Consolidated comments from the public consultation on GAVI's draft Vaccine Supply and Procurement Strategy

September 2011

1. Introduction

In July 2011 the GAVI Secretariat launched a public consultation process on the draft Vaccine Supply and Procurement Strategy for 2011-2015. The consultation was open from 4 to 29 July 2011. This document provides an overview of the process, as well as a summary of the main themes that emerged from the comments received. It does therefore not necessarily reflect the views of the GAVI Alliance.

At the end of September 2011, GAVI's Programme and Policy Committee (PPC) will consider the updated version of the strategy. A summary as well as the full detailed comments received during the public consultation will be made available to the PPC members in advance of this meeting. In November 2011, the GAVI Alliance Board will review and make a decision on the Vaccine Supply and Procurement Strategy.

2. Description of the consultation

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). On average the feedback consisted of 1.5 typed pages and varied in terms of the breadth and depth of comments. 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.

3. Key themes

This section summarises the comments received, noting in particular the major themes and issues and appraising the level of agreement/disagreement of different stakeholders. Participant quotes are included in order to contextualise the theme and highlight the various viewpoints. The section is divided into the following main headings: Objectives, Supply Strategy, Procurement Strategy, Roles and Responsibilities and Monitoring and Evaluation.

3.1. Strategy objectives

Overall the objectives were considered appropriate. A few respondents suggested that the objectives should be ranked in the case of potential "trade-offs". Three respondents suggested that the objectives should also take into account graduating countries and the market conditions that they will face.

"The objectives should also take into account the countries that will graduate from GAVI support and the market conditions that they will face. It also might take into account how the market shaping actions of GAVI might influence the markets faced by never-GAVI supported lower-middle income countries that are similar to many GAVI graduates." (Individual, Marty Makinen)

"I would consider ranking the objectives to be clear on which would be prioritised in the case of potential trade-offs. For example, strategies of volume concentration won't increase competition/diverse supplier base but may minimize cost. (Individual, Robert Doble)

3.2. Supply Strategy

Price/cost/affordability

The issue of vaccines prices/costs was recurrent in the consultation responses. Two respondents emphasised in their submissions that GAVI should take a "holistic view of price", for example by considering not only the vaccine cost, but also the total delivery cost. Two respondents emphasised the importance of ensuring low and sustainable prices for graduating countries. Three respondents suggested that the importance of competition should be made more explicit with two respondents suggesting it should be added as a principle of the strategy, along with price transparency.

"The article [strategy] mentions price of purchasing the vaccines but GAVI should also be looking at the heat sensitivity of products much more closely – it has long term cost implications." (Individual, Faheem Merchant)

"We recognise that there may be some situations where competition is not possible, but outside of these specific circumstances, competition should be the default since it has been the most effective price driver." (CSO Constituency Steering Committee)

"The most effective method to minimize vaccine price in a sustainable way and in supply security conditions remains to create an attractive market for several manufacturers: maximizing the visibility, predictability, volume and reliability of demand. [...] the notion that 'competition drives prices down' may not always apply for new vaccines, especially in developing countries where vaccine prices are already minimized, significant volumes have been shown to be impacting drivers of vaccine price." (IFPMA)

"Manipulating the market through donor subsidies can be a high risk, high cost strategy, which could affect the willingness/ability of countries to take ownership of new vaccines and fund them domestically if prices are not significantly reduced in the longer-term. The need to balance short-term availability (at higher costs) and leveraging longer term low costs could be better addressed." (Donor, AusAID)

"GAVI could more explicitly support industry in its efforts to provide intra-country differential pricing in these (and other?) middle-income countries. [...]" (Individual, Amanda Glassman)

"In this context it is more appropriate to speak in terms of "affordable prices" than "low prices". Affordability is a multifaceted concept that must apply to all stakeholders involved: countries, GAVI and manufacturers. There are a number of aspects to affordability: cost of vaccination (total delivery cost and not only the simple price of the vaccine); availability of funds; willingness to commit these funds to immunization programs." (IFPMA)

Role of emerging market and new manufacturers

Several contributions requested that GAVI expand upon its approach to new manufacturers entering the market. Other respondents suggested that the strategy should focus more on removing barriers faced by emerging market manufacturers specifically.

