

Annex B: Update on the Operationalisation of the Humanitarian Buffer

1. Background

In March 2021, the Board approved the Secretariat reporting back to the Programme and Policy Committee and Board by end 2021 on the operationalisation of the COVAX Humanitarian Buffer. The Board requested that this report include available key performance metrics, the number of requests received, and update on delivery support funding, as well as a report back on activities undertaken to ensure the Humanitarian Buffer is a measure of last resort.

Financing for the COVAX Buffer, which includes both the Humanitarian Buffer and the Contingency Provision¹, at 5% of COVAX AMC funding, was approved by the Board in March 2021. The Board also approved in March delegating decision making on Humanitarian Buffer dose allocation to the Inter-Agency Standing Committee (IASC) Emergency Directors Group, following which, applications for the Humanitarian Buffer opened in May 2021. Gavi has worked closely with Alliance partners, UNICEF and WHO, as well as the humanitarian sector to operationalise the Humanitarian Buffer.

2. Humanitarian Buffer as last resort

The Humanitarian Buffer is a mechanism established within the COVAX Facility to act as a measure of 'last resort' to ensure access to COVID-19 vaccines for high-risk and vulnerable populations in humanitarian settings. It is a real-time allocation of up to 5% of doses procured through the COVAX Facility, based on demand. The Humanitarian Buffer is only to be used where there are unavoidable gaps in coverage in national vaccination plans and micro-plans, despite advocacy efforts. National governments are responsible for ensuring access to COVID-19 vaccines for all people within their respective territory. The 'first resort' for all populations of concern, irrespective of legal status, is that they are included in national vaccination plans and reached during the implementation of those plans. Gavi Alliance, IASC partners, civil society and others have been and will continue to advocate with national governments to ensure the inclusion of all populations regardless of their legal status in line with the WHO Strategic Advisory Group of Experts on Immunization (SAGE) 'Values Framework' and 'Roadmap for Prioritizing Uses of COVID-19 Vaccines in The Context of Limited Supply' and will advocate for the revision of national plans and micro-plans if required.

Since the outset of 2021, both high-level global advocacy and national level advocacy has been carried out to ask for the inclusion of populations at risk of being left behind in national vaccination plans and to remind governments that the COVAX Humanitarian Buffer is not an alternative to state obligations. This has included, for example, inclusion of relevant language in the UN Security Council resolution 2565, COVAX briefing UN Resident Coordinators in priority contexts, and country level bi-lateral advocacy by

¹ As reported to the Board in September 2021, given the current levels of vaccine coverage among Facility participants and the global prevalence of the new variants, the Contingency Provision is not considered an appropriate intervention at this point, and in its absence the Humanitarian Buffer will continue to form the full scope of the COVAX Buffer.

COVAX partners urging national governments to include populations of concern irrespective of legal status.

The results of this advocacy have been mixed, with some governments including populations of concern in their vaccination plans, but others excluding them. Extreme global vaccine inequities have had a trickle-down effect on populations of concern for the Humanitarian Buffer. According to WHO, 86% of refugees and asylum seekers live in developing countries. Many of these countries also host high number of migrants and internally displaced persons. The shifting global mortality and morbidity burden to these settings has compounded the need for the Humanitarian Buffer.

Several countries have responded to calls for vaccine equity by revising and expanding their vaccination plans. However, coverage for these populations in the vaccination plans and their implementation are not universal. Refugees and asylum seekers have begun to receive vaccinations in 101 of the 162 countries that the United Nations High Commissioner for Refugees has been monitoring as of August 2021². The International Organization for Migration reported in May 2021 that only regular migrants (those who entered a country lawfully and remain in the country in accordance with their admission criteria) were included in vaccination campaigns, while migrants in irregular situations in many countries were not.

3. Demand and Supply

As of 30 September, the Humanitarian Buffer Secretariat has received seven applications. Two applications have been approved by the IASC Decision Group - one submitted by a humanitarian agency for a vaccination campaign in Thailand, another one submitted by Iran to vaccinate displaced people from Afghanistan. One application was found not viable as the applicant did not provide sufficient information for the IASC DG to take a decision, another application was withdrawn while four further applications are currently under review. The first delivery of 1.6 million Humanitarian buffer doses took place in mid-November to Iran, with the next delivery of 72k doses expected to arrive in Thailand in December to fulfil the second application.

The Humanitarian Buffer Secretariat has seen an increase in the number of applications being received and expect this upward trend to continue during the last quarter of 2021 and into 2022. Our understanding is that the recent uptick is related to availability of doses for which some manufacturers agreed to waive indemnity & liability (I&L) requirements for humanitarian agencies (see section 6a below). The Secretariat, our Alliance partners and the IASC, have been reaching out at regional and local levels to ensure that humanitarian agencies and country governments are aware of the Humanitarian Buffer and the principles under which it operates.

