



## Report to the GAVI Alliance Board

16-17 November 2011

<b>Subject:</b>	<b>Vaccine supply and procurement strategy for the period 2011-2015</b>
<b>Report of:</b>	Nina Schwalbe, MD, Policy and Performance
<b>Authored by:</b>	Aurelia Nguyen and Eliane Furrer, Policy and Performance
<b>Agenda item:</b>	12
<b>Category:</b>	For Decision
<b>Strategic goal:</b>	SG4 - Shape vaccine markets

### **Section A: Overview**

#### **1. Purpose of the report**

- 1.1 The purpose of this paper is to seek approval by the GAVI Alliance Board of GAVI's new Vaccine Supply and Procurement Strategy. The strategy focuses on the period defined by GAVI's five-year strategic plan (2011-2015), although the recommendations do consider and impact the period beyond.
- 1.2 The strategy does not address vaccine-related supplies (e.g. autodisable syringes, safety boxes), the selection of GAVI's procurement partners<sup>1</sup> or downstream (in-country) supply-chain and efficiency.<sup>2</sup>

#### **2. Recommendations**

- 2.1 The Programme and Policy Committee (PPC) recommends that the GAVI Alliance Board approve the proposed revised Vaccine Supply and Procurement Strategy for the period 2011-2015 as presented in detail in Annex 2.

#### **3. Executive summary**

- 3.1 GAVI's Vaccine Supply and Procurement Strategy aims to support the achievement of GAVI's mission to save children's lives and protect people's health by ensuring adequate and secure supply of quality vaccines to meet demand, minimising the costs of vaccines to GAVI and countries and fostering development of appropriate and innovative vaccines. This requires timely, transparent and accurate market information.

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<sup>1</sup> GAVI has a series of Memoranda of Understanding (MOUs) with the procurement partners, which run through to the end of 2012 for some vaccines and beyond for pneumococcal vaccines.

<sup>2</sup> In-country supply chain and delivery issues are addressed through other areas of the work of the GAVI Secretariat and of the GAVI Alliance.

- 3.2 GAVI's vaccine supply strategy addresses the short-, medium- and long-term view of how the market should evolve for particular vaccines and the tools and mechanisms used to influence the supply environment in which GAVI operates.
- 3.3 In the past GAVI primarily relied on so-called "market forces" to influence price and supply security (e.g. competition over time will lead to supply security and price decrease). This was only partially successful. Moving forward GAVI will actively approach market shaping by (i) determining upfront GAVI's long-term market ambitions and the envisaged means of achieving these, and by (ii) influencing the future supply base through the use of longer-term supply acceleration tools and through explicit signalling to manufacturers.
- 3.4 GAVI's vaccine procurement strategy refers to the mechanisms used to buy vaccines in order to achieve the supply and procurement objectives. Through the procurement strategy GAVI aims to influence the market by (i) choosing from a wide set of procurement mechanisms and tactics to apply those that best respond to the prevailing market conditions for a particular vaccine (taking into account market maturity, vaccine complexity, and GAVI's market power); (ii) managing product portfolios; (iii) appropriately mitigating risks associated with the approach employed.

## 4. Context

### Background

- 4.1 GAVI's current Vaccine Supply and Procurement Strategy was approved by the Alliance Board in 2005 and focuses on HepB and Hib containing vaccines. It has three broad objectives<sup>3,4</sup>: (i) Ensuring a sustainable quantity of supply through a diverse supplier base; (ii) Selecting products and presentations that best meet the needs of client countries; and (iii) Achieving a long-term affordable price that can eventually be sustainably financed by developing countries. At the time of adoption of these objectives, no hierarchy was placed on their relative weight.
- 4.2 Although countries have the option to use GAVI funds to self-procure vaccines, the majority of procurement with GAVI Alliance funds is conducted by procurement partners. Currently, UNICEF Supply Division (UNICEF SD) acts as the GAVI Alliance's main procurement partner. For GAVI-eligible countries in Latin America and the Caribbean, the PAHO Revolving Fund is GAVI's procurement partner.

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<sup>3</sup> GAVI Board meeting (6-7 December 2005 - Doc AF.7. Supply Strategy). Recommended Supply Strategy for Hib and HepB Containing Vaccines. <http://www.gavialliance.org/library/gavi-documents/supply-procurement/supply-strategy-for-hib-and-hepb-containing-vaccines/>

<sup>4</sup> In addition, GAVI's current supply and procurement principles are outlined in the GAVI long-term vaccine procurement strategy development approved by the GAVI Board, May 2005. <http://www.gavialliance.org/library/gavi-documents/supply-procurement/gavi-procurement-principles/>

## Vaccine Supply and Procurement: Progress to Date and Challenges

- 4.3 Thanks primarily to the work of its procurement partners, the Alliance has had a number of successes with regard to vaccine supply and procurement. A few examples are noted below:
- (a) Supply security: GAVI has succeeded in ensuring supply security, even in situations where global supply has been constrained. For example, GAVI has met country demand (in terms of meeting country requirements for timing of introduction, providing an uninterrupted supply) for pentavalent vaccines for more than five years through an increased and diverse supplier base despite some production problems. GAVI has also ensured routine immunisation needs for yellow fever of GAVI countries despite global supply shortages. Supply security has been supported by the establishment of the GAVI forecasting platform of Strategic Demand Forecasts through the Accelerated Vaccine Introduction Initiative. This initiative has strengthened and made consistent forecasting methodologies across vaccines, increased transparency and improved dissemination, thereby contributing to better matching of supply and demand over time.
  - (b) Affordability: The Advance Market Commitment (AMC) for pneumococcal vaccines has allowed for a long term price ceiling of US\$ 3.50 which represents more than a 90% reduction compared to high-income country prices. For pentavalent vaccines, the weighted average price paid has decreased from \$3.62 in 2007 to projected \$2.58 in 2011, corresponding to a 29% decrease over 4 years.
  - (c) Meeting country preferences: GAVI's procurement partners managed to meet country preferences for product presentations. However, the unintended consequence in some cases (e.g. preference for liquid pentavalent) was the proliferation of micro-markets, which in turn resulted in reduced supplier options and inability to take advantage of decreasing prices. There are important lessons to be taken to ensure the adequate balance of country preferences versus the impact on market dynamics.
- 4.4 Despite these successes, the 2<sup>nd</sup> GAVI Evaluation concluded that vaccine prices have been an “*area of weak performance*” for the Alliance. It also points out that “*the assumption that creating a large market for vaccines would lead to a rapid reduction in vaccine prices has not occurred*” and that “*GAVI has not actively addressed strategies for reducing vaccine prices and has relied on natural market force*”.<sup>5</sup> Other issues raised in the Evaluation and elsewhere include the following:
- (a) The need for more clarity around the individual vaccine supply and procurement objectives and the strategy overall. For example, there is a need to be more explicit in prioritising objectives to inform any necessary

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<sup>5</sup> CEPA LLP, Applied Strategies (September 2010). *GAVI Second Evaluation Report*  
<http://www.gavialliance.org/library/gavi-documents/evaluations/second-gavi-evaluation-2006-2010/>

trade-offs and providing guidance on how to deal with multiple product presentations/ formulations within each vaccine market.

- (b) The need for more active market management rather than reliance on natural market forces alone and strategies that focus predominantly on short to medium term procurement activities (i.e. 3-5 year horizon). This more active market management would include an explicit end-to-end vision to define GAVI's longer-term approach to shaping each vaccine market, charting market entry considerations, potential supply and procurement strategies over the course of involvement in the market, to potential future transitioning to full country funding, where feasible.
  - (c) The need to set and communicate realistic and evidence-driven market shaping expectations to break the cycle of misalignment between expectations and outcomes.
  - (d) The need for GAVI to re-evaluate and more explicitly articulate a toolkit of procurement approaches to address the complexity of operating in multiple markets and the relatively higher costs of new vaccines in GAVI's portfolio (e.g. rotavirus, pneumococcal and human papillomavirus vaccines).
- 4.5 In February 2010, GAVI's Programme and Policy Committee (PPC) began a review of GAVI's overarching Vaccine Supply and Procurement Strategy and requested that a time-limited task team be formed to steer the work. Membership of the task team chaired by Susan McKinney from USAID is listed in Annex 1. The PPC was consulted four times between February 2010 and September 2011.
- 4.6 McKinsey & Co undertook consultations on behalf of the task team (see Section 12). This informed the development of in-depth assessments of market dynamics for key GAVI vaccines. These assessments were used as case studies to understand the vaccine complexity, the market maturity, and GAVI's potential influence in shaping individual vaccine markets (rotavirus, pneumococcal, pentavalent and yellow fever).
- 4.7 Given the amount of highly sensitive information covered in this project, and numerous stakeholders with conflicts of interest and/or competing interests, the Secretariat recognised that it was critical to define clearly upfront how sensitive information would be handled. The consultants from McKinsey acted as a "filter team" with access to all information and then sanitised / disguised information as appropriate when shared with the Secretariat project team and the task team. Members of the task team and GAVI staff working on the project were under individual confidentiality agreements and data (except for demand forecasts) were not shared with any party outside the task team. Manufacturers did not see data, detailed or aggregated, from other manufacturers.
- 4.8 To manage conflicts of interest, the PPC decided upfront that representatives from both industrialised and developing country vaccine manufacturers should

not be part of the task team. However, as mentioned above, manufacturers were consulted both to provide data but also to provide their perspectives on GAVI-funded procurement.

