For public comments

GAVI Alliance's Draft 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[1] that have been recommended or will be recommended in the future for use in GAVI-eligible countries. The strategy does not address 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.

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 section outlines how the strategy will be implemented, including the monitoring and evaluation plan.

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.[2] Demand and supply dynamics do not work according to the economic theory of perfect competition. First, in comparison to other health products and markets, the total potential revenue for vaccines in developing countries is relatively small. Expected revenues and profits are relatively

1 The term 'vaccine' refers to the antigen class (or combination of antigens) and includes all presentations and formulations recommended for use in GAVI-eligible countries

2 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

low and companies face competing interests when making investment decisions. Second, vaccine development from basic research to production and distribution usually takes more than a decade and the risk of failure of candidate vaccines is high. These factors coupled with other barriers to entry for manufacturers imply that vaccine markets are generally characterised by a limited number of competitors, particularly for innovator products and new vaccines.

Third, the difficulty to access adequate 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 not optimised in terms of either price or presentation for GAVI-eligible 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-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. 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-eligible 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. GAVI and its members[3] 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.

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.[4] For each of these vaccine markets, GAVI's market shaping potential differs.[5] These differences should influence the strategy the Alliance employs to ensure affordable and consistent supply.[6]

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

- **Market maturity and competition**. This relates to the number of suppliers 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

3 The term 'GAVI Alliance members' refers to all institutions and countries that are represented on the GAVI Alliance Board

4 Vaccines currently supported include pentavalent, rotavirus, pneumococcal conjugate virus, 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 vaccines.

5 For more information see Nguyen A, Furrer E and Schwalbe N. Market shaping: strategic considerations for a healthy vaccine marketplace. GAVI Alliance: May 2011. www.gavialliance.org

6 A time-limited Supply and Procurement Strategy Task Team appointed by Programme and Policy of the GAVI Alliance Board steered the review and analytical work.

and pneumococcal vaccine markets are in the early stages of the market lifecycle with currently only two global suppliers.[7] 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 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 costs of production.

- **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. Of the current vaccines that GAVI purchases and money spent, GAVI has the most relative market power in the pentavalent market, a moderate[8] influence in the rotavirus and yellow fever markets and much less market power in the pneumococcal market. With regard to quantities, GAVI has increasing market power in all these markets.

3. Objectives of the vaccine supply and procurement strategy

The GAVI Alliance's supply and procurement strategy aims to contribute to GAVI's market shaping goal by balancing supply and demand, minimizing the cost of vaccines to GAVI and countries, and fostering development of appropriate and innovative vaccines. In order to achieve these aims, the GAVI Alliance must ensure timely, transparent and accurate market information for both purchasers and providers (e.g. price transparency for countries; accurate demand forecasts for manufactures). For the definition of terms, see Annex A. The GAVI Alliance's supply strategy is realized in part through its procurement strategy. Both are described below.

7 A third rotavirus supplier exists in China 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.

8 Due to slower than anticipated growth in other markets, GAVI may play a more dominant role in the short to medium term.

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
▪ Ensure sufficient supply of vaccine is available to at least meet total GAVI demand ▪ Provide consistent, uninterrupted supply to GAVI countries	▪ Minimize the per course vaccine cost ▪ Minimize the cost implications of vaccines to GAVI countries	▪ Ensure procurement of appropriate, quality vaccines to meet GAVI country needs ▪ Foster an environment for innovative vaccines
Information: Communicate timely, transparent and accurate market information		

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 the tools and mechanisms used to influence the supply environment in which GAVI operates. Although this may be implemented in the context of the current 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). Moving forward 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 longer-term (i.e. beyond five years) supply acceleration tools and through explicit signalling to manufacturers. This approach will require the following actions:

4.1 Creation of end-to-end roadmaps, including the definition of appropriate market interventions, for each vaccine

End-to-end roadmaps determine the GAVI Alliance's long-term market ambition including considerations and timing of entry, time frame for engagement, price targets, and supply acceleration plans/investments, as appropriate. Before entering a market the GAVI Alliance would, among other things, consider the prospects of a vaccine becoming affordable to countries over some timeframe[9] as well as the vaccine supply and procurement interventions that GAVI might employ to shape the market in order to get to that point. The end to end road

9 "Affordability" 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 (new) 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 basically a function of the government's political will).

map would also prioritise the objectives described above for a given type of vaccine (e.g. price vs. supply security, etc) and take into account lessons learnt from the medicines market that can be translated to the vaccines market.

