

DEVELOPMENT OF ADAPTIVE CHANGE MANAGEMENT PRINCIPLES IN THE PHARMACEUTICAL INDUSTRY UNDER THE INFLUENCE OF THE PANDEMIC

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Abstract: The COVID-19 pandemic significantly impacted the global economy, healthcare, and the pharmaceutical sector. In response to new challenges, international organizations and governments implemented unprecedented measures aimed at mitigating the effects of the pandemic, particularly in the areas of healthcare and pharmaceutical security. This article analyzes the pandemic's impact on patient care, pharmaceutical safety, and the actions taken to minimize these effects. It examines organizational and logistical challenges in drug supply, the development of telemedicine and remote communications, and Ukraine's experience in developing COVID-19 treatment protocols. The article concludes with a discussion on the need for further study of both the short- and long-term consequences of the pandemic for the pharmaceutical industry.

Keywords: COVID-19, pandemic, pharmaceutical safety, treatment protocols, healthcare, telemedicine, drug shortages, economic impact.

1 Introduction

The coronavirus has become the most serious challenge to the global economy since the financial crisis of 2008. The measures taken by international organizations and leading world nations are unprecedented. A unique feature of this crisis is its natural origin, along with a shift in the global trajectory from globalization to a stronger focus on localized production and increased independence of national economic from the global market.

Transport and logistics chains were disrupted, and air travel was nearly halted, which had a profound impact on the modern globalized world where the manufacturing operations of leading companies are often outsourced to optimize costs. Border closures for several months brought normal trade exchanges to a standstill, resulting in significant losses for many corporations. The service, transportation, and tourism sectors were hit hardest, with unemployment rates doubling in some countries and nearly tripling in others. Companies began transitioning their employees to remote work, prompting people to purchase gadgets and computer equipment to enable them to work from home.

The World Health Organization's (WHO) declaration of the COVID-19 pandemic and the associated quarantine restrictions significantly impacted Ukraine's economy. According to data from the State Statistics Service of Ukraine (SSSU), the country's economy experienced a year-long decline: GDP dropped by 1.3% in Q1, by 11.4% in Q2, by 3% in Q3, and a 3% in Q4. The pandemic and quarantine restrictions affected nearly every sector, resulting in a rise in unemployment rates [52].

The objective of presented study is to analyze how the pandemic affected patient care and the pharmaceutical safety of the population. Additionally, the research aims to identify and describe the interventions implemented in healthcare management and pharmaceutical services during the COVID-19 pandemic.

2 Materials and Methods

A review of the literature was conducted, along with an analysis of data from IQVIA and PharmaProxima Research, searches in PubMed, Embase, and the Virtual Health Library, and information gathered from pharmaceutical industry experts during specialized conferences and webinars. The data were analyzed to identify the interventions and practices adopted for managing pharmaceutical care during the COVID-19 pandemic.

3 Results and Discussion

The pandemic required government bodies and the healthcare sector to implement new measures aimed at preventing the

spread of infection, saving lives, and minimizing the overall impact of the disease. Healthcare systems across the globe were overwhelmed and had to reorganize processes to improve service efficiency. These factors also influenced the development of pharmaceutical market. Table 1 outlines the sequence of actions taken by the World Health Organization leading up to the designation of COVID-19 as a pandemic.

Table 1: COVID-19: WHO Action Timeline [56]

