

Frequently Asked Questions: The COVAX Humanitarian Buffer

This FAQ document has been prepared by the IASC Working Group on the Humanitarian Buffer. The Working Group was tasked by the IASC Emergency Directors Group to work with Gavi, the Vaccine Alliance, on the establishment and operationalization of the COVAX Humanitarian Buffer. These FAQs are intended for all IASC entities, humanitarian partners, and external stakeholders. The FAQs will be updated and re-circulated as required to ensure they reflect the most relevant and up-to-date information.

GENERAL

1. What is the COVAX Humanitarian Buffer?

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. 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, IASC partners, civil society and others 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.

2. Is the Humanitarian Buffer open for applications?

Yes. Applications to the COVAX Humanitarian Buffer have been open since May 2021, and COVAX doses have been set aside for distribution to successful applicants. Application materials and guidance documents can be found on the [COVAX](#) and [IASC](#) websites.

3. How many doses are available through the Humanitarian Buffer?

The COVAX Buffer includes both the Humanitarian Buffer and the Contingency Provision (see question 6). Up to 5% of the COVAX Facility's available supply from COVAX advance purchase agreements will be made available to the COVAX Buffer throughout periodic COVAX allocation rounds, while recognizing that the Humanitarian Buffer is a flexible and demand-driven mechanism. Doses delivered to a country through the Humanitarian Buffer will be in addition to any standard country allocations through the COVAX Facility (i.e. a 'top up'). The humanitarian buffer can also access doses shared with the AMC, depending on feasibility.

4. In what scenarios is it envisaged the Humanitarian Buffer will be used?

Gavi and IASC partners continue to advocate for the inclusion of populations of concern that are at risk of exclusion from national vaccination plans and micro-plans. However, we anticipate there will be four broad scenarios in which the Humanitarian Buffer will need to be used:

- i. National authorities are unwilling to include populations of concern in their national plans despite high-level advocacy.

- ii. National authorities include populations of concern in their national vaccination plans, but the subsequent micro-planning process and/or implementation process highlights an unwillingness or inability to support vaccination for these groups.
- iii. National authorities do not have full control over all or parts of their territory and have no access to populations of concern in certain locations.
- iv. An unforeseen humanitarian crisis (e.g. a cross-border displacement or natural disaster) that occurs after the finalization of the national vaccination planning process and requires a national authority to receive a 'top-up' of additional doses. In such a scenario, a national government will be asked to clearly demonstrate why the population of concern cannot be vaccinated through national planning processes and standard COVAX allocations, rather than the Humanitarian Buffer.

5. What is the difference between the COVAX Contingency Provision and the COVAX Humanitarian Buffer?

The COVAX Buffer was originally designed to comprise of two components: The Humanitarian Buffer and the Contingency Provision. The Contingency Provision intended to provide 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 is not yet operational and based on the evolution of the pandemic, the general level of coverage in COVAX supported countries and potential endemicity of the virus, it isn't considered an appropriate intervention at this point in time. Until the Contingency Provision comes into effect, all doses that are made available for the COVAX Buffer will be for the Humanitarian Buffer.

POPULATIONS OF CONCERN FOR THE HUMANITARIAN BUFFER

6. Which groups are considered as populations of concern for the Humanitarian Buffer?

Populations of concern in humanitarian settings may include refugees, asylum seekers, stateless persons, internally displaced persons, minorities, populations in conflict settings or those affected by humanitarian emergencies, and vulnerable migrants irrespective of their legal status.

7. What is the estimated size of the populations of concern?

The IASC estimates 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.). The current number of refugees, IDPs and stateless populations is over 80 million. Even in the ideal scenario of all countries including all populations of concern in their national plans, it is estimated that 60-80 million people in non-government-controlled areas could remain beyond national authorities' reach.

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. 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 or not they are included in the 2021 GHO.

8. How will populations of concern be prioritized? Will the Humanitarian Buffer vaccinate everyone caught up in humanitarian crises?

The Humanitarian Buffer is neither designed nor intended to cover the entirety of populations of concern, nor to prioritize them over any other population. Prioritization decisions will be in line with WHO SAGE guidelines, and will ensure parity with coverage levels and the standard COVAX vaccine rollout in a specific country. The Humanitarian Buffer intends to provide enough doses for high-risk groups within a given population of concern to cover frontline healthcare workers, the medically vulnerable, and those who meet nationally set age criteria. Based on IASC estimates, 20-30% of the 167 million people at risk of exclusion from COVID-19 vaccination would account for approximately 33-50 million people. Assuming a two-dose regimen, this would mean that a rough, indicative planning assumption would be that 66-100 million doses would be required for the Humanitarian Buffer. This target may shift with the evolution of the pandemic and the availability of supply globally.

