

**SUBJECT: STRATEGY, PROGRAMMES AND PARTNERSHIPS:
PROGRESS, RISKS & CHALLENGES**

Agenda item: 03

Category: For Decision

Section A: Executive Summary

This report provides an update on progress in implementing the Gavi 4.0 strategy and associated risks¹. The final report on progress on the achievement of Gavi 4.0 strategic goals will be presented at the next Board meeting, after the WUENIC (WHO and UNICEF Estimates of National Immunization Coverage) estimates become available. This paper focuses mostly on Gavi's strategic performance and risks in light of the pandemic, as well as on providing an update on the operationalisation of the zero-dose agenda as part of Gavi 5.0.

While COVID-19 sharply impacted immunisation services, there were clear signs of restoration in the second half of 2020. Vaccine introductions have slowly started to resume. Notably, country performance on co-financing remains strong despite the fiscal constraints caused by the pandemic.

However, the risk of new disruption during 2021 remains real. Countries are focused on mitigating the impact of second and third waves of infection and the spread of new variants of SARS-CoV-2, while also shifting attention to the delivery of COVID-19 vaccines. The pandemic will also continue to affect the macro-economic and fiscal stability of Gavi-supported countries.

Maintaining, restoring and building back more resilient, equitable and integrated routine immunisation systems has become the main focus of the Alliance's broader support to countries, besides laying the foundation to reach more zero-dose children and missed communities during Gavi 5.0.

To reflect the increase of Gavi's overall risk profile in the context of Gavi 5.0, the COVID-19 pandemic and the COVAX Facility, **the Board is requested to approve the updated Risk Appetite Statement.**

The **Programme and Policy Committee (PPC) also recommended an adjustment to the structure of the Partners' Engagement Framework (PEF)** at global and regional level and asked the Secretariat to address a number of open questions before requesting Board approval. Working closely with the Partnerships' Team the Secretariat has started to engage in extensive consultations with countries, partners and civil society organisations (CSOs) and will revert to the PPC and Board in due course, as appropriate.

¹ Associated risks refer to the top risks described in the 2020 Risk & Assurance Report (see <https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2020>). A mid-year update on the top risks to the AFC is included in Appendix 6.

Section B: Content

1. **Gavi 4.0 Strategy: Progress, Challenges, Risks and the impact of COVID-19**
 - 1.1 **2020 was the last year of the Gavi 4.0 strategic period and turned out to be the most turbulent in the history of the Alliance.** The COVID-19 pandemic has impacted Gavi’s core mission, requiring the Alliance to focus on maintaining and restoring immunisation services in countries on top of its ambitious equity agenda. In line with the Alliance’s mission to ensure equitable use of vaccines, COVAX has become an additional priority, requiring resources and attention at all levels.
 - 1.2 In addition to monitoring Gavi’s **progress against its four strategic goals**, the Secretariat is closely monitoring the impact of, and response to, the pandemic through a set of **key parameters** (see dashboard below).

