Annex B: Gavi's future role in Pandemic Preparedness and Response (PPR)

This annex outlines the evolving global health architecture related to pandemic preparedness and response (PPR), including Gavi's historical involvement and engagement through COVAX, and most recently Ebola Sudan, and provides an overview of three areas for a potential targeted additional role for Gavi in PPR: 1) Required capabilities for the next pandemic; 2) Financial innovations; and 3) Resilient Routine Immunisation programmes, with a fourth area – supporting African vaccine manufacturing – presented in separate document. These build on PPC and Board guidance on Gavi's potential role in PPR as first presented in June 2022, and refined at the July 2022 Gavi 5.1 mini-workshop, September 2022 Gavi 5.1 deep-dive consultation, and October 2022 PPC meeting. The Board is invited to provide guidance on Gavi's additional future role in PPR as part of the discussion on Gavi 5.1.

- 1. Pandemic Preparedness and Response immunisation landscape
- 1.1 Over the past two and a half years, a range of profound societal, geopolitical, economic and technological shifts have occurred, many as a consequence of the COVID-19 pandemic. The pandemic has disrupted essential health services, including routine immunisation, and exacerbated existing inequities in access to health and immunisation between and within countries. At the same time, the global community has responded to the pandemic with unprecedented investments, political attention, and engagement that allowed new health interventions such as COVID-19 vaccines to be developed and scaled in record time.
- 1.2 Consequently, the global health architecture has been evolving. The pandemic required organisations to leverage their comparative advantages, but also new structures and actors as illustrated in Figure 1. For example, the Access to COVID-19 Tools Accelerator (ACT-A) was launched to coordinate across vaccines, therapeutics and diagnostics. As part of ACT-A, COVAX brought together CEPI, Gavi, UNICEF and WHO to ensure fair and equitable access to COVID-19 vaccines. Financial and economic bodies traditionally less focused on health such as the World Bank, IMF, G7 and G20 also increased their engagement on the global health security agenda. New regional collaboration mechanisms have been launched, such as the African Vaccine Acquisition Trust, which aims to secure vaccine doses for African countries. Bilateral funding and vaccine donations played an important role in the delivery of COVID-19 vaccines. At the same time, the global health landscape has become more crowded and fragmented. For example, a multitude of players including the World Bank and multilateral development banks, Gavi, WHO, UNICEF, AU-AVAT and bilateral donors now fund COVID-19 vaccine delivery. while other vaccines are almost exclusively supported through Gavi.

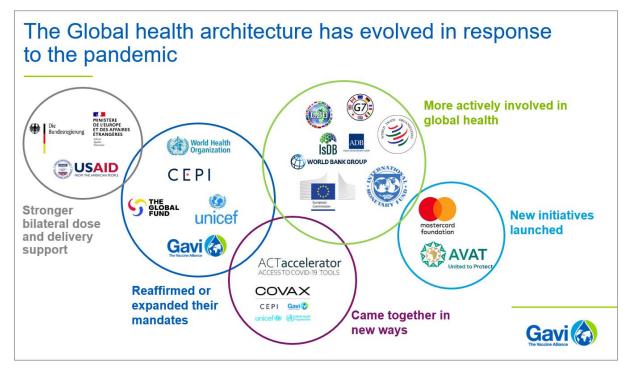


Figure 1: High level mapping of the global health architecture

- 1.3 Against this backdrop, the global community, including G7 and G20 leaders, is calling for a new pandemic preparedness architecture, and key global health actors are responding. Indonesia has taken concrete steps forward and made PPR a cornerstone of its G20 presidency. In November 2021, The Global Fund set forth a new strategy placing pandemic preparedness at the heart of its mission with a focus on building resilient and sustainable health systems. In September 2022, the World Bank launched a financial intermediary fund —the Pandemic Fund—to fill critical PPR financing gaps and strengthen preparedness capacities at global and national levels, with more than US\$ 1.4 billion pledges to date. Gavi was accredited alongside CEPI and The Global Fund as initial implementing partners of the Pandemic Fund, allowing the Alliance to both play a role in shaping its future direction and access funding, where appropriate. Collaboration with global actors in both the design and implementation of PPR interventions will help ensure coordinated, effective responses.
- 1.4 Vaccines are central to global health security. Every Public Health Emergency of International Concern declared since 2007 except one¹ has eventually used vaccination to help address the disease prompting the emergency. COVID-19 has shown the importance and impact of vaccination on a global scale. Going forward, it is to be expected that vaccines, and thus the Alliance, will continue to play a central role in PPR.

