ADVANCE MARKET COMMITMENT FOR PNEUMOCOCCAL VACCINES

IMPLEMENTATION WORKING GROUP REPORT

Presented to the AMC Donor Committee

July 10th, 2008

CONTENTS

1. BACKGROUND

The Advance Market Commitment (AMC) Donor Committee created the Implementation Working Group (IWG) in March 2008, after receiving the report from the Economic Expert Group (EEG) that had been convened to examine the structure of the AMC for pneumococcal vaccines. The EEG presented its findings on March 10, 2008, in Rome, Italy, to the AMC Donor Committee. The EEG recommended a number of enhancements to the structure of the AMC, and suggested follow-on work to refine key terms. The recommendations were made public in the EEG report of April 1, 2008. As a result of that work and additional deliberations, the AMC Donor Committee asked the IWG to undertake technical work on specific terms and parameters for the enhanced structure (see terms of reference in Appendix A) and mandated that the group include a subset of the EEG for continuity, and representatives from organizations that will participate in AMC implementation, including the GAVI Alliance, World Bank and UNICEF (see IWG membership in Appendix B). The IWG's task was to make specific recommendations for key terms and features of the AMC, including the length of supply commitments, frontloaded pricing, the process for sequential tendering and the level for a tail price cap. The IWG was asked to arrive at recommendations that are sufficiently specific, detailed and operationally feasible to be applicable to the finalization of the offer to be presented to industry in the legal documentation.

This report presents the group's operational recommendations to inform donors' decisions on AMC design and implementation. It is intended as an addendum to the EEG report, rather than a stand-alone document; therefore, readers will find a number of cross-references.

Process Followed. The group held weekly teleconferences and engaged in on-going e-mail exchanges from late March to mid-May 2008. Upon request of the IWG, individuals providing expert technical support developed a set of additional analyses. Members of the group who had been a part of the EEG provided a briefing for civil society organizations (CSOs) on April 3, 2008, and an industry-wide briefing on April 4, 2008. They extended an offer of a further consultation to pharmaceutical manufacturers and CSOs. IWG members then participated in one-on-one discussions with representatives from several

pharmaceutical manufacturers (Wyeth, GlaxoSmithKline, Merck and Serum Institute of India) upon their request. Médecins Sans Frontières representatives discussed the AMC with IWG members, as well. Representatives from the chair of the Donor Committee observed the IWG's work and provided guidance regarding process questions, such as when to obtain additional information from donors. A draft version of the report was presented to the Donor Committee, and input from members of the Committee, as detailed below, is reflected in this final version. Furthermore, the terms were presented to the GAVI Board on June 26, 2008, for review and approval and the specific inputs of the Board are reflected in the report.

The members of the IWG appreciate the resources and input provided for this work by the Donor Committee and the GAVI Alliance, as well as the information and views offered by representatives from GAVI-eligible countries, civil society organizations and pharmaceutical industry representatives. Group members are grateful for insights and suggestions provided by the PneumoADIP, CRA International, Applied Strategies and by members of the EEG, who themselves have devoted many hours of voluntary effort to careful consideration of how to make the most of the opportunity to improve health outcomes in poor countries that has generously been provided by the donors to the AMC.

1.1 OBJECTIVES OF THE AMC

As agreed by the AMC Donor Committee, the objectives of the pneumococcal AMC upon which the IWG grounded its deliberations are:

1. To accelerate the **development** of pneumococcal vaccines that meet developing country needs (e.g. serotype composition and vaccine presentation) as specified in the Target Product Profile (TPP).

2. **To bring forward the availability** of effective pneumococcal vaccines for developing countries by guaranteeing the initial purchase price, for a limited quantity of the new vaccines, that represents value for money and incentivizes manufacturers to invest in scaling-up production capacity to meet developing country vaccine demand.

3. **To accelerate vaccine uptake** by ensuring predictable vaccine pricing for countries and manufacturers, including binding commitments by

participating companies to supply the vaccines at low, long-term and sustainable prices after the AMC finances are depleted.

4. **To pilot test the effectiveness** of the AMC mechanism as an incentive for needed vaccines and to learn lessons for possible future AMCs.

1.2 CONTEXT FOR IWG RECOMMENDATIONS

A discussion of the relationship among parameters, such as AMC price and tail price, can be found in the EEG report of April 1, 2008. Appendix C includes an excerpt from the EEG with definitions of terms.

