INTRODUCTION

The rapid rate at which scientists produced multiple highly effective COVID-19 vaccines was an epic public health achievement. Yet as the data reflect, efforts over the past year to equitably distribute those vaccines have been a failure. No country has been unaffected by the COVID-19 pandemic, but one year after the first vaccine authorisations, too many countries are being denied access to life-saving COVID-19 vaccines. As of 27 November 2021, more than 73% of people in high-income countries (HICs) had received at least one dose of a COVID-19 vaccine, yet less than 6% of people in low-income countries had.¹

Such condemnations are needed, but moral and ethical failures are a result of deliberate decisions by individuals, organisations and governments. The ethical and public health failures that have unfolded over the past year are partly due to political realities and the current biomedical innovation system and partly a result of the shortcomings of the global mechanism created to try to safeguard equitable access to COVID-19 vaccines, the COVAX Facility (COVAX).

With new variants emerging, COVID-19 will remain a global health threat for the foreseeable future. Critical discussions are underway on how to address the current inequities in COVID-19 vaccine access and deliver the vaccines that are available to end the current pandemic, and how to better prepare for the inevitable next one. While COVAX is being positioned by its sponsors and some governments as a model for future pandemics, considering its vast shortcomings, Médecins Sans Frontières (MSF) has significant reservations about replicating this model for future pandemics.

If governments are committed to improving equitable access to COVID-19 vaccines, they must move beyond rhetoric, critically assess why COVAX has thus far failed to deliver on its ambitious goals and commit to a better way forward for pandemic preparedness.

This brief offers an analysis of COVAX based on a desk review of internal and externally available material, and 25 interviews with global health actors, civil society representatives and government officials (Annex). It does not examine other aspects of the broader ACT-A COVAX Pillar (the COVAX Vaccines Pillar), including vaccine development and manufacturing, the vaccine allocation system, and country readiness to receive vaccines. Throughout this brief “COVAX” refers to the Gavi-managed COVAX Facility, not the broader “COVAX Vaccines Pillar.”

In September, United Nations Secretary-General António Guterres told world leaders that vaccine inequity:

“... is a moral indictment of the state of our world. It is an obscenity. We passed the science test. But we are getting an F in Ethics.”²

Muhammad Sarwar receives a COVID-19 vaccine administered by an MSF nurse in Karachi, Pakistan, in October 2021.
COVAX: A broken promise to the world

On 24 April 2020, the World Health Organization (WHO), the President of France, the President of the European Commission, and the Bill & Melinda Gates Foundation (the Gates Foundation)4 launched the Access to COVID-19 Tools Accelerator (ACT-A), touted as a “groundbreaking global collaboration to accelerate development, production and equitable access to COVID-19 tests, treatments and vaccines.”5

ACT-A is a multi-stakeholder partnership including UN bodies, private philanthropies, and pre-existing public-private partnerships (PPPs). It is comprised of four pillars: Diagnostics, Therapeutics, Vaccines, and a Health Systems Connector.

The COVAX Vaccines Pillar is co-led by Gavi, the Vaccine Alliance (Gavi), the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO.3 Within this pillar, CEPI leads research and development (R&D), investing in a range of vaccine candidates, and WHO leads vaccine policy and allocation.

Gavi leads and is the legal entity behind COVAX, the global vaccine procurement facility developed to deliver equitable access to COVID-19 vaccines across all countries, regardless of income. UNICEF and the Pan American Health Organization (PAHO) are delivery partners.5 Notably, both Gavi and CEPI were founded with major participation by the Gates Foundation and are heavily funded by the philanthropy. The Gates Foundation is also one of the largest funders of WHO.

COVAX’S VISION

Gavi set high expectations for COVAX; it aimed to deliver two billion doses of COVID-19 vaccines by the end of 2021. According to Gavi, COVAX was “…our best hope of ending the acute phase of the pandemic,” and “the only true global solution.”6

The world’s poorest countries would gain access to doses via the Advance Market Commitment (AMC). Wealthier countries would access doses through a self-financing participation option.

The AMC financing mechanism launched in June 2020 and aimed to enable countries to access donor-funded doses of COVID-19 vaccines based on income and other eligibility criteria; 92 countries currently qualify. Its launch called for US$2 billion in start-up funding and announced COVAX’s first agreement for vaccine doses between AstraZeneca, Gavi and CEPI.7,8

Gavi then developed its self-financing option to allow other middle- and high-income countries to procure doses through COVAX. Self-financing participants were expected to commit to advance purchase agreements with Gavi, confirmed with a down payment and future financial commitments.

Through COVAX AMC donor funding, largely raised through official development assistance (ODA), and payments by self-financing countries, COVAX would serve as a pooled procurement mechanism. It would invest in a portfolio of promising vaccines and aim to use collective purchasing power to negotiate prices from manufacturers to ensure vaccine availability and reduce risk for all participants.

COVAX would allocate doses based on the WHO Fair Allocation Framework, which provides guidance on ethical and public health considerations surrounding the allocation of COVID-19 vaccines.9 Phase one distributions of WHO Emergency-Use-Listed vaccines were to be allocated to all participating countries at the same rate proportional to their total population size, up to 20% of their population. This 20% was intended to cover priority groups, including frontline health and social care workers, people over 65 years, and those under 65 years with underlying health conditions.

Vaccine distributions would occur in rounds, depending on availability of vaccines. Decisions on which countries would receive vaccines and in what quantity for a given round were to be made by COVAX’s Joint Allocation Taskforce (staff from Gavi’s Office of the COVAX Facility and WHO). These allocations would then be reviewed and validated by COVAX’s Independent Allocation Validation Group, which includes an MSF staff member.10

Countries would enter a second phase of allocations once all countries reached 20% vaccination coverage. Additional AMC doses would then be made available depending on funding. Self-financing participants could request COVAX doses for up to 50% of their population, but no country could receive more than 20% until this second phase.

The mechanism also includes a COVAX Humanitarian Buffer of up to 5% of available doses set aside to ensure vaccine access for high-risk populations in humanitarian settings.10 The Buffer is intended to provide a “path of last resort” for populations overlooked by government-led processes, such as refugees, asylum seekers, or other crisis-affected people.