¹ The only outlier is Zika, for which a licensed vaccine is not yet available.

- 1.5 The Alliance responded to the most pressing challenges in COVID-19 immunisation through COVAX, raising US\$ 12.5 billion for COVID-19 response to support 92 lower income economies access and deliver vaccines. COVAX built upon on the existing Alliance model (with the important addition of CEPI) with coordination across a wide range of stakeholders with end-to-end expertise toward a common goal. The effort was predicated on investments in routine immunisation as well as the capacity, partnerships, and networks that have underpinned the Alliance over the last two decades to establish end-to-end solutions all the way along the vaccine value chain.
 - CEPI supports vaccine research, development, and manufacturing scale-up
 from laboratories to production facility. As part of this work, CEPI has
 secured first right of refusal for the COVAX Facility to access doses of
 multiple vaccines and made strategic investments in vaccine manufacturing.
 CEPI is also investing in 'next generation' and 'variant-proof' vaccine
 candidates.
 - UNICEF coordinates and pools procurement and shipment of vaccines, syringes, and cold chain across COVAX participants.
 - WHO provides normative guidance and global coordination on vaccine policies, safety, regulatory and vaccine allocation. For instance, the Strategic Advisory Group of Experts on Immunization develops evidencebased immunisation policy recommendations, while WHO Emergency Use Listing / prequalification programmes ensure the harmonized regulatory review and authorisation of vaccines across Member States. In addition, PAHO handles vaccine procurement and distribution in the Americas.
 - Finally, the Gavi Secretariat administers the COVAX Facility, oversees the COVAX Facility supply portfolio, and coordinates vaccine allocation together with WHO. It holds financial and legal relationships with 193 COVAX participants and manages the COVAX deals portfolio. The Secretariat coordinates the design, operationalisation and fundraising for the Gavi COVAX AMC, the mechanism that provides access to donorfunded vaccines to 92 lower-income countries. As part of this work, Gavi Secretariat provides funding for UNICEF procurement and shipment of vaccines to AMC participants. As part of COVAX the Secretariat developed new procurement mechanisms at pace to ensure timely access to a large and diversified portfolio of vaccines. In response to supply challenges, dose donations and dose sharing mechanisms were established.
 - 1.6 At the country level, the Alliance stepped up to enhance surge capabilities to deliver COVID-19 vaccines. Gavi Secretariat has raised more than US\$ 1.6 billion for delivery support, providing support to countries for the scale-up of their COVID-19 vaccination programmes. This is complemented by additional funding from the UNICEF HAC (US\$ 0.8 billion) and WHO (US\$ 0.6 billion). From 2020 until the end of 2021, the Alliance's Country

readiness and Delivery (CRD) work coordinated and supported planning and preparedness to introduce and scale up the delivery of COVID-19 vaccines in all countries. In January 2022, recognising the urgency of increasing COVID-19 vaccine coverage, WHO, UNICEF and Gavi Secretariat, launched the COVID-19 Vaccine Delivery Partnership (CoVDP). The CoVDP focuses primarily on the 34 countries that were at or below 10% coverage in January 2022, with WHO, UNICEF and other partners supporting countries' on the ground to scale up delivery.

