



**Public submission on the
GAVI Alliance Draft Vaccine Supply and
Procurement Strategy for the period
2011-2015
Médecins Sans Frontières & Oxfam**

July 22nd, 2011

Oxfam International and Médecins Sans Frontières welcome the opportunity to contribute to this public consultation. We congratulate GAVI for its successful efforts to meet and exceed its replenishment goals, and hope this process produces a supply and procurement strategy that will allow for the most effective and efficient use of new donor financing.

While we recognize that numerous factors contributed to the financial crisis GAVI faced in the past year, one critical factor was the inability of the Alliance to effectively shape markets.

We hope this strategy will provide a way to effectively reduce prices through an explicit commitment to competition, when possible, while ensuring that products more closely meet the needs of resource-poor countries. We also hope the strategy identifies and removes barriers that prevent emerging market vaccine manufacturers from entering the market, since emerging market manufacturers can help foster competition, drive down prices and generate innovation and adaptation that meets the needs of target populations in GAVI-eligible countries. Finally, the strategy should also explicitly address those business strategies adopted by manufacturers, particularly vaccine donations, which would undermine sustainable strategies to supply developing country markets.

In tandem with this strategy, we expect that commercial conflicts of interest with the pharmaceutical industry will be explicitly addressed, especially the presence of vaccine manufacturers on the GAVI Board

Our comments offer general reflections and observations as well as specific suggestions for text changes for each section of the Draft Strategy.

1. INTRODUCTION

No comments.

2. THE GAVI ALLIANCE AND THE VACCINE MARKETPLACE

Overall observations:

To ensure a healthy long-term market for the growing range of vaccine products required for public health, GAVI must encourage manufacturers based in developing countries to enter the market for new vaccines in developing countries. GAVI should also encourage both multinational manufacturers and emerging country manufacturers to develop and/or adapt products to resource-poor countries' needs. When products already have significant markets in wealthy countries, multinationals should leverage their sales in these markets in order to offer lower prices to GAVI-eligible countries.

Specific comments and edits:

1. On page 1, the strategy states: "The total potential revenue for vaccines in developing countries is relatively small".

Comment and suggested edit: We do not agree with this statement. For example, GAVI purchases generate one-third of Crucell's overall revenue. The statement should be qualified to read: 'potential revenue from developing countries is relatively lower for multinational companies compared to higher returns in rich countries'. Furthermore, the text should mention that GAVI has made developing country markets more attractive

and that its revenues are an important stimulus for developing country manufacturers. Additionally, GAVI also has the potential to make the market for adapted vaccine products more attractive.

2. On page 2, the strategy states: "...ramping up or changing manufacturing capacities in vaccine production to satisfy increasing demand from GAVI-eligible countries (i.e. GAVI birth cohort is approximately 4 times the size of the birth cohort of high income countries) often takes years and additional investments"

Comment: Experience so far indicates that GAVI-eligible country uptake of newer vaccines is more gradual than had been anticipated, greatly mitigating the supply risks.

3. On page 2, the strategy states: "The result of these vaccine market conditions are limited competition"

Comment: 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.

4. On page 2, the strategy states: "GAVI and its members can play a strategic role to help address market failures by increasing certainty of demand and ensure a sustainable quantity of appropriate quality vaccines is available through a diverse supplier base at a low and sustainable price for GAVI and countries."

Suggested edit: We suggest replacing "through a diverse supplier base at a low and sustainable price for GAVI and countries" with 'by stimulating competition when possible, especially by increasing the role of developing country manufacturers.'

5. On page 3, the strategy states: "Of the current vaccines that GAVI purchases and money spent, GAVI has the most relative market power in the pentavalent market, a moderate influence in the rotavirus and yellow fever markets and much less market power in the pneumococcal market."

Suggested edit: We think this should be qualified by saying that: 'GAVI could have strong market power for potential future rotavirus, pneumococcal, and other vaccines that are specifically adapted to developing country contexts, e.g., higher thermostability, lower-volume, more flexible dosing schedules, etc.'

3. OBJECTIVES OF THE VACCINE SUPPLY AND PROCUREMENT STRATEGY

Overall observation

The principle of competition is missing from the overall aims of the supply and procurement strategy. It should be included explicitly as an important principle in parallel with price transparency.

Specific comments and edits:

1. On page 4, Table 1, under the Objective: "Cost of the vaccine to GAVI and Countries",

Comment and suggested edit: A bullet should be added: 'Influence prices for non-GAVI, or GAVI-graduating countries to ensure sustainability of immunization gains.'

2. On page 4, Table 1, under the Objective: "Appropriate and Innovative Vaccines",

Suggested edit: Change "Foster an environment for innovative vaccines" to read 'Foster development of innovative vaccines adapted to specific needs of GAVI countries.'

4. SUPPLY STRATEGY

Overall observations:

We welcome the commitment to affordability for graduating countries. GAVI must also look beyond its responsibility to graduating countries to its potential to set global benchmark prices. The stress on enhanced competition, coordination of pull and push incentives, technology transfer and work to support incremental innovation will all be essential to sustain greater innovation and access to vaccines at a global level.