9. Does the establishment of the Humanitarian Buffer create an incentive for national authorities to exclude populations of concern from their national vaccination plans?

From February to March 2021, WHO conducted a review of 104 NDVPs submitted to the COVAX Facility, of which 86 were Advanced Market Commitment (and 16 were self-financing countries and economies). The results indicate that the majority of these NDVPs did not explicitly include migrants (72%). Just over half explicitly included refugees and asylum seekers (53% of 64 countries that have more than 500 refugees). Only 17% of 104 NDVPs explicitly included migrants in irregular situations. Through continued advocacy at all levels, Gavi and IASC partners are encouraging national authorities to include populations of concern in their national plans and micro-plans, in line with the main provisions of UN Security Council resolution 2565 (2021). National Deployment and Vaccination plans should be updated and uploaded to the Partner Platform by the national governments and should include populations of concern. Moreover, given the limited number of doses available to the Humanitarian Buffer, applications to the Humanitarian Buffer will need a strong justification for why a population of concern has not been included in a national vaccination plan.

10. What advocacy have you undertaken to ensure that populations of concern are included in national vaccination plans?

IASC agencies consistently brief their respective country representatives on the importance of advocating with national authorities to include populations of concern. Review and monitoring of national vaccination plans for inclusion of populations of concern is taking place at country, regional and global level, and targeted advocacy is undertaken based on these reviews. The IASC has also held several senior-level dialogues with Humanitarian Coordinators to emphasize their role in advocacy. Gavi and IASC partners will continue to work closely with operational partners in-country to monitor the implementation of national vaccination plans and micro-plans to ensure the inclusion of populations of concern.

11. Do you envisage a situation in which a population of concern has better access to COVID-19 vaccines than other groups in that country?

One of the key principles that will guide allocation through the Humanitarian Buffer is 'contextual parity'. This means that the allocation process will be sensitive to intra- and inter-country disparities and ensure there is no privileged access or improper prioritization of one population or country over another.

12. Will UN and NGO staff be vaccinated through the Humanitarian Buffer?

No. The UN is implementing its own system-wide vaccination effort for its staff and UN implementing partners in duty stations in which they cannot receive vaccinations from the host governments.

WHO CAN APPLY FOR DOSES THROUGH THE HUMANITARIAN BUFFER?

13. Can national governments apply to receive doses from the Humanitarian Buffer?

Both national governments (as long as they are COVAX participants) and humanitarian agencies can apply for buffer doses. However, if a national government applies, they will be asked to clearly demonstrate why the population of concern for which they are applying for doses were not included in national vaccination plans and what other attempts have been made to cover them. (e.g. a recent cross-border displacement after the submission of the national vaccination plan).

14. Can Humanitarian Agencies apply to receive doses from the Humanitarian Buffer?

Yes. All national and international humanitarian agencies will be eligible to apply to the Humanitarian Buffer, including UN agencies, ICRC, IFRC, National Red Cross and Red Crescent Societies, and civil society organizations (as long as they meet the eligibility criteria to apply set out in the COVAX Humanitarian Buffer Application). Humanitarian agencies will be asked to demonstrate that there is a clear, demonstrable gap in vaccine coverage, that the agency is able to access the population of concern in question, and that they have both the experience and the necessary competence to deliver successful vaccination campaigns in a humanitarian setting. Contextual parity will also be a key consideration in decision-making for allocations to the Humanitarian Buffer (see question 12 above).

15. Can both AMC-eligible and Self-Financing Participants receive doses through the Humanitarian Buffer?

Both Advanced Market Commitment (AMC)-eligible countries and territories and self-financing countries and territories participating in COVAX can receive doses from the Humanitarian Buffer. Both self-financing countries and AMC countries and territories will receive these doses as an addition ('top-up') to their COVAX Facility allocation.

16. Will the COVAX Facility finance the costs of doses through the Humanitarian Buffer to both AMC-eligible countries and Self-Financing Participants?

For AMC-eligible countries, the cost of the doses allocated through the Humanitarian Buffer will be financed by the Gavi COVAX AMC. For self-financing participants of the COVAX Facility the cost of the doses will have to be borne by the country. Some exceptions could be considered if the doses allocated will be delivered to a population that originates from an AMC country or territory. Decisions on financing of Humanitarian Buffer doses for self-financing countries and territories will be taken on a case-by-case basis. Operational costs associated with Humanitarian Buffer doses will be financed separately (see section below on Financing of Operational/ Delivery Costs).

