Gavi, the Vaccine Alliance:
Supply and Procurement Strategy 2016-20

Executive Summary

Four strategic goals guide the mission of Gavi, the Vaccine Alliance. Its fourth strategic goal (SG4) is to shape markets for vaccines and other immunisation products to the benefit of the countries that Gavi supports.

During 2011-15, Gavi made considerable progress on its market-shaping goal, including increased supply security and reduced prices in several key vaccine markets through successful approaches such as vaccine 'roadmaps' and the refinement of strategic demand forecasts. Procurement partners used different mechanisms to pursue sustainable prices and reliable supply, although challenges remain in some vaccine markets. The market landscape has evolved significantly since 2011; the manufacturer base has diversified and Gavi's vaccine portfolio has doubled from 6 to 13 vaccines[1].

The Alliance is well-positioned for 2016-20 to take bolder action across existing and new product markets, and to manage higher levels of risk for potentially greater gain. In 2016-20, the Alliance will continue to deploy successful tools that have yielded results thus far, while also improving key processes such as procurement decision-making and coordination among partners. In addition, Gavi's market-shaping activities are expanded to other immunisation products such as cold chain equipment. Most importantly, three priorities define the new strategy.

First, in this next strategic period, the Alliance has set more ambitious goals to shape markets, taking a holistic view of 'healthy markets' beyond narrower objectives such as the number of suppliers or vaccine price. The Alliance will advance a more comprehensive vision of a healthy market, recognising that individual markets are at different stages of evolution, requiring tailored approaches to address unique market needs while continuing to challenge assumptions about the impact of market interventions. To hold itself accountable in this area, the Alliance will measure success in terms of improved healthy market dynamics for vaccines and other immunisation products.

Secondly, the Alliance will apply a longer-term view to market-shaping activities, recognising the potential impact of its interventions on markets and countries in the longer term, with a particular focus on market conditions for countries transitioning out of Gavi support. Complementing activities under its third strategic goal (SG3: 'improve sustainability of national immunisation programmes'), the Alliance will seek to share market-shaping tools and strengthen coordination with partners who regularly engage with middle-income countries.

Thirdly, the strategy defines the Alliance's role in product innovation to contribute to Gavi's ambition to significantly advance coverage and equity. In particular, the Alliance will strive to accelerate innovation in products that better suit country needs through alignment of partners around common definitions, development of an analytical framework to evaluate the financial and non-financial benefits of new products, and clear communication of the Alliance's priorities.

This document sets out the strategic framework to deliver on these ambitions. It highlights accomplishments and lessons learned in the past strategic period; external and strategic developments affecting market-shaping going forward; desired outcomes and new strategic priorities for 2016-20; strategic enablers to deliver on these aspirations; and the approach to monitoring and evaluation.

[1] Vaccines supported include: Pentavalent (diphtheria, tetanus, pertussis, hepatitis B, Haemophilus influenzae type B), pneumococcal conjugate, rotavirus, human papillomavirus, inactivated polio, meningococcal A conjugate, meningococcal ACYW polysaccharide (stockpile), Japanese encephalitis, measles, measles-rubella, yellow fever , oral cholera (stockpile), Ebola virus (stockpile) vaccines.

Structure of this document

Introduction

In well-functioning markets, supply meets demand; products are of high quality and available presentations meet country preferences; supply is consistent, timely and reliable as regulatory processes are efficient and potential risks related to individual suppliers are minimised; manufacturers have resources, information and incentive to overcome barriers to enter and compete in the market; customers consider cost comprehensively, that is, beyond price per unit; and product innovation is incentivised. Underpinning these attributes is a clear flow of information between stakeholders that conveys reasonable certainty around demand, supply, and cost to all parties involved.

Market forces do not always serve low-income countries well. Uncertain financing and demand for vaccines and a consequent lack of manufacturer incentives to supply suitable products at an affordable price for these countries have historically resulted in a long lag time between availability of new vaccines in high-income countries and availability in low- or lower-middle income countries.

Gavi was created to address these market failures, to dramatically increase access to life-saving vaccines in these countries and to accelerate the development and availability of vaccines for which there is no market in high-income countries.

Gavi's investments in large-scale procurement of vaccines were envisaged as time-limited and catalytic, enabling a rapid transition of Gavi-supported countries from external support to independent financing of affordable vaccines in a transformed market. However, lessons learned from the first 10 years of Gavi's existence (2000-2010) suggested that market forces alone would not sufficiently improve supply security and pricing for low-income country markets, and more active influence on Gavi-supported vaccine markets was required.

Drawing from these lessons, Gavi shifted to a more explicit and proactive approach to shaping vaccine markets with the development of a strategic goal on shaping markets (SG4) and the 2011-15 Vaccine Supply and Procurement Strategy. As Gavi enters the 2016-2020 strategic period, important lessons have been learned from the past five years of active market-shaping. Shifts in strategic focus, such as increased effort to improve coverage and equity and apply tested market-shaping approaches to new areas like cold chain equipment, drive other elements of change in the new Supply and Procurement Strategy for 2016-2020.

1. Review of the 2011-15 Strategic Period

1.1 Accomplishments

In 2011-15, the Alliance made notable progress on its market-shaping objectives:

- **Supply:** Gavi surpassed its set target of 24 products[2] for the number of vaccines offered to UNICEF for procurement (25), meaning that the Alliance was able to identify and attract new entrants with suitable products in several markets (most notably, for pentavalent vaccine). Countries experienced no disruptions in routine immunisation despite some supply constraints and interruptions. This was achieved while significantly increasing scope and volume, including six new vaccines in Gavi's portfolio.[3]
- **Cost:** the Alliance was successful in bringing down the weighted average vaccine price per child to fully immunise with pentavalent, pneumococcal conjugate and rotavirus vaccines from US$35 in 2010 to US$20 in 2015, a 43% reduction.
- **Suitable products:** this period saw important improvements in product suitability: the transition from lyophilised to liquid pentavalent eliminated the need to mix vaccine components, reducing time needed to administer the vaccine, and saving space in the cold chain. Additionally, the first vaccines labelled for use in a controlled temperature chain (CTC) were prequalified, allowing for example meningitis A campaigns to be conducted without reliance on traditional cold chain infrastructure.
- **Information:** Transparency and information sharing improved over time. By 2015, one hundred percent of awarded prices were published on time on UNICEF's website with manufacturers' agreement. During this period, the Alliance also routinely shared strategic demand forecasts, UNICEF market updates and public roadmaps with partners, including industry, to improve visibility into market dynamics.

During this period, the Alliance put in place various processes and tools that laid a strong foundation for market-shaping.

- One such example of a foundational tool is the vaccine supply and procurement '**roadmap**'. Roadmaps articulate individual product strategies and are designed to direct Gavi's actions within specific markets to align market-shaping objectives and product strategies across the Alliance partners, and to inform procurement decisions. As of 2015, Gavi has developed roadmaps for ten vaccines.[4] Roadmaps are intended to be updated on a regular basis before new strategic procurement activity.

[2] *Number of novel presentations for each antigen*

[3] *Japanese encephalitis, human papillomavirus virus, measles-rubella, and inactivated poliovirus vaccine programmes; and stockpiles for oral cholera and Ebola virus vaccines were added in the 2011-2015 period.*

[4] *Roadmaps have been developed for pentavalent, pneumococcal conjugate, rotavirus vaccine, human papillomavirus, inactivated polio v, meningococcal A conjugate , Japanese encephalitis, measles-containing, yellow fever , and oral cholera vaccines.*

- Gavi's demand forecasting function has served as another enabler to provide a consolidated view of required dose volumes. Since the introduction of the **Strategic Demand Forecast**, designed to project longer-term demand, Gavi has evaluated and refined the methodology to improve accuracy. Gavi has also initiated improvements in country-level short-term forecasting and stock management to enhance the accuracy of country requests in line with actual vaccine needs.
- UNICEF continued to lead tender preparation and execution for most of Gavi's vaccine **procurement**.[5] To achieve market-shaping objectives, UNICEF used different procurement and contracting approaches, including pre-tender activities (eg, annual industry consultations), buying models (eg, 'hybrid' model[6]), procurement tactics (eg, leaving doses unawarded) and negotiation tactics and contract terms (eg, staircase pricing[7]). These practices have succeeded in improving the health of markets such as pentavalent vaccine, where Gavi and UNICEF have attracted new suppliers and significantly reduced the weighted average price.

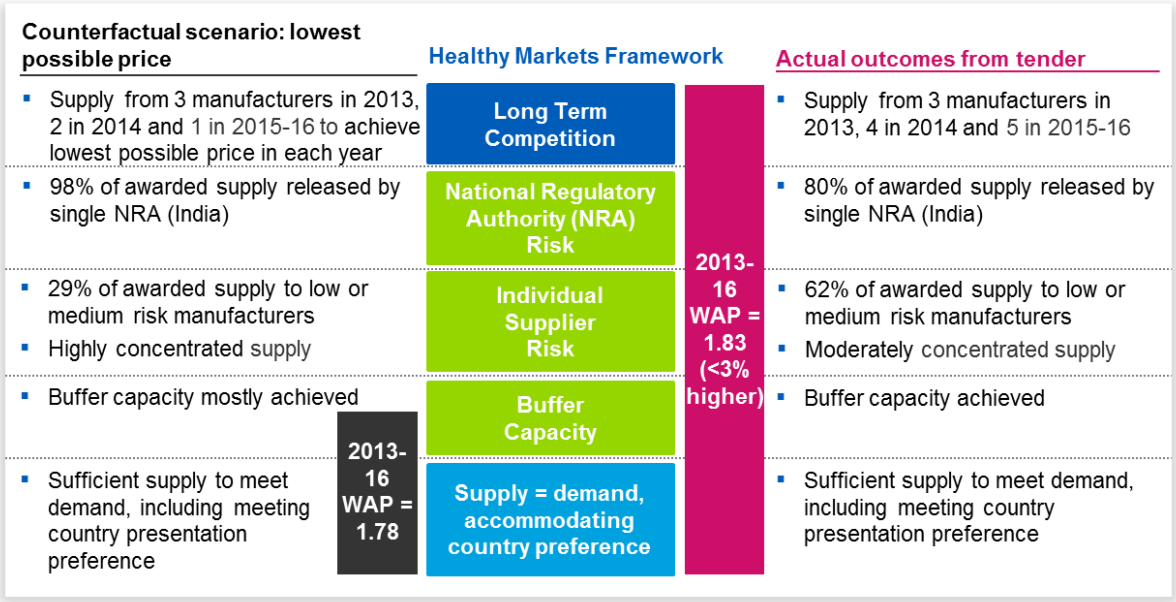
The pentavalent market demonstrates both the increasing complexity and sophistication with which the Alliance approaches markets. Figure 1 highlights the outcomes of the strategic procurement approach (eg, retention of un-awarded quantities in the initial tender awards) to the pentavalent tender for 2013-2016. This approach resulted in the achievement of a higher level of healthy market dynamics by improving supply security and long-term competition (eg, with new market entrants), and a projected weighted average price that was $0.05 per dose higher compared with the counterfactual of choosing only the lowest possible prices. Overall, due to other market factors including increased use of multi-dose vials and volume guarantees, there was a reduction in the weighted average price (WAP) per course from US$ 7.47 in 2011 to US$ 5.04 by 2015.

[5] For Gavi-supported countries in Latin America - namely Honduras, Nicaragua, Haiti, Guyana and Cuba - the Pan-American Health Organisation (PAHO) procures vaccines through the Revolving Fund.

[6] A hybrid model is a combination of some aspects of other models, such as the single-round, multi-round, and direct negotiation buying models. For example, a hybrid model could incorporate the manufacturer submission of one formal bid, which would then be followed up with specific manufacturer negotiation once the initial bids have been reviewed.

