



COVID-19 - ECONOMIC, TECHNOLOGICAL AND LEGISLATIVE CHALLENGES FOR THE MEDTECH INDUSTRY AND SOCIETY

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ABSTRACT

The new coronavirus COVID-19 has caused a severe pandemic that has affected all countries with a devastating effect on the economies of many developed and developing countries struggling to cope with the damages.

Purpose: The purpose of the present work is to analyze the impact of the COVID-19 infection on the MedTech industry.

Methods: A literature study was conducted of data on health and economic indicators, the world market, national markets, and that of specific industrial sectors.

Results: It was found that the total economic losses of labor amounted to 55.5 billion dollars, due to the COVID-19 crisis. A negative trend is marked by almost all industries except the food industry, healthcare, pharmaceutical industry, production and distribution of medical devices.

Conclusion: The analysis of the economic impact of COVID-19 on the MedTech industry shows that it is not among the most severely affected, it even shows growth unlike other industries. However, in order to adequately satisfy the market for medical devices, it is necessary to introduce additional measures to ensure faster access of these products to the market.

Key words: Medical Devices (MD), Personal Protective Equipment (PPE), COVID-19, 3D printing, Regulatory Sciences, Medical Device Design.

INTRODUCTION

COVID-19 caused by the new coronavirus SARS-CoV2 (severe respiratory syndrome - CoV2) first appeared in Wuhan, China in December 2019 (1). Previously, SARS-CoV was identified in 2003. Gaudun China, infecting over 8000 people with more than 8% mortality (2). COVID-19 is considered more lethal in comparison with the SARS-CoV. The disease was spread in several Chinese provinces, but very quickly covered other countries and continents, and by March 2020 affected the whole world.

Given the significant impact of COVID-19 on the world social and economic life it was declared a pandemic by the World Health Organization (WHO). Almost all countries, no matter their social economic situation, suffered enormous damages in terms of loss of human lives, finance, economics, employment, and education.

The acceptance of strict quarantine measures failed to prevent the development of the pandemic. In the middle of August 2021, the number of confirmed cases of patients are over 207 million with more than 4.37 million deaths globally (4).

The medical professionals, health authorities, research organizations and scientists around the world are constantly trying to slow down

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the spread of COVID-19 and to develop vaccines and drugs for prevention and treatment of the disease.

The use of artificial intelligence (AI) is one of the technologies that contribute to tracking the spread of this virus, identifying the severity of the disease and infected patients and provide real-world control of the infection in real time. However, to overcome the global problem of COVID-19, medical devices (MD) are needed through which to meet the high demand for medical equipment, apparatus, isolation centers and personal protective equipment (PPE).

To keep the medical industry vital, it is important to produce products with specially adapted features, with minimal contact between the patient and the medical workers treating them.

The aim of the present work is to analyze the impact of the COVID-19 infection on the MedTech industry.

MATERIALS AND METHODS

To analyze the impact of COVID-19 on the MedTech industry we did an extensive literature study by collecting data from different sources that include a review of

scientific publications. Inclusion criteria of the publications in this review were to look at the problems of the MedTech industry and to include data on changes in the industry during COVID-19.

The identified 17 publications were analyzed with a comment on and a possible application of MD and PPE in medical institutions, industries and the global supply chain system, the impact on the economy and the impact of the regulatory environment in the creation and implementation of new and innovative products.

RESULTS

Loss of productivity

The influence of COVID-19 on the human production factor is indisputable. The study shows that 70% of the total number of cases are in only eight of the large countries - Figures 1 and 2 (5). COVID-19 is first and foremost a health and humanitarian crisis with serious impact on people and their way of life. These humanitarian losses lead to productivity losses and indirect costs to the world economy. Not counting mortality, if these 22.5 million people were absent from work for at least 10 days, then you lose productive days for 225 million for the world's leading markets (Figure 1).

