

Impact of the COVID-19 Pandemic on Bulgaria's Pharmaceutical Industry

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ABSTRACT

In December 2019, a novel coronavirus, SARS-CoV-2, was first detected in Wuhan, Hubei Province, China. The virus quickly spread to multiple countries, with Italy, Spain, and the United States among the hardest hit. Consequently, in March 2020, the World Health Organization (WHO) officially declared COVID-19 a global pandemic. Despite timely interventions aimed at controlling the spread, the total number of confirmed cases has reached 119,452,269, with fatalities totaling 2,647,662. The pandemic has had profound effects on all aspects of human life, including health, social interactions, and the economy. Various restrictions and mandates were introduced, such as mandatory mask-wearing, widespread use of disinfectants, online education, and limitations on restaurant and retail operations. The healthcare sector was especially impacted, compelling all participants in the pharmaceutical system to reorganize and adjust their activities in pursuit of the shared goal of combating the COVID-19 pandemic.

Keywords: Pharmaceutical system, Pandemic, Health sector, COVID-19

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Introduction

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic following its emergence in China and rapid international spread. Despite prompt interventions aimed at controlling infection rates, as of now, there have been 119,452,269 confirmed cases and 2,647,662 deaths worldwide [1].

The pandemic has influenced all aspects of human life, including health, social interactions, and the economy [1-3]. The pharmaceutical industry played a key role in combating the virus, focusing on potential treatment strategies while maintaining the stability of supply chains during the crisis. All stakeholders within the pharmaceutical sector had to reallocate resources to address pandemic-related challenges [4].

Scientific research primarily concentrated on developing antiviral drugs and vaccines, as well as identifying existing medications with potential therapeutic effects against COVID-19. Globally, 113 drugs and 53 vaccines have entered clinical trials [5]. Regulatory frameworks and market authorization procedures were also adapted to support early access pathways and facilitate early interactions between regulators, healthcare professionals, and the industry. These measures aimed to accelerate the collection of efficacy and safety data and streamline benefit-risk assessments [6].

Several studies highlighted challenges in medicine production and importation, including risks of shortages in active pharmaceutical ingredients and finished products, as well as supply chain disruptions. Wholesale and retail distribution, along with healthcare services, were affected, emphasizing the increasing importance of pharmacists [7, 8].

Anti-epidemic measures also promoted remote consultations between physicians and patients—particularly those with chronic conditions—and interactions with pharmacists for prescription dispensing, accelerating the integration of telehealth solutions [9, 10]. Additionally, there was increased demand for chronic medications, personal protective equipment, medical devices, and respiratory treatments [11].

The aim of this review was to critically examine published studies assessing the COVID-19 pandemic's impact on various facets of the pharmaceutical sector and to evaluate legislative changes in Bulgaria's health and pharmaceutical system related to the pandemic.

Materials and Methods

A literature review was conducted using the keywords “pandemic,” “COVID-19,” and “pharmaceutical sector” in databases including PubMed, Scopus, and Google Scholar, focusing on studies that evaluated the pandemic's impact on pharmaceutical activities and analyzed the challenges faced by industry stakeholders.

A legislative review was performed to identify amendments to Bulgarian health and pharmaceutical laws in 2020 that arose in response to COVID-19-related changes in the pharmaceutical sector.

Additionally, a pilot, online, anonymous survey was administered to employees of pharmaceutical companies in Bulgaria to assess how the pandemic affected their work and to explore strategies for coping with its impacts. A specialized questionnaire was distributed to staff from both innovative and generic pharmaceutical companies between May 1 and May 31, 2021. Descriptive statistics were applied using Microsoft Excel to analyze the results.

Results and Discussion

The literature search identified 31 relevant studies: four focused on clinical trials and drug development, two on legislation and market authorization, six on drug supply processes, two on wholesale and retail distribution, five on medical care, nine on pharmaceutical care, and three on patient usage patterns. The review demonstrated that COVID-19 affected every segment of the pharmaceutical sector.