[7] A supply agreement signed with the manufacturer which included volume-dependent pricing, providing the potential for lower pricing when certain volumes were reached.

Figure 1. Comparison of lowest-possible price scenario with actual outcomes of procurement tender for 2013-2016.[8]



1.2 Lessons learned

Important lessons were learned through implementation of the 2011-15 strategy. While the overall **objectives** of balancing supply and demand, minimising cost and supporting the development of suitable products provided a useful framework for identifying outcomes and interventions to pursue within vaccine markets, some areas of improvement remained:

- The *cost objective* maintained a narrow view on minimising price rather than taking a broader consideration of value such as costs related to delivery and administration.
- Less progress was made in driving *innovation* to increase the number of suitable products, in part due to the prioritisation of supply security and achievement of appropriate and sustainable prices, and a lack of clarity on Alliance prioritisation of preferred product innovations and strategies to pursue these.

There was also a lack of consistency in how market-shaping objectives for specific vaccines were prioritised and translated into target outcomes, and a lack of transparency around the process of developing market interventions to achieve those outcomes. While there is no one-size-fits-all approach to making vaccine markets 'healthy', failure to define this concept more specifically has implications for the Alliance and its relationship with manufacturers and other market-shaping actors, such as the potential confusion generated for manufacturers when Alliance partners are not consistent or clear. Trade-offs could also be more systematically managed to consider long-term consequences on market health.

Inadequate synchronisation of activities and insufficient transparency of information. While roadmaps are intended to guide decision-making on supply and procurement activities, in practice, due to resource constraints, most roadmaps were not developed until after or coincident with the corresponding procurement tenders. As a result, there was lack of alignment between partners on the

[8] *Outcomes of the pentavalent tender period for 2013-2016 were assessed using the Healthy Markets Framework, which is described further in Section 4.1.1 and Annex G. Per the framework, specific desired attributes were prioritised and procurement was tailored to achieve those attributes. The Healthy Markets Framework makes explicit the trade-off (in this case, a slightly higher price) that was needed in order to achieve this higher state of 'market health'.*

priorities and market-shaping objectives articulated in the roadmaps and UNICEF's Procurement Strategies.

Lack of clarity around actors and their coordination. While the roadmap process has strengthened coordination, there is scope for further improvement in defining which actors own or are responsible for specific interventions and in creating clarity around decision-making processes of core partners. For example, stakeholders reported a relative lack of visibility into the procurement decision-making process, including around assessed procurement scenarios and rationale of the award decisions. Additionally, several aspects of the Alliance's engagement with industry could be enhanced, including on communication of roles and responsibilities, consistency in communication of Alliance priorities to industry, and balanced communication of market-shaping results.

The yellow fever vaccine market illustrates the **importance of a long-term strategy**. Despite being a mature market with multiple suppliers, yellow fever vaccine supply has not been able to meet demand, in part due to sharp increases in demand generated by Gavi's investment decision to support campaigns. Additionally, low pricing may have been a barrier to incentivise manufacturers to make timely investments to generate sufficient and reliable supply. Other manufacturers might have lacked the capability to increase supply without external support. This highlights the importance of considering capacities and risks on an individual manufacturer basis in addition to assessing global risks and supply and demand trends within a vaccine market.

2. Desired Outcomes in the 2016-20 Strategic Period

In this next strategic period, Gavi looks to achieve the following:[9]

- 'The **healthy markets**[10] objective': the Alliance will have achieved moderate or high levels of 'healthy market dynamics' in six markets. While the individual objectives of this Strategy are of importance within specific markets, they only measure one characteristic amongst several that collectively create an overall picture of 'market health'. In 2016-20, the Alliance will focus on a more comprehensive and longer-term vision of a healthy market.
- Additionally, as key singular outcomes of interest within specific markets, Gavi has also set targets in terms of supply, price and innovation:
    - Ensure adequate and secure supply ('the **supply** objective'): eleven Gavi vaccine markets have sufficient and uninterrupted supply. Ensuring that countries can sustainably administer vaccines requires that sufficient supply of vaccines is available to meet demand from Gavi-supported countries without interruption.
    - Reduce prices to an appropriate and sustainable level ('the **cost** objective')**.** The weighted average price per child to fully vaccinate with pentavalent, pneumococcal and rotavirus vaccines – the three largest vaccine purchases of Gavi – decreases.[11]
    - Incentivise development of suitable and quality products ('the **innovation** objective'): ten innovative products, with measurable improved characteristics that advance progress on coverage and equity and meet country needs at a sustainable cost, are included on the menu of products offered to countries.

[9] Gavi's overall strategy describes four indicators to measure progress against strategic goal four. Further details can be found in Annex D.

[10] Markets are assessed as having no, low, moderate, or high 'healthy market dynamics', defined and measured through the Healthy Markets Framework, which is described further in section 4.1.1 and Annex G.

[11] Price targets are not publicly disclosed in order to avoid unintended consequences (e.g., setting price ceilings)

3. Developments Influencing the 2016-20 Supply and Procurement Strategy

3.1 Evolution of Gavi's strategic direction and market shifts

Gavi's strategic direction and objectives have evolved, impacting the priorities and scope of market-shaping activities. The emphasis on coverage and equity in Gavi's 2016-20 strategy affects the relative prioritisation of market-shaping objectives (eg, potentially favouring products that can achieve breakthroughs in coverage even if they come with higher prices). The new strategy also extends market-shaping to other immunisation products and specifically cold chain equipment (CCE), given its importance to immunisation delivery and opportunities for Gavi to help countries strengthen their supply chains.

Gavi-supported countries are starting to transition from Gavi support as their Gross National Incomes (per capita) surpass the eligibility threshold. By 2020, it is projected that 19 countries will have transitioned from Gavi funding, and will have assumed full responsibility for vaccine financing. As countries enter transition, they are expected to begin taking more active roles in selecting their preferred product (further discussed in section 4.2). Greater country choice, such as a preference for a lower-priced product, has implications for how the Alliance balances market-shaping objectives to achieve healthy markets.

Beyond Gavi's evolution, the vaccine market landscape has also evolved significantly since 2011. Several important changes now influence the supply and procurement objectives and market-shaping activities:

The manufacturer landscape is diversifying, and so is the pipeline of new products. In addition, improvements on existing products (eg, lower multi dose vials for certain vaccines) have been developed and more transformative innovations (eg, vaccines that extend serotype coverage) are expected. Some of these products could offer higher value (eg, improvements in effectiveness) or improved coverage. With these improved products, there is a new impetus for the Alliance to evaluate and incentivise innovations (further discussed in section 4.3).

Markets evolve at different rates and often on different pathways, with important implications for market-shaping priorities across the portfolio. For example, the pentavalent vaccine market is in a healthier state, having achieved several of the desired attributes within this market, such as stable, sufficient and diverse supply and more sustainable prices. For other markets, different challenges might persist in their evolution towards improved health based on their specific market needs. For example, in the PCV market, technical complexities are limiting the pace of new vaccine development.

Emerging diseases and outbreaks are rising in importance on the global health agenda. Outbreaks of known diseases, such as meningitis, yellow fever and cholera, continue to impose a high disease burden which could be substantially reduced through improved routine immunisation and/or enhanced outbreak preparedness and response. Diseases that have emerged more recently as new global threats include Ebola virus. Vaccines for diseases with outbreak potential – whether existing vaccines (eg, yellow fever) or in development (eg, Ebola) – have distinct market dynamics, and challenges including poor predictability of demand, potential supply constraints, and increasing prices for some products.

3.2 Implications for strategy scope

These developments have implications for the directions of the new strategy, as well as the scope of the Alliance's market-shaping activities:

- **Countries:** as per Gavi's Eligibility and Transition Policy,[12] approved by the Board in 2015, Gavi's market-shaping activities for 2016-2020 cover all countries receiving Gavi support, including countries in accelerated transition as well as fully-self-financing countries that participate in UNICEF tenders for up to five years after the end of Gavi's support. These fully self-financing countries 'opt in' to UNICEF tenders on behalf of Gavi-supported countries for specific vaccines, where they may benefit from manufacturers offering Gavi or similar prices. As these countries are fully responsible for financing the procurement of vaccines, this creates a potentially higher uncertainty around their projected demand.
- **Vaccines:** Gavi's market-shaping activities concern those vaccines prioritised through the Vaccine Investment Strategy (VIS) or via specific Board decisions (eg, Ebola). In 2016-20 all vaccines[13] that Gavi funds, regardless of whether they are procured for routine use (eg, pentavalent), specific populations and/or geographies (eg, Japanese encephalitis), or for outbreak preparedness and response (eg, meningitis stockpile) are in scope for market-shaping. Within Gavi's portfolio of vaccines, new products and presentations are offered through the 'product menu' offered to countries in alignment with product portfolio management principles outlined in section 4.3 and Annex F.
- **Other Immunisation Products:** Following the Board approval of Gavi's overall strategy for 2016 – 20 and the Cold Chain Equipment (CCE) Optimisation Platform,[14] Gavi will give priority to CCE as a new area for market-shaping given its importance to coverage and equity.[15] Gavi has an opportunity to shape markets for both the equipment itself as well as related core services such as delivery, installation, and end-user training (see Annex H).

4. Strategic Priorities in Market-Shaping for 2016-20

In addition to the expanded scope of activities as described above, the 2016-20 strategy reflects three priorities: 1) Deliver on healthy markets, 2) Take a long term view of markets as countries become increasingly independent financiers of immunisation programmes, and 3) Support product innovation to better meet country needs.

4.1 Deliver on healthy markets

Recognising that each market is unique and evolves at a different pace depending on a range of factors, the Alliance will take a more holistic approach to viewing healthy markets. This means moving beyond the more narrow assessment of supply, cost, and innovation as discrete objectives towards a more holistic view of the overall 'health' of each vaccine market. The Alliance has set ambitious targets for market health improvements for a number of vaccines. This will require tailored approaches to address unique market needs while continuing to challenge assumptions about the impact of market interventions.

[12] See Eligibility and Transition Policy

[13] Currently, Gavi supports 13 vaccines: Pentavalent (diphtheria, tetanus, pertussis, hepatitis B, Haemophilus influenzae type B), pneumococcal conjugate, rotavirus, human papillomavirus, inactivated polio, meningococcal A conjugate, meningococcal ACYW polysaccharide (stockpile), Japanese encephalitis, measles, measles-rubella, yellow fever , oral cholera (stockpile), Ebola virus (stockpile) vaccines.

[14] In June 2015, the Board approved the Cold Chain Equipment Optimisation Platform, under which Gavi co-invests with countries to upgrade cold chain equipment in country supply chain systems.

[15] The following CCE is included: solar direct drive (SDD) refrigerators and/or freezers without ancillary battery, ice-lined refrigerators (ILRs) and/or freezers, long-term passive devices, cold boxes, vaccine carriers, and temperature monitoring devices including 30-day loggers and/or remote technologies.

4.1.1 The Healthy Markets Framework

The ultimate goal of market-shaping is to create healthy vaccine markets in support of Gavi countries' immunisation needs. In 2015, Alliance partners developed the Healthy Markets Framework, whose aim is to enable a clear and consistent definition of what constitutes market health (see Annex G).

The framework enables the Alliance to better articulate desired market outcomes, to improve its assessment of risks and benefits of market interventions and procurement tactics, and to measure improvements in 'health' across markets in a clear and consistent manner. It elicits a meaningful description of the specific components of a 'healthy market' (eg, supply security, competition, reduced regulatory risk) and illustrates the trade-offs between these components as a measure of what the Alliance is willing to pay to achieve a healthy market.

