

Subject            **2026-2030 Strategy: Market Shaping Strategy**

Agenda item      **05c**

Category          **For Guidance**

### Executive Summary

**The Board's guidance on key elements of a Market Shaping Strategy for Gavi 6.0 (MSS6.0)**, to be approved in mid-2026, will ensure it fits with the Gavi 6.0 strategy and Strategic Goal 4 (SG4), while accounting for recalibration outcomes. Important trade-off decisions are anticipated to balance the proposed priorities of **optimising affordability and supply security** without backsliding on market health and specifically to balance reduced weighted average prices (WAP) of vaccines with acceptable levels of regionally diverse supply security and sustainable markets in the long term. The proposed priority of **anticipatory shaping of future markets** for Vaccine Investment Strategy (VIS)-endorsed vaccines and vaccines against outbreak, epidemic and pandemic (OEP) diseases, aims to ensure successful future introductions and supply availability.

Gavi's Programme and Policy Committee (PPC) has provided guidance on the MSS6.0 framework. The MSS6.0 framework was **developed in collaboration** with market shaping Square Group partners Gates Foundation, UNICEF Supply Division and World Health Organisation Immunization, Vaccines and Biologicals department. Secretariat teams, additional PPC members and Alliance partners - International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Developing Country Vaccine Manufacturers Network (DCVMN), Africa CDC (A-CDC), Implementing and donor countries - were consulted.

### Action Requested of the Board

The Gavi Alliance Board is requested to **provide guidance** on:

- a) Interrelated Strategic Priorities (SPs) 1 & 2, and their associated Target Outcomes (TOs), specifically the increased focus on optimising for affordability of vaccine costs (SP1) balanced with the imperative to maintain access, supply security and market health (SP2);
- b) Two proposed direct enablers supporting SPs 1 and 2, specifically:
  - i) Revision of the Healthy Markets Framework, with expansion of Supply Security definitions, to better evaluate trade-offs between SPs 1 & 2; and
  - ii) A Procurement Framework to be articulated within MSS6.0; and
- c) The ambition for SP3 as specific to Vaccine Investment Strategy (VIS)-endorsed vaccines and vaccines against select outbreak-, epidemic- and pandemic-prone (OEP) diseases, and the associated TOs and proposed enablers.

The Gavi Alliance Board is requested to **note** that Gavi's Board Chair is convening the MSDC in an advisory capacity for a time-limited period to provide guidance on

the most material trade-offs and risks related to achieving price-related budget savings.

### Next steps/timeline

In July 2026, following a PPC recommendation, the Board will be requested to approve a Market Shaping Strategy for Gavi 6.0, including all enablers and indicators.

### Previous Board Committee or Board deliberations related to this topic

**In October 2025 Programme and Policy Committee meeting book:** Doc 06b *Gavi 6.0 Operationalisation: Market Shaping Strategy*

**In July 2025 Board meeting book:** Doc 06 *Funding Policy Review* - Annex A, *Eligibility and Transition policy*; and Annex B, *Co-financing policy*

**In July 2025 Board meeting book:** Doc 01 *Governance pathways for next generation vaccine innovation*; Annex C *Product Portfolio Management principles*

**In June 2022 Board meeting book:** Doc 08 *Gavi's Role in Regional and African Vaccine Manufacturing*

**In June 2021 Board meeting book:** Doc 01f Annex D *Market Shaping Strategy 5.0* – as part of the consent agenda.

## **Report**

- 1. The Market Shaping Strategy for Gavi 6.0 (MSS6.0) is guided by the Board-approved SG4 objectives contributing to the Gavi 6.0 strategy**
  - 1.1 Gavi 6.0's SG4 objectives provide the guidance for the proposed Strategic Priorities of MSS6.0 (see Annex B). Gavi's principle of being country-led, as reaffirmed in *Gavi Leap*, will guide important aspects of MSS6.0.
  - 1.2 The constrained funding environment necessitates an increased focus on affordability<sup>1</sup> by procurement of vaccines with similar benefit at a lower weighted average price (WAP) to sustain Gavi's health impact. Affordability must be balanced with supply security to ensure continuous vaccine supply for countries' programmes and to minimise market health backsliding. The PPC recognised that MSS6.0 and its implementation will require difficult trade-offs and emphasised the need to ensure that short-term actions do not compromise the long-term imperative of regionally diversified supply and sustainable markets that serve countries' needs beyond Gavi support.
- 2. MSS6.0 builds on previous success & trends (see Annex C)**
  - 2.1 Assured procurement financing and predictable, high demand are the primary forces shaping markets for Gavi-supported vaccines. These forces, along with Alliance strategies and investments, have resulted in ten markets with acceptable levels of market dynamics in 2024 (see Doc 02b).
  - 2.2 Despite successful portfolio expansion<sup>2</sup> being driven by greater availability of lower-priced products, demand for them has been limited<sup>3</sup>. Until now, incentives for countries to consider cost in vaccine product choice decisions have been weak, resulting in underuse of lower priced products.
  - 2.3 Despite R&D investments for OEP vaccines, these markets are unpredictable with limited incentives for developers to invest in investigational vaccine reserves, product licensure, or production scale-up.
- 3. Several challenges and imperatives are critical to address in Gavi 6.0**
  - 3.1 Gavi resourcing versus the Gavi 6.0 recalibration baseline of July 2025 will result in ~US\$ 1.7 billion (~20%) less for procurement of vaccines in Gavi 6.0, of which ~US\$ 800–950 million<sup>4</sup> is assumed to be WAP-driven (see Doc 05a) and the remainder via volume reductions.

