Discussion Paper

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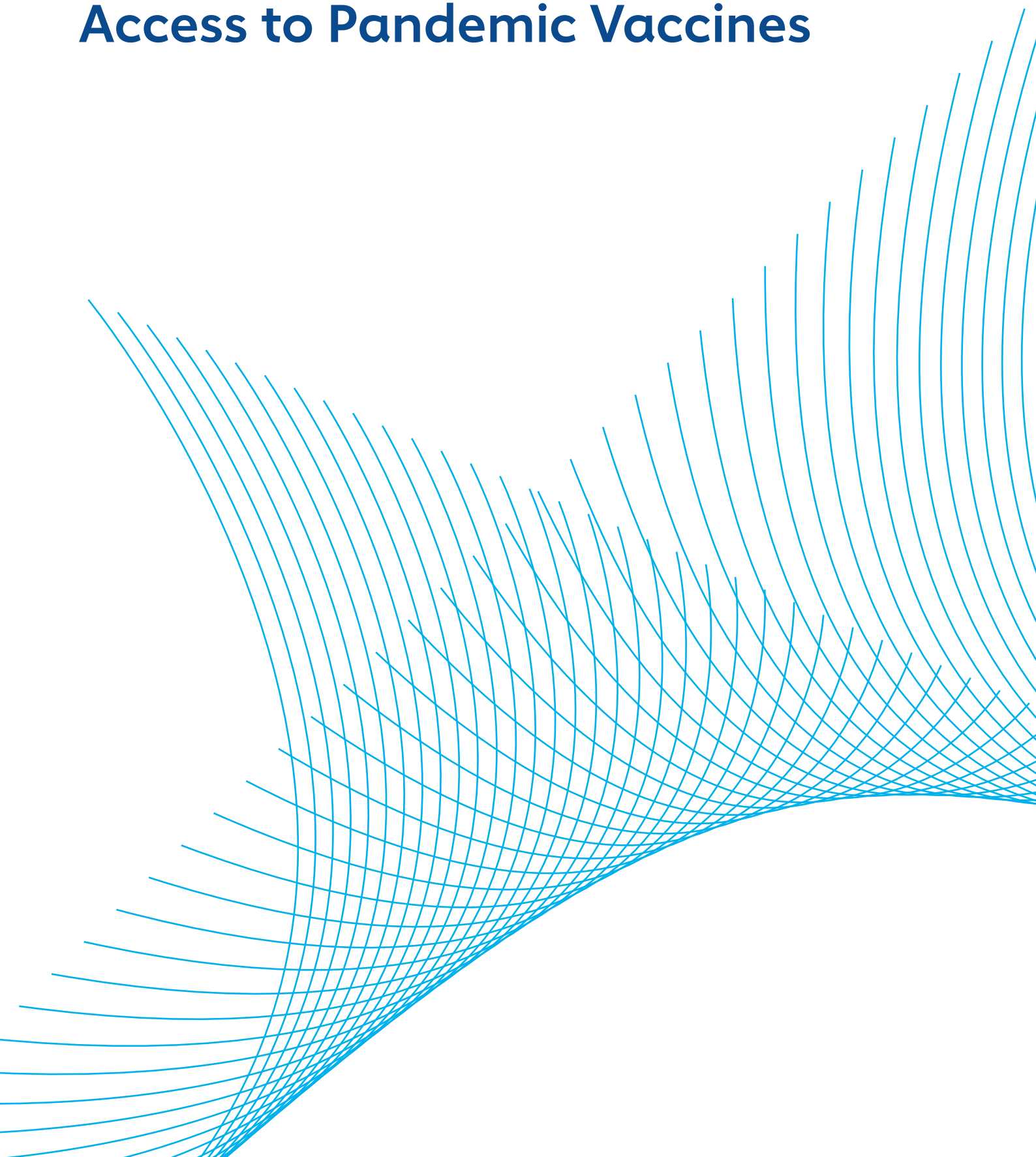
Taking Stock of Humanitarian Access to Pandemic Vaccines



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1 The origin of the COVAX Humanitarian Buffer

COVAX was launched in 2020 with equity as its foundational principle, and fundamental to its design from the outset was a vision to address the most unpredictable and hardest to fill gaps in global COVID-19 vaccine access.

To address this challenge, the COVAX Buffer was set up as an innovative tool to dedicate up to 5% of the volume of doses available to the COVAX Facility to reach vulnerable populations in humanitarian settings. In the early stages of its design, it also included a potential contingency mechanism that could be used to address the most severe surges of the virus around the world, not only in humanitarian settings.