- 4.9 The task team's final recommendations on the Vaccine Supply and Procurement Strategy were presented to the PPC at its meeting in May 2011. The PPC strongly endorsed the proactive market shaping approach with an expanded set of supply and procurement mechanisms suggested in the paper and provided additional feedback. The PPC requested that the Secretariat redraft the supply and procurement strategy paper based on its comments and conduct a public consultation.
- 4.10 The revised strategy was then made public for comments by GAVI stakeholders and interested parties. The consultation aimed to be inclusive in its approach to soliciting and consolidating feedback on the draft strategy. In addition to advertising the consultation on the GAVI website and through other social media (including Facebook and Twitter), the Secretariat also reached out to Alliance Board and Committee members/constituencies, as well as targeted outreach to other individuals and stakeholders. The feedback on the strategy was provided using an online submission form on the GAVI Alliance website. The consultation generated significant interest: there were over 620 visits to the website and over 230 visits to the feedback form specifically. In total, 15 feedback forms were submitted from individual respondents and those representing a broader constituency: individuals (6 responses), donors (4), civil society (4), and pharmaceutical industry (1).
- 4.11 The majority of feedback consisted of concrete suggestions in response to the main themes in the strategy, while others provided particular text edits or asked for further clarification on some topics. The detailed comments are available to GAVI Alliance Board members on the myGAVI website and will be made available to the public on the GAVI website following the Board review.
- 4.12 The PPC reviewed the revised strategy incorporating the consolidation of comments from the consultation in September 2011. The PPC was satisfied with the approaches suggested and level of detail of the strategy. Further comments were added regarding the role of CSOs, required support to manufacturers, reporting of progress and noting that beyond this strategy countries also need support to strengthen their procurement capabilities. The strategy as revised during the PPC meeting is recommended for approval by the GAVI Alliance Board.

## 5. Next steps

- 5.1 The Secretariat, in consultation and collaboration with technical partners, will implement the vaccine supply and procurement strategy.

### **6. Conclusions**

- 6.1 The proposed strategy is expected to facilitate the achievement of GAVI's strategic objectives to ensure adequate supply of quality vaccines to meet demand, to minimise the cost of vaccines to GAVI and countries and to foster the development of appropriate and innovative vaccines. Active engagement in market shaping will also set the stage for GAVI's impact beyond the current strategic planning period over the next decade.

### **Section B: Implications**

#### **7. Impact on countries**

- 7.1 A more active market management can improve GAVI's ability to meet countries' needs with regard to availability, price and appropriateness of products. Specifically increased communication and transparency on vaccine prices and other market information will support decision making at country level on product preferences and product specific demand forecasting; communication and appropriate signalling to manufacturers can optimise industry's investment decisions and increase alignment of product characteristics with countries' needs; efficient procurement of quality vaccines should optimise tender outcomes by achieving supply security to countries.
- 7.2 Of note, in order to achieve GAVI's vaccine supply and procurement objectives, GAVI may need to limit presentation/ formulation choices and/ or select product presentations and formulations offered to countries. In practice, this means that individual countries may not always receive their first choice product formulation/ presentation or may be asked to switch at some point in time.

#### **8. Impact on GAVI Stakeholders**

- 8.1 Many of the procurement mechanisms (e.g. multi-round tenders, direct negotiations) will likely require more intensive resourcing to implement and, in some cases, may require GAVI's procurement partners to explore and adopt new practices. The ability of GAVI's procurement partners under their own policies and procedures to employ these practices will need further assessment. The application of the proposed procurement mechanisms will need to be carefully managed to ensure they are not in conflict with the principles of good public procurement.<sup>6</sup>
- 8.2 The use of an expanded set of buying models and vaccine specific procurement strategies may require manufacturers to adapt their bids and processes accordingly.

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<sup>6</sup> [http://www.unicef.org/supply/files/UN\\_Practitioners\\_Handbook.pdf](http://www.unicef.org/supply/files/UN_Practitioners_Handbook.pdf)

## 9. Impact on the Business Plan / Budget / Programme Financing

- 9.1 The GAVI Alliance would need to substantially enhance its market insight capabilities to implement this strategy. The proposed arrangements to collect, analyse and use market dynamics information is outlined in the roles and responsibilities section of Annex 2.<sup>7</sup>
- 9.2 There may be a need in some instances to commit GAVI funds upfront over a longer period than has been the practice in the past.

## 10. Risk implications and mitigations

- 10.1 The procurement mechanisms defined in this strategy offer GAVI a wider range of options to address the broader variety of market situations in which GAVI is operating. Most of the proposed tools and mechanisms have specific strengths, but also potential weaknesses and/or risks. For example, while some of the procurement strategies (e.g. volume concentration) might positively contribute to lowering costs for GAVI and countries, they might also reduce security/stability of supply. These risks will need to be carefully assessed and managed on a vaccine by vaccine basis.
- 10.2 Some of the procurement tools proposed, such as direct negotiations or enhanced supplier engagement, expose the GAVI Alliance to a perception risk that it may be “overly friendly” with some or all manufacturers and thus not appropriately serving the interests of countries or donors. GAVI will continue to define clear rules of engagement and reporting to minimise this risk and manage conflicts of interest.
- 10.3 While increased transparency on individual historical product prices has evident benefits, the GAVI Alliance must be aware of the risk of inadvertently “setting a price” as there is a limited number of manufacturers in the market.<sup>8</sup> Similarly, sharing all components of the vaccine specific roadmaps which outline the long-term vision for the market and potential supply and procurement strategies may undermine GAVI’s ability to negotiate with manufacturers. To mitigate these risks, procurement tactics and targets will remain confidential as will prices until contracts are awarded.
- 10.4 Achieving the appropriate balance or prioritisation across the supply and procurement objectives is inherently challenging. While focusing on price is critical, prices pushed too low may drive some manufacturers out of the market. Although this may lead to cost savings in the short-term, the long-term effects on supply security and price are less clear. Short-, mid- and long-term benefits and risks have to be carefully assessed when developing the

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<sup>7</sup> The impact of such additional demand is addressed in the 2012 workplan and budget.

<sup>8</sup> Previously only weighted average prices (WAP) were shared by UNICEF. PAHO shares prices offered with manufacturers at the time of opening of bids and publishes the weighted average prices (WAP) on its website.

roadmaps. Periodic updates of the roadmaps will allow for course corrections over the evolution in maturity of each vaccine market.

- 10.5 Finally, the risk of insufficient financial resources for GAVI to fully fund countries' vaccine demand will impact GAVI's ability to shape markets. It reduces the predictability of GAVI-supported procurement of vaccines, and therefore the predictability of funded demand. In formulating the vaccine specific roadmaps GAVI should be mindful of potential funding gaps and other challenges that may affect the long term sustainability or predictability of demand in the market.

### **11. Legal or governance implications**

- 11.1 If adopted, the Vaccine Supply and Procurement Strategy will need to be implemented in a manner that manages conflicts of interest and is consistent with applicable regulatory and legal requirements, including relevant anti-trust and competition laws.

### **12. Consultation**

- 12.1 The strategy was developed under the guidance of a task team chaired by Susan McKinney from USAID. Consultations were undertaken by McKinsey & Co on behalf of the task team with the UNICEF SD, PAHO, and 15 vaccine manufacturers from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Developing Countries Vaccine Manufacturers Network (DCVMN). The PPC was also consulted four times between February 2010 and September 2011.
- 12.2 As described in Section 4.10, the draft version of GAVI's Vaccine Supply and Procurement Strategy was made available for public comments by GAVI stakeholders and other interested parties.

### **13. Gender implications / issues**

- 13.1 The proposed Vaccine Supply and Procurement Strategy has no specific implications on gender equality or on gender related barriers to access and utilisation of vaccines.

### **14. Implications for the Secretariat**

- 14.1 As outlined in Annex 2, a market insight capacity will be created within the Secretariat. This has been addressed in the 2012 workplan and budget.

**ANNEX 1: Membership of the time-limited Supply and Procurement Strategy Task Team (June 2010 to May 2011)**

The PPC requested that a time-limited Supply Strategy Task Team be formed to steer analytical activity and deliver recommendations to the PPC. The Task Team was supported by a Secretariat-led project team working with experts from McKinsey & Co (funded by the Bill & Melinda Gates Foundation). Affiliation and titles as of May 2010.

