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Legal agreements: barriers and enablers to global equitable COVID-19 vaccine access

Published Online
September 7, 2020
[https://doi.org/10.1016/S0140-6736\(20\)31873-0](https://doi.org/10.1016/S0140-6736(20)31873-0)

Law can serve as both an enabler and a barrier to global health, equity, and justice.¹ The impact of legal determinants of health on the COVID-19 pandemic is evident where law is being used as a mechanism to enable or prevent global equitable access to COVID-19 vaccines. Barriers to equitable access are partly driven by vaccine nationalism² with governments seeking to use law to secure priority access to future vaccines through Advance Purchase Agreements (APAs) with vaccine manufacturers. These bilateral legal agreements can be in a nation's interest, but given the uncertain success of individual COVID-19 vaccine candidates and the global spread of SARS-CoV-2, APAs are a gamble and erode collaboration between countries. Importantly, such bilateral legal agreements are likely to contribute to inequities and potentially extend the pandemic's time frame. By contrast, multilateral legal agreements could be the path back to global health security and justice by re-establishing norms of international solidarity, committing to global equitable vaccine access initiatives, and laying a foundation for a post-pandemic era built on multilateralism and cooperation.

In the lead-up to the World Health Assembly (WHA) in May, 2020, current and former politicians and civil society leaders from around the world,

including the President of Ghana, Nana Akufo-Addo, the Prime Minister of Pakistan, Imran Khan, and the President of South Africa and Chair of the African Union, Cyril Ramaphosa, called for a "bold international agreement" that guarantees global equitable access to vaccines as global public goods.³ At the WHA, China's President Xi Jinping stated that any Chinese vaccine developed will be a "global public good", and contribute to "ensuring accessibility and affordability in developing countries".⁴ The only resolution adopted during the truncated WHA recognised immunisation, rather than vaccines themselves, as a global public good.⁵ However, since then, the global legal landscape has shifted from a rhetoric of global public goods to a reality largely based on nationalism. According to WHO, there are more than 170 COVID-19 candidate vaccines in development.⁶ Although only eight of those vaccine candidates are now in phase 3 trials,⁷ some wealthy nations have secured more than 2 billion doses of potential future COVID-19 vaccines using APAs.⁸

APAs are legally binding contracts whereby one party, such as a government, commits to purchasing from a vaccine manufacturer a specific number or percentage of doses of a potential vaccine at a negotiated price if it is developed, licensed, and proceeds to manufacture. These bilateral agreements often secure priority access to vaccine and manufacturing capacity. Governments of countries that disagree with the ethics and effectiveness of APAs or that do not have the financial resources to purchase vaccines at comparable prices or engage in commercial negotiations are at risk of not having access to vaccines when they first become available and of having access delays while manufacturing capacity is fulfilled first by wealthy countries' orders. This was the case during the 2009 influenza A H1N1 pandemic when many APAs held by high-income countries (HICs) were used to secure their priority access to vaccine, making procurement in other countries more difficult.⁹ APAs were used so extensively in 2009 that more than 56% of pandemic influenza vaccine manufacturers surveyed by WHO were unable to commit to guaranteeing 10% of real-time vaccine production



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for purchase by UN agencies due to pre-existing commitments under APAs with HICs.¹⁰ Governments that enter into APAs for candidate vaccines that do not demonstrate evidence of safety and efficacy also risk not getting immediate or sufficient access to successful vaccine candidates.

APAs are not always legal tools for vaccine nationalism but can be used by global health organisations to secure vaccines for low-income and middle-income countries (LMICs) as part of an Advanced Market Commitment (AMC). Global health organisations, most notably Gavi, The Vaccine Alliance, have used donor-funded AMCs to enter into APAs with vaccine manufacturers to supply a guaranteed number of vaccine doses to countries with limited profit-based markets; AMCs were used in this way for childhood pneumococcal vaccines and Ebola vaccines.¹¹ In June, 2020, Gavi established the COVID-19 Vaccine Global Access (COVAX) AMC to use funds from donors and HIC governments to purchase a guaranteed volume supply of COVID-19 vaccines to be distributed to LMICs participating in the COVAX Facility.¹²

