



Background Information

To GAVI Alliance's Draft Vaccine Supply and Procurement Strategy for the period 2011-2015

Section A: Overview

1. Purpose of this document

- 1.1 The purpose of this document is to provide background information to GAVI's Draft Vaccine Supply and Procurement Strategy made available for public consultation. This document covers information related to GAVI's past experience with vaccine supply and procurement, the scope of the revised strategy, the process by which the new strategy was drafted and its potential implications, risks and risk mitigation approaches.

2. Public consultation process

- 2.1 The draft version of GAVI's Vaccine Supply and Procurement Strategy is made available for public comments by GAVI stakeholders and other interested parties. The public consultation is undertaken via a web-based electronic forum on the GAVI website from 4th – 24th July, 2011.
- 2.2 All comments submitted through the online form will be reviewed, compiled and incorporated as appropriate into a revised version of the Supply and Procurement Strategy. This revised version as well as the consolidated comments and feedback received during this consultation process will be presented to the Programme and Policy Committee (PPC) of the GAVI Alliance Board in September for review and further comments. The PPC will then present the strategy to the Board for final review and decision in November 2011.

Section B: Context

3. Background

- 3.1 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 objectives¹: (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.²

- 3.2 Although countries have the option to use GAVI funds to self-procure vaccines, the majority of procurement with GAVI Alliance funds is conducted by UNICEF. For GAVI-eligible countries in Latin America, PAHO is GAVI's primary procurement partner.
- 3.3 Procurement activities for most vaccines include the involvement of a Procurement Reference Group (PRG). Vaccine specific PRGs are created to provide advice to UNICEF throughout the procurement process, including on the evaluation of bids, structuring of awards and allocation of supply. The PRGs are also supposed to monitor and track key indicators towards achieving the vaccine supply and procurement objectives. The composition of the PRGs is jointly determined by UNICEF and GAVI and members usually serve for the duration of the procurement round.
- 3.4 In February 2010, GAVI's Programme and Policy Committee (PPC)³ 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 review. The task team had three face-to-face meetings over the course of the project. Membership of the task team is listed in Annex 1. The PPC was also consulted three times between February 2010 and May 2011.
- 3.5 McKinsey & Co undertook consultations on behalf of the task team with the UNICEF Supply Division, PAHO Revolving Fund, and 15 vaccine manufacturers both from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Developing Countries Vaccine Manufacturers Network (DCVMN). 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. Conclusions are provided in Annex 2.
- 3.6 Given the potential conflicts of interest that exist for different Alliance members, the PPC requested that the Secretariat report back to the PPC after

¹ In addition, GAVI's 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/resources/Final_procurement_strategy_including_principles.pdf

² 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/resources/17brdj_SupplyStrategy_7Dec2005.pdf

³ The Programme and Policy Committee (PPC) serves as the principal advisory body to the GAVI Board on all GAVI programme areas and leads the development of new policies. It is staffed by high-level technical experts from partner organisations and constituencies, with knowledge in areas such as epidemiology, public health, research, health systems and financing.

completion of the project on how conflicts of interest and confidentiality were handled throughout the process (Annex 3).

- 3.7 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.
- 3.8 The PPC also recognised the good work that was already taking place by the key partners in putting in practice some of the key recommendations of the strategy and recommended that this continue. The PPC requested that the Secretariat redraft the supply and procurement strategy paper based on its comments and make the revised strategy publicly available for comments by GAVI stakeholders and interested parties.

4. Vaccine Supply and Procurement: Progress to Date and Remaining Challenges

- 4.1 The Alliance has had some success with regard to vaccine supply and procurement. A few examples are noted below:
 - (a) *Ensuring a sustainable quantity of supply through a diverse supplier base:* 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, matching country preferences on product presentation and providing an uninterrupted supply) for pentavalent vaccines for more than five years through an increased and diverse supplier base. GAVI has also ensured routine immunisation needs for yellow fever are met despite global supply shortages.
 - (b) *Selecting products and presentations that best meet the needs of client countries:* GAVI's procurement partners managed to meet country preferences for product presentations and formulations across all supported vaccines.
 - (c) *Achieving a long-term affordable price that can eventually be sustainably financed by developing countries:* Through the launch of the pilot Advance Market Commitment (AMC) for pneumococcal vaccines, long-term contracts create incentives for producers to commit to large volumes of appropriate, high quality vaccines at a long-term price ceiling of US\$3.50 which represents a significant reduction compared to prevailing prices for non GAVI countries. For combination vaccines, such as tetravalent vaccines (DTP-HepB) weighted average prices have dropped by 45% from a peak of US\$ 1.26 in 2006 to US\$ 0.69 in 2010. For pentavalent vaccines (DTP-HepB-Hib), a more modest decline of 29% was achieved between 2007 and 2011 from US\$ 3.61 to US\$ 2.58, and further price declines are projected in the near term.

