Subject	**Gavi's Role in Pandemic Prevention, Preparedness and Response**
Agenda item	**08**
Category	**For Decision**

Section A: Executive Summary

In December 2022, as part of the Gavi 5.1 discussions, the Gavi Board supported the Alliance's engagement in four key targeted additional Pandemic Prevention Preparedness and Response (PPPR) areas building on its existing role, experience and comparative advantage: 1) retain and enhance required capabilities for the next pandemic; 2) financial innovation 3) resilient routine immunisation (RI) programmes; and 4) diversification of regional manufacturing. The Alliance is institutionalising, embedding, and coordinating activities in line with these areas to strengthen the Secretariat's and Alliance's preparedness and response to public health events (PHE)[1] while simultaneously contributing to the evolving global PPPR ecosystem and political discourse.

This paper provides an update on the Secretariat's work with the Alliance and other partners, including the Coalition for Epidemic Preparedness Innovations (CEPI) and regional institutions, to advance global, regional, and local mechanisms for PPPR and highlights progress in the four targeted PPPR areas. It also requests the Gavi Board provide a time limited approval for Global Virtual Pooled Inventories (GVPIs) for Ebola Sudan and Marburg candidate vaccines to be deployed for expanded access. The GVPIs will serve a dual purpose of accelerated outbreak response and incentives to manufacturers to accelerate vaccine development.

Questions this paper addresses

- How is the Alliance engaging with and influencing the dynamic PPPR ecosystem?
- How is the Secretariat working alongside the Alliance and other partners to advance the four targeted additional PPPR areas?
- Does Gavi have a role to play to ensure timely access to pre-licensed vaccines for expanded access and to complement partners' actions to help accelerate vaccine access and bolster outbreak response?

[1] Public health events include outbreaks, epidemics, and pandemics.

Section B: Content

1. Ensuring that the value of immunisation is embedded into the global PPPR ecosystem

1.1 Vaccines have been the core response intervention for six of the seven Public Health Emergencies of International Concern (PHEIC) declared since 2007. Long-term investments in routine immunisation and outbreak response are essential to strengthen country systems so that they are better prepared for and can respond to future epidemics/pandemics.

1.2 Following the COVID-19 pandemic, a reshaping of the global health architecture and its PPPR mechanisms is underway. The Alliance has been advocating that the foundational role of immunisation in PPPR be appropriately incorporated into the various initiatives. **The Alliance is well-placed to play a leading design and execution role where vaccines have a key role to play, building on our programmatic and innovative financing expertise.**

1.3 **The Secretariat is actively working with Alliance partners, countries, donors, and other international and regional organisations to coordinate and align our contributions to contribute to the conversations happening through** the International Group of 7 (G7), the International Group of 20 (G20), the United Nations (UN) High-Level Meeting on PPPR and WHO-led processes underway to establish future medical countermeasures (MCM) platforms, to develop and institutionalise a coordinated approach for surge financing for future pandemics, and to negotiate and implement a Pandemic Accord through the Intergovernmental Negotiating Body (INB) under the framework of strengthening Health Emergency Preparedness, Response and Resilience (HEPR). Gavi is also an Implementing Entity of the Pandemic Fund and has been working closely with other entities and countries to develop future proposals. These global discussions are shaping the future of the global health architecture, and the Secretariat's engagement is positioning the Alliance to respond to countries' needs in alignment with areas in which the Alliance has a clear comparative advantage.

1.4 **The recently concluded Japanese G7 summit in Hiroshima helped to reinforce Gavi's position as a critical contributor in the PPPR ecosystem**. The contribution Gavi can make in securing access to MCMs was recognised in the Leaders communique. Health Ministers also recognised Gavi's essential role in the context of global health partnerships to help advance Universal Health Coverage, and in the new MCM Delivery Partnership for Equitable Access (MCDP) launched at the summit.