Launched in April, 2020, and co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO, the COVAX Facility is a platform for all participating governments to access a diversified portfolio of COVID-19 vaccines when they become available, distributing risk across multiple vaccine candidates. The COVAX Facility aims to have enough doses of COVID-19 vaccines for at least 20% of participating countries' populations, with a goal of 2 billion doses by the end of 2021. Civil society has criticised COVAX for negotiating prices that include profit rather than vaccines at cost as a global public good, the lack of transparency of contracts entered into with vaccine manufacturers, limits on civil society participation, failure to address potential impacts of intellectual property rights on pandemic vaccines, and governance questions, including the role of WHO and limited experience procuring vaccines for middle-income countries and HICs.¹³ The latter point led the EU to decline using the COVAX Facility for purchasing vaccines, stating that bilateral APAs enable it to access vaccines faster and at a lower cost. On Aug 24, 2020, the WHO Director-General noted that although 172 countries are in discussions about joining the COVAX Facility, more support, particularly from wealthy countries, is "urgently

needed" to "secure enough doses to rollout the vaccines" and address equitable vaccine access.¹⁴ Despite not participating in the COVAX Facility for purchasing its own COVID-19 vaccines, on Aug 31, 2020, the EU made a €400 million commitment to participation in parallel to existing APAs.¹⁵

Allocation questions for COVID-19 vaccines have focused on equitable distribution within countries, including prioritising vulnerable populations and health-care and essential workers. However, justice also demands consideration of the equitable vaccine distribution between countries. Under the Pandemic Influenza Preparedness (PIP) Framework—the only international legal instrument for the global equitable distribution of vaccines—WHO intends to distribute pandemic influenza vaccines that are secured under contracts with manufacturers to countries on the basis of public health risk and needs.¹⁶ However, in a pandemic with a restricted supply of available vaccine, public health need alone is unlikely to guide decisions, especially in the early stages of vaccine distribution when supply will be limited and the need will be equally high across many countries. Furthermore, unlike pandemic influenza, there is not an international legal instrument, agreed to by all WHO member states, for COVID-19. Nor is there yet public international agreement on how distribution of COVAX Facility (or alternative platforms) vaccines should occur. WHO has developed a proposal for a Global Framework to Ensure Equitable and Fair Allocation of COVID-19 Products, highlighting how a global access mechanism would distribute risk and maximise equitable allocation between countries; however, the legal process and form for adoption of such a framework has not been publicly proposed.¹⁷ Despite the lack of a specific international agreement for COVID-19 vaccines, 171 countries already have legally binding obligations under the International Covenant on Economic, Social, and Cultural Rights (1966) to take steps, individually and through international assistance, to realise the right to health and the right to enjoy the benefits of scientific research and its applications, without discrimination. Respecting, protecting, and fulfilling these rights in the context of COVID-19 would mean ensuring that COVID-19 vaccines are available, accessible, acceptable, and of good quality, in all countries.¹⁸

Multilateral commitment is needed to help pre-empt an additional legal risk arising from vaccine nationalism that could render multilateral and some bilateral APAs ineffective, such as the use of government export controls. During the 2009 influenza A H1N1 pandemic, governments in HICs with vaccine manufacturers restricted export of vaccines until domestic needs had been met.¹⁹ As a result, even where governments or international institutions have entered into APAs, vaccine nationalism in the country of manufacture could embargo or requisition vaccines, delaying global distribution.

Any international governance platform for COVID-19 vaccines, including the COVAX Facility or a new mechanism, will only succeed if there is global momentum and commitment to global equitable COVID-19 vaccine access, particularly from HICs. Yet many HICs are currently driving the proliferation of bilateral APAs, entrenching nationalism, and directing future vaccine distribution. In November, 2020, countries will meet for the second part of the pandemic segmented WHA. This meeting might be the last chance all countries have to adopt an international instrument and agree on a mechanism for COVID-19 vaccines before they become available. Any international COVID-19 vaccine allocation framework, even as a non-binding resolution, must establish governance principles, including accountability, transparency, and participation, and define decision makers, increase country commitments to financing and acceptable conduct, and set principles and a mechanism for equitable distribution within and, importantly, between countries. Such an agreement is necessary to protect human rights and ensure transparency, accountability, participation, and equity.³ Finally, at the G20 in late November, 2020, HICs have a crucial opportunity to choose the world we will face if successful COVID-19 vaccines are developed: one where law is not a barrier but a tool for achieving global health equity with justice.

ALP is a consultant for WHO and has previously consulted to Gavi, The Vaccine Alliance. ME-T has previously consulted for WHO on equitable access to pandemic influenza vaccines. ALP, ME-T, and MR are supported by the Arts and Humanities Research Council of the UK, grant: AH/V006924/1. AM and CW declare no competing interests.

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