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The Sustainability Goal

Improve sustainability of national immunisation programmes

The Market Shaping Goal

Shape markets for vaccines and other immunisation products

A Roadmap for the Future

Country-owned decisions in vaccine procurement

Public Summary

Public summary

Many countries eligible for Gavi support to introduce new vaccines into their immunisation programs have procurement systems in place to manage their traditional EPI programs, whereas others secure supply of vaccines through UNICEF. As per Gavi policy, supply and procurement of vaccines funded in the Gavi portfolio and in some cases vaccine related devices has been managed by UNICEF, and there has been considerable advantages in this approach where demand has been consolidated, including the availability of financing and use of special contracting such as the AMC for PCV introduction. In addition, Alliance partners provide Gavi-supported countries with technical assistance and support functions relevant to procurement of vaccines. Since Gavi eligibility is designed to be temporary, a number of countries have already started or completed transitioning¹, and several more will undergo the process by 2020. As countries transition from Gavi support, it is assumed that countries will self-procure vaccine requirements. For those countries that have procurement systems in place, this transition may be managed. For countries that do not have procurement systems in place for vaccines, the risk of procurement failure could increase.

For the purposes of this strategy and document, we define vaccine procurement as the set of several steps and considerations that ultimately result in vaccines being purchased and delivered into the hands of a country government for distribution and immunisation among its people. Immunisation includes routine immunisation (RI), supplementary immunisation activities (Supplementary Immunization Activities (SIA), campaigns), and vaccination for epidemic response. Successful vaccine procurement therefore relies on government capacity to plan, execute their plans (including on decisions on optimal channels), and then evaluate for improvement in subsequent years in order to secure supply of quality assured vaccines to support immunisation programs.

At the country level, good procurement practices reduce the chance of supply shortage while improving cost effectiveness, and ensures that the right quantities of appropriate and quality assured products are purchased at affordable prices and delivered at the right time. Conversely, failure to procure quality assured vaccines on time can lead to government overspending on vaccines. Even worse, it can cause supply shortages that interrupt immunisation programs, increasing the risk of susceptibility of individuals to preventable diseases and outbreak, which can ultimately result in expected loss of life.

At the global level, if countries do not approach vaccine markets with accurate forecasts/demand, unstable financing or tendering and contracting increases risk for suppliers, prices may increase and security of supply at the global level may be compromised, destabilising vaccine markets. The recovery of the markets to an improved state of health then takes a long period of time, as experienced in the early 1990s.

¹ 17 countries are fully self-financing in 2018: Bhutan, Honduras, Mongolia, Sri Lanka and Ukraine (since 2016); Guyana, Indonesia, Kiribati and Moldova (since 2017); and Angola, Armenia, Azerbaijan, Bolivia, Congo, Georgia, Timor-Leste and Cuba (since 2018). 9 countries are currently in the accelerated transition phase: India, Lao, Nicaragua, Nigeria, Papua New Guinea, São Tome e Principe, Solomon Islands, Uzbekistan, and Vietnam.

As a part of its 2016-2020 Supply and Procurement Strategy, the Gavi Alliance has prioritised taking a long-term view of markets. In the context described above, a long-term view of markets requires a shift away from Alliance-supported decisions to informed, country-owned decisions, especially around procurement, a critical enabler of immunisation.

In this context and in order to inform a cohesive Gavi Alliance approach to supporting country-owned decisions in vaccine procurement, an assessment of typical Gavi country challenges and needs related to successful procurement has been conducted, complemented by a landscaping of existing stakeholder interventions and outstanding gaps. An Alliance working group prioritised those gaps and defined target outcomes and associated interventions to address them.

Procurement-related country challenges in Gavi-supported countries

The below lists common country-related challenges which jeopardise successful procurement. (Note: Global challenges related to vaccines supply and security are excluded as they are addressed in other Alliance workstreams).