As part of the operationalisation process, and in particular to aid with outlook planning and negotiations with manufacturers regarding I&L requirements for humanitarian agencies, a global demand mapping has been carried out with inputs from Alliance partners and member agencies of the IASC. This analysis suggested that roughly 80- 90% of the demand for the Humanitarian Buffer doses is likely to be situated in AMC

² COVID-19 immunization in refugees and migrants: principles and key considerations Interim guidance 31 August 2021

countries and territories. In coordination with these stakeholders the Secretariat team is actively monitoring how demand is evolving due to inclusion or exclusion of populations of concern in the roll-out of vaccines and from humanitarian crises where unforeseen demand may arise. The IASC estimated at the outset of the year that there are approximately 167 million people at risk of exclusion from COVID-19 vaccination, noting that these numbers are highly variable and subject to change due to unexpected shocks (such as conflicts, natural disasters etc.). These estimates are based on data from the 2021 Global Humanitarian Overview (GHO). However, the populations of concern for the Humanitarian Buffer will not be limited to populations in the 2021 GHO and the Humanitarian Buffer will remain operational in 2022 whereby latest analysis and statistics will inform its output. The Humanitarian Buffer is designed to be flexible and agile to respond to dynamic situations and risks of exclusion and can be used to reach any population of concern in a humanitarian setting that is not being vaccinated by national authorities, regardless of whether they are included in the 2021 GHO or not.

The Humanitarian Buffer is eligible to draw upon up to 5% of COVAX procured doses. This translates as a certain number of doses ringfenced for any Humanitarian Buffer applications at each allocation round. Given the time needed to process applications and issue Purchase Orders, and uncertainty of immediate demand, there is a risk of mismatch between supply to the Humanitarian Buffer and demand at any one time. At each re-allocation timepoint, the risks of having idle doses are weighed up against not being able to meet the demands of approved applicants in a timely manner. As more manufacturers waive I&L requirements and supply to COVAX and the Buffer can increase, there will be more flexibility in the system.

4. Funding available for Operational costs

In March 2021 the Board also approved that of the (at the time) US\$ 150 million allocated to provide exceptional support for operational costs of delivering COVID-19 vaccines, up to 5%, amounting to US\$ 7.5 million, could be used to support the deployment of the Humanitarian Buffer to address critical operational gaps.

It is well noted that the amount will not be sufficient to cover all the Humanitarian Buffer operational costs. Led by UNICEF, the Humanitarian Community is mobilising additional resources to support operational costs of delivering Humanitarian Buffer doses. Funding is being centralised in UNICEF's ACT-A Humanitarian Appeal for Children (HAC)³, an existing mechanism that can ensure efficient and timely disbursement of funding to approved partners for approved requests. UNICEF has partnership agreements in place with many of the agencies we expect to apply to the Humanitarian Buffer and can set up, as needed, a range of new partnerships in a timely manner, with strong, established, and standardised oversight mechanisms in place.

UNICEF is seeking to contribute US\$ 270 million delivery costs needed for the humanitarian buffer and humanitarian settings through its country offices. Thus far, about US\$ 25 million has been secured for the operational costs of doses supplied under the Humanitarian Buffer, which includes the US\$ 7.5 million allocated by the Gavi Board

³ See further information here: <https://www.unicef.org/media/94126/file/2021-HAC-ACT-A.pdf>

in March 2021. Of the first three approved applications, only one has requested funding for operational costs for US\$ 4.96 million which would come from the HAC mechanism.

Operational costs can be requested through the Humanitarian Buffer Application and necessitate a budget to be submitted alongside. Funds are allocated to an applicant if the IASC Decision Group approves an application. Based on available evidence from humanitarian settings, UNICEF estimates that per dose vaccine operational costs are significantly higher than in non-humanitarian settings. The IASC has set the standard unit cost for vaccine operational costs in humanitarian settings at US\$ 3.00 per dose, noting that the actual cost may be lower or higher depending on context. Based on the budget provided, up to US\$ 3.00 per dose will be allocated to applicants; in some cases, UNICEF will be able to cover the additional costs if justified, in other cases, other sources of financing will be required. UNICEF and partners are reviewing incoming requests and budgets from humanitarian settings and learnings from this exercise will be used to review the standard/ average unit costs per dose delivery in humanitarian settings.

