Market shaping strategy 6.0
2026–2030

MSS 6.0
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Cover image: Portrait of Brou and her one-year-old daughter, Odelia; rural health centre, Côte d'Ivoire
Credit: Gavi/2026/Miléquêm Diarassouba

Executive summary

Since 2011, in Gavi's 2011–2015 strategic period (Gavi 3.0), the Vaccine Alliance has focused its fourth strategic goal (SG4) on market shaping. To achieve this goal, the market shaping strategy sets out how Gavi, the Vaccine 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's sixth strategic period, from 2026–2030 (Gavi 6.0).

In Gavi's fifth strategic period, from 2021–2025 (Gavi 5.0/5.1) the market shaping strategy focused on three areas: foster a sustainably competitive future supplier base, leveraging expanded supply capacity and improved product choice; support healthy demand; and establish an enabling environment for transformational innovation. While elements such as supplier viability and predictable demand remain critical, the Gavi 6.0 context requires complex trade-offs and to recalibrate Gavi's market shaping focus.

Vaccine budgets and the co-financing policy (which was updated in January 2026) 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 strategic 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 in which 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 Vaccine Investment Strategy (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 novel tuberculosis (TB) vaccines, interventions aim to anticipate supply risks, clarify demand pathways and accelerate readiness. For OEP vaccines, for which 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 vaccine 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 strategic goal and strategy for the Gavi 6.0 period (2026–2030) builds on the success and lessons of previous strategic 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 (see *figure 3* below for more details).

Market shaping in the context of Gavi

The objectives established under the SG4 healthy markets goal 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 equipment and immunisation medical devices (IMD) – all of which are eligible for Gavi funding – have all fallen within the scope of market shaping, although the focus in Gavi 6.0 is vaccines.

The predictable and high demand generated by Gavi's assured vaccine procurement funding has become one of the core foundations of market health for Gavi-supported vaccines and immunisation-related products. 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 (i.e. countries) and sellers (i.e. suppliers) – markets in which market forces such as supply, demand, pricing, competition and investment incentives are sufficiently aligned – there is little need for interventions from governmental, global health and other 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 who need them most. Market shaping aims to correct these failures by setting objectives and strategies to intervene, mitigate risks, and 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 allocating newly reduced budgets. 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, which must 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 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 – MSS 6.0 – provides the general public, Alliance stakeholders (e.g. Gavi Board members, including industry and country constituencies) and the entities responsible for executing the strategy – Gavi's Market Shaping team, 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 Gavi 6.0 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 *Annex G*), 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 stepwise manner throughout the strategic period. For example, the MSS 6.0 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 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 fiscal constraints. 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.

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

The structure of MSS 6.0 flows from the three Gavi 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 that 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

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 for countries and Gavi	**SP2 Maintain supply access security and market health**	**SP3 Develop future markets for Vaccine Investment Strategy (VIS)- endorsed and OEP vaccines**

These priorities require trade-offs in short and long terms

Target outcomes What we want to achieve		
Availability of **lower-cost products** for Gavi-supported countries	Maintain **uninterrupted vaccine supply** in each vaccine market through Gavi 6.0	Accelerate introduction of select **affordable, new high-impact vaccines**
Decrease in weighted average price (WAP) for specified Gavi-supported vaccines	**Maintain as acceptable long-term outlook for supply security & market viability** for all Gavi vaccine marketsfor 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 **geographically diverse supplier base** that can endure to serve countries beyond transition out of Gavi support	**Sustainable supply access** for outbreak- and epidemic-focused vaccines

Strategic enablers How outcomes can be achieved

Healthy demand	Funding predictability; Holistic prioritisation and country decisions; Demand predictability
Alliance collaboration	Guidelines and policies; Vaccine regulatory systems; Vaccine Alliance partnerships
Market shaping roadmaps, 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 policy and principles; African Vaccine Manufacturing Accelerator (AVMA); Financial tools
Decision-making pathways	Product portfolio management principles; Next-generation vaccine governance pathway; Market-Sensitive Decisions Committee

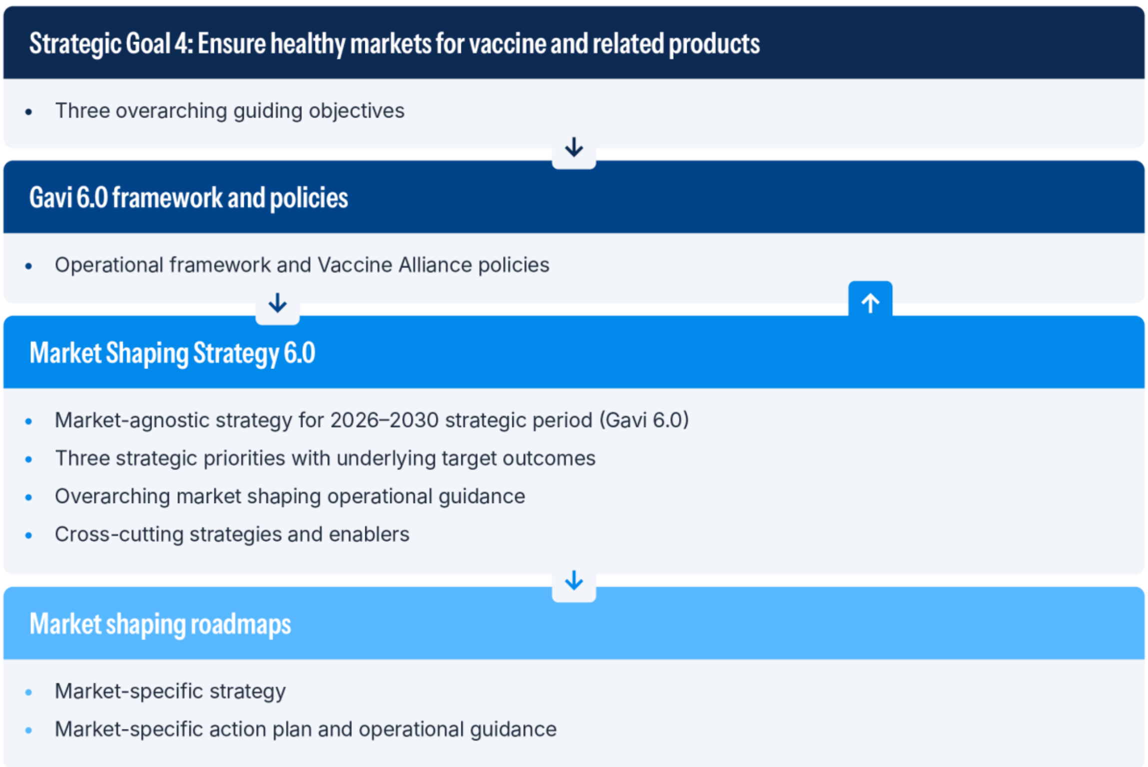
Strategic goal 4 (SG4) – "Ensure healthy markets for vaccines and related products"

SG4, the Gavi Board-approved "market shaping goal" for Gavi's 2026–2030 strategic period (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 Gavi 6.0. 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:
Gavi Market Shaping Strategy context



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 reform agenda. 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 that 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, defining how the available budget to Gavi for vaccine procurement will be allocated to countries (see more details under *Vaccine budgets*). 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's high-level pledging summit in June 2025, the Gavi 6.0 strategy recalibration aimed to address the US$ 3 billion funding gap in multiple ways by narrowing the scope of Gavi support to certain vaccine programmes, and by capping vaccine procurement costs through country-level vaccine budgets. Nonetheless, there remains an approximate US$ 400 million gap in vaccine procurement costs compared to the financial forecast put forward for Gavi 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 within a finite budget navigate critical trade-offs between increasing co-financing requirements and their ambitions to reach 'zero-dose' children (i.e. who have not received even a single vaccine shot). These risks are especially salient for vaccines covered by discretionary budgets (i.e. vaccines that depend on a country's allocation of its 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 vaccine).[2]
- The revised **Eligibility, Transition and Co-financing (ELTRACO) policy**, specifically the revised co-financing policy for initial self-financing countries[3] and changes to preventive vaccination campaign co-financing rules, is expected to impact market shaping, including:

[2] See definition of next generation vaccines under *Annex E*.
[3] The revised co-financing Policy directly links country co-financing contributions to the price of the vaccines for specific vaccine markets for initial self-financing countries, where certain conditions are met.

