Report to the Board
22 March 2021

SUBJECT:	COVAX BUFFER FOR HIGH-RISK GROUPS IN HUMANITARIAN SITUATIONS
Agenda item:	03
Category:	For Decision

Section A: Summary

Context

In December 2020, the Gavi Board approved the concept of the COVAX Buffer with its dual purpose to ensure access to COVID-19 vaccines for high-risk populations in humanitarian settings (the "Humanitarian Buffer"); and to provide a contingency provision to enable an emergency release of doses to help mitigate the most severe clusters of high mortality where normal vaccine allocation timelines may not be sufficient (the "Contingency Provision"). The Board asked the Secretariat to consult with the Programme & Policy Committee (PPC) to further develop the details of the COVAX Buffer prior to approval of the high-level parameters and funding needs. Given the widespread calls for urgency to implement the Humanitarian Buffer, and the evolution of thinking on the Contingency Provision whereby it will only be relevant after end June 2021, the Secretariat is now bringing forward the Humanitarian Buffer for review and approval by the Board.

Questions this paper addresses

- What are the proposed target populations for the Humanitarian Buffer?
- Which entities are proposed to be eligible to apply to the Humanitarian Buffer?
- How is it proposed that the doses for the Humanitarian Buffer and associated delivery costs be funded?
- What is the proposed decision-making process for allocating Humanitarian Buffer doses?

Conclusions

In March 2021 the PPC recommended to the Gavi Board that, noting the scope of the Humanitarian Buffer, it (i) approve reserving 5% of Gavi COVAX AMC ("AMC") funding for doses to be deployed via the COVAX Buffer; approve an amendment to expand where previously approved exceptional delivery funding can be used and to assign 5% of this delivery funding to the Humanitarian Buffer; (iii) approve the delegation of decision making on the allocation of Humanitarian Buffer doses to the Inter-Agency Standing Committee (IASC) Emergency Directors Group; and (iii) approve that the Secretariat report back to the PPC and Board on the operation of the Humanitarian Buffer.

Section B: Background to the COVAX Buffer

1. The COVAX Buffer

1.1. Since the COVAX Facility's (the "Facility") inception, there has been a clear intent to explore creating a flexible, revolving 'buffer' of doses to act as a safety net in case needs arise that cannot be serviced through standard processes and which, if left unmet, would undermine both the Facility's goal of ensuring equitable access to COVID-19 vaccines and the Alliance's strategic goal to increase equity in immunisation.

1.2. Gavi currently supports neglected at-risk populations with routine immunisation and outbreak response programmes through its Fragility, Emergencies, Refugees (FER) policy and four emergency vaccine stockpiles. Experience has shown that stockpiles are an essential and effective mechanism to enable rapid and equitable access to vaccines and that FER policy flexibilities facilitate access to vaccines for populations in humanitarian contexts that are otherwise at risk of being left behind. The design of the COVAX Buffer has drawn on the principles of flexibility and exceptionality of these approaches and has considered the lessons learnt from the investment in stockpiles and FER policy implementation.

1.3. In December 2020, the Gavi Board approved the creation of the COVAX Buffer and its six organising principles, with a dual purpose: to ensure access to COVID-19 vaccines for high-risk populations in humanitarian settings (the "Humanitarian Buffer"); and to provide a Contingency Provision to enable an emergency release of doses to help mitigate the most severe clusters of high mortality where normal vaccine allocation timelines may not be sufficient (the "Contingency Provision"). The Board also noted that the total size of the COVAX Buffer could be a real-time allocation of up to 5% of doses procured through the COVAX Facility[1].

1.4. The Board asked the Secretariat to consult with the PPC to further develop the details of the COVAX Buffer prior to approval of the high-level parameters and funding needs. The PPC reviewed the design of the Humanitarian Buffer portion of the COVAX Buffer in early February, and in early March recommended it to the Board for approval.

2. The Contingency Provision

2.1. The Contingency Provision (CP) element of the COVAX Buffer provides the ability to enable an emergency release of doses to meet public health needs where normal vaccine allocation timelines may not be sufficient. However, this ability to provide a surge of doses towards addressing extraordinary situations is only considered relevant and appropriate once all COVAX Facility participants have been allocated a base amount of vaccines. There is also much to learn from the initial roll out of COVID-19 vaccines, and the developing epidemiology and the emergence of variants merits further understanding that will feed into the design of the CP. The

[1] Based on an estimation of 2 billion doses in 2021, this would amount to 100 million doses.