Vaccine procurement process-related challenges:

Poor cross-functional coordination

Vaccine procurement typically requires coordination and alignment across a wide range of government actors: the expanded program on immunisation (EPI); the National Regulatory Authorities (NRAs); the ministry of health (MOH); a procurement entity; the ministry of finance (MOF). Misalignment or asynchrony among these actors can lead to procurement failures. The lack of communication and alignment (or even understanding) across functions has commonly been reported among Gavi-supported countries. In addition, procurement processes are not well documented.

Inefficient payment and poor budget execution

It is not uncommon for governments to delay in paying for vaccines. Approval for vaccine budgets can be extended and inefficient, bureaucratic processes can impede payment even when vaccines are fully budgeted for. Access to foreign exchange or hard currency also remains a bottleneck. These hurdles can prevent vaccines from being delivered on time.

Vaccine procurement knowledge-related challenges:

Limited awareness of vaccine markets dynamics

An understanding of global vaccine market dynamics can help governments anticipate and prepare for supply gaps (or gluts), while strategically positioning themselves within such a global context. However, without proper and consistent exposure, market dynamic information is difficult to digest and apply. The research capabilities and bandwidth required to develop a functional understanding of market dynamics across each vaccine in the immunisation schedule can be very time-consuming and would detract from routine obligations of most EPI professionals. Finally, government counterparts have cited limited awareness of already existing market dynamic resources.

Inaccurate forecasting of vaccine demand and weak forward budgeting

Accurate forecasting for vaccine demand supports governments' activities to ensure that every child can be immunised, while reducing both supply and financial wastage. The reliance on outdated data and

globally-recommended assumptions can result in miscalculation at the country-level. Actual consumption, stock level, and wastage data are either not collected, inaccurate, or unreported. Additionally, weak forecasting processes may also generate weak forward budgeting for vaccine needs in government processes, which subsequently have knock-on effects on funds availability and delayed procurement.

Inadequate capacity

The combination of limited understanding of global vaccine markets and persistent issues in inaccurate forecasting suggest that additional work needs to be prioritised in supporting governments in their strengthening around vaccine procurement. While institutional strengthening measures (e.g., training, experience sharing) have been pursued, additional efforts are required across Gavi-supported countries.

Vaccine procurement policy-related challenges:

Poorly-informed procurement method restrictions

Gavi country governments do not systematically or thoroughly analyse the costs and benefits of different procurement channel options (e.g., via UNICEF SD, self-procurement or other mechanism). This has led to misconceptions around exactly what those costs and benefits are, which may lead to misinformed procurement-related policies. This issue could be particularly acute for transitioning countries, where some governments are considering transitioning towards self-procurement, which for some is in line with their respective national procurement policies.

Restricted supplier competition

Vaccine markets with limited competition among suppliers (e.g., monopolistic or duopolistic markets) have a higher risk to result in high prices and/or supply constraints. In addition, at country level, competition can also be restricted by strict government policies around registration and tendering, when they represent barriers to manufacturer entry and hence artificially reduce competition.

Existing stakeholder interventions

Recognising the importance of procurement for the maintenance of immunisation programs across Gavi-supported countries, various Alliance partners and other stakeholders have supported governments with tools, services, initiatives and other resources to help governments procure vaccines. For the most part, these interventions have been developed independently, and would benefit from improved coordination across organisations, partners and countries.

Figure 1: Key area-specific stakeholder interventions

NOT EXHAUSTIVE	Governance	Plan			Execute		Evaluate
		Products	Quantities	Method	Tendering	Order mgmt	
Information	Market conditions	<ul style="list-style-type: none"> Market roadmaps Strategic demand forecasts Supply and market overviews Price, volume data Market dashboard table UNICEF supply catalogue V3P / vaccine market intelligence hub; Market analysis The Right Shot report SAGE; TPP; Position papers 	<ul style="list-style-type: none"> Historical procurement data Forecasting tool 				<ul style="list-style-type: none"> Previous UNICEF SD contract awards Gavi shipment plans
Processes			<ul style="list-style-type: none"> Forecasting tool ViVa EPI forecasting tool (cMYP) 				
Capabilities			<ul style="list-style-type: none"> Effective Vaccine Management Initiative 	<ul style="list-style-type: none"> UNICEF SD procurement Gavi pricing post-transition PAHO revolving fund 	<ul style="list-style-type: none"> UNICEF SD procurement PAHO revolving fund VII World Bank innovative financing SIF 	<ul style="list-style-type: none"> NRA strengthening 	
Policies and regulation		<ul style="list-style-type: none"> GMRH initiative African Medicines Regulatory Harmonization GLO/VQ 					

