

SUBJECT: COUNTRY PROGRAMMES: COLD CHAIN EQUIPMENT OPTIMISATION PLATFORM (CCEOP)

Agenda item: 07b

Category: For Decision

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Section A: Overview

1. Executive Summary

- 1.1 In June 2015 the Board approved the establishment of the Cold Chain Equipment Optimisation Platform (CCEOP) to strengthen country cold chain systems and to advance the Alliance’s Supply Chain Strategy. Improvements in the cold chain are a vital building block towards delivering vaccines more equitably and to increasing vaccine coverage, while shifting towards more reliable, energy efficient, environmentally “green”, and sustainable equipment. Improvements in cold chain are also among the most effective interventions the Alliance can make to mitigate risks to its vaccine investments of over US\$ 1 billion per year. In addition, the CCEOP has contributed to promising market shaping developments.
- 1.2 The 2015 Board decision noted that an amount of US\$ 50 million would be allocated to launch the CCEOP and fund the initial applications in 2016-2017 and that this would be reassessed and potentially increased based on initial applications. Since the CCEOP was launched, 15 countries¹ have had proposals approved, recommended for approval by the Independent Review Committee (IRC) or are under review via the Country Engagement Process (CEF), totaling requests for US\$147 million in CCEOP support² from Gavi over five years. As of end November, 12 countries have been approved or recommended for approval. The total CCEOP support requested by these 12 countries in 2017 is up to a maximum of US\$ 49.3 million, and US\$ 133.7 million over five years. Eight of these country proposals were recommended in the fourth quarter of 2016, reflecting 68% of the requested support and the accelerating demand from countries. Three other proposals are under review via CEF with an estimated maximum CCEOP request of US\$ 6.1 million in 2017, and a total from the CCEOP of US\$ 12.9 million over five years. The Board is therefore being asked to decide whether to allocate additional funding to the Cold

¹ Haiti, DRC, Uganda, Cameroon, Kenya, Niger, Madagascar, Pakistan, South Sudan, Uzbekistan, Guinea, Liberia, Malawi, Togo, Sierra Leone

² The total value of the proposed cold chain investments is US\$ 213 million with countries’ joint investments of US\$ 67 million.

Chain Equipment Optimisation Platform to meet country demand and maintain the momentum in implementing the platform.

2. PPC discussion

2.1 The PPC in October 2016 discussed the possibility of allocating additional funding to the CCEOP. They expressed concerns with the process in that the Secretariat had read the 2015 Board decision as allowing it to add additional resources whereas the PPC would have expected being involved in making a recommendation on allocating additional funding. The PPC was also concerned about the fact that proposals have already been recommended (although not approved) worth more over five years than the initial allocation of US\$ 50 million. The PPC noted the difficulty of deciding on allocating further funds without a more detailed review of lessons learned from the early implementation.

2.2 However, after discussion and given the increased demand from countries, and recognising the original Board decision was based upon estimates of the platform requiring US\$ 50-60 million per year, the PPC recommended that in the period up to the Board meeting in June 2017, total multi-year commitments of grants for CCEOP should not exceed US\$ 250 million. The Secretariat was requested to establish a mechanism to allocate the amount available to meet the country demand for CCEOP funding in an equitable manner. The PPC also emphasised the importance of the PPC and Board receiving a full review of progress and lessons learned in May and June 2017 and further elaborated the content it anticipated to be included in this review. Based on that review, the Secretariat will present to the PPC and Board future options for the implementation of the CCEOP.