Secretariat will therefore come back to the PPC and Board later in 2021 with further details regarding the design and operationalisation of the CP.

2.2. This deferral of the CP does not pose any risk to the ability to implement it, should it be approved. On the availability of AMC-funding, it is currently expected that doses provided through the CP would be a 'surge' of doses against a participant's overall allocation ceiling and would therefore not require any additional AMC-funding. For the availability of doses, the COVAX Buffer (covering both elements) only has access to up to 5% of real-time COVAX Facility doses, so there is a limit on what can be allocated, and it is not possible to allocate against future doses. Even if the Humanitarian Buffer absorbs the full 5% of COVAX Facility doses allocated up and until the CP is operationalised, future doses will still always be available for the CP.

Section C: The Humanitarian Buffer

3. Updates since December 2020

3.1. Following the Gavi Board meeting, the Gavi Secretariat, with WHO and the Interagency Standing Committee (IASC) working group, has been elaborating on the design of the Humanitarian Buffer (HB). Consultations on the HB's design have been held with civil society organisations, manufacturers, UN Humanitarian Coordinators, the IASC Emergency Directors Group (EDG), and other Alliance Partners, including UNICEF.

3.2. Humanitarian organisations, Alliance partners and Gavi's Country Managers have been increasingly concerned that countries are not planning to include populations in humanitarian settings in their national vaccination plans. These concerns are being countered by joined-up advocacy efforts to work with countries to develop national plans that include all high-risk groups, as per the SAGE guidelines, regardless of their legal status. For example: Médecins Sans Frontières has developed and disseminated guidance to country-based staff; Regional Review Committees and regional COVAX working groups are being advised to include humanitarian agencies such as IOM, UNHCR, IFRC and CSOs in their expert consultations; and Gavi, WHO and the IASC briefed UN Resident Coordinators in a number of priority countries with significant humanitarian needs on the importance of advocating with respective host governments to ensure inclusion of high-risk populations in national plans, as well as to help identify where populations may be missed.

3.3. Despite these efforts, a preliminary analysis of 89 National Deployment and Vaccination Plans (NDVPs) undertaken by WHO revealed that the majority of countries did not specifically indicate the inclusion of high-risk groups in humanitarian settings in their plans, implying a likely need for more effective and sustained advocacy on this point. Just 28% of relevant[2] NDVPs include migrants and just 17% include irregular migrants.

[2] NDVPs for countries which are known to include such populations

Furthermore, only 42% include refugees or asylum seekers and only a similar proportion include internally displaced persons (IDPs).

3.4. Such omissions have further galvanised existing calls supporting the urgency of bringing forward the HB so that as the roll out of COVID-19 vaccines gets underway, no one is left behind. Nowhere have these calls been stronger than at the UK-hosted UN Security Council (UNSC) session on 'Vaccines for Vulnerable Populations'[3]. The objective of the session was to discuss the role of the Security Council, Member States and the UN in ensuring that COVID-19 vaccines are made available equitably in contexts affected by conflict and insecurity. The Gavi CEO was given the opportunity to brief the UNSC and following the session, Resolution 2565 (2021) was unanimously passed by all UNSC members which supported funding to COVAX and called for national vaccination plans to include at-risk groups of refugees, internally displaced people, stateless people, indigenous people, migrants, persons with disabilities, detained persons, and people living in areas under the control of any non-state armed group[4]. During the session, many members noted the importance of the HB.

3.5. Finally, following the request of the Board to present further details on the design of the COVAX Buffer to the PPC, an informal consultation session was held in early February. The PPC then met formally in March to review the proposals. The discussion raised questions around the role of advocacy on national vaccination plans to ensure the inclusion of all high-risk groups, including those in humanitarian settings; indemnification and liability issues for humanitarian agencies; monitoring, evaluation and learning for the implementation of the HB; and finally how delivery costs for HB doses would be met. Following the discussion, the PPC was satisfied to recommend to the Board all the proposed decision points for approval, and made two additions: to approve that 5% of the previously approved exceptional delivery support would be available to the HB; and to approve that the Secretariat report back to the PPC and Board on the operation of the HB.