Critical analysis

Table 1. Areas of the pharmaceutical sector impacted by the COVID-19 pandemic

Area	Changes	Measures
Research and Development & Clinical Trials	Many clinical trials for various indications were suspended or delayed	Implementation of updated guidelines for conducting clinical trials by EMA and FDA
	Rapid initiation of multiple clinical trials targeting COVID-19 treatments and vaccines	
Marketing Authorization & Quality Control	Increased use of conditional marketing authorizations for COVID-19 medicines	Conducting clinical studies to assess the efficacy of selected medications
	Adjustments in therapeutic use of off-patent medicines	
Manufacturing of Medicinal Products	Disruptions in global supply chains	Focus on optimizing supply chain efficiency
	Shortages of active pharmaceutical ingredients	Implementation of risk management strategies
	Limited availability of essential and life-saving drugs	
Wholesale & Retail Trade	Elevated risk of shortages in essential medicines and personal protective equipment	Restriction on the quantity of medicines purchased per customer
		Home delivery of medicines
Medical Care	Shift to remote healthcare provision	Expansion of telemedicine services
		Introduction of telemonitoring devices to collect patient health data
Pharmaceutical Care	Enhanced role of pharmacists in patient health management	Providing accurate information and guidance to patients
	Introduction of new pharmacy services	Ensuring uninterrupted access to medications
	New challenges for industrial pharmacists	Ensuring safe and appropriate use of medicines during clinical trials
Drug Utilization	Reduced access to medications	

Psychological and mental health impacts

Pharmacist-led care and support

Critical analysis of changes in Bulgarian pharmaceutical legislation during the pandemic

The legislative review focused on amendments to Bulgaria's health and pharmaceutical laws implemented in 2020 in response to the COVID-19 pandemic. The findings indicate that several key health-related laws were revised during this period, with the specific changes summarized in **Table 2**.

Table 2. Updates in Bulgarian Health and Pharmaceutical Legislation During the COVID-19 Pandemic

Legislative Document	Change	Reason for Update
Health Legislation		
Bulgarian Health Law	The Minister of Health is authorized to impose mandatory isolation for patients and carriers, and quarantine for contacts and inbound travelers, in cases of epidemic emergencies or health threats beyond listed diseases.	To curb COVID-19 transmission, enforce anti-epidemic measures, ease healthcare system burden, ensure worker safety, and incentivize staff in adverse conditions during emergency states.
	Home-based isolation for patients or contacts is permitted at the treating physician's discretion.	
	Contacts of infectious disease patients cannot refuse diagnostic testing under imposed anti-epidemic measures; non-compliance (unless criminal) incurs a BGN 5,000 fine.	
	Telework or remote work arrangements are regulated during complex epidemiological situations.	
	The Minister of Health may grant performance-based bonuses to Ministry staff working in unfavorable conditions during declared emergencies, including COVID-19 vaccination activities.	
Bulgarian Law on Medical Establishments	Hospital wards and facilities may be restructured for COVID-19 patient care.	To deliver quality treatment, secure bedding capacity, allocate funds for pandemic response, accelerate herd immunity, and address post-COVID syndrome.
	The Ministry of Health may subsidize hospital care providers to maintain emergency readiness.	
	Vaccination centers are established under the amended law.	
	Programs for recovery and rehabilitation of COVID-19 survivors are enabled.	
Bulgarian Law on Health Insurance	Funding is allocated for protective gear and medical equipment to treat COVID-19 patients.	To safeguard personnel in high-risk settings, treat patients, monitor viral spread, ensure adequate therapy, enhance drug prescription/dispensing controls, minimize errors, and limit COVID-19 transmission.
	General practitioners may issue electronic PCR test referrals.	
	Funds are provided for procuring medicines to combat COVID-19.	
	Electronic prescriptions are progressively implemented.	
	Until two months after emergency revocation, pharmacies may dispense prescription medicines using the prescription book alone, based on the latest recorded data, per National Health Insurance Fund rules.	
Pharmaceutical Legislation		

Bulgarian Law on Medicinal Products in Human Medicine	Parallel import conditions are relaxed during emergencies and epidemics.	To expedite drug supply, ensure availability of essential COVID-19 treatments for Bulgarian patients, provide adequate care, protect consumers from exploitative practices, and guarantee authentic, safe medicines.
	Export of medicines is prohibited by the Bulgarian Drug Agency (BDA) in emergency situations.	
	The Transparency Commission may authorize use of EU-market-authorized medicines (with Bulgarian MA) unavailable locally when no alternative exists for specific patients.	
	A common EU logo for online pharmacies is introduced.	
	A Europe-wide medicinal product verification system is implemented.	