1.5 **Gavi supports global action now that takes into consideration the needs of countries and communities to bolster mechanisms for future PHEs, recognising there is a narrow window of opportunity to act given the shifting current global health architecture and political commitments**. The Secretariat supports building upon established organisations and networks for each countermeasure, importantly retaining the agility and flexibility needed to respond to as-yet-unknown threats.

1.6 **Member States and partners look to the Alliance to advise on key technical topics being debated in the broader global health discourse – in particular where new proposals are made which may impact Gavi's ability to fulfill its mission.** This includes areas such as, sustainable financing, market shaping, healthy supply and procurement, immunisation, strengthening primary health care, and pathogen access and benefit sharing (PABS), and to share key learnings from the COVAX Pillar including the COVID-19 Vaccine Delivery Partnership (CoVDP) and the administration of the COVAX Facility and COVAX AMC.

2. Implementation of targeted additional PPPR areas for Gavi 5.1

2.1 **The Alliance has long been a significant contributor to PPPR through its core activities. Over the last two strategic periods, the Alliance has invested over US$ 6.5 billion in PPPR-related activities**[2], excluding COVAX. This section provides an update on the four areas where the Board in December 2022 supported targeted expanded engagement in PPPR.

3. Area 1: Retain and enhance required capabilities for the next pandemic

3.1 Alongside Gavi's existing programmes responding to outbreaks of epidemic-prone diseases, such as yellow fever, and attention to challenges in advancing candidate vaccines for recent Ebola Sudan and Marburg outbreaks, **work is progressing on several fronts to ensure the Secretariat and Alliance partners are better prepared and positioned to meet country needs to prevent, prepare, and respond to PHEs**.

3.2 To inform the ongoing discussions on the MCM platforms highlighted above, **the Secretariat is engaged in coordinated discussions with Alliance and other partners including regions and countries to outline clear roles and responsibilities across the immunisation end-to-end value chain,** informed by key learnings from COVAX and previous health emergencies. A key input will be an "Alliance-wide plan for PPPR" that captures the work the Alliance partners do together on PPPR, including how we can build more agile, empowered Alliance decision and coordination mechanisms for responding to PHEs.

3.3 **Along with operational plans, the Secretariat is working with Alliance and other partners to develop a "PPPR Playbook" that retains the knowledge and experience from COVAX and other PHEs and builds on learnings and capacity to respond, including delivery and protecting routine immunisation (RI);** it includes tools, levers, processes, and interventions to refine and strengthen decision-making around responses to PHEs. This work is informed by United Nations Children's Fund's (UNICEF), WHO, and others'

[2] Including ~US$ 3.3 billion in investments for routine investments and campaigns for the prevention and response to outbreaks against 17 infectious diseases; ~US$ 2.7 billion of investments for strengthening health systems; and ~US$ 400 million of investments in pandemic, epidemic, and outbreak response through the establishment of global vaccine stockpiles for epidemic-prone diseases.

analyses of PHE archetypes to determine relevant interventions. Based on Alliance and partners' experience and learnings, tools and interventions could include a dose-sharing platform, approaches to initiate surge human resources capacity, proposals to amend indemnity and liability and no-fault compensation (including for humanitarian actors working in humanitarian settings), support for delivery in country including dedicated funding and technical assistance. It will also include a pandemic decision-making framework meant to be considered alongside the Secretariat's existing epidemics evaluation framework and living assessments[3] to support swift action during a pandemic. The framework aims to enable the Alliance to react promptly to different PHEs, balancing the risks of early action with less information against a more well-informed but too late response, including consideration of measures to be taken to safeguard RI.