4. Design of the Humanitarian Buffer

4.1. Target populations

4.2. The obligation to provide access to COVID-19 vaccines for all people within their respective territory rests with national governments. Accordingly, the 'first resort' for all high-risk groups, irrespective of legal status, is their inclusion in national COVID-19 vaccination plans. As previously described, all COVAX partners and the humanitarian community are working to ensure that national plans also include those in humanitarian settings. Some countries are already demonstrating leadership on this issue. For example, Afghanistan, Bangladesh, Chad, Djibouti, Nepal, South Sudan,

[3] https://www.un.org/press/en/2021/sc14438.doc.htm
[4] https://undocs.org/en/S/RES/2565(2021)

Sudan and Yemen have already indicated their intention to include refugees and/or internally displaced persons in vaccination plans.

4.3. The HB is designed as a mechanism of 'last resort', only to be called upon where there are unavoidable gaps in coverage. It is particularly relevant in instances of state-failure and conflict, and for covering people in areas controlled by non-state armed groups (NSAG), inaccessible to governments. Indeed, disputed territories and areas controlled by NSAG challenge standard allocation and deployment scope[5].

4.4. In such instances, target populations served by doses released through the HB will be those included in the Global Humanitarian Overview (GHO). The GHO builds on assessments and plans prepared by countries, as well as regional refugee plans and other appeals, to provide an evidence-based assessment of global humanitarian needs, response, and trends. It is a dynamic resource that covers individuals who require humanitarian assistance due to conflict, natural disaster or other factors[6]. The GHO 2021 includes dedicated sub-sections on gender-based violence, gender, persons with disabilities as well as older persons and mental health and psychosocial support providing greater focus on these vulnerabilities, which have also been aggravated by COVID-19[7].

4.5. The IASC estimates there are ~167 million[8] people at risk of exclusion from COVID-19 vaccination, noting that these numbers are highly variable and subject to unexpected shocks (due to conflicts, natural disasters etc.). Approximately over two-thirds these are in AMC-eligible economies[9]. Even in the ideal scenario of all countries including all high-risk groups in their national plans, 60-80 million people in non-government-controlled areas could remain beyond national reach.

4.6. The Humanitarian Buffer does not seek to cover the entirety of these target populations but rather, in line with SAGE guidelines, only intends to provide sufficient doses to cover high-risk groups within a given target population, i.e. 20% to cover frontline healthcare workers [10] and the vulnerable elderly[11]. This will, amongst other design elements of the HB, ensure that the principle of 'contextual parity' is observed, whereby the provision of HB doses is sensitive to intra- and inter-country contexts to avoid any perception of improper prioritisation of any one group above another.

[5] See Appendix 3 for examples
[6] People in need are defined as those whose living conditions and basic rights have been disrupted and whose current level of access to basic services, goods and social protection is inadequate to re-establish normal living conditions without additional assistance
[7] The GHO 2021 covers 56 countries, includes 34 response plans and combines the analysis of humanitarian needs due to COVID-19 and other causes of humanitarian problems. Available online at: https://reliefweb.int/sites/reliefweb.int/files/resources/GHO2021_EN.pdf
[8] At-risk populations in humanitarian settings may include refugees, asylum seekers, stateless persons, internally displaced persons, populations in conflict settings or those affected by humanitarian emergencies, and vulnerable migrants, regardless of their legal status.
[9] This excludes individuals living in territories controlled by non-state armed groups
[10] This may also include international workers where they are employed as frontline healthcare workers
[11] The COVAX Facility would work actively with local implementing partners to ensure best efforts are made to identify vulnerability status of individuals in data poor environments

Based on the IASC estimates, 20% of the ~167 million people at risk of exclusion from COVID-19 vaccination could account for ~33 million people.

4.7. Finally, it is worth noting that by reaching conflict settings and other hard-to-reach areas, the gains in terms of access to health made through the HB could be built upon and leveraged for Gavi 5.0 priorities of identifying and reaching zero-dose children and strengthening of routine immunisation (RI). An estimated 40% of zero-dose children in Gavi-supported countries live in fragile and conflict settings, some of whom could be relevant to the HB. Addressing the challenges in providing them vaccinations is critical for increasing coverage and improving equitable access to RI. HB requests will provide further insight into overlooked, high-risk populations that likely also do not receive RI, and therefore would help inform RI strategies to reach these groups.