- Similar to country budgets, ELTRACO is expected to put greater pressure on countries to optimise the affordability of their vaccine portfolios, leading to shifts in country preferences towards lower-priced products, and to similar effects as described above.
- Unpredictable and most likely lower demand for preventive vaccination 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*).

MSS 6.0: strategic priorities and target outcomes

The guiding SG4 objectives were developed as part of the Gavi 6.0 strategy design prior to Gavi's high-level pledging summit in June 2025 and before the extent of financial constraints was known. The MSS 6.0 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 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 *table 1* below).

By having a significant and sustained impact on the supplier base, and by facilitating access to centralised pooled procurement, the Vaccine 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. Therefore, this MSS 6.0 – to benefit Gavi-eligible low- and lower middle-income countries[4] and Catalytic Phase-eligible self-financing MICs – is conceived to continue perpetuating this crucial, positive 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), in order to sustain country and Gavi health impact. 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. It must also ensure that short-term actions do not compromise the long-term imperative of regionally diversified supply and sustainable markets that serve countries' needs beyond transition from Gavi support. Reflecting these needs, SP1 (Optimise vaccine programme affordability to countries and Gavi) and SP2 (Maintain supply access, 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's third objective: 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

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[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 *Annex A* ***Error! Reference source not found.***.

for strategic reasons. This SP addresses the first SG4 objective of accelerating access to 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 the section below on *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, in recent years the availability of newer, lower-cost pneumococcal conjugate vaccine (PCV) and human papillomavirus (HPV) vaccine has provided countries with the opportunity to reduce the proportion of their immunisation programme budgets attributed to these vaccines (see *HPV vaccine case study*).

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

  Within individual markets, this can be accomplished through a redistribution 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 vaccines that are complex to manufacture.

SP2: Maintain supply access, security and market health

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 shortsighted 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 more than 25 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* **Error! Reference source not found.**) will allow objective and quantitative comparisons across markets; 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 Immunization Agenda 2030 (IA2030) strategic priority 6 on supply and sustainability;[7] and UNICEF Supply Division (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 vaccine 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 transition from 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 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 vaccine 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 over-reliance 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).

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[6] See definition of supply security in *Annex A*.
[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 immunization programmes.

This TO 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 out of Gavi support, contributing to a sizeable, stable market, essential for maintaining attractive pricing and supply resilience; hence, the Alliance's market shaping 'spillover benefit' for MICs, especially in terms of pricing, is a key feature both historically and for the future. The YF vaccine 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 case study*).

- **Target outcome 2.3: Emergence of a geographically diverse supplier base that can endure to serve countries beyond transition from 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* (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 International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) manufacturers, (2) increasing reliance on particular suppliers, (3) increasing reliance on supply from particular countries.

STRATEGY TO ACTION
CASE STUDY 1: HPV vaccine (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 vaccine 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.

The three case studies presented in this strategy 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 5.0/5.1, they helpfully illustrate how such market situations would have been addressed during Gavi 6.0 under the umbrella of MSS 6.0.

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 early definition of regulatory, policy, procurement, and financing pathways or mechanisms can accelerate licensure and vaccine roll-out, to the benefit of both Gavi-eligible and other countries.

SP3 target outcomes

- **Target outcome 3.1: Introduction of affordable, new, high-impact vaccines is accelerated**

  This TO pertains only to future VIS-endorsed programmes and seeks to ensure that market-specific risks that might slow or prevent impactful introductions in Gavi-supported 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) is looking 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, propose market interventions for their mitigation as needed. Supporting affordable, 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. Global Fund to Fights AIDS, Tuberculosis and Malaria; Stop TB Partnership, etc.).

- **Target outcome 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 (approved by the Gavi Board 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.

- **Target outcome 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 the Coalition for Epidemic Preparedness Innovations (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 vaccine case study*).

This target outcome focuses on OEP vaccines for which Gavi has an explicit Board mandate, but which are not part of Gavi programmes with routine immunisation and/or preventive vaccination components supplied outside of a small-volume emergency stockpile (i.e. the scope is Ebola, mpox and hepatitis E). 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.

STRATEGY TO ACTION
CASE STUDY 2: Ebola vaccine (SP3, TO3.2 and TO3.3)

Before the 2014–2015 West Africa Ebola outbreak, Ebola vaccine candidates existed primarily for biodefence purposes, with no commercial market due to the disease's rarity and unpredictable demand. Although the large outbreak accelerated research and development (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.

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.

As indicated in figure 3 below, enablers broadly fall into five categories: (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; (4) 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

* Strategic enabler

Healthy demand	Funding predictability *; Holistic prioritisation and country decisions *; Demand predictability *
Vaccine Alliance collaboration	Guidelines and policies; Vaccine regulatory systems; Vaccine Alliance partnerships
Market shaping roadmaps, 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 policy and principles *; African Vaccine Manufacturing Accelerator (AVMA) *; Financial tools
Decision-making pathways	Product portfolio management principles; Next-generation vaccine governance pathway; Market-Sensitive Decisions Committee (MSDC)

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.

During the Gavi 5.0/5.1 strategic period, demand-side challenges were key barriers for several markets. The lack of predictable demand volumes in certain markets (e.g. oral cholera vaccine) 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, Gavi's Market Shaping Strategy 5.0 (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.

Due to resource constraints, changes to the Gavi 6.0 strategy and policies bring critical market implications – 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 their ambitions to reach 'zero-dose' children 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; 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 that guides Gavi's programme funding and implementation. The Strategic Advisory Group of Experts on Immunization (SAGE) 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 of quality assurance (e.g. WHO Emergency Use Listing) 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).

STRATEGY TO ACTION
CASE STUDY 3 Yellow fever (YF) vaccine (SP2)

With yellow fever (YF) vaccine 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 YF vaccineV market shaping roadmap highlights the importance of maintaining at least two WHO-prequalified vaccines released by different National Regulatory Authorities (NRAs), 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, YF vaccineV has been designated a pPriority vaccine under AVMA, enabling eligible African manufacturers to access AVMA subsidies and competitively contribute to the long-term supplier base.

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 (*Annex B*) 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 Centres for Disease Control and Prevention (Africa CDC), the Clinton Health Access Initiative (CHAI), MedAccess, the European Investment Bank (EIB), the Global Fund to Fight AIDS, Tuberculosis and Malaria, 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 with and complementary to 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.

  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 as well as decisions to seek 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 ten-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, Gavi remains vigilant in monitoring trends in its supplier base at a portfolio/above-market level and across suppliers, namely: (1) declining overall supply from IFPMA manufacturers; (2) increasing overall market dominance by particular companies; (3) increasing reliance on supply from particular countries; and (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 respiratory syncytial virus (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 (VBs):** 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 vaccination campaigns are in scope of VBs, while outbreak response vaccines – for example, International Coordinating Group (ICG) on Vaccine Provision-managed 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 Gavi 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 vaccine and PCV in the 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 vaccination 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 2026–2027 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 prospects of African products. At time of publication, there is also an opportunity to have a significant portion of excess AMVA pledges (up to US$ 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 and 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 the fourth quarter of 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 lower-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 and access benefits also spread widely across MICs (whether former or never Gavi-eligible), upheld market competitiveness, and generated substantial savings for countries and the Alliance, all while managing the inherent logistical complexities of global vaccine supply.

  The Gavi 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 partner 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 that 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 partners 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 immunisation 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 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 Gavi 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

[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 20 years before the Alliance.

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 *Annex D*.

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 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 *Annex E*.)

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. The MSDC charter can be found in *Annex F*.

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 membership). 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 that were more prominent in Gavi 5.0/5.1. 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 table 1 below. These will monitor operational performance and certain intermediate market outcomes associated with the MSS 6.0 strategic priorities that contribute to SG4 objectives.

Table 1: SG4 indicators

SG4 objectives	SG4 indicators	MSS 6.0 strategic priorites
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. 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 African Vaccine Manufacturing Accelerator (AVMA) indicators framework, including expressions of interest to AVMA, letters of intent to begin 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

Annexes

Annex A: Glossary of market shaping terms

This glossary has been developed to provide a common reference point for terminology used in Gavi's vaccine market shaping work. It is intended to support clarity and consistency in the way technical concepts, strategic approaches, and market dynamics are described and understood, and to serve as a resource for all readers of this document.

The terms included in table 2 reflect both widely recognised definitions and those tailored to the specific context of Gavi's work.