In 2016-20, the Alliance will systematically apply the Healthy Markets Framework as follows:

- Ensuring consistency in measuring the progress of Gavi's market-shaping efforts against a transparent framework that is connected to strategies in each product roadmap.
- Strategically as a key tool to help define the target outcomes of the Gavi supply and procurement roadmaps and their related action plans, to help arbitrate trade-offs between competing market objectives and to ensure alignment between Alliance partners. The analysis supported by the framework in each roadmap in turn informs the procurement strategies.
- Operationally in each procurement strategy to align tender priorities and formulate the tender approach for analysis and award.

4.1.2. Market 'health states'

Vaccine markets evolve along different trajectories, and the markets that Gavi operates in are in varying stages in their evolution towards higher states of health. A cross-sectional view of the markets in Gavi's portfolios reveals a range of market profiles:

- Mature markets with potential supply capacity risks driven by rapid increases in demand. Yellow fever vaccine could be an example of such a market.
- Markets where uncertainty over commercial potential (eg, products with low margins) limits vaccine development. These markets include vaccines for diseases with high disease burden occurring only or mainly in Gavi-supported countries, such as conjugate meningococcal A vaccines.
- Markets with a limited number of suppliers and high technical barriers to entry, such as pneumococcal conjugate and rotavirus vaccine.
- Markets with demand volatility and supply security risks associated with diseases of outbreak potential, such as cholera.

Market-shaping approaches, even to achieve similar objectives, can vary widely based on the specific needs of each market. For example, attracting new manufacturers to a market could improve long-term competition. However, interventions to achieve this objective can range from co-investment in research and development or facilitated technical support to providing greater demand certainty or pricing signals, depending on other contextual factors (eg, the characteristics of existing suppliers in the market).

The Alliance will continue to elucidate the unique trajectories and timelines that markets follow, and will more proactively address the specific needs of markets based on these insights. Gavi will also continually challenge its own assumptions about how markets evolve. For example, the assumption

that new market entrants will provide stability may not hold if those suppliers themselves have high production risks.[16]

4.1.3 Tailored, data-driven approaches

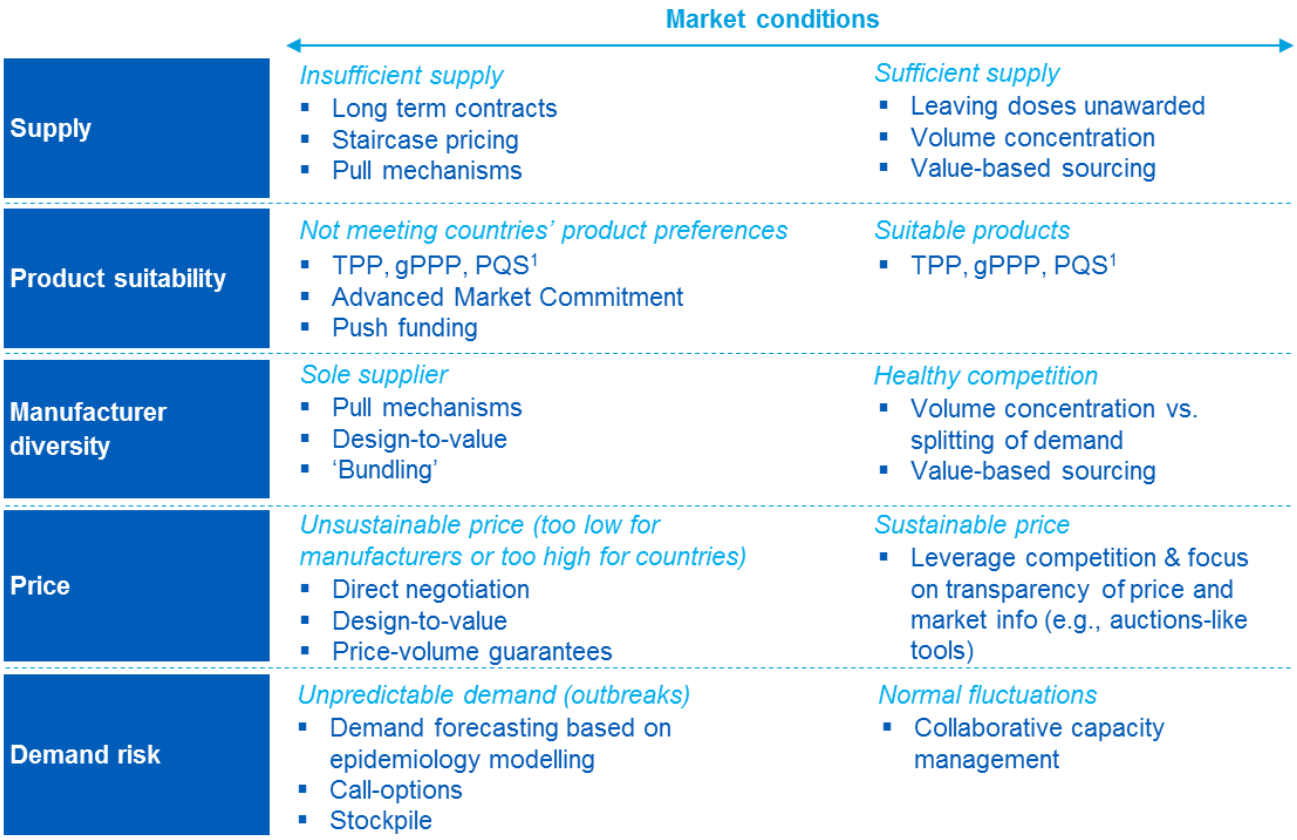
The Alliance has in place an established set of approaches to forecast, incentivise suppliers, and procure products. Moving forward, as market profiles evolve and diverge, Gavi will increase the rigor of its decision-making to tailor the deployment of these approaches and tools to market conditions. This includes increased sophistication in the analysis that informs market-shaping decisions such as a comprehensive view of vaccine cost beyond price per dose, increased transparency on the analyses informing procurement strategies, regular assessment of tender outcomes, and strengthening accountability for roadmap execution through active tracking of progress for high priority interventions. While Gavi's supply and procurement objectives are prioritised within individual markets, the increasing number of products and manufacturers presents an opportunity to consider a manufacturer portfolio review to identify any possibilities for buying across the portfolio as opposed to individual products (eg 'bundling'). However, this approach will need to take into account the implications for manufacturers with small portfolios. Figure 2 below illustrates a sample of market situations and some potential options for tools to deploy in each (a description of tools is provided in Annex G).

When multiple tools are identified to solve a particular market failure, Gavi will select and sequence its market-shaping approaches based on the prioritised objectives and target outcomes developed through the Healthy Markets Framework. For example, the highest priority for the PCV market is to achieve a sustainable price. Gavi would therefore identify approaches and tools that achieve that objective (eg, through direct negotiations with suppliers or volume discounts).

Gavi now supports several antigens that are recommended for special target groups, or in selected geographies or circumstances. This means a move away from universal, routine-only vaccines with relatively clear market characteristics. As Gavi takes a more active role in markets requiring a higher risk tolerance, it will examine whether it has the necessary tools to operate in this new space or whether it should explore new approaches. For example, demand unpredictability and supply constraints for vaccines used in response to outbreaks might require different procurement tools such as call options or leveraging different demand forecasting inputs from partners, such as enhanced epidemiology modelling.

[16] The yellow fever vaccine market is one example where certain assumptions did not necessarily hold true. Despite several manufacturers, the increased competition did not resolve global supply constraints or reduce prices further.

Figure 2. Illustrative examples of market conditions and options for potential tools (not intended to be prescriptive or exhaustive)



[1] Target Product Profiles (TPP), generic Preferred Product Profiles (gPPP), Performance Quality and Safety (PQS)
[2] For definitions and more details on these tools, see Annex G

4.2 Taking a long term view of markets as countries become increasingly independent financiers of immunisation programmes

To better align its objectives of healthy markets to the often long lead-time to impact, Gavi will take a longer-term view of markets while recognizing the constraints of its 5-year strategic and funding cycle. Additionally, as a large number of countries transition out of Gavi support in the next strategic period, the Alliance will work to equip these countries to not only to sustain their immunisation gains but also to become strategic customers in the vaccine market.

4.2.1 Long term view of markets

Taking a longer-term view of markets requires 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. Successful transitioning of Gavi's role in such mature, healthy markets will require long-term planning and coordination with other partners. The Alliance will integrate into its product roadmaps criteria or milestones designating the path towards reducing market-shaping interventions to active procurement only.

4.2.2 Support for informed, country-owned decisions

Governments of Gavi-supported countries make decisions on new vaccine introductions and sources of financing and express preference for a specific presentation (or presentations),[17] outlining the programmatic suitability of the product. While Gavi's business model uses pooled procurement to leverage its purchasing power and stabilise supply and price, countries might choose to self-procure vaccines. In this case, provided that self-procured vaccines are of assured quality (eg, WHO-prequalified), they may request financial support from Gavi in lieu of in-kind support. Gavi would then provide the funding (based on the presentation-specific weighted average price) to the country directly rather than the procurement agency (UNICEF or PAHO's Revolving Fund). Guidelines for Gavi-funded self-procurement of vaccines have been updated and are outlined in Annex C.

As countries transition out of Gavi support and increase their co-financing levels as per Gavi's Co-financing Policy,[18] governments take a more active role in product choices. Though outside the scope of the Supply and Procurement Strategy, Gavi has committed, under its third strategic goal ('the sustainability goal') and the strategic focus area on sustainability,[19] to support Gavi-eligible countries towards successful transition. For vaccines, this includes supporting country governments to make well-informed introduction and product decisions by sharing with them the full set of trade-offs[20] to consider in evaluating the options. For CCE, the Alliance will provide information on Total Cost of Ownership (TCO),[21] to encourage investments in innovative, high-performing technologies whose higher upfront costs are often off-set by lower operating costs over the lifetime of the equipment.

Through its market-shaping activities, the Alliance could additionally support these activities by sharing key information, tools, methodologies that can help strengthen the forecasting and product strategy development capabilities of market-shaping intermediaries. This could include, for example, best practices such as elements of the roadmap development methodology.

After the end of Gavi support, individual Alliance partners, including UNICEF, PAHO and WHO, have an important role in supporting continued country transition. Various models will be explored by individual Alliance partners through platforms such as the WHO MICs Task Force.[22] Gavi will support clarification of the roles of partners in this area to support greater alignment and help identify where there might be gaps post-transition.

[17] As more products become available for countries to procure, some countries might choose to introduce multiple presentations as a strategy for minimising missed opportunities or reducing wastage. For example, a 1-dose vial might be more suitable for health facilities serving smaller populations, while a 10-dose vial would be more cost-effective where population density is higher. Countries will need to weigh the risks and benefits of 'mixing' presentations, including the implications for co-financing.

[18] All countries applying to Gavi for new vaccine support are required to co-finance a portion of the cost of the requested vaccines. The co-financing requirements are established on the basis of a country's income and are calculated on a per dose level. The three country groupings and their related co-financing requirements established under the co-financing policy are listed on Gavi's website and explained in the Co-financing Policy.

[19] One of the cornerstones of Gavi's development model is that support is time-limited and catalytic, and that support for countries diminishes and ultimately ends as their economies grow. Gavi thus works with the countries it supports to ensure that they successfully transition from Gavi's financial support and can sustain and continue to improve the performance of their immunisation programmes. Through the Sustainability Framework, Gavi and its partners, such as UNICEF, WHO, and PAHO, will invest in strengthening national capacity in vaccine procurement, financing, and regulation during transition.

[20] This implies a better understanding of 'total systems effectiveness', including supply chain requirements, transportation and delivery, as well as human capital costs and cost variability.

