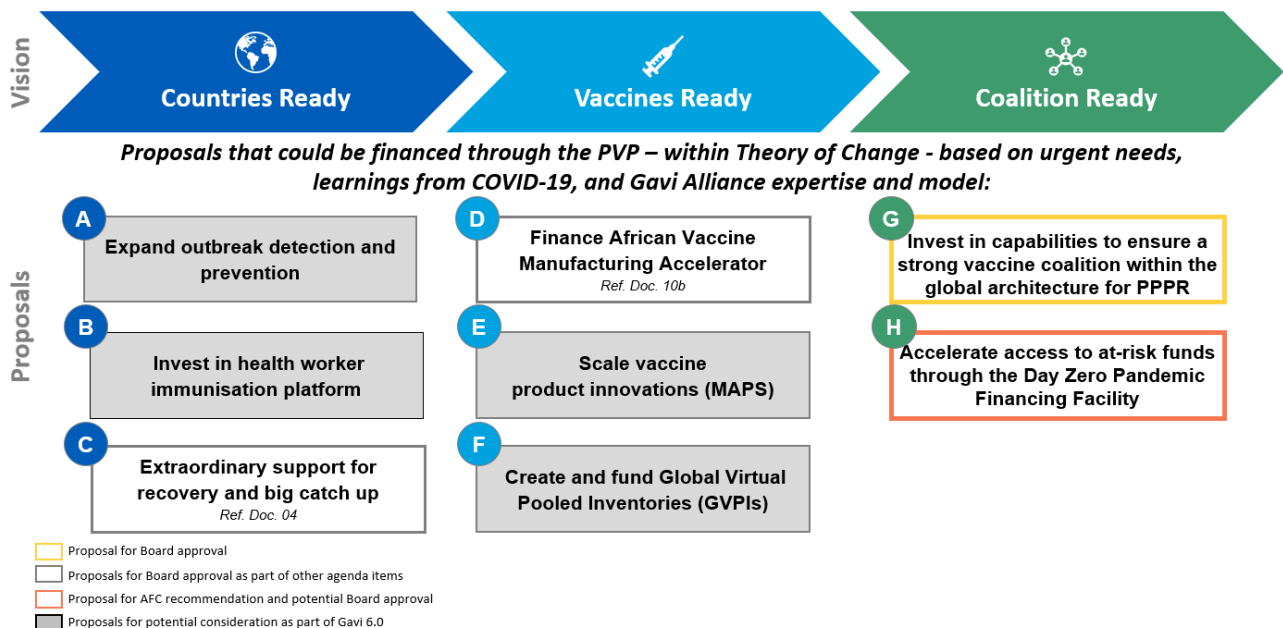


Annex A: Investment Proposals

As requested by the Board in June 2023, the Secretariat is proposing investments to advance the approach to pandemic prevention, preparedness, and response (PPPR), building on the Alliance’s expertise and historic contribution to PPPR. These investments cover a spectrum of public health events (PHEs) to strengthen the Gavi Alliance’s approach to outbreaks, epidemics, and pandemics and demonstrate the Alliance’s critical role in preventing, preparing for, and responding to PHEs. These proposals align with the PPPR priority areas for the Gavi 5.1 strategy and support the ambition of ‘Country Ready’, ‘Vaccines Ready’ and ‘Coalition Ready’, as illustrated in Figure 1 below.

Six proposals were presented to the COVAX AMC Investors Group for funding consideration using COVAX AMC PVP funding. They consider current grant agreements and possibilities for reprogramming, relate to preparing and responding to COVID-19 and future health emergencies, and were developed in full consideration of enhanced collaboration with other pandemic recovery and pandemic prevention, preparedness, and response initiatives.

Figure 1: Proposals in support of the Countries Ready, Vaccines Ready, Coalition Ready ambition



Of the six proposals presented, three proposals aligned with funding terms for the COVAX AMC PVP and were subsequently considered by the PPC. At its meeting in October 2023, the PPC considered proposals B and G (Figure 1) for Board recommendation and proposal H for guidance. It recommended one (G) for Board approval. The other proposals which do not meet funding criteria for COVAX AMC PVP funds and/or the PPC chose not to recommend at this time, are presented for Board awareness and transparency and may be considered for Gavi 6.0. PPPR is a critical area under consideration for Gavi 6.0, and these proposals do not constitute the full extent of the future ambition.

Part I: Proposals to support coalition readiness

The following proposals aim to support Gavi's contribution to coalition readiness as part of its PPPR approach through a coalition of financed global, regional, and local vaccine partners equipped with the right capabilities and capacities and prepared with a clear plan and resources to respond on Day Zero, based on lessons from COVID-19 and other outbreaks.