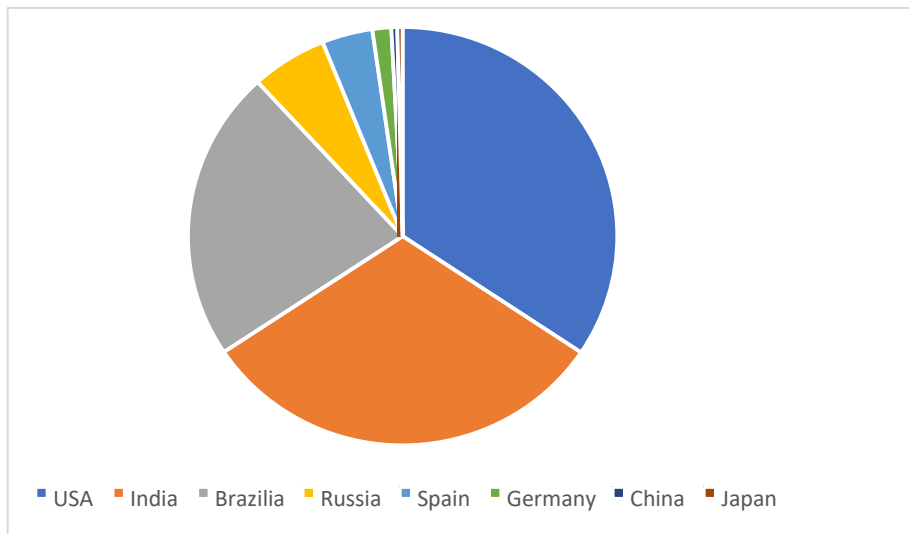


Figure 1. Number of infected in millions

If we add the 543 100 deaths in large markets and assume that the average loss of productive life is 10 years per person, then the lost years

of life equals nearly 5.5 million years (Figure 2).

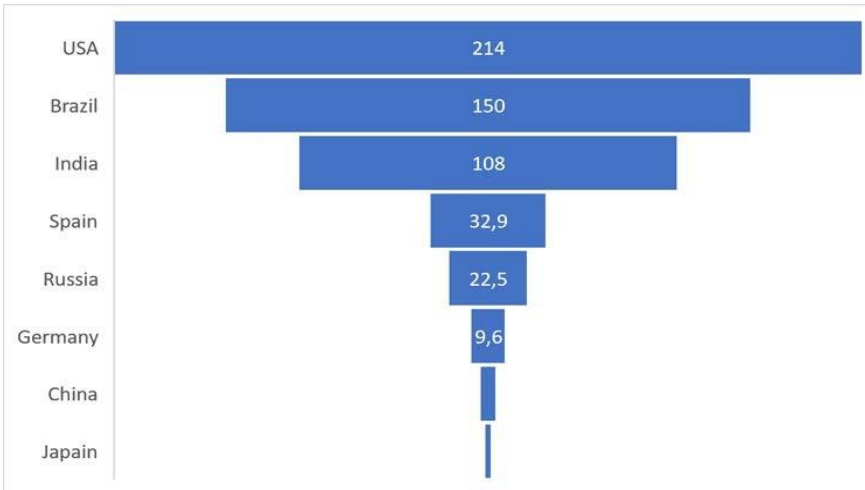


Figure 2. Mortality from COVID-19 in large countries (thousands).

GDP per capita according to the World Bank data for countries with average economic development is \$ 9191.7 (17). With these data, the global losses of premature mortality are equal to 49.9 billion dollars. The losses of temporary incapacity for work of 225 million days with daily incapacity for work of \$ 25 per day are equal to 5.6 billion dollars. Given the assumptions thus made, the general one's economic losses of labor are equal to 55.5 billion dollars.

Impact on world production and consumption:

Figure 3 shows the impact of COVID-19 on the world production. It shows that before the period 2008 - 2009 the manufacturing industry is severely affected by an outbreak of SARS. The analysis of the impact of COVID-1 shows that the industrial production decreased by an average of 7.5% in 2020 compared to the last 12 years and it is assumed that this process will continue if the effect of the pandemic cannot be controlled (10).