17. Will applicants have a choice over the type of vaccine they will receive?

No. The choice of vaccine allocated in each context will be based on available supply, regulatory landscape, and the readiness of the specific country/ territory to administer a certain type of vaccine. A primary consideration is for the vaccines to be those already in use in the country so that indemnity and liability agreements are already in place. All vaccines delivered through the COVAX Humanitarian Buffer will have received WHO Emergency Use Listing/ Prequalification.

DECISION-MAKING FOR ALLOCATIONS

18. What is the role of the Inter-Agency Standing Committee (IASC) in decisions on Humanitarian Buffer allocations?

The Gavi Board has delegated decision making on Humanitarian Buffer doses to the IASC Emergency Directors Group (EDG). This process has been designed to ensure that humanitarian experts are involved in decision-making so that doses are appropriately prioritized, and judgements on the feasibility of delivery to populations of concern are made by those with experience of vaccination campaigns in humanitarian settings. An expert “decision group” reporting to the IASC EDG has been established to take decisions on allocations from the Humanitarian Buffer. Decision-making will be guided by the humanitarian principles of neutrality, impartiality, independence, and humanity.

19. How will Humanitarian Buffer allocation decisions be made?

A decision group comprising experts from IASC entities has been established to take decisions on allocations to the buffer and will report to the IASC EDG. They will receive secretariat support from the Joint Allocation Taskforce (JAT) of the COVAX Facility. As part of the application process, applicants are requested to approach the UN Country Team, Humanitarian Country Team, or equivalent to provide an opinion as to whether or not the request meets the eligibility criteria (see above question 14). Where this is not possible due to contextual factors, the applicant will need to provide a rationale for not liaising with UN Country Representation. The decision group will only consider requests by humanitarian agencies which meet the eligibility criteria to apply and for which the Resident/ Humanitarian Coordinator (or equivalent senior official) has offered their opinion. Exceptions to this will need to be justified in writing.

The decision group will decide by consensus, based on the information provided. If, in exceptional circumstances, the decision group cannot reach consensus, it may refer the request to the Emergency Directors’ Group (EDG) for input before deciding. The final decision remains with the decision group. Applications will be received on a rolling basis.

20. Which agencies are part of the IASC decision group?

The decision group will comprise of up to 10 IASC agencies: WHO, UNICEF, OCHA, IOM, UNHCR, ICRC, IFRC, MSF and a representative from the IASC’s NGO consortia. Gavi will be an observer. WHO will chair the decision group. If a member of the decision group represents an organization which is applying to the buffer, that member will recuse themselves from consideration of the request in question.

21. Who does the decision group report to?

The decision group reports to the IASC EDG. The decision group will provide the Gavi Board with twice yearly reporting on the allocations through the Humanitarian Buffer.

22. How quickly will allocation decisions be taken?

Once the decision group receives all the required information related to a request and the application is deemed complete by the Secretariat, the decision body will review the application within a maximum of 5 working days. The decision body may request further information from the applicant, if required. Once a decision has been taken, the JAT Secretariat will then inform the requesting entity of the decision, and if the request has been approved, the process of delivery of the vaccines will begin.

23. How long does it take for applicants to receive a shipment at port of entry after an application for Humanitarian Buffer doses is approved by the IASC decision group?

Once the decision is communicated to the Humanitarian Buffer Secretariat, a number of steps are necessary before a shipment arrives at the port of entry. These steps are reliant on Gavi Secretariat, UNICEF Supply Division, applicant, manufacturer of the allocated product, and national government of the territory of deployment. It is currently estimated to take between 2 to 3 months to deliver Humanitarian Buffer from the approval of the application. In some cases, where vaccines are deployed in territories subject to relevant bilateral or UN sanctions, additional time will be needed to obtain the necessary licenses and undertake preparedness checks. Global supply of injection devices and shipping containers may also impact final shipment timelines:

- Issuance of allocation letter to Humanitarian Agency/Country by Gavi confirming vaccine allocation
- If Humanitarian Agency, signing of Commitment Agreement between Gavi and Humanitarian Agency
- If country, signing of Decision Letter between Gavi and Country
- If Humanitarian Agency, Signing of Memorandum of Understanding between UNICEF and Humanitarian Agency (in case new client of UNICEF Supply Division) and UNICEF to send COVID Letter to Applicant explaining procurement process
- Issuance or confirmation of Import Authorisation from national authorities (to humanitarian agency) for allocated product
- Confirmation (to humanitarian agency) of Regulatory Authorisation from national authorities for allocated product
- Cold chain checks and approval by UNICEF
- (If COVAX Financed) Budget request submission for approval to Gavi Secretariat
- Purchase Order submission by Gavi to UNICEF Supply Division
- Corresponding device procurement undertaken by UNICEF Supply Division (in parallel to dose procurement process)
- Issuance of Purchase Order to manufacturer from UNICEF Supply Division
- Completion of packing and labelling as per UNICEF Purchase Order by manufacturer
- Collection and shipment of doses and devices to Humanitarian Agency/Country undertaken by UNICEF Supply Division

FINANCING OF OPERATIONAL/ DELIVERY COSTS

24. What activities and goods are covered under operational/ delivery costs?

Operational/ delivery costs refer to all costs associated with administering the vaccines once they have arrived in a country. This includes personal protective equipment for staff; hand hygiene; per diems for staff involved in service delivery and supervision; transportation of vaccines, equipment, and vaccinators; transportation of staff to undertake community engagement; social mobilization; training; planning and coordination; cold chain; waste management; vaccine certificates; pharmacovigilance ¹.

¹ Operational and delivery costs currently comprise the following budget lines: 1. Planning and Coordination; 2. Training; 3. Social Mobilization; 4. Cold chain (recurrent); 5. Pharmacovigilance; 6. Vaccination certificates and cards; 7. Infection prevention and control (includes PPE, Hand hygiene related costs, waste management cost); 8. Transport (includes transport of vaccines and supplies, transportation for services delivery and supervision and monitoring)

25. What are the operational/ delivery unit costs of COVID-19 vaccines in humanitarian settings?

Operational/ delivery costs will vary from country to country based on several factors. [A COVAX working group](#) estimated it would cost around \$1.66 per dose in a stable and relatively well-developed setting. Based on available evidence from humanitarian settings, UNICEF estimates that per dose vaccine delivery is significantly higher than in non-humanitarian settings. The IASC has set the standard unit cost for vaccine delivery in humanitarian settings at \$3.00.

26. What are the consequences of insufficient funding for operational/ delivery costs for the Humanitarian Buffer?

Vaccines are useless without effective delivery systems. Donors will not see a return on their financial investment in the COVAX Facility if there is no funding available for operational/ delivery costs to accompany standard COVAX allocations. The Humanitarian Buffer is no different: it will not succeed without sufficient funds being available to humanitarian agencies and national authorities for operational/ delivery costs. Since the Humanitarian Buffer is a last resort, demand-driven mechanism, it is not possible to accurately cost the amount of funding required for operational/ delivery costs.

27. Does the COVAX Facility or Gavi cover operational/ delivery costs for the COVAX Humanitarian Buffer?

For Humanitarian Buffer doses financed through the Gavi COVAX AMC, Gavi will cover the cost of doses and their shipment to the designated port of entry. Funding is being centralised in UNICEF's ACT-A Humanitarian Appeal for Children (HAC). Operational costs can be requested through the Humanitarian Buffer Application and necessitate a budget to be submitted alongside the application. Funds are allocated to an applicant if the IASC Decision Group approves an application.

28. How will UNICEF's HAC be used as the centralized mechanism for financing delivery costs for Humanitarian Buffer doses?

Once the IASC decision group has agreed to allocate doses to a humanitarian agency or national authority, and it is clear that financing is required for operational/ delivery costs, UNICEF will use existing mechanisms to transfer funds to implementing partners (IPs) based on the timeline and budget proposed by the applicant and endorsed by IASC decision body.

UNICEF has over 6,000 partnership agreements valid and signed across the globe already, and can set up, as needed, a range of new partnerships (inter-agency agreements, small scale funding agreements (SSFAs, if under USD 50,000) and partnership cooperation agreements (PCAs, if over USD 50,000), in a timely manner. Strong, established, and standardized oversight mechanisms are in place for all partnerships. Existing, standard rules and regulations, normal/usual cost-recovery rates and agreements are applied to the management of funds at UNICEF and all IPs.

