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## Symposium Articles

# Vaccine Inequity in the COVID-19 Crisis: Lessons to Leverage Global Health Law through Market-Shaping Policies

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**Abstract**

This article critically examines the inequities in the access to COVID-19 vaccine and the lessons for global health law. Despite the rapid development and approval of COVID-19 vaccines, the rollout exposed severe systemic failures rooted in preexisting economic distortions and market inefficiencies. The article argues that addressing vaccine inequity requires more than improved distribution and solidarity, but effective reinvention of the global vaccine supply chain through evidence-based and meaningful market-shaping measures. It calls for a transformative approach to global health governance, emphasising the need for a comprehensive, human rights-compliant policy framework to correct structural problems in international markets, moving beyond superficial exhortations to equity.

**Keywords:** COVID-19; human rights; inequity; vaccine; market reform

## Introduction

In October 2020, Gostin and colleagues made the following prediction on COVID-19 vaccine access:

> While vaccine development holds great promise, the discovery phase is only the first step.… a prospective [COVID-19] vaccine could heal the rifts of a bitterly divided world, or it could exacerbate them if countries hoard necessary vaccines and undermine equitable access.[1]

It was only a month later that the mRNA vaccine produced by Pfizer-BioNTech was proven effective. By December 2020, the Pfizer vaccine was authorized for emergency use in the United States, and soon thereafter, other vaccine candidates announced positive results.[2] For many, these scientific breakthroughs signalled the end of the COVID-19 pandemic, but in reality, the vaccine rollout represented a major governance failure in the crisis response.

The source of this vaccine inequity is a pattern of systemic economic distortions that existed long before 2020, symptomatic of longstanding legal barriers to access to vaccines. Achieving vaccine equity transcends issues of distribution, solidarity, or resource allocation in public health emergency responses. It represents a cumulative effect of structural deficiencies within market dynamics and supply chains, necessitating broader, evidence-based global health law reforms.

Mainstream discourse on inequity merely scratches the surface of profound market failures – with calamitous humanitarian impacts. Addressing this inequity requires enhanced global governance and transformative solutions in a "mission-driven" economy that adapts and rises to the challenge of reimagining global vaccine supply chains, placing public health goals at its heart.[3] The large-scale inequities in access to vaccines during COVID-19 also draws renewed attention to the need for accountability of States to human rights standards. Deeper commitments to human rights in global health law frameworks requires more than merely securing current vaccine manufacturing capacities, especially in light of technological imbalances among States.[4]

In this article, we highlight the critical issues surrounding COVID-19 vaccine access arising from a dysfunctional global vaccine development and distribution model. We emphasize the need for a comprehensive, human rights-compliant policy framework in global health law, drawing lessons from COVID-19 vaccine inequities to tackle underlying structural challenges in the global pharmaceutical sector. In accordance with State human rights commitments, ongoing global health reforms must advance more robust strategies to tackle structural market flaws. We conclude that global health law reforms must prioritize a transformative approach that addresses fundamental distortions in international vaccine production and distribution, rather than focusing solely on securing a minimal share of the vaccine supply for low- and middle-income countries (LMICs) in the name of charity or equity.

## The COVID-19 Pandemic as an Extension of Historical Disparities

Vaccine access, historically, is tainted with global inequity. While the eradication of smallpox through, among other things, the scaling up of childhood immunization, is noted as a great success story, access to and implementation of vaccine programs has been a

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significant challenge in the Global South.[6] Many LMICs cannot afford to sustain their own childhood vaccination programs — relying on private donor or philanthropic funding to procure and deliver childhood immunization.[7] Inequity also arises out of the vaccine development landscape, where vaccines for neglected diseases such as Ebola or malaria languish in development due to the lack of a "profitable market" for commercialization.[8] Insufficient regulatory capacity to approve vaccines contributes to substantial delays to effective vaccines being rolled out in low-income countries.[9] As early as 2005, it was recognized that the patent flexibilities and affordability measures of the Doha Declaration would not be effective for vaccine access unless vaccine manufacturing capacity was scaled up substantially in LMICs.[10]

Given this context, it is clear that, going into the COVID-19 pandemic, the global economic, political, and legal system was designed to perpetuate rather than address inequitable access to vaccines. Most of the vaccine development and manufacturing capacity, particularly using a novel platform such as mRNA, were heavily concentrated in high-income countries and among a small number of large pharmaceutical companies.[11]

These features would have yielded some inequity under any circumstances, but the degree of inequity that unfolded during the COVID-19 pandemic was exacerbated by the limited supply of vaccines and the heavy investment high-income countries made in vaccine development to secure access to the first doses.[12] The result of this combination was extreme vaccine nationalism — poorer countries not only got fewer vaccine doses with much longer (and often unpredictable) waiting times but such procurement was also often at a higher cost and on punitive contractual terms.[13] Consequently, reforming the vaccine landscape is a monumental undertaking that requires more than improved coordination and reallocation efforts which rely on the current capacity to produce vaccines (such as envisaged in the ongoing global health reforms) and must address the threat of domestic stockpiling or "vaccine nationalism" (largely attributable to the proliferation of early supply contracts), which remain significant drivers of inequity.[5]

## Beyond Distributive Equity: Global Health Law as a Market-Shaping Tool

The inequities in COVID-19 vaccine access have resulted in a significant push toward reforming global health governance with equity as a central ideal, despite the lack of clear consensus on States' precise obligations under global health law and international human rights law.[14] Moreover, understanding the concept of equity in vaccine access is also crucial to reforming global health law. To determine solutions to market inequalities, a critical task is distinguishing equity from the rights-based obligations inherent in current global health governance to determine solutions to market inequalities.