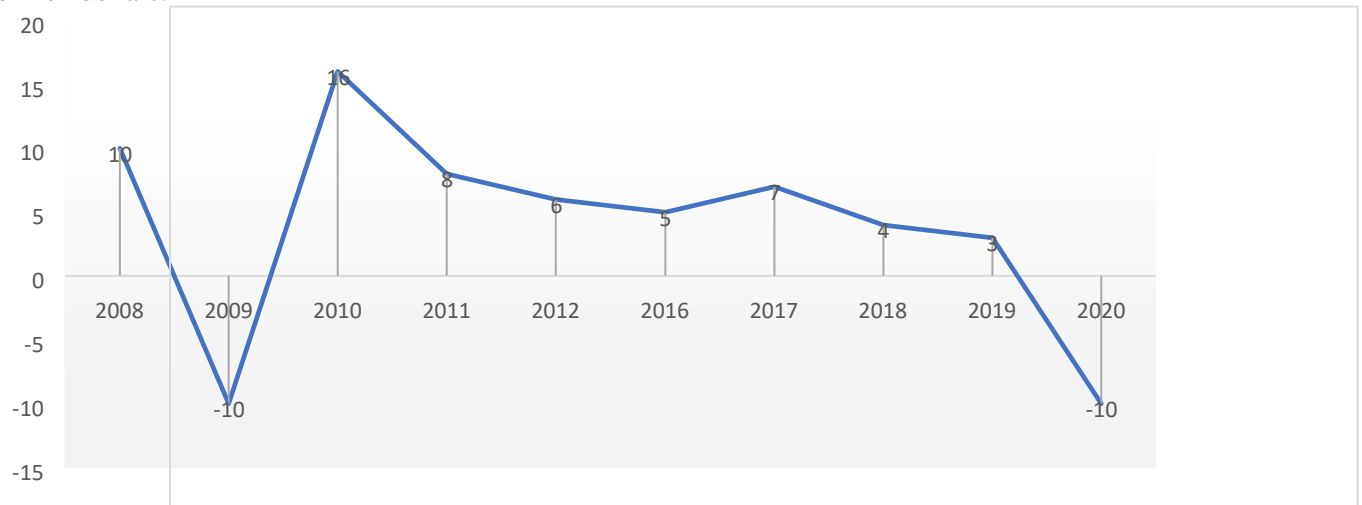


Figure 3. Impact of COVID 19 on world production.

The economic analyses develop different scenarios for forecasting the economic impact of the pandemic (**Figure 4**). In the absence of a pandemic the economy of all countries is on the rise. Under normal exposure to COVID-19

the economic growth is not severely affected, with the exception of some countries such as Germany and Italy, but in a pandemic all the world's economies are with negative economic indicators.

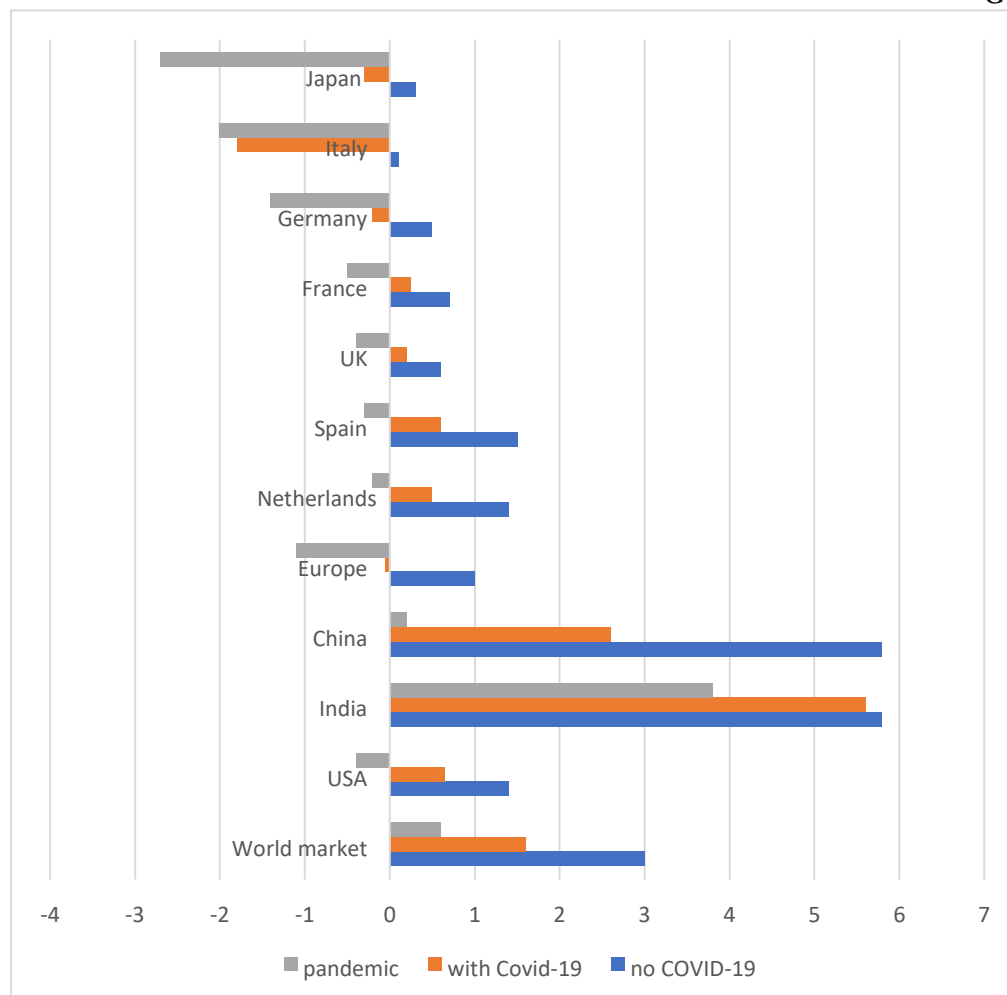


Figure 4. Scenarios of economic impact of COVID 19 on the world and leading markets.