31.12.2019	The Wuhan Municipal Health Commission in China reported a cluster of pneumonia cases in Wuhan, Hubei Province. It was later determined that the cause of the illness was a novel coronavirus.
01.01.2020	The WHO established an Incident Management Support Team across its three levels (headquarters, regional offices, and countries) and shifts into the Organization's emergency response mode for the outbreak.
04.01.2020	The WHO announces on social media the emergence of a cluster of pneumonia cases in Wuhan, Hubei Province, noting that all patients are alive.
05.01.2020	The WHO publishes the first issue of disease outbreak news focused on the new virus. This marks the organization's initial technical publication on the subject, aimed at the scientific community, health authorities, and global media. The issue includes a risk assessment, recommendations, and information received from China regarding the status of patients and the health measures implemented in response to the emergence of pneumonia cases in Wuhan.
10.01.2020	The WHO publishes a comprehensive set of technical recommendations online for all countries regarding the detection, diagnosis, and management of potential cases of illness, based on the data available at that time about the virus. To protect healthcare workers and drawing on experiences from combating SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome), as well as known transmission models for viral respiratory pathogens, guidelines were issued for infection prevention and control. These guidelines emphasized the need for medical personnel to adhere to precautions against airborne and contact infections while providing care to patients, as well as measures to protect against aerosol transmission during procedures that generate aerosols.
11.12.01.2020	China released the genetic sequencing data for COVID-19.
13.01.2020	The first officially confirmed case of COVID-19 outside of China was reported in Thailand.
14.01.2020	At a press briefing, the head of the Technical Response Division stated that limited human-to-human transmission of the coronavirus infection cannot be ruled out, particularly among a group of 41 patients, mainly between relatives. He also noted the risk of potential expansion of the outbreak. Furthermore, he indicated that confirming the possibility of human-to-human transmission would not be surprising, given the experience with MERS, SARS, and other respiratory pathogens.
20.21.01.2020	WHO experts based in its office in China and the Regional Office for the Western Pacific undertook a brief trip to the outbreak area in Wuhan.
22.01.2020	The WHO mission in China issued a statement confirming evidence of human-to-human transmission of the virus in Wuhan; however, further research was needed to fully understand the extent of this transmission.
22.23.01.2020	The WHO Director-General, in accordance with the International Health Regulations (IHR 2005), convened a meeting of the Emergency Committee to determine whether this outbreak constitutes a Public Health Emergency of International Concern. At that time, the available data did not allow independent members of the Committee from various countries to reach a consensus on the issue. They request that a follow-up meeting be scheduled in 10 days when additional information will be available.

28.01.2020	To study China's response measures to the outbreak and assess the possibilities for providing technical assistance, a high-level WHO delegation led by the Director-General was sent to Beijing for discussions with Chinese leadership. In Beijing, Dr. Tedros negotiated with the Chinese government to send an international group of leading scientists to the country to gain a more comprehensive understanding of the situation, the response measures taken, and to facilitate the exchange of information and experiences.
30.01.2020	The Director-General of WHO reconvened the Emergency Committee (EC). This occurred earlier than the initially planned 10-day period and just two days after the first reports of isolated instances of human-to-human transmission outside of China. This time, the EC reached a consensus and recommended that the Director-General declare the outbreak a Public Health Emergency of International Concern (PHEIC) [13-16]. The Director-General agreed with the recommendation and declared a PHEIC due to the outbreak of the novel coronavirus infection (2019-nCoV). This marked the sixth declaration of a PHEIC since the International Health Regulations (2005) came into effect. In the WHO situation report on January 30, there were 7,818 confirmed cases of infection worldwide, the majority of which were reported in China, with 82 cases in other countries [18]. WHO assessed the risk of further virus spread in China as very high, while at the international level, it was considered high.
03.02.2020	WHO presented the Strategic Preparedness and Response Plan, developed by the international community to assist countries with weak health systems in safeguarding public health.
11-12.02.2020	WHO convened the COVID-19 Science and Innovation Forum, featuring over 400 experts from various countries. The forum includes presentations by Dr. George Gao, Director-General of the Chinese Center for Disease Control and Prevention, and Dr. Zhong Nanshan, Chief Epidemiologist at the Chinese Center for Disease Control and Prevention.
16-24.02.2020	A joint mission of WHO and China, featuring experts from Canada, Germany, Japan, Nigeria, the Republic of Korea, Russia, Singapore, and the United States, was working in China and visiting Wuhan as well as two other cities. The mission held meetings with representatives from health authorities, scientists, and medical staff at healthcare facilities, all while maintaining physical distancing. The report of the joint mission can be found at https://www.who.int/docs/default-source/coronavirus/who-china-joint-mission-on-covid-19-final-report.pdf
11.03.2020	WHO concluded that the COVID-19 outbreak can be characterized as a pandemic.

In the following months, COVID-19 spread rapidly across the globe, infecting approximately 2.5 million individuals by April 23, 2020 (according to WHO). The COVID-19 pandemic became a source of significant panic, concern, and a sense of uncertainty.

According to social research by Gradus, there was an increase in anxiety, uncertainty, disappointment, and hopelessness regarding a swift end to the pandemic and a return to normal life in Ukraine (see Figure 1) [17].