2. Gavi's current role and investments in PPR

- 2.1 The Alliance has long been a significant contributor to PPR as part of its core activities (see figure 2), with investments of over US\$ 6.5 billion in PPR-related activities during Gavi 4.0 and 5.0 (until H1 2022). More than 90% of Alliance investments in PPR are directed towards preparedness. Those investments consist primarily of:
 - ~US\$ 3.3 billion in routine immunisation investments and campaigns for the prevention of and response to outbreaks against 17 infectious diseases. By end 2021, the Alliance supported more than 561 routine vaccine introductions and campaigns in Gavi eligible countries (not including COVID-19 vaccines), preventing outbreaks and saving lives. The Alliance had, for example, supported countries in immunising more than 339 million people against meningococcal meningitis A. As a critical enabler for these routine immunisation programmes and campaigns, Gavi has been at the forefront of setting up innovative financial and procurement mechanisms such as the International Finance Facility for Immunisation (IFFIm) to provide upfront funding to address immunisation needs.
 - ~US\$ 2.7 billion of investments in strengthening health systems, which aim to address major bottlenecks to equity and effectiveness of immunisation programmes. Since 2015, the primary objective of Gavi's health systems funding has been to increase coverage and equity of immunisation, including against vaccine-preventable and outbreak diseases. In Gavi 5.0, the zero-dose agenda introduced a sharper focus on missed communities that are often affected by outbreaks of vaccine-preventable diseases like measles. Approximately 85% of health systems investments are considered PPR² with the largest investments made to strengthen supply chains and service delivery including expanding and extending cold chains, which proved a critical platform

² Gavi's total contribution includes the procurement cost and vaccine introduction grants for all vaccines, incl. stockpiles, except for PCV, rotavirus, HPV and pentavalent vaccines, campaign operational costs, CCEOP and cash-based programs, HSS investments in service delivery, capacity building for HR, procurement and supply chain management, health information systems, advocacy, communications and social mobilization as well as associated PEF funding (~84% of total HSS and PEF funding over the period)

for distributing COVID-19 vaccines. These investments include the modernisation and scale up of countries' electronic information systems and strengthening leadership, management and coordination. Gavi also plays an important role in strengthening diagnostics of vaccine-preventable diseases with outbreak potential.

• ~US\$ 0.4 billion of investments in pandemic, epidemic and outbreak response through the establishment of global vaccine stockpiles for epidemic prone diseases (e.g. Cholera, Yellow Fever, Meningitis, Ebola).

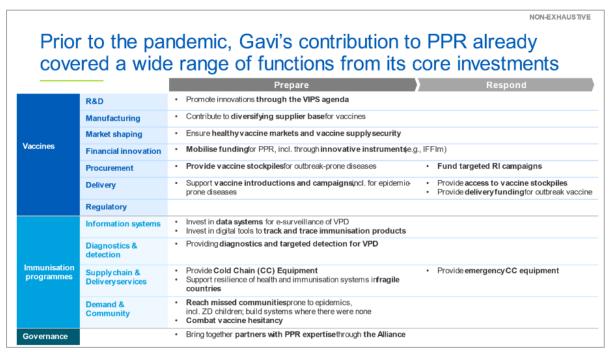


Figure 2: Overview of Gavi's PPR contributions prior to the pandemic

- 3. Critical pandemic response gaps at global and country levels
- 3.1 At the global level, the COVID-19 pandemic revealed missing response capabilities at every step of the vaccine value chain for Emergency Use Listing Procedure products. There are gaps across vaccines, immunization programs and Governance based on mapping work (see figure 3). The lack of pre-existing pandemic preparedness plans and an agile coordination structure able to take on risk given the uncertainty in the early stages of the pandemic further compounded these gaps. These challenges were highlighted in the emerging insights from the ongoing, Gavi-commissioned, independent evaluation of the COVAX Facility and COVAX AMC and of Gavi's Response to COVID-19 and the more recent example of Ebola Sudan.

