



APPLICATION GUIDELINE: COLD CHAIN EQUIPMENT (CCE) SUPPORT FOR COVAX AMC PARTICIPANTS

OVERVIEW

KEY AUDIENCES

Immunisation and supply chain programme managers, Gavi Secretariat country teams, Alliance partners including civil society organisations, and other stakeholders responsible for and supporting the delivery of COVID immunisation in the 92 COVAX AMC-eligible participating geographies^{1,2}.

DOCUMENT PURPOSE

Use this guidance to understand the structure and processes for accessing cold chain equipment (CCE) support related to the introduction of COVID-19 vaccine through the COVAX Facility (“COVAX CCE Support”).

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¹ India's package of COVAX support is tailored and will be approved by the Gavi Board. Some of these guidelines and parts of this process will not apply.

² The list of AMC participating countries can be [found at this link](#).



1.0 INTRODUCTION & ELIGIBILITY

Cold chain equipment (CCE) is an essential component of the supply chain that ensures that lifesaving vaccines reach every target beneficiary. To enable the safe and timely delivery of the COVID-19 vaccine by the 92 COVAX AMC participants, the Gavi Board approved funding for cold chain needs (hereafter, 'COVAX CCE Support').

All COVAX AMC participants who confirm participation through the submission of a Vaccine Request (VR) form are eligible to apply for COVAX CCE support (hereafter, "Applicants"). This represents \$60M of funding available to the 92 AMC participants.³ Per the decision of the Gavi Board, funding priority has been given to the 56 Gavi-eligible participants, who will receive indicative ceilings for their needs. The remaining AMC 92 participants will be assessed on a case-by-case basis at the time of application, according to need and available funding.

This support is targeted towards the incremental cold chain storage requirements associated with COVID-19 immunisation and service delivery strategies. Accordingly, it emphasizes strengthening the upper levels of the supply chain, where the additional volumes of vaccine are expected to cause greatest challenges. Support is available for strengthening lower levels of the supply chain (e.g. districts) on an exceptional basis, where strongly justified and possible within available funding. Please note that while this equipment is expected to supplement the routine immunization (RI) supply chain, it is not meant to close storage gaps associated with RI. However, this equipment can be redeployed with the RI cold chain when no longer required for COVID immunization.

NOTE: Accounting for vaccine allocation timelines

For many applicants, this support will be applied-for and approved before vaccine allocation decisions are made. As such, the decision on the type of cold chain to deploy must be made using the best available information on the presentation and requirements of vaccines in the COVAX portfolio.

This support is based around the current operating assumptions of the COVAX facility, which are (i) a 2C-8C storage profile and (ii) presentation assumptions detailed in the Technical Annex (Section 4.0) of this document. This reflects the latest analysis of the vaccine pipeline by COVAX and associated partners, in which an overwhelming majority of available doses will meet this profile. As such, this support model is believed to be the best approach to ensure COVAX participants are well positioned to receive sufficient doses to immunize up to 20% of their population (divided over several deliveries, per details in Technical Annex).

If this outlook changes, Gavi will update and adjust processes accordingly.

³ Noting India's tailored package of support, per preceding footnote.





2.0 ELIGIBLE FORMS OF CCE SUPPORT

Under the COVAX CCE support, Gavi will support eligible applicants (see 1.0) with the purchase or leasing of high-performing CCE, as well as (i) the deployment and installation of that equipment and (ii) the training of healthcare workers and technicians by suppliers or the suppliers' in-country service providers. In addition, procured CCE will come bundled with monitoring devices, and Applicants will have the option to request spare parts and passive transport devices.

2.1 TYPES OF EQUIPMENT AVAILABLE FOR PROCUREMENT

Under the COVAX CCE support, the following forms of equipment are eligible for procurement. All equipment procured through this platform must have WHO PQS certification, with some categories (e.g. fridges and freezers) requiring more stringent standards (e.g. Grade-A freeze protection) to be met (See COVAX CCE Tech Guide for more details, [Link](#)). For all platform-eligible equipment, Applicants may use the unit prices provided for such devices in the COVAX CCE guidelines, noting that the exact price may be different.