1. **Capabilities to contribute towards a strong, functioning coalition of vaccine partners for PPPR across the “Ready Countries, Ready Vaccines, Ready Coalition” vision**
 - 1.1 **Context and problem statement:** **The COVID-19 pandemic and other recent outbreaks, including mpox and Ebola Sudan, demonstrate persistent gaps in the PPPR ecosystem for equitable and timely access to vaccines for low- and middle-income countries, gaps in country preparedness for such vaccine rollout, and the need for clear coordination across all partners.** These events also highlighted the importance of inclusive, strategic partner planning and coordination of resourced networks across geographies and sectors – public, private, civil society, industry – and along the value chain to prepare and respond to PHEs.
 - 1.2 **Lessons from the COVID-19 response, including COVAX and the COVID-19 Vaccine Delivery Partnership, Africa Vaccine Acquisition Task Team, and the Access to COVID-19 Tools Accelerator (ACT-A) showed a need for an intentional effort to increase inclusivity and coordination, encompassing a wide range of communities and stakeholders extending beyond existing Alliance partners.** There is a time-sensitive opportunity to build on these lessons to sustain the momentum of strengthening global health security on the heels of the COVID-19 pandemic and to prepare for the next, which can come at any time.
 - 1.3 **Proposed solution:** This proposal recognises the important work underway through the Intergovernmental Negotiating Body to establish the Pandemic Accord and is intended to contribute towards and not preempt the deliberations on the structures for future pandemic response. **It proposes to contribute towards an expanded, resourced, and functional coalition of vaccine partners, within and beyond the Gavi Alliance, for PPPR that considers prevention, preparedness and response activities.** The Gavi Alliance, leveraging its networks from routine and outbreak immunisation programs, experience from COVAX, and ongoing work with partners through mechanisms and partnerships, including but not limited to, the working group XVAX, WHO R&D Blueprint, the Medical Countermeasures Delivery Platform and others, is well-positioned to act now to address and support the PPPR needs of Gavi-eligible countries.
 - 1.4 Beyond the importance of strengthening partnerships for future pandemics, a coalition of vaccine partners enables better coordination and stronger support of prevention, preparedness and responses to epidemics and outbreaks as they occur, working to prevent them from escalating into more severe and widespread PHEs. These efforts would also link to and leverage, as

appropriate, the support to countries to increase the resilience of their immunisation and health systems, which helps to strengthen both routine immunisation as well as response to outbreaks, epidemics, and pandemics.

1.5 Key activities: The proposed investment, working through existing mechanisms and partnerships, would fund the Secretariat to:

- Make resources available **to support approximately 15 focal points across key partner and regional organisations** to ensure dedicated capacity to advance priorities collectively defined across involved partners, including the identification and filling of gaps to advance PPPR initiatives across Gavi-supported countries and to launch and implement responses per agreed plans between partners. In this way, the network would be “always on”—coordinating preparedness activities and plans and ready to pivot to respond to PHEs as they emerge.
- One key deliverable to guide response would be a cross-partner *PPPR Playbook for Operational Capabilities*, which would outline potential capabilities and ways of working needed to prepare for and implement a rapid, effective and equitable response. The Playbook could include, for instance, sections on research, development and manufacturing, contracting vaccines, dose sharing, access for humanitarian contexts, equitable dose allocation, day zero delivery support for countries. Issues being debated through the Pandemic Accord, such as intellectual property and technology transfer, would not be included in the Playbook until the negotiations have concluded. The focal points’ deep understanding of how their own and the other organisations work, the nature and scale of support that they may provide to respond to PHEs and intimate knowledge of tools and decision-making pathways would be utilised and are central to triggering any surge plans as required. Importantly, Gavi does not aim to supplant governance and decision-making of individual partners; each organisation would retain their own governance and decision-making processes.
- **Support convenings, through existing mechanisms and partnerships, of broad sets of partners including CSOs and regional bodies towards increased coordination and transparency** across outbreaks, epidemics, and pandemics, as well as synergies between vaccines and other medical countermeasures. Incorporating diverse views into the development of plans is a key lesson from the COVAX experience and one which the Secretariat recognises will be critical to strengthen response in the future. Via greater intelligence sharing, but also greater understanding of how each partner determines the scale and nature of their response to outbreaks and deeper appreciation for key respective strengths, opportunities to enhance response effectiveness and efficiencies will be actively pursued. Networked partners can also provide a united voice and vision for vaccines as part of any future global response.
- Working through existing mechanisms and partnerships, **develop robust, coordinated PPPR plans and strategies** across the vaccine value chain among key organisations to ensure rapid, coordinated response. While

each pandemic will be different, this planning will enable a faster and more effective response through pre-established blueprints with initial solutions to previous pain points, and the familiarity of the coalition partners established with each other will enable agility and help minimise bottlenecks and complexity. Importantly, these plans and strategies will be living documents, evolving in nature, and fully open to further refinement and changes as the interim Medical Countermeasures Network discussions advance.