Influence of national markets and economic sectors:

In addition, the global industries and economy are also severely affected. Many prosperous industries suffered unexpected losses or completely stopped working. In India, lockdown has put a lot of pressure on the industry and led to loss of almost 20% of GDP. Compared to economic surveys from 2017-2018 and 2018-2019, the growth rate was negative during the crisis. A negative rate of change in India (average -4.1%) was registered by almost all economic sectors, with

construction being affected the most with -6% growth, followed by production (-5.6%), trade, hospitality, transport, and communications by -1.5%, etc.

In China, the virus led to a 20.5% drop in retail sales and unemployment rose to 6.2% in February 2020 (7). The impact of COVID-19 is different on the individual economic sectors, but the basic rule is that almost 90% are negatively affected with a decline in their economic indicators such as volume and value of production and sold products (**Figure 5**).

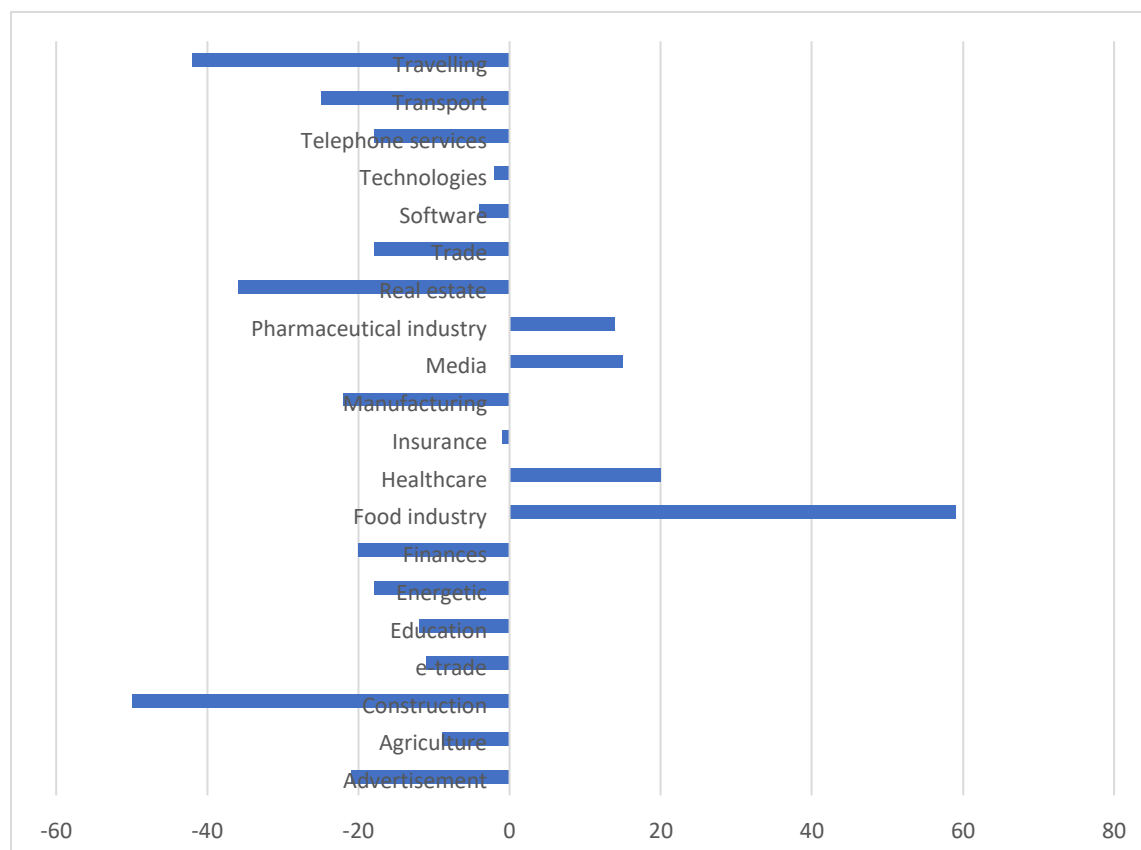


Figure 5. Impact of COVID 19- on economic sectors (growth in %)

The growth rate in the manufacturing industry and construction is the lowest. Only the food industry, the healthcare, pharmaceutical and media industries are developing positively. A global survey shows a huge reduction of production orders and sales in many industries (8, 9).