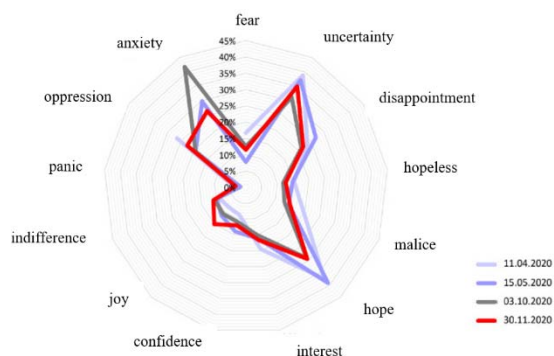


Figure 1. Dynamics of the emotional state of the urban population of Ukraine

The pandemic had a significant impact on healthcare and the pharmaceutical sector, leading to substantial consequences that emerged in the short term and may continue in the long term [2]. These effects require identification and appropriate planning to mitigate their socio-economic impact.

Data collected (Table 2) indicate that the pandemic's influence on the pharmaceutical sector and consumer sentiments in the Middle East, Europe, and the United States exhibited similar trends [54]. In the initial weeks, people were overwhelmed by fear and uncertainty, resulting in a panic demand for various medications: an increase in self-medication through over-the-counter drugs (or stockpiling) and a rise in prescriptions for chronic conditions [21-23]. Countries faced logistical challenges due to quarantine restrictions, leading to shortages of certain medications or active pharmaceutical ingredients.

Globally, investments in new clinical research and the development of vaccines against SARS-CoV-2 increased. Conversely, the launch of new drugs was delayed, and existing studies slowed down or were halted due to their secondary nature [24-29]. Telemedicine and remote communications experienced significant momentum and a growing trend, with WhatsApp calls becoming the most popular digital channel for patient consultations and communication among colleagues.

Table 2: Impact of the Pandemic on the Pharmaceutical Sector and Consumer Changes in the Middle East, Europe, and the United States

Impact	Middle East [53]	EU5 countries [53]	The USA [2]
Drug shortage due to induced demand	Increase of 10.8% in the over-the-counter category (vitamin and mineral supplements)	Increase of 10.8% in the over-the-counter categories (cold remedies)	Research treatment methods doubled
	Increase of 62% in personal hygiene products	Increase of 403% in personal hygiene products	Consumption of medications used in hospitals for the treatment of COVID-19 increased from 100% to 700% since early January.
	Increase of 67% in the hospital sector.		
Overall (panic demand)	Increase of 23%, hypolipidemics	Increase of 7%, the largest volume growth in the ATC Class N, RX category in Spain	7, 6, 5, 4, and 2 million excess prescriptions for hypertension, mental health, respiratory diseases, diabetes, and anxiety
	Increase of 40%, antidiabetics		
	Increase of 29.1%, antihypertensives		
Supply shortage	Medications for chronic diseases face a high risk of shortages or supply chain issues.		A deficit of both active pharmaceutical ingredients (APIs) and finished products, with approximately

				by 40% of APIs for the U.S. generic drug market sourced from India.
				Shortage of treatments for complications related to COVID-19.
R&D Changes		156 clinical trials initiated for COVID-19	140 clinical trials initiated for COVID-19	
Shifts Toward Telemedicine and Remote Communication	WhatsApp calls have become the most popular digital channel for both patient consultations and communication among colleagues.	There has been a 320% increase in remote interactions in Spain compared to the previous year, with a corresponding growth of 471% in Italy.		
	The digital channel is becoming widely adopted (over 75% of doctors), yet physicians still prefer traditional face-to-face communication.	There has been a 51% decrease in specialist consultations and a 25% decline in visits to general practitioners.	Telemedicine interactions have increased, accounting for 23% of all engagements.	
Delays in the confirmation of clinical trials and registrations (products unrelated to COVID-19).		Pharmaceutical companies report delays in the initiation of new trials.		
	New trials are delayed by 16%, and the registration of existing patients is delayed by 32%.	Launches of new medications are being postponed. COVID-19 disrupts these processes or negatively impacts their rollout.		

On March 11, 2020, the WHO declared a pandemic for the new disease [56]. Humanity faced the challenge of a lack of vaccines and treatment experience. However, it was crucial to treat patients with varying degrees of severity and to ensure the non-spread of the infection. On March 30, 2020, the Verkhovna Rada of Ukraine adopted Law No. 539-IX "On Amendments to Certain Laws of Ukraine Regarding the Provision of Treatment for Coronavirus Disease (COVID-19)" [50] This law mandated the development of a local protocol for "Providing Medical Care for the Treatment of Coronavirus Disease (COVID-19)" [50].