3. Recommendation

3.1 The Gavi Alliance Programme and Policy Committee recommended to the Gavi Alliance Board that it:

a) **Note** that:

i. In June 2015 it

a) **Approved** the creation of an innovative mechanism to strengthen country cold chain systems and advance the Alliance's Supply Chain Strategy and, ultimately, its coverage and equity goals (the "CCE platform"), the design of which is set out in Section 3 of Doc 15 to the PPC and includes a funding model tiered by country GNI level;

b) **Noted** that an amount of US\$ 50 million (to be reassessed and potentially increased based on initial applications to the CCE platform) will be allocated from the resources pledged for 2016-2020 (which envisage funding for strategic initiatives to realise Gavi's new strategy) to launch the implementation of the CCE platform and fund the initial applications in 2016-2017 and **requested** the Secretariat to report back to the PPC and to the Board in 2017 on the implementation of the CCE platform;

- ii. At that time, the Secretariat noted that the proposed initial investment of US\$ 50 million by Gavi is to launch the platform. The total estimated funding for the platform required for Gavi countries, excluding India, was estimated to be between US\$ 240 million and US\$ 310 million for five years;
 - iii. Following the approval of the CCE platform and its subsequent launch, demand for support under the platform has exceeded initial expectations foreseen in the 2015 CCE platform Board decision;
 - iv. Additional funding is now required for 20 countries that have applied in 2016 for an amount of approximately US\$ 150 million; and
 - v. Additional applications are expected to be received before the first Board meeting in June 2017.
- b) **Decide** that:
- i. Consistent with the 2015 Board decision, a review of progress and lessons learned of the CCE platform should be presented to the PPC at its meeting in May 2017 and the Board in June 2017, including its links with HSIS, anticipated impact on the market and the quality of the overall immunisation systems, country case studies, an updated demand forecast, and taking into account feedback provided by the IRC on applications reviewed;
 - ii. Based on that review, the Secretariat will present to the PPC and Board future options for the implementation of the CCEOP; and
 - iii. In the period up to the Board meeting in June 2017, the total multi-year commitments of grants for CCEOP should not exceed US\$ 250 million, requesting the Secretariat to develop strategies for equitable allocation of the funds available.

Section B: Content

4. Cold Chain Equipment CCEOP

- 4.1 Poorly functioning cold chain equipment puts Alliance investments in immunisation at risk, undermining vaccine introductions and efforts to reach under-immunised children as well as putting vaccine stocks at risk of damage. Conversely, investing in dependable and high-performing cold chain equipment is key to ensuring reliable vaccine storage; vaccine safety and effectiveness; and sustainable, equitable immunisation coverage. To address this, the Board approved the CCEOP in June 2015 through which Gavi and countries jointly invest³ to upgrade cold chain equipment to high-

³ Countries jointly invest 20 or 50% of resources needed for a request to the CCEOP, through national funds, partner funds, or HSS funds given that such HSS funds could have been spent on less optimal equipment in the absence of the CCEOP. The degree to which countries need to contribute varies, based on the country's joint investment grouping at the time of the review of the application: initial self-financing countries qualify for up to 80% joint investment from the platform; while preparatory transition countries for up to 50% joint investment from the platform. Lastly, the

performing and lower maintenance technologies. By facilitating reliable demand forecasts for cold chain equipment and securing predictable funding, similar to its approach for vaccine markets, the CCEOP also gives manufacturers confidence to invest in new technology and production, thereby allowing the Alliance to shape relevant markets.

Demand for Support

- 4.2 Following the approval of the CCEOP the March 2016 Independent Review Committee (IRC) recommended the first CCEOP proposal (**Haiti**) for approval, worth US\$ 5.9 million over five years. The first equipment, along with bundled services by the manufacturer (including in-country distribution, installation, training of technicians and healthworkers on maintenance) is projected to arrive in Haiti in early 2017.
- 4.3 **Four countries** submitted CCEOP proposals to the **June 2016 IRC** - Chad, Democratic Republic of Congo (DRC), Ethiopia (re-submission) and Uganda. The IRC recommended approval of the proposals from DRC (US\$ 13.4 million) and Uganda (US\$ 8.6 million) and required Chad and Ethiopia to resubmit.
- (a) **DRC** will expand its cold chain coverage and will address geographic inequity with additional cold chain equipment. DRC's 2013 baseline of 25% of health facilities with appropriate cold chain equipment has increased to 51% through Gavi's HSS2 support, and will achieve 75% of facilities with CCEOP support recommended in June.
 - (b) **Uganda's** request will improve last mile equitable access to immunisation services. It complements the country's ongoing and new HSS proposals and prioritises districts with low immunisation access and hard-to-reach areas.
- 4.4 **Guinea** and **Liberia** have been recommended for approval for CCEOP support by in-country IRCs in August and October under the Country Engagement Framework (see agenda item 03b of the 25-26 October 2016 PPC) for US\$ 14.3 million. The support will complement the countries' Ebola recovery plans and contribute to the two countries reinforcing their overall system following the epidemics.
- 4.5 **Eight further proposals** have been recommended for approval by the November 2016 IRC, worth US\$ 91.5 million, while three further countries are requesting CCEOP under the CEF, worth approximately US\$ 12.9 million.