Entry decisions 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[10] and the prospects for long-term affordability should be key considerations for market entry, they may not act as a 'deal breaker' in cases where there is a significant health imperative. For vaccines that are already considered affordable, GAVI's entry decision 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 end-to-end roadmaps would provide strategic considerations for how the market should evolve going forward and for transitioning to full country funding. Despite the envisaged long-term nature of the vaccine-by-vaccine roadmaps, it is likely that the roadmaps would be updated periodically to take into account new market dynamics and refine the necessary activities/tactics to manage the market particularly with respect to procurement.

In order to sustain immunisation programmes in countries that graduate from GAVI Alliance support, it is important to ensure that these countries continue to have access to affordable vaccine prices. 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 UNICEF or PAHO pays for GAVI-eligible countries. 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 end-to-end roadmaps should also consider methods to ensure low and sustainable prices for graduating countries where this is not currently the case.

Within these vaccine specific end-to-end road maps, 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 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 advocacy and supply strategy development and collect relevant market information. The aim of these activities is to reduce supplier concentration and monopoly/oligopoly power, reduce barriers to entry for new suppliers and accelerate new product introduction. The GAVI Secretariat would also help establish clear links between push and pull mechanisms to help ensure that push and pull funding

10 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

efforts are complementary, encourage innovation, and optimise the outcome for countries in terms of suitability of available 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, and to improve production processes and/or vaccine delivery mechanism. GAVI Alliance members 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 for innovation to accelerate and secure supply for GAVI-eligible countries. Methods include demand guarantees, leaving quantities unawarded while meeting current demand, firm contracting, advance purchase commitments or other advance market commitment (AMC)-like mechanisms. Based on the objectives and opportunities regarding a particular vaccine, the GAVI Alliance's engagement could range from being stakeholder to leader in this area and could seek new partners to ensure optimised liquidity of financing.

- **Facilitate incremental innovations.** Incremental innovations would provide improvements to existing products leading to either cost reductions for GAVI (and/or countries), increased supply security, increased programmatic suitability (such as improved thermostability, novel preservatives, new combination products or optimised delivery mechanisms) or to improved health outcomes. The GAVI Alliance would also encourage and facilitate the development of target product profiles (TPP) to defining desired incremental innovations, investment in push funding or process engineering improvements, and other actions, as appropriate. The extent of GAVI's engagement in such innovations will depend on the specific vaccine market and the potential opportunities that GAVI can see to encourage and reap rewards.

4.2 Develop market insight capabilities. Market insight capabilities are required to 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' capacity, product launch timelines, vaccine characteristics and cost drivers, and business/investment strategies. Multiple partners, including civil society, UNICEF, PAHO, and donors supporting push funding currently possess market insight capacity, however, the information and intelligence will need to be brought together through the Secretariat to ensure maximal benefit for the Alliance.

To this end, improved partnering with those Alliance members that already possess some market intelligence and other stakeholders (e.g. product development partnerships (PDPs)), as well as increased engagement with manufacturers will help the GAVI Alliance to build strong market insight

capabilities and should also enable manufacturers to supply products that better align with countries' needs and better meet GAVI's objectives.

4.3 Increased transparency

For both manufacturers and countries, timely, transparent and accurate information on demand and supply forecasting and prices is critical. An increased level of transparency is sought in order to provide greater accessibility of information to country programmes and other GAVI Alliance members. 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 standardised forecasting methodologies across vaccines, increased transparency and improved dissemination, thereby contributing to a better matching of supply and demand over time. Increased information transparency is also critical to improved forecasts for projected volume growth to encourage new entrants. Furthermore, working with UNICEF, GAVI now requires vaccine manufacturers to make their awarded prices public.