- **Create a living PPPR global repository of resources**, such as case studies, organisational reports, evaluations and learnings from experiences, to drive continuous learning across outbreaks, epidemics, and pandemics via after-action reviews across partners and diverse stakeholders, monitoring, evaluation and learning efforts and reflections to continue refining and strengthening PPPR. Global, regional, and country access and use is a priority and could be enabled through innovative and digitally-enabled approaches for capturing, synthesising, and communicating collected learnings.

1.6 **The work to build a strong coalition with a broad set of vaccine partners will benefit not just PPPR but also core Gavi programmes.** For example, expanding and bridging the global health and humanitarian communities will bring benefits to both humanitarian access challenges in future PPPR as well as Gavi’s ongoing work in fragile, conflict and emergency settings.

1.7 **Financial envelope: The PPC recommends a total financial envelope of US\$ 22 million** to be operationalised through Secretariat operational expenses for the coalition of vaccine partners, as outlined in Table 1 below.

Table 1: Total cost, US\$, millions

	Gavi 5.1	Gavi 6.0	Total
Operational Cost (Including PEF Operational)	9.022	12.877	21.899
Total	9.022	12.877	21.899

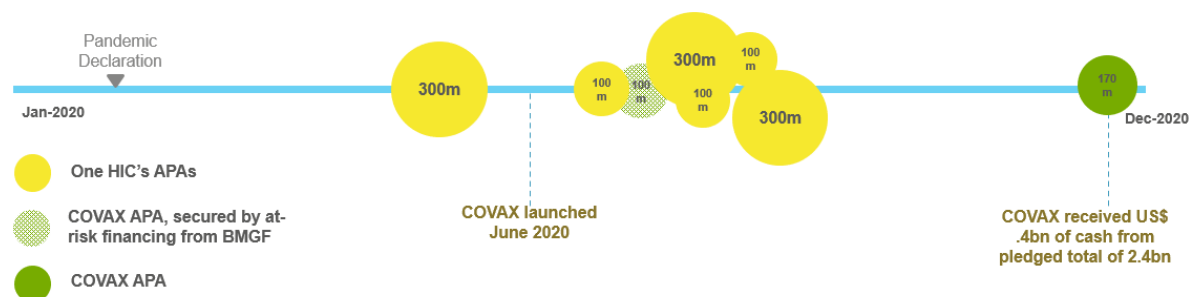
2. First Response Fund for the Day Zero Financing Facility for Pandemics

2.1 **Problem statement: The G7 and G20 have highlighted that delayed access to financing was a significant contributing factor to inequitable vaccine access during the COVID-19 pandemic.** The August 2023 G20 Joint Finance and Health Task Force report *Mapping Pandemic Response Financing Options and Gaps* noted: “At-risk financing made available at day zero is critical to enabling more equitable access to medical countermeasures (MCMs) for pandemic response”, and that there is a priority need to “optimize existing response financing for speed, coordination, and at-risk” capabilities, including by adapting existing tools that funded COVID-19 response.

2.2 **This is also a key learning from Gavi’s administration of the COVAX Facility. It took several months to mobilise financial pledges for COVAX,**

and then only US\$ 400 million of US\$ 2.4 billion pledged in 2020 was paid by the end of that year. This created the twin challenges of low financial headroom and low liquidity that limited the extent to which Gavi could act quickly in the market to secure vaccine access for AMC countries. High-income countries (HICs) were able to enter into advance purchase agreements (APAs) in the first two months after the PHEIC declaration, while it took more than nine months for Gavi (COVAX) to have its own resources to do so (Figure 2). HICs also used superior liquidity and risk-tolerance to rapidly secure a more diversified portfolio. In terms of public health impact, recent analysis suggests more than 50% of deaths in some lower income countries could have been averted had vaccine inequities been mitigated during the initial months of COVID-19 vaccine distribution and administration. Flexible, early and at-risk financing in the first 100 days is critical to equitable pandemic response.

Figure 2: 7 Months from COVAX Launch to US\$ 400 million in Cash Receipts



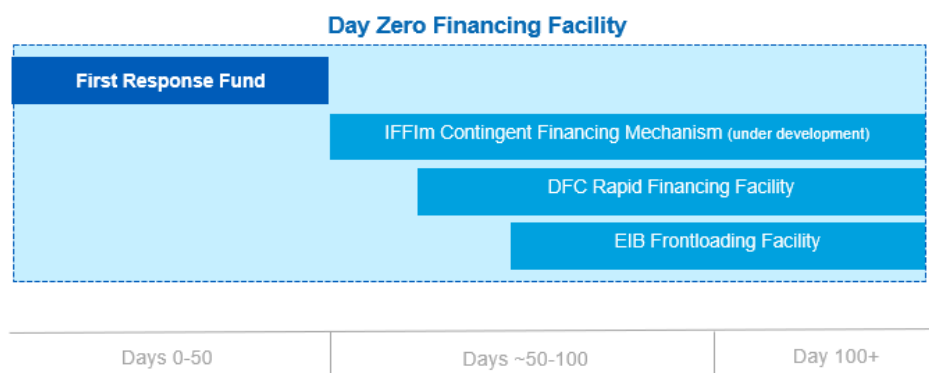
Note: Figures in each circle and the size of circle represent the volume of doses secured with each APA. It covers publicly announced doses for one HIC's APA. It may not cover every APA made during the given period.

