Abstract



## Immediate and long-term effects of COVID-19's on the pharmaceutical industry

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Vilvoorde Hospital - A.Z. Jan On March 11, 2020, the WHO declared the new coronavirus disease 2019 (COVID-Portaels, Gendarmeriestraat 65, 1800 Vilvoorde, Belgium 19) to be a worldwide pandemic. This pandemic has significant repercussions on the Julez.Audrick@out pharmaceutical industry and the health market. These effects could manifest in the short or long term and require planning and detection to lessen their socioeconomic cost. This brief communication research evaluated the COVID-19 pharmaceutical market problem and discussed the immediate and long-term effects of the pandemic on the Vilvoorde Hospital - A.Z. Jan pharmaceutical industry. Portaels, Gendarmeriestraat 65, 1800 Vilvoorde, Belgium in consumer trends for health-market products, and ethical guandaries. pharmaceutical industry and other health markets. Introduction

Demand adjustments, regulatory changes, modifications to the research and development process, and a move toward telemedicine and telecommunication are some of the short-term effects of the COVID-19 pandemic. Additionally, the COVID-19 pandemic may have long-term effects on the pharmaceutical industry at both the global and local levels, including a slowdown in industry growth, delays in approvals, a shift toward self-sufficiency in the pharmaceutical production supply chain, changes

The discovery of these consequences may help policymakers create more evidencebased plans to address the issues that the COVID-19 pandemic presents to the

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The World Health Organization (WHO) declared the COVID-19 outbreak to be a worldwide pandemic. <sup>1</sup> COVID-19 quickly spread over the world in the months that followed, infecting roughly 7 million people.<sup>1</sup> The global economy, especially the pharmaceutical industry, was impacted by the COVID-19 epidemic. Although there is presently no proven cure for this new infectious disease, the pharmaceutical sector is helping governments fulfill the unmet needs of COVID-19 by helping with everything from research and development activities on prospective treatment techniques to managing the supply chain for medications during emergencies. The recent pandemic has affected access to affordable, critical medications, which is the primary objective of any pharmaceutical system.<sup>2</sup> As a result, pharmaceutical sectors are finding it difficult to sustain natural market flow. In addition to assessing the difficulties facing the pharmaceutical system on a worldwide scale, a situation study of this sector in a developing nation with a growing pharmaceutical market could reveal additional effects due to diversities. An excellent illustration would be the evaluation of Iran as a developing nation that was severely impacted by the COVID-19 pandemic. As far as we are aware, this is the first to mention these difficulties in relation to a developing nation with a pharmerging market. The generic-based pharmaceutical industry in Iran, a developing middle-income nation, is governed by the local national drug policy (NDP), which was last revised in 201 Iran's NDP is mostly composed of the following: price control, formulation-based national industry, local production promotion, and generic-based medication policy. <sup>3, 4</sup> In order to increase the availability and affordability of medications, the Iranian Ministry of Health (MOH) encouraged domestic production, which boosted access to high-quality medications in Iran.<sup>5</sup> Although over 95% (based on sales volume) of Iran's marketed pharmaceuticals are made domestically <sup>6</sup>, the production of these medications' reliance on imported raw materials presents a difficult problem. At the moment, the nation produces over half of its active pharmaceutical ingredients (API), with the remainder coming from reliable suppliers in China and India, as well as occasionally from European and eastern European businesses.<sup>3</sup>

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One of the major issues facing the pharmaceutical industry is the reliance on imports of raw materials from COVID-19-affected nations like China for the production of medicines. As of April 28, 2020, there were 0.9 million SARS-CoV-2 infections in Iran, <sup>7</sup> with a 38% fatality rate. These figures were in line with global corrected numbers. <sup>8</sup> According to global data, the overall cumulative COVID-19-associated hospitalization rate increased from less than 0.1% in those aged 10 to 19 to 3% in those aged 40 to 49 and doubled to 8.2% in those aged 50 to 59. <sup>8</sup> Using Iran as a case study for developing nations, the current short-communication study evaluated the pharmaceutical market crisis during the COVID-19 era, addressing both the short-term and long-term effects of the pandemic on the natural flow and regulations of the pharmaceutical market, first globally. For policymakers to be guided toward more evidence-based planning to solve related difficulties, these consequences must be identified.