Name	Institution	Title	In-depth understanding of supplier (industry) behaviour	Procurement expertise within other GHPs or other industries	In-depth understanding of or involvement in vaccine demand forecasting	In-depth understanding of vaccine R&D pathways	Involved in current/previous PRGs/GAVI procurement activity	From and working in developing country	Unaffiliated	Male (8)/ Female (3)
Susan McKinney	USAID	Senior Technical Advisor for Immunization	✓	✓	✓	✓	✓			F
Julie Milstien	Independent Consultant	Independent Consultant	✓	✓		✓			✓	F
Rehan Hafiz	Former Pakistan MOH	Former EPI Manager, Pakistan MOH					✓	✓	✓	M
Robert Matiru	WHO		✓	✓						M
Raja Rao	Bill & Melinda Gates Foundation	Senior Program Officer – Procurement Issues	✓	✓			✓			M
Hanne Bak Pedersen (Ann Ottosen delegate)	UNICEF SD	Deputy Director Programme	✓	✓	✓		✓			F
Daniel Rodriguez	PAHO Revolving Fund	Advisor		✓	✓					M
Stefano Malvolti*	PATH, AVI-SVS team	AVI Strategic Vaccine Supply Director	✓		✓		✓			M
Daniel Berman**	Médecins Sans Frontières	Deputy Director	✓	✓		✓				M
Jon Pearman	GAVI Secretariat, P&P	Director, Accelerated Vaccine Introduction	✓	✓	✓	✓	✓			M
Gian Gandhi***	GAVI Secretariat, P&P	Head, Policy Development	✓		✓	✓	✓			M

\* Attended all Task Team deliberations but did not review the Task Team's final paper to the PPC in May 2011

\*\* Resigned from Task Team after the first face-to-face meeting

\*\*\* Managed and led the analytical work between Feb 2010 - Feb 2011; drafted study reports, but did not review the Task Team's final paper to the PPC

## ANNEX 2: Vaccine supply and procurement strategy for the period 2011-2015

### 1. Introduction

The GAVI Alliance's success in terms of saving children's lives and protecting people's health requires adequate supply of vaccines to meet demand and ensure minimal cost of vaccines to GAVI and countries. For this reason, the GAVI Alliance has adopted an explicit strategic goal to shape vaccine markets in the coming five year period.

In order to achieve its market shaping objectives, the Alliance is redesigning its vaccine supply and procurement strategy, as described below. The strategy focuses mainly on the period defined by the GAVI Alliance's five-year strategic plan (2011-2015). However, the recommendations do consider and impact the period beyond. The strategy relates to vaccines that have been recommended or will be recommended in the future for use in GAVI countries.<sup>9,10</sup> The scope of the strategy does not include issues related to vaccine-related supplies (e.g. autodisable syringes, safety boxes), the selection of GAVI's procurement agents/agencies or downstream (in-country) supply-chain and efficiency. In-country supply chain and delivery issues are addressed through other areas of the work of the GAVI Secretariat and of the GAVI Alliance.

The first section of this document reviews the dynamics of the vaccines marketplace in which GAVI operates. The second section puts forward the objectives of the strategy. The third and fourth sections describe the supply and procurement mechanisms by which the new strategy will be effected. The final two sections outline how the strategy will be implemented, including the monitoring and evaluation indicators and roles and responsibilities of different stakeholders.

### 2. The GAVI Alliance and the Vaccine Marketplace

There are important market failures in the health sector and particularly in the vaccines market for low income countries.<sup>11</sup> Characterised by a limited number of manufacturers and buyers, demand and supply dynamics in the vaccine market do not work according to the economic theory of perfect competition. First, in comparison to other health products and higher income market segments, the total potential revenue from vaccines sales in developing countries is relatively small.<sup>12</sup> Second, there are relatively high barriers to entry for new vaccine manufacturers due to high

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<sup>9</sup> The term 'vaccine' refers to the antigen class (or combination of antigens) and includes all presentations and formulations recommended for use in GAVI countries.

<sup>10</sup> In this document, the term 'GAVI country' refers to all GAVI-eligible countries and all countries graduating from GAVI support ('graduating countries')

<sup>11</sup> Some of the key challenges related to vaccines markets are described in Barder O, Kremer M, Levine R, *Making Markets for Vaccines: Ideas to action*. Working Group Report. Washington DC, Center for Global Development, 2005. <http://www.cgdev.org/section/initiatives/archive/vaccinedevelopment/chapters>

<sup>12</sup> The relative importance of revenues generated from sales of vaccines in developing countries varies across manufacturers. While for some companies the vaccine business, especially in developing countries, represents a very small percentage of total revenue, for others (in particular emerging market vaccine manufacturers), it is their core business.

capital investments and technological know-how needed for vaccine development from basic research to production and distribution and the high risk of failure of candidate vaccines.

Third, the difficulty to access adequate and timely information for both purchasers (e.g. regarding supply capacities, pricing) and manufacturers (e.g. regarding demand forecasts, desired product characteristics) can create uncertainty and risks in decision making. For instance, demand is not only driven by public health needs and disease control progress, but also by the availability of country and donor funding, which makes forecasting difficult. Fourth, historically many products available on the market had been developed for high income markets and were thus often not optimised in terms of price, formulation or presentation for GAVI countries. Finally, even when a product may be appropriate and affordable, ramping up or changing manufacturing capacities in vaccine production to satisfy increasing demand from GAVI countries (i.e. the GAVI birth cohort is approximately four times the size of the birth cohort of high income countries) often takes years and additional investments. This makes supply security a significant issue for the GAVI Alliance to manage.

The result of these vaccine market conditions are limited competition, vaccine costs not generally sustainable to GAVI countries, lack of sufficient supply or risk of supply disruptions, and lag time between availability of vaccines in high income and availability in low or lower-middle income markets. The GAVI Alliance and its members<sup>13</sup> have helped to increase certainty of demand from developing countries and thereby made this market segment more attractive to industry and provided an important stimulus for participation of developing country manufacturers. Going forward, the GAVI Alliance should continue to play a strategic role to help address market failures by increasing certainty of demand, stimulating competition where possible and fostering a sustainable quantity of appropriate quality vaccines is available through a diverse manufacturer base (including developing country manufacturers) at an affordable and sustainable price for GAVI and countries.

The GAVI Alliance currently supports the purchase of six different vaccines and has prioritised four additional vaccines for future inclusion in its portfolio of products.<sup>14</sup> For each of these vaccine markets, GAVI's market shaping potential differs.<sup>15</sup> These differences should influence the strategy the Alliance employs to ensure affordable and consistent supply.<sup>16</sup> While the strategy focuses on GAVI countries, as well as on vaccines in GAVI's current and future portfolio, when implementing the strategy, the GAVI Alliance will be mindful of the potential impact on prices and availability of

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<sup>13</sup> The term 'GAVI Alliance members' refers to all institutions and countries that are represented on the GAVI Alliance Board.

<sup>14</sup> Vaccines currently supported include pentavalent (DTP-HepB-Hib), rotavirus, pneumococcal conjugate, yellow fever, meningococcal A, and measles vaccines. GAVI's investment strategy for future support also includes typhoid, rubella, HPV and Japanese encephalitis vaccines. A very small number of markets are still supported with hepatitis B and tetravalent (DTP-HepB) vaccines.

<sup>15</sup> For more information see Nguyen A, Furrer E and Schwalbe N. Market shaping: strategic considerations for a healthy vaccine marketplace. GAVI Alliance: May 2011. <http://www.gavialliance.org/library/gavi-documents/white-papers/market-shaping--strategic-considerations-for-a-healthy-vaccine-marketplace/>

<sup>16</sup> A time-limited Supply and Procurement Strategy Task Team appointed by Programme and Policy Committee of the GAVI Alliance Board steered the analytical work and review of options.

vaccines to other buyers in the market, particularly Lower Middle Income Countries (LMICs) and on vaccines not currently supported by GAVI.

Key factors influencing GAVI's market shaping potential are as follows:

- **Market maturity and competition.** This relates to the number of manufacturers willing and able to supply the market, the balance of supply to demand, and the expected supply dynamics in the short to medium term. For example rotavirus and pneumococcal vaccine markets are in the early stages of the market lifecycle with currently only two global suppliers.<sup>17</sup> Pentavalent vaccines, in contrast, have been in the market for over 10 years. This market is still deemed attractive for potential new suppliers, which means increased competition and potential for excess supply capacity in the future. Price and supply security are thus both affected favourably.
- **Vaccine complexity.** This can have an important impact on the production technology required and the costs of production. More complex vaccines tend to have bulk antigen production as a major cost driver, whilst for lower complexity vaccines, the fill and finish costs may be the more significant driver. The type of complexity also determines the overall costs of production and the extent to which improvements in yield and utilisation affect production cost.
- **GAVI's relative market power.** To understand how GAVI can be effective in market shaping, it is important to consider the role and relative importance of the Alliance for a given vaccine. Relative market power is measured in several ways, e.g. in terms of volumes, revenues, and profits relative to other purchasers/markets, and in terms of the relative importance within manufacturers' portfolio of products. GAVI could have strong relative market power for pentavalent, rotavirus, pneumococcal, and other vaccines that are specifically adapted to developing country contexts.