Table 2: Market shaping terms and definitions

Term	Definition
Access	The ability of countries to obtain appropriate vaccines in a timely, affordable and sustainable manner.
Affordability	The extent to which vaccine prices and associated programmatic costs of delivery are within the financial reach of countries and Gavi, considering both immediate budgets and long-term sustainability.
Buffer stock	A reserve of vaccine product held at a country level to ensure programme continuity during periods of demand surge, supply delays or other emergencies.
Demand forecasting	The process of estimating future country vaccine needs based on demographic data, disease burden, policy decisions, availability of financial resources and programmatic capacity.
Developer, manufacturer, supplier	Organisations involved in different stages of vaccine development and production: developer designs and tests new vaccine candidates; manufacturer and supplier are used interchangeably for an organisation that produces licensed vaccines at scale and sells them to procurers. One entity can serve in multiple or all roles.
Domestic procurement	Under specific circumstances, Gavi funding may be used by Gavi-supported countries to procure locally produced vaccines, subject to normal country co-financing obligations and other conditions described in the policy. Also referred to in the past as self-procurement.

Future supplier base	The process of building a comprehensive view of supplier profiles and portfolios, identifying risks to supply availability and affordability, interventions to support capabilities and sustainability, influencing the environment (e.g. mitigation of risks of over-reliance on single NRAs, inputting to discussions on local/regional manufacturing hubs, aligning with other procurement entities on supply risks, managing impact of pandemics on market health), and improving alignment between support for vaccine development and market strategies.
Gavi vaccine product menu	The list of vaccine products supported by Gavi for procurement, offering countries options based on criteria described in the Product Portfolio Management (PPM) principles.
Healthy Markets Framework (HMF)	A strategic tool used by Gavi partners to enable a clear and consistent definition of what constitutes market health and a minimum threshold of supply security. The framework establishes a common way of thinking about market health; enables clear communication about how the Alliance assesses individual markets; and improves how potential trade-offs between different market dimensions and vaccine procurement costs are analysed. More details can be found here: https://www.gavi.org/news/document-library/healthy-markets-framework-hmf
Indicator	A metric used to measure progress toward vaccine market shaping objectives. Outcome indicators track progress towards market shaping goals (e.g. healthy markets, supply, cost of fully vaccinating a child, innovation). Process indicators monitor the operational performance of core Alliance partners against priority interventions (e.g. demand forecasting).
Innovation	The development and adoption of new or improved vaccines or vaccine products (e.g. vaccines against new pathogens, improved protection through new vaccine types, new delivery mechanisms) that address unmet public health needs.
Intellectual property (IP)	Legal rights that protect inventions, including vaccine composition and manufacturing technologies, which can influence market entry, pricing and competition.
International vaccine regulatory systems	The frameworks of laws, standards and institutions at global, regional and national levels that oversee the evaluation, approval and monitoring of vaccines – spanning clinical trial oversight, Good Manufacturing Practices (GMP), vaccine licensure by National Regulatory Authorities (e.g. FDA, EMA), regional harmonisation platforms (e.g. AVAREF), global mechanisms such as WHO prequalification, and post-market surveillance including pharmacovigilance – to ensure vaccines are safe, effective and of assured quality worldwide.

Long-term agreements (LTAs)	Contracts between UNICEF Supply Division and suppliers that establish a framework for vaccine volumes and pricing over multiple years, providing stability for both the buyer and manufacturers.
Market shaping	Deliberate actions by stakeholders to improve how vaccine markets function, with the goal of increasing access, affordability, supply security and/or innovation.
MSS strategic enabler	A partnership, activity, mechanism, or actor that supports and facilitates the achievement of market shaping objectives, such as financing tools, technical assistance or partnerships.
MSS strategic priority	A high-level area of focus within the market shaping strategy that guides Gavi's efforts during the strategic period to address critical market challenges.
MSS target outcome	A specific result or market outcome that Gavi aims to achieve through its market shaping interventions. Each target outcome is aligned with one or more strategic priorities, and the work to achieve them is carried out through MSS enablers.
National Regulatory Authority (NRA)	National agencies that are responsible for ensuring that products released for public distribution in their country (normally pharmaceuticals and biological products, such as vaccines) are evaluated properly and meet standards of effectiveness, safety and quality.
MSS target outcome	A specific result or market outcome that Gavi aims to achieve through its market shaping interventions. Each target outcome is aligned with one or more strategic priorities, and the work to achieve them is carried out through MSS enablers.
National Regulatory Authority (NRA)	National agencies that are responsible for ensuring that products released for public distribution in their country (normally pharmaceuticals and biological products, such as vaccines) are evaluated properly and meet standards of effectiveness, safety and quality.
Pooled procurement	Aggregated purchasing based on the aggregated demand of multiple customers (typically countries) to reduce procurement resourcing needs for each customer, ensure reliable and resilient supply, lower transaction costs of suppliers and improve negotiation influence.
Prequalified (PQ)	Vaccine products that have been deemed by WHO as acceptable for procurement by UN procurement agencies and countries. More details can be found here: https://extranet.who.int/prequal/

Procurement mechanisms	The methods and systems through which vaccines are purchased, including direct procurement (e.g. national tendering) and pooled procurement mechanisms.
Product Portfolio Management (PPM) principles	Specific conditions (i.e. SAGE recommendation, WHO PQ, reliable supply base, cost, meeting country preferences) that must be met for a vaccine presentation or product to be added to Gavi's vaccine product menu and offered to countries. In specific circumstances, the Alliance might need to limit the choices offered in the portfolio, for the purpose of consolidating demand, leveraging purchasing power, or ensuring uninterrupted supply. Decisions on active portfolio management are taken in consultation with countries and communicated to manufacturers in a timely manner to prevent interruption of programmes and supply.
Product profile (TPP/PPC)	A document describing the desired characteristics of a vaccine (e.g. efficacy, safety, presentation, thermostability) to guide R&D and market preparation.
Procurement Reference Group (PRG)	A technical and advisory forum convened by UNICEF Supply Division to guide procurement strategies for vaccines. PRGs bring together UNICEF procurement specialists, technical experts, partner organisations (such as WHO, Gavi Secretariat and other UN agencies), donors and country representatives to review market dynamics, establish product requirements and inform procurement approaches. A PRG's role is to ensure that procurement decisions are based on the latest technical standards, clinical guidance and market intelligence, while balancing supply security, affordability and innovation. Outputs from PRGs typically include product specifications, reference pricing, supplier engagement strategies and risk assessments, which collectively support evidence-based and market-smart procurement practices.
Quality, quality standards	A comprehensive concept encompassing safety, efficacy, manufacturing consistency and compliance with international standards. Quality standards can be upheld by National Regulatory Authorities and/or WHO through its prequalification service.

Roadmap, market shaping roadmap	Documentation of the Alliance's long-term market strategy for each Gavi-supported market. A roadmap includes an assessment of Gavi's past and potential future market shaping activities, Gavi demand scenarios, global demand estimates, information on supply dynamics and future entrants, pricing and costs of production, and suitability of existing vaccine or immunisation products for immunisation programmes in Gavi-supported countries. Based on analysis using the *Healthy Markets Framework (HMF)*, it prioritises objectives for the short, medium and long terms, through consideration of the trade-offs that may exist between different components of market health (e.g. supply security versus overall costs). For each objective in the roadmap, Alliance partners set target outcomes. Included in the roadmap is an action plan that describes interventions, responsible actors, a timeline and measurement indicators. Roadmaps are updated periodically to take into account new market information; and refine the necessary interventions and tactics needed to influence the market.
Supply disruption/shortage	A situation where available vaccine supply is insufficient to meet demand, either temporarily (disruption) or over a sustained period (shortage), potentially causing delays or gaps in immunisation.
Square Group	The Alliance's market shaping partnership comprising the Gavi Secretariat's Market Shaping team, the Gates Foundation Immunisation team, UNICEF Supply Division and WHO-IVB.
Supply security	Conditions within a vaccine market that impact the risk of interruptions to vaccination caused by a lack of vaccine supply, in the short and long terms. Interruptions to vaccine supply can be caused by individual supplier risks, supplier choices to discontinue production of some vaccines or unplanned demand surges. High or adequate supply security indicates lower risk of interrupted vaccination; low or minimal supply security indicates a higher risk of interrupted vaccination. Actions to manage supply security are different in each vaccine market, given their unique dynamics, and often rely on the number, capacity, production capabilities (i.e. drug substance, drug product, fill/finish), location and reliability of suppliers in a market, combined with the predictability of demand. A new set of definitions and tolerances around the concept of supply security has been generated with Square MS partners as part of the MSS 6.0.
Sustainable	The ability of an immunisation programme or a supplier to endure over the long term, typically referring to the financial aspects of financing immunisation or continuing as a vaccine supplier.

