Evaluation of the Gavi Supply and Procurement Strategy

Gavi, the Vaccine Alliance

25 November 2020

FINAL REPORT

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Contents

Acronyms

Acronym	Full description
AMC	Advance Market Commitment
BBIL	Bharat Biotech International Limited
BFS	Blow-fill-seal
Bio M	Bio Manguinhos
BMGF	Bill and Melinda Gates Foundation
CCE	Cold chain equipment
CCEOP	Cold Chain Equipment Optimization Platform
CEPA	Cambridge Economic Policy Associates
CHAI	Clinton Health Access Initiative
COVID-19	Coronavirus disease
CTC	Controlled temperature chain
DCVM	Developing Country Vaccine Manufacturer
DCVMN	Developing Countries Vaccine Manufacturers Network
DFID	UK Department for International Development
DPP	Detailed product profiles
EMA	European Medicines Agency
EYE	Eliminate Yellow Fever
fIPV	Fractional IPV
Gavi	Gavi, the Vaccine Alliance
GMP	General Manufacturing Practices
GPEI	Global Polio Eradication Initiative
gPPPs	Generic preferred product profiles
GSK	GlaxoSmithKline
GVMM	Global Vaccine Market Model
HIC	High-income country
HMD	Healthy market dynamics
HMF	Healthy Markets Framework
HPV	Human papillomavirus
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
ILR	Ice-lined refrigerators
IP	Intellectual property
IPV	Inactivated polio vaccine
JE	Japanese encephalitis
KII	Key informant interview
LIC	Low-income country
MAP	Microarray patch

Acronym	Full description
M&E	Monitoring and Evaluation
MenA	Meningitis A
MIC	Middle-income country
MR	Measles-rubella
NIH	United States National Institutes for Health
NRRV	Non-replicating rotavirus vaccines
NVS	New and under-used vaccine support
OCV	Oral cholera vaccine
OECD-DAC	Organisation for Economic Co-operation and Development, Development Assistance Committee
PAHO	Pan-American Health Organisation
PCV	Pneumococcal conjugate vaccine
PQ	Pre-Qualification
PQS	Performance Quality Safety
PRG	Procurement Reference Group
R&D	Research and development
RfP	Request for proposal
SAGE	WHO Strategic Advisory Group of Experts
SCM	Gavi Senior Country Manager
SDD	Solar Direct Drive refrigerator
SG4	Strategic Goal 4
SII	Serum Institute of India
TCO	Total cost of ownership
TERG	Global Fund Technical Evaluation Reference Group
TO	Target outcome
ToC	Theory of Change
TPP	Target product profiles
TSE	Total systems effectiveness
UNICEF	United Nations Children's Fund
UNICEF SD	United Nations Children's Fund Supply Division
VI	Gavi Vaccine Implementation team
VIPS	Vaccine Innovation Prioritisation Strategy
VIS	Vaccine Investment Strategy
WAP	Weighted average price
WHO	World Health Organization
WHO PQ	WHO Prequalification

EXECUTIVE SUMMARY

Market shaping is core to Gavi's identity, with the need to address market failures and improve access to new and underutilised vaccines for children in poor countries being the very basis for its establishment. Recognising that market failures are often a formidable obstacle for low-income countries to achieve increased, equitable and sustainable coverage, Gavi's Strategy 2016-20 includes a fourth Strategic Goal (SG4) that focuses on shaping markets for vaccines and related products. To support the achievement of this goal, Gavi developed the 2016-20 Supply and Procurement Strategy (hereafter referred to as the Strategy). Within the Strategy, Gavi set out three priority areas, including: (i) taking a holistic view of "healthy markets"; (ii) applying a long-term view to market-shaping activities; and (iii) supporting product innovation.

Cambridge Economic Policy Associates (CEPA) were appointed by Gavi to conduct an independent, external evaluation of Gavi's Supply and Procurement Strategy 2016-20. The purpose of the evaluation was to generate evidenced-based data and learning to inform the Gavi Supply and Procurement Strategy 2021-25. Overall, the evaluation has maintained a strategic perspective, as opposed to being a detailed monitoring exercise.

The evaluation framework is organised using the three dimensions of: (i) relevance and design; (ii) implementation; and (iii) achievement and sustainability of results, across the three Strategy priority areas. The evaluation methodology comprises a Theory of Change (ToC) based approach, with use of mixed methods including document review, data analysis, stakeholder consultations (global and country), key vaccine market analysis and counterfactual analysis.

Key findings

Overall, the Gavi Supply and Procurement Strategy 2016-20 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, with a conclusion on three critical innovations to be taken forward. The strategic alignment would not have been possible without this initiative and VIPS has been espoused as best practice within the Alliance in terms of a model for coordinating and aligning partner views, as well as garnering country input for a global-level output.

Building on the Alliance partners' long-term work, Gavi has contributed to improved health across a number of vaccine markets. For example, markets such as pneumococcal conjugate vaccine (PCV), rotavirus, measles-rubella (MR) and inactivated polio vaccine (IPV) have witnessed new market entrants over the past five years. Several Gavi-funded vaccines also have strong product pipelines, which will inevitably 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. Exploring the counterfactual of whether Gavi has led to observed results, the evaluation has clearly found that many of these market entries 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.

A number of markets have also seen improvements in supply security, though this has not been consistent. For example, the yellow fever market has seen marked improvements in supply security, 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 the rollout of such vaccines in Gavi-supported countries, while production challenges were also experienced in the rotavirus market over the period.

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. Such markets have faced major supply-side challenges, predominately due to the fact that supply capacity could not keep up with rapid demand expansion on account of WHO and Gavi policy changes.

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 to date, partly because of countries favouring incumbent products and general "vaccine stickiness" experienced in countries. The rotavirus market, despite the entry of two new manufacturers and new products coming to market, is expected to remain highly concentrated in the medium term. The PCV market may also see the exit of a key existing manufacturer in the near future, which could result in significant disruption in Gavi-supported countries unless appropriately managed. These nuances highlight the extremely challenging and dynamic context for the achievement of results in these markets.

Some markets have also experienced significant price declines, particularly pentavalent, over the 2016-20 period, although the long-term impact of these price reductions on market health has divided opinion. Other markets have seen either prices remaining relatively stable or increasing, reflecting the challenging supply situation and also Gavi's appropriate balancing of trade-offs beyond an exclusive price focus. The estimated 53% price declines in the pentavalent market have resulted in US$350 million in savings in procurement costs when considering prices prior to this period. These price reductions also resulted in some high-income country (HIC) manufacturers exiting, which could be considered a natural market development, but there has also been no new entrants to the Gavi market since 2014. On balance, the outcomes for the market suggest that the Alliance may have pushed the limits of what could be done to reduce prices while not significantly damaging the health of the market in other respects, and if Gavi wishes to attain higher levels of market health, further downward pressures on price are unlikely to facilitate this. Relatively modest price declines have been experienced in the rotavirus (16%) and PCV (12%) markets, but new entrants into these markets are expected to lead to even further price reductions in future. For some markets, prices have increased, partly to improve the supply situation in such markets (including IPV and yellow fever), while prices in the HPV market have remained relatively stable, reflecting the challenging supply situation faced in this market that meant further price reductions were not possible.

More generally, activities to support innovation have worked well with several improved vaccine products receiving WHO Prequalification (PQ) and being procured by the Alliance. Key examples include the PCV 4-dose products, as well as new presentations for oral cholera vaccines (OCV). A careful consideration of the counterfactual has shown that a key contributing factor to these products being developed has been the signalling Gavi has provided that such products would be demanded in Gavi-funded countries, in addition to the ongoing engagement by Alliance partners during product development.

Further, at the global level, stakeholders have praised Gavi for its improved information sharing and coordination on market shaping. Industry stakeholders noted that they have seen a marked improvement in how transparent the Secretariat has been during engagements over the period. **The other best practice area is with regards to externality monitoring,** a unique and much praised endeavour within global market shaping organisations. There has been a strong working relationship between the Gavi Secretariat, UNICEF Supply Division (UNICEF SD) and the Bill and Melinda Gates Foundation (BMGF), which has been considered as a cornerstone of the successful implementation of the Strategy and the positive market shaping outcomes seen.

Notwithstanding these successes and areas of progress, some of the key lessons learnt with regards to aspects that could have been done better and need improvement upon going forward are as follows:

- **There has been limited progress on the objectives and workstreams with regards to supporting country-owned decisions and building country 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, driven by the Secretariat and partner structures, where market shaping functions and priorities have not been fully understood and coordinated with country teams. In general, countries have not fed into the design of the Strategy and its priorities, and country capacity building with regards to procurement, vaccine, and non-vaccine decision making is a recognised area of weakness. 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.

- **There is a need to better think through the most appropriate HMF structure for CCE products** to better capture both product aspects as well as installation, services and maintenance components. In addition, the country preferences component for CCE warrants further reflection. More generally, market shaping for CCE is at an earlier stage than for vaccines and as such, there is a particular need to support demand shaping activities for CCE.

Further, recognising where Gavi markets are today as well as wider external developments, Gavi is well-positioned at this stage to consider the following for 5.0:

- **There is a need to more actively consider demand-side issues under 5.0.** In particular, this will involve moving from a largely one-sided approach to cover both arms of the market i.e. demand and supply. This is in terms of the Strategy as a whole, and all its pillars, and would warrant greater coordination within and across Secretariat and Alliance partners.

- **Related to the above, and while considered of much value by the Secretariat, partners and broader community involved in market shaping, there are specific suggestions for an improved second iteration of the HMF for 5.0.** Critical enhancements proposed for the next iteration include: (i) need for a more formalised representation of demand; (ii) reduce ambiguity in assessing the individual market attributes, which results in differing views on performance against these attributes; (iii) need for more clarity on the total systems effectiveness (TSE) definition and its application in the HMF; (iv) varying applicability across markets (especially for CCE, where both the product aspects as well as the services components need better reflection); and (v) provide more visibility on the variation of health and progress across markets.

- **While the endeavour to have a long-term view under the Strategy was a step in the right direction based on learning from the preceding strategy, how this has been set out in the Strategy is not adequate**. In particular, "long-term considerations" are a cross-cutting objective relevant to all Strategy pillars. There is a need to strengthen components on long-term vision and strategic outlook in the roadmaps to bring clarity on the "end-game" amongst partners and possibly also encourage more proactive market shaping, noting that a five-year time frame is somewhat artificial in relation to the nature of the market shaping work.

- While not within scope for the current Strategy, the **VIPS initiative needs to actively consider cost-effectiveness, financing and supply in the next strategy period**.

More widely, several vaccine and CCE markets continue to need active market shaping interventions to support improved health and sustainability over time. This is particularly relevant for markets that account for a large proportion of Gavi's budget while still being dominated by high-income country manufacturers (such PCV, HPV and rotavirus). CCE will require market shaping interventions for an extended period of time before reaching a position of market sustainability**.** This is due to a number of factors, including the limited number of suppliers in the market, lumpy and unpredictable demand, and limited innovation as result of to the ongoing tension between maintaining market share, by keeping prices low, and making resources available for long-term investments. The Alliance will need to ensure that it actively monitors trends in this and related markets, to determine whether active market shaping is needed in the future. For some other vaccine markets, while they may not exhibit the full range of desired criteria for a healthy market, they are in a "steady state" by virtue of their unique context. These markets would also require ongoing monitoring and assessment of their health, particularly those where there is a limited amount of supplier diversity.

Recommendations

Building on the positives and successes of the Supply and Procurement Strategy 2016-20, recommendations are proposed for the next strategy with regards to: (i) Strategy design and implementation; (ii) Country capacity building and coordination; and (iii) Global partnerships and coordination (see Figure E.1 over page). While (i) would be core for the Gavi Secretariat Market Shaping team, as well as UNICEF and BMGF, (ii) and (iii) are considered to have wider implementation responsibility, albeit much needed to drive positive market shaping outcomes.

Figure E.1: Summary of evaluation recommendations for the next Strategic period

Looking beyond the set of recommendations provided above for the next strategy period, key issues for Gavi to think about over the longer term include: i) the expected rise in vaccines produced by China, and how the Alliance should engage with Chinese manufacturers; ii) implications of the potential availability of new vaccines for communicable diseases such as malaria, TB and HIV, in terms of coordination with other global partners; iii) implications of African countries being the main beneficiaries of Gavi funding, yet having limited vaccine production capacity, and what this may mean for country and vaccine manufacturer portfolios in future; iv) exploring the role of overcoming intellectual property (IP) barriers to stimulate competition, in parallel with a more active effort to facilitate both technology transfer and access for Developing Country Vaccine Manufacturers (DCVMs); and v) drawing on lessons from the COVID-19 experience to consider Gavi's market shaping role in relation to future epidemic diseases.

1. INTRODUCTION

Cambridge Economic Policy Associates (CEPA) were appointed by Gavi, the Vaccine Alliance (Gavi) to conduct an independent, external evaluation of Gavi's Supply and Procurement Strategy 2016-20 (hereinafter referred to as the Strategy). This report presents CEPA's analysis, findings, conclusions and recommendations.

This introduction section presents the evaluation objectives and scope (Section 1.1), a summary of the context and overview of the Gavi Supply and Procurement Strategy (Section 1.2) and the structure of this evaluation report (Section 1.3).

1.1. EVALUATION OBJECTIVES AND SCOPE

As set out in the Request for Proposal (RfP), the purpose of this evaluation is to generate evidenced-based data and learning to inform the new Gavi Supply and Procurement Strategy for 2021-25. The evaluation explores whether Gavi and its partners have undertaken the right activities to bring about the outcomes sought by the Strategy. The evaluation assesses three priority areas: (i) design; (ii) implementation; and (iii) results achieved and sustainability of the Strategy. The key target audience for the evaluation is the Gavi Secretariat and Board.

Overall, the evaluation is expected to maintain a strategic perspective, rather than a detailed monitoring exercise, as the latter is already being undertaken by the Secretariat. In addition, the following has been agreed with regards to the scope of work:

- Providing validation as to what has worked well, including highlighting what those aspects are and what is required for these aspects to continue being successful.
- Outlining where there have been gaps and areas requiring improvement, alongside suggestions for potential remediations within the context of Gavi's operating model.
- Considering the extent to which Gavi has achieved its market shaping objectives.
- Emphasising the (i) appropriateness and utility of the Healthy Markets Framework (HMF); (ii) the appropriateness and utility of the innovation work; (iii) assessing the counterfactual question of what would have happened in absence of the Strategy; and (iv) providing recommendations for the next strategy.
- Given recently conducted reviews, the evaluation has not focused on cold chain equipment (CCE) and the Cold Chain Equipment Optimisation Platform (CCEOP),[1] market shaping externalities assessment and an evaluation of the implementation of the eighth Memorandum of Understanding (MOU8) between Gavi and UNICEF Supply Division (SD). Rather, relevant findings from these reviews will be brought in, including if there are any discrepancies.
- The scope of the evaluation was determined prior to the start of the COVID-19 pandemic. While reference to the implications of COVID-19 are discussed where relevant, the scope of this evaluation has been to evaluate the Alliance's Supply and Procurement Strategy in the context of when it was implemented. That said, some key aspects related to COVID-19 are brought out in our findings and recommendations.

The evaluation considers developments in the 2016-2020 period, until the commencement of the detailed review in July 2020. For data, the assessment cut-off period may be earlier, depending on the specific data source.

[1] The CCEOP was developed as a pooled funding mechanism to procure new products once they arrive in the marketplace. Through the CCEOP, a dedicated funding envelope of $250m will be provided over 2017-2021 to jointly invest with countries to purchase and install equipment that meets specific technology requirements.

1.2. CONTEXT AND OVERVIEW OF SUPPLY AND PROCUREMENT STRATEGY 2016-20

One of the reasons for the establishment of Gavi was that market forces alone have historically not resulted in the widespread supply of high-quality, affordable vaccines to prevent the spread of key diseases in low-income countries (LICs). Despite the launching of the Expanded Programme on Immunization (EPI) in 1974, LICs were failing to catch-up with high income countries (HICs) in terms of coverage of key vaccines. The availability of financing and uncertainty of demand meant that manufacturers had limited incentives to supply vaccines relevant to these markets, and at affordable prices, which inevitably contributed to a significant time lag between availability of new vaccines in HICs and that in LICs. Gavi was established to address these market failures by acting as a financing mechanism that would enable increased access to key 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 arguably took a more passive approach to shaping markets, acting as a procuring agency and largely allowing market forces to determine the extent to which new competition, products, price trends and supply security would be determined. However, experience during this period showed that this was not adequate to support improvements in market dynamics; early evaluations highlighted that the Alliance's more passive approach had resulted in limited price declines, lack of competition in key markets and unstable supply in others, and called for the Alliance to take a more strategic and proactive role in shaping markets.[2]

Because of this lack of progress, the Alliance first developed its 2011-15 Supply and Procurement Strategy for Gavi 3.0, which set out specific objectives related to: i) balancing supply and demand; ii) reducing the cost of vaccines (both in terms of the cost of vaccines themselves and the wider costs vaccines imposed on countries); iii) encouraging the development of appropriate and innovative vaccines; and iv) communicating timely, transparent and accurate market information. Drawing on the lessons learnt from the 2011-15 period, Gavi continued to adopt an explicit approach for its 2016-20 Strategy through the inclusion of the fourth Strategic Goal (SG4) that focuses on shaping markets for vaccines and related products. The Gavi Supply and Procurement Strategy 2016-20 contributes to SG4, and an overview of its priorities and objectives is provided in Figure 1.1.

Figure 1.1: Overview of Gavi Supply and Procurement Strategy 2016-20[3]

[2] CEPA (2010), Second Gavi Evaluation.

[3] Gavi Supply and Procurement Strategy Summary. Accessed at: *www.gavi.org/sites/default/files/document/supply-and-procurement-strategy-2016-20--overviewpdf.pdf*

In particular, Gavi has set out three priority areas under the Strategy with the following content (which form the framework for our analysis under this review):[4]

(i) **Facilitate healthy markets:** Gavi has set more ambitious goals to shape markets, taking a holistic view of healthy markets beyond narrow objectives on number of suppliers and vaccine price. The Strategy aims to advance a more comprehensive vision of a healthy market through the HMF and measures success in terms of improved healthy market dynamics for vaccines and immunisation products.

(ii) **Take a long-term view of market health:** The Alliance aims to apply a longer-term view to market-shaping activities, through: (i) identifying the point at which a product market is deemed sufficiently healthy and self-sustaining to no longer require market-shaping interventions from Gavi beyond active procurement; (ii) empowering countries to take ownership of their immunisation programmes and support transition; and (iii) monitoring potential externalities of market shaping activities and their effect on the sustainability of vaccine markets.

(iii) **Drive innovation to better meet country needs:** The Alliance has historically sought to expand and improve the product offering that countries have access to, in order to advance progress on coverage and equity and meet country needs at a sustainable cost. The Strategy gave special consideration to both short and long-term innovations. For short term innovations, these focused on potential 'incremental' innovations including aspects such as product formulation, packaging and delivery technologies and next generation vaccines for antigens in Gavi's portfolio. The longer-term innovation focus stemmed from the recognition that stimulating certain innovations would require a longer-term, coordinated approach and a consensus from the Alliance partners. In this context, Gavi and its partners launched the Vaccine Innovation Prioritisation Strategy (VIPS) in 2017.

1.3. STRUCTURE OF THE REPORT

The rest of the document is structured as follows:

- Section 2 provides the evaluation framework and methodology, including limitations and approach to evidence synthesis;
- Sections 3-5 provide our analysis and assessments on the design, implementation and results of the Strategy; and
- Section 6 presents overall conclusions, lessons learnt and recommendations.

The following appendices are also provided in two separate documents: Appendix A includes a bibliography; Appendix B presents a list of consultations; Appendix C sets out the interview guides; Appendix D contains a results analysis of the strategic goal indicators; Appendix E outlines the approach to selecting countries with whom to consult with as part of the evaluation, as well as the list of countries selected; Appendix F includes the Theory of Change (ToC) for the Strategy; Appendix G includes further details regarding the robustness assessments for each finding; Appendix H details some issues highlighted through individual HMF assessments of markets (in support of our assessment of whether the HMF facilitated a holistic assessment of markets); and Appendix I provides further details regarding the alignment of HMF assessments between Alliance partners (in support of our assessment of how the HMF has helped assess market health). In addition, a separate (confidential) document is submitted on the individual vaccine market analysis, as these are based on several confidential documents and information.

[4] Gavi (2015), Supply and Procurement Strategy 2016-2020

2. EVALUATION FRAMEWORK AND METHODOLOGY

This section presents the evaluation framework and methodology, including our approach to assessing and collating the evidence and key limitations.

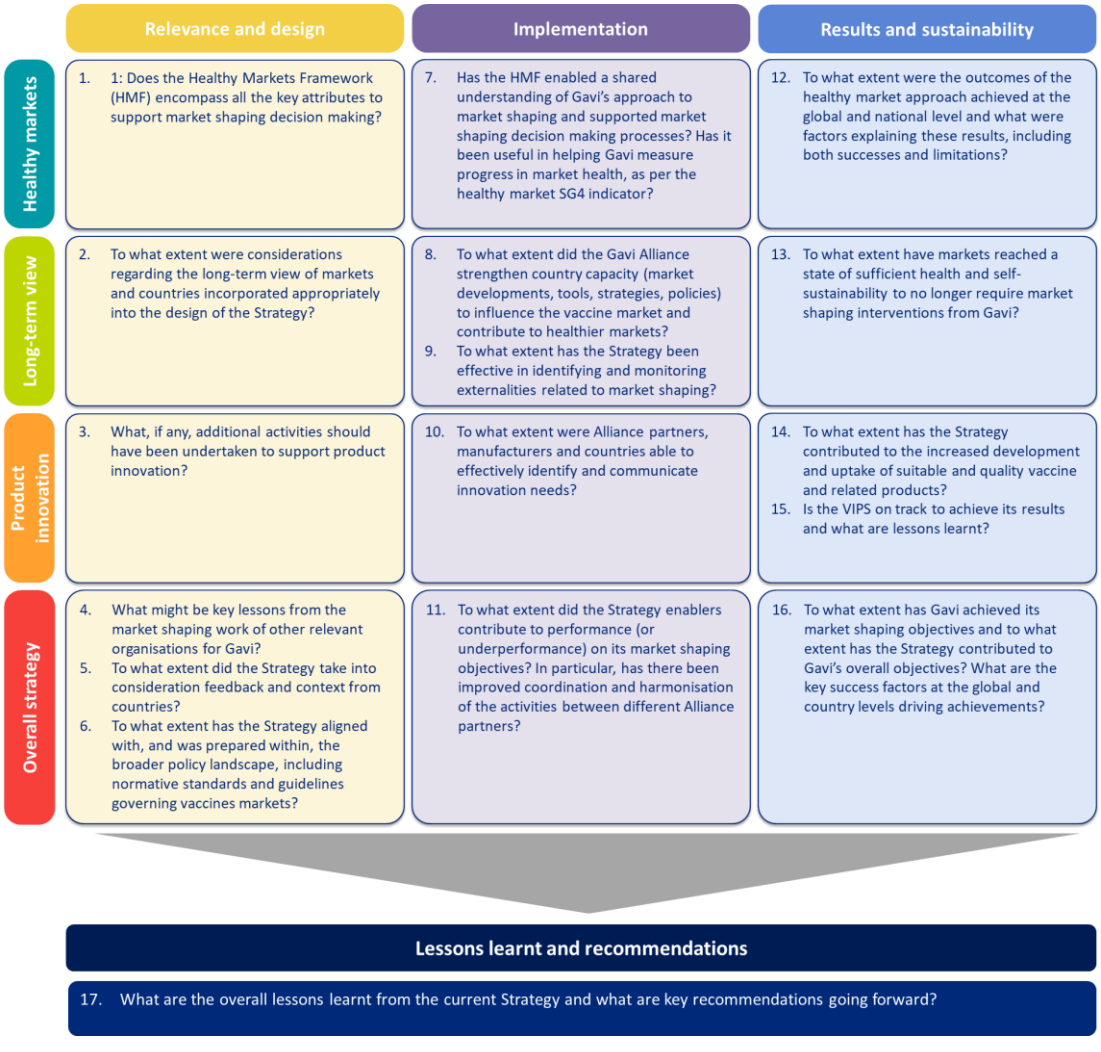
2.1. EVALUATION FRAMEWORK

In line with the evaluation objectives and scope, the evaluation framework has been organised as three dimensions of relevance and design, implementation, and achievement and sustainability of results, across the three strategic priorities of the Strategy, as well as some overarching issues for the Strategy as a whole (Figure 2.1). Specific evaluation questions have been posed under each dimension, covering the following scope:

- **Relevance and design**: including an assessment of the appropriateness of the design of each of the strategic priorities as well as the overall Strategy;
- **Implementation**: including a review of how the Gavi Secretariat and Alliance partners have implemented the Strategy, as well as assessing the important role played by countries, manufacturers and other stakeholders in shaping vaccine and related product markets;
- **Achievement and sustainability of results**: including an assessment of the extent to which planned results have been achieved, alongside their long-term sustainability.

The evaluation was primarily retrospective, reviewing the Alliance's work related to the Strategy over the 2016-20 period. Drawing on this retrospective approach, the review across these questions informs conclusions and recommendations for the next Supply and Procurement Strategy 2021-25.

Figure 2.1: Evaluation framework



2.2. EVALUATION METHODOLOGY

Sections 2.2.1 and 2.2.2 present the evaluation methodology, comprising a ToC-based approach, with use of mixed methods including document review, data analysis, stakeholder consultations, key vaccine market analysis and counterfactual analysis. The evaluation findings and conclusions are grounded in a sound and robust approach to the assessment of the evidence base which is described in Section 2.2.3. Methodological limitations are included in Section 2.2.4.

2.2.1. Theory of Change based approach evaluation

The evaluation adopts a ToC based approach (included in Appendix F), which means that the evaluation is grounded on a theory of what the different areas of work/activities were seeking to achieve, considering the pathways of change from inputs to outcomes and ultimately impacts/goal, whilst being cognisant of relevant assumptions as well as the broader context within which the Strategy is operating. The ToC has supported an understanding of the expected aims and outcomes of the Strategy, as well as informed and guided the analysis around which factors have contributed to the achievement and non-achievement of the Strategy.

2.2.2. Mixed-methods approach

The evaluation adopts a concurrent design mixed methods approach, incorporating both quantitative and qualitative data collection and analysis, including:

Document review

A comprehensive document review has been conducted including all key Gavi documents relevant to the review (e.g. Gavi 4.0 Strategy, available documents for the Gavi 5.0 Strategy, market shaping notes from Board and PPC meetings, Gavi documentation related to Supply and Procurement Strategy 2016-2020 (e.g. the Strategy itself, restricted and public roadmaps, Detailed Product Profiles), Healthy Markets Framework overview, Gavi monitoring reports and annual reports for 2016 onwards, existing monitoring systems in place at Gavi (e.g. strategic goal indicators), the externalities monitoring report, previous evaluations and assessments (e.g. CCEOP evaluation, evaluation of the MoU between UNICEF and Gavi). The wider document review encompasses documents such as Product Menu for Vaccines Supplied by UNICEF for Gavi, UNICEF Vaccine Supply and Market Overview, WHO Global Vaccine Action Plan for Immunisation 2011-2020 and vaccine product profiles. A detailed list of received and reviewed documentation can be found in the bibliography in Appendix A.

Key informant interviews

Semi-structured Key Informant Interviews (KIIs) comprise an important methodological tool for the evaluation. Key stakeholder groups that have been consulted include:

- Gavi Secretariat and Alliance partners including UNICEF, the Bill and Melinda Gates Foundation (BMGF) and WHO;
- Wider partners and donors including the UK Department for International Development (DFID), the Clinton Health Access Initiative (CHAI) and PATH;
- Vaccine manufacturers;
- Country stakeholders: including with government stakeholders and in-country partners, alongside Secretariat Senior Country Managers (SCMs). Consultations have been conducted for nine countries with a mix of transition status, vaccine portfolios, regional mix, high-low DTP3 coverage rates, etc., and include: Bangladesh; Bolivia; Côte d'Ivoire; Ethiopia; Ghana; India; Indonesia; Nigeria; and Tanzania, with the

consultations aimed at enhancing country input into the review rather than to conduct detailed country case studies. Details on country selection is provided in Appendix E.[5]

- Other relevant organisations involved in market shaping work for any lessons on offer, including Global Fund and Unitaid; and
- Select technical experts.

In total, we have consulted with 94 individuals across 29 organisations at the global and country level.

Individual market analyses

Market analysis has been conducted for key Gavi-supported vaccine markets including: pentavalent, rotavirus, pneumococcal conjugate vaccine (PCV), human papillomavirus (HPV), inactivated polio vaccine (IPV), yellow fever and measles-rubella (MR), which is included as a separate appendix document given confidentiality of the analysis. These markets have been selected based on a range of factors including: (i) their relative importance in terms of Gavi's overall procurement of vaccines by value; and (ii) important lessons that can be drawn from these markets, based on our understanding of these markets from previous assignments and our team's expertise. Other vaccines have also been considered for specific review questions and CCE markets in particular have not been reviewed under this method, given this evaluation focuses on CCE only at a high level.

The market analyses review how markets have changed over time, and what the Alliance's role has been in shaping these developments. The analysis focuses on the evaluation period, although we also consider relevant historical information to provide context to the developments since 2016.

Quantitative data analysis

In addition to the vaccine market analysis described above, additional quantitative analysis has been conducted for: (i) results data, including an analysis of the Supply and Procurement Strategy results against the indicators under SG4; and (ii) analysis of country presentation preferences and use, including an analysis of the vaccine presentations requested, the actual choices provided and the vaccine presentations used by Gavi-supported countries. (i) has been used for the results review questions and (ii) to analyse the use of innovative products.

Counterfactual analysis for results assessment

Part of our assessment of results entails observing outputs and outcomes from a counterfactual perspective. In general terms, the counterfactual can be defined as: *"outputs and outcomes in the absence of an intervention. The counterfactual is necessary for comparing actual outputs and outcomes to what they would have been in the absence of the intervention, i.e. with versus without."*[6] In the context of this evaluation, we do not assess the extent to which outputs and outcomes would have been achieved in the absence of the Alliance itself, and the wider market shaping function it performs through its pooled procurement of vaccines and other immunisation products, since this is beyond the scope of the review. Rather, we define the counterfactual in terms of the outputs and outcomes (including intermediate outcomes) that would have been observed in the absence of the priorities, activities and processes carried out as part of the Supply and Procurement Strategy. The intention of having this tighter definition is to analyse more closely what the implications of the Strategy were for the outcomes observed, both in the individual markets that Gavi supports as well as the cross-cutting outputs and outcomes that have been achieved over the five year period.