The revisions to the Health Act, the Medical Establishments Act, and the Health Insurance Act were introduced to define measures across Bulgaria aimed at preventing, controlling, and mitigating the effects of COVID-19 infection. These amendments focus on regulating healthcare actions to slow the spread of the virus, while enabling the health system to prepare for pandemic-related challenges and ensure sufficient medical care for the population. Key modifications in pharmaceutical legislation were primarily designed to allow a more rapid response to the COVID-19 crisis. These include adjustments in the regulation of drug production, the conduct of clinical trials, and mechanisms for faster access to COVID-19 treatments.

Questionnaire survey

An online survey was distributed to employees of pharmaceutical companies operating in Bulgaria. The majority of respondents (87%, $n = 26$) were employed by innovative pharmaceutical firms. Factors such as the shift to remote work and economic uncertainty have likely contributed to reduced hiring, increased role hybridization, and restructuring of employees' duties and responsibilities at both local and global levels.

The pandemic accelerated digitalization, necessitating remote work and greater reliance on technology to manage daily tasks. Restrictions on travel, conferences, and office access have led to frequent virtual meetings, which have added to employees' workloads. The activities of medical representatives, particularly their in-person interactions with physicians, were significantly disrupted, partially mitigated by the adoption of digital communication platforms and online promotional channels.

Remote work and social distancing during the pandemic also encouraged the implementation of innovative practices to maintain employee morale and engagement, such as virtual coffee breaks and online competitions that promote physical activity and social interaction (**Figure 1**).

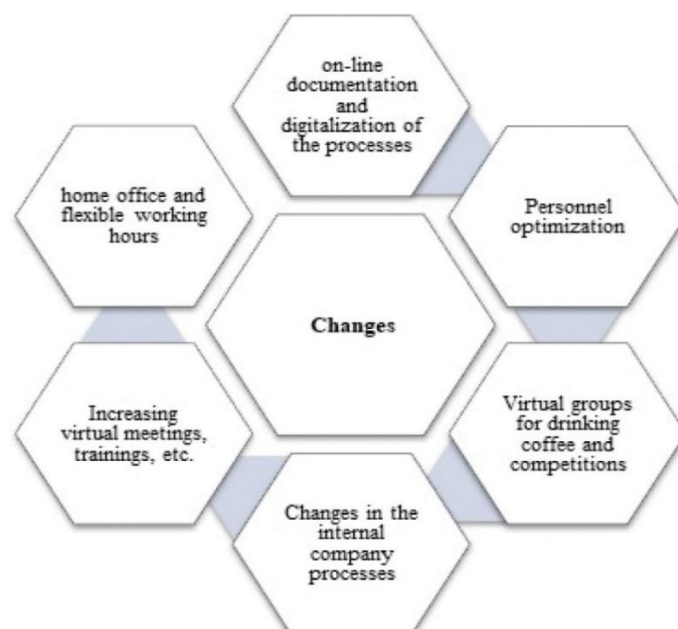


Figure 1. Changes in Workflow in Pharmaceutical Companies During the COVID-19 Pandemic

Survey respondents identified several areas most impacted by the pandemic, including new hiring processes, sales of specific medicines (e.g., common products), marketing initiatives, as well as planning for research and

development (R&D) and investment in innovation (**Figure 2**). The IT departments and sales of products used to manage COVID-19 symptoms were reported as the areas experiencing the most positive effects (**Figure 3**).

