Annex A: Gavi Market Shaping Strategy 2026-2030

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Executive summary

Guided by Gavi's fourth Strategic Goal, the market shaping strategy sets out how the Alliance will ensure healthy markets for vaccines and related products, operating within Gavi's policies and partnership model while building on lessons from previous strategic periods and adapting to the realities of Gavi 6.0.

Under Gavi 5.0/5.1, the strategy focused on three areas: sustainably competitive supplier base leveraging expanded supply capacity and improved product choice, improving demand health to reduce uncertainty, and enabling transformational innovation that best meets country needs. While elements such as supplier viability and predictable demand remain critical, the Gavi 6.0 context requires sharper trade-offs and a recalibrated focus.

The most significant shift in Gavi 6.0 is the constrained fiscal environment. Vaccine Budgets (VBs) and an updated co-financing policy will increase countries' price sensitivity, influence prioritisation decisions, and create short term demand uncertainties and supply-side pressures. Although single country applications should help with predictability over a five-year horizon, manufacturers will operate in a leaner environment, with pressure on price reductions and finding efficiencies. The short-term demand uncertainties and an absolute reduction in procured vaccines could well have a lasting (but unpredictable) impact on supply security with a greater risk of supplier exits, delayed investments or reduced buffer capacity. At the same time, regional manufacturing ambitions, particularly in Africa, require sustained support to become commercially viable. Global health security needs have also expanded Gavi's role in outbreak preparedness, highlighting the unique challenges of outbreak, epidemic and pandemic (OEP) vaccine markets and associated market shaping interventions.

In response, the Market Shaping Strategy for Gavi 6.0 (MSS 6.0) adopts a more targeted and risk-based approach compared to previous periods, aiming to balance affordability imperatives with supply security to maintain supply access and long-term vaccine market viability. It is structured around three strategic priorities:

- **Optimising programme affordability to countries and Gavi**. Given funding constraints and the direct link between price and volume under VBs, ensuring access to lower-cost products and reducing weighted average prices (WAP) becomes central to sustaining health impact. However, a cost driven approach may weaken incentives for innovation and increase supply side risks. MSS 6.0 therefore recognises situations where price premiums may be strategically warranted to protect supply security, long term sustainability, or programmatic suitability.
- **Maintaining supply access, security and overall market health**.

MSS 6.0 introduces a clearer, quantifiable definition of supply security, covering aggregate supply capacity, individual supplier reliability and supplier diversity. This reflects concerns that a leaner, more competitive, environment may limit supply flexibility and long-term market viability. The strategy highlights risks that may require careful mitigation, such as over-reliance on single suppliers or regions and insufficient innovation pipeline resilience. It also emphasises the need for uninterrupted supply and a sustainable, geographically diverse supplier base capable of serving countries beyond Gavi support.

- **Developing future markets for VIS endorsed and OEP vaccines.** The discipline of early market shaping will be further developed and used selectively, focused where delays between licensure and country access would significantly impair public health outcomes. For VIS-endorsed vaccines such as TB, interventions aim to anticipate supply risks, clarify demand pathways and accelerate readiness. For OEP vaccines, where demand is structurally insufficient to sustain suppliers, Gavi will work with partners to develop financing and procurement models that secure rapid, equitable and sustainable access.

Effective execution of MSS 6.0 relies on a coherent set of enablers that strengthen demand predictability, coordination and well-informed market interventions.

Healthy demand, driven by evidence-based country decisions, predictable funding and clear policy guidance remains foundational. In Gavi 6.0, Holistic Prioritisation, VBs and co-financing policy changes will shape country product choices and programme prioritisation. Ensuring countries understand the financial and programmatic implications of their decisions will be essential to sending transparent demand signals to manufacturers.

MSS 6.0 also relies on **structured analytical tools and governance processes**, including Market Shaping Roadmaps, a revised Healthy Markets Framework (HMF) with quantifiable supply security metrics, and leveraging the Market-Sensitive Decisions Committee (MSDC). These tools and mechanisms ensure that decisions involving complex trade-offs or financial risk receive appropriate oversight and remain aligned with Alliance-wide goals.

Finally, the **African Vaccine Manufacturing Accelerator** (AVMA) and a definitive set of **procurement principles** are central enablers of MSS 6.0. AVMA aims to strengthen Africa's manufacturing base with financial incentives to offset higher initial production costs, thereby supporting affordable, sustainable and regionally diverse supply. The intent to review and codify Alliance procurement principles during Gavi 6.0 reflects openness to evolve with the global context and emergence of complementary procurement channels, while safeguarding core tenets of a unified demand pool and reliance on quality-assured supply, critical to preserving Gavi's market shaping successes.

Together, these enablers provide the operational backbone needed for MSS 6.0 to navigate a more constrained and complex landscape, while maintaining access, protecting supply security and ensuring readiness for future needs.

The Market Shaping model

Gavi's Market Shaping Goal and Strategy for the period 2026-2030 builds on the success and lessons of previous periods and is calibrated to meet the needs of Gavi 6.0. The strategy seeks to uphold one of Gavi's founding principles: predictable demand backed by assured long-term financing and implemented through well-established enablers that are tailored to fit Gavi's evolving context.

Market shaping in the context of Gavi

Since 2011, in Gavi 3.0, the Alliance has focused its fourth strategic goal (SG4) on market shaping. The objectives established under SG4 determine the market shaping strategy that is executed within the boundaries of Gavi policies and the Alliance partnership model defining distinct institutional roles and implemented through market-specific strategies outlined in market shaping roadmaps, as well as cross-cutting market strategies and enablers. Vaccines, cold chain and immunisation devices funded by Gavi have all been within the scope of market shaping, though the focus in Gavi 6.0 is on vaccines.

In the Gavi-supported vaccine or immunisation product markets, the predictable and high demand generated from Gavi's assured vaccine procurement funding has become one of the core foundations of market health. This demand signal directly influences market attractiveness and efficiency and suppliers' willingness and ability to satisfy the demand under favourable conditions. See *Healthy demand* for more on the importance of this foundation of market shaping.

In markets that operate favourably for both consumers (countries) and sellers (suppliers), i.e., where market forces such as supply, demand, pricing, competition, and investment incentives are sufficiently aligned, there is little need for interventions from government/public actors to shape the market. Many markets important to Gavi do not naturally operate favourably for Gavi-eligible countries or for suppliers, and cannot reliably deliver vaccines or immunisation products in the right quantities, at the right times, or at affordable prices, to the populations that need them most. Market shaping aims to correct these failures, by setting objectives and strategies to intervene, mitigate risks, create opportunities and incentives, and find a balance that is acceptable for all stakeholders (including countries, donors and suppliers) and that can be sustained over the long term.

Gavi 6.0 funding constraints will put a strain on Gavi's market shaping model; an absolute reduction in procured vaccines, country prioritisation choices and increased co-financing obligations will create new demand uncertainties and supply-side pressures, especially in the near-term. Single country applications covering the full strategic period should improve demand predictability over time with a five-year view on country plans. However, during the transition period to this new approach, demand predictability for new vaccine introductions or vaccines covered by discretionary budgets[1] may temporarily decrease while countries grapple with newly reduced budgets and need to make decisions on how best to allocate them. Supplier decisions taken during this period of uncertainty may have longer-lasting consequences that are not easily reversible, requiring a more proactive, adaptive and differentiated market shaping approach under MSS 6.0. The constrained fiscal environment will increase focus on affordability that will need to be carefully balanced with supply security to ensure that countries' immunisation programmes are not compromised by supply disruptions or lack of supply sustainability. Such trade-offs will be a defining feature of the MSS 6.0.