3.4 **One key focus of the work described above is to delineate the Alliance's role in future pandemic vaccine delivery.** Building on the Alliance's strengths and integrating learnings from COVAX, including the Country Readiness & Delivery (CRD)/CoVDP workstream the Alliance will adopt an agile vaccine delivery approach in the next pandemic to support countries. To do so, the Alliance will build on its current model and unique strength as a 'one-stop shop' for country immunisation needs with delivery partners (including UNICEF, WHO, international non-governmental organisations, and regional and local partners) coming together and using an end-to-end approach encompassing the vaccine value chain. The model for future pandemics will integrate learnings from the Alliance experience from early 2020 onwards on country readiness and delivery including and beyond CoVDP, such as the importance of early and sufficient surge capacity for technical assistance, intensified monitoring systems, clear policy recommendations, political advocacy in country, agile decision-making and funding disbursements, and deliberate focus on select priority countries. It will have five key dimensions: i) noting delays in mobilising flexible **delivery funding** during the COVID-19 pandemic, using the financing innovations discussed in Area 2 below for countries to access day zero rapid and at-risk financing support to delivery; ii) a decision-making process backed by senior leadership to respond swiftly to priority country needs; iii) a single source of delivery funding and technical assistance (in addition to vaccine procurement) under 'one plan, one budget' for the Alliance support to countries; iv) strong country engagement and advocacy; and v) a deliberate focus on pandemic vaccine delivery while also keeping the protection of routine immunisation as a core priority.

4. Area 2: Financial innovation

4.1 **The issue of timely, sufficient, flexible pandemic response financing remains under discussion in global forums**. Whilst pandemic surge and

[3] Gavi's living assessments are updated on a regular basis as and when new evidence emerges to monitor data, highlight data gaps, and facilitate timely decision-making. They are developed for WHO's R&D Blueprint priority pathogens for which a vaccine in the R&D pipeline has obtained preliminary safety and immunogenicity data and can also be triggered on an ad-hoc basis by a public health event. The Secretariat currently maintains living assessments for chikungunya, Ebola, hepatitis E, hantavirus, Marburg, Rift Valley Fever, MERS, Nipah, and mpox.

contingent financing feature in G20 and G7 Health and Finance Track discussions, it is important that the lessons from COVAX AMC and the unique requirements of pandemic vaccine financing are reflected.

4.2 **The Secretariat is conducting consultations on a potential *Day Zero Pandemic Financing Facility for Vaccines.* In line with the recent G7 Summit call for such instruments,** the Secretariat is exploring ways to leverage and update Gavi's existing suite of innovative financing instruments to mobilise, for example, up to US$ 2 billion in risk-tolerant surge and contingent capital for vaccines at the onset of a pandemic – designed to have no funding or balance sheet implications until the moment the funding needs to be utilised.

4.3 **The aim of the Day Zero Facility would be to provide immediate funding that could be used to secure access to vaccines for lower-income countries and provide surge financing for delivery**. Adaptations to the International Finance Facility for Immunisation (IFFIm) are being designed to offer donors pathways to contribute resources in a manner which keeps commitments off national balance sheets until they are activated, while adaptations to the European Investment Bank (EIB) liquidity facility and US Development Finance Corporation (DFC) Rapid Financing Facility are being developed to provide frontloading capacities for future pandemics. An additional key attraction of this 'umbrella' facility in the context of the ongoing global discussions on surge financing is that Gavi's proposals are based on reforms and adaptions to our pre-existing instruments – and so would not require complex and lengthy negotiations to establish new legal entities. Although it is clear that fundraising mechanisms for all countermeasures will be critical, there is an advantage of structuring a prototypic funding mechanism using existing financial instruments for vaccines that can be a model for other countermeasures. Further details on this proposal are provided in Annex A.

5. Area 3: Resilient routine immunisation programmes

5.1 **Findings from the recent external evaluation of Gavi's Respond and Protect and Maintain, Restore, and Strengthen flexibilities[4] underscored the need for an Alliance-wide approach to sustaining RI in the event of a future pandemic and continued investment in health systems strengthening activities that both support RI and contribute to long term PPPR.**

5.2 After initial COVID-19-related backsliding, RI systems have demonstrated a strong rebound, with early data suggesting the number of children receiving three doses of diphtheria-tetanus-pertussis (DTP3) in 2022 returned to pre-pandemic levels in many Gavi- supported countries. More must be done in future pandemics to sustain RI and ensure that the necessary capacities and