### 3. Objectives of the vaccine supply and procurement strategy

- 3.1 The GAVI Alliance's supply and procurement strategy aims to contribute to GAVI's market shaping goal by balancing supply and demand and ensuring security of supply, minimising the cost of vaccines to GAVI and countries, and fostering development of appropriate and innovative vaccines (see Table 1). In order to achieve these aims, the GAVI Alliance must ensure timely, transparent and accurate market information for both purchasers and providers. For the definition of terms, see Annex A.

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<sup>17</sup> A third rotavirus supplier exists. However, it is not able to supply the GAVI market because its product is not prequalified by WHO and it does not meet WHO's definition of a quality vaccine.

Table 1: GAVI Vaccine Supply and Procurement Objectives

Balance of supply and demand	Cost of the vaccine to GAVI and Countries	Appropriate and Innovative Vaccines
<ul style="list-style-type: none"> <li>• Ensure sufficient supply of vaccine is available to at least meet total GAVI demand</li> <li>• Provide consistent, uninterrupted supply to GAVI countries</li> </ul>	<ul style="list-style-type: none"> <li>• Minimize the per course vaccine cost</li> <li>• Minimize the cost implications of vaccines to GAVI countries</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure procurement of appropriate, quality vaccines to meet GAVI country needs</li> <li>• Foster an environment for innovative vaccines</li> </ul>
<p><b>Information:</b> Communicate timely, transparent and accurate market information</p>		

3.2 **Prioritisation of objectives.** The GAVI Alliance will aim to satisfy all of its supply and procurement objectives for each vaccine. However, trade-offs will inevitably be required between different objectives due to market conditions (e.g. ensuring supply security may come at additional cost if part of a tender needs to be awarded to a higher-priced manufacturer). Another example is that there may be trade-offs when trying to ensure early access to life-saving vaccines when a competitive market and affordable prices are not yet in place. To address such tensions or conflicts, the priority of objectives in the short-, medium- and long-term will be determined on a vaccine-by-vaccine basis in the roadmaps (see Section 4.1) depending on the market environment and adjusted if required during the procurement process.

3.3 **Transparency of information.** For both manufacturers and countries, timely, transparent and accurate information on demand and supply forecasting, current and expected future vaccine product characteristics and prices is critical. An increased level of transparency is sought in order to provide greater accessibility of information to recipient countries and other GAVI Alliance members. The establishment of the GAVI forecasting platform of Strategic Demand Forecasts has contributed to a better matching of demand and supply over time, helping to improve supply security. This platform has strengthened and standardised forecasting methodologies across vaccines, increased transparency and improved public dissemination of demand related information. Increased information transparency is also critical to improved forecasts for projected volume growth to stimulate competition and encourage new market entrants. Furthermore, UNICEF Supply Division (UNICEF SD) and GAVI now require vaccine manufacturers to make their awarded prices public.<sup>18,19</sup> However, a more nuanced approach will be required in terms of specific GAVI Alliance price targets: these may not be publicly disclosed in order to avoid unintended consequences (such as setting price ceilings), which would

<sup>18</sup> The prices offered to GAVI countries illustrate the “tiered pricing” practice whereby manufacturers offer the lowest price to countries with the lowest income levels. While these published prices may act as global benchmarks, countries with higher income levels may not have access to these prices.

<sup>19</sup> On an exception basis, where disclosure of awarded prices would hold a strong risk for GAVI’s ability to undertake a vaccination programme, awarded prices may not be disclosed.

compromise the execution of the strategy. Where appropriate, the GAVI Secretariat will make non-proprietary or non-commercially sensitive vaccine market information available.

#### **4. Supply Strategy**

*Definition: The GAVI Alliance's vaccine supply strategy is the short-, medium- and long term view of how the market should evolve for particular vaccines and mechanisms used to influence the supply environment in which GAVI operates. Although this may be implemented in the context of the current GAVI Alliance strategy plan (2011-2015), some of the gains will not be realised until 2016 and beyond.*

*Strategic approach:* In the past, the GAVI Alliance primarily relied on so-called "market forces" to influence price and supply security (e.g. competition over time will lead to supply security and price decrease). In the future, GAVI will actively approach market shaping by (i) determining upfront the Alliance's long-term market ambitions and the envisaged means of achieving these, and by (ii) influencing the future supply base through the use of supply acceleration tools and explicit signalling (of estimated demand and desired product characteristics) to manufacturers.

This approach will require the following actions:

##### **4.1 Creation of roadmaps, including the definition of appropriate market interventions, for each GAVI supported vaccine**

Roadmaps determine the GAVI Alliance's long-term market ambition for each vaccine in the current and future portfolio. The roadmaps will include five main components for each vaccine: i) an analysis of the market; ii) considerations of when and how the GAVI Alliance should start engaging in the market; iii) prioritisation of objectives (described in Table 1) for the short-, medium-, and long term including an analysis of the tensions and tradeoffs that may exist between them and setting of targets; iv) definition of options for supply-side interventions and signalling to manufacturers; and v) considerations of the timeframe for engagement and when GAVI financial support may end.

Detailed market analyses for each vaccine, including supply and demand landscaping, mapping of current and future products, Target Product Profiles (TPPs) and product characteristic guidelines and considerations of cost and price drivers will inform the definition of roadmaps. The GAVI Secretariat will lead and coordinate the development of the vaccine specific roadmaps. Alliance members with technical competencies and disease and vaccine experts, as well as experts from other global health organisations with experience in market-based approaches, will be consulted to define the GAVI Alliance's long term approach to shaping each vaccine market.

Before starting to support a vaccine the GAVI Alliance would, among other things, consider the potential for the vaccine to become affordable to countries

over time<sup>20</sup> and the vaccine supply and procurement interventions that GAVI might employ to shape the market in order to get to that point. Decisions to start supporting the purchase of a particular vaccine would therefore be made with “eyes wide open” particularly to the possibility that the GAVI Alliance’s leverage on price and/or supply may take several years to achieve. While financial sustainability<sup>21</sup> and the prospects for long-term affordability should be key considerations for market entry, they may not be a ‘deal breaker’ in cases where there is a significant health imperative. For vaccines that are already considered affordable by recipient countries, GAVI’s decision to start influencing a market may be motivated by other objectives such as improving health impact or improving supply security.

For vaccines where the GAVI Alliance has already entered the market, the roadmaps highlight strategic considerations for how the market should evolve and for transitioning to full country funding.

Despite the long-term nature of the vaccine-by-vaccine roadmaps, these plans would be updated periodically to take into account new market dynamics and refine the necessary activities/tactics to influence the market particularly with respect to procurement.

On the basis of these vaccine specific roadmaps, the GAVI Alliance would conduct the following activities to influence the supply environment and foster innovation to ensure supply of appropriate and quality vaccines:

- **Coordinate across Alliance members and other players’ activities to enhance competition in the market and expand the supplier base.** To support the entrance of new suppliers to the market and intensify competition between manufacturers, the GAVI Secretariat would play a lead role in supply strategy development and collection of relevant market information and engaging supply strategy advocates. The aim of these activities is to promote ‘healthy markets’ with characteristics such as increased competition or reduced supplier concentration, reduced barriers to market entry for new suppliers and accelerated new product introduction. Factors that may limit the participation of developing or emerging market country manufacturers, such as the lack of capital to invest in development, bottlenecks in manufacturing processes, intellectual property rights barriers and lack of technological know-how as well as needs of other manufacturers should be investigated and action considered by the roadmaps. The GAVI Secretariat would also help establish clear links between push and pull mechanisms to help ensure that these efforts are complementary, encourage innovation, improve the outcome

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20 “Affordable” in this context is defined as the country’s ability to pay (based on a fiscal space analysis). It is recognised that the ability to pay will vary by country and is likely to depend on the cumulative number of vaccines included in a country’s routine immunisation programme. Beyond a country’s economic ability to pay, the sustainability of a country’s immunisation programme will also depend on the country’s willingness to pay (which is linked to the government’s level of political support).

21 In the context of GAVI’s co-financing policy, the GAVI Alliance Board defined ‘financial sustainability’ as the ability of a country to mobilise and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunisation performance.

for countries in terms of suitability of products and optimise the use of GAVI and partner funds. In this regard, the GAVI Alliance may also engage in activities targeted at products in early phases of development by catalysing or brokering push-funding methods and technology transfers to ensure appropriate and affordable new and follow-on products are brought to market, to improve production processes and/or routes of administration of the vaccine. The GAVI Alliance may engage at different points of the vaccine development continuum, for example, through process improvements to reduce cost, increases in production scale, supporting incremental innovation and encouraging new entrants.