4.2 Despite these successes, the 2nd 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.*”⁴ 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 trade-offs.
- (b) The need for more explicit guidance on how to deal with multiple product presentations/ formulations within each vaccine market in order to avoid unintended consequences from the emergence of micro-markets, such as for example a reduced ability to take advantage of decreasing prices through larger volumes.
- (c) 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).
- (d) The need to set and communicate realistic and evidence-driven market shaping expectations to break the cycle of misalignment between expectations and outcomes.
- (e) The need for GAVI to 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) versus traditional vaccines.

5. Key Revisions to Current Strategy

- 5.1 Whereas the current supply and procurement strategy was developed specifically for Hep B and HiB containing vaccines, this new Strategy applies to all vaccines in the portfolio including for pipeline vaccines as defined in the Vaccine Investment Strategy.
- 5.2 In addition to proposing tailoring “vaccine by vaccine”, the new strategy also proposes the development of longer term end-to-end roadmaps for vaccines currently supported by GAVI and to new vaccines prior to adding them to the GAVI portfolio. In other words, long-term plans should be laid out with “eyes

⁴ CEPA LLP, Applied Strategies (September 2010). GAVI Second Evaluation Report http://www.gavialliance.org/resources/GAVI_Second_Evaluation_Report_Final_13Sep2010.pdf

wide open” about the possible timeframe for achieving low and sustainable prices or other objectives driving the entry decision. This is distinct from earlier practice, whereby GAVI’s entry decisions have not included up-front analysis about how GAVI’s entry would impact the market and potentially affect prices and market structures. Thus, the new strategy should enable GAVI to more effectively set realistic expectations for the short, medium and long term and also to define at a high level how GAVI will achieve those expectations.

- 5.3 The new strategy identifies a series of specific supply management approaches to avoid exclusive reliance on “natural market forces” in all market situations to achieve GAVI’s vaccine supply and procurement objectives.
- 5.4 The procurement mechanisms and tactics recognize the need for a vaccine–by-vaccine approach in terms of setting objectives and achieving them.
- 5.5 As a key part of the strategy, GAVI Alliance members will continuously exchange information and consult with countries to make sure GAVI’s strategic choices with regard to the product menu offered meet countries needs. In some cases, GAVI may need to limit product presentation/formulation choices in order to ensure that its objectives related to price reductions and supply security as laid out in the GAVI Alliance strategy 2011-2015 are met.

Section C: Implications of the revised strategy

6. Impact on countries

- 6.1 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; product specific demand forecasting, communication and appropriate signaling 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.
- 6.2 Of note, in order to achieve GAVI’s objectives, GAVI may need to limit presentation/ formulation choices and/ or selecting 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.

7. Impact on the GAVI Alliance Business Plan / Budget / Programme Financing

- 7.1 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 strategy's implementation plan.

- 7.2 Creating the market insight capacity within the Secretariat is likely to affect the work load of several teams (e.g. P&P, Finance, Legal and Governance).⁵

8. Risk implications and mitigations

- 8.1 The tools and 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 case-by-case basis.
- 8.2 Some of the procurement tools proposed, such as direct negotiations or enhanced supplier engagement, expose GAVI to a perception risk that GAVI may be “overly friendly” with some or all manufacturers and thus not appropriately serving the interests of countries or donors. GAVI will need to define clear rules of engagement and reporting to minimise this risk.
- 8.3 Many of the procurement tools (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 willingness and ability of GAVI's procurement partners to employ these practices will need further assessment. Finally, the application of these procurement tools will need to be carefully managed to ensure they are not in conflict with the principles of good public procurement.⁶
- 8.4 The use of an expanded set of buying models and vaccine specific procurement strategies may require manufacturers to adapt their bids and processes accordingly.
- 8.5 While increased transparency on individual historical product prices has evident benefits, GAVI must be aware of the risk of inadvertently “setting a price” as there is a limited number of manufacturers in the market.⁷ Similarly, sharing the vaccine specific end-to-end 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 will remain confidential as will prices until contracts are awarded.