Never before has a life-saving health intervention against such an immediate global health threat been made available to people in the Global North and South simultaneously at such speed:"

Gavi, the Vaccine Alliance

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5 Médecins Sans Frontières Access Campaign  |  COVAX: A broken promise to the world
**COVAX’S DESIGN SHORTCOMINGS**

The COVAX vision gave hope for how COVID-19 vaccines could be fairly distributed among all countries, but unfortunately this vision has not translated to reality for several reasons. The reasons most cited by Gavi and others are vaccine hoarding by wealthy countries, not having enough upfront funding to negotiate vaccine agreements early in the pandemic, and governments imposing export bans on vaccines.

While these and other factors beyond Gavi’s control have significantly disrupted its ability to procure vaccines, today’s unacceptable disparities in COVID-19 vaccination rates cannot be attributed to external factors alone. COVAX’s success was tethered to shaky assumptions, predictable challenges were not factored into the mechanism’s design, and some poor policy decisions were made. Fundamental design flaws, an opaque governance structure and problems with implementation have all contributed to COVAX’s failure to realise its initial objectives.

**EXCLUSION OF KEY STAKEHOLDERS: AMC COUNTRIES AND CIVIL SOCIETY**

From its design to its governance to its accountability mechanisms, the exclusion of meaningful involvement by key stakeholders, including AMC governments and civil society organisations, has undermined COVAX’s ability to succeed.

**COVAX design**

COVAX was designed with limited stakeholder input. Instead of countries collectively developing a vaccine procurement and allocation platform that ensured equal access to scarce and urgently needed vaccines, the design process for this critical platform was led by Gavi and CEPI, effectively by self-appointment. That Gavi would play a role in pooling procurement and negotiating prices for COVID-19 vaccines for countries where they had already been doing this work was logical, but the global COVID-19 response went well beyond their existing mandate.

Given that COVAX was intended to be a global mechanism, it raises the question of why WHO and member states did not propose a government-led process to decide what the global mechanism should be and who should run it. According to reports, Dr Seth Berkley and Dr Richard Hatchett, the CEOs of Gavi and CEPI, respectively, developed the idea for COVAX during the World Economic Forum in January 2020. Berkley then met with Bill and Melinda Gates to discuss how the Gavi model might be used once a vaccine was discovered. The Gates Foundation was a main driver behind the COVAX initiative. Over the next few months, Gavi and CEPI leadership further developed the idea for COVAX with limited engagement from others, backed by Gates and the European Union (EU).

Three weeks before the COVAX AMC launch, Gavi convened an “AMC design kick-off call.” Based on emails exchanged between Gavi and members of the group, participants included representatives from Gavi, the Gates Foundation, CEPI, WHO, World Bank, UNICEF, PAHO, several academics, a financial investment advising firm, and McKinsey & Company. Notably missing in this group and the broader COVAX design process were representatives from AMC countries and civil society organisations. Regional representatives for many AMC countries, like the Africa Centres for Disease Control and Prevention (CDC) representing 55 countries, were also excluded. By the end of July 2020 when the Gavi Board made a final decision on the scope of countries to be included in the COVAX AMC, there had been minimal opportunity for the governments that would be ultimately affected by the COVAX AMC to help shape its structure. That these regional and country perspectives were not involved in the discussion about the AMC, which directly impacted their countries, is indicative of how COVAX continued to evolve and operate.

Civil society started advocating for a seat at the table in May 2020, before the AMC launched. Between May and October, through numerous appeals from nearly 200 civil society organisations and individuals, these stakeholders made recommendations to improve the COVAX design process and request formal inclusion. It was not until the end of October 2020, long after the opportunity to shape COVAX’s design had passed that a compromise for civil society’s inclusion in the COVAX Vaccines Pillar was reached.

While AMC countries and civil society organisations were excluded from the process, HICs had significant influence over their terms for participation as self-financing countries. In its initial design, self-financing countries could join COVAX in one way, through a “Committed Purchase Arrangement.” Under this arrangement they would be allowed to use the mechanism to purchase vaccines to cover up to 20% of their populations, without the ability to select which vaccines they received. Wanting more flexibility, the UK, on behalf of a few HICs, pushed Gavi to add an “Optional Purchase Arrangement” to give self-financing participants more flexibility and perks.

The new option allowed self-financing participants to opt out of specific vaccines offered by the mechanism, giving them more choice in which vaccines they purchased. The trade-off for the countries that chose the Optional Purchase Arrangement was that they would be required to pay a higher proportion of the total cost per dose upfront. A second option, unavailable to countries in the AMC group, allowed self-financing participants to use the mechanism to purchase vaccines for anywhere from 10 to 50% of their populations.

The inequity of self-financing countries choosing how many and which kinds of vaccines they would receive while AMC countries could only receive 20% coverage with vaccines selected by Gavi invalidated COVAX’s original commitment to equal treatment among AMC members and self-financing participants.
COVAX governance and accountability

The lack of transparency and inclusiveness that characterised COVAX’s design process is also reflected in its governance structure. According to Gavi, COVAX’s governance structure is “complex for a reason: to ensure accountability and transparency, and diversity of geographic and thematic representation.” Yet governments depending on it for vaccine deliveries and civil society organisations trying to monitor accountability have consistently been frustrated by COVAX’s opaque governance arrangement, closed decision-making processes, and lack of any avenue for accountability.

COVAX’s governance was ultimately largely built on Gavi’s existing governance and policy-making bodies. As with most Gavi activities, the Gavi Board is responsible for overseeing the role of the Gavi Secretariat and the Alliance in COVAX. The Market-Sensitive Decisions Committee and Audit and Finance Committee, both part of Gavi’s regular governance structure and largely comprised of Gavi board members, have also taken a role in overseeing COVAX. In addition to these existing Gavi structures, Gavi also developed the Office of the COVAX Facility, which sits within the Gavi Secretariat, as the “dedicated team to support Facility operations.”

Government participation in COVAX happens through two groups, the Shareholders Council and the AMC Engagement Group. The COVAX Shareholders Council represents and is open to all self-financing participants. The AMC Engagement Group is meant to represent COVAX AMC countries and is open to representatives from both AMC-eligible countries and AMC-donor countries. According to the COVAX Structure and Principles document, both the Shareholders Council and AMC Engagement Group are “self-organizing” and “convene with the aim of supporting real-time information exchange and providing strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility.”