The Market Shaping Strategy 6.0

Guided by Gavi SG4 objectives, MSS 6.0 establishes strategic priorities and target outcomes applicable to all Gavi-eligible product markets. This document – the MSS 6.0 – provides lay readers (e.g., the public), Alliance stakeholders (e.g., Governance members including industry and country constituencies) and the entities responsible for executing the strategy (Gavi Market Shaping, the Gates Foundation Immunisation department, UNICEF Supply Division and WHO Department of Immunization, Vaccines and Biologicals - IVB) with a transparent understanding of the overall strategic direction for the Gavi 6.0 period and a description of what are referred to as "enablers" that will form the basis of the operationalisation that will follow out of this strategy. The MSS 6.0 lays out an overarching strategic intent, co-created through alignment with Gavi market shaping partners (i.e., *The Square Group* and relevant other entities as listed in *Appendix 1*), and is not intended to reflect strategies, analysis or action plans for any individual market or product, neither does it seek to predict the eventual operational outcome of initiatives launched within MSS 6.0 such as the review of Gavi's procurement model. Instead, cross-cutting operational activities and market-specific strategies will be detailed and treated as part of relevant workstreams in a step-wise manner throughout the strategic period. For example, the MSS 6.0

[1] See definition of discretionary budgets in *Gavi 6.0 initiatives* section.

strategic priorities, target outcomes and operational guidance will inform market-specific strategies and operations outlined separately in Market Shaping Roadmaps available on Gavi's website, noting that all market shaping documents must balance the need for transparency of the Alliance strategies and objectives with confidentiality, to ensure that commercially sensitive information is managed responsibly. The MSS 6.0 is further supported by Gavi's long-standing, trust-based relationships with vaccine manufacturers which remain central in Gavi 6.0 despite the more constrained environment. A strategic, Alliance-wide manufacturer engagement plan for Gavi 6.0 will guide deliberate, coordinated interactions throughout the period, reinforcing collaboration and ensuring alignment on shared market objectives.

The structure of MSS 6.0 flows from the three Board-approved SG4 objectives for Gavi 6.0 and is articulated by strategic priorities and associated target outcomes. MSS 6.0 is further supported by a suite of enablers which provide guidance for the operational execution of the strategy. Figure 1 lays out the high-level structure of MSS 6.0.

Figure 1: SG4 objectives, MSS 6.0 strategic priorities and target outcomes and strategic enablers

SG4 Objectives	Drive healthy vaccine markets for Gavi-supported and self-financing countries, including acceleration of access to new high-impact affordable vaccines and delivery innovations
	Enhance regional vaccine supply security, in support of regional manufacturing and increased self-reliance expansion ambitions
	Develop sustainable markets for vaccines against outbreak, epidemic, and pandemic-prone (OEP) diseases

MSS 6.0 Strategic Priorities What guides us	**SP1 Optimise vaccine programme affordability to countries and Gavi**	**SP2 Maintain supply access, and security, and market health**	**SP3 Develop future markets for VIS-endorsed and OEP vaccines**
	These priorities require trade-offs in short and long-term		
Target Outcomes What we want to achieve	Availability of **lower-cost products** for Gavi-supported countries	**Uninterrupted supply** of vaccine for countries is maintained in each vaccine market through Gavi 6.0	Introduction of **select affordable new high-impact vaccines** is **accelerated**
	Materialisation of **WAP decreases** for specified Gavi-supported vaccines	**The long-term outlook for supply security** and **market viability** for all Gavi markets is **maintained as acceptable** for the benefit of countries in all transition phases	**Access to vaccines for outbreaks, epidemics and pandemics** is rapid and equitable
	Limitation of WAP increases to cases that are justified by market health, programmatic, or strategic benefits	Emergence of a **geographically diverse supplier base** that can endure to serve countries beyond transition out of Gavi support	**Supply access** for outbreak and epidemic-focused vaccines is **sustainable**

Strategic Enablers How the outcomes can be achieved	**Healthy demand**	Funding predictability	Holistic Prioritisation and country decisions	Demand predictability
	Alliance collaboration	Guidelines and policies	Vaccine regulatory systems	Alliance partnerships
	Market Shaping roadmaps and analytical support	Demand, supply and price forecasts	Future supplier base	
		Healthy Market Framework	Early and standard market shaping roadmaps	
	Implementation mechanisms	Gavi 6.0 initiatives (VB, ELTRACO, Holistic Prioritisation)	Procurement principles and Procurement Policy	
		African Vaccine Manufacturing Accelerator	Financial tools	
	Decision-making pathways	Product Portfolio Management principles	Next-gen vaccine governance pathway	MSDC

Strategic Goal 4 (SG4) – "Ensure healthy markets for vaccines and related products"

SG4, the Board-approved "market shaping goal" for Gavi 6.0 is to "ensure healthy markets for vaccines and related products". The three Board-approved objectives for SG4 are:

1. Drive healthy vaccine markets for Gavi-supported and self-financing countries, including acceleration of access to new high-impact, affordable vaccines and delivery innovations
2. Enhance regional vaccine supply security, in support of regional manufacturing expansion ambitions
3. Develop sustainable markets for vaccines against outbreak, epidemic, and pandemic-prone diseases

These SG4 objectives, together with the Gavi 6.0 policy and operational framework, provide primary guidance for MSS 6.0, which articulates a market-agnostic approach to how the Alliance will shape vaccine markets during the Gavi 6.0 period. At the same time market shaping considerations provided inputs to the definition of Gavi 6.0 policies. MSS 6.0, in turn, influences market-specific strategies and interventions defined in market shaping roadmaps, as well as cross-cutting strategies and enablers. Figure 2 illustrates the hierarchy and interdependencies between these different components.

Figure 2: Context of the Gavi Market Shaping Strategy

Gavi 6.0 framework and policies

In addition to the specific SG4 objectives, the MSS must be designed to adhere to and be implemented within the framework and policies governing Gavi 6.0, including funding and process reforms driven by the Gavi Leap. Several changes are expected to directly or indirectly impact demand and the resulting market shaping strategy. The most significant changes under Gavi 6.0 are:

- **Single country applications** for vaccine procurement and cash support, covering a five-year period (aligned with Gavi strategic periods), are expected to improve clarity on future demand. The impact of this change should indirectly benefit market shaping and demand predictability, after a period of transition which will come with demand uncertainties linked to implementation in the near term.
- **Vaccine budgets** (VBs) are set budget allocations provided to Gavi-eligible countries for their vaccine procurement support in Gavi 6.0 and represent a major strategic shift in Gavi 6.0 defining how the available budget to Gavi for vaccine procurement will be allocated to countries (see more details under

Vaccine Budgets (VB)). The envelope ceiling and the approach to guaranteed budgets and discretionary budgets mean that VBs will not cover all existing country commitments and planned introductions and campaigns. Following Gavi Replenishment in June 2025, the Gavi 6.0 strategy recalibration aimed to address the US$ 3.0 billion funding gap by adopting a more targeted approach to new vaccine introductions and preventive campaigns and by reducing overall procured volumes. Nonetheless, there remains an approximate US$ 400 million gap in vaccine procurement costs compared to the financial forecast put forward for Board approval in December 2025. This is expected to have multiple impacts on market shaping, including:

  - Highly unpredictable demand in the short term and potentially lower demand over the medium term as countries navigate critical trade-offs between increasing co-financing requirements and Zero Dose ambitions within a finite budget. These risks are especially salient for vaccines covered by discretionary budgets (i.e. vaccines that depend on countries' allocation of their discretionary budget). Overall funding constraints may also result in less predictable timing of new vaccine introductions under guaranteed budgets.
  - Greater pressure on countries to optimise the affordability of their vaccine portfolios, leading to shifts in country preferences towards lower priced products, negatively affecting the predictability of product-level demand outlooks during 2026 while these decisions play out, with possible impacts on supply security persisting thereafter.
  - The shifts in demand predictability and materialisation at both vaccine and product levels will likely impact supplier production planning decisions in the short-term (e.g., how many doses to produce) and investment decisions with long-term implications on supply availability (e.g., production capacity expansion or R&D investment for a next generation product[2]).

