
Subject	Pandemic Prevention, Preparedness and Response Approach
Agenda item	10a
Category	For Decision

Section A: Executive Summary

Gavi, the Vaccine Alliance (the Alliance) is a critical contributor to pandemic prevention, preparedness, and response (PPPR) through its support of routine immunisation and outbreak response. In the aftermath of the COVID-19 pandemic, multiple global and regional initiatives are on-going to address gaps in the global response. The Secretariat is collaborating with Alliance members, the Coalition for Epidemic Preparedness Innovations (CEPI) and additional regional and global partners on PPPR to build upon the lessons from COVID-19 and contribute to the evolving PPPR architecture. These contributions build on the four areas for targeted additional roles in PPPR presented to the Board, as part of the approval of the Gavi 5.1 Strategy: i) retain and enhance required capabilities for the next pandemic; ii) financial innovation; iii) resilient routine immunisation programmes; and iv) diversification of regional manufacturing.

This paper provides an update on the Alliance's approach to PPPR and proposes investments for the remainder of Gavi 5.1 aligned with the approach. In June 2023, the Board requested the Secretariat to present options for the use of remaining COVAX Advance Market Commitment (AMC) Pandemic Vaccine Pool (PVP) funding, that include but are not limited to preparing for and responding to COVID-19 and future health emergencies. The Programme and Policy Committee considered three PPPR proposals during its October 2023 meeting: the proposal on support for a coalition of vaccine partners is being recommended for Board approval; the proposal on the Day Zero Financing Facility for Pandemics received guidance from the PPC and elements of this facility are being taken to the December meeting of the Audit and Finance Committee (AFC) ahead of the Board meeting for its recommendation as is the practice with financial instruments; and a third proposal on a healthcare worker immunisation platform will be discussed in the context of Gavi 6.0. The Board will have an opportunity to consider the level of ambition for Gavi's approach for PPPR more broadly as part of the process of developing the 6.0 Strategy. The PPPR approach and associated investment proposals have been developed in consultation with Alliance and additional partners.

Questions this paper addresses

- What is the vision and theory of change for Gavi's PPPR approach?
- What are the recommended investment options for use of COVAX AMC PVP funding to support the PPPR approach?

Section B: Content

1. Context

- 1.1 PPPR is core to the Alliance’s mission and an integral part of its four strategic goals (SG).** In pursuit of SG1, Gavi supports the introduction and scale up of routine immunisation (RI) and vaccination campaigns that prevent the outbreak of multiple diseases. Gavi-supported vaccine stockpiles improve the equity of access during outbreaks. As part of SG2, Gavi’s health system and immunisation strengthening investments support greater equity and resilience during pandemics, combat vaccine hesitancy, contribute to surveillance and pharmacovigilance, and enhance national regulatory, policy, and planning capacity. Gavi’s investments in diagnostics contribute to enhancing countries’ abilities to detect outbreaks and stimulate earlier response. In SG3, Gavi’s approach to improving the sustainability of RI programmes has strengthened the political and social commitment to PPPR. As part of SG4, Gavi’s support for healthy vaccine markets has expanded and diversified vaccine supply for both RI and outbreak response.
- 1.2 The COVID-19 pandemic was an unprecedented test of the Alliance’s model and support for PPPR.** The COVAX partnership built on the capacity, partnerships, and networks that underpin the Alliance. US\$ 12.5 billion was raised, and as of November 2023, over 1.97 billion COVID-19 vaccine doses were shipped, and approximately US\$ 1.2 billion was committed to support COVID-19 vaccine delivery. Despite disruptions to routine immunisation in 2021, Gavi-supported countries administered over 2.7 times more vaccination doses as compared to 2019. These investments built on more than US\$ 6.5 billion invested in programmes that contribute to PPPR, excluding COVAX, over the last two strategic periods.
- 1.3 Gavi’s strategy evolved in response to the COVID-19 pandemic, resulting in the Gavi 5.1 strategy.** This paper details Gavi’s PPPR approach, based on the Gavi 5.1 strategy, bringing together Gavi’s core and additional PPPR roles into a holistic theory of change.