NON-EXHAUSTIVE

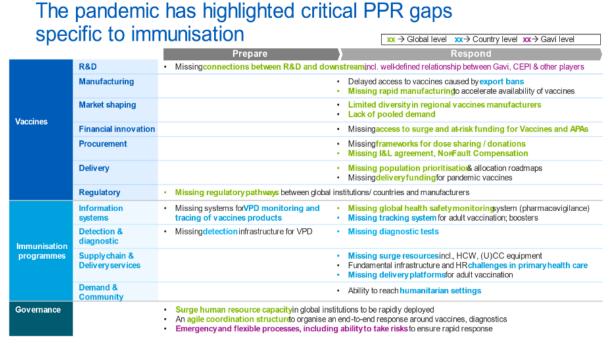


Figure 3: Overview of critical PPR gaps highlighted by the COVID-19 pandemic³

- 3.2 At the country level, the most significant response gaps emerged in routine immunisation programmes. A lack of surge resources and systems in primary health care hindered at-scale COVID-19 vaccine delivery, particularly for reaching those most at risk healthcare workers and the elderly and adults generally, including the capacity to reach those same populations with booster doses, while simultaneously maintaining routine immunisation services. Another critical gap highlighted by a mapping of the gaps in the COVID-19 pandemic was the absence of adequate information systems for immunisation. Emerging lessons captured in the ongoing evaluation of Gavi's Response to COVID-19 shed light on the challenges countries faced in simultaneously carrying out routine immunisation programmes and responding to the pandemic due to insufficient capacity across all levels, including that of Ministry of Health EPI teams.
- 3.3 The Alliance responded to these most pressing challenges in immunisation through COVAX (see section 1.5)
- 4. Gavi's potential expanded role in PPR as part of Gavi 5.1
- 4.1 The Alliance is well positioned to help sustainably address PPR gaps in immunisation further leveraging its comparative advantages. The COVID- 19 pandemic demonstrated that immunisation response capabilities are predicated on long-term investments in routine immunisation, and on the

³ Noting that this figure does not include the gaps in RI resilience which is a critical part of PPR

ability to establish end to end solutions all the way along the vaccine value chain. This requires the capacity, partnerships, and networks that have underpinned the Alliance over the last two decades. Gavi's set-up as an alliance of partners enables it to coordinate across a wide range of stakeholders with end-to-end expertise toward a common goal. Gavi has a long-standing track-record in shaping healthy markets for immunisation products making life-saving vaccines more accessible and affordable for lower-income countries. Finally, Gavi has built a strong track record of mobilising funding including through innovative, at-risk mechanisms for immunisation such as the COVAX AMC 92 or the Pandemic Vaccine Pool (PVP); and more generally by its ability to innovate and take risks as demonstrated by at-risk purchase agreements with vaccine manufacturers. The Alliance has proven to be a global leader in all these dimensions and an important player in closing gaps in PPR architecture as related to vaccines and immunisation, building on its unique role and comparative advantage.

- 4.2 Gavi has a unique opportunity to build on its significant experience in outbreak, epidemic and pandemic response, using learnings from the COVID-19 pandemic, the experience of setting up and running COVAX, and the Alliance's comparative advantage to enhance its engagement in PPR in targeted ways. Based on the guidance provided by the Board in June 2022, ongoing learning related to COVAX's journey and experiences, early findings from COVID-19 response evaluations, and consultations with the Board and PPC over the summer, Gavi has been exploring four areas for targeted additional roles to close PPR gaps:
 - a) Required capabilities for next pandemic: Retaining and enhancing essential capabilities, including organisational and process capabilities, to support equitable and timely access to vaccines and their delivery in the next pandemic as well as to protect routine immunisation;
 - b) **Financial innovation:** As one of the key capabilities, providing rapid access to at-risk funding for pandemic vaccines, building on innovative financial mechanisms such as the Pandemic Vaccine Pool:
 - c) Resilient routine immunisation programmes: Supporting select, targeted additional investments in routine immunisation programmes, building on the very large existing investments (see 2.1), to strengthen pandemic preparedness and response in areas with proven impact and a comparative advantage of the Alliance, namely the modernisation and scale-up of information systems for immunisation (e.g., by scaling up integrated e-HMIS systems for real time monitoring); and
 - d) **Market shaping:** Supporting diversification of regional manufacturing particularly in Africa given Gavi's experience and comparative advantage in market shaping.