- Revised **Eligibility, Transition and Co-financing (ELTRACO) policy,** specifically shift A implementation[3] and changes to campaign co-financing rules, is expected to impact market shaping, including:
  - Greater pressure on countries to optimise the affordability of their vaccine portfolios, leading to shifts in country preferences towards lower

[2] See definition of next generation vaccines under *Appendix 1.*
[3] Shift A adjusts the Co-financing Policy by directly linking country co-financing contribution to the price of the vaccines for specific vaccine markets for Initial Self-Financing Countries, where certain conditions are met.

priced products, negatively affecting the predictability of product-level demand outlooks during 2026 while these decisions play out, with possible impacts on supply security persisting thereafter.

- Unpredictable and most likely lower demand for preventive campaigns and increased demand for outbreak response.

While MSS 6.0 must account for these framework and policy changes, several of them also serve as enablers for the implementation of the strategy, and market shaping considerations were instrumental in informing the design of these different elements (see *Gavi 6.0 initiatives*).

Market Shaping Strategy: strategic priorities and target outcomes

The guiding SG4 objectives were developed as part of the Gavi 6.0 strategy design prior to Gavi Replenishment and before the extent of financial constraints was known. The MSS translates these objectives into strategic priorities, taking into account the Gavi 6.0 recalibration decisions. The primary elements of the MSS are strategic priorities (SP) and related overarching target outcomes (TO) which guide market-specific strategies and operational actions. *Figure 1: SG4 objectives, MSS 6.0 strategic priorities and target outcomes and strategic enablers* lays out the three SPs and nine TOs of the MSS 6.0. Progress towards achieving each target outcome will be measured leveraging SG4 indicators established as part of a *Monitoring and evaluation framework* with pre-defined indicators (see *Figure 4 SG4 indicators*).

By having a significant and sustained impact on the supplier base, and by facilitating access to centralised pooled procurement, the Alliance's market shaping work has historically had significant "spillover" benefit for middle-income countries (MICs) in terms of access to sustainable and affordable supply; hence this MSS 6.0 (whose direct application is to Gavi-eligible countries[4] and Catalytic Phase-eligible self-financing MICs), is conceived to continue perpetuating this critical spillover effect.

The constrained funding environment of Gavi 6.0 necessitates a re-focus on affordability[5] of procurement of vaccines with similar benefit at a lower weighted average price (WAP) to sustain country and Gavi health impact with more limited funds. In the context of VBs and their financial ceiling for vaccine procurement, vaccine prices will directly affect the volume of vaccines available to each country. Balancing affordability and supply security will require difficult trade-offs that must ensure continuous vaccine supply and that short-term actions do not compromise the long-

[4] Defined as a country in one of the three phases of Gavi support (initial self-financing, preparatory transition and accelerated transition).
[5] Definitions of key market shaping terms used are provided in *Appendix 1.*

term imperative of regionally diversified supply and sustainable markets that serve countries' needs beyond Gavi support. Reflecting these needs, SP1 (Optimise vaccine programme affordability to countries and Gavi) and SP2 (Maintain supply access, and security, and market health) will operate in tandem to guide strategies primarily for ongoing vaccine and immunisation product programmes. By contrast, and as a secondary priority, SP3 looks to the future to anticipate and mitigate market risks for Vaccine Investment Strategy (VIS) - approved programmes expected to launch in the second half of the strategic period or beyond. SP3 also focuses on SG4 third objective and outbreak, epidemic and pandemic (OEP) markets, which operate across a diverse range of partners and have different considerations.

SP1 - Optimise vaccine programme affordability to countries and Gavi

This SP on affordability refocuses the MSS on a priority found in previous strategies, which will evolve in Gavi 6.0 to encompass the importance of availability of lower cost products and of lowering the weighted average price (WAP) of procured vaccines, or justifying WAP increases for strategic reasons. This SP addresses the first SG4 objective of "accessing affordable vaccines and delivery innovations". Importantly, the SP emphasis is placed on total costs (i.e. "affordability") rather than narrowly on pricing, promoting cost-effectiveness and enabling product and delivery innovation where relevant. Nonetheless, innovation is not a priority of MSS 6.0, and the stronger focus on affordability is expected to weaken incentives for vaccine product innovation, particularly for innovator companies aiming to serve low-income and lower-middle-income markets. A market analysis based on a revised Healthy Markets Framework (HMF), detailed in *Market Shaping Strategy: enablers*, will guide the approach to achieve this SP in each market and how to achieve the right balance between affordability and other prerequisites to supply security, including innovation.

SP1 target outcomes

Target Outcome 1.1: **Availability of lower-cost products to Gavi-supported countries**

This recognises the importance of sustaining manufacturers' interest and ability to provide lower-cost products for Gavi-funded procurement, through relevant market shaping interventions. The availability of these lower-cost products provides the foundation of affordability. For example, the availability of lower-cost PCV and HPV vaccines that has emerged in recent years has provided countries with choices that can reduce the proportion of countries' budgets attributed to these vaccines. (See *HPV case study* (*SP1 TO1.1)*

Target Outcome 1.2: **Materialisation of WAP decreases for specified Gavi-supported vaccines**

Within individual markets this can be accomplished through a re-distribution of the purchased volumes of vaccines at different price points towards more volume of the lower-priced vaccines, through accessing or negotiating lower prices, or through a combination of these two approaches. Where justified, market-specific strategies to achieve WAP decreases will be developed, acknowledging this TO may not be achievable in markets impacted by significant volume reductions. For example, the availability of multiple products of the same presentation in ample quantities to satisfy country demand enables consideration of the procurement of the lowest cost products in larger quantities, resulting in lowering the overall WAP. Such opportunities will need to be carefully balanced against any supply security or broader market health trade-offs. Furthermore, countries supported through the Holistic Prioritisation approach (see *Holistic Prioritisation* for definition) will need to assess their product choices by weighing potential price savings against the additional resources required to operationalise product switches.

Target Outcome 1.3: **Limitation of WAP increases to cases that are justified by market health, programmatic or strategic benefits**

This acknowledges that affordability is not at odds with accepting instances, supported by analysis, of higher WAP to address market vulnerabilities (e.g. supply security, long-term sustainability), programmatic suitability (including uptake of higher-cost innovation) or other strategic challenges. For example, a higher priced vaccine supplied by a strategically important manufacturer may be maintained at a comparatively significant share of procurement for the strategic benefit of ensuring sufficient buffer capacity remains available in the market to mitigate the risk of supply disruptions, especially for complex to manufacture vaccines.

SP2 - Maintain supply access, security, and market heath

The SP on supply access, security and market health is a critical pairing with SP1 on affordability as prioritising lower cost vaccines and lower WAP is short-sighted if it comes at the expense of supply disruptions or manufacturers' inability to remain in the market, depriving countries of needed supply. The Alliance has spent over 20 years building market health and supply security to ensure sustainable access, and this SP ensures these achievements are safeguarded and preserved as much as possible. A specifically defined status of minimum supply security[6] (as per the *Healthy Markets Framework* *(HMF)*) will allow objective and quantitative comparisons across markets,

[6] See definition of Supply Security in *Appendix 1.*

inform trade-offs with vaccine procurement costs and support decision-making for required interventions where supply security might need to be increased or where there is latitude to accept some level of deterioration. Enhancing regional vaccine supply security as per SG4 objective 2 requires a longer-term lens, because vaccine manufacturing is highly complex and regions without existing capacity need time to build the necessary supportive ecosystem including infrastructure, regulatory systems, specialised workforce, sustainable financing and procurement mechanisms among others.

SP2 target outcomes

Target Outcome 2.1: **Uninterrupted supply of vaccine for countries is maintained in each vaccine market through Gavi 6.0**

This represents the fundamental need to have vaccines available to supply immunisation programmes. This TO is closely aligned with the WHO IA2030 strategic priority 6 on supply and sustainability[7] and UNICEF SD indicator of timely supply availability. For example, the supplier base in each market should be able to recover from a supplier production problem with sufficient systemic contingencies so that immunisation is not interrupted in any country. This TO aims to address the particular risk that a more uncertain demand environment and an absolute reduction in procured volumes may have on supply flexibility. Under Gavi 6.0, this leaner, more competitive, environment refers to the expectation that manufacturers will need to find efficiencies, reduce prices and likely operate with smaller profit margins.