2. Gavi’s PPPR Approach

- 2.1 Several global and regional level efforts are underway to strengthen and shape the global health and PPPR architecture.** At the heart of these efforts is the negotiation of a Pandemic Accord through the Intergovernmental Negotiating Body (INB) and amendments to the International Health Regulations under the framework of strengthening Health Emergency Preparedness, Response and Resilience (HEPR). In line with these, the United Nations General Assembly in September 2023 adopted the first Political Declaration on PPPR. There are also global efforts to develop a coordinated approach for surge financing for future pandemics. The Secretariat is an Implementing Entity of the Pandemic Fund and has been working with other entities and countries to develop future proposals. The Alliance is actively working together with other immunisation partners to contribute to the

processes initiated by the G7, G20, and the UN High-Level Meeting on PPPR and the WHO-led processes underway to establish an interim coordination mechanism on medical countermeasures through a network-of-networks (I-MCM-Net). Gavi is supporting these large-scale efforts with the aim of better responding to countries' needs, focusing on areas where the Alliance has a clear comparative advantage.

- 2.2 **The Alliance's PPPR approach anticipates and responds to shifts in the global health architecture and the learnings from COVID-19 and recent outbreaks.** Figure 1 summarises key gaps in the COVID-19 and other recent outbreaks' vaccine response and lessons for the Alliance based on evaluations findings, which are incorporated in the approach and inform the proposed investments.

Figure 1: Summary of key gaps in response to COVID-19 and other outbreaks

 Country-level gaps	<ul style="list-style-type: none"> • Missing or weak delivery platforms to reach the population groups most at risk and lack of institutionalised demand generation platforms (including to address vaccine hesitancy) • Insufficient strategy and processes to ensure access for humanitarian populations • Weak VPD outbreak detection and tracking systems limiting the responsiveness of country public health strategies, vaccine investments, and global coalition-level support during an outbreak • Insufficient capacity to protect routine immunisation during an outbreak • Limited surge infrastructure and human resources required for delivery • Inconsistent national policies for outbreak and pandemic immunisation
 Vaccine gaps	<ul style="list-style-type: none"> • Gaps (and opportunities) in innovative vaccine products, delivery, supply chain and data technologies required for a pandemic • Lack of regional diversification of manufacturing capacities, in face of vaccine nationalism • A lack of reserves/ inventories of pre-licensed vaccines and stockpiles for licensed vaccines • Challenges in the commercial viability of inter-outbreak markets for outbreak/pandemic vaccines • Missing regulatory pathways between global institutions, countries and manufacturers • Unclear strategy for indemnity and liability (I&L) including in humanitarian situations
 Coalition gaps	<ul style="list-style-type: none"> • Misalignment on how to adapt roles, responsibilities and processes for outbreak/pandemic • Insufficiently agile structure to organise end-to-end response across Alliance and broader partners; lack of inclusion and transparency in decision-making • Lack of coordination structure for delivery funding and support for countries and partners • Very limited day-zero financing to deliver activities and to support vaccine and country readiness • Limited surge human capacity in global and regional institutions for rapid deployment