- **Catalyse the design and implementation of pull mechanisms.** The GAVI Alliance aims to create and promote incentives to accelerate and secure vaccine supply for GAVI countries. Methods to achieve this could include demand guarantees, leaving quantities unawarded while meeting current demand, firm contracting, advance purchase commitments or other advance market commitment (AMC)-like mechanisms. The pilot AMC for pneumococcal vaccines is one of GAVI's existing pull tools to influence the market: long-term procurement contracts create incentives for manufacturers to commit to large volumes of appropriate, quality vaccines at a long-term price ceiling. On-going and planned monitoring and evaluation activities will provide further information to inform the future applicability of this mechanism. The GAVI Alliance's level of engagement in the design and implementation of pull mechanisms will depend on the objectives and opportunities for a particular vaccine.
- **Facilitate incremental innovations.** To ensure procurement of appropriate, quality vaccines and to foster an environment for innovative vaccines, the Alliance will seek to catalyse the development of products that are adapted to the needs of GAVI countries. This may cover aspects of increased programmatic suitability (such as improved thermostability, more flexible dosing schedules, longer shelf life, novel preservatives, new combination products or optimised administration mechanisms). Other innovations may lead to overall cost reductions for GAVI and/or recipient countries, increased supply security, or improved health outcomes. In order to determine desirable innovations, the GAVI Alliance will seek information from technical partners, in-country stakeholders, CSOs and other experts. To this end, the GAVI Alliance will: encourage and facilitate the development of technical guidelines such as target product profiles (TPPs) to define desired incremental innovations and share these with manufacturers; encourage the investment in push funding or process engineering improvements; and other actions as identified in the roadmaps. The extent of GAVI's engagement in such innovations will depend on the specific vaccine market and the potential GAVI can see to reap rewards.
- **Strengthen graduating countries' ability to sustain immunisation gains<sup>22</sup>:** In order to sustain immunisation programmes in countries that

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<sup>22</sup> Graduating countries are those whose Gross National Income (GNI) per capita has crossed the GAVI eligibility threshold and that can no longer apply for new vaccine or cash-based programme support from the

graduate from GAVI Alliance financial support, it is important to ensure that these countries continue to have access to affordable vaccine prices and on-going government support for immunisation. Some vaccines including pentavalent, measles, polio, yellow fever and meningococcal vaccines are already available to graduating countries at a price similar or equal to the price procurement partners pay for GAVI countries. Through pro-active communication with manufacturers, GAVI can help secure sustainable access to affordable vaccine prices for graduating countries as evidenced by recent commitments made by industry ahead of GAVI's pledging conference in June 2011.<sup>23</sup> Under the pneumococcal Advance Market Commitment (AMC), graduating countries will be able to access pneumococcal vaccines at the same long-term price paid by GAVI. The roadmaps should therefore also consider methods to ensure affordable and sustainable prices for graduating countries and potentially for other LMICs where this is not currently the case. Together with technical partners, GAVI will seek continuous exchange of information with countries on price related issues. In addition to affordable prices, it is equally important to support the graduation process in these countries according to their needs, for example through mobilisation of support for vaccination at the political and leadership level, capacity building in areas of vaccine procurement, financing, regulation and advocacy for immunisation.

**4.2 Develop market insight capabilities.** Market insight capabilities ensure that the GAVI Alliance (and the procurement partners acting on its behalf) has a thorough understanding of important market characteristics, including product specific demand, manufacturers' supply capacity, product launch timelines, vaccine characteristics and cost drivers, and business/investment strategies. Such knowledge is required to implement the strategy, in particular, to develop and update the vaccine specific roadmaps, including the definition of supply and procurement options, to have a realistic view of the Alliance's relative market power, and to set appropriate targets and timelines for achieving its objectives. In addition, such intelligence will help the Alliance to take a wider view of the market to better appraise the potential impact of its supply and procurement decisions on other buyers in the market and/or on vaccines not currently supported by GAVI. The GAVI Secretariat and multiple GAVI Alliance members, including civil society, procurement partners, WHO and donors supporting push funding currently possess market insight capacity relevant for their respective work. For instance, the GAVI Secretariat maintains a well-functioning demand forecasting platform for all GAVI-supported vaccines. Forecasting methodologies have been strengthened and standardised across vaccines and regular updates have facilitated a better matching of supply and demand over time. However, information on other important market and product characteristics is currently diffused across different organisations. The GAVI Secretariat will play a coordinating role across Alliance members to facilitate

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GAVI Alliance. According to GAVI's co-financing policy, these graduating countries have to linearly ramp up their contribution to the cost of vaccines over a four year period and are expected to assume the full cost thereafter.

23 GAVI Press Release, 'GAVI welcomes lower prices for life-saving vaccines', Geneva, 6 June 2011 <http://www.gavialliance.org/library/news/press-releases/2011/gavi-welcomes-lower-prices-for-life-saving-vaccines/>

collection and exchange of information so as to maximise the benefit for the Alliance.

To this end, improved partnering with those Alliance members that possess some market intelligence data, partner countries and other stakeholders (e.g. product development partnerships), as well as increased engagement with manufacturers will help the GAVI Alliance to build strong market insight capabilities. Consolidated non-proprietary and non-commercially sensitive information may then be made available. This aims to enable manufacturers, for instance, to supply products that better align with countries' needs and better meet the GAVI Alliance's objectives.

### 5. Procurement Strategy

*Definition: The GAVI Alliance's vaccine procurement strategy refers to the mechanisms used to buy vaccines in order to achieve the supply and procurement objectives.*

*Strategic approach: Through the procurement strategy the GAVI Alliance aims to influence the market by (i) choosing from a wide set of procurement mechanisms and tactics to apply those that best respond to the prevailing market conditions for a particular vaccine (taking into account market maturity, vaccine complexity, and GAVI's market power); (ii) manage product portfolios; (iii) appropriately mitigate risks associated with the approach employed.*

#### 5.1 Procurement mechanisms

To support the implementation of the 2011-2015 supply and procurement strategy, the following mechanisms and tactics will be used to help address the increased complexity of operating in different market environments. Each mechanism has specific strengths and benefits as well as potential risks and/or costs (Annex B). The selection of the appropriate mix and the timing of application of different approaches will be informed by the specific vaccine market situation and by the relative weighting of supply and procurement objectives, as outlined in the roadmaps.<sup>24</sup>

##### 5.1.1 Buying models and pre-tender activities

Buying models determine the tendering approach for purchasing vaccines. They differ in the nature of interaction between procurer and potential suppliers and in the number of bidding rounds undertaken to finalise awards. Depending on the specific market characteristics, and in particular on the number of incumbents, the following buying models will be considered:

- **Single round tenders.** These are tenders in which only one bid is provided by each manufacturer (e.g., price, volume, length of commitments) based on which the procurer selects the winning bid. The formal bid can be complemented by pre-tender approaches and by post-

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<sup>24</sup> Adherence to the principles of good public procurement and any applicable legal and regulatory requirements would have to be ensured with any of these mechanisms.

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.** These are tenders in which several rounds of bids are requested of the manufacturers before awards are finalised. After each round the procurer evaluates the bids/offers against predetermined criteria. This provides manufacturers with an opportunity to improve their bids in each tender round. Multi-round tenders may be appropriate in markets with surplus supply and multiple manufacturers with proven capacity.
- **Direct negotiations** with individual manufacturers may be appropriate where there is a lack of natural competitive pressures in the market (i.e. in situations of one or two dominant players). Direct negotiations can help deepen knowledge and relationships between negotiators and manufacturers and may help to achieve better procurement deals while new manufacturers are preparing for market entry.
- **Hybrid model.** This is the model that has been used most frequently to date. It represents a combination (i.e. hybrid) of some aspects of the single-round, multi-round, and direct negotiation buying models. One prominent hybrid model could be to use a single-round tender approach, however, instead of manufacturers submitting one formal bid, which could include alternative options, they engage with the procurer in a direct negotiation after the initial bids have been reviewed.

A number of pre-tender activities can be employed in order to gain insight and develop relationships with manufacturers without involving any binding offers from the manufacturers or buyers. Pre-tender mechanisms differ in the level of information requested from the potential manufacturers and in the nature of the interaction between procurer and suppliers. Potential pre-tender tools include: Request for Information (RFI), Registration of Interest (ROI), Expression of Interest (EOI) and in person pre-tender meetings. The latter can be used in conjunction with the previously mentioned approaches.

### 5.1.2 Procurement tactics

A range of procurements tactics will be applied in procuring GAVI supported vaccines. These tactics must be considered in view of the objectives agreed in the roadmaps. Regardless of the objectives pursued, a long-term view is critical to ensure that unintended consequences such as key manufacturers leaving the market place do not occur in the pursuit of short term price decreases.

Tactics include:

- **Use of volume concentration versus splitting of demand.** Manufacturers have different levels of ability or willingness to supply the markets of GAVI supported vaccines based on available manufacturing capacity, levels of commitment to GAVI countries and profitability of GAVI vaccines within their vaccine portfolio. They also have different cost

structures and drivers of manufacturing costs and hence varying abilities to offer low prices. As such, the effect on vaccine pricing of increased competition and volumes awarded by procurement partners to each competing manufacturer will vary. While splitting demand across multiple manufacturers with a suitable WHO pre-qualified product may increase supply security, concentrating volume with certain (lower cost) manufacturers may enhance the Alliance's 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 (i.e. where utilisation of production capacity is a key driver of manufacturing cost). Concentrating volume implies risks for supply security, which will need to be carefully balanced and potentially mitigated with other interventions.

