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PERSPECTIVE

# Should COVID-19 Vaccines Authorized for Emergency Use Be Considered "Essential" Medicines?

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## Abstract

A critical debate in the race to develop, market, and distribute COVID-19 vaccines could define the future of this pandemic: How much evidence demonstrating a vaccine's safety and efficacy should be required before it is considered "essential"? If a COVID-19 vaccine were to be designated an essential medicine by the World Health Organization, this would invoke special "core" human rights duties for governments to provide the vaccine as a matter of priority irrespective of resource constraints. States would also have duties to make the vaccine available in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at an affordable price. This question is especially critical and unique given that COVID-19 vaccines have in many cases been authorized for use via national emergency use authorization processes—mechanisms that enable the public to gain access to promising medical products before they have received full regulatory approval and licensure. In this paper, we examine whether unlicensed COVID-19 vaccines authorized for emergency use should ever be considered essential medicines, thereby placing prioritized obligations on countries regarding their accessibility and affordability.

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## Introduction

A critical debate in the race to develop, market, and distribute COVID-19 vaccines could define the future of this pandemic: How much evidence demonstrating a vaccine's safety and efficacy should be required before it is considered "essential"? The World Health Organization's (WHO) concept of "essential medicines" suggests that COVID-19 vaccines that satisfy priority health care needs and have public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness should be considered strong candidates for being listed as "essential medicines."[1] This is important because if a COVID-19 vaccine were to be designated an essential medicine by WHO, this would invoke special "core" human rights duties for governments to provide the vaccine as a matter of priority irrespective of resource constraints.[2] States would also have duties to make the vaccine available in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at an affordable price.[3]

This question is especially critical and unique given that COVID-19 vaccines have in many cases been authorized for use via national emergency use authorization (EUA) processes—mechanisms that enable the public to gain access to promising medical products before they have received regulatory approval and licensure.[4] With some countries poised to vaccinate their entire populations under emergency use authorizations, in addition to many other COVID-19 vaccines in the pipeline and the potential need for new vaccines to address variants of concern, vaccination under EUAs could continue to be the norm for COVID-19 vaccination programs.

Might it be possible for COVID-19 vaccines to meet WHO's standards to be considered an essential medicine? Undoubtedly, any COVID-19 vaccine would satisfy the condition of disease prevalence and public health relevance. Whether a COVID-19 vaccine is comparatively cost-effective will depend on the product, its price, and its alternatives. Vaccine pricing may invoke legal and political challenges regarding intellectual property rights well-traversed in relation to other essential and non-essential pharmaceuticals over the past decades.[5] The critical gray area we focus on in this paper—and therefore the crux of essentiality in this case—is determining the evidentiary standard of clinical efficacy and safety that must be met in the context of a public health emergency in order for a COVID-19 vaccine to be deemed an essential medicine. In this paper, we focus specifically on whether unlicensed COVID-19 vaccines authorized for emergency use should ever be considered essential medicines, thereby placing prioritized obligations on countries regarding their accessibility and affordability. We first outline the implications of right to health standards for essential medicines, then consider whether EUA COVID-19 vaccines should ever be considered as candidates for essential medicines status, and conclude by evaluating WHO's Emergency Use Listing procedure as a potential mechanism for categorizing emergency use vaccines for the purposes of being considered for essential medicines status.

## Essential medicines and the right to health

Essential medicines, which include vaccines, hold considerable importance in the interpretive frameworks of the right to health, as they are critical to individual and population health. According to article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), states have obligations to prevent and control epidemics.[6] In General Comment 14, the Committee on Economic, Social and Cultural Rights notes that the provision of vaccines is critical to fulfilling this objective.[7] The committee has also firmly positioned the provision of essential medicines defined by WHO as a "core obligation" under the right to health. Such obligations are defined in General Comment 3 as the minimum standards that must be met by states in order to give meaning to the enjoyment of covenant rights.[8] Core obligations to provide essential medicines under the right to health do not necessarily constitute a strictly binding (rather than authoritative) legal standard, even for the 171 states that have ratified the ICESCR.[9] However, national governments have enshrined the state duty to guarantee

access to essential or needed medicines for all in various domestic legal frameworks, from binding constitutional law and universal health coverage laws to national medicines policies guiding the pharmaceutical sector.[10] For instance, at the height of the AIDS crisis, state provision of "essential" antiretrovirals as part of the fulfilment of the right to health recognized in domestic constitutions and international treaties was enforced through domestic courts.[11] This evidence suggests that core obligations hold a customary legal status.

