the pharmaceutical industry, as well as the possibility to take corrective action through recommendations and identify untapped opportunities to increase competitiveness. The results of the study determine two main factors for the competitiveness of pharmaceutical manufacturers – the quality and the price of pharmaceutical products. The leading place of quality as factor defines the manufacturing of pharmaceutical products mainly as part of healthcare system and at next place – as part of the economy. The conclusions reached are crucial in defining the purpose of pharmaceutical policy for safe, effective and affordable pharmaceutical products.*

**Keywords:** Bulgaria; SWOT analysis; Porter's five forces analysis

**JEL Codes:** D22; I11; L11

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### 1. Introduction

The pharmaceutical industry is unique in its nature. On the one hand, it is a part of the healthcare system and, on the other hand, a part of the industrial production. The dual nature of the pharmaceutical industry is a consequence of the purposes of each of the two sectors: achieving health efficiency and economic effectiveness. Balancing between these purposes leads to difficulties in determining and assessing the competitiveness of pharmaceutical manufacturers.

The importance of competitiveness for pharmaceutical industry is a consequence of the combination between healthcare system and industrial production. Conducting a competitiveness assessment will identify the factors that are leading to production effectiveness as well as healthcare efficiency. The two components of

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<sup>1</sup> South-West University “Neofit Rilski”, Blagoevgrad, Department of Management and marketing, Professor, PhD, e-mail: emili2000@abv.bg; ORCID ID: <https://orcid.org/0000-0002-5003-006X>

<sup>2</sup> South-West University “Neofit Rilski”, Blagoevgrad, Department of Management and marketing, PhD Student, e-mail: yulia.nedelcheva@abv.bg; ORCID ID: <https://orcid.org/0000-0002-0252-1825>

competitiveness, production and healthcare, are of particular importance for both the economy and society. The results of the competitiveness assessment are intended for a wide range of stakeholders and can be laid down in a national strategy for economy competitiveness.

## **2. Top pharmaceutical manufacturers in Bulgaria**

The manufacturing of pharmaceutical products, in contrast to import and distribution, is concentrated in the Southwest Bulgaria (Ilieva-Tonova et al., 2016) – over 70% of the volume of pharmaceutical production in Bulgaria. A question remains valid why pharmaceutical manufacturers are not located close to clusters of chemical companies, for example in cities such as Burgas (East Bulgaria) and Ruse (Northeast Bulgaria), which are major suppliers of raw materials for pharmaceutical manufacturing. Perhaps the answer should be sought in the way the pharmaceutical industry established and in particular in the arguments for privatization wave in the 1990s (Madgerova & Kyurova, 2014).

For all administrative regions, pharmaceutical manufacturers are a main employer, determining the level of employment and contributing to raising living standards (Nedelchev, 2019). Local authorities balance between the purposes of maintaining both production and availability of pharmaceutical products nationwide. A major problem for both manufacturers and local stakeholders is compliance with environmental requirements (Petrova, 2018).

The subject of the study are the top manufacturers of pharmaceutical products in Bulgaria. The list of manufacturers has taken into account companies that are registered as manufacturers in the Register of Manufacturers, Importers and Wholesalers of Active Substances of the Bulgarian Drug Agency and with highest volume of manufactured pharmaceutical products as per data from annual reports (Keremidchiev & Nedelchev, 2022).

A cluster of seven pharmaceutical manufacturers is formed from the adopted limitations:

- Adipharm, Sofia. Established as a wholesale distributor of pharmaceutical products in 1994. Performs activities for both production and wholesale distribution. A significant part of the production is intended for export to the Middle East.

- Balkanpharma Dupnitsa, Dupnitsa. Established as a pharmaceutical plant in 1954 and owned by Teva Pharmaceutical Industries Ltd., Israel. The product list includes over 150 items, which are sold in over 50 countries, incl. through subsidiaries of the Teva Group worldwide.

- Balkanpharma Razgrad, Razgrad. The manufacturer has over 60 years of experience in the development, production and sales of generic drugs for human and veterinary use. Owned by Antibiotic Razgrad, Razgrad. Production is related to industrial microbial synthesis, genetics, and pharmaceutical products for the markets of more than 20 countries.



– Balkanpharma Troyan, Troyan. Established in 1953 as a chemical laboratory. Since 2016, has been owned by Teva Pharmaceutical Industries Ltd, Israel. The production is related to gels, tablets, capsules and other forms of pharmaceutical preparations.

– Bul Bio-National Centre of Infectious and Parazitic Diseases, Sofia. Established in 1881 as a chemical laboratory. Fully state owned. The only manufacturer in Bulgaria of vaccines, serums, immunostimulants, allergens, diagnostic drugs.

– Sopharma, Sofia. Originated 100 years ago as a professional organization. Currently is local private ownership acquired through privatization. Includes over 10 plants in Bulgaria and 3 plants abroad, united in Sopharma Group. Over 20% of the Group's activity is related to production and the rest – to distribution. The production is focused on both medicinal products and chemical products.

– Tchaikapharma High Quality Medicines, Varna. Established in 1999 from private local capital. Owns three plants in Sofia, Varna and Plovdiv. The production is related to generic and licensed medicinal products.

### **3. Research tools**

In assessing competitiveness, a survey was used as a research tool. The survey is based on the interpretation of data, which through inductive conclusions create explanations and conceptual frameworks, develop hypotheses and understanding of the studied processes. The survey creates a discussion with the reader and achieving his conviction of the results achieved. Last but not least, this qualitative research collects and interprets data, creating a sense of participation in the research process for survey participants as well as for the reader.

The survey as a research tool tests the expectations and perceptions of the respondents. As a specific form of communication, the survey data provide a snapshot of the situation. The main advantages of the survey are short time, low costs and understandable data. For us, the leading feature of qualitative research is to overcome most of the imposed limitations arising from the dynamics in the pharmaceutical industry.

The survey as a research tool ensures that all respondents will receive the same opinions at the same time. The equality of the respondents is guaranteed by observing the deadline for answering, as well as reflecting the answers in aggregated and synthesized form.

At the heart of our survey are questions related to the views and experiences of the participants, i.e. we developed two surveys for both type of respondents – manufacturers and consumers of pharmaceutical products. The questionnaire is our original development after an in-depth review of the scientific literature and local regulations. This approach will help to identify practices, strategies and factors that contribute to competitiveness in the pharmaceutical industry.

Given the high level of regulation in the pharmaceutical industry, the importance of random selection of a participant is reduced, including the socio-demographic characteristics of the participants are neutralized. The survey was conducted through a direct survey, i.e. each participant fills in the questionnaire himself. The questions and opinions are prepared and set in Bulgarian, i.e. in the mother tongue of the respondents. From the received answers a database was created, the results of which are graphically presented using Microsoft Excel.

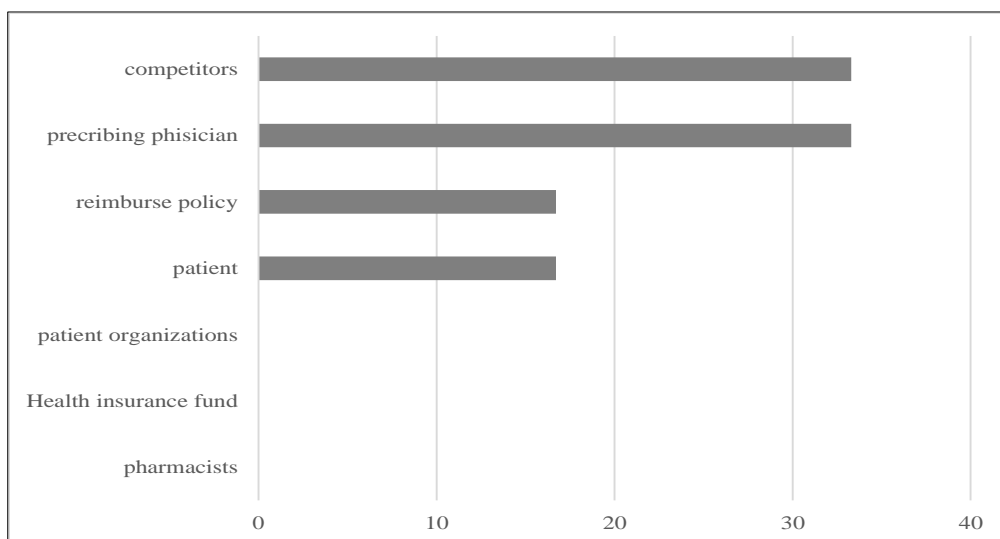
#### 4. Discussions

Following the continuation by the government of the restrictive measures to tackle the pandemic, we conducted a study in March 2021, which covers 78 respondents. The respondents covered of survey are a combination of different levels of society and educational degree, which helps the researcher to accumulate wide data.