"Other factors that have limited competition by developing country manufacturers are omitted, e.g., limited capital to invest in R&D, process patents and lack of technological know-how. These factors delay product development for emerging country companies, yet there has been a lack of action by GAVI and other stakeholders to stimulate technology transfer and overcome these barriers." (Oxfam/MSF)

"Is GAVI being ambitious enough and thinking outside the box in how it can promote competition and really enable a diverse supplier base and an environment for new innovations particu[I]arly in terms of addressing barriers to entry for developing country manufacturers and putting in place incentives for adapted vaccines to best meet GAVI-country needs?" (Individual, Robert Doble)

"We think the strategy needs to acknowledge the rapidly increasing capacity of emerging countries such as Brazil, China and India to develop and produce state-of-the-art vaccines, as well as the ability of some emerging countries to produce prequalified vaccines at prices dramatically lower than industrialized country producers." (CSO Constituency Steering Committee)

"We welcome the focus on enhancing competition and expanding the supplier base in order to make vaccines more affordable, but is not clear from the strategy what specific support to emerging suppliers is being offered. We would like to see more detail on how GAVI and its partners will support technology transfer to speed the entry of new suppliers to the vaccine market." (Save the Children, UK)

"Ways to facilitate tech transfer to additional manufacturers should also be considered." (Individual, Marty Makinen)

Information transparency

There were diverging views with regards to the potential impact of information transparency on the market. Two submissions suggested that price transparency should be a principle of the strategy, including during pending tender processes. Another respondent recommended that a nuanced view of the benefits of information transparency be adopted. One respondent suggested that the strategy should include a set of agreed principles on transparency.

"...we suggest that prices offered by each manufacturer during multi-round tenders should also be published. The Background document provided by GAVI states [...] that 'procurement tactics will remain confidential as will prices until contracts are awarded'. However, this lack of transparency makes it difficult for donors and GAVI countries to hold GAVI accountable to its goal of market shaping, and ensure that vaccines will be affordable for GAVI and countries in the long term." (Oxfam/MSF)

"Finally, we urge GAVI to be nuanced when talking about the positive impact of information transparency. A careful analysis should be conducted on how best to apply transparency of prices without unintended adverse effects on availability and affordability." (IFPMA)

"Transparency is vital. [...], we believe that the strategy needs to be underpinned by a sophisticated and systematic approach. As noted above, it is hard to shape behaviour of

complex markets without clear communications and disclosure. It may make sense for the supply and procurement strategy to include a policy or set of agreed principles on transparency and disclosure." (Donor, DFID)

Adapted products

In different ways respondents emphasised the importance of adapted products to meet the needs of GAVI-eligible countries. Several respondents suggested that the strategy encourage the allocation of resources to develop adapted products for GAVI-eligible countries. Furthermore three respondents suggested resources be put towards reducing vaccine costs or improving programmatic suitability (e.g. heat sensitivity, volume and dosing) including through support to clinical studies.

"We would like to see the addition of support to clinical studies on a selective basis, especially those that could reduce vaccine cost or improve programme suitability, e.g. studies to explore more flexible dosing schedules (reduction of the number of doses required, or vaccines that can be administered over a broader age range)." (CSO Constituency Steering Committee)

"GAVI's supply and procurement strategy should also give support to innovators with ideas of how to make existing vaccines more adaptable to conditions and delivery in GAVI-eligible countries. Again, these will shape markets in beneficial ways, especially when using suppliers in emerging economies." (Individual, Donald Light)

"The value of an innovation such as thermostability could be estimated by a cost-benefit analysis examining the annualized per dose or course cost of the cold chain and its management and maintenance, plus the vaccine that is lost due to cold chain failures." (Individual, Marty Makinen)

Sustainability

Many respondents emphasised the importance of sustainability and country ownership (funding, procurement capacities, governance) facilitating country-level decision-making. In addition to affordable prices, the importance for political will, country level expertise in procurement, funding and advocacy for immunisation was highlighted.