In reality, the voices of AMC countries are largely absent in any strategic discussions or decision-making. The AMC Engagement Group is the only formal avenue for these 92 countries to interact with COVAX. This group only convenes through bi-monthly calls with 300 to 400 participants, offering little opportunity for meaningful discussions and decision-making.

Civil society organisations have fared somewhat better in comparison to AMC countries, but their participation is still restricted. As agreed in October 2020, civil society representatives participate in some broader ACT-A COVAX Vaccines Pillar working groups. But the civil society representatives MSF spoke with said they have been given minimal opportunities to engage with COVAX decision-making, that the process is unclear and when they are included it is tokenistic.

Though there are mentions of “decision-making principles,” notably absent from the COVAX Structure and Principles document is any explanation of how decisions are made, by whom and where the accountability rests. The only mention of who makes decisions is in reference to the Gavi Board, which has “ultimate responsibility for decisions and effective implementation of the COVAX Facility.” What remains unclear is what level of decision-making rests with senior Gavi officials and advisors and what decisions are made by the Gavi Board.

In contrast to a multilateral entity like WHO, Gavi’s closed decision-making process and its status as a Swiss-based foundation operating outside of any larger governance structure means there are no avenues through which external actors can hold them accountable for their performance. The governance and accountability systems that Gavi had in place were not going to be suitable for a global initiative such as COVAX, thus there was an expectation that a more transparent and accountable governance system would be established. A year and a half since COVAX’s launch, however, the governance system remains predominately the pre-existing Gavi structure, which does not represent all of the countries included in COVAX. This has been an ongoing source of frustration for those depending on COVAX for vaccines.

For example, Uganda aimed to vaccinate 22 million people by the end of 2021 but did not receive doses from COVAX in time and had no avenues for recourse when faced with this delay. COVAX was supposed to supply the country with 3.5 million doses by June but only supplied 864,000 of the allotment. These doses were quickly exhausted. While Ugandans went without vaccines, cases surged; infections jumped by 39% between May and June.

A MARKET-BASED “SOLUTION” CANNOT RESOLVE WHAT ARE ALSO POLITICAL AND ETHICAL PROBLEMS

COVAX is a market-based solution, which does not address the inevitable political and ethical complexities of COVID-19 vaccine access. The initiative pinned success on an AMC model that not only failed to improve upon an earlier iteration but was also fundamentally ill-suited for the challenges low- and middle-income countries face when trying to access COVID-19 vaccines. This strategy can be explained in part by ACT-A’s and COVAX’s structures as public-private partnerships (PPP). Given the partnership with pharmaceutical companies and other private entities, PPPs rely on companies’ cooperation and thus perpetuate the status quo. Despite these shortcomings, this model is a common solution proposed by wealthy countries and donors and is the model of Gavi itself.

Advance Market Commitment limitations

At the inception of the COVAX AMC, Gavi touted its experience managing the pneumococcal conjugate vaccine (PCV) AMC as a basis for its experience and legitimacy to manage another similar endeavour. According to Gavi, the COVAX AMC “builds on the successes of the AMC for PCV, which has helped vaccinate an estimated 225 million children across 60 low- and lower-middle-income countries against pneumonia.”

Launched in 2009 with $1.5 billion from six donors (the Gates Foundation, Canada, Italy, Norway, Russia and the UK), the PCV AMC was designed to be used as a subsidy that enabled Gavi to top up payments to manufacturers for each dose of PCV. This theoretically provided manufacturers with an additional financial
reward that would motivate them to produce PCV doses for developing countries. The PCV AMC became a hallmark of Gavi’s public-private partnership model.

However, there were significant shortcomings with the PCV AMC that prevented it from fully achieving all of its goals. As identified in two Gavi-commissioned evaluations, major weaknesses in the performance of the PCV AMC include:

1. R&D was not accelerated.
2. Competition remained low among manufacturers.
3. Pricing negotiations lacked transparency and Gavi lacked expertise to secure affordable pricing.
4. Supply capacity of existing manufacturers did not meet full PCV demand.
5. There was no improvement in the technological capacity of low- and middle-income countries to produce and supply PCV to their own populations.

These lessons, however, were not incorporated into the COVAX AMC design. Instead, Gavi pursued an approach grounded in the current market paradigm, which has repeatedly failed low-income countries: start negotiations from a fixed donor-funded budget, accepting that companies will ultimately decide what can be delivered when for that budget.

More fundamentally, the logic of using an AMC model for the COVID-19 pandemic does not hold. The PCV AMC targeted a disease mainly impacting a subset of the population in the poorest countries. Its premise – that demand for vaccines may be insufficient or overly uncertain and therefore not attractive to manufacturers – was not the same situation for COVID-19. Every country in the world needed COVID-19 vaccines which was all the incentive pharmaceutical companies needed. The COVID-19 vaccine problem that needed to be tackled was overdemand, not incentivising the interest of manufacturers.

Public-private partnership limitations

COVAX’s focus on market-based solutions is a result of their design as a PPP – the primary model used by global health actors like the Gates Foundation and the Global Fund to Fight AIDS, Tuberculosis and Malaria to address health challenges affecting low- and middle-income countries. In PPPs, pharmaceutical corporations are critical partners as they ultimately decide whether to supply life-saving medicines or vaccines to the partnership.

A challenge with PPPs is their general unwillingness to challenge unsound but politically sensitive issues such as trade protection of intellectual property (IP) to be essential to attract companies and wealthy governments. This role has been secured largely by funding PPPs to combat a range of health issues, including a $750 million investment to launch Gavi 20 years ago. Through these investments, the Gates Foundation positioned themselves as the essential intermediary between manufacturers and low- and middle-income countries, forming alliances with these manufacturers and wealthy governments.

The Gates’ model of corporate philanthropy also considers protection of intellectual property (IP) to be essential to innovation. Early in the pandemic there was space for the Gates Foundation to push for the sharing of technology and open models for producing COVID-19 vaccines, but they sent out a very clear message that IP would not be an access barrier. Gates’, and thus COVAX’s, refusal to acknowledge the pitfalls of that approach in addressing a global pandemic meant that COVID-19 vaccine development operated within the current IP status quo.

