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The Market Shaping Goal

Shape markets for vaccines and other immunisation products to achieve moderate or high levels of healthy markets dynamics.

Supply and Procurement Roadmap

Ice-lined (ILR) & Solar Direct Drive (SDD) Refrigerators/ Freezers

Public Summary

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The Cold Chain Equipment (CCE) Section of the 2016-2020 Supply & Procurement Strategy introduces the Alliance’s foray into market shaping for cold chain equipment. Gavi established the Cold Chain Equipment Optimization Platform (CCEOP) in June 2015 as a strategic and targeted approach to address the challenges of improving the vaccine cold chain with higher-performing CCE as a critical component of the immunization supply chain system. An improved immunization supply chain strengthens the immunization program and supports the Alliance’s coverage and equity goals. The CCEOP’s \$50 million co-investment funding scheme was made available for one year initially, and subsequently increased five-fold to \$250 million over five years to match the anticipated demand. CCEOP implementation commenced in early 2016 with the first country applications recommended for approval in March 2016 and November 2016.

The hallmark characteristics of the CCEOP is the requirement for all CCE to be “platform-eligible” and for product procurement, to be accompanied by delivery, installation and commissioning - a “service bundle”. Platform-eligibility entails a higher-level of technology and performance standards than current WHO prequalification standards that is derived from the WHO Target Product Profiles (TPP). Future TPPs span two year cycles and provide guidance to manufacturers. The service bundle helps to ensure that equipment is installed properly and can be maintained properly.

Two CCE product categories, Ice-lined Refrigerators/ Freezers (ILR) and Solar Direct Drive (SDD) refrigerators/ freezers, represent critical nodes in the cold chain and account for between 80-90% of all annual CCE expenditures according to the 2014 UNICEF Supply Division procurement data. Therefore, Gavi focuses its initial market shaping strategies on these two products.

The CCE section of the Alliance Supply & Procurement Strategy leverages extensive market analyses conducted as part of the design and establishment of the CCEOP. The figure below summarizes CCE market failures to address with Gavi’s market shaping strategies. Augmenting demand-side levers in the CCEOP, the Alliance Strategy applies an underlying theory of change to positively influence the CCE market dynamics towards optimal total cost of ownership (TCO)¹.

Summary of “Unhealthy” Market Conditions

Demand Side Factors	Supply Side Factors
<ul style="list-style-type: none"> Unpredictable demand due to weak forecasting and demand volatility due to irregular purchases Fragmented procurement, partly driven by fragmented funding Limited optimal technologies selected by countries, partly due to lack of knowledge and variable planning Unreliable CCE maintenance, driven by lack of planning, capabilities and funding 	<ul style="list-style-type: none"> Limited incentives to develop and commercialize new technologies for target market, mainly driven by lack of certainty on demand Lack of feedback on device field performance to guide technology improvements, resulting in low performance of equipment once at use site Higher costs and production complexity, due to volatile demand and limited scale Variable prices across countries, with limited transparency

¹TCO refers to total cost of ownership, i.e. costs over the lifetime of the device including capital expenses (CAPEX) referring to prices according to the PQS catalogue and UNICEF SD plus operating expenses (OPEX) including maintenance and energy costs. The lower operating costs largely off-set higher upfront costs.

Market overview

In the next five years, CCE demand is expected to increase up to five-fold with the implementation of the CCEOP. Between 2010-2014, total procurement through UNICEF SD of vaccine refrigerators represented just 12% of potential CCE needs at lowest distribution levels in Gavi-eligible countries. In the next five years, demand is forecasted to align to CCE need, with annualized quantities of around 16,000 to 20,000 units of ILRs and SDDs combined.

Demand for Vaccine Refrigerators in Platform Eligible Countries

ILRs	Timeframe	# of Units, '000s	Annualized # Units, '000s
Historical demand – UNICEF Procurement ¹	5 years: 2010 – 2014	8.7	1.7
Estimated Demand – Forecast Analysis ²	5 years: 2016 – 2020	44.8 – 51.9	9.0 – 10.4
Short-term Demand – Country Questionnaire ³	3 years: 2016 – 2018	11.8	9.4 ⁴

SDDs	Timeframe	# of Units, '000s	Annualized # Units, '000s
Historical demand – UNICEF Procurement ¹	5 years: 2010 – 2014	10.2	2.0
Estimated Demand – Forecast Analysis ²	5 years: 2016 – 2020	35.6 – 47.5	7.1 – 9.5
Short-term Demand – Country Questionnaire ³	3 years: 2016 – 2018	22.4	11.2 ⁴

1. Based on UNICEF CCE Demand Forecast for Gavi-support eligible countries, May 2015; includes aggregated demand of SDD, absorption, and battery powered equipment. 2. Based on Analysis for Gavi CCE Optimization Platform, June 2015. 3. Based on Gavi Country Survey, October 2015; responses received from 23 Platform eligible countries. 4. Based on reported expected demand for 2016 & 2017 (not based on average of 3-year demand)

CCE demand can be segmented by CCE vaccine storage volume. ILRs and SDDs are offered in five size segments according to vaccine storage capacity: <30 Litres (l), 30l-60l, 60l-90l, 90l – 120l, and ≥120l. Smaller size volume segments, or <30l and 30l-60l, are forecasted to account for the larger share of CCE demand in the next five years according to stated preferences. Particularly for SDDs, this is consistent with accepted trends to expand the reach of immunization programs to more remote, and likely smaller population clusters in target countries.

