The International Conference on Interdisciplinary Humanities and Communication Studies
DOI: 10.54254/2753-7048/4/2022279

Unequal Accessibility to COVID-19 Vaccination Calls for Improvements for Future Pandemics

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Abstract: COVID-19 vaccine accessibility emphasized the importance of balancing the TRIPS Agreement to support both research and societal goals. From 2020 to 2022, the TRIPS waiver was proposed, opposed, and countries now reached an agreement on the compromised waiver, but it has still received much criticism. Furthermore, the current situation of unequal accessibility emphasizes the importance of reforming the system of intellectual property protection to ensure the human right of individuals in low-middle-income countries. The essay analyzed the measures used in two past cases, which are HIV/AIDS and cancer, to allow for equal accessibility treatment, combined with the current situation of COVID-19, to suggest future improvements required for states to be more prepared for the next pandemic.

Keywords: Accessibility to medical treatment, Inequality, COVID-19, TRIPS Agreement, WTO, WHO

1. Introduction: Current Situation in Covid-19 and Proposals for the Vaccine Waiver

1.1. Three-year Waiver Proposal

Due to unequal access to COVID-19 vaccines between countries, India and South Africa petitioned for a temporary waiver of IP rights for vaccines treating COVID-19, aiming to increase the number of manufacturers globally, increase supply, and make vaccines to be more affordable to low-middle-income countries (LMIC), since no single nation can combat either COVID-19 or future pandemics [1].

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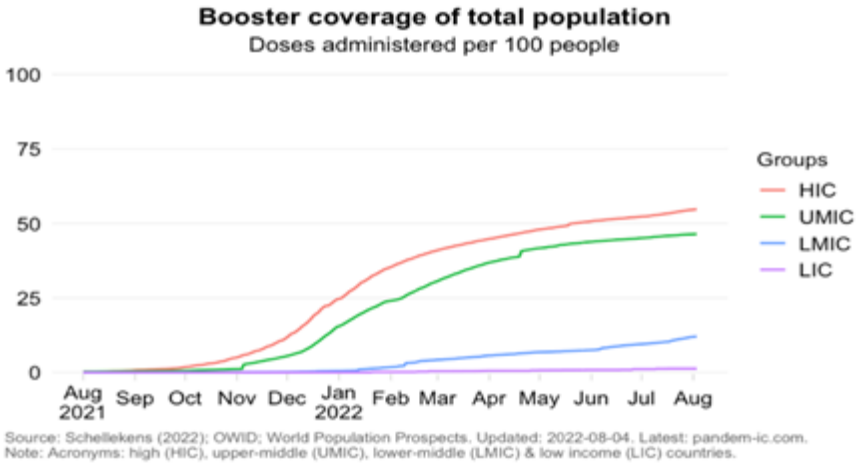

Figure1： Booster coverage in high (HIC), upper-middle (UMIC), lower-middle (LMIC), and low-income countries (LIC) of the total population [2].

1.2. The Opposition to the Waiver Proposal

The UK and the EU opposed the proposal, with the EU proposing the use of existing TRIPS flexibilities for the compulsory license as an alternative to a waiver.

1.3. Compromise on the TRIPS Waiver Agreed

WTO-led negotiation between the Quad group, comprising EU, India, South Africa, and the US, reached a compromise on May 3 on the TRIPS waiver much narrower than the proposals that South Africa and India initially put out [3]. Most provisions concentrate on waiving particular patent-related requirements for vaccinations and the ingredients and processes necessary to manufacture the vaccines under paragraphs 1 and 2 [4]. In addition, it clarifies that any WTO Member can au-thorize the benefits of compulsory licenses by approving the use under their domestic law, but ex-clusively limited to vaccines. Para 3 (c) marks the only explicit waiver in the document as it removes the constraints on exporting products manufactured under the compulsory license, which is currently restricted under Article 31 (f). According to paragraph 5, WTO Members must inform the TRIPS Council of any compulsory licenses they grant due to the waiver [5]. Overall, for five years, the developing nations will be permitted to use patented components and materials for producing COVID-19 vaccines for local and approved export markets [6]. Notably, the draft text does not include 'trade secrets' being shared, which protects the complex manufacturing processes of vaccine production. The waiver without trade secrets could be meaningless as it does not provide a mechanism to address vaccine production and supply challenges [7].

Even though the compromise deal was agreed upon, countries and businesses have criticized the agreement. At the same time, some companies expressed concerns about the extension, as many COVID-19 treatments are used to treat other infectious diseases [8].