[21] TCO refers to costs over the lifetime of the device including capital and operating expenses such as maintenance and energy costs. For optimal equipment, lower operating costs largely off-set higher upfront costs

[22]. The WHO MICs Task Force is one example of a platform for ensuring continued sustainability of programmes post-transition. The WHO Middle Income Countries (MICs) Strategy seeks to address the immunisation challenges of non-Gavi middle-income countries, such as strengthening regulatory and decision-making bodies, providing technical assistance to strengthen mechanisms and structures, and raising the profile of immunisation as a cost-effective preventive intervention.

4.2.3 Externalities of market-shaping

Gavi's market-shaping activities may have both positive and negative externalities on the market place, including manufacturers, countries and partners. While primarily intended to benefit the countries it supports, the ultimate goal of market-shaping is to improve the health of markets as a whole. Indeed, Gavi's ability to attract new entrants into the vaccine market, stimulating competition and reducing prices across the market – as illustrated by the pentavalent vaccine market example – has benefits well beyond Gavi countries.

Conversely, on occasion, tools which Gavi utilises to reduce short term risk might have negative long term consequences. Examples of such externalities include:

- Downward pressure on vaccine prices might raise uncertainty about the long-term return on investment for vaccine development and deter manufacturers from developing new products that are needed or from entering the market. Such pricing pressure might also cause manufacturers to exit the market, and put supply security at risk.
- Gavi's influence on pricing could have negative consequences for other lower-middle-income countries. Some manufacturers may feel they need to recoup a higher margin in those countries to compensate for the low margin achieved in selling to UNICEF on behalf of Gavi, thus increasing the price those countries secure (eg, through a tiered pricing structure).
- Volume commitments, which drive short term supply and price certainty, could compromise opportunities to negotiate better terms with new manufacturers as they enter or when conditions change.
- Pooled procurement, which leverages purchasing power to stabilise supply and price, can result in reduced country ownership if product choice is limited so as to maintain higher volumes per product.

Risks and consequences must be weighed against the potential benefits. For example, push funding for manufacturer production or advance market commitments could attract new market entrants to drive long-term competitiveness in the market, which in the future exerts a downward pressure on price, improves supply stability and increases product choices.

In this next strategic period, Gavi will monitor the unintended consequences of its activities in Gavi and non-Gavi countries. This could include measuring supply sufficiency in middle income markets and relative price differences between Gavi and non-Gavi countries. Gavi will also work with manufacturers to determine which non-commercially sensitive information can be shared that provides insight into the impact of market-shaping on innovation and research and development.

4.3 Support product innovation to better meet country needs

While the timeframe for this strategy aligns with Gavi 2016-2020 strategy, product innovation often occurs over a longer time horizon. The Alliance encourages product innovations in suitability and quality for Gavi-supported countries, towards a shared vision where future vaccines are increasingly well adapted to the programmatic needs of Gavi countries and improve coverage and equity.[23]

4.3.1 Definition, value and prioritisation of innovation

'Product innovation' refers to adaptations to existing products that would add value to the market in the future, or to completely new products that provide measurable financial or programmatic benefits

[23] *This could include innovations in thermostability; presentation and packaging optimisation; delivery technologies; combination vaccines and new schedules; and epidemiological appropriateness, effectiveness, new technologies & safety (these categories were developed by the Secretariat as a way of grouping vaccine innovation into themes).*

to Gavi-supported countries, such as increased coverage and equity (eg, by overcoming a 'last mile' barrier) or vaccine effectiveness.

Innovations fall into four broad categories:

1. *Vaccines for new antigens*. Regardless of time horizon, this category includes vaccines for antigens which are not yet in Gavi's portfolio. Gavi actively monitors this pipeline, and the Gavi Board decides whether they should be added to Gavi's portfolio through the VIS process. As and when new vaccines are added, they immediately come into scope for market-shaping.
2. *Next generation vaccines for antigens in Gavi's portfolio*. This category includes combination vaccines (eg, Meningoccal A-yellow fever combination vaccine) and vaccines with additional serotypes (eg, nine-valent HPV vaccine). These innovations will be assessed on a case-by-case basis based on principles outlined below to determine whether they are within the scope of Gavi's original investment decision or whether they require a new assessment and decision through Gavi's governance processes.
3. *Improvements on existing products*. This includes incremental innovations where existing products are optimised, for example, in their packaging, formulation, presentation, or delivery (eg, MR low-multi-dose vial, CTC for oral cholera vaccines).
4. *New platforms and delivery technologies*. This would include for example jet injectors, microneedle patches, and novel adjuvants. When 'paired' with an antigen in Gavi's portfolio, such an innovation would be captured under one of the two previous categories but would not be assessed on its own.

In the **short-term**, any innovation in categories 2 and 3 with potential to reach the market in this strategic period that improves product suitability for Gavi-supported antigens is considered and evaluated within the vaccine supply and procurement roadmap development process. Decisions on whether and how to incentivise these innovations are included as part of market analysis and decision-making on prioritised objectives within a given market. When a new presentation or product enters the market, Gavi will consider whether to make it available for countries to request by including it on the 'product menu' based on the following principles.[24] When these conditions are met, the procurement of the new vaccine presentation or product is considered to fit, in principle, in the context of the original Board decision. The presentation or product must:

1. Be consistent with SAGE recommendations and the WHO position paper for the related antigen;
2. Be WHO prequalified (to facilitate timely availability, a product offering may be communicated to countries in advance of prequalification);
3. Have a reliable supply base;
4. Have an estimated cost within the range of the current fully-loaded, wastage-adjusted vaccine costs to immunise an individual and should account for any increased procurement costs that are commensurate with evidence-based benefits of the new vaccine presentation or product and/or with decreased costs in vaccine delivery;
5. Be likely to respond to country demand and preferences. Where required to avoid supply security risks or to further other market-shaping objectives, a new presentation may be added to replace an existing one.

If one of these conditions is not met, the vaccine presentation or product would be discussed with the Gavi CEO for a decision on whether to proceed with offering the vaccine to countries, followed by

[24] *More details can be found in Annex F*

procurement or be referred to the Programme and Policy Committee or other escalation process for information or further guidance.

In the **longer-term**, Gavi is often restricted by its 5-year strategic cycle in making binding commitments to accelerate innovation. However, Gavi can engage in activities to align partners around a common definition of innovation, develop a joint approach on how to value long-term innovation and communicate this understanding to partners and industry. To this end, the Alliance will undertake a number of activities in 2016-20:

- Develop common principles across the Alliance to make the assumptions underpinning the value proposition for innovations explicit. This would include considering the full trade-offs between financial and non-financial benefits for countries and feasibility to implement in countries. This would include further developing and refining the Total Systems Effectiveness[25] model.
- 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 in a non-binding manner to vaccine development partners. As a number of individual Alliance partners and other market-shaping intermediaries already engage in the innovation space, the Secretariat will convene these actors and leverage their relative capabilities, data and expertise.
- Understand countries' needs by leveraging countries', and technical partners' field experience to consider financial and non-financial impact of innovations (eg, safety, efficacy, equity and coverage).

Finally, the Alliance will monitor innovation through 1) the strategic goal 4 indicator on number of short term innovations available on Gavi's 'product menu', and 2) an indicator that tracks progress on the convening of Alliance partners and development of principles to evaluate innovation (see Annex D).

4.3.2 Acceleration of innovation

The Alliance also engages in a number of activities to more directly incentivise innovation. For example, UNICEF collects information from low- and middle-income countries on product suitability and preferences, which informs innovation priorities. WHO develops generic preferred product profiles (gPPPs) to guide manufacturers on these desired improved characteristics for products. Other actors such as CHAI and PATH will play an increasingly important role in close collaboration with core Alliance partners by supporting the development of new technologies.

Financial incentives, such as 'push' funding and 'pull mechanisms' also accelerate innovation. Donors such as BMGF and DFID support early-stage development through direct funding and loans. Other financial incentives such as 'pull mechanisms' (eg, volume or price guarantees) encourage manufactures to develop products by guaranteeing uptake once the product is prequalified or approved. In the future, Gavi could also consider the creation of financial incentives for future products meeting specifications outlined in a target product profile (TPP), similar to the model of the pneumococcal advance market commitment (AMC).

4.3.3 Innovation for Cold Chain Equipment

Gavi's overall 2016-2020 expands the scope of market-shaping to include CCE as a means of achieving gains in coverage and equity. Sufficiently deployed, high-performing and well-maintained cold chain

[25] *Total systems effectiveness (TSE) considers the multiple cost dimensions associated with fully immunising a child (price, cold chain, operational requirements, other vaccine-specific features), as well as safety, efficacy, and ease to achieve coverage.*

equipment is a critical component of the supply chain, and vital to ensure that vaccines are available and potent to protect those vaccinated reliably, efficiently and sustainably.

Gavi-supported CCE[26] is included in the WHO Performance Quality Safety (PQS) Catalogue.[27] The Alliance aims at having a comparable impact on **CCE market dynamics** as it aspires to in vaccine markets by leveraging market interventions and tools, adapting as required for the unique CCE market considerations.

CCE is different from vaccines in many ways, including shorter development timelines (often less than 18 months to market), which could enable market-shaping results to be attained in relatively short time periods. This also presents opportunities to develop and test **innovative approaches** to CCE markets, such as bundling services (eg, installation and commission or maintenance) with equipment procurement or continuously improving products through a 'feedback loop'. 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. These improvements reduce risk related to wastage and quality of vaccines. As Gavi-supported CCE is deployed and field experience (eg, regarding product performance and quality, issues with installation and maintenance, etc.) is gained, amendments and additions to the TPPs may be made to accelerate product innovation.

The CCE Optimisation Platform was developed as a pooled funding mechanism to procure new products once they arrive in the marketplace. Upfront investment in CCE presents long-term value to increase coverage and equity.[28] Building on the vaccine model, the Alliance stimulates demand and supply of more reliable and efficient equipment by offering stable demand to manufacturers and funding to countries choosing Platform-supported technologies. By providing a mechanism for existing donors to channel their funding through the Platform and a risk-sharing model for manufacturers, a larger, more predictable market is being created.

5. Critical Enablers to Execute the Strategy

To deliver on its goals, the Alliance can build on a solid foundation of established market-shaping practices, while selected processes, tools and capabilities will be strengthened for greater impact.

5.1 Strengthen data collection and analytics

In addition to existing data[29] from partners and countries used to inform decision-making, Gavi will invest in generating new data and analyses to inform its market-shaping efforts. For example, some attributes of the Healthy Markets Framework will be further developed into analytical tools to become fully actionable. This includes the 'Total System Effectiveness' component which aims to reflect a more comprehensive view of costs (including wastage, delivery cost) and programmatic impact. As another example, in the CCE market, Alliance partners and others (eg, CHAI, PATH) will introduce a 'feedback loop' to capture information from countries on current and desired CCE product characteristics, prices and causes of failure.

Procurement decision-making will be enhanced through the use of improved analytical tools to more systematically weigh procurement award options. This includes the use of an 'optimisation tool', which models procurement outcomes to assess costs, benefits, and risks.

[26] *For more information on the subset of CCE that Gavi supports, see Annex F*

[27] *PQS qualification means that a device has passed a series of performance, quality and safety tests set by WHO.*

[28] *The lower operating cost of Platform-supported CCE results in a lower TCO and supports greater sustainability of CCE due to reduced on-going financial and technical requirements.*

[29] *For example, countries provide information such as anticipated introduction dates, projected short-term demand including coverage and wastage rates, and product preferences and experiences.*

5.2 Increase timeliness and transparency of information

Timely, transparent and accurate information on demand and supply forecasts, current and expected future vaccine product characteristics and prices is critical for recipient countries, manufacturers and other Alliance members. The Alliance will continue to publish awarded prices, public roadmaps, and UNICEF market updates. However, specific price targets will not be publicly disclosed in order to avoid setting price ceilings. Alignment around healthy market dynamics (eg, through application of the Healthy Markets Framework) and innovation (eg, through the development of a common evaluative framework) will also provide greater transparency on Alliance priorities in these areas.