In general, the counterfactual assessment involves the following: (i) a timeline and key events analysis that maps out the timing of activities and processes that were implemented as part of the Supply and Procurement strategy, and observing the extent to which they align with the timing of outputs and outcomes observed, reflecting on time lags;

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[5] The full list of planned country consultations were not conducted due to reduced stakeholder availability on account of COVID-19. However, we do not view this as a limitation per se as a large number of interviews have been conducted for the country perspective in relation to the scope and objectives of the review.

[6] OECD (undated), Outline of Principles of Impact Evaluation, Accessed at:

http://www.oecd.org/dac/evaluation/dcdndep/37671602.pdf

and (ii) consultations with both Alliance partners and industry stakeholders to obtain a more nuanced view of whether observed outputs and outcomes have been observed because of actions that took place as part of the Strategy, or whether such outcomes would have taken place in the absence of these activities.

2.2.3. Approach to collating and assessing robustness of evaluation findings

Evidence has been collated across the range of methods described above, starting with document and data review, where the evaluation team has applied its expertise and experience to critically assess the various issues covered in the evaluation. On the back of this document and data review, consultations have been conducted with global and country stakeholders, aimed at validating our findings and garnering additional views on the functioning of the Strategy and recommendations going forward. Ultimately our findings, conclusions and recommendations are based on the range of evidence, with the evaluation team's expert judgment applied across the piece to bring out key issues and relevant recommendations going forward.

In line with good evaluation practice, we assess the strength of the evidence by assessing both the "quality" as well as triangulation/"quantity" of the evidence. In terms of quality, we review the quality of the documentation and feedback by considering aspects such as the source and reliability of the quantitative data and qualitative information (where possible/relevant), and involvement of the consultee providing feedback on a specific issue (e.g. implementers may be conflicted to provide positive rather than critical feedback, etc.). In terms of quantity, we assess the extent to which findings are consistent after being triangulated across sources of information. In terms of consultations, we considered how many consultees responses supported the same view, or instances in which views might have been contradictory.

Bringing together these aspects of quality and quantity, ratings describing this assessment as well as an explanation of the rating is shown in Table 2.1. All robustness rankings are *relative* robustness rankings, based on careful consideration and are ultimately judgement-based.

Table 2.1: Robustness rating for emerging themes/main findings

Rating	Assessment of the findings by strength of evidence
Strong (1)	• The finding is supported by data and/or documentation which is categorised as being of good quality by the evaluators; **and** • The finding is supported by majority of consultations, with relevant consultee base for specific issues at hand
Good (2)	• The finding is supported by majority of the data and /or documentation with a mix of good and poor quality; **and/or** • The finding is supported by majority of the consultation responses
Limited (3)	• The finding is supported by some data and/or documentation which is categorised as being of poor quality; **or** • The finding is supported by some consultations as well as a few sources being used for comparison (i.e. documentation)
Poor (4)	• The finding is supported by various data and/or documents of poor quality; **or** • The finding is supported by some/few reports only and not by any of the data and/or documents being used for comparison; **or** • The finding is supported only by a few consultations or contradictory consultations

Robustness scores are provided for each evaluation question outlined in the summary sections found in Sections 3-5. Further details on the rationale for our scoring of findings can be found in Appendix G.

2.2.4. Key limitations and mitigation measures

Table 2.2: Key limitations and mitigating measures

Limitations	Mitigating measures
Consultation limitations including: (i) possible respondent bias given stakeholder roles within the market; (ii) some challenges in securing the most appropriate interviewee given staff turnover and in	(i) We have triangulated our findings against other evidence and (ii) initiated contact with prospective consultees as early as possible. If a key informant has been unavailable, we have identified a replacement

light of the demands of responding to COVID-19; (iii) some possible political sensitivities.	interviewee with comparable insight or experience and (iii) we have anonymised comments and informed respondents.
Challenges with regards to measuring attribution of impact, recognising the role of multiple factors in vaccine markets.	We have attempted to understand the pathways to impact as outlined in the ToC and the results that Gavi has been responsible for as much as possible, in particularly through the counterfactual approach.
Extent of generalisability of findings, especially relating to findings from countries given that every country situation is unique, and we have only been able to obtain feedback from a small number of countries and a sub-set of other stakeholder groups.	This has been mitigated through purposive sampling of countries based on selection criteria to ensure a spread of vaccines, geographical locations, etc.

3. RELEVANCE AND DESIGN

The first dimension of the evaluation reviews the extent to which the Supply and Procurement Strategy was appropriately designed and relevant to context. Review questions for each of the three Strategy pillars are considered in turn below (Sections 3.1-3.3), followed by cross-cutting Strategy-wide issues (Section 3.4).

3.1. HEALTHY MARKETS

1: Does the HMF encompass all the key attributes to support market shaping decision making?

Key findings

The HMF is a well-developed and much needed framework for assessing market health and supporting decision-making. Its first and current iteration has seen some challenges including: i) limited formalised representation of demand; ii) loose definitions of some attributes creating ambiguity; iii) lack of clarity of Total Systems Effectiveness (TSE) aspects and the application of this attribute; iv) limited applicability of the HMF in its current form to some markets, particularly CCE; and v) current approach to scoring attributes masking significant variability between markets.

Strength of evidence – Strong

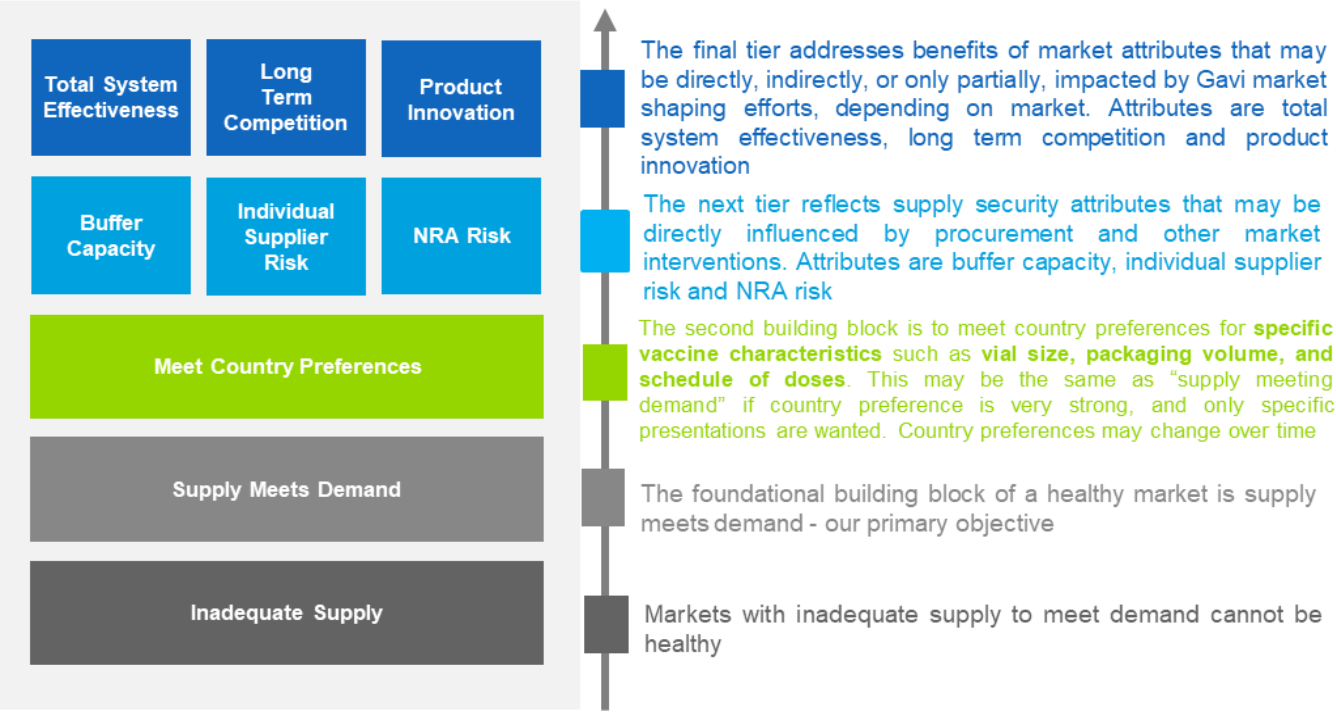
3.1.1. Background to the HMF

The HMF was developed specifically for Gavi 4.0 with input primarily from the Gavi Secretariat, UNICEF and BMGF, alongside support from external consultants. The rationale for its development was that, on account of their different roles and positions within the Alliance, partners often discussed market health in somewhat different and relatively abstract terms; in fact it was found that while partners were using this term it did not necessarily mean they had a common understanding of what constitutes a healthy market, and what was needed to ensure that markets could reach a sufficient state of health. Further, there was a view that Gavi had previously placed too much emphasis on minimising the cost of vaccines and maintaining supply security, while other factors for achieving healthy markets were given relatively little consideration. With this in mind, the main aims of the HMF were to: (i) have a common way of thinking about market health for vaccines important for the countries supported by the Alliance; (ii) better communicate how the Alliance assesses individual vaccine markets and their ability to best meet the needs of Gavi countries; and (iii) improve how potential trade-offs between different market elements are analysed.[7]

Figure 3.1 summarises the HMF building blocks, and includes a description of each individual tier within the HMF. As shown, the HMF is split into different tiers, each of which include individual healthy market "attributes".

[7] Gavi (2017), Healthy Markets Framework – Technical Overview.

Figure 3.1: Overview of HMF[8]



Source: Gavi

To determine the overall healthy market dynamics (HMD) for individual markets, each attribute is assessed individually to determine whether it is not met, partially met or met, with each receiving a red, amber or green scoring accordingly. This scoring is carried out annually by the Gavi Secretariat, UNICEF and BMGF. Markets are then given an overall HMD score of inadequate supply (total market supply is insufficient to meet demand), low (total supply for a vaccine or CCE product equates to demand, but country preferences are not met with the vaccines available), moderate (both supply meets demand and country preferences are met and there is some degree of supply security for markets), and high (all attributes are met, albeit not necessarily to a full extent). As such, markets are considered healthier when they have demonstrated evidence of meeting the different building blocks of the HMF; and without meeting the foundational building blocks they are not considered healthy.

3.1.2. Review of the HMF design

From a design perspective, the HMF has been highly praised across the Alliance for being an important first step in helping Gavi conceptualise and define market health. The HMF has also been praised by Gavi donors and wider partners for capturing key elements of market health through a helpful, and relatively user-friendly framework. Our own assessment of multiple vaccine markets under this review indicates that the HMF captures a number of different components of market health, particularly from a supply security perspective. Finally, as discussed in Section 3.4 below, the development of the HMF has been regarded among global health partnerships as a leading example of taking a comprehensive perspective towards identifying market issues and solutions.

By highlighting the different components of market health and assigning relative importance to these, the HMF has been designed in a way that has helped the Alliance to collectively consider key aspects beyond price in when establishing whether markets are on the path to ultimately not requiring active market shaping interventions. The HMF appropriately captures many aspects of the supply-side of the market that are important to consider, including the extent to which supply is sufficient in the market, the degree of reliance on a limited number of suppliers, the state of long-term competition, as well as whether current products supplied are meeting country preferences.

[8] In addition to this framework, the Alliance adapted the HMF slightly for the CCE and yellow fever diagnostic markets.

While generally positive, select challenges with the current iteration of the HMF, for potential improvement in the next iteration, include the following:

- **Need for more formalised representation of demand:** The HMF focuses on supply-side attributes, with insufficient consideration of demand-side factors, which would enable it to truly represent a "market" framework. From a market shaping perspective there are several aspects of demand that are important to consider including: country presentation/product preferences for different vaccines and what this means for supply, greater clarity on patterns of demand for campaign vaccines, improvements in demand forecasts that more actively reflect "bottom-up" demand in terms of cold chain capacity, as well as implications of the co-financing requirement on actual demand and its timing, changes to demand dynamics as countries transition and non-Gavi countries (e.g. China) introduce and scale-up products, amongst others. While the Gavi Secretariat, particularly the Market Shaping and Vaccine Implementation (VI) teams, are well aware of the issues related to the demand side in practice, the HMF itself lacks formal representation of these factors and needs further consideration going forward.

- **Ambiguity in assessing the individual market attributes:** Aside from assessing supply against demand which is relatively clear to see for partners, the definitions for other attributes were left somewhat ambiguous, which in practice meant that these attributes of market health were open to interpretation. One example of this is buffer capacity where, in the context of the PCV market, increases in capacity have not led to an improvement in health, despite supply meeting demand in this context for a number of years. While the ambiguity allows for flexibility in application to account for the peculiarities of different markets, it also results in differing views on performance against these attributes (see Section 4.1.3 for a further discussion on this). With this in mind, tighter definitions to describe whether markets are meeting, or not meeting, attributes may have been warranted.

- **Lack of clarity on TSE definition and its application in the HMF:** A key example of an attribute that is ambiguous in the HMF is TSE. While clearly an important attribute (stakeholders welcomed the inclusion of TSE in the Strategy and professed keenness for Gavi to advance on its definition/measurement and use in decision-making), the Alliance has struggled with defining TSE, and in practice partners have often had limited data on the components within TSE for a robust assessment.[9] Some consultees noted that it has often been seen as a "proxy for price" or a "catch-all attribute". Because of the limited data on its different components, which can vary significantly by country (for example, in the context of vaccine delivery costs), TSE has often not been adequately considered when applying the HMF. While some efforts have been made to understand TSE better, particularly by WHO, this work has not been closely integrated into how the Alliance considers healthy markets.

- **Lack of clarity on the inclusion of innovation in HMF:** While not emphasised as widely as the aspects above, some partners highlighted that the way in which innovation was captured within the HMF was not adequate. In particular, partners have their own perspectives on what should be regarded as an innovation, and while important to include this attribute, the extent to which different innovations should be given different weighting in the HMF was not fully considered. For example, some partners place greater weight on innovations that improve administration in country, while others see key innovations in the vaccine products themselves, such as higher valency vaccines.

- **Varying applicability across markets, particularly CCE**: With regards to CCE, stakeholders generally noted that the HMF is a good starting point but further consideration needs to be given for the specifics of this market. For example, installation, service, warranty, and maintenance bundles for CCE are considered critical within the overall market dynamics. Stakeholders consider that the HMF should better capture both the product aspects, as well as the services components. In addition, country preferences for CCE has been quite distinct from vaccines, as CCE markets are not yet as generic as most vaccine markets. Based on the early work, a few stakeholders considered that this part of the HMF was not that well suited to CCE. Market shaping for CCE can be regarded as being at an earlier stage than for vaccines, and there is a particular

[9] We understand that there is ongoing work by WHO to better define and assess TSE.

need to more actively support demand shaping activities for CCE. A small number of stakeholders also noted that consideration would be needed as to how well the current HMF would account for an expanded number of technologies and products.

- **Masking of variability in health and progress across markets**: While a traffic light system allows partners to score markets in a simple manner, this approach can mask relatively large differences across markets. For example, both the pentavalent market and the yellow fever market have both been considered to have "moderate" health in recent years, yet in reality most observers would agree that these markets are at different levels of overall health. This also applies to the assessment of individual attributes where, for example, supplier diversity is valued, but may not be universally applicable for all vaccines, such as meningitis A (MenA). A related challenge is also that incremental progress, or progress that has a long implementation lead time is difficult to capture.

While the above points highlight some of the issues with the HMF, these should not detract from the overall positive assessment of the design of the HMF and its various attributes, emphasised across all of our stakeholder consultations for this review.

3.2. LONG-TERM VIEW

2: To what extent were considerations regarding the long-term view of markets and countries incorporated appropriately into the design of the Strategy?

Key findings

While incorporation of this objective is a step in the right direction, its framing and operationalisation in the Strategy has been inadequate and represents an area for improvement for the next strategy.

Strength of evidence – Good

As described in Section 1.2, the second pillar of the strategy is on long-term view, incorporating: (i) taking a long-term view of markets; (ii) supporting countries in their long-term transition from Gavi funding; and (iii) recognising the potential externalities of Gavi's market shaping work. This review question seeks to assess the relevance, appropriateness and effectiveness of the design of this strategy pillar, and is based on a review of the Strategy document and consultations with relevant stakeholders, primarily Secretariat and Alliance Partners.

One of the key learnings from the 2011-15 Supply and Procurement Strategy was the importance of a long-term strategy, and indeed consultations for this review have emphasised this further. As such, clear articulation and inclusion of an endeavour to incorporate a long-term lens in the Strategy has been a critical development – a step in the right direction. However, from a design perspective, how this has been included in the Strategy has been largely inadequate – in particular:

- This is an "all-encompassing" objective and hence, framing as a stand-alone pillar is not helpful. Adopting a long-term approach is relevant for the Strategy as a whole and all of its activities, with regards to supporting healthy markets and innovation, and hence is more of a cross-cutting principle than an independent objective.
- Specific components of the pillar are not well articulated or planned for/operationalised within the Strategy. In particular:
    - There is only a fleeting discussion on the need to adopt a long-term lens on markets. In practice, as is discussed in Section 4.1.2, a long-term strategy has not been espoused at length in a number of vaccine roadmaps, with this being better articulated in more recent roadmaps, such as the 2020 joint pentavalent, IPV, hexavalent, and second booster roadmap.
    - The importance of adopting a long-term view on countries, and especially transition countries, is emphasised in the Strategy, but there has been limited consideration of how this will be taken forward and who bears responsibility/ownership for the workstream to support informed country owned decisions. Some Secretariat consultations indicated that the intentions and commitments made under this pillar were less clear than in other areas, which meant there were many aspects open to interpretation, and that it was unclear what the intended outcomes for this pillar were.

- There is no reflection of this objective in the Strategy M&E. For example, the SG4 goals and objectives do not make reference to any indicators that capture the long-term view of markets and countries and there is no additional/supporting M&E specific to the Strategy that attempts to pick this up as well.

Drawing on these findings, we provide recommendations on how long-term aspects can be better incorporated into the next strategy in Section 6.

3.3. SUPPORTING PRODUCT INNOVATION

3: What, if any, additional activities should have been undertaken to support product innovation?

Key findings

- Innovation objectives in the Strategy are well supported by stakeholders but would benefit from further clarity, especially regarding: (i) the "end goal" for the different markets; and (ii) how to address the tension between the five-year strategic period and innovations, which can take a longer time period to develop.
- The choice of innovations were generally considered to be appropriate, as well as the activities needed to progress this work, although further consideration regarding take up at the start would have been beneficial.
- The inclusion of CCE in the Strategy aimed to support activities to encourage take up of existing and emerging products rather than prioritising stimulating innovation. The tool selected for driving innovation is a set of TPPs which were noted to be appropriate for the baseline for CCEOP innovation.
- The objectives for VIPS were sufficiently ambitious. However, specifics regarding the objectives as set out in the Strategy itself, and especially how the activities would reach the objectives, lacked clarity.

Strength of evidence: Limited/Good

In the Supply and Procurement Strategy 2016-20, Gavi defines innovations as falling into four categories: (1) vaccines for new antigens (included under the Vaccine Investment Strategy (VIS)); (2) next generation vaccines for antigens already in Gavi's portfolio (e.g. HPV9); (3) improvements in existing products (including changes in packaging, formulation and/or number of doses in presentations); and (4) new platforms and delivery technologies (i.e. the work undertaken through VIPS). As noted in Section 1.2, Gavi had short- and long-term innovation objectives. Categories 2 and 3 fall within its short-term objectives through prioritising key innovations in its roadmaps, and providing guidance on how it will evaluate whether such innovations should be included in its portfolio. VIPS activities were implemented in line with Gavi's longer term innovation objectives. Innovations within categories 2-4 are in scope of the Strategy and as such are included in this review.[10]

Key issues examined within this question include: (i) whether the Strategy provided sufficient clarity to stimulate the acceleration of innovation; (ii) the extent to which the activities supporting innovations under categories (2) and (3) as well as the inclusion of new non-vaccine products (especially related to CCE) have been considered to be appropriate; and (iii) the extent to which the Strategy provided sufficient clarity regarding the aims for Category 4 innovations (i.e. those under VIPS). These are discussed in turn below.

3.3.1. Clarity regarding acceleration of innovation within the Strategy

In general, the broad objectives for innovation in the Strategy were well supported by stakeholders consulted. It is noted that specific innovations are not outlined in the Strategy, but instead outlined in the individual roadmaps, which drew upon the Alliance's market intelligence of the pipeline and what was regarded as achievable for the strategic period. So the Strategy provided a high-level overview of what the scope of innovations covered under the Strategy would be, but not details of individual innovations for categories 2, 3, and 4. Based on consultations, stakeholders considered that the detail on categories 2 and 3 was sufficient in the Strategy and roadmaps, and there was sufficient clarity regarding the overall objectives for VIPS (discussed further below).

A number of stakeholders considered there to be a need to further clarify some of the overarching aims, alongside a need to clarify the activities needed to implement the innovation objective of the Strategy. Some specific aspects include:

[10] Some innovations under category 2 are included in VIS and therefore have not been included in this review

- The “end goal” of innovation for the different markets is not clear (in some instances it appears to “support innovation for innovation sake”), and which selected aspects the Alliance is trying to incentivise in the markets and specifically prioritise through innovation lacks clarity. In this regard, thinking through a ToC for the innovation objectives and activities, including examining linkages with other Strategy pillars would be effective.
- There is a tension between the timeframe required for the achievement of the goals and how to capture progress within a five-year strategic period for Gavi, when many innovations require a longer timeframe. In this regard, there is a small degree of mismatch between the Secretariat’s views on managing the VIPS objectives and activities, in terms of what might be tangibly manageable within the timeframe of the Strategy, and some wider stakeholder views on ideally progressing with implementation activities earlier.

3.3.2. Incremental vaccine and CCE innovations

The incremental innovations (categories 2 and 3) selected were reportedly based on the GVAP and market intelligence collected by Gavi and its partners over the years. As such, many innovations had been developed before this strategic period and some were near market ready, with their inclusion in the Strategy list a continuation of work undertaken previously. In general, the focus on incremental gains for vaccine products was seen as appropriate given the supply conditions in most markets, and the focus under this strategic period to encourage the entry of new products at affordable rates. In terms of the activities to support innovations under category (2) and (3), these were well articulated in the roadmaps and generally these were considered appropriate. However, one aspect we note is that in general, the approach to choosing the innovations requires careful consideration regarding the potential uptake and country demand from the outset, as some innovations have been more successful than others.

The inclusion of CCE into the Strategy was unanimously commended as a positive change from the previous Strategy.[11] The main aims were to support activities that encourage take up of existing and emerging products, rather than prioritising stimulating innovation, and that has been considered to be appropriate by stakeholders. In addition, within the CCE Roadmap, there is a strategic objective of ‘Innovation driven by country preferences and future Target Product Profiles (TPPs)’.[12] Innovation priorities are guided by TPPs to propose improvements which address identified market failures, such as the causes that lead to temperature excursions and device failures. As noted in the CCEOP evaluation, the tool selected for driving innovation is a set of TPPs (desired features of a product category for future WHO PQS prequalification).[13] Stakeholders noted the value of requiring some of the optional elements, detailed in the TPP and beyond, to be included in the specifications as a requirement for support. Stakeholders in the CCEOP evaluation also noted that, while the TPPs have helped to achieve the baseline for CCEOP, innovation should now be focused on incremental aspects, questioning the value of this innovation activity.[14]

3.3.3. VIPS

The broad objectives for innovations that required a longer term approach (i.e. which were then included under VIPS) were set out in the Strategy and included: (i) develop common principles across the Alliance to make the assumptions underpinning the value proposition for innovations explicit; (ii) convene a platform to enable articulation of a clear and aligned perspective on how and what to prioritise in long-term innovation, with a view to ultimately accessing the Gavi market, and communicate these priorities; and (iii) to better understand country needs by leveraging countries’ and

[11] Included the introduction of Ice-lined Refrigerators (ILRs) and Solar Direct Drive (SDD) Refrigerators/Freezers though the CCEOP.

[12] Gavi (2019). ILR and SDD Supply and Procurement Roadmap, June 2019.

[13] A TPP lists the desired features of a product category for future WHO PQS prequalification with the purpose of steering manufacturers toward product development that responds to the operational needs of countries. WHO releases these TPPs as part of their PQS process, and Gavi then selects which parts of the TPP will be part of next round of “optimal” criteria or characteristics for CCEOP eligibility by a certain date. (JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings).

[14] JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings.

technical partners' field experience to consider financial and non-financial impact of innovations (e.g. safety, efficacy, equity and coverage).[15]

Feedback from partners and Secretariat considered the objectives to be appropriate, and particularly valued the ambition to convene a platform to align on what innovations to prioritise. In addition, the aim to better understand country needs was highly welcomed. As such, the objectives were seen as appropriately ambitious. However, the specifics as to how to implement the objectives for VIPS - as set out in the Strategy - were not that well defined in a few ways. Firstly, there was limited clarity as to how these innovations would fit within the Strategy and contribute to the Strategy's overarching objectives and goals. Secondly, it was not clear how these innovations would link to the wider objectives under Gavi 4.0. Finally, the activities required to implement the objectives needed to be developed, alongside developing a full understanding as to what was intended by the objectives. As a result, this required seven months to obtain alignment from partners on the objectives and activities and more than two years to arrive at a consensus on prioritised technologies. This is a notable achievement within the timeframe but delayed the start of the implementation of these activities.

3.4. OVERALL STRATEGY

3.4.1. Lessons from comparator organisations

4. What might be key lessons from the market shaping work of other relevant organisations for Gavi?

Key findings

Consultations with the range of stakeholders have emphasised that the Strategy is "ahead of the game", with work on framing the HMF in particular being "exemplar".

The recent TERG review on Global Fund market shaping identified similar challenges to that being brought out in this review, with associated recommendations particularly regarding suggestions to: ensuring market shaping results can continue to be beneficial to transitioning countries; supporting product selection by providing guidance to countries on how to conduct cost-effectiveness analysis; expanding and improving M&E indicators linked to market shaping, including the development of counterfactuals; and ensuring an institution-wide approach to market shaping

Key lessons from Unitaid include: i) considering how different aspects of market shaping work are linked to the wider ecosystem in which its operates; ii) considering interventions through both a demand and supply-side lens; iii) maintaining a long-term vision for innovation with a clear linkage to the practicality of delivery from the outset; iv) taking a long-term and holistic approach when considering interventions in markets; and v) focusing of impact on ultimate scale-up and uptake of products.

More generally, consultations noted that an important step for global health organisations going forward was a need to coordinate and collaborate collectively on cross-cutting issues related to shaping health markets.

Strength of evidence: Good

This review question seeks to consider any learnings from other organisations involved in market shaping, specifically the Global Fund and Unitaid. Relevant learnings are discussed below, and any proposed recommendations from these are elaborated upon in Section 6.

Consultations with the range of stakeholders have emphasised that Strategy is "ahead of the game", with work on framing the HMF in particular being "exemplar". For example, the Global Fund Technical Evaluation Reference Group (TERG) recommended as part of the recent market shaping mid-term review that: *"The Global Fund should consider broadening the Sourcing and Supply Chain team's approach to market shaping along the lines of the approach taken by Gavi ('Healthy Market Framework'), which adopts a more comprehensive perspective towards market problems and solutions."* [16]

[15] Gavi (2017), Market Shaping – Projects Hub. Presentation to VI.

[16] MSS Mid-Term Review and TERG's Position (2019). Accessed at: https://www.theglobalfund.org/media/9235/terg_marketshapingstrategymidterm_review_en.pdf?u=637319006509530000

Lessons from the Global Fund

While noting the very different structure and markets for Gavi and the Global Fund, we note that the Global Fund's market shaping strategy 2016-21 has a broadly similar scope and objectives to that of Gavi's Supply and Procurement Strategy, namely to: (i) ensure continued availability and affordability; (ii) promote consistent quality standards; (iii) support efforts to stimulate innovation; (iv) accelerate adoption of new and/or cost-effective products; (v) prepare for country transition and long-term market viability; and (vi) strengthen key foundational elements for market shaping.[17] A recently concluded TERG-commissioned review of their market shaping work identified a number of issues and related recommendations that we view as relevant for Gavi as well, namely:[18]

- **Challenges with market shaping efforts for transition countries:** The mid-term review identified the risk of backsliding on market shaping achievements in transitioning countries as a key risk for the coming years. Areas for improvement that the mid-term review identified include: (i) benchmarking information to assess risks and bottlenecks in country procurement capacity and to prioritise solutions associated with country abilities and context; (ii) development of a proposal on how Global Fund functions should be organised for this (e.g. coordination between market shaping teams, country teams and others); (iii) consideration of effective channels for the provision of TA and financing to build country capacity (e.g. existing grants); (iv) exploration of expanding the Wambo procurement platform to allow access to long-term agreements through domestically procured financing. Transition is a critical issue facing Gavi as well, with a core need to consider country capacity building and related risks early on.

- **Importance to provide clear guidance to the Principal Recipients of country grants on product selection, especially with regard to cost-effectiveness:** A recommendation by the mid-term review included that when gaps exist from partners on guidance for product selection, especially for cost-effectiveness analysis, the Global Fund should fill these gaps either by developing internal guidance for grantees based on existing evidence, or by commissioning necessary research for specific product categories and/or for specific contexts. The TERG specifically suggested that Global Fund should consider piloting cost-effectiveness analysis for selected health products and interventions and that this could be carried out more efficiently and effectively in collaboration with Unitaid, GDF and/or Gavi.[19]

- **Further expansion and improvement of existing M&E indicators:** The Global Fund currently focuses its KPIs for market shaping on assessing the availability and affordability of products. A key recommendation in the mid-term review included expansion of the availability metrics such as on (i) new product introductions; (ii) availability and affordability of spending beyond the Pooled Procurement Mechanism; and (iii) severity level and closure rate for quality incidents (aspects of M&E that we understand are also measured by Gavi but outside of SG4). The TERG also stressed that the indicators need to be rightly interpreted and that for the next strategic period the development of appropriate counterfactuals should be considered that take account of general trends in the market in the absence of the Global Fund. Developing such counterfactuals could also be a useful way for Gavi to consider how its market shaping activities are resulting in different outcomes and impacts are realised.

- **Need for an institution-wide coordinated approach:** It was recognised that market shaping goes beyond the core activities on the supply-side conducted by the Sourcing and Supply Chain team and requires stronger institution-wide effort to market shaping by ensuring that internal teams and core partners align on issues, priorities, and roles/accountabilities. Specific recommendations from the mid-term review in this regard included: (i) the development of cross-team perspectives that articulate market shaping contributions and clearly link market shaping with other related issues; (ii) biannual joint stock-take meetings between Global Fund team and partners; (iii) the need to clarify the governance/accountability between teams with

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[17] https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf?u=637319003681830000

[18] There is a long list of findings and recommendations and we have sought to bring out aspects in line with the issues being identified at present for Gavi.