From the moment of implementation of quarantine measures until March 2022, the COVID-19 treatment protocol underwent 12 revisions. The first and latest protocols exhibit significant differences, reflecting the accumulation of experience and adjustments in treatment regimens [30-34; 36]. During its development, certain medications were added to or removed from the list [10-11]. The protocol included hydroxychloroquine (chloroquine), favipiravir, remdesivir, ibuprofen, acetaminophen, antibiotics, tocilizumab, glucocorticosteroids (hydrocortisone, prednisone, methylprednisolone), low molecular weight heparins (enoxaparin), immunoglobulin preparations, convalescent

plasma, direct-acting antiviral medications, and monoclonal antibodies.

Simultaneously, experiences and treatment practices from other countries were disseminated [43-48]. The most popular protocol came from the United States, where the prevention list recommended, among other things, vitamins D, C, and zinc, as well as nasal interferons.

All these trends were reflected in the changes in consumer demand dynamics, with an increase in the aforementioned categories during the virus spread (See Figure 2).



Figure 2. Ranking of the Top 20 ATC classes at level 2 by retail sales volume, YTD 07_2020 [39]

According to IQVIA, one of the largest contract research organizations in the world [19], the consumption of personal hygiene products increased by 62% and 403% in the Middle East and Europe, respectively (Figure 2). As shown in Figure 3, Ukrainians purchased 13,000% more masks than before the pandemic began.



Figure 3. Distortion of mask consumption due to quarantine restrictions [39]

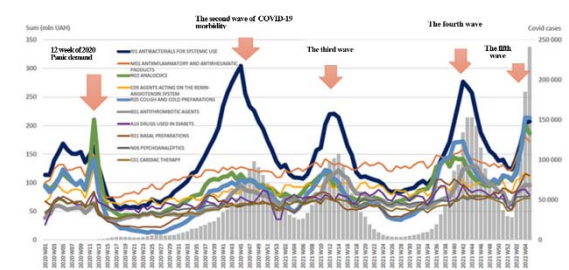


Figure 4. Dynamics of demand for various classes of pharmaceuticals since the start of the pandemic

Quarantine restrictions significantly modified the growth rates of certain ATC groups [53]. The graph (Figure 4) illustrates that the panic demand in week 12 of 2020 prompted the public to purchase all medications in anticipation of the uncertain future of the situation. During the second wave, the COVID-19 treatment protocol already included the necessity of using antibiotics at certain levels of disease severity, followed by the addition of analgesics (ibuprofen, paracetamol) and antithrombotic agents

(enoxaparin) [58-61]. The virus mutated, strains changed, and various symptoms began to manifest alongside the illness. As a result, the consumption of traditional cold and cough medication groups increased.

Let us examine the distortion of demand using the example of low molecular weight heparins (Figure 5), which were in high demand for hospitalized patients with moderate to severe disease. At that time, both domestic and foreign-produced enoxaparin were available in Ukraine [51; 55]. As previously mentioned, this category of medications was essential worldwide due to its evidence base and inclusion in most treatment protocols. Foreign manufacturers primarily addressed the needs of their domestic markets, treating their own citizens first [3-4]. As shown in the graph, a shortage of foreign-produced enoxaparin arose in Ukraine in 2020. During this period, patients had the option to be treated with domestic alternatives [1; 39]. Therefore, the presence of local players in the market directly impacted the pharmaceutical safety of citizens.

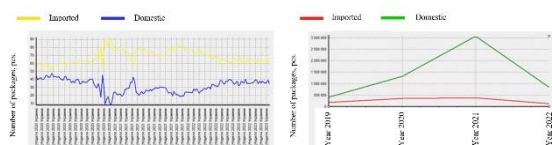


Figure 5. Fluctuations in retail sales of imported and domestic enoxaparin (MS% and Quantity)

Since vaccines are not produced in Ukraine, the domestic market was completely reliant on vaccine supply. It is important to note that the prioritization was determined by manufacturers and suppliers [20]. The chart below (Fig. 6, 7) illustrates the distribution of vaccine doses among countries and manufacturers.