The socio-demographic characteristics of the respondents-manufacturers are the following: 67% occupy a tactical level in the managerial hierarchy; 33% manage a production department; 50% have 10-20 years of experience; 50% have an average degree of participation in decision-making in the enterprise; 50% have an education in economics and management; 67% have a master's degree; 50% are aged 36-49 years; 50% are women.

In their activities, manufacturers take into account opinions that are closer to market factors (competitors, the state as a financial source, prescribing physician and ultimate consumer) than opinions from healthcare system (Figure 1).

*Figure1. Opinions taken in account by manufacturers in the production of pharmaceutical products, %*



Source: authors' data

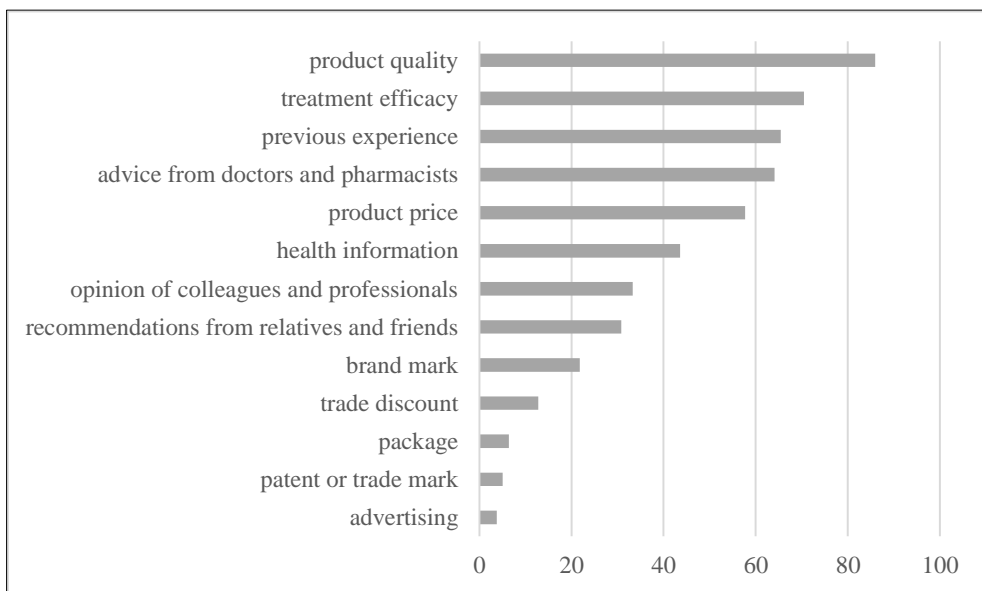
Socio-demographic structure of the respondents-consumer are:

- 23% work in the pharmaceutical sector;
- 64% have a master's degree;
- 41% are aged between 36 and 45;
- 69% are women;
- 64% are ultimate consumer of pharmaceutical products;
- 47% have a high level of health culture.

65% of the respondents are ultimate consumer of pharmaceutical goods, which affects the results. Largely, precisely the economic logic and the average level of management form the results of the survey.

To all questions from the survey, the assessment of consumers is lower than those of manufacturers is. Ultimate consumers when purchasing a pharmaceutical product take into account factors related to health: product quality and efficacy (Figure2).

*Figure 2. Factors taken in account by consumers in buying a pharmaceutical product, %*

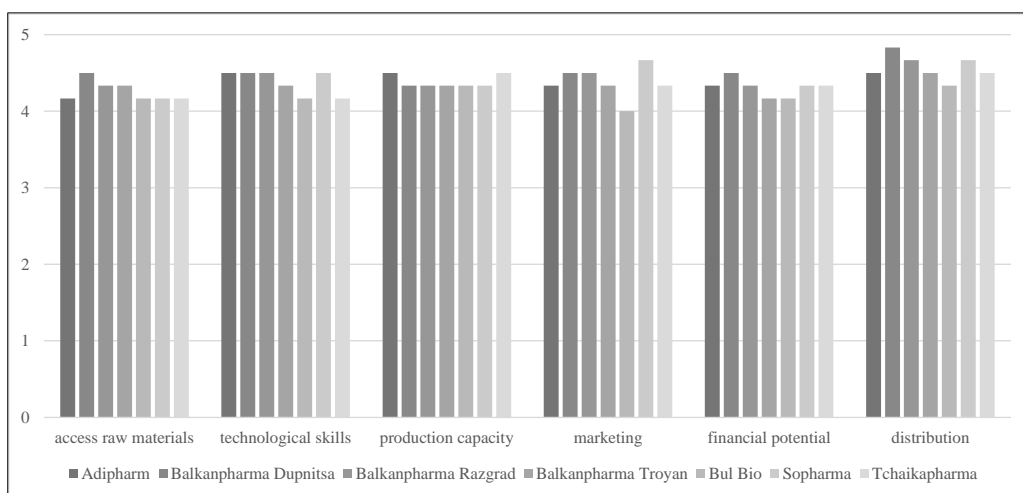


Source: authors' data

We will present the results of the survey using Porter's five forces analysis:

*Rivalry among existing competitors.* The existing competitors were survey in three areas of competitiveness: resources, workflows and distribution (Figure 3).

Figure 3. Ranking of manufacturers by input, operating and output areas of competitiveness (the maximum score is 5)



Source: authors' data

The highest results at the input were reported for Balkanpharma Dupnitsa, followed by Balkanpharma Razgrad. We can discuss for competitive advantages from supplier relationships for a limited number of manufacturers (Yuleva, 2019). These manufacturers apply a strategy to focus on a narrow market segment, which in fact determines the status quo for future periods (Borisova, 2017).

Work processes are activities by the manufacturer to add economic value to the input raw material. We accept *ad hoc* that these processes include technological skills, production capacity, marketing activities and financial potential. The highest scores are reported in the technological skills of manufacturers while production capacities have relatively equal opportunities. The financial potential and the marketing activities show similar scores for the individual manufacturers. Again, Balkanpharma Dupnitsa and Balkanpharma Razgrad have the best results in the four work processes.