2016 as a learning year for the Platform

- 4.6 The first three rounds of proposals, and particularly the first approved proposal for Haiti, have helped the Secretariat and the Alliance to further

accelerated transition countries, with at least two full years from date of review by IRC prior to becoming fully self-financing, qualify for up to 50% joint investment from the platform.

develop and tailor processes, and strengthen integration with health system and immunisation strengthening (HSIS) support.

- (a) The June 2016 IRC observed that, compared with the March 2016 proposals, **countries increasingly identified cold chain bottlenecks to coverage and equity**, were synergistic with other Gavi supply chain strategy fundamentals, made clearer justifications for Platform requests and presented better developed supporting documents.
- (b) The IRC also made recommendations on how to **further improve future proposals**, including through developing even stronger synergies between Platform requests and ongoing support from Gavi (especially HSIS) and other partners, better demonstrating how Platform requests will contribute to achieving equitable immunisation coverage and through ensuring complementarity with other ongoing and planned supply chain activities (e.g. management and system design).
- (c) Building upon the IRC feedback, as well as Alliance partner and country input, **linkages were strengthened between the CCEOP, HSIS and other forms of Alliance support. Revised guidelines** were distributed for the September 2016 review round which further the requirement that countries, for example, prioritise CCE for facilities that will considerably contribute to equitable immunisation coverage (such as in remote and hard to reach communities). Proposals are required to clearly articulate how the CCEOP support relates to other HSIS investments, and vice versa, particularly relative to supply chain fundamentals (e.g. data on stock management, strengthening human resources).
- (d) The first two rounds of proposals also illustrated other opportunities to refine the programme design. The Platform now provides an **initial support phase** to address the most urgent CCE needs for the first one to two years (e.g. where there are the highest risks to vaccine stocks or greatest bottlenecks to coverage and equity). This allows the country additional time to further elaborate and fine tune its long term CCE needs as part of a **scale-up support phase**, in the context of wider supply chain improvements, re-design and health system strengthening progress. This two phased approach will also allow the Secretariat to implement a strategy for equitable allocation across countries.

Market Shaping

- 4.7 The CCEOP is designed to achieve more favourable market conditions for cold chain equipment which, in turn, will encourage innovation and bring down costs in the long term. The Alliance has been engaging closely with manufacturers to shape the market including by providing **greater visibility of demand and predictability of supply** (e.g. through a consultation convened by UNICEF Supply Division with all WHO pre-qualified ice-lined

refrigerator (ILR) and solar direct drive (SDD) manufacturers)) and establishing a market-shaping roadmap as done for vaccines. The results of these efforts to which the CCEOP has contributed in 2016 include:

- (a) There has been an acceleration of products that meet not only the **WHO Pre-Qualification Specifications** for Cold Chain Equipment but also the more stringent CCEOP eligibility criteria. 15 devices have been pre-qualified since January 2016, increasing the quality and variety of available CCE.
- (b) Two manufacturers announcing a 10-year warranty for SDD refrigerators and one announcing the first ever five-year warranty for their electric ILR.
- (c) One manufacturer announced the first ever integrated temperature data logger that will last for the life cycle of a refrigerator (i.e. 10 years) and is offering maintenance for the same time period.
- (d) The first ever Grade A⁴ cold boxes, which reduce vaccine exposure to freezing (which can impact vaccine potency) during both transport and storage will be WHO pre-qualified by the end of 2016/beginning of 2017.
- (e) A number of manufacturers are working on further CCE innovations including multiple prototypes of new vaccine carriers.
- (f) Manufacturers are working with local service providers to establish platform service bundles (including in-country distribution, local training on maintenance, and installation) which will be part of the support provided to countries approved under the CCEOP.
- (g) It is as yet too early to determine future procurement price shifts, but the financial forecasts in the June 2015 Board decision assumed a decrease over time of at least 10-20% on 2015 cold chain equipment costs.