There is increasing consensus in the international community of an emerging custom that essential medicines should be part of the human right to health. For instance, the international community has used the human rights language of access to medicines to create new global health institutions such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, which provides free access for developing countries that cannot provide relevant medicines for their citizens. This seems to imply a wider recognition that access to medicines should be part of a broader realization of the right to health.[12]

Irrespective of the precise legal status of core obligations to provide essential medicines, in a global pandemic such as COVID-19, a vaccine's designation as an essential medicine by WHO would clearly invoke strong and urgent human rights and public health responsibilities of states articulated in international norms and domestic law, and raise fundamental questions about whether states should make such products widely available at an affordable price.

## National emergency use authorizations of unlicensed COVID-19 vaccines

The urgent need to alleviate the global crisis caused by COVID-19 perhaps necessitates a departure from traditional vaccine regulatory pathways, but not at the expense of vaccine safety, efficacy, and quality.[13] Emergency use authorization processes (or similar regulatory mechanisms) allow national regulatory authorities to authorize the use of unapproved medical products in a public health emergency in order to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives, but prior to there being sufficient evidence to meet the standards required for regulatory approval.[14] For example, at the time of writing, the US Food and Drug Administration (FDA) had issued EUAs for three COVID-19 vaccines, 10 drug and biological therapeutic products, and 346 *in vitro* diagnostic products.[15] Also of note is that the FDA issued EUAs for chloroquine and hydroxychloroquine, which were later revoked following the removal of hydroxychloroquine as a COVID-19 treatment in WHO's Solidarity Trial.[16]

Given these national-level authorizations, a pertinent question is whether unlicensed medical products authorized for emergency use, including vaccines, should ever be considered essential medicines, thereby placing prioritized obligations on countries regarding their accessibility and affordability. On the one hand, this is an attractive idea. For example, COVID-19 vaccines that have promising safety and efficacy profiles and are issued EUAs could be critical to combatting the pandemic in a timely manner. Yet, if such vaccines are neither accessible nor affordable, then the least advantaged will be disproportionately harmed. If listing COVID-19 vaccines that have received EUAs as essential medicines would trigger responsibilities to make these products available and accessible at an affordable price, this could have the potential to address the problem of accessibility.[17] However, it is important to note that human rights obligations with respect to essential medicines are not absolute and are subject to gradual fulfillment, and so being listed as an essential medicine would of course not guarantee accessibility. Listing COVID-19 vaccines as essential medicines only once they receive market licensure—that is, long after they are likely to have received EUAs in many countries—means that many months may pass in which many people, including the least advantaged, are less able to benefit from these vaccines. Proposals exist for the fair allocation of unlicensed medical products autho-

rized for emergency use, but they do not establish obligations in the same way that being listed as an essential medicine does.[18]

While listing an EUA vaccine as "essential" would have important advantages, it may seem counterintuitive to consider a medical product "essential" when evidence for that product has not met traditional standards of safety and efficacy. There are several reasons that militate against considering unlicensed medical products to be essential medicines even if there are countries that have authorized them for emergency use. First, as the US FDA's issuance and later revocation of EUAs of chloroquine and hydroxychloroquine for COVID-19 highlights, evidence may quickly emerge that a medical product's safety or efficacy profile no longer supports its emergency use. Given the attenuated evidentiary standards that exist for EUAs compared with market licensure, it may be too hasty to consider such medicines "essential." Second, as the global race for a COVID-19 vaccine demonstrates, political factors, including vaccine nationalism, can have a perverse influence on the issuance of EUAs. In other words, vaccine nationalism could inappropriately incentivize governments to issue EUAs. Given that countries have been criticized for hurried approvals of vaccine candidates because of concerns over a lack of safety and efficacy data, it is hard to imagine how such products could at the same time be considered "essential."[19] That the US FDA has resisted political pressure to abruptly issue EUAs for COVID-19 vaccines emphasizes the paramount need to ensure a high degree of safety and efficacy prior to the procurement and widespread dissemination of a potentially dangerous vaccine by a government to its population.[20]