- 2.3 **During COVID-19, Gavi was at the forefront of developing innovative solutions to secure earlier access to vaccine financing.** The Secretariat worked closely with new development finance institution (DFI) partners to develop a suite of financing tools to build Gavi's response financing capacity. This included the European Investment Bank's (EIB) Frontloading Facility and the U.S. Development Finance Corporation's (DFC) Rapid Financing Facility, both of which were developed for COVAX. Additionally, close to US\$ 1 billion in financing was frontloaded for COVID-19 response through IFFIm, Gavi's longstanding innovative financing vehicle that offers valuable funding flexibility. Gavi's role as a partner to DFIs and as an innovator in pandemic response financing tools has been recognised by both the recent G20 mapping, and through the new G7 DFI Collaboration Framework for Health Emergencies, which featured several instruments pioneered by Gavi.
- 2.4 **Proposed solution: Gavi is preparing now to meet the need for faster response in the next pandemic in two ways: (1) by creating a new First Response Fund that will enable funds to be deployed faster than any other mechanism in Gavi's PPPR toolkit, and (2) by expanding the use and effectiveness of existing frontloading mechanisms so that they can be used beyond COVID-19.** The DZF is a suite of financing instruments that will enable the Alliance to deliver a rapid and more equitable end-to-end vaccine

response in the next pandemic. Existing surge financing tools (including an adapted EIB Frontloading Facility and DFC Rapid Financing Facility, and the under-development IFFIm Contingent Financing Mechanism) are in the process of being amended so that they will be able to provide liquidity for the next pandemic, at least for the remainder of Gavi 5.1 and Gavi 6.0.

- 2.5 **The First Response Fund will enable faster deployment than any other mechanism in the Day Zero Financing Facility, bridging 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. It is unique in enabling access within the first 50 days of a pandemic, as Gavi's other surge financing mechanisms are expected to require at least this amount of time to either mobilise the collateral required to release financing, in the form of new publicly announced pledges or signed grants, or to activate contingent grants. By contrast, the First Response Fund will have funds that can be deployed from the moment Gavi approves a response. Such funds are needed in part because they will help Gavi secure vaccines faster and in larger quantities for lower income countries compared to what occurred during the COVID-19 pandemic. In addition to entering into APAs within the first 50 days, the funding could also be used to support other critical first response activities, including early vaccine demand generation and delivery, protection of routine immunisation, or fast-tracking manufacture of promising vaccines. Additionally, the DZF could fund early R&D and synergies with other global health organisations, as was done during the COVID-19 response with CEPI. Access to the First Response Fund, as well as the other instruments in the DZF, would be subject to standard Gavi governance processes.

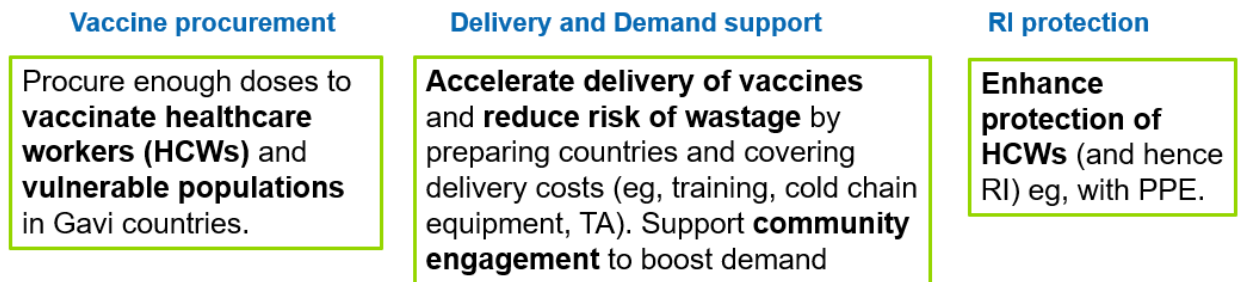
Figure 3: Access to Financing Within the First 50 Days