Progress review in 2017

4.8 While 2016 has allowed the Alliance to further tailor processes around the CCEOP and to ensure a stronger engagement with CCE manufacturers, no CCE has yet been delivered. As mentioned above, the first equipment is projected to arrive in Haiti in early 2017 and subsequently in DRC and Uganda by Q3 2017. Given these timelines the Secretariat will, as requested by the PPC, submit to the PPC and Board at their respective meetings in May and June 2017 an initial report that includes the following:

⁴ In order for devices to qualify for the CCEOP, they must be Performance Quality Safety (PQS) approved by WHO. PQS defines three grades of freeze protection: A (user-independent), B (requiring one user intervention to prevent freezing), C (requiring more than one user intervention to prevent freezing). The CCEOP subsidises equipment that is Grade A only.

- (a) Analysis of initial proposals, progress and lessons learned of the CCEOP (e.g. allocation of country demand, purpose of applications, types of equipment, linkages to HSIS, contributions to coverage and equity)
 - (b) IRC feedback on CCEOP applications
 - (c) Options for further strengthening CCEOP design
 - (d) Updated demand and financial forecasts
 - (e) CCEOP impact on market shaping and the quality of the overall immunisation systems, and
 - (f) DRC case study (for additional information see Appendix D to Doc 07a).
- 4.9 The Secretariat will also, based on this report, present to the PPC and Board future options for the implementation of the CCEOP including how to ensure an equitable allocation of CCEOP funding across countries going forward (noting that the original financial projections presented to the Board in June 2015 assumed that Gavi would aim to support deployment and replacement of CCE in all facilities where it was required during the current and subsequent Gavi strategic periods).

Financial Forecast Update and Programme Funding Envelope

- 4.10 In June 2015, the Board approved the CCEOP and noted that an initial amount of US\$ 50 million would be allocated from the resources pledged for 2016-2020 to fund initial applications in 2016-2017 to operationalise the Platform. This amount was intended to be reassessed and potentially increased based on initial applications to the CCEOP.
- 4.11 The Secretariat has now extended its financial forecast for the CCEOP from 2020 to 2025 in line with Gavi's overall financial forecast update. The updated forecast anticipates approximately US\$ 50 million a year being spent on the CCEOP from 2017 to 2025. This is in line with initial projections presented to the Board in June 2015 which indicated that the platform would require US\$ 50-60 million per year for equipment purchases to support all 55 Gavi-eligible and graduating countries (excluding India).
- 4.12 This will enable the Platform to scale-up and meet country demand, contributing to the achievement of Gavi's strategic goals and helping to mitigate risks to the Alliance's vaccine investments. Depending on future demand, changes in the mix and pricing of supported products, and progress with further scaling up the Platform, the Secretariat may return to the PPC and Audit & Finance Committee and Board in 2018 with an updated financial request.
- 4.13 The Secretariat is also proposing the creation of a specific envelope for the CCEOP, in order to provide an efficient process for allotting funding under

the CCEOP to individual programmes. This proposal is reflected in the paper "Revision of the Programme Funding Policy" for Board approval.

- 4.14 The AFC has confirmed that funding is available for the proposed envelope, from which the Secretariat would allot funding to CCEOP programmes for an initial amount of US\$ 250 million. Of this, US\$ 180 million is currently estimated to be spent in 2016-2020 (including the initial US\$ 50 million allocated in June 2015) and US\$ 70 million in 2021-2025.

