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**COVID-19 AND COUNTERFEIT VACCINES: GLOBAL IMPLICATIONS, NEW
CHALLENGES AND OPPORTUNITIES**
ABSTRACT

This research note (RN) examines the drivers and consequences of proliferation of counterfeit (substandard and falsified) COVID-19 vaccines. An integrated framework was advanced which sheds light on the domestic contributory factors such as a desperation by citizens to “return to normalcy”, institutional impediments, minimum standards of enforcement of laws related to intellectual property rights and lack of access to vaccines in tandem with international environmental drivers such as the growth of online pharmacies, international market intermediaries and vaccine nationalism. Consequently, counterfeit COVID-19 vaccines appear to serve as a disincentive to innovation and investment in research and development activities. The analysis highlights health-related consequences including providing a false sense of security against a dangerous virus and potentially loss of confidence in reliable medicines. This analysis led to the generation of some vital socio-economic implications for public policy and enterprises, which are discussed.

Keywords: COVID-19; counterfeits; COVID vaccine; global.

Highlights

- Literature on the influences of COVID-19 and global counterfeit market analyzed.
- COVID-19 pandemic and counterfeit COVID-19 vaccines examined.
- Proliferation of counterfeit COVID-19 vaccines explored.
- Policy and practical practice outlined.

INTRODUCTION

In this integrated global economy, no nation is immune to the flow of illicit trade of goods and services [4, 27, 39, 43]. In recent times, the traditional focus of counterfeiters on currency, goods and artworks has made a sharp turn to encompass COVID-19 vaccines [9]. Indeed, substandard or falsified products and medical medicines have emerged to become a feature of the global access to vaccines [27, 39, 43, 24]. The growing importance of COVID-19 vaccines as means of counteracting the negative consequences of the crisis and bringing the world into normality cannot be overstated. Indeed, so far there has been over 467,258,968 cases globally and over 6,090,553 fatalities [45] bringing many nation economies and businesses to their ground hampering development and growth [5, 6]. The problem of counterfeits preceded the COVID-19 vaccine but has surged in many developing nations. Globally, the total amount of counterfeiting products in 2017 was 1.2 trillion USD and expected to grow to 1.82 trillion USD by 2020 [32]. According to the World Health Organization, about 1 in 10 medical products in low- and middle-income countries are either substandard or falsified [40]. In view of the popularity of COVID-19 vaccine and growing numbers of counterfeits around the globe, the extant research has overwhelmingly sidestepped the issue of counterfeit COVID-19 vaccine and its wider implications for society and government. Although the current literature is replete with studies on the COVID-19 and health implications, to date, scholars have largely circumvented examining the issue of counterfeiting as an outcome of this global crisis.

Against this backdrop, this research note (RN) seeks to address this paucity of scholarly works by examining the drivers and consequences of counterfeit COVID-19 vaccines. Theoretically, whilst there is a growing body of research on both the COVID-19 pandemic [13, 33] and counterfeits products [12], thus far scholars in these two domains have operated in silos and thereby hampering scholarly advancements. This research addresses this lacuna by identifying and examining how the COVID-19

pandemic has triggered waves and proliferation of counterfeit products. The cross-fertilization pursued here helps to enrich our understanding of this emerging phenomenon. The study further contributes to the discourse on the COVID-19 pandemic [33, 48] by focusing on how it has amplified many existing global trends including the growth of pirated trade goods and acceleration of counterfeiting related to this vaccine. In addition, although many scholars have contributed to the discourse on the pandemic [1, 2, 3, 13, 47], there has been limited insights into the negative aspects of vaccine nationalism that has come to typify global unequal access to COVID-19 vaccines. By examining the drivers and consequences of the emergence of counterfeit COVID-19 vaccines, our study extends and outlines a pathway toward enhancing our understanding of the unintended consequences of vaccine nationalism. In this direction, an integrated framework that elucidates the underlying drivers to the outcomes is advanced.

The rest of the paper is organized as follows. First, a brief review of relevant literature is presented. The historical evolution of global counterfeit and pirated products is examined followed by analysis of the drivers and consequences. The broader implications of counterfeit COVID-19 vaccines for policy and practice are then discussed.

