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Access to a COVID-19 Vaccine and Prevention of Counterfeiting in Indonesian and International Health Law: A Comparative Approach

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Abstract

International forums have discussed the need for the original/genuine COVID-19 vaccine to cure and protect the populace from the deadly virus and the issue of its counterfeiting. The International Criminal Police Organization issued global alerts to the law enforcement agencies of its 194 member nations to be aware of Covid-19 vaccine counterfeits. Consequently, the present study's focus has been on the international laws associated with the fundamental rights of individuals to have equitable access to the COVID-19 vaccine worldwide. It has also addressed the international laws used to combat COVID-19 vaccine counterfeits. In addition to the objectives mentioned above, the current study examined the case of Indonesia as a low- and middle-income nation to assess the presence of laws governing the rights of citizens to access COVID-19 vaccination and their protection from counterfeits. The researchers utilized a normative judicial research methodology based on secondary data from the available literature and legal documents. Globally, diverse organizations and agencies have stepped forward to secure the rights of individuals to have access to the COVID-19 vaccine without discrimination and to safeguard against counterfeits, according to the findings. Similarly, the results revealed the laws in Indonesia that address infectious diseases and provide citizens with health care protection. The current study is an important addition to the existing body of literature because it not only presents international laws for the prevention of COVID-19 vaccine counterfeiting but also discusses the case of a developing country as a starting point for future researchers.

Keywords: COVID-19 vaccine, prevention of counterfeiting COVID-19 vaccine, international health law, Indonesian health laws, Intellectual property rights

Introduction

The COVID-19 pandemic, which has been declared a global health crisis, has had a significant impact on the lives of billions of people worldwide. This has resulted in numerous challenges, including disruptions to public activities, the strain on healthcare systems, and the development of vaccines to address the population's

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needs (Hidayati & Rachman, 2021). The SARS-CoV-2, a highly pathogenic virus causing severe acute respiratory syndrome, has significantly impacted the global community for over two years (Cahyadi et al., 2022).

The World Health Organization (WHO) declared the Covid-19 pandemic on March 11th, 2020, due to its widespread presence in 114 countries and the reported 118,000 cases, which resulted in 4000 deaths (Di Gennaro et al., 2020). The swift transmission of the pandemic across various regions, including Indonesia, can be attributed to its high level of mobility. On March 2nd, 2020, Joko Widodo, the President of Indonesia, announced the country's first coronavirus case. The primary objective of the COVID-19 vaccination campaign was to attain herd immunity, safeguard public health, and facilitate economic and social productivity (Djalante et al., 2020). In contrast, a significant global endeavor has been undertaken by scientists to create vaccines that are both efficacious and safe to prevent transmission and confer immunity against the virus (Yahaghi et al., 2021). The primary objective of the COVID-19 vaccination campaign was to attain herd immunity, safeguard public health, and promote economic and social productivity (Firdaus, 2022).

According to Kanozia and Arya (2021), vaccines are biological preparations that confer active acquired immunity against certain deadly diseases. In 1796, Edward Jenner pioneered the development of the first vaccine, specifically the smallpox vaccine (Poska, 2022). The COVID-19 vaccine has occurred at an unprecedented pace in the history of vaccine development. Various types of vaccines are available, such as nucleic acid, viral vectors, protein-based vaccines, whole virus life-inactivated vaccines, and attenuated vaccines (Ndwandwe & Wiysonge, 2021). As of June 2021, regulatory authorities have granted emergency use approval to approximately 18 different types of vaccines. The ongoing progress in developing COVID-19 vaccines entails utilizing pre-existing knowledge through accumulating research innovations, as noted by Gorzelany-Dziadkowiec (2021) and Hartanto, Agussani, and Dalle (2021). Despite numerous conscious efforts made during the pandemic to mitigate the impact of the deadly COVID-19 virus, widespread panic has ensued, resulting in millions of casualties (Barua & Barua, 2021). Sheikh et al. (2021) conducted a study that revealed that developing nations had encountered numerous obstacles and difficulties in the organization and dissemination of the COVID-19 vaccine. These challenges include insufficient resources for administering the vaccine, impediments to its distribution, and a scarcity of global supply, among other factors.

The present study seeks to address the abovementioned research by providing a comprehensive examination of the rights and accessibility of individuals to a COVID-19 vaccine. Additionally, the current investigation provides a comprehensive analysis of the global health law about the surplus of COVID-19 vaccination as an inherent entitlement of all individuals across the globe and a crucial factor in safeguarding public health. The present research enhances the extant scholarly literature by presenting the prevailing global patterns concerning counterfeiting and the proliferation of piracy associated with vaccines. This study contributes to the current literature by elucidating the emergence of counterfeit COVID-19 vaccines and expounding on the availability of international laws to address the repercussions of vaccine nationalism.

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Furthermore, the present investigation was carried out specifically within a developing country, Indonesia. Like other parts of the globe, Indonesia has encountered various instances of counterfeit COVID-19 vaccination, as per Lasmadi (2021). As reported by Wardiono et al. (2021), individuals involved in the production of counterfeit vaccines in Indonesia, such as Rita Agustina and Hidayat Taufiqurhman, were responsible for the creation of various fraudulent vaccines, including the Penta-Bio Vaccine, Tripacel Vaccine, Euvax B Vaccine, Pediaccel Vaccine, Engertx B Vaccine, and Forged Vaccine. The production of counterfeit vaccines is not a new phenomenon in the context of the COVID-19 pandemic. However, it has been prevalent in Indonesia since 2003, when a tragic incident occurred in which a baby passed away after receiving a vaccination. This event gained significant attention on social media platforms, thereby contributing to the popularity of counterfeit vaccines in the region (Kang & Disemadi, 2021). Consequently, the Indonesian government implemented proactive measures to combat counterfeiting and established multiple regulatory frameworks to address the potential threat of counterfeit products. Therefore, the extant laws and regulations about counterfeiting offer a benefit in managing counterfeit vaccines amidst the COVID-19 pandemic.