The food, pharmaceutical, MedTech and media industries are growing thanks to the large food supply, the growing use of drugs, MD and PPE and media coverage of the pandemic situation around the world. With the increase in e-employment at home, only the market for smart devices is growing (11), however, the analyses claim that it is currently severely affected, and the effect is expected to continue for the next three to four years. The accelerated spread of COVID-19 has led to a shortage of MD and PPE, especially those

related to the safety and the health of healthcare professionals, the general public, and professionals who examine infected persons.

According to a study on the medical supplies market, it is expected to increase by \$ 22 billion in 2021 compared to 2019 (12).

The increase is related to the growing awareness for personal hygiene and transmission of infections by airborne droplets, increasing the number of places for medical care of the infected, the increased requirements for PPE, the use of filter particles, personal protective equipment such as masks type N95, respirators, in vitro diagnostics, and others.

The high demand and shortages of PPE and MD have left millions of medical professionals

unprotected and vulnerable to the virus because governments were unprepared to deal with the pandemic and to stop the rapid spread of the infection, health systems needed a rapid supply of medical equipment and products (13).

DISCUSSION

In the context of the emergence of COVID-19 worldwide, as well as the rapid spread of the virus in various regions of the EU, the EC, taking into account the Treaty on the Functioning of the European Union, and in particular Article 292 thereof, adopted RECOMMENDATION (EU) 2020 / 403 OF THE COMMISSION of 13 March 2020 (14) on the procedures for conformity assessment and market surveillance of medical devices in the context of the COVID-19 threat.

The observed exponential increase in demand for personal protective equipment (PPE), such as face masks, gloves, protective overalls or eye protection, as well as medical devices such as surgical masks, examination gloves and some aprons are products that fall into the scope of Directive 93/42 / EEC and Regulation (EU) 2017/745 that are in line with the anti-epidemic measures. In particular, the supply chain of some types of PPE, such as disposable face masks, is under severe pressure due to the exponential increase in demand through both existing and new channels.

In addition, there have also been significant disruptions in the global supply chain for these products, which have had implications for the EU market, and given that the health and safety of EU citizens is a top priority, it is of the utmost importance to ensure that the most appropriate PPE and medical devices, which provide adequate protection, are provided in a timely manner to the people who need them most. In order to mitigate the effects of the various adverse factors, economic operators are also restructuring their supply chains by launching new production lines and or diversifying their contingent of suppliers.

These efforts by industry stakeholders could not have their full impact if increased supply

was not available on the market due to unjustified delays.

In the context of the COVID-19 threat, these PPE and medical devices are of paramount importance to healthcare professionals, first aiders and others involved in controlling and preventing the spread of the virus. In order to ensure the availability of PPE and medical devices for adequate protection in the context of the spread of COVID-19, the Commission invited all economic operators throughout the supply chain, as well as notified and market surveillance authorities, to resort to all measures, which are at their disposal to support efforts to ensure that supplies of PPE and medical devices within the EU market are in line with ever-increasing demand.

However, such measures should not have a negative impact on the overall level of health and safety, and relevant stakeholders should ensure that all PPE or medical devices placed on the EU market continue to provide an adequate level of protection of the health and safety of users.

Against the backdrop of the coronavirus crisis, the MedTech Europe Trade Association has announced that it calls on the EU institutions to postpone the implementation of the new regulation on medical devices and the in vitro diagnostic regulation (IVDR) to facilitate the fight against COVID-19 and protect health systems (16)

The European MedTech industry has said it is fully engaged with all healthcare stakeholders in the fight against COVID-19 - one of the worst pandemics in a hundred years.

The medical industry is constantly working to provide PPE, diagnostics, respiratory equipment and other important medical equipment to patients, healthcare professionals and hospitals on the COVID-19 front line.

Simultaneously with the fight against the pandemic, it is extremely important to maintain the smooth availability of all other medical technologies necessary for the diagnosis, treatment and monitoring of patients

suffering from other critical or chronic diseases and health diseases.

At present, supporting health systems to overcome the pandemic is a top priority and focus for all. Manufacturers seek to keep and develop the necessary medical technologies available to health systems, while dealing with the effects of the pandemic on their organizations.

CONCLUSION

The analysis of the economic impact of COVID-19 on the MedTech industry shows that it is not among the most severely affected, it even shows growth unlike other industries. However, in order to adequately satisfy the market for medical devices, it is necessary to introduce additional measures to ensure faster access of these products to the market.

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