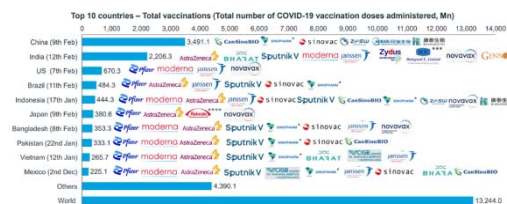


Figure 6. Top 10 countries by total number of vaccine doses administered as of February 2023.

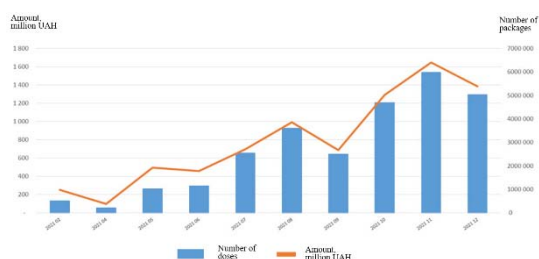


Figure 7. Dynamics of COVID-19 vaccine supplies to Ukraine [35]

In 2020, as part of anti-epidemic measures, a series of regulatory changes were adopted, among which the following should be noted:

- Exemption from VAT for a list of anti-epidemic goods: to improve public access to anti-epidemic goods, the Government exempted the import of medicines, medical devices, and disinfectants necessary for preventing, localizing, and eliminating outbreaks, epidemics, and pandemics of COVID-19 from import duties and VAT [42]. The relevant Resolution No. 224 was adopted on March 20, 2020 (this Resolution was valid until the end of quarantine) [37].

- Simplification of procurement procedures: in accordance with Law No. 530 [39], the Government adopted Resolution No. 225 on March 20, 2020 [38], which approved the procedure for procuring goods, works, and services necessary for preventing, localizing, and eliminating outbreaks, epidemics, and pandemics of acute respiratory disease COVID-19 caused by the SARS-CoV-2 coronavirus within Ukraine [40]. This Resolution also approved a list of such goods, works, and services. This was necessary as Law No. 530 exempted the procurement of these goods, works, and services from the Law of Ukraine on Public Procurement. (This Resolution was valid until the end of quarantine).
- Introduction of distance selling of medicines: in the spring, the Government adopted Resolution No. 220 on March 23, 2020 [41], which temporarily allowed pharmacies to conduct remote sales of medicines and related goods and organize their delivery directly to consumers while adhering to the storage conditions specified by the manufacturer during transportation, including engaging postal operators on a contractual basis.

At the same time, restrictions were established on conducting such types of trade for:

- Prescription medications, except for those included in the “Affordable Medicines” program.
- Controlled substances: This includes medicines whose circulation requires a license for the cultivation of plants listed in Schedule I of the narcotic substances list, as well as psychotropic substances and precursors [6-9]. This pertains to the development, production, manufacturing, storage, transportation, acquisition, sale, importation into Ukraine, exportation from Ukraine, usage, and destruction of narcotic substances, psychotropic substances, and precursors included in this list.
- Potent and toxic medications: Any medications classified as having strong effects or that are toxic.
- Medications requiring special storage conditions: These are medicines that must be kept under specific conditions to ensure their efficacy and safety.

4 Conclusion

The COVID-19 pandemic has sparked an important epidemiological discussion regarding the rise in the frequency and proportion of new infectious diseases capable of becoming pandemics in this century [5]. There are several indicators pointing to this shift: the emergence of new infectious agents or mutations of existing viruses that may be more contagious; the development of resistance to antimicrobial drugs; an increased incidence of infectious diseases due to globalization, international movement of people and goods, climate change, weakened public health measures, and the introduction of infectious diseases into isolated areas [57]. In this context, the experience gained during the COVID-19 pandemic, particularly in defining strategies developed across various scenarios, becomes a vital resource for formulating emergency action plans and training for potential new diseases.

The COVID-19 pandemic has reshaped the priorities of the healthcare system, revealing its vulnerabilities. The experience demonstrated that patients in Ukraine lacked access to certain medications, and the pharmaceutical safety of the population was compromised. The pharmaceutical sector faced industry shortages due to distorted demand and a lack of local production for specific groups of medicines. The COVID-19 pandemic introduced new challenges and lessons for health services. This situation prompts an exploration of development pathways and innovations in public policy concerning pharmaceutical safety in light of changing market structures.

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