5. Key learnings from operationalisation

a. Indemnity & Liability

Secretariat teams are in active discussions with all manufacturers who supply the COVAX Facility to request that doses provided to humanitarian agencies through the Humanitarian Buffer have the indemnification requirement waived. The Secretariat is also regularly liaising with the humanitarian sector during on-going negotiations. Without a resolution to the indemnification requirement for humanitarian agencies, Humanitarian Buffer doses may only be deployed by countries or by humanitarian agencies in partnership with countries. In some of the most acute humanitarian settings, such as active conflict zones, where this may not be possible, and access is only possible via humanitarian agencies, these agencies will remain unable to deploy most vaccines in the COVAX portfolio to reach populations of concern until a waiver is granted. To date, only four manufacturers: Clover, J&J, Sinopharm and Sinovac have agreed to waive their I&L requirement for humanitarian agencies, of which only three (J&J, Sinopharm and Sinovac) are currently supplying to the COVAX portfolio. Discussions on the portfolio strategy are ongoing and so there is not full certainty of additional doses from these manufacturers in 2022. Gavi Secretariat is in active discussions with other manufacturers to ensure continued supply of doses available to Humanitarian Agencies in 2022.

Gavi and the IASC are mobilising the donor community and advocacy channels to pressure manufacturers to waive I&L requirements, which seems to be gaining traction. Without all COVAX manufacturers waiving the indemnification requirement for humanitarian agencies for the doses in the Humanitarian Buffer, COVAX is unable to leverage its whole portfolio to support vulnerable populations in humanitarian settings. Given other challenges in humanitarian settings, supply challenges and to ensure the most appropriate products are available for each setting, it is crucial that the full range of COVA X portfolio products are at the disposal of the Humanitarian Buffer.

b. Transparency

Specifics of each application, such as the applicant agency and population of concern, are kept confidential by default, at least until such a time as they are approved. This is done to ensure independence of decision making and so that implementation in conflict settings does not create any security or other protection risks for populations of concern and implementing partners. To reconcile confidentiality needs and transparency requirements to the best possible extent, the IASC and Alliance partners are developing an information sharing protocol.

c. Gavi's role and partnerships in the humanitarian space

Due to Gavi's limited organisational experience as a humanitarian organisation, new ways of working and thinking have been required to operationalise the Humanitarian Buffer, which can be leveraged to achieve Gavi's zero-dose goals. Whilst the Gavi Secretariat maintains a country-driven focus, primarily engaging with and providing funding via national governments and core partners, the Humanitarian Buffer has stretched the COVAX Facility to act as a humanitarian organisation, striving to reach individuals often not represented (or sometimes recognised) by a country government. This dichotomy has created system challenges and necessitated significant shifts away from Gavi's usual ways of working on delivery in this area.

Developing the requisite systems, governance processes and teams from the ground up has had a heavy start-up cost, which is paying dividends now that the Humanitarian Buffer is delivering doses. The Secretariat has developed the internal processes to be as close as possible to COVAX's 'business as usual' and continues to look for opportunities to streamline.

Creating the Humanitarian Buffer necessitated developing new partnerships in the humanitarian space. The Humanitarian Buffer was co-created and is being implemented with COVAX partners, notably WHO and UNICEF, with a much broader spectrum of humanitarian partners represented through the Inter-Agency Standing Committee Emergency Director's Group. Building these relationships took time, as does maintaining these relationships and ensuring alignment on direction of travel.

6. Future Outlook

Several factors are expected to shape the future outlook of the roll-out of doses from the Humanitarian Buffer. If the indemnification requirement for Humanitarian Buffer doses is not fully lifted for the whole of the COVAX portfolio of products, access to vaccines for some populations will remain a challenge. This will exacerbate global inequities and potentially contribute to the worsening of human development and broader humanitarian outcomes in fragile and conflict affected settings. New crises, such as the ones in Afghanistan and Ethiopia, will generate additional demand to cover displaced populations, as has been the case with some of the initial applications received for the Humanitarian Buffer.

As the coverage ambition for the COVAX Facility changes, it is expected that the same shift will take place for the Humanitarian Buffer to ensure contextual parity, a core principle of the mechanism. This will also mean applications will seek to cover higher proportions

of the populations of concern, and thus more doses may be required. There is generally an expectation that the number of applications to the Humanitarian Buffer increases into 2022, as the combination of supply constraints and I&L challenges had tended to suppress the demand from humanitarian agencies during the past few months, despite mounting needs in the populations of concern they serve.

Learnings from creating the Humanitarian Buffer will provide further insights into reaching communities with zero-dose children in humanitarian settings. These learnings are also expected to shed some light on new ways of working in Gavi 5.0, for example, the need for a greater focus on human-centred approaches and humanitarian health expertise to reach populations of concern, as compared to traditionally country-driven approaches which may not be optimal in humanitarian and other fragile and conflict-affected contexts. The Humanitarian Buffer team are collaborating with the zero-dose workstream and with the review of the Fragility, Emergencies and Refugees Policy to share experiences, learnings, and work towards an integrated view of Gavi's role in the humanitarian sector in the future.

We will routinely report to the Board through the COVAX Reporting Framework and draft at minimum an annual report to the PPC and Board on the progress of the Humanitarian Buffer. These reports will include learnings gathered from reporting forms which are mandatory for dose recipients to provide post-implementation.