Target Outcome 2.2: **The long-term outlook for supply security and market viability for all Gavi markets is maintained as acceptable for the benefit of countries in all transition phases**

This emphasises the need to ensure that countries retain predictable, affordable, and sustainable access to vaccine doses over the long term, which requires maintaining market viability with sustained manufacturers' participation. In this context, long term refers to the period extending beyond the Gavi 6.0 strategic period, ensuring that foundational market conditions established in Gavi 6.0 continue to benefit countries well after they exit Gavi support.

A market's supply security goes beyond ensuring uninterrupted supply and that supply meets demand. It is determined by several factors: 1) the overall (aggregate) production capacity available across all suppliers and their collective

[7] WHO IA20230 Strategic Priority 6 goal: All countries have a reliable supply of appropriate and affordable vaccines of assured quality, and sustainable financing for immunisation programmes.

ability to meet more or less predictable demand, 2) the reliability and risk profile of each supplier, and 3) the degree of supplier diversity or concentration. Ensuring an acceptable level of supply security for a given market will help protect affordability, support necessary innovation (to the extent strategically important for competition along the dimensions of price and product profile), and underpin the long-term sustainability of access. Achieving this may require short-term trade-offs, such as temporarily higher procurement costs when diversifying suppliers or securing buffer capacity, before the benefits of improved supply security are fully realised. Sustaining long-term supply security will require close monitoring of key market trends such as overreliance of vaccine procurement on a single supplier for a given vaccine or across several markets, or a single country, as well as risks of market exits, and devising appropriate mitigation strategies (e.g. adjusting procurement strategy or supporting manufacturer transitions). This target outcome applies not only to Gavi-eligible countries but also to former Gavi-eligible and never Gavi-eligible MICs included within Gavi's new Catalytic Phase. Many of these countries continue to procure through UNICEF after transitioning, contributing to a sizeable, stable market, essential for maintaining attractive pricing and supply resilience; hence the "spillover benefit to MICs" of the Alliance's market shaping, especially in terms of pricing, is a key feature both historically and for the future. The YFV market shaping roadmap is a clear example of this long-term, sustainability focused approach in a market serving both current and former Gavi-eligible countries. (See *Yellow fever vaccine (YFV)* case *study (SP2)*

Target Outcome 2.3: **Emergence of a geographically diverse supplier base that can endure to serve countries beyond transition out of Gavi support**

This directly speaks to SG4 objective 2 on regional supply security and Gavi's regional manufacturing strategy. This TO also supports the other TOs under this strategic priority, although the timeframe may differ given the complexities of building a new and sustainable manufacturing capacity in regions where it doesn't yet exist. It might also be in tension with the affordability objectives under SP1 and require justification for a strategic benefit under TO 1.3, although enablers such as the *African Vaccine Manufacturing Accelerator (AVMA)* are designed to offset higher development and production costs. Furthermore, active monitoring of the trends impacting the supplier base through the *Healthy Markets Framework (HMF)*(e.g. over-reliance on a specific supplier, overall change in supplier mix to the benefit of a single country or region and to the detriment of incumbent suppliers) will be critical to find the right balance between affordability and supply security. In other words, supplier-base trends from Gavi 5.0 will continue to be strategically monitored in the context of regional ambitions and supply security imperatives: (1)

declining overall supply from IFPMA manufacturers, (2) increasing reliance on particular suppliers, (3) increasing reliance on supply from particular countries.

SP3 - Develop future markets for VIS-endorsed and outbreak, epidemic and pandemic (OEP) vaccines.

This SP builds on the Alliance's experience demonstrating the value of early market shaping for newly Board-approved vaccine programmes and addresses SG4 objectives 1 (VIS-endorsed vaccines for upcoming Gavi programmes) and 3 (OEP vaccines). In several cases, a significant time lag between vaccine licensure and the launch of a Gavi programme, combined with limited supply, have led to substantial delays in country implementation (e.g., malaria). In contrast, when early market shaping interventions were applied, they enabled faster and timelier programme launches, as seen with the Ebola emergency stockpile.

Market shaping of VIS-endorsed and select OEP markets through Gavi's early engagement can provide important demand signals, strengthening vaccine developers and manufacturers' confidence in the value of at-risk supply capacity investments, helping to reduce the typical delay between licensure and programme impact. Gavi and partners' efforts in defining regulatory, policy, procurement, and financing pathways or mechanisms early, can accelerate licensure and vaccine rollout, to the benefit of both Gavi-eligible and other countries.

SP3 target outcomes

TO 3.1: **Introduction of affordable new high-impact vaccines is accelerated**

This TO pertains to future VIS-endorsed programmes only and seeks to ensure that market-specific risks that might slow or prevent impactful introductions in Gavi countries (including overall funding constraints linked to VBs) are identified and mitigated against. For example, the early market shaping roadmap for novel TB vaccines (a Board-approved new VIS programme) currently in development will look into the potential market shaping risks of supply scarcity of the novel vaccines that could delay country introductions and prevent a successful programme launch. Gavi is working with partners to refine their understanding of these risks, transparently communicate the findings to vaccine developers and, if necessary, propose market interventions for its mitigation. Supporting new high-impact vaccines will rely on collaboration with key partners, including from the broader global health ecosystem leveraging existing resources and systems, e.g. The Global Fund, Stop TB Partnership, etc.

TO 3.2: **Access to Outbreak, Epidemic and Pandemic (OEP) vaccines is rapid and equitable**

This recognises Gavi's critical role in providing the financing and implementation support to countries through pre-established response mechanisms, a thorough understanding of the markets and pre-positioning of supply where relevant. For example, utilising the newly established First Response Fund (Board approved in June 2024), Gavi's response to the declaration of a public health emergency of international concern (PHEIC) for mpox triggered disbursement of funds and the execution of an advance purchase agreement (APA) enabling the procurement of supply-limited vaccine within 35 days of the PHEIC declaration in August 2024.

TO 3.3: **Supply access for outbreak and epidemic-focused vaccines is sustainable**

This responds to the fact that demand for many outbreak and epidemic-focused vaccines is insufficient to be sustainable for suppliers of these vaccines under normal market conditions. Working with partners such as CEPI, and funders, to identify and implement solutions where needed that allow for the availability of such vaccines through specific financial mechanisms is critical to maintaining preparedness and enabling rapid outbreak response. For example, the market shaping roadmap for Ebola vaccines speaks to the requirement of a *higher financial risk appetite in order to enable a necessary insurance mechanism* for outbreak preparedness. This may result in occasional vaccine wastage in the absence of outbreaks and country demand but ensures contracting predictability for suppliers supporting supply sustainability (see *Ebola case study*). This target outcome focuses on OEP vaccines for which Gavi has an explicit Board mandate but that are not part of Gavi programmes with routine and/or preventive vaccination components supplied outside of a small-volume emergency stockpile, i.e., the scope is Ebola, mpox and HepE. The list may expand over Gavi 6.0 if relevant conditions are met for other investment approvals building on the VIS 'living assessments' (e.g. major outbreak, vaccine with clear licensure pathway and meeting VIS epidemics criteria, etc.) and will rely on Gavi's Global Health Security mandate.

Market Shaping Strategy: enablers

The Alliance has developed a suite of enablers over its market shaping history that are central to implementation of the strategy. Developing the market-specific roadmaps and strategies and implementing the underlying action plans and interventions are all done through these "enablers". Healthy demand is a foundational enabler, supported in different ways, but unwavering in its importance as an anchoring element of markets and market shaping. Other enablers are created, evolved or retired as is required to best serve the needs of the Alliance, specific to each Gavi strategic period and the circumstances of each MSS. Some of the enablers are more strategic in nature while others are tools and processes.