According to Bian et al. (2016), to combat the production of counterfeit COVID-19 vaccines, it is necessary to trace criminal activity through a sequence of actions. This approach is supported by existing research. Identifying key actors in the counterfeit industry can be facilitated by examining patterns that manifest across various geographic locations and regions (Hamma-Adama & Labaran, 2021). Following health regulations, the law requires credible evidence to be presented in cases involving counterfeit vaccines before pursuing criminal charges and holding responsible the entities involved. The production of counterfeit medicines may be facilitated by the aforementioned fake medicine production practices, as noted by Ziavrou, Noguera, and Boumba (2022). Therefore, it is imperative to meticulously adhere to the laws and regulations about counterfeiting to address such illicit activities (Lasmadi, 2021). The COVID-19 pandemic has resulted in a significant number of fatalities globally. In response, efforts have been made to administer vaccinations to interrupt the transmission of the virus (Taufiqurrohman et al., 2021). According to Parums (2021), most worldwide scientific research indicates that vaccination is an effective means of reducing the incidence of Covid-19 patients and mitigating associated risks.

Furthermore, this contributes to the development of herd immunity, as noted by Kim, Marks, and Clemens (2021). Nevertheless, it has challenges; the distribution of vaccinations in Indonesia encounters obstacles. The government is contemplating implementing a more rigorous approach to attain the vaccination targets in light of the emergence of skepticism surrounding the Covid-19 vaccine. As a result of this restrictive methodology, numerous discussions have been initiated. According to Pigai (2021), there is a belief that mandatory vaccination may infringe upon human rights as it can be perceived as a form of coercion.

On the other hand, some contended that stringent measures are necessary to address the issue of low compliance and to cater to the community's inclination toward involvement in the vaccination drive (Pardede, 2021). The legal scholars in Indonesia were prompted to engage in discourse and seek efficacious solutions for

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enforcing Covid-19 vaccination laws. The resolution of the multifaceted issues arising from the impact of Covid-19 on the economy and health sectors necessitates implementing a well-planned strategy, which should include the appropriate utilization of law enforcement and a suitable approach (Pardede, 2021). The present investigation aims to provide insights into this particular matter's discourse. Initially, it is pertinent to inquire whether vaccination is a responsibility or a right incumbent upon all individuals. What are the applicable legal mechanisms in Indonesia for enforcing the vaccination law? Thirdly, what is the extent of the state's liability for adverse events following Covid-19 vaccination, given the mandatory nature of the vaccination requirement?

Hence, the current study aims to.

- Present an overview of individuals' rights and access to a COVID-19 vaccine globally and in Indonesia.
- Highlight global laws/regulations/measures linked with preventing counterfeiting of the COVID-19 vaccine.
- Highlight laws/regulations/measures linked with preventing counterfeiting of the COVID-19 vaccine in Indonesia as a developing nation.
- Present recommendations and future research directions to improve the existing laws/regulations/measures to enhance public health security in developing and developed nations.

Literature Review

The confluence of economic hardship, a public health crisis, and the spread of misinformation has resulted in challenges associated with the availability and surplus of crucial health products and medications. This has led to fluctuations in pricing, ambiguity, concerns regarding quality, and shortages of medicines (Bidisha, Mahmood, & Hossain, 2021). The tumultuous circumstances incited both merchants and buyers to contemplate the issue of counterfeit pharmaceuticals, as per Amankwah-Amoah's (2022) findings. According to Bian et al. (2016), utilizing a trademark belonging to another individual or entity without their express permission is commonly referred to as counterfeiting. Counterfeiting is a grave offense involving fraudulent replication or forgery of established products or brands. According to Hamma-Adama and Labaran (2021), counterfeit pharmaceuticals exhibit inferior efficacy, safety, and quality compared to their authentic counterparts. Concurrently, they elicit deleterious hazards to the general public's well-being, engendering a deficiency in trust in the healthcare system, healthcare professionals, and pharmaceuticals (Ziavrou et al., 2022).

The historical record illustrates the widespread adoption of imitative business practices in various cultures, particularly developing countries. The issue of intellectual property rights infringement and counterfeit production is subject to various constraints globally, even in developing countries, as noted by Amankwah-Amoah and Hinson (2022). Despite the considerable amount of scholarly literature that has been produced to elucidate the COVID-19 pandemic and its deleterious effects on the worldwide economy, there is a dearth of research on the issue of disparate access to COVID-19 vaccines among various nations (Amankwah-Amoah, 2022; Ndwandwe & Wiysonge, 2021). Yahaghi et al. (2021) have observed that only

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a limited number of studies have drawn attention to the rising prevalence of counterfeit COVID-19 vaccines and their implications for governmental and societal use. Concurrently, there has been a lack of emphasis on the legal and regulatory frameworks for producing counterfeit COVID-19 vaccines, as noted by Amankwah-Amoah (2022). Conversely, researchers have emphasized the importance of examining counterfeiting due to the current worldwide crisis (Hamma-Adama & Labaran, 2021; Ziavrou et al., 2022).

Methodology

The present investigation pertains to socio-legal research. Furthermore, a socio-legal inquiry has the potential to incorporate both doctrinal and non-doctrinal analysis while maintaining an interdisciplinary approach. According to Blandy (2016), there exists a shared belief among socio-legal scholars that the law constitutes a sphere or constituent of the societal milieu that can be scrutinized and conceptualized through the application of diverse methodologies and tools derived from the social sciences. Socio-legal researchers increasingly recognize the need to employ various methods and be cognizant of theoretical and methodological concerns in traditional social science fields when examining law and legal phenomena. In contrast, it is common for socio-legal studies to employ sociology to gather data rather than for substantive evaluation, as noted by Banakar and Travers (2005). According to ADCO Law (2022), a socio-legal study pertains to examining the law that incorporates legal and social sciences methodologies. There exist two principal characteristics of such investigations. This study, conducted as socio-legal research, utilized a textual analysis approach to examine legislative policies and articles. The aim was to critically analyze and explain their implications and meanings for legal subjects. The study has contributed novel methodologies that merge social sciences and legal investigations, such as socio-legal ethnography and socio-legal qualitative research. Firdaus (2022) posits that socio-legal research endeavors to scrutinize a predicament using examining and comprehending legal doctrines or norms and conducting a thorough analysis of the context and characteristics of legal norms and their implementation. The field of socio-legal studies can scrutinize the impact of COVID-19 vaccine strategies and legal frameworks on the equitable distribution and accessibility of vaccines, particularly in Indonesia. Analyzing societal and legal obstacles such as socioeconomic disparities, geographical constraints, and institutional inequalities can provide a valuable understanding of the impediments to equitable vaccination availability.