[19] MSS Mid-Term Review and TERG's Position (2019), page 8. Accessed at: https://www.theglobalfund.org/media/9235/terg_marketshapingstrategymidterm_review_en.pdf?u=637319006509530000

regard to issues and decision-making related to country-level, technical and sourcing topic. In the case of Gavi as well, market shaping functions has key linkages and ramifications on the work of other Secretariat teams (especially country facing teams, transition focused teams, etc.) and coordinating better/further and building synergies in areas of work would be critical for Gavi to consider going forward.

In addition, select lessons shared during our consultation with the Global Fund include:

- **Importance of a clear link with organisation strategy**: The inclusion of market shaping as a pillar under the resource mobilisation objective of the current Global Fund strategy 2017-22 was not seen as very helpful. Instead Gavi's approach to including marketing shaping as its own strategic objective under Gavi 4.0 and to have specific Strategic Goal indicators was seen as a more fruitful approach in terms of positioning and profile.
- **Focusing and prioritisation of work**: Similar to Gavi, the Global Fund has experienced an expansion in magnitude and complexities of its market shaping activities and emphasised that the objectives, scope and tasks of market shaping function should focus on the highest priority issues to match with the availability of resources.

More generally, consultations not only with the Global Fund but other stakeholders for this review highlighted the need for greater coordination and collaboration between Gavi and the Global Fund in terms of the broader aspects related to their market shaping work (recognising that the markets themselves are very different) e.g. country capacity building, regulatory aspects in countries, etc. It is recognised that these aspects may not all fall exclusively within the purview of the market shaping team within the Gavi Secretariat, but as noted above, require close coordination and synergies between the different teams within the Secretariat and partners.

Lessons from Unitaid

Unitaid's Strategy 2017-21 aims at affordable price reductions and accelerated availability for treatment for HIV/AIDS, malaria and TB, with three strategic objectives on innovation, access and scalability. CEPA's key thoughts on relevant learnings from the Unitaid strategy alongside feedback received during a discussion with Unitaid are as follows:

- **Joint-up thinking and approaches:** Within the three strategic objectives, the market barriers or failures largely relate to the access objective, however we understand that learning within Unitaid has resulted the positioning of this within the spectrum of innovation on one side (linkage with upstream issues) and scalability on the other (entailing downstream issues). In other words, Unitaid's strategy very much considers the flow/linkages of their work on market failures within the wider context and ecosystem of their functioning.
- **Demand side factors and interplay with supply:** Within the access objective, Unitaid has defined several access barriers namely innovation and availability, quality, affordability, demand and adoption, and supply and delivery. As such, their framing considers both the demand and supply aspects of the market. How Unitaid defined these barriers (and as also explained during our consultations with them) is to avoid a demand-supply dichotomy per se, and rather consider both a demand and supply lens in defining and considering each of these barriers, which may also be a useful approach for Gavi to consider in its next Strategy. For example, affordability is considered in terms of prices offered by suppliers in relation to being a key driver of demand and often prices are not affordable as manufacturers do not have demand visibility.
- **Long-term and downstream vision for innovations:** While Unitaid's work on innovation is very different from that of Gavi and for very different market contexts where product specific/bespoke approaches are the focus, one of their main learnings communicated was the ineffectiveness of considering innovation in isolation, and rather the need to maintain a long-term vision along with clear thinking on the practicality of delivery of the innovation from the outset (e.g. healthcare resources, financial implications, etc.).
- **Long-term vision and holistic approach:** More generally, Unitaid's long-term vision has supported their work on co-infections i.e. supported a country-based view to improvements in health. Unitaid's approach also considers a lateral view across the disease as a first step to identifying interventions (there are disease narratives developed for each of its focus diseases) – so for example, under the test-treat-prevent approach for HIV to consider the availability of good diagnostics as well as the vaccine pipeline.

- **Approach to M&E:** Unitaid's impact measurement is on scalability and uptake by countries, as the ultimate aim of their market shaping work. They also distinguish between the direct and indirect impact of their work, with the latter being projected estimations of impact into the future.

3.4.2. Country feedback and perspectives in design

5. To what extent did the Strategy take into consideration feedback and context from countries?

Key findings

The extent to which the Strategy took into account context and feedback from countries directly was relatively limited. More broadly, Gavi has recognised the need for country perspectives to be taken into account to a greater degree in its market shaping work.

Strength of evidence: Strong

One of the questions proposed as part of the review of the design of the Strategy was the extent to which country feedback and perspectives were considered, which is discussed below.

The Strategy highlights that a key component of delivering against its objectives is to provide "support for informed, country-owned decisions". In most cases, Gavi's vaccines are procured through UNICEF or PAHO on a pooled basis, enabling countries to benefit from greater purchasing power that comes from pooled procurement, which in turn can lead to lower prices.[20] While the pooled approach arguably brings benefits, there are certain aspects of individual country vaccine programmes that mean that they have differing, and in some cases unique, preferences.

While countries were clearly considered within the overall Strategy, the extent to which they were consulted with during the Strategy development and their feedback taken into account was believed to be relatively limited, as indicated by Secretariat and Alliance partner individuals involved in the Strategy design. Instead, stakeholders noted that the Strategy was developed in close consultation with the Alliance partners who brought in the country perspective, and that gathering and incorporating country views on what should be included in the Strategy was limited to a high-level consideration of country needs. Further, members of the Gavi Secretariat who work closely with countries also provided high-level inputs on what was seen as being important to consider in the Alliance's market shaping work.

As such, there was no clear engagement process to solicit country perspectives, which some have argued is adequate given the global level of the Strategy, while others have emphasised that should be considered in the next strategy development process as countries are key, especially with many transitioning under 5.0 and market shaping objectives being more relevant for them. More generally, it was commented by several country stakeholders that they find it difficult to keep up with frequently changing and evolving Gavi strategies, policies and priorities over time.

The Market Shaping team within the Secretariat have recognised that their direct engagement with countries is relatively limited, and they are often reliant on other teams within the Secretariat for country perspectives. Our interviews have shown that country-focused teams within the Secretariat have a limited understanding of Gavi's market shaping work, with SCMs being largely unaware of the objectives and priorities. There was also a call from the SCMs and several in-country stakeholders to make countries more aware of the movements in the global market so they are better informed of the context within which they are receiving vaccines, and particularly implications for transition/sustainability. As such, there is a recognition of the need to develop suitable mechanisms to allow for the smooth flow of this information within the Secretariat and with Alliance partners.

[20] Some countries are able to self-procure their vaccines. Guidelines on this can be found in Annex C of the 2016-20 Strategy.

3.4.3. Alignment with broader policy landscape

6. To what extent has the Strategy aligned with, and was prepared within, the broader policy landscape, including normative standards and guidelines governing vaccines markets?

Key findings

The Strategy was well-aligned with wider policy and normative guidance supporting vaccine markets, and shows the importance of partnership between WHO and Gavi in ensuring that market shaping goals can be met.

Strength of evidence: Strong

This area of the review assesses whether the Strategy was well aligned with the broader policy landscape at the time of its development, with particular attention on WHO standards and guidelines.

WHO is a key Alliance member, and the leading international health organisation for developing standards and guidelines for health commodities. Through its engagement as a core member, WHO is an important contributor to the wider priorities set by the Alliance as well as specific activities and priority areas, including market shaping. In the context of this Strategy, key areas of alignment with WHO's normative guidelines and standards include:

- **WHO recommendations on the use of vaccines:** As noted in the Supply and Procurement Strategy, the Alliance's support for vaccines, including its market shaping efforts, are guided by recommendations made by the WHO Strategic Advisory Group of Experts (SAGE), particularly on how the Alliance supports the development and uptake of new vaccine products. The Strategy also notes that Gavi will only funds vaccines that align with relevant WHO position papers for given products.
- **Supporting the rollout of quality assured products:** Similar to the above, the Strategy notes that Gavi takes a lead from WHO on what vaccines it funds, in that the vast majority of Gavi-supported vaccines must have received WHO prequalification (WHO PQ), which is obtained once vaccines have been rigorously tested and assessed for their quality, efficacy and safety based on internationally accepted regulatory practices. Only in exceptional circumstances will Gavi fund vaccines that have not yet received WHO prequalification.[21] In the context of CCE, Gavi also only supports equipment that is included in WHO's Performance Quality Safety (PQS) catalogue.[22] In addition to UNICEF procurement, countries that undertake self-procurement must ensure that all products have been quality assured by WHO.
- **Alignment with WHO's desired product characteristics**: WHO also develops generic preferred product profiles (gPPPs) to guide manufacturers on the desired improved product characteristics for products. In the context of Gavi's focus on innovations in the Strategy, we understand that the Alliance used WHO's gPPPs as a benchmark for assessing whether new incremental innovations displayed improved characteristics.

On the overall focus of the Strategy itself, there are key areas of overlap with WHO's Global Vaccine Action Plan (GVAP) 2011-20. GVAP's Guiding Principles include: 1) Country ownership; 2) Shared responsibility and partnership; 3) Equity; 4) Integration; 5) Sustainability; and 6) Innovation.[23] Many of these aspects align with Gavi's overarching principles and strategic priorities for 4.0, particularly country ownership, shared responsibility and partnership, equity and sustainability. Particular areas of the Supply and Procurement Strategy that align with these principles include:

- **Country ownership**: Notwithstanding the issues highlighted in review questions 2 and 8, we note that under the long-term view pillar of the Strategy, Gavi aimed to promote country-owned decisions on the management and selection of its vaccine products, aligning with GVAP's principle of countries having "primary ownership

[21] One example of this includes Gavi's funding for the pilot phase implementation of the RTS,S malaria vaccine, where in 2019 the Gavi Board approved US$11.6 million of funding to support malaria vaccine implementation programmes in Ghana, Malawi and Kenya.

[22] There is one exception to this - long term passive devices - because PQS does not have a product category /specifications for these particular devices currently.

[23] WHO (2013), Global Vaccine Action Plan 2011-20

and responsibility for establishing good governance and for providing effective and quality immunization services for all".

- **Sustainability**: Similar to above, the Strategy highlights the need to consider the sustainability of markets and countries, which GVAP also highlights as being a key principle of immunisation programmes.
- **Innovation**: The sixth principle of GVAP calls for continuous improvement and innovation in research and development (R&D) efforts for immunisation, as well as innovation and quality improvement across all aspects of innovation – to which the third pillar of the Supply and Procurement Strategy enabled a particular focus in Gavi's market shaping work.
- **Gavi's role in communication and coordination:** While not a specific principle, GVAP called for Gavi to play an expanded role in communicating and coordinating countries, manufacturers and public sector organisations to ensure that both the supply and demand side of vaccine markets could talk more effectively to each other.[24] This was a particular aspect that Gavi recognised and wished to improve upon within the Supply and Procurement Strategy over its previous strategy in this area (and was included as one of the enablers within the Strategy).

The above examples show that the Strategy was well-aligned with wider policy and normative guidance supporting vaccine markets, and shows the importance of partnership between WHO and Gavi in ensuring that market shaping goals can be met.

[24] WHO (2013), Global Vaccine Action Plan 2011-20, p. 63.

4. IMPLEMENTATION

The second evaluation dimension assesses how the Gavi Secretariat and Alliance partners have implemented the Strategy, as well as the role played by countries, manufacturers and other stakeholders. We consider key questions by strategy pillar below (Sections 4.1-4.3) followed by cross-cutting issues (Section 4.4).

4.1. HEALTHY MARKETS

7: Has the HMF enabled a shared understanding of Gavi's approach to market shaping and supported market shaping decision making processes? Has it been useful in helping Gavi measure progress in market health, as per the healthy market SG4 indicator?

Key findings

- The HMF has facilitated an improvement and alignment of understanding on market health and Gavi's priorities, particularly so amongst the core Alliance partners for market shaping but less so amongst industry (who still view Gavi as having a largely price focus) and countries.
- The analysis of key markets has demonstrated that the HMF has been able to identify most of the key issues to support a holistic assessment. That said, some aspects less well-captured include: i) issues and challenges linked to country demand; ii) extent to which non-Gavi markets could affect Gavi market health; and iii) varying production complexities between markets and how these could impact market health.
- The analysis of planned market shaping interventions indicates that some interventions have been more relevant for certain markets (e.g. procurement driven results for pentavalent) and efficacious (BMGF support for pipeline manufacturers, Secretariat and UNICEF manufacturer engagement), while others have not borne fruit per se (e.g. TSE related targeted interventions). But across the piece, the HMF has helped create greater clarity and transparency on market shaping activities and aligning partner views on interventions. There appears to be greater scope for further collaboration and coordination on planned interventions with non-core market shaping teams within the Secretariat and partner organisations.
- The Alliance has suitably considered trade-offs between the price of vaccines and the different HMF attributes, albeit that the focus on price reductions has differed between markets depending on their overall health. While in some markets there may have been a greater focus on price reductions (e.g. pentavalent), in others, the price objective has been balanced with other objectives on increasing competition and supply security.
- The HMF has been seen as a useful tool for monitoring overall market health, but there have inevitably been instances where partners have not been fully aligned on their views of monitoring markets, which highlight some of the challenges related to its design.

Strength of evidence: Good/Strong

This review question explores how the HMF has been used in practice to support the Alliance's activities, including:

- The extent to which the HMF has been useful in facilitating a shared understanding between Alliance partners, as well as a communicating the Alliance's healthy market objectives to external stakeholders (Section 4.1.1).
- How the HMF has been used to support Alliance activities, including: supporting the roadmap processes and procurement strategies of the Alliance, as well as consideration of trade-offs between different market outcomes (Section 4.1.2); and monitoring the development of healthy markets (Section 4.1.3).

4.1.1. Use of HMF to facilitate shared understanding

Shared understanding between key Alliance partners

The core Alliance partners for market shaping (i.e. the Secretariat, UNICEF and BMGF) have noted that prior to the HMF being developed, each partner had different views on what was meant by market health, based on their unique role in the context of markets. In addition, neither the partners themselves nor external stakeholders had a specific reference or detail on what market health specifically meant, and as such it was often implicitly assumed that everyone was speaking about the same issues, which was not always necessarily the case.

With the development of the HMF, Alliance partners have noted that this has been a key contributor to improving alignment amongst themselves on market health. That said, Alliance partners have also noted that there continue to

be some small areas of misalignment on how partners perceive markets, based on their respective areas of focus (e.g. BMGF focus on development of new vaccines, UNICEF focus on supply security and sustainable prices).

Shared understanding amongst wider stakeholders

From an external perspective, stakeholders have praised the HMF for being an essential tool for articulating that the Alliance does not just prioritise price, and that other factors, including supply security, long-term competition, innovation and accommodating country preferences, are important in determining market health and sustainability. Our consultations have indicated that the extent to which this has improved external stakeholders' understanding of Gavi's objectives for different markets has differed – for example:

- **Donors and other global partners** have strongly welcomed the development and introduction of the HMF, and in particular, noted that having a common framework to assess market health is an important step to understanding the market shaping work of the Alliance in more detail.
- With **industry,** Alliance partners have noted that the HMF has been useful for providing greater visibility on what they are trying to achieve across different markets. Industry stakeholders however generally noted that aspects such as supply security, competition and innovation have been recognised as important by the Alliance, but price has still been given a priority in practice. The recurring example given of this during our consultations was the pentavalent tender of 2016 (discussed in Section 5.4). Manufacturers in other markets also noted that price pressures still remained a priority; and members of the Developing Country Vaccine Manufacturers Network (DCVMN) in particular noted that they are put under a lot of pressure to lower prices while at the same time to meet the high regulatory and quality standards such as the WHO General Manufacturing Practice (GMP) standards for their products.
- Understanding of Gavi's approach to healthy markets and the HMF **within countries** has been the most limited, which is largely a result of the limited engagement countries have had with the HMF (as indicated in Section 3.4.2).[25] Within the Secretariat, a number of SCMs have also noted that there is limited knowledge of market shaping objectives within the country teams and regular updates are not provided to the country teams on developments and innovations on vaccines and CCE.

4.1.2. Use of HMF in supporting Alliance partner activities

In addition to supporting the development of a common approach to market health and serving as a communication tool, the HMF was also intended to guide Secretariat and Alliance partner market shaping activities. Several aspects are assessed as summarised in Figure 4.1 below and considered in turn below.

Figure 4.1: Key questions on use of HMF in supporting activities

Did the HMF support a holistic assessment of markets?

The development of Gavi's vaccine roadmaps is an important activity for core Alliance partners. First implemented in Gavi 3.0, these roadmaps set out what the Alliance wants to achieve, largely over the short (2-3 years) to medium (3-5 years) term. While the roadmaps themselves are not a new inclusion, the use of the HMF in setting out key market constraints by the different attributes is a new addition for the Gavi 4.0 period. Each roadmap includes a summary assessment of market health by the different attributes, and based on this the Alliance sets out what interventions it will carry out for improvements in market health.

[25] The level of knowledge and capacity within countries reportedly varies according to the subject. While countries have been provided information on the introduction of new vaccines, information about different vaccine product characteristics and pricing within the market has been relatively limited.

In assessing whether the HMF has supported a holistic assessment of markets, a first step has been a critical review of the roadmaps by the evaluation team, where we find that indeed the HMF-based assessments were able to capture most of the pertinent issues in these markets. For example, in the roadmaps:

- Across a number of markets, the HMF highlighted the basic issue that supply was simply not sufficient to meet demand (HPV, IPV and yellow fever), which in many cases had implications for meeting country preferences and buffer capacity. In some markets, particularly rotavirus, supply was regarded as meeting demand, but because countries had a clear preference for one product, country preferences were considered not to be met as supply from this manufacturer could not meet all of country's demands, and in turn buffer capacity was also not considered sufficient.
- In markets with a limited number of suppliers, the HMF rightly highlighted individual supplier risk (IPV, MR) being a key issue, and when manufacturers were based in countries that had the potential to lose their WHO functional status, NRA risk (MR). Long-term competition was also highlighted as a potential issue in markets where the short-term pipeline of potential new manufacturers was limited (HPV, MR). Further, future exits were also highlighted in roadmaps as part of the HMF assessments of long-term competition.
- TSE issues were highlighted in markets where the cost of the vaccine was regarded as being high and where products did not have positive attributes related to cold chain capacity and administration of the vaccines (HPV, IPV).

Appendix H provides more details on key areas of the HMF that were highlighted as not being met and requiring particular attention.

CEPA's generally positive assessment of the capturing of relevant issues within the roadmaps was discussed extensively with informed Alliance members (i.e. Secretariat, UNICEF, BMGF and WHO) as well as industry, which further confirmed this assessment. In this regard, the Alliance partners noted that the HMF has been a useful tool in articulating the challenges markets have faced, although all were in agreement that the actual conclusions would probably have been the same had it not been for the HMF. Rather, the HMF has generally replaced previous tools to help identify issues and justify the need for certain interventions, with partners seeing it as an improvement on previous approaches for helping identify the range of issues pertinent in different markets. In addition it is also recognised that the HMF supports an assessment of market health from the perspective of Gavi, and industry in particular may have different views in relation to their bottom-line (which is expected, and this is not the function of the HMF either).

The above notwithstanding, we note that there are some key aspects that are less well-captured in the assessments – however this is more a function of how the HMF was designed (with specific such issues discussed in Section 3.1), as opposed to the Alliance not considering these issues in their market shaping work more generally. These include:

- **Demand-side issues.** As highlighted in Section 3.1, this has been a key attribute missing from the HMF design, and correspondingly is not adequately captured in the market assessments. For example, challenges presented due to issues with country's switching and inherently preferring incumbent products on market supply despite new entrants (e.g. for PCV, HPV, rotavirus) are not adequately captured. This is also discussed in more detail in Section 5.1. In addition (and as discussed further in Section 5.1), the demand-side instability of the yellow fever market has been difficult to future capture in the assessments of the HMF.
- **Extent to which developments in non-Gavi markets affect market health.** While an important market from a volume perspective across a number of vaccines, for some vaccines the Gavi market contributes only a small proportion of total market revenue. For example, UNICEF share of the global PCV market in terms of revenue (which accounts for the large majority of Gavi-supported PCV procurement) was just 8% in 2019, while for HPV this was less than 3% in 2020.[26,27] Although non-Gavi markets have been considered to some degree as part of the externalities work, developments and stability of the markets not served by Gavi has

[26] UNICEF (2020), Pneumococcal Conjugate Vaccine: Supply and Demand Update.

[27] UNICEF (2020), Human Papillomavirus Vaccine: Supply and Demand Update.

not been considered explicitly in HMF assessments. These markets have had an important impact on health, either positively (in the case of pentavalent, where tenders in India had implications for tenders in the Gavi market, as discussed further in Section 5.2 below) or negatively (such as HPV, where it has been noted that, although global supply could not have been met, the need for the main supplier to meet non-Gavi markets has limited supply to Gavi markets further).

- **Production complexities in specific vaccine markets and their impact on market health.** Across several of Gavi's markets, while the HMF does look at overall supply meeting demand, as well as the extent to which markets rely on individual suppliers, the HMF itself has not been sufficient to highlight the differences between markets as regards the complexity and specificities in production processes that can ultimately affect supply. The rotavirus and HPV markets are key examples of where production challenges were experienced with the main supplier in these markets during the 2016-20 period (see Section 5.1 for further discussion on this). Clearly it would not have been possible for the Alliance partners to fully foresee such challenges. But the fact that the HMF assessment in itself does not explicitly allow for differences in the complexity of production to be considered (to some extent, this may be included in TSE, but for reasons outlined in Section 3.1 on definition it has not been given significant priority in assessments of markets) means that the use of the HMF as an indicator of the market health stability in this respect has been more limited to date.

Did the interventions respond to the issues highlighted in the HMF and were these implemented as planned?

Through the vaccine market analyses conducted as part of this evaluation, we have reviewed the overall scope and nature of the market shaping interventions planned to address the poorly performing HMF attributes, and the extent of their implementation. This review has also been supplemented by stakeholder consultations on the topic.

Table 4.1 below summarises some of the key interventions that have been implemented to address different HMF attributes (with each HMF attribute coloured as per its representation in the framework itself). We have also colour-coded the extent to which interventions have been effective in achieving objectives, based on our review of these individual markets as well as through consultations with Alliance partners and industry stakeholders (with these assessments being relative and judgement-based). It should be noted that this table has been included largely to provide a high-level summary of the types of interventions that have been used by the Alliance to address certain attributes, but many of these interventions affect multiple HMF attributes.

Table 4.1: Examples of interventions and findings regarding their effectiveness in addressing issues

HMF attribute	Example of relevant interventions	Effectiveness of interventions
Supply meets demand	"Hard" interventions such as supply agreements with manufacturers (by exception), but more focused on manufacturer technical support and engagements/ information sharing	Limited implementation of supply agreements (except AMC) due to movements in market "Softer" interventions on manufacturer engagements well done and useful, but with limited impact in particularly challenging markets
Country presentation preferences	Gavi Secretariat VI & BMGF reviews of country decision-making processes, as well as development of detailed product profiles	Unclear regarding the extent to which such information has been used in by countries in practice
Buffer capacity	UNICEF procurement	Particularly useful for the pentavalent market, less so for other markets with poorer health
Individual supplier risk		Objectives broadly achieved in context of prices and buffer capacity, and where possible to reduce reliance on individual manufacturers, though in some markets, limited competition has meant this has been a challenge
NRA risk		

HMF attribute	Example of relevant interventions	Effectiveness of interventions
Product innovation	BMGF & PATH support for pipeline manufacturers coming to market	Effective over long-term in bringing manufacturers to market
Long-term competition		
TSE	Gavi signalling objectives for reducing wastage rates, fractional dosing and	Limited outcomes achieved in these contexts

Source: CEPA analysis

Key findings are presented below in terms of first the interventions to ensure supply meets demand and to meet country preferences (i.e. the base HMF attributes), and then interventions to improve other "higher" market attributes.

Interventions aimed at ensuring supply meets demand and meeting country preferences

A review across vaccine roadmaps indicates that the main types of interventions aimed at tacking these base HMF attributes include:

- **BMGF and PATH technical support to manufacturers** to increase production capacity. For example, in the yellow fever market, technical assistance and support was provided to LMIC manufacturers to overcome supply side issues, and stakeholders interviewed viewed this support as important for improving market health (see Section 5.1 for further details).
- **Gavi Secretariat Market Shaping team engagement with manufacturers**. Examples of this include planned regular engagements with manufacturers to help find solutions to increase supply. Similarly, **UNICEF Supply Division (UNICEF SD) also undertook reviews and engagements with manufacturers as part of upcoming tenders.** Consultations with industry stakeholders suggested that the Market Shaping team has been effective in engaging with the different manufacturers over the evaluation period, with the team praised for their openness to discussing issues with manufacturers. That said, the efficacy of such "soft" interventions in particularly challenging markets such as HPV is limited. Rather, the HPV case has shown that early and transparent engagement with suppliers ahead of key Gavi policy decisions alongside better engagement with the Gavi Board on the market shaping work would be useful.
- **Gavi's supply agreements with manufacturers** such as volume guarantees for suppliers, providing them with long-term stability to enable scale up in production and offer vaccines at suitable prices. The main example of this is the PCV Advanced Market Commitment (AMC) contracts.[28] However, a number of other smaller scale supply agreements were planned for but not implemented as envisioned, largely because of wider supply challenges faced within markets. In general, we understand that the Alliance has tried to avoid entering into such agreements unless there is a clear need to do so, preferring to allow competition to determine individual market supply.
- **Gavi Secretariat VI team and BMGF have examined** decision-making processes for vaccine selection at the country level. This includes helping countries understand the implications of selecting different vaccine products in terms of programmatic, cost and cold chain implications. These interventions essentially were aimed to address TSE as well as country preference related issues in markets. Stakeholders have noted that useful information has been shared by the Alliance to support country decision-making (e.g. detailed product profiles), however this information has often not been provided in a systematic, timely and coherent manner,

[28] The most recent AMC agreements being signed in 2018 with Pfizer and 2020 with SII for 19 million and 10 million additional doses of PCV to be procured each year for the next ten years respectively. The AMC has historically differed from other volume guarantee arrangements, in that it also includes top-up payments for the initial years of the agreements that are provided on top of the "tail price" offered to the manufacturers, with the top-up payments being funded by the US$1.5 billion amount of funding provided by governments of Canada, Norway, Italy, Russia, the UK and BMGF, whereas other supply agreements that have been established between Gavi and manufacturers generally only include volume guarantees for a given per dose price for a vaccine.

and it is unclear the extent to which countries are genuinely considering this information in their decision-making processes.

Other interventions to support meeting HMF attributes

Given the interrelationships between the HMF attributes, where sufficient supply has existed in markets, the Alliance has implemented interventions aimed to address multiple aspects. For example:

- **UNICEF procurement**, aimed at achievement of healthy market objectives, with the key example being the pentavalent market, where achieving many of the target outcomes (TOs) was based around the execution of the pentavalent tender for 2017-21. In particular, through this tender the Alliance aimed to maintain a minimum level of buffer capacity, maintain a diverse supplier base, reduce prices (and in turn improve TSE), and introduce new products, particularly lower multi-dose vials. According to Alliance partners, there was a considerable level of analysis that went into the development of the procurement approach for this market in 2017, where the Alliance felt that the market had reached a level of health sufficient to drive greater competition in this market. For other markets, their lower levels of health generally meant that it was not actively influence the upper tiers of the HMF through procurement. That said, the HMF and wider roadmap process has been important for aligning Alliance partner objectives with regards to price targeting, which in turn has helped guide UNICEF SD negotiations with manufacturers.[29] In some cases, this has worked particularly well, but in others where timing of the roadmaps was not aligned with procurements it has worked less well. Across markets, pricing data suggests that the Alliance was able to achieve most of the objectives set out in its roadmaps, and in some cases significantly exceeded initial expectations on what could be achieved on price. For other attributes such as buffer capacity where UNICEF is able to influence the amount of supply it tenders, it has also been able to achieve objectives set out. However, as noted below and in Section 5.1, in the context of the pentavalent market some aspects of the HMF could not be met.

- **To reduce individual supplier and NRA risk, increase buffer capacity and stimulate innovation, BMGF has been engaging with pipeline manufacturers to ensure they received continued funding for product development activities.** Such interventions were particularly important in markets for relatively new vaccines, including HPV, PCV, IPV and rotavirus, where BMGF has been continuing its long-term support for Developing Country Vaccine Manufacturers (DCVMs) entering the market. According to information available on BMGF's website, more than US$587 million has been provided to support the development and introduction of vaccines across these markets since 2003, with US$217 million being approved since 2016, suggesting that a number of interventions in the different markets outlined in the roadmap have been carried out as planned.[30] Examples of specific interventions include support to key partners such as PATH to undertake early stage clinical trials in partnership with manufacturers of these vaccines, as well as direct support to manufacturers to support scale-up of production facilities for their vaccines and meet WHO PQ standards.

- **Gavi also identified TOs and market shaping activities aimed at reducing the overall costs of administering vaccines and thus to improve TSE.** Examples of this include target outcomes with regard to lowering the wastage rate in the yellow fever market, exploring the delivery and adoption of fractional IPV (fIPV) devices in the IPV market, encouraging reduction of cold chain capacity of presentations in the pentavalent market and supporting CTC implementation and evaluation of 1 dose schedules in the HPV market. However there have been mixed outcomes on the implementation of these aspects. For example, while there have been discussions between WHO, UNICEF and Gavi VI team around the wastage reductions for yellow fever but there have been no concrete outcomes in this regard; countries have not yet administered HPV outside of the cold chain despite a product with CTC; and delayed funding and WHO PQ issues with

[29] For example, consultees noted that the HMF has been used extensively in Procurement Reference Group (PRG) discussions ahead of UNICEF tenders. While consultees agreed that the HMF specifically may not have necessarily changed the specific approach adopted in tender processes (and that it was not expected to do so), it has been noted as highlighting issues, providing a common language and facilitating agreement between partners on objectives going into procurement activities.

[30] CEPA analysis based on data published at: https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database

regard to fIPV together with an improvement in supply have meant that the technology is no longer included in the new roadmap. As such, several of the TSE-related interventions have not borne fruit, although it is recognised that these are fairly challenging and complex to achieve. Most of these interventions are also planned for outside of the core market shaping teams within Gavi Secretariat, UNICEF SD and BMGF, suggesting a need for greater internal coordination. They also entail influencing country decision making to some degree, which has its own challenges.

Did the HMF help the Alliance sufficiently consider trade-offs?

In terms of balancing the trade-offs between different HMF attributes and price, the review suggests that this has varied by market. Figure 4.2 provides a summary of the assessment, with more details below.