[4] Respond and Protect was designed as an immediate response to the acute COVID-19 situation to allow countries to draw on existing Gavi funds to support the COVID-19 response, as defined by WHO guidelines at the time. Maintain, Restore, and Strengthen had a longer-term focus on the restoration and maintenance of RI services and on the strengthening of efforts to reach ZD children and missed communities.

systems are in place in Gavi-supported countries. The Secretariat is working with partners to develop an RI response plan based on lessons learnt from the COVID-19 pandemic to: ensure dedicated and flexible funding support options to countries; put in place and coordinate surge capacity resources across the Secretariat and partners; ensure country engagement and advocacy around RI protection; and leverage aggregate real-time analytics from partners on pandemic evolution and key metrics to inform decision-making.

5.3 **To support Gavi's core mission and strengthen systems that can be leveraged in the event of a future public health event, the Alliance will build on existing health system strengthening (HSS) and partners' engagement framework (PEF) funding and draw on COVID-19 Delivery Support (CDS) funding to further advance work on the three priority areas supported by the Board in December 2022**, including strengthening electronic health management information systems; scaling electronic logistics management information systems; and adapting and scaling digital surveillance systems for vaccine preventable diseases. Work on supporting vaccines at different age groups also strengthens countries' abilities to handle vaccination at different ages and subgroups during a pandemic. The Secretariat continues to discuss with partners other areas where targeted investments could help strengthen the capacity of routine immunisation programmes to prevent, detect and respond to future pandemics.

5.4 **In addition to the investment areas above, the Secretariat has been nominated as an Implementing Entity (i.e. eligible to manage and co-finance grants) of the Pandemic Fund (PF) and is closely engaged in its continuing evolution.** The Secretariat is working in alignment with WHO, the Global Fund and other Implementing Entities to improve the harmonisation and alignment of PF grant-making with national plans. The Secretariat has also been working with interested implementing countries to explore progressing a proposal for a health worker vaccination programme to be submitted during 2023, which would be piloted in several countries and ready to scale ahead of the next pandemic. These pilots can be used to inform future Gavi programming, including future support to immunisation platforms for specific target populations, potentially to be explored in the Vaccine Investment Strategy (VIS) 2024 (see Doc 09), as well as other future programmes potentially financed by the Pandemic Fund.

6. Area 4: Diversification of regional manufacturing

6.1 **In December 2022, the Board approved a four-pillar regional manufacturing strategy to use Gavi's market shaping and innovative financing capacity to play a specific 'downstream' role to support the expansion of sustainable regional vaccine manufacturing, with a focus on the African continent**. Work has progressed at pace across all four pillars. A new working partnership is being established with Africa Centres for Disease Control and Prevention (CDC) to ensure ownership by, and coordination with, the many broader regional manufacturing initiatives led by African partners. A

short update on each pillar follows.

6.2 **Pillar 1:** To better inform upstream investors in manufacturing initiatives, including in previously under-represented geographies, Gavi will provide **targeted market intelligence and guidance** on vaccine market dynamics and the opportunities therein. This will ultimately foster better decision-making, more efficient market outcomes and improved sustainability of new market entrants, including in Africa. The public resource will draw on existing databases such as the WHO Market Information for Access Initiative, as well as Gavi data and UNICEF Market Notes, and will be regularly reassessed for usefulness in a dynamic market environment. Antigen-by-antigen deep dives are currently being held in close coordination with Alliance partners, as a first step to creation of the final resource.

6.3 **Pillar 2:** Gavi has modified its **healthy market framework** to explicitly recognise the value of regional diversification in markets and better accommodate new products across all Gavi-eligible countries. Discussions are ongoing with Alliance partners, and this remains on track to be operationalised in 2023.

6.4 **Pillar 3:** Country demand for new African products will be key to success of Pillar 4 (below) and of the overall undertaking. In most cases, country choice is the ultimate determinant of "offtake", for both Gavi and non-Gavi business. Gavi is working with the African Union (AU), Africa CDC and others to improve regional **demand predictability** for locally manufactured products. This work, still in a nascent phase, will safeguard the primacy of country choice in the Gavi model, whilst recognising the importance of predictable demand for aspiring manufacturers. Discussions are also ongoing in line with the AU's 2023 focus on the operationalisation of the African Continental Free Trade Area (AfCFTA).