- **Increased supply security through the use of back-up supply.** Supply risks related to the production of vaccines (e.g. vaccine quality issues), to the regulatory environment (e.g. functionality of the National Regulatory Authority in the manufacturing country) or to the selection of a particular procurement strategy can be mitigated through establishing back-up supply. Possible back-up supply strategies include the signing of options contracts or the creation of a vaccine stockpile. When considering any of these back-up supply approaches, the GAVI Alliance would have to be mindful of the feasibility of such options, associated costs, additional management burden and related risks.
- **Pull mechanisms.** As described in paragraph 4.1, the GAVI Alliance can also use "pull mechanisms" to create incentives for new manufacturers in the later stages of vaccine development to bring their products to market sooner and/or to expand planned production.

### 5.2 Product portfolio management

On occasions, the existence of multiple product formulations and presentations may impede the GAVI Alliance from achieving its supply and procurement objectives. When this occurs, the GAVI Secretariat may need to "manage the product portfolio" (or optimise product selection). This may result in a limitation of presentation or formulation choices available to countries in order to optimise procurement, to achieve the appropriate balance among different supply and procurement objectives and improve the outcome for GAVI countries as a whole. Decisions on if and how to limit presentation/formulation choices will be informed by early, intensive and continued consultations with countries, partner organisations and other experts and will be based on a careful assessment and weighting to the respective interests of the majority of countries (that would benefit from a lower weighted average vaccine price or increased supply security) and of individual countries' that may be negatively affected by such a decision. This process should also be supported by capacity building and information sharing at country level by Alliance members to enhance evidence-based decision making on vaccine introduction and product selection. In the management of its product portfolio, the GAVI Alliance will be informed by countries' preferences as expressed during these consultations and in the countries' application

documents for new vaccine support, as well as through third party information. Any decision to limit presentation and/or formulation choices will take into account potential programme implications at country level, as well as the impact on market competition and number of manufacturers.

Activities linked to capacity building in areas of vaccine procurement should also be supported by GAVI Alliance members.

## 6. Monitoring and evaluation

The GAVI Secretariat will compile on a yearly basis a combination of indicators from data provided by Alliance members. The indicators serve to track the GAVI Alliance's progress in implementing its vaccine supply and procurement strategy and will be reported on an annual basis.<sup>25</sup> Reporting on these indicators will include accompanying commentary to provide context on the market evolution for each vaccine.

A combination of indicators could include (Definitions and data sources are provided in Annex C):

1. Vaccine price per dose and per course for all GAVI-supported vaccines purchased through GAVI's procurement partners:<sup>26</sup>
  - Weighted average vaccine price
  - Lowest and highest vaccine price points
2. Number of vaccines not available to meet shipment plan as agreed with the procurement partners due to delisting from the WHO list of prequalified vaccines, downgrading of NRA functionality or other quality issues occurring after supply had been awarded.
3. Security of supply: number of products offered as a percentage of five year target.
4. Percentage of awarded prices published on time by presentation and by manufacturer.

Qualitative information will also be reported by GAVI Alliance partners on an annual basis to describe progress made on fostering an environment for innovative vaccines adapted to country needs and on ensuring the communication of timely, transparent and accurate market information.

The GAVI Alliance's impact on price and supply security will be monitored on a vaccine by vaccine basis. For instance, information currently tracked on a regular basis and shared internally between UNICEF SD as procurement partner and the GAVI Secretariat includes:<sup>27,28</sup>

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<sup>25</sup> Targets will be established for each indicator. However, some targets may not be publicly disclosed to avoid unintended consequences such as setting price ceilings.

<sup>26</sup> On an exceptional basis, where disclosure of awarded prices would hold a strong risk for GAVI's ability to undertake a vaccination programme, awarded prices may not be disclosed.

<sup>27</sup> The frequency and level of reporting on these indicators varies across vaccines in accordance with the Memoranda of Understanding (MoUs) between the GAVI Alliance and its procurement partners. Additional indicators are being monitored for the Pneumococcal AMC.

- Demand forecasting: comparison of forecasted quantities, by type of vaccine and by year, with actual purchases and actual shipments
- Number of manufacturers from which products are procured by vaccine type and presentation For each type of vaccine procured on behalf of GAVI:
  - Number of pre-qualified products by manufacturers in developed and developing countries as per year end
  - Total supply (prequalified and non-prequalified) offered over demand
  - Price per dose development over time (including comparison of the benchmarks of other comparable or regional purchasing groups)
- On-time delivery performance (and reasons for delays in delivery)
- Actual weighted average price of each vaccine for the reporting year and the projected weighted average price for the following year
- Explanation of how best-value for freight was obtained through the applicable year
- Report on Vaccine Arrival Report data

Finally, the supply and procurement strategy will be reviewed in 2014, in preparation for the development of the GAVI Alliance 2016-2020 strategy, and progress will be reported on a regular basis to the PPC.

### 7. Roles and responsibilities

Implementation of the new vaccine supply and procurement strategy requires close collaboration of a number of Alliance members. Roles and responsibilities are outlined below:

GAVI Secretariat: Facilitating the participation and contribution of key Alliance members<sup>29</sup>, the Secretariat will lead in the development and implementation of the vaccine roadmaps<sup>30</sup>, including: maintaining vaccine-by-vaccine supply landscapes, providing guidance on prioritisation of objectives where conflicts may arise between them; charting market entry considerations and modelling short- and long-term funding implications; and developing potential supply and procurement strategies and related targets. The GAVI Secretariat also has primary responsibility for producing strategic demand and pricing forecasts and will continue to share demand forecasts on a vaccine-by-vaccine basis, including with manufacturers. Cross-cutting strategy development will support the roadmaps with activities such as: convening consultations with technical Alliance members, additional disease/vaccine experts, and other global health organisations with relevant expertise, to define longer term approaches to shaping markets; and engaging with manufacturers for instance to identify barriers and bottlenecks in R&D and production where this is not being

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28 Of note, sustainability as measured by fulfilment of co-financing will also be tracked under strategic goal 3.

29 In line with Article 7, GAVI Alliance By-Laws

30 As defined in Section 4.1

addressed by other Alliance members; and leading and coordinating the development and implementation of innovative financing tools, including pull mechanisms. For example, the GAVI Secretariat will explore new financing mechanisms with partners such as members of the World Bank Group and regional development banks. The GAVI Secretariat will seek continuous exchange of information through consultations with countries to ensure product suitability in terms of programmatic use as well as price (in the case of graduating countries<sup>31</sup>). These functions will be coordinated within an agreed framework for exchanging information by the market insight capability housed within the Secretariat, in partnership with Alliance members.

Procurement partners, currently UNICEF SD and PAHO: procuring vaccines on behalf of GAVI countries and being responsible for ensuring transparency and accountability of procurement. Developing and implementing the procurement strategies to achieve the vaccine-by-vaccine objectives developed through the roadmaps, including: conducting formal consultations with suppliers, managing the procurement processes, establishing supply arrangements and contracting modalities, forecasting the balance of supply and demand, delivery and monitoring of supplies, and ensuring transparency on pricing information. Building on expertise and past experience in the vaccines (and where appropriate medicines) markets to support the development and achievement of supply and procurement strategies and the development and tracking of monitoring and evaluation indicators, including the provision of key data as indicated in Section 6 above. Procurement partners will ensure countries are informed about product presentations, availability and prices. They also offer further capacity building work beyond the scope of procurement, including: technical support to countries on forecasting, budgeting, procurement, distribution and monitoring of vaccines and in-country logistics support.

World Health Organization (WHO): supporting the development and achievement of supply and procurement strategies and supporting the development and tracking of monitoring and evaluation indicators as indicated in Section 6. Developing target product profiles to inform development of next generation vaccines; and conduct prequalification activities for vaccines in the GAVI portfolio/pipeline, including definition of programmatic suitability.<sup>32</sup> WHO will also assess compliance of national regulatory authorities (NRAs) against international standards to enable manufacturers to submit vaccines for the WHO pre-qualification process and participate in tenders of GAVI's procurement partners. WHO is also responsible for providing countries with programmatic guidelines around the introduction of new vaccines and recommendations on their use.

GAVI countries: inform the selection of GAVI-supported products offered to countries, the roadmaps (e.g. – balancing of objectives), and target product profile development by WHO. Countries also provide programmatic feedback to WHO and manufacturers on product suitability and ensure the provision of accurate information in comprehensive multiyear plans (cMYPs), GAVI application forms and annual

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<sup>31</sup> The GAVI Secretariat and Alliance members also look to support the graduation process with capacity building in areas such as regulatory affairs, domestic financing, product selection, procurement and supply chain management. This is supported through the Business plan.

<sup>32</sup> A proportion of these activities are currently supported through the GAVI Alliance business plan.

progress reports on planned timing of introduction, quantities required including wastage rates (forecasting) and preferred presentation/formulation.

Manufacturers: to reliably supply quality-assured vaccines at competitive prices. To support the development of vaccine-specific strategies, manufacturers will be invited to provide to the GAVI Secretariat, on a confidential basis, development timelines and product profiles. Manufacturers would also provide feedback on the effectiveness of the GAVI Alliance's supply side interventions and procurement tactics.