5. Procurement Strategy

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

Strategic approach: Through the procurement strategy the GAVI Alliance will aim to influence the market by (i) employing a wide set of procurement tools, mechanisms and tactics, and applying these 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 tools, mechanisms and tactics will be used to help address the increased complexity of operating in different market environments.[11] 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 noted above.[12]

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 finalize awards. Depending

11 In applying these mechanisms the relevant regulatory environment will be taken into account.

12 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.

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 supplier (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-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 suppliers before awards are finalised. After each round the procurer evaluates the bids/offers against predetermined criteria. This provides suppliers 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 suppliers 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 suppliers or buyers. Pre-tender mechanisms differ in the level of information requested from the potential suppliers and in the nature of the interaction between procurer and suppliers. 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 as outlined below should also be applied in procuring GAVI supported vaccines. These tactics must be considered in view of the objectives agreed in the “end to end” roadmaps. Regardless of the objectives pursued, a long-term view is critical to ensure that unintended consequences such as key suppliers 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.** Depending on the market situation (and in particular on manufacturers' ability and willingness to supply the market segment supported by the GAVI Alliance) and the cost structures of the vaccine, concentrating volume with certain manufacturers (instead of splitting demand across a greater number of suppliers) may enhance the GAVI Alliance's ability to secure lower prices.

- **Increased supply security through the use of back-up supply**. Supply risks related to the production of vaccines, to the regulatory environment 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 an incentive for new suppliers 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, when country preferences are too diverse to be efficiently managed, the GAVI Secretariat will need to "manage the product portfolio" (or optimise product selection) and limit presentation or formulation choices available to countries in order to optimise its procurement and to achieve the appropriate balance among different supply and procurement objectives. Decisions on if and how to limit presentation/formulation choices will be informed by intensive and continued country consultations and 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. In the management of its product portfolio, GAVI should be mindful of potential programme implications of a more centrally managed approach to product choices.

6. Roles and responsibilities

Implementation of the new vaccine supply and procurement strategy requires close collaboration of a number of Alliance members. Roles and responsibilities will be defined for the GAVI Secretariat, procurement partners, Civil Society Organisations, the World Health Organization, GAVI-eligible countries, manufacturers, and GAVI donors including information flows on research and development.

7. Monitoring and evaluation

The following indicators will serve to track the GAVI Alliance's progress towards its strategic goal to shape markets and will be reported on an annual basis to the Board.[13]

1. Reduction in price (change in weighted average price per child fully immunized with pentavalent, pneumococcal and rotavirus vaccine and change in lowest and highest price points to GAVI for these three vaccines).[14]
2. Number of country stock outs caused by global supply or quality issues for vaccines for routine usage (by antigens).[15]
3. Time between the date stated in country proposal for vaccine introduction and first shipment of vaccine, and driver for any noted delays.[16]
4. Number of valid offers by antigen and by manufacturer.[17]
5. Percentage of planned GAVI vaccines (forecasted intro in the next 5 years) with complete target product profile (TPP) available.

In addition, the GAVI Alliance's impact on price and supply security will be monitored on a vaccine by vaccine basis through reports of the PRG and procurement partners to the GAVI Secretariat. Information to be tracked on a regular basis includes:[18]

- 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:
  - Number of awarded suppliers, by vaccine type and by presentation, quantities procured in doses
  - Number of developed and developing country suppliers, based on county of manufacture and WB country classification by vaccine type, quantities procured from each supplier segment

13 Pending review of the strategy and proposed indicators by the PPC and the open consultation process, targets will be established for each indicator. However, some targets may not be publicly disclosed to maintain due process in pricing negotiations.

14 Already approved.

15 Definition is incidents of stock outs of vaccines for routine usage at country central level for more than 30 days for quantities approved by GAVI for continuing programmes and as forecasted by countries, due to insufficient supply availability or quality issues at the global level.

16 Country demand as per timing stated in the application form (or any official amendment to it formally communicated by the country) of those proposals recommended for funding by the Independent Review Committee. Time to be measured by quarter.

17 Offers must be submitted in response to a tender for GAVI-supported vaccines and the vaccines offered must be WHO pre-qualified. No double count if several tenders issued in one year for same antigen.

