



COVAX AMC APPLICATION GUIDANCE

#ONEWORLDPROTECTED



BACKGROUND

3

APPLICATION PROCESS

4

COST SHARING

11

SUMMARY

13

BACKGROUND

In July 2020, the Gavi Board approved Gavi as the legal entity to administer the COVID-19 Vaccine Global Access Facility (the “COVAX Facility” or “Facility”), a global mechanism to pool resources and demand for COVID-19 vaccines with the goal of accelerating the availability of and equitable access to safe and efficacious vaccines. The Board also approved the establishment of the Gavi COVAX AMC (the “COVAX AMC”), a financing mechanism to accelerate and reserve COVID-19 vaccines to ensure that low income and lower-middle income economies, as well as other IDA-eligible economies, have access to COVID-19 vaccines at the same time as wealthier economies (COVAX AMC, which includes 92 eligible economies (“AMC92”). The COVAX AMC has been established to raise funding to enable Gavi to subsidise vaccine dose purchase through the COVAX Facility for AMC92 through Official Development Assistance funding from donors, as well as through support from private foundations. The COVAX AMC helps ensure that all economies can participate in the COVAX Facility and access vaccines through it. The details on AMC participants’ involvement in the COVAX Facility are set out in the **Vaccine Request Annex A: COVAX Facility Terms and Conditions for AMC Group Participants**.

Through the COVAX Facility, AMC-eligible economies have the opportunity to benefit from a portfolio of vaccine candidates to provide security of demand with greater scope than governments or regional groups can support on their own, giving their populations early access to safe and efficacious vaccines. Gavi and/or UNICEF and PAHO Revolving Fund will enter into advance purchase commitments with manufacturers for supply of vaccines for the benefit of COVAX Participants. The COVAX Facility aims to procure 2 billion doses of a safe and efficacious vaccine by the end of 2021. By participating in the COVAX Facility and the COVAX AMC, AMC Group Participants will have access to doses of vaccine candidates as a result of the advance purchase commitments that Gavi will conclude with vaccine manufacturers. The achievement of this will be subject to the availability of funding.

The objective of this document is to provide complementary information and a practical guide to AMC92 on how to request **COVID-19 approved vaccines, Technical assistance, and Cold Chain Equipment (CCE) support**. The guideline outlines the process that AMC-eligible economies will be required to follow as well as elements to consider in requests. All documents referenced in this guideline can be found on the [Gavi COVAX webpage](#).

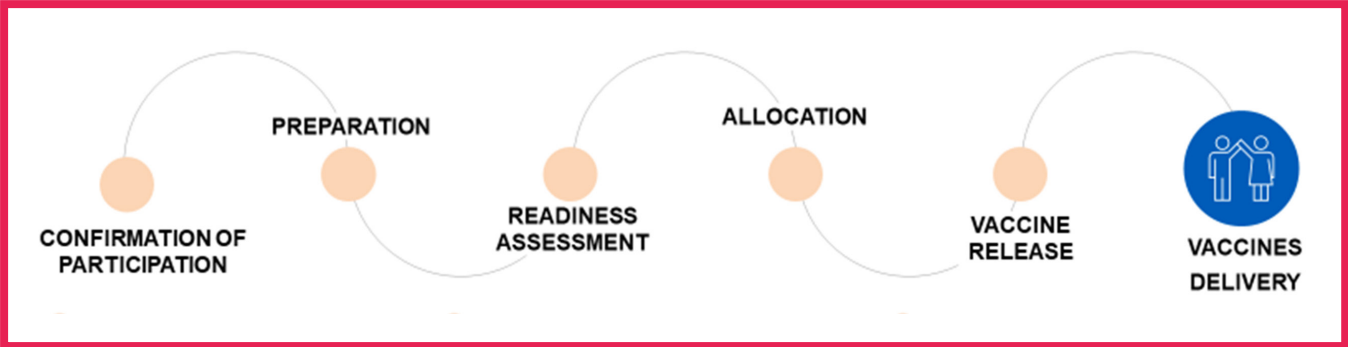
For further information, Gavi-eligible countries should reach out to their Senior Country Manager. All other AMC-eligible economies should reach out to their focal point.