Visibility for key stakeholders into the procurement process will be enhanced, including greater transparency around decision-making methodology, such as through the use of the Procurement Reference Group (PRG), a group of experts convened to advise on key elements of the procurement strategies and processes.

Public messaging, such as media communication, will aim for a balanced tone. For example, when communicating around reduced prices, the Alliance will be transparent in describing if special conditions or other circumstances led to a specific price agreement.

Finally, Detailed Product Profiles (DPPs), provide countries with easy access to up-to-date and comprehensive information on Gavi-supported vaccines. The DPPs include information on vaccine presentations, pricing, indicative wastage rates, manufacturers, cold chain volume and handling. This information aims to help countries decide which vaccine presentation is the best 'fit' for their specific country context, which contributes to the sustainability of the immunisation programme. The DPPs will be regularly updated and improved to better support country decision making.

5.3 Strengthen coordination with countries, partners and industry

Gavi will strengthen coordination with governments and other country decision-makers as they become more informed customers with stronger local decision-making processes (eg, NITAGs[30]). Gavi-supported countries also provide important information on programmatic suitability of products; projections for introductions and required doses; and challenges and opportunities in improving immunisation uptake, coverage, and equity. As countries transition from Gavi support, they will increasingly take on forecasting and procurement roles as well (more information can be found in Section 4.2).

In addition, the expansion of scope and increased complexity of activities will require Gavi to identify and use capabilities, resources and expertise across and outside the Alliance in an increasingly large number of domains, such as modelling, negotiation, or training. Thus, other expert partners become increasingly important, and the Alliance will consider the advantages of each to determine where their comparative strengths could best be leveraged. Alliance partners will clarify responsibilities and role ownership, particularly in markets that might require new or different approaches (eg, vaccine markets for diseases with outbreak potential).

Finally, as the manufacturer base grows and diversifies, Alliance partners will engage with industry in a deliberate and partnership-minded way, with sensitivity to the different business needs of individual manufacturers and mutual transparency. This includes the need for visibility over longer time horizons for product development and tailoring market interventions to the varying constraints of individual manufacturers, who are geographically diverse and can face very different challenges around product development, registration and prequalification, and production. To address these needs, Alliance partners will communicate to manufacturers aligned priorities and opportunities as early as is feasible

[30] *A National Immunisation Technical Advisory Group (NITAG) is a technical resource in countries that provides guidance to national policy-makers and programme managers to enable them to make evidence-based immunization-related policy and programme decisions*

through the VIS and the supply and procurement roadmaps. The Alliance will engage in regular dialogue, both formal (eg, UNICEF through tender negotiations), and informal (eg, discussions to share updates and information). The Secretariat will also convene regular informal bilateral meetings in which Gavi and industry will review individual and joint business priorities. This bilateral discussion will be mirrored where possible at the CEO level by Gavi and industry, to forge further alignment at senior leadership levels.

6. Monitoring and Evaluation

The Alliance will monitor key indicators to track progress in implementing the Strategy and will report on these indicators on an annual basis (see Annex D).[31]

Outcome indicators will track progress towards market-shaping goals around healthy markets, supply, price of fully vaccinating a child and innovation. In addition, the Alliance monitors the information and transparency level as a key enabler to healthy markets.

Process indicators will monitor operational performance of core Alliance partners against priority interventions such as demand forecasting, to ensure execution of the described improvements.

Evaluations will be conducted either during or after the implementation of the Supply and Procurement Strategy to identify areas of strength and recommendations for improvement as needed. These could include evaluations of:

- Impact of roadmap strategies and procurement outcomes;
- The procurement agency, at the mid-term of the Memoranda Of Understanding (Supply and Logistics), (MOU) period[32], to assess and compare the value for money and impact obtained;
- Procurement outcomes as part of the evaluation of Gavi's support for countries conducted after support ends;
- The 2016-2020 Supply and Procurement Strategy prior to development of a revised strategy for 2021-2025.

[31] Some targets and outcomes may not be publicly disclosed to avoid unintended consequences such as setting price ceiling

[32] Gavi has an MOU with its main procurement agency, UNICEF-SD. The MOU contains further information on reporting requirements.

Gavi, the Vaccine Alliance:

Supply and Procurement Strategy 2016-20

Annexes

Annex A: Definitions

Antigen: a toxin or other foreign substance which induces an immune response in the body, especially the production of antibodies.

Vaccine: the antigen class (or combination of antigens) and includes all presentations and formulations that have been recommended or will be recommended in the future for use in Gavi supported countries.

Vaccine Product: a specific presentation of a vaccine. For example, the current PCV market has several products including the 10-valent and 13-valent product.

Vaccine Formulation: the dosage form of a vaccine. For example formulation could be liquid, lyophilised (freeze-dried), etc.

Vaccine Presentation: vaccine presentation is defined by three factors, the formulation; the container type (eg, vial/ampoule vs tube vs pre-filled syringe); and the number of doses per container (eg, 1-dose vial vs 10-dose vial). Vaccine products which differ from one another on any of these three factors are considered different presentations of the vaccine. Likewise, each unique combination across these three factors is considered a separate presentation of the vaccine. Beyond these three factors, vaccines are also considered to be of different presentations if they are not interchangeable. Vaccines are considered not to be interchangeable for three reasons: (1) the number of doses to achieve full immunisation is different (eg, 2-dose per course rotavirus vaccine vs 3-dose per course); (2) the WHO position is that vaccine interchangeability has not been established for administration of a complete course in an individual (eg, PCV-10 vs PCV-13); and (3) if the vaccines are intended for different usage or age groups (eg, meningococcal A vaccine for use in routine settings for infants vs campaign for children over 1 year).

Vaccine Packaging: the primary, secondary and tertiary containers used to hold and transport vaccines.

Vaccine Price: the purchase price of product per unit or per course.

Fully Loaded Price: the vaccine purchase price plus peripheral costs associated with transportation and freight, and costs of associated devices or supplies (eg, syringes, safety boxes, etc).

Vaccine Cost: the fully loaded price plus the cost of operations to deliver, administer or maintain the product. Costs could also be non-financial, such as the need for more training for health care workers to administer a vaccine.

Weighted Average Price: (WAP), a methodology for determining an average price across a set of vaccines, for example across multiple manufacturers of a vaccine or across multiple presentations of the same vaccine. It is calculated by dividing the total value of vaccines purchased across the set of vaccines by the total volume of vaccines across the set. Thus, this type of average takes into account not only the price of each individual vaccine but also the volume purchased.

Prequalified: (PQ), vaccines that have been deemed by WHO, as acceptable for procurement by UN procurement agencies and countries.[33]

Controlled Temperature Chain: an approach to vaccine stability assessment and management, which permits the use of products outside the traditional 2°C to 8°C cold chain, for limited periods of time, under monitored and controlled conditions.

National Regulatory Authorities: (NRAs), national agencies who are responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, such as

[33] *See http://apps.who.int/prequal/*

vaccines) are evaluated properly and meet international standards of quality and safety. Fully functional NRAs exercise six critical control functions: a published set of requirements for licensing; surveillance of vaccine field performance; system of lot release; use of laboratory when needed; regular inspections for good manufacturing practice; evaluation of clinical performance.

Self-procurement: under specific circumstances, Gavi-supported countries are able to procure their vaccines with Gavi funding, rather than through the procurement agency (see Annex C).

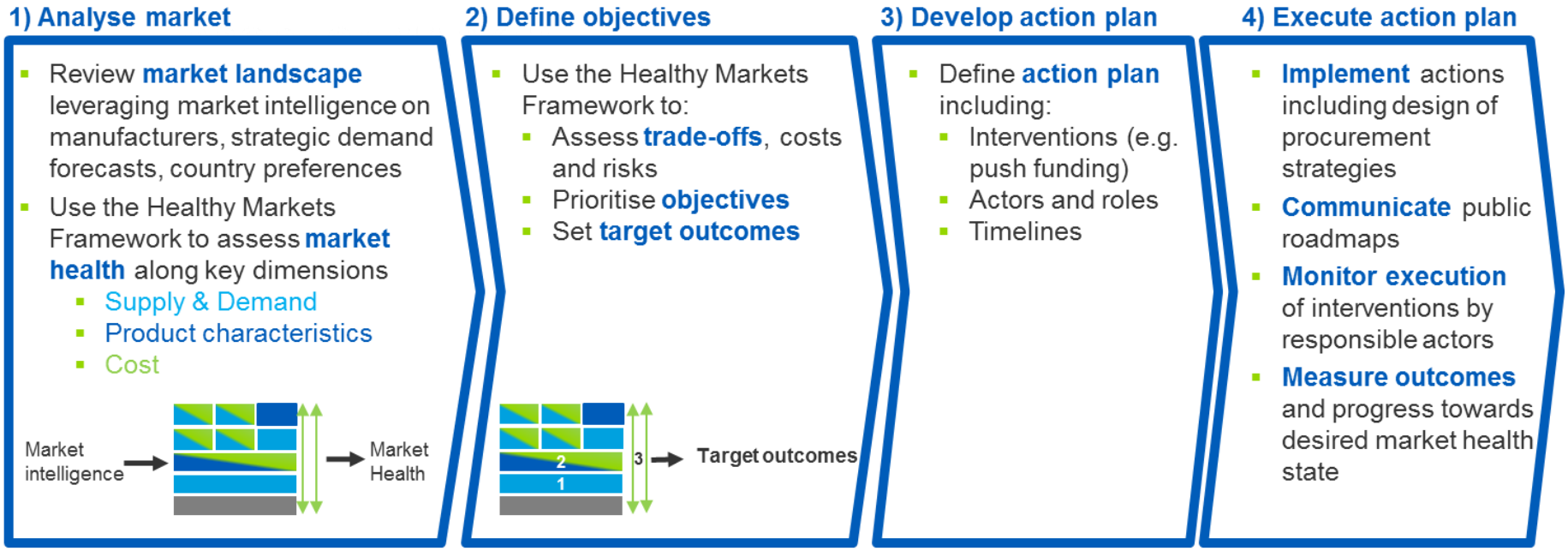
Supply Security: lowered risk of interruptions to supply, even when problems arise.

Tiered Pricing: a form of price differentiation in which different prices, in different markets, are charged for the same product. Generally, manufacturers charge higher vaccine prices in high-income countries, and lower prices for lower income countries.

Annex B: Supply and Procurement Process

Figure 3. Sequence and Timing of Strategic Elements

Figure 4. Product market strategy by vaccine market[1]



[1]Captured in Product Roadmaps developed by Gavi Secretariat, BMGF and UNICEF

Annex C: Self-procurement Policy

Policy for self-procurement of vaccines and injection safety devices

1. Goal and scope

1.1. This policy outlines the requirements for countries self-procuring vaccines and injection safety devices using Gavi financial support in lieu of in-kind support.

1.2. In line with the Paris Declaration[33] and the principles regarding aid effectiveness, Gavi countries have the option to self-procure vaccines and injection safety devices with Gavi support. This policy aims to ensure that only vaccines and injection safety devices of assured quality are purchased using Gavi funding.

1.3. Vaccines self-procured by countries as part of their co-financing obligation are out of scope of this policy. However, Gavi strongly encourages countries self-procuring co-financed vaccines to ensure that vaccines are of WHO-defined assured quality, such as those on the WHO list of pre-qualified products.

1.4. Vaccines and vaccine supplies subject to specific procurement terms, eg those procured under the Advance Market Commitment, which specify procurement requirements and/or the procurement modality, are out of scope of this policy.

