

Frequently Asked Questions: The COVAX Humanitarian Buffer

This FAQ document has been prepared by the IASC Working Group on COVID-19 vaccines. The Working Group was tasked by the IASC Emergency Directors Group to work with Gavi, the Vaccine Alliance, on the establishment 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. Has the Humanitarian Buffer been operationalized? When will doses from the Humanitarian Buffer become available?

Applications to the COVAX Humanitarian Buffer are now open. Application materials 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 5). Up to 5% of the COVAX Facility's real-time doses will be made available to the COVAX Buffer as they become available. This 5% could reach up to 100 million doses by the end of 2021, 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').

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 will comprise of two components: The Humanitarian Buffer and the Contingency Provision. The Contingency Provision will 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 will be designed and implemented at a later stage. 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. In line with WHO SAGE guidelines and to

ensure parity with the standard COVAX vaccine rollout in a specific country, the Humanitarian Buffer only 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% of the 167 million people at risk of exclusion from COVID-19 vaccination would account for approximately 33 million people. Assuming a two-dose regimen, this would mean that a rough, indicative planning assumption would be that 66 million doses would be required for the Humanitarian Buffer.

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

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. We have also held a senior-level dialogue 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 11 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.

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 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 to 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. A UN Country Team, Humanitarian Country Team, or equivalent will receive the requesting entity's request and provide an opinion as to whether or not the request meets the eligibility criteria (see above question 14). The decision group will only consider requests by humanitarian agencies which meet the eligibility criteria to apply and have been approved by the Resident/ Humanitarian Coordinator (or equivalent senior official) if appropriate.

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. A request form and a 'process description' document along with relevant guidelines is currently in preparation. The applications will be received on a rolling basis. Decisions taken by the decision group will be final.

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.

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 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 complete, the body will decide within a maximum of 5 working days. 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.

FINANCING OF OPERATIONAL/ DELIVERY COSTS

23. 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.

24. 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

¹ Operational and delivery costs currently comprises 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)

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.

25. 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. Additionally, the Gavi Board has set aside US \$7.5m to finance operational/ delivery costs in exceptional cases where other funding is not available. US \$7.5m is unlikely to be enough to cover all the costs associated with the delivery of doses through the Humanitarian Buffer, and additional resources will need to be mobilized. The IASC and Gavi are in discussions on the allocation process for the \$7.5m that has been available by the Gavi Board.

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. Will there be a centralized mechanism to finance operational/ delivery costs of doses from the Humanitarian Buffer?

Yes. The IASC has agreed that UNICEF's [ACT-A Humanitarian Action for Children \(HAC\)](#) appeal will be used as the centralized mechanism for financing operational/ delivery costs associated with allocations from the Humanitarian Buffer. When the decision body allocates doses from the Humanitarian Buffer to humanitarian agencies or national governments, resources to cover operational/ delivery costs will be transferred quickly and efficiently to the humanitarian agency or national government that has made the request and has been allocated the doses by the decision body.

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:

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

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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

34. Could the World Bank and Regional Development Banks cover delivery costs for the Humanitarian Buffer?

The World Bank and other regional development banks have pledged to support national authorities with preparedness, readiness, and vaccine delivery. The World Bank pledged \$12 billion in October 2020 to support countries with their COVID-19 response. This includes vaccine delivery, but also procurement of vaccines, testing, diagnostics, and therapeutics. We do not have clarity yet whether any of these funds could be used to finance delivery costs from doses allocated through the Humanitarian Buffer. 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 also be noted that several countries in the GHO are not eligible to receive World Bank funding.

35. 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.

36. 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

37. 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-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

1. 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.

2. 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.

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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 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).

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

When humanitarian agencies apply for doses allocated through the COVAX Humanitarian Buffer, manufacturers are likely to request that liability will need to be addressed directly by the agencies themselves.

For the Humanitarian Buffer, there are two potential scenarios:

- 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.

4. 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.

COMPENSATION

5. 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.

6. What information should humanitarian agencies administering doses 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.

Humanitarian agencies should -in consultation with the government of the AMC Eligible Economy in question- use all reasonable efforts to take the following actions:

- 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 Program’s independent claims administrator to the EPI manager at the Ministry of Health in each AMC-Eligible Economy, but can also be found (in English, French and Spanish) under the “Printable Program Forms and Other Documents” page of the NFC Program’s web portal, available at www.covaxclaims.com);

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.

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- Raise awareness about the NFC Program so that eligible individuals are aware of the Program's existence and can submit an application to the Program's administrator;
- 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):
 - Full name and address of the individual
 - Name of the COVID-19 vaccine (and of its diluent, if any) administered to such individual.
 - Dose(s) of the vaccine and dose(s) administered
 - Batch or lot number(s) of dose(s) administered
 - Place and date(s) of administration to the individual; and
 - Expiry date(s) of the vaccine dose(s) in question.
- Work with the Program's independent claims administrator to facilitate the submission and investigation of claims, as well as the exchange of safety information.

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

7. 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.

8. 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.

9. 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).