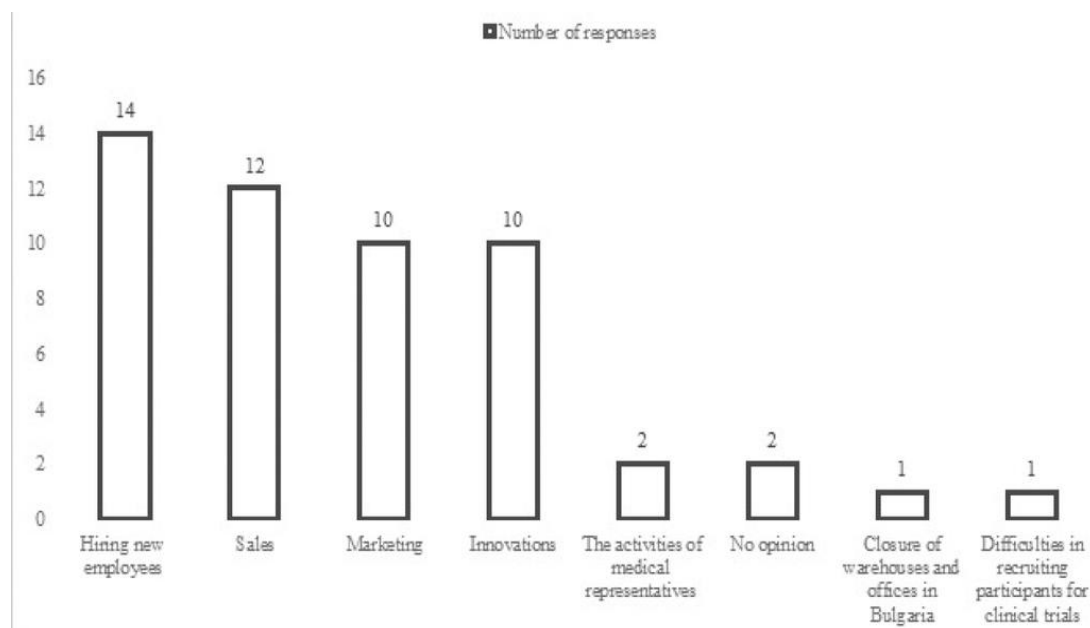


Figure 2. Pharmaceutical Sectors Adversely Impacted by the COVID-19 Pandemic

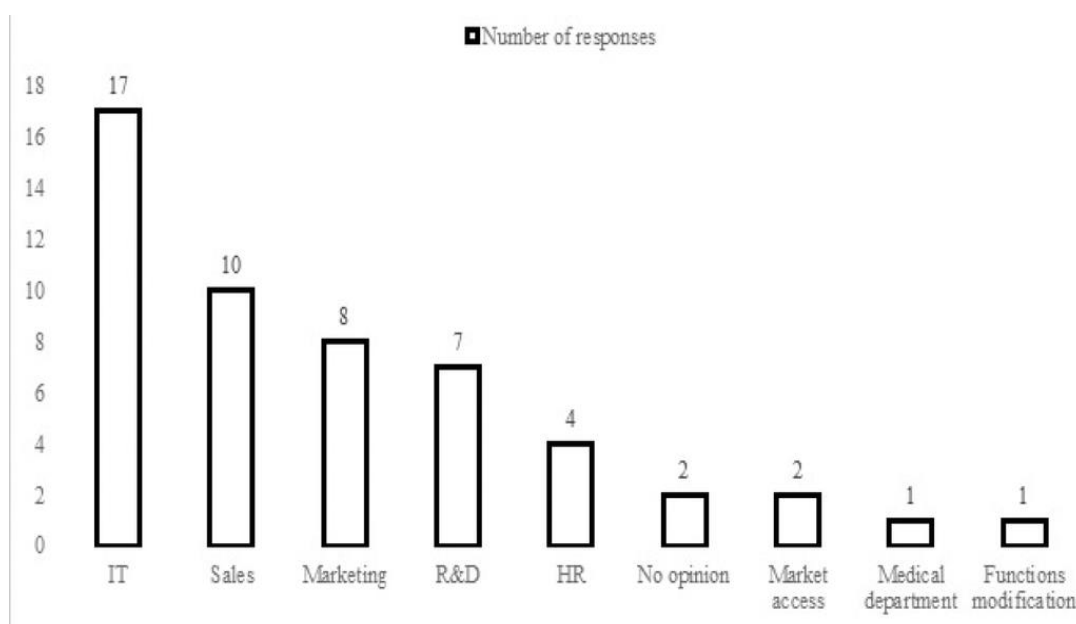


Figure 3. Pharmaceutical Sectors Benefiting from the COVID-19 Pandemic

All respondents highlighted that the most notable positive outcome of the pandemic was the accelerated digitalization within the sector, alongside improvements in workflow efficiency and employee productivity. Interactions with medical professionals were reported as particularly challenging, prompting the adoption of new communication methods, innovative marketing strategies, and digital advertising channels.

Challenges were noted in the production, importation, and distribution of certain medicines, as well as in financing for innovative projects due to budgetary constraints. Access to healthcare for patients with chronic conditions worsened, leading to delays in diagnosis and early detection of serious and socially significant diseases. These issues have negatively affected pharmaceutical companies, contributing to a decline in sales (**Figure 4**).