6.5 **Pillar 4:** The Secretariat continues to explore a potential **financial instrument, likely an Advance Market Commitment (AMC)**, to support sustainable manufacturing capacity on the African continent. The Secretariat is undertaking extensive consultations with all partners involved in African regional manufacturing to assess the need, scope and scale for such an instrument.

6.6 These stakeholder consultations have revealed broad support for an AMC to help emerging manufacturers overcome the inevitable higher costs of entry, amplify the impact of the first three pillars of Gavi support, and support pandemic preparedness. To this end, **two core objectives have been defined**:

a) Support a regionally diversified vaccine supplier base to contribute to a substantial and sustainable manufacturing base in Africa (with reference to AU targets)

b) Improve pandemic preparedness and response – strengthen regional manufacturing capacity and capability to produce vaccines for pandemic response.

6.7 Further analyses, together with the outcome of extensive internal and external expert consultation will continue through Q3/4 2023. This will offer a full treatment of design options, including product eligibility, country eligibility and incentive structure, plus suggestions for how to operationalise the AMC, including governance, treasury, monitoring and evaluation and other core functions. Following an open consultation process, it is anticipated that further details will be shared with the Gavi PPC and Board for comment in late 2023 with any appropriate programmatic implications for decision. A treatment of design options currently under consideration is provided in Annex B to this paper.

7. Proposal for a global virtual pooled inventory for outbreak response

7.1 Recent outbreaks have exposed a gap in the Alliance's outbreak response capabilities with the lack of early access to sufficient candidate vaccines doses for expanded access of vaccines. **Together with partners, and building on existing gaps and the learnings of COVID-19 and the Ebola Zaire outbreak programme, we are proposing Gavi establish Global Virtual Pooled Inventories (GVPIs) of candidate vaccines,** which could be used in an outbreak under expanded access[5], guided by Alliance technical advisory groups, such as the WHO Technical Advisory Group-Candidate Vaccines Prioritisation, with the aim to protect at risk individuals and stop a deadly outbreak before transmission is widespread. Where typically vaccines are only available after licensure, which can take 5-10 years if not longer[6], the GVPI proposal aims to accelerate availability to rapidly respond to outbreaks and save lives.

7.2 **In the case of rare but high-consequence pathogens, there are limited incentives for developers/manufacturers to establish candidate vaccine reserves which could support early outbreak response.** With recent Ebola Sudan and Marburg outbreaks, the lack of sufficient candidate vaccines at the immediate onset of the outbreak readily available for immediate use[7] has hindered the ability to take advantage of these outbreaks for clinical trials in a timely manner and, if shown to be efficacious, to deploy candidate vaccines under expanded access. Furthermore, these outbreaks spread, with Ebola Sudan spreading to nine districts in Uganda including the capital city Kampala.

[5] Also referred to as compassionate use, expanded access allows the use of an unauthorised medical product (drug, biologic, or medical device). Under strict conditions, candidate vaccines in development can be made available to vulnerable individuals at serious or immediate risk of a life-threatening disease or condition, when no comparable or satisfactory therapy options are available.

[6] https://coronavirus.jhu.edu/vaccines/timeline#:~:text=Typical%20Timeline,vaccine%20doses%20for%20widespread%20distribution.

[7] In the case of the Ebola Sudan outbreak in Uganda, investigational vaccines were not available for 79 days, 10 days after the last confirmed case. Whilst the overall response was unprecedented in terms of national and supranational leadership, partners' commitments, and speed of vaccine deployment considering the very early stages of development, it was too late for vaccines to support the outbreak response or to have a chance of pursuing true efficacy data and ultimately vaccine licensure. For Marburg, candidate vaccines are even less advanced and only several hundred vials are currently available in finished form, meaning it would take several months before expanded access is possible should clinical trials be initiated as part of the outbreak response and yield evidence of efficacy.

