

EVALUATION OF THE GAVI 2016-20 SUPPLY AND PROCUREMENT STRATEGY

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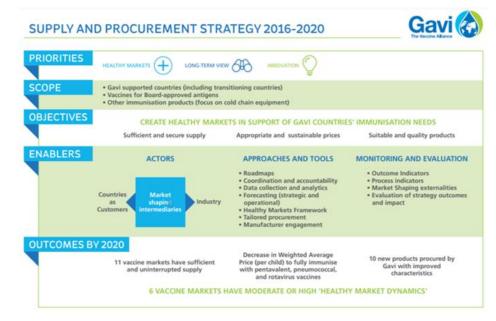
1. BACKGROUND

Market forces alone have historically not resulted in the widespread supply of high-quality and affordable vaccines to prevent the spread of key diseases in low and middle-income countries (LMICs). Despite the launch of the WHO Expanded Programme on Immunization (EPI) in 1974, LMICs were lagging behind high income countries (HICs) in vaccine coverage. Limited availability of financing and uncertainty of demand meant that manufacturers were not adequately incentivised to supply vaccines relevant to these markets, or at affordable prices, which inevitably contributed to a significant time lag between availability of new vaccines in HICs and LMICs.

Gavi was established to address these market failures by acting as a financing mechanism that would enable increased access to vaccines in these countries, as well as accelerate the development of vaccines where markets in HICs did not exist. Following its establishment in 2000, and through the first ten years of existence, Gavi took a more passive approach to shaping markets, focusing more on bulk procurement. However, experience during this period showed that this was not adequate to support improvements in market dynamics; with markets experiencing limited price declines, lack of competition in key markets and unstable supply in others, resulting in calls for Gavi to take a more strategic and proactive role in shaping markets.¹ In light of this, the Alliance developed its 2011-15 Supply and Procurement Strategy under its third strategic period (Gavi 3.0). Drawing on lessons learnt from the 2011-15 period, Gavi

continued to adopt an explicit approach for its 2016-20 Supply and Procurement Strategy aimed at "shaping markets for vaccines and related products" (Gavi's Strategic Goal 4), with its main components summarised in Figure 1.

Figure 1: Overview of Gavi Supply and Procurement Strategy 2016-202



¹ CEPA (2010), Second Gavi Evaluation

² www.gavi.org/sites/default/files/document/supply-and-procurement-strategy-2016-20-overviewpdf.pdf



In 2020, CEPA was appointed by Gavi to conduct an evaluation of the 2016-20 Supply and Procurement Strategy. This policy brief summarises the key findings and recommendations from this evaluation.

2. KEY FINDINGS

The Gavi 2016-20 Supply and Procurement Strategy has been very relevant, appropriate and significant in the context of the evolving/ maturing market shaping role of Gavi and the supply context over the period. In particular, the development of the healthy markets concept as a holistic view of markets, beyond narrow considerations of price and number of suppliers, has been instrumental in aiding an improved and well-rounded approach to markets and market shaping, and the Healthy Markets Framework (HMF) within this has been a seminal tool to encourage shared understanding and perspectives across partners. The Vaccine Innovation Prioritisation Strategy (VIPS) has created considerable value by bringing about partner alignment and strategic coordination on vaccine innovation and the approach to monitoring externalities from market shaping is best practice in the field.

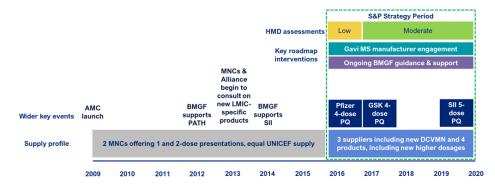
2.1. HEALTHY MARKETS

Building on the Alliance partners' long-term work, Gavi has contributed to improved health across a number of markets by facilitating increased competition. In particular, the pneumococcal conjugate vaccine (PCV) market has attracted new entrants. Figure 2 provides a timeline of activities that have been key contributing factors to improved market health. The figure shows how Gavi's long-term interventions such as the Advanced Market Commitment (AMC) and upstream manufacturer support have been important for improving market health, while specific interventions within the strategy period built on these long-term interventions.

Other markets with improved health include rotavirus, measles-rubella (MR) and inactivated polio vaccine (IPV), where there have also been new entrants. Several Gavi-funded vaccines also have strong product pipelines, which will contribute to improved market health in the future. In addition to these vaccine market developments, Gavi has also helped facilitate the phasing out of low-quality cold

chain equipment (CCE), while significantly increasing the uptake of high-quality products.

Figure 2: Timeline analysis of key events contributing to improved market health for PCV



Source: CEPA analysis. NB: HMD = Healthy Market Dynamics; MS = Market Shaping; MNC = Multinational Corporation; SII = Serum Institute of India; PQ = WHO Prequalification; DCVMs = Developing Country Manufacturers.

Exploring the counterfactual of whether Gavi has led to observed results, the evaluation has clearly found that many of these market improvements can be attributed in part to the result of long-term commitments to develop and procure vaccines by Gavi, and that without these efforts, these markets would not be in their current state of health, or, at least, would have taken longer to reach these levels.

Several markets have seen improvements in supply security, though this has not been uniform. In particular, the yellow fever market has seen marked improvements, which can be partly attributed to a concerted effort by the Alliance to work with manufacturers to realise this. However, human papillomavirus (HPV) and IPV markets continued to face supply-side challenges that have limited their rollout in Gavi-supported countries, while production challenges have been experienced in the rotavirus market.