For the purposes of the IWG's work, we recognized that a range of possible combinations of supply commitments, AMC price, tail price and other features could yield important health benefits and be cost-effective (compared to other uses of an equivalent amount of resources). However, the AMC can only do this if:

(a) Vaccine suppliers participate in the AMC;

(b) The resource requirements, including the financial demands on the GAVI Alliance and on recipient country governments, fall within the willingness and ability of those entities to pay;

(c) The terms and features are reasonably robust to a range of unforeseen changes, such as unanticipated variations in demand and cost increases associated with regulatory changes; and

(d) The "mechanics" or procedures can be implemented with reasonable transaction costs.

Therefore, when assessing possible options, IWG members focused primarily on how a given option performed relative to the dimensions of likelihood of industry participation, affordability, resilience and ease of implementation. Of note, in the original EEG report frontloaded pricing and firm-order timing were presented as two complementary methods for sharing of demand risk with industry. The report described how different combinations of frontloaded price could be combined with firm-order timing to achieve essentially comparable results. The IWG terms of reference reflect the initial preference of the donors to emphasize frontloaded pricing to the exclusion of firm order timing. During the IWG process, however, companies continued to express an explicit interest in

firm order timing and the AMC Donor Committee reconsidered the appropriate degree of front-loaded pricing. Based on that additional input, the final IWG recommendations include an element of firm order timing and limit front-loaded pricing to the maximum AMC price ($7) discussed during the formative phase of the pneumococcal AMC. As a final step, we affirmed that the complete package of recommendations obtained health benefits in a cost-effective manner.

2. NEW INFORMATION UNDER CONSIDERATION

2.1 ADDITIONAL ANALYSIS

Several quantitative analyses were conducted using a spreadsheet model originally constructed as part of the work of the EEG (see Appendix D for a summary of the analytic results and Appendix E for description of the spreadsheet). The spreadsheet model is a tool to assess the impact of different program rules on firms, public health outcomes and affordability to donors. For firms, the operative metric was net present value (NPV); for public health outcomes, the metric used was net disability-adjusted life years gained (DALYs), which represent the public health benefits of the pneumococcal vaccine less the DALYs that could be gained with alternative uses of AMC, GAVI and country funds; and for affordability to donors, the analysis focused on GAVI expenditures and draw-down of the AMC funds. While the model does not generate precise recommendations, it provided guidance in the discussions that led to the IWG's current recommendations.

- The EEG, and subsequently the IWG, used the spreadsheet model in three ways:
    - To evaluate "what would happen" if the firms committed to a certain supply commitment (say for 100 million doses per year), under different assumptions and program rules: how much money would the firm make, how many DALYs would be gained, and how much would it cost the donors/GAVI?
    - To ask "how much would the firms want to supply?" under different assumptions and program rules. This involves a net present value calculation as well as analysis to assess the combinations at which NPV to firms would be maximized: what

happens with 10, 25, 50, 75 and 100 million dose supply commitments? Which one most effectively generates the highest net present value for firms?

- To introduce some uncertainty, by considering the decreasing probability that a firm will enter at successively lower tail prices. Here the model weighs a core tradeoff around low tail prices, which can achieve higher net DALYs gained – but not if firms do not participate.

The model examined the likelihood of participation of firms. For that, attention was placed on NPV, a standard method for the financial appraisal of long-term projects. It is widely used in economics for capital budgeting, and measures the excess or shortfall of cash flows, in present value terms. The spreadsheet model was used to generate mock profit and loss statements for each of the potential participants in the AMC, as a point of departure for individual discussions with officials from those firms.

The NPV calculation, which has been the main focus in thinking about industry participation, required several inputs, including demand forecasts (updated by GAVI from the PneumoADIP's original work); assumptions about capital and marginal costs of production (based on a 2005 study by Mercer, now known as Oliver Wyman); and several other assumptions about the lag time for new capacity to come on-line, discount rate, wastage, price elasticity of demand, plant outages and additional costs. It is important to note that these NPVs represent optimistic figures for industry. Companies' internal risk considerations used to inform decisions about whether to invest in a new plant to serve the GAVI market could discount these significantly.