Section C: Risk implication and mitigation and Financial implications

5. Potential risks related to the CCEOP

- 5.1 **Insufficient investment and scale-up** of the CCEOP may pose a risk to the achievement of the Alliance's core strategic goals (**coverage & equity**) and exacerbate one of its key risks (vaccine **wastage**, as discussed at the Board retreat in April 2016.) Postponing scale up will also constrain the ability of the CCEOP to meet **country demand and could lead countries to deprioritise efforts to optimise their equipment, undermining the credibility of the Alliance's commitment to improve supply chains**. Improvements in the cold chain are a vital building block towards delivering vaccines more equitably and to increasing vaccine coverage. The CCEOP also plays a key role in ensuring vaccine potency and preventing vaccine wastage and allows for market shaping collaborations that lead to innovations. Sufficient and strategically designed investments through the CCEOP, complemented by investments in other fundamentals of the supply chain through HSIS support, are key mitigation strategies. The approach to phased support, as described above, will also help ensure that countries prioritise CCEOP support to first address urgent needs that have more impact on equitable immunisation coverage.
- 5.2 Countries could request **CCEOP support without sufficient integration with or leveraging of wider supply chain and HSIS investments**. This would lead to equipment being installed without the associated fundamentals and systems in place for the equipment to contribute to sustainably improving coverage and equity. To mitigate this, the CCEOP guidelines were extensively revised in 2016 following review of the initial rounds in 2016. Proposals must explicitly describe linkages for the CCEOP with other supply chain and HSIS investments, an element which is a critical area of scrutiny by the IRC. These linkages will continue to be improved based upon country, partner and IRC input in future rounds.
- 5.3 There is a risk that countries request **more equipment than is essential or than they can absorb and manage**. Mitigating this risk, the IRC considers equipment quantities, types, maintenance approach, and history of the equipment in the country. Based on this information, the IRC has already recommended several countries resubmit applications. Countries also develop a detailed operational deployment plan in close collaboration with UNICEF. Actual procurement of CCE is approved on an annual basis according to performance and need.

Section D: Implications

Implications of CCEOP remain largely consistent with those presented to the June 2015 Board. In addition, the Secretariat wishes to further highlight the information below.

6. Impact on countries

6.1 The CCEOP will support countries to revamp and extend their cold chains improving the reliability and accessibility of their immunisation services. This will engender a better management of both current and future vaccine investments by safeguarding the potency of vaccines during storage and transport. Through CCEOP proposals, countries must identify funds for their joint investment as well as make clear investments in cold chain management and maintenance. Collaboration with early countries requesting CCEOP support, particularly DRC, will be critical to informing the progress and options for further scale up of the platform as part of the supply chain strategic focus area.

7. Impact on Gavi stakeholders

7.1 The successful implementation and management of the CCEOP requires collaborative efforts by Alliance partners to assist countries in improving their supply chain system in a systematic and country by country basis.

7.2 The WHO efforts on continuing to set standards for CCE and pre-qualify equipment will remain important. UNICEF SD will play a critical role as the procurement agent for the platform, liaising with manufacturers to ensure the full implementation of the service bundle. In addition, UNICEF will also work with countries to develop operational plans.

8. Impact on Secretariat

8.1 The Secretariat will work with Alliance partners to ensure implementation of PPC recommendations and Board decisions, including around the progress review in 2017. It will build upon the breadth of expertise in the Secretariat, including Finance, Monitoring & Evaluation and others.

8.2 The Secretariat will continue to integrate the CCEOP into Gavi funding mechanisms and reporting (e.g. performance frameworks), further reinforcing the linkages to HSIS and the Country Engagement Framework.

8.3 The Senior Country Manager, Regional Heads and Country Teams, will engage in-country stakeholders during the development, implementation and monitoring of the CCEOP.

9. Legal and governance implications

9.1 The Secretariat and UNICEF SD have prepared an annex to the existing procurement Memorandum of Understanding between UNICEF and Gavi governing the procurement processes for the CCEOP.

10. Gender implications

- 10.1 There are not anticipated to be any gender implications, however the CCEOP investments will prioritise equipment for areas that will contribute to address equity barriers including those related to gender.