A Brief Review Of Relevant Literature

Historically, copying or replicating other businesses' activities and their "modus operandi" is generally accepted in many cultures [4]. What is less acceptable is infringement of intellectual property rights and the productions of counterfeit goods and services [17]. One relevant literature in seeking to explain this is the institutional impediments hypothesis [22], which contend that institutional constraints such as lack of or weak institutional facilities, poor legal system, and weak legal enforcement structures that characterize developing nations often have curtailed governments' ability to regulate and monitor business activities. This void then creates conditions for illegal activities to occur. Consistent with the

preceding arguments, in a market where such illegitimate activities are rampant, the basis for fair market competition is undermined as well as erodes incentives for firms to invest [12, 17]. Crucially, illicit trade of goods can undercut legitimate businesses, stifle their revenue streams and direct financial resources towards illegal actors and criminal activities [see 17]. In a series of prior studies [e.g. 37], scholars have attributed the development of counterfeit production and spread to weak government and consumers' desire for cheap products. Such products also appear to appeal to low-income consumers.

One of the foci of research counterfeit interest has been the effects of illicit trade on global brands. Within this domain, some studies have focused on the damage to reputation of popular and luxury fashion brands and loss of revenues [29]. In an environment with weak intellectual property rights and brand-protection legal framework, studies indicate that counterfeiting grows as a result [30, 31]. Intellectual property generally denotes ideas or works developed by a firm/business including discoveries and inventions; symbols, and designs [11].

Another vital domain for copyright infringement and counterfeits is the unauthorized downloading and file sharing via peer-to-peer (P2P) networks which has been found to impact on the revenues streams of the music and entertainment industries [17]. A stream of prior scholarly works has demonstrated that the displacement of sales from genuine producers by counterfeiters diminishes businesses' financial resources needed for investment in innovation and research related activities [12, 17]. Besides the investment effects of IPR infringement, the illegal use of trademarks and counterfeiting also has the potential to undercut trust in the legal system and thereby forcing some market players and businesses to operate outside the rules-based systems [17].

RESULTS

Covid-19 And The Evolution Of Global Counterfeit: An Overview

According to OECD/EUIPO and EU's Intellectual Property Office's report, trade in fake goods accounts for around 3.3% of world trade and continues to surge affecting every country around the globe [27]. Indeed, the value of imported fake goods worldwide based on custom seizures data alone accounted for USD 509 billion in 2016 representing an increase from USD 461 billion in 2013 (which was 2.5% of world trade) [27]. The problem is further amplified for the European Union given that the counterfeit trade represented 6.8% of imports from non-EU countries [27]. The trade in counterfeit goods not only infringe on trademarks and copyrights of existing enterprises, individuals and governments, but also have a potential to create a vital source of revenue for organized crime [26]. As observed by Global Financial Integrity, counterfeit medicines remain "the single most lucrative market of all transnational crimes" with up to 25 times more lucrative than narcotics trafficking [9, p. nd]. Counterfeit goods also have the potential risk to health and safety risks associated with products such as medical supplies, food and cosmetics brands and electrical goods with potential to damage to human health. Indeed, fake pharmaceutical products not only can they cause side effects but also cause fatalities in vulnerable populations. Another negative consequence includes ineffective drugs and fire hazards associated with fake electronic appliances [27].

Following the limited access to COVID-19 vaccines is a rise of pandemic-exploiting crime including the productions of counterfeit versions of AstraZeneca, Sinovac, Moderna, Cansino, Sinopharm and Pfizer COVID-19 vaccines in countries such as Mexico and Poland [9]. The black market for counterfeit COVID-19 Vaccines continues to grow as much as 400% due to desperation by citizens to "return to normalcy" [34].

COVID-19 has had varying effects on different types of industries and companies. Whilst some companies such as online technology companies such as (Zoom and Amazon) and pharmaceutical companies (such as Moderna, GlaxoSmithKline, BioNTech and Pfizer) have experienced surge in stock value and multi-billion-dollar profitability [see also 28]. In parallel in other sectors, airlines such as KLM, Air France and British Airways have been heavily impacted by the pandemic following the border closures around the globe. Indeed, Pfizer alone made around \$37bn (£27bn) in sales from just its COVID-19 vaccine in 2021 and thereby making the vaccine one of the most profitable vaccines in history [23, 28]. According to Amnesty International, the pandemic has delivered an “extraordinary power” to few pharmaceutical firms [8]. Some practitioners have argued that pharmaceutical companies have been profiteering from the pandemic (i.e. “pandemic profiteering”) at the expense of human life via high prices of vaccines and failure to waive patents to allow wide scale production for global vaccination [23, 8].