4.8. **Eligibility of applicants**

4.9. **COVAX Facility participants:** All COVAX Facility participants, both self-financing participants[12] and AMC-eligible economies, will be eligible to apply to the HB. Applicants will be asked to clearly demonstrate why the target populations for which they are applying for doses were not included in national vaccination plans and what other attempts have been made to cover them. AMC-eligible economies will be asked to demonstrate that the target population is either 'new' (e.g. a recent cross-border displacement) or 'uncounted' in population statistics (e.g. irregular, undocumented, stateless etc.). This merits the provision of HB doses as additional to their existing AMC-funded allocation of doses whilst guarding against any preferential treatment of one AMC-eligible economy over another[13].

4.10. Following discussion, the PPC agreed that countries who are not participants in the COVAX Facility be first required to join the Facility before applying to the HB[14]. In cases of urgent need for HB doses in a non-COVAX Facility participant, HAs are still able to apply directly (see paragraph 4.11).

4.11. **Humanitarian Agencies**: All national and international humanitarian agencies (HAs) will be eligible to apply to the HB, including UN agencies, ICRC, national red cross and red crescent societies, and civil society organisations. HAs will be asked to establish that there is a clear, demonstrable gap in vaccine coverage amongst the HB target groups, that the HA is able to reach the relevant individuals with vaccination activities, and that they have both the experience and the necessary competence (including human resources, systems for follow up and surveillance, logistics etc.) to deliver successful vaccination campaigns in a

[12] Note that COVAX does not currently offer other means for SFPs to procure additional doses through the Facility

[13] Applications to the Humanitarian Buffer will also be carefully reviewed alongside national vaccination plans to prevent any 'double counting' of target populations.

[14] Whilst pending design and approval, the Contingency Provision (CP) is expected to be open to all countries, regardless of whether they are Facility participants, although non-COVAX Facility participants would be required to join the COVAX Facility in return for access to the CP. This may, following operationalisation, enable non-COVAX Facility participants to access emergency doses in cases of extreme public health need, including for Humanitarian Buffer target populations.

humanitarian context. At national level, the Health Cluster Coordinator and the Humanitarian Coordinator[15] would provide a positive opinion of the HA and their proposed plan. At global level, the IASC would bring their deep expertise to validate HAs and their plans.

4.12. **Funding HB doses and associated delivery costs**

4.13. The funding for HB doses and associated delivery costs have largely been aligned with standard COVAX Facility provisions so as not to create an incentive for countries to intentionally omit populations in humanitarian settings from their national vaccination plans to access more favourable terms through the HB. The approach to funding dose and delivery costs varies by the applicant to the HB and where the doses would be deployed.

4.14. **Doses**

4.15. AMC-funded doses would be available for AMC applicants and HAs deploying doses in AMC-eligible economies. Exceptionally, AMC-funded doses may also be available for HAs deploying doses in non-AMC-eligible economies, and for self-financing participant applicants who seek to vaccinate AMC-originating populations. Up to 5% of AMC funding is proposed to be made available to finance the costs of HB doses, for use in the situations described[16]. This will be progressively financed as the funding for the AMC increases, with the final amount spent dependent on both fundraising success and the demand for HB doses. If at least US$ 7 billion is fundraised for the AMC by June 2021, this would mean reserving at least US$ 350 million for the HB. The number of doses that this would buy would depend on the price per dose[17]. As and when the Facility is terminated, any remaining funding for the HB will be reviewed[18].

4.16. **Delivery costs**

4.17. In most instances, in line with the rest of COVAX, delivery costs for HB doses will not be covered. However, to ensure that some delivery funding is available in cases of exceptional need, 5% of the US $150 million exceptional delivery support[19] approved by the Board in December is proposed to be available. This would amount to US$ 7.5 million. From the Alliance's experience of implementing the Fragility, Emergencies & Refugees (FER) policy, delivery costs vary widely based on the geographic location and type of humanitarian setting.