Category	Equipment Type	Description
Walk-in Cold Rooms	Walk-in Cold Rooms (WICR)	<ul style="list-style-type: none"> WICRs are only eligible for procurement if the applicant certifies that the site is – or will be – ready to deploy this equipment. Gavi will not be providing resources associated with site readiness activities though this funding, but applicants may seek other sources. If the site cannot be made ready in a timely manner (e.g. within 3-4 months of application), Gavi recommends applicants to explore the leasing options described in Section 2.2.
Fridges & Freezers	Ice-Lined Refrigerators (ILRs)	<ul style="list-style-type: none"> All ILR and SDD equipment procured through the platform must meet the standards set by the Gavi Cold Chain Equipment Optimization Platform (CCEOP). This information can be found in the COVAX CCE Technology Guide. (Link) Voltage regulators will be bundled with newly purchased on-grid ILRs and freezers;
	Solar Direct Drive (SDD) Refrigerators	
	Mains-powered & SDD Freezers	
Passive Devices	Vaccine carriers (traditional and freeze-preventative)	<p>Support for passives should be exceptional and strongly demonstrated as necessary for COVID-19 immunization in the submitted application.</p> <ul style="list-style-type: none"> Freeze-preventive carriers will come bundled with training materials to orient users to their proper use. Due to the special nature of these devices, Applicants are requested to demonstrate how they will conduct this training for users. Applicants will need to demonstrate how the number of passives was calculated and their association with the COVID-
	Cold boxes (traditional and freeze-preventative)	





		19 service delivery strategies described in the application document.
Monitoring Devices	Remote Temperature Monitoring (RTM) Devices	<ul style="list-style-type: none"> Remote temperature monitoring devices will be required to monitor all CCE procured or leased through this support and is included in the mandatory reporting guidance. Applicants may also request RTM for upper level sites (e.g. national, regional) where COVAX Vaccine will be stored in existing CCE, if they are not currently covered by RTM.
Additional Resources	Spare parts	<ul style="list-style-type: none"> Spare parts can only be procured for equipment acquired through this support (not existing equipment).

Equipment that does not meet the above standards described here and in the associated COVAX CCE Tech Guide is not eligible for procurement.⁴ This includes, but is not limited to, the following groups of products:

- Absorption refrigerators;
- Non-PQS listed CCE;
- Solar battery-powered CCE;
- Refrigerated vehicles;

2.1.1 BRAND SELECTION FOR PROCURED EQUIPMENT

When applying for cold chain equipment (across all categories), Applicants will be requested to submit a minimum of three (3) brand preferences.⁵ UNICEF SD will develop a cost estimate for procurement from within these preferences, prioritizing product availability and delivery timing considerations. In the unlikely event that there is no reasonable access to any of the preferred products, UNICEF SD will seek equivalent supply from an alternative provider.

2.2 SERVICES AVAILABLE UNDER COVAX CCE SUPPORT

There are also several groups of services that are supported through this platform, described below:

- CCE delivery, installation and training services;
- Long-term leasing of cold storage at national and regional levels;
- Short-term (“bridge”) leasing of cold storage at national level;
- Remote temperature monitoring (RTM), including device, installation, training and data components.

2.2.1 CCE DELIVERY, INSTALLATION AND TRAINING SERVICES

Delivery, installation, and user training services are bundled with all walk-in cold rooms (WICRs), as well as Ice-Lined Refrigerators (ILR), Solar Direct Drive (SDD) refrigerators and freezers. This service will be provided by the manufacturer or their agent of choice, which must meet requirements established by UNICEF Supply Division (SD). Note that the applicant will be responsible for ensuring close coordination with the service provider, and that failure to prepare sites accordingly can lead to additional costs and delays that are detrimental to the program.

⁴ Some of these requirements may be relaxed for leasing solutions. These details will be found in the contracting guidance.

⁵ If less than three brands are available for the equivalent category, the Applicant should provide as many alternatives as is possible (two or none).





Exceptions to this service bundling may only be made for situations where the service providers would not be able to access the site due to issues of physical security and/or other safety concern. The rationale and evidence for such exceptions must be provided in the relevant section of the main application narrative. Applicants that receive this exception will have service bundle funding transferred to the UNICEF Country Office (CO), who will support the sourcing of installation, commissioning, and training capacity locally.

2.2.2 OPTION TO LEASE COLD STORAGE IN LIEU OF PROCUREMENT

Where applicants have demonstrated a storage gap at the two highest levels of the cold chain (e.g. national, regional), they will have the option to secure cold storage services from private sector providers (regional, local) via UNICEF COs in lieu of procurement. The rationale for this decision must be provided in the relevant section of the application, with possible reasons including (but not limited to) the following:

- Inability to secure site readiness for equipment deployment;
- Familiarity and preference for leasing solutions to manage surge capacity;
- Lack of interest or requirement for additional CCE, post-COVID pandemic.