As of April 2021, the COVAX Vaccines Pillar had invested $1.2 billion of R&D funding into a portfolio of 12 vaccine candidates, but the funding came with minimal access strings attached. Not only have there not been conditions for affordable pricing, open licensing or sharing technology, but COVAX has also not taken a stand on important proposals to advance these strategies. For example, Gavi has not publicly supported a proposal to ease technology transfer and help increase and diversify supplies of COVID-19 vaccines through the WHO COVID-19 mRNA vaccine technology transfer hub. They have also been silent on the proposed World Trade Organization waiver of IP rules (the so-called TRIPS waiver), which could help alleviate some of the barriers for additional manufacturers to produce and supply COVID-19 vaccines.

Through COVAX, Gavi has also accommodated unprecedented manufacturer demands for countries to indemnify the companies and assume financial and legal liabilities for any possible serious adverse events following COVID-19 immunisation. While COVAX established a time-bound fund (the No-Fault Compensation Programme) to support AMC countries to pay for these potential costs, the complete transfer of legal responsibility for COVID-19 vaccines from manufacturers to COVAX and countries sets an alarming precedent for the future. In the case of the COVAX Humanitarian Buffer, most manufacturers are currently requiring legal responsibility to fall to humanitarian treatment providers, but it is unfeasible for these organisations to accept liability costs in lieu of pharmaceutical corporations.

Gavi missed an opportunity to use its political voice to challenge the market paradigm that consistently leaves people in low- and middle-income countries behind. It could have used both its political and financial position to negotiate terms and conditions with companies that advanced important measures in the public’s interest, such as transparency (for both contracts and pricing), solutions for liability and indemnification issues and pushing for open licensing and broader IP ownership of these publicly funded vaccines. Instead, Gavi pursued a market-based solution to what was inevitably going to also be a political and ethical problem. The resulting mechanism was prone to all the pitfalls of market dynamics, maintaining the inequitable status quo.
COVAX: A broken promise to the world

ISSUE BRIEF

Failure to Grasp That High-Income Country Nationalism Would Prevail over Multilateralism

The “market-shaping” premise of COVAX – that by aggregating so much global demand for future COVID-19 vaccines, COVAX would be the most attractive customer for industry and thus secure the most affordable prices in adequate supply – was dependent on HICs participating as self-financing participants. This would provide adequate funding for COVAX to make advance purchase agreements with manufacturers.

Gavi was not blind to the fact that HICs would make bilateral deals, but they were betting on the fact that HICs would also purchase through COVAX, seeing it as an “invaluable insurance policy” in case bilateral deals failed to produce approved vaccines. An additional incentive was that purchasing through COVAX meant that HIC governments were providing their populations an extra layer of protection by ensuring that the rest of the world gets access to doses too. Through this lens it was a win-win situation.

But HICs’ primary concern was to do everything in their power to end the epidemic within their borders as fast as possible. This meant vaccinating as many people as possible as quickly as possible. Gavi hoped EU countries would join as self-financing participants despite restrictive contract proposals that limited purchases to 20% of the population without an ability to choose which vaccines and without guaranteed delivery. But the EU sought to purchase vaccines for 70-80% of EU country populations and were already negotiating bilaterally with vaccine manufacturers to secure doses.

Gavi’s rationale suggests a potential lack of risk analysis and either an underestimation or a significant misreading of the reality that was apparent to many others. With so much at stake, it was predictable that countries with massive manufacturing capability would not relinquish autonomy and put their fate in the hands of a newly established mechanism that had never negotiated vaccine deals for wealthy countries. Gavi had no experience negotiating with pharmaceutical companies on behalf of any HICs and most middle-income countries, nor did it have experience procuring vaccines for this group of countries.

Though HICs came on board as COVAX AMC financial donors, the absence of some key HICs as participants using the mechanism to procure vaccines – such as the 27 EU member states – undermined COVAX’s ability to succeed. COVAX’s pursuit of these countries also wasted time and effort that could have been redirected to supporting countries in greater need of COVAX doses and planning for the smaller budgets and procurement pool that inevitably resulted.

Rather than use COVAX as their main procurement mechanism, many HICs and some upper-middle-income countries, including Russia, pursued bilateral agreements for large quantities of vaccines. The first vaccine purchases were made in May 2020 by the US and the UK. By the end of the summer of 2020, Canada, EU countries, the UK and the US had purchased enough doses through advance bilateral deals to cover significantly more than their entire populations.

The UK alone had bought into five bilateral deals for access to 270 million doses, equivalent to 225% of its population. The US, which hosts some of the largest vaccine producers in the world, voiced support for COVAX and contributed $4 billion for the COVAX AMC, but there were no illusions that the US would join COVAX as a self-financing participant. Under Operation Warp Speed, a US initiative to combat COVID-19, the government quickly struck deals with six companies for approximately 1.2 billion doses. Almost immediately, COVAX was in a position of having to compete with the very countries they were busy recruiting. Without other sources of funding, COVAX was not able to secure their own deals fast enough. This pushed COVAX, and the AMC countries that were counting on them, to the back of the vaccine queue, leaving them in a precarious position. Once the HIC deals were done and supply spoken for, it was difficult for COVAX to negotiate advance deals for the limited supply that remained.

COVAX Predominantly Relied on One Vaccine Supplier for AMC Countries

At the launch of the COVAX AMC it was announced that AstraZeneca was licensing its technology to the Serum Institute of India (SII) to supply one billion doses of COVID-19 vaccines for low- and middle-income countries. More than 111 million doses were to be delivered mainly to countries in Africa and Asia-Pacific regions between February and May 2021, following the vaccine’s WHO emergency-use approval. For example, according to COVAX’s first round of allocations, Bangladesh was to receive nearly 11 million doses. Ethiopia was expecting 7.6 million doses, and Pakistan 14.6 million. But in March, COVID-19 was wreaking havoc in India, and at the government’s request, SII halted all vaccine exports. This left COVAX and, by extension, dozens of countries in the lurch.

Strive Masiyiwa, Special Envoy to the African Union for the COVID-19 response and coordinator of the African Vaccine Acquisition Trust, warned COVAX in January 2021 “not to put all its eggs in one basket” and that they should spread the risk by working with more suppliers. But COVAX, he said, vouched for the reliability of SII.

Like vaccine nationalism, that an event such as this would occur was a clear possibility. India is a middle-income country and home to roughly 17% of the world’s population. It should have been anticipated that a large domestic COVID-19 outbreak was possible. However, if a risk assessment of the decision to rely heavily on SII was conducted and factored into the decision-making of the COVAX AMC, it is not publicly available.