2. Self-procurement of vaccines

2.1. Countries wishing to self-procure vaccines and associated injection safety devices, in lieu of procurement through a Gavi Alliance procurement agency (eg, UNICEF or PAHO's Revolving Fund), may request financial support from Gavi equivalent to the amount Gavi would have provided to its procurement agency.

2.2. Countries that choose to self-procure vaccines using Gavi support must purchase vaccines of assured quality. This can be done through:

a) Selecting vaccines from the list of WHO pre-qualified products; or,

b) Ensuring that the vaccines purchased comply with WHO's definition of quality vaccines (as described in WHO's Technical Report Series[34]), for which there are no unresolved quality problems reported to WHO, and for which compliance is assured by fully functional National Regulatory Authorities (NRAs), as assessed by WHO in the countries where they are manufactured and where they are purchased.

2.3. The amount of financial support provided by Gavi is based on the presentation-specific weighted average price for the vaccine (or similar presentation) as forecasted by the Gavi Secretariat, in consultation with Gavi's procurement agencies.

2.4. If a country's negotiated procurement price is higher than the amount of financial support provided by Gavi, the government is required to pay the difference in order to purchase enough vaccines to reach the target population. If the price is lower than the amount of financial support provided by Gavi, the country shall invest the excess funds in the immunisation programme and report on the use of these funds in subsequent monitoring reports to Gavi.

[33] *For more information, see: http://www.oecd.org/dac/effectiveness/parisdeclarationandaccraagendaforaction.htm*

[34] *Available at: http://who.int/biologicals/technical_report_series/en/*

2.5. Countries cannot use Gavi resources to procure vaccines not supported by WHO recommendations as outlined by SAGE[35]. To ensure the most efficient use of its resources, and in the interest of programmatic and financial sustainability, where self-procured products differ from Gavi-procured products, Gavi strongly encourages countries not to use its resources to procure less cost effective vaccines.

3. Self-procurement of injection safety devices

3.1. Countries using Gavi's funds to self-procure auto-disable syringes are required to procure products pre-qualified under WHO's Performance, Quality and Safety system.[36]

3.2. For disposal boxes, countries self-procuring with Gavi funds must either:

a) Procure devices that appear on the relevant WHO list of prequalified products; or,

b) Submit to WHO a certificate of quality from a relevant national authority.

3.3. The amount of financial support provided by Gavi is based on the weighted average price for the product as forecasted by the Gavi Secretariat, in consultation with Gavi's procurement agencies.

3.4. If a country's negotiated procurement price is higher than the amount of financial support provided by Gavi, the government is required to pay the difference in order to purchase enough supplies to reach the target population.

3.5. If the price is lower than the amount of financial support provided by Gavi, the country shall invest the excess funds in the immunisation programme and report on the use of these funds in subsequent monitoring reports to Gavi.

3.6. To ensure the most efficient use of its resources, and in the interest of programmatic and financial sustainability, where self-procured products differ from Gavi-procured products, Gavi strongly encourages countries not to use its resources to procure less cost effective products.

4. Approval and monitoring for vaccine and injection safety devices

4.1. Prior to self-procurement, Gavi or its designate will review the procurement mechanism proposed by the country to assess whether it adheres to the principles of good public procurement and the requirements of this Policy and make recommendations on minimum reporting requirements and possible improvements.

4.2. Following self-procurement, the country must submit a full report outlining the total quantities of vaccine and injection safety devices, as applicable, procured, and final costs to be compared against the budget allocated under the relevant Gavi Decision Letter. The country must submit satisfactory evidence that it purchased the vaccine doses (including the co-financing portion) and related supplies communicated by Gavi in the Decision Letter, by submitting purchase orders, invoices and receipts. Any balance of Gavi funds disbursed in support of country self-procurement should be reported to Gavi together with satisfactory evidence that the leftover funds have been used within the immunisation programme.

5. Timeline for implementation and review

5.1. This policy comes into effect immediately upon Board approval.

5.2. The policy will be reviewed and updated as and when required by the Gavi Alliance Board.

[35] Strategic Advisory Group of Experts on Immunisation. See: http://www.who.int/immunization/policy/sage/en/

[36] WHO Performance, Quality and Safety catalogue: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

Annex D: Monitoring and Evaluation Framework

Indicators	Definition	Data source and frequency of measurement	Targets
Goal level outcome indicators: Strategic Goal 4 of Gavi 2016-2020 strategy (approved by December 2015)			
1. Healthy Market Dynamics (HMD)	Number of Gavi vaccine markets with moderate or high levels of healthy market dynamics (HMD) as measured through the Healthy Markets Framework. No HMD exist where there is inadequate supply. Low HMD exist where supply meets demand. Moderate HMD exist where the country's presentation preference is accommodated and there is moderate supply security (eg some level of buffer capacity, but some individual supplier and NRA risk might exist) High HMD exist where country presentation preferences are accommodated, there is high level of supply security, and the market supports long-term competition and innovation where appropriate.	Data will be collected annually from Gavi Secretariat, UNICEF, WHO	Six markets have moderate or high level of HMD by 2020 (as of 2016, only one market was considered to have moderate and no markets were considered to have high HMD)
2. Sufficient and uninterrupted supply	Number of Gavi vaccine markets with sufficient and uninterrupted supply of appropriate vaccines. Sufficiency of supply is measured as the number of doses offered to Gavi through UNICEF tenders, which meets demand as defined by number of doses requested by Gavi in UNICEF tenders (based on in-country demand). Uninterrupted supply is measured as suppliers delivering doses to meet supply commitments. Supply will be counted as interrupted if the cause is a	UNICEF Supply Division (SD) annual shipment plans through MOU	Eleven markets[37] have sufficient and interrupted supply

[37] *Includes all vaccines in scope for market-shaping in 2015.*

Indicators	Definition	Data source and frequency of measurement	Targets
	result of supplier failure and UNICEF has not been able to reallocate supply plans.		
3. Change in vaccine price	Change in the weighted average vaccine price per child to fully vaccinate with pentavalent, rotavirus and pneumococcal vaccines.	UNICEF SD reports bi-annually	Target not publicly disclosed to avoid unintended consequences such as setting price ceilings
4. Innovation	Number of vaccines and other immunisation products with improved characteristics procured by Gavi as compared to the baseline year. Improved characteristics for vaccines will be measured against objective criteria of programme suitability as developed by WHO (eg prequalification, gPPPs). For cold chain, these objective criteria are captured in WHO's PQS standards or TPPs.	Secretariat reports annually	Ten products with improved characteristics offered to Gavi/UNICEF to procure on behalf of countries
Process and operational indicators: vaccines			
1. Number of vaccines not available to meet shipment plan	Number of vaccines not available to meet shipment plan, as agreed with procurement partners, due to delisting from the WHO list of prequalified vaccines, downgrading of NRA functionality or other quality issues occurring after supply has been awarded.	UNICEF Supply Division reports bi-annually	Zero
2. Vaccine price per dose and per course for all Gavi-supported vaccines purchased through Gavi's procurement partners	For all Gavi-supported vaccines purchased through Gavi procurement partners: • Full year weighted average actual price per dose and per course • Full year highest and lowest actual price points per dose and per course	Awarded prices reported by UNICEF SD; indicator is reported annually	Target for key vaccines – pentavalent, rotavirus, and pneumococcal – included in goal-level indicator

Indicators	Definition	Data source and frequency of measurement	Targets
	(Price refers to FCA[38] and does not include cost of freight, syringes, and safety boxes.)		
3. Percentage of awarded prices published on time	Percentage of awarded prices published on time by presentation and by manufacturer. Frequency of reporting is agreed in advance.	Per manufacturer offer through UNICEF SD	One hundred percent
4. All monitoring indicators under the MOU reported in a timely manner by UNICEF	This indicator will track implementation of the MOU with UNICEF by monitoring the timeliness of reporting on the agreed indicators in the MOU. For example: • Number of prequalified products by manufacturers available per year end; • Total supply (prequalified and non-prequalified) offered over demand; • On-time delivery performance (and reasons for delay). This will be a YES or NO indicator. YES if all indicators are reported and reported in time. Otherwise NO.	UNICEF reports bi-annually to Gavi secretariat	YES (for all years)
5. Externalities from market-shaping activities beyond Gavi countries	In conjunction with partners, a set of indicators will be developed in 2016 to monitor the impact of market-shaping on former Gavi countries, non-Gavi countries, and stakeholders including manufacturers (per section 4.2).	Procurement partners, expert partners, and industry partners report annually	Annual reporting on indicators

[38] *FCA: International commercial term that indicates 'free carrier', a type of transaction where the seller is responsible for arranging transportation but is acting at the risk and expensive of the buyer.*

Indicators	Definition	Data source and frequency of measurement	Targets
6. Percentage of roadmaps that include the criteria or milestones to determine when market-shaping interventions would be reduced to active procurement only	A set of criteria or milestones will be developed in 2016 and included in each roadmap to designate the path towards reducing Alliance engagement to active procurement only.	Secretariat, BMGF, UNICEF will report as roadmaps are developed and updated	By 2020, one hundred percent of updated roadmaps will include these criteria
7. Convening of Alliance partners and development of principles to evaluate innovation	The convening of Alliance partners and other experts and the development of principles to evaluate innovations (per Section 4.3). These principles will draw upon relevant tools (eg, Total Systems Effectiveness) to understand and articulate countries' needs. The Alliance will communicate these principles and related innovation priorities.	Gavi Secretariat WHO	By 2020, the convening platform and evaluative principles will be established and used, and innovation priorities communicated.
Process and operational indicators: Cold Chain Equipment (CCE)			
1. Supply of Gavi-supported CCE	This indicator will track: • Amount of platform-eligible equipment available in the market • Number of suppliers providing equipment meeting platform requirements	Secretariat reports annually	To be developed by end of 2016

Indicators	Definition	Data source and frequency of measurement	Targets
2. Price of all CCE purchased through the CCE Optimisation Platform	Weighted average purchase price for CCE to assess progress towards sustainable prices for countries and monitor risk of potential price 'inflation' due to fewer potential suppliers and higher CCE performance requirements.	UNICEF SD reports annually	Target not publicly disclosed to avoid unintended consequences such as setting price ceilings
3. Suitable CCE supported by Gavi available to countries	This indicator will track: • Percentage of UNICEF-procured devices meeting platform requirements • Amount of Platform-eligible equipment purchased	UNICEF SD reports annually	To be developed by end of 2016

Annex E: Description of Actors

This section contains a non-exhaustive list of the key stakeholders and their roles.

The Gavi Secretariat coordinates the participation and contribution of key Alliance members, leads in the development and implementation of the product roadmaps, and monitors progress against indicators in the Supply and Procurement Strategy. Where possible, the Secretariat shares available non-proprietary or non-commercially sensitive vaccine market information. The Secretariat produces vaccine-specific strategic demand forecasts and shares these within the Alliance, including with manufacturers. As part of product roadmap development, the Secretariat organises consultations with technical Alliance members, additional disease/vaccine experts, and other global health organisations with relevant expertise. The Secretariat also engages with manufacturers to identify barriers and bottlenecks in Research and Development (R&D) and production where this is not being addressed by other Alliance members; coordinates with UNICEF to ensure procurement decision-making aligns with roadmap objectives; and supports WHO to develop product standards and specifications and communicate this information to manufacturers.

Procurement partners (UNICEF and PAHO) purchase vaccines on behalf of Gavi countries and are responsible for ensuring transparency and accountability of the procurement process. Procurement partners develop and implement product procurement strategies to achieve the objectives prioritised through the roadmaps, including: conducting formal consultations with manufacturers; managing the procurement processes; establishing supply arrangements and contracting modalities; forecasting the balance of supply and demand, delivery and monitoring of supplies; ensuring transparency on pricing information; and developing and tracking of relevant indicators. They also engage in capacity building at the country level, including: technical support on forecasting (including operational forecasts for vaccines and CCE), budgeting, procurement, distribution and monitoring of vaccines and in-country logistics support. While **UNICEF** procures vaccines for the majority of countries, **PAHO's Revolving Fund** procures on behalf of Gavi-supported countries in the Latin America and Caribbean region. PAHO additional works with its Member States to increase awareness of vaccine market dynamics and challenges and support demand planning.