Some markets have also experienced significant price declines, while others have seen prices either remaining relatively stable or increasing. There has been an estimated 53% price decline in the pentavalent market during the



strategy period, which is expected to result in US\$350 million in procurement cost savings, when considering prices prior to this period. These reductions have also resulted in HIC manufacturers exiting, which could be considered as a natural market development, but there has also been no new entrants to the Gavi market since 2014. On balance, the outcomes suggest that the Alliance may have pushed the limits of what could be done to reduce prices while not significantly damaging market health in other respects.

The rotavirus and PCV markets experienced modest price declines, while for some markets, prices have increased, partly to improve the supply situation (including IPV and yellow fever), suggesting that the Alliance has appropriately considered trade-offs.

Despite these achievements, Gavi is likely to miss its overall target of achieving moderate to high levels of health across six vaccine markets. Key markets that are not expected to reach these levels include the HPV and IPV markets. In addition, while the achievements related to healthier markets have been significant, more work is needed to ensure that such markets benefit from "true competition". For example, while the PCV, rotavirus and MR markets have seen new entrants, actual uptake of new products has been relatively low, partly because of countries favouring existing products.

A key tool developed as part of the Strategy was the **Healthy Markets Framework (HMF)**. This was used to help track market health and determine which interventions would be implemented. The HMF captures key supply side components of the market, although there is a lack of adequate representation of demand side issues. There are also some challenges with defining and assessing certain HMF attributes which represent areas for improvement for the next HMF iteration. Overall, the HMF has been a very useful tool and contributed to facilitating a shared understanding of markets amongst partners.

2.2. Long-term view

There has been limited progress on the objectives and workstreams with regards to supporting country-owned decisions and capacity for

procurement and market-related capacity for transition. This has mainly been on account of lack of ownership and responsibility for this aspect of the Strategy within Gavi, driven by the Secretariat and partner structures, where market shaping functions and priorities have not been fully understood and coordinated with country-oriented functions.

There is limited linkage and understanding of Gavi market shaping priorities within countries, and a core need for better information sharing on Gavi's market shaping work and key market developments.

At the global level, stakeholders praised Gavi for improved information sharing, data collection, analytics and coordination on market shaping. Industry representatives have seen an improvement in transparency from the Secretariat during their engagements. There has also been a strong working relationship between the Gavi Secretariat, UNICEF Supply Division (UNICEF SD) and the Bill and Melinda Gates Foundation, which has been considered as a cornerstone of the successful implementation of the Strategy and the positive market shaping outcomes seen.

2.3. Innovation

The Vaccine Innovation Prioritisation Strategy (VIPS) has created value by bringing about partner alignment and strategic coordination on vaccine innovation. The work under VIPS has culminated with the selection of three innovations that will be prioritised (microarray patches, heat-stable and controlled temperature chain vaccines and barcodes on primary packaging). While not within scope for the current Strategy, VIPS needs to consider cost-effectiveness, financing and supply in the next strategy period.

Activities to support innovation have worked well with several improved vaccine products receiving WHO Prequalification (PQ) and being procured by the Alliance. Examples include PCV 4-dose products and new presentations for oral cholera vaccines (OCV). A consideration of the counterfactual has shown that Gavi signalling of demand has been a key contributing factor to development.



3. RECOMMENDATIONS

Strategy design and implementation

- Build up the Strategy to be truly a "market" strategy, reflecting both demand and supply aspects
 - Greater consideration of impact of country preferences on supply, and a managed approach to campaign scheduling, whilst balancing with country ownership
 - Requires coordinated working across multiple Gavi Secretariat teams and partners
- 2) Long-term should be guiding principle across all Strategy, including planning for vaccine and non-vaccine markets and the operationalisation of VIPS
- 3) Adopt a more consolidated, joint-up and long-term approach to innovations in the next strategy
 - Adopt a long-term lens by considering country demand for specific innovations, planned procurement and financing approaches and delivery issues
- 4) Integrate approaches within the strategy that more closely consider the wider ecosystem within which Gavi's market shaping work functions
 - Evolve from a vaccine-by-vaccine approach to consider manufacturer portfolios overall, and consider impact of non-Gavi market developments
- 5) Incorporate key updates to the next iteration of the HMF
 - Include stronger linkages to demand, re-work for CCE and improve definitions and assessment approaches for individual attributes
- 6) Incorporate suggestions for improvements in the development of roadmaps
 - Include long-term strategic vision, annual updates to align with market developments and considerations of wider ecosystem (e.g. MICs/HICs)
- 7) Consider additional processes and metrics to improve the monitoring and evaluation of the activities and results of the Strategy
 - Develop theory of change aligning with overall Gavi Strategy, include qualitative information alongside quantitative metrics, conduct counterfactual assessments, and define indicators to more appropriately capture ultimate objectives

Country capacity and coordination

- 8) Work with wider Secretariat teams and partners to more effectively engage with countries in relation to Gavi's market shaping work, especially for transition countries
 - Implementation will require improved coordination between different teams in Gavi Secretariat and wider partners

Global partnerships and coordination

- 9) Build on current successes in partnerships with key stakeholders, while expanding coordination with other market shaping stakeholders where relevant
 - Including more regular updates with manufacturers and countries, improving alignment and communication on demand forecasting and ensure closer engagement with WHO and wider Alliance partners
- 10) Move away from approaching vaccines as a vertical intervention, with better coordination with global partners on cross-cutting issues such as country regulatory requirements
 - Work with wider global health community (e.g. WHO PQ and WHO's work on national regulatory authority strengthening, Global Fund and the United States
 Agency for International Development (USAID)) on addressing common challenges (e.g. regulation and country registration of new products), as well as facilitate
 information sharing on best practices for market shaping