Research Design

The present investigation employed a normative judicial research approach that relied on secondary data from extant literature and legal documents, as reported by Musarrofa et al. (2022). Legal research can be classified into two main categories: normative and empirical. The results of the normative legal study are prescriptive, as they guide how individuals ought to behave to maintain established norms and standards. According to Christiani (2016), normative legal research is restricted to the law as a subject matter, with non-legal information being excluded from consideration. According to Geovani et al. (2021), a normative juridical approach to

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research pertains to the regulations and laws that are relevant and applicable. Furthermore, this methodology is widely employed in the research methodologies of the field of legal studies. According to Pertasari et al. (2023), the normative legal research method involves investigating the historical background of current laws, legal comparisons, horizontal and vertical legal synchronization, legal systematics, legal principles, and legal products.

The study has centered on the descriptive analytical methodology typically employed to elucidate a current scenario or provide an outline of legal regulations and scrutinize and investigate specific phenomena within the purview of the law (Sehnálek, 2022). Descriptive analytics, a branch of data analytics, pertains to depicting the current state of affairs using past data. Data aggregation and mining techniques are employed to analyze data insights and facts to address the query. These tools facilitate the analysis of past behavior and aid in understanding its potential impact on future outcomes for researchers. Utilizing a descriptive-analytical approach, scholars can comprehensively examine and elucidate prevailing regulations, statutes, and protocols concerning the accessibility and counterfeiting of vaccinations within the framework of Indonesian and worldwide health legislation. Scholars can identify the benefits, drawbacks, and deficiencies inherent in the current framework through a comprehensive evaluation of the legal landscape.

Data collection

Moreover, the researchers employed a document analysis methodology to gather the requisite information for the present investigation. Document analysis involves systematically examining and assessing both physical and electronic written materials. Document analysis entails a thorough examination and comprehension of data to extract meaningful insights and generate knowledge based on empirical evidence, akin to other qualitative research analytical methods. Using document analysis as a triangulation technique is a common practice in conjunction with other qualitative research methods. The qualitative researcher is expected to employ multiple sources of documentation to seek convergence and confirmation through diverse data sources and research methods. The sources utilized in research encompass a variety of mediums, such as records, interviews, unbiased observation of respondents, and physical artifacts, as noted by Bowen (2009). Within the present research framework, all legal documentation and regulations are interconnected with health law, specifically focusing on medical emergencies and unforeseen outbreaks of infectious diseases. In addition, the researcher obtained secondary data from various sources, including institutional reports, online resources, regulatory documents, scholarly publications, books, and digital libraries. Scholars analyze legal tactics, establish optimal methodologies, and grasp the importance of diverse legal frameworks by examining records from Indonesia and other countries or global institutions.

Furthermore, statistical and analytical data from the World Health Organization (WHO) was utilized as evidence. The World Health Organization (WHO) is a specialized agency of the United Nations (UN) that is dedicated to promoting and facilitating access to medical health on a global scale. World Health Day is observed

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annually on April 7th, a commemoration established in 1948 (Sax et al., 2009). The World Health Organization (WHO) establishes partnerships with various governmental entities and law enforcement organizations to address medical crises and other health-related concerns and affairs. Providing high-quality healthcare services to individuals globally, without discrimination, has been effective (Bodrud-Doza et al., 2020; Mansoor, 2021). Additionally, a growing body of research examines the legal aspects of ensuring equitable access to the COVID-19 vaccine and preventing the distribution of counterfeit vaccines. The present investigation has additionally gathered legal data within an emerging country, specifically the Indonesian milieu, to assess the efficacy of established laws and regulations in safeguarding the basic health entitlements of the populace and their protection against fraudulent producers and suppliers of medication.

Results

- *Individuals' Rights and Access to A COVID-19 Vaccine Globally*

According to Saah et al. (2021), the COVID-19 pandemic has posed a significant threat to the global community, with potential ramifications for economic stability, social relationships, and human well-being. Governments across the globe have implemented various measures to address the adverse impact of the COVID-19 pandemic. These measures include extensive public health interventions such as physical distancing, widespread use of masks, contact tracing, and diagnostic testing, as Qing et al. (2021) and Mansoor (2021) reported, subsequently, upon the recognition by the competent authorities that the vaccine was the sole remedy for the dissemination of COVID-19. Aldila et al. (2021) reported that healthcare centers have intensified vaccine development efforts. Consequently, the global community observed the rapid development of the COVID-19 vaccine within the annals of medical history. The subsequent obstacle pertained to the equitable distribution of the COVID-19 vaccine, irrespective of any predispositions, as posited by Hamma-Adama and Labaran (2021). Consequently, there has been a call for global legal reforms to ensure equitable access to the COVID-19 vaccine for all individuals. The present study's primary objective is to examine the accessibility and modifications of worldwide health regulations to ensure equitable dissemination of vaccines to all impacted individuals worldwide, following fundamental global health laws and the rights of all individuals.

Forman and Kohler (2020) assert that human rights laws establish a legal structure for human rights on a global scale, which facilitates the gradual realization of individual access to vaccines. The COVID-19 pandemic threatens not only individuals' health and lifespan but also imposes a significant burden on vulnerable populations, including those who are marginalized, disadvantaged, sick, and impoverished, on a global scale. The COVID-19 pandemic threatens not only individuals' health and longevity but also vulnerable populations, including those who are marginalized, disadvantaged, sick, and impoverished, on a global scale. The legal framework of human rights law serves as a universal foundation for the progressive realization of vaccine accessibility. According to Gostin, Karim, and Mason Meier (2020), COVID-19 poses a threat not only to health and life expectancy but also to a greater extent to individuals who are economically disadvantaged, ill, socially disadvantaged, and marginalized.