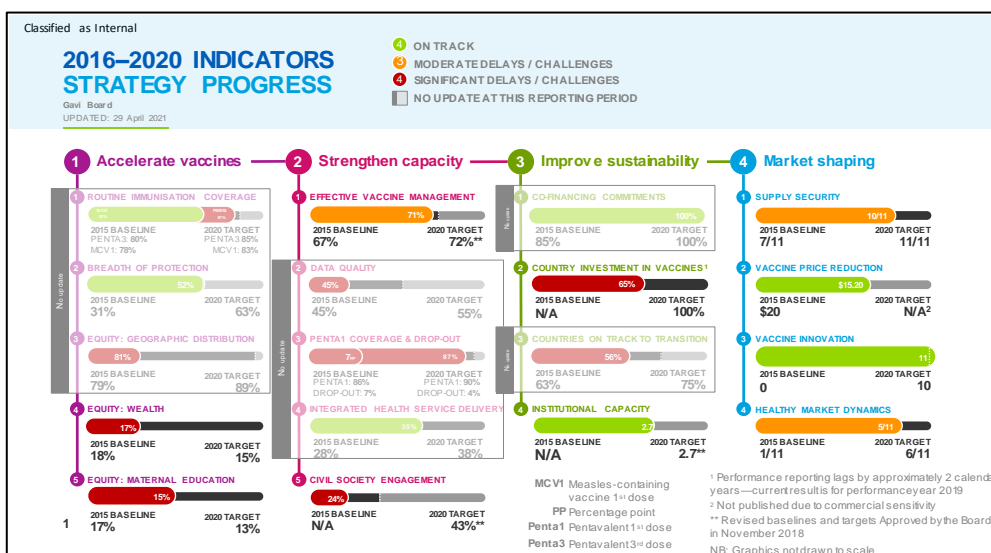


Figure 1

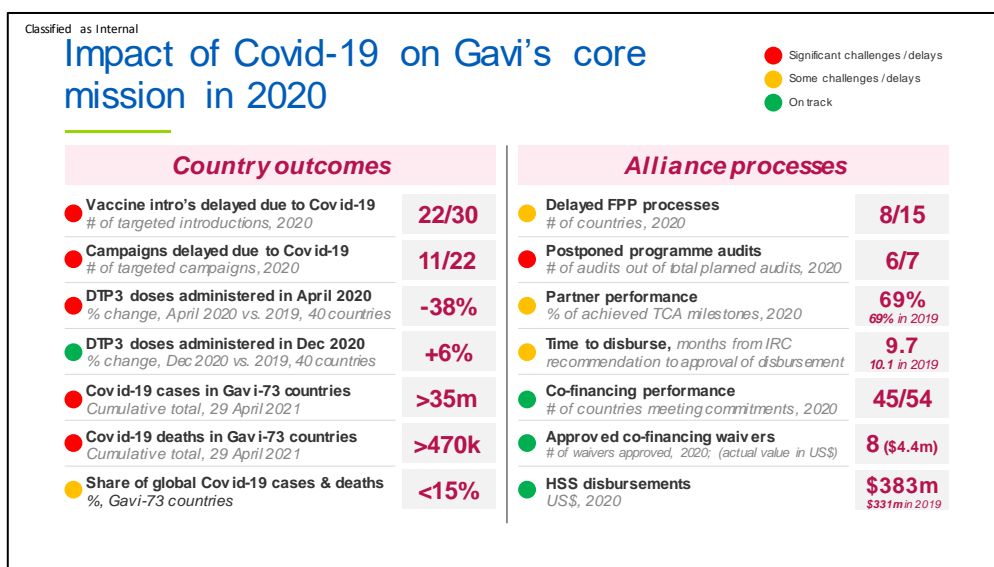


Figure 2

Strategic Goal 1: Accelerate Vaccines

- 1.3 **COVID-19 disrupted routine immunisation in 2020, with signs of restoration in the second half of the year.** Lockdowns at the start of the pandemic seem to have led to sharp drops in immunisation coverage, with available administrative data from 40 Gavi-supported countries² indicating a 38% reduction in Penta3 doses administered in April 2020 vs. 2019 levels (See Figure 3 below). The Alliance has strongly advocated with countries that by sustaining routine immunisation (RI) during the pandemic, modelling suggests that they can save 84 children’s lives versus the risk of one COVID-19 related death. Data from later months indicates that vaccination has mostly been restored and there is evidence that catch-up vaccination of missed children began in some countries. Overall, routine immunisation coverage in Gavi-supported countries in 2020 is anticipated to drop by 5-10% compared to 2019.