However, this section fails to address the barriers to more affordable vaccine production that can be created by process patents and other forms of intellectual property. Apart from limited mention of "brokering technology transfers" (page 6), no mention is made of a role GAVI can play in helping producers overcome these barriers. Given the number of new vaccine products in the pipeline, and the potential for intellectual property rights to hinder competition and the production of lower-cost vaccines, we would suggest GAVI invest in better understanding and working to overcome the potential barriers created by intellectual property rights.

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. The analysis will have to account for the total cost of the vaccines, including the \$1.5 billion subsidy as well as the funds for the US\$3.50 per dose purchase price. GAVI also needs to learn from and adopt lessons from the very different experience of the Meningitis A Vaccine development process.

Specific comments and edits:

1. On page 4, Section 4.1, the strategy states: "Before entering a market the GAVI Alliance would, among other things, consider the prospects of a vaccine becoming affordable to countries over some timeframe as well as the vaccine supply and procurement interventions that GAVI might employ to shape the market in order to get to that point."

Suggested edit: We suggest adding after "timeframe," the following: 'whether or not there is a need for product adaption for practical use in low resource contexts,'. *Note: this refers to challenges such as developing less bulky and more heat-stable rotavirus vaccines.*

2. On page 5, the strategy states: "Coordinate across Alliance members and other players' activities to enhance competition and expand the supplier base."

Suggested edit: We would suggest adding at the end of the sentence, 'and better adapt vaccines to low-resource contexts.'

3. On page 6, the strategy states: “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, and to improve production processes and/or vaccine delivery mechanism.”

Comment: We would like to emphasize that we strongly support this notion and consider it crucial for the success of the strategy.

4. On page 6, concerning the bullet ‘Catalyze the design and implementation of pull mechanisms’,

Suggested edit: We would suggest adding at the end of the paragraph: ‘Regarding future AMCs, lessons will be drawn from the experience with the first AMC before any additional AMC is considered.’

5. On page 6, concerning the bullet, ‘Facilitate incremental innovations’,

Suggested edit: We would suggest adding as the penultimate sentence to the paragraph: ‘The GAVI Alliance could support clinical studies on a selective basis if results could reduce cost or increase programmatic suitability, e.g. studies to explore improvements to dosing schedules.’

5. PROCUREMENT STRATEGY

Overall observations:

Again, we emphasize that competition offers long-term assurance of sustained, lowest-possible prices, and that support to speed-up the development pipeline of lower-cost versions of products should be central to GAVI’s strategy. Secondly, while we welcome the commitment to publish prices upon completion of procurement, we suggest that prices offered by each manufacturer during multi-round tenders should also be published. The Background document provided by GAVI states in Section 8.5 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. We therefore feel it is essential GAVI engage in a more open, transparent procurement process than has been seen in the past, whereby price offers can be critiqued and evaluated. GAVI states in the Draft strategy it does not want price to act as a “deal breaker” when significant health imperatives are at stake (page 5), but we believe a transparent procurement process acts to strengthen donor support and subsequently GAVI’s negotiation power with suppliers, and is therefore one tool for pressuring companies to lower prices for priority vaccines.

Specific comments and edits:

1. On page 9, with respect to the sub-heading ‘Use of volume concentration *versus* splitting of demand”:

Specific edit: We would suggest adding as a final sentence to the paragraph: ‘As a principle however GAVI Alliance will seek to stimulate competition, whenever possible, given its known potential to reduce prices over time.’

2. On page 9, with respect to the sub-heading ‘Pull mechanisms’

Specific edit: We would suggest adding to the end of the paragraph: ‘However, as multinational companies are increasingly partnering with, or acquiring low-cost emerging country suppliers and as independent emerging country suppliers have dramatically lower costs, pull mechanisms might not be necessary to expand production capacity.’

6. ROLES and RESPONSIBILITIES

No comments.

7. MONITORING AND EVALUATION

Overall observation:

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.

Specific comments and edits:

1. On page 10, with respect to the indicators set out by GAVI, the indicators do not match in full the ambitions of the strategy.

Specific comment and edits: 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.).

ADDITIONAL AREA OF POLICY: VACCINE DONATIONS

GAVI should develop a clear policy on vaccine donations. We are increasingly concerned that vaccine manufacturers are considering vaccine donations in lieu of sustainable strategies to supply vaccines to developing country markets. GAVI should ensure that companies do not use ad hoc vaccine donations to avoid their responsibilities. Furthermore, they should not use vaccine donations to influence country choices for new vaccines. Before accepting further donations, we strongly recommend that GAVI follow the path of Global Fund in commissioning studies on the practice of manufacturer donations. In particular studies are needed on 1) the market impact of donation and 2) countries’ attitudes toward donation. Based on a high-quality study presented to companies, civil society and other stakeholders at the Global Fund, the Global Fund decided not to accept donation of health products.

CONCLUSION

We would like to reiterate our appreciation for the opportunity to provide our feedback to GAVI as it develops its Supply and Procurement Strategy, and look forward both to communication of all public comment submissions and the resulting new version of the strategy.