29. Will all allocations made through the humanitarian buffer receive funds to cover operational/ delivery costs?

Each Humanitarian Buffer allocation will be different. The requesting humanitarian agency (or national authority) selected may:

- (i) not require funds for delivery costs or already have all needs met through other sources
- (ii) have partial funding, and request funding for the gap;
- (iii) may require/request funding based on the standard unit cost (see question 8); or
- (iv) request funding (based on the standard unit cost) but indicate that actual amount needed is higher and has provide a justification for this in its request.

Any applicant indicating a need for resources for operational/delivery costs will be required to submit a budget on a standard template and indicate the source and amount of funding already available at the time of submission of the application.

30. Will there be a standard unit cost per dose for humanitarian buffer allocations?

Yes. The unit cost per dose of delivery will be set at between \$3.00 per dose. Certain contexts may have higher operational/ delivery costs, in which case additional funding will need to be mobilized. In some cases, UNICEF will be able to cover the additional costs of delivery. In other cases, other sources of financing will be required.

31. How can a donor finance operational/ delivery costs for Humanitarian Buffer doses?

The UNICEF ACT-A HAC offers donors a clear route through which they can finance delivery costs associated with the Humanitarian Buffer. Funding through the HAC should give donors confidence that their funding will be used by the humanitarian agencies best placed to deliver to populations of concern as determined by the IASC decision making body and based on the endorsement of the HCT, UNCT or equivalent.

Donors that have earmarked funds for specific agencies/population groups to deliver through the Humanitarian Buffer, and do not wish to/ cannot channel through HAC, should allocate funds to agencies of their choice.

32. How does this mechanism relate to the appeals launched by some IASC agencies that also include requests for funds to cover delivery costs in humanitarian settings generally?

Donors are encouraged to contribute unearmarked funds for operational/ delivery costs in humanitarian settings generally – whether the vaccines are allocated through the standard COVAX mechanism, its Humanitarian Buffer, or other sources.

Several IASC partners have launched appeals to fundraise for the costs of COVID-19 vaccine delivery. Resources mobilized through these appeals will mainly cover the costs of delivery for vaccine doses that have been allocated through the COVAX Facility's standard allocations to countries (i.e. non-buffer doses). This will constitute the bulk of COVID-19 vaccine delivery in humanitarian settings.

The overwhelming majority of COVID-19 vaccine doses that will be delivered in humanitarian settings will not be from the Humanitarian Buffer but will be delivered through the COVAX Facility's standard allocations and channeled through national authorities. Humanitarian agencies are likely to be involved in the delivery of those doses, especially in contexts with weak national capacity. There is currently insufficient financing to cover the costs of delivery for doses delivered through standard COVAX Facility allocations. It is therefore essential that relevant IASC entities are adequately funded to support the delivery of non-buffer doses in humanitarian settings.

33. What is CDS and how is COVAX supporting AMC countries through it?

The COVID-19 vaccine Delivery Support (CDS) seeks to immediately enable rapid roll-out and scale up of COVAX-funded doses until the end of 2022. To this end, Gavi is providing a funding opportunity to all AMC-eligible COVAX participants to support vaccine delivery. CDS is intended to be closely aligned and complementary to domestic funding, support from other donors, multilateral development banks and agencies.

34. Could the World Bank cover delivery costs for the Humanitarian Buffer?

The World Bank has pledged to USD20 billion to support developing countries for the purchase and deployment of COVID-19 vaccines. In addition to procurement of vaccines, the finance can cover vaccine deployment and health system strengthening, such as vaccine cold-chains, training health workers, data and information systems and outreach to overcome vaccine hesitancy. In most cases, the financing is provided to national governments, however the World Bank has indicated that they would be willing to channel financing through “partner organizations”, with the agreement of the national government. It should be noted that as only IBRD/ IDA eligible countries are eligible, several countries in the GHO are not able to receive the World Bank Funding. For more information: [World Bank Support for Country Access to COVID-19 Vaccines](#). To track World Bank vaccine financing to GHO countries [COVID-19 Data Explorer \(humdata.org\)](#)

35. Will COVID-19 vaccine delivery in humanitarian settings impact on the delivery of other humanitarian assistance?

It is crucial to sustain financing for core humanitarian activities, including routine immunizations and enabling activities such as community mobilization and engagement (which are as critical to successful vaccination activities as vaccine delivery itself). The international humanitarian system is facing an unprecedented level of humanitarian need, as set out in the Global Humanitarian Overview (GHO). COVID-19 may not be the most acute public health or humanitarian issue facing countries with humanitarian crises. Financing for COVID-19 vaccines must not come at the expense of other humanitarian activities, and operational capacities should not be diverted from other priorities. Additional resources will be required to meet the costs of COVID-19 vaccine delivery.