4.18. It is well noted that this support will not meet all the HB delivery costs. The Secretariat understands that work is already underway by WHO, UNICEF

[15] Where not present, this role will be played by the UN Resident Coordinator and WHO Representative.
[16] Contingency Provision doses will act as a 'surge' of existing allocations, so no additional funding is required.
[17] The feasibility and modalities of the HB accessing a proportion of doses donated to the COVAX Facility is also being explored.
[18] Whilst the lifespan of the COVAX Facility is uncertain, the AMC is expected to outlast it.
[19] Subject to fundraising. Gavi has received generous donations from several donors towards COVID-19 Vaccine delivery support costs. We are precising how these funds will be allocated across the variety of support needs, including technical assistance, cold chain equipment, and broader delivery support.

and the wider Humanitarian Community towards fundraising additional resources for delivery costs to complement the Gavi financing of doses for the HB. Gavi is coordinating with these efforts to ensure alignment across different fundraising efforts and will evaluate their success over time, coming back to the PPC and Board if there are any challenges.

4.19. The ability for discretion with regards to exceptional cases helps to protect AMC resources, but creates some flexibility to reduce the barriers for the vaccination of missed communities, as per the objectives of the COVAX Buffer. Criteria for accessing exceptional delivery funding would include identifying a clear need and lack of adequate access to any other source of funding, and clear budget gaps which pose a major risk to delivery, in conjunction with a robust and well costed NDVP. This approach to exceptional delivery funding is also in line with Gavi's FER Policy which provides the framework through which Gavi can provide financial or non-financial flexibilities in exceptional circumstances. As with the FER Policy, each request will be evaluated on its own merits, taking into consideration previous decisions on similar requests, where they exist. The Secretariat will endeavour to ensure that the application process for HB doses and delivery costs is integrated, with decisions taken in the same timeframe.

Table 1: Eligibility for AMC-funded doses & associated delivery costs

Applicant	**Deploying in**	**Dose costs covered?**	**Delivery costs covered?**
Self-Financing Participant (SFP)	SFP	No – self-financed	No – self-financed
	SFP but for AMC-originating populations	*Exceptional cases only*	No *Barring exceptional cases for which 5% of the US$150 million exceptional support would be available*
AMC-eligible economy	AMC-eligible	Yes	
Humanitarian Agency	Non-AMC (SFP or non-COVAX Facility participants)	*Exceptional cases only*	
	AMC-eligible	Yes	

4.20. **Decision-making on the allocation of HB doses**

4.21. The process for decision-making on the allocation of HB doses has been designed to adhere to both the principles of COVAX and of the COVAX Buffer, including the humanitarian principles of humanity, neutrality, impartiality, independence, and "do no harm". It has also been designed to ensure the involvement of humanitarian experts in the review and approval process, so that the limited doses available are appropriately prioritised and that feasibility of delivery is adequately assessed by those who have experience in downstream delivery in these settings.

4.22. It is proposed to delegate decision-making for the allocation of HB doses to the Inter-Agency Standing Committee Emergency Directors' Group (IASC EDG). Under their auspices, a decision-making body (the "Body"), made up of representatives from the IASC, would review, prioritise and

approve applications to the HB, fully documenting their decisions and supporting the collection of monitoring data. Recognising that this is a new venture and there will doubtless be much to learn, the Body will also ensure that any 'lessons learnt' are reflected in the practices of the Body and will provide regular updates to the Gavi Board.

4.23. The Body will be supported by the Joint Allocation Taskforce (JAT) who, as well as playing a Secretariat function, will ensure the critical alignment of HB allocation decisions with 'standard' country allocations. This will include ensuring that HB doses are not deployed in countries any quicker than 'standard' country allocations and that there is alignment (where feasible) of products allocated to ease regulatory and indemnification and liability requirements. The JAT will also: ensure that applications for the Humanitarian Buffer doses meet a set of minimum viability criteria, monitor the number of (funded and un-funded) HB doses available within the overall 5% ceiling of the COVAX Buffer, and be responsible for communicating the decisions of the Body onwards for implementation.

4.24. The proposed decision-making process ensures accountability and transparency for all stakeholders, including countries, humanitarian agencies, Alliance partners and donors and is supported by a clear system for real time monitoring and learning (see paragraph 5.4).

5. Operationalisation of the Humanitarian Buffer

5.1. In response to the high level of interest from PPC and Board members, this section speaks to some key aspects of the operationalisation of the HB.