Figure 4.2: Summary of assessment on managing trade-offs between price and other HMF attributes

Active reduction in prices where market health relatively strong	Limited price changes to increase competition	Actively facilitating price increases to improve supply security
• Example market: **Pentavalent** • State of market health supported active consideration of price through procurement • Significantly lower prices achieved, and while impacting other aspects, there has not been any significant consequence in terms of market health reduction	• Example markets: **rotavirus, PCV, HPV and MR** • Single/limited supplier markets, meaning focus was on managing price changes to increase competition • Approach also supported greater innovations	• Example markets: **Yellow fever and IPV** • Price increases were facilitated to ensure better supply situation in markets where supply challenges remained

Source: CEPA analysis based on analysis of markets and consultations with key stakeholders

Trade-offs in the pentavalent market

In the context of the pentavalent market, the Alliance felt that the health of the market was sufficient to undertake a new approach to procurement during the 2016 tender.[31] To inform this, the Alliance utilised the HMF in a more quantitative manner to assess potential trade-offs between what prices would be paid for achieving the upper tiers of the HMF attributes, with the underlying assumption being that to achieve the upper tiers of the HMF, a higher price would have to be paid. This approach was applied in the 2016 pentavalent roadmap, where BMGF, Linksbridge and Gavi developed a decision supporting tool to estimate the cost of meeting individual healthy market attributes through UNICEF procurement. However, this quantitative approach has not been used more recently, mainly because in most

[31] As part of the 2016 UNICEF tender, a two-stage process was used whereby bidders submitted their offers to supply UNICEF during the first round, following which UNICEF published the lowest price offered for 1-dose and 10-dose presentations during this phase. Following this, all suppliers had the opportunity to re-submit their offers with the possibility of obtaining greater volumes should they offer the lowest relative price.

other Gavi markets competition and/or supply security has not been sufficient to consider such trade-offs in a significant level of detail.[32,33]

As we note in further detail in Section 5, the outcomes of this procurement activity resulted in a significant reduction in prices across both presentations of pentavalent, meaning that the Alliance and countries could benefit from large savings in their programme costs. On the other hand, the tendering process resulted in one manufacturer from a high-income market exiting, leading to greater NRA risks, since the main manufacturers left in the market were primarily based in India. Manufacturers from higher income markets exiting can be regarded as a natural development of the market maturing and transitioning to supply being provided by DCVM. Further, consultees noted that a DCVM that had received WHO PQ also did not supply to the UNICEF market due to the need to meet their own country demand. Beyond these manufacturers, Alliance partners and market observers have recognised that the low prices achieved in the market has affected long-term competition and the desire of new manufacturers to enter the market. This is evident from no new manufacturers receiving WHO PQ since 2014 despite manufacturers supplying their domestic markets. Although maintaining existing supplier sustainability, rather than introducing new manufacturers, is the priority, this does not negate the fact that that this is a market where long-term competition is likely to be limited, and that should existing manufacturers exit this market it is unclear whether new manufacturers will replace them. Manufacturers that have supplied UNICEF have also faced some challenges in their production processes, which while UNICEF has been able to manage such issues to ensure countries continue to receive their supply of pentavalent vaccines, shows that even with a relatively high number of manufacturers supply risks can remain.

The outcome of the pentavalent tender has divided opinion among stakeholders with regards to whether the right balance was struck in terms of trade-offs between price achievements and these other factors. Alliance partners note that the price reductions have clearly had an impact on other aspects of market health, yet the market has not suffered from major supply challenges seen elsewhere – and given the situation at the time, it was right to enable competition to drive these low prices. On the other hand, industry stakeholders were almost unanimous in their view that the tender process placed too much emphasis on price, and that this has ultimately meant that the market is far less attractive to manufacturers and has put long-run market supply at risk. On balance, the outcomes for the market suggest that the Alliance **may have pushed the limits of what could be done to reduce prices while not significantly damaging the health of the market in other respects**, and if it wishes to attain higher levels of market health further downward pressures on price are unlikely to facilitate this.[34]

Trade-offs in other markets

Contrary to the experience for pentavalent, in other markets objectives were related to limiting price increases rather than seeking to lower prices further. For some markets such as MR, competition has been relatively limited, and as a result the Alliance felt that because of this, it was more appropriate to try and limit price increases and attract new entrants. But for other markets such as yellow fever and IPV, the Alliance made a conscious choice to allow for price increases, while also providing technical support to key manufacturers, in an attempt to improve global supply security in what is historically a market that suffers from both uncertain demand and frequent production challenges linked to how vaccines are produced.[35] These examples show that in certain contexts, the **Alliance has considered wider factors when procuring vaccines beyond price.**

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[32] For those that have multiple suppliers (IPV, yellow fever, HPV), security was not regarded as sufficient to enable the Alliance to consider price trade-offs without affecting vaccines being available to countries.

[33] An interesting point to note is that in the context of pentavalent, the WAP achieved in the market was far lower than what was expected to be achieved by the Alliance, and yet at these prices it was suggested that supply security and country preferences could not be met (see Section 5 for further details). This suggests that while the modelling approach may have been useful for illustrative purposes, actual outcomes of tenders could be significantly different to what was anticipated through applying the HMF in this way.

[34] The sustainability of the pentavalent market was highlighted as a concern in a recent peer-reviewed publication. See Malhame et al. (2019), Shaping markets to benefit global health – A 15-year history and lessons learned from the pentavalent vaccine market.

[35] Yellow fever vaccines have historically relied on the use of chicken eggs to produce the vaccine, which means that production needs to be planned years in advance to ensure sufficient supply is available.

For other markets, stakeholders firstly noted that the primary objective was to improve competition by ensuring that new manufacturers received WHO PQ for their vaccines. Examples of this include the HPV, rotavirus, PCV and MR markets in particular, where the primary focus was to introduce new competition into the markets, which meant that detailed objectives on what procurement strategies to take were not possible (including securing buffer capacity, manufacturer and NRA diversity, for example). Similarly, these markets have also focused on the introduction of incremental innovations, such as the blow-fill-seal (BFS) vaccine development in the rotavirus market, 4-dose presentations for PCV and plastic tube products in the oral cholera vaccine (OCV) market, all of which have meant focus has been more on product development activities, rather than on procurement strategies and tactics undertaken by the Alliance. With regards to price, the Alliance did have objectives to drive lower prices from current manufacturers, which in the context of PCV and HPV in particular was due to these being considerably more expensive than other vaccines in the portfolio, despite still being a fraction of HIC prices. In such contexts, while the Alliance appears to still be considering price factors, other factors related to introducing competition to expand product choice, including from DCVMs that would offer lower prices, appear to have been given primary consideration. But reasons for encouraging manufacturers to enter the market has **not solely to benefit from lower prices**, but also to alleviate supply security concerns and encourage products with improved characteristics (including lower cold chain capacity).

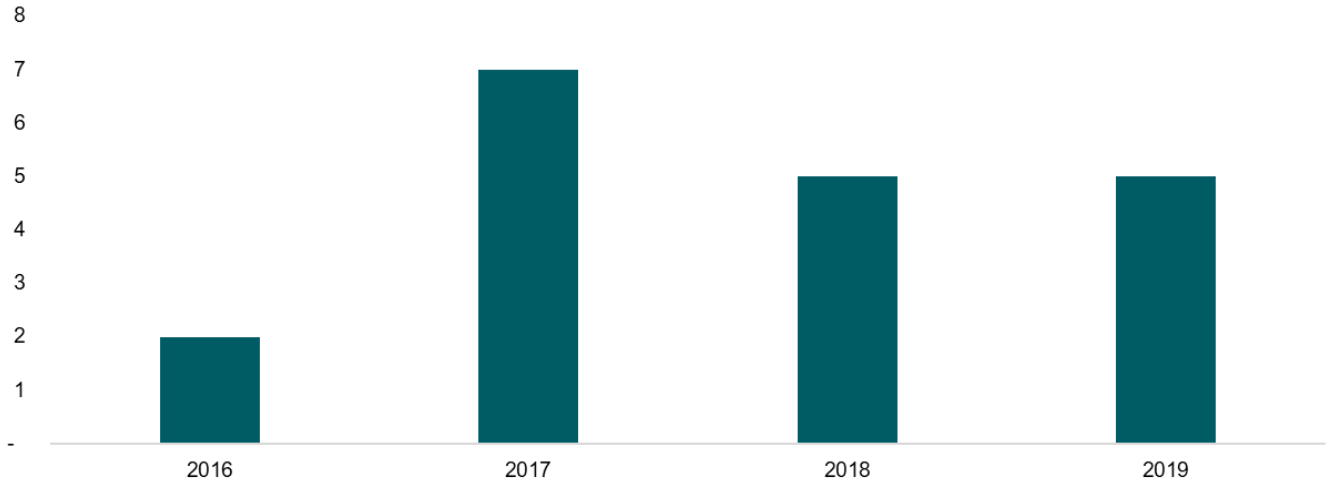
4.1.3. HMF and monitoring healthy markets

The monitoring of healthy markets has been carried out by the Gavi Secretariat, UNICEF and BMGF, each of whom have provided inputs into the annual assessments of the SG4.4 indicator, where HMDs for every market is assessed in terms of whether the market is characterised with inadequate supply, low, moderate and high market health. When the assessment is complete, the final summary of overall health for each market is compared between partners. Should there be disagreements between the final HMD score for individual markets, the Alliance partners have held alignment calls to discuss the reasons for this misalignment and try to come to an agreement on what the final HMD assessment should be. This final assessment of HMD then feeds directly into the SG4 indicator and is summed to provide an indication of the extent to which markets are characterised as having moderate to high health.

Based on consultations with the Gavi Secretariat, the inclusion of this indicator was a welcome addition to the indicators measured under SG4.4, since it allows the Alliance to more closely monitor progress against one of the key pillars of the Strategy. External partners have also professed the value of this indicator in providing a snapshot view of the health of Gavi markets.

The actual process to arrive at this assessment has however not been easy. Based on an assessment of this monitoring for each market, there have been a number of instances where the Alliance have disagreed on the overall assessments of individual markets. As shown in Figure 4.1, disagreements on market health have persisted over the evaluation period, with 2016 having just two instances where partners disagreed while in other years this occurred for five or more markets out of the eleven that were consistently assessed. While Alliance partners were ultimately able to agree on overall health for different markets through the alignment calls, the extent of initial misalignment highlights how markets can be interpreted differently using the HMF.

Figure 4.3: Instances where Alliance partners have not agreed on overall HMD scores for vaccine markets[36]



Source: CEPA analysis based on HMD assessments

Areas where disagreements have tended to be the highest were between scoring markets as low or moderate, which is important for the monitoring of the overall indicator since this determines whether or not the Alliance achieves its SG4.4 targets. On the other hand, markets that have consistently been classed as having inadequate supply tended to be scored as such consistently between partners, mostly reflecting the unambiguity of this score.

Notwithstanding these disagreements, the Alliance partners were all in agreement that the HMF has been a useful tool for tracking and monitoring market health in general. But the monitoring experience has highlighted some of the challenges with the HMF, as indicated in Section 3.1. The monitoring experience has also shown the potential limits with what can be done with a relatively simple tool to use for communication purposes with external partners, while simultaneously using it for monitoring what are complex market dynamics.

4.2. LONG-TERM VIEW

4.2.1. Country capacity building

8: To what extent did the Gavi Alliance strengthen country capacity (market developments, tools, strategies, policies) to influence the vaccine market and contribute to healthier markets?

Key findings

The planned workstream to support country capacity building on making informed/owned procurement decisions has had limited progress mainly on account of lack of ownership of this work. More generally, country capacity building with regards to procurement, vaccine and non-vaccine decision making, etc. is a recognised area of weakness. There is also a need for better information sharing on Gavi's market shaping work and key market developments.

Strength of evidence: Strong

This review question considers the extent to which the objectives under the Strategy pillar on long term view with regards to supporting informed country-owned decisions was implemented in practice. The workstream links closely with Gavi's third Strategic Goal on sustainability, with the aim to support country governments in making well-informed introduction and product decisions (vaccines) and providing information on total cost of ownership (CCE).

Overall, it has been recognised that this workstream has not progressed as well as other workstreams within the Strategy. As indicated in Section 3.2 on Strategy design, the scope and intended outcomes for this work were not made adequately clear within the Strategy. While some work progressed in developing a document on "Country owned decisions in vaccine procurement roadmap", which aimed to present this work across Gavi's SG3 and 4, this

[36] As discussed in Section 5, HMD assessments have been carried out for all Gavi 4.0 years, with the 2020 assessment to be completed in March of next year.

did not progress further, largely because of lack of clarity on who bears ownership and responsibility for this work within the Secretariat across the market shaping and country/transition focused teams as also in relation to the Alliance partners.

Notwithstanding the above, we have considered to what extent support in this area has progressed more generally (i.e. not specifically within the aegis of the Supply and Procurement Strategy 2016-20). Key points are as follows:

- **Long list of tools but not necessarily accessible:** There are a range of tools and knowledge products available on supporting country procurement and vaccine/CCE-related decision making, but these are not well organised in terms of the priority documents and when and how countries should access them. Stakeholders mentioned that countries are not always able to access useful and coherent information especially as some of the tools are not user-friendly or available in languages other than English and French.
- **Need for more capacity building work especially in key areas relevant to transition:** Some capacity strengthening work has been undertaken, but both the Gavi Secretariat and partners recognise that more is needed. Stakeholders interviewed observed that so far capacity building of countries by Gavi has focused on vaccine forecasting and introduction of new vaccines, whereas capacity building of transitioning countries in other areas, such as vaccine switching, effectiveness and cost-effectiveness of their vaccine portfolio, CCE equipment management and maintenance, has been limited. Several issues with technical assistance (TA) were flagged across countries including the reliance on international rather than national consultants alongside limited training of government staff per se, frequent turnover in government resulting in loss of built capacity, need to reply on TA partners beyond the traditional partners of WHO and UNICEF, etc.
- **Limited progress on capacity building per se:** Informants are also not sure to what extent country capacity building by Gavi has translated to increased capacity in some countries (although this varies by country), as a number of countries reportedly continue to exhibit lack of capacity in various areas, including in vaccine management and switching, supply chain management and in CCE equipment management and maintenance. Some countries also noted that capacity building is not the key issues as there is capacity, but government bureaucracy will prevent efficient management of these processes post Gavi support (e.g. in Bangladesh).
- **Limited information on market shaping work and market developments:** There is limited awareness and information amongst Gavi country teams on market developments, and specially the scope, objectives, activities and results of the market shaping work of Gavi, with countries and the country-facing teams with the Secretariat and Alliance partners (as also discussed in Section 3.4.2). This has been recognised as a particular weakness as countries need to be made aware of the wider market developments, especially as they look to transition in the coming years. For example, information on agreements made with manufacturers on pricing post transition is apparently not always clear to countries.

In addition, our country consultations highlighted some key aspects with regards to capacity building for supply and regulatory aspects. It was indicated that the Gavi relationship with India in terms of planning for supply and demand, national and international, could be enhanced. For example, India produces CCE to WHO PQ standards, but does not apply for WHO PQ approval as they already export to Gavi supported countries; and as such, technical support, to make the testing authority of CCE equipment WHO PQ approved, would have a significant impact on the international price and availability of CCE equipment. Similarly, technical support to improve the production and regulatory oversight for the underutilised vaccine production in Indonesia, Bangladesh and potentially Nigeria, initially for national use, would help reduce wide swings in international demand for some vaccines, as well as enhancing sustainability.

4.2.2. Monitoring externalities

9: To what extent has the Strategy been effective in identifying and monitoring externalities related to market shaping?

Key findings

The inclusion of monitoring externalities within Gavi's market shaping strategy has been viewed as best practice and the work done to date has been well received, although going forward there is a need to better link learnings from externality monitoring to strategy design and implementation, as well as better consider upfront data sources and availability.

Strength of evidence: Strong

Under the long-term view pillar, the Strategy identified the need to identify and monitor any unintended consequences, or "externalities" that could result from Gavi's market shaping activities for countries (Gavi and non-Gavi supported), manufacturers or other key partners. While the Strategy emphasised the need to understand both potential positive and negative externalities, a key motivation has been to ensure that Gavi identifies and monitors any negative long-term consequences that could rise from market shaping activities aim to reduce short term risks.

Based on the Strategy, Gavi developed a monitoring framework[37] in close collaboration with market stakeholders, which identified eight potential externalities that should be closely monitored relating to three overarching categories: i) investments in research and development; ii) supply security for countries and sustainability for manufacturers; and iii) affordability for countries. The first monitoring exercise on the externalities was commissioned by the Gavi Secretariat and carried out by CEPA between 2018 and 2019.

Given that this work has been recently concluded, the focus of this evaluation has been to (i) summarise key findings and learnings from the externalities monitoring exercise; (ii) provide reflections on the design and implementation of the externality project; and (iii) to suggest improvements for the work going forward.

Key findings from the first monitoring exercise

The findings of the first monitoring exercise of potential externalities of Gavi's market shaping work have been published on Gavi's website in a public note.[38] Key findings from the exercise were as follows:

- There was no clear evidence of definite negative externalities from Gavi's market shaping work, but **two potential negative impacts were identified**, and in each case the evidence was mixed. First, although the number of suppliers to the pentavalent market grew from 2006-14, the market saw a manufacturer exit in 2018. This could be interpreted as attrition in a market in which competition became intense and where prices have fallen, and the current number of suppliers remains healthy. Nevertheless, many stakeholders interviewed noted that the price level achieved could be unsustainable in the long-run reading to further exits from the market, raising potential future risks to supply security. Second, the human papillomavirus (HPV) market saw a supply shortfall in 2017. This was more closely associated with Gavi (and ultimately WHO) policy shifts (resulting in rapid demand increases) than being an unintended consequence of Gavi's market shaping interventions.
- A **positive externality was found in the pentavalent market**, where available evidence suggests Gavi's market shaping activities contributed to stimulating competition, resulting in increased access at more affordable prices for non-Gavi-supported countries. There were also a range of further positive outcomes of Gavi's market shaping activities (as opposed to positive externalities per se) such as increased PCV and MR supply security and improved manufacturer diversity for oral cholera, yellow fever, rotavirus and pentavalent.

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[37] Gavi (2018). Gavi Market Shaping Externalities. Available at: https://www.gavi.org/sites/default/files/document/gavi-market-shaping-externalities-framework---public-summarypdf.pdf

[38] Gavi (2019). The Externalities of Gavi Market Shaping: Findings from First Monitoring:

https://www.gavi.org/sites/default/files/document/gavi-market-shaping-externalities-framework---public-summarypdf.pdf

The first monitoring exercise made several suggestions to improve and guide future externalities' monitoring and assessment, including:

- **Support for more robust data of vaccine prices in non-Gavi supported countries:** the price data in non-Gavi supported countries was highlighted as an area for improvement under the monitoring exercise and it was suggested to closely monitor the evolution of WHO's MI4A initiative and to explore any room for Gavi to support data gathering efforts that are also complementary to other Gavi efforts.[39]
- **Taking account of country needs with regard to product diversity**: Total presentation numbers were considered to provide limited information and should be complemented by qualitative analysis to take account of countries' actual needs.
- **Conduct qualitative assessments for markets with continued supply security and manufacturer diversity issues** especially in cases in which there are sustained supply constraints or significant market changes (e.g. market exits or severe supply reductions).
- Some of the initially identified potential externalities faced large limitations with regard to the availability of robust data (such as externalities regarding investment in new improved vaccines and cold chain equipment). If these externalities are of continued interest, Gavi should **reconsider the current approach by either starting the collection of additional data or rely on qualitative assessments for these externalities**.

Observations on overall approach

In many regards, Gavi's work on the potential externalities of its market shaping activities constitutes best practice. This was reflected in stakeholder opinions that commended the Strategy for including a component on the potential externalities of Gavi's market shaping work. The consideration for, and understanding of, externalities was widely considered to be an important aspect given the continued growth in the magnitude and complexities of Gavi's market shaping interventions.

In general, the externality work stream was considered to be well implemented both with regard to the identification and selection of key potential externalities as well as the completion of the first monitoring exercise. A key outstanding issue has been around the implications and next steps of the externality work. The findings of the first monitoring exercise have been published as a public note but many stakeholders were more aware of the consideration of externalities rather than the specific results. Additionally, more informed stakeholders commented that the Alliance should take the next steps to consider how the thinking and findings around unintended consequences can be taken forward more directly in the strategy and work done by the Alliance. For example, this could include the consideration of externality aspects when designing the roadmaps and specific market shaping interventions. Additionally, the first monitoring exercise identified a range of suggestions for future externality monitoring work including to complement the quantitative assessment with a more detailed qualitative assessment. Furthermore, upfront work is needed to verify data sources, and where needed to start data collection mechanism. In particular, given the evolving landscape and transitioning of key countries, the Alliance should support the gathering of more robust vaccine price data in non-Gavi supported countries.

[39] There are also challenges in Gavi Secretariat accessing what is considered as proprietary information from UNICEF and WHO as well as accessing country-specific data.

4.3. SUPPORTING PRODUCT INNOVATION

10: To what extent were Alliance partners, manufacturers and countries able to effectively identify and communicate innovation needs?

Key findings

- The VIPS process, has been managed extremely well, with strong engagement by Alliance partners, appropriate level of involvement from manufacturers (especially given conflict of interest issues) and an extensive effort at garnering country input.
- Engagement and coordination on incremental innovations has largely been viewed positively, though there are examples outside of the prioritised innovations, where communication of demand could have been better done.

Strength of evidence: Good/Strong

Under this question, we consider how different partners were able to contribute to the innovation-related activities. This is described in turn below for VIPS and incremental innovations.

VIPS

By establishing VIPS, Gavi aimed to bring together Alliance partners and key stakeholders involved in innovation. The process involved convening a platform to articulate a clear and aligned perspective on what to prioritise in long-term innovation, and communicate these priorities, to provide greater clarity for manufacturers and partners to make investment decisions.[40] VIPS included an Alliance working group made up of representatives from Gavi Secretariat, WHO, BMGF, PATH and UNICEF who developed and executed the methodology for prioritising the innovations,[41] as well as a Steering Committee which offered independent and expert advice.[42] Stakeholder engagement was also extended to manufacturers, regulators and country stakeholders through interviews and surveys. We discuss the involvement of partners, manufacturers and country stakeholders in turn below:

- **Partners**: The VIPS process, used to gain consensus around prioritisation, has reportedly been managed extremely well and has been very well received. Stakeholders considered the communication and dialogue to be very well done which has facilitated participation from stakeholders within the working group. Building a consensus among all active partners is considered to probably be the most significant achievement of the VIPS. As one stakeholder noted, "*the work done on getting alignment across stakeholders has been astonishing*" and another stated, "*I wish we could do all projects across the Alliance this way with such a coordinated and aligned approach*". One trade-off noted is that it was time consuming to obtain alignment across stakeholders. However this alignment is expected to provide the necessary political momentum to implement the next steps.

- **Manufacturers**: Feedback regarding manufacturer involvement was generally positive but was slightly more mixed. Most stakeholders agreed that there was good engagement and industry stakeholders were able to contribute. However some industry stakeholders considered that manufacturers should have been further engaged with the process given there needs to be manufacturer buy in.[43] However we understand that VIPS reduced involvement in the prioritization process in order to reduce the potential for conflict of interest. In addition, it is expected that industry will have a greater involvement during subsequent steps.

- **Country stakeholders**: The VIPS process was guided by country perspectives as input was solicited from a large number of stakeholders though two online surveys and in-depth face-to-face interviews regarding

[40] Gavi (2017). Market Shaping – Projects Hub. Presentation to VI August 2017

[41] 24 innovations were considered in phase I that fitted within the scope of VIPS. The innovations were assessed against an evaluation framework which included a range of criteria such as health impact, coverage and equity impact, safety impact, economic costs and environmental impact (primary criteria) as well as potential breadth of innovation use, technology readiness and commercial feasibility (secondary criteria). The 24 innovations was reduced to a shortlist of nine in phase II using a modified framework. [The VIPS Prioritisation Process: Methodology and Outcomes. Accessed online].

[42] The VIPS Prioritisation Process: Methodology and Outcomes. Accessed online.

[43] https://www.sciencedirect.com/science/article/pii/S2590136220300152

immunisation implementation barriers as well as vaccine product attributes that countries value the most, vaccine-specific challenges that could be solved by innovations and countries' feedback and interest in the innovations being assessed.[44] This has been commended as country needs have been considered to be appropriately captured. VIPS reportedly took into account country-level realities that may have prevented innovations from being adopted and avoided the marketing of products that are not desired programmatically or which are not met by demand. The one exception raised was whether the Ministry of Finance should have been consulted given their key role in country level budget decision making and to assist with thinking through the longer term budget implications, although it is recognised that the questions were asked of the procurement decision makers. We therefore note that the lack of inclusion has not detracted from the excellent work undertaken under VIPS.

Incremental innovations

A total of 15 target products for innovation were identified by Gavi prior to the start of the Strategy. The list of potential innovations was based on Gavi's market intelligence of products that were already in the pipeline in 2015 and that were expected to enter the market during the strategic period. In addition to including these products in its target for SG4.3, these were included as products to target as part of the individual vaccine roadmaps. For these innovations, Alliance partners and industry stakeholders have noted the positive engagement and signalling work that the Alliance has given to emphasise the importance of these products for development. This was particularly the case for PCV 4-dose products, as well as improved packaging of OCV products.

Although not prioritised in the Alliance SG4.3 indicator, a number of stakeholders frequently noted the miscommunication that took place between some Alliance partners and SII to develop its CTC product for rotavirus. Based on consultations, it was expected that this product would be demanded by countries, but in practice this product has not been taken up, largely because the product is not suitable for a number of factors in Gavi countries (e.g. number of steps required before administration, inability to store product at higher temperatures that are prevalent in many Gavi countries, attractiveness of alternative products in the market). While this point was not made in relation to the communication of the market shaping team, it does highlight the importance of coordinated communication between Alliance partners and industry for innovation products.

[44] The VIPS Prioritisation Process: Methodology and Outcomes. Accessed online.

4.4. OVERALL STRATEGY

4.4.1. Strategy enablers

11: To what extent did the Strategy enablers contribute to performance (or underperformance) on its market shaping objectives? In particular, has there been improved coordination and harmonisation of the activities between different Alliance partners?

Key findings

- Data collection and analytics in terms of HMF related assessments, the roadmaps and UNICEF market notes have been very good, but work has not really progressed on other planned analytical tools (TSE in particular). Roadmaps have been noted as useful documents, but some challenges include: (i) high burden to produce; (ii) quickly outdated; (iii) need to take a more holistic view of individual supplier health and strategies across markets; and (iv) need for more details on the long-term version in the market.
- There has been an improvement in vaccine and CCE market information availability and transparency over the years as a result of the greater visibility and coordination brought about under the Strategy.
- Coordination with countries requires improvements and a more systematic approach going forward. There has been strong coordination between Gavi Secretariat, UNICEF SD and BMGF, considered to be a cornerstone of the achievements of the Strategy. Coordination with industry has been strengthened especially through Gavi Secretariat engagement with manufacturers, but there also was a demand for more regular and systematic engagement.

Strength of evidence: Good/strong

This review question explores the contribution of the three "critical enablers" identified in the Strategy, including:

- **Strengthened data collection and analytics** through the introduction of new analytical tools in the area of TSE, the generation of more data for CCE and the development of an optimisation tool to model procurement outcomes. This also includes the roadmap development process.
- **Increased timeliness, accuracy and transparency of information** through existing information channels including roadmaps, UNICEF market updates and published awarded prices, the use of Procurement Reference Groups, more balanced public messaging and detailed product profiles (DPPs) for countries.
- **Strengthened coordination with countries, partners and industry** especially with regard to some of the challenges identified in the Strategy such as countries transitioning out of Gavi support, the expansion of scope and complexity of activities and the need for additional partners, and a growing and diversifying manufacturer base.

Each of these aspects is considered in turn below.

Data collection and analytics

In general, the data collected and analysed as part of the HMF, roadmaps and UNICEF demand updates was considered as strong, providing key inputs into various decision-making processes. However, there have been mixed results with regard to introducing new analytical tools set out in the Strategy. For example:

- The Strategy aimed to improve the measurement of TSE, however as noted in Section 3.1, the TSE component remains loosely defined and challenging to draw on for decision-making. WHO has started the development of TSE tool under the Country-led Assessment for Prioritisation on Immunisation (CAPACITI) project that is currently being piloted in countries and received positive feedback.[45]
- The Strategy also set out to improve analytical tools to weigh procurement awards to assess costs, benefits and risks, however, as described in Section 4.1.2, the quantitative approaches tested in the pentavalent market were ultimately not taken forward.

[45] WHO (2020). Country-led Assessment for Prioritization on Immunization (CAPACITI): Strengthening priority-setting in low-income and middle-income countries (Forthcoming).

- With regards to CCE, efforts were introduced to monitor CCE field performance in order to help inform country investment decisions. These include the Gavi-led Intelligent Maintenance and Procurement Tool, post market monitoring and post installation inspection. However currently, apart from infrequent surveys, there still is not a systematic way to collect and report on the data to inform decision making.[46]

As mentioned previously, the roadmaps have been viewed as useful, however some challenges and areas for improvements have also been highlighted as follows:

- Alliance partners have commented that their development is a "heavy lift" and would be helpful if streamlined and simplified further.
- Partners have also emphasised that roadmaps often become obsolete very quickly due to rapidly changing market developments (including both supply-side issues (e.g. in the case of rotavirus) or demand-side shifts (e.g. in the case of HPV and IPV)). A request for frequent updates to stay relevant was made by partners.
- Alliance partners noted that the roadmaps have historically focused to a lesser extent on developments and impacts of non-Gavi market activity, with many calling for future roadmaps to take a more holistic view of individual supplier health and strategies across markets (particularly in the context of DCVMs).
- Stakeholders have highlighted the importance of reflecting upon a long-term vision for the markets within each of the roadmaps, to help align and drive Alliance partner activities towards a common longer-term goal. More recent roadmaps highlight some long-term objectives, including the 2020 joint pentavalent, IPV, hexavalent and second booster roadmap.

Timeliness and transparency of information

There has been an improvement in vaccine and CCE market information availability and transparency over the years as a result of the greater visibility and coordination brought about under the Strategy. Gavi has continued to publish awarded prices, public roadmaps and UNICEF market updates, all of which were considered to be highly informative and useful by stakeholders. Similarly, global stakeholders also commended the use of PRGs that increased information sharing and alignment of market shaping activities between actors and also provided a forum to solicit feedback and input from independent market experts.

An area that has seen important progress under the Strategy was the detailed product profiles (DPPs), especially the latest version for rotavirus and PCV.[47] Global and country stakeholders considered the DPPs to be useful, evidence-based and an important reference point for countries. DPPs were also seen as an example to gather available evidence that avoid duplications and ease the burden for countries.