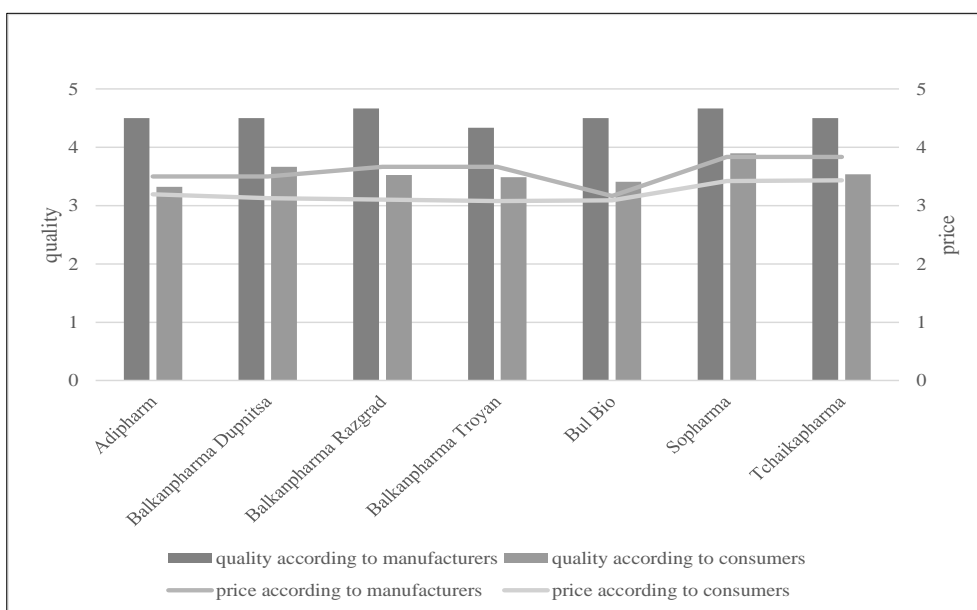
At the output of the manufacturers there is a dependence between the data on the distribution and two of the indicators of the work processes – the data on the distribution to a large extent repeat the dynamics of the financial potential and of the marketing activities. Once again, Balkanpharma Dupnitsa and Balkanpharm Razgrad have the highest results. The presence of Sopharma's own network of pharmacies is not significant factor in the data on the distribution of the pharmaceutical products.

Distribution data are the highest for all manufacturers. Sopharma has the biggest difference between input and output indicators – low value for access to raw resources and high value for distribution at average values of work processes. This case observes a kind of accelerator to increase low input resources to high output results, i.e. achieve an impressive profit. As a general opinion for all manufacturers

are higher indicators for technological skills and marketing activities, while for production capacity and financial potential the values are lower. All manufacturers have similar values in terms of production capacity.

Sopharma products are of the highest quality according to the opinion of both manufacturers and consumers (Figure 4). Sopharma also has the highest product prices.

*Figure 4. Quality and price of products according to the opinion of manufacturers and consumers (the maximum score is 5)*



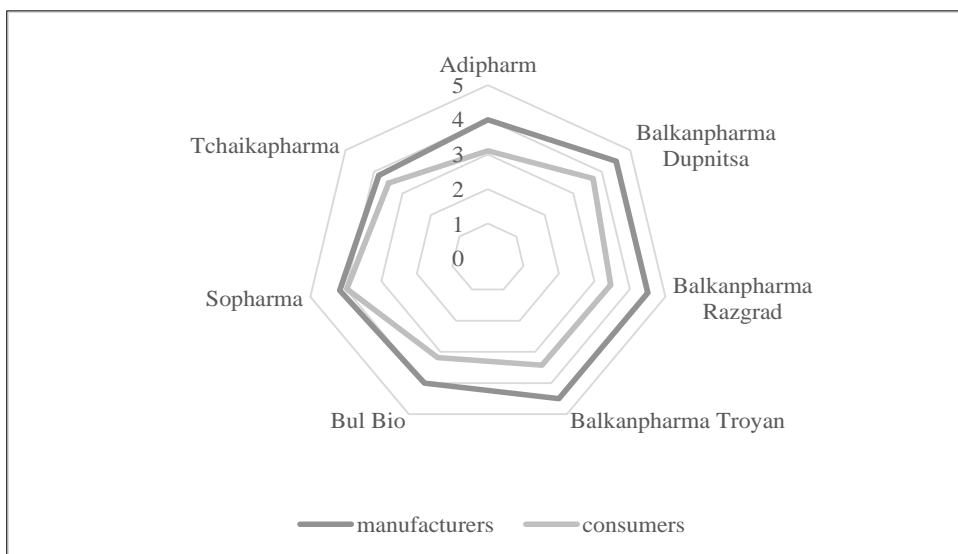
Source: authors' data

The lowest prices are at Bul Bio and only for this manufacturer the assessments of both the manufacturers and the consumers regarding the price of the products coincide. In all indicators, consumer ratings are lower than those of manufacturers are.

As a consequence of product quality and price, the reputation of individual manufacturer is formed (Figure 5). Consumers' perceptions of reputation are lower compare those of manufacturers are.

The highest reputation is assigned to Balkanpharma Dupnitsa, Balkanpharma Razgrad and Balkanpharma Troyan according to the opinion of both the manufacturers and the consumers. Reputation data largely correspond to manufacturers' responses to product quality.

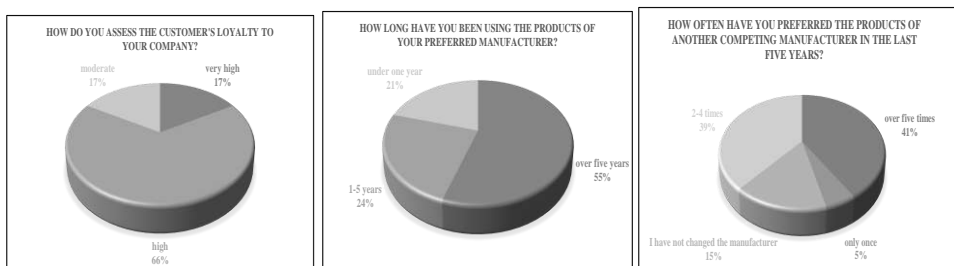
*Figure 5. Comparison between the opinions of manufacturers and consumers about the reputation of manufacturers (the maximum score is 5)*



Source: authors' data

The reputation of manufacturers is high – in 66% of responses (Figure 6). We can discuss for the formation of traditions in choosing a manufacturer, as more than half of consumers (55%) use the products of a particular manufacturer. Regardless of the determination of the preferred manufacturer, there is a practice of changing the manufacturer for the last five years in 85% of the responses. Most often, the change of the preferred manufacturer with another manufacturer is due to higher quality (92%) and lower price (78%). It should be noted that the chosen five-year period is significant for the Bulgarian reality given the transition period of the economy, health care reforms, the establishment of social norms (Nedeltchev, 2005) and the age of the respondents.

*Figure 6. Reputation of manufacturers according to the opinion of manufacturers and consumers*

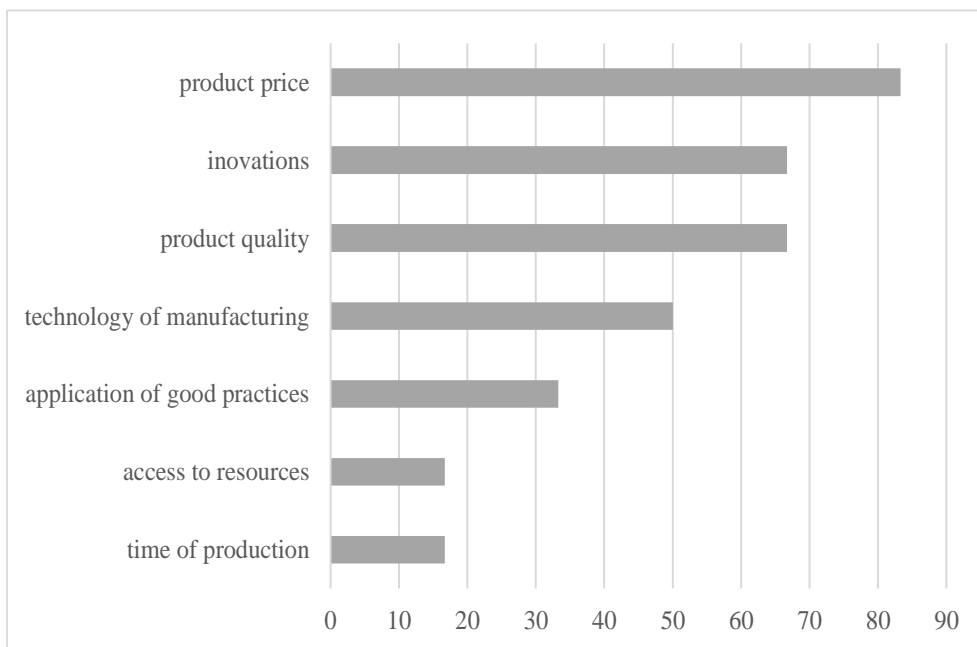


Source: authors' data

*Suppliers.* All respondents identified suppliers as a competitive advantage. In most cases, a supplier means access to raw materials. Suppliers are at the heart of a competitive strategy to diversify products.