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Numerous individuals across various global regions have received vaccinations against the coronavirus. Additionally, certain countries have proposed the implementation of vaccine passports, which would be available to individuals who can provide proof of vaccination. The primary objective of the vaccination passports implemented by governments is to enable individuals to resume their work, access public venues, attend large gatherings, and travel while safeguarding public health and personal safety (Osama, Razai, & Majeed, 2021). Furthermore, it has been observed that the administration of COVID-19 vaccines was initially prioritized in developed nations, while low-income countries experienced delays and inefficiencies in their vaccine distribution. In light of this circumstance, the World Health Organization has issued a cautionary statement indicating that the global community is on the brink of a catastrophic ethical breakdown—the study conducted by Osama et al. (2021). According to So and Woo (2020), insufficient efforts and nationalism have resulted in approximately 25% of the global population being unable to access the vaccine by the conclusion of 2022. The circumstance mentioned above is likely to exacerbate the pre-existing global north-south dichotomy. It has engendered a scenario wherein individuals from high-income nations can embark on international travel and avail themselves of the convenience of vaccination. In contrast, their counterparts from low-income countries are precluded from traversing the globe and cannot access the vaccine.

The health policy paper examined by Wouters et al. (2021) highlights the presence of several bilateral agreements between vaccine manufacturers and various governments. These agreements can potentially impede the supply of vaccine doses outside of COVAX, posing a significant threat. According to the authors, high-income nations have provided nominal support to COVAX while procuring ample vaccine doses for their populations. According to Wouters et al. (2021), a significant disparity exists in the distribution of the top five coronavirus vaccines, with approximately 70% of the available doses being obtained by a mere 16% of the world's population in 2021. As a result, numerous regions across the globe remain devoid of any vaccination doses, while conversely, other regions have achieved higher levels of vaccination coverage among their populace. According to Wouters et al. (2021), it would be advantageous for countries to establish agreements with COVAX that allocate a just and predetermined proportion of vaccines to each country based on bilateral agreements.

Upon recognizing the limitations of national measures to contain the spread of the pandemic, competent authorities across the globe acknowledged the COVID-19 vaccine as the sole remedy for the lethal virus, leading to its development within a matter of months (Kanozia & Arya, 2021). Establishing global governance was deemed necessary for ensuring universal vaccination coverage worldwide. Therefore, the World Health Organization (WHO) has declared that all countries can offer free access to COVID-19 vaccines without any profit motive (Ndwandwe & Wiysonge, 2021). The temporal evolution of the governmental response to the pandemic in Indonesia is depicted in Figure 1.

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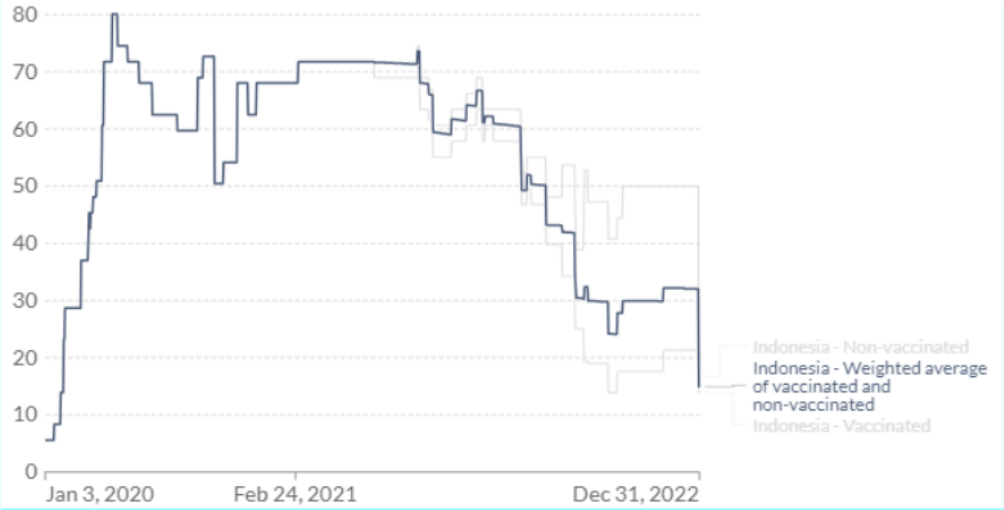

Figure 1. Government Stringency Index
Source: (Mathieu et al., 2022)

Gavi, the Vaccine Alliance, was the initial Global Public-Private Partnership (GPPP) entity to procure COVID-19 vaccines in large quantities at reduced prices. Additionally, Gavi collaborated with market communities to facilitate the accessibility of COVID-19 vaccinations for individuals. Concurrently, coalitions such as the Epidemic Preparedness Innovations (CEPI) were established to facilitate the widespread availability of the COVID-19 vaccine. Simultaneously, the World Health Organization (WHO) has collaborated with the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi to facilitate the COVID-19 Vaccine Global Access (COVAX) Facility and institute a novel Global Partnership for Pandemic Preparedness (GPPP). Furthermore, the WHO Pandemic Influenza Preparedness (PIP) Framework is a global instrument that mandates governments to exchange genetic sequences and biological specimens to expedite the development of COVID-19 vaccines (Kheirallah et al., 2022). Furthermore, it promoted the fair distribution of vaccines on a global scale. Nonetheless, the scope of this framework is restricted to pathogenic agents that cause pandemics.

Despite the efforts of multiple Global Public-Private Partnerships (GPPPs) aimed at raising awareness and promoting knowledge exchange to advance COVID-19 vaccine research, a deficiency persists in the form of a universal regulatory framework to ensure equitable distribution of COVID-19 vaccines worldwide, rather than hoarding them (Kheirallah et al., 2022). Therefore, establishing a unified agreement for sharing vaccination benefits through global governance can guarantee the fair allocation of vaccinations on a global scale. The tension between public health and intellectual property rights challenges the accessibility of the COVID-19 vaccine (Halbrook et al., 2022). Following the governance of the World Trade Organization, the Trade-Related Aspects Of Intellectual Property Rights (TRIPS) offer patent protections that enable the monopolization of vaccine production, resulting in the

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maximization of profits and rendering life-saving medicines unaffordable (Jecker & Atuire, 2021).

In 2001, the World Health Organization (WHO) issued the Doha Declaration, which granted lower and middle-income countries flexibility concerning Trade-Related Aspects of Intellectual Property Rights (TRIPS) to safeguard public health (Aji, 2022). Furthermore, it was imperative to expedite the production of vaccines in lower and middle-income nations by augmenting their vaccine manufacturing capabilities by disseminating technical production procedures and providing novel legal frameworks (Runtunuwu & Kotib, 2021). To address these concerns, fruitful negotiations were conducted by the Medicines Patent Pool and UNITAID, with an international patent clearing house, to facilitate the production of vaccines at an affordable cost (Khan et al., 2020). Concurrently, the COVID-19 Technology Access Pool (C-TAP) has acknowledged the intricate nature of producing cost-effective vaccines and has consequently resolved to exchange information and expertise by remunerating patent holders, irrespective of intellectual property rights.