Distribution of Demand by CCE Size Segments

ILRs				
UNICEF size segments	Historical Demand ¹	Long Term Forecast ¹	Gavi size segment	Long-Term Forecast ²
<30l	54%	23%	<50l	62%
30l – 60l		31%		
60l – 90l	39%		50-100l	27%
90l – 120l	6%	6%	>100	11%
>120l		0%		
Total	100%	100%	Total	100%

SDDs				
UNICEF size segments	Historical Demand ¹	Long Term Forecast ¹	Gavi size segment	Long-Term Forecast ²
<30l	68%	19%	<50l	62%
30l – 60l		49%		
60l – 90l	7%		50-100l	30%
90l – 120l	25%	25%	>100	8%
>120l		0%		
Total	100%	100%	Total	100%

1. Based on UNICEF CCE Demand Forecast for Gavi-support eligible countries, May 2015. 2. Based on Analysis for Gavi CCE Optimization Platform, June 2015.

Demand is expected to shift to CCE meeting higher-performance quality standards, or future TPPs to move the supply market toward higher-performing CCE. The figure below is a summary of these expected product characteristics of future CCE demand. The CCEOP relies on WHO TPPs to inform platform-eligibility and funding decisions for ILR and SDD products. Two-year intervals are provided to manufacturers to comply with defined TPPs and maintain existing PQS status. Since the publication of the CCEOP TPP requirements, several CCE product categories have seen unprecedented reductions in the lead times between definition of WHO TPPs and suppliers bringing products to market, most notably with more than two SDD manufacturers incorporating TPP-2017 and TPP-2019 into 2016 product lines i.e., SMS alerts enabled for remote temperature monitoring, energy harvesting capabilities, well ahead of the timelines set for these requirements.

Product Profiles Targeted by CCE Optimization Platform Grants

TPPs for 2015 inclusion to PQS

- Net vaccine storage capacity definition
- Primary container
- Water-pack freezing compartment
- No bulb and capillary tube thermostats
- Humidity control
- Design of vaccine storage compartment
- Low ambient temperature operation
- Refrigerant specifications
- Extended product life of ancillary battery (if included)
- Adequate input voltage
- Performance degradation over time
- service provision (zero-repair for 10 y.)
- User and maintenance instruction
- Shipping and storage condition
- **Extended ambient temperature range**
- **User-independent freeze protection**
- **Type 1 temperature monitor (e.g., temperature logger)**
- **Technical maintenance/installation kit**
- **Operation & maintenance sticker**
- **Spare parts inclusion**

TPPs for 2017 inclusion to PQS

- Energy harvesting
- Type 2 temperature monitor (fully integrated)
- Vaccine storage capacity
- Optional storage container for vial
- Separate compartment to hold non-vaccine (e.g., oxytocin)
- Well-positioned control panel (not floor-level)
- ...
- ...

TPPs for 2019 inclusion to PQS

- Extended autonomy
- Type 3 temperature monitor (enabling sms alerts)
- Design for simplified maintenance
- Bar code sticker
- ...
- ...

Share with WHO learning of field deployment for potential inclusion as TPP

Sub-set of TPPs accelerated by the platform for existing products in 2016

CCE platform

Eight ILR and SDD suppliers are active in the CCE market with PQ-ed products considered for UNICEF procurement. The business size and focus of the eight suppliers vary significantly, as well as their products' platform-eligibility status, which in turn will affect Gavi's market shaping approach and influence.

Suppliers also vary in their readiness and capacity in implementing the service bundle for ILR & SDD products in CCEOP countries. UNICEF's request for information (RFI) indicated that local service providers in Gavi countries cater to a disproportionately small number of CCE manufacturers.

The cost of delivering & commissioning CCE at use points is also significant, and influences final TCO. Service markets are segmented into 4 categories, or archetypes, based on travel time and customs clearance costs. This framework is used to price service bundles and can result in 20%-60% additions to SDD product prices, and 20%-110% additions to ILR product prices. This environment makes it necessary for Gavi to engage in short and longer term strategies to mitigate the risks associated with the service bundle i.e., sole source markets and service bundle inflation, while working towards a cost-effective maintenance market in the long term.

Compared to the number of platform-eligible ILR and SDD products in the market or in pipeline in each of the size segments, there is a paucity of data on field performance of CCE. Gavi's market shaping influence is needed to promote transparent flow of information for better monitoring of post-delivery, on-site product performance and user-experiences. This can prevent product failure and ensure continuous technology improvements.