⁵ The impact of any such additional demand will be addressed in the 2012 workplan and budget.

⁶ http://www.unicef.org/supply/files/UN_Practitioners_Handbook.pdf

⁷ Previously only weighted average prices were shared by UNICEF. PAHO has published prices offered by manufacturers at the time of opening of bids.

- 8.6 Achieving the appropriate balance or prioritisation across the supply and procurement objectives is inherently challenging. While focusing on price is critical, prices are 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 affects on supply security and price are less clear. Short, mid and long term benefits and risks have to be carefully assessed when developing the end-to-end roadmaps. Periodic updates of the roadmaps will allow for course corrections.
- 8.7 Finally, the risk of insufficient financial resources for GAVI to fully fund countries' vaccine demand will impact GAVI's ability to shape markets by reducing the predictability of demand. In formulating the vaccine specific end-to-end 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.

9. Legal implications

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

10. Gender equality implications

- 10.1 The proposed Vaccine Supply and Procurement Strategy has no specific implications on gender equality.

ANNEX 1 - Membership of the time-limited Supply and Procurement Strategy Task Team

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).

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

** 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 – SUMMARY OF MARKET DYNAMICS ASSESSMENTS FOR ROTA, PNEUMO, PENTA AND YELLOW FEVER VACCINE MARKETS

Market characteristics	Rotavirus vaccine market	Pneumococcal vaccine market	Pentavalent vaccine market	Yellow Fever vaccine market
Market maturity	▪ Early in the market maturity lifecycle ▪ Currently 2 incumbents, both multinational companies (MNCs) ▪ Several new players possible but entry of next players at least 3-5 years off ▪ Supply expected to roughly equal demand in short-run	▪ Very early market maturity lifecycle and can expect slow evolution ▪ Currently 2 incumbents, both MNCs ▪ Incumbents adapting products to serve GAVI market (e.g. multi-dose vials) ▪ Several new players possible but entry likely to be more than 5 years away ▪ Supply expected to roughly equal demand in short-run	▪ Moderately advanced/advanced in the market maturity lifecycle ▪ Currently 4 incumbents ▪ Several new players likely, 2012-2015+ ▪ Market evolving (in terms of presentation, dosage, and addition of new antigens) ▪ Increasing reliance on emerging market players ▪ Supply/capacity starting to exceed demand ▪ Large overcapacity in coming years (+2012)	▪ Mature market that is in flux ▪ Currently 4 players, but one is the dominant global player ▪ Limited new player entry expected ▪ Global demand has more than doubled since 2000 and price has increased 5X ▪ Shortages expected to continue in short-term due to demand spike – limited incentives for capacity expansion due to uncertainty around long-term demand
Vaccine complexity	▪ Low manufacturing complexity relative to pneumo and penta ▪ The ‘fill and finish’ costs are big driver of manufacturing cost ▪ Utilization is less of a driver of manufacturing costs ▪ Incumbents have very different cost structures	▪ Very high manufacturing complexity because of multivalent conjugation ▪ Driver of manufacturing cost is bulk antigen production ▪ Incumbents have very different cost structures	▪ Medium manufacturing complexity ▪ Driver of manufacturing cost is bulk goods production, particularly Hib antigen ▪ Differences in complexity between liquid vs lyophilized products (but expect lyo exit due to country preferences) ▪ Highly utilization driven (volume is key) ▪ Incumbents have very different cost structures	▪ Low manufacturing complexity relative to pneumo and penta ▪ Fill and finish (including lyo) are primary cost drivers; impacting by presentation ▪ Bulk costs can vary across manufacturers due to efficiency
GAVI’s relative “market power” to access volume	▪ GAVI has a moderate market power and, subject to financing availability, GAVI could represent >50% of total market volume by 2015 ▪ Differences in dosing and serotypes of incumbent products could drive market fragmentation unless managed ▪ GAVI’s market power is manufacturer specific with different capacity availability and market focus across the two players	▪ GAVI has less market power looking ahead (but a success in establishing tail price and a guaranteed market volume through the pilot AMC) ▪ Differences in serotypes may drive market fragmentation unless managed ▪ GAVI’s market power is manufacturer specific given different capacity levels and expansion plans	▪ GAVI has significant market power representing a large proportion of market volumes and value (roughly 75% currently) ▪ Current fragmentation between liquid and lyophilized product is declining as lyo demand decreases, but fragmentation may occur in future due to new formulations/presentations unless managed ▪ Demand in steady state: GAVI’s influence on market will come through its procurement strategy ▪ GAVI segment is also more valuable to some players than others	▪ GAVI has moderate market power - representing almost half of global demand, ▪ However, GAVI competes for capacity with middle income buyers (PAHO) and countries with local capacity (e.g., Brazil) ▪ Price doubled when GAVI entered the market in 2001 and has continued to increase, partially due to supply-demand imbalance