## Short- and long-term effects of COVID-19 on the pharmaceutical industry

Given the rise in demand for prescription drugs, vaccinations, and medical equipment, COVID-19 may present the pharmaceutical industry with a once-in-a-century chance. This is one of the primary short-term effects of the COVID-19 pandemic, but there are also other short- and long-term ramifications, which will be covered below: Short-term effects of COVID-19 on the health market include changes in demand, supply shortages, panic buying and stocking, changes in regulations, and the shift in communication and promotions to remote interactions through technology and research and development (R&D) processes .

In the case of stimulated demand and panic-buying of oral home pharmaceuticals, particularly for chronic diseases, the pandemic (linked to COVID-19) and supply-chain inconsistencies may be the cause of the shortage. & COVID-19-related: Related prescription medication shortages are exacerbated by a rise in hospitalizations, the prevalence of pneumonia linked to COVID-19, and the need to place patients on ventilators. "A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent" is the definition of a medicine shortage. Numerous regulatory bodies throughout the world have declared a proven shortage list, which primarily consists of possible COVID-19 therapies as well as related illnesses. <sup>9</sup> For instance, hydroxychloroquine (HQC) and chloroquine (QC), two anti-COVID-19 potential pharmacotherapies, as well as commonly prescribed drugs for COVID-19 hospitalized patients exhibiting respiratory symptoms in critical care units, such as azithromycin, dopamine, dobutamine, fentanyl, heparin, midazolam, propofol, and dexmedetomidine, were on the FDA's shortage list for the United States. <sup>10</sup> Furthermore, the American Society of Health-System Pharmacists (ASHP) declared a shortage of 11 medications, primarily hospital-level antibiotics and anesthetics, such as vecuronium and rocuronium as anesthetics and meropenem, ceftazidim, ampicillin, and doxycycline as antibiotics. Additionally, this list contained fluticasone and albuterol, which are used to open the lungs' airways.<sup>11</sup> The influence on medicine shortage varied by kind, retail versus hospitalonly, and the degree of medicine access on a worldwide scale. Over the past month, the use of medications that are still in clinical trials but have not yet received FDA approval, or so-called investigational treatments, such as hydroxychloroquine, lopinavir+ritonavir, tocilizumab, and sarilumab, has doubled, with hospital use being eight times higher. <sup>12</sup> Since the beginning of January, the number of medications used in hospitals for COVID-19 has increased by 100% to 700%, including sedatives, respiratory treatments, and pain relievers. <sup>12</sup> At the local level, Iran Food and Drug Administration (IFDA) sales data show that HQ, QC, and lopinavir+ritonavir see monthly sales volumes that are 2, 6, and 23 times higher, respectively. However, there was no shortage of the aforementioned medications or the medications needed by hospitalized COVID-19 patients with pneumonia, according to IFDA's list of medicine shortages for emergency supplies. The excessive raw material stock, which is justified by market uncertainty brought on by Iran's political and economic circumstances, could be one of the reasons for this. The government's allotment of funds for the importation of COVID-19-related drugs was the other factor. In the case of raw materials, completed pharmaceuticals, and nutritional formula, for instance, lopinavir+ritonavir amounted for 0.18% (2 of 1101 billion US dollars) of the six-month approved currency order by IFDA to the Iranian central bank. The health market for medical products and personal protective equipment (PPE), such as protective goggles and visors, mouth-nose protection equipment, and protective apparel and gloves, was similarly impacted by the COVID-19 scarcity, prompting governments to enact laws in this area. One example at the international level is the European Commission's 2020/403 of March 13, 2020, which facilitates market entrance and restricts the export of PPE and some medical equipment. <sup>13</sup> On March 1st, 2020, Iran's national medical device directorate declared that the Iranian customs office has passed legislation restricting the export of personal protective equipment. <sup>14</sup> Additionally, the process of issuing emergency licenses for medical equipment supplies has been accelerated by sending them to the online communication system and receiving initial approval within one business day. This has been done to speed up the supply of necessary goods and decrease the number of in-person visits. In response to this epidemic, customs officials prohibited the export of masks, medical gowns, gloves, disinfectants, soap, detergents, and alcohol. They also accelerated the process of issuing clearance licenses for imported coronavirusrelated commodities and granted exemptions from costume taxes. <sup>15</sup> Induced demand and panic purchasing: The public's induced demand for stocking medication, often known as "panic buying," may occasionally result in a shortage in the market, particularly for medications used to treat chronic illnesses. According to studies, by March 2020, the global pharmaceutical market's induced demand-primarily from "panic buying" of medications for chronic illnesses—was predicted to be +8.9%. <sup>16</sup> According to a US study, between March 13 and 21, 2020, the number of prescriptions for asthma and type 2 diabetes rose by 65% and 25%, respectively. <sup>17</sup> Similarly, there was