2. Impact of IP System on Low-income Countries

It has long been argued that the IP system significantly impacts LMICs. The compulsory license mechanism is present in most patent regimes, and the TRIPS Agreement recognizes it as a legal option or flexibility. However, its practical use can be constrained for states with little or no pharmaceutical manufacturing capacity. By the revised Article 31bis of the TRIPS Agreement, low-cost generic drugs can be produced and exported with a compulsory license to satisfy the demands of

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countries unable to do so [9]. The TRIPS flexibilities have been used a few times, the most commonly applied of which include the Doha Declaration on transition provisions and Article 31 of TRIPS on compulsory licensing [10].

Pharmaceutical corporations and the host governments, primarily in the Global North, have consist-ently fought against the international consensus on IP, which has continued in the current COVID-19 crisis [11]. As a result, there is a trend to circumvent TRIPS flexibilities in bilateral and multilat-eral free trade agreements ("TRIPS-plus" measures) that "use TRIPS as a minimum standard but push for stronger intellectual property rights (IPR) protections" [12].

BMJ journal compares the regulations to colonial framing, stating that “many low-income countries have long been active in resisting the IP system as an unjust extension of a colonial trade system” [13]. Due to limited knowledge of the manufacturing or regulatory procedures in many countries, political and economic constraints, and lack of transparency for COVID-19 vaccines, the IPR sys-tem can worsen global health disparities [14]. The lack of vaccine access can entrench inequalities between and within countries [15, 16]. Decolonizing human rights in health is a transformational initiative for Global South nations, helping to ensure that vaccines are administered "equitably, transparently, freely, and universally." [17]

3. Potential Waiver Prompting Scepticism from High-income Countries

High-income countries tend to be sceptical about TRIPS waiver due to concerns about its scope, duration, and potential negative impacts on future innovation incentives and drug quality [18], in which the scope remains a crucial issue. The Biden Administration supported a narrower concept of a TRIPS waiver [19], and some other high-income countries remain sceptical, such as the EU, which has proposed alternatively for equitable vaccines and treatments [20]. Even if the WTO were to adopt a potential TRIPS waiver, it would not immediately change the states’ domestic IP protec-tions.

Facing advocates of TRIPS waiver, the Parliament Magazine argues that “the willingness to pass some sort of deal on patent waving is prevailing over common sense” [21]. Despite the accessibility to vaccines, the hesitancy is high in developing and least developed countries, such as the current situation in Malawi, and the hesitancy can be even higher when the third-party supplier produces the vaccines without patents [22].

As of 11 March 2022, just 4.4% of the population has gotten all three doses of the COVID-19 vaccine, well below 70%. Additionally, the vaccine acceptance rate is poor, necessitating increased involvement from medical professionals [23]. The vaccine hesitancy results from several interconnected variables, including confidence, practicality, and complacency, mostly brought on by multiculturalism, unstable political climate, and mistrust [24].

In addition, if the waiver passed, it could significantly impact or even destroy the future of innovation, as pharmaceutical companies might not obtain the expected repayment of their investment in vaccine development. The author claims that "the TRIPS waiver would remove every incentive for innovators to solve the world's most pressing problems." [25]

4. Past Cases of Unequal Access to Medical Treatment and Their Potential Resolutions

4.1. HIV/AIDS Treatment

Since 2000, accessibility to HIV drugs has increased dramatically in developing countries due to the combined effort of developing countries, multinational pharmaceutical companies, host governments, and intergovernmental organizations [26], with antiretroviral therapy, now reaching almost three million people [27], due to allowed access to drugs on the global political agenda, safe and effective treatment available in nations lacking resources, as well as the low prices.

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4.1.1. Clash between Healthcare Provision and Intellectual Property

The AIDS crisis has fundamentally altered conceptions of and legislation on drug or disease treatment patents [28], as the conflict between providing healthcare for AIDS patients and protecting the property rights of the global pharmaceutical sector was revealed [29]. TRIPS was enforceable through the WTO dispute resolution processes and mandates that all WTO members provide a min-imum standard of intellectual property protection [30], with the International Intellectual Protection law requiring member countries to grant patents for pharmaceutical products the same as other products [31].

Growing discontent culminated in 1999 with a call to "humanize the trade agreements", as develop-ing countries providing ARV therapy began to pay for drug patents. In addition, it strengthened International human rights law, which emphasized the right of an individual to obtain health requir-ing active intervention by governments and organizations [32].