Enablers broadly fall into five categories (see *Figure 3 Market shaping enablers*). 1) healthy demand that is grounded in country decisions and influenced by specific actions; 2) Alliance collaboration that indirectly supports healthy demand and market shaping as well as partnerships directly engaged in market shaping; 3) market-level strategies established in roadmaps and 4) the implementation mechanisms that allow these strategies to be operationalised and 5) formal decision-making structures and pathways that ensure transparent oversight of strategy implementation.

Figure 3 Market shaping enablers

Healthy demand	Funding predictability *	Holistic Prioritisation and country decisions *	Demand predictability *
Alliance collaboration	Guidelines and policies	Vaccine regulatory systems	Alliance partnerships
Market Shaping roadmaps and analytical support	Demand, supply and price forecasts	Future supplier base	
	Healthy Markets Framework	Early and standard market shaping roadmaps	
Implementation mechanisms	Gavi 6.0 initiatives (VB, ELTRACO, Holistic Prioritisation) *	Procurement principles and Procurement Policy *	
	African Vaccine Manufacturing Accelerator *	Financial tools	
Decision-making pathways	Product Portfolio Management principles	Next-gen vaccine governance pathway	MSDC

* Strategic enabler

Healthy demand

Gavi's market shaping operates upon a foundation of "healthy demand" generated from predictable and transparent funding, policies, processes and country decisions. These factors translate into demand certainty that lowers investment and production risks for manufacturers, allowing for balanced supply and demand and the resultant market efficiencies.

In the 5.0/5.1 context, demand-side challenges were key barriers for several markets. The lack of predictable demand volumes in certain markets (e.g., OCV) created risks for suppliers' capacity and production planning and the lack of new product uptake in markets with product choice (e.g., PCV) hindered long-term competition. To address these challenges, MSS 5.0 identified healthy demand as a strategic priority and aimed to create a supportive environment for demand to be timely, predictable, sustainable, and driven by evidence-based decisions.

However, changes to the Gavi 6.0 strategy and policies bring different changes with critical market implications and may require different demand-side outcomes. The implementation of Vaccine Budgets will create demand uncertainties through decreased volume of demand and low demand predictability in the near-term as countries make decisions on how to prioritise and optimise their vaccine portfolios. In the long-term, the critical trade-offs that countries are navigating to balance increasing co-financing obligations against healthcare impact and Zero Dose ambition will shape the supplier base and resulting market dynamics, potentially affecting long-term supply security and market viability. To address these short-term and long-term challenges, the Holistic Prioritisation approach will be a key Gavi 6.0 market enabler by supporting countries in making evidence-based and cost-conscious product choice decisions and by providing better demand visibility through early country engagements and single country applications (see *Gavi 6.0 framework and policies*). In addition, cross market and programme coordination will be critical for the implementation of Gavi 6.0 policies. (See *Gavi 6.0 initiatives*).

Finally, healthy demand is influenced by fundamental building blocks of the global immunisation system that include efficient regulatory systems and global, regional and national policy development and guidelines that are timely and recognise market realities. (See *Guidelines and policies at global, regional and national levels* and *Efficient and innovative national and international vaccine regulatory systems* for initiatives implemented through Alliance Coordination).

Alliance collaboration

Technical agencies of the Alliance collaborate and lead on critical functions that support healthy demand, timely supply and innovations, and strategies shaping specific market challenges.

Guidelines and policies at global, regional and national levels

WHO has a lead role in establishing healthy demand through developing and issuing vaccine Position Papers that recommend vaccine policy which guides Gavi's programme funding and implementation. The Strategic Advisory Group of Experts (SAGE) on Immunization is the principal advisory group to WHO for vaccines and immunisation, advising WHO on overall global policies and strategies. Prior to licensure of vaccines, WHO leads in defining the scope of evidence useful for such vaccine policy recommendations to be made through its Evidence Consideration for Vaccine Policy. Timely availability of evidence, SAGE recommendations and subsequent WHO position papers provide the evidence base for country decisions and support healthy demand.

Efficient and innovative national and international vaccine regulatory systems

National and regional regulatory bodies (e.g., the Food and Drugs Authority of Ghana, the European Medicines Agency), together with WHO play critical roles in facilitating access of affordable vaccines to countries, by providing registration and prequalification services and supporting regional manufacturing and supply security.

- By promoting efficient regulatory pathways reliant on harmonisation, collaboration, mutual recognition and prequalification, WHO contributes to timely and equitable access to quality-assured products that balance the need for robust regulation of vaccines with resource efficiencies for countries and manufacturers.
- Prequalification services are, in 2026, a critical component of assisting countries in their regulatory evaluations and approvals and provide the basis of quality-assurance for UN agency procurement and Gavi funding. Future evolution of prequalification or alternative WHO certifications (e.g. EUL) of quality-assurance will be equally important and will be the subject of further evaluation during Gavi 6.0 as guided by the procurement principles within this document.
- Regional manufacturing and supply security depend on strong national and regional regulatory oversight that provides the quality-assurance required for Prequalification and hence for incentives available through the African Vaccine Manufacturing Accelerator (AVMA).

Alliance strategic and operational partnerships

The development and implementation of market shaping strategies is coordinated through several partnerships.

The Square Group

The leadership structure for market shaping will continue under the previously-established Terms of Reference (*Appendix 1*) between Gavi Market Shaping, UNICEF-SD, GF-IMM and WHO-IVB. The Square group provides high-level direction and support with decision-making, problem-solving, conflict resolution and evaluation of topics related to Gavi market shaping, ensuring alignment across Alliance market shaping partners. Depending on the specific market challenges, other partners may be consulted to inform the market shaping interventions under consideration. This includes partners such as PAHO Revolving Fund, Africa Centers for Disease Control and Prevention (Africa CDC), the Clinton Health Access Initiative (CHAI), MedAccess, the European Investment Bank (EIB), The Global Fund and Stop TB Partnership, among others.

The Vaccine Innovation Prioritisation Strategy (VIPS) Alliance

This group including the Gavi Secretariat, WHO, UNICEF-SD, the Gates Foundation, and PATH established an integrated framework to evaluate, prioritise and drive forward access to vaccine product innovations. Within the Gavi 6.0 financially constrained environment and with its work substantially complete during Gavi 5.0/5.1 and overseen by MSS 4.0 and 5.0, the VIPS Alliance has transitioned to a monitoring phase and will re-engage during MSS 6.0 on an as-needed basis.

Coalition for Epidemic Preparedness Innovations (CEPI)

An expanded partnership with CEPI exists under a Memorandum of Understanding covering 2024 – 2026 (with intent to renew through 2028) that facilitates sharing of information and expertise to prepare for and respond to future epidemics and is aligned with SP3. A number of areas under CEPI 3.0 strategic pillars are directly aligned and complementary of Gavi 6.0 strategy such as regional manufacturing capabilities for supply security or the approach to vaccine platforms and viral families to address viability challenges of OEP markets. Further collaboration focused on SP3 will be built with implementation of MSS 6.0.

Market Shaping roadmaps and analytical support

Market Shaping Roadmaps

Roadmaps have served as the main platform for developing and communicating Alliance market-specific market shaping strategies since Gavi 3.0. They determine Gavi’s short- and long-term market ambition, and mechanisms to influence the markets for each vaccine or immunisation product. While the focus of each roadmap is an individual market, long-term cross-market externalities of the strategies are a critical consideration of each strategy. Transparency for stakeholders is achieved by publishing a summary of each roadmap, providing visibility into influencers of procurement strategies and other implementation tools. To further transparency and consistency in the definition of market shaping strategic priorities, each roadmap is developed on the basis of a market analysis applying the Healthy Markets Framework and Future Supplier Base lens.