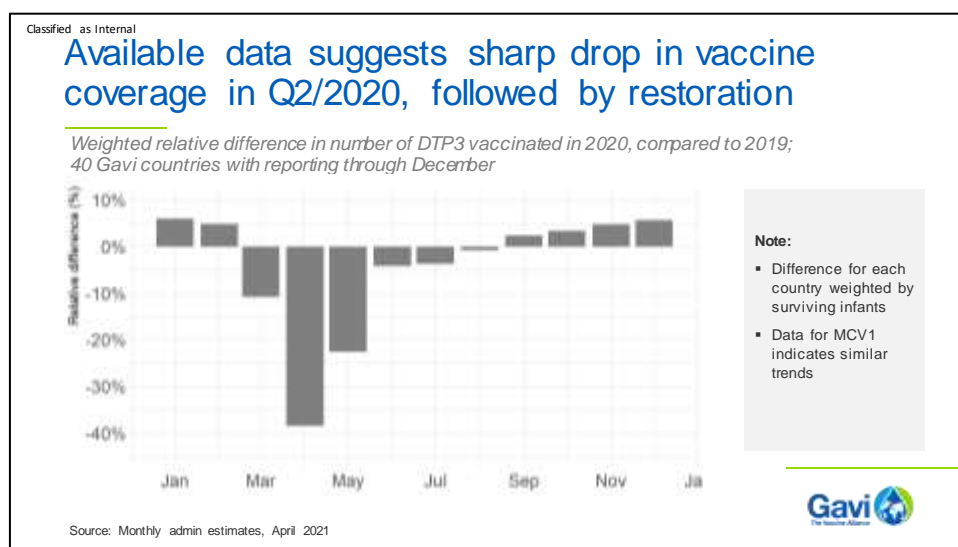


Figure 3

- 1.4 **The pandemic affected vaccine introductions, preventive campaigns and outbreak response vaccination activities across all Gavi-supported vaccines.** Of the 52 targeted vaccine introductions and campaigns in 2020³, 19 took place and 33 were delayed.
- 1.5 **Most delayed introductions and campaigns are now targeted for launch in 2021.** Gavi currently anticipates 39 introductions this year. **This includes 7 expected measles campaigns in 2021**, which are in addition to the 34 measles follow-up and 20 measles-rubella catch-up campaigns the Alliance has supported with nearly US\$ 600 million over the last five years (~11% of total vaccine-related costs⁴). **Measles cases and deaths have nonetheless continued to increase, highlighting the need to reimagine current approaches.** The Secretariat is updating its campaign

² The effect of the pandemic on Gavi’s strategic indicators relating to coverage and geographic equity will become more visible with the expected release of 2020 WUENIC data in July 2021.

³ The original target for 2020 was 52 introductions and campaigns; 16 additional launches were registered as upsides.

⁴ Vaccines, operational support and vaccine introduction grants.

funding guidelines to ensure that identifying and reaching zero-dose children is prioritised, including through differentiation of operational costs, and to encourage countries to conduct multi-antigen campaigns and co-deliver other services, where appropriate.

- 1.6 **The risk of further delays to introductions and campaigns, backsliding of coverage and increase in vaccine-preventable disease (VPD) outbreaks remains real in light of new waves of COVID-19 infections and constrained health system capacities.** India, Nepal and other countries are now experiencing second and third waves and the proliferation of more dangerous variants, potentially triggering new lockdowns. Health systems capacity may become more constrained as the delivery of COVID-19 vaccines picks up rapidly starting in Q3. The Alliance is trying to mitigate this delivery risk by supporting rapid COVID-19 vaccine delivery in countries through exceptional support and proposes a new COVID-19 Delivery and System Strengthening (CDSS) envelope. For further details, see Doc 06.