COVID-19 vaccination rollout should not be a stand-alone activity in most humanitarian contexts. As doses are allocated through the Humanitarian Buffer to humanitarian agencies and national authorities, those agencies and authorities will be encouraged to support the delivery of a package of services where needed and/or support provision of routine immunizations where the pandemic may have adversely affected it in the past year, or use access to a population to fulfil other unmet humanitarian needs

36. Do you plan to launch another Global Humanitarian Response Plan, amend the GHO or launch a new consolidated appeal to integrate the costs of vaccine delivery?

No. We do not intend to launch a new GHRP, or adjust the GHO, or launch a new consolidated appeal in 2021.

37. Will Humanitarian Response Plans or Refugee Response Plans need to be adjusted to incorporate vaccine delivery costs?

The decision on which country-level planning tool is the most appropriate to support Humanitarian Buffer dose delivery will need to be considered on a case-by-case basis.

MONITORING AND EVALUATION

38. How will monitoring and evaluation and learning be undertaken for Humanitarian Buffer doses?

Countries, territories, and humanitarian agencies that receive doses through the Humanitarian Buffer will be responsible for reporting on their use. When applying for Humanitarian Buffer doses, applicants will be required to provide information on specific metrics within a specified timeframe following the implementation. UNCTs/HCs/RCs, and Health Clusters/Sectors will also support monitoring at country-

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level. With secretariat support from the JAT, the decision group will ensure that lessons learned are incorporated into its decision making.

LIABILITY, INDEMNIFICATION, COMPENSATION, AND OTHER LEGAL CONSIDERATIONS

DISCLAIMER:

The information provided herein aims to inform on certain liability, indemnification, compensation and other legal considerations associated with the humanitarian buffer for COVID-19 vaccines under the COVAX Facility as of the date this document was produced. However, due to the nature of the mechanism itself, this information should not be understood as a contractual agreement of any kind or as providing any legal advice or legal rights to the humanitarian agencies seeking to obtain and use vaccines via the COVAX humanitarian buffer; in addition, these agencies will remain liable and responsible for their own actions, including their medical practices, and for making their own assessment of the risks and potential liability exposure related to the procurement and use of those vaccines.

INDEMNITY AND LIABILITY

39. Who assumes indemnity and liability for COVID-19 vaccines, and how is this different from other vaccines?

For routine (non-COVID-19) immunization activities, the administration of a licensed vaccine creates risks and liabilities for all parties involved (manufacturer, transporter, distributor, administrator). To mitigate these risks, insurance is normally available, with coverage taken out by each entity involved to cover their respective liability and financial risk (e.g. transporter and distributor insuring the value of the goods, manufacturers covering product liability).

For most vaccines and medical products in most countries, manufacturers accept full liability and are insured against any potential losses. However, due to the rapid development and scale up of the COVID-19 vaccines, including the authorizations under emergency provisions, manufacturers have stated that they are unable to access the standard insurance available for other (non-COVID-19) vaccines and medical products.

COVID-19 vaccine manufacturers have therefore required countries receiving COVID-19 vaccines to indemnify them through bilateral indemnification arrangements in the event there are claims against the manufacturers for any adverse events suffered by individuals caused by the vaccines.

40. How is liability addressed within the COVAX Facility for vaccines distributed by COVAX to countries or territories? (outside the COVAX Humanitarian buffer doses)?

When COVID-19 vaccines are allocated through the COVAX Facility to countries or territories, the state or government (or equivalent) receiving the doses is required to take on the liability related to the product, in the same way that they would if they were procuring vaccines directly from a manufacturer(s) outside of the COVAX Facility.

To this end, the state or government (or equivalent) signs an indemnity agreement, which protects the manufacturer in the event of an individual (i) claiming that they have been injured by a vaccine made available through COVAX; and (ii) pursuing a civil claim on this ground against the manufacturer.

If an affected individual is in an AMC country or territory, they would have the option either to seek compensation from the COVAX No-Fault Compensation (NFC) Program or to pursue a civil claim; if the

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individual is located in a self-financing participating country or territory (SFP), the COVAX NFC Program is not available.

Should an individual claiming that they have been injured by a vaccine successfully pursue a civil case, the national authority would be responsible for the costs associated with it (such as legal defense fees and any potential judgments or settlements) pursuant to the indemnity agreement between the country or territory and the manufacturer. The state or government (or equivalent) would not be liable under the indemnity if the loss is caused by a manufacturer in one of the circumstances covered by a “carve-out” under the indemnity agreement (e.g. willful misconduct by the manufacturer or non-compliance with good manufacturing practices).