- 4.3 The following section describes Gavi's potential targeted additional roles across areas a, b, and c. Gavi's approach to supporting regional manufacturing is described in document 05.
- 4.4 Area a: Required capabilities for the next pandemic: The PPC requested Gavi map Alliance capabilities and gaps in the context of the broader ecosystem to inform its future engagement in PPR. The next step based on the mapping, presented during the Gavi 5.1 deep dive sessions and summarised in the document, is a cohesive plan to improve critical path capabilities and fill gaps, including on the potential need to augment Alliance partner resources, where appropriate. These critical areas to be included in an Alliance-wide plan are i) earlier access to vaccines; ii) earlier and stronger delivery support to countries; and iii) clearer processes and more rapid, flexible decision-making. The initial strokes are as follows:
 - i. Early access to vaccines: Gavi proposes to develop capabilities to ensure earlier and more equitable access to vaccines in the next pandemic and reduce risks to supply. For instance, the Alliance could pre-align on risk appetite for different pandemic scenarios and mobilise contingent at-risk funding to allow earlier advance purchasing agreements with vaccine manufacturers. Developing such capability would require the Secretariat to design a financial instrument to mobilise early contingent and at-risk funding for pandemic response (see section 4.4). Beyond funding, the Alliance can work more proactively with donors, R&D organisations and manufacturers to secure earlier access to doses. As an example, the Alliance could better coordinate its pull funding with R&D organisations and donors providing push funding, aligning vaccines procurement terms with push funders' to move more rapidly from the discovery of suitable pandemic vaccines candidates to procured appropriate vaccines. This could be operationalised by further strengthening the Alliance's relationships with R&D organisations building off the work with CEPI, already a COVAX partner. In addition, the Secretariat could build on lessons from the COVID-19 APA negotiations and dose donation mechanism, and work with high-income countries and manufacturers to turn commitments on equitable vaccine access into concrete interventions for early access and dose donations for future pandemics.
 - ii. Earlier and stronger delivery support to countries: Key learnings from the pandemic and CoVDP include the need for greater role clarity between the Alliance and other actors in the global health space (e.g. development banks), the capacity to mobilise delivery funding early on, the ability to provide access to mobilised funding to countries rapidly while ensuring quality country plans, and the need for strong coordination, advocacy and accountability mechanisms across global, regional, and country levels. In the established Alliance model, the Secretariat is the main funder, coordinates allocation and provides oversight. The availability of delivery funding for immunisation from multiple sources (e.g., World Bank, WHO, UNICEF, Gavi Secretariat) caused some confusion and impeded efficient

and effective fund raising, funding allocation and implementation. This was partially mitigated later in the pandemic through the CoVDP, which brought an important spotlight and focus to the delivery work, while also adding an additional layer of coordination across Alliance partners and countries. It also became apparent that delivery approaches should ensure that the Alliance's routine immunisation investments are protected from the start delivery support should also take a medium-longer term implementation perspective as countries move out of the acute phase of the pandemic. Building on these learnings, Gavi Secretariat should strengthen its coordination and advocacy capabilities to ensure agile mobilisation of delivery funding from the start, more rapid delivery support to countries and uptake in next pandemic, avoiding the need for additional layers of coordination and complexity, and protecting its RI investments. To do so, building on the Alliance model and each partners' comparative advantage, the Secretariat would mobilise funding, ensure rapid allocation of funding and technical assistance based on country needs and accountability for use of funds, with strong collaboration with key partners in the response, including regional bodies (i.e., AU, Africa CDC, PAHO). WHO, UNICEF and other context appropriate partners (e.g., NGOs, local CSOs, private sector partners) would provide agile in-country technical support as well as technical coordination within the Alliance and between partners at global and regional level.

- iii. Clearer process and more rapid, flexible decision making: The lack of pre-established business processes and roles, clearly defined stage gates for decision making during the pandemic, and agile decision-making structures slowed down the response to the pandemic at the onset. Going forward, the Alliance could take steps to remedy this situation. For instance, Gavi Secretariat is considering how to develop internal enablers to surge capacity, and other learnings from COVAX on policy and processes to more quickly respond in the event of a pandemic. It will be critical to align with Alliance partners to address gaps in coordination for a more efficient response. As an example, building a common understanding of when and how to respond to different pandemic scenarios (stage-gate), as well as of roles and responsibilities of Alliance partners in pandemic response would enable a more rapid, systematic end-to-end response. In addition, the Secretariat should retain and enhance contractual enablers. It could review, and where appropriate, improve contractual enablers such as Indemnity and Liability agreements, or Memorandum of Understandings with countries, partners and vaccine manufacturers.
- 4.4 Area b: Financial innovation: Whilst it is not possible to predict the course of the next pandemic, there is mounting evidence that early at-risk funding to support access to vaccines for LICs and LMICs will be required to form some part of the response⁴. A recent IMF working paper on finance and vaccine equity found that 60-75% of the delay in COVID-19 vaccine deliveries to low- and middle-income countries was attributable to their signing purchase