COVAX AMC APPLICATION GUIDANCE: APPLICATION TO ACCESS COVID-19 VACCINES THROUGH THE COVAX FACILITY

1. APPLICATION PROCESS

Economies eligible for the COVAX AMC are required to confirm participation in the COVAX Facility and complete a Vaccine Request in order to be allocated doses of COVID-19 vaccine. Additional data submissions described in this document are required for doses to be delivered. In addition to Vaccine Support, all AMC Group Participants are eligible to request technical assistance (TA) and support for cold chain equipment (CCE). Priority will be given to the Gavi-eligible countries¹. The Vaccine Request is a prerequisite for requests for CCE support. Requests for TA can be made independently of any other applications to the COVAX Facility. Participants may request WHO and UNICEF Country Offices and World Bank and relevant regional development banks to provide TA to complete their applications to the COVAX Facility.

Overview of process to receive COVID-19 vaccines through the COVAX Facility



1 A list of Gavi-eligible economies can be found here: <https://www.gavi.org/types-support/sustainability/eligibility>

STEP 1 : CONFIRMATION OF PARTICIPATION

COVAX AMC-Eligible Economies should confirm participation in the AMC by submitting a completed and signed Vaccine Request:

- Part A to covaxproposals@gavi.org, copying the relevant Gavi Senior Country Manager or focal point (whichever is applicable) by December 7, 2020. To complete the submission;
- Part B should be submitted to covaxproposals@gavi.org, with a copy sent to the relevant Gavi Senior Country Manager or focal point (whichever is applicable) by 14 December 2020. Submissions thereafter will be accepted but, on a schedule to be determined.

STEP 2 : PREPARATION

To assist the preparations for a successful vaccine introduction, AMC Group Participants can indicate a need for TA and/or support for CCE.

TECHNICAL ASSISTANCE

To prepare all AMC-eligible economies for COVID-19 vaccine introduction, WHO, UNICEF, Gavi, and partners are working together at the global and regional levels to (1) develop and disseminate adaptable guidance, trainings, planning and monitoring tools, and advocacy materials and (2) provide TA and support to AMC Group Participants. All AMC-eligible economies are eligible to request TA although priority will be given to Gavi-eligible countries¹. The TA aims to support the AMC-eligible economies in the planning and preparation for introducing the COVID-19 vaccine. Advance financing has been made available to WHO and UNICEF Country Offices to provide TA to every AMC-eligible economy. Further TA will be provided in alignment with areas of support needs, as identified by the COVAX [Vaccine Introduction Readiness Assessment Tool \(VIRAT\)](#) (which is set to be merged with the World Bank's Vaccine Introduction Readiness Framework in due course).

For the 57 Gavi-eligible economies¹, the Senior Country Manager in collaboration

with WHO and UNICEF will provide additional guidance on funding available for TA in each AMC-eligible economy and the process to identify TA needs and request support. For AMC-eligible economies that are not Gavi-eligible, WHO and UNICEF Regional Office will provide additional guidance on how to identify TA needs and request support for the planning and preparation for the introduction of COVID-19 vaccine.

- For Gavi-eligible countries, country stakeholders should share COVAX TA plans with Senior Country Managers by November 27, 2020.
- Other AMC-eligible economies should reach out to WHO/UNICEF country / regional offices which will submit compiled needs of this group to Gavi Secretariat by November 27, 2020.

Additional support is available for COVID-19 vaccine delivery, for example, from the World Bank and other multilateral development banks. AMC Group Participants can discuss the potential to allocate resources for COVID-19 vaccine delivery with their respective multilateral development bank focal points.

Note that there is no requirement to request TA in order to receive vaccines from the COVAX Facility.

COLD CHAIN EQUIPMENT

The COVAX Facility is making CCE support available to AMC Group Participants. All AMC Group Participants are eligible to request CCE support, although priority will be given to the 57 Gavi-eligible economies¹. In line with assessments of cold chain needs conducted by the Gavi Alliance (including WHO, UNICEF and partners), this support will prioritize addressing gaps in storage capacity at the upper levels of the cold chain (national/central, regional/provincial), with more limited support provided for district levels, where justified.

In many cases, Participants seeking to apply for CCE support will be doing so before their vaccine allocation is known. To that end, the application is based on a set of assumed vaccine properties which are expected to be adaptable across the vast majority of vaccine candidates – including a specification of 2-8°C stability. A description of these assumptions and rationale can be found in the [Technical Annex of the Application Guideline](#).

Participants can gain access to this support by completing a CCE Application package. This package includes guidance on how to complete the application, descriptions of supported technologies and services, and the necessary forms and templates to complete.

- Applications for CCE support should be submitted to covaxproposals@gavi.org, copying the relevant Gavi Senior Country Manager or focal point (whichever is applicable).
- These applications will undergo a pre-review by a UNICEF- and WHO-led body, and will then be reviewed by Gavi's Independent Review Committee (IRC).
- For a CCE Application package to be reviewed by the IRC, the AMC Group Participant must have also submitted a completed and signed Vaccine Request (see Step 1).