Strategic Goal 2: Health System Strengthening

- 1.7 **Maintaining, restoring and building back more resilient, equitable and integrated RI systems has become the main focus of the Alliance's broader support to countries.** Multi-stakeholder dialogues convened in Gavi-supported countries revealed that outreach services, demand and programme management were disrupted across countries, while the impact on vaccine stocks and health workforce availability was more variable. Countries used the dialogues to identify programmatic adjustments to maintain, restore and strengthen immunisation programmes and how Gavi's support can be repurposed for this. For example, Ethiopia identified innovative RI catch-up activities such as house-to-house screening to identify missed children for RI referral, and defaulter tracking with coloured bracelets in underserved and hard to reach communities. It also developed an immunisation road map to address challenges reaching zero-dose children, underserved and hard-to-reach urban and rural communities. While multi-stakeholder dialogues allowed a robust discussion in most countries despite logistical challenges of remote working, many countries have struggled to consistently implement the discussed strategies given the other competing priorities of managing the pandemic.
- 1.8 **The Alliance continues to accelerate the disbursement of cash grants.** Annual health systems strengthening (HSS) disbursements nearly doubled over the course of Gavi 4.0 to reach US\$ 383 million in 2020, totalling US\$ 1.42 billion for 2016 to 2020, compared to the original Board-approved envelope of US\$ 1.3 billion. Increased disbursements reflect the high uptake of Board-approved flexibilities such as additional HSS for fragile countries through the Fragility, Emergencies, Refugee's policy, higher country absorption as they reprogrammed funds for COVID-19 response, as well as improved disbursement timelines. **The average time from Independent Review Committee (IRC) recommendation to disbursement for HSS, vaccine introduction (VIG) and operational support (Ops) grants**

decreased to 9.7 months⁵ in 2020, close to the target of nine months. This is a significant improvement from the average of 14 months observed over the past three years.

- 1.9 **Disbursement timelines are expected to improve further with the new portfolio management processes the Secretariat has started to roll out in Q2 2021.** By the end of 2022, all countries are anticipated to shift to the new model which simplifies applications for Gavi support through a single, integrated, strategic 'Theory of Change' across all streams of support (Vaccines, PEF targeted country assistance (TCA) and health systems and immunisation strengthening (HSIS) support) and provides long term visibility to countries and partners through multi-year approvals of support. The new model also moves away from a one-size fits all approach to a differentiated model that takes into account a country's expected impact on reaching zero-dose children and overall risk profile.
- 1.10 **In parallel to HSS support, the Alliance has also rapidly scaled up support through the Cold Chain Equipment Optimisation Platform (CCEOP) in Gavi 4.0.** Nearly 59,000 units of cold chain equipment (CCE) were procured through CCEOP by Q1 2021. Due to pandemic-related disruptions, the Alliance missed its objective of 65,000 units by the end of 2020 but expects to hit this target by Q3 2021. **Beyond CCEOP, the Alliance's approach to strengthen supply chains has contributed to consistent improvements in effective vaccine management (EVM) assessment scores.** The average composite score reached 71% in 2020, up from 66% in 2014 and 1 percentage point short of the 2020 target of 72%. The nine countries⁶ that conducted an EVM assessment in 2019 and 2020 have all improved their score, with an average increase of 6 percentage points over their last assessment. The impact of COVID-19 is not yet visible in EVM scores given that assessments have been delayed in many countries.
- 1.11 **Progress of partners' support in country remained below pre-pandemic levels.** Partners have achieved at least 80% of all milestones in only 16 out of 57 of countries, compared to 30 out of 58 countries last year. This reflects the impact of COVID-19 on the agreed technical assistance (TA) plans and timelines as well as the diversion of resources to support the COVID-19 response and vaccine delivery. To mitigate this, the Alliance has increased resources in each partner organisation with a focus on preparing for COVID-19 vaccine delivery and for overall COVAX engagement. Out of US\$ 60 million of partner funding approved by the Board in September 2020, US\$ 55 million has been programmed⁷. Additional partner funding to

⁵ On including grants that were impacted by vaccine supply constraints and audit issues, the average was 14 months.

⁶ Burkina Faso, Comoros, Democratic People's Republic of Korea (DPRK), Democratic Republic of Congo (DRC), Ethiopia, Guinea-Bissau, Mozambique in 2019; Afghanistan and Zimbabwe completed EVM 1.0 assessments in 2020.

⁷ Separately, US\$ 21 million have been allocated to COVAX TA in India, out of US\$ 30 million approved by the Board in December 2020 for CCE and TA assistance to India.

increase TA resourcing for COVID-19 vaccine is proposed through CDSS (see Doc 06).