The influence of the Gates Foundation in the decision to centralise so much reliance on vaccine supply from SII should not be underestimated. The Foundation provided $300 million to SII to “de-risk” vaccine manufacturing with the intention of SII supplying doses to the COVAX AMC. As Gavi lacked funding, this financial support from the Gates Foundation was supposed to ensure SII’s delivery of up to 200 million doses to COVAX in 2021.

Reports suggest that the Gates Foundation similarly influenced the University of Oxford’s decision to exclusively license their COVID-19 vaccine technology to AstraZeneca. Weeks after the
University of Oxford committed to working non-exclusively with multiple partners on a royalty-free basis to further develop their vaccine, they reversed this position and signed an exclusive deal with AstraZeneca, reportedly after the Gates Foundation influenced them to team up with one large manufacturer.43,44 In Spring 2021, as Gavi continued to pursue additional vaccine supply deals, including with the newly WHO Emergency-Use-Listed Chinese vaccines from Sinopharm and Sinovac, it was too late for countries that were relying on the SII doses. Countries planned their national vaccination strategies around their expected initial SII allotments from COVAX, which were supposed to arrive between February and May. Countries in Africa were expecting 66 million doses through COVAX, but at the end of May 2021 they had received just over 18 million.46 What they got instead were third and fourth waves of the pandemic, overwhelmed hospitals, and shortages of critical medical supplies.

COUNTRY PLANS ARE DERAILED, AND VACCINE ACCESS CHASM WIDENS

With their largest COVID-19 vaccine supply route shut down, COVAX turned its attention towards mitigation strategies and external communications waned. Numerous regional and country informants shared with MSF their frustration with COVAX’s lack of transparency and poor communication around supply problems. Common complaints include countries given short notice before shipments arrive, minimal information about the specifics of shipments, limited doses, and receiving doses too close to their expiration dates.

AFRICAN COUNTRIES MISS AN OPPORTUNITY TO ACCESS VACCINES AND LOSE THEIR FAITH IN COVAX

Forty-seven African countries joined the COVAX AMC. With few other options at the outset of the pandemic, there was cautious optimism that it would provide the “lifeline” to COVID-19 vaccines that Gavi promised.

In early 2021, countries were gearing up to launch vaccination campaigns based on COVAX’s first round of allotments. Ghana and Cote d’Ivoire were the first to receive shipments in late February – 600,000 and 504,00 doses, respectively. “For months, WHO teams in the region and partners have been supporting countries to prepare for the complex challenges of such a massive vaccination campaign. We now look forward to seeing these plans put into action with an effective and efficient vaccine rollout,” said Dr Matshidiso Moeti, WHO Regional Director for Africa.45

On 25 March 2021, Gavi informed participating countries that their allotments of SII/AstraZeneca vaccines would be delayed during March and April. On 26 April, they sent a follow-up letter announcing that deliveries would not resume in May, derailing vaccination campaigns in multiple countries.

Internal supply forecasts from April 2021 showed COVAX expected SII to provide most of COVAX’s supply until September 2021: up to 560 million doses.46 Though Africa is the second largest continent by size and population,47 it has received just 3% of global doses administered as of 28 November 2021. Europe and North America, with significantly smaller populations, have received 12% and 9.5%, respectively.48 In Germany, 68% of the population is vaccinated compared to 0.1% in the Democratic Republic of Congo.49
MIDDLE-INCOME COUNTRIES IN LATIN AMERICA AND THE CARIBBEAN PAID FOR COVAX DOSES BUT WERE LEFT EMPTY-HANDED

It is not just the 92 countries of the COVAX AMC that were let down; self-financing middle-income countries lost out as well. Encouraged by PAHO, COVAX’s procurement partner to the region, 28 Latin American and Caribbean countries and territories joined COVAX as self-financing partners. They signed agreements with Gavi representing approximately 33% of the projected global procurement volume for the COVAX self-financing participants group, or about 202 million COVID-19 vaccine doses.52 As of 7 December 2021, PAHO reported that just over 41 million doses had been delivered.53

In October 2020, Paraguay made a payment of $7 million to COVAX for 4.3 million vaccine doses. As of November 2021, COVAX has only provided 304,800 of those vaccines.54,55

On 25 July 2021, Paraguay’s President Mario Abdo Benitez had blunt words for COVAX:

“We bet on the COVAX mechanism to generate equity. I cannot stay quiet; COVAX didn’t work.”56

Like many Latin American and Caribbean countries, Paraguay has had to make bilateral deals to quickly compensate for COVAX’s shortfalls. They have also become more reliant on donations. Of all the available doses in Latin America, only 9% have been channelled through COVAX, the other 91% come through direct purchase or other arrangements, as of September 2021.57 Most countries have only received around 30% of the supply they contracted through COVAX.58

According to sources we spoke to in Latin America, the great disappointment of delayed and unfulfilled deliveries was compounded by poor communication and a lack of transparency. Others have similarly identified this sentiment of countries being let down by COVAX, with the Bureau of Investigative journalism reporting one Latin American official asking, “How are we going to justify that you put so much money upfront and still you have not received what was promised?”48

DONATIONS BECOME A SIGNIFICANT PORTION OF COVAX DOSES

Instead, HICs only relatively recently started making significant donation commitments in the face of mounting political pressure and criticisms about dose hoarding. Commitments though are not translating into doses for COVAX fast enough to make up their significant shortfalls. The US announced it will donate 800 million doses to COVAX, but only 120 million of those donations have been delivered. The EU announced it would donate 446 million doses, but just 47 million have been delivered.60

COVAX appears to be evaluating donations on a case-by-case basis and in some cases accepting donations that do not adhere to its original donation criteria. Donated doses present their own set of challenges for COVAX: transaction costs such as shipping fees need to be negotiated, and there are added logistical challenges, such as the possibility of short expiration times and limited time for countries to plan.61

By the end of October, over 35% of COVAX doses were donated.62 The overreliance on donations has created a seemingly haphazard and piecemeal approach to dose allocation in AMC countries. Countries are receiving multiple types of vaccines and given little notice on when to expect shipments. Receiving doses close to their expiration dates is a much-cited problem, as well as receiving small quantities.