a notable rise in claims for medications used to treat hypothyroidism, migraines, and high cholesterol.<sup>17</sup> Additionally, excessive purchasing for respiratory, mental health and anxiety, diabetes, and hypertension was 0.6%, 0.3%, 0.4%, and 0.1% in the USA, correspondingly. <sup>12</sup> In Australia, the issue of panic buying is being addressed in part by a one-month-stock regulation for the distribution of prescription medications. <sup>18</sup> In March 2020, the German Federal Institute for Drugs and Medical Devices (BfArM) released an allocation order regarding the demand-driven supply and storage of human medications. Pharmaceutical businesses and wholesalers were asked by the allocation order to refrain from supplying more medications than is typically needed.<sup>19</sup> The "stay at home" edict, on the other hand, may have reduced demand in some nations; but, in Iran, where there is no such restriction, retail pharmacies only reported induced demand unofficially. & Lack of supply for both active pharmaceutical ingredients (APIs) and completed goods: The world's primary suppliers of APIs, key starting materials (KSMs), and completed pharmaceuticals are China and India. Due to the disease and a slowdown in production, there may be a shortage and a rise in the cost of necessary prescription medications, such as antibiotics. This is especially important when it comes to non-substitutional vital APIs like ciprofloxacin, amoxicillin, potassium clavulanate, potassium sterile ceftriaxone, meropenam, vancomycin, and gentamycin. The Indian Pharmaceutical Alliance (IPA) requested that the government limit the use of pharmaceutical formulations, APIs, and products to domestic use only. API and bulk prices in Indian party transactions are already being impacted by this shortage. According to reports, the average increase was between 10% and 15%, but it might occasionally reach 50%.<sup>20</sup> Globally, the FDA and European Commission published and proposed policies that prioritized reasonable supply and demand optimization in order to prevent shortages. <sup>21</sup> Fast-track approvals for COVID-19-related treatments are among the changes to the regulations. In Iran, this refers to the Iran Medicine List (IML) inclusion and registration procedure. & Mandatory licensing for possible COVID-19 treatments; however, this is not applicable to Iran and is only applicable to nations who are members of the World Trade Organization (WTO) and adhere to intellectual property regulations. Additional rules to promote importation are necessary to keep the supply chain integrated, but they are not relevant to the current situation given Iran's economic crisis, currency shortage, and NDP component on increasing domestic production and minimizing imports. This effect has not yet been fully felt in Iran, where overstocking is again a result of political and economic unpredictability. Nevertheless, since the country imports roughly 50% of its API and accounts for 5% of its finished pharmaceutical sales volume and 30% of its sale value, <sup>12</sup> the local pharmaceutical industry will be impacted by this shortage.

Communication and promotion shift to remote interactions through tele-communication and tele-health: Locally and globally, marketing and promotions of health-care products to providers are shifting from in-person interactions to remote interactions and tele-communications, for both patient-support and promotional purposes, as a result of social distancing measures. In the United States, between 70 and 80 percent fewer patients visited doctor's offices or clinics. <sup>16</sup> In May 2020, the Iranian High Council of Insurance passed legislation allowing insurance coverage for telemedicine for the first time. Long-term behavioral changes in the health market could result from this.

Research and development modifications As treatments for patients with COVID-19, at least 113 medications or regimens and 53 vaccines are in the pipelines or are undergoing clinical trials on a global scale. <sup>16</sup> Around 924 COVID-19 therapy trials are currently underway worldwide. About 40% of these trials are not even randomized, while just 15% are based on traditional RCT techniques, which include double-blind, multicenter randomized with comparator arm. <sup>16</sup> HCQ is being studied in 64 MOH-registered clinical trials on COVID-19 patients and is available in Iran through local manufacture with five active vendors at a cost of 0.1 US\$. Lopinavir/ritonavir, which is part of the Iran local COVID-19 management guideline for high risk patients as an additive to CQ or HCQ regimen and is available through generics importation from Indian suppliers with a registered price of 0.82 US\$ per unit, is being investigated in 20 Iran MOH trials on patients with confirmed COVID-19. <sup>22</sup> CQ, which is also available from one local manufacturer at a price of 0.03 US\$. Furthermore, a number of clinical trials are being carried out to evaluate drugs that are not included in IML, such as remdesevir and favipiravir. Three MOH-supervised clinical trials are presently testing favipiravir in Iran, while three local manufacturers are analyzing the pharmacokinetics and stability of the aforementioned medication. Additionally, Remdesivir, an antiviral in the initial stages of medication development, is being studied clinically through clinical studies registered with the Iranian Ministry of Health. Essentials of Aerosol Therapy in Critically ill Patients On May 1st, 2020, the FDA approved an emergency authorization for this medicine for hospitalized patients with serious conditions. <sup>23</sup> As previously mentioned, there is a problem with pseudo-research and industrial investments in medications that may soon be found to be ineffective; this could ultimately place a significant strain on the healthcare system. When deciding whether to employ therapeutic procedures based on the findings of these pseudo-researchs, ethical considerations must be taken into account 24.