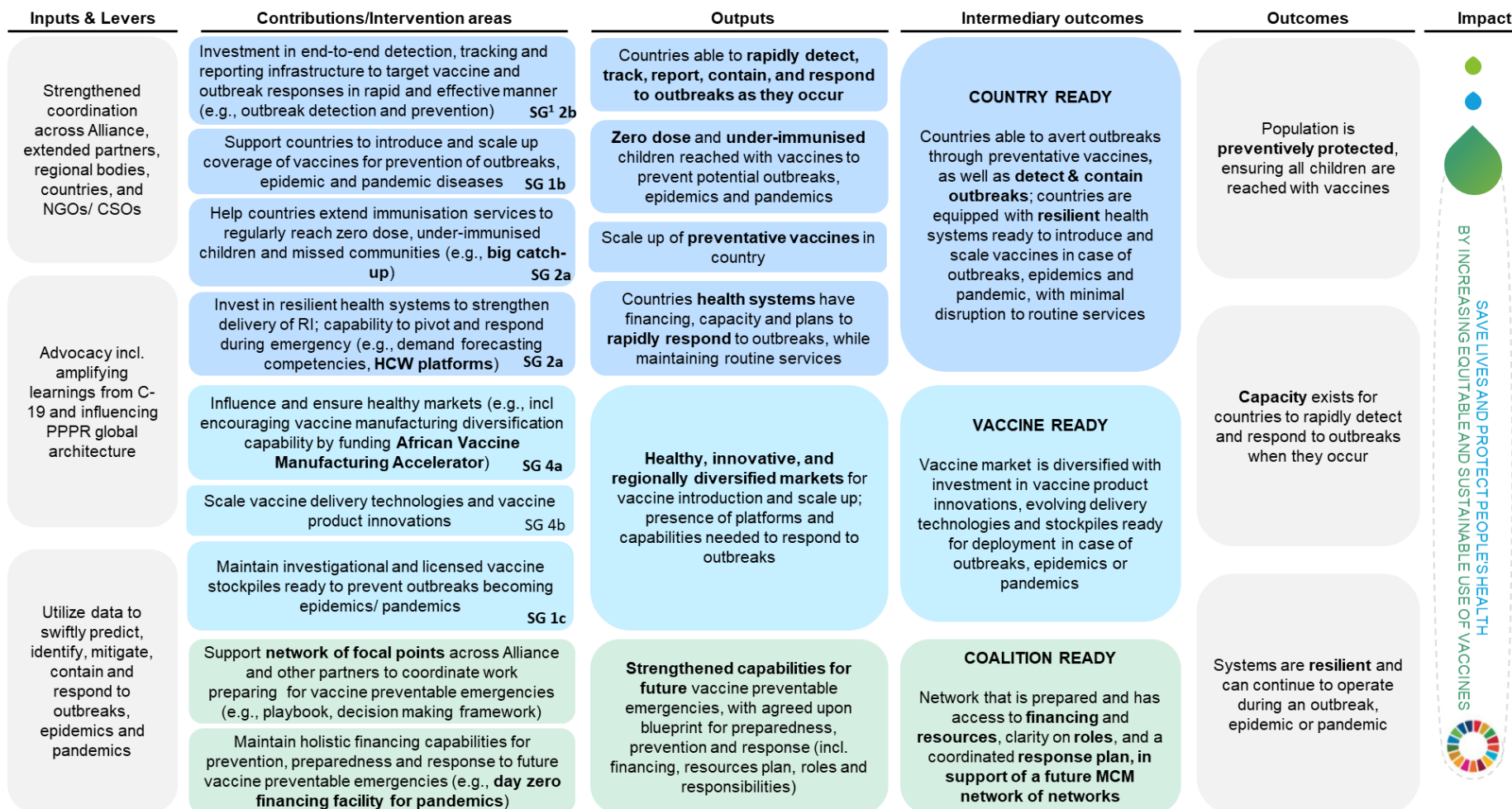
- 2.3 **Given the increasing risk of outbreaks and pandemics, Gavi is proposing key investments to urgently address operational gaps in PPPR to support Gavi-eligible countries.** The work would be driven and strengthened by an expanded coalition of vaccine partners, including and building on the group that came together to fight COVID-19. Gavi recognises the important work ongoing through the INB to establish a Pandemic Accord, and these proposals do not prejudge the structures for future pandemic response. The aim is to integrate these partnership efforts into any future medical counter-measures network.

3. Gavi's PPPR Vision and Theory of Change

- 3.1 **Gavi has the ambition for countries to be ready to respond to outbreaks, epidemics, and pandemics with rapid access to vaccines, supported by a coalition of partners: "Ready Countries, Ready Vaccines, Ready Coalition".**