Access to resources has low effect over the competitiveness of enterprises (Figure 7). In determining competitiveness, input resources and working processes are of the least importance.

*Figure 7. Factors for determining competitiveness according to manufacturers, %*

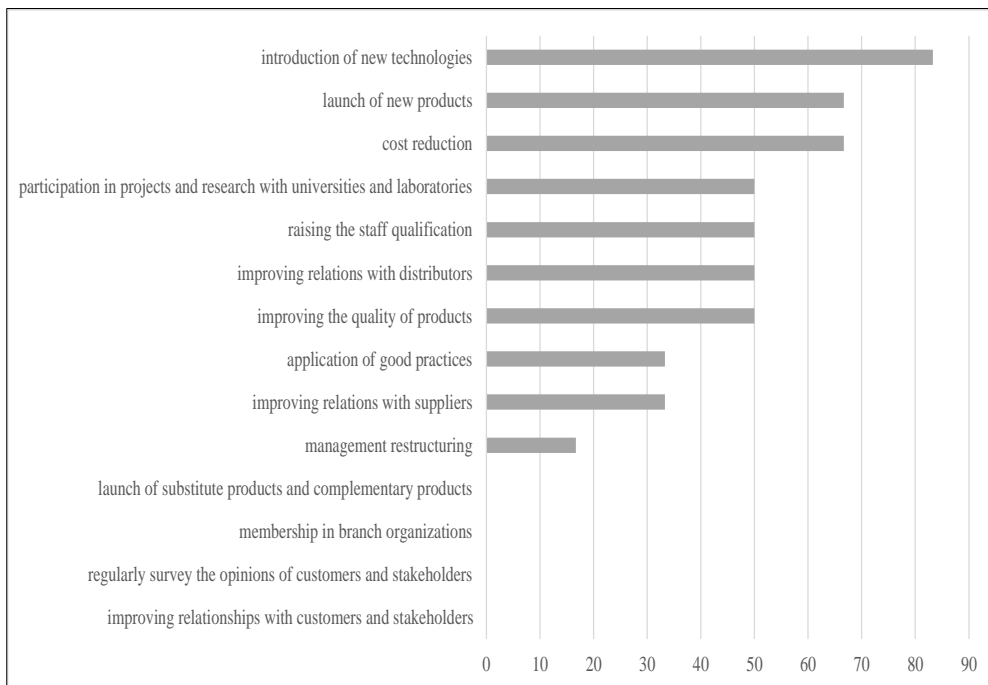


*Source:* authors' data

Suppliers are reflected in the responses of respondents who are at a strategic level and practice in areas such as distribution, logistics and marketing. In most cases, the influence of suppliers on competitiveness is associated with opinions about increasing sales, customer loyalty and taking into account the views of competitors in the production of pharmaceutical products.

*Buyers.* Their impact on competitiveness is average. Buyers have twice as much of a role in improving competitiveness as suppliers (Figure 8).

*Figure 8. Factors for improving competitiveness according to manufacturers, %*



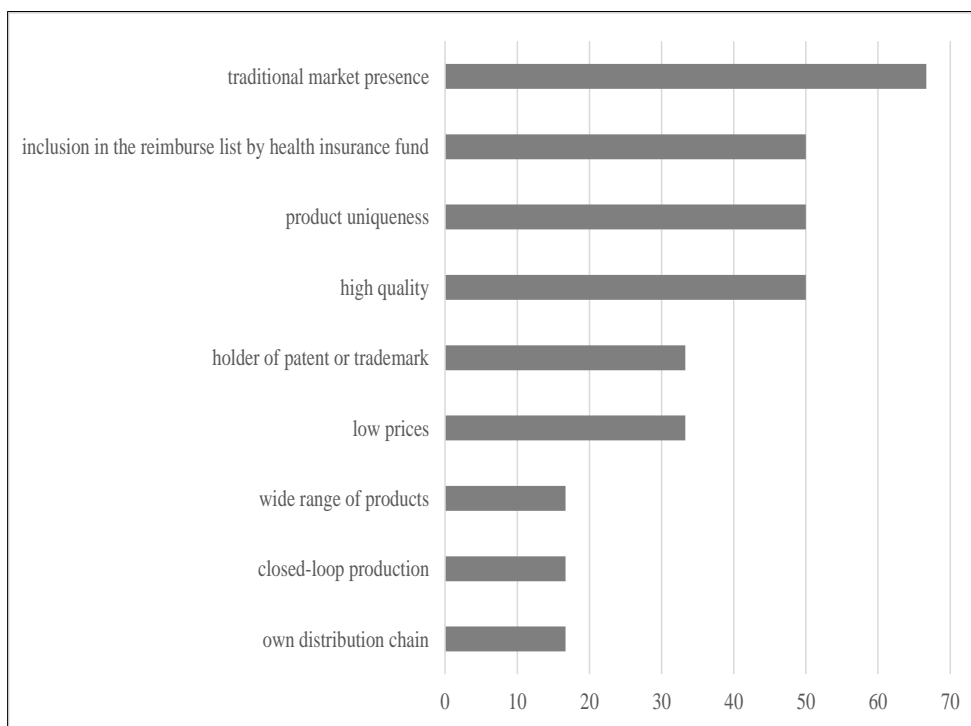
*Source:* author's data

Distribution is reflected in the opinion of the respondents not so much in the distribution network, but rather in the methods of distribution – product price and trade discounts (Stoimenova et al., 2019). Despite the fact that manufacturers take an interest mainly in the opinion of competitors, the improvement of the competitive position is presented as a consequence of focusing on a narrow market segment, high quality and low prices. Own distribution network is a weak participant in competitiveness, as well as the closed production cycle.

*New entrants.* The constitution of new competitors in the pharmaceutical industry is related to the licensing regime, which is not the subject of our study. All other things being equal, new competitors should overcome the momentum created by existing competitors both in terms of brand and to impose new market niches. Given the short period of the recent economic history of Bulgaria, it can be argued that for the last 30 years, traditions have been successfully established in relation to existing competitors (Chart 6). New entrants should take into account the limitations of the local market in terms of capacity and requirements of competent authorities at both national and EU level. Our analysis identified as a key threshold for new entrants to overcome the established traditions between manufacturers and consumers (Figure 9).



*Figure 9. Competitive advantages of manufacturers, %*



*Source:* authors' data

When overcoming the traditions, the new entrants should take into account the advantage of including in the reimburse list by the health insurance fund (Gergova et al., 2019). The up-to-date list includes three of the studied manufacturers:

- Actavis (Balkanpharma Dupnitsa and Balkanpharma Troyan) – the state health insurance fund pay for 74 pharmaceutical products of this manufacturer. The level of reimburse for the products of this manufacturer is 67%, i.e. the health insurance fund covers most of the price and the rest is borne by the ultimate consumer.
- Sopharma – the state health insurance fund pay for 84 pharmaceutical products and has reimburse at 60% of the price,
- Tchaikapharma – for 117 pharmaceutical products and reimburse at 62% of the price.