## Long-term effects

Long-term effects of COVID-19 on the pharmaceutical and health markets may include delays in approvals, the shift to self-sufficiency in the supply chain for pharmaceutical production, a slowdown in industry growth, and potential shifts in consumer trends.

Approval delays for pharmaceutical products unrelated to COVID-19: Since all nations, including Iran, are feeling the strain of the crisis and managing COVID-19 is their top priority, approval delays may result from several months of application review postponements. Decisions about IML inclusion, registrations, and reimbursement were being

made slowly in Iran because of the economic crisis; this might make it worse. Additionally, it is impacted by the regulatory agencies' about one-month semi-closure.

Moving toward self-sufficiency in the pharmaceutical industry: Governments in many nations have considered supply chain self-sufficiency and have announced regulations to prevent shortages in such a crisis due to possible shortages caused by export bans in China and India, which are major suppliers of API and generics. <sup>25</sup> Regarding this, the European Commission released a new guideline in March 2020 regarding foreign direct investment and the free flow of capital from third countries. It states that foreign investments, particularly those that have an impact on the EU's health market, must undergo risk assessments to prevent any negative effects on the EU's ability to meet its citizens' health needs. <sup>26</sup> Prior to this crisis, Iran's pharmaceutical industry was moving toward self-sufficiency due to importation challenges and sanctions; nevertheless, the COVID-19 epidemic may result in more importation limits and regulatory incentives for domestic production.

Growth slowdown in the pharmaceutical sector: The coronavirus pandemic caused economic slowdowns in many nations, which may result in a slowdown in the growth of the pharmaceutical industry, which is sensitive to national economic growth, particularly in nations with developing pharmaceutical markets like Iran. The introduction of more recent drugs is primarily to blame for this decrease in market expansion. Because pharmaceutical corporations' portfolio priorities fluctuate. It should be highlighted, nevertheless, that in some instances during past recessions, the health sector did not always follow this pattern and was less susceptible to slowing economic growth.<sup>27</sup>

Ethical considerations: The use of inadequately evidence-based treatments is one of the long-term consequences of the expansion of clinical research pertaining to the present epidemic. When using these medications off-label, ethical considerations should be taken into account. <sup>24</sup> In confirming the recommended therapies, the long-term clinical implications of the usage of these techniques in the coming years should be evaluated and healthcare practitioners should make educated decisions on employing off-label therapies in clinical practice.

Changes in consumption trends for health-related products: Emerging telemedicine may have an impact on changing prescription refilling and consumption patterns, particularly in areas that treat chronic diseases. Currently, public is concerned with personal hygiene maintenance; employing mainly nose/mouth protection, anti-infections material for environment and clothing and hand sanitizers. The prolonged epidemic may cause this consumption to persist in local and global public behavior. The short-term and long-term effects discussed in this paper can be seen in many reported trends around the world <sup>28, 29</sup>, and in countries in other regions, such as Africa, these effects will be predictable with increasing the COVID-19 prevalence. The effects that have been reported.

## Conclusions

The COVID-19 global pandemic can may be associated with numerous short- and long-term impacts on the health market, mainly the pharmaceutical sector; which can be seen from both global and local perspectives. Identifying these impacts may guide policy-makers in evidence-informed planning and decision-making to combat associated challenges. For proper planning to prevent long-term complications, short-term impacts should be identified and further be measured with appropriate data-analysis. Identification of these effects is essential for policy-maker guidance towards more evidence-informed planning to overcome accompanying challenges; and this may be more important in the context of developing countries with more scares healthcare resources and pharmerging markets. **References** 

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