
Subject **Gavi 5.1 (including Pandemic Preparedness and Response)**

Agenda item **06**

Category **For Decision**

Section A: Executive Summary

In light of the impact of the COVID-19 pandemic on global health and immunisation, the Board, at its April 2022 retreat, asked for a renewed focus on Gavi's 5.0 priorities and to lay out how COVID-19 vaccination, COVAX and its learnings will come together with Gavi's core strategy. **This is being articulated as Gavi 5.1.**

Gavi 5.1 is not a new strategy but rather a natural evolution of 5.0; serving as a bridge to 6.0 and reflecting the changing context in recent years. Building on the lessons from the pandemic, Gavi 5.1 recognises the profound societal, geopolitical, economic and technological shifts that have transformed the environment the Alliance operates in. It also acknowledges the new challenges to global health security posed by the increasing number of outbreaks of vaccine preventable diseases. **Gavi 5.1 was developed through a consultative process between June and November 2022,** involving Board and Programme and Policy Committee (PPC) members, country stakeholders and the Alliance.

Gavi 5.1 will continue the 5.0 focus on preventing further backsliding of routine immunisation (RI), catching-up missed children, and reaching zero-dose children and missed communities. The introduction of key Gavi-supported vaccines not yet included in countries' national schedules will continue at pace and remain central. The Alliance will accelerate its support to help countries optimise their vaccine portfolio and prioritise the most critical vaccines in an evidence-based, country-driven way. Gavi 5.1 continues to highlight the importance of improving the sustainability of immunisation programmes and ensuring healthy markets. **It will entail an evolution of the Alliance's role in Pandemic Preparedness and Response (PPR), including increased support to regional manufacturing diversification.** Gavi 5.1 would also see a **relaunch of the Human Papillomavirus (HPV) vaccine programme, and include a COVID-19 vaccine programme for 2024 and 2025** depending on the evolving epidemiology of the disease. Docs 08, 07, and 10 respectively describe these three latter areas in detail.

This document provides an overview of the updated Gavi 5.0 strategic framework (strategy 'one pager') for Gavi 5.1. The Alliance's future contribution to PPR, cutting across all four strategic goals is summarised in Annex B of this document. The approach to operationalising the 5.1 strategy, and the financial implications are included in Annex C. **The Board is requested to approve the targeted updates to the strategy 'one-pager' and provide guidance on the Alliance's future role in PPR.** Of note, it is proposed that the 5.0 strategy indicators and targets will remain unchanged. Gavi will monitor on an ongoing basis whether updates are needed. The Secretariat will revert to the PPC and Board on progress in implementing Gavi 5.1 on a bi-annual basis as part of regular progress updates on the Alliance's strategy.

Section B: Gavi 5.1

1. Context of Gavi 5.1

- 1.1 In June 2019 the Board approved Gavi's five-year strategy for 2021-2025 ('Gavi 5.0'),** aiming to accelerate the journey towards universal immunisation. The Gavi 5.0 vision highlights the importance to leave no one behind with immunisation by 2030, contributing to the achievement of Sustainable Development Goal (SDG) 3.
- 1.2 Considering the disruptions to Routine Immunisation and Primary Health Care caused by the COVID-19 pandemic, the Board recalibrated Gavi 5.0 strategic priorities in December 2020.** The focus of the recalibrated priorities was on maintaining, restoring and strengthening immunisation services, reaching zero-dose children and missed communities, ensuring access to COVID-19 vaccines, and safeguarding domestic financing for immunisation. The Board also recognised that other areas of Gavi 5.0 such as new vaccine introductions and the Middle-Income Countries (MICs) approach would need to advance at a slower pace than planned. Support for four vaccines from the Vaccine Investment Strategy (VIS) 2018 including rabies, Hepatitis B birth dose, DTP boosters and respiratory syncytial virus (RSV) was therefore paused during the acute phase of the pandemic¹ based on Board recommendation.
- 1.3 In light of the prolonged impact of the COVID-19 pandemic on global health and immunisation, the Board at its April 2022 retreat asked for a renewed focus on Gavi's recalibrated 5.0 priorities and to lay out how COVID-19 vaccination, COVAX and its learnings will come together with Gavi's core strategy.** This has been articulated as **Gavi 5.1, starting in 2023 and ending in 2025.**
- 1.4 The Board confirmed at its June meeting that it would be leading on the development of Gavi 5.1.** Over the summer, the Gavi Secretariat held a series of extensive informal consultations with Board and PPC members, at technical levels across the Alliance, with countries and other partners. Three sessions were held with PPC and Board members, starting in July with a 'mini-brainstorming workshop' to gather early perspectives on Gavi 5.1 priorities and to consider potential trade-offs. This was followed by two sessions in September to dive deeper into specific themes. Following the PPC meeting, a final informal session took place in November to bring together the feedback from the various meetings and gather input into the updated Gavi 5.1 strategy 'one-pager' and narrative.