5.2. **Indemnification and liability:** Manufacturers require countries and territories receiving COVID-19 vaccines to indemnify them in the event there are injury claims associated with vaccination. Where HAs are directly allocated doses through the HB, where possible the HA would leverage existing indemnification arrangements in the country or territory of deployment. Where this is not possible, the Secretariat would endeavour to obtain a waiver from the manufacturer or, as a final resort, look for a risk-share arrangement. Work is already ongoing with manufacturers to identify solutions to potential challenges and the Secretariat welcomes the continuation of these discussions. Now the No Fault Compensation scheme is live, which covers all individuals in AMC-eligible economies, the Secretariat will explore if and how this might be extended to cover HB target populations outside of the AMC92, knowing that there are some important implications, such as obtaining additional funding, operational challenges, disparity between recipients in the humanitarian settings and the general population, and potential manufacturer resistance.

5.3. **Application processes and timelines:** Given the widespread calls for urgency and the desire to ensure that high-risk groups in humanitarian settings are not left behind, the Gavi Secretariat is working closely with WHO and the IASC EDG working group to prepare to implement the HB as soon as possible pending a formal Gavi Board approval. Work has already begun to draft the application form and guidance materials for

applicants and the Secretariat is working with WHO to determine the frequency at which requests will be assessed and how we can ensure alignment with standard country allocation processes, including that doses are rolled out through the HB no quicker than 'standard' country allocations. It should be noted that doses will be gradually allocated to the HB, based on demand. No doses will at any point sit idle: doses not required will be allocated to countries as normal.

5.4. **Monitoring, evaluation and learning (MEL):** Monitoring for the HB will be integrated into broader COVAX MEL procedures and will incorporate process, design, implementation and results. In circumstances whereby doses are granted to countries, reporting on vaccine uptake and use will be integrated into routine reporting via WHO-UNICEF Joint Reporting Form. For doses granted to HAs, a standardised reporting form with core reporting needs will be developed for all HAs to complete. The HB will be included as a specific disaggregation to the COVAX Reporting Framework routinely shared with the Gavi Board and Governance Bodies. Additionally, learnings from the HB will be included as part of the broader COVAX learning agenda and the planned independent COVAX evaluation. We will work closely with all partners to seek to understand any challenges that HB applicants are facing related to implementation and proactively mitigate any issues and gaps.

Section D: Actions requested of the Board

The Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

a) **Note** the scope of the Humanitarian Buffer as outlined in Annex B to Doc 03 and **approve** reserving 5% of COVAX AMC funding for doses to be deployed via the COVAX Buffer, **noting** that this will be progressively financed as AMC funding increases. The funds reserved for the Buffer will be reviewed at such a time that the Facility is terminated with a presumption that unused funds will be released to the Gavi COVAX AMC;

b) **Approve** amending the decision approved by the Board in December 2020 to read as follows: "Approved US$ 150 million to provide exceptional support, if required and on a case-by-case basis, to AMC92 participants, *and in cases of support for the delivery of humanitarian buffer doses to also include Self Financing Participants and humanitarian agencies*, to address critical vaccine delivery gaps for which no other funding is available, subject to this funding being mobilised by Gavi";

c) **Approve** that of the US$ 150 million for delivery costs up to 5% be used to support the deployment of the Humanitarian Buffer;

d) **Approve** delegating decision making on Humanitarian Buffer dose allocation to the Inter Agency Standing Committee (IASC) Emergency Directors Group, which will report back to the Gavi Board on allocation of the Humanitarian Buffer doses and associated AMC funding; and

e) **Approve** the Secretariat reporting back to the Programme and Policy Committee and Board by end 2021 on the operation of the Humanitarian Buffer, including against available key performance metrics, the number of requests received and approved and the timeliness of that approval, the number of Humanitarian Buffer doses allocated and delivery support funding. The Secretariat will also report back on activities undertaken to ensure the Humanitarian Buffer is a measure of last resort.

Annexes

Annex A: Implications/Anticipated impact

Annex B: Sections referenced in decision points

Additional information available on BoardEffect

Appendix 1 (in December 2020 Board meeting book): Document 08 *COVAX Facility Operationalisation and Vaccine Programme*

Appendix 2 (in March 2021 PPC meeting book): Document 02 *COVAX Buffer*

Appendix 3: Examples of situations where the Humanitarian Buffer may be relevant