According to Amnesty International [7, 8, p. 5], pharmaceutical firms have not only systematically “controlled technology, blocked and lobbied against the sharing of intellectual property” but also charged high prices for COVID-19 vaccines and elevated supplies to advanced nations to the top of their priorities. Indeed, BioNTech, Pfizer and Moderna together accumulated revenue of around £40 billion in just 2021 [8]. Although pharmaceutical companies have benefited from public investments in the development of COVID-19 vaccines, little effort has been made to bridge the global unequal access to vaccines with around 2% of their vaccines to low-income nations [7, 8].

In recent times, multiple cases of counterfeit COVID vaccine have been reported in Africa and South- East Asia such as Uganda and India (WHO, 2021c). Seizures of substandard and falsified COVID medicines have occurred in countries such as Mexico, South Africa and US amounting to millions of dollars [34]. Indeed, the COVID vaccine market value is over \$150 billion for just the 2021-2022 period

and thereby enticing these illegitimate players to the market [9]. The potential crimes have also been extended to production of fake vaccine passports and fake immunization cards [see also 9, 34]. Although there have been relentless efforts by governments and national border officials around the globe have culminated in customs seizures of counterfeit and pirated products, these are yet to tame the crisis and the share of global trade continue to rise permeating industries such as watchmaking, electronics and pharmaceuticals [see 44].

Driver of counterfeit COVID-19 vaccines market

As countries experience different waves of COVID surges, demand for COVID-19 vaccines has also increased considerably with demand exceeding the supply around the globe. This global trend where largely developed nations have access to COVID-19 vaccines has created conditions where individuals, countries and businesses seek alternative sources of treatment [24]. Indeed, whilst many in the first-world nations talk of a third dose COVID-19 vaccine, many in developing nations are yet to get vaccinated. In the vacuum of lack of access, counterfeits COVID-vaccines have flourished ranging from local herbal vaccines, cooking recipes and all sorts of ingredients purporting to be a cure for COVID-19 [see also 34]. Below we outline the other drivers.

Online shopping and growth of counterfeiting

Accompanying the COVID-19 pandemic has been a massive surge in online shopping and online pharmacies across both developed and developing nations and thereby offering ample opportunities for counterfeit goods to be traded [44]. In Europe, for instance, around one out of 10 consumers purchased a fake product by mistake and “many popular online platforms are used as distribution channels” [44, p. nd]. The COVID-19 pandemic has transformed and accelerated the retailing industry forcing many businesses and consumers to transition from using traditional brick-and-mortar outlets to online

shopping outlets (5, 6, 20). Coupled with growth of online pharmacies have provided more opportunities for counterfeiting to occur. The ease to which one can purchase vaccines online has also helped to expand the scope of illegitimate businesses leveraging online platforms to advance their unauthorized activities. This is amplified by the fact that consumers are generally ill-equipped to be able to differentiate product characteristics and indicates whether a given pharmaceutical product encompasses the required chemical ingredients [17].

“Fake news is counterfeit news”

In many countries, misinformation grounded in complete disregard for evidence has created grounds to fake information to spread further cementing resistance among some individuals [16]. One can argue that the misinformation era and disregard for facts/evidence in which we have entered is typified by public figures, political and officials noting "fake news" to dismiss factual information, "truth isn't truth" and "alternative facts" [21, 16]. No longer is misinformation only generated and distributed by people at the bottom of organizational hierarchies, but at all levels of organizations. The World Health Organization employed the term "infodemic" to denote the overwhelming amount of inaccurate and false information on social media and websites that provide fake information to dispute scientific evidence [19]. As Fallis and Mathiesen [16, p.1] succinctly put it, "fake news is counterfeit news" - fake news can lead many people to acquire false beliefs, absorb misinformation and insights. The point here is that misinformation undermines trust in legitimate outlets such as pharmacies and therefore likely to create a vacuum that allows fake vaccines to be distributed and passed as originals. Accordingly, these then drive individuals' purchasing behavior.