Coordination with countries, partners and industry

Coordination with countries has improved over time, but continues to be a challenge and requires a more systematic approach

While there have been overall improvements in coordinating and engaging with countries over time, key issues remain. In addition to those that have been discussed in previous sections (e.g. limited country engagement in strategy design and limited ownership of country capacity building work), there were also calls for systematic engagement with countries, rather than ad-hoc or piecemeal engagement as has occurred to date. While not solely related to Gavi's market shaping work, a number of country stakeholders noted that their applications for vaccine support were followed by considerable delays in introduction due to supply shortages/unavailability (see Section 5 for further discussions of markets where this has taken place). Although such changes in rollout may have been unavoidable, multiple stakeholders felt that communication around such issues could have been carried out more clearly and effectively. In addition, more systematic country engagement is likely to be needed when considering

[46] JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings.

[47] Gavi (2020). Accessed at: https://www.gavi.org/our-alliance/market-shaping/product-information-vaccines-cold-chain-equipment

implications for transition countries/middle-income countries (MICs) and their access to information and approaches (such as the negotiated price commitments for transitioning countries) through Gavi's market shaping efforts.

Strong coordination with Alliance Partners over the strategic period

A key strength of the current strategic period has been the continued improvement in the coordination and alignment of market shaping objectives and activities between the Gavi Secretariat, UNICEF SD and BMGF. Consultees especially emphasised the strong and improving working relationship between Gavi Secretariat and UNICEF SD. This is also reflected in evaluation of the MoU8 between Gavi Secretariat and UNICEF SD that found the MoU8 was implemented as expected and that both agencies considered the partnership to be working well.[48]

Consultees also felt that responsibilities and ownership were clearly defined which was credited partly to the roadmap process and that the three organisations have played largely to their respective comparative advantages. One point made was that the three organisations need to ensure a united face for manufacturers and ensure they are all abreast of key engagements that each of these organisations makes with industry.

The above positive outcomes also apply to the coordination with other wider partners, albeit to a lesser extent. For relevant markets, the inclusion of the Global Polio Eradication Initiative (GPEI) and PATH was considered to have been beneficial, with the two organisations adding value with regard to their comparative strengths. For the next strategy period, some additional partners have been suggested to be leveraged, including closer collaboration with CHAI. Beyond these partners, stakeholders generally felt that detailed levels of coordination with a wider set of partners would not be warranted beyond existing periodic reporting. For example, some consultees cautioned to enlarge the field of partners too much further as they felt that this could increase the risks that discussion were becoming too formal and too cautious losing out on the open dialogue and discussion that has currently been created.

Coordination with industry has been strengthened but could be further improved

In general, industry stakeholders considered the engagement with the Gavi Secretariat Market Shaping team to be timely, open and transparent, contributing to a stronger partnership-minded relationship between industry and Gavi.

The existing information and engagement channels were largely seen as adequate, with the VIS process, demand forecasts, price publications and the direct engagement with the market shaping teams of Alliance partners (including periodic roadshows) considered to be particularly useful. In contrast, the public roadmaps were not used as frequently by manufacturers. In addition, some commented that direct engagement was at times on an ad-hoc basis, suggesting that more systematic and regular communication could improve this even further. There have also been some other areas that were suggested by manufacturers as further opportunities to improve engagement with Gavi, including with regards to improvements in demand forecasts, dealing with the challenges posed by the highly fragmented regulatory system across countries, and facilitating more regular communication between countries and manufacturers.

[48] Hera (2019). Mid-Term Evaluation of MOU8

5. RESULTS AND SUSTAINABILITY

The third evaluation dimension seeks to assess the extent to which the strategy has achieved its intended results, and whether these results will be sustainable in the long term. We detail our proposed approach and methods to the review question by strategic priority below followed by cross-strategy questions.

5.1. HEALTHY MARKETS

12: To what extent were the outcomes of the healthy market approach achieved at the global and national level and what were factors explaining these results, including both successes and limitations?

Key findings

- Gavi is expected to miss its overall target of achieving moderate to high health across six markets, largely because of the challenges seen in the HPV and IPV markets. Though the target for overall markets may not be achieved, some markets have seen some particularly strong improvements over Gavi 4.0 (especially PCV and rotavirus).
- Many of the factors explaining the success in certain markets have been driven by long-term efforts of the Alliance, as opposed to being specific outcomes of the Strategy. That said, the Strategy ensured a continued and concerted effort towards the realised achievements.
- Challenges faced in key markets have often been a result of wider developments affecting the supply-side of the market, as well as conditions at the country level. While the Alliance partners market shaping efforts may have not been able to majorly influence these outcomes in the short-term, the experiences offer lessons for how market shaping should be considered in more detail going forward.

The experience of different vaccine markets during the strategic period has provided important lessons in terms of Gavi's strategy going forward, such as the need to better consider demand issues, taking a holistic view of suppliers and considering factors beyond Gavi-supported markets.

Strength of evidence: Good/Strong

This question specifically explores whether the Alliance has been able to achieve healthy market outcomes for the markets it supports. As part of this review, we consider:[49]

- The extent to which the Alliance **has achieved targets set out as part of the SG4.4 indicator**, and assessing the extent to which this aligns with stakeholder views on the achievement of such outcomes.
- As part of assessing the healthy market outcomes, assessing **the extent to which targets set for healthy markets were appropriate**, both within individual markets and overall.
- The **key factors explaining the results that were achieved**, including the successful interventions and initiatives by the Alliance, as well as some of the challenges that have been faced across key markets. As part of this assessment we provide a **counterfactual analysis of the heathy market results**, which assesses whether markets would have developed in a similar manner had it not been for the interventions by the Alliance, which considers how specific activities set out over the Strategic period contributed to the healthy market developments, relative to other factors. This includes wider market developments related to supply and demand in the markets and activities of Gavi, other Alliance partners and industry that were likely to have occurred in the absence of the change in focus taken as part of the Supply and Procurement Strategy.

5.1.1. SG4.4 targets and results

Table 5.1 below summarises the HMD targets and outcomes for key vaccine markets, measured as part of the SG4.4 indicator. As the table shows, during the initial years of the Strategy, the Alliance was able to achieve above its overall target for the number of markets achieving moderate to high health. However, in more recent years the Alliance has fallen behind its targets, and in 2020 current market dynamics suggest that **the Alliance will not achieve its initial SG4.4 targets**.

[49] The Inception Report for the evaluation set out that differences between how Alliance partners considered market health would be reviewed under this question, but in the report this has been discussed in detail in Section 4.1.

Table 5.1: SG4.4 target and actual assessments 2016-2020

	2016	2017	2018	2019	2020 (expected)[50]
Planned moderate & high markets	Pentavalent (M)	Pentavalent (M)	Pentavalent (H) MR	Pentavalent (H) MR IPV Yellow Fever	Pentavalent (H) MR IPV Yellow Fever PCV HPV
Achieved moderate & high markets	Pentavalent (M) HPV	Pentavalent (M) PCV Yellow Fever	Pentavalent (M) PCV Yellow Fever	Pentavalent (M) PCV Yellow Fever	Pentavalent (M) PCV Yellow Fever Rotavirus MR
Total planned	**1**	**1**	**2**	**4**	**6**
Total actual	**2**	**3**	**3**	**3**	**5**
Achieved above target	**HPV**	**PCV** **Yellow Fever**	**PCV** **Yellow Fever**	**PCV**	**Rotavirus**
Missed moderate & high markets	N/A	N/A	**Pentavalent (H)** **MR**	**Pentavalent (H)** **MR** **IPV**	**Pentavalent (H)** **IPV** **HPV**

Source: CEPA analysis based on Gavi monitoring data, market analyses and consultations. With the exception of pentavalent, all references in the above table refer to markets reaching moderate health, while for pentavalent the status of the target or result for this market is indicated by (M) or (H) respectively.

Further details regarding the key success factors and challenges faced by the markets outlined in the table are provided below.

5.1.2. Successes and challenges in achieving market health

This sub-section provides a summary for the key vaccine markets that were targeted for achieving moderate to high health over the period, with each summary outlining the key drivers behind the summary trends outlined in Table 5.1 above. We also carried out a counterfactual analysis for each market, aiming to understand the extent to which outcomes are attributable to plans set out in the Strategy. We also assessed whether the individual target for each market was sufficiently ambitious, based on our detailed market analyses, desk review and consultations related to each market.

[50] The assessments of each market has not been carried out by the Alliance partners at the time of writing, and consequently the assessments for individual markets may be different than those indicated in this report. The final assessments for individual markets will not be carried out until March 2021.

Table 5.2 below summarises the main findings in this section, while further details are provided below (as well as in Section 5.2 for the pentavalent market). Note that while this summary is intended to provide a snapshot, there are many detailed nuances for each of the markets which are more fully reflected in the vaccine sub-sections below.

Table 5.2: Summary of successes and challenges across different markets

Vaccine	Expected HMD score	Successes	Challenges	Contributory factors	Forward-looking issues
PCV	**Moderate**	• New products introduced • New manufacturers entering Gavi market	• New manufacturers took longer than expected	• Long-term commitments through AMC • Support to pipeline manufacturers • Engagement by Alliance on new presentations • Commitments to PCV rollout • Strategy contributed to continuation of long-term efforts, rather than being solely responsible for outcomes	• Managing potential exit of GSK • Facilitating uptake of new products in countries • Balancing long-term competition with price reductions
Rotavirus	**Moderate**	• New manufacturers entering Gavi market • Improved presentations (e.g. BFS) • Encouraging pipeline	• Key manufacturer exit, though to some extent replaced by new entrants • Limited rollout of BFS product to date • Supply challenges with main supplier	• Long-term support from Alliance partners to BBIL clearly contributory • Entry of SII less attributable to Alliance activities • Gavi signalling important for development of BFS	• Need for better understanding of how Alliance can facilitate “true competition” in the market
Yellow fever	**Moderate**	• Increased capacity of existing manufacturers • Maintaining suppliers in market	• Continued unpredictability of demand • Continued challenges with individual manufacturer capacity • High wastage rates	• Alliance engagement with, and funding to, manufacturers important for improving stability • Price increases seen as important	• Highlights need to consider demand-side
MR	**Moderate**	• New entrants into market	• Reaching moderate health took two years longer than anticipated	• Pipeline support by Alliance important for facilitating new entrants	• Highlights need to provide guidance to DCVMs on product

			• Lack of rollout of new entrant products due to registration requirements		registration, including WHO processes
Pentavalent	**Moderate**	• Significant price reductions	• Unlikely to achieve high level of health • High levels of NRA risk • Limited long-term competition and innovation (though not an Alliance priority)	• Long-term market shaping work critical for market being in current level of health • Indian tenders provided important signal for Gavi on what prices could be achieved	• Developments in other related markets highlights need to consider these in conjunction to assess market health • Need to consider how manufacturer strategies will influence pentavalent market supply going forward, in both Gavi and non-Gavi markets
IPV	**Low**	• Very strong pipeline likely to result in improved health	• Numerous supply challenges in market • Prices increases brought in to facilitate improved supply	• Strategy not a cause of supply shortages, but rather driven by universal routine introduction in 2016 • BMGF support for IPV pipeline critical • Alliance engagement in market important for overcoming supply challenges	• Need to consider production capabilities robustly in rollout of new recommendations
HPV	**Inadequate supply**	• New manufacturer expected in 2021 • Five manufacturers committed to increasing and prioritising HPV to supply Gavi market	• Supply unable to meet surge in demand • Delay in new market entrants • Reduction in LTA commitments from one manufacturer • High valent product not entering Gavi market	• SAGE recommendations primary reason behind increases in demand • Production complexities main driver for delays in introduction to Gavi market	• Need for long-term planning and coordination of disease elimination efforts with supply availability • Consideration of demand shifts in non-Gavi markets needed • Improved communication and understanding of manufacturer ability to meet demand important • Improved understanding of country preferences to facilitate “true competition”

Source: CEPA analysis.

PCV – Long-term commitments show results in 4.0

As shown in Table 5.1, the PCV market was able to achieve moderate market health in 2017, three years earlier than targeted by the Alliance. Figure 5.1 tracks the key events in the market as an indication of key contributory factors. As the figure shows:

- In terms of the improvements in market health, the main initial driver of improved scoring was the addition of Pfizer and GSK's 4-dose presentations being made available to countries, resulting in an improvement of the TSE attribute within the HMF due to the products requiring 71% (Pfizer) and 79% (GSK) less cold chain storage.[51]

- Based on consultations with stakeholders, the development of the 4-dose presentations followed from **the commitments made by Gavi under the AMC** (which both Alliance Partners and industry noted as being critical to enable manufacturers to scale-up their production to meet the needs of Gavi-supported countries) as well as longer-term commitments made by WHO to ensure PCV was rolled out in Gavi countries. These commitments have been noted as being key to contributing to PCV supply security, where despite some challenges being faced in the rollout of PCV in years prior to the Strategy, has been stable over this period, especially when compared to other vaccine markets. This suggests that the long-term commitments by the Alliance and other partners to this market have been important for ensuring that supply meets demand and that country vaccine preferences are met.

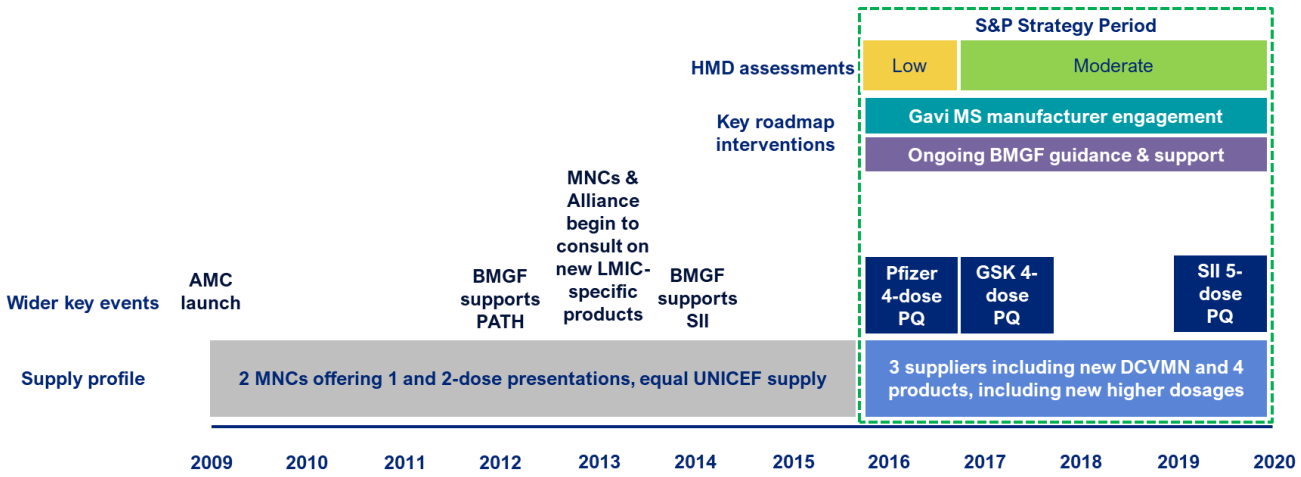
- In addition, the **Alliance partners (including WHO) have been engaging with the PCV manufacturers since 2013** to bring in a presentation to specifically meet lower income markets, and during the evaluation period the Alliance partners (including the Secretariat) continued to signal to manufacturers the ongoing need for a higher dose presentation. This need has been evident from the rollout of these products, where as noted in Section 5.3 now accounts for the vast majority of UNICEF procurement for Gavi countries, and have been rolled out relatively quickly over the Gavi 4.0 period. This suggests that **these coordinated efforts, while not solely a result of the Strategy, were important for ensuring improved market health.**

- More recently, **SII has entered the PCV market,** receiving WHO PQ in December 2019 at a WAP to UNICEF of just US$2 per dose.[52] A key factor contributing to SII's entry into the market has been the **long-term support for developing pneumococcal vaccines, including efforts funded by BMGF and others**, which started way back in 2004 through collaborations with PATH and other global partners (with a US$35 million grant to PATH in 2012 being a particularly large form of support to increase the rollout of affordable pneumococcal vaccines). While this support was commendable, many stakeholders noted the very long development time that has been experienced for PCV. This is largely a function of the highly complex nature in producing a conjugate vaccine at scale, and there have been a number of challenges and delays in achieving this WHO PQ status. Direct support to **SII began in 2014, where BMGF provided US$15 million** to support the development of its 10-valent PCV vaccine. BMGF's continued support to SII and more widely to the development of PCV vaccine candidates has been seen as critical to improving market health. While BMGF's funding for vaccine development is not specific to the Strategy, it has been closely coordinated with it. For example, these commitments were highlighted as something that should **continue to be prioritised by the Alliance as part of the PCV roadmap** during the implementation of the Strategy. BMGF's support to SII was specifically to support clinical trials for its candidate vaccine, and while SII noted that the vaccine probably would have been developed in the absence of this support, this funding allowed it to be developed much faster than it would have been otherwise.

[51] UNICEF (2018), Pneumococcal Conjugate Vaccine: Supply and Demand Update.

[52] In February 2020, SII entered into a supply agreement whereby it would supply Gavi countries 10 million doses per year for ten years at a tail price of US$2 per dose, where US$75 million of AMC funds were allocated to the agreement. While SII will receive these subsidy payments through the AMC, the outstanding US$177.5 million of AMC funds available have now been reallocated to the COVAX Facility, based on a decision taken by the AMC donors.

Figure 5.1: Timeline analysis of key events contributing to improved market health for PCV



Source: CEPA analysis

The new 4-dose products and the entry of SII into the market have been important successes witnessed during the implementation of the Strategy. Given the market conditions at the start of the Strategy, aiming for a moderate level of market health by the end of 2020 appears to be reasonable. Exploring the counterfactual of whether the above noted developments would have happened in the absence of the work of the Supply and Procurement Strategy, we find that the Strategy was not instrumental per se, rather played a facilitating role. The Strategy has contributed to ensuring prioritisation of improved presentations and additional suppliers, and the long term commitments from partners have enabled progress within the noted timeframe.

To ensure market health is maintained going forward, key factors that the Alliance need to consider include:

- **Managing the potential exit of GSK:** A long-term concern of the Alliance has been the extent to which GSK continues to supply the UNICEF market, since its PCV10 products has long been less preferred to the PCV13 products offered by Pfizer. Despite the entry of SII, the exit of a key manufacturer will undoubtedly cause short-term supply issues for countries if it is not managed properly, particularly at the country level where countries will need to become accustomed to administering a new vaccine in their schedules.

- **Facilitating the take up of new products in countries:** As noted in Section 4.1, countries are often reluctant to switch to new vaccine products for a number of reasons, and this is a particular issue for the PCV market. Consultees noted some recent examples of where countries had the opportunity to switch to new PCV products, yet continued to favour existing manufacturer products instead. One reason for this is countries preferring the PCV13 product over the PCV10 products available due to more serotypes being covered by the former, although WHO's position paper notes that these products provide comparable immunogenicity to the main serotypes that cause more than 70% of invasive pneumococcal disease.[53][54] To ensure further take-up, the Alliance needs to better understand the reasons why countries wish to stay with existing products, as well as understand how it can support and encourage countries to make decisions on the vaccines used in their programmes based on a sound assessment of their epidemiological situation, the cost of the vaccines, their ease of administration and their programmatic benefits. This in turn will help facilitate increase demand for new vaccine products where suitable and contribute to genuine competition in the market. Further support may also be needed to facilitate the registration of new PCV products in countries, which has also been highlighted as a key barrier to countries switching to new products.

- **Balancing long-term competition with price reductions:** While the recent price reductions offered by SII have been welcomed by global partners, it will be important for the Alliance to ensure that new entrants

[53] Gavi (2020), Detailed Product Profiles.

[54] WHO (2019), Pneumococcal conjugate vaccines in infants and children under 5 years of age: WHO position paper – February 2019.

continue to be attracted to the PCV market going forward. PCV remains one of the most expensive vaccines in Gavi's portfolio, with Pfizer's 4-dose product costing US$8.70 to fully immunise a child in 2020 and SII's product costing US$6, compared to US$2.10 for pentavalent when procuring 10-dose presentations.[55] This, combined with the extensive rollout of PCV programmes in Gavi countries has resulted in US$4.1 billion of Gavi funds going towards supporting PCV, accounting for 28% Gavi's country support programme budgets or 38% of new and under-used vaccine support (NVS), with US$2.1 billion being committed over the 2016-20 period.[56] Despite this, many stakeholders, particularly industry partners, noted that further price reductions for PCV could limit the extent to which manufacturers wish to enter the market. This shows that in order to make the vaccines affordable for LMICs, especially during and after Gavi transition, the Alliance will need to balance affordability with promoting long-term competition to ensure market health remains high.

These issues have important implications on Gavi's market shaping approach going forward, including the need to more deeply consider (and potentially manage) demand health, as well as having a wider lens to consider the ecosystem for Gavi markets in terms of the health of DVCMN manufacturers and pricing during country transitions. These aspects are discussed in the recommendations section 6.

Rotavirus – Potential for moderate health with new entrants, following supply challenges

According to Alliance alignment discussions and our review consultations, the rotavirus market is expected to achieve moderate levels of market health in 2020, despite Gavi not specifically setting a target for this vaccine. This does not suggest that the Alliance was less ambitious in its objectives for market health, since rotavirus continues to face a number of challenges as outlined below.

The key drivers of the success in attaining moderate market health include:

- **New entrants:** Both Bharat Biotech International Limited (BBIL) and SII received WHO PQ for their 5 and 10-dose frozen (BBIL) and 1 and 2-dose lyophilised (SII) rotavirus vaccines in 2018, thus increasing the potential for manufacturer diversity across these markets. In addition to receiving WHO PQ, these products have also started to be rolled out in some Gavi-supported countries. For example, while the two Indian manufacturers were not prequalified at the time of the UNICEF tender in 2017, they were still awarded doses given the expectation that they would receive WHO PQ during this period. As a result, BBIL was originally awarded more than 36 million doses, while SII was awarded 9.2 million doses.[57] In addition, to ensure that large country introductions could take place, UNICEF awarded an additional 14.5 million and 9.2 million doses to BBIL and SII respectively for the 2019-21 period.[58] In the context of the BBIL, receiving WHO PQ was the culmination of decades of work in developing this vaccine, which included support from a wide range of international partners and extensive work by BBIL. From a counterfactual perspective, the support of key Alliance partners including funding from BMGF and technical support from PATH have been essential for ensuring the development and scale up of BBIL's vaccine, and without this support the vaccine would have taken a number of years longer to come to market. For example, in 2015 BMGF provided US$18.5 million in direct support to BBIL to support the construction of a manufacturing facility that would enable it to received WHO PQ for its vaccine, which has been seen as essential for accelerating the process for receiving WHO PQ by a range of stakeholders. While such activities took place prior to the Strategy's development, the continued prioritisation by the Alliance for stimulating healthy market competition was welcomed by stakeholders involved in the development for ensuring this product could get to market, but it is recognised that such introduction cannot specifically be attributed to the Strategy's focus on healthy markets. For SII's product, stakeholders were in agreement that the support from the Alliance for these products has been more limited, and that it is likely that the wider attractiveness of the rotavirus vaccine market to new entrants

[55] Gavi (2020), Detailed Product Profiles.

[56] Gavi (2020), Total commitments and disbursement date.

[57] Gavi (2020), Total commitments and disbursement date.

[58] Ibid.

was the key reason for its development. Having said this, in 2014 BMGF provided US$2.4 million of funding to PATH to support the development of bovine-human reassortment rotavirus strains which characterises SII's products. Stakeholders also noted that because of BMGF's support to SII via PATH, the Alliance was able to benefit from global access prices for these products, which may had been difficult to obtain had this support not been provided.

- **Replacement of Merck as a manufacturer with new suppliers:** While Merck's Rotateq is successfully marketed globally, particularly in high income markets in the US and Europe (with US$791 million of global sales reported in 2019)[59], as of 2020 Merck has signalled that it will no longer supply its Rotateq vaccine to the four Gavi-supported countries using its vaccine (Burkina Faso, Cote d'Ivoire, Mali and Sao Tome and Principe). This was largely due to the overarching preference for GSK's product, up to December 2019 accounted for 76% of the UNICEF rotavirus vaccine procurement.[60] This product not only requires two rather than three doses in its schedule, but also takes up significantly less country cold chain capacity (34.2cm^3 for Rotarix 1-dose liquid, compared to 138.9cm^3 for Merck's 1-dose product).[61] Given the relatively limited number of suppliers and the important role Merck plays in this market globally, its exit was viewed as a significant development that could have adverse implications for supply and more generally long-term health. However, in this context procurement from Merck has to some extent been replaced by lower cost products from DCVMs which require significantly less cold chain capacity. In addition, for the four countries mentioned above, two of these (Mali and Burkina Faso) have switched to SII's and Sao Tome will switch to BBIL's product.[62] Given these switches and the long-term potential for competition in this market, stakeholders with detailed knowledge of this market regarded this exit as not having a significantly detrimental impact on long-term market health.

- **New products expected to be prequalified and offer more attractive alternatives:** In addition to its main 1-dose liquid product, in 2019 GSK received WHO PQ for its BFS product, which offers all the programmatic benefits of GSK's product (particularly the 2-dose schedule) yet requires 30% less cold chain capacity. The BFS product has now begun the pilot phase of producing the BFS product, with scale-up expected after 2023, depending on whether GSK decide to do so. Should this be scaled up, it is likely to be the primary rotavirus product that the Alliance procures. In the development of this product, Alliance partners noted that the signalling by Gavi was key, and that GSK clearly had the Gavi market in mind for developing this product. The product was also set out by the Alliance as a priority during this strategic period as part of its SG4.3 indicators. This suggests that from a counterfactual perspective, the Alliance's engagement was an important component in encouraging GSK to focus on its development, and that in the absence of this the BFS product may not have been given as much priority/focus. In addition, BBIL and SII have been developing liquid forms of their vaccines, which are far more attractive programmatically to countries than their frozen and lyophilised product. Both these products are expected to receive WHO PQ by the end of 2020. BBIL has received US$19.5 million to partly support the development of this presentation type from BMGF, suggesting that Alliance has played an important role in accelerating the development of this new product, although the development of SII's product seems to have been carried out independently of Alliance support.[63]

- **Encouraging pipeline of innovative products:** In addition to BBIL's and SII's products mentioned above, there are 12 rotavirus vaccine candidates in various stages of development by various institutions in high income and emerging markets.[64] Some manufacturers have been developing non-replicating rotavirus

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[59] Merck (2020), 2019 Financial Results. Available at: Merck (2020), 2019 Financial Results. Available at: https://investors.merck.com/news/press-release-details/2020/Merck-Announces-Fourth-Quarter-and-Full-Year-2019-Financial-Results/default.aspx

[60] UNCEF (2020), Rotavirus Vaccine: Supply and Demand Update.

[61] Ibid.

[62] Ibid.

[63] BMGF (2020), Grants database.

[64] GVMM (2020, Product pipeline data.

vaccines (NNRVs). These inactivated vaccines are administered intra-muscularly rather than orally (the common administration method for rotavirus vaccines). This will allow the vaccine to be administered earlier and in turn could increase efficacy in low-resource settings, decrease interference from the high concentration of maternal antibodies in the digestive system and eliminate all risks of intussusception associated with the vaccine, as well as being offered at a lower cost. The NRRV P2-VP8 vaccine being developed by PATH and the US National Institutes for Health (NIH) is currently in phase III clinical trials, with SK Vaccines of South Korea as the commercial partner. However, this vaccine is not expected to receive WHO prequalification until 2026, suggesting that GSK's product is likely to remain the most favoured product by Gavi-funded countries until this period.

Despite these achievements, the rotavirus market has experienced a number of challenges that have highlighted the importance of maintaining supply security. These include:

- **GSK supply challenges:** During the 2017-19 period GSK experienced some production challenges related to its Rotarix product that meant it was unable to developed sufficient yield of its antigen to meet global demand for its vaccine. The first issues arose in 2017, which were related to the product not achieving the necessary vaccine vial monitor (VVM) compliance, while problems in 2018-19 were related to issues around its yield production. As a result, 3.7 million less doses of its Rotarix product were available in 2017, while the production challenges in 2018 meant that some countries had to delay the introduction of the vaccine into their programmes.[65] While there was little the Alliance could have done to prevent these production challenges, the experience highlighted the risks of relying on one manufacturer for supplying a market.

- **Suitability of new products for meeting country preferences:** Despite the entry of new manufacturers into the market, most Gavi-supported countries continue to prefer the incumbent manufacturer's product. For example, of the 220 million courses awarded by UNICEF for the 2017-21 period, 75% was for GSK's products.[66] This dominance could be strengthened once the BFS product becomes more widely available. It has been noted that GSK's product is likely to remain is likely to remain the preferred option for countries in the short to medium-term, suggesting "true competition" is not currently present in the market, even if the new manufacturers are producing liquid products. Unlike GSK's product, the BBIL and SII have not demonstrated the ability to offer sufficient protection with two doses, making the GSK product preferred programmatically, even against the liquid products that will receive WHO PQ in the near future. The frozen and lyophilised products also require four and eight preparation steps before being administered, compared to just one for GSK's liquid product.[67] According to stakeholders, the main reasons for manufacturers developing these formulation of the vaccines were related to i) cost of vaccine development; and ii) intellectual property (IP) issues that prevented the development of a similar product to GSK. While BBIL's and SII's future products offer programmatic benefits, the cost to fully immunise a child (adjusting for expected wastage) is estimated to be US$3.80 for BBIL's product (for 5-dose vial presentations) and US$4.84 for SII's product, compared to US$4.45 for GSK's BFS product.[68] All this demonstrates that although new market entrants is a clear positive step, development of true long-term competition will remain a challenge going forward.

The rotavirus market is an particularly pertinent example of where the Alliance will need to better understand what is needed to promote true competition in the market in future, and whether there is more that can be done to support the demand-side of the market to enable healthier competition, particularly those that offer significant cost savings for countries in transition or are expected to offer improved efficacy in resource-limited settings.[69] Further details regarding this are discussed in Section 6.

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[65] UNICEF (2020), Rotavirus Vaccine: Supply & Demand Update.

[66] Ibid.

[67] Gavi (2020), Gavi-supported rotavirus vaccines profiles to support country decision making.