- 2.6 **Key activities: The Secretariat seeks to establish a First Response Fund of up to US\$ 500 million, under Gavi's Day Zero Financing Facility for Pandemics, contingent on the available funding from the COVAX AMC PVP.** This will allow the First Response Fund to function as a longer-term mechanism that can respond to COVID-19 variants of concern as well as other pandemics that may arise in the future. This amount is based on costs that Gavi reasonably expects to commit within the first 50 days of a pandemic. Based on

the experience with COVID-19, the Secretariat has estimated that up to US\$ 2 billion will be needed to vaccinate healthcare workers and vulnerable populations, accelerate delivery support, and enhance protection of routine immunisation. This response would also include surge workforce capacity to minimise impact on core business. Learning from COVID-19, cash in hand at the start of the pandemic will strengthen Gavi's ability to deliver an equitable vaccine response to affected countries.

Figure 4: Funding Needs During the First 100 Days of a Pandemic



- 2.7 Any approvals required to release funds for the programmatic utilisation of the First Response Fund will be brought back to the Gavi Board through the relevant Board Committees, following standard Gavi governance processes. The Board will be the ultimate governance body for the fund.
- 2.8 **The PPC provided guidance on the proposal to extend the use of PVP funds to create a First Response Fund for the Day Zero Financing Facility at its meeting in October 2023.** The PPC 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 several programmatic considerations including the governance arrangements and triggers for use of the funds, the duration for which funds will be available, and the potential use of funds outside of pandemics, for example in multi-country outbreaks. The Gavi Audit and Finance Committee will review the funding and risk implications of the instrument at its meeting on 4 December 2023 at which it will be asked to consider making a recommendation to the Gavi Board at this meeting.
- 2.9 **Proposals to further leverage the First Response Fund will continue to be developed post-Board approval.** Early discussions have started with several G7 DFIs to develop proposals that can deliver leverage on the First Response Fund. Any such proposals that would involve increased financial risk to Gavi would be brought back to the AFC at the appropriate time, in line with the Delegation of Authority (DOA) policy. The initial focus has been on two proposals identified in the September 2023 G7 DFIs' report, Advancing DFI Financing for a More Equitable Response to Health Emergencies: (1) providing early access to liquidity facilities for donor-financed procurement (such as early access to Gavi's existing DFC and EIB surge financing facilities); and (2) providing additional capital for Low Income Country (LIC) and Middle Income Country (MIC) surge vaccine manufacturing at the onset of a pandemic.

- 2.10 The First Response Fund and broader DZF align with the G20's recent "mapping pandemic response financing and identifying gaps" report and recommendation to capitalise and further optimise innovative financing tools developed under COVID-19.
- 2.11 Financial Envelope: The Secretariat seeks to establish a First Response Fund of up to US\$ 500 million, under Gavi's Day Zero Financing Facility for Pandemics, pending AFC recommendation and contingent on the available funding from the COVAX AMC PVP.

Part II: Proposals for Board information

The Secretariat presented the following proposals to the COVAX AMC Investors Group. The COVAX AMC Investors Group supported the proposal for the Health Worker Immunisation Platform (Section 3), but the PPC had concerns about the timing aligned to the VIS 2024 and did not recommend it for Board approval. Despite general support for the proposals in Sections 4, 5, and 6, legal constraints on the use of the COVAX AMC PVP funds result in the inability to fund these proposals. All four of these proposals can be considered alongside other future potential investments for Gavi's 6.0 PPPR approach as part of Gavi 6.0 strategy development.

3. Health Worker Immunisation Platform

- 3.1 The proposed health worker immunisation platform detailed below would support a health system better able to pivot to respond to outbreaks with a trained and vaccinated health workforce. While many PPC members supported the proposed programme, some had questions about how it relates to the health worker immunisation touchpoint proposed as part of VIS 2024 with concerns that it preempts a decision for Gavi to expand into adult vaccination and a life course approach. The PPC opted not to recommend it for Board approval at this time.
- 3.2 Context and problem statement: **Healthy health workers are essential to Gavi's vaccine, equity, sustainability, and healthy market goals.** During COVID-19 health services were interrupted due in part to health workers becoming ill and unable to work. Protecting health workers reduces absence due to illness, meaning more health workers are available to deliver services, including reaching zero-dose children and underserved communities. Health workers will also be on the frontline for responding to any future outbreak, epidemic or pandemic. Currently, very few Gavi-eligible countries have health worker immunisation programmes, and Gavi support could address challenges in developing health worker vaccination platforms.
- 3.3 Strengthening and supporting health workforce vaccination, as well as broader upskilling and development, promotes gender equity as about 70% of health workers are female. In addition, anecdotal evidence suggests that countries with a health worker seasonal influenza immunisation programme achieved higher COVID-19 coverage. This likely led to lower absenteeism, more active and engaged workers, and a health system better staffed and able to respond to pandemics and outbreaks. Vaccinated front line health workers including community health workers are ideally placed to address individual and

community concerns about vaccine safety and potentially increase vaccine demand.