- *Global Laws/ Regulations/ Measures Linked with Prevention of Counterfeiting of COVID-19 Vaccine*

The increasing importance of COVID-19 vaccines has resulted in several adverse outcomes, including various difficulties and temporal limitations, as noted by Jecker and Atuire (2021). The demand and supply of high-quality health products and essential medicines give rise to various issues. According to Yahaghi et al. (2021), there has been an increase in the sale of falsified healthcare products. Moreover, there has been a significant surge in the counterfeiting of medications essential for managing COVID-19. Counterfeit products associated with COVID-19 were found to include medical supplies and antiviral medications such as soap, cleaning wipes, gels, disinfectants, ventilators, gloves, coronavirus testing kits, face masks, herbal medicines, antibiotics, painkillers, vitamin C, and antimalarial chloroquine (Ziavrou et al., 2022).

Moreover, there have been reports of fraudulent individuals marketing counterfeit COVID-19 vaccines in various regions across the globe. Before the onset of the COVID-19 pandemic, the global community was already grappling with a number of difficulties stemming from inadequate legal and regulatory structures pertaining to the production and distribution of fraudulent medical goods and cyber security vulnerabilities. The COVID-19 pandemic has exacerbated pre-existing deficiencies and challenges at an expedited rate.

The COVID-19 pandemic necessitated modifications to the prevailing healthcare system, including revised laws and regulations, as a protective measure for the global population, even though healthcare and medicines regulatory agencies were present in less than 30% of the affected regions (Mishra et al., 2021). The counterfeiting problem was initially brought to attention and resolved during the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985 (Cheruto, 2021). Consequently, several measures were implemented to combat counterfeit or pharmaceutical-related offenses. After this, the World Health Organization (WHO) issued a circular in 1992 entitled "WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs" (Sweileh, 2021). In 2006, the International Medical

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Products Anti-Counterfeiting Taskforce (IMPACT) was established to form a coalition among non-governmental organizations, industry, enforcement agencies, and international organizations to address the issue of counterfeit health products facilitated by criminal networks on the Internet (Ziavrou et al., 2022). Concurrently, in 2013 and 2017, the World Health Organization (WHO) initiated its worldwide system for surveillance and monitoring of counterfeit and inferior in-vitro diagnostic tests, vaccines, and medications. Hagen, Hauk, and Heide (2022) proposed a three-pronged approach to combat counterfeit pharmaceuticals involving detection, response, and prevention.

Subsequently, in 2019, The United Nations introduced a comprehensive manual to elucidate the essential measures for averting offenses related to counterfeit pharmaceuticals. Simultaneously, there was an increase in the pace of collaboration between drug control and law enforcement agencies at both international and local levels to combat the distribution and sale of counterfeit pharmaceuticals. Following the detection of a smuggling enterprise involving the distribution of Lipitor medication in the United Kingdom, regulatory bodies initiated a recall of more than 18 million atorvastatin tablets (White, 2021). According to Ziavrou et al. (2022), approximately 2,000,000 oral contraceptive tablets were intercepted from being illicitly imported into the United States. Similarly, according to a report by the US Food and Drug Administration (FDA) in 2019, a total of 1159 batches of irbesartan, losartan, and valsartan were recalled due to elevated levels of N-Nitrosodiethylamine (NDMA) (Ziavrou et al., 2022).

The effective implementation of vaccination to boost and achieve community immunity was crucial in controlling the potential effects of the coronavirus. In response to the COVID-19 pandemic, several pharmaceutical companies, such as Covishield, Covaxin, and Pfizer, have developed and launched their respective vaccines to mitigate the spread of the virus (Kumar et al., 2021). Governments and companies encountered several challenges in effectively executing their vaccination and immunization initiatives. These challenges included data tampering, security concerns related to patient registration, distribution of vaccines, vial security, and counterfeiting, as Ramakanth et al. (2021) noted.

Ramakanth et al. (2021) reported that the United States Food and Drug Administration had established standards and guidelines for vaccine manufacturers to monitor the temperature of vaccines and minimize their storage. In anticipation of the potential adverse effects of waste on individuals, UNICEF procured auto-disabled syringes as a preventive measure for the COVAX initiative in 2021. UNICEF has procured one billion auto-disabled syringes for this objective. Vaccine packaging is crucial in ensuring prompt and appropriate delivery to end consumers. To mitigate potential risks associated with vaccine transportation and delivery, the packaging system has been designed to incorporate secondary and tertiary packaging and the primary packaging of glass vials. Furthermore, Ramakanth et al. (2021) have highlighted the significance of cushion packaging as a crucial measure to avert the occurrence of breakage and cracking of glass bottles containing vaccines during their storage and transportation, a notion that the World Health Organization has endorsed.

Moreover, the International Criminal Police Organization (INTERPOL) has played a noteworthy role in identifying counterfeit items. Deflem (2022) reported that

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Pangea XIII conducted global operations in March 2020, resulting in approximately 34,000 counterfeit medical goods being seized. The operation was prompted by identifying illicit medical devices and medicines associated with COVID-19. The text above highlights the collaborations between professionals in counterfeit goods, illegal trade, law enforcement, customs, healthcare regulations, and cyber and financial crimes. The initiative integrates the objectives of 194 member nations on a global and regional scale to combat counterfeit and illicit activities associated with the pharmaceutical industry. Additionally, it collaborates with the International Intellectual Property Crime Investigators College to facilitate webinars and online training sessions to improve various agencies' capabilities in addressing crime threats related to COVID-19 (San, 2022).

The United Nations Organization for Drugs and Crime (UNODC) has implemented various measures to increase public awareness regarding counterfeit products. One such initiative is disseminating messages such as "Counterfeit: Don't Buy," which aims to educate individuals about the dangers of counterfeit products and organizations, thereby preventing them from falling prey to such fraudulent activities (Manduca, 2018). The I-Check it initiative, also known as "INTERPOL Check it," has been developed to offer the general public product verification tools that can be used to differentiate between authentic products and counterfeit ones (Feddema et al., 2020) and within the framework of Operation Pangea XIII, member countries of INTERPOL implemented diverse initiatives, including presentations and displays at educational and medical institutions, dissemination of pamphlets and audiovisual materials aimed at augmenting public consciousness about the perils of counterfeit pharmaceuticals, discouraging their purchase, and promoting vigilance against fraudulent online sources.