As with other parts of COVAX, the Buffer was built to try and address working assumptions around several unknowns. This meant mapping the potential need and scope of response while the paths of the pandemic, vaccine development and manufacturing, and the geopolitics and market dynamics of vaccine access remained unclear – and also leaving enough flexibility to adapt as the pandemic evolved and working assumptions inevitably shifted. There were other "unknown unknowns" too, in the absence of any precedent for a mechanism that had provided novel, non-WHO-prequalified products in these humanitarian contexts during a pandemic.

The concept of the COVAX Buffer was initially taken to the Gavi Board in December 2020 in the form of guiding principles. The guiding principles of the Buffer brought together the global health ambition of equitable access with humanitarian principles of neutral, impartial, and independent allocation. Thereafter, the conceptualisation, design, approval and roll-out of the mechanism was an iterative, multi-stakeholder process, with the final design of the mechanism approved in March 2021 – and focusing on reaching the hardest to reach in humanitarian contexts. The key, and perhaps most ambitious, innovation included in the design was the idea of direct allocation of Emergency Use Listed (EUL) vaccines to non-governmental entities, i.e. humanitarian agencies, alongside allocations to sovereign countries. This meant no geographic limit on allocations: the Buffer was designed as a tool available to respond to humanitarian need in any region, regardless of COVAX participant status (meaning self-financing, AMC-supported or non-COVAX members could all be eligible).

Since that time, it has become clear that where governments do reach and provide services to vulnerable groups in humanitarian contexts, enabling access in a pandemic setting is possible, even if overall coverage rates reflect systemic challenges. COVAX has made a significant contribution to humanitarian settings broadly. In the 28 countries around the world with a humanitarian response plan, COVAX has been the majority supplier of COVID-19 doses administered in these settings, with 320 million doses supplied as of mid-June 2022. Allocations and deliveries via the Buffer itself have enabled governments to protect refugees and other vulnerable groups in Iran and Uganda.

When it comes to enabling access through non-governmental actors, however, the challenges, lengthy timelines and legally-complex hurdles encountered in the process of operationalizing the Buffer have reflected the monumental nature of the challenge: putting in place a solution to reach the hardest to reach, acting as the measure of last resort, when all other efforts, and traditional mechanisms, have failed. In that way, the COVAX Buffer has mirrored COVAX operations on a smaller scale – undertaking emergency response in the unknowns of an unprecedented pandemic – but with added complexities pertaining to risk, decision making, and highly politicised and conflict-affected contexts.

The following paper lays the groundwork for discussions on how to address this continued bottleneck to equity, and highlights critical lessons for future pandemics.

2 Flexibility as a rule

It is no surprise, then, that a general COVAX takeaway also applies to the more targeted effort to reach the hardest to reach. Flexibility, and the ability to adapt in response to an evolving pandemic situation, must be built into any access model. While the original design for the Buffer included a "contingency provision" for surges around the world (in addition to the humanitarian focus) the scale and spread of the pandemic, extreme inequity between nations at the start of the global rollout, and the characteristics of the products developed – ability to drive down severe disease, hospitalization and death – changed this calculus. It meant that the "COVAX Buffer" needed to be oriented not towards suppressing the worst variant-driven outbreaks on the planet – like a fire brigade – but rather towards those parts of the planet where populations of concern were at risk of not being included in national vaccination plans at all, and thus going without basic protection against severe disease and death. The flexibility of the design, and the in-built two-pronged strategy – contingency/ humanitarian – amidst an evolving pandemic, allowed for a smooth progression and allocation of resources to the humanitarian portion of the Buffer in full without needing to redesign the whole mechanism.

3 Unprecedented collaboration

The design, operationalisation and implementation of the Humanitarian Buffer has been a multi-stakeholder and multi-sectoral endeavor, and this has laid the foundation – and must be an essential element – for joint efforts in the future.

At the outset, the UN system's highest level humanitarian coordination platform, the Interagency Standing Committee (IASC) was asked by the Gavi Board to undertake independent expert decision making for doses channeled via the Humanitarian Buffer, and the World Health Organization (WHO) chaired this decision group. A COVID-19 Working Group under the IASC, chaired by UN Office for the Coordination of Humanitarian Affairs (OCHA), was engaged to work through analysis, assumptions, policy frameworks and design of this mechanism jointly with COVAX partners Gavi, WHO and UNICEF.