"Points on financial sustainability should also include some reference to the political will/leadership of countries to support immunization." (Donor, Italy)

"We recommend adding: "influence global prices for non-GAVI and GAVI-graduated countries by acting as a price benchmark to ensure sustainability of historical GAVI immunization gains" as an objective." (CSO Constituency Steering Committee)

"We would stress the importance of giving sustainability issues more prominence in this area of the strategy. Over time, sustainability of markets demands that countries develop their own procurement capacity – either at the country-level or pooled at the regional-level. We would like to see the strategy take on this developmental angle much more strongly." (Donor, DFID)

"Does this strategy sufficiently address issues of sustainability and transfer of ownership, including funding, to the countries? [...] the Strategy may fail to leverage sustained and significant decreases in vaccine prices. This would have significant implications for the sustainability of increases in access to new vaccines – if vaccine prices are not brought down sufficiently graduating countries will not be able to afford them." (Donor, AusAID)

Advance Market Commitment (AMC)

There were diverging views on the pilot AMC for pneumococcal vaccines and its potential for market shaping. Whereas four respondents requested that more attention be paid to the AMC as an example of market shaping, two other submissions urged careful analysis of the pilot AMC be conducted before considering future AMCs.

"The brief mention of the AMC and the lack of reference to any future AMC, for example for a malaria vaccine, seems like a missed opportunity. The AMC addresses all three of GAVI's 'Supply and Procurement Objectives' and we would be keen to see how the organisation will deploy this mechanism in future to help shape the vaccine market." (Save the Children, UK)

"...the AMC initiative is an example of market shaping which could be a little more described." (Donor, Italy)

"In addition, we would discourage use of an additional AMC (Advance Market Commitment) until data can be analysed showing whether or not the Pneumococcal Vaccine AMC has been and will be a cost-effective mechanism." (Oxfam/MSF)

"Volume commitments through various mechanisms including AMC represent incentives for manufacturers to support GAVI's objectives (1) by encouraging manufacturers to invest in vaccines adapted to the need of developing countries (diseases, production capacity, programmatic suitability,...) and (2) by mobilizing manufacturers to participate in the development of these markets with operational and technical support for the introduction of new vaccines." (IFPMA)

Enhanced market insight capabilities

Several respondents asked that the scope of market insight capabilities of the Alliance, such as how the information will be collected and shared with stakeholders, be addressed in more detail. Two donors suggested that to conduct this work, the Secretariat may need to strengthen its internal technical capacity.

"...measuring demand, supply capacity, prices, cost drivers- is a highly specialized task, carried out in many countries by IMS. Measurement of these elements may involve current GAVI partners, but will ideally collect independent information. Will GAVI contract IMS or start its own operation? How will information be collected independently? How will this information be shared with governments, institutional purchasers and industry? How will conflicts of interest be addressed? How much transparency will be desirable, for what reason?" (Individual, Amanda Glassman)

"A strategic objective to enhance GAVI's market insight capability is a welcome move, but we would like the strategy to elucidate the mechanism by which this insight will be shared with CSO. Such insight would prove invaluable to CSOs carrying out vaccine advocacy and would increase transparency in the vaccine industry." (Save the Children, UK)

"Tapping partners with market intelligence and outsourcing is OK, however the GAVI Secretariat has to strengthen its internal capacity. We need to transition from the idea that Alliance as such will do everything, light touch, etc, to a more structured setting, at least 'to be good consumers of what we buy'." (Donor, Italy)

End-to-end roadmaps

Several respondents requested that the process on the development of the end-to-end roadmaps be clarified, in particular their scope and who will be involved in defining them. In addition several respondents called for a clearer articulation of strategies and procurement options for each vaccine.

"I would like to see the particular vaccine analysis (included in the background document) expanded to include all the vaccines which GAVI supports and wishes-to-support [...]. Then an analysis of which strategies and measures GAVI thinks will work best in each of these is necessary. Until you do this it will be difficult for experts to know whether the strategies you are proposing are going to work - therefore, will the 'end-to-end roadmaps' also be made public and open for consultation?" (Individual, Robert Doble)

"Vaccine markets are shaped by a number of factors beyond supply and procurement issues. Examples include (i) evidence on burden of disease and cost-effectiveness; (ii) policy, advocacy and priority-setting capacity within developing countries on vaccine introduction; (iii) financing (from both domestic resources and donors) and; (iv) regulatory frameworks. [...] The roadmaps could serve as platforms for identifying market-shaping interventions from among this wider set of areas." (Donor, DFID)