There are also several potentially negative implications of listing EUA COVID-19 vaccines as essential medicines. Namely, labeling such products "essential" could create the impression that the safety and efficacy of such products is more certain than it actually is. One can only imagine the consequences had chloroquine or hydroxychloroquine been deemed "essential medicines" for COVID-19 when they received EUAs in the United States. In addition, considering such medical products as essential medicines candidates could have profound and far-reaching effects on the perceived value of investigational medical products more generally, such as by emboldening "right to try" movements for medical products whose clinical value and safety is unknown.[21] Finally, recognizing an EUA product as "essential" would trigger the obligation on states to provide it affordably to all. Consider in this scenario the potential for states to pour significant investments into "essential" EUA products of questionable added value for diagnosing, preventing, or treating COVID-19. Worse yet would be the opportunity costs if those investments precluded a state's future purchase of other COVID-19 products that are proven resolutely safe and effective. For example, because of the FDA's issuance and subsequent revocation of an EUA for hydroxychloroquine, the US federal government was left with a stockpile of 63 million doses of a drug that is ineffective in treating COVID-19 and whose cost could have been spent elsewhere.[22]

These arguments suggest that the mere fact that a COVID-19 vaccine has received emergency authorization should not automatically render it a candidate for essential medicine status. Conversely, in a public health crisis, it may seem imprudent to require that COVID-19 vaccines receive licensure before they can be considered essential medicines, particularly if vaccination programs are likely to continue under EUAs for some time. Given the dire need for COVID-19 vaccines and the real prospect that the least advantaged will not have the opportunity to access or afford them if and when they are authorized for emergency use, a middle ground is needed.

## WHO's Emergency Use Listing procedure

A potential middle ground would be to leverage the WHO Emergency Use Listing procedure, a risk-based procedure for assessing and expediting the listing of unlicensed diagnostics, therapeutics, and vaccines for use during public health emergencies.[23]

At the time of writing, three COVID-19 vaccines had been issued emergency use validation through this process.[24]

Utilizing this procedure would have the benefit of considering (but not guaranteeing) essential medicine status only among those medical products that have undergone a global, systematic, consistent, transparent, and coordinated process for assessing and listing medical products for emergency use. Relying on a global process with harmonized standards could help identify vaccines that should be considered for essential medicine status without the risks associated with national EUAs. COVID-19 vaccines that have been listed via WHO's Emergency Use Listing procedure could therefore serve as the authoritative roster of medicines authorized for emergency use that WHO may further independently consider for the purposes of being listed as essential medicines.

## Conclusion

Given the lower evidentiary standards for EUAs relative to market licensure, political factors that can influence the issuance of EUAs, and the possibility that labeling such products "essential" could create the impression that the safety and efficacy of such products is more certain than it actually is, COVID-19 vaccines authorized for emergency use should not automatically be considered as candidates for essential medicine status. Yet, in the context of a pandemic and large-scale vaccination programs rolled out under EUAs (or similar regulatory mechanisms), it may be imprudent to require that COVID-19 vaccines wait to receive licensure before they can be considered as essential medicines. We therefore argue that COVID-19 vaccines authorized for emergency use should not necessarily be precluded from being considered as essential medicines candidates, but rather be considered for essential medicine status only if they have undergone a systematic, consistent, transparent, and coordinated process for being assessed and listed for emergency use. WHO's Emergency Use Listing procedure comprises harmonized standards and can serve as an authoritative roster of vaccines that may be further independently considered for essential medicines status.

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