41. How will liability be addressed for doses distributed through the COVAX Humanitarian Buffer for Humanitarian Agencies?

For the Humanitarian Buffer, there are two potential scenarios to addressing liability:

- a) A humanitarian agency successfully applies for COVAX Humanitarian buffer doses jointly with a COVAX participating country, or territory. In this scenario, the doses are allocated to the country, on the basis that the existing indemnification arrangement between the country and the manufacturer(s) would apply (as long as the type of vaccine delivered through the buffer is covered under the existing indemnification agreement).
- b) The humanitarian agency applies for doses through the COVAX humanitarian buffer independent of a participating country or territory. In this scenario, the humanitarian agency will have to work with or through Gavi to determine the conditions under which the manufacturer(s) will or will not require to be indemnified by the humanitarian agency in the event of litigation against the manufacturers by individuals claiming to have suffered a serious adverse effect by COVAX Humanitarian Buffer doses distributed by the humanitarian agency concerned.

Unless these issues regarding indemnity requirements are resolved, manufacturers are unlikely to be willing to accept a purchase order and deliver doses for which humanitarian agencies are the recipient and end-user.

42. What is being done to resolve these issues?

The IASC and Gavi are working closely together to try to resolve these issues through discussions Gavi is having with manufacturers. The IASC’s over-arching objective is to ensure that the COVAX Humanitarian Buffer is operationalized as swiftly as possible and is able to fulfil its goal to ensure that populations of concern not included in national vaccination plans (or equivalent) have access to vaccines in all relevant contexts, including AMC, SFP and non-COVAX countries, as envisaged by the Gavi Board and IASC Emergency Directors’ Group.

As part of these efforts, Gavi and the IASC is calling on manufacturers of all vaccines in the COVAX portfolio to lift all remaining barriers to humanitarian access to COVID-19 vaccines, including by waiving the requirement for indemnification, particularly where the most vulnerable populations of concern can only be reached by humanitarian agencies utilizing the COVAX Humanitarian Buffer.

COMPENSATION

43. What is the COVAX Non-Fault Compensation Program (NFC), and does it apply to doses delivered through the COVAX humanitarian buffer?

The purpose of the COVAX NFC Program is to provide no-fault compensation in full and the final settlement of any claims to eligible individuals who suffer a Serious Adverse Event² resulting in permanent impairment or death associated with a COVID-19 vaccine, or through the administration of such a vaccine, procured or distributed to any AMC Eligible Economy, until 30 June 2022. This includes any doses administered as part of the COVAX Humanitarian Buffer by humanitarian agencies.

The COVAX NFC Program does not cover any adverse events (whether serious or non-serious) arising from a COVID-19 vaccine administered in any country, territory or economy that is not an AMC Eligible Economy (i.e. Self-Financing Participants). While applying for compensation through the NFC Program is voluntary (i.e. individuals can choose whether to apply for compensation under the NFC Program or pursue a claim in court), the Program is designed as a fast, fair, robust and transparent process that aims to make it easier for eligible individuals to receive compensation. As such, the Program aims to significantly reduce the need for individuals in the Gavi AMC eligible economies to seek compensation for serious adverse events through the court system (a process which is often lengthy, complex and expensive and has a higher burden of proof and therefore a more uncertain outcome). A reduction in litigation through the court system will in turn reduce the need to indemnify manufacturers for any losses they may incur as a result of any possible court awards against them

The COVAX NFC Program does not preclude individuals from pursuing civil claims in their competent national court if this is their preferred option. However, if they pursue this route, then the COVAX NFC Program would no longer be available for them.

More information about the COVAX NFC can be found on www.covaxclaims.com.

44. What information should humanitarian agencies administering doses that they have received through the COVAX humanitarian buffer provide to individuals on liability and access to compensation in case of a Serious Adverse Effect prior to their vaccination?

Humanitarian agencies administering COVID-19 vaccines allocated through the humanitarian buffer need to ensure that an adequate level of information is given to the individual being vaccinated in the most practical and efficient way possible. This information will help eligible individuals who suffer a serious adverse event resulting in permanent impairment or death associated with the administration of a COVAX distributed vaccine to gain access to the NFC Program. It is highly recommended that this information be provided to vaccinated individuals in the form of vaccination cards.