agreements later than high-income countries, which placed them further behind in the delivery line. Such pandemic response is likely to require substantial finance at scale, very early on, delivered through robust and innovative financial mechanisms to help ensure equitable access to vaccines. This requires an organisation equipped to rapidly adapt existing structures to the nature of the pandemic.

In that context, building on its experience of innovative financing mechanisms and on the Pandemic Vaccine Pool, the Gavi Secretariat has a role to play in complementarity with other instruments such as the World Bank Pandemic Fund. Today, Gavi's Pandemic Vaccine Pool is an innovative financial response mechanism to manage further COVID-19 risks, for instance by providing up-front cash to secure doses in the event of a reactive scenario. In the future and pending discussions with donors, the Pandemic Vaccine Pool could potentially integrate contingent funding mechanisms, that allow rapid access to funds for equitable access to pandemic vaccines, thanks to its experience with IFFIm and potentially through partnerships with the European Investment Bank and the Development Finance Corporation. This instrument could be used to prepone at-risk funding for the procurement of pandemic vaccines, but also for early country delivery support and technical assistance.

- 4.5. Area c: Resilient routine immunisation programmes: Gavi would continue its core investments into RI through its HSS and PEF support that already facilitate the prevention and response to pandemics, epidemics and outbreaks (see 2.1). Building on Board and PPC guidance, the Alliance could carefully expand select investments in the modernisation and scale-up of information systems, an area identified as a key gap and where the Alliance has a strong comparative advantage. Lessons from COVID-19 highlight that the absence of resilient information systems in lower-income countries delayed the speed and quality of the response to the pandemic. The lack of resilient electronic information systems hampered the detection of COVID-19 cases at the onset of the pandemic, the dynamic monitoring of vaccine stock levels, service delivery activities and vaccination coverage among other. The pandemic also demonstrated the Alliance's comparative advantage in this area. For example, it was able to leverage its existing investments to scale-up pandemic response with more than 40 countries repurposing existing WHO-DHIS2 surveillance modules to monitor COVID-19 cases within a couple of weeks. This was enabled be the Alliance's investments into digital health information over the past six years, with an estimated USD \$360 million invested during Gavi 4.0 to increase data availability and use in countries.
- 4.6. Given the gaps identified, the Alliance's COVID-19 experience, and existing Alliance investments in information systems, Gavi could **expand its investments in three priority areas within information systems:**
 - Electronic health management information systems (e-HMIS) for realtime monitoring for pandemic response (e.g., enabling weekly coverage

reporting, extending reporting to new vaccination points, and improving data triangulation and use at sub-national level). This would also benefit routine programmes;

- Digital supply chains including the scaling up of electronic logistics management information systems (e-LMIS) to reinforce facilities' visibility on stock of vaccines, maximise efficient usage of limited vaccine stock and as a prerequisite for implementing track and trace innovations in countries (e.g., bar coding); and
- Amplifying support to adapt WHO COVID-19 DHIS2 surveillance modules for other vaccine preventable diseases as Gavi funded the development and roll out of DHIS2 immunisation modules, and by ensuring the interoperability between laboratory and national systems.
- 4.7. The total cost of these additional efforts is estimated at US\$ 40 million for 2024-2025, of which approximately US\$ 20 million would help to accelerate the scale-up of e-HMIS and DHIS2 investments in 20 countries; and approximately US\$ 20 million to accelerate eLMIS investment in 15 countries, and test barcoding at scale in three countries. There is also the potential need to augment Alliance partner resources around critical path capabilities pending further development of an Alliance-wide response plan. Pending availability of funding and discussion with COVAX donors, the source of funding could be the COVAX funding envelope starting in 2024.