- 3.1.1 **Ready countries: The Alliance envisions greater country-level readiness and resilience.** This includes strengthening the vaccine response to outbreaks, epidemics, and pandemics, and strengthening the resilience of RI services. Countries would be better prepared to detect and contain outbreaks and immunisation systems could better pivot to respond to public health events. Countries would have timely access to surge funding and technical assistance for outbreak response, and there would be minimal disruption to RI during outbreaks.
- 3.1.2 **Ready vaccines: The Alliance envisions stronger vaccine readiness and more regionally diversified vaccine markets.** Gavi will provide targeted support to the vaccine ecosystem that incentivises the rapid development and scale up of vaccine innovations and aims for healthy vaccine markets that are more regionally diverse. Countries would have ready access to reserves of investigational vaccines and stockpiles of approved vaccines to facilitate rapid outbreak response.
- 3.1.3 **Ready coalition: The Alliance will support an agile, financed coalition of partners—within and beyond existing Alliance partners—at the local, national, regional, and global levels that work together to prepare for and coordinate PPPR activities along the vaccine value chain.** Operating through partners is foundational to how the Alliance executes its mission. During COVID-19, many actors came together to forge new partnerships to support the response. Some did not have prior experience working together. There were gaps in the inclusion of new partners and in how they coordinated and operationalised their roles. The “Ready coalition” ambition is aligned with and remains responsive to the current trajectory of G20, G7, INB and WHO I-MCM-Net deliberations, and builds on on-going work with partners through the working group XVAX, WHO R&D Blueprint, the Medical Countermeasures Delivery Platform, and others.

3.2 The Theory of Change describes how the Alliance is delivering on its vision.



1. Strategy Goals from Gavi 5.1 strategy

- 3.3 **In line with the Ready Countries, Ready Vaccines, Ready Coalition ambition, this paper includes one proposal (coalition of vaccine partners) for Board approval, which complements existing Alliance PPPR work in Gavi 5.1.** Following the request by the Board in June 2023, the Secretariat brought six PPPR proposals to the COVAX AMC Investors Group for funding consideration, of which three met the criteria for funding via the COVAX AMC PVP. One proposal (First Response Fund for the Day Zero Financing Facility for Pandemics) is being presented to the AFC for recommendation at its December 2023 meeting. These proposals are summarised below with additional details in Annex A. The process of consulting the COVAX AMC Investors Group was necessary because Gavi does not have core funds in the Gavi 5.1 period for these proposals, and the majority of COVAX AMC donors have restrictions on how COVAX AMC PVP funds can be deployed. Associated proposals for the African Vaccine Manufacturing Accelerator and the Big Catch Up, which can also contribute to vaccine readiness and country readiness respectively, are detailed in Doc 10b and Doc 04, respectively.
- 3.4 **Capabilities to support a coalition of vaccine partners:** Through existing mechanisms and partnerships, Gavi aims to contribute towards the critical work of strengthening and expanding vaccine partner networks, funding focal points at key partner organisations, including regional bodies, to help build capabilities in prevention, preparedness, and response. This includes strengthening partner coordination and visibility on key PPPR activities, the development of a cross-partner “playbook” outlining the capabilities for a future pandemic response, and co-defining priority needs and initiatives which incorporate learnings from COVAX and more recent outbreak responses. The PPC considered this proposal at its meeting in October 2023 and was broadly supportive, noting the importance of inclusivity and transparency in decision-making. The Secretariat is committed to working through established mechanisms and partnerships, which avoids creating parallel or duplicative processes with other ongoing global discussions, including i-MCM-net and negotiations on the Pandemic Accord, for which this work would support.
- 3.5 **The First Response Fund for the Day Zero Financing Facility for Pandemics (DZF):** Gavi will prepare for the next pandemic by extending and supplementing its innovative financing mechanisms under the umbrella of a new Day Zero Financing Facility. The DZF is a suite of tools that will enable the Alliance to meet the immediate needs for vaccines within the first 100 days of a pandemic. It consists of two elements that complement each other: (1) the creation of a new First Response Fund that will enable funds to be deployed faster than any other mechanism in Gavi’s PPPR toolkit, and (2) the expansion of the use and effectiveness of Gavi’s existing surge financing mechanisms so that they can be used beyond COVID-19 (this includes IFFIm and amendments to the frontloading facilities with the European Investment Bank and U.S. Development Finance Corporation). The First Response Fund will bridge immediate funding needs until further resources can be unlocked. By creating a pool of immediate, at-risk financing, the First Response Fund will provide the Alliance with both the financial headroom and the cash liquidity needed at the start of a pandemic. Access to the First Response Fund would be subject to