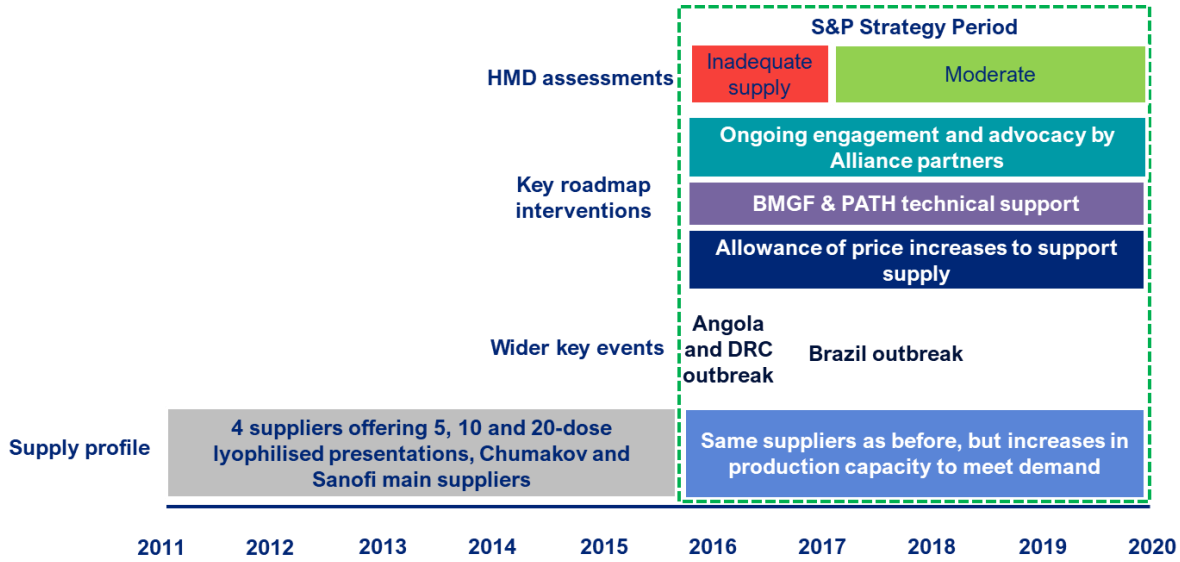
[68] Gavi (2020), Detailed Product Profiles.

[69] A recent study funded by BMGF on country product preferences for rota, HPV, IPV, Penta/Hexa was perceived as a very useful starting point that could be expanded upon to create a more regular and formal assessment of country preferences.

Yellow fever – Moderate health achieved but challenges remain

The yellow fever market achieved moderate market health in 2017, two years earlier than targeted, and has maintained this score as of 2019 and is expected to do so in 2020. As shown in Figure 5.2 below, this assessment follows the previous year in which it was deemed to have inadequate supply, and highlights how the HMF scoring can vary significantly from year to year in markets where demand is quite volatile.

Figure 5.2: Timeline analysis of key events contributing to improved market health for yellow fever



Source: Gavi.

The key factor behind the improvement in market health is improved supply security. In 2016 the Alliance partners felt that supply for yellow fever vaccines did not meet demand, largely as a result of the yellow fever outbreaks experienced in Angola, DR Congo and Uganda. Additionally, following the yellow fever outbreak in Brazil in 2017-19, Bio-Manguinhos, as a state-owned company, received a directive from the Brazilian Government to allocate supply to their national demands. Despite these challenges, the supply situation has steadily improved since 2016:

- **Increase in capacity of existing manufactures with majority of market share:** Sanofi Pasteur and Chumakov, the two suppliers responsible for the vast majority of yellow fever supply to UNICEF in 2019, have been able to expand their capacity over time and as a result, overall supply to the market has increased. From a counterfactual standpoint, consultees have noted that the Gavi Alliance has been working closely with manufacturers in this market to ensure capacity could be increased, which has contributed to this improvement in supply security.

- **Stable supplier numbers in the market:** The other two manufacturers Bio Manguinhos (Bio M) and Institut Pasteur de Dakar (IPD) both have received funding from BMGF and PATH. In addition, the Alliance has continued to advocate to the Brazilian government to ensure that Bio M does not exit the global yellow fever market. This led to the removal of export barriers that have been in place, which has contributed to enabling Bio M to supply Gavi countries, albeit at significantly lower volumes than Sanofi and Chumakov.

The price of the yellow fever vaccine has increased by around 15% between 2015 and 2019 albeit from a very low level. The price increase was largely seen as adequate, providing needed incentives for manufacturers to invest and increase capacity during a time of supply constraints. This interpretation is supported by the fact that the vaccine price remained below the target price that was set out in the yellow fever roadmap. While not covered under the HMF assessment for yellow fever, the Alliance has also started funding yellow fever diagnostics in a bid to improve demand predictability.

Despite the improvements in supply security, the yellow fever market continues to suffer from a number of challenges, including:

- **Unpredictable and lumpy demand:** While supply has clearly improved since 2016, timing of country campaigns in certain years resulted in the need to prioritize campaigns to meet supply, explaining the continuously low scoring of buffer capacity and partly explaining why Alliance partners have had disagreements on the overall health of this market (see Section 4.1.2 for further details). For example, in 2019 the DRC yellow fever campaign was partly delayed due to simultaneous campaigns being carried out in Ghana and Sudan. This suggests that there may be a need for the Alliance to better coordinate the demand side of this market going forward in order to enable supply to be sufficient.

- **Individual manufacturer capacity:** While the yellow fever market is characterised as consisting of four main suppliers, as mentioned above, two suppliers are responsible for almost all of UNICEF procurement, and as such should one of these suppliers exit, there would be significant challenges to the overall supply of the market. These experiences show that the Alliance partners should ensure that they continuously engage with these manufacturers to ensure that they remain available and capable of supplying the UNICEF market, particularly in the short to medium term given the limited innovation that is expected in the market.

- **High wastage:** The roadmap identified the high wastage rate as an opportunity to reduce the overall TSE in the market. There also have been recently discussions between WHO, UNICEF and Gavi VI team around the wastage reductions for yellow fever but there have been no concrete activities or outcomes in this regard.

The yellow fever market is a good example of where Gavi's market shaping work has contributed to results in terms stabilising supply and improving supply security. The market example also highlights the need for a greater role of demand-side considerations in the market assessment, intervention planning and coordination with regard to TSE target outcomes.

MR – Lack of new entrants delaying improved market health

The MR market was anticipated to reach a moderate level of health by 2020, which despite being a positive development, is taking place two years after anticipated. The key reason for the expected improvement in market health is the entry of Biological E as a manufacturer into this market, which the Alliance is hoping will add a competitive dynamic to a market previously dominated by SII. Based on consultations with stakeholders, there was general agreement that had it not been for BMGF's support to Biological E in the development phase, it is questionable whether this entry would have happened without the support. In particular, given that MR are low-priced products, it may have been difficult for Biological E to justify investing in the vaccine without external support, given that it may have been difficult to recover such costs at these low prices. Given the Biological E vaccine has similar characteristics to SIIs products, there should be more competition in the market going forward. However, consultees noted that even though Biological E obtained WHO PQ in 2019, it has not been able to offer its product to the UNICEF market. This is largely because of the requirement to have products registered across Gavi-funded countries after receiving WHO PQ, which was regarded by stakeholders as a key barrier to future competition. In relation to this and other markets, consultees felt that better guidance could be provided to DCVMs, especially those with smaller vaccine portfolios, on processes to speed up country vaccine registration when they are seeking WHO prequalification, including sharing guidance on using WHO's fast-track registration process, while further efforts were needed to support countries with ensuring products already WHO prequalified can be quickly registered.

Pentavalent – High market health unlikely to be achieved in short-term

The pentavalent market is the only market that was targeted to achieve high levels of market health by 2020. As discussed further in Section 5.2, the market was able to reach this state as a result of the Alliance's long-term market shaping work. Yet given the current situation in the market a high level of market health is unlikely to be achieved. In fact, the monitoring data from Gavi suggests that there has been very limited improvement in the individual HMF attributes over the evaluation period.

Taking the HMF as the basis, the key areas where the Alliance is unlikely to achieve high levels of health include:

- **Diverse NRA risk:** As mentioned previously, the vast majority of manufacturers in the UNICEF market are Indian manufacturers, and despite global manufacturers having pentavalent products in their portfolio have not entered the UNICEF market, meaning that high levels of NRA risk will remain. This outcome is partly a function of high income manufacturers exiting the market during the previous UNICEF tender, which could

be argued as a characteristic of a market reaching a more mature status, since prices reach levels where IFPMA manufacturers cannot compete, but equally industry stakeholders have noted that the competitiveness in this market has meant that it is no longer attractive to other DCVMs outside of India. From a counterfactual perspective, this competitiveness is partly a function of the market itself, with manufacturers themselves driving the competitive pressures to gain a higher market share, but consultees also noted that the tender process for pentavalent is likely to have contributed to the competitive pressure experienced.

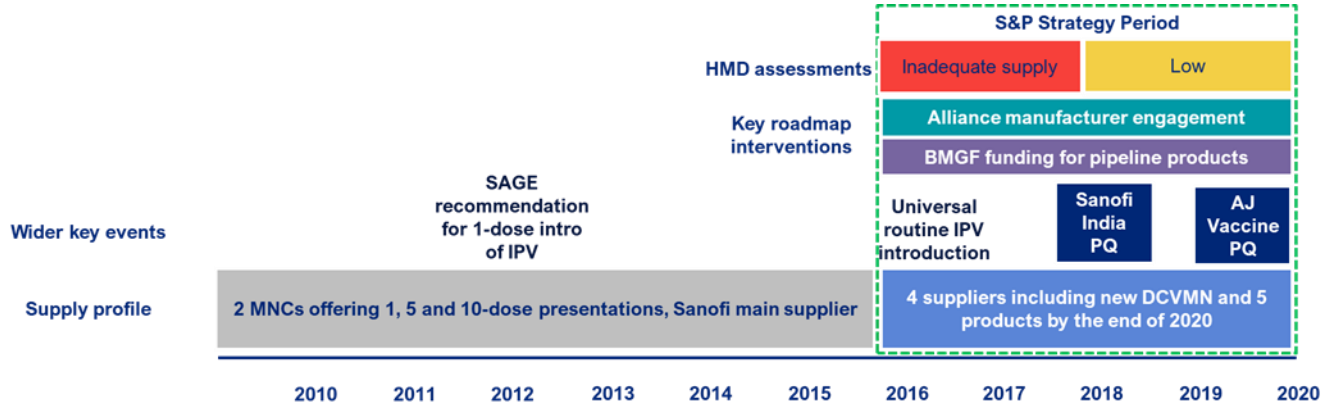
- **Individual supplier risks and long-term competition:** Related to the above, the long-term competition in the pentavalent market is limited relative to other vaccine markets. As noted in Section 4.1, existing supplier sustainability rather than long-term competition is not a priority in this market, though the lack of long-term competition could become a particular issue should additional manufacturers decide to exit the market. For the manufacturers that are in the market, the Alliance recognises and has experienced some supply issues, which has possibly been related to some manufacturers looking to reduce costs in the production of their vaccines. UNICEF has responded to these issues with the reallocation of awarded vaccines to other manufacturers, demonstrating that Alliance partners have been active in ensure that the supply in the market can be maintained. But this does highlight that the Alliance needs to continuously monitor this market to ensure that supply can be maintained and that it remains healthy (see Section 5.2 for further discussion on this).
- **Innovation:** The pentavalent market is a relatively mature market with a wide range of manufacturers, and as a result the Alliance is not expecting innovations to take place specifically linked to pentavalent products. That said, several pentavalent manufacturers are looking to develop hexavalent products, which while not a specific innovation of pentavalent products per se, could offer countries greater choice for vaccine programme implementation.

Further details on the state of the pentavalent market are discussed in Section 5.2.

IPV – High demand inducing supply-side challenges and price adjustments

As outlined in Figure 5.3 below, the IPV market has faced a number of challenges with supply security. The initial target to reach moderate levels of market health suggests that there was not a good understanding of the true supply and demand situation in the IPV market at the time of target setting. Specifically, there was an overestimation of the true ability of manufacturers to respond to the rapidly expanding demand and to scale-up capacity accordingly as well as an underestimation of the development challenges that new manufacturers face to enter the market.

Figure 5.3: Timeline analysis of key events contributing to changes in market health for IPV[70]



Source: CEPA analysis

In particular, in 2016 universal routine IPV introduction was initiated as part of the switch from trivalent to bivalent OPV, which expanded IPV demand whilst the delay in eradicated polio further increased the demand for IPV in endemic countries. At the same time, manufacturers were unable to significantly scale-up production as planned and

[70] Suppliers include AJ Vaccine expected to enter the market in 2020 and also counts Sanofi Pasteur and Shanta /Sanofi Healthcare India separately.

had initially communicated to GPEI leading to severe supply shortages. Similar to the experience in the HPV market, from a counterfactual perspective the Supply and Procurement Strategy itself was clearly not the cause of demand and supply misalignment, nor was the general work of the market shaping team, but it does provide further evidence of the need for the Alliance as a whole to consider the implications of global efforts on the supply side of the market, and set objectives and targets taking these factors into account. This lesson has already been partly applied with consultees mentioning that the discussion regarding the WHO recommendation for an increase in the IPV routine immunisation schedules from 1-dose to 2-dose has been more mindful of the global supply situation of IPV. The IPV experience also highlights the importance to realistically consider production challenges and lead times and to provide feasibility checks of (often overly optimistic) manufacturers scale-up scenarios.

To ensure that manufacturers are able to meet the demands from Gavi countries, UNICEF prices have gradually increased from US$1.09 in 2016 to US$2.31 in 2019 to accommodate supplier constraints in the market. Most consultees considered this to be necessary given the supply constraints in the market and the additional investment from manufacturers needed to scale-up capacity and/or overcoming development challenges.

Notwithstanding these supply-side issues, to the IPV market has a very strong pipeline of potential products that can be supplied to the market, with BMGF, as part of its wider efforts in eradicating polio, has invested significantly in the development and introduction of new products onto the market. According to publicly available information, the Foundation has invested nearly US$140 million in various initiatives to support the development of IPV vaccines, including more than US$105 million to directly support three key pipeline manufacturers undertake clinical trials and increase their production capacity to supply LMIC countries.[71] With the entry of these manufacturers, the market health for the IPV market could significantly improve going forward. In addition to these development efforts, consultees were in agreement that the Alliance has played a key role in ensuring that this market could overcome the supply-side challenges previously faced, primarily through the signalling and engagement the Alliance has given to this market which many noted a contributory to overcoming the supply-side challenges.

In conclusion, the IPV experience underlines the importance of aligning demand policies and market shaping efforts and to ensure that the true capacity of manufacturers to enter the markets and to scale-up capacity is understood. It is clear that the strong pipeline and expected market entries would not have emerged without Gavi's market shaping activities, especially BMGF substantial financial incentives in the market.

HPV - Supply-side challenges after demand expansion in 2017

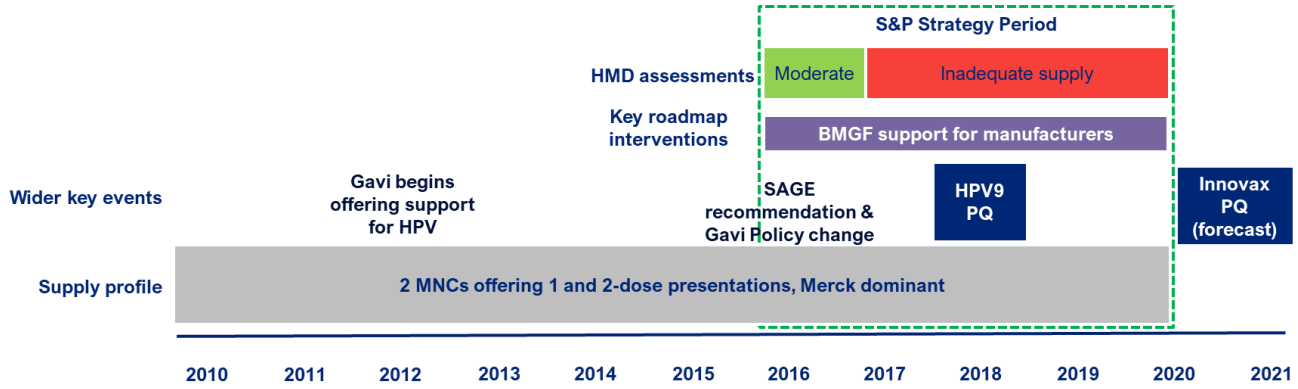
As shown in Figure 5.4 below, the HPV market initially received a moderate score in 2016. At this time, the supply situation in the market was sufficient for the low levels of demand that were required at that time. This scoring was prior to the vast expansion of global HPV immunisation programmes following the WHO-SAGE recommendation in October 2016, which recommended that countries vaccinate multiple age cohorts of girls aged 9-14 when the HPV vaccine is first introduced.[72] However, following the SAGE recommendations the market supply & scale up efforts for this vaccine has not been able to accommodate rising total global demand.[73] As a result of rises in global demand, the dominant manufacturer in this market has been unable to meet all Gavi country demand for HPV vaccines, resulting in the market being assessed as moderate in 2016 to inadequate supply in 2017, as well as in future years.

[71] BMGF (2020), Grants database.

[72] This recommendation led to Gavi making the following two changes to its HPV programme: i) rather than first completing a pilot HPV vaccination programme, countries could apply to Gavi to fund a full-scale national programme, with the option of introducing the national programme in a phased manner; ii) countries could opt to vaccinate multiple age cohorts simultaneously for girls aged 9-14, in the first year of their programme, depending on supply availability.

[73] As part of 4.0, Gavi planned to immunise 40 million girls by 2020, averting an estimated 900,000 deaths. Because of these issues, the market is not expected to reach its target of moderate market health by 2020. Gavi has also revised down its targets to immunising 14 million girls and averting 300,000 deaths.

Figure 5.4: Timeline analysis of key events contributing to changes in market health for HPV



Source: CEPA analysis

In addition to the above global challenges, the following have also contributed to lower levels of market health:

- **Lack of new entrants into the market:** Based on the HMF targets from the SG4 indicators, Gavi was initially expecting at least two new entrants into the HPV market between 2018 and 2020, which has not taken place. This has primarily been due to the complexity associated with developing HPV vaccines that has meant receiving WHO PQ has been delayed, although it should be noted that key candidates for WHO PQ are supplying the Chinese domestic market with at least one supplier expected to start supplying to Gavi supported countries in 2021.
- **Reduction of LTA commitments:** According to consultations, there also has been a reduction in the commitment of one manufacturer under its LTA in 2019 and 2020. The reduction was communicated to the Alliance in 2019 and was driven by increases in global demand (outside of the Gavi market) as well as ongoing constraints in bulk manufacturing capacity.
- **New high valent products not coming to Gavi-supported market:** This is primarily because of the wider bulk supply challenges mentioned above which are augmented by the higher need for bulk for HPV nine valent products. The product is not expected to come to the Gavi supported market before the bulk capacity constraints are resolved, and because of these challenges entry of this product is not being prioritised by the Alliance in the short to medium-term.

The HPV experience has shown a mismatch between Gavi policy and market shaping efforts, an area that would benefit from greater synchrony going forward. Taking a counterfactual lens, it is clear that the Supply and Procurement Strategy nor Gavi's specific market shaping work could have avoided the outcomes seen in this market, since the key driver of these outcomes appears to be a lack of consideration of the supply side issues in global eradication efforts.

More recently, as indicated during our consultations, there have been some positive developments in the market that would have not materialised in the absence of the Alliance. For example, five manufacturers recently committed to increasing and prioritising HPV vaccine supply to Gavi-supported countries which allowed an increase in Gavi's target of reaching 84 million girls instead of 50 million during the next five year period.[74] The counterfactual analysis shows that the expected market entries would have not materialised without Gavi, with consultations suggesting that additional market entries would have still been a few years away without Gavi support (such as technical assistance for the preparation and application for WHO PQ).

A number of lessons can be drawn from the HPV experience with regards to encouraging market health. These include:

- **Long-term planning and coordination of disease elimination efforts with supply-side of markets:** The ambitions set out for HPV vaccine rollout, while commendable for expanding the coverage of this vaccine,

[74] Gavi (2020) https://www.gavi.org/news/media-room/hpv-vaccine-manufacturers-commit-provide-enough-supply-immunise-least-84-million

could have been more effective in its consideration of the extent to which the market was ready for such significant global demand increases. For future vaccines, Alliance partners should consider the feasibility of their plans in relation to what the markets can supply, as consultees were almost universal in their view that there was not sufficient time for planning and engaging with manufacturers on the implications of what the new recommendations would mean in terms of overall supply security. Importantly, there should be early and transparent engagement with manufacturers ahead of key Gavi Board decisions to ensure that an accurate picture of the supply situation is considered in the decision-making.

- **Consideration of demand shifts in non-Gavi supported markets:** The experience in HPV shows (i.e. the reduction in LTA commitments) that changes in global demand can have a direct impact on supply availability for Gavi markets.
- **Improved communication and understanding of manufacturer ability to meet increased demand:** Related to the above, a number of consultees noted that prior communication with the key manufacturer of HPV did not indicate the extent to which such supply-side issues would be realised. This may partly be because the demand forecasts issued by the Alliance were not regarded as being credible, especially as forecasted demand for HPV did not materialise between 2013-2015. Notwithstanding the unpredictability of these issues and challenges with demand forecasting, this suggests that better communication was needed between the Alliance and manufacturer on the scale of demand and what this would mean for the supply side of the market. More generally, the experience shows that further explaining of what forecasts mean in practice, and giving confidence to manufacturers on the accuracy of forecasts, is needed.
- **Improved understanding of country preferences and how Alliance can facilitate take-up of new products going forward:** The HPV market, both at the global level and in Gavi countries, is dominated by one manufacturer, whose products include a greater number of serotypes (four) than its competitors (two, though it should be noted that there is evidence that the bivalent product could offer cross-protection against serotypes not included in the vaccine).[7576] This is not only the case for existing products that are prequalified, but also applies to products that will receive WHO PQ in the near future, with a bivalent product expecting to receive WHO PQ by 2021.[77] Despite this product expecting to offer a price discount to UNICEF at up to US$3 per dose compared to the incumbent suppliers' US$4.50 and 4.60 per dose price, consultees have noted that they expect that some countries may not necessarily switch to this product, partly because of the general vaccine stickiness experienced at the country level, but also because this product is still perceived as offering less protection relative to the incumbent manufacturers main product. This is despite the fact that the vaccine offers similar levels of protection against HPV-16 and HPV-18, the two types of HPV most prevalent worldwide and the highest risk.[78] Given this information and to ensure greater competition in the HPV market, more work is needed to understand how the Alliance can ensure countries can use this information to make informed decisions about their vaccine programmes, and provide assurances that new vaccines are sufficient for their programmes in the context of their epidemiological needs.

Facilitating competition through a better understanding of demand will also be important for ensuring that future products can also be taken up more widely. Similar to PCV and rotavirus, the HPV market, partly thanks to efforts of key Alliance members, has a very strong pipeline of products that could significantly contribute to improved overall market health, provided that countries take up these new products once available to them.

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[75] WHO (2017), Human papillomavirus vaccines: WHO position paper.

[76] Malagón et al. (2012), Cross-protective efficacy of two human papillomavirus vaccines: a systematic review and meta-analysis.

[77] Gavi (2020), Gavi-supported HPV vaccines profiles to support country decision making.

[78] WHO (2017), Human papillomavirus vaccines: WHO position paper, May 2017.

5.2. LONG-TERM VIEW

13: To what extent have markets reached a state of sufficient health and self-sustainability to no longer require market shaping interventions from Gavi?

Key findings

- The pentavalent market has shown signs in recent years that active interventions such as push funding and/or pull mechanisms may no longer be required. But this may not always be the case, and the Alliance will need to ensure that it actively monitors trends in this and related markets to determine whether active market shaping is needed in the future.
- For some other vaccine markets, while they may not exhibit the full range of desired criteria for a healthy market, they are in a "steady state" by virtue of their unique context. These markets would also require ongoing monitoring and assessment of their health, particularly those where there is a limited amount of supplier diversity.
- There continue to be a number of vaccine markets where active market shaping interventions are required to support improved health and sustainability over time.
- CCE will require market shaping interventions for an extended period of time before reaching a position of market sustainability.

Strength of evidence: Strong

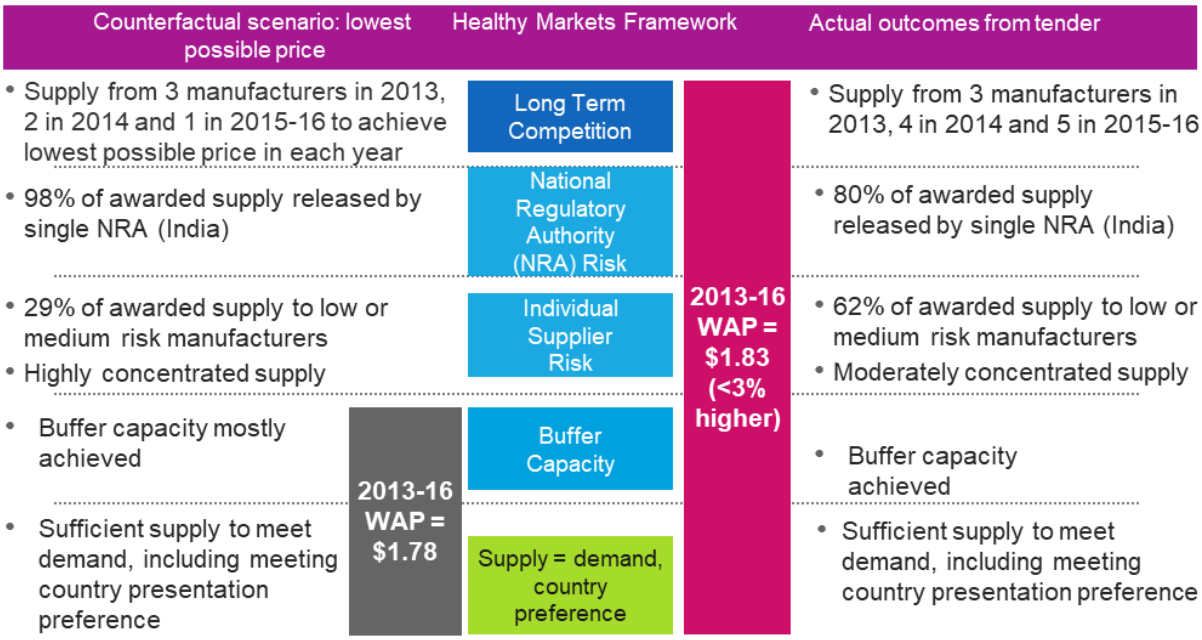
Under this question we assess the extent to which the Alliance has been able to achieve its long-term objective of ensuring that its markets have reached a sustainable state and do not rely on Gavi and its partners using active market shaping tools and approaches to improve market health beyond active procurement.

Pentavalent market

Over the long-term, the greatest achievement of the Alliance's market shaping work has been in the pentavalent market. During the initial years of the Alliance's existence, this market was supplied by just one manufacturer from a high income market, supplying well below 50 million doses to Gavi-supported countries. The WAP for Gavi-supported countries was around US$3.50 per dose for a lyophilised product, which was less suitable for administration due to the steps required to reconstitute and administer the vaccine. Over the next fifteen years, Gavi played a key role in stimulating demand for pentavalent vaccines in its countries, which contributed to significant increases in demand. This increase in demand encouraged new DCVMs to enter the market with higher-dose, liquid products that would better meet the needs of Gavi countries. These manufacturers invested considerably in the development of their vaccines, with support from Alliance partners such as BMGF and PATH. In addition to this, technical support by WHO to NRAs and UNICEF's approach to tendering that aimed to bring sustainability to the market ensured that by 2016, supply security and longer-term competition was present in the market with significant buffer capacity at prices that were just US$0.05 per dose higher compared to the counterfactual scenario of aiming to achieve the lowest possible price, as summarised in Figure 5.5 below.[79]

[79] Gavi (2016), Supply and Procurement Strategy 2016-20.

Figure 5.5: Comparison of lowest-possible price scenario with actual outcomes of procurement tender for 2013-16



Source: Gavi.

As noted in Section 5.4, since 2016 the pentavalent market has experienced fierce price competition, which has contributed to significant price reductions that have ultimately saved the Alliance more than US$350 million in procurement costs when considering prices prior to this period.[80] The period under the current Strategy witnessed one of the first tenders in which the Alliance could implement procurement approaches that would allow competitive pressures to determine market outcomes, which was also facilitated by the procurement approach taken in this market as well as signals on prices offered during the 2015 India tender, which were lower than the prices offered to the Alliance at the time. While this does suggest that the pentavalent market has reached a state where active market shaping efforts in the form of push funding and/or pull mechanisms are no longer needed, but to say that the market will always be characterised as this requires a more nuanced consideration of market dynamics. In particular:

- At a WAP of US$0.68 for UNICEF since 2017, such prices have been widely recognised as unsustainable by Alliance partners and industry, and going forward the Alliance will need to carefully consider how prices offered could affect the long-term interest of both active and non-active manufacturers in the UNICEF market.
- Unlike other markets such as PCV, HPV and rotavirus, the pentavalent market is almost solely focused in LMIC countries, since products in other markets offer acellular as opposed to whole cell pertussis by IFPMA manufacturers, while the whole cell market is mainly comprised of DCVMs. This means that because manufacturers in the pentavalent market cannot draw on higher income country revenues, the role of the Alliance and key MICs is even more important in this market than others, where certain risks such as NRA and individual supplier risk could be even more pertinent in the long-term.

More generally, an important observation on analysing the long-term sustainability of markets is that what the Alliance as the procurer and purchaser of vaccines might consider "healthy" is not always aligned with how manufacturers consider a healthy and attractive market and how they might respond to it. In the context of markets that are reaching levels of maturity as witnessed in the pentavalent market, industry stakeholders have noted that manufacturers will consider the overall attractiveness of the market for stimulating revenues relative to other markets that they operate or could operate in future, and in turn assess how they can increase their market share through reducing costs, obtaining favourable procurement contracts, differentiating and improving upon their products and exploring next generation or completely new products. Should manufacturers view a market as being too competitive for them to

[80] Malhame et al. (2019), Shaping markets to benefit global health – A 15-year history and lessons learned from the pentavalent vaccine market.

offer any real advantage, they may exit. With this in mind, the Alliance will need to take a balanced view on how manufacturers are viewing the pentavalent market to ensure that it remains healthy, not only from a purchaser but also a supplier perspective.

With this in mind, going forward the Alliance should consider how it monitors demand and supply sides for markets with higher levels of health to maintain the level of competition and security to ensure regular and affordable supply going forward. This may require a more sophisticated set of parameters to monitor both the demand and supply sides. For example, it may be appropriate to keep a balanced share for each manufacturer in the pentavalent market to avoid any unexpected disruption of the supply, as well as anticipate any key changes in the market from the demand side. There is also a need to consider the market in the context of the switch to hexavalent. Many eligible countries are moving towards this switch for epidemiological and programmatic reasons, while manufacturers are also promoting hexavalent as a superior product. A number of DCVMs have hexavalent vaccines in their pipeline and regard this as the next niche and an alternative to the pentavalent vaccine which no longer offers manufacturers significant margins. This highlights that as the hexavalent market develops, the Alliance may need to consider alternate market shaping tools and approaches to support healthy market growth.