These partnerships and the inclusive development process were unprecedented: the IASC, utilising the country presence of its member agencies, helped establish the need and provided the data that was the basis of the Buffer design as well as the basis for negotiations with manufacturers; the International Committee of the Red Cross (ICRC) took lead in helping COVAX develop the Terms of Reference of the decision making body under the auspices of IASC; Médecins Sans Frontières (MSF) took lead in developing the application form for the Humanitarian Buffer, utilising its frontline experience in emergency healthcare as well as its experience as a founding member of the ICG mechanism; and Gavi took lead in negotiating indemnification waivers from vaccine manufacturers on behalf of humanitarian agencies. Other IASC members, including those from civil society platforms like the International Council of Voluntary Agencies (ICVA) have helped inform the evolution of the mechanism, conducting "lessons learned" exercises that have informed the continued improvement of the design.

4 Correctly diagnosing the risk

Because it was developed through cross-sectoral collaboration, the business case for the Humanitarian Buffer, unfortunately, correctly diagnosed the systemic risk that lay ahead: populations in humanitarian settings were and sadly continue to be the furthest left behind and the hardest to reach with COVID-19 vaccines.

Most of the countries that have not yet achieved 10% vaccination coverage are indeed ones that could be categorised as humanitarian settings, as reflected by the existence of Humanitarian Response Plans, Joint Response Plans or Flash Appeals for these countries. As of May, 17 countries had not achieved 10% coverage and of these, 14 had on-going humanitarian crises. This statistic hides another tragedy: amongst countries with humanitarian crises, the ones that have least access are poorer than the rest; at the same time, analysis also show the general trend that areas with high numbers of people in need of humanitarian assistance, and vulnerable groups such as internally displaced, have lower vaccination coverage compared to others. This is true for routine vaccines as well.

5 Identifying the issues

Entrenched systemic barriers

While there are Humanitarian Buffer-specific lessons that shed light on at least some aspects of why populations of concern in humanitarian contexts remain unreached, it must be acknowledged at the outset that there are systemic issues that are beyond the power of any single multilateral effort to fix.

Humanitarian access in some contexts requires negotiation with sovereign countries controlling cross-border movement into areas of active conflict or strife, with armed groups and other sanctioned or otherwise complex actors, while also navigating logistical challenges such as storage and maintaining the cold chain. Given the highly regulated nature of vaccines, cross-border operations mean navigating multiple regulatory and sanctions regimes, while being reliant on the willingness and cooperation of all parties to a conflict, as well as of manufacturers whose products are being shipped, and donor countries whose official development assistance (ODA) may be part of the financing.

As an example, the first two approved and planned Humanitarian Buffer deliveries via humanitarian agencies were both cross-border programs that entailed navigating contexts where humanitarian access generally, and not only for the Humanitarian Buffer, is highly fraught due to conflict. There are barriers with far reaching implications beyond access to vaccines, and many other relevant stakeholders involved in identifying viable solutions to addressing these.

This means that while the COVAX Facility, aside from the Humanitarian Buffer, has played a key role in minimising these inequities as the leading source of COVID-19 vaccines for the countries with a Humanitarian Response Plan, the last mile within these settings as well as some other conflict zones remains an enduring challenge. The Humanitarian Buffer was created for this very last mile, but the results to date illustrate that the original design requires a significant shift, in line with the evolution of the pandemic, and lessons must be learned for the future.

Impact of other pandemic innovations and approaches

For the last two years, many stakeholders – confronted with an unprecedented situation – asked themselves "how can this be made to work?". These innovations and practices formed a part of the novel pandemic architecture constructed during COVID-19 and had operational implications for the ability to ensure humanitarian access.

In 2020, precedents were set by sovereign states and manufacturers' on the overall approach to manufacturer indemnification requirements for novel emergency products, and the use of WHO Emergency Use Listing (as opposed to the traditional approach of WHO prequalification) allowed these products to be rapidly approved for distribution and delivery around the world. However, during the course of the Humanitarian Buffer's design and operationalisation, these factors generated product liability and other residual risks and created a range of roadblocks for humanitarian access.

First, with the general precedent set being that indemnity and liability (I&L) obligations would fall on those receiving vaccines, it was critical to secure I&L waivers for doses delivered via the buffer. This was essential because humanitarian agencies – particularly those operating in specific national contexts – in no way have the ability to take on this risk as sovereign states can. This involved lengthy negotiations with manufacturers to secure these waivers. These began in summer 2021, and by May 2022, 5 manufacturers – Clover, Johnson&Johnson, Novavax, Serum Institute of India, Sinopharm and Sinovac – had agreed to waive general I&L obligations for doses delivered via the Buffer.

However, these waivers did not cover the full gamut of risks as vaccines move through the chain from procurement to delivery to administration, and the general approach of shifting liability away from manufacturers obligated someone else to take on those risks. This necessitated extended risk-sharing negotiations between manufacturers, Gavi, WHO, UNICEF and applicant agencies over end-to-end residual risks.