Technology transfer	The process by which a vaccine developer or manufacturer licenses IP and shares knowledge, data, skills, equipment and processes with another manufacturer or partner to enable them to produce, test, register and/or supply a vaccine to required quality standards.
Tiered pricing	A form of price differentiation in which different prices are charged for the same product, in different markets. Generally, manufacturers charge higher vaccine prices in higher-income countries and lower prices for lower-income countries.
Vaccine, vaccine group	The antigen class (or combination of antigens) that has been recommended or approved by the board through the Vaccine Investment Strategy (VIS) process for current or future funding in Gavi-supported countries (e.g. pneumococcal conjugate vaccine).
Vaccine market	The system of interactions between vaccine manufacturers, procurers, funders, regulators and national immunisation programmes that determine the availability, affordability, quality and sustainability of particular vaccines and vaccine products against one or more diseases. (e.g. pentavalent vaccine market; malaria vaccine market).
Vaccine presentation	As presented in the Gavi Detailed Product Profiles (DPP), a vaccine presentation is defined by three factors: doses per primary container (e.g. 1, 5, 10), primary container type (e.g. vial/ampoule, plastic tube) and pharmaceutical form (e.g. liquid, lyophilised). Vaccine products that differ from one another on any of these three factors are considered different presentations of the vaccine.
Vaccine product	A specific vaccine with distinct characteristics such as valency, presentation and/or manufacturer. For example, the PCV market has several products with different valency, including 10-valent, 13-valent and 15-valent; and presentations such as 1, 4 and 5 doses per vial.
Vaccine product price	The monetary cost per dose, influenced by manufacturer pricing strategies, procurement mechanisms and market dynamics.
Vaccine type	Within each vaccine or vaccine group, there can be variations in characteristics that differentiate the vaccine (e.g. number of serotypes in PCV such as 10, 13 or 14), while often all vaccine types are considered equivalent (by WHO) in reducing the incidence of the targeted disease.
Weighted average price (WAP)	A methodology for determining an average price across a set of vaccines or vaccine products, accounting for the volume of each that is procured. It is calculated by dividing the total value of purchased vaccines or vaccine products by the total volume of the same vaccines or vaccine products. Thus, this type of average accounts for not only the price of each individual vaccine, but also the volume of each purchased.

Annex B: Square Group Terms of Reference, July 2026

Background

The leadership structure for market shaping across Gavi Market Shaping, UNICEF SD, GF-IMM and WHO-IVB will continue under Gavi 6.0, in accordance with the Square Group Terms of Reference established in 2021.

These arrangements were introduced as part of Gavi's Market Shaping Strategy 5.0 (MSS 5.0), which aimed to strengthen and optimise the market shaping partnership. The MSS 5.0 specified that the partnership model is organisational mandate- and competency-based and led by Gavi's core market shaping Partners.

The Square Group is composed of the market shaping leaders of the four core Gavi Alliance market shaping Partners (Square Partners): Gavi-MS, UNICEF SD, GF-VDCP, and WHO-IVB. These Square Partners are responsible for the implementation of the MSS 5.0 and for the coordination of all other Partners that will be involved.

The Square Group evolved organically over Gavi's 4.0 period to respond to various coordination and decision-making issues that are common to the Square Partners. The MSS 5.0 Partnership Optimisation Workstream identified that the Square Group was efficient, that its further development is key to the implementation of Gavi's MSS 5.0 (in particular the Partnership Optimisation efforts defined in MSS 5.0), and that it would benefit from formalisation, including a ToR.

1. Purpose

The Square Group is formalised as the market shaping leadership structure for implementation of the Gavi Alliance's MSS 5.0. It assists Gavi Alliance market shaping Partner teams in fulfilling responsibilities in a coordinated and timely manner in respect to Gavi's Strategic Goal 4 (SG4) to ensure sustainable, healthy market dynamics for vaccines and immunisation-related products at affordable prices; incentivise innovation for the development of suitable vaccines; and scale up innovative immunisation-related products.

It provides high-level direction, tracking, decision-making, solution-finding, and conflict resolution on topics related to Gavi's market shaping, and ensures a clear and unified signal from market shaping partners to the industry. It adapts to the changing environment as needed, and is the forum to discuss shifts in timing or priorities for Gavi's MSS 5.0.

It supports partnership optimisation and provides direction to other market shaping actors within the Alliance, acting as a resource to ensure high-level coordination with WHO's IA 2030 SP6 (supply security), SP7 (research and innovation) and alignment of other initiatives beyond Square Partners.

2. Governing principles

2.1 Ownership

The Square Group is co-owned by Gavi's Square Partners who decide together how to implement its ToR in the spirit of solidarity and interdependency to achieve Gavi's SG4 and MSS 5.0.

Each Square Partner commits to Gavi's MSS 5.0 and to its Operational Plan that are co-owned and jointly tracked.

The Square Group is led by a chairperson that is selected once a year by the Square Partners on a rotational basis.

2.2 Membership and chair

The Square Group comprises eight members, two per SquarePartner organisation: one Square Group member and one alternate Square Group member. Members are nominated by each SquarePartner organisation for the duration of the Gavi 5.0 Strategic Period. For reasons of continuity, no substitution or delegation of authority is authorised beyond the eight members.

The Square Group members may choose to invite relevant people from Square Partner organisations or from extended Partner organisations as relevant to agenda items and subject to confidentiality or conflict of interest. While extended Partner organisations (e.g. CHAI, PATH, etc.) may frequently be invited on specific topics, there are no standing observers.

The secretariat of the Square Group is provided by the Gavi MS team and supports the Chairperson to perform its duties.

Each year, the Square Group nominates a chairperson who serves for one year. The chairperson may be from a different Square Partner organisation each year so that there is a rotational chair responsibility between Square Partners. The chairperson will perform the following duties:

- Convene the Square Group meetings,
- Manage the Square Group agenda and moderate sessions,
- Invite additional contributors on an as-needed basis,
- Consolidate discussions, ensure meeting notes are recorded, take ownership of final recorded points, and ensure distribution,
- Receive requests for support, advice or coordination related to Partners' market shaping activities, examine if the topic is to be raised to the Square Group, and propose the best way to operate (meeting agenda or other).

2.3 Confidentiality

Square Group discussions are, on principle, subject to strict confidentiality and each Square Group member or invited contributor is expected to respect the confidentiality of information and debate unless content is public or made public by the Square Group.

Sensitive items such as commercially sensitive information shared by manufacturers may be shared on a need-to-know basis with selected and limited members of the Square organisations, but will not be shared beyond. For such sharing, the Square Group will apply the rules of the roadmap process for restricted and highly restricted information. The Chairperson will ensure that observers or invited guests exclude themselves from discussions and presence where there might be issues of confidentiality or conflict of interest.

The Square Partners' process of sharing, marking and storing such sensitive information will be reviewed by the Gavi MSS Partnership Optimisation Workstream within its 'Information Sharing' activity due for Square decision 2Q2022.

2.4 Authority, reporting and coordination

The Square Group is empowered by Gavi to take the responsibilities described in section 1 (Purpose) of this ToR.

It ensures oversight, coordination, review, and advisory functions for Gavi's MSS 5.0.

It does not have executive powers within Square Partner organisation but acts as a high-level direction-setting, tracking, decision-making, solution-finding and conflict-resolution resource for Gavi's MSS 5.0.

The Square Group is empowered to and will adjudicate to achieve alignment over Square Group working duties, e.g. strategy decisions, market shaping tactics, coordination, resolution in case of differing Partner views.