- *Individuals' Rights and Access to COVID-19 Vaccines in Indonesia*

Indonesia has implemented various regulations about the accessibility of fundamental healthcare amenities to all citizens, irrespective of any form of discrimination, across the nation. The 1945 Constitution of the Republic of Indonesia stipulates in Article 28H clause (1) that every individual is entitled to the right to lead a prosperous life, both physically and mentally, and to have access to adequate housing and a healthy living environment. Clause (2) stipulates that each individual is entitled to receive convenience and customized assistance to attain equal opportunities and advantages toward fairness and impartiality. The abovementioned regulations fall within the purview of "Law No. 4 of 1984 on Infectious Disease Outbreak and Law No. 6 of 2018 on Health Quarantine". The laws mentioned above pertain to the ingress and egress of individuals to and from locations designated for outbreak containment, including quarantine, isolation, and vaccination.

Furthermore, the legal statute numbered 36 of 2009 about health outlines the regulatory standards for public health. This statement elaborates on the entitlement of individuals to access healthcare services. Concerning the COVID-19 pandemic, there is a need to ensure equitable distribution of vaccines to all population members without discrimination or prejudice. Furthermore, the legal framework in Indonesia upholds ethical principles associated with healthcare regulations. According to Article 56 clause (1) of the Law on Health, individuals are entitled to either accept or

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decline any or all medical interventions proposed to them, provided they have been presented with and comprehended all relevant information about the intervention. The provision outlined in Article 56, Clause 2 of Law No. 36 of 2009 on Health may apply to implementing measures aimed at controlling and treating COVID-19. The statement mentioned above posits that individuals afflicted with a contagious ailment that has the potential to rapidly and extensively spread throughout the populace is not entitled to exercise their right to accept or decline certain courses of action. This measure is implemented to safeguard the general public from the adverse effects of such diseases. Therefore, the integration of justice, law, and ethics in addressing social safety concerns is deemed imperative in upholding the basic rights of the populace. Concurrently, the provision outlined in "Article 45 of Law No. 29 of 2004 on Medical Practices" serves as a protective measure for the rights of citizens, mandating healthcare professionals to disclose all pertinent information before initiating medical procedures.

Simultaneously, it is noteworthy that individuals are entitled to participate, as delineated in "Article 32 letter k of Law No. 44 of 2009 on Hospitals." The provision specifies that patients possess the agency to either consent to or decline the actions of healthcare professionals, and their endorsement holds significant value in managing the ailment. Article 56 clause (2) appears to contradict the Law on Health by prioritizing individual rights over the welfare of society. Nevertheless, governments retain the authority to make collective decisions about infectious diseases, such as the current COVID-19 pandemic. Conversely, it is incumbent upon the state to discharge its duties with honor and in the optimal interest of its citizens, as posited by Lasmadi (2021).

Therefore, it can be asserted that the patient's entitlement to treatment for various illnesses is explicitly outlined in the constitutional framework of the Indonesian Republic. The text provides a lucid exposition of the governmental policies and regulations about infectious diseases, focusing on the involvement of the general populace as opposed to individual patients. Therefore, considering the existence of regulations about the Declaration on Human Rights, the Law on Hospitals, the Law on Medical Practices, the Law of infectious diseases outbreak, and the Law of Quarantine, among others, it can be posited that the government bears the responsibility of ensuring the equitable and impartial provision of COVID-19 vaccines to all citizens as a fundamental entitlement. Alternatively, the government possesses the power to address contagious illnesses most advantageously for the general population. As a result, the government may enforce and require citizens to receive the COVID-19 vaccine to mitigate its dissemination, safeguard the entire nation, and attain optimal public health.

The COVID-19 pandemic has emerged as a significant issue in Indonesia since the initial detection of the virus. The initial shipment of the COVID vaccine arrived in Indonesia and was poised for dissemination to the wider populace in January of 2021. In June 2021, the Indonesian government implemented measures to guarantee the availability of vaccination supplies within the country. However, the vaccination rate per 100 citizens was reportedly 143 doses, significantly lower than the global average of 375 amounts per 100 citizens. This information was reported by BBC News (2021).

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Furthermore, Puspita (2021) noted that Indonesia encountered obstacles in distributing vaccines to remote regions, particularly those across the archipelago. The Indonesian government was responsible for the distribution and accessibility of vaccinations to patients. The individuals in question implemented measures to prevent adverse outcomes during the measurement process, administer vaccines, and regulate the parameters of vaccination. As such, they were the principal agents responsible for these actions. The administration of vaccinations to private institutions was carried out following the prevailing regulations. The action mentioned above has elicited inquiries and concerns about the ethical comportment of non-public entities, as posited by Aziz, Tavares, and Azhima (2021).

Moreover, this issue pertains to matters of social justice and human rights, specifically regarding the vaccine's status as a public good and the Indonesian government's commitment to the nation's welfare. Indonesia is classified as a state with a minimal welfare model due to the limited and intermittent provision of welfare programs and social security (Aziz et al., 2021). As per the 1945 constitution of Indonesia, it is incumbent upon the government to ensure the provision of fundamental services and necessities to its citizens and foster the welfare state. The government should prioritize the equitable distribution of COVID-19 vaccination in Indonesia without discriminatory policies. As per the provisions of the constitution, it is the government's responsibility to fulfill the fundamental human rights of its citizens, which encompasses the right to healthcare. As per the provisions of the constitution, it is mandatory for the government to furnish social security and fundamental amenities to its citizens, with a special emphasis on healthcare services, and to uplift the underprivileged and susceptible segments of the community. The independent vaccination policy of the Indonesian government has raised several issues and concerns due to its potential to result in unequal distribution of COVID-19 vaccines and immunization. According to Aziz et al. (2021), it was observed that individuals received vaccinations despite not meeting the standard eligibility criteria or receiving them earlier than necessary.