Strategic Goal 3: Improve Sustainability

- 1.12 **2020 confirmed the robustness of the Alliance's co-financing approach and the steady commitment of countries despite the pandemic.** Countries contributed US\$ 128 million in co-financing in 2020, nearly the same level as in 2019, bringing their total contribution in Gavi 4.0 to US\$ 655 million, or US\$ 1.6 billion when including self-financing⁸. 45 out of 54 countries met their co-financing commitments on time⁹. These achievements reflect the Alliance's intense engagement with countries to protect domestic investments in vaccines and to strengthen the financial sustainability of immunisation programmes.
- 1.13 **Gavi approved co-financing waivers for eight countries¹⁰ under the COVID-19-related flexibility approved by the Board.** Five further countries¹¹ initially requested a waiver but succeeded in settling their commitments with government resources or through World Bank support. **The cost of co-financing waivers to Gavi amounted to US\$ 4.4 million, about 3% of total co-financing obligations.** In light of the continued impact of COVID-19 on the fiscal stability of Gavi-supported countries, the Board agreed last year to roll over US\$ 85 million (out of the original ceiling of US\$ 150 million) for co-financing waivers from 2020 to 2021. **Safeguarding domestic financing for immunisation will remain a priority for the Alliance in 2021 and any flexibilities will continue to be applied judiciously and as a measure of last resort.**
- 1.14 **The number of countries that have transitioned to self-financing remained stable at 16 by the end of Gavi 4.0,** as a result of the eligibility freeze approved by the Board last year in response to the pandemic. While most transitioned countries have maintained or increased programmatic performance, Penta3 coverage has dropped in Honduras and Bolivia and the pandemic may further affect transitioned countries' programmatic performance. To address the **risk of backsliding**, the Gavi Board approved targeted support to former Gavi-eligible countries in June 2020. Operationalisation is moving ahead in the identified priority countries: Indonesia, Angola and Honduras, although political uncertainty has led to some delays in Bolivia.

⁸ For comparison, Gavi's expenditure on vaccines in 2016 to 2020 amounted to US\$ 5.4 billion.

⁹ The strategic indicator on the share of countries meeting their co-financing commitments for 2020 will be updated at the end of 2021.

¹⁰ Full waivers: Ethiopia, Sudan, Syria, Guinea-Bissau, Central African Republic (CAR) and Zambia; Partial waivers: Liberia, Papua New Guinea (PNG); In addition, Pakistan was granted a conditional waiver for the fiscal year 2020-2021 which will be reflected in Gavi's 2021 budget. Madagascar, which originally requested a waiver before withdrawing its request, has so far paid 47% of its commitment and received an extended deadline until June for the remainder. Finally, the Board also granted a co-financing waiver to South Sudan before (and unrelated to) the pandemic.