- a) Share instructions on “How to Submit an Application” to the NFC Program with vaccination centers, vaccine adverse event causality assessment committees, and registered healthcare professionals so that they can make these instructions available to recipients of COVAX distributed vaccines. (These instructions have been provided by the NFC Program’s independent claims administrator to the EPI manager at the Ministry of Health in each AMC-Eligible Economy and will also be provided to humanitarian agencies’ identified focal points. These instructions can also be found (in English, French and Spanish) under the “Printable Program Forms and Other

² Serious Adverse Event refers to life-threatening events, those resulting in death, hospitalization (or an existing hospital stay being lengthened) or persistent or significant disability/incapacity.

Documents” page of the NFC Program’s web portal (available at www.covaxclaims.com);

- b) Raise awareness about the NFC Program so that eligible individuals are aware of the NFC’s Program’s existence and can submit an application to the Program’s administrator.
- c) Establish adequate and sufficient measures for personal data protection and identity protection to prevent identifying data being shared (e.g on people from areas not under government control or irregular migrants, where risk of attack, detention or deportation may result). Such personal data protection and identity protection measures will need to be in accordance with applicable laws, rules and regulations, and follow relevant IASC and WHO guidance on data sharingⁱ and ensure individuals are informed of the safety of their data.
- d) Inform registered healthcare professionals within areas covered by the Humanitarian agency about the need to carefully track and keep records of the following information (particularly because this information will be required as part of the supporting evidence that must accompany an individual’s application for compensation under the Program).
- e) For each individual within the AMC Eligible Economy to whom a humanitarian buffer COVID-19 vaccine procured or distributed through the COVAX Facility is administered it is necessary to record:
 - Informed consent of the individual
 - Full name and address of the individual
 - Name of the COVID-19 vaccine (and of its diluent, if any) administered to such individual. Expiry date(s) of the vaccine dose(s) in question.
 - Batch or lot number(s) of dose(s) administered
 - Number of Dose(s) of the vaccine and dose(s) administered
 - Place and date(s) of administration to the individual; and
 - Expiry date(s) of the vaccine dose(s) in question
 - Name and full address of the humanitarian agency administering the vaccine, and of the contact person at the Humanitarian Agency, in the AMC Eligible Economy where the vaccine has been administered
- f) Work with the Program’s independent claims administrator to facilitate the submission and investigation of claims, as well as the exchange of safety information.
- g) ensure that registered health care professionals are provided with the information described above, and receive proper training in the effective implementation of the actions outlined in the above, as well as in the need to inform eligible individuals who suffer a serious adverse event resulting in permanent impairment or death associated with the administration of a COVAX distributed vaccine, of the NFC Program’s existence and providing such individuals with the Program’s How to Submit an Application instructions
- h) In settings where consultations with the government of the AMC Eligible Economy in question is not possible (e.g. in Non-State Armed Group-controlled areas), humanitarian agencies should nonetheless use all reasonable efforts to take the above-mentioned actions in order to facilitate that eligible individuals who suffer a serious adverse event resulting in permanent impairment or

death associated with the administration of a COVAX distributed vaccine have access to the NFC Program.

OTHER LEGAL ISSUES

45. Is medical confidentiality applicable to the COVAX Humanitarian Buffer vaccination process?

Yes. The vaccination of an individual should benefit from the medical confidentiality and medical ethics principles that apply to any patient and any personal data cannot be disclosed to third parties without the vaccinated individual's consent. Lists of vaccinated individuals might be kept by the humanitarian agencies delivering the doses, or by the medical facilities involved, but they must be kept confidential and shared with third parties only in adherence to relevant and applicable national laws, and with the concerned individuals' consent. Any lists and personal data must be kept secure, no longer than necessary and be destroyed thereafter. The individual must be informed about collection and disclosure of the personal data, including health information, in relation to the vaccination, including the purpose of disclosure and to whom personal data will be disclosed.

46. Will people who are eligible for a vaccination through the humanitarian buffer be forced to receive their shots?

No. Vaccination under the COVAX humanitarian buffer must be voluntary.

47. Will humanitarian agencies need to secure consent to medical treatment from an individual being vaccinated with a humanitarian buffer dose?

Yes. As for other vaccinations, valid and informed consent to medical treatment should be secured (both a key legal and ethical concern).

¹ See the [IASC Operational Guidance on Data Responsibility in Humanitarian Action 2021](#), and [WHO Policy Statement](#) on Data Sharing by the World Health Organization in the Context of Public Health Emergencies, 2016