Institutional impediments hypothesis

The COVID-19 pandemic has revealed the weaknesses inherent in the governance and legal system of governments. Country-specific risks such as weak intellectual property protection and burdensome administrative rules that typified developing nations can curtail effective enforcement of rule of law. When the legal protection granted to inventions is not strictly enforced, it creates conditions for counterfeit products at lower prices to thrive. In developing economies such as those in the Economic Community of West African States (ECOWAS) including Burkina Faso, Cape Verde, Ghana, Nigeria, Senegal and Togo, often laws and rules that govern and safeguard intellectual property rights are weak in tandem with minimum standards of enforcement of laws related to intellectual property rights [see also 11, 17]. Also, in countries such as China, Indonesia and Russia infringement of such protection remain common. Indeed, attempts to halt shipments of pirated products and confiscation are often relatively slow and thereby creating conditions for rampant and unauthorized copying and production of other businesses' products can discourage investment by foreign firms [11]. Given the variations of intellectual property rights and enforcement around the globe, with developing countries having weaker institutional surroundings [11], which then create a fertile ground for counterfeiters to sidestep strict trademark enforcement regimes.

Lack of access to vaccines and “vaccine nationalism”

As countries largely in the developed world elevate their national interest above all, unequal or lack of access to COVID vaccines have flourished. “Vaccine nationalism” has emerged to characterize the global access to COVID-19 vaccine. Indeed, it can take “the form of overt export bans or limits—that aim at increasing domestic availability of vaccines at the expense of foreign supply—or they can take less transparent but often equally effective forms” [14, 15, p. 1]. It has been projected that the global economy could lose around \$9.2 trillion due to the prevalence of “vaccine nationalism” [10]. Indeed,

about 85% of developing nations are yet to have effective vaccination programs whilst advanced nations are surging ahead with vaccinating most of their citizens [36, p. 9–10]. This so-called vaccine “hoarding” by many leading nations has fermented the “vaccine nationalism” [25] and thereby pushing citizens and developing nations to explore other avenues to access vaccines. Although there is the COVAX initiative led by organizations such as GAVI, UNICEF, and the World Health Organization with the aim of delivering over a billion vaccines in 190 nations including developing nations [18, 25], these are inadequate in addressing the fundamental issue of access to all global citizens. The inequitable distribution of vaccines has forced many to seek alternatives including substandard and falsified medicines.

According to the World Health Organization [43, p. nd], around two billion people around the globe do not have “access to necessary medicines, vaccines, medical devices including in vitro diagnostics, and other health products”. The failure to fill this gap has created an opportunity for other illegitimate businesses to develop and distribute substandard and falsified products. In the face of desperation for access to life saving drugs, individuals have been forced to rely on illegitimate middlemen for access to vaccines. The World Health Organization [43] observed that more than one in ten medicines in low- and middle-income countries are of substandard or falsified and thereby leaving a gap between developed and developing nations in terms of access to vaccines. The COVID-19 vaccine merely replicated this unequal access to vaccines around the globe and thereby creating the conditions for counterfeiters and their products to flourish.

Global manufacturing networks

The global supply chains become more integrated and complex which create conditions for many products to be “manufactured in one country may be packaged in a second country and distributed across borders to be marketed or sold to consumers in a third” [43, p. nd]. As global manufacturing and

distribution systems adopted by MNEs around the globe become more integrated and complete, it has also become very difficult to trace the source of many vaccines and thereby creating space for substandard and falsified medical products to take roots and grow [39].

Outcomes/Effects of counterfeiting

As noted by World Health Organization [39], substandard and falsified medical products are often of low quality, unsafe or ineffective and threaten the health of patients/citizens. Another consequence of the spread of substandard vaccines is that counterfeit antibiotics have the potential to stimulate antibiotic resistance and ferment drug resistant organisms throughout communities [34]. The spread of substandard and falsified COVID vaccines can also fuel a false sense of security against a dangerous virus and thereby, encouraging risky behaviors. Indeed, substandard and falsified medical products that fail to prevent disease as well as “contribute to antimicrobial resistance, waste precious resources and lead to a loss of confidence in medicines and distrust of healthcare providers [43, p. nd]. Counterfeiter COVID-vaccines has the potential to fool buyers into believing that they are protected against the virus only to rediscover later with deadly consequences. It also forces individuals to project false information to their families and co-workers that they are now a high level of protection against the virus.