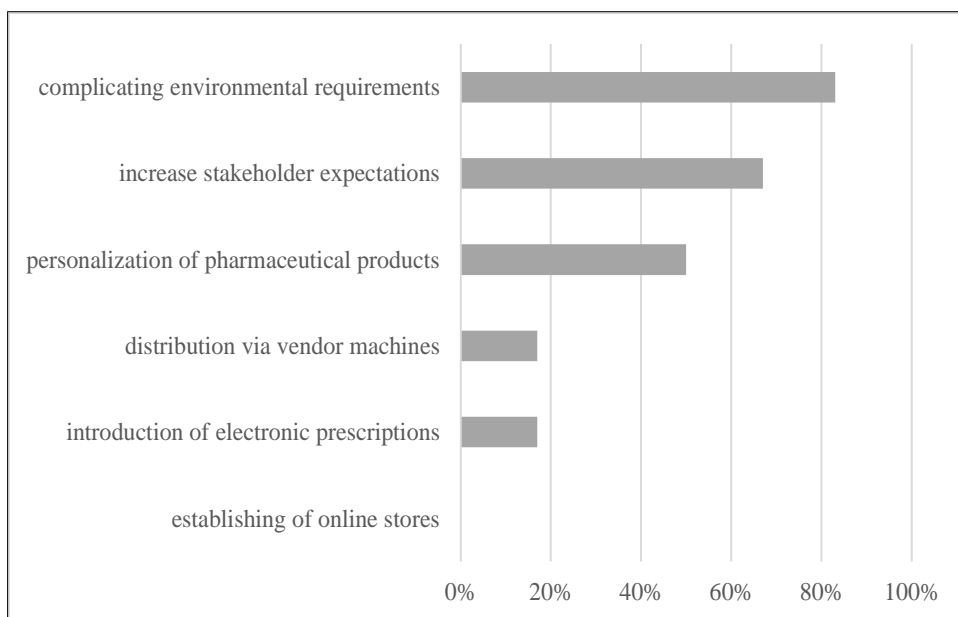
For all other manufacturers, the price of the pharmaceutical products is borne entirely by the ultimate consumer. Preconditions are created for the transition from oligopoly to monopoly in patients who use preferential prices under the state health insurance fund. Given the predominant age of respondents (36-45 years), it is understandable that 47% of respondents do not consider the presence of a pharmaceutical product in the reimburse list by the health insurance fund and 80% do

not think that the price of the pharmaceutical product is important, as the health insurance fund pays part of the price.

*Substitute products.* The annual reports of manufacturers reveal low cost for research, which reduced likelihood of launching substitute products.

New entrants are more likely to enter new market niches in both manufacturing and distribution (Ilieva-Tonova et al., 2022). The view of manufacturers that there is no threat of market changes identifies stakeholders and competent authorities as creation of new opportunities (Figure 10).

*Figure 10. Changes in the market as a threat to competitiveness*



*Source:* authors' data

## 5. Conclusion

Based on the results obtained from the study of the competitiveness of pharmaceutical manufacturers in Bulgaria we can draw the following conclusions:

First, the data from the benchmarking of producers by a set of competitiveness factors do not identify a clear leader. Our interpretation of this fact is the large number of dimensions of competitiveness. Perhaps only product quality should be taken into account when determining competitiveness, as the study concerns healthcare system, and in particular the pharmaceutical industry.

Second, the winner is Balkanpharma Dupnitsa because the production is aimed at a wide range of ultimate consumers and is easily accessible, i.e. due to manufacturing of pharmaceutical products without a prescription. In this case, the

importance of the prescribing physician, pharmacist, state health insurance fund and patient organizations is reduced. This explains the exclusion from the list of winners of Bul Bio, which is aimed at the hospital market, and Adipharm, which manufactures mainly for export and is not sufficiently recognizable to Bulgarian consumers.

Third, the quality of pharmaceutical products determines the competitiveness of pharmaceutical manufacturers. Other factors to increase competitiveness are the cost of pharmaceutical products and the effects of treatment. Marketing tools have the weakest impact on competitiveness. We can answer the question posed in the introduction that the pharmaceutical industry is mainly a part of healthcare system rather than a part of economy.

When summarizing the results of the study, two leading factors for the competitiveness of pharmaceutical manufacturers are formed:

- Product quality. The participation of quality in determining competitiveness is justified by the fact that pharmaceutical production is part of healthcare system. The main goal of healthcare system is to achieve the efficiency of the pharmaceutical product. No correlation of the product quality with other factors for competitiveness such as promotion and advertising was found.

- Product price. It has a place in determining competition due to the fact that pharmaceutical production is part of the economy. In manufacturing, the leading goal is to achieve effectiveness and is close to market principles. In countries with a low standard of living, consumers prefer a manufacturer mainly by the price and to a lesser extent because of the quality of the product.

## **6. Recommendations**

In addition to the results and conclusions, we will make recommendations to pharmaceutical manufacturers to improve their competitiveness. We will use SWOT analysis as a research tool.

Through SWOT analysis, we will try to establish the optimal strategy, including recommendations for corrective action, which we accept as opportunities to improve competitiveness. The analysis consolidates the individual results for these manufacturers (Figure 11).

*Figure 11. Strategies for improvement of competitiveness for pharmaceutical manufacturing*

	<p><b>Opportunities</b></p> <p>O1 good infrastructure for business location</p> <p>O2 state policy for mass use of generic pharmaceutical products</p> <p>O3 a large number of external distributors</p> <p>O4 increasing demand for generic pharmaceutical products</p> <p>O5 significant foreign investment, incl. acquisitions from local producers</p> <p>O6 positive attitude towards generic pharmaceutical products</p> <p>O7 availability of a list of pharmaceutical products for reimbursement from the state health insurance fund</p> <p>O8 availability of export potential</p> <p>O9 possibility to influence the price of some pharmaceutical products</p> <p>O10 price inelasticity of demand for pharmaceutical products</p>	<p><b>Threats</b></p> <p>T1 new competitors and importers after European Union membership</p> <p>T2 decline in customers' solvency</p> <p>T3 unpredictable regulatory environment</p> <p>T4 weak financial results of the main customer (hospital market)</p> <p>T5 organizing public tenders for the purchase of pharmaceutical products by the state</p> <p>T6 international commitments to protect intellectual property</p> <p>T7 increased environmental requirements</p> <p>T8 low health care costs in the state budget</p> <p>T9 traditional export markets remain outside the European Union</p> <p>T10 small national market</p>
<p><b>Strengths</b></p> <p>S1 reputation as a manufacturer</p> <p>S2 good provision with qualified staff</p> <p>S3 positive image in society</p> <p>S4 a quality management system is applied</p> <p>S5 sole manufacturer of a specific pharmaceutical product in Bulgaria</p> <p>S6 possession of a production license</p> <p>S7 high transparency of the activity and the results due to the adopted shareholder form</p> <p>S8 customer recognition</p> <p>S9 contractual relations with universities and laboratories</p> <p>S10 knowledge of the infrastructure of the national market</p>	<p><b>SO strategy</b> (increase market share)</p> <p>SO1 bargaining to change the prices (S1, O9)</p> <p>SO2 discovering new market niches (S10, O4)</p>	<p><b>ST strategy</b> (cost reduction)</p> <p>ST1 new product launch (S8, T5)</p>
<p><b>Weaknesses</b></p> <p>W1 lack of energy-saving technologies in manufacturing</p> <p>W2 low level of feedback from stakeholders</p> <p>W3 limited range of pharmaceutical products for production</p> <p>W4 the need for a long period of time when switching to new production</p> <p>W5 constant updating of knowledge and skills of the staff</p> <p>W6 maintaining a significant number of contracts with distributors</p> <p>W7 the adopted organizational structure does not provide an opportunity for quick reaction to changes in the external environment</p> <p>W8 insufficient investment in R&amp;D</p> <p>W9 mandatory hiring of certified staff</p> <p>W10 dependence on the chemical industry as a major supplier of raw materials</p>	<p><b>WO strategy</b> (promotions)</p> <p>WO1 new technologies to improve quality (W8, O5)</p>	<p><b>WT strategy</b> (new policy towards distributors)</p> <p>WT1 establishing cooperation with biotechnology companies (W7, T6)</p> <p>WT2 increasing R&amp;D costs (W8, T1)</p> <p>WT3 finding new distributors (W2, T8)</p> <p>WT4 divestment and closing of losing production (W10, T9)</p>