Donors: developing and implementing investments where they relate to GAVI portfolio vaccines or relevant technologies and working closely with the GAVI Secretariat and other key Alliance members to ensure appropriate complementarity of push and pull funding efforts. For example, the Bill & Melinda Gates Foundation is involved in push funding efforts, including financial and technical support for manufacturers to help accelerate R&D and WHO prequalification of new vaccines, and supports developing country vaccine manufacturers in optimisation of manufacturing processes. The donor role may also entail engagement in developing and supporting innovative financing mechanisms. These may be applied to so called "pull funding" efforts, which include market mechanisms aimed to incentivise manufacturers such as the AMC or guaranteeing procurement of volumes to secure lower prices.

Civil Society Organisations: to continue with a strong advocacy voice to ensure the value of vaccination and the need for long term, reliable funding is widely understood and recognised. CSOs also serve as advocates and informants on product suitability and affordability. CSOs educate and strengthen community systems to create sustained demand for immunisation, undertake social mobilisation, education and awareness to dispel misconceptions and increase sustained immunisation uptake. Furthermore, CSOs play an important role as technical partners and in supporting the Alliance members to gain an understanding of the successes and challenges in achieving GAVI's objectives at the global and country level.

**ANNEX A: Supply and procurement objectives and definitions**

		Objective	Definitions of terms
1	Balance of SUPPLY AND DEMAND	Ensure sufficient supply of <i>vaccine</i> is available to at least meet total <i>GAVI demand</i>	<p><i>Vaccine</i>: The term ‘vaccines’ refers to 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 countries. The term ‘products’ refers to the specific formulations and presentations of particular vaccines. For example, the current pneumococcal conjugate vaccine market has several products including the 10-valent and the 13-valent products.</p> <p><i>GAVI demand</i>: Refers to GAVI financed demand and demand for co-financed doses</p>
2		Provide <i>consistent, uninterrupted</i> supply to GAVI countries	<p><i>Consistent</i>: Country should not have to unnecessarily and frequently switch product (i.e. lyophilized product, 10 dose product) as a result of procurement decisions</p> <p><i>Uninterrupted</i>: no global stock-out of vaccines in a particular vaccine market</p>
3	COST OF THE VACCINE to GAVI and Countries	Minimize the per course vaccine cost	<i>Cost</i> : Landed cost, which is the ex-factory cost of the vaccine, plus freight, syringe(s) and safety box (if necessary) costs but excluding wastage
4		Minimize the <i>cost implications of vaccines to GAVI countries</i>	<i>Cost implications of vaccines to GAVI countries</i> : The co-financing and systems costs to countries including wastage, cold chain requirements, and programmatic delivery (e.g., training required to switch product)
5	Appropriate and Innovative VACCINES	Ensure procurement of <i>appropriate, quality</i> vaccines to meet GAVI country needs	<p><i>Appropriate</i>: Vaccines that are suitable with regards to their presentation and formulation (e.g., liquid/lyophilized, number of doses, packaging, volume and cold chain requirements ) to ensure significant public health benefit for GAVI countries</p> <p><i>Quality</i>: Reliance on WHO definition for vaccines of assured quality. WHO considers a vaccine to be of known good quality provided that the National Regulatory Authority (NRA) independently controls the quality of the vaccine in accordance with the six specified functions defined by WHO and that there are no unresolved confirmed reports of quality-related problems</p>
6		Foster an environment for <i>innovative</i> vaccines	<i>Innovative</i> : Novel improvements that are more beneficial to countries and/or GAVI than the status quo and at a cost that would offer real value comparatively speaking
7	INFORMATION	Communicate timely, <i>transparent</i> and accurate <i>market information</i>	<p><i>Transparent</i>: Shared appropriately and openly</p> <p><i>Market information</i>: Data and insight that informs GAVI portfolio choices, country product choices, and the choices manufacturers make in production planning, capacity investments, and pricing</p>

### ANNEX B: Description of procurement mechanisms

To date, UNICEF SD, which is the GAVI Alliance's primary procurement partner, has used a multi-faceted tendering approach for purchasing GAVI-funded vaccines, which might be described as a “**hybrid procurement model**”. This involves a series of **pre-tender meetings**, to inform manufacturers of demand, countries' emerging preferences for particular product formulations/presentations, and the issuance of a **Request for Proposals (RFP)** to specify the terms of the tender. Tendering usually requires manufacturers to make a single round of bids (“**single round tenders**”). UNICEF SD conducts follow-up clarifications and discussions with manufacturers based on their bids to optimise the outcomes. Finally, following consultation with a Procurement Reference Group (PRG), if applicable, UNICEF SD seeks to match available supply to GAVI demand whilst balancing price, product characteristics, volume concentration, and supply security considerations, including taking future manufacturers into account when deciding on quantities to potentially be left unawarded.

The GAVI Alliance Procurement Strategy for 2011-2015 proposes a number of tools, mechanisms and tactics, as described below. Some of these tools have already been applied in the past, others are new or complementary to existing approaches. The selection of tools will be dependent on the specific market conditions and the relative prioritisation of the different vaccine supply and procurement objectives for individual vaccines at specific points in time.

#### 1. Pre-tender activities (non binding)

In general, pre-tender mechanisms permit the procurer to gather detailed information on market insights, including detailed manufacturer and product information and can be used to condition and prepare manufacturers to provide bids that align with the procurer's objectives. Furthermore, pre-tender mechanisms allow procurers to compare responses of manufacturers to identify best strategic options, lower cost alternatives, and overall cost reduction opportunities. However, these mechanisms require resources and time to be conducted and, given the non-binding nature of the information, manufacturer comparisons remain preliminary (e.g. manufacturers may vary widely in the strength of non-binding price information). The following pre-tender activities may be employed:

- The *Request for Information (RFI)* is an open enquiry issued as a preliminary document seeking information from potential manufacturers.
- A *Registration of Interest (ROI)* and *Expression of Interest (EOI)* are closely related, sometimes synonymous, to RFIs. The former is often a simpler document (only a few pages) asking for managerial, financial, and technical details of the potential offering, while the latter is usually a more detailed enquiry that can include references, approach and possible solutions, company details and capabilities. Financial estimates and opinions may be expressed but remain non binding.
- *Pre-tender meetings* can be used in conjunction with these other pre-tender approaches and allow for less formalised interactions, manufacturer questions, and open procurer-supplier discussions.

### 2. Buying models

Buying models determine the tendering approach for purchasing vaccines. They differ in the nature of interaction between procurer and potential suppliers and in the number of bidding rounds undertaken to finalise awards. Depending on the specific market characteristics, and in particular on the number of incumbents, the following buying models may be used:

- *Single round tenders* are tenders in which only one bid is provided by each manufacturer (e.g., price, volume, length of commitments). After all manufacturers submit their single bid in response to an Invitation to Bid, the procurer selects the winning bid. 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 (i.e. there is only capacity for a one-round tender process). While single-round tenders are inexpensive and quick to implement, the procurer may not always obtain the most competitive bids during the one and only tender round and bids may not contain sufficient information to make well-informed selections.
- *Multi-Round tenders* are similar to single-round tenders in that manufacturers respond with bids to a request from the procurer and the procurer then evaluates the bids/ offers. However, in multi-round tenders, this process occurs multiple times before awards are finalised. This provides suppliers with an opportunity to improve their bids with each tender round. After each round, some manufacturers may be eliminated from the tender process. Such approaches are used frequently in the private sector (health and non-health related industries) and are employed when there are multiple manufacturers with adequate/excess capacity compared to demand, and margins are relatively high, and when the product and potential pricing are not well understood. However, such approaches are more onerous for both manufacturers and procurers. Also, the procurer needs to have a credible threat of not awarding any supply or awarding small amounts of volume to some manufacturers in order to assure that quality bids are received each round.
- *Direct negotiations* can be used where there is a lack of natural competitive pressures in the market (one or two dominant players). They can be based on a Request for Proposals (RFP) to ensure clarity on objectives and requirements. Addressing challenges arising from tendering in low competition environments, direct negotiations can help deepen knowledge and relationships between negotiators and manufacturers. However, direct negotiations require more extensive engagement from both procurers and manufacturers and also rely greatly on mutual trust and transparency among parties particularly with respect to each party's objectives and manufacturer's production economics. The outcome of direct negotiations with manufacturers should not compromise new market entrants' incentives to bring their products to the market as fast as possible.
- *The 'hybrid model'* is a combination (i.e. hybrid) of some aspects of the single-round, multi-round, and direct negotiation buying models. One prominent hybrid model could be to use a single-round tender approach, however, instead of manufacturers submitting one formal bid, which could include alternative options,

they engage with the procurer in a direct negotiation after the initial bids have been reviewed. Such an approach enables the procurer to get the benefit of (a) manufacturers providing a formal bid, (b) more than a single round which can increase competitive pressure without the time and resource costs of a multi-round approach, (c) talking through contracting modalities that can benefit both the procurer and manufacturer(s), and (d) forming long-term relationships with the manufacturers. For a hybrid model, many of the same conditions need to be in place as for a single-round or multi-round tender. For example, there needs to be multiple players in the market, and the procurer needs to have a credible threat of not awarding quantities to a manufacturer. As with a multi-round tender, a procurer may want to use this method for complex products (or not well-understood products, or product categories, where there are differences in manufacturers' presentations not allowing for one specification) or if the procurer is uncertain if the manufacturers' bids will be of sufficiently high quality. For the direct negotiation portion of the tender process, while giving equal opportunities to all bidders, the procurer may want to narrow down the field to a smaller set of players to ensure the hybrid approach is not more onerous than a multi-round tender. As with a multi-round tender, the risk of a hybrid approach is that it may be more timely and expensive to execute than a pure single-round tender. Safeguards need to be in place to guard against non-competitive bids during the first round of the process.