¹ Gavi would continue its investments in endemic cholera and multivalent meningitis preventive programmes. This considered the role of these vaccines in outbreaks and their existing vaccine programmes. The lead candidate for respiratory syncytial virus (RSV) did not meet its primary endpoint and therefore would not meet the timelines seen in the VIS.

2. Gavi 5.1 updated strategy 'one pager'

2.1 Figure 1: Proposed targeted updates to Gavi 5.0 'one-pager'

Gavi 5.1: proposed targeted updates to Gavi 5.0 'one-pager'

Change vs. Gavi 5.0 'one-pager'

Vision		Leaving no one behind with immunisation				Sustainable Development Goals	
Mission 2025	To save lives and protect people's health by increasing equitable and sustainable use of vaccines		Mission indicators	<ul style="list-style-type: none">Under-five child mortality reductionFuture deaths avertedFuture DALYs averted	<ul style="list-style-type: none">-10% 7–8m 320–380mReduction in zero-dose children (equity indicator)Unique children immunisedEconomic benefits unlocked	<ul style="list-style-type: none">-25% 300m US\$80–100bn	
Principles	<ul style="list-style-type: none">Missed communities, first priority: Prioritise children missing out on vaccination, including among migrants, displaced and other vulnerable populationsGender-focussed: Identify and address gender-related barriers to promote immunisation equityCountry-led, sustainable: Bolster country leadership to sustainably deliver and finance immunisationCommunity-owned: Ensure community trust and confidence in vaccines by engaging communities in planning, implementation and oversight of immunisationDifferentiated: Target and tailor support to national and subnational needs, including fragile contexts <ul style="list-style-type: none">Integrated: Strengthen immunisation as a foundation for integrated primary health care to reach unserved communities in support of universal health coverageAdaptive, resilient: Help countries leverage immunisation to address the challenges of climate change, Global Health Security, antimicrobial resistance and other major global issuesInnovative: Identify and leverage innovative products, practices and services to reach everyone with immunisationCollaborative, accountable: Collaborate across stakeholders to achieve the SDGs and global health security in a transparent, coordinated and accountable manners						
Goals	1 INTRODUCE AND SCALE UP VACCINES		2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION		3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES		
Objectives	A Strengthen countries' prioritisation of vaccines appropriate to their context		A Help countries extend immunisation services to regularly reach under-immunised and zero-dose children to build a stronger primary health care platform		A Strengthen national and subnational political and social commitment to immunisation		
	B Support countries to introduce and scale up coverage of vaccines for prevention of endemic, and epidemic and pandemic diseases		B Support countries to ensure immunisation services are resilient, well-managed, sustainable, harness innovation and meet the needs of all caregiver		B Promote domestic public resources for immunisation and primary health care to improve allocative efficiency		
	C Enhance outbreak and pandemic response by ensuring equitable access to relevant vaccines including through stockpiles through availability and strategic allocation of vaccine stockpiles		C Work with countries and communities to build resilient demand , and to identify and address gender-related barriers to immunisation		C Prepare and engage self-financing countries to maintain or increase performance		
Enablers	<ul style="list-style-type: none">Secure long-term predictable funding for Gavi programmesEnsure global political commitment for immunisation, prevention and primary health care		<ul style="list-style-type: none">Use evidence, evaluations and improved data for policies, programmes and accountabilityLeverage the private sector, including through innovative finance mechanisms & partnerships				
	4 ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS						
	<ul style="list-style-type: none">A Ensure sustainable, healthy markets dynamics with diversified supply for vaccines and immunisation-related products at affordable pricesB Incentivise innovation for the development of suitable vaccinesC Scale up innovative immunisation-related products						