2.3 RESULTS OF INDUSTRY CONSULTATIONS

The one-on-one discussions with industry representatives revealed several views, summarized below:

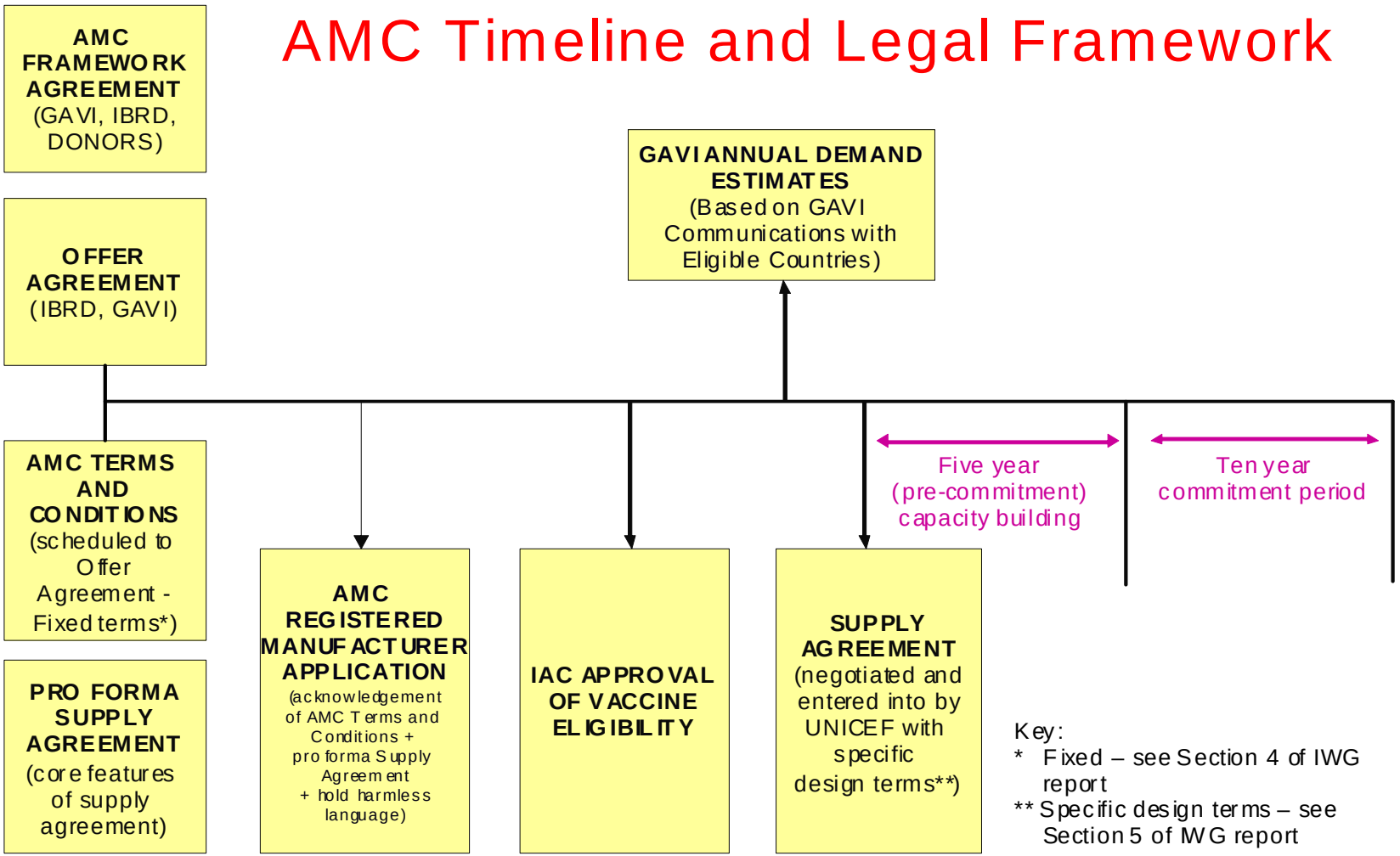
- The lack of demand assurance together with a relatively low, hard cap on the tail price (as recommended by the AMC Donor Committee in their response to the EEG report) was by some perceived to impose significant risks and limited flexibility on industry.
- The cost of goods sold used in the analysis to date were by some perceived to be too low and out-of-date.