ANNEX 3 – CONFIDENTIALITY AND CONFLICTS OF INTEREST

The Supply and Procurement Strategy Task Team developed the strategy with the support of the GAVI Alliance Secretariat,⁸ assisted by McKinsey and Co. The services of McKinsey were paid for by the Bill & Melinda Gates Foundation. The McKinsey team was responsible for providing some background information and conducting analysis as directed by the Task Team and GAVI Secretariat. The paper for the May PPC meeting was developed by the GAVI Secretariat under the oversight of the Task Team. McKinsey and Co. was not involved. The paper for the September PPC was developed by the GAVI Secretariat with input from the PPC and a public consultation process.

Confidentiality

The previous supply strategy analytical work (e.g. Mercer 2002 study undertaken on behalf of GAVI) used only publicly available information “given the open nature of the Alliance”. It was recognised early during the design phase of the current revision of the Vaccine Supply and Procurement Strategy that the quality and depth of available information could be compromised if it needs to be shared publicly. 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 will be handled. To that end, the Secretariat and project team sought to find a middle ground where:

- 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.
- When the aggregated/disguised data was shared with the Task Team, no electronic copies of the data were distributed. Hard copies, distributed during the meeting were collected from all participants before the end of the meeting and destroyed.
- McKinsey recapped with each manufacturer the key data shared (if desired) which was used in the analyses in order to provide manufacturers with the opportunity to quality check their data/perspectives.
- Manufacturers did not see data, detailed or aggregated, from other manufacturers.

The information of interest was data pertaining to manufacturer prices, production capacities and likely costs of goods. Much of this information was collected directly from manufacturers themselves (where they were prepared to share such information) or produced by the McKinsey consultants using an ‘outside-looking-in’ methodology. In addition, UNICEF Supply Division supported the McKinsey team in

⁸ The project team from the Secretariat included Gian Gandhi, Eliane Furrer, Nina Schwalbe and Aurelia Nguyen.

interpreting the previous bids received from manufacturers. Figure 1 illustrates how the various types of information were handled:

Figure1: Model for handling confidential information

Area	Information access rights		
	McKinsey only	TaskTeam	Public
COGS	●	◐	○
Supply	●	●	◐
Demand	●	●	●
Price Projections/ Targets	●	◐	○

● Full detail
◐ Averaged/aggregate
○ Not shown

The Task Team agreed to this model of information sharing upfront. In retrospect, the Task Team all agreed that the level of information shared during meetings was sufficient for them to take informed decisions in order to steer the development of the strategy.

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. The Task Team took these views into account while formulating their recommendations and indeed, the desire to strengthen GAVI's communications with suppliers is a direct result of manufacturer feedback that this was an area that could be strengthened to the benefit of the Alliance as a whole.

Representatives from GAVI's procurement partners (UNICEF, PAHO) were part of the Task Team. This too was beneficial in that it helped the project team and Task Team as a whole better understand the complexity and nature of previous procurement decisions. However, it was recognised that at times it was difficult for the Task Team to impartially assess the strengths and weaknesses of previous procurement methodologies.

McKinsey and Co. has a policy in place to safeguard client confidentiality. This implies that McKinsey and Co. consultants are prohibited from discussing details of their work with members of other teams within the firm, effectively providing a firewall for sensitive information.

The analytical work and consultations undertaken by the McKinsey team was funded by the Bill & Melinda Gates Foundation (BMGF) and a BMGF representative was also part of the Task Team. As such, there was some concern that the BMGF was in a

position to have undue influence on the direction and nature of study recommendations. However, the recommendations were defined and unanimously agreed to by the Task Team as a whole.

During the May 2011 PPC discussion, the two vaccine industry representatives (industrialised and developing countries) and the UNICEF representative participated in the early discussion on this topic and then left the meeting for a full discussion and did not vote on the decisions due to a conflict of interest