Overview of Vision, Mission, Principles, Enablers

- 2.2 **Gavi 5.1 reaffirms the Alliance's 5.0 vision of 'leaving no one behind with immunisation', in line with the Immunisation Agenda 2030. It also reaffirms its mission to 'save lives and protect people's health by increasing equitable and sustainable use of vaccines'.** The Alliance's aspiration of reaching all children with immunisation by the end of the SDG era in 2030 remains the north star of the Alliance's strategy. Every child ought to receive a full course of vaccines and there is a real possibility that immunisation could be truly universal by 2030. Achieving this, however, requires an urgent acceleration of efforts to provide a strong platform for equitable primary health care (PHC) as a pathway to universal health coverage (UHC) and the SDG vision of 'leaving no-one behind'. Gavi's mission will continue to put equity at its heart, as the disruptions of routine immunisation caused by the pandemic reinforce this focus.
- 2.3 **The Gavi 5.0 principles continue to be highly relevant for 5.1 with one adjustment proposed.** The wording of the "collaborative, accountable" principle is updated to recognise the vital role of collaboration in achieving global health security in light of the learnings COVID-19 pandemic and the increasing number of outbreaks of vaccine-preventable diseases. Going forward, the Alliance will strengthen its collaboration with global health security actors along the vaccine value chain such as the Coalition for Epidemic Preparedness Innovations (CEPI) for research and development or the Africa Centre for Disease Control and Prevention.
- 2.4 The Gavi 5.0 enablers are still fit for purpose.

Strategic Goal #1: Introduce and scale up vaccines

- 2.5 **As in Gavi 5.0, the introduction and scale-up of high-impact vaccines in Gavi-supported countries will be a priority;** and continue at pace considering the multiple competing priorities that countries are facing. 20 new routine vaccines have been introduced in Gavi-eligible countries since the beginning of Gavi 5.0. Yet, the COVID-19 pandemic has left countries and Alliance partners stretched at national and subnational levels, hampering routine immunisation activities. This has impacted the ability of many countries to both introduce new routine vaccines and scale them up. Going forward, Gavi aims to introduce another 62 vaccines by 2025, including a focus on the malaria and HPV vaccines.
- 2.6 **If approved by the Board, the Alliance will put a specific emphasis on relaunching the HPV programme in Gavi 5.1 (see document 07).** The HPV vaccine remains one of the most impactful vaccines in the portfolio with 17.4 deaths averted per 1,000 children vaccinated, and yet coverage rates are

1 INTRODUCE AND SCALE UP VACCINES

- A** Strengthen countries' prioritisation of vaccines appropriate to their context
- B** Support countries to introduce and scale up coverage of vaccines for prevention of endemic, **and** epidemic and pandemic diseases
- C** Enhance outbreak **and** pandemic response by ensuring equitable access to relevant vaccines including through stockpiles through availability and strategic allocation of vaccine stockpiles

lagging. The new recommendation from the Strategic Advisory Group of Experts on Immunization (SAGE) permitting countries to opt for a single-dose schedule, followed by an anticipated increase in global supply of HPV vaccines provides a critical opportunity to inject renewed momentum. This **relaunch of the HPV programme** aims to accelerate the number of girls reached from 9.8 million in 2021 to ~86 million by 2025. The Alliance will also focus on the **timely rollout of the malaria programme** and implement the market shaping strategy roadmap for malaria vaccines (see Doc 02b).