Table 1: Cross-cutting stakeholder interventions

Intervention	Stakeholder	Functions and comments	Countries covered
Transition missions, assessments, plans	Gavi	<ul style="list-style-type: none"> Assess challenges that Gavi-supported countries expect to face during / after transition (however, method for assessing procurement not standardized) Develop plans to address challenges before end of transition 	17+ countries nearing Gavi transition
Vaccine Procurement Practitioners' Exchange Forum and Network (VPPEF, VPPN)	UNICEF SD	<ul style="list-style-type: none"> Bring together vaccine procurement leads across countries procuring both via UNICEF SD and self-procurement to share best practices and solve challenges jointly Virtual Vaccine Procurement Practitioners Network (VPPN) has been launched in Oct. 2017 creating a community of practice around vaccine procurement. Identify specific challenges that countries face and develop solutions with action plan (that may be supported through PEF for Gavi-supported countries) 	UNICEF- and self-procuring countries

Ad hoc procurement practitioners' forums / workshops	WHO	<ul style="list-style-type: none"> • Bring together vaccine procurement leads to share best practices and solve challenges • Identify challenges that countries face • Organised by WHO HQ with EMRO, AFRO, SEARO and WPRO in 2008-2013 and EURO region in 2013 and 2015 • WHO SEARO has organised similar workshops with ASEAN • PAHO organises regular meetings 	WHO EURO region ASEAN countries
Comprehensive Multi-Year Planning (cMYP)	WHO	<ul style="list-style-type: none"> • Broader resources that tangentially relate to procurement 	All Gavi-supported countries
Learning Network for Countries in Transition (LNCT)	BMGF / Gavi / R4D	<ul style="list-style-type: none"> • Bring together 15 Gavi transitioning country MOH leaders to share best practices and solve challenges jointly • Scope includes any challenges related to transition (not limited to procurement) 	15 countries nearing Gavi transition (or already-transitioned)

Outstanding gaps

Despite the above efforts and based on the needs assessment, significant gaps remain, primarily:

Vaccine procurement process-related remaining gaps:

Lack of a vaccine-specific procurement guideline

Guidelines to help governments procure commodities exist; however few procurement guidelines focusing specifically on vaccine, a unique commodity even within pharmaceuticals and biological products, are available and need to be updated. Consequently, government procurement practitioners often apply the same standards for other commodities to vaccines, despite substantial differences in product (e.g., biological, perishable, long lead times, significant quality considerations) and market dynamics (e.g., limited number of suppliers, high barriers to entry). There is thus the need for a methodology to assess and improve in-country procurement processes.

Vaccine procurement knowledge-related remaining gaps:

Limited awareness of vaccine markets dynamics

While a variety of vaccine market intelligence resources are available for download and use by Gavi-supported country governments, these resources are not tailored to and proactively distributed for government use. Additionally, while partners provide ad hoc coaching for government employees on how to utilise these materials and conduct their own customised research where necessary, this process is not standardised and scaled-up across countries.

Inaccurate forecasting of vaccine demand and weak forward budgeting

While the majority of Gavi-supported countries have some method for forecasting vaccine demand, not all governments understand (1) the specific costs and risks of inaccurate forecasting, e.g. the impact on budget planning and availability of funds or (2) the methods for potentially improving forecasting accuracy.

Lack of understanding of the implications of different procurement methods and tendering

Despite the steady progress toward transition from Gavi support, most government policymakers lack the information and do not have a full understanding of the respective costs and benefits of different procurement channel options (through UNICEF SD versus self-procurement versus other mechanisms), as well as of the tendering criteria beyond price. This incomplete understanding extends to other elements of procurement, as well, including basic good practices.