Marburg outbreak was declared over on 2 June 2023 in Tanzania, but is ongoing in Equatorial Guinea. Not having enough product to use in outbreaks could lead to a repeat of the large-scale West African epidemic of Ebola Zaire[8]. Sadly, this shows that lessons regarding early availability of vaccines have not been learnt from the 2014 West Africa Ebola outbreak, where the lack of available candidate vaccines was one of the factors that slowed the outbreak response allowing unprecedented spread.

7.3 **The GVPI proposal complements interventions and preparedness activities that Alliance and other partners (e.g. CEPI, the Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health (NIH)) are moving forward to put in place in advance of outbreaks to accelerate response and vaccine development timelines**, such as pre-approving study protocols, pre-arranging clinical trial sites, and pre-approval of studies by Ethics Committees. Push funding efforts provide essential support in the form of US Government investments in Phase I and II clinical trials and manufacturing through BARDA, CEPI's support to in-country clinical and surveillance studies, and WHO R&D Blueprint role in the coordination of clinical studies and prioritisation of candidate vaccines[9]. While CEPI provides funding for doses and clinical trials, it does not fund doses for expanded access during an outbreak. There are currently no partners supporting production and maintenance of candidate vaccines for Lower Income Countries to have early access to such vaccines for expanded access use as part of rapid outbreak response. In response to this gap, **at WHO and CEPI's request to collaborate in this area, Gavi is moving alongside partners' efforts to contribute its capabilities in a coordinated response, for which a GVPI can play an instrumental role in providing early access to vaccines as soon as the clinical data show benefit, under technical advisory groups' guidance.**

[8] Over 28,600 people were infected and 11,325 people died in the 2014-2016 Ebola Zaire outbreak in West Africa, although these numbers are likely underestimated. The World Bank estimates the overall impact of the Ebola crisis on Guinea, Liberia, and Sierra Leone to be US$ 2.8 billion.

[9] Following the Ebola Sudan outbreak in Uganda, WHO asked the existing multi-disciplinary and independent COVID-19 Vaccine Prioritisation Working Group to extend its COVID-19 remit to rapidly evaluate the suitability of candidate Ebola vaccines for inclusion in the planned trial in Uganda using similar considerations on safety, likely efficacy and logistic issues relating to availability and implementation. This further led to the establishment of the WHO Technical Advisory Group - candidate vaccines prioritisation (TAG-CVP) which supported Marburg outbreak responses by the rapid evaluation and prioritisation of candidate Marburg vaccines for use under WHO protocol.