Demand, supply and price forecasts

Following or anticipating WHO guidance and considering programmatic and financial constraints, Gavi develops market-specific strategic demand forecasts as a transparent reference for stakeholders and a key input informing strategic objectives and target outcomes in market shaping roadmaps. Similarly, regularly updated supply and price forecasts provide further inputs to define the roadmaps’ action plans.

Healthy Markets Framework (HMF)

The HMF is a key strategic tool, developed by Alliance partners in 2015, that aims to create a standardised way of defining market health, communicate how the Alliance assesses individual markets, and improve how potential trade-offs between different market attributes are analysed. It has consistently evolved with each MSS to adapt to the realities of each strategic period, and the Gavi 6.0 version includes updated definitions of market health attributes to support a structured evaluation of the Alliance's risk appetite for supply security and associated trade-offs (see *Appendix 1)*. Specifically, the new *HMF* allows for the quantification of supply security risks based on concrete and standardised criteria, leveraging existing HMF attributes, such as supply meeting demand and demand predictability, individual supplier reliability assessments, and supplier diversity/level of reliance on individual sources. The tool allows monitoring key trends impacting the supplier base, such as a possible over-reliance on a single supplier across several vaccine programmes, or the overall supplier mix with changes in distribution across IFPMA and DCVMN (including emergence of African vaccine manufacturing) constituencies or manufacturing countries and regions. The proposed HMF adjustments, including the new methodology to quantify supply security, will be used as an internal decision support tool for Square Group partners to develop market shaping roadmaps, trigger discussion and alignment on risks and trade-offs, and decisions to seek *Market-Sensitive Decisions Committee (MSDC)* or Board guidance, and support SG4 indicator monitoring.

Future supplier base (FSB)

MSS 5.0 established Future Supplier Base (FSB) as a strategic pillar to foster a sustainable and competitive future supplier base. Given the significant number of potential new market entrants anticipated in the next 10-year horizon and the rapidly evolving landscape, marked by regionalisation and increased interdependencies, Alliance partners developed a strategic tool to assess supplier reliability and risk profile. Assessment outputs would support industry engagement and roadmap strategies by clarifying which suppliers are critical for each Gavi market and identifying related business sustainability and access-disruption risks.

FSB remains central and more relevant than ever to market shaping during Gavi 6.0 as a tool to support supply security. Optimising affordability and supply security requires a resilient future supplier base and an understanding of supplier specific reliability risks, which will directly contribute to market analyses and inform action plans across all roadmaps, including for existing Gavi programmes and those that are VIS-endorsed for future launch and introduction.

As alluded to elsewhere in this strategy, vigilance will be maintained to trends in Gavi's supplier base that apply at a portfolio / above-market level, namely: (1) declining overall supply from IFPMA manufacturers, (2) increasing overall market dominance by particular companies, (3) increasing reliance on supply from particular countries, (4) the advent of African-sourced supply into Gavi programmes.

Early market shaping roadmaps

Specifically supporting SP3, early market shaping roadmaps are intended to align market shaping objectives and target outcomes across Alliance market shaping partners for vaccines in development with an emphasis on the short-term uncertainties, challenges and risks that may prevent timely and successful implementation of a Board-endorsed future Gavi programme. These roadmaps are developed after a vaccine programme has been endorsed by Gavi's Board as part of the VIS, but prior to the vaccine's licensure, WHO-prequalification or SAGE recommendations and WHO position paper. Early roadmaps are updated frequently and simplified to provide the agility to add or change objectives as necessary during the period of higher uncertainty. At the beginning of Gavi 6.0, such early market shaping roadmaps are anticipated to be developed for TB and RSV.

Implementation mechanisms

Gavi 6.0 initiatives

Several aspects of the Gavi 6.0 strategy serve both as frameworks and policies that inform the market shaping strategy, and as indirect enablers, particularly of target outcomes under SP1 and SP2.

Vaccine Budgets (VB)

VBs are set budget allocations provided to Gavi-eligible countries for their vaccine procurement support in Gavi 6.0. All existing routine programmes, new vaccine introductions, and preventive campaigns are in scope of VB, while outbreak response vaccines (e.g. ICG stockpiles) are out of scope. VBs are made up of two components: 1) "Guaranteed budgets" for specific vaccine programmes, and 2) "Discretionary budgets", where countries can allocate funds across eligible vaccine programmes, at their discretion based on national priorities. The VB design based on guaranteed and discretionary budgets may provide countries with incentives to be more cost sensitive to certain markets, directly supporting TO1.1 and TO1.2. The overall capped VB budget may incentivise countries to optimise their vaccine portfolios with cost consciousness. This incentive is especially critical in vaccine markets where countries may choose at the product level and where multiple products with price differentials exist. Countries will need to consider the price and characteristics of different products and weigh the financial and programmatic benefits of choosing or changing to a lower cost product with any potential trade-offs. Depending on how aggregated country choices impact supply security and affordability, a VB 'top-up' mechanism may be activated to help rebalance these outcomes. This would help maintain minimum levels of supply security by supporting the viability of additional suppliers, thereby contributing to TO1.2, TO1.3 and TO2.2 where strategically relevant.

ELTRACO / Country Co-financing

As a part of the Gavi Funding Policy Review for Gavi 6.0, the Board approved an updated country co-financing policy (Shift A) that calculates co-financing obligations for Initial Self-Financing (ISF) countries based on percentage of vaccine cost, moving away from the US$ 0.20 per dose approach. For Gavi 6.0 specifically, the policy shift will apply to HPV and PCV in a first instance. This provides an incentive for ISF countries to consider price in product choices and make cost-conscious decisions, and is designed to encourage healthy demand and a diverse vaccine supplier base through the uptake of new lower-cost market entrants' vaccines, therefore supporting TO1.1 and TO1.2. Furthermore, the Board also approved the introduction of co-financing requirements for Gavi-supported vaccines for use in Gavi supported campaigns (excluding outbreak response campaigns) which now applies to all Gavi-eligible countries regardless of their transition status, further exposing countries to the price of chosen vaccines.

Holistic Prioritisation

An increasingly complex vaccine landscape presents countries with challenges in selecting vaccines suited to their contexts and deciding when to introduce them. The Holistic Prioritisation approach was developed by Alliance Partners to support countries in building capacity for informed, independent decision-making, enabling countries to prioritise vaccine and cash budgets and optimise immunisation programmes based on their unique contexts, supported by a cohesive, evidence-informed strategy that provides clear guidance on navigating global trade-offs and integrates the resources and expertise of global health agencies. Holistic Prioritisation support will be a critical enabler of VB implementation and MSS 6.0 SP1 target outcomes, enabling countries to understand the VB mechanism and make evidence-based and cost-conscious product choices based on a clear view of financial and programmatic implications.

African Vaccine Manufacturing Accelerator (AVMA)

The recalibration of Gavi's 6.0 priorities post replenishment has lowered procurement volumes for 2026-2030 for key vaccines expected to be produced in Africa (including cholera, yellow fever and hexavalent) and put downward pressure on prices. This may reduce the size of commercial opportunities for African manufacturers. However, these challenges are not unusual for a long-term market-shaping instrument. This introduces a need to ensure that AVMA's incentive structure remains adequate in a more price-sensitive environment.

AVMA will undergo a 2026–27 course correction (AVMA 2.0, as already planned within

AVMA's governance framework), which is the key opportunity to revisit design elements, ensuring that AVMA continues to maintain its relevance as an important enabler for African manufacturers to enter the market competitively and sustainably. Upward adjustment to subsidies and applicable caps will likely be necessary to address the impacts of Gavi 6.0 recalibration on the commercial prospects of African products. At time of publication, there is also an opportunity to have a significant portion of excess AMVA pledges (up to $189 million / "AVMA+") used for full buy-down of African-manufactured vaccines expected to reach the market through 2030, supplementing Gavi 6.0 vaccine procurement budget. This addresses the most significant near-term risk to the commercial viability of the AVMA eligible pipeline vaccines that AVMA is set up to support, i.e. the reduced Gavi procurement volumes and price pressure through Gavi 6.0.