Though donated doses are urgently needed, it is a short term, unsustainable solution, as recognised by Gavi leadership.63 Beyond the logistical issues, there is a more insidious consequence of the overreliance on donations: it reinforces neo-colonial power dynamics and an outdated charity model, leaving low-income countries’ ability to vaccinate their populations dependent on the “generosity” of wealthy countries.
LET DOWN BY COVAX, REGIONAL INITIATIVES FILL THE VOID

Though Gavi discouraged regional bodies from playing a procurement role for their countries and did not include them in the development and implementation of COVAX, some have now become leading COVID-19 vaccine procurers for their member states. Africa’s COVID-19 Vaccine Acquisition Trust (AVAT) and the PAHO Revolving Fund, have begun securing doses for governments in their respective regions to augment COVAX distributions.64

The African Union launched AVAT in November 2020. In partnership with the African Export-Import Bank (Afreximbank), owned by African member states, they secured $2 billion to create a purchasing platform to improve their buying power. In March 2021, AVAT and Johnson & Johnson (J&J) signed an agreement to purchase 220 million doses of the J&J single-shot COVID-19 vaccine, with an option to order an additional 180 million doses. This would be enough to immunise a third of the population and bring countries in Africa halfway to their goal of vaccinating at least 60% of the population. International donors have committed to deliver the remaining half of the doses required through COVAX.65

PAHO’s Revolving Fund acts as a delivery partner for COVAX, serving as an intermediary between countries and COVAX for the Americas region. Despite the Revolving Fund’s 42 years of success as a regional vaccine procurement mechanism, PAHO decided early on to not do direct deals with manufacturers. Instead, they encouraged countries to join COVAX, assuming it would provide access to an extensive portfolio of vaccines at reasonable prices. By August 2021, with COVAX still behind schedule and growing disparities in the region, PAHO changed course and announced that it would use its Revolving Fund to help countries in the region “go beyond the 20% COVAX offer.”66

COVAX is now cooperating with regional bodies and publicly acknowledging the critical role they play in ensuring vaccine equity around the globe, but sources report that until recently Gavi had been trying to discourage regional procurement. According to one, Gavi was unhappy when AVAT started negotiating directly with major pharmaceuticals, simply seeing it as competition, and tried to dissuade them from buying from SII and Pfizer.

COVAX TODAY: ADAPTATIONS UNDER CONSIDERATION

COVAX is not the global equaliser that was envisioned. Eighteen months and multiple vaccine approvals later, COVAX has failed to meet its original goal of providing two billion COVID-19 vaccine doses by the end of 2021, enough to cover 20% of the population in participating countries.

In September, Gavi cut anticipated deliveries for 2021 by 25%, to 1.4 billion, but as the year draws to a close COVAX deliveries are far from that goal. As of 17 November, COVAX had shipped 508 million doses of vaccines, of which 408 million have gone to AMC participants; 207 million of those doses were donations.62

In AMC countries, that translates to 3.8% of the population receiving at least a first dose of a COVID-19 vaccine through COVAX supplies. Of the total population of COVAX recipients, just 1.7% have been fully vaccinated through COVAX-supported doses.62 There are 18 active COVAX participating countries who are still awaiting receipt of any COVAX doses.62

However, recent developments indicate that Gavi is trying to course-correct some of the problematic elements of COVAX. At its June 2021 meeting, the Gavi Board approved a proposal to redefine the way COVAX engages with self-financing countries, essentially allowing them to drop out of the mechanism.67 Gavi is also in the process of making the terms for the countries that choose to remain firmer. These changes are meant to reduce COVAX’s financial risks, give more stability to the mechanism in determining forecasted needs, and increase focus on the countries most in need,62 recognising the fact that only four self-financing participants rely on COVAX as their primary source of COVID-19 vaccines.68

Changes are also underway for the COVAX AMC as just 45 (of 92) countries currently rely on COVAX as the source for more than 50% of their doses. In October, COVAX used a different allocation model, delivering doses to only those greatest in need. In 2022 the focus will be on lower-income countries that urgently need support. COVAX will provide more targeted financial support and enhanced technical support to AMC countries with a heightened focus on the 25 highest-risk countries.62 It will also provide increased support for in-country delivery for AMC countries.69

Acknowledging that most countries have other sources of COVID-19 vaccines and therefore the potential vaccination coverage is highly variable across COVAX countries, the allocation system will also be adjusted away from the initial intention of allocating doses at the same pace and proportion to all countries. These changes to AMC and self-financing countries’ rules and allocation processes reflect a more realistic vision of how COVAX can support low- and middle-income countries struggling to access COVID-19 vaccines. This also inherently acknowledges that COVAX is not the global procurement mechanism that it set out to be. Instead, it has primarily become a mechanism serving some of the poorest countries of the world that did not have other options for COVID-19 vaccine supply.
CONCLUSION

Though COVAX has failed to deliver on its vision, it was developed with good intentions during a time of unprecedented crisis. The shortcomings of COVAX cannot be blamed on Gavi alone given the enormous challenges faced, the speed needed in developing an approach for COVID-19 vaccine equity, and the environment in which the mechanism was developed.

It is improbable that there would have been any way to circumvent vaccine nationalism and that Gavi could have raised enough money quickly enough to compete with HICs for doses early on. Nevertheless, these challenges should have been anticipated, and mitigation strategies should have been implemented earlier. Not only were wealthy countries buying up all the doses before vaccines even existed, but they also imposed export bans and restrictions both on raw materials and finished doses during the first months of production.

ACT-A and COVAX were built on the PPP model that dominates global health. COVAX’s shortcomings lay bare the fundamental problems with the PPP approach and leave little doubt that the model in its current iteration is unfit to respond to a global pandemic. COVAX relies too heavily on traditional market dynamics and voluntary actions from pharmaceutical companies and HIC governments. The lack of sufficient oversight and accountability mechanisms make it difficult to address AMC country concerns or incorporate lessons learned along the way.

While much about the COVID-19 pandemic has been unpredictable, COVAX’s shortcomings were rather predictable. Civil society organisations and other stakeholders flagged vital issues of concern with COVAX early on, but Gavi continued forward while failing to address these concerns. To date, there have been no published reviews or mid-term evaluations of COVAX and no acknowledgment from Gavi that the design of the mechanism itself has anything do to with COVAX’s failure; instead, all responsibility for its shortcomings has been laid on external factors beyond their control. According to recent documents prepared for the December 2021 Gavi Alliance Board meeting, Gavi believes they are well positioned to play a central role in future pandemic response.