*Source:* authors' data

We recommend that each of the surveyed pharmaceutical manufacturers to implement a specific strategy (Figure12):

Figure 12. Recommended strategies

<b>SO strategy</b>	<b>ST strategy</b>
Bul Bio Adipharm	Sopharma
<b>WO strategy</b>	<b>WT strategy</b>
Balkanpharma Razgrad Tchaikapharma	Balkanpharma Troyan Balkanpharma Dupnitsa

Source: authors' data

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## CHALLENGES TO THE HEALTHCARE SYSTEM IN BULGARIA AFTER THE OCCURRENCE OF THE CORONAVIRUS

Viktoriya Todorova<sup>1</sup>

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### Abstract

*At the end of 2019, humanity was facing one of the most serious challenges that had a negative impact on the entire world economy. The new coronavirus (COVID-19) has been declared a pandemic by the World Health Organization (WHO). It is appearance led to widespread fear, which in turn affected everyone's daily life. As if the international community was suddenly paralyzed, life began to move at a slow pace and people wondered if they too would be affected by a disaster called the coronavirus. The current study aims to analyze the changes and provocations that occurred with the onset of the pandemic. The results show that there are significant gaps in the country's health information systems and that the Coronavirus Disease (COVID-19) has had serious consequences for the country's health, social security and economic growth. The main research methods used in the development are analysis, method of analysis and synthesis, intuitive and systematic approach.*

**Keywords:** health; disease; Covid-19; pandemic; health system

**JEL Codes:** I1; I15

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### 1. Introduction

The emergence of the Covid pandemic has undoubtedly struck a blow to Bulgaria's healthcare system and confronted it with the challenges of an aging population, new technologies, rising healthcare costs and the growing burden of chronic diseases. Despite decades of transition, life expectancy in our country is far below the EU average before the pandemic, amounting to 75.1 in 2019 compared to 81.3 in the EU as a whole (Eurostat, 2021). This gap is likely to increase further as a result of the COVID-19 pandemic.

The spread of the coronavirus posed many challenges to all, but most affected were medical professionals, tasked with curbing epidemiological infections. Internationally, it has been established that:

- the new virus affects people with chronic diseases and adults over 65;
- the new virus has a specific feature - high morbidity compared to other known viruses;

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<sup>1</sup> South-West University "Neofit Rilski", Blagoevgrad, Faculty of Economics, PhD student, e-mail: viki\_todorova.92@abv.bg; ORCID ID: 0000-0003-1431-0176

- due to the high morbidity, the health system is burdened.

The coronary heart disease pandemic has drastically changed the healthcare landscape. The influx of patients threatens to deplete resources, from ventilators and critical care beds to personal protective equipment and staff. Clinics' basic ethical commitments to patients remain, but they must make difficult choices on a daily basis. As acknowledged in a statement from the National Academy of Crisis Care, Engineering and Medicine, "clinicians are ethically justified - and in fact ethically obliged - to use the available resources to sustain life and well-being as much as possible" (The National Academies of Sciences Engineering Medicine, 2020).

Three ethical challenges are of particular importance in the care of cardiovascular disease during the COVID-19 pandemic (Khazanie, Wynia, Dickert, 2020):

1) First, the cessation of emergency clinical care forces cardiologists to make difficult judgments about which patients need urgent and which can be postponed without undue risk;

2) Second, as institutions develop frameworks for the allocation of critical care resources, cardiologists must develop equitable approaches to patients with heart disease;

3) Third, cardiologists should advise patients and their families in situations where treatment cannot be provided due to deficiency.

The ethical duty of physicians to improve patient well-being is no different in the COVID era than in other times, but the bar of urgency has been raised, the assessment more complex, and the uncertainty greater. In the short term, the risk of delaying care for chronic patients is usually low, but because the pandemic runs periodically over time and personal care is limited, the risk for patients escalates (Stoykov, Zdravkov & Dimov, 2020).

These solutions are more common, potentially more impactful, than triage ventilation or intensive care triage decisions, which have received more public attention, but these decisions are left to individual cardiologists.

## **2. Literary review**

A number of scientists and researchers are examining the appearance and causes of the corona virus. Among them is Adam Kucharski, Associate Professor in The London School in hygiene and tropical medicine (LSHTM). Key for work on Kucharski are two main questions: which are the factors that provoke epidemics and how they can be traced and controlled better. "We need it from two key parts from information: for everyone infected person on how much others people him transmit?" (Kucharski, 2020).

In his new book "Rules on infection ", proposing theory about patterns of virus spread on the Internet or in the human body. He argues that misinformation about the coronavirus can be just as harmful as the spread of the disease itself.

Another scientist, David Heiman, who is a professor in epidemiology on infectious diseases in LSHTM, say that the coronaviruses was particularly dangerous because, such as the original mu spread is passed a lot faster from previous similar flu epidemics.

The professor of medicine in the university on Eastern England - Paul Hartman claims that, "Infections se spread easier through winter than through summer, so that is quite a lot probably if -this continue in the north hemi sphere, at least yes observes decline through the following months. The big one question will be whether will appeared again" (Hunter, Bunn, Kilet & Brainar, 2021).

### **3. Analysis and discussion**

#### *3.1. National Pandemic Preparedness Plan*

At the beginning of the COVID-19 pandemic, Bulgaria took a number of measures to control the outbreak and minimize shock to the health system. This includes providing sufficient hospital capacity and healthcare professionals for the care of seriously ill patients from COVID-19, setting up supply chains for personal protective equipment and other essential devices and medicines, and minimizing disruption to health services (Puca, Čivljak & Arapović, 2020). To tackle the Coronavirus pandemic, a national pandemic preparedness plan has been drawn up, stating that we are not prepared to deal with such a pandemic, which threatens global health. It is clarified that the challenges of the COVID-19 pandemic create unprecedented cooperation within the European Community, with the cross-border nature of the crisis necessitating the search for common solutions and actions in order to enforce a comprehensive and effective policy.

The main goal of the National Pandemic Preparedness Plan is to create an adequate organization by taking action:

- limiting the scale of morbidity;
- optimal treatment options;
- maintaining the functionality of key sectors;
- providing constant, reliable and up-to-date information (Ministry of health, 2020).

The actions to be taken in a pandemic situation are:

- 1) Strengthening the epidemiological, microbiological and virological surveillance of communicable diseases;
- 2) Development and approval of a plan for providing vaccines;
- 3) Deepening research in the field of epidemiology.

Strategic planning at the national level is an important necessity, which is based on a chronological detailed assessment of events, a systematic procedure for opening the risk assessment (Grossman, 1972). Operational planning requires the identification of those who have the primary responsibility for planning action during



a pandemic, at national level, and that plans and steps must be defined in sequence and coherence.

The early warning and surveillance system determines the mode of transmission of the infection, the clinical symptoms and the severity of the disease. Indicators help to determine the clinical behavior of patients, risk factors that can lead to severe disease. The continuous exchange of information is of particular importance for identifying possible changes in the genome of the causative agent, which helps to develop appropriate recommendations and guidelines to combat infection. Coordination between the various units, both at national and regional level, is crucial for the development and impact of the pandemic.