¹¹ Afghanistan, Burkina Faso, Kyrgyzstan, Sierra Leone and Somalia

Strategic Goal 4: Shape Markets

- 1.15 **Market shaping indicators mostly achieved their Gavi 4.0 targets in 2020.** The indicators on vaccine innovation and vaccine price reduction fully met 2020 targets, while the other two indicators (supply security and healthy market dynamics) fell just short of their overall Gavi 4.0 targets.
- 1.16 **Healthy market dynamics: In 2020, five markets¹² were assessed to be in moderate or high health, up from one in 2015 and three in 2019.** The 2020 target of six markets with high or moderate health was missed due to either supply challenges or lack of supplier diversity. Of the six markets assessed to be of low health¹³, three (Measles, Meningitis A, Japanese Encephalitis) were scored as such because of low supplier diversity but are considered within acceptable risk levels due to sufficient capacity and strong track record of the dominant supplier.
- 1.17 **Vaccine price reduction: The cost of fully vaccinating a child with pentavalent, rotavirus and pneumococcal conjugate vaccine (PCV) has decreased by 24% in Gavi 4.0.** The weighted average price for a full course of the three vaccines now stands at US\$ 15.20, down from US\$ 20.01 in 2015 and US\$ 15.57 in 2019. The improvement of the past year was driven by price reductions for PCV and rotavirus vaccines, thanks to an increasing market share being taken by lower-priced alternatives. Pentavalent is experiencing market volatility due to heightened competition over supply, and the focus is now to stabilise prices in this market.
- 1.18 **Vaccine innovations: One additional product with improved characteristics was newly procured during 2020, bringing the Gavi 4.0 total to 11, compared to a target of 10.** Adjuvanted-Salk IPV (inactivated polio vaccine) is produced by AJ Vaccines using a formulation technology that allows for a smaller dose of active substances compared to other IPV presentations, thus decreasing production cost and making the vaccine more affordable to use by Gavi-supported countries.
- 1.19 **Supply security: Ten out of eleven vaccine markets had sufficient and uninterrupted supply in 2020, an improvement from six in 2015 and eight in 2019.** While supply security for IPV and OCV (oral cholera vaccine) was re-established, global demand for HPV (human papillomavirus) vaccine continues to outpace available supply, despite the manufacturing capacity expansion efforts of a major supplier to Gavi. Countries were unable to scale up HPV vaccination programmes as originally envisioned, with multi-age cohort vaccination (MAC) deferred until supply availability improves. This translated into ~14 million girls vaccinated by the end of 2020 compared to the original target of 40 million. In Gavi 5.0 we expect increased supply from both existing and new manufacturers, with one new supplier currently

¹² Pentavalent, PCV (pneumococcal conjugate vaccine), yellow fever, IPV (inactivated polio vaccine) and rotavirus markets all exhibit moderate health

¹³ Measles, Measles-Rubella, Meningitis A, Japanese Encephalitis (JE), Human Papillomavirus, Oral Cholera

completing the WHO prequalification process with possible availability from the second half of 2021.

1.20 **In 2020 COVID-19 impacted production of at least three UNICEF-procured routine vaccines**, although programmatic disruption was avoided in each case due to buffers and alternative products in the respective markets. The dramatic reduction in air travel and the interruption in international freight and cargo capacity, particularly in the second quarter of 2020, impeded delivery to countries. UNICEF led a successful effort to clear a significant shipment backlog, with the help of US\$ 6.4 million from Gavi to support increased freight costs and the use of chartered flights. The risk to future supply is driven by compromised availability of raw materials and inputs to production, and potential trade-offs with COVID-19 vaccine production. Alliance partners are closely monitoring the situation and are taking proactive steps to address challenges, including political advocacy, contribution to prioritisation and trade-off decisions, financial risk-shares, facilitation of contract manufacturing organisation involvement and programmatic adaptation to potential shortages.

2. Operationalising the approach to reaching zero-dose children and missed communities

2.1 In December 2020, **the Board confirmed the Alliance's recalibrated priorities for Gavi 5.0 in light of the pandemic and the successful replenishment**, confirming that Gavi should focus on **maintaining, restoring and strengthening immunisation services, and on reaching zero-dose children and missed communities**. It also reconfirmed the importance of ensuring **access to COVID-19 vaccines and safeguarding domestic financing for immunisation**. In addition, potential future investment priorities were also noted, including in innovation, VPD surveillance, Gavi's strategic partnership with India, and Gavi's approach to financial management and fiduciary risk assurance. Some of these priorities will be discussed further at this meeting, while the Board will also be asked to consider an investment in a malaria vaccines programme at a later point, subsequent to a WHO recommendation for wider use.

2.2 **Reaching zero-dose children and missed communities with a full range of routine vaccines is key to deliver on Gavi's vision to leave no one behind with immunisation by 2030**. Gavi continues to build momentum within the entire Alliance and beyond to create a broad movement for equity at global, country and subnational levels. Within the Alliance, following PPC guidance, a dedicated cross-Alliance working group has taken the lead in defining a joint programmatic approach, identifying required tools and technical guidance to support countries reach zero-dose communities. The approach builds on previous work on improving coverage and equity in Gavi 4.0 while increasing its specific focus on supporting countries to identify and sustainably reach zero-dose children and missed communities with a full range of routine vaccines.