Operating outside state-based architecture

Many of these roadblocks were particular to working outside the purely state-based immunisation architecture, where sovereign states have established systems and resources for making procurements and assessing and taking on risks. Even though working with non-governmental agencies is at times the only viable route for hard-to-reach communities – a truth acknowledged by the innovative design of the Buffer mechanism – it was exactly here that the limits of novel pandemic approaches, crafted mainly with state-based immunization architecture in mind, were felt the most.

In an example of the challenge, facilitating the importation of novel vaccines into conflict-zones and cross-border movement where governments are not directly supporting or undertaking the product consignment is extremely difficult in terms of securing regulatory approvals and, particularly, import licenses. The lack of the mechanisms that are usually triggered by WHO prequalification (PQ), such as import waivers and the ability to bypass the need for specific approval from national regulatory authorities, already presented a process challenge in getting doses rapidly to countries – and this was intensified in the case of working with non-governmental organisations.

Evolving pandemic context

The Buffer was created in a supply constrained environment as a measure of last resort to meet the needs of populations in humanitarian settings. This operating context, heavily influenced the design. It established, for example, the need for all stakeholders to also prioritize advocating with national governments to include all populations of concern as a first resort. Further, it required an independent, expert driven allocation process led by the IASC so that scarce supply could be channeled in a just and high-impact manner.

Today's context, however, is very different. Supply is no longer the biggest constraint. Instead, demand for COVID-19 vaccines in humanitarian settings is low despite the persistence of inequitable access. Other competing needs of populations of concern in humanitarian settings, for example unprecedented hunger and malnutrition, are surpassing the importance of "vertical" deliveries of COVID-19 vaccines.

The shifting context highlights yet another gap in pandemic operating assumptions within existing global mechanisms. In-country delivery financing is mostly directed to governments (that need to sign off on any sub-grants to non-governmental organisations) – yet another limitation of working outside state-based architecture. For the current Buffer model, this funding, provided via the UNICEF Humanitarian Actions for Children Fund (HAC), remains somewhat tied to dose allocation or application approval, noting active discussions are underway on how to shift this approach. No global direct-funding pot currently exists for non-governmental organisations (NGOs) to make "integrated" or bundled COVID-19 deliveries to last mile communities, with very little visibility on more piecemeal support that may be provided by various stakeholders.

In order to effectively deliver vaccines, delivery support is needed for preparation prior to introduction, including supply chain capacity and management, human resources including at sub-national level, communication between organisations and with the public, and data collection systems among other things. Efficiently combining these with other health and humanitarian services will require further thinking.

6 Identifying the impact

While the Humanitarian Buffer was not designed as an outbreak response mechanism, the drawn-out indemnification waiver negotiations, multi-stakeholder contracting negotiations and complex product importation processes have meant that the windows of opportunity for the highest impact for the populations of concern are closing or have closed.

The withdrawal of a Médecins Sans Frontières application for a conflict zone was illustrative of this core takeaway: the lead time from application to delivery cannot be long for volatile contexts. The window of opportunity for deliveries in such settings could close unpredictably due to political, operational or other factors, making speed of action important for success.

Lengthy periods of "problem solving" also increase the risk that the pandemic environment – and thus the nature of the needs – may shift again, necessitating going back to the drawing board and losing further time solving additional challenges. Furthermore, this places a high burden on the implementing organisations involved, and may disincentivize them from engaging fully with the process as they deal with problem solving fatigue and seek to balance other competing priorities in an emergency, resource-limited situation.

7 Takeaways for COVID-19 response

Based on these elements – including lessons learned and the significant evolution in the supply-demand dynamics of COVID-19 vaccination – implementing a fit-for-purpose mechanism for humanitarian access to COVID-19 vaccines currently requires the integration of COVID-19 vaccines with other essential services. This will also require the provision of delivery financing that enables integrated delivery, and availability of flexible, direct funding for non-governmental implementing partners.

Given the demand and uptake barriers highlighted above, the need has shifted. The vertical delivery of COVID-19 vaccines imagined via the original iterations of the Buffer, for a supply-limited pandemic situation, is likely no longer an appropriate intervention in acute humanitarian emergencies. Integrated delivery (meaning COVID-19 with other vaccines, medicines, essential non-health services) – which does not imply a one-size fits all package, but rather context-specific and tailored "baskets" of services for people in need – offers greater opportunities for access within the current environment.