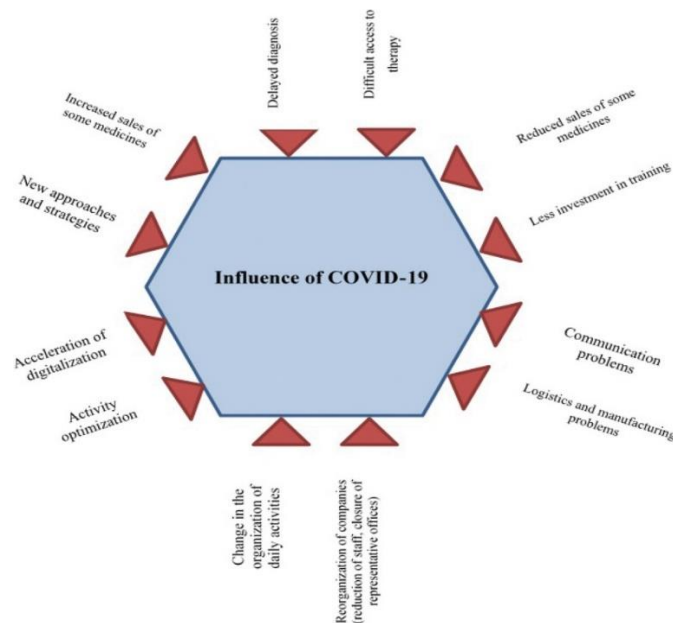


Figure 4. Impact of the COVID-19 Pandemic on Bulgaria's Pharmaceutical Industry

The emergence and rapid spread of SARS-CoV-2, the virus responsible for COVID-19, created a critical public health crisis both nationally and globally. Health systems worldwide faced immense challenges in preventing and mitigating the effects of the virus, providing timely medical care, ensuring adequate drug therapy, and managing the risk of shortages in essential medicines.

The production of medicines was significantly disrupted due to restrictions on company operations, infected personnel, limited availability of raw materials, and obstacles to cross-border transport [12]. Simultaneously, widespread public attention on unproven treatments led to stockpiling of drugs required for critically ill patients, particularly sedatives and opioids [13]. The sharp rise in severely ill patients generated unprecedented demand for medicines, resulting in shortages of essential and life-saving drugs, as well as medications needed for intensive care. The main driving factor behind these shortages was the surge in demand, which directly affected medicine supply and accessibility [14].

The wholesale and retail pharmaceutical sectors were also heavily affected. Factors contributing to increased risk of stock shortages included large-scale pharmacy orders for stockpiling, supply chain disruptions, production limitations, and panic buying of medicines and personal protective equipment by the public [15, 16]. In response, authorities in many countries implemented urgent measures, such as limiting the quantities of medicines that could be purchased by individuals and allowing pharmacies to deliver medicines directly to patients' homes in line with EU guidelines.

Ensuring patients' uninterrupted and safe access to medications was crucial to prevent disease progression or worsening of symptoms due to treatment delays. The pandemic forced healthcare systems to adapt rapidly, with telemedicine emerging as a key tool in this transformation. Telemedicine allows physicians to provide remote care, including reviewing patients' medication histories and managing therapy, while supporting social distancing by reducing in-person visits and minimizing contact between doctors and patients. Physicians can utilize telemedicine-approved video and audio platforms to limit viral transmission [17].

Innovations during the pandemic also included mobile telemedicine devices for efficient collection, processing, and transmission of patient health data to attending physicians. Telemedicine technologies are generally accessible, cost-effective, and well-received by both patients and doctors. However, challenges remain, such as improving patients' digital literacy, ensuring data confidentiality, providing reliable equipment for quality communication, and addressing limited internet access or hospital resources to support increased virtual care [18, 19].

Healthcare professionals hold differing opinions on telehealth: some view it as a major advancement in patient care, while others remain cautious about its practical application. Despite these challenges, telemedicine is expected to significantly enhance healthcare delivery in the future. During the pandemic, it has been rapidly deployed on a large scale, becoming a frontline tool in combating COVID-19 [20, 21].

Among the recent innovations in healthcare is telepharmacy, a practical extension of telemedicine that enables the remote delivery of pharmaceutical services. This approach is particularly valuable not only for COVID-19 patients but also for individuals with chronic illnesses or limited mobility during quarantine. Pharmacists, often considered the most accessible healthcare professionals, play a critical role on the “front line” during crises like the current pandemic, serving as both the first and last point of contact for patients [22]. They contribute to disease prevention and control, patient care, and treatment management throughout the COVID-19 outbreak [23].