- The manufacturing complexity of the pneumococcal vaccine was overall described as high, resulting in relatively high costs even for suppliers based in emerging markets.
- It was seen by some as essential to have specified exit and force majeure provisions and other ways to ensure that companies and sponsors do not get "locked in" to unworkable conditions that could not be foreseen at the outset.
- The concept of sequential tendering or tranches was not fully understood by some industry representatives and required lengthy explanation. During several of the discussions, some industry representatives indicated that sequential tendering could introduce additional uncertainty.
- Firms requested assurance of a "level playing field," without special favor to any supplier or type of supplier.
- Considerable interest was shown in the expectations about the timing of pneumococcal vaccine introduction into India, and the implications of Indian policy decisions for aggregate demand and other aspects of the market over the medium- and long-term.
- Some firms were concerned about the timing of public disclosure of their participation in the AMC, and about the confidentiality of the terms and details of their specific agreements.

3. OVERVIEW OF LEGAL STRUCTURE

At the launch of the pneumococcal AMC, a set of legal agreements will be entered into setting out the agreement between stakeholders, fixed terms and conditions of the offer of $1.5 billion, and the fixed terms and conditions of the pneumococcal AMC design. The structure of these legal agreements and the general time line of the pneumococcal AMC are illustrated in Figure 1 (next page).

AMC Timeline and Legal Framework



3.1 CORE AMC DOCUMENTS

1. Stakeholders Agreement*:* This acts as the umbrella agreement outlining the agreement between the GAVI Fund, the World Bank and the donors. Suppliers will not be part of this agreement. Rather, it has specific details as to the governance of the AMC between stakeholders.

2. Offer Agreement: This agreement is a unilateral offer from the GAVI Fund and the World Bank, reflecting the arrangements among stakeholders in the Stakeholders Agreement, of $1.5 billion to industry under specified terms and conditions. The co-payment from GAVI and countries would be reflected in the actual supply agreement (see below).

***3. Terms and Conditions*:** Certain fixed terms and conditions will be scheduled to the Offer Agreement and will outline design features that are not subject to negotiation by an AMC-eligible manufacturer – e.g. AMC contribution, tail price cap, supply commitment requirements, and others.

4. Pro Forma Supply Agreement: AMC-registered manufacturers will be required to enter into Supply Agreements with the procurement agency (UNICEF) once the AMC-specific registration and approval conditions are met in order to access funding through the AMC. To maximize transparency and certainty for all manufacturers (and to minimize transaction costs and lead-in time), most of the key features and terms are hard-wired in advance, ensuring limited negotiations at the stage of entering into each final Supply Agreement. UNICEF is working closely with GAVI and the World Bank to develop this pro-forma Supply Agreement on the basis of the final IWG design recommendations. There will of course be specific terms for a specific manufacturer that will be made only at the stage of entry into the actual Supply Agreement (e.g. level of supply commitment, tail price and start date for dedicated capacity). These will be the negotiated elements of the Supply Agreement.

Prior to UNICEF entering into a Supply Agreement with a specific manufacturer, the GAVI Board will be asked to approve the provision of funding to support the

firm order timing[1] commitment, acknowledge the financial commitments made for specific country approvals (done in rolling 2 year periods) for the AMC period and approve a budget envelope of funding needed for the duration of the Supply Agreement. [2]

In accordance with the terms of the relevant Supply Agreement, and adapted from current UNICEF practices, specific orders will be issued to participating manufacturers based on country approvals received from GAVI and annual shipments plans agreed to with countries. Manufacturers will be paid following delivery of goods.

3.2 ANCILLARY AMC DOCUMENTS

***1. AMC Registered Manufacturer Application*:** To express an interest to participate in the AMC and to create a contractual nexus between manufacturers and the World Bank and GAVI, manufacturers will be expected to apply to become "AMC Registered Manufacturers." During this application phase, a manufacturer would acknowledge the core AMC features and agree to abide by them – in particular, the AMC Terms and Conditions, the pro-forma Supply Agreement and the roles and responsibilities of the Independent Assessment Committee (IAC) in the AMC framework. Each manufacturer would also be asked to voluntarily report to UNICEF as the procurement agency and the IAC on a regular (annual) basis an updated estimate of the timeline of progress towards WHO prequalification and intended availability of supply. A regular dialogue with the procurement agent would be critical to ensure supply and demand are well matched.

[1] The firm order