The Bill & Melinda Gates Foundation (BMGF) focuses on product innovation and developing long-term competition in markets mainly through financial and technical support for manufacturers to help accelerate R&D and WHO prequalification of new vaccines. BMGF also coordinates with the Secretariat to gather market intelligence and insights on the state of different markets and to develop appropriate market incentives to meet objectives identified in product roadmaps. Much of this work is achieved by funding other global health partners (some described below) to leverage their specific technical expertise.

The World Health Organization (WHO) develops product specifications and standards for existing vaccines and other immunisation products as part of its normative function. Through working groups such as the IPAC Delivery Technologies working group and the WHO/EMP Packaging working group, WHO advances recommendations and target product profiles to inform priorities for new vaccines. WHO plays a key role in guaranteeing the quality and safety of vaccines funded by Gavi; it manages the prequalification process for vaccines and other immunisation related products, including definition of programmatic suitability; and it assesses compliance of national regulatory authorities (NRAs) with international standards to enable manufacturers to submit vaccines for the WHO prequalification process and participate in tenders of procurement partners. WHO also works with

countries to strengthen decision-making through National Immunisation Technical Advisory Groups[40] and political advocacy, and leads on the MICs Strategy per Section 4.2.[41] WHO hosts the Secretariat of the International Coordinating Group (ICG) for diseases with outbreak potential and in the capacity of Secretariat, plays a role in ensuring availability of vaccine including interactions with manufacturers and sometimes vaccine procurement.

Donor agencies, such as DFID, USAID, and several Scandinavian donors fund product development through different investment vehicles and technical partner organisations. Furthermore, some donors may also engage in innovative financing mechanisms such as the AMC or sovereign funds. These funding opportunities can either be "push" or "pull" mechanisms based on the product market and need.

Technical experts – core partners draw on and collaborate with a range of technical partners including PATH, the Clinton Health Access Initiative, academic researchers, and disease experts with specific expertise in certain domains to implement or supplement activities to shape product markets. Specific areas of contribution include upstream product development support, market intelligence gathering, capacity building at emerging manufacturers, long-term forecast development (eg, for CCE markets), support in negotiations, and policy guidance through evidence generation.

Civil Society Organisations (CSOs) advocate to ensure the value of vaccination and the need for long term, reliable funding is widely understood and recognised. CSOs also serve as informants on product suitability and affordability and provide public market information annually. CSOs educate and strengthen community systems to create sustained demand for immunisation, undertake social mobilisation and create awareness to dispel misconceptions about vaccination and increase sustained immunisation uptake. CSOs also play a role in delivering vaccines, particularly in fragile settings.

Manufacturers develop quality and affordable vaccines and other immunisation products suitable for Gavi countries. They invest in R&D, manufacturing capacity, and capacity to meet regulatory requirements. They share information with market-shaping actors and countries regarding research and development priorities, business cycles, and product development timelines. The Alliance engages with industry as the suppliers of vaccines and as partners in product strategy development. While individual manufacturers develop and supply vaccines and other immunisation products for Gavi-supported countries, industry as a whole is also represented as a partner in the Alliance through the industrialised countries' and developing countries' manufacturer constituencies on the Gavi Board. While mindful of both of these areas of engagement, this Strategy focuses primarily on the former.

[40] NITAGS are national advisory committees that guide immunisation policies: http://www.who.int/immunization/sage/national_advisory_committees/en/

[41] http://www.who.int/immunization/programmes_systems/sustainability/mic_strategy/en/

Annex F: Product Portfolio Management

Vaccines

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

1. The new vaccine presentation or product must be consistent with SAGE recommendation(s) and the relevant WHO position paper (where one exists) for the related antigen.
2. The new vaccine presentation or product must be WHO prequalified, unless a compelling reason to make an exception exists (eg to provide countries with a new vaccine presentation in a manner timely for uptake of this new presentation with as few delays as possible following first availability to enable a shift to a preferred presentation for programmatic and/or cost reasons, and where WHO prequalification is anticipated).
3. The new vaccine presentation or product must have a reliable supply base. Adding the new presentation or product to Gavi's 'product menu' should contribute to an environment of consistent and uninterrupted supply. The product should be manufactured by a reliable supplier and be available in sufficient quantities to contribute to the supply base without creating risks to supply security.
4. The estimated costs of the new vaccine presentation or product should be within the range of the current fully-loaded, wastage-adjusted vaccine costs to immunise an individual and should account for any increased procurement costs that are commensurate with evidence-based benefits of the new vaccine presentation or product and/or with decreased costs in vaccine delivery.
5. The new vaccine presentation or product must be likely to respond to country demand and preferences. Where required to avoid supply security risks or to further other market-shaping objectives, a new presentation may be added to replace an existing one (eg, a 2 dose vial presentation may be replaced by a 5 dose vial presentation, rather than expanding the market to include both presentations).

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

Cold Chain Equipment

With regard to CCE, Gavi only supports equipment included in the WHO Performance Quality Safety (PQS)[42] Catalogue that meets the following requirements:

- **User-independent ("Grade A") freeze protection** to prevent freezing of vaccines,

[42] *PQS qualification means that a device has passed a series of performance, quality and safety tests set by WHO.*

- **Extended operating temperature range** to ensure the equipment operates correctly even during large changes in ambient temperature,
- **Temperature monitoring and logging** to assure better temperature control of vaccines, and
- **Voltage regulation (for on-grid devices only)** to protect equipment from electrical damage.

Annex G: Tools and Approaches for Shaping Vaccine Markets

This section describes some examples of new and existing market shaping tools and illustrates potential applications from vaccine strategy development to procurement execution.

Vaccine strategy development

The Alliance's long-term market strategy for each vaccine in the portfolio is captured in 'supply and procurement **roadmaps**'. Development of the roadmap begins with the analysis of the supply and demand context for a given vaccine. Intelligence is gathered through a variety of formal and informal channels, compiled and analysed by core Alliance partners. This includes an assessment of Gavi's current engagement in a given market as well as the implications of past and future potential market-shaping activities. The roadmap includes Gavi demand scenarios, global demand estimates, information on supply dynamics and future entrants, pricing and costs of production, and suitability of existing vaccine products for immunisation programs in Gavi countries. Based on analysis using the Healthy Markets Framework, it prioritises objectives for the short, medium, and long term, through consideration of the trade-offs that may exist between different components of market health (eg larger supplier base or buffer capacity vs overall costs).

For each objective in the roadmap, Alliance partners set target outcomes. Included in the roadmap is an action plan that describes interventions, actors, a timeline, and measurement indicators. The action plan also includes high-level options for procurement tactics that are later developed as part of the UNICEF Procurement Strategy. Roadmaps are updated periodically to take into account new market information and refine the necessary interventions and tactics needed to influence the market.

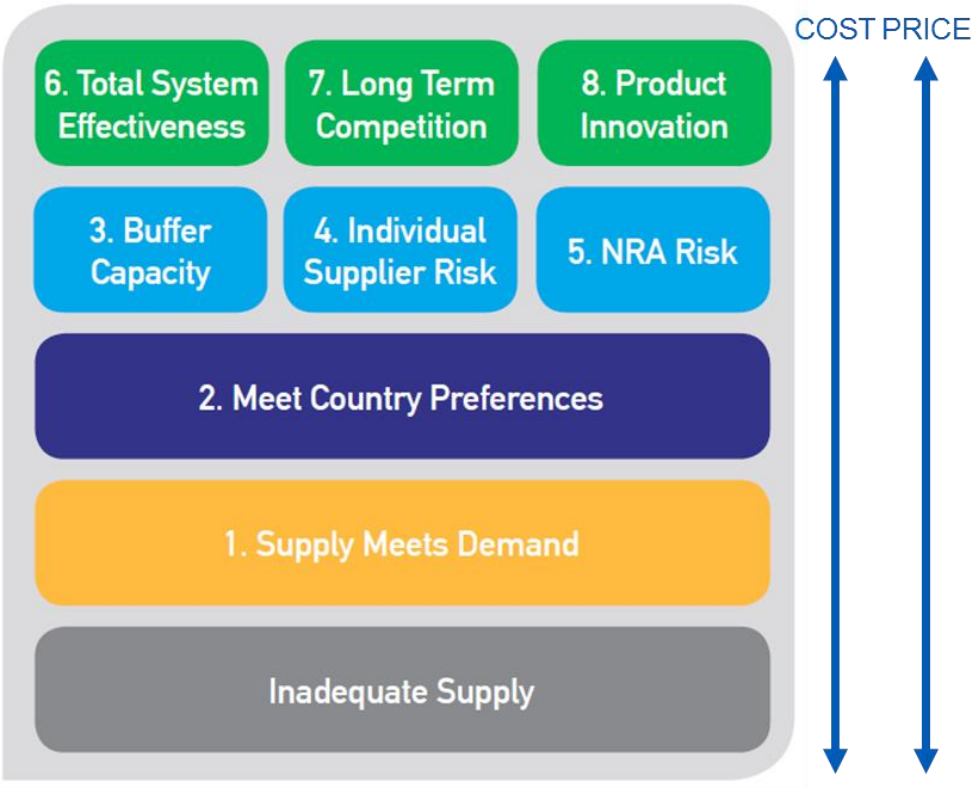
The Alliance uses the **Healthy Markets Framework** to explicitly and consistently articulate characteristics of 'healthy' vaccine markets and the trade-offs between market-shaping objectives. The framework enables the Alliance to better articulate desired market outcomes, to improve its assessment of risks and benefits of market interventions and procurement tactics, and to measure improvements in 'health' across markets in a clear and consistent manner. It elicits a meaningful description of the specific components of a 'healthy market' (eg, supply security, competition, reduced regulatory risk) and illustrates the trade-offs between these components as a measure of what the Alliance is willing to pay to achieve a healthy market.

Eight building blocks make up the framework, as shown in Figure 5.

- Markets with inadequate supply (grey) that does not meet demand cannot be healthy. Thus, the foundational building block of a healthy market (yellow) is **supply meets demand**. The primary objective is to ensure developing countries have the vaccines required to meet their immunisation needs.
- The second building block (dark blue) is to **meet country preferences** for specific vaccine characteristics such as, vial size, packaging volume, schedule of doses and valency.
- The third, fourth and fifth building blocks (light blue) reflect **supply security** attributes that can be directly influenced by procurement and other market interventions, ie enough buffer capacity in the market to be able to manage unexpected shortages; management of risks associated with procuring from individual suppliers; and, lower reliance on one National Regulatory Authority (NRA) due to procuring too much from any one country.
- The sixth, seventh and eighth building blocks (green) address **supply efficiency** that may be indirectly, or only partially, impacted by procurement and other market interventions. Total

Systems Effectiveness (TSE) considers the multiple cost dimensions associated with fully immunising a child (eg price, cold chain, operational requirements, and other vaccine-specific features) as well as safety, efficacy, and ease to achieve coverage. These building blocks also consider the benefits of longer term competition in a market and the opportunity for product innovation that addresses the shortfalls of current vaccines.

Figure 5. Healthy Markets Framework



Risk-sharing and collaborative tools

Financial incentives are a way to address barriers to innovation by sharing risks with manufacturers more explicitly. This ideally produces results in the market more rapidly or at a lower cost, compared to paying the manufacturer for a product only when it gets to market. Financial incentives can largely be grouped into two categories: push funding and pull mechanisms.