Beyond their usual responsibilities, pharmacists have faced new challenges during the pandemic, highlighting their essential role in safeguarding patient health [24, 25]. Pharmacies have expanded their services, supported by legislative changes, to strengthen the healthcare system's efficiency. New measures include enforcing social distancing within pharmacies despite increasing patient numbers, educating patients on infection prevention, and instructing proper use of protective masks.

The pandemic has also driven the introduction of novel pharmaceutical services aligned with e-health initiatives. In some countries, pharmacists have been authorized to prescribe medications for themselves, family members, and emergency patients, as well as actively participate in vaccination campaigns [26]. They provide guidance on disease mechanisms and transmission, helping to reduce public confusion and discourage self-medication.

As myths about COVID-19 treatments and preventive measures spread rapidly, pharmacists play a pivotal role in delivering accurate information to the public [27]. They are responsible for maintaining patients' continuous access to medicines, managing shortages, and ensuring timely supply despite disrupted distribution chains [28]. To improve accessibility, particularly in smaller towns, pharmacists may arrange home delivery services.

In the absence of a specific cure for COVID-19, society relies heavily on clinical guidelines and treatment protocols. Pharmacists, together with physicians and other healthcare professionals, can contribute to developing these frameworks. Beyond physical health, pharmacists also provide emotional support, monitoring patients' mental well-being, and identifying those experiencing excessive anxiety or fear during the pandemic.

The primary challenges faced by the pharmaceutical industry during lockdowns were related to logistical disruptions and delivery delays [29]. Our study indicates that, according to employees of pharmaceutical companies in Bulgaria, the impact of COVID-19 on the sector can be categorized into positive and negative effects. During the pandemic, pharmaceutical companies affiliated with EFPIA (European Federation of Pharmaceutical Industries and Associations) have been actively involved in developing vaccines, diagnostic tools, and treatments for COVID-19, while ensuring that patients have adequate access to medicines. Globally, more than 100 vaccine candidates are under development, and over 600 clinical trials are underway to identify effective treatments for COVID-19 [30].

While these intensified efforts have provided significant societal benefits, pharmaceutical companies have also encountered various difficulties. The pandemic has accelerated the digital transformation of the industry, a process essential for enhancing patient care, increasing cost-effectiveness, improving transparency, and streamlining drug manufacturing and development. A survey by Pharmaceutical Technology (2021) found that 30% of respondents believe the pandemic accelerated digitalization in the sector by over six years [31].

Our findings align with this, as Bulgarian pharmaceutical employees similarly recognize the positive impact of COVID-19 on digitalization and the optimization of operational activities. Other major benefits include increased demand for medicines related to COVID-19 prevention and treatment, and heightened focus on vaccine development. The pandemic has allowed companies to showcase the value of their investments in vaccines and therapies and to demonstrate their crucial role in society. Moreover, COVID-19 highlighted the importance of ensuring sustainability in the drug supply chain and reducing dependence on China, the largest producer of active pharmaceutical ingredients.

Conversely, negative impacts have also emerged, including reduced sales of medications for chronic diseases and limitations in funding for innovation [32]. This assessment is supported by international reports; for example, The Irish Times noted that Pfizer's third-quarter sales declined by \$500 million (4%) due to the pandemic [33]. Eli Lilly experienced reduced revenues from key diabetes therapies as economic challenges led patients to seek cheaper alternatives, while Merck Sharp & Dohme reported global losses of \$475 million due to decreased sales of non-COVID therapies, such as Gardasil for HPV [4]. Bulgarian pharmaceutical and cosmetic companies were similarly affected financially. Comparing 2020 to 2019, Tchaikapharma VL showed a 20% increase in share returns, whereas Lavena and Sopharma experienced a 6% decline [34].

Companies involved in COVID-19 vaccine and therapy development reported strong financial gains. Firms such as Moderna, Novavax, and BioNTech experienced substantial revenue growth in the third quarter of 2020

compared to the same period in 2019 [35-37]. Despite significant investments in vaccine development and financial market uncertainties, mergers and acquisitions remained active in 2020 and 2021. Notable transactions include Eli Lilly's \$1 billion acquisition of gene therapy company Preveil, and Cadent Therapeutics' \$770 million acquisition agreement with Novartis and other partners [38, 39].

Conclusion

During the COVID-19 pandemic, Bulgaria implemented timely and appropriate amendments to its pharmaceutical and drug legislation to enable a more rapid response to the crisis, which impacted all facets of public and social life. Despite these challenges, the pharmaceutical sector has managed not only to maintain operations but also to optimize and adapt its activities to the evolving circumstances.

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