The Square Group will support smooth coordination between Partners (Square and others), in particular:

- It will ensure coordination and complementarity between Gavi's MSS 5.0 and WHO's Immunization Agenda 2030 SP6 (supply security).
- It will foster integration of other market shaping actors within the Alliance to better develop close coordination and alignment of multiple initiatives beyond Square Partners and to integrate country insights into market shaping.
- It will support the deliberate leveraging of partner organisations' comparative strengths and mandates in composing the market shaping collaboration, roles and responsibilities. This will be supported by implementation of new engagement frameworks (to be developed as per MSS5.0), aiming to:
    - Optimise contribution of the diverse WHO functions that impact market dynamics towards the desired outcomes defined in the MSS 5.0;
    - Optimise communication and interaction with manufacturers to ensure alignment, avoid unintended confusion, and avoid duplication/waste;
    - Explore improving/establishing country interfaces and define leaders according to specific issues and needs.
    - Harmonise information sharing and reporting across Partners.

2.5 Mode of operation

Square Group members shall prepare for and actively participate in Square Group standing meetings (see section 3. deliverables).

Dates for Square Group standing meetings will be defined in January of each year to ensure effective presence of each Partner organisation.

Ad hoc support, advice, and coordination will be provided on a 'best-option' basis as judged by the Square Group.

2.6 Resources and budget

The Square Group's human resources are provided by the Partner organisations in the format of members' time. There is no specific budget allocated to the Square Group.

2.7 Performance, review and amendments

The Square Group will review its performance once every two years (method to be determined by the Square Group) or upon request if a Square Partner requests such a review.

The Square Group ToR will be reviewed by Partners once every five years for each strategic period or earlier if judged necessary by the Square Group. Amendments to the ToR can be proposed by any Square Partner at any time and adopted by consensus.

3. Deliverables

3.1 Square Group standing meetings

The Square Group meets quarterly. Each meeting requires the presence of at least one of the two representatives of each Square Partner organisation.

The agenda is prepared by the chair with input from all Partners and made available five working days before the meeting. Each meeting is followed by meeting notes vetted by the Square Group chair within five working days.

3.2 Other MSS meetings

The Square Group may choose to perform other MSS meetings such as the VMDC (Vaccine Market Dynamics Convening) meeting.

3.3 MSS 5.0 Operational Plan

The Square Group has the specific task of tracking and supporting Gavi's MSS 5.0 Operational Plan. The Square Group is the forum where issues related to the implementation of Gavi's MSS 5.0 Operational Plan are discussed when required. The Square Group decides how to operate this task (meeting agenda or other).

3.4 Support, advice and coordination

Any topic related to Partners' market shaping activities may be brought up to the Square Group for support, advice or coordination. This can be proposed as an agenda item for a Square Group's standing meeting or any other option as preferred by the Square Group members and the Square Group chair.

Annex C: Healthy Markets Framework, revised for Gavi 6.0

Figure 4:
Gavi 6.0 Healthy Markets Framework

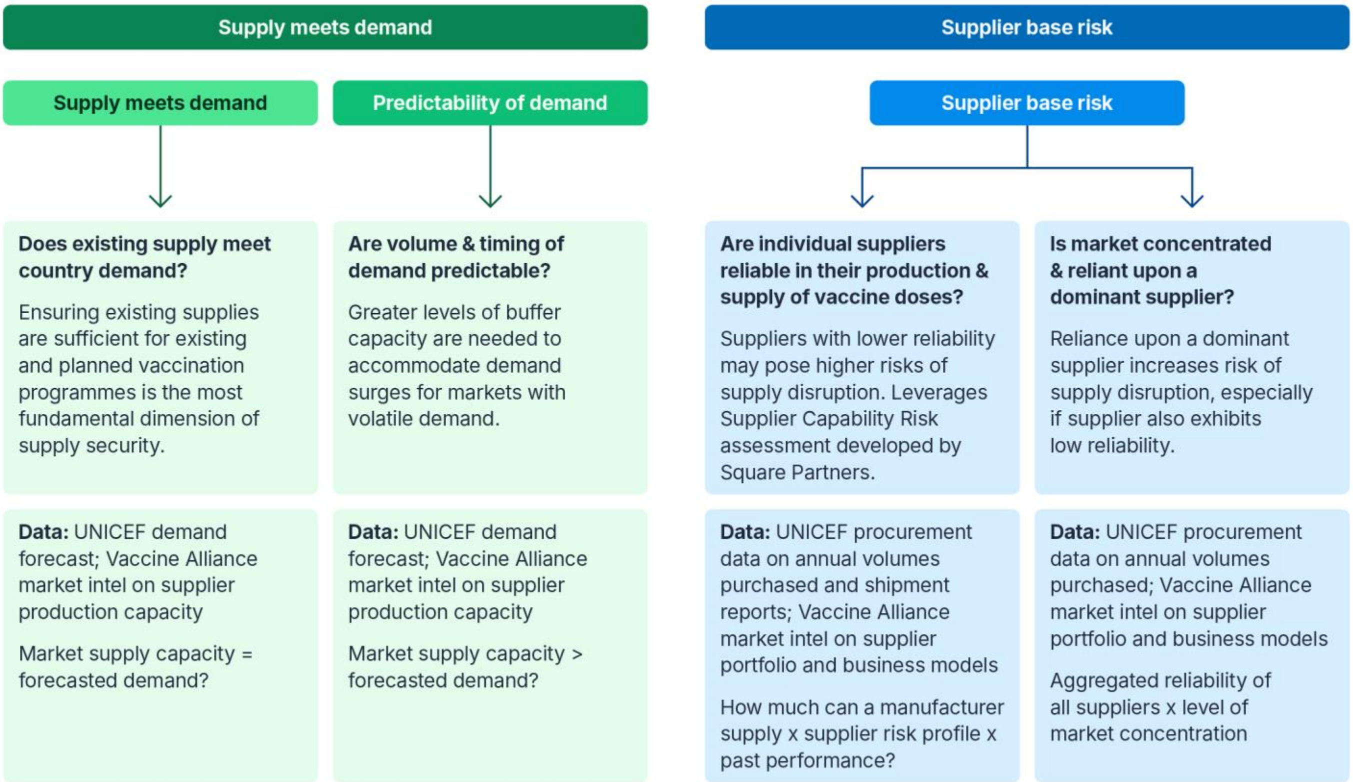
HMF criteria	HMF attribute
Demand health	**Materialisation of demand** The degree to which country introductions and campaigns materialise
	Predictability of demand The degree to which both the quantity and timing of demand can be accurately predicted and sustained by countries
	Balanced demand of appropriate products & timely uptake of new innovative products The degree to which country product choices are data-driven, value-based and leading to balanced demand for appropriate products & timely uptake of new innovative products
Supply dynamics	**Market sustainability & attractiveness** The degree to which the market remains sufficiently attractive for incumbent suppliers to remain or for new suppliers to enter
	Regulatory/NRA risk The degree to which doses can be reliably released or exported from the country of production in accordance with shipment plans
	Supplier-base risk The degree to which the supplier base can reliably supply expected doses
	Meeting country product preferences The degree to which available supplies can meet countries' product choices
	Supply meets demand The degree to which the overall supply can meet total forecasted demand
Innovation	**Incentivising & scaling up innovations** The degree to which ongoing innovations address countries' unmet needs and may be adopted by countries in the future
Geopolitical & health security exposure	**Geopolitical & regional diversity risk** The degree to which regional diversification across suppliers mitigates geopolitical and health security risks

Market rationale for each HMF criterion can be found here:
https://www.gavi.org/news/document-library/healthy-markets-framework-hmf

Square Partners developed a methodology to quantify supply security across markets. The methodology assesses whether supply is sufficient to meet demand, including in markets with greater demand volatility, and the extent to which the supplier base can reliably deliver expected doses. This assessment helps inform the definition of acceptable levels of supply security across markets and supports key trade-off decisions between SP1 and SP2.

To ensure that supply security is appropriately balanced with the objective of optimising programme affordability, the HMF has also been updated to elevate supply security attributes as high-priority factors across all markets.

Figure 5:
Supply security quantification methodology



Annex D: Gavi's Product Portfolio Management (PPM) principles

Vaccines

Vaccine Investment Strategy (VIS) decisions to include a new antigen in the Gavi portfolio are informed by analyses of impact, cost and cold chain requirements, among other attributes, as they relate to the available or expected vaccine presentations and products for the antigen. However, beyond the antigen approved by the Gavi Board, the decision does not specify which specific product presentation(s) are to be offered to countries and then procured through Gavi's procurement agencies.

The following principles guide the Gavi Secretariat for adding a new vaccine presentation or product to the Gavi vaccine product menu:

1. The new vaccine presentation or product must be **consistent with Strategic Advisory Group of Experts on Immunization (SAGE) recommendation(s)** and the relevant WHO position paper (where one exists) for the related antigen.