Supply and Procurement Objectives and Target Outcomes

The CCE supply and procurement objectives were analysed and weighted according to timeframe, to potential market shaping impact, and to Gavi's potential capacity to influence the market. The desired goal is to incentivize a market where CCE is made available at an optimal total cost of ownership (TCO). The long term goal is to create a healthy CCE market where high performing equipment and services are widely available from a solid supplier base at sustainable prices.

1st Strategic Objective: Stimulate supply to meet demand

Based on the current 18 month demand forecast for Gavi countries, CCE demand is expected to increase up to five-fold with the implementation of the CCEOP. Gavi aims to ensure that sufficient supply of high-performing CCE is available to meet total Gavi demand through two market shaping target outcomes:

- At least 2 suppliers of ILRs and of SDDs in each of the 5 size segments reach platform-eligibility by 2019 for TPP-2017, and by 2021 for TTP-2019.
- Market access barriers created by the service bundle requirement are addressed in the short term through increased information and guidance to suppliers on in-country logistics and service landscape.

2nd Strategic Objective: Achieve fair and sustainable prices for both devices and commissioning service bundles

Costs must be reduced long-term to ensure optimal total cost of ownership and country sustainability, especially as countries transition from Gavi support. Gavi should seek competitive prices for high-performing ILR and SDD products that meet platform-eligibility and can achieve economies of scale through pooled volume procurements, as well as allocate supply to manufacturers offering the best value for both product and services that are tailored to local service delivery landscapes. This results in four market shaping target outcomes:

- For ILRs: Targeted price reductions in weighted average prices achieved.
- For SDDs: Targeted price reductions in weighted average prices achieved.
- For service bundle: Cost of service bundle further benchmarked and controlled.
- Cost-effective models for local service provision and maintenance incentivized.

3rd Strategic Objective: Continuously innovate high performing, optimal TCO products

High-performing CCE should reach platform-eligibility with time bound lead times and have the following two characteristics:

- Manufacturers adopt TPP-2017 and TPP-2019 by 2019 and 2021 respectively.
- Product improvements with optimal TCO achieved as a result of functional feedback loop on product field performance findings.

4th Strategic Objective: Information - a cross-cutting objective and strategic enabler for all CCE

Specific to ILR and SDD products are two targeted outcomes:

- Suppliers offer locally customized service bundles in response to information on product and service market demand.
- CCE prices lowered within CCE size segments through CCE price transparency.

Supporting Stakeholder Action Plan

A concerted action plan ensures the coordination between Gavi Alliance stakeholders, designed to lead to the achievement of the above supply and procurement objectives. The Action Plan is significantly informed by market analysis and feedback from a stakeholders' consultation to define desired market shaping outcomes. The interventions for each Strategic Objective are as follows:

1. Strategic Objective: Stimulate supply to meet demand

- Transparent communication with industry around CCEOP application rounds and longer term forecasts.
- Case study on service bundle implementation to obtain lessons learned on contracting terms & conditions, and obstacles to local provider capacity development.
- Evaluation on service bundle implementation, and complemented by case study, to inform models & standards for service delivery solutions.

2. Strategic Objective: Achieve fair and sustainable prices for both devices and commissioning service bundles

- Economies of scale in production and volume based price reductions achieved through demand volume aggregated from country orders that represent inflection points for economies of scale.
- Joint industry consultations with other major CCE buyers explored.
- Cost analysis conducted for SDD cost/price drivers to understand baseline/target cost of bringing technology to market that meets minimum & desired platform-eligibility criteria, as well as inflection points to achieve economies of scale in production.
- Design-to-value analysis conducted to understand product pricing relative to target costs (above) and programmatic and financial value of exceeding minimum performance requirements.
- Cost and value analyses leveraged for evidence-based product procurement.
- Combined procurement of "best" product & "optimally priced" service bundle through evidence-based, two-step process.
- ILR & SDD service landscape analysis conducted & market strategy developed to inform strategic interventions.

3. Strategic Objective: Continuously innovate high performing, optimal TCO products

- Accelerate definition of 2017/2019 TPPs for all products, through strong consultative process involving key partners.
- Support suppliers to (re)design their products to optimize/ reduce TCO of their products, and strengthen the lifespan of products, leveraging existing/planned partner initiatives in this area.
- Incorporate "expressed preferences" in procurement tools for products meeting future TPPs and WHO PQS.
- Strengthen existing feedback loops on field performance established by WHO & UNICEF with countries and suppliers; improve data systems (collection/mining), and proactive coordination mechanisms.

4. Strategic Objective: Information

- Information sharing with suppliers and stakeholders on in-country supply chain and logistics landscape, local providers of logistics and technical services, especially in target countries.
- Expand efforts to increase ILR & SDD price transparency, among clients and suppliers.