- 2.7 **The Alliance would move from the COVAX-led emergency response to a more planned COVID-19 programme in 2024 and 2025**, based upon the epidemiology of the disease and if approved by the Board (see Doc 10). In 2023, COVAX will continue to support the AMC91 countries to deliver COVID-19 vaccines with an increased focus on high-risk populations and in line with national strategic ambitions (see Doc 9). In 2024 and 2025, a Gavi-supported COVID-19 vaccine programme could be implemented post-COVAX, while retaining the ability to quickly respond in the case of the pandemic evolving towards a 'worst-case' scenario². Such a programme would entail a gradual pivot towards delivering annual doses for higher priority user groups through routine Primary Health Care (PHC) services.
- 2.8 At its last meeting, the PPC did not wish to recommend that **the Vaccine Investment Strategy (VIS) 2018 vaccines that were paused during the COVID-19 pandemic be reassessed as part of the VIS 2024 process at this time** to allow for a more in depth review of the Board's previous decision within the current context³. PPC members requested as next step that these vaccines be discussed at its next meeting in May 2023. The options for consideration at that meeting could include recommending to the Board, for example, unpausing for all the paused vaccines, partial unpausing, or reassessing the paused vaccines as part of the VIS 2024 process.
- 2.9 Given the multiple competing priorities for countries and growing fiscal constraints, the Alliance will **accelerate its support to help countries optimise their vaccine portfolio and prioritise the most appropriate vaccines** for their specific context in an evidence-based, country-driven way. To do so, the Alliance will leverage its work on diagnostic support to countries (e.g. on yellow fever diagnostics) for timely and accurate disease detection to inform decision making for vaccination programmes.
- 2.10 As outbreaks of vaccine-preventable diseases (VPDs) will only become more likely and frequent in the future, **Gavi, building on its current role and**

² As one of the three scenarios defined by WHO for the evolution of the COVID-19 pandemic <https://www.who.int/publications/i/item/WHO-WHE-SPP-2022.1>

³ VIS 2018 vaccines paused by the Board in December 2022 are Rabies, Hepatitis B birth dose, DTP-containing boosters and Respiratory Syncytial Virus vaccines. Other VIS 2018 vaccines were not paused and include Cholera preventive programme and Multivalent Meningococcal conjugate vaccines

experience, will deepen its engagement in responding to VPD outbreaks, epidemics, and pandemics. As a result, objectives 1b and 1c are updated to reflect this role:

- **The Alliance will retain and enhance critical immunisation capabilities from the COVID-19 pandemic to support equitable and timely access to vaccines for future pandemics, including in humanitarian settings.** This includes organisational and process capabilities to ensure earlier access to vaccines, earlier and stronger support for vaccine delivery, and clearer processes and more rapid, flexible decision-making. Financial innovation will play a critical role for mobilising significant early and at-risk funding for future pandemic vaccines and their delivery in low-income countries (LICs) and lower-middle income countries (LMICs) building on mechanisms such as the Pandemic Vaccine Pool or Advanced Purchasing Agreements. It is proposed to build on pandemic learnings to inform an Alliance-wide plan for the next pandemic, focusing on critical path interventions and capabilities (see Annex B on PPR for more details).
- **The Alliance will continue its role in VPD outbreak response.** This includes funding of global vaccine stockpiles and supporting immunisation campaigns for outbreak response (e.g. for measles). With the resurgence of outbreaks in countries caused by the slowdown in preventive campaigns and hampered responses during the pandemic (see document 02) such engagement is more critical than ever.