"While there are a number of procurement options listed, the Strategy would be improved by more clearly articulating which procurement option will be used for each vaccine, with a clear indication of the costs and benefits for the chosen procurement option for each vaccine." (Donor, AusAID)

"Such end-to-end roadmaps should be subject to some kind of peer/expert review at first assembly, then to review and revision at regular intervals (annually, every 18 months?) again reviewed by peers/experts as conditions change and additional information becomes available." (Individual, Marty Makinen)

3.3. Procurement Strategy

Product portfolio management

Several queries were raised with regard to product portfolio management to the extent that under the proposed strategy GAVI has the ability to limit presentation or formulation choices for countries. Questions focused on how this will work in practice and what criteria will guide the decisions.

"We strongly urge building into the strategy a mechanism to assess and understand product preferences. This will require consultations with Ministries of Health as well as in-country physician communities and CSOs." (CSO Constituency Steering Committee)

"We would note that the 'appropriate balance' on presentation and formulation choice should ultimately depend on country-led decision-making. This would be expressed through strong priority-setting capacity and institutions within countries (and/or at the regional-level) that is not only able to choose between vaccines but also 'within' them (i.e. on presentations and formulations)." (Donor, DFID)

"Why doesn't GAVI play a role in eliciting user preferences for vial presentations?" (Individual, Robert Steinglass)

"Restricting country choice's for presentation / formulation of vaccines is not aligned with the global objective of developing ownership and sustainability of immunization programs. GAVI can

not rely only on "affordable" vaccine price to sustain immunization programs after GAVI's support ends. To be sustainable, the introduction of a new vaccine must be an informed consent/choice of the country." (IFPMA)

"Finally, we'd like to see more detail in the strategy about the process by which 'product portfolio management' consultation will be carried out. The broad principle of streamlining the number of products available to enable GAVI to do more effective bulk procurement makes sense but we'd be interested to see a more transparent account of the decision-making process and which parties will be consulted and accountable." (Save the Children, UK)

3.4. Roles and Responsibilities

A few respondents provided suggestions for the section on roles and responsibilities, that will be included on in the revised strategy. For example, one respondent urged GAVI to explore the potential role of/partnerships with universities.

"Roles and responsibilities for strategy implementation - When will they be assigned? Document doesn't say. How will these decisions be taken? Thinking about the different roles and added values of GAVI Alliance members is key to devising an effective strategy and implementing it - this analysis seemed to be missing." (Individual, Robert Doble)

3.5. Monitoring and Evaluation

Several respondents welcomed the proposed monitoring and evaluation framework as a key aspect to the Strategy. There were several suggestions to the indicators and targets, including requests for more clarity around who will have oversight of them and how data on these indicators will be collected.

"We suggest there should be an indicator for innovation/incremental innovations. We are glad to see an indicator for numbers of vaccine suppliers, and that this includes developing country manufacturers. [...] The indicators should be reworked to include, (1) Reduction in price for additional new GAVI vaccines (HPV, yellow fever etc); (2) Vaccines with improved presentations under development and/or coming to market (e.g., incremental innovations such as improved heat stability, reduction of required number of doses, etc.)." (Oxfam/MSF)

"[...] I think a cost per dose delivered (which indeed would include program cost) would be very useful, although difficult to collect." (Robert Steinglass)

"Finally, we welcome the proposed M&E metrics. A strong tracking framework is of course essential. The indicators look appropriate although more prominence for quality should be considered. It will be important to establish a robust process for annual review – including early identification of baselines." (Donor, DFID)

"We were disappointed to see that the price reduction target is not more specific and would like to see a measureable and time bound objective with at least an indication of what a significant price reduction would look like. Without a clear target of what price GAVI is aiming for, it will be difficult to advocate and to measure success." (Save the Children, UK)

4. Miscellaneous comments

Some comments went beyond the scope of the vaccine supply and procurement strategy. However, below are other suggestions for improvement of the effectiveness of GAVI support:

- Addressing issues related to vaccine-related supplies (e.g. autodisable syringes, safety boxes)
- Creating incentives for countries to reduce coverage gap between rich and poor.
- Influencing global prices for non-GAVI countries