At the World Health Assembly Special Session from 29 November to 1 December 2021, member states agreed to establish an intergovernmental body to draft a new WHO-led international instrument on pandemic preparedness and response. WHO’s Director-General, Dr Tedros Adhanom Ghebreyesus, and a number of world leaders are in favour of the idea of a global pandemic preparedness and response mechanism, recognising the gross inadequacies of the COVID-19 response.

As pandemic preparedness work proceeds, WHO and governments must ensure we do not repeat the mistakes of the past one and a half years by replicating the COVAX model in future pandemic responses. If medical innovations are going to be shared fairly and applied in the most effective strategy to improve global health, radical change is needed. The first step towards this change is critically evaluating the COVAX experience and rebalancing the power dynamics between the private sector and the public interest.
RECOMMENDATIONS

Moving forward, there are immediate adjustments to COVAX that should be made to improve transparency, accountability and confidence in the mechanism and help improve access to COVID-19 vaccines. In addition, there are broader systemic changes that must finally be addressed if the world is going to avoid repeating the gross injustice of hundreds of millions of people denied access to the fruits of medical innovation. Despite the rhetoric of world leaders at the launch of the ACT-A that COVID-19 vaccines would be “global public goods,” to date the COVID-19 response has perpetuated the status quo. It is time for that to change.

MAKE IMMEDIATE ADJUSTMENTS TO COVAX

Gavi should:
• Restructure COVAX’s governance and decision-making processes so that AMC countries, regional bodies, and civil society have meaningful inclusion and influence in the decisions of COVAX.
• Improve external communications to all stakeholders, including but not limited to participating governments, regional bodies, and civil society organisations on all aspects of operation and delivery.
• Provide more timely and accurate information on allocation decisions and delivery timelines to recipient countries with enough advance notice to allow them to prepare adequately to receive vaccines.
• Create a clear roadmap for 2022 in consultation with regional bodies, procurement experts and funders, and provide ongoing updates on progress against goals.

URGENTLY DELIVER COVID-19 VACCINES TO AMC COUNTRIES

Gavi should:
• Focus efforts on procuring vaccines for those countries most in need, in close coordination with regional bodies.

HICs should:
• Cease making bilateral deals for vaccines and exercising options on existing contracts that undermine equitable global allocation of COVID-19 vaccines according to public health needs.
• Urgently redistribute excess doses to AMC countries via COVAX or regional bodies without earmarks to ensure doses are directed to where they are most needed. Doses should have sufficient remaining shelf life to allow for countries to plan vaccination campaigns.
• HIC governments that are self-financing participants of COVAX but already have adequate supply through their own bilateral deals should refrain from drawing on their doses available through COVAX.
• Support the rollout of COVID-19 vaccines in AMC countries by providing financial, technical, logistical and community preparedness support for vaccine delivery, and should work together with all stakeholders to urgently reach marginalised groups.

Manufacturers should:
• Prioritise and fulfil COVAX and regional contracts (such as AVAT and PAHO) as a matter of urgency and remove contractual barriers to HICs redistributing doses to AMC countries.
• Coordinate with countries that have over 40% coverage and have contracted high volumes of vaccines, to allow the prioritisation of those doses to COVAX, AVAT and PAHO.

IMPROVE TRANSPARENCY AND ACCOUNTABILITY AROUND PURCHASING AGREEMENTS

Gavi should:
• Realise its commitment to transparency by publishing in full COVAX’s contracts with manufacturers including delivery schedules, prices for AMC countries and self-financing countries, and treatment of liability. This should also include CEPI’s contracts with manufacturers for R&D funding.
• Require that companies receiving funding from COVAX be transparent with product development costs and pricing.

HICs should:
• Publish in full their contracts with manufacturers to advance transparency and accountability to the public.
• Insist that any money given to Gavi for COVAX has product cost information as a requirement.

Manufacturers should:
• Insist that any money given to Gavi for COVAX has product cost information as a requirement.
• Publish in full their contracts with manufacturers to advance transparency and accountability to the public.

EXPAND GLOBAL MANUFACTURING CAPABILITIES FOR COVID-19 VACCINES AND BEYOND

Gavi and CEPI should:
• Attach concrete conditions to all funding for COVID-19 vaccine research, development and manufacturing that guarantee technology transfer and provision of open, non-exclusive, and royalty-free licensing for pre-existing and future IP related to COVID-19 vaccines.
• Support the calls of government to alleviate IP barriers on COVID-19 medical tools by publicly supporting the WTO TRIPS waiver.

HICs should:
• Attach enforceable conditions to R&D funding to ensure benefit-sharing and access to resulting medical technologies for low- and middle-income countries and to decentralise production.
• Support existing global initiatives like the WHO COVID-19 mRNA Vaccine Technology Transfer Hub and use their power to compel manufacturers to share vaccine technology and know-how with such globally recognised platforms.
• Pursue all legal avenues for removing IP monopolies and other exclusivities of manufacturers on COVID-19 vaccines to facilitate national and regional production and supply, and enable regional self-sufficiency for future health needs.
• Express support for the WTO TRIPS waiver to remove IP barriers on COVID-19 medical tools, and encourage other countries, especially those currently in opposition, to do the same.

Manufacturers should:
• Facilitate technology transfer and sharing of know-how with globally recognised platforms, such as the WHO mRNA Vaccine Technology Transfer Hub, and provide transparent, non-exclusive voluntary licenses to all capable manufacturers. Manufacturers should not pursue patents or enforce them in areas where patents have already been granted.
ANNEX

MSF’s analysis illustrates the shortcomings in COVAX’s design and implementation, which have prevented it from achieving its original objectives. This analysis relies in part on key informant interviews with 25 global health actors, civil society representatives and government officials. Many of the key informants interviewed highlighted specific concerns regarding COVAX’s key stakeholder inclusion, communications, decision-making processes, and accountability measures. Below are select interview quotes. Many interviewees chose to be anonymous.