2.3 Building a **global movement for equity and zero-dose requires engagement beyond the Alliance to amplify the message and catalyse**

progress. The Alliance continues to engage with a broader set of civil society and community organisations (see Doc 08) and has established new partnerships with humanitarian organisations.¹⁴ The Secretariat has also intensified engagement with other financing institutions, including with the World Bank which is receiving SFA (strategic focus area) funding to support country offices to integrate a focus on zero-dose into their operations as a critical tracer for equity in primary healthcare, as well as with the Global Financing Facility (GFF) to work together on data to identify and build strategies to reach missed communities. Finally, Gavi has heightened its advocacy work on zero-dose by promoting and positioning the issue in global and regional policy fora and socialising it with stakeholders in health, education, humanitarian affairs, nutrition, gender, and parliamentary affairs.

- 2.4 In December 2020, the Board approved the allocation of an additional **US\$ 500 million to accelerate progress on sustainably reaching zero-dose children and missed communities** with a full range of routine vaccines. The Secretariat has been working with Alliance partners to operationalise this “**Equity Accelerator Funding**” (EAF). Based on PPC and Board guidance, several key principles frame the overall design of the EAF, namely: (i) equality in access; (ii) performance-driven; (iii) evidence-based comprehensive approach to programming (based on the IRMMA¹⁵ framework); (iv) incentivise innovative strategies and partnerships, and integrated service delivery; and (v) flexibility and alignment to other Gavi support processes to minimise transaction costs for countries.
- 2.5 The Secretariat is planning to allocate US\$ 400 million of EAF funding to countries using the Board-approved HSS allocation formula. Countries will be able to programme this funding on top of their HSS grants to further accelerate efforts to sustainably reach zero-dose children and missed communities. **To access this funding, country governments will need to demonstrate that they are able to identify who and where zero-dose children are, why they are being missed, and develop robust, tailored and differentiated plans to sustainably reach them based on their context** (e.g. urban slums versus conflict or remote rural settings). To access their full potential allocation, countries would also need to set ambitious targets for reaching zero-dose children that are consistent with Immunisation Agenda 2030 and Gavi 5.0 aspirations. They will be encouraged to test innovative strategies and to identify the right partners to help implement sustainable strategies. To minimise transaction costs, EAF funding requests will be integrated into the new integrated Theory of Change and application kit for all Gavi support.

¹⁴ To date, partnerships have been established with the International Federation of the Red Cross, the International Rescue Committee, the International Organisation for Migration (IOM), United Nations High Commissioner for Refugees (UNHCR), United Nations Office for Project Services (UNOPS) and Save the Children UK

¹⁵ As presented at December 2020 Board, the Alliance has developed the ‘Identify-Reach-Monitor-Measure-Advocate’ framework to ensure a more systematic approach to programming Alliance support to sustainably reach zero-dose and under-immunised children.