Strategic Goal #2: Strengthen health systems to increase equity in immunisation

2.11 As described in Doc 02b, the COVID-19 pandemic **has stress-tested** immunisation systems at an unprecedented scale. Despite pandemic-related disruptions, **immunisation systems showed encouraging signs of resilience, stretching to deliver more vaccines than ever before in history⁴**. Gavi's support to health systems through its Health System Strengthening (HSS) and Partners' Engagement Framework (PEF) investments have contributed to these achievements. Gavi's HSS investments will thus continue to be at the heart of Strategy Goal 2, with the focus on resilience against future pandemics more clearly articulated in objective 2b.

2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION

- A** Help countries extend immunisation services to regularly reach under-immunised and zero-dose children to build a stronger primary health care platform
- B** Support countries to ensure immunisation services are **resilient**, well-managed, sustainable, harness innovation and meet the needs of all caregiver
- C** Work with countries and communities to build resilient demand, and to identify and address gender-related barriers to immunisation

2.12 **As in Gavi 5.0, equity will be the primary focus of Gavi's investments in health systems.** The Alliance will heighten its efforts to prevent backsliding, catch-up missed children and reach additional zero-dose children and missed communities (see Doc 02b). Gavi 5.1 reaffirms the importance of context-

⁴ In 2021 alone Gavi-supported countries delivered nearly ~3.5 time more routine and C19 vaccines than in 2020.

appropriate partnerships including with Civil Society Organisations (CSOs) to reach zero-dose children and missed communities. Reaching missed populations in fragile and conflict-affected countries will remain a key priority and require the use of flexibilities from the Board-approved Fragility, Emergencies and Displaced People policy and new partnership approaches with CSOs and humanitarian organisations⁵.

- 2.13 The Alliance will continue its 5.0 focus to enhance the efficiency and sustainability of immunisation programmes, and therefore their ability to stretch.** In doing so, the Alliance will continue to invest into stronger comprehensive vaccine management, enhancing the quality and use of data, and strengthening detection of and response to vaccine-preventable diseases. For example, Gavi will carefully expand investments to accelerate the modernisation and scale-up of information systems for immunisation to contribute to stronger PPR. This would build on its current investments and experience, expanding for instance routine investments in electronic health management information systems (e-HMIS), and in electronic logistics management information systems (e-LMIS). The Alliance has a strong track record and comparative advantage in that area. The estimated cost are US\$ 40 million in 2024 and 2025, pending Board confirmation of available funding in June 2023 (see Annex B).
- 2.14 The HPV relaunch (see Doc 07) and the potential Gavi's future COVID-19 vaccination programme in 2024 and 2025** (see document 10) will entail a focus on continuing to **strengthen health systems' capacities to reach adolescents and adult target populations** in Gavi 5.1. It would also allow countries to leverage synergies between investments in infant, adolescent and adult immunisation. Learnings from these efforts will help inform the consideration of a potential life course approach to immunisation in Gavi 6.0.

Strategic Goal #3: Improve sustainability of immunisation programmes

- 2.15 In Gavi 5.1, the Alliance reaffirms its 5.0 approach to sustainability,** including the approach to strengthening political and social commitment for immunisation at both national and subnational levels, prioritisation of mobilisation of domestic public resources (including domestic co-financing) and transition out of Gavi's support. The Alliance will continue to place an emphasis on subnational political will as this is the level where much of the funding for immunisation delivery lies and where immunisation programmes are operationally managed; and on

3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES

- A** Strengthen national and subnational political and social commitment to immunisation
- B** Promote domestic public resources for immunisation and primary health care to improve allocative efficiency
- C** Prepare and engage self-financing countries to maintain or increase performance

⁵ Such as the US\$ 100 million Zero-dose Immunisation Programme (ZIP) in the Sahel and Horn of Africa regions, described in Doc 02b

working with civil society organisations to foster this commitment.