The main activities for pandemic preparedness are within the competence of the Ministry of Health and are aimed at:

- 1) Forecast and assessment of the epidemic situation in order to prepare the health and medical institutions and the medical and non-medical specialists in them for action during a pandemic;
- 2) Establishment of an organization for the medical insurance of the population and for optimal opportunities for treatment of the sick;
- 3) Establishment of an organization for conducting anti-epidemic measures and control on the territory of the country;
- 4) Conducting and strengthening the epidemiological and laboratory surveillance of communicable diseases in Bulgaria;
- 5) Preparation of a national plan/strategy/guidelines for providing, in the conditions of a pandemic, with pandemic vaccines and anti -infectious medicinal products for priority groups of the population;
- 6) Preparation of a proposal for the establishment of a reserve of antiviral drugs, other medicines, personal protective equipment, apparatus and consumables as part of the state reserve managed by the State Agency "State Reserve and Wartime Stocks";
- 7) Conducting research in the field of epidemiology and prevention of pandemic disease and providing scientifically reliable information about the pandemic to the medical and general public.

During a pandemic, the Ministry of Health played an exceptional role. During a pandemic, vaccine prophylaxis is administered in accordance with the antigenic characteristics of the causative agent. The vaccination strategy has been developed on the principle of equality and ethics, and at first a vaccine is applied to the risk groups (priority groups), to the staff of the medical establishments, to the employees who are on the first line. Vaccines are the main means of prevention, and the strategic goal is to reach the maximum part of the population (Dimova & Rohova, 2018).

### *3.2. Economic analysis of the means to deal with the pandemic*

Economic measures for business, made it possible to obtain interest-free loans, to defer tax payments, to reduce municipal rents. One of the main problems in

maintaining employment was that it supported companies that make profits, distribute dividends and bonuses. That is, "taxpayers provided the profits of private structures, instead of these funds to be used to support citizens, the health system, self-insured persons" (Grigorova, Popova & Ganeva, 2021).

*Table № 1 Breakdown of individual programs*

<b>Measure</b>	<b>Disbursed funds (million BGN)</b>	<b>Number of companies</b>	<b>Number of employees</b>
PMS 55	186.2	8985	168.814
PMS 151	345.2	4929	142.469
PMS 278	307.5	6803	144.959
PMS 416	62.5	3260	74.020
Save me	23	8949	
80/20	66	2044	32.150
Employment for you	79.5	7502	
<b>Total</b>	<b>1069.9</b>		

*Source:* Own research

As can be seen from the data in the table, the measure "3-10" aims to allocate between BGN 3 and 10,000 to small enterprises, without any complex requirements and obstacles. The problem arose when the budget allocated for the measure turned out to be too small and included a small part of these enterprises. Companies with a 20% drop in turnover for the month preceding the one in which the application was submitted could apply. Similar to measure 60/40, the requirement here was that the company should be without liabilities such as taxes and social security contributions and that it should have registered at least BGN 30.000 turnover in 2020. The next measure "30-150" is analogous to the previous one, as the funding is between BGN 30 and 150.000, and the applicants are medium-sized enterprises. "Save me" is the measure adopted in November 2020, and the government's intentions were to close a number of businesses again, which it did - restaurants, malls, gyms, schools. Pursuant to the Council of Ministers Decree 325 of 2020, BGN 24 per day was paid to those working in sectors with limited activity. This measure did not take into account the fact that in case of unpaid leave, health insurance is paid by the employee, and there are no pension contributions. The measure "80/20" - provides for the payment of BGN 290, as well as it is permissible to combine it with "60/40", as the support itself should not exceed 80% of the insurance income. It covers sectors such as tourism, hospitality, restaurants, transport. Under the Employment for You program, employers can hire the unemployed, giving them European funding. The costs of the minimum wage or a proportional part of it shall be borne.

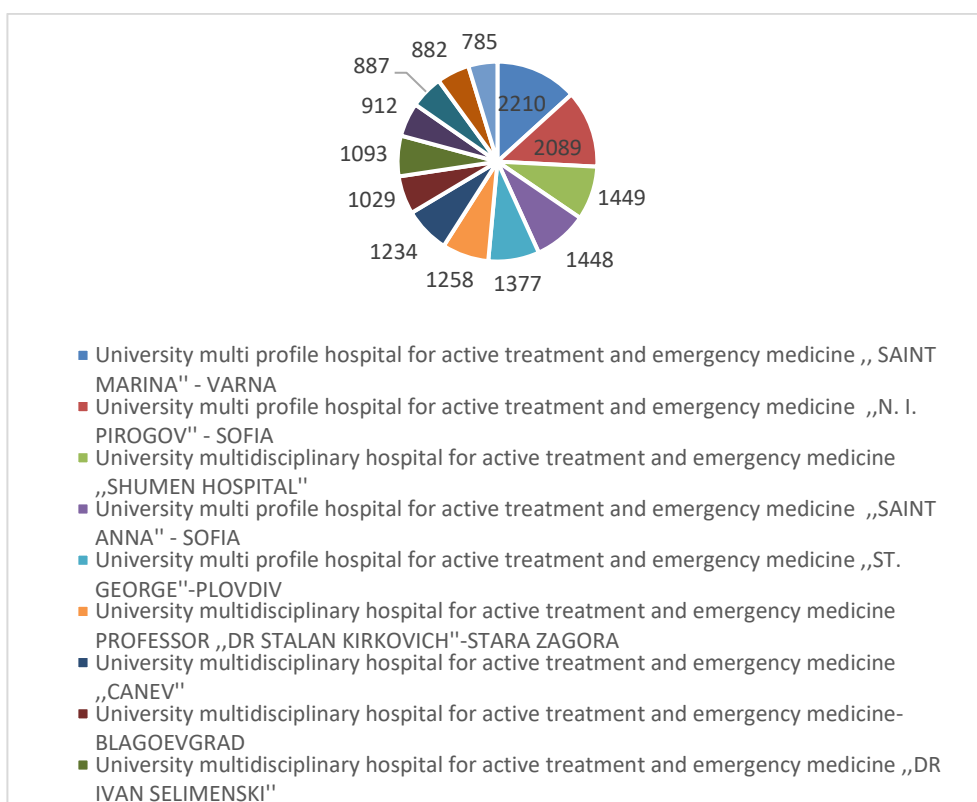
*Table 2. Key health system indicators*

Health expenditure per capita (PPS)	Out-of-pocket payments as % of current health expenditure	Medical doctors per 100.000 population	Practizing nurses and midwives per 100,000 population	Curative hospitals beds per 100,000 population
1307	37.8	424	485	641

Source: European Observatory on Health Systems and Policies, 2021

Analyzing the data in the table, confirms the fact that the outbreak of COVID-19 posed major challenges to the health system in Bulgaria and thus faced it with underdeveloped primary and preventive care, low health care costs and many other challenges in the organization of health care and the health status of the population (European Observatory on Health Systems and Policies, 2021). Here are some of the key indicators of the health system.

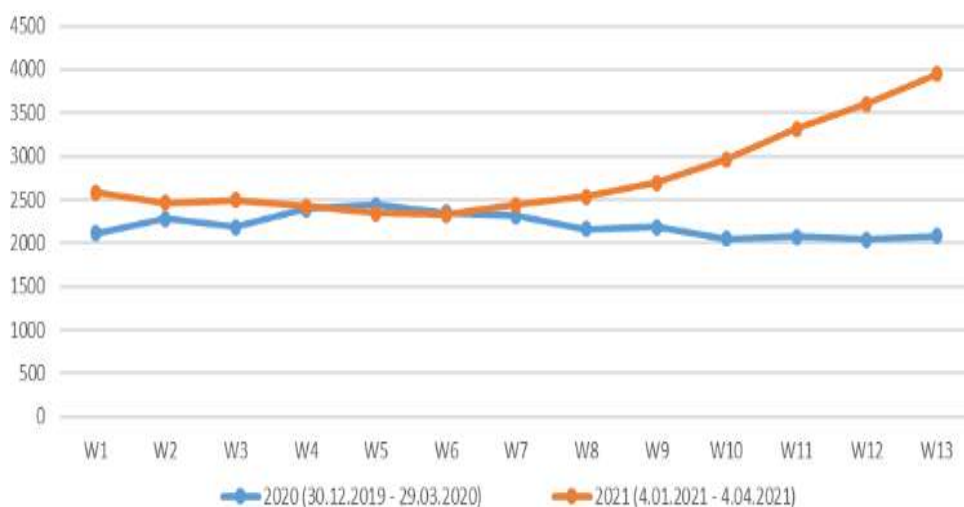
*Figure 1. Hospitals with the highest number of patients treated with Covid-19*