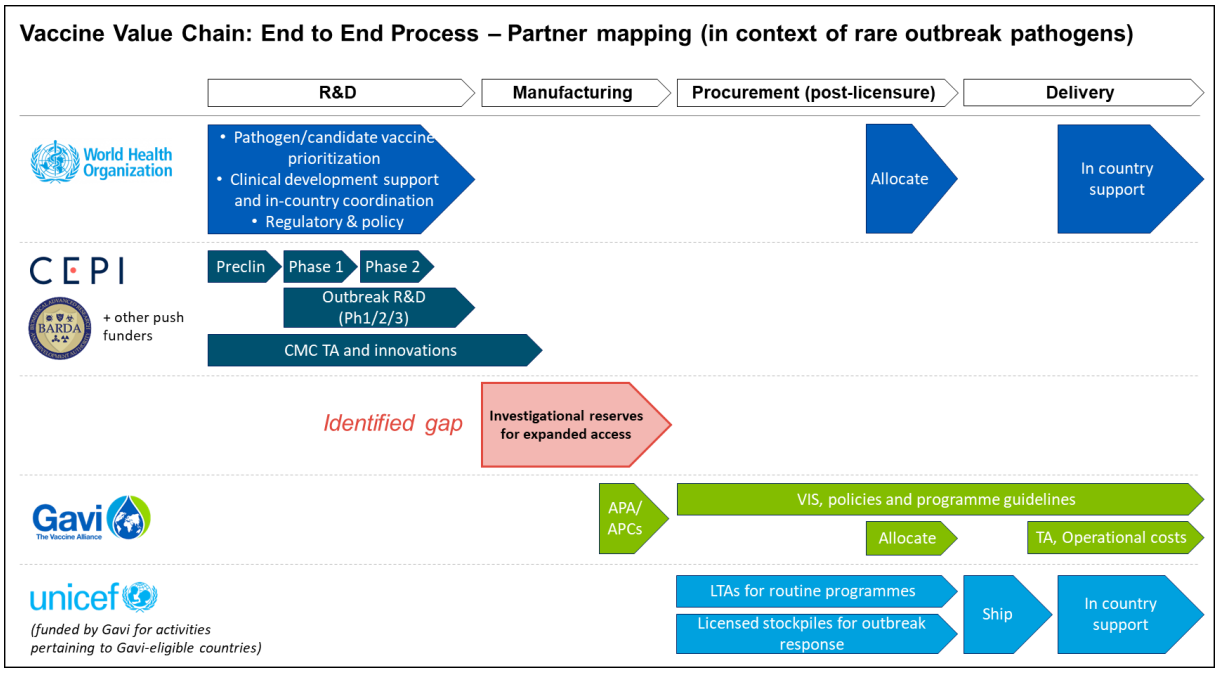

Figure 1: Vaccine value chain partner mapping

7.4 **Gavi's support has previously extended upstream in the immunisation end-to-end value chain for outbreaks and pandemics when rapid response is critical to accelerate access to and availability of these life-saving vaccines**. This was the case with COVID-19 and COVAX Advance Purchase Agreements mostly executed before candidate vaccines obtained any form of emergency use authorisation. For Ebola Zaire and the 2015 Advance Purchase Commitment, Gavi's early intervention ensured the availability and maintenance of over 300,000 doses of candidate vaccine[10] for deployment under expanded access as part of outbreak response and incentivised late-stage development to successfully license the vaccine. Gavi's intervention eventually enabled UNICEF to tender for the licensed product to constitute the Ebola Zaire licensed vaccine stockpile, managed by the International Coordination Group on Vaccine Provision, which continues to provide outbreak response support.

7.5 WHO R&D Blueprint have prioritised a number of pathogens like Ebola Sudan, Marburg, Nipah, and Lassa fever, which disproportionately affect Gavi-eligible countries. This highlights a risk that existing funders concentrated in high-income countries may not systematically prioritise funding development of these vaccines. Partners like CEPI are providing R&D support and funding for some of these antigens, but support is missing to maintain candidate vaccines ready for outbreak response more holistically. **Gavi is well positioned to address this gap and complement partners' and push funders' interventions, which will also be necessary to incentivise vaccine**

[10] This material was entirely held with the manufacturer, with the exception of a limited number of doses held at University Hospital in Geneva for vaccination of international organisation's staff deployed to outbreaks. Over 300,000 investigational doses were subsequently deployed to support outbreak response in the DRC and Guinea.

manufacturing and licensure. **Ebola Sudan and Marburg candidate vaccines provide the use-case for the proposed GVPI concept, which could eventually also apply to other pathogens, if there are needs for it.**

7.6 After reaching pre-defined milestones, including satisfactory data from Phase II clinical trials, the Secretariat would provide funding to prioritised candidate vaccine manufacturers to produce and store candidate vaccines constituting the GVPIs. Gavi's intervention would:

a) Support outbreak response by making candidate vaccines available under expanded access protocol as soon as efficacy and safety data are available (from early phase studies of candidate vaccines funded by WHO, CEPI, or other partners), in line with Gavi's commitment to saving lives;

b) Contribute to generating evidence in support of licensure, in alignment with WHO, CEPI and country vaccine development and licensure plans; and

c) Ensure availability of a continual "ready inventory of vaccines" by replenishing the GVPIs as doses expire, for as long as deemed required until a licensed stockpile is established for any successful candidate vaccines.