If applicants elect to take this option and are approved, the support will be subject to conditions including (but not limited to):

- Funding for equipment leasing will be equivalent (at most) to benchmark prices for the size and number of CCE that would need to be procured to address the storage gap. The requested amount must not exceed the indicative ceiling. This information can be found in the Budget Template ([Link](#)).
- The funding request will be subject to Independent Review Committee (IRC) review, identical to if the equipment had been requested for procurement.
- Funds will be disbursed-to and held-by the respective UNICEF country office.
- UNICEF SD will provide a draft contract and associated requirements (e.g. monitoring, duration, safety, price thresholds) that must be met to ensure vaccines are kept in safe and reliable conditions.⁶
- The UNICEF CO will be responsible for identifying the supplier and negotiating terms in coordination-with and subject to approval by the government, with the final arrangement subject to review by the Gavi Senior Country Manager (SCM) or equivalent officer.

In the event funds remain unspent, Gavi and the UNICEF CO will arrange their transfer back to Gavi. If the UNICEF CO is unable to secure a local or global provider of services, the applicant will have the option to procure the CCE through UNICEF SD's procurement services modality. All equipment procured this way must meet the standards set out in Section 2.1 and is subject to Gavi SCM (or equivalent) approval.

2.3.3 SHORT-TERM LEASING TO BRIDGE NATIONAL CAPACITY GAPS

In some cases, applicants may need to receive COVID-19 vaccine before procured equipment has or can be installed. Where this risk exists at the national store and is likely to impact initial COVID-19 vaccine arrival (e.g. batches for first 3% of population), applicants will have the option to request funding to secure private cold storage services for a short (3 - 4 month) period.

⁶ As of this version (November 2020), this draft contract guidance is still in development. Applicants interested in this option are requested to reach out to their COVAX contact to receive regular updates on this guidance.





This funding will be provided on an exceptional basis. Approval will be contingent on (1) Applicant providing a strong rationale for the request and (2) demonstrating that alternative approaches – such as pushing routine vaccines to lower levels or alternative storage sites – have been evaluated.

If approved, this support will be subject to the same contractual and disbursement requirements as described in 2.3.2. The level of support scales to the size of cold storage required, with indicative ranges provided in the Budget Template ([link](#)). However, Applicants are encouraged to (i) inform these figures from relevant domestic experience in the associated section of the Main Application Form ([link](#)), and (ii) reach out to UNICEF Country Offices for input on providers and pricing. Please note that given the exceptional nature of this support, approved amounts may vary.

2.3.4 REMOTE TEMPERATURE MONITORING

Remote temperature monitoring systems comprise both device (hardware) and a service (data transfer and access) components. All CCE procured or leased through this support must be monitored with RTM devices. For the upper levels of the supply chain (national, regional), applicants will have the option to request additional devices for CCE that will store COVID-19 vaccine. All devices will come bundled with installation services, as well as data access and transmission costs for three years, after which these costs will be the responsibility of the Applicant.

3.0 APPLICATION PROCESS AND REQUIREMENTS

The COVAX CCE support process is designed to provide applicants with rapid and urgent access to necessary CCE, while meeting Gavi governance requirements. Both participants that are applying for Gavi support for the first time and those that are familiar are requested to review the process closely, as there have been changes to better match COVAX timelines and processes.

3.1 APPLICATION PROCESS & TIMELINES

The COVAX CCE application process is designed to move as quickly as possible, while operating within Gavi governance requirements. Applicants are encouraged to review the following steps and timelines and ensure that applications are submitted with enough time to ensure timely deployment.

With regards to the timing of Pre-Reviews and IRCs, the aim is to have frequent review cycles (e.g. every two weeks) to avoid delays. Applicants are suggested to signal as early as possible their intent to submit applications (e.g. once application development begins), so that sufficient reviewer time and capacity can be allotted for each period.

#	Step	Description	Target Timeline
1	Applicant assembles materials		----
2	Applicant submits full set of materials	Once all documentation and approvals have been secured, the applicant	----
3	Alliance Pre-Review	The application will be reviewed by a panel of technical experts from Alliance members, who will check the contents for completeness and quality. They	5 - 10 Days