Approach to Procurement Principles

Aligning procurement to a changing global context

Gavi 6.0 is the period when additional or alternative Alliance procurement partners must be contemplated, given rapid evolutions in the global environment, in large part precipitated by the COVID-19 pandemic during Gavi 5.0, and subsequently the principles of Gavi Leap (notably *Country Centricity, Self-Reliance & Sovereignty* and *Finite Lifespans*). Gavi has closely followed the evolving landscape of (continental / regional) procurement initiatives, and as these continue to develop their structures, scope, capabilities and operational models, Gavi will remain engaged with them to assess their implications and applicability to the broader global procurement architecture.

A review of the centralised procurement approach will hence be a major Gavi undertaking during Gavi 6.0. While the MSS 6.0 does not prescribe specific solutions or new operating models at this stage, it establishes an openness to evolve with the global context, and a mandate to review and codify Alliance procurement principles in the first half of Gavi 6.0. These principles will be developed through engagement with, and informed by, Gavi-eligible countries' preferred approaches to procurement, and will guide Gavi's consideration of potential collaboration with complementary procurement channels while safeguarding the core principles set out in this strategy and without backsliding on the decades of market-shaping gains achieved by the Alliance to date.

The review of the current model and any recommendations will aim to be ready for governance milestones in Q4 2027, after which an updated Alliance Procurement Policy will be considered. This would include an updated and clarified Domestic/Self-Procurement Policy, revising the language and conditions in the existing Self-Procurement Policy to ensure coherence with an evolved procurement and regulatory context and the overall eventual procurement approach.

Context and background: Gavi's historical and current procurement model

The unified demand pool has been crucial to Gavi's market shaping success and historically anchored in the centralised procurement function performed by UNICEF SD. High-volume procurement of Gavi-financed vaccines and related immunisation products, relying on clearly defined regulatory and quality assurance standards, will necessarily continue under UNICEF's stewardship. The Gavi Board has repeatedly acknowledged that maintaining an intact demand pool, serviced by a coherent procurement strategy, remains central to preserving both value for money and global vaccine security.

The pooled procurement function also serves as a central and strategic lever for delivering the Alliance's mission. Envisioned from the founding of Gavi, the unified procurement channel has been a core enabler of cost efficiency, price control and supply security, thereby acting as the single most potent market shaping lever. By aggregating otherwise fragmented low demand from low-income countries and combining it with predictable, long-term financing, the centralised procurement model has reduced transaction inefficiencies, improved reliability, and created stable and predictable markets for vaccine and immunisation-related devices. This model has incentivised manufacturers to maintain or expand production capacity for LMIC populations, with pricing & access benefits also spread widely across MICs (whether former- or never-Gavi), upheld market competitiveness, and generated substantial savings for countries and the Alliance, all while managing the inherent logistical complexities of global vaccine supply.

The Board also recognises that the savings, supply security, and market shaping outcomes expected under Gavi 6.0 are hard to achieve if the demand pool is fragmented. In other words, procurement fragmentation, *if conducted without a deliberate strategy*, could undermine scale efficiencies, erode negotiation leverage, and reduce the Alliance's ability to sustainably ensure affordable, reliable and predictable supply.

UNICEF, as a founding Alliance member and permanent Gavi Board member, has held its procurement agency role since Gavi's inception, and is continually required to meet specific criteria to procure on behalf of the Alliance. UNICEF's procurement services to the Alliance are governed by a complex and periodically updated Memorandum of Understanding (currently MOU9). The MOU, in conjunction with UNICEF's internal policies, serves as a basis not only for ensuring value for money, compliance, transparency, and quality, but also for a market shaping partnership which has served the Alliance successfully for over two decades[8].

UNICEF, therefore (from its position as both legacy procurer for the Alliance and its most prominent development agency), would be expected to play a role assisting new procuring entities into the ecosystem, and to help them meet the standards and criteria that will be non-negotiable for any such entity to procure vaccines on behalf of Gavi, concurrently with a deliberate Alliance approach to ensuring scale efficiencies, negotiation leverage and reliable supply are preserved.

Regulatory and quality assurance standards

Highly complex products such as vaccines are subject to international quality standards. As one of the founding members of Gavi, WHO is the normative health authority within the Alliance, that sets global technical specifications for vaccines and immunisation medical devices (IMDs), regulates vaccine quality and prequalifies all vaccines and IMDs supported by Gavi, and provides standards and evidence-based policy recommendations that guide the Alliance. Therefore, WHO quality and safety standards remain Gavi's criteria and benchmark for what is considered a *quality-assured vaccine or immunization device* across all procurement pathways. In practice, this makes Gavi-financed vaccines among the most regulated and quality-assured products available.

However, Gavi recognises that the regulatory ecosystem is gaining in sophistication, including the development of WHO Listed Authorities (WLAs), strengthened reliance mechanisms, pilot parallel review pathways, etc. As global regulatory oversight evolves, Gavi will continue to follow WHO guidance on applicability, regulatory pathways, standards and prequalification for demonstrating assured quality. Gavi's criteria for quality-assured vaccines and immunisation devices will therefore evolve in line with WHO's norms and standards as they are updated and expanded. Concurrently, any future Domestic/Self-procurement Policy may consider pathways for the accommodation of locally licensed products, specifically those licensed by a National Regulatory Authority (NRA) that has achieved WHO maturity level 3 (ML3) for vaccine production or above, provided such approaches are developed in close consultation and alignment with WHO during Gavi 6.0 as part of the broader Procurement Policy development process.

Financial tools

Alliance partners (e.g., the Gates Foundation or UNICEF Vaccine Independence Initiative) often use financial grants and tools as a component of their contribution to

[8] A very limited amount of procurement for selected vaccines for Gavi-eligible PAHO member states takes place through the PAHO Revolving Fund, which was established more than twenty years before the Alliance.

market shaping and developing vaccine and immunisation product markets. Occasionally the Alliance itself deploys a financial instrument using Gavi funds to achieve a specific market shaping outcome.

Risk-bearing transactions

When warranted by a market need and strategy, the Alliance has deployed risk-bearing financial tools (e.g. Advance Market Commitment, Advance Purchase Agreement, firm order commitments) as important market shaping interventions. When Gavi funding is put at risk under such financial instruments, the Market-Sensitive Decisions Committee (MSDC) of the Board is responsible for implementation approval.

First Response Fund (FRF)

A component of Gavi's Day Zero Financing Facility for Pandemics (DZF), the First Response Fund provides up to US$ 500 million of surge financing for vaccine procurement during a WHO declared Public Health Emergency of International Concern (PHEIC) or a Grade 2 or 3 emergency and involving a disease for which Gavi has no established programme. By accelerating access to surge financing, the FRF enables a rapid vaccine response in emergencies, directly supporting the target outcomes under SP3.

Decision-making pathways

Strategic priorities and action plans endorsed as part of market shaping roadmaps can represent important strategic or financial choices for the Alliance and are reviewed through appropriate governance processes.

Product Portfolio Management (PPM)

Following a Gavi Board VIS decision on Gavi funding support for a type of vaccine, the Product Portfolio Management (PPM) principles guide which specific vaccine products and/or presentation(s) are offered to countries through the Gavi vaccine product menu and procured with Gavi funding. Immunisation-related devices follow similar guidance and cold chain equipment is limited to a subset of equipment in the WHO Performance Quality Safety (PQS) Catalogue. These principles are detailed in *Appendix 1: Gavi's Product Portfolio Management (PPM) Principles.*

Next-generation vaccine governance pathway

Upstream of the PPM process, the next-generation vaccine governance pathway (approved by the Board in July 2025) aims to evaluate Gavi's support of innovative next-generation vaccines such as higher valencies, alternative delivery technologies and novel combination vaccines that address one or more pathogen that is already Gavi-supported. If the budget impact and programmatic, regulatory, demand, and market health risks of the considered vaccine are deemed material, an investment case is presented to the PPC and Board for approval. Once the approved vaccine is close to prequalification, it is assessed against Gavi's PPM principles for inclusion on the Gavi vaccine product menu. (See more details on the next-generation vaccine governance pathway in *Appendix 1)*

Market-Sensitive Decisions Committee (MSDC)

The MSDC supports Gavi's Board by making market and/or commercially sensitive decisions as they arise, in support of broader market strategies and approaches. Implementation of market shaping strategies may include financial mechanisms or transactions that entail a financial risk or a risk to the Gavi model. When a potential mechanism or transaction, with clearly analysed financial and risk parameters, is expected to pass MSDC scrutiny, the Gavi Secretariat prepares and presents the structure, risks, benefits and implications of the proposed intervention to the MSDC for decision. An example of the use of this decision pathway was the approval of the tender-based transaction that yielded a significantly lower price for the R21 Malaria vaccine, as announced in November 2025.