7.7 **WHO, CEPI, UNICEF, Gavi Secretariat and other key partners are collaborating to further define the parameters and operationalisation of the GVPI**, including, for example, aspects related to prioritising antigens, sizing the need, ensuring smooth coordination with clinical trial efforts, and establishing framework models for expanded access (including a coordination mechanism, allocation framework, MEL (monitoring, evaluation and learning) framework, and legal collaboration with countries as it relates to indemnity and liability arrangements). This will inform a technical and financial assessment of the GVPI proposal with detailed partners' roles and responsibilities and governance oversight to be brought back to the PPC and Board by end of 2023.

7.8 **The Secretariat is seeking time limited Board approval to establish GVPIs for Ebola Sudan and Marburg ahead of a full proposal for PPC and Board consideration later this year**. In addition to an explicit ask from WHO and/or CEPI, the establishment of the GVPIs would at a minimum require: 1) an outbreak; and 2) satisfactory Phase II clinical data. **Despite such odds being low for the remainder of this year, if these conditions were met and the Alliance was unable to rapidly respond, this would mean another missed opportunity to provide early access to vaccines, respond to an outbreak, and save lives**.

7.9 **The GVPIs build on the recent Gavi/UNICEF Expression of Interest (EOI)** designed to gather intelligence from developers/manufacturers of Ebola Sudan and Marburg candidate vaccines. Under high level assumptions that would need to be refined as more information becomes available on candidate

vaccine prioritisation, the needs of candidate vaccine manufacturers[11], and the appropriate size of each GVPI, the budget required for an Ebola Sudan or Marburg GVPI is estimated at US$ 2.5-5 million per pathogen[12].

7.10 **The Board is requested to approve a time-limited envelope of up to US$ 10 million to establish GVPIs for Ebola Sudan and Marburg candidate vaccines, contingent on an explicit ask from WHO and/or CEPI** and with WHO TAG-CVP (Technical Advisory Group – Candidate Vaccines Prioritization) recommendation. This would enable negotiations with vaccine manufacturers for candidates for the two pathogens should Phase II data emerge between now and the next PPC and Board meetings. Any contract proposed would require approval from the Market-Sensitive Decisions Committee (MSDC). The Secretariat believes this is an agile approach, with limited and manageable financial implications and which would position Gavi to better respond to new Ebola Sudan and Marburg outbreaks whilst also shaping sustainable markets for the eventual licensed vaccines. The Secretariat will bring a fully-scoped proposal for the GVPI concept to include confirmation of Gavi's and other partners' roles and a financial assessment to the PPC and Board by the end of 2023.

Section C: Actions requested of the Board

Noting that the Secretariat plans to return to the PPC in October 2023 and the Gavi Board in December 2023 with a fully scoped proposal for Gavi in GVPI (Global Virtual Pooled Inventories), which would include, inter alia, confirmation of the role of Gavi and other partners and a financial assessment with a suggested cost envelope, the Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

Approve a time limited envelope until the December 2023 Board meeting of up to US$ 10 million, for GVPIs for Ebola Sudan and Marburg vaccines if there is a need and an explicit ask from WHO and/or CEPI to Gavi. Any individual agreements with manufacturers would require Phase II data for Ebola Sudan or Marburg candidate vaccines to be available. The individual agreements would be subject to review and approval of Gavi's Market-Sensitive Decisions Committee. This decision would not set a precedent for future Gavi investments.

Annexes

Annex A: Gavi's Proposed Day Zero Pandemic Financing Facility for Vaccines

Annex B: Design Considerations for an Advance Market Commitment to Support Sustainable Vaccine Manufacturing Capacity

[11] Considering that many candidates are originating in academic institutions or small biotechs that do not have experience in bringing a vaccine to licensure or manufacturing them at scale, further support may be necessary beyond the GVPI to ensure successful vaccine licensure and availability for countries

[12] This funding envelope relies on high level pricing estimates based on Merck Ebola Zaire vaccine, which UNICEF currently procures at US$ 98.6 per dose. At a similar price, each GVPI would support a reserve of approx. 25-50k investigational doses which could be split across several candidate vaccines.