- *Laws/ Regulations/ Measures Linked with Prevention of Counterfeiting of COVID-19 Vaccines in Indonesia*

As for legal issues, Indonesia has specific regulations regarding counterfeit pharmaceuticals and vaccines. As an amendment to the 1945 Constitution of the Republic of Indonesia, Act No. 36 of 2009 recognizes health as a human right and a requirement for community welfare. Moreover, issues such as counterfeit vaccines that pose health risks result in significant economic losses for the nation. Alternatively, advances in a nation's public health reflect the nation's progress and the well-being of its citizens (Wardiono et al., 2021). Therefore, states that view the control of viruses and the provision of vaccines to the populace as their responsibility are always economically successful and grow rapidly (Amankwah-Amoah & Hinson, 2022). This study's primary focus is examining the criminal laws and regulations, as well as the health protection laws, applicable to COVID-19 vaccine counterfeiting in Indonesia.

The vaccination is a preventative measure against the coronavirus pandemic, as stipulated by Article 28 H (1) of the Indonesian Constitution 1945. According to this

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article, every Indonesian citizen has the right to spiritual and material well-being. Their right is to have a safe place to reside, a healthy and pleasant living environment, and access to quality health services. Vaccination is now a fundamental health entitlement for Indonesian citizens to receive quality health care. In addition, article 28 H (2) states that every individual has the right to receive special treatment in institutions to achieve justice and equality in society. This article emphasizes the significance of an individual's right to good health, which must be carried out just and equitably, such as through vaccination distribution and immunization. In the interim, Article 34 (3) establishes that a state is liable for providing its citizens with adequate healthcare facilities and health services (Aziz et al., 2021).

In recent years, counterfeiting in multiple industries, including the health sciences, in counterfeit medicines and fake vaccines, has reached a hazardous level affecting individuals of all ages. This counterfeiting offense also violated "Article 386, Paragraph 1 of the Criminal Code about fraud and forgery, and Act No. 36 of 2009 about the health law." In addition, the safety and use of vaccines in Indonesia are governed by "Article 98, Article 104, Article 105, Article 106, and Article 108 of Health Act No. 36 of 2009." In addition, "Article 98 requires that pharmaceutical preparations and medical devices be safe, nutritious/beneficial, of high quality, and reasonably priced." In addition, "Articles 196, 197, 198, and 201 of Act No. 36 of 2009 concerning Health" govern the punishment and abundance of manufacturers and distributors of falsified vaccines in Indonesia.

In addition, under "Article 98 paragraph (2) and paragraph (3)," anyone who intentionally manufactures and distributes falsified pharmaceutical products and medical equipment that do not meet international standards for security, safety, efficacy, and quality is subject to "imprisonment for a maximum of ten (10) years and a maximum fine of one billion rupiahs" according to Article 106 paragraph (1), anyone who manufactures or distributes pharmaceutical products without a distribution permit is subject to "imprisonment for up to 15 (fifteen) years and a maximum fine of IDR 1.500.000.000. 00 (one billion five hundred million rupiahs)" (Lasmadi, 2021).

In addition, these laws address the authenticity of semi-finished drugs into completed drugs and impose severe penalties for counterfeit medical equipment and drugs. Concurrently, the government has specified some good drug manufacturing practices (CPOB) with certain quality requirements that all drug manufacturers must meet to maintain the quality of pharmaceuticals and ensure public health (Azka & Firdaus, 2023). Lastly, following the criminal act presented in "Article 190 paragraph 1, Article 191, Article 192, Article 196, Article 197, Article 198, Article 199, and Article 200," specifically impose penalties on institutions committing counterfeiting crimes independent of individuals and management with three times the weightage of criminal fines (Munawaroh & Ayuningtyas, 2019). In addition, they may face the revocation of their business licenses and legal entity status if they commit the offense of counterfeiting medicines.

These laws and regulations provide an adequate regulatory framework in Indonesia for providing health services to the populace and safeguarding them from ingesting counterfeit medicines, which pose health risks. To provide the public with the greatest health benefits, it is necessary to analyze the implementation of these laws and regulations in the presence of accountability cells.

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Discussion

WHO defines health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (Lasmadi, 2021). Simultaneously, no individual or institution was granted intellectual property rights. In addition, human rights law establishes an international legal basis for providing vaccine access to the populace. The global supply chain's affordability, acceptability, and accessibility, as well as the widespread production of COVID-19, facilitated simple access to the general population (Amankwah-Amoah, 2021). Global governance contributes to keeping prices low by assuring global distribution and boosting industrial production via Global Public/Private Partnerships (GPPPs) (Legrand & Stone, 2021). Since then, the Indonesian government has attempted to combat the COVID-19 pandemic by implementing the necessary regulations, such as restricting community events and increasing financing for the healthcare sector and social support for those affected. The Indonesian government launched the PEN Programme (National Economic Recovery Program) as the primary tool to manage the health and financial downturn caused by the pandemic in 2020 and 2021 (Putera et al., 2022). The Indonesian government has decided to combat COVID-19 using the Contagious Diseases Law rather than the Emergency Situation Law. The Contagious Diseases Law specifies the guidelines for establishing infection boundaries and managing activities. According to this law, the Ministry of Health may designate specific areas as infectious based on epidemiological and local factors (Sulistiawati, 2020). Due to the severity of COVID-19, the Indonesian government has decided to initiate a pervasive social quarantine. It entails shutting down schools and places of worship and producing social distance in public spaces.

In addition, several countries (including the United States, Switzerland, South Korea, Singapore, New Zealand, Morocco, Mexico, Japan, the European Union, Canada, and Australia) took collective actions against COVID-19 vaccine counterfeiting under the Anti-Counterfeiting Trade Agreement (ACTA), the European Medicines Agency (EMA), the US Agency for International Development (USAID), the Food and Drug Administration (FDA), and the Directive 2011/62/EU. In addition, the Bill & Melinda Gates Foundation, the Global Fund, the United Nations Population Fund, and the United Nations Children's Fund (UNICEF) have undertaken numerous initiatives to trace counterfeit medicines and medical equipment made possible by new technologies. Several programs have been initiated in some lower-middle-income countries (LMIC) to strengthen regulatory agencies to encourage and assure quality, affordable, safe, easily accessible, and appropriate medicines. In addition, prominent forums have highlighted the significance of legitimate pharmaceutical manufacturers in the struggle against pharmaceutical counterfeits (Ziavrou et al., 2022).