Given the financial constraints of Gavi 6.0 and the renewed emphasis on affordability, there will be instances where trade-offs between market-specific costs/WAP (i.e. SP1 target outcomes) and supply access and security (i.e. SP2 target outcomes) require additional guidance to the Secretariat because of their potential financial and reputational implications. In such cases, the MSDC may be asked to advise on acceptable levels of supply security risk or cost associated with a proposed approach to a market or product. For example, guidance may be needed if a proposal seeks to diversify the supplier base for a specific market to raise supply security above the minimum threshold, but doing so increases procurement costs due to a higher WAP. Conversely, MSDC input may be sought if a proposal seeks to achieve savings while elevating risks that may be detrimental to the market's supply security (despite available alternative strategies). Relevant considerations would include: over-reliance on a single supplier (for a specific vaccine or across several vaccine markets), over-reliance on a single manufacturing country or region, or changes in supplier mix (exemplified by the current trend of supply shifting away from the multinational innovator companies within the IFPMA constituency). Approaches that increase the risk of supplier exit, weaken incentives for innovation, or reduce supply security below the minimum threshold (increasing the likelihood of supply disruptions) would all be candidates for MSDC guidance. The PPC or Board may also request MSDC consideration of any matter, such as may be highlighted in the yearly SG4 and market shaping retrospective reporting.

Monitoring and evaluation framework

The Alliance will monitor key indicators to track progress in implementing MSS 6.0 and will report on these indicators on an annual basis. SG4 objective-level indicators were developed following monitoring and evaluation best practices and will track progress towards achieving sustainable healthy markets, enhancing regional vaccine supply security and scaling up access to impactful innovations with metrics that are clear, measurable, and over which the Alliance has clear influence. The indicators were also designed to reflect the evolved Gavi 6.0 context, emphasising supply security and affordability, and deprioritising broader notions of market health and access to innovations which were more prominent in Gavi 5.0. To provide a more comprehensive picture of incremental progress or challenges in achieving SG4 objectives, the Alliance will also monitor key MSS target outcomes leveraging SG4 indicators as shown in *Figure 4 SG4 indicators*. These will monitor operational performance and certain intermediate market outcomes associated with the MSS 6.0 strategic priorities that contribute to SG4 objectives.

Figure 4 SG4 indicators

SG4 objectives		SG4 indicators	MSS 6.0 Strategic Priorities
4A	Drive healthy vaccine markets for Gavi-supported and self-financing countries, including acceleration of access to new high-impact, affordable vaccines and delivery innovations	4A1 - Number of markets with acceptable levels of supply security	Monitors supply security risks associated with SP1, ensuring an adequate balance is achieved between affordability and supply security as per TO1.3 and TO2.1
		4A2 - The weighted average price (WAP) of Gavi-supported vaccines	Monitors progress of SP2 by tracking WAP trends for TO1.2
4B	Enhance regional vaccine supply security, in support of regional manufacturing and increased self-reliance expansion ambitions	4B - Composite metric demonstrating progress in African vaccine manufacturing drawing on indicators from Board approved AVMA indicators framework including expressions of interest to AVMA, letters of intent to begin the WHO prequalification process, applications for AVMA in-principle eligibility and AVMA payments approved	Monitors progress of SP2 by tracking TO2.3 progress on establishment of sustainable vaccine production capacity on the African continent; aligned with AVMA MEL framework

4C	Develop sustainable markets for vaccines against outbreak, epidemic, and pandemic-prone diseases	4C - Access to supply for vaccines against outbreak, epidemic and pandemic-prone diseases	Monitors progress of SP3 by tracking TO3.2 and TO3.3 progress, ensuring access to OEP vaccine doses remains timely and sustainable

Case studies – Strategy to action

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These case studies demonstrate how MSS strategic priorities and target outcomes are translated into market-specific strategies and dependent on enablers to be achieved. They also demonstrate the need to take a bespoke approach to each market and to consider longer-term ecosystem externalities of the strategies. Although the following case studies reflect historical examples from Gavi 5.0, they helpfully illustrate how such market situations would have been addressed during Gavi 6.0 under the umbrella of MSS 6.0.

HPV case study (SP1 TO1.1)

Gavi has strengthened the HPV vaccine market by encouraging investments to increase production capacity and the entry of new, lower-cost manufacturers to expand supply and improve affordability for countries. The 2023 HPV market shaping roadmap highlights how Alliance market shaping activities and manufacturer investments helped ease earlier supply constraints and tripled vaccine supply between 2022 and 2025, enabling ambitious immunisation goals to be met by the end of 2025. These efforts, combined with revitalised programme investments, new WHO recommendations, and close engagement with industry, have also opened the market to new, lower-cost vaccines, giving countries more product options to consider in meeting their budget and programme needs, without compromising health impact. Looking forward, these market developments will directly support SP1 target outcomes 1 and 2 aiming for increased affordability and WAP decreases. VBs, the latest ELTRACO policy updates and Holistic Prioritisation will all serve as supportive enablers guiding country choices and prioritising vaccine affordability where relevant.

Yellow fever vaccine (YFV) case study (SP2)

With YFV demand expected to fall significantly during Gavi 6.0 as preventive mass vaccination campaigns (PMVCs) conclude, ensuring long-term supply security will require a sustainable and diverse supplier base capable of responding to unexpected demand surges driven by immunity gaps and outbreaks. The YFV market shaping roadmap highlights the importance of maintaining at least two WHO-prequalified vaccines released by different National Regulatory Authorities, alongside sufficient buffer capacity to absorb fluctuations in demand. In addition, the African region's high strategic vulnerability to yellow fever presents an opportunity to enhance regional supply resilience. To support this, YFV has been designated a Priority vaccine under AVMA, enabling eligible African manufacturers to access AVMA subsidies and competitively contribute to the long-term supplier base.

Ebola case study (SP3, TO3.2 and TO3.3)

Before the 2014–2015 West Africa Ebola outbreak, Ebola vaccine candidates existed primarily for biodefense purposes, with no commercial market due to the disease's rarity and unpredictable demand. Although the large outbreak accelerated R&D efforts, long-term market viability remained uncertain. To address this, Gavi provided an incentive to manufacturers by offering a prepaid commitment to purchase licensed doses, which led to the 2015 Advance Purchase Commitment (APC) with Merck. The APC also required Merck to maintain investigational doses for use pre-licensure, which proved critical for outbreak response in the Democratic Republic of the Congo (2018–2020). Gavi further supported the establishment of a 500,000-dose global emergency stockpile of licensed vaccines, enabling both rapid response and preventive vaccination. Despite these successes, the Ebola vaccine market relies on a single supplier and remains fragile due to low and unpredictable demand, high wastage and cost, and limited commercial appeal. The Ebola market shaping roadmap highlights the need to advance pipeline candidates that address current product limitations while meeting sustainability requirements. Working closely with CEPI and leveraging their upstream investments, the Alliance will aim to adapt investment and procurement models to promote long-term sustainability for countries, manufacturers, and funders, in a way that uniquely addresses the specificities of OEP markets.