In contrast to equity, a rights-based approach, grounded in States' legal obligations, requires more than just a fair allocation of existing funds and vaccine supplies. Under the international right to health, States are obligated, for example, to deploy maximum available resources — including human, financial, technological and informational resources — to provide essential health technologies as part of their public health response.[15] Meeting this obligation involves leveraging legal frameworks and regulatory powers to enhance vaccine development, manufacturing and distribution.[16] Sensitive to deeper structural issues and inequalities, a rights-based approach also demands an efficiently functioning global system for vaccine development, production and distribution. For this rights-based approach to be achieved, a systemic overhaul of market structures is required alongside a clarification of and a recommitment to legal obligations to reorganize supply chains and foster vaccine production at affordable prices.[17] Such an overhaul also necessitates increased attention to both the human rights obligations of the States and the human rights responsibilities of private companies, especially in the context of public health emergencies, in line with the Principles and Guidelines on Human Rights and Public Health Emergencies.[18]

Economic policy research and experiences from other vaccine access initiatives indicate that ensuring immunization supplies requires market interventions to create an optimal environment for availability, quality, and affordability of vaccines — in accordance with international law and standards under the right to health.[19] For example, GAVI has implemented market-shaping initiatives that extend beyond funding management, aiming to foster a conducive market environment for vaccination programs.[20]

These market-shaping policies can pursue a wide range of pathways under global health law. In relation to research and development, access clauses and procedures need to be built into the studies and investments leading to a new vaccine, so that equitable access is not only considered after a scientific discovery is released.[21] Through binding agreements, global health actors must devise commitments to long-term investments in industrial complexes and local manufacturing capacities for those countries currently without them.[22] To this end, technology transfer and product development partnerships must support innovation and expedite scaling-up of production to meet surges in vaccine demand. Similarly, greater efforts are needed to enhance cooperation and regulatory alignment for the approval and registration of new vaccines across markets.[23] To ensure affordability, prospective global health law must also explore more effective mechanisms for price control and negotiation, ensuring transparency in contracts, and creating fast-tracked avenues for pooled procurement.[24]

## Structural Transformation of the Vaccine Supply Chain Will Require Ongoing Global Health Law Reforms

Drawing on equity as a guiding principle, proposals amid the COVID-19 pandemic emerged to revise global health governance and regional cooperation initiatives to support the fair distribution of medical countermeasures. Through negotiations under the World Health Organization (WHO), these proposals have included the Pandemic Agreement (currently under negotiation) and the recently adopted amendments to the International Health Regulations (IHR). Yet neither of these instruments embody the full range of reforms needed in global health to deal with the root causes of market distortions in vaccine production. Moreover, and importantly, neither is adequately grounded in States' human rights obligations.

A central component of codifying equity in global health law under the future Pandemic Agreement focuses on establishing a fair Pathogen Access and Benefit-Sharing (PABS) model. As envisioned by its proponents, PABS should operate on a reciprocity basis between countries — where LMICs share pathogens in exchange for equitable and affordable access to the health technologies developed from those pathogens.[25] However, this framework remains

transactional (compensation through vaccines in exchange for pathogen access) and is unlikely to be transformative or empowering for health system resilience.[26] The adoption of PABS in other instruments over the past 30 years has yet to yield equitable results.[27]

The equity-focused clauses in the proposed Pandemic Agreement aim to ensure a fair distribution of resources when production is predominantly controlled by technologically advanced states as anchored in duties of international cooperation. Even though some provisions refer to support and promotion (in more weak terms) of technology transfer and local development, they do not constitute a comprehensive agenda (with concrete and targeted enforceable commitments towards LMICs) for overhauling the global health architecture by reducing the vaccine production and development divide. The continued dilution and weakening of these provisions throughout the drafting process also indicates tensions in trying to make the Agreement a meaningful reform.

In laying the foundation for Pandemic Agreement negotiations, the new amendments to the IHR are a positive step toward improving access to vaccines, but they lack strong reforms to reorganize markets to ensure the availability and affordability of medical countermeasures. Article 12.8 of the amended IHR establishes the WHO's role in supporting and coordinating access to health products;[28] however, this monitoring and guidance may not be directly enforceable, and the effectiveness of these recommendations in terms of distributive impact remains uncertain. Additionally, such recommendations would only operate in the context of a public health emergency, whereas the COVID-19 pandemic has demonstrated that manufacturing and development capacity must exist before the emergency begins. The IHR amendments do not include market coordination and state interventions to strengthen local or regional vaccine production among the core capacities subject to the compliance mechanism.[29] This omission highlights a critical gap in ensuring robust and equitable global health responses in future emergencies. It is likely, therefore, that this approach also falls short of States' existing human rights obligations.

## Conclusions

Those seeking to access vaccines today face significant production and affordability constraints that are deeply embedded in the global pharmaceutical market. While global health law has aimed to create innovative tools, the current framework has not adequately prepared markets to support sustained and widely available vaccine production. Drawing from Gostin, the role of global health law in promoting health justice involves exploring "creative ways" to coordinate and mobilize resources to establish an international order that guarantees health access for all.[30] Forthcoming global health frameworks must, in keeping with States' human rights obligations, adopt innovative market interventions to increase the availability and affordability of vaccines in all countries and to all people.

Critical market-shaping policies, which correspond to State obligations of progressive realization and resource mobilization in terms of the rights to health and equal benefit from scientific progress, must be in place under global health law at different stages and areas of a vaccine life cycle. States' human rights obligations, if they are considered in global health reforms, are most commonly an afterthought instead of the basis for action. Given that vaccine access is market-dependent, interpreting equity as merely an allocative scheme or a share of the available production capacity falls short of what is required. Unless and until this approach changes fundamentally under global health law, equity and solidarity in global health is unlikely to be embedded in concrete and effective access policies worldwide.

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