Lack of understanding of the impact of regulatory and registration requirements on supplier competition restrictions

Certain registration requirements (particularly those which are artificial), can either unintentionally or intentionally create barriers for manufacture entry into markets, thereby artificially reducing competition. Countries should be aware of the implications and interplay of such on competition and vaccine procurement.

Training and mentorship

In general, while Gavi Alliance partners and other stakeholders provide ad hoc training and support to government counterparts on procurement processes, the deployment at scale requires further refinement and standardisation. Similarly, in order to better support countries, Alliance staff require enhanced awareness of Gavi co-financing timelines as well as procurement cycles.

Target outcomes and supporting stakeholder action plan

The outstanding gaps were analysed and resulted in the below four target outcomes. The associated action plan ensures the coordination between Gavi Alliance stakeholders and is designed to facilitate the achievement of the target outcomes.

- 1. Ensure processes, roles and responsibilities, chains of command and capabilities relevant to vaccine procurement are well-defined and understood by in-country procurement professionals.**
 - Create a vaccine-specific standardised methodology to assess and improve in-country procurement processes (including cross-functional coordination), organisations and capabilities in Gavi-supported countries.
 - Prioritise countries and deploy the above procurement assessment and improvement methodology through existing interventions.
 - Ensure that cMYP estimates of vaccine and supply requirements are realistic and can be used for budgeting purposes.

- 2. Ensure country governments have timely access to and apply useful information on: procurement methods and tendering implications; global vaccine market conditions (e.g., price, availability of products, manufacturers – All vaccines); forecasting information.**
 - Develop a document supporting countries' decision process on vaccine procurement method / channel options (through UNICEF SD versus self-procurement versus other) & the tendering implications.
 - Collect intelligence based on country queries to inform country needs in terms of market information.

- Repackage content of existing market information resources (from WHO, UNICEF, GAVI) to make them 'country-friendly' and ensure country governments know how to use them.
- Ensure country government procurement professionals use historic country-specific delivery data (provided by UNICEF to countries supplied by UNICEF) to forecast, e.g. highlight differences between UNICEF delivery and country forecast to approximate long-run vaccine consumption.
- Promote information and resources developed in above interventions through existing channels (e.g. VPPN and VPPEF, Peer Learning Network, existing Global Fund and World Bank initiatives and Global Learning Opportunity center of excellence network).
- Tailor generic information and resources developed in above interventions to specific countries (e.g. countries transitioning, or who need more support) and distribute proactively to governments, ahead of procurement and budgeting cycles.

3. Ensure country government procurement professionals and EPI managers and staff can have access to quality training on vaccine procurement.

- Develop a standardised course on vaccine procurement for individual procurement practitioners as well as EPI managers and staff.
- Prioritise countries and deploy the course developed in above intervention.
- Provide ad hoc technical assistance for individual procurement strategies as needed (e.g. funding or a consultant).
- Explore the idea of top performing institutions serving as centers of excellence in procurement.
- Increase awareness of Gavi co-financing policy for Gavi Alliance partners (UNICEF, WHO, BMGF), and of timelines of procurement cycle and UNICEF SD role in procurement in countries and at HQ (i.e. for Gavi SCMs, to better inform country staff).

Another target outcome was defined and seen as an important enabler to achieve procurement improvements. However it was seen as out of the scope of this project and will be addressed outside of this project.

4. Regulatory requirements ensure quality vaccines while not unduly restricting competition among suppliers

- Facilitate harmonisation of regional regulations around vaccine registration in collaboration with existing efforts by BMGF, WHO, the World Bank, African Medicines Regulatory Harmonisation (AMRH), ASEAN.
- Increase funding and bandwidth for WHO efforts on NRA strengthening.
- Incorporate procurement-related indicators into the WHO NRA assessment tool to link NRAs more strongly with procurement needs.
- Ensure MOHs understand the implications of various product registration decisions.