Participants are requested to note the following as they prepare the CCE application materials:

- The support provides applicants with options on how to meet their needs, but also restricts what types of equipment and services are eligible for support. AMC Group Participants are encouraged to read the [Tech Guide](#) and [Application Guideline](#) to understand these aspects and assess their needs accordingly.
- This support is only for incremental needs associated with the COVID-19 vaccine; storage gaps associated with routine immunization are not eligible.
- Support is contingent on a clear demonstration of capacity gaps at targeted storage sites. Participants are encouraged to collect updated cold chain inventory (CCI) data for the targeted storage levels as early as possible, to facilitate application completion.
- Submission of a completed and signed Vaccine Request is a requirement for CCE Application package review, however there is no requirement to apply for CCE to receive vaccines from the COVAX Facility.

TOOLS TO SUPPORT PREPARATION

AMC Group Participants are requested to develop a National Deployment and Vaccination Plan (NDVP) to elaborate introduction strategies for the COVID-19 vaccine. The NDVP will provide approaches to address potential gaps identified in the COVAX Vaccine Readiness Assessment Tool for COVID-19 vaccines (VIRAT). These plans will be developed at national level within the Ministry of Health with

support from key stakeholders. AMC Group Participants will work with WHO and other relevant local and regional partners to develop the NDVP as well as associated operational plans, including detailed microplans to ensure efficient vaccine deployment to the point of administration. Regional review of the NDVP is envisaged towards ensuring country readiness, identification of gaps and provision of ongoing technical support. Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines will be available soon and guidance for completing the VIRAT is available [here](#).

INDEMNITY REQUIREMENTS AND NO-FAULT COMPENSATION MECHANISM

Due to the unprecedented speed and scale of deployment of COVID-19 vaccines, manufacturers are looking to countries receiving and deploying vaccines against COVID-19 to indemnify them against product liability claims associated with the use or administered of vaccines in the Country. AMC Group Participants are requested by signing and returning the Vaccine Request - Part B to agree to indemnify manufacturers on the terms substantially in the form of the model indemnification provision and to confirm who has authority to sign the indemnity agreement or alternatively if legislation would need to be passed for the country to enter into such an indemnity, and if so, to indicate the timing needed to pass such legislation.

The COVAX Facility is developing a mechanism to provide compensation to those individuals in any of the AMC Group Participant economies receiving an approved vaccine through COVAX that suffer serious adverse events associated with the vaccine or administration of the vaccine. AMC Group Participants will be required to agree to the model indemnity provision to be able to have access to the compensation scheme. The mechanism is designed to provide compensation as full and final settlement of any claims. As part of the Vaccine Request - Part B, AMC Group participants will be required to indicate if legislation is required to make effective the full and final settlement provision of the compensation, and if so, to indicate the timing needed to pass such legislation.

A briefing note has been prepared by the COVAX Facility on how the COVAX Facility is seeking to address potential liability, and compensation in the event of serious adverse events arising from the manufacture, storage, transportation and administration of COVID-19 vaccines for AMC Countries is available.

STEP 3 : READINESS ASSESSMENT

Work done by AMC Group Participants jointly with partners to prepare for receipt and use of vaccines will be leveraged to establish country readiness and inform distribution of vaccines. No AMC Group Participant will be left behind and all efforts will be put in place to ensure the necessary actions are taken to strengthen systems and encourage early deployment of vaccines. Key to this effort will be for the AMC Group Participant to share timely information and rapidly undertake planning processes. Further details on readiness assessment will be communicated at a later date.

STEP 4 : ALLOCATION

Data provided in the Vaccine Request (see Step 1) contributes to allocation of COVID-19 vaccines to COVAX Participants. The approach to the allocation of COVID-19 vaccines is described in the [WHO Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility](#) as well as in a short associated [explainer](#).

The allocation framework follows a two-phase approach:

- Phase 1: COVAX Participants are allocated doses proportional to their population size to reach allocation of doses that would amount to 20% of each COVAX Participant's population², to be delivered in sequential manner as supply availability increases.
- Phase 2: After all COVAX Participants have reached 20% population coverage (or less if they have chosen so) they are allocated doses guided by risk and vulnerability criteria.

The allocation process will consider supply and demand considerations and will aim to optimise allotments so that allocated doses are matched to COVAX Participant needs and context.