In view of the growing interconnectedness of national and regional economies via regional trading blocs (e.g., the European Union, ECOWAS, and African Union), counterfeiting is now increasing cross-border activities impacting on most nations. The counterfeit COVID-19 vaccine has the potential of disincentivizing innovation activities [see 44]. The counterfeit trade and IPR infringements demotivate legitimate businesses from investing in research and development activities. This stems from the fact that counterfeits represent a leak in the revenue of legitimate businesses, governments and individuals and then direct the revenues towards potentially other criminal activities [26]. This is more so in areas where the upfront cost of investment in doctors, scientists and designers are simply too high

and beyond the reach of most businesses and nations. This is also likely to divert resources away from investments to capitalize on current patents and thereby hampering long-term development.

By undermining the intellectual property system, counterfeits pose risk in terms of job losses in legitimate business and the growth continues to eat into their market share. For governments, the effects of the growth of counterfeits can manifest in terms of unpaid tax and rampant infringement of intellectual property rights can also incentivize foreign investors. Revenues from counterfeits are also likely to be redirected to criminal activities such as money laundering and sponsoring terrorism. There are a number of drivers and outcomes can be classified into a range of factors internal (domestic) and external factors/outcomes, as depicted in Figure 1. The figure also attempts to connect the drivers and consequences.

Insert Figure 1 about here

DISCUSSION

The objective of this research note (RN) has been to advance the growing literature on the COVID-19 pandemic by examining the drivers and consequences of counterfeit (substandard) COVID-19 vaccines. An integrated framework was advanced which shed light on domestic contributory factors such a desperation by citizens to “return to normalcy”, institutional impediments and lack of access to vaccines in tandem with international environmental drivers such as the growth of online shopping and online pharmacies, vaccine nationalism. At the root of the spread of counterfeits are weak regulatory systems, weak intellectual property protection regimes around the globe coupled with poor governance and lack of technical capacity and capabilities to identify and detect such products [43].

The preceding analysis further suggests that vaccine nationalism and weak institutional framework have amplified the situation of many developing nations further pushing citizens towards counterfeit products. Consequently, counterfeits appear to serve as disincentive innovation, discourage investments in research and development activities, and undermine intellectual property systems. The analysis highlights some health-related consequences including false sense of security against a dangerous virus and potentially loss of confidence in reliable medicines. Although counterfeit COVID-19 vaccines are surging, this trend merely replicates and accelerates an existing global trend. In this direction, this finding supports the COVID-19 as “the great accelerator” hypothesis [6] in terms of fast-tracking the existing global trend of trade of substandard and falsified products. The channels for diffusion of counterfeit products includes online/digital channels and brick-and-mortar outlets. One of the challenges in stemming the spread of counterfeit products is that such products and their packages are often identical to the genuine brand/products and thereby making it difficult for consumers to spot the differences.

CONCLUSIONS

From a practical standpoint, there is a need for government investments in robust border enforcements, training of technical experts to oversee and inspect products to identify and remove substandard ones. Education of the general public will also go a long way in ensuring that people are informed about the negative consequences of the use of counterfeits and dissuaded from buying such products. Harnessing new technologies and social media to combat COVID-19 pandemic misinformation can help to arrest the growing problem. Individuals irrespective of their education status, income and position in society are susceptible to fake information and must be alert against inflow of potentially false information. To combat the spread of counterfeit vaccines requires governments, pharmaceutical companies, and regulatory agencies and law enforcement to work in tandem to remove misinformation and provide alternative sources of reliable information to replace the vacuum.

For most developing countries, especially in Africa with abundance of natural resources but low level of research and development activities in industries, stronger enforcement of intellectual property rights has the potential to yield benefits in terms of removal of dangerous counterfeit products and ineffective medicines [17]. In view of the centrality of COVID-19 in influencing many aspects of life, vaccinations and vaccines are seen as an effective means of helping to bring the world back to some semblance of normalcy [35]. In addition to examining the long-term effects on counterfeiting, future research can also examine the human and social costs. Considering the limited studies on counterfeiting in developing countries in the wake of COVID-19, future research efforts could be directed towards examining businesses' responses. Ultimately, to quench the developing world's thirst for cheaper products and vaccines, the global unequal access to vaccines will have to be addressed to tackle the problem effectively.

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