4.1.2. Collective Effort among Countries and Organizations

During the HIV pandemic, the WTO Declaration acknowledged human rights. It permitted states to employ all the TRIPS regime's flexibility to defend public health, take advantage of the compulsory licenses, and prompt collective effort in African nations [33]. The effort of WTO cannot be ignored, even though pharmaceutical corporations and their host governments have long opposed the consensus on intellectual property since then [34]. The Doha Declaration on the TRIPS Agreement and Public Health adopted in 2001 contributed to framing the intellectual property system's context for health policy [35]. It is regarded as the first significant push back to strengthening private IP rights regardless of developing countries, vital to the widespread availability of patented medicines in generic form at cheaper prices [36], by including flexibilities to a government authority or a court to have the right to grant compulsory licenses [37].

The WHO also entered the conversation and expressed concern that IP protections for essential medication could impede human rights. As a result, it adopted resolutions granting developing nations access to TRIPS flexibilities and regarded essential medicine access as a component of the right to health [38].

4.2. Cancer Treatment

4.2.1. Compulsory Licenses Related to Cancer Treatment

According to the AMA Journal of Ethics, only two states have enacted compulsory licenses for cancer treatment to lower drug costs [39]. The minimal number of countries benefiting from the TRIPS flexibility was due to the countries being unilaterally targeted by the U.S. and reluctant to employ compulsory licensing as the U.S. reduced the cost of cancer treatments. In addition, economics can impact the states' actions relating to intellectual property rights. For example, developing and least developed countries can be unimportant to the commercial decision-making of originator pharmaceutical companies without adequate remuneration [40]. In addition, data exclusivity delays the release of generic drugs for pricey prescriptions like cancer drugs until the data protection period has passed, and thus inadvertently permits the pharmaceutical company that invented the drug to dominate the market for even off-patent materials [41].

4.2.2. Improvements in Drug Control and Expansion of the WHO Essential Medicines List

The international drug control system is another essential international agreement for determining equitable accessibility of treatment besides patent protection under the TRIPS agreement [42]. Opi-

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oid analgesics, for instance, as an essential drug for cancer treatment, are regulated as narcotic drugs under UN Single Convention on Narcotic Drugs (CND) [43], and the international legal regime has always focused more on preventing misuse than on ensuring availability, which led to the indispensability of the drugs [44].

The WHO established the Essential Medicines List (EML) in 1977, a reference for the essential medications that should be included in national formularies [45]. To secure accessibility and affordability of cancer treatment patents globally, WHO added 16 cancer medicines to the EML in 2015, which is the first significant update to the EML oncology section [46, 47]. However, through examination, only six medicines for cancer listed on the EML were still covered by patents [48]. Whereas the changes in patent status for the treatments or drugs can directly impact the affordability of essential cancer medications, the revision can be crucial for many LMICs that rely on EML to establish national formularies and to negotiate medicine pricing with organizations and public health advocates acting as well to protect the accessibility of the states in the international trade regime.

5. Conclusion: Improvements Required for Future Pandemic

5.1. Expanded TRIPS Flexibility

Strict patent protection continues to be a barrier to medication access, despite recent steps taken in the right direction to serve the interests of low-income populations. Increasingly, developed countries face even more robust IP protection than TRIPS Agreement, and host companies might continue to sue developing governments. Additionally, the flexibility can result in fewer pharmaceutical companies entering their markets [49].

According to Hoen, some nations, including South Africa, have not yet fully utilised the flexibilities. This demonstrates that the TRIPS agreement does not forbid a member state from adopting actions to safeguard public health and advance medication access [50]. Failure to employ adaptable measures could be viewed from the public health and human rights perspectives as a breach of sovereign duty [51]. It calls for improvement before the next pandemic, including favourable policies, especially for the least-developed countries, which can include the non-binding agreement of support in finance, workforce, and technology for vaccine production instead of a waiver as the less binding agreement might be easier for acceptance.

6. WHO Involvement

Additionally, the WHO demonstrated this to be essential, which was demonstrated during the AIDS crisis. According to the Journal of the International AIDS Society, "WHO recommendation is a critical step toward improving the efficacy of treatment in developing countries" [52], and the importance of the involvement of WHO can be essential for COVID-19 or future pandemics as well, with prompt action ensuring state’s accessibility to treatments or drugs.

The previous history of the international legal regime has raised the need for drug control law to be improved and balance between ensuring accessibility and reducing abuse shown in the unequal ac-cess to cancer treatment. In addition, to achieve more equal accessibility for the next pandemic, WHO can involve by including the essential treatment or drugs in EML, which allow the states to be more persuasive in negotiation with pharmaceutical businesses or other states for support in technology or finance and compulsory licensing of the drugs or treatments.

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