COVAX’S LACK OF KEY STAKEHOLDER INCLUSION IN ITS DESIGN PROCESS AND IMPLEMENTATION:

“A small group of experts sat down and defined the problem and defined the solution for a continent of 1.3 billion people. They packaged it in an attractive way, marketed it, and drove the narrative about their solution. Had there been more people in the room, right from the beginning, from African governments, African academia and civil society, it probably wouldn’t have happened this way.” — Head of an African health institute

“Because it was just the good old boys club in the room, and they didn’t bring in low- and middle-income countries, it ended up looking like what the good old boys always do: development aid.” — Expert on global vaccine supply

“It was clear that the private sector was saying we don’t want them [CSOs] because they cause trouble, and Gavi was enthralled with these relations so blocked our involvement.” — ACT-A civil society representative

“We finally got in only to realise the majority of the working groups didn’t meet and when they did it was clear that separate discussions and meetings were happening where decisions were being made....There is very little transparency, and a lack of clarity in decision making processes and who is involved.” — ACT-A civil society representative

On the AMC Engagement Group, meant to represent AMC countries in COVAX’s governance: “It’s a place to share information where we can pretend countries are involved, but they are not properly involved. It is not a group that discusses things, where they exchange ideas, where they suggest answers to problems.” — Member of Gavi Board constituency

OTHER COVAX DESIGN SHORTCOMINGS:

“Gavi made serious early missteps by factoring high-income countries’ participation into their plans. In July 2020, Gavi sent contracts to EU states that included a 20% purchasing cap, no choice in vaccines and no guarantees, and yet they hoped European countries would sign. But by June, the EU already had their own process well underway, negotiating with multiple manufacturers with the goal of covering 70-80% of EU countries’ populations...It didn’t make any sense for them to join. Politically, it was just a nonstarter.” — Dr Clemens Auer, Special Envoy for Health and Vice-Chair of WHO’s Executive Board

“They’re [Gavi] not political people, they’re technical people...The whole thing was built in a totally apolitical way. It was like politics didn’t exist.” — Member of Gavi Board constituency

“They had such faith in the multilateral system because it is what their entire belief system is based on. I don’t think they could understand or foresee a world where countries would not work together on this.” — Andrea Taylor, Duke University’s Global Health Innovation Center

“We will never fix vaccine nationalism, so we need to bake it into the plan...You will never get a national leader who is going to make a decision that prioritises a different population over their own...We kept being surprised by this, but that was actually what they were supposed to do.” — Andrea Taylor, Duke University’s Global Health Innovation Center

“What I cannot understand is how they [Gavi] thought that it was OK to ask all of these poor countries to put their hopes on this extremely vulnerable supply chain when they didn’t have a backup plan. And we all saw the export restrictions coming. They were just crossing their fingers and toes and it just wasn’t enough.” — Andrea Taylor, Duke University’s Global Health Innovation Center
REGional Procurement Mechanism Concerns:

“They wanted to keep the power with COVAX and keep the financing mechanism relevant. But why discredit a regional body financed to do these things when you know that you will not be able to deliver vaccines? It is a very neo-colonialist approach.” – Expert on global pharmaceutical supply chains

“Donors who are putting money into COVAX, the USG and the EU, need to see the value in investing in regional structures.” – Hitesh Hurkchand, epidemiologist and expert on pharmaceutical supply chains

Countries Lose Faith in COVAX:

“The fact that we are relying on COVAX, and this is where we are, shows that it is not delivering. But what mechanisms are there to make COVAX accountable?” – Salima Namusobya, Executive Director of the Initiative for Social and Economic Rights (Uganda)

“Kenya, like most low- and middle-income countries, lined up behind COVAX. COVAX seemed to be the hope... COVAX has not been open and transparent. We received one shipment in March, but then there was an extensive gap of about six months before more doses arrived. We didn’t have information on what was coming down the pipeline during that time, no clarity on COVAX’s allocation plans. It was frustrating, and it was tough to plan. Some days I wake up and ask myself, COVAX is accountable to whom?” – Jack Ndegwa, senior vaccine advisor at KANCO (Kenya)

“Latin American countries believed that COVAX would negotiate with the best interest of countries, but they didn’t. It was a huge disappointment. Colombia, like many countries, gave up on COVAX quickly.” – Carolina Gómez, founder of Colombia’s Center for Medicines, Information, and Thought

“COVAX had no added value, neither in the multilateral negotiation nor equitable distribution. It had some added value on price because it can purchase cheaper, but there is much room for improvement.” – Senior Latin American government official

“COVAX is no different from negotiating bilaterally and is worse because of the communication difficulties.” – Senior Latin American government official

Countries Rely on Donations

“It’s very difficult when you get limited quantities of near expiry doses. You have to select a priority group to vaccinate but also rush to distribute to beat the expiry period. This rush feeds misinformation and disinformation to the public, which increases hesitancy.” – Denis Kibira, Executive Director at the Coalition for Health Promotion and Social Development (Uganda)

“The whole vaccine supply system to Africa is now dependent on donations and goodwill. It keeps us totally dependent and unable to control how we deal with the pandemic.” – Head of an African health institute
REFERENCES


40 Findlay S, Pilling D. Indian vaccine maker extends freeze on exports. That’s a problem for the planet’s most vulnerable. CNN. [Online]. 2021 May 18 [Cited 2021 Dec 6]. Available from: https://www.ft.com/content/63fbbb79-f657-4e6c-b190-cffd0d630593


55 PAHO. Tracker COVAX initiative – COVID-19 vaccines deliveries in the Americas. [Online]. 2021 [Cited 2021 Dec 1]. Available from: https://p.powerbi.com/view?rsv=eyJrIjp0MiJ9MjA5ZDAxMmEyTiyNjC0XM210LWZ5MjUvYVQzZC0xNDc4TThlMw1C61U2MxBnZjLTtYzATNGUwZi04YTE0LTFlNFgxdMDE1MThnYVJISmjMQiJ9


63. Berkley S. Donations are surely not the answer for equitable supply. When we formed COVAX there was no donation mechanism. We only asked for donations due to export bans, vaccine hoarding & manufacturers delays because there were few doses for LICs. The solution is ample paid supply. [Twitter]. 2021 Nov 17 [Cited 2021 Nov 30]. Available from: https://twitter.com/Gavi-Seth/status/1461105242020401152


ACKNOWLEDGEMENTS

MSF would like to thank the many individuals who so generously gave their time to be interviewed. Special thanks to Jessica Malter for extensive research, analysis and writing support.