2. The new vaccine **presentation or product must be WHO-prequalified**, unless a compelling reason to make an exception exists (e.g. to provide countries with a new vaccine presentation in a manner timely for uptake of this new presentation with as few delays as possible following first availability to enable a shift to a preferred presentation for programmatic and/or cost reasons, and where WHO prequalification is anticipated).

3. The new vaccine presentation or product must have a **reliable supply base**. Adding the new presentation or product to Gavi's vaccine product menu should contribute to an environment of consistent and uninterrupted supply. The product should be manufactured by a reliable supplier and be available in sufficient quantities to contribute to the supply base without creating risks to supply security.

4. The **estimated costs** of the new vaccine presentation or product should be within the range of the current fully loaded, wastage-adjusted vaccine costs to immunise an individual; and should account for any increased procurement costs that are commensurate with evidence-based benefits of the new vaccine presentation or product and/or with decreased costs in vaccine delivery.

5. The new vaccine presentation or product must be likely to **respond to country demand and preferences**. Where required to avoid supply security risks or to further other market shaping objectives, a new presentation may be added to replace an existing one (e.g. 2-dose vial presentation may be replaced by a 5-dose vial presentation, rather than expanding the market to include both presentations).

When the above conditions are met, the procurement of the new vaccine presentation or product is considered to fit, in principle, in the context of the original Gavi Board decision. The presentation or product would then be added to the Gavi vaccine product menu and offered to countries. On occasion, the Alliance might need to limit the choices offered in the portfolio, for the purpose of consolidating demand, leveraging purchasing power, or ensuring uninterrupted supply. Decisions on active portfolio management will be taken in consultation with countries and communicated to manufacturers in a timely manner to prevent interruption of programmes and supply.

Immunisation-related devices

A new set of principles were developed in the Gavi 5.0 strategic period to guide the Gavi Secretariat on procurement management of other immunisation-related products, including vaccine delivery devices (with exception of syringes for injection/reconstitution and safety boxes, as well as cold chain equipment that is covered below). These include the five principles mentioned above as well as a few additional ones:

6. The use of the new device must ensure at least equivalent equitable access and coverage of the associated antigen.
7. The new device must be adapted for use by health workers for immunisation activities in Gavi-supported countries.
8. The new device must be acceptable by parents and children in Gavi-supported countries.

Cold chain equipment (CCE)

With regards to CCE, Gavi's 6.0 updated requirements for consolidated cash grants supports equipment included in the WHO Performance Quality Safety (PQS)[9] Catalogue that meets the following requirements for relevant CCE product categories:

- User-independent ("Grade A") freeze protection to prevent freezing of vaccines for stationary, passives[10] and active transport devices;
- Extended operating temperature range to ensure the equipment operates correctly even during large changes in ambient temperature;
- Temperature monitoring and logging to assure better temperature control of vaccines, including a new requirement for all refrigerators/combined refrigerator-freezers to be equipped with new Equipment Monitoring Systems (EMS) with either EMS Level 2 or L3 functionality;
- Voltage regulation (for on-grid devices only) to protect equipment from electrical damage; and
- Countries are considered the owners of data generated by CCE procured with Gavi support.

For Gavi-funded stationary equipment, new pricing requirements (maximum pricing threshold against average prices) are being put in place for Gavi 6.0.

[9] PQS qualification means that a device has passed a series of performance, quality and safety tests set by WHO.
[10] In select cases, countries will be able to procure traditional (non-freeze preventive) passives (e.g. vaccine cold boxes and carriers) in Gavi 6.0 following the consolidation of funding levers into one consolidated cash grant.

Annex E: Next-generation vaccines governance pathway

The current governance pathway to include a vaccine on the Gavi vaccine product menu starts with a Vaccine Investment Strategy (VIS) assessment of vaccines against pathogens not supported by Gavi every five years. Once the Gavi Board approves support against these pathogens, in-scope vaccines that are prequalified or close to prequalification are evaluated using the PPM principles (see *Annex D*) before taking a decision to include them on the Gavi vaccine product menu. In some cases, Gavi Secretariat can submit an investment case to the Board for vaccines against already-supported pathogens, if a new product or presentation is expected to have substantial programmatic and/or financial impacts to the Alliance. These principles have already been used by Gavi to select the appropriate decision pathway for innovative vaccines like hexavalent.

In the coming years, new vaccines incorporating one or more antigens relevant to Gavi-supported programmes may reach licensure and WHO prequalification; and some may present substantial risks, benefits and/or budget impact to the Alliance. For simplicity, these upcoming products are referred to as "next-generation vaccines". The following outlines decision pathways for next-generation vaccines.

1. **Assessment of next-generation vaccines with one or more antigens relevant to non-supported programmes**

   - A next-generation vaccine that includes antigens relevant to both supported and non-supported programmes will require opening of a funding window for the newly supported programme. In this case, the vaccine will be assessed through VIS to ensure a full evaluation of the disease to be supported (even if the new vaccine is offered at the same or lower price than the already supported antigen). If the disease is shortlisted, the Policy team will lead the development of an investment case to the PPC and Board.

   - The Gavi Secretariat Strategic, Policy and Foresight (SPF) team is currently working on defining the best approach to assess combination vaccines that include antigens relevant for programmes currently supported by Gavi and others that are not.

   - If the development of this vaccine is faster than anticipated and it is expected to be available in between the five-year VIS cycles, Gavi Secretariat will evaluate on a case-by-case basis whether an ad hoc VIS assessment is appropriate, considering information about health benefits, price attractiveness and cost implications.

2. **Assessment of next-generation vaccines with one or more antigens relevant to non-supported programmes**

   2.a. Relevance of next-generation vaccines for Gavi countries

   - The relevance of a next-generation vaccine to Gavi-supported countries will be assessed using the following criteria: disease burden, epidemiology and relevance to Gavi populations; vaccine characteristics; affordability screening; and potential interest of manufacturers in low- and middle-income country (LMIC) markets. Where possible, Gavi Secretariat can use the existing VIS assessments to confirm this relevance.

   - Gavi Secretariat will leverage partners' expertise to collect necessary data supporting the assessment.

   - Gavi Programme Leadership Team (PLT), co-chaired by the Chief Vaccine Programmes & Markets Officer (CVPMO) and the Chief Country Delivery Officer (CCDO), is responsible for reviewing the result of this assessment. The CVPMO will then determine the appropriate next steps based on PLT's recommendation and inform the CEO accordingly. If the next generation vaccine is relevant to Gavi countries based on the criteria described above, the CVPMO will instruct the Gavi Market Shaping team to initiate the assessment of benefits, risks and budget impact of next-generation vaccines (as described in the next paragraph). However, if the next-generation vaccine is not relevant to Gavi countries, the CVPMO will decide to stop the assessment of the next-generation vaccine innovation.

2.b. Assessment of benefits, risks and budget impact of next-generation vaccines

- Gavi's Market Shaping team, with support from other Secretariat teams and partners, will assess the impact of a next-generation vaccine on health and programmes, the regulatory pathway for prequalification, the relevant market, and anticipated demand shifts and cost, to evaluate its expected benefits, risks and budget impact.

Dimensions	Assessment
Health and programmes	Impact on coverage targets (considering immunisation schedule, country feasibility, etc.), impact on programme costs
Regulatory	Pathway and timelines for prequalification
Market	Impact on market dynamics, including supply availability, affordability, diversity, competition and sustainability
Demand	Alignment with understanding of country preferences and suitability in country context
Budget	Costs of vaccine and operational support (switch grants) to Gavi and countries

- The new vaccine's expected price will be compared to equivalent presentations on the Gavi vaccine product menu. In case of a price premium versus a defined benchmark, an analysis will determine if it is commensurate with the vaccine's benefits and if the budget impact is favourable, neutral or unfavourable (where relevant and based on available resources, this analysis could include a health economic assessment). Depending on market health and price dynamics, the relevant Gavi teams will decide whether to assess the value of new vaccines in a standalone manner, as incremental in comparison to incumbent supported vaccines or compared to pipeline vaccines with in-principle support decisions.

- The results of the assessment should be presented to PLT for review. The CVPMO will approve the next steps based on PLT's recommendation and inform the CEO accordingly. In case of substantial risks and/or a budget impact commensurate with the vaccine's benefits, the standard approach would be to update the financial forecast in the AFC paper and present an investment case to the PPC and Board to confirm support. Additionally, guidance from MSDC may be requested for sensitive information.

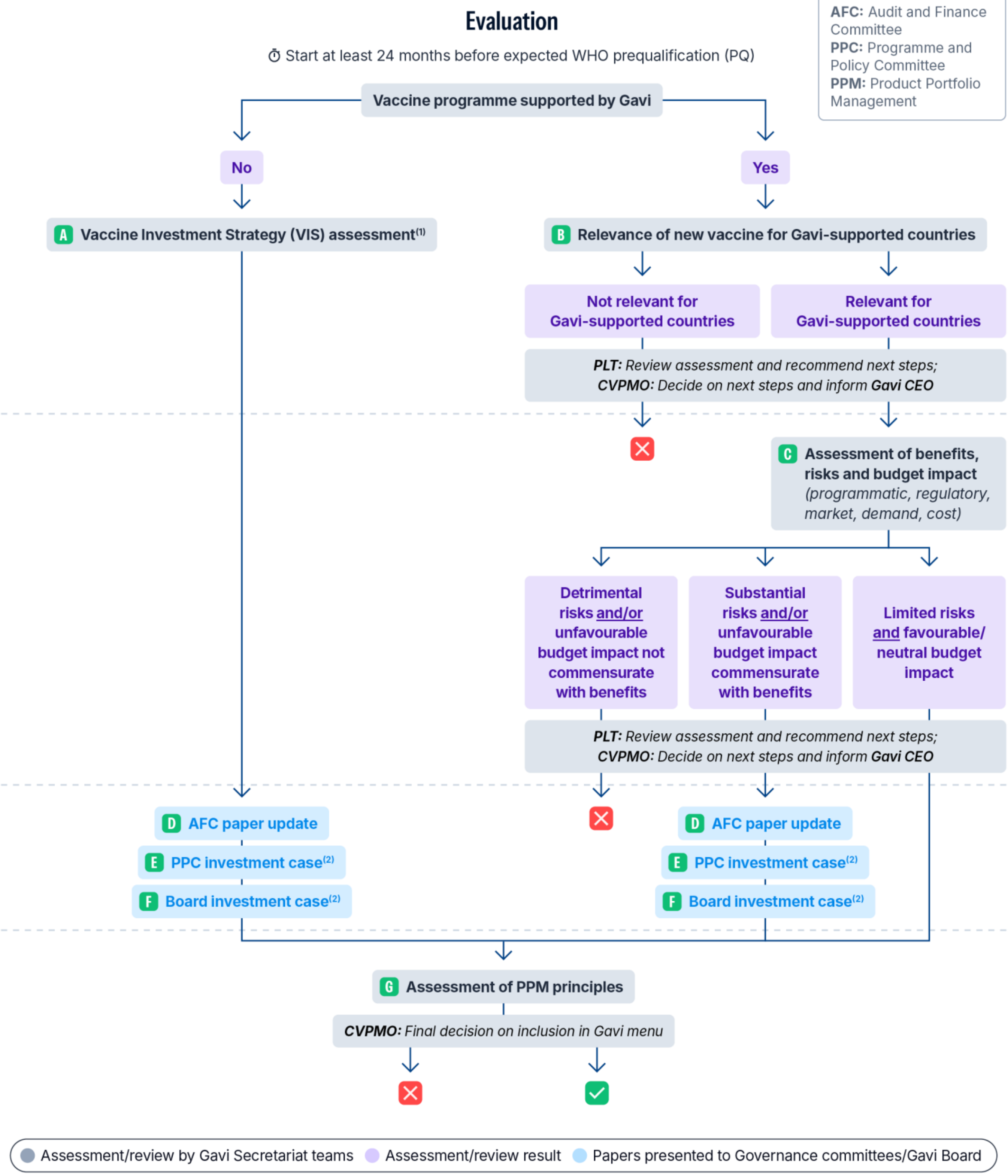
- If the assessment shows limited or no risks and a favourable or neutral budget impact, based on PLT's recommendation the CVPMO can decide not to submit an investment case to the PPC and Board, and will inform the CEO of this decision. Ultimately, the vaccine will be assessed based on the PPM principles once it nears WHO prequalification.

- The CVPMO can decide not to pursue additional steps to support the vaccine if the impact in one or more of the dimensions is considered detrimental to countries, programmes and markets, or if the price premium is not commensurate with the vaccine's benefits. In that case, based on PLT, CEO and Governance's input, Gavi Secretariat can present a paper to the PPC and Board to inform them about the assessment and the decision not to pursue support.

See below for figure 6: Governance pathways for next-generation vaccines.

Figure 6:
Governance pathways for next-generation vaccines

PLT: Programme Leadership Team
CVPMO: Chief Vaccine Programmes & Markets Officer
AFC: Audit and Finance Committee
PPC: Programme and Policy Committee
PPM: Product Portfolio Management



(1) In case the vaccine development timelines are faster than anticipated and the vaccine is expected to be available before the next Vaccine Investment Strategy (VIS), the teams will evaluate the possibility of an ad hoc VIS assessment considering information about health benefits, price attractiveness, cost implications, etc.

(2) Exceptionally, Gavi Secretariat could reach out to Market-Sensitive Decisions Committee (MSDC) for guidance on sensitive information prior to submitting the investment case to the Programme and Policy Committee (PPC)/Gavi Board.

In some cases, the Vaccine Alliance might define specific market conditions that must be met before starting to procure the next-generation vaccine, to ensure market health attributes are met (e.g. number of prequalified vaccines, vaccine price).These conditions will be shared with relevant manufacturers when available.

Annex F: Market-Sensitive Decisions Committee Charter

January 2023

1. PURPOSE

The Market-Sensitive Decisions Committee ("Committee" or "the MSDC") is established by the Board ("Board") of the Gavi Alliance ("Gavi") to support the Board in fulfilling its oversight responsibilities.

The Committee will make decisions which are market and/or commercially sensitive, subject to powers reserved specifically to the Board in Article 13 of the Statutes.

Words and expressions used in this Charter shall, unless the context requires otherwise, have the meaning attributed to them in the Gavi Board and Committee Operating Procedures ("Operating Procedures").

2. MEMBERSHIP

The membership, resources, responsibilities and authorities of the Committee to perform its role effectively are stipulated in this Charter, which may be amended by the Board as and when required or deemed necessary and are specifically governed by Article 18 of the Statutes and Section 18 of the Operating Procedures.

A. Composition and size

The composition of the MSDC shall allow it to function efficiently and effectively in fulfilling its functions and responsibilities.

The MSDC shall comprise up to 14 members ("Members") according to the following representational composition and shall be chaired by the Board Chair:

- One seat for the Board Chair;
- One seat for the Board Vice Chair;
- Two seats for representatives of the multilaterals (World Health Organization, UNICEF, World Bank);
- One seat for a representative of the Gates Foundation;
- Two seats for representatives of implementing country governments;
- Three seats for representatives of donor country governments;
- One seat for a representative of the civil society organisations;
- One seat for the Chair of the Audit and Finance Committee;
- One seat for the Chair of the Programme and Policy Committee; and
- The CEO, who shall serve as a non-voting Member of the MSDC.

Only Board members and Alternate Board members may be Members of the Committee.

B. Competencies and Skills

All MSDC Members shall be able to act independently, to ask relevant questions and evaluate answers, act professionally, and maintain the highest ethical standards and loyalty to the interests of Gavi.

The overall balance of skills on the Committee shall be periodically evaluated to respond to the needs of Gavi and its Board.

The criteria for MSDC membership shall be consistent with Gavi's guiding principles on gender for Board and Committee nominations.

The Chair of the MSDC shall:

- Plan and oversee the conduct of meetings;
- Report to the Board on relevant and material matters as appropriate; and

- Participate in and advise on the selection of MSDC Members in conjunction with the Board and the Governance Committee.

In the event that the Chair is unable to attend a scheduled meeting, the meeting shall be chaired by the Board Vice Chair and in the event of their simultaneous absence, the Chair will, after consultation with other MSDC Members, nominate a suitable substitute from the membership of the MSDC.

C. Appointment and term of office

MSDC Members shall be appointed by the Board on the recommendation of the Governance Committee, in consultation with the Chair of the MSDC. MSDC members shall be appointed once every two years, with renewable terms.

The Secretary to the Board or their designated appointee shall be the Secretary of the Committee. The Secretary shall:

- Provide the link between the MSDC, the Board and the Secretariat and, as appropriate, COVAX Facility;
- Assist the MSDC in developing good governance practices; and
- Ensure that the agenda, meeting papers and minutes and other materials to support the MSDC are provided in a timely manner.

3. AUTHORITY

The MSDC is established by the Board under Article 18 of the Statutes and is a Standing Board Committee. It is empowered by the Board to undertake the responsibilities outlined in this Charter. The MSDC will operate under Gavi's Statutes and Operating Procedures.

The MSDC is a decision-making body as set out in 5. below. It shall regularly report on MSDC activities to the Board and shall maintain open communications between MSDC Members and the Board.

The MSDC shall have reasonable access to information, Gavi personnel and relevant other Gavi parties, and external expertise as appropriate.

The mandate of the MSDC is established in this Charter.

4. RESPONSIBILITIES

The MSDC is authorised by the Board to:

- Approve market and/or commercially sensitive decisions as part of the implementation of the supply and procurement strategy;
- Approve transactions presented in respect of the COVAX Facility which would ordinarily have market and/or commercially sensitive implications as part of the administration by Gavi of the COVAX Facility; and
- Perform such other duties required by Gavi under its Statutes or Operating Procedures or otherwise as are necessary or appropriate to further the Committee's purposes, or as the Board may assign to the MSDC.

5. MODE OF OPERATION

A. Meeting attendance

Only Board members and Alternate Board members appointed to the MSDC shall be entitled to attend meetings of the Committee.

Members of the Secretariat shall make themselves available to attend all MSDC meetings as appropriate.

MSDC Members shall prepare for and actively participate in Committee meetings.

B. Frequency of meetings

The Committee shall meet as required to discharge the responsibilities outlined in 5. above and at the request of the CEO, in consultation with the MSDC Chair.

C. Notice of meetings and confidentiality

Notice of a meeting of the MSDC shall be given to each Committee Member at least five business days prior to such meeting. All such notices shall be given in writing and sent by mail to the last recorded address of the Committee Member or by email if the Committee member has consented to receipt of notice by email. Notice of any such meeting need not be given to any Committee Member who submits a signed waiver of notice or who participates in a meeting without protesting, prior thereto or at its commencement, the lack of notice to them.

The MSDC Chair may call a meeting on less than five business days' notice if in their reasonable opinion there exist exceptional circumstances requiring an MSDC meeting to be held on short notice, provided however that the minimum notice that must be provided to Committee Members is two business days; unless urgent circumstances require that the MSDC should meet in an even shorter period and which shall be solely at the discretion of the Chair to grant such waiver and this will only be in relation to a discussion and/or decision specific to the COVAX Facility.

The notice will normally include relevant supporting papers for the agenda items to be discussed. All papers circulated to MSDC Members shall be retained in the strictest confidence for their specific reference and use and may not be circulated or distributed in any manner or form.

D. Agenda

The MSDC Chair shall establish Committee meeting agendas with the Secretary of the Committee and in consultation with Committee Members and relevant members of the Secretariat.

E. Quorum

The quorum for the MSDC shall be a majority of voting MSDC Members. The Committee may only carry out its business while the quorum requirement is met. In the event that an MSDC meeting ceases to be quorate, at the option of the Chair, discussions may continue, but no decisions may be made. The Chair may choose to end the meeting on it becoming inquorate.

F. Conflict(s) of interest and declarations of interests

All MSDC Members shall adhere to Gavi's Conflicts of Interest for Governance Bodies and Ethics Policies and shall annually complete an Annual Declaration Form in accordance with these policies. The Declaration shall be updated by MSDC Members when required.

At the commencement of each meeting, each MSDC Member if present, shall declare any actual or perceived conflict of interest arising in the matters before the Committee and the relevant provisions in the Statutes, Operating Procedures and the Conflicts of Interest Policy for Governance Bodies shall regulate participation.

G. Voting

All decisions of the MSDC shall be taken by vote and considered approved if a majority of those present in the meeting, and entitled to vote, vote in favour of the decision.

H. Minutes

The Committee shall keep minutes of its meetings in accordance with Gavi's Statutes and Operating Procedures. Minutes shall be shared with MSDC Members, noting that the minutes will be confidential and shared solely and exclusively for their reference and shall not be circulated or shared.

I. Executive sessions

From time to time, at the discretion of the MSDC Chair, the Committee may hold closed sessions with such parties as it deems appropriate, together or separately without members of the Secretariat present (including the CEO).

6. ACCESS TO INFORMATION AND EXPERTISE

The MSDC is authorised by the Board to obtain independent professional advice as it considers necessary, at the expense of Gavi.

Should the professional advice sought by the MSDC relate to a transaction specific to the COVAX Facility, the costs shall be borne by the budget dedicated to the COVAX Facility.

7. PERFORMANCE AND REVIEW

The Committee will normally evaluate its performance at least once every two years in conjunction with the Board Evaluation having regard to the principles and requirements of its mandate as set out in this Charter, and any additional activities undertaken during the year at the request of the Board.

The MSDC shall report to the Board the results of its review and development actions arising.

The Board shall review the MSDC Charter at least every three years, normally to coincide with the regular performance evaluation, to ensure its adequacy and that it remains relevant to its programme of work and in accordance with developments in best practice.

Annex G: Authors and contributors

Authors, contributors, and involved organisations (Working Group)

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Annex H: Acronyms and abbreviations

4.0	Gavi strategic period covering 2016–2020
5.0	Gavi strategic period covering 2021–2025
6.0	Gavi strategic period covering 2026–2030
CCE	Cold chain equipment
CEPI	Coalition for Epidemic Preparedness Innovations
CTC	Controlled Temperature Chain
DCVMN	Developing Countries Vaccine Manufacturers Network
EUL	WHO Emergency Use Listing
Gavi	Gavi, the Vaccine Alliance
Gavi-MS	Gavi Secretariat Market Shaping team
GF	Gates Foundation
GF-IMM	Gates Foundation Immunisation department
HIC	High-income country (World Bank classification, as of 1 July 2018, GNI/capita ≥ US$ 12,055)
HMF	Healthy Markets Framework
HPV	Human papillomavirus
IA2030	Immunization Agenda 2030: A Global Strategy To Leave No One Behind, led by the World Health Organization
IF&S	Gavi Secretariat Immunisation Financing and Sustainability team
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IPV	Inactivated polio vaccine
KPI	Key performance indicators
LIC	Low-income country – World Bank classification • as of 1 July 2025 (for FY26): GNI/capita ≤ US$ 1,135 • as of 1 July 2026 (for FY27): GNI/capita ≤ US$ 1,175
LMIC	Lower middle-income country – World Bank classification • as of 1 July 2025 (for FY26): GNI/capita US$ 1,136–4,495 • as of 1 July 2026 (for FY27: GNI/capita ≤ US$ 1,176–4,635
LTA	Long-term agreement
M&E	Monitoring and evaluation
MS	Market shaping
MSS 6.0	Gavi's Market Shaping Strategy for the 2026–2030 strategic period
NRA	National Regulatory Authority
PAHO	Pan American Health Organization
Partners	Partners of Gavi, the Vaccine Alliance
PATH	Program for Appropriate Technology in Health, Seattle, USA
PPC	Gavi's Programme and Policy Committee
PPM	Product Portfolio Management
PQ	Prequalification of vaccines by the World Health Organization for purchase by United Nations agencies
PRG	UNICEF Procurement Reference Group
SAGE	Strategic Advisory Group of Experts on Immunization
SG4	Gavi Strategic Goal 4
SPF	Gavi Secretariat Strategic, Policy and Foresight team
Square Group	Partnership of Gavi market shaping partners from: Gavi Secretariat, UNICEF SD, WHO-IVB, & GF
TCV	Typhoid conjugate vaccine
UNICEF SD	UNICEF Supply Division

VFSM	Gavi's Vaccine Forecasting and Supply Management team
VIPS	Alliance's Vaccine Innovation Prioritisation Strategy
VIS	Gavi's Vaccine Investment Strategy
WAP	Weighted average price
WHO	World Health Organization
WHO-PQ	WHO prequalification
WHO-IVB	WHO Department of Immunization, Vaccines and Biologicals
YF	Yellow fever