- 3.4 **Proposed Solution: The Secretariat proposes to establish or expand existing health worker immunisation platforms and complementary health workforce development efforts in three to six countries to learn how Gavi can best support countries to prepare for, implement, monitor, evaluate and improve their health worker immunisation platforms and broader health workforce programmes.** This support would leverage and help maintain prior investments, including those made during the COVID-19 pandemic that may have been established to reach health workers.
- 3.5 **Health worker platforms are likely to be critical for future PPPR – as such, this investment will generate much needed additional evidence, grounded in a sample of country experiences towards future PPPR efforts.**
- 3.6 **Notably, this investment also aims to foster learning that extends beyond the vaccination of health workers.** It encompasses a broader spectrum of initiatives, including – to the extent feasible – upskilling health workers, with particular emphasis on community health workers, introducing innovative learning methods, optimising utilisation of digital technologies, and enhancing foundational aspects of health information systems, such as health worker registries. Improved registries have the potential to improve recruitment, retention, tracking and performance of health workers at all levels. With new knowledge and skills, community health workers can plan, implement, and manage health worker immunisation at tertiary health facilities, expanding access to hard-to-reach communities and increasing the number of vaccinators available in a future pandemic.
- 3.7 **Vaccine Selection: The 2022 WHO Implementation Guide for Vaccination of Health Workers identifies eleven vaccine-preventable diseases to which health workers should be immune. The highest priority vaccines were identified based on high expected health impact and demand by Gavi-supported countries; SAGE-recommended and WHO-prequalified vaccines currently available or likely to be available by 2030; and consideration of Gavi’s key strengths. COVID-19, seasonal influenza, and hepatitis B vaccines are the highest priority.** COVID-19 was approved by the Gavi Board in June 2023 for the highest priority populations as defined by SAGE, including health care workers. Seasonal influenza and hepatitis B for health workers will be considered as part of VIS 2024 for inclusion in Gavi’s vaccine portfolio. Gavi would work with participating countries to define which vaccines would be part of the health worker immunisation platform. If a participating country experiences an outbreak of Ebola or cholera, the platform could expand vaccination for these antigens accordingly.
- 3.8 **Key Activities: In addition to vaccine support, the Secretariat would also provide additional health systems strengthening support and work with implementing partners to provide technical and operational support.** The Secretariat would maximise the utility and benefits of these increased touchpoints with health workers to upskill health workers, particularly community health workers, in vaccination programme planning, implementation

and management through accelerated deployment of innovative, digitally enabled learning and training and other available technologies, and significantly strengthen health worker registration. Where feasible, the Alliance will also use this opportunity to address broader constraints to a strong community health workforce (e.g. policy, coordination) in alignment with efforts of the Community Health Development Partnership, recently launched under the leadership of UNICEF and USAID.

- 3.9 Country selection criteria: **Four criteria will be taken into consideration in country selection**: geography (WHO region), size as measured by the number of health workers; Gavi eligibility phase; and presence of an existing and active health worker vaccination programme that includes at least one vaccine in addition to COVID-19 vaccine. The Secretariat is planning for up to two small, two mid-size, and two large countries but country size and number included in the final design could be reduced.
- 3.10 Timeline: **This work will be conducted over four years, with yearly reports with recommendations for improvements and a final report**. By the end of the first quarter of 2024, countries and implementing partners will be identified. By the end of 2024, preparatory work will progress with the goal of completing national-level policies, recommendations, and regulations so that beginning in 2025, all participating countries can initiate health worker immunisation platforms along with other parallel efforts, including expanded training and capacity building. By the end of 2027, all selected countries will deliver vaccines to all health workers nationally through health worker immunisation platforms.
- 3.11 Integration with other programmes and global initiatives: **Effective, sustainable health worker immunisation platforms integrated into existing health systems support Gavi 5.1 strategic goals** and global initiatives to strengthen PPPR, including the WHO I-MCM-N and the World Bank Pandemic Fund. The funding for this proposal would allow Gavi to potentially access another 18% of complementary funding during the second-round proposals for the Pandemic Fund, for which the Secretariat seeks to make a joint application to help expand the impact of this proposal.
- 3.12 Key Partners: Based on discussions to date and recommendations from various stakeholders consulted, implementing partners will include host governments, WHO, UNICEF, local Civil Society Organisations (CSOs), and other stakeholders with relevant experience. Initial discussions with partners have resulted in a draft implementation project.