In choosing target populations for vaccination, AMC Group Participants are rec-

2 Subject to adequate financing. Given its tailored approach, India will be allocated doses after consultation with the country and as determined and approved by the Gavi December 2020 Board.

ommended to follow the **WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply** and **WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination**, which can be found here: https://www.who.int/immunization/sage/covid-19_documents/en/.

STEP 5 : VACCINE RELEASE

In order to have COVID-19 vaccines released for delivery, AMC Group Participants are required to provide proof of the following to the COVAX Facility:

- National regulatory approval of the vaccine granted by the relevant National Regulatory Agency or proof of recognition or reliance on another type of regulatory approval;
- Import license and other shipment related documentations (as applicable at national level);
- Indemnification (see indemnity requirements and no-fault compensation mechanism under Step 3)

After shipment of COVID-19 vaccines is received, all necessary custom clearance procedures will need to be performed. Inspection at the airport or central cold store should be performed within 24 hours of shipment arrival. For shipments that are procured through UNICEF, a copy of the Vaccine Arrival Report (VAR) should be sent to the respective UNICEF Country Office within 3 working days of shipment arrival. UNICEF Country offices will support to ensure the VAR process is followed at each location and send the VAR to UNICEF Supply Division. For further information on VARs, please refer to WHO guidelines on the international packaging and shipping of vaccines or contact UNICEF Supply Division at sd.var@unicef.org.

PROGRAMMATIC REPORTING

AMC92 Group Participants must ensure that all support received from the Facility is managed in a transparent and accountable manner and they are required to report on programmatic performance and implementation.

AMC Group Participants are allocated doses on the understanding that key

monitoring and performance data is reported back to the COVAX Facility for multiple uses:

- to inform future dose allocations and shipments;
- to inform future TA and support needs; and
- from an accountability perspective to help ensure programmes are well managed, target populations are reached, and risks are mitigated.

Programmatic monitoring and reporting are required to assess the use of COVID-19 vaccines. Initial guidance on monitoring is provided in the Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines with more detailed guidance forthcoming.

AMC Group Participants will be required to report on a standardised set of metrics and questions (at a minimum related to vaccines administered across different target populations) through a COVID-19 module in the WHO/UNICEF Joint Reporting Form (JRF). As of 2021, the JRF will be online and virtual training sessions will be provided to help people navigate the tool. In addition, technical partners may facilitate programmatic evaluations and reporting on lessons learned across AMC Group Participants.

2. COST SHARING

During the Global Vaccine Summit on June 4, Gavi launched the COVAX AMC as the first building block of the COVAX Facility – with the goal to ensure rapid equitable access to safe and effective COVID-19 vaccines to all countries, regardless of income level.

Gavi is currently fundraising to finance the costs of at least 1bn COVID-19 vaccine doses through the Gavi COVAX AMC. These fully subsidized donor-funded doses will jumpstart new COVID-19 vaccine introductions in AMC-eligible economies, allowing early doses to be reserved to ensure that lower income countries are not left behind. Whilst mindful of uncertainties on vaccine pricing, resource availability and manufacturing supply, Gavi aspires to be able to cover ~20% of the population of AMC-eligible economies with these donor-funded doses, thereby making a very real impact towards stopping the spread of the pandemic by end 2021.

Gavi usually works with countries through a co-financing approach to promote country ownership and financial sustainability of routine immunisation programmes. Once more is known about the COVID-19 vaccine, for example if it will be routinised, it is Gavi's will apply

its normal co-financing policies to its engagement with countries for COVID-19 vaccine support. However, given the urgency of the pandemic, the fiscal pressures facing countries, and the high degree of uncertainty, Gavi is proposing an exceptional ‘cost-sharing’ approach. The Gavi Board confirmed this approach at its meeting in September.

Through this cost-sharing approach, countries will have an opportunity to complement and build on the essential foundation built by these early, donor funded doses if they wish to achieve a higher population coverage³.

Cost-sharing will work as follows. Firstly, fully subsidized donor-funded doses will be distributed across AMC Group Participants until donor resources are exhausted. AMC Group Participants will then have the opportunity to allocate additional funds to receive further doses, fully paid for with these cost-sharing contributions. Participants can use MDBs financing, e.g. from the World Bank and regional development banks, to support these cost-sharing contributions, and it is expected that many participants will do so. The Office of the COVAX Facility is working closely with MDBs to ensure there is alignment between the parameters of MDB financing and the COVAX Facility, and that processes between the two bodies are both smooth and efficient.