		will prepare feedback (if any) for the applicant, identifying areas that can/should be addressed to better ensure the success of the project.	
4	Applicant addresses comments from Pre-Review	The applicant then has a period of time to address the comments made by the Pre-Review group. There is no set timeline for this, but it is recommended to complete this as quickly as possible.	5 – 10 Days
5	Applicant submits materials to Gavi portal / email	Once all desired changes have been made, the applicant submits the updated materials to Gavi and confirms submission with the SCM (or equivalent)	2 Days
6	Application review by Independent Review Committee (IRC)	The IRC is made up by immunisation and health systems experts who are independent of Gavi. They will review the application to ensure it meets all requirements. They will have the option to recommend for approval, recommend for approval pursuant to clarifications, or request a resubmission and re-review. <ul style="list-style-type: none"> • If the application is approved with clarifications, those must be addressed before moving to Step 7. Gavi guidance allows for up to 90 days to receive clarifications, but Applicants are encouraged to process these as quickly as possible. • If the application is declined, the applicant must return to Step 1. 	10 - 17 Days <i>(If no clarifications required)</i>
7	Gavi issues decision letter	Once an application recommended for approval, Gavi will review the recommendation, and – if approved -- issue a decision letter that approves disbursement of funds. <ul style="list-style-type: none"> • For procurements, UNICEF SD will then use this to prepare cost estimates. • For cash grants (e.g. leasing) disbursement to UNICEF country offices will occur at this time. 	14 – 21 Days
8	The Applicant reviews cost estimate	For CCE procurements, UNICEF SD will prepare a cost estimate concurrently with decision letter processes, which will then be shared with the Applicant. Once the Applicant approves the cost estimate, it is sent to the Gavi SCM (or equivalent).	7 - 10 Days
9	Gavi disburses funds UNICEF SD and procurement begins	Once all approvals have been secured, Gavi and UNICEF initiate the order for equipment and associated services.	2 – 3 Days
10	Manufacturing and delivery		1 – 3 months
11	Arrival at port of entry	<ul style="list-style-type: none"> • Please note that the Applicant is responsible for facilitating customs clearance and any associated waivers. 	2 – 5 Days
12	Deployment and installation	<ul style="list-style-type: none"> • The applicant is responsible for coordinating with service providers on the delivery, installation and commissioning of procured equipment. 	1 – 3 Weeks

3.2 SUBMISSION REQUIREMENTS

The following documents must be provided for an application to be considered complete. Incomplete applications cannot be reviewed, so applicants are encouraged to review the requirements here and in the main application document closely.





#	Element	Notes
1	COVAX CCE Application Document (completed and signed, Link)	The application document provides a narrative overview of the Applicant's context, the COVID-19 delivery plan, and the associated CCE request. It also includes guidance on how to complete the budget template and reporting requirements.
2	Signature sheet for the Minister of Health or their delegates	
3	Minutes of the Coordination Forum meeting (ICC, HSCC or equivalent) endorsing the proposal	
4	Updated cold chain inventory (CCI, Link)	<ul style="list-style-type: none">• CCI is only required for targeted levels at or above CCE is being requesting through COVAX CCE support.• Applicants are requested to use the WHO CCI template. Gavi-eligible applicants that have an ongoing investment through the Cold Chain Equipment Optimization Platform (CCEOP) may use the format they submit their updates in.• CCI must have been updated within preceding 12 months of application to be considered valid.
5	Completed WHO CCE Sizing Tool. (Link)	<ul style="list-style-type: none">• This tool helps to establish the excess capacity needs associated with COVID-19 immunization.• The tool can be found on the WHO website. Please ensure calculations align with the assumptions provided in the Technical Annex (Section 4.0).
6	Operational Deployment Plan (ODP, link)	The operational deployment plan (ODP) summarizes the readiness and accessibility of target sites. It is also used by the CCE service provider to plan deployment. This template can be found in the application pack.
7	Budget Template (link)	Guidance for completing the budget template can be found within the document itself, and in the main application document.
8	Proof of exemptions for CCE tariff exemptions waiver and customs clearance	The Applicant is responsible for ensuring that the procured equipment can enter clear customs without fees or delay. Any delays in clearance and incurred demurrage costs will be the sole responsibility of the Applicant.
9	Proof of Vaccine Request (VR) submission	Applicants must have submitted a completed Vaccine Request form to have their application reviewed by the IRC. Pre-review can occur without a VR, but Applicants are encouraged to ensure all necessary information is provided.





4.0 TECHNICAL ANNEX

4.1 ASSUMPTIONS FOR NEEDS CALCULATIONS

Assumption	Value
Vaccine temperature storage range	2-8° C
Number of doses per person in schedule	2
Vaccine dose volume	0.5ml
Volume per dose (secondary packaging)	4.6 cm ³
Closed-vial wastage rate	3%
Maximum peak volume at national store (expressed as % of total population)	5% ⁷
See calculation note below for details	

Calculation Note for peak volume: Peak volume represents the maximum volume of COVID-19 vaccine doses that can be stored at the national level, expressed as a % of the population that can be immunized. To calculate, multiply the total population by the maximum peak volume, and then apply the other assumptions (wastage, dosing scheduling, volume assumptions) above. This further assumes routine vaccines are at peak supply levels as well.

⁷ In practice, this assumes doses sufficient to immunize the 20% population are divided into a minimum of 4 shipments, and that no single shipment exceeds the 5% volume. Applicants may modify peak volume downwards (3%, 4%) if they provide rationale.