Other vaccine markets

Outside of pentavalent, some of Gavi's markets have demonstrated supply security and low prices, even if dominated by a single supplier. For example, in the meningitis A market, Gavi-funded countries currently benefit from a 1-dose schedule to fully immunise a child for US$0.54 per dose (before considering cost of wastage) and have benefited from secure and uninterrupted supply over the last five years.[81,82] Yet as discussed in Section 4.1, the Alliance has struggled to come to an agreement on the health of this market, and what seems to have prevailed is that even if a market demonstrates positive characteristics with regards to supply security and price, it cannot be considered healthy unless there is some degree of manufacturer diversity. However, stimulating competition in this market is likely to require at least some form of push funding from the Alliance, however this may not be feasible given that MenA has been implemented largely through campaigns and the overall demand for MenA vaccines is also not likely to be significant in future years i.e. suggesting additional entry into this market may not be needed. The meningitis A example shows that markets exist where even though health may be considered "low", there is limited need or rationale for significant market shaping interventions. This could also be said for historical vaccines such as measles where market dynamics and the availability of alternative, multivalent products preclude the need to increase competition further. Campaign vaccine markets such as yellow fever, characterised by a number of incumbent suppliers and where demand is expected to reduce or stabilise over the long-term could also be included as an example where there is less need to encourage new entrants.

More widely, in vaccine markets where, through a combination of health interventions (including vaccination, treatment as well as non-medical interventions) means that if there is potential for a disease to be eradicated, relying on a single supplier may be an acceptable risk for the Alliance to take should the long-term need for a functioning vaccine market not be present.

Beyond these above noted examples, Section 5.1 highlights that there are a number of markets where active interventions will likely be needed to ensure that the Alliance can benefit from markets characterised by long-term, stable supply security with active manufacturer competition and innovation at sustainable and affordable prices for the markets it serves.

Cold chain equipment

The overall market shaping goal for CCE is 'to incentivise a market where CCE is available at an optimal total cost of ownership (TCO) and ultimately, to create a market where high performing equipment and services are available to countries from a solid supplier base at sustainable prices'.[83] There has been significant progress made in some

[81] Gavi (2020), Detailed product profiles.

[82] Gavi (2020), SG4 monitoring data.

[83] JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings.

aspects in recent years through the introduction of CCEOP, however stakeholders consider that a lot of intervention will still be required. In particular, the market for CCE is lagging behind vaccines. As outlined in the CCEOP evaluation report as well as stakeholder feedback, some of the ongoing key issues include:[84]

- Supply challenges including challenges sustaining a healthy market for CCE with the current number of suppliers;
- Demand is 'lumpy' and unpredictable, and countries have shown a strong preference for products from only three major suppliers; and
- Innovation is not being encouraged as much as hoped with a tension between price reduction and market share aims and innovation aims as the former are discouraging investment from manufacturers in innovation.

As such we conclude that CCE will require ongoing market shaping interventions for an extended period of time before reaching a position of sustainability.

5.3. SUPPORTING PRODUCT INNOVATION

14: To what extent has the Strategy contributed to the increased development and uptake of suitable and quality vaccine and related products?

Key findings

- There has been progress with regard to product innovations most clearly demonstrated in the PCV and OCV markets. The uptake and use of product innovations in other markets has been less pronounced.
- There has been an increase in the number of CCE products available and a number of innovative products have come to market ahead of schedule.
- Uptake of CCE products has been strong due to the funds made available through CCEOP. However uptake has been predominantly limited to three main suppliers.

Strength of evidence: Strong

Within this question we consider the extent to which vaccine product innovations from 2016-20 have been developed and taken up by countries and whether the Strategy has encouraged an increase in the development of CCE products.

5.3.1. Development and country uptake of product innovations

Development of vaccine product innovations

Gavi is currently on track to meet its market shaping goal indicator on innovation which measures the number of vaccines and other related products with improved characteristics procured compared with the baseline year.[85] The total number of innovative products increased from 0 products in 2015 to 10 products in 2019 (see Appendix D) regarding Strategic Goal results for more details).[86] Most of these include "quick wins" (such as granting CTC status, container changes or multi dose vials) but more substantial innovations are in the pipeline and expected to come to market soon (e.g. new multivalent products in PCV and an adjuvant vaccine from AJ Vaccine in IPV).

As outlined in the section 5.1, there has been a clear link between the vaccine product innovations and Gavi's market shaping activities with the innovations in PCV and OCV seen in particular to be driven by signalling and engagement with manufacturers, funding through the AMC (in the case of PCV) and support from BMGF (for both vaccines). However, given the inherent time-lag it should be noted that the new innovations coming into the market are not just driven by the activities under this strategic period but also relate to actions under Gavi 3.0 (this holds especially for the product receiving WHO PQ in 2016 and 2017).

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[84] Ibid.

[85] Gavi (2020). Accessible at: https://www.gavi.org/our-impact/measuring-our-performance/2016-2020-indicators/market-shaping-goal

[86] Gavi (2020), Strategic Goal 3.3 data

Country uptake of product innovations

Whilst strong progress has been made regarding the number of products available, the progress on product innovation measured under Strategic Goal 4.3 becomes more nuanced when the uptake and use of the innovations is more closely considered. The uptake of product innovations with regard to total volume and market share has been determined using confidential purchasing data from UNICEF SD.[87] The analysis was conducted up until the end of 2019 and was complemented with insights from consultations. The results show the following:

- The key success stories are the high uptake of the 4-dose PCV presentations as well as the plastic tube presentation, and to a lesser degree the CTC product, in the OCV market. The multi-dose vial presentations in the PCV market were well received by countries and are now the dominant products in the market.[88] Similarly, the plastic tube presentation dominates the markets and was considered to be an important innovation with regard to easing in-country storage and delivery.
- Some other product innovations have only recently received WHO PQ and, thus, the uptake has been limited as of the end of 2019. This includes the 5-dose presentation in MR, BFS product presentation in rotavirus and the shelf-life extension of one product in PCV. With regard to the rota, the product is not expected to be widely available in the short-term, with a potential full-rollout starting 2023.
- One product in the OCV market, the glass vial presentation, has already been replaced by the plastic tube and is no longer used in the market. Therefore, this shows very limited uptake.
- The HPV product with CTC had a large uptake but this was due to the market power of the manufacturer rather than the additional value from the innovation. In fact, consultees stated that no country has so far started to administer HPV outside of the cold chain suggesting that this has not been a key priority for country stakeholders.
- There also has been a good uptake of the penta product that had improved cold chain requirements for the 1-dose presentation.

Overall, there has been some important progress with regard to product innovations most clearly demonstrated in the case of PCV and OCV, whose introduction was also clearly linked to Gavi's market shaping activities. Nevertheless, the uptake analysis illustrates a more nuanced picture suggesting that further monitoring of the uptake and use is needed. In addition, it highlighted the importance of understanding country preferences.

5.3.2. CCE

Development of CCE product innovations

There has been an increase in the number of CCE products available and a number of innovative products have come to market ahead of schedule. In 2015 (prior to CCEOP approval), there were six manufacturers of ILRs, in 2020 there are seven with platform eligible CCE, while for SDDs, there were four suppliers, now there are eight manufacturing platform-eligible equipment.[89] As another stakeholder put it, "*innovation has been core to CCEOP and we have moved from unreliable kerosene and gas products in many countries direct to modern equipment*[90]*".* When asked about the counterfactual scenario (i.e. what would have happened without Gavi's support), stakeholders noted

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[87] We have used purchase orders with a delivery date for a given calendar year (regardless of purchase order placement date or first shipment date) as this was considered closely proxy the actual demand for the product in a given year.

One limitation of the analysis has been that the database only allows to differentiate by supplier, vaccine, presentation and doses per unit. This is enough to determine the market share of specific products, but it assumes that a supplier would provide the innovative product (rather than offering the previous products with the same presentation and doses per unit).

[88] The country demand for this presentation is also reflected in the increase in market share by the one manufacturer that introduced the 4-dose presentation one year early.

[89] JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings.

[90] These technologies satisfy a higher standard of performance criteria beyond minimum WHO PQS requirements

that a key benefit of support from Gavi is that innovative equipment has been brought to market much more quickly than before due to the work under CCEOP. For example this includes remote temperature monitoring devices for which the number of suppliers has reportedly expanded more rapidly than otherwise expected.

That notwithstanding, there have been some concerns raised by manufacturers that the efforts under CCEOP to reduce prices, and spread the market share across a larger number of suppliers as well as the lack of clarity regarding demand may limit innovation initiatives by manufactures if the R&D investments into these innovations cannot be recovered.[91]

In addition to the innovations noted above, an innovative concept regarding service bundles[92] has been piloted. Reportedly this has aided CCE items not just to be procured but also to ensure that they are distributed and then maintained. Stakeholders consulted in this evaluation consider it to be a success, with one noting, "*there has now been a market developed for service bundles*". However we note that feedback was more mixed in the CCEOP evaluation and as such it may be too premature to assess the success of this approach.

More generally, CCE provided to countries is considered to be a solid investment in supporting equitable immunisation coverage by extending equipment availability into remote areas and better enabling outreach activities.[93] As such the activities under CCEOP has significantly contributed to meeting needs of countries.

Country uptake of CCE products

Building on the vaccine model, through the CCEOP, the Alliance has aimed to stimulate demand and supply of more reliable and efficient CCE through offering stable demand to manufacturers and funding to countries choosing Platform-supported technologies. Over the course of the first three years of CCEOP (2017-2019), where purchase orders were placed, nearly 40,000 units of ILRs and SDDs (18,265 ILRs and 21,650 SDDs) were procured for 38 countries.[94] This is notable progress against the original aim of 65,000 units by end of 2020 and stakeholders consider that if this aim is not met, it will mostly be due to the disruption from COVID-19 given the good progress before the pandemic. Partners and the Secretariat were all positive about the very strong progress regarding uptake with one stakeholder noting, "*the additional CCEOP funding has created a lot of leverage and has generated excitement about replacing obsolete equipment and doing that quickly*". In general, the uptake in CCE has been a big success since the introduction of CCEOP.

However within this positive take up, countries have procured products predominately from three suppliers.[95] This has therefore raised concerns regarding the sustainability of so many suppliers in the market, especially the smaller ones. Reportedly this is related to the acceptability of some of the new entrants into the market by some countries. To address this issue, high-volume countries are requested to receive 25% of their procurement from a non-dominant supplier. So far this has not adequately addressed the challenge as not all manufacturers have benefitted equally. In addition stakeholders noted the impact on negotiation process has resulted in protracted dialogue and delayed tendering. More broadly, this has raised questions regarding the balance between country ownership and being prescriptive in order to support healthy markets. The ability to use procurement muscle to reward the suppliers with the most cost effective option is only still in its infancy. We consider that this approach could potentially serve as lessons for other markets, however it is too early to conclude on its efficacy.

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[91] JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings.

[92] Under the CCEOP, Gavi is requiring manufacturers to deliver the successful implementation of the service bundle for Ice-Lined Refrigerators (ILR), Solar Direct Drive (SDD) and temperature monitoring device (TMD) products (30-day temperature recorders (30-DTR) or remote temperature monitoring devices (RTMD)).

[93] https://www.gavi.org/sites/default/files/publications/Cold-chain-equipment-technology-guide.pdf

[94] JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings.

[95] JSI (2020), CCEOP Market Shaping Evaluation Report August 2020. Final Report is still forthcoming and as such there may be updates to the findings.

5.3.3. Progress on VIPS and lessons learnt

15: Is the VIPS on track to achieve its results and what are lessons learnt?

- VIPS has achieved its aims for this strategic period. There have been key value adds from the VIPS process, especially creating alignment enabling partners to work on the innovations in a strategic way. A number of lessons and good practices can be applied to other work in the Alliance.
- VIPS is considered to be on track for the next stage of implementation.

Strength of evidence: Good/Strong

Within this question we consider the extent to which VIPS is on track to achieve its results, the value added of VIPS and any lessons learnt from the VIPS process.

As noted in Section 3.3, VIPS aims to (i) develop common principles, (ii) convene a platform, (iii) better understand country needs. Significant activities towards these aims included:

- Development of an analytical framework to enable the assessment of innovations in an objective and transparent manner. Primary and secondary criteria were developed, enabling a comparison of the added value of different types of innovations which could be measured against each other despite some being very different in nature. Consideration regarding financial and non-financial trade-offs for countries was also taken into account.[96] Stakeholders have considered this framework to be robust and comprehensive and therefore enabled them to assess and compare the innovations. As one stakeholder noted, "*VIPS spent a great deal of effort to landscape and consider all aspects of the potential impacts of each innovation on public health*."

- A thorough process obtaining feedback from a broad range of stakeholders through interviews, consultation and surveys (more detail provided in Section 4.3).

- Prioritisation process: this included firstly selecting 24 innovations grouped into six categories (primary vaccine containers, delivery technologies (not prefilled), integrated primary containers and delivery technologies, packaging and safety, labelling on primary packaging and formulations). Out of these original 24, nine innovations were selected and then finally three were chosen: microarray patches (MAPs); heat stable and controlled temperature chain (CTC) qualified vaccines and barcodes on primary packaging.[97] Innovations were prioritised by a VIPS working group and Steering Committee. Stakeholders considered this process to be well done especially given the transparent discussions and ability to solicit input from a range of partners, many of whom had strong expertise in relevant technical areas.

Stakeholders agree that these achievements are significant and VIPS has achieved what it set out to do within this strategic period. Reportedly the key value add of VIPS is that it has created alignment on these innovations in a transparent and rationale way. A number of partners had been working on innovations within this space, but not in a strategic way or a coordinated manner, which VIPS has helped them to agree on. As one stakeholder put it, "*I fully believe the results thus far are appropriate and really monumental given that many groups have tried and failed to prioritise vaccine technology innovations before*". Furthermore a number of stakeholders commended the fact that a clear message will now be signalled to manufacturers which was not there before.

Overall, the key lessons learnt from the VIPS experience under this strategy period are as follows:

- VIPS serves as an excellent model for bringing together and aligning Alliance partners (as described in Section 4.3);

- The evaluation framework approach has provided a transparent and effective mechanism to compare innovations with a wide range of attributes which may provide an example for other innovation prioritisation work in the Alliance;

[96] VIPS-Background document Steering Committee, May 27th – 28th 2020

[97] The VIPS Prioritisation Process: Methodology and Outcomes, accessed <https://www.gavi.org/sites/default/files/about/market-shaping/Overview%20of%20the%20VIPS%20Prioritisation%20Process%20and%20Outcomes_July%202020.pdf>

- The various mechanisms used to obtain input from country stakeholders has represented good practice in ensuring country level input into the process with a number of stakeholders commending this approach;
- It is helpful to think through additional details while devising an overall strategy, especially regarding the details related to the objectives, which can then subsequently reduce time and costs during the implementation phase (as described in Section 3.3);

Going forward, Gavi will now take work to develop clear action plans to accelerate the advancement of the three prioritised innovations. Therefore while stakeholders think that it is on track to achieve the next stage of results, a number of stakeholders noted that the next steps will be important to fully determine impact. As one stakeholder noted, "*VIPS results can only be determined once implementation occurs as they've only got to the prioritisation stage now*". The one aspect that was highlighted as potentially being an issue in terms of achieving results in the next stage is regarding the funding and willingness to pay for the innovations (i.e. countries, Gavi or other funding sources). VIPS did consider the costs of the products to some extent but some stakeholders considered that more emphasis could have been placed on the financing aspect. We note that this was not a key objective for the strategic period and VIPS has delivered on its intended objectives well. Going forward though, the longer term view of implementation and financing will be important to consider, especially now that the prioritisation of the three products has been finalised.

5.4. Overall strategy

16. To what extent has Gavi achieved its market shaping objectives and to what extent has the strategy contributed to Gavi's overall objectives? What are the key success factors at the global and country levels driving achievements?

Key findings

- Gavi is unlikely to meet its targets for SG4.1 (supply security) and SG4.4 (healthy markets), but is expected to reach its target on SG4.3 related to innovations. While no specific target was set on prices, the Alliance has achieved considerable price reductions for key vaccines, particularly pentavalent.
- While the SG4 indicators are critical, high-profile and provide a good snapshot overview of the key objectives of Gavi market shaping, M&E for the Supply and Procurement Strategy presents several areas for improvement, including with regards to comprehensiveness, relevance, completeness and adaptability.
- There have been some significant supply-related achievements over 2016-2020, and in general, the Alliance's market shaping work under the Strategy has contributed to the Alliance's long-term support for markets. This includes supporting new manufacturers and products to come to market, as well as encouraging a strong pipeline of products across a range of key vaccine markets.
- Some good progress has been made towards the CCE objectives especially given the fact that the CCE market has been relatively static for many years However there is still a need for further improvement in a number of areas, especially regarding demand predictability.

Strength of evidence: Good/Strong

This review question seeks to assess:

- The extent to which Gavi has achieved its market shaping objectives – we consider here progress made against Gavi's M&E framework for the Strategy, including a review of the M&E framework itself. Building on the critique of the M&E framework, we provide an overall assessment of Gavi's performance on the Strategy.
- The extent to which the Strategy has contributed to Gavi's overall market shaping objectives, as well as the key success factors explaining these achievements.
- Finally, we explore the linkages with other Strategic Goals under Gavi's overall Strategy.

The analysis is based on a desk-based review of the Strategy M&E framework and reporting as well as consultations with a range of stakeholders to gather perspectives on the results and added value of Gavi's work in this regard.

5.4.1. Progress against SG4 indicators

Appendix D provides a detailed mapping/assessment of progress made against Gavi's SG4 indicators, with a summary in the table below.

Table 5.3: Progress against SG4 indicators

Indicator	Target and achievement	Comments
SG4.1 Sufficient and uninterrupted supply	The target of 11 vaccine markets meeting the criteria for sufficient and uninterrupted supply being reached by 2020 unlikely to be met.	• This is due to the ongoing supply constraints in HPV as well as challenges in the Cholera market. • Critical supply issues in the yellow fever, rotavirus and IPV have been resolved over the course of the Strategic period.
SG4.2 Cost of fully vaccinating a child with pentavalent, pneumococcal and rotavirus vaccines	Gavi has made strong progress on price declines in key vaccine markets, especially penta (53% decrease since 2015) and, to a lesser degree, rotavirus (16.3%) and PCV (12.3%).	• In markets not measured by the SG4.2 indicator, prices have tended to remain at relatively low levels, or in some cases increase, although as mentioned in Section 4.1, some of these increases were partly to help improve the supply situation in the markets (including in IPV and yellow fever).[98] • For HPV, prices have also remained relatively stable, reflecting the challenging supply situation faced in this market that meant further price reductions were not possible
SG4.3 Innovation	Gavi has achieved its Strategic Goal on innovations which set a target of ten innovative products to gain WHO PQ and procured through Gavi.	• Most of these include incremental innovations on specific products (such as products gaining CTC status, container changes or multi dose vials) but more substantial innovations are in the pipeline and expected to come to market soon (e.g. new multivalent products in PCV and adjuvant vaccines in IPV). • However, as shown in Section 5.3, once the uptake and use of the innovations are considered the findings are a bit more nuanced, with PCV 4-dose and OCV plastic tube being the main success stories in terms of uptake, while others (e.g. BFS for rotavirus and 5-dose for MR) have not yet been widely procured, have been replaced by other innovations (OCV glass vial) or have not been used in practice (CTC for HPV).
SG4.4 Healthy markets	As noted in Section 5.1, the target of six markets reaching moderate to high health by 2020 is unlikely to be met.	• The HPV and IPV markets in particular are unlikely to reach moderate health, as targeted. • That said, the rotavirus market is expected to achieve moderate levels of health, which is better than was targeted for Gavi 4.0. • The PCV market also achieved moderate levels of health far earlier than expected, which can be considered a relative success. • While the IPV market is not expected to reach moderate health, significant progress has been made, particularly with regards to improve the supply situation in the market. • As also noted in Sections 5.1 and 5.2, the pentavalent market (or any other market) is not expected to achieve high levels of health. The pentavalent experience should also be considered in the context

[98] In the IPV market, the WAP per dose for this market increased from €1.25 per dose in 2015 to €2.21 per dose in 2019, while over the same period the yellow fever WAP increased from US$1.02 to US$1.18, according to Gavi monitoring data.

		of the significant cost savings brought about by the reductions in price, while going forward the Alliance will need to consider the sustainability of such outcomes in this market.

5.4.2. Review of M&E framework

While the SG4 indicators are critical, high-profile and provide a good snapshot overview of the key objectives of Gavi market shaping (particularly with regard to monitoring market health), M&E for the Supply and Procurement Strategy in specific presents several areas for improvement:

- **Comprehensiveness:** While a balance needs to be struck with over-monitoring, some aspects of the Strategy are not captured in the current SG4 M&E framework. In particular, the objectives linked to achieving the long-term view pillar are not sufficiently captured in these overall indicators. This is particularly the case for support linked to country-owned decisions, where none of the current indicators have captured this nature of the work in any detail.
- **Relevance:** While the existing indicators do capture key aspects of the Alliance's market shaping work, there are some aspects where the indicators do not capture outputs as fully intended. In particular, as we have shown in Section 5.2, the extent to which the incremental innovations have been taken up by countries has varied, yet this indicator counts the procurement equally, regardless of the rollout of these products.
- **Completeness:** The Strategy includes a number of process and operational indicators, yet these have not been monitored centrally nor periodically, making it difficult to fully monitor how and when such activities were carried out, as well as map out how and whether such activities link to changes in the SG4 indicators. More generally, a number of stakeholders within Gavi noted that the Strategy and the SG4 indicators fail to capture what the Alliance is doing on an operational basis, including some of the specific activities and interventions that the Alliance sets out during the roadmap process for individual vaccines.
- **Adaptability:** The targets for each indicator were set at the start of Gavi 4.0, largely based on the Secretariat and Alliance's partners views on the feasibility of achieving them.[99] Although the targets that have been set seem suitable, there was little consideration of revising targets as markets evolved to ensure they were appropriate for the situation that was in place. It is recognised that the SG4 indicators may be complex to revise given these are Board-approved and there is a process in place for these within Gavi, but linking to the point above on the need for more operational indicators, we view merit in having a relevant and adaptable "internal" framework (i.e. managed by the Secretariat Market Shaping team) for more detailed monitoring.

Taking these points into account, details on how the Alliance could add to their monitoring of the next strategy are provided in Section 6.

5.4.3. Overall assessment of Gavi's performance on the Strategy

Overall, the Strategy has been relevant in relation to the evolving/maturing market shaping role of Gavi over time and given the supply context over 2016-2020; however, there are now some key aspects to consider for 5.0.

Gavi's performance in the vaccine markets

When assessing Gavi's overall performance against its market shaping objectives, it is important to consider the substantial and inherent time lag between Gavi's market shaping activities and observable market outcomes. For example, Gavi market shaping support may incentivize manufactures to start (or continue) vaccine developments and licensing processes but the market outcomes in form of market entries, supply security or price reductions will only be observed in a later period. As such, the market outcomes that can be observed are not only a reflection of the current strategy but also market shaping activities under Gavi 3.0. Similarly, a lot of the conducted work under this strategic period will not be directly reflected in market outcomes between 2016-2020 but will impact on the vaccine markets under Gavi 5.0 (and thereafter).

[99] Specific targets on price under SG4.2 were not released publicly to avoid creating price ceilings for products.

There have been some significant supply-related achievements over 2016-2020, and in general, the Alliance's market shaping work under the Strategy has contributed to the Alliance's long-term support for markets. For example, as noted in Section 5.1, the Alliance's work has helped bring suppliers to market faster than would have been the case without the Strategy. This includes financial support by BMGF to manufacturers in the IPV, PCV, rotavirus and MR markets. In addition, the Alliance's ongoing engagement has been important for ensuring new and improved products are brought to market, with the PCV 4-dose and OCV presentation improvements highlighted as key examples of this. Stakeholders also noted the UNICEF has helped to maintain supply security in a number of markets where individual suppliers faced challenges through its management of contracts and procurement. Finally, as mentioned in Section 5.2, price reductions as part of the latest pentavalent tender alone have ultimately saved the Alliance more than US$350 million in procurement costs when considering prices prior to this period.[100]

Our vaccine market analyses as well as consultations indicated that the Gavi's market shaping activities conducted under the Strategy has led to positive developments that are not yet captured in the market outcomes. This includes a promising pipeline in markets such as IPV, HPV, PCV, rotavirus and hexa that would not exist in its current form without the Alliance's market shaping activities, with the analyses suggesting that some products would have faced a delayed entry and other would have not taken place at all. In addition to the above markets, recently Gavi has also played an important role in providing manufacturers a market for vaccines fighting key epidemic diseases. This includes its commitment in 2019 to a US$178 million funding window for its Ebola vaccine programme, which will create an emergency stockpile of vaccines for the disease.[101] This stockpile agreement was essential for stopping the 2020 Ebola outbreak in DRC, and his commitment provides a clear signal for vaccine manufacturers that a market will exist for these products going forward.

From a counterfactual perspective, the focus on market health in the strategy is likely to have contributed to a continued focus in these areas, with the Alliance noted as being more coordinated in how it considers wider market health than was previously the case.

Gavi's performance in CCE markets

Through the CCEOP, the dedicated provision of funding for CCE has had an impact on CCE markets. In terms of the original Strategy objectives, the following progress had been noted by April 2019 (which was confirmed to mostly still hold true in our interviews):[102]

- **Stimulating supply to meet demand**: there has been an increase in the availability of platform-eligible CCE models and a significant update for CCE products.
- **Minimise costs of devices and services by promoting healthy competition**: progress towards reducing prices for CCE goods has been mixed. Prices have come down for some CCE goods. However, some of the products that countries frequently select have not had price reductions. This has also been complicated by the service bundle inclusion, including where cheaper products have higher service bundle costs.
- **Promote CCE innovation**: TPP targets for SDDs and ILRs were achieved ahead of schedule but stakeholders are not consistently prioritizing innovation due to a lack of incentives to do so related to market share issues, lower pricing and a lack of market predictability.
- **Information sharing to better connect supply and demand**: Information flow and transparency among partners, countries and manufacturers has been commended. However forecasts have remained unpredictable which has been a key weakness.

We therefore note that some progress has been made against the CCE objectives, especially given the fact that the CCE market has been relatively static for many years. Stakeholders note than many lessons have been learnt over

[100] Malhame et al. (2019), Shaping markets to benefit global health – A 15-year history and lessons learned from the pentavalent vaccine market.

[101] Gavi (2019), Gavi Board approves new Ebola vaccine programme.

[102] JSI (2019), Evaluation of the Cold Chain Equipment Optimization Platform Pre-Midline Cross-Country Report: intermediate Assessment (Market-Shaping, Kenya, and Pakistan) April 2019

this strategic period, However there is still a need further improvement on the aspects noted above, particularly around demand predictability.

Contribution to Gavi's wider objectives

The work conducted by under the Supply and Procurement Strategy is critical for achieving Gavi's wider mission to *"to save children's lives and protect people's health by increasing equitable use of vaccines in lower-income countries"*. Most importantly, the **availability of sufficient and uninterrupted supply is a prerequisite for the implementation of successful routine, campaign and emergency outbreak immunisation programmes**. Without sufficient supply, Gavi would have not been able to make the seen progress against its mission indictors which are all on track against their 2020 targets, including (i) children immunised, (ii) future deaths prevented; (iii) reduction in under-five mortality and (iv) DALYs averted.[103] Ensuring sufficient supply contributes towards Gavi's aims of improving coverage and equity. Additionally, the **introduction of products with better characteristics** (e.g. lower wastage rates, reduced cold chain requirement or CTC) can provide additional cost savings and contribute to successful delivery in-country. Lastly, the Strategy has also **contributed to Strategic Goal 3 on improving sustainability and a successful transition** by improving market conditions for transitioning countries (i.e. through spill overs of prices such as in the penta, PCV and HPV market or through direct price freeze agreements with manufacturers). As noted in several areas previously, a key area where Gavi's market shaping work could increase its contribution to wider objectives is through a more explicit and formalised consideration of demand-side aspects of markets. Specific recommendations on how it can do this is provided in Section 6.

6. LESSONS LEARNT AND RECOMMENDATIONS

The final section of the report concludes and provides recommendations for Gavi's market shaping strategy.

17: What are the overall lessons learnt from the current Strategy and what are key recommendations going forward?

6.1. CONCLUSIONS AND LESSONS LEARNT

Overall, the Gavi Supply and Procurement Strategy 2016-20 has been very relevant, appropriate, and significant in the context of the evolving/maturing market shaping role of Gavi, given the supply context over this period.

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 a better and well-rounded approach to markets and market shaping; and the HMF within this has been a seminal tool to encourage shared understanding and perspectives across partners. While Gavi will probably miss its target of six vaccine markets with moderate or high healthy market dynamics by 2020, there have been significant achievements in a number of markets (vaccine and non-vaccine), with important contributions through Gavi's market shaping work, including:

- new entrants in key vaccine markets, including PCV, rotavirus, MR and IPV, alongside a growing supply pipeline for several vaccines, with many of these market entries being a result of long-term support from Alliance partners;
- strong progress on price declines in key vaccine markets, especially penta, and to a lesser degree, rotavirus and PCV; in other markets the developments were more mixed, especially in markets with supply constraints where it was not possible to advance on price reductions (e.g. HPV, IPV and yellow fever);
- several improved vaccine products receiving WHO PQ and being procured by the Alliance, with PCV 4-dose products and new presentations for OCV being particular successes, and a direct result of Gavi's signalling to manufacturers;

[103] Gavi (2020). Gavi Annual Progress Report

- maintaining sufficient and uninterrupted supply across a number of vaccine markets, with marked improvements in yellow fever supply security, although other markets have witnessed several challenges (particularly HPV and IPV, and to a lesser extent rotavirus); and
- facilitating the phasing out of low-quality CCE and significantly increasing the uptake of high-performing products.

While these achievements have been significant, more work is needed to ensure that these 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 to date, partly on account of countries favouring incumbent products and general "vaccine stickiness" experienced in countries. The rotavirus market, despite the entry of two new manufacturers and new products coming to market, is expected to remain highly concentrated in the medium term. The PCV market may also see the exit of a key existing manufacturer in the near future, which could result in significant disruption in Gavi-supported countries unless appropriately managed. These nuances highlight the extremely challenging and dynamic context for the achievement of results in this area.

At the same time, there have also been some significant challenges in some markets, such as HPV and IPV, that have faced key issues with supply security, predominately due to the fact that supply capacity could not keep up with rapid demand expansion induced by WHO and Gavi policy changes.