Like other developing nations, the Indonesian government prioritizes the welfare of its citizens by providing education, housing, food, and essential health care (Syahza et al., 2020). Certain laws, acts, and regulations govern various domains of life, including the healthcare sector, to provide these services to the citizens and enable them to achieve economic prosperity (Lestari et al., 2021). Health laws encompass all regulations and rules about the care and maintenance of harmed or endangered health (Yusri, 2022). A combination of criminal and civil law also serves as the legal foundation for health services. Following Indonesian law, the state is obligated to

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carry out for the benefit of society those laws that are essential to its welfare (Lasmadi, 2021). Following "Articles 1-6 of Act No. 9 of 1960, which were revised by Act No. 23 of 1992 and then revised again by Act No. 36 of 2009 concerning Health," the implementation of the fundamental health rights of citizens is the responsibility of doctors and health workers who have been designated as authorized state operators (Bella et al., 2021).

Conclusion

Given the importance of the COVID-19 vaccine in preventing widespread infection with the fatal virus and loss of life, the current study has focused on the availability of international laws and highlighted the fundamental rights of individuals to have justifiable and easy access to the COVID-19 vaccine globally. It has also addressed the COVID-19 vaccine counterfeits and the availability of international laws to combat them. In addition to the objectives mentioned above, the current study evaluated the laws governing the rights of citizens to access COVID-19 vaccination and their protection against counterfeit COVID-19 vaccines in the low- and middle-income country of Indonesia. Using normative judicial research methodology based on secondary data from available literature and legal documents, the results revealed that various international organizations and agencies protected the rights of individuals to access the COVID-19 vaccine. Several international laws and regulations exist concurrently to address COVID-19 vaccine counterfeits. However, regulatory authorities, governments, and practitioners must consider certain flaws to safeguard the populace from becoming victims of these counterfeits.

Similarly, the results revealed the laws and regulations in Indonesia about infectious diseases, the provision of health care protection for citizens, the right of patients to have equal access to the COVID-19 vaccine, and the protection against counterfeit medicines. However, the government should mandate the implementation of these laws with stringent measures to guarantee the safety of public health. The current study is a valuable addition to the existing corpus of literature because it presents a consolidated discussion of general laws and regulations and recommendations for the future course of action in developed and developing nations. In addition to offering international laws, it also discusses the case of a developing country as a foundation for future researchers.

- *Recommendations*

With the assistance of ongoing industry efforts, there is a dire need to accelerate the anti-counterfeiting teams' efforts to identify and combat counterfeit medicines worldwide. These teams also aid in the detection of unlawful counterfeit drugs through the use of cutting-edge technologies and the development of measures to make the production of counterfeits difficult. Concurrently, pharmaceutical industries must have the necessary facilities to strengthen their working relationships with health and regulatory authorities and law enforcement agencies to trace and deal with counterfeit medications, medical equipment, distributors, and manufacturers. Due to the critical nature of detecting counterfeit pharmaceuticals, deduction methods must be improved regarding reliability and actual applicability.

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For instance, the visual inspection of suspected product packaging must be strengthened. The system for inspecting seals and scanning barcodes for counterfeit and incorrectly labeled drugs should be vigilant. Implementing Roman and (Infrared spectroscopy) IR spectroscopy-optimized geometric models is necessary. In addition, methodologies based on GC-MS or LC- that use subsequent analysis to detect the falsification of suspected or falsified samples must be introduced and accelerated. In addition to these efforts to combat counterfeit pharmaceuticals, there is an urgent need to increase public awareness through seminars and online focus groups utilizing multiple digital channels and intensive advertising. In addition, citizens must be educated to distinguish between information regarding medicines and healthcare facilities and evidence-based claims.

In addition, the need for global health law increased to rigorously implement the measures initiated by the C-TAP to make COVID-19 vaccine licenses feasible for low- and middle-income nations. This issue can be resolved following global health laws and national vaccine regulations. In addition to the efforts of the World Health Organization (WHO) to expedite the global availability of COVID-19 vaccines with simple access for the masses, there is a need to harmonize national approval processes to circumvent national governments' stringent regulatory requirements. Based on global concerns about the COVID-19 vaccine's efficacy and safety, there is a need to reduce national regulatory obstacles during the vaccine's approval process in various nations. Similarly, there is an urgent need to strengthen the regulatory capacity of low- and middle-income countries to address the issues of substandard or counterfeit products entering the pharmaceutical sector and delayed implementation.

Lastly, the pharmaceutical industry should be entirely accountable and involved in the fight against falsified drugs, especially the COVID-19 vaccination. To accomplish this, they can provide leverage to patients in low- and middle-income countries by lowering the prices of original pharmaceuticals and other facilities. They must also ensure the security of the supply chain by employing vigilant storage and distribution procedures. Likewise, they should not rely solely on limited pharmaceutical supply sources. Instead, they should diversify their supplies to ensure prompt and continuous global supply. In addition, domestic production of raw materials should be encouraged and facilitated to shorten the supply chain and guarantee the authenticity of products by minimizing supply chain disruptions. In addition, regulations, transparency, and accountability procedures must be outlined to monitor the manufacturing sites of medical ingredients and medications to ensure uninterrupted quality control.

- *Limitations and Future Research Directions*

To improve the quality of public health, future researchers must consider the limitations of the current study, despite its numerous strengths. The current study focused on the availability of the COVID-19 vaccine to the general population worldwide, specifically in Indonesia, a developing nation. In contrast, future researchers will be able to compare the availability and access of citizens from various nations to the COVID-19 vaccine by contrasting laws and regulations to provide valuable recommendations for countries with inadequate systems to control infectious diseases. In addition, the current study revealed the existence of laws and

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regulations that address the counterfeiting of COVID-19 vaccinations in international forums and the context of developing nations. However, neither the application of these laws and regulations nor the resulting cases were reported during COVID-19. Therefore, future researchers will be able to identify and report such issues to demonstrate the significance of existing laws and regulations and the need for further amendments in case of loopholes. In addition, it is necessary to provide an overview of the regulatory bodies charged with upholding transparency, accountability, and the strict application of the law in the public's best interest. Future researchers can expand the literature on the availability of COVID-19 vaccinations and the intellectual property rights of coping with counterfeits in other disciplines to protect the general public from their consequences.

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