Source: Adapted by the author according to data of the NSI, 2020

As can be seen from the data in the figure, for the last 2020, most large hospitals in our country have an extremely high number of patients treated for coronavirus. The analyzes show that the absolute record holder is Sveta Marina, Varna, where 2210 people have been admitted for treatment. Among the first positions are University multi profile hospital for active treatment and emergency medicine N.I. Pirogov Sofia, with 2089 people accommodated and University multidisciplinary hospital for active treatment and emergency medicine Shumen, respectively with 1449 clinically accommodated. To the last positions are Tokuda Hospital, where less than 1,000 people were admitted (882) and University multidisciplinary hospital for active treatment and emergency medicine Saint Ivan Rilski - Razgrad, where 785 people are treated for coronavirus. The statistics are alarming, as the patients who are hospitalized exceed the specified hospital beds and it is necessary to open new covid-wards in most of the hospitals in our country. In support of these results, it should be noted that once the outbreak enters the community transmission phase, it can double every 3 to 5 days. The need for hospitalization is growing by leaps and bounds - so fast that it can overwhelm the country's health system. On average, 20 percent of those infected develop severe or critical symptoms with a mortality rate of more than 1% and much higher in the elderly and in people with underlying diseases. The speed and scale of the spread, the severity of the cases, and the social and economic disruption are already dramatic and could be even greater as they become established in poorer nations. Analyzing the results, it is clear that the situation in Bulgaria is quite worrying, the infection and morbidity are throughout the country. This implies a huge collapse of our healthcare system, as it is chronically underfunded.

*Figure 2. Mortality in Bulgaria in the first quarter of 2020 and 2021*



*Source:* Adapted by the author according to data of the NSI, 2021

Based on the analysis of the figure, it is clear that the number of deaths from the pandemic in Bulgaria for the first quarter of 2021 is 36.152 people. Comparing mortality for the same period from the previous 2020, it is obvious that there is a huge increase. This statistic is worrying, as the overall mortality rate for 2021 is 21.1%. It is also reported that mortality in men is about 23% higher than in women, which is approximately 20%. The data speak for themselves that the coronavirus is a disease that is severe and unfortunately in most cases fatal. We are facing a global health crisis different from any other in the coming years. A crisis that kills people, spreads human suffering and endangers people's lives. But this is much more than a health crisis. This is a human crisis. Coronavirus disease (COVID-19) attacks societies at its core.

### *3.3. The consequences for Bulgaria and the EU after the COVID-19*

Following the first confirmed case of coronavirus infection, a series of restrictive measures were introduced to limit the spread of the virus. Authorities in Bulgaria initially decided to implement preventive measures such as closing borders and suspending international flights. However, when the number of COVID-19 cases began to rise, they resorted to more restrictive measures to restrict human movement. These measures include the closure of educational institutions, quarantine in certain areas, restrictions on international travel, restrictions on local traffic and self-isolation measures.

The isolation/self-isolation measure was imposed at the very beginning of the pandemic for returnees from severely affected countries. The measure is reviewed periodically, and the criteria for isolation/ self-isolation change gradually, depending on the development of the pandemic in the country.

Migration was an important factor in the initial spread of the disease, with people returning home from severely affected countries such as Italy. In Bulgaria, where more than 1 million Bulgarians live abroad, there is an increase in emigrants returning home due to the general instability during the COVID-19 pandemic worldwide.

EU countries introduced early blocking restrictions, which helped curb the spread of the disease in the spring of 2020. Initially, compliance was high, but it also became clear that there was no systematic approach to implementation or effective management of regional and local level.

The pandemic also had major implications for the wider economy, leading to business closures, rising unemployment, and new financial uncertainty for many. Studies conducted in Croatia found that lockdown restrictions had a negative impact on mental health, physical activity and eating habits (Đogaš, Kalcina & Dodig et al., 2020).

This far-reaching impact created economic and political pressures to ease restrictions. In Croatia for instance, there was widespread recognition of the need for resources generated in the summer tourist season, which impacted crisis management.

The situation was similar in other countries, where strategic priorities gradually changed, and the goal of protecting the health of the population was sometimes superseded by political or economic interests (OECD, 2021).

Another challenge was the far-reaching impact of the blocking measures, with the effects of the interventions being much greater than expected. The pandemic has necessitated significant changes not only in health and healthcare systems, but also in the social and economic life of the population, limiting or banning gatherings and social contacts and forcing the process of learning and working online. Economic activities have declined significantly and people's daily lives have been.

However, the pandemic revealed existing weaknesses in human resource planning (Nathan, Muscat, Middleton, Ricciardi & Permanand, 2021). Not surprisingly, the shortage that existed before the COVID-19 pandemic persists. In Croatia and Romania, for example, there is a general shortage of health workers and shortages, and in Bulgaria there is a shortage of nurses (European Observatory on Health Systems and Policies, 2021).

This shortage must be overcome in order to improve the resilience of the health system and to protect the health and well-being of the current workforce.

#### *3.4. The provision of health services other than those related to COVID-19 patients has been seriously disrupted*

The provision and use of health services other than COVID-19 has been negatively affected by the pandemic response. However, some countermeasures have been taken to continue the provision of basic health services. Formally in Bulgaria the provision of health services in outpatient care was not limited, with the exception of some preventive services. However, the access difficulties typically faced by people in rural and remote areas have been exacerbated by the restrictions imposed on travel in the spring of 2020. In Croatia, health professionals who do not deal with patients with COVID-19 have had a drastically reduced workload. The resulting inadequate provision of patients without COVID-19 may have long-term consequences for the health of the population. In Romania, the provision of health services other than COVID-19 was limited not only by public health measures, but also by patients' fear of contracting COVID-19 and the closure of entire hospitals due to staff infections caused by a lack of protection and safety measures.

## **4. Conclusion**

Based on the analysis, the following conclusions can be made:

*First*, the COVID-19 pandemic has had devastating and catastrophic impacts on economies around the world. Economies are entering a recession that could be extremely traumatic for households.

*Second*, COVID-19 revealed persistent inequalities in income, age, race, gender, and geographical location. People face complex, interrelated threats to their

health and well-being, rooted in the social, economic, political and environmental determinants of health.

*Third*, the pandemic also revealed significant gaps in the country's health information systems. While high-resource settings face challenges of overcapacity and fragmentation, weaker health systems run the risk of jeopardizing the hard-earned health and development gains of recent decades.

*Fourth*, the loss of income mainly affects the general population living or vulnerable to poverty, and people working in activities that are more exposed to cuts and wage cuts, and those with precarious employment in general.

*Fifth*, civil society considers the priority of the healthcare system in terms of information, transparency and quality of health services and care to be significant.

*Sixth*, good governance, underpinned by state capacity, political leadership, community engagement, accountability, transparency, trust and clear lines of communication, is key to responding effectively to a pandemic such as COVID-19. The initial response benefited from a centralized governance approach and high levels of public trust but this proved to be only a short-term solution. Over time, broader governance challenges surfaced, political and economic considerations took precedence over expert opinions, and public trust declined. Responsibility and blame were shifted to lower levels of administration.

*Seventh*, health workforce strategies need to be put in place and implemented to ensure sufficient numbers of well-trained health workers. The COVID-19 crisis in Southeastern Europe highlighted pre-existing shortages, but also policy failures to protect health workers from infection. The countries adopted a number of measures to increase the supply of health workers, but for them to become sustainable, they need to be part of comprehensive workforce strategies.

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