<sup>1</sup> Definitions of key market shaping terms used in this paper are provided in Annex D.

<sup>2</sup> The choice of vaccine products available during Gavi 6.0 will potentially include four human papillomavirus (HPV), five rotavirus (RV) and six pneumococcal conjugate vaccine (PCV) products.

<sup>3</sup> Currently, 2 of 26 initial self-financing and 3 of 30 preparatory or accelerated transition countries are using the lowest priced PCV or HPV vaccines.

<sup>4</sup> Comprised of US\$ 300-450 million applied to the base Gavi 6.0 forecast + US\$ 350 million identified in the recalibration process + an additional US\$ 150 million ambition requested by the Board at its retreat in July 2025.

- 3.2 Realising lower WAPs will require a collective effort to achieve new lower prices and increased use of already lower price products, often through greater reliance on fewer suppliers and increased country adoption of lower priced products. The impact of revenue reduction, which will vary by market and supplier, combined with inflationary and other pressures, may limit suppliers' ability to lower prices or to continue serving Gavi countries. The critical challenge of MSS6.0 will be to achieve the appropriate balance of these short-term efforts with ensuring long-term sustainable markets, including regionally diverse supply. The PPC guidance emphasised the important recognition by the Alliance that additional market risks and externalities will emerge, and that "you cannot have it all".
- 3.3 In markets where product choice falls to countries, close monitoring of adoption of lower priced vaccines will be necessary, in case intervention is needed to uphold a minimum market position for higher-priced products if considered necessary for overall supply security (see also 6.3.3.).
4. **Key pillars of MSS5.0 will be embedded as foundational principles**
  - 4.1 Three pillars of the prior strategy will support MSS6.0; (1) The concept of a **sustainably competitive future supplier base** that applies a holistic lens to the overall business & sustainability of manufacturers, (2) improving demand materialisation, reducing volatility & uncertainty and supporting cost-consciousness through **demand health** activities that will now be part of Vaccine Portfolio Optimisation and Prioritisation (VPOP), and (3) **establishing an enabling environment for transformational innovation** including the Vaccine Innovation Prioritisation Strategy (VIPS) and early landscaping for new high-impact, VIS-endorsed vaccines (e.g. novel tuberculosis (TB)). Access to vaccine innovations for existing programmes will continue via the Board-approved pathway for evaluation of next generation vaccines (see Doc 09).
  - 4.2 The scope of markets for MSS6.0 is unchanged from Gavi 5.0<sup>5</sup> with the addition of VIS- endorsed and OEP vaccines expected to receive future Gavi funding.
5. **Proposed MSS 6.0 Strategic Priorities (SP) and Target Outcomes (TO)**
  - 5.1 **SP1: Optimise vaccine programme affordability to countries and Gavi.** Implementation will require informed and considered trade-offs with maintaining supply access, security and market health (SP2). Proposed TOs that would be measured through indicators are:
    - 5.1.1. Availability of lower-cost products available to Gavi-supported countries
    - 5.1.2. Materialisation of WAP decreases for specified Gavi-supported vaccines
    - 5.1.3. Limitation of WAP increases to cases that are justified by market health, programmatic or strategic benefits

<sup>5</sup> Includes vaccines, cold- chain and immunisation devices funded by Gavi.

5.2 **SP2: Maintain supply access, security, and market health.** This addresses the need to have uninterrupted access to vaccine supply, supply security, and the confidence that markets will serve countries over the long term. PPC provided guidance that target outcomes for this SP require additional specificity, particularly how preserving competitive dynamics will be measured against competing target outcomes and how critical strategies impacting such dynamics would be reviewed and decided. The PPC also noted giving greater prominence to a geographically diverse supplier base. The TOs proposed to PPC, and retained below, will be revised based on PPC and Board guidance, followed by additional consultations, and brought to the Board with related indicators for approval in June 2026:

5.2.1 Uninterrupted supply of vaccine for countries is maintained in each vaccine market through Gavi 6.0

5.2.2 Competitive dynamics are preserved within key vaccine markets as the key driver of competitive pricing and long-term healthy markets