4. Expand outbreak detection, prevention, and response

- 4.1 Context and problem statement: **The COVID-19 global response showed gaps in country capacities and systems to detect outbreaks, make informed decisions, and implement timely response activities to save lives**. Many investments in human resources, systems innovations and technologies responsive to the COVID-19 pandemic were temporary stop-gap measures but reflect capacities and advancements that should be institutionalised and strengthened to ensure countries and global support systems are better prepared for future responses. In 2022 alone there were 40

outbreaks across Gavi-supported countries that required global reactive vaccination campaigns.

4.2 **Proposed solution: This proposal aims to increase the impact of Gavi’s investments to combat high-impact epidemic prone diseases and improve preparedness to quickly detect and react to future pandemic threats by expanding support for timely detection and decision-making and supporting countries to rapidly implement outbreak response activities.**

4.3 **Key activities:**

- **Strengthening outbreak detection** by expanding access to “gold-standard” testing for earlier detection to prevent outbreaks from spreading and disrupting RI and other health services and diverting resources from existing programmes for outbreak response. This would include increased access to multiplex diagnostics for viral haemorrhagic fevers and acute febrile illnesses and expediting validation and access to innovative PCR bacteriology tests for Typhoid.
- **Enhancing outbreak intelligence for rapid decision-making** by consolidating digital microplanning, geospatial and real-time monitoring into one system that countries can use to plan, implement, and monitor campaigns to ensure coverage and reduce gaps that could lead to future outbreaks. The system would build on existing systems that were developed quickly during COVID-19 but could be used for both reactive and preventative campaigns.
- **Timely vaccination campaigns for outbreak response** by establishing an outbreak response reserve to provide rapid funding to countries experiencing outbreaks and extend the roster of technical assistance providers to additional partners to fill critical gaps to ensure a timely response.
- **Rapid access to vaccines for outbreak response** by creating national buffers of select vaccine stocks where risk of outbreak is assessed as high and risk of wastage is low to be able to quickly respond in the event of an outbreak. It would also support accelerating country registration of vaccines used for outbreak response but not RI, i.e. Ebola and cholera, in AFRO and EMRO via strengthened norms and processes.

4.4 **These activities build on existing foundations and COVID-19 investments and learnings and are complementary to existing support.** It would benefit both existing Gavi programmes and Gavi’s approach to PPPR by supporting prevention activities, quickly detect and respond to outbreaks of vaccine-preventable diseases, protect other health investments and RI, and save lives.

5. **Advance purchase commitment for Measles-Rubella Microarray Patches and capabilities for future outbreak response**

5.1 **Context and problem statement: The COVID-19 pandemic exposed challenges associated with rapidly transporting, storing, and administering traditional vaccines and syringes at scale – particularly with the advent of mRNA vaccines that require ultra-cold chain.** Microarray

patches (MAPs) are an innovative vaccine delivery technology that are more stable at non-refrigerated temperatures, lighter to transport, and easier and safer to administer than traditional vaccines. MAPs can therefore be easily administered by community health workers including in settings with limited health infrastructure, removing the need to set up complex logistics and delivery structures in difficult-to-reach areas in the midst of a pandemic. As they do not require syringes and vials, MAPs will simplify and reduce waste management and avoid the challenges faced during COVID-19 related to competition for manufacturing capacity and materials. This technology could be transformational in a pandemic where rapid and widespread access to vaccines is essential, as well as for addressing hard-to-reach populations including Zero-Dose Children and preventing routine backsliding.

- 5.2 While MAPs have been in various stages of early development for many years, a critical milestone was recently reached with the first clinical proof-of-concept demonstrated in May 2023 in infants in The Gambia, using a Measles and Rubella MAPs (MR-MAPs). However, demand uncertainties mean that no commercial partner has yet committed to late-stage development or to bringing this technology to market. **As the most advanced vaccine-MAP product, a licensed MR-MAP will be the breakthrough that paves the way for other vaccines to be used on MAPs, including antigens with outbreak and pandemic potential** and will be critical to building a commercially sustainable “routine” MAPs industry which can then rapidly pivot to producing MAPs for pandemic pathogens.
- 5.3 **The launch of MR-MAPs in lower-income countries will increase coverage and expand reach to hard-to-reach populations such as Zero-Dose Children, reducing the risk of measles and rubella outbreaks.** It is estimated that an additional 80-110 million children could be immunised between 2030 and 2040 through the use of MR-MAPs, averting up to 37 million measles infections and up to 397,000 measles-related deaths.
- 5.4 Proposed solution: **The Secretariat proposes to design and launch an Advance Purchase Commitment (APC) by 2025 to incentivise and accelerate the development of MR-MAPs** to: i) ensure availability of a first vaccine-MAP in LMICs by 2030; and ii) ensure the capabilities for vaccine-MAPs development and manufacturing are established and ready to serve future outbreak responses. The APC will help to de-risk manufacturer investments in MAPs and accelerate their availability by several years to 2030.
- 5.5 Key activities: Together with partners, Gavi will:
- Develop a detailed investment case for the APC mechanism, building on existing work with partners and Gavi’s extensive experience designing similar mechanisms.
 - Provide upfront funding to support a limited number of commercial partners to accelerate late-stage development of a MAPs product, based on a signed agreement and contingent upon certain conditions being met;
 - Procure licensed MR-MAPs that meet the pre-defined criteria that make it suitable for use in Gavi-funded programs.