### 3. Procurement tactics

Different tactics can be pursued when structuring the awards and allocating supply. Again, the appropriate approach (or combination of tactics) will depend on the specific market conditions and the relative emphasis placed on individual supply and procurement objectives.

- *Volume concentration versus splitting of demand*  
Manufacturers tend to have different abilities to supply the markets of GAVI-supported vaccines based on available manufacturing capacity, levels of commitment to GAVI countries and profitability of GAVI vaccines within their vaccine portfolio. They also have different cost structures and drivers of manufacturing costs and hence varying abilities to offer low prices. As such, the effect on pricing of competition and volumes awarded to each competing manufacturer will vary. 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 Alliance's 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 (i.e. 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 (e.g., back-up supply options).
- *Supply Acceleration - Pull Mechanisms*  
A range of "pull mechanisms" can be used to create an incentive for new manufacturers in the later stages of vaccine development to bring their products to

market sooner and/or to expand planned production to better meet GAVI countries' demand needs. The GAVI Alliance already employs several approaches here:

- *Leaving doses unawarded* means that while meeting current demand not all doses are awarded to existing suppliers such that there is an incentive for other manufacturers to come to market. Experience to date and feedback from manufacturers suggests that this has worked well.
  - *Long-term awards* provide manufacturers with multi-year awards. UNICEF SD currently makes 1-3 year awards which are codified in non-legally binding 'Long-Term Arrangements' (LTAs). The long term awards ensure visibility and an appropriate planning horizon for manufacturers of products with long production lead times. Although there is no procurement obligation on UNICEF SD's side, the use of LTAs ensures that the uncertainty with respect to future demand that manufacturers' perceive and therefore the risk premiums that they build in to prices are reduced. The GAVI Alliance could in theory offer longer-term awards of this kind (e.g., five or possibly even ten years) as these might further reduce uncertainty and create greater incentives for manufacturers. The risk lies in locking in pricing for the duration of the award, preventing the purchaser from taking advantage of any nearer-term improvements in market prices; and they may also precipitate excluded manufacturers to exit the market.
  - *Firm contracting* means that the GAVI Alliance could sign legally binding contracts with manufacturers as opposed to just the looser non-binding awards that GAVI currently offers in most instances. The risks and benefits of this approach are similar to those of long-term awards.
  - *Demand guarantees* effectively combine long-term awards and firm contracting and hence can create incentives to accelerate development and/or scale production capacity to meet GAVI-funded demand by guaranteeing some portion of future demand at a given price. This type of procurement pull mechanism requires the Alliance to take on a financial commitment and hence GAVI needs to add those risks to its balance sheet.
- *Options to increase supply security through back-up supply*  
There are several types of supply risks when procuring vaccines. Some risks are related to the production of bulk or finished goods (e.g., batch failures, facility malfunctions) or to the national regulatory authorities (NRAs) that oversee the quality of supply (e.g., these may not remain 'functional' as determined by WHO standards). Some other risks may result from the selection of particular procurement approaches. For example, by concentrating volume to a limited number of manufacturers the GAVI Alliance may create supply security risks at the expense of emphasis on other objectives, such as lowering prices. Backup supply is an approach that the purchaser can use to help mitigate against these supply security risks. It entails having on hand or having access to sources of supply that can be used to buffer against sudden peaks in demand (e.g., outbreaks; earlier than foreseen adoption by a country or countries) or mitigate sudden shortages in supply (e.g., batch failures). Two examples of backup supply for use during emergencies, disruptions, or unanticipated peaks in demand are *vaccine stockpiles* or *options contracts*. When considering any of these back-up supply approaches, GAVI would have to: (i) Quantify the supply risks and weight them up against the

expected costs of options on or to stockpile additional supply to insure against these risks; (ii) Evaluate the ability to access these alternative supply sources on time to avoid supply interruptions; and finally (iii) Assess the challenges related to the establishment, management and effective utilisation of a stockpile.

- *Product portfolio management*

To effectively optimise procurement and to achieve the appropriate balance between different vaccine supply and procurement objectives, the GAVI Alliance requires a means of rationalising “micro-markets”, which are developing through the emergence of multiple formulations and presentations of vaccines within its portfolio. For example, for pentavalent vaccines, there are liquid and lyophilized formulations and 1,2 and 10-dose vial presentations; for pneumococcal conjugate vaccines, there are 10- and 13-valent formulations<sup>33</sup>; and for rotavirus products, there are currently 2 and 3 dose per course product formulations available. All of these product permutations are pre-qualified by WHO and as such, they have been made available to eligible countries by the GAVI Alliance. Procuring multiple presentations or formulations for the same antigen may limit the value GAVI can add through pooling demand.

GAVI and partners should involve countries well in advance and repeatedly over time in the process to inform decision making on the suitable and preferred presentations/formulations to be made available and offered. Strategic demand forecasting by product presentation (rather than vaccine only) and elicitation of a rank order product presentation and formulation preference in country applications for new vaccines should enable the Alliance to offer a menu of product options that best meet countries’ needs. On some occasions, however, the GAVI Secretariat may need to “manage the product portfolio” and limit presentation/ formulation choices and/ or select product presentations and formulations available to countries. This means that countries may not always receive their first choice product formulation/presentation or may be asked to switch products at some point in time. Rather than a blanket policy, such decisions require careful assessment and weighting to the respective interests of the majority of countries (that would benefit from a lower weighted average vaccine price or increased supply security) and of individual countries’ that may be negatively affected by such a decision. In the management of micro-markets, GAVI should be mindful of potential programme implications of a more centrally managed approach to product presentation choice.<sup>34</sup>

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<sup>33</sup> Under the AMC, GAVI currently procures PCV10 in a 2 dose vial presentation and PCV13 in a monodose vial presentation. There is also a 7-valent product – although this vaccine does not meet the target product profile characteristics necessary to be eligible for GAVI/AMC funding.

<sup>34</sup> While some product switches within the same vaccine antigen class (e.g. from a liquid to a lyophilized product or from 1 dose liquid to 10 dose liquid) can pose important challenges to a country’s immunization programme, some products are “switchable”, i.e. easily replaced by each other without major programmatic implications or differences in health impact.

## ANNEX C: M&E indicators definitions and data sources

#	Short Indicator name	Indicator definition	Numerator	Denominator	Level of disaggregation	Data source
1	Weighted average vaccine price	Full year weighted average actual price per dose and per course for all GAVI-supported vaccines purchased through GAVI's procurement partners* (price refers to FCA** and does not include cost of freight, syringes and safety boxes).		NA.	By vaccine	Procurement partners prices
	Lowest and highest vaccine price points	Full year highest and lowest actual price points* to GAVI per dose and per course for all GAVI-supported vaccines purchased through GAVI's procurement partners (price refers to FCA** and does not include cost of freight, syringes and safety boxes).		NA.	By vaccine	Procurement partners prices
2	Number of vaccines not available to meet shipment plan	Number of vaccines not available to meet shipment plan as agreed with the procurement partners due to delisting from the WHO list of prequalified vaccines, downgrading of NRA (National Regulatory Authority) functionality or other quality issues occurring after supply had been awarded. Vaccines will be counted by manufacturer and for the duration of the period of award.		NA.	By vaccine, by manufacturer	WHO IVB official communications on prequalification and NRA status; procurement partners communication on number of vaccines not available to meet shipment plans
3	Security of supply: number of products offered as a percentage of five year target	Number of products offered in response to tenders (expressed as a percentage of target number of products offered for 2015, including WHO prequalified and non-WHO prequalified products). Different presentations and/or formulations of the same vaccine offered by the same manufacturer count as one. There will be no double counting if several offers are made in one year for the same vaccine by the same manufacturer.	Number of products offered in response to tenders	Target number of offered products for 2015	By vaccine	Procurement partner manufacturer offers
4	Percentage of awarded prices published on time	Percentage of awarded prices published on time by presentation and by manufacturer. Frequency of reporting is to be agreed in advance.	Awarded prices published on time	Total number of awarded prices	By presentation, by manufacturer	Procurement partners website publication date

\* On an exceptional basis, where disclosure of awarded prices would hold a strong risk for GAVI's ability to undertake a vaccination programme, awarded prices may not be disclosed \*\* FCA Incoterm: Free carrier - Type of transaction where the seller is responsible for arranging transportation but is acting at the risk and the expense of the buyer.