Push funding includes providing resources directly to a company through a grant or direct financial support or through a loan.

- For example, individual Alliance partners may directly finance R&D for a new product or modifications to an existing product to accelerate its availability for Gavi countries.
- *Milestone payments* which are paid out on the achievement of specific milestones (eg, clinical or regulatory). This tool explicitly shares the cost of product development but limits exposure of the donor.
- With the provision of *subsidies*, or a buy-down, the manufacturer is given a payment for each dose of vaccine sold. For example, a $4 vaccine would only cost Gavi or national governments $2, because of a $2 co-payment from a donor (this concept is built into the PCV pilot Advance Market Commitment).
- *Loans* can provide financing for R&D activities. Manufacturers may be issued loans with special terms that could include low interest rates or which could be forgiven under specific

circumstances. Repayment can be done through sales in higher-income markets (for dual-market products) or the loan could be forgiven (effectively turning it into a grant) under certain targets or timelines (eg, a certain level of pricing or date of availability). Related to this is royalty-based development funding, which subsidizes R&D activities and repays this through a royalty stream driven off of sales in high-income markets.

Pull mechanisms aim to incentivise manufacturer investment and accelerate product development.

- *Volume guarantees* provide certainty on the purchase of a certain volume of product at a specific price. This tool can be used for products in different stages of development. It provides an incentive for companies developing products by providing security on uptake once the product is approved.

Collaborative approaches provide opportunities to engage with manufacturers prior to tender rounds to align on product characteristics that reduce cost, manage manufacturer capacity.

- *Design-to-value* (on services and ancillaries): a collaboration approach in which customers share information on desired or undesired product characteristics. This allows manufacturers to reduce costs through re-design of services (eg, delivery lead time) or other ingredients such as preservatives or stabilisers that do not create value for the customer. The collaborative aspect of this tool makes it compatible with any market situation including monopolies.
- *Manufacturer portfolio review and/or 'bundling'*: while each Gavi-supported procurement strategy is currently considered on a vaccine-by-vaccine basis, there can be value in buying across the portfolio of a given manufacturer as opposed to individual products. There is some experience of using tenders covering several vaccines to allow for more informed offers and tender outcomes. The use of this approach for Gavi vaccines will need to be assessed and enabled at the strategic 'roadmap' level to enable the commercial dialogue to encompass more than one product. This approach would make sense where there are production or resource interdependencies. However, it could have negative implications that need to be carefully assessed for manufacturers with small portfolios.

Procurement planning

At the operational level, roadmaps inform the Procurement Strategy developed by UNICEF for each vaccine. Taking into account the latest market information, the Procurement Strategy includes mechanisms and tactics to be used in the tender cycle to meet strategic objectives and obtain value for money. Different buying models can be used to procure a vaccine.

Single round tenders are tenders in which only one bid is provided by each manufacturer. The formal bid can be complemented by pre-tender approaches and by post-bid clarifications. Single-round tenders are used primarily for simple, well understood products and/or if the procurer is resource or time constrained.

Multi-round tenders involve multiple rounds of bid offers before awards are finalised. This provides suppliers with an opportunity to improve their bids with each tender round. Such approaches may be employed when there are multiple manufacturers with adequate/excess capacity compared to demand.

Direct negotiations can be used where there is a lack of natural competitive pressure in the market (one or two dominant manufacturers) and can help deepen knowledge and relationships between negotiators and manufacturers. Direct negotiations rely on mutual trust and transparency among parties particularly with respect to each party's objectives and each manufacturer's production economics.

A 'hybrid model' is a combination of some aspects of the single round, multi-round, and direct negotiation buying models. For example, a single-round tender approach, after which manufacturers engage with the procurer in a direct negotiation after the bids have been reviewed.

Tools with auction-like features are based on a form of multi-round tender that can yield greater transparency of competition. Rounds include a sequence of bids where the best bid is in a winning position until a better offer is made. Higher visibility and frequency of bids can lead to lower prices. This approach could yield results in markets with high healthy market dynamics (eg high level of supply security, where competition and/or innovation are supported) and products that are comparable, and where the outcome of the procurement decision based on price only is not considered to have a negative long-term effect on the market.

Procurement execution

Once a buying model is selected for a given tender, different tactics and mechanisms can be used for negotiation, awards, and definition of specific contract terms. Analytical tools can help quantify optimal award scenarios, and Procurement Reference Groups can advise on choosing the best mix of tactics to maximise outcomes.

Value-based sourcing: this strategic principle states that factors other than immediate value for money could be taken into account in supplier selection. For example, parameters such as the innovation potential and commitment to a given disease area can be considered in the procurement decision.

Collaborative capacity management: this is used to arrange the phasing and size of orders in such a way that it reduces costs and constraints for the supplier, without risking supply interruptions for countries.

Payment terms (including pre-payment): this mechanism can be considered to address specific demand and supply risks, such as pre-payment in case of uncertain demand to reduce risk for manufacturer.

Options on capacity: this type of tool can be used to incentivise suppliers to keep some production capacity when there is a risk of supply constraint. These options can take a number of forms, including but not limited to a fee for pre-booking capacity or a fee for volume deviation from predicted demand.

Long term agreements: these agreements facilitate manufacturers' investment in new capacities, new markets and innovations by providing different advantages: long term visibility, facilitated investment planning, production regularisation and optimisation (including material cost and capacity planning).

Staircase pricing: a supply agreement signed with the manufacturer which includes volume dependent pricing, providing the potential for lower pricing when certain volumes are reached.

Volume concentration versus splitting of demand: while splitting of demand across all manufacturers with a suitable WHO pre-qualified product can be a way to increase supply security, concentrating volume with certain manufacturers may enhance the ability to secure lower prices. This is particularly the case where overall production capacity exceeds demand and where prices are driven by high fixed costs that could be spread across a larger number of units (eg, where utilisation of production capacity is a key driver of manufacturing cost). Concentrating volume implies risks for supply security which would have to be carefully balanced and potentially mitigated with other interventions (eg, back-up supply options).

Leaving doses un-awarded: during initial supply, awards can incentivise other manufacturers to enter the market later in the tender period, while still meeting current demand. These additional manufacturers might provide products with improved characteristics or lower prices, and increase the long-term competition of the market.

Annex H: Tools and Approaches to Cold Chain Equipment Markets

The Alliance will shape markets for Cold Chain Equipment (CCE) market by leveraging similar interventions and tools, adapted for the unique CCE market considerations.

CCE market strategy development

The Alliance develops long-term product 'roadmaps' for CCE describing the supply and demand context (including Gavi demand scenarios and global demand estimates), an assessment of the market (including supply dynamics and future entrants), suitability of existing CCE, and pricing and costs of production and services. Supply and procurement roadmaps prioritise objectives, set target outcomes, and formulate an action plan. The strategic objectives for CCE are aligned with those for vaccines, with required adaptations as follows:

- Stimulate demand and **supply** of higher-performing, cost-effective and quality products that meet specific technology requirements and user characteristics of Gavi-supported countries[43] by increasing demand visibility, improving information exchange between manufacturers and buyers, financially supporting equipment that meets Gavi's requirements, and including focus on the total cost of ownership (TCO).
- Minimise **costs** of devices and services by leveraging pooled volume in product procurement, using financing levers (eg, 'push funding') to de-risk manufacturer production planning, improving price transparency and 'bundling' installation and commission with the purchase of equipment.[44]
- Promote **innovation** by leveraging country and partner (eg, UNICEF) feedback mechanisms to share user needs with manufacturers and WHO Performance Quality Safety (PQS) [45] through a continuous 'feedback loop'.

Demand forecasts are also created to complement existing tools used by partners to share information on the state of product markets and key market drivers (eg, 'Market Notes' disseminated by UNICEF). A short-term demand forecast, currently owned and updated by UNICEF, leverages and integrates a range of existing data sources from countries and partners (eg, Gavi Secretariat, CHAI) in addition to actual procurement data. The Secretariat develops longer-term strategic forecasts in collaboration with expert partners such as PATH.

Financial incentives

The Alliance provides financial incentives to manufacturers under the CCE Optimisation Platform, through which countries can apply for grants;[46] the grants cover not only the purchase cost of the product but also the cost of a 'service bundle'. Through this pathway, the Alliance creates improved

[43] This includes high-performing equipment that operates across a spectrum of electrical grid access and that functions reliably while reducing the burden of operation, management, and maintenance placed on the health system.

[44] The Service Bundle is a core component of the CCE Platform and is intended to ensure timely equipment delivery, quality installation, and comprehensive end-user training. The service bundle will address common CCE issues related to improper installation and inadequate end-user skills to provide preventative maintenance. Alongside this bundle, manufacturers will continue to provide two-year warranties guaranteeing repairs for major device malfunctions. Gavi will monitor CCE manufacturers' ability to provide a service bundle component in country markets and assess value for money of the service bundle as the CCE Platform is implemented.

[45] PQS leverages established mechanisms for obtaining data on field performance in a systematic manner. These data on product performance and quality as well as issues relating to installation and maintenance are used to revise and set new product specifications. Additionally, since 2014, TPPs are used to propose modifications designed to improve performance and better meet users' needs, leading to revised PQS performance specifications and verification protocols through an iterative process between PQS, manufacturers and partners, ultimately resulting in products with improved overall performance.

[46] Countries' jointly invest in the purchase of Platform-eligible CCE. Based on countries' Gross National Income per capita, Gavi will cover 50-80% of the total purchase, delivery and installation costs. Countries are expected to fund the remaining cost.

security of demand and a mechanism to accelerate the uptake of new technology, reducing risks for CCE manufacturers by providing an assured funding source for new equipment.

The Platform also aims to reduce funding fragmentation in CCE markets by providing a mechanism for donors to consolidate funding for CCE. This pooled investment creates a larger, more predictable market for manufacturers, enabling manufacturers to better plan their production and capture scale economies.

The Alliance through its individual partners can provide 'push funding' – financial and/or in-kind support to manufacturers – to help meet CCE-specific strategic objectives Initiatives supported by partners such as CHAI, PATH and BMGF include R&D 'grants' to new entrants, technical assistance to positively influence a supplier's role in the market, and support in the development of technologies to meet the needs of the desired market.

Tailored procurement for CCE markets

The roadmaps developed by Alliance partners define and prioritise market levers that guide procurement to reach the CCE strategic objectives outlined above. In turn, UNICEF will develop and implement tailored Procurement Strategies for each tender cycle, applying the latest market information available, to leverage tactical procurement opportunities to obtain value for money. These strategies will be consulted with core stakeholders and Procurement Reference Groups when suitable to ensure alignment on priorities. Procurement Strategies use best practices to achieve these strategic objectives, including tools to achieve savings in CCE procurement, to leverage volume to obtain competitive prices and to attract suppliers to the market.

Procurement tools may include:

- **Direct supplier negotiations for product markets with limited suppliers:** UNICEF engages in direct negotiations with manufacturers in monopoly or oligopoly markets (ie markets which lack 'natural competition') to seek agreements that achieve lowest prices on orders.
- **Multi-product manufacturer pooled volume agreements:** these supply agreements enable the Alliance to engage with a manufacturer to 'bundle' multiple products in a single agreement. This provides an opportunity to lower product pricing by leveraging economies of scale due to larger production volume.
- **Long-term agreements with volume-based price scales and flexibility to incorporate future price reductions:** these agreements enable the manufacturer to pass on savings from economies of scale in production achieved through supplying larger orders, as well as passing on savings from significant reductions in input costs or from gains in production efficiency.
- **Payment/pre-payment terms**: these can be used to incentivise production (both production at scale by smaller suppliers and prioritising manufacturing capacity by larger ones) and manufacturer investment in the service bundle by providing payment upfront as part of a supply agreement.