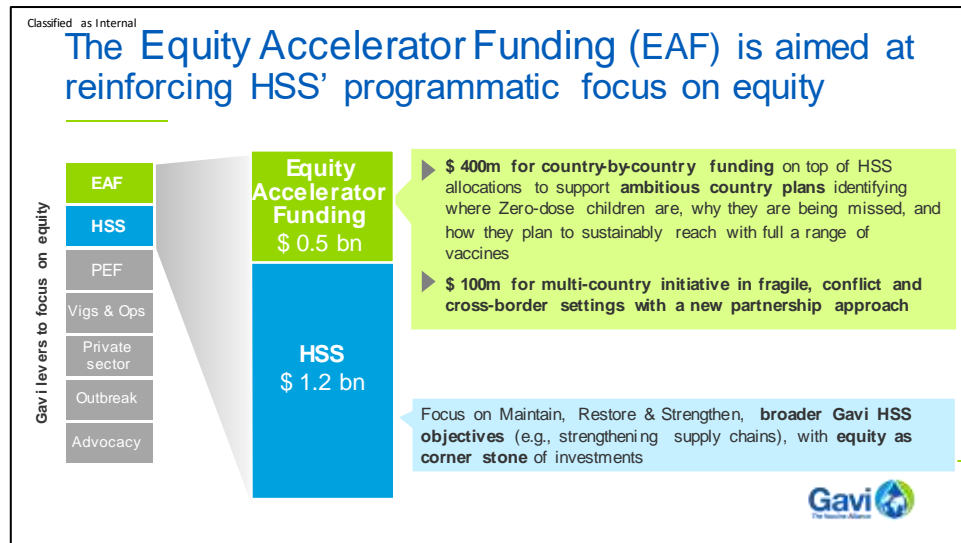


Figure 4

- 2.6 **US\$ 100 million of the EAF will be allocated to a new multi-country initiative to reach zero-dose children and missed communities in fragile, conflict and cross-border settings outside government reach with a new partnership approach.** Following analysis of affected geographic regions impacted by prolonged humanitarian crisis, conflict and displacement resulting in high number of zero-dose children, the focus of this support will be to the Sahel region and Horn of Africa¹⁶. The approach recognises the constraints of the Gavi support model of working through national governments in settings which government services cannot reach. Hence, building on recent agreements with new humanitarian partners, the Alliance will launch a dedicated call to identify the best partners to reach zero-dose children and missed communities with immunisation, integrated with other primary health care (PHC) and child survival services. Gavi will ensure deliberate engagement and coordination with governments and other partners and implement a learning agenda, including in the innovation space, as well as an ambitious performance-based results framework to monitor progress and manage performance. **The PPC endorsed the proposed approach and emphasised the importance of creating space for country perspectives in the design and programming of the funds.**

3. Updated Risk Appetite Statement for Gavi 5.0

- 3.1 Gavi's last Risk & Assurance Report, approved by the Board in December 2020, showed that **Gavi's overall risk profile in the context of Gavi 5.0, the COVID-19 pandemic and the COVAX Facility has increased across the board.** It highlighted the need to accept some of this higher risk exposure as Gavi is pursuing a riskier strategy in a riskier world and faces limitations in its ability to mitigate some of these risks.
- 3.2 **Clarity on risk appetite – the amount of risk an organisation is willing to take, accept, or tolerate to achieve its goals – is needed to limit**

¹⁶ There are 4.6 million zero-dose children across 12 Gavi-eligible countries in the Sahel and Horn of Africa regions alone (out of 9.7 million zero-dose children across Gavi-eligible countries) – WUENIC 2019.

excessive and unrewarded risk-taking as well as undue risk aversion which can impede progress and success. Gavi's Risk Appetite Statement defines on a broad level the criteria and trade-off considerations that guide the Alliance's appetite for risk at the mission, strategy and organisational level.

- 3.3 **The Secretariat has prepared a draft updated statement for approval by the Board at this meeting** (see Annex A). It builds on the existing Board-approved statement¹⁷ and has been brought in line with the new mission and strategic goals of the 2021-2025 strategy. It furthermore incorporates existing risk appetite considerations as described in the Risk & Assurance Reports over the past years and reflects guidance from the Board in response to the initial suggestions for a recalibrated risk appetite shared at the December 2020 Board meeting. The Audit and Finance Committee (AFC) – in line with its mandate to oversee the effectiveness of risk management systems and processes – has reviewed the statement and recommends it to the Board for approval.

Section C: Actions requested of the Board

The Gavi Alliance Audit and Finance Committee **recommends** to the Gavi Alliance Board that it:

Approve the updated Risk Appetite Statement attached as Annex A to Doc 03.

Annexes

Annex A: Updated Risk Appetite Statement

Additional information available on BoardEffect

Appendix 1: Updated Alliance KPIs dashboard

Appendix 2: Strategy Indicators reported as originally defined

Appendix 3: COVID-19 Impact Tracking Parameters

Appendix 4: IRC/HLRP recommendations

Appendix 5: Update on the Malaria Vaccine Implementation Programme

Appendix 6: (in May 2021 AFC meeting book): Doc 04 *Risk Management Update*

¹⁷ See the current version: <https://www.gavi.org/news/document-library/risk-appetite-statement>