The other significant achievement under the aegis of the Strategy has been with regards to VIPS, which has created considerable value by bringing about partner alignment and strategic coordination around vaccine innovation, with a conclusion on three critical innovations to be taken forward. VIPS has been espoused as best practice within the Alliance in terms of a model for coordinating and aligning partner views, as well as garnering country input for a global-level output. The other best practice area is with regards to externality monitoring, a unique and much praised endeavour within global market shaping organisations.

Further, at the global level, stakeholders have praised Gavi for its improved information sharing and coordination on market shaping, with industry noting that they have seen a marked improvement in how transparent the Secretariat has been during engagements over the period. There has been a strong working relationship between the Gavi Secretariat, UNICEF SD and BMGF, which has been considered as a cornerstone of the successful implementation of the Strategy and the positive market shaping outcomes seen.

Notwithstanding these successes and areas of progress, some of the key lessons learnt with regards to aspects that could have been done better, and need improvement upon going forward, include:

- There has been limited progress on the objectives and workstreams with regards to supporting country-owned decisions and building country 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, driven by the Secretariat and partner structures, where market shaping functions have not been well-coordinated with country teams. Countries have not fed into the design of the Strategy and its priorities, and country capacity building with regards to procurement, vaccine and non-vaccine decision making is a recognised area of weakness. There is limited linkage and understanding of Gavi market shaping priorities amongst countries and Secretariat/partner teams that support country engagement, with a core need for better information sharing on Gavi's market shaping work and key market developments.
- There is a need to think through the most appropriate HMF structure for CCE products to better capture both product aspects as well as installation, services and maintenance components. In addition, the drivers for country preferences for CCE and how this might be appropriately "shaped" warrants further reflection. In general, market shaping for CCE is at an earlier stage than for vaccines and as such there is a particular need to support demand shaping activities for CCE.

Further, recognising where Gavi markets are today as well as wider external developments, Gavi is well-positioned at this stage to consider the following for 5.0:

- The Strategy has helped facilitate understanding and progress on the supply-side of the market, but there is a need to evolve from this largely one-sided approach to cover both arms of the market i.e. demand and

supply. This is in terms of the Strategy as a whole and all its pillars and would warrant greater coordination within and across Secretariat and Alliance partners.

- While the endeavour to have a long-term view under the Strategy was a step in the right direction based on learning from the preceding strategy, how this has been set out in the Strategy is not adequate. There is also a need to strengthen components on long-term vision and strategic outlook in the roadmaps, to bring clarity on the "end-game" amongst partners and possibly also encourage more proactive market shaping.
- While not within scope for the current Strategy, the VIPS initiative needs to actively consider cost-effectiveness, financing and supply, in the next strategy period.
- While considered of much value by the Secretariat, partners, and the broader community involved in market shaping, there are specific suggestions for an improved second iteration of the HMF for 5.0.

These issues and forward-looking aspects are picked up in more detail in the next section on recommendations.

6.2. RECOMMENDATIONS FOR THE NEXT STRATEGIC PERIOD

Building on the positives and successes of the Supply and Procurement Strategy 2016-20, the following recommendations are proposed for the next strategic period in terms of: (i) strategy design and implementation; (ii) country capacity building and coordination; and (iii) global partnerships and coordination. As indicated above, many of the recommendations relate to building on the strengths of the current Strategy, and responding to the evolution of the market shaping function, rather than reforming areas of weakness, though some recommendations also relate to the latter.

For each recommendation, a brief summary on the key findings supporting the recommendation is presented upfront, followed by the detail of the recommendation. Indications on implementation responsibility and considerations for operationalisation are also included.

An important next step in implementing these recommendations would be for the Gavi Secretariat to consider prioritisation of relevant recommendations, in relation to available resources, and also clearly set out roles and responsibilities for different Gavi Secretariat teams and Alliance partners (building on the indications included here).

Overall, notwithstanding the range of recommendations described below to "do more", it would be important for the next strategy to be simple and relatively light-touch, avoiding complexity and inflexibility.

6.2.1. Strategy design and implementation

Recommendation 1: Build up the Strategy to be truly a "market" strategy, reflecting both demand and supply aspects

Summary of key issues

As noted throughout the findings and in the overall conclusions, the current Strategy has focused primarily on addressing supply-side challenges – e.g. in the HMF design (Section 3.1), the extent to which the HMF supported a holistic assessment of the markets, where the main gap is in terms of considering demand side issues (Section 4.1.2), and the review of successes and challenges in achieving market health, where issues with regards to country demand are identified for several markets (Section 5.1.2). Within the Strategy pillars, there is also an emphasis on meeting supply-side objectives, with the possible exception of the long-term view aspects, where although in the design of the Strategy, country-owned decisions were emphasised, during implementation this aspect of the strategy has been given lower priority and seen more limited results.

Recommendation detail

Building on the successes on the supply side of the market, and recognising that with these successes the time is also ripe to consider the demand side of the market better, a fundamental recommendation for the next strategic period would be to enhance the strategy to reflect both arms of the market – demand and supply. This would require a careful consideration of what specific demand-side attributes could be effectively incorporated, noting that the strategy itself is being implemented at the global cross-country level. Some relevant aspects include:

- **A more detailed consideration of country product and presentation preferences**, to consider drivers for these preferences in relation to the scientific evidence-base, and how best to guide country demand for new products that could offer real improvements in market health. This is particularly relevant in markets where IFPMA manufacturers are currently the main suppliers to Gavi countries, such as PCV, HPV and rotavirus, where as outlined in Section 5.1 there is evidence that some countries are not always basing product selection on what products would be most suitable to them in terms of long-term affordability, programmatic suitability and efficacy between different products. This is also relevant for CCE where countries require even more guidance regarding product choices. In this regard, a healthier demand where barriers to product switching are removed would support a healthier and more diverse supply landscape. More detailed and regular understanding of country product and presentation preferences should be incorporated into Gavi's market shaping activities, with the noted challenge of how to effectively gather this information from countries, as well as coordinate for this across Secretariat teams and partners.
- **A more "managed" or planned approach by the Alliance to scheduling of campaigns** across countries to help improve predictability of demand for campaign vaccines and therefore, supplier response. This is particularly relevant for markets such as yellow fever where, as noted in Section 5.1, lumpy demand continues to be a challenge, but also applies across other campaign-based vaccine markets. Profiling in this manner will require global level coordination and understanding of demand from countries, and as such will require multiple Secretariat teams within Gavi to work closely, alongside coordination with UNICEF and other implementing partners in countries, to determine the viability of different profiling of demand.

For both of the above, an appropriate balance in approach would need to be sought, which reflects the priority of country ownership and country-owned decisions, alongside a "pareto optimal" outcome for all countries globally. Value for money considerations on behalf of Gavi's donors also come into play here, especially in contexts where more affordable and suitable product alternatives exist. There may also be merit in conducting a risk-reward assessment to ascertain how best to incorporate these aspects within the next strategy – e.g. a full consideration of demand-side aspects across the strategy, or focused application on a few key areas such as campaign vaccines.

With regards to strengthening demand-side factors more generally within Gavi's market shaping strategy, it would also be important to continue to support improvements in demand forecasts that build on ongoing work to account for multiple factors, including country readiness, stock management, and complexity of immunization planning and management at the country level. As noted in Section 4.4.1, while improvements have been made in demand forecasting, several stakeholders, particularly industry stakeholders, would like to see greater clarity and communication around demand forecasts so that they are able to plan and supply markets effectively. While not the core focus of Gavi's market shaping work per se, the strength of the demand forecasts would contribute to stronger supply side and overall market dynamics.

Looking at demand from a more global perspective, and specifically building on findings discussed in Sections 4.1 and 5.1 across vaccine markets, there needs to be greater (and well planned/early) consideration of how rapid increases in demand, driven by global policies and/or eradication efforts, will impact supply.

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat, including Market Shaping, VI, IF&S and Country Programmes. **Secondary:** UNICEF, WHO (global, regional, country) and other country implementing partners for immunisation planning, product selection and demand forecasting at country level; countries more generally; Gavi PPC and Board for decisions on balancing country ownership and vaccine policy decisions (latter aspect also relevant for WHO).[104]
Select considerations	• Accessing relevant and timely information on country product and presentation preferences would require introduction of a system to effectively capture this information from countries. • Requires coordination across multiple Secretariat teams and partners, which can be challenging to implement. • Requires a careful consideration of how far "demand shaping" is aligned with Gavi's core principles on supporting country ownership.

Recommendation 2: Long-term considerations should be a guiding principle across all aspects of the Strategy, including planning for vaccine and non-vaccine markets and the operationalisation of the VIPS initiative

Summary of key issues

As discussed in Section 3.2, the evaluation has found that while incorporation of the long-term is a step in the right direction, its framing and operationalisation in the Strategy has been inadequate and represents an area for improvement.

Recommendation detail

Rather than describing a specific strategy pillar on long-term view, as has been the case in the current strategy, long-term considerations should be a guiding principle across the strategy in its next iteration. This would enable a more joint-up view of the long-term rather than considering as an independent objective.

While long-term considerations have been reflected in different components of the current strategy, we emphasise that going forward, the next strategy should make this a core focus and clearly bring out long-term considerations and implications. For example:

- **The strategy should articulate a long-term vision for Gavi market shaping work as a whole**, across markets and across initiatives, with a follow through in terms of how this is sensibly picked up through strategy M&E (SG related indicators or strategy-specific indicators, as appropriate).[105] While the strategy itself would be for the standard five-year Gavi period, there is merit in including a longer term (e.g. 10-15 year) vision, which would also need to align with the WHO 2020-2030 immunisation strategy.
- **The roadmaps in particular should elaborate on a strategic long-term vision** for all markets to guide active market-shaping, as the case may be. As noted previously, more recent roadmaps highlight some long-term objectives, which is a step in the right direction, and going forward, should provide timeframes for when

[104] More specifically – Gavi Secretariat for drafting the new approach to better reflect both arms of the market – demand and supply. Gavi Programme and Policy Committee (PPC) for the review of the enhanced strategy and Gavi Board for the strategic orientation and policy decision on balancing country ownership and global vaccine policy decisions.

[105] While it is recognized that Gavi's M&E framework as a whole is structured for its strategy period, additional monitoring that picks up longer-term impacts should be incorporated such as describing the proposed state of the market in the longer term and tracking milestone achievements along the way (both quantitatively and qualitatively), tracking an externalities (positive and negative), etc.

Gavi would hope to achieve moderate to high health in individual markets, and broad steps for how it will facilitate this. Where Gavi does not feel it is feasible to reach these levels of market health (i.e. because of individual market dynamics that would mean the Alliance has to invest significant resources for relatively modest changes in the market), the roadmaps should indicate what end-state the Alliance hopes to achieve in these markets in the long-term.

- **The approach to innovations should carefully consider long-term issues** in terms of what is needed to reach every child (i.e. the implementation and results following the availability of any new innovative product). This involves thinking through approaches to procurement, financing, timing, expected country demand and relevant markets for these innovations, incentives, etc.

Implementation considerations

Responsibility	**Primary**: Gavi Secretariat, particularly Market Shaping team, along with other key partners such as UNICEF, and BMGF. **Secondary**: Gavi Board for approval of market shaping role and objectives, WHO including SAGE for long term objectives.
Select considerations	Long-term considerations will inevitably evolve with changing market dynamics and evolutions in the vaccine landscape, including not only new vaccines and products but also changes in Gavi's role more broadly with countries transitioning from Gavi funding.

Recommendation 3: Adopt a more consolidated, joint-up and long-term approach to innovations in the next strategy

Summary of key issues

The evaluation has found that Gavi has made notable achievements in the context of incremental innovations and the VIPS work has been regarded as a key value-add that has achieved its intended objectives. Going forward, Gavi should work towards providing greater clarity on the innovation agenda within market shaping, in terms of how the various supported innovations fit within the "broader picture" of Gavi's aims for market health and overall strategy, and also consider the next stage of VIPS in terms of the use of the supported innovations.

Recommendation detail

This recommendation also links with the recommendation above, regarding a need to adopt a long-term lens on innovations in terms of considering country demand for specific innovations, planned procurement and financing approaches, as well as delivery issues. This relates to the VIPS initiative in particular which, while not in scope for the current strategy, requires detailed consideration going forward. It also relates to the set of incremental innovations where country uptake needs to be considered upfront.

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat, particularly Market Shaping **Secondary:** Alliance Partners
Select considerations	No specific aspects to highlight.

Recommendation 4: Integrate approaches within the strategy that more closely consider the wider ecosystem within which Gavi's market shaping work functions

Summary of key issues

The evaluation has highlighted the need for Gavi and its Alliance partners to consider how its market shaping activities in individual markets affect, and are affected, by the wider landscape in which these activities are implemented. For example, as discussed in Section 4.4.1, the roadmaps have only focused, to a limited extent, on the how manufacturers in certain markets can be affected by outcomes in other markets in which they operate. Our review of the externalities work in Section 4.2.2 also highlighted that the next steps for this work could be to consider implications of activities in non-Gavi markets within Gavi's market shaping work. Section 5.1 on review of results by individual vaccines highlights the need to consider the wider eco-system across the piece.

Recommendation detail

As Gavi's strategy and approaches as a whole progress under 5.0, and its market shaping function in particular matures further, the following should be considered for a more comprehensive approach:

i. **Evolve from a vaccine by vaccine approach to consider the manufacturing portfolio as a whole and how this may impact individual vaccine markets.** This includes closely monitoring supplier health across the portfolio (particularly DCVMs), i.e. go beyond vaccine specific roadmaps to consider tracking/analysing supplier strategies and market landscape in terms of issues impacting multiple suppliers, potential supplier exits (e.g. if business sustainability is affected when procurement awards are not made), etc. This would also apply to the CCE market, where there are multiple suppliers, although Gavi mainly procures from three large suppliers.

ii. **More deeply consider non-Gavi markets, in terms of HICs and MICs, and their implications on Gavi markets**.[106] This includes both understanding in more detail individual manufacturer strategies in MICs and HICs, alongside a more explicit and conscious consideration of evolving market dynamics in HICs and MICs within Gavi's assessments of market health and roadmap process (including the rollout of vaccines in these countries, key MIC and HIC tenders, the role of non-Gavi manufacturers in these markets and how they might affect Gavi markets, etc.).

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat, particularly the Market Shaping team **Secondary:** Alliance partners (particularly UNICEF and BMGF), WHO
Select considerations	• Understanding non-Gavi markets, as well as portfolio-wide strategies of manufacturers is likely to require additional resources and staff time. • Detailed understanding of each manufacturer's internal strategies may be difficult to obtain without extensive, ongoing engagement.

Recommendation 5: Incorporate key updates to the next iteration of the HMF

Summary of key issues

As discussed in Section 3.1, the HMF has been regarded as an important, well developed and much needed framework for assessing market health, with the need to consider improvements in identified areas in its next iteration.

[106] Data on vaccine market estimates in industrialized countries are regularly published by country, product, manufacturer, and year by market intelligence firms such as IQVIA/IMS, SCRIP, marketwatch, Mordor, datamonitor,etc. These estimates are to be considered with great cautions but may be helpful after checking and compared to other sources. Information and data on MICs are relatively well covered by MI4A's work but could be improved with closer collaborations with regional offices of WHO and UNICEF particularly in MENA, Europe Asia and Latin America regions.

Recommendation detail

Noting the several positives, Gavi should consider the following with regards to the next iteration of the HMF:

i. **Stronger linkage with demand**, whether incorporated in a simplistic manner as an additional attribute, or included within existing attributes (e.g. expanding the attribute on "meet country preferences" to better reflect issues with country preferences and switching), or linked with a demand side "dashboard" that comprehensively captures key issues.

ii. **Potential reworking for CCE products**. In particular, further differentiation should be provided to better capture both the product aspects as well as the broader service package components of CCE.

iii. **Improved definitions and assessment approaches for all attributes to facilitate coordinated assessment.** The assessment scale in particular could be reworked, to better capture market nuances by not applying a standard set of criteria across markets to award improvements in health. For example, rather than a traffic light scoring, a quantitative scoring, coupled with clear explanations/definitions for how HMF attributes should be scored, may be appropriate.

iv. **Tighter definition and measurable approach to TSE** – while some have opined that the TSE attribute should be excluded all together, we view it as an important attribute with further work needed to aid its assessment. A simplified measurement approach that includes aspects that can be well captured/quantified and consistently applied across markets should be considered. Evidence towards measuring TSE should be gathered from all relevant partners e.g. WHO, CHAI, countries, etc.

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat, particularly the Market Shaping team **Secondary:** Alliance partners (particularly UNICEF and BMGF) and WHO in relation to TSE work
Select considerations	• Agreement on the specific nature of how updates are incorporated into the HMF will require a consultative process and agreement between Gavi Secretariat Market Shaping team and the key Alliance partners. • Updates to the HMF will also need to consider whether additional complexity should come at the expense of it providing a high-level and digestible snapshot of market health to external stakeholders.

Recommendation 6: Incorporate suggestions for improvements in the development of roadmaps

Summary of key issues

As highlighted in Section 4.4.1, while a broadly functional and effective process, there are some areas for improvement in the roadmaps process.

Recommendation detail

In particular, the following options should be considered to further enhance the effectiveness of the roadmaps:

i. In line with recommendation 2, ensure that roadmaps include a long-term strategic vision for the markets.[107]

ii. Continue to follow more recent roadmap processes and structures that have adopted a more streamlined approach.

[107] We note that some of the more recent roadmaps are being developed with some of the above in mind.

iii. Conduct annual updates of short-term roadmap sections (including short-term TOs) to remain relevant (including aligning with tenders).

iv. Expand the approach to more formally/deeply consider implications of wider ecosystem for Gavi markets – specifically interconnected markets with HICs and MICs. See recommendation 10 below for additional aspects in this regard.

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat, particularly the Market Shaping team **Secondary:** Alliance partners (particularly UNICEF and BMGF)
Select considerations	In the context of the need to more regularly update the roadmaps, Gavi will need to ensure mechanisms are put in place so that updates are simple to make and do not become overly burdensome for the Market Shaping team nor the Alliance partners involved in the processes.

Recommendation 7: Consider additional processes and metrics to improve the monitoring and evaluation of the activities and results of the Strategy

Summary of key issues

As highlighted in Section 5.4.2, the M&E framework for the 2016-20 period has been able to effectively track developments on some aspects of the strategy, but in many areas, the activities, outputs and outcomes have not been comprehensively and systematically monitored.

Recommendation detail

Gavi should incorporate the following with regards to M&E:

i. **Develop a ToC framework** for the strategy that effectively captures key activities of Gavi's market shaping work and links these to the desired outputs, outcomes and ultimate impacts.

ii. Based on this ToC, **develop a series of more detailed indicators that pick up the scope of the strategy**, (including centrally/systematically tracking interventions set out in the roadmaps) and then ultimately linking with a smaller set of strategic indicators for Gavi's overall market shaping goal (SG4). That is, we specifically recommend that the Market Shaping team include a detailed M&E framework to be used internally to monitor progress, recognising that the SG4 indicators are high-level and do not cover the full scope of the Strategy.

iii. **Supplement quantitative indicators with relevant qualitative assessments** to better bring out the nuances of different markets. This could include enhancing quantitative metrics with market context (e.g. in cases where price declines have been limited, providing context that might help explain results achieved, such as the presence of long-standing monopolies or where price declines are not a primary objective, better bringing out key aspects of supply security related to an assessment of "true competition").

iv. **Rolling in the assessment of counterfactuals within the M&E framework** as a better measure of success in the context of the complexity and dynamics of market developments. This would specifically involve identifying what the Gavi believes would happen across markets should they not undertake activities and achieve certain outputs prioritised in the Strategy, and comparing key outcomes with these counterfactual scenarios (recognising the inevitable variability of outcomes and that they are driven by a wide range of factors). An example of where Gavi has done this within its market shaping work includes the baseline assessment carried out as part of the AMC for PCV.[108] While it is unlikely to be feasible to undertake detailed counterfactual of all of Gavi's individual interventions as was done in this context, there may be some useful

[108] Swiss Centre for International Health (2010), Baseline Study for pneumococcal vaccine AMC.

lessons that Gavi can draw from this in how it applies counterfactual analysis more widely, even if this is carried out at a higher level, or for the most significant interventions made.

v. **Define indicators more comprehensively and to reflect desired objectives.** For example, in the context of the innovations work, the indicators should measure progress both with regards to incremental innovations as well as the work being undertaken through VIPS. For incremental innovations in particular, the focus should be on measuring the extent of rollout, as opposed to development, given that uptake is the ultimate aim for introducing them.

vi. **In terms of monitoring externalities**, we recommend that this practice is continued under 5.0, with a greater effort to link up with the overall strategy in terms of incorporating learning from the monitoring to inform future directions and actions (in line with Recommendation 4), define indicators and data sources clearly upfront, and include qualitative assessments where beneficial.

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat, particularly the Market Shaping team **Secondary:** Not applicable
Select considerations	• An appropriate balance will need to be struck between improving monitoring of activities, while not overburdening the Secretariat teams. • In some cases, there may be challenges with aggregating quantitative indicators across markets to provide an overall picture of progress, given differences in individual market dynamics as well as the activities undertaken by the Alliance within them.

6.2.2. Country capacity building and coordination

Recommendation 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

Summary of key issues

As noted in Sections 3.4.2 and 4.2.1, the extent to which countries have been engaged in Gavi's market shaping work, and the progress on implementing activities linked to country-owned decisions has been more limited compared to other areas of the Strategy. In some respects, continuous engagement of countries in such aspects may not be appropriate, but throughout the evaluation both global and country stakeholders emphasised the need for more engagement with countries to input into and understand Gavi's work on market shaping. This would enable a closer linkage between what countries see as priorities and what is being implemented through Gavi market shaping, as well as better inform countries on market shaping overall which would enable them to be better prepared for transitioning form Gavi support.

Recommendation detail

With regards to some of the issues identified in the evaluation on country engagement and capacity building, the following range of recommendations are proposed. Many of these are beyond the direct scope of work of the Gavi Secretariat Market Shaping team and will involve other Secretariat teams to take lead responsibility alongside Alliance Partners.

i. **Develop a formalised process for countries to input into any lessons learnt** from the current Strategy and priorities for the next. Consider the most effective way of doing this in consultation with other Secretariat teams and Alliance partners working at the country level.

ii. **Work more actively to ensure better socialisation of market shaping objectives**, activities and results within the Gavi Secretariat, and especially with country facing teams. And further, develop mechanisms to ensure flow of this information to countries, especially where transition is in the horizon.

iii. More generally, **build up better and more coordinated systems with regards to the market shaping** and country sustainability functions within Gavi Secretariat and also with the Alliance partners.[109]

iv. **Systematically organise capacity building work with regards to country decision making and procurement of vaccines and CCE** in terms of available tools and resources and delivered to countries. This should be carried out in close coordination with NITAGs and NRAs who should be included and involved in the capacity building efforts supported by Gavi and made more aware about the implications of their recommendations and actions on vaccine market shaping and vaccine security at global and national level. Particular areas for further work include issues related to vaccine switching, vaccine introduction and forecasting, cost effectiveness analysis, vaccines for campaigns, assessing vaccine procurement performance, vaccine pipeline, guidance about recommended immunisation schedules, new vaccine delivery technology, fast track regulation procedures, mutual recognition of registration, exchange between NITAGs and NRAs on best practices and common tools.[110]

v. **Support the provision of technical assistance in the areas of local vaccine production and regulatory oversight,** for key countries such as India, Indonesia, Nigeria, etc., aiding a reduction in their need to utilise international supply. Also provide technical support to India to get their testing authority able to certify their locally produced CCE as meeting WHO PQ standards.

vi. **Consider relevant approaches for price stability for transitioning countries alongside wider coordination with MICs,** in order to better reflect country contexts within the market shaping function. At a minimum this would entail ensuring better/regular communication around market shaping developments with countries, greater predictability and consistency (rather than ad hoc) approaches across transitioning MICs.

Implementation considerations

Responsibility	**Primary:** (i) and (ii) could be led by the Secretariat Market Shaping team, in consultation and coordination with other Secretariat teams including country facing teams. (iii) and (vi) also needs a key role of the Market Shaping team, but in joint working with IF&S and Country Programmes. All of these would also involve Alliance Partners, including regional offices. The remaining points are largely beyond the scope of the Gavi Secretariat Market Shaping team, but would benefit from their pushing forward with other implementers (i.e. other Secretariat teams, Alliance Partners) to support achievement of overall market shaping objectives. **Secondary:** To be considered in relation to the detail described above.
Select considerations	We appreciate this is a "heavy" recommendation to implement with a lot of past and ongoing work amongst Secretariat and Alliance Partners, and as such will require careful consideration of who should be the responsible parties for implementation and how these would be effectively implemented.

6.2.3. Global partnerships and coordination

Recommendation 9: Build on current successes in partnerships with key stakeholders, while expanding coordination with other market shaping stakeholders where relevant

Summary of key issues

As highlighted throughout our findings, Gavi has made improvements in its coordination with several stakeholders involved in market shaping during the implementation of the Strategy, with coordination between Alliance partners

[109] As discussed in Section 3.4.1, this is similar to one of the key recommendations made for the Global Fund in its recently TERG commissioned review of its market shaping function.

[110] This is also similar to one of the key recommendations made for the Global Fund in its recently TERG commissioned review of its market shaping function.

highlighted as being a particular area of improvement. While these improvements were welcomed by stakeholders, there are specific areas where further coordination and engagement would be welcomed to support the functioning of Gavi's market shaping work, particularly in with regards to engagement with manufacturers and global partners beyond UNICEF and BMGF.

Recommendation detail

Continue to support improved working and coordination with key partners for the market shaping strategy including:

i. **ensure and improve regular engagement/updates with manufacturers** and their representatives (with relevant Alliance partner responsibility) – including regular formalized engagements in addition to the ongoing ad hoc engagements and facilitating manufacturer and country communication;

ii. **improve alignment and communication on demand forecasting and vaccine introduction** to ensure manufacturers have more clarity around developments and can plan accordingly;

iii. **continue to improve coordination between Secretariat and Alliance Partners on market shaping work**, and in particular ensuring unified and coordinated engagement with industry and countries;

iv. **ensure a closer coordination with WHO** especially regarding policy recommendations that expand demand, regulatory challenges for manufacturers and TSE;

v. **consider engaging additional partners on a more formalized basis** when relevant and there is a clear added value within the market shaping function e.g. CEPI, FIND, CHAI, PATH, etc.; and

vi. **consider if there are any key learnings given the experiences under the COVID-19 vaccine development** in terms of partnerships between manufacturers and with biotech and universities.

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat Market Shaping team, UNICEF, BMGF especially for the industry partnerships, and in coordination with Secretariat and Alliance country facing/country teams for the country engagements. **Secondary:** Manufacturers and country stakeholders.
Select considerations	No specific aspects to highlight.

Recommendation 10: Move away from approaching vaccines as a vertical intervention, with better coordination with other global partners on key cross-cutting issues particularly with regards to the challenges posed by country regulatory requirements

Summary of key issues

Dynamics in individual vaccine markets are clearly the primary drivers of market outcomes, but the evaluation has also highlighted that manufacturers face considerable challenges with regards to regulation and country registration, which in turn impact their ability and willingness to supply Gavi-supported countries, and at affordable prices. For example, this is highlighted as an important barrier in the results assessment for several vaccines in Section 5.1. NRA capacity is a key attribute within the HMF framework and can be an important issue especially for vaccines where supply is concentrated in select countries.

These challenges are not unique to Gavi-supported markets and indeed are wider issues that affect all health commodity markets. Section 3.4.1 on lessons from the Global Fund market shaping work also brings out the need for considering such issues and also coordinating with other partners in this regard. It is recognised that across organisations this issue is beyond the direct scope of the market shaping function per se.

Recommendation detail

This recommendation is wider than Gavi's market shaping function but has implications for the success of it. As such, we recommend that the following be considered, in conjunction with the priorities and work of partners and other related organisations working on market shaping:

- **Coordination with WHO PQ and NRA strengthening work** to ensure better information and support for suppliers. This may also include working with WHO to provide technical support to India to get their testing authority able to certify their locally produced CCE as meeting WHO PQ standards.
- **Coordination with WHO, Global Fund, USAID and other relevant stakeholders** on strengthening country pharmaceutical and vaccine regulation. More generally, coordinated and leveraged working may be considered for a range of other issues such as country procurement and supply chain management capacities.
- **Information sharing on approaches and best practices** across different market shaping organisations in the global health architecture.

Implementation considerations

Responsibility	**Primary:** Gavi Secretariat, particularly Market Shaping team in close collaboration with WHO, UNICEF SD, Global Fund, USAID and other relevant stakeholders
	Secondary: Not applicable.
Select considerations	This is a challenging recommendation to implement given the dynamics of how coordination works across these organisations. Discrete actionable projects may be considered within the wide scope of the recommendation outlined above.

6.3. GAVI MARKET SHAPING IN THE LONG TERM

Looking beyond the set of recommendations provided above for the next strategy period, our views on key issues for Gavi to think about over the longer term include aspects such as:

- The expected rise in vaccines developed and produced by and in China, and what this would entail in terms of working with Chinese manufacturers, regulators and policy makers as well as working with countries to accept, adopt, and register Chinese PQ products. Lessons from the first Chinese PQ vaccine (JE) would be useful to monitor in this regard.
- Potential availability of vaccines for communicable diseases such as malaria, TB and HIV in the future, and implications for Gavi in terms of coordination with the Global Fund, UNAIDS and others.
- The country transition pipeline means that Africa will be the main beneficiary for Gavi in the next ten years, while there is no vaccine development and production capacity in the continent (except yellow fever at the Pasteur Institute in Dakar Senegal with a heavy technical support from PATH and funding from Gavi and BMGF). Implications of this on country and manufacturer portfolios in the future may need to be considered.
- Intellectual property (IP) is one among many factors delaying development and production of required vaccines for Gavi countries. With newer vaccines, patent applications tend to cover many aspects including starting materials, composition, process technologies, and methods of using vaccines, including age groups, vaccine presentations and schedules. The Medicines Patent Pool (MPP) and other UN organisations are developing tools and mechanisms to ease collaboration and better management of patent issues in the case of essential and new medicines, particularly for HIV and TB drugs. Gavi may consider if there is any appetite for exploring options in the case of vaccines considered as public goods and or lifesaving products, e.g. commission further studies on priority new vaccines identified by WHO/SAGE and VIS to better understand the role of IP vis a vis encouraging competition, access and potential "real world" solutions. This could be done in parallel to a more active effort to facilitate technology transfer and access to new technologies for DCVM.

- The current experience of COVID-19 (and the potential for future epidemics as well) brings to fore the need to consider Gavi's market shaping role in relation to epidemics. Lessons from the ongoing work on the Covax facility would be critical in this regard.

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