Procuring additional cost-shared doses via the COVAX Facility offers several advantages in contrast to bilateral or other procurement arrangements. Firstly, participants can benefit from the wide range of advantages offered by the COVAX Facility including: access to a large, diverse, and actively managed portfolio of vaccine candidates, maximizing the probability of receiving effective, high quality vaccines in the near-term; access to second generation candidates that may have benefits on cost, ease of use or scalability; access to COVAX-negotiated prices; and assurance of safety and efficacy through WHO pre-qualification or stringent regulatory approval. Additionally, through this cost-sharing approach, AMC Group Participants will benefit from a streamlined process for accessing both donor-funded doses to cover their highest risk groups as well as cost-shared doses to, if desired, protect a higher proportion of their population.

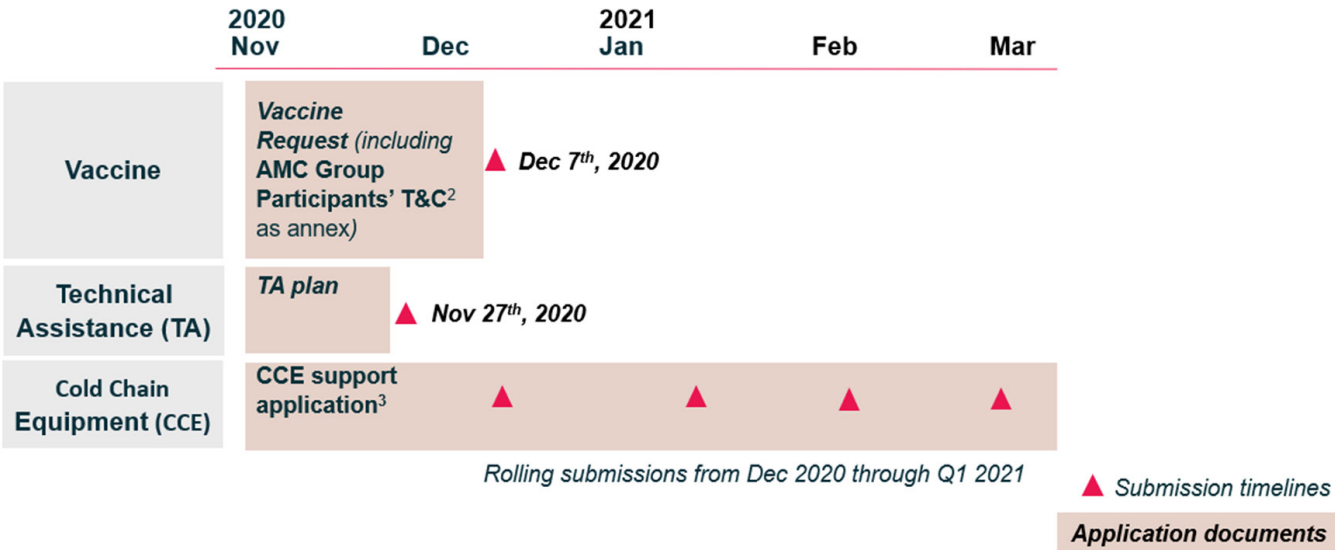
It is critical to note that an inability to cost share will not affect AMC Group Participants’ ability to access the fully subsidized donor-funded doses provided through the Gavi COVAX AMC. In addition, should AMC Group Participants choose not to cost-share, they would still receive their share of donor-funded doses.

AMC Group Participants are invited to work with the Office of the COVAX Facility and MDBs, including the World Bank and regional development banks, as relevant, to allocate cost-sharing funds to purchase supplemental doses. AMC Group Participants will be requested to indicate how many additional doses they wish to procure via the Facility with

³ Given projected supply constraints for 2021, additional doses beyond 20% will be subject to availability and may be distributed in 2022.

cost-sharing funds (subject to dose availability) during this first phase, based on the population percentage they aim to cover, and, as relevant, to work with multilateral development banks to allocate financing for these doses. Additional details are still being finalized, and further materials outlining the process for allocating cost-sharing funds will be sent to AMC Group Participants following the AMC Engagement Group Meeting.

3. SUMMARY OF APPLICATION COMPONENTS AND SUBMISSION TIMELINES FOR AMC GROUP PARTICIPANTS¹



¹ India will follow a distinct submission cycle vs. other AMC eligible economies, given its tailored approach and December Board approval process
² The Terms and conditions for AMC Group Participants shared in late October 2020 is pre-read, and the English-language Terms and Conditions for AMC Group Participants shared as annex to the Vaccine Request is the formal, legally-binding version
³ Submitting the Vaccine Request is required prior to submitting the CCE support application



#ONEWORLDPROTECTED

November 13, 2020.

<https://www.gavi.org/covax-facility>