- 5.6 Key partners: Gavi has collaborated closely with partners on vaccine-MAPs development and future commercialisation since 2020 – when it was identified as the most important novel vaccine delivery technology to accelerate under the Vaccine Innovation Prioritisation Strategy. Gavi will continue to align and engage with VIPS partners, and others, going forward to ensure continued alignment and complementarity with existing investments.
- 5.7 Some PPC members at the October 2023 meeting encouraged further development of this proposal for consideration for Gavi 6.0, recognising the innovative potential of vaccine-MAPs to support both routine immunisation and antigens with outbreak and pandemic potential.

6. Global Virtual Pooled Inventories (GVPIs)

- 6.1 Context and problem statement: **Vaccine stockpiles for outbreak-prone diseases are a critical tool in preventing widespread transmission and the evolution of outbreaks into epidemics or pandemics.** Recent outbreaks of Ebola Sudan and Marburg viruses exposed a gap in the global community's outbreak response capabilities to diseases for which licensed vaccines are not yet available. The limited availability of investigational vaccines for these antigens (and for some antigens, no availability of vaccines) makes it difficult to deploy vaccines in time to advance: i) clinical development; and ii) expanded access use under research protocols – thereby slowing down the pathway to vaccine licensure and costing lives. If licensure cannot be accelerated for these rare but high-consequence pathogens, we risk a repeat of, for example, the 2014-16 West African Ebola epidemic, where the unprecedented spread led to the deaths of more than 11,000 people.
- 6.2 Proposed solution: **Together with partners – and building on the learnings of COVID-19 and the Ebola Zaire outbreak programme – Gavi could contribute to the establishment of GVPIs of investigational vaccines for select high-consequence pathogens.** This will ensure doses are available immediately at the onset of an outbreak to ensure rapid response, accelerate research and the pathway to licensure, protect at-risk individuals, and stop deadly outbreaks before transmission is widespread.
- 6.3 In June 2023, the Gavi Board approved a time-limited envelope to establish GVPIs for two pathogens (Ebola Sudan and Marburg), if certain conditions were met (new outbreaks and Phase II clinical data available). Given these conditions have not materialised, it is unlikely that these GVPIs will be established by end-2023. As such, the Secretariat will continue to work with partners to refine the GVPI concept and operational roles for consideration for Gavi 6.0.
- 6.4 Key activities: Together with partners – including WHO, CEPI, UNICEF, countries and manufacturers – GVPIs could be established for Ebola Sudan and Marburg and two other pathogens, pending prioritisation by WHO and relevant technical advisory groups. Within this GVPI partnership, Gavi's specific role will be to:
- Support outbreak response by funding investigational vaccines for expanded access use, as soon as efficacy and safety data are available

(note that other partners e.g. CEPI will continue to fund the GVPI doses for clinical trial use);

- Contribute to the accelerated licensure of these vaccines via the evidence generated under expanded access use; and
- Ensure continued availability of a ready reserve of vaccines by replenishing the GVPIs as doses expire, for as long as deemed required until a licensed stockpile is established for successful and recommended candidate vaccines.

6.5 **The GVPIs build upon Gavi's previous upstream interventions to accelerate access to life-saving vaccines in the event of outbreaks.** This includes i) Gavi's Advance Purchase Agreements for COVID-19 vaccines, that were mostly executed before vaccine candidates obtained any form of emergency use authorisation; and ii) Gavi's Advance Purchase Commitment for Ebola Zaire in 2015, which created a reserve of investigational vaccines for expanded access use as part of outbreak response – and which incentivised late-stage development, eventually leading to the establishment of the Gavi stockpile of licensed Ebola Zaire vaccines in 2021.

6.6 **Key Partners: GVPIs would bring partners together to ensure availability of reserves of investigational vaccines that can be used for clinical trials and expanded access use under research protocols during outbreaks.** This includes WHO's leadership in prioritising pathogens of concern and promising vaccine candidates and coordinating clinical trials, as well as other partners', i.e., CEPI and the United States Biomedical Advanced Research and Development Authority (BARDA), critical investments in early-stage clinical trials and manufacturing. While vaccine supply for clinical trials has often been funded by partners, there is a clear gap for certain pathogens in establishing ready reserves for expanded access use in outbreaks. In response to this gap, Gavi intends to continue collaborating with key partners to design a coordinated response and further refine the GVPI concept in advance of Gavi 6.0.