- 2.16 **Gavi's model has been successful in bolstering country ownership of vaccine programmes** and in driving domestic public resource allocation towards immunisation. Despite slow economic growth, inflation and increasing debt, 2022 co-financing payments are ahead of the levels seen in previous years. Such results are a testament to the Alliance approach of working with multilateral technical and health financiers for advocacy, policy dialogue, technical assistance and funding to ensure sustainable immunisation programmes. **However, the pandemic and political events have led to unprecedented fiscal challenges for countries putting Gavi's co-financing and transition model at risk.** In conflict and fragile countries, the risk of default is increasing in a deteriorating macroeconomic situation. Moreover, countries entering or currently in Accelerated Transition are facing unprecedented fiscal challenges and transition risks. To address these immediate challenges, the Funding Policy Review (FPR) proposes adjustments to transition with an extension of the accelerated transition phase from five to eight years and the introduction of a 35% co-financing threshold for countries to enter transition (see Doc 11). More substantive considerations on Gavi's eligibility, co-financing and transition model will be included in the Gavi 6.0 strategy process.
- 2.17 **As decided at the 2022 June Board meeting, the Alliance will implement the approach to support post-transition and never eligible Middle-Income Countries (MICs)** to maintain and enhance their immunisation performance. The implementation of the Board-approved MICs strategy will build on the recent engagement through COVAX in those AMC countries that were never eligible for Gavi support.

Strategic Goal #4: Ensure healthy markets for vaccines and related products

- 2.18 **The Gavi 5.0 market shaping objectives and priorities will remain central.** In the past, the Alliance's market shaping efforts have helped attract new manufacturers, improve supply security and decrease vaccine prices. However, supply security challenges persist in some vaccine markets. For instance, supply disruptions in the rotavirus vaccine market have made it challenging for the Alliance to continue to meet country product preferences. Limited initial capacity for malaria vaccine is also expected against high potential demand, resulting in limited ability to influence prices in the medium term (see Doc 02b). The Alliance will continue to evolve its market shaping efforts to mitigate risks of supply disruption and monitor average price dynamics.

4 ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS

- A** Ensure sustainable, healthy markets **dynamics with diversified supply** for vaccines and immunisation-related products at affordable prices
- B** Incentivise innovation for the development of suitable vaccines
- C** Scale up innovative immunisation-related products

- 2.19 **In Gavi 5.1, the Alliance will use its market shaping capabilities to support diversification in regional manufacturing of vaccines, notably in Africa.** Limited regional manufacturing capacity, particularly in Africa, contributed to serious delays in progressing toward equitable access of COVID-

19 vaccines. This has renewed commitment at the highest levels of government to establish industrial capacities on the continent for both pandemic response and routine immunisation. The Alliance will use its comparative advantage to **focus on a downstream, markets-based approach**. Gavi will offer partners and investors operating upstream both incentives and a path to commercial viability. The Alliance will balance its greater involvement in regional manufacturing diversification with other objectives of its markets shaping efforts, including improving supply security and maintaining vaccine affordability (see Doc 08). To reflect this new priority, objective 4a is updated to “ensure sustainable, healthy markets with diversified supply for vaccine and immunisation related products at affordable prices”.

- 2.20 **Incentivising innovation for vaccine-related products will continue to be a key part of strategic goal 4.** Gavi has started to implement its new innovation approach approved by the Board in June 2022 to promote transformational innovations across immunisation products, services and practices to help deliver on Gavi’s equity ambition.

Section C: Actions requested of the Board

The Gavi Alliance Board is requested to:

Approve the updated framework for Gavi 5.1 (updated ‘strategy one-pager’) attached as Annex A to Doc 06.

The Gavi Alliance Board is also requested to **provide guidance** on Gavi’s targeted additional roles in Pandemic Preparedness and Response as outlined in Annex B to Doc 06.

Annexes

Annex A: Gavi 5.1 strategy ‘one-pager’

Annex B: Gavi’s future role in Pandemic Preparedness and Response

Annex C: Gavi 5.1 operationalisation and financial considerations