standard Gavi governance processes and will be critical in delivering a more rapid and equitable end-to-end vaccine response for lower income countries. The PPC in its October meeting was supportive of the need to extend the use of the PVP in this way to form a First Response Fund for future pandemic response and provided guidance on a number of programmatic considerations that the Secretariat will consider in implementation (including the governance and trigger mechanism for the First Response Fund, the duration for which these funds would be available, and the potential use of funds outside of pandemics, for example, in multi-country outbreaks). The Gavi Audit and Finance Committee is reviewing the funding and risk implications of the First Response Fund at its 4 December 2023 meeting and is being asked to recommend to the Board that it approve the establishment of a First Response Fund of up to US\$ 500 million, as part of the Day Zero Financing Facility for Pandemics, contingent on the available funding from the COVAX AMC Pandemic Vaccine Pool (PVP); noting that approvals required to release these funds will be brought back to the Board through the relevant Board Committees as per standard Gavi governance process.

- 3.6 The PPC also considered a proposal for a health worker immunisation platform but did not recommend it for Board approval at this stage. The PPC recognised the value of investing in health worker protection in a PPPR context, including with a gender lens, but raised concerns about the timeline and interaction with the proposed health worker touchpoint that was included as part of the Vaccine Investment Strategy (VIS) 2024 (see Doc 11). In line with the discussion on the health worker touchpoint within the VIS 2024, which will be reviewed as part of the development of Gavi 6.0 through the revised Health Systems Strengthening strategy, the PPC requested that elements of this proposal be considered alongside other potential investments within the 6.0 design process. The proposal is provided in Annex A for Board information.

4. Link to Gavi 6.0 (2026-2030)

- 4.1 **The evolution of the Alliance's role in PPPR in Gavi 6.0 will be discussed during the 6.0 design process**, including at the Gavi 6.0 retreat in Ghana preceding the December 2023 Board meeting. As discussed by the Board and PPC at the 'mini workshop' on 10 October 2023, PPPR is an opportunity for impact in Gavi 6.0.
- 4.2 **Three proposals presented to the COVAX AMC Investors Group did not meet donors' funding criteria for COVAX AMC PVP funds which require strong linkages to COVID-19.** The Secretariat is not seeking Board approval for these proposals at this time, but they are included in Annex A for transparency. PPC members encouraged further consideration in particular for the proposal for Measles-Rubella microarray patches (MR-MAPs) for Gavi 6.0. **These proposals were deemed of interest for further exploration in Gavi 6.0, alongside other potential future investments.**

Section C: Actions requested of the Board

The Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

- a) **Approve** up to US\$ 22 million to support a coalition of vaccine partners outlined in Annex A to Doc 10a as amended by discussions at the Programme and Policy Committee (PPC) to be committed during the Gavi 5.1 strategic period, in line with Gavi's approach to pandemic prevention, preparedness and response (PPPR);
- b) **Note** that the investment would be to vaccine partners, coordinating through existing mechanisms, ensuring that the scope of activities covers critical linkages across outbreaks, epidemics, and pandemics, and resilient routine immunisation programmes and continues to align with the Intergovernmental Negotiating Body (INB) and medical countermeasures (MCM) network deliberations;
- c) **Note** the PPC's guidance on the programmatic aspects of the investment proposals outlined in Annex A to Doc 10a for the Day Zero Financing Facility for Pandemics for which an estimated amount of up to US\$ 500 million could be allocated, noting that the Gavi Audit and Finance Committee would recommend the Day Zero Financing Facility for Pandemics to the Board for approval;
- d) **Note** that this approval and any additional approvals are contingent on available funding from the COVAX Advance Market Commitment (AMC) Pandemic Vaccine Pool (PVP) as confirmed by the Gavi Audit and Finance Committee;
- e) **Note** that any additional approvals required in the further development of these proposals will be brought back to the Board through the relevant Board committees as per standard Gavi governance process and in line with Gavi policy;
- f) **Note** that the investment proposals were developed with full consideration of enhanced collaboration with other pandemic recovery and PPPR initiatives and considered by the COVAX AMC Investors Group, as requested by the Board in June 2023, and were supported as options for the use of COVAX AMC PVP funds; and
- g) **Note** that the PPPR approach will be further refined for Gavi 6.0, and associated investments considered as part of Gavi 6.0 strategy development, including but not limited to investments presented to the AMC Investors Group that did not receive funding.

Annexes

Annex A: Investment Proposals