Depending on the evolution of the COVID-19 pandemic, integrated humanitarian access to COVID-19 vaccines (and other vaccines/services) could be supported through a policy framework that promotes access to vaccines more broadly in these settings e.g. Gavi's revised Fragility, Emergencies and Displaced populations (FED) policy, and/or via a stockpile under an existing mechanism like the International Coordinating Group for Vaccine Provision (ICG) at the WHO, if the risk of outbreaks and surges remain likely. Both of these avenues as they currently exist would place limits on the scope of the Humanitarian Buffer (for example, Gavi-eligibility in case of FED) and would require working through a set of existing assumptions (e.g. longer shelf-life and WHO PQ requirement in case of ICG stockpiling).

Moving forward, Humanitarian Buffer partners must discuss how to evolve and align the Buffer model with other relevant discussions, as this will be critical to planning for the next phase of humanitarian access to COVID-19 vaccines. For routinised deliveries, this includes conversations around integration of COVID-19 vaccines into Gavi's routine programmes – to identify opportunities under Gavi's equity agenda, the revised FED policy and fragile Middle Income Countries that will be discussed by the Gavi Board – and work with the COVID-19 Vaccine Delivery Partnership which focuses on support for low-coverage countries, many of whom represent fragile and conflict settings. An outbreak response stockpile model (with a view to new COVID-19 variants) could be considered under the ICG.

All of these options would require further exploration of themes such as the adaptation of the ICG policies to allow for increased access for humanitarian organisations (including UN, Red-Cross, NGOs, CSOs), flexible delivery funding, and flexibilities on reimbursement requirements. The revised FED policy has already allowed for direct support for vaccines and delivery

support for humanitarian organisations, in areas where governments are not willing or able to engage. The application process, contracting templates and other related items developed for the Buffer could be leveraged as part of the learning and adaptation process. It will also be necessary to understand and take-stock of the role of existing processes, such as the Humanitarian Buffer allocation process and application review and approval by the IASC, and their relevance for routinised deliveries or for a stockpile under ICG.

8 Takeaways for future pandemics and humanitarian access to novel vaccines

The current iteration of pandemic preparedness and response architecture does not fully consider and account for systemic limitations on humanitarian access to novel tools, and the potential impact a new pathogen with pandemic potential can have in hard-to-reach areas and humanitarian settings. The challenges faced by the Humanitarian Buffer are illustrative of this and the lessons learned will be critical for future strategies.

Pandemic preparedness and response in the future should consider the issue of humanitarian access as a core component of the pandemic response from the outset and this integrated approach must be reflected in the design of all parts of the global health architecture. This will entail leveraging the innovations and lessons learned from the Humanitarian Buffer and creating solutions before a pandemic hits, so that systems are already in place to enable access in these unique contexts as well.

To deliver vaccines to every corner of the world, it is necessary to think beyond relying solely on sovereign partners i.e. national governments. That means ensuring that product liability and manufacturer indemnification requirements are not barriers to humanitarian access via non-sovereign implementing partners. A mechanism enabling indemnification waivers for humanitarian agencies should already be negotiated and in place before a pandemic strikes. Precious time, and lives, are lost when these complex negotiations drag on for months on end while a deadly pathogen spreads and evolves.

Tied to this, are the end-to-end residual risks and liabilities that emanate from novel EUL-ed products when manufacturers do not assume full liability in the first stage of a pandemic. While sovereign countries have the capacity to absorb these risks via contracting and procurement instruments, non-sovereign entities do not have this same capacity and are not naturally structured to take these risks on. Coming to a common understanding and agreement on risk-sharing entails negotiation of legal contracts, while accounting for other limitations such as earmarked budgets, differences in risk appetites between organizations, and the lack of insurance on the market to cover these residual risks. This yet again results in prolonged interagency legal negotiations, which should be avoided during a pandemic. Therefore assessing the risk capacity of stakeholders, and developing agreement on risk sharing obligations in advance, is critical.

These Buffer-related negotiations, which resulted in an agreed template for UN agencies in this specific situation, can be a useful tool for the future. However, the exceptional risks generated by deliveries of novel vaccines via non-governmental entities in humanitarian settings should be considered in future pandemic preparedness and response (PPR) financing. The Buffer experience has shown that leaving these risks to be handled by the insurance market or resolved via risk sharing between manufacturers and humanitarian and multilateral agencies is not a viable option.

Finally, the importation of novel products into conflict zones via non-governmental or humanitarian agencies during a pandemic can be highly challenging, especially in contexts involving cross-border movement. This could entail navigating multiple regulatory regimes and import procedures that, if left to a case-by-case basis, result in delays, and other political and humanitarian access challenges vis-à-vis de facto authorities. Humanitarian exceptions for importation of novel products in a pandemic context should be explored and constitute a key aspect of PPR.