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

- For each type of vaccine:
  - Number of pre-qualified products
  - Total capacity offered to UNICEF over demand
  - Price per dose evolutions over time (including comparison of the benchmarks of other comparable or regional purchasing groups)

- On-time delivery performance:
  - By vaccines type, by year, by manufacturer, total number of recipient countries, total number of deliveries and on-time deliveries, % on –time deliveries
  - Cause of delayed deliveries, by vaccine product type.

Finally, the supply and procurement strategy will be reviewed in 2014, in preparation for the development of the GAVI Alliance 2016-2020 strategy.

ANNEX A: SUPPLY AND PROCUREMENT OBJECTIVES AND DEFINITIONS

		Objective	Definitions of terms
1	Balance of SUPPLY AND DEMAND	Ensure sufficient supply of *vaccine* is available to at least meet total *GAVI demand*	*Vaccine:* 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. *GAVI demand*: Refers to GAVI financed demand and demand for co-financed doses
2		Provide *consistent*, uninterrupted supply to GAVI countries	*Consistent:* Country should not have to unnecessarily and frequently switch product (i.e. lyophilized product, 10 dose product) as a result of procurement decisions *Uninterrupted*: no global stock-out of vaccines in a particular vaccine market
3	COST OF THE VACCINE to GAVI and Countries	Minimize the per course vaccine cost	*Cost:* 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 *cost implications of vaccines to GAVI countries*	*Cost implications of vaccines to GAVI countries:* 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 *appropriate, quality* vaccines to meet GAVI country needs	*Appropriate:* 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 *Quality*: 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
6		Foster an environment for *innovative* vaccines	*Innovative:* 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, *transparent* and accurate *market information*	*Transparent*: Shared appropriately and openly *Market information*: Data and insight that informs GAVI portfolio choices, country product choices, and the choices manufacturers make in production planning, capacity investments, and pricing

ANNEX B: DESCRIPTION OF PROCUREMENT MECHANISMS

To date, UNICEF, 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 suppliers 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 suppliers to make a single round of bids ("**single round tenders**"). UNICEF conducts follow-up clarifications and discussions with suppliers based on their bids to optimise the outcomes. Finally, following consultation with a Procurement Reference Group (PRG), if applicable, UNICEF seeks to match available supply to GAVI demand whilst balancing price, product characteristics, volume concentration, and supply security considerations, including taking future suppliers 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 supplier and product information and can be used to condition and prepare suppliers to provide bids that align with the procurer's objectives. Furthermore, pre-tender mechanisms allow procurers to compare responses of suppliers 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, supplier comparisons remain preliminary (e.g. suppliers 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 suppliers.
- 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, supplier 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 supplier (e.g., price, volume, length of commitments). After all suppliers 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 suppliers 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 suppliers 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 suppliers 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 suppliers and procurers. Also, the procurer needs to have a credible threat of not awarding any supply or awarding small amounts of volume to some suppliers 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 suppliers. However, direct negotiations require more extensive engagement from both procurers and suppliers and also rely greatly on mutual trust and transparency among parties particularly with respect to each party's objectives and supplier'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)*
  Suppliers tend to have different abilities to supply the GAVI Alliance market (in terms of production capacity); different willingness to supply the GAVI market (in terms of the volumes) based on available capacity and their levels of commitments and profitability in other markets; and different cost structures and drivers of manufacturing cost and hence different abilities to offer low prices. As such, the effect on pricing of competition and volumes awarded to each competing supplier will vary. While splitting of demand across all suppliers can be a way to increase supply security, concentrating volume with certain manufacturers may enhance the Alliance's ability to secure lower prices in a market where 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 has a certain risk in terms of 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 suppliers in the later stages of vaccine development to bring their products to market sooner and/or to expand planned production to better meet GAVI-eligible 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 suppliers with multi-year awards. UNICEF 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 suppliers of products with long production lead times. Although there is no procurement obligation on UNICEF's side, the use of LTAs ensures that the uncertainty with respect to future demand that suppliers' 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 suppliers to exit the market.
- *Firm contracting* means that the GAVI Alliance could sign legally binding contracts with suppliers 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 suppliers 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[19]; 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 (rather than antigen 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.[20]

19 Under the AMC, GAVI currently procures PCV 10 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.

20 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.