5.2.3 Emergence of a geographically diverse supplier base that can endure to serve countries beyond Gavi support

5.3 **SP3: Develop future markets for VIS-endorsed and OEP vaccines.** Countries and Gavi can benefit from early shaping of VIS-endorsed and select OEP markets by mitigation of introduction risks, pathways for supply availability, and successful developer market entry with sufficient supply. Proposed TOs that would be measured through indicators are:

5.3.1 Introduction of select affordable new high-impact vaccines is accelerated

5.3.2 Access to OEP vaccines is rapid and equitable

5.3.3 Markets for outbreak and epidemic-focused vaccines are sustainable

## 6. Proposed enablers for implementation of the strategy

6.1 Gavi's market shaping relies on foundational "enablers" which continue in Gavi 6.0. These include market shaping roadmaps, manufacturer engagement, demand forecasting, partnerships for coordination and implementation, financial tools for procurement, and Product Portfolio Management principles. Acknowledging PPC feedback, indicators to assess the effectiveness of select enablers will be proposed as part of MSS 6.0.

6.2 Supporting SP1 and SP2, the PPC acknowledged the importance of the three enablers proposed for further development within MSS6.0:

6.2.1 The **HMF** provides a common basis for evaluation and comparison of markets. It is proposed that the HMF be updated with definitions and concepts that are fit-for-purpose in this environment and provide a more structured basis for evaluating trade-offs across its dimensions, including affordability, in the short- and long-terms. Definitions of supply

security levels, applicable to any market, against which the Alliance's risk and cost tolerance can be evaluated will be developed.

- 6.2.2 Achieving specific market objectives while maintaining an appropriate balance between decreasing WAP and acceptable levels of supply security may require significant trade-offs and/or acceptance of new risks. Hence an escalation process for **Board-level guidance on market strategies with the most material trade-offs** across market health dimensions is required. The Gavi Board Chair has engaged the MSDC in an advisory capacity for a time-limited period to provide guidance to the Board on trade-offs and risks under Strategic Goal 4. MSS6.0 will incorporate detail on triggers for seeking guidance, the nature of the advice sought, and the necessary supporting analyses.
- 6.2.3 Leveraging the aggregated demand and operational efficiencies of centralised procurement remains essential in Gavi 6.0. It is proposed that MSS6.0 include a **Procurement Framework** that: (1) reaffirms the default of centralised procurement, with potential exceptions for countries hosting domestic manufacture of eligible vaccines, (2) clarifies the regulatory standards guiding Gavi-funded procurement, (3) identifies criteria for considering regional pooled procurement mechanisms as a channel for Gavi-funded vaccines in future periods.
- 6.3 Also critical for SP1 and SP2 will be four enablers to be referenced in MSS6.0; all are the subject of separate agenda items at this Board:
  - 6.3.1 For SP1: **CVBs** will provide countries with incentive to optimise health impact within their budget by choosing lower cost products (see Doc 05b);
  - 6.3.2 For SP1: evidence to better inform **country product optimisation decisions** will be operationalised as part of **VPOP**, supporting countries to make cost-conscious product choices within their CVBs (see Doc 05b);
  - 6.3.3 For SP1&2: establishment of a **financial contingency for supply security** & market health, and associated processes, are proposed to address the CVB implications when they are required to use a more expensive product than their first choice to preserve global supply security or market health. This, along with a CVB design option that aims to safeguard programmes with specific supply-side risks, forms part of the proposed CVBs approach (see Doc 05b); and
  - 6.3.4 For SP2: the **AVMA** is critical for establishing Africa's contribution to global supply resilience and the planned 2026 review will ensure fitness for purpose against its original objectives (see Doc 10).
- 6.4 Three direct enablers in support of SP3 are proposed for MSS6.0 inclusion:



- 6.4.1 **Early market shaping roadmaps** for select VIS-approved vaccines will support optimised Gavi programme launch(es), including financing modalities as relevant, and evidence generation to inform future policy;
- 6.4.2 Collaboration with **CEPI** to coordinate our complementary tools to drive the viability of future markets within scope; and
- 6.4.3 Efficient deployment of Gavi's **outbreak financing mechanisms** (e.g. First Response Fund, Day-Zero Financing) to transact with vaccine developers and manufacturers addressing in-scope OEP pathogens.

### **Annexes**

**Annex A:** Implications/anticipated impact

**Annex B:** Market Shaping Strategy (MSS) high-level summary graphic

**Annex C:** Trends and influences on market shaping

**Annex D:** Glossary of market shaping terms

### **Additional reference materials online**

Market Shaping Strategy 5.0: <https://www.gavi.org/sites/default/files/about/Gavi-Alliance-Market-Shaping-Strategy-2021-2025.pdf>

Market shaping roadmaps: <https://www.gavi.org/our-alliance/market-shaping/market-shaping-roadmaps>

Healthy Market Framework: <https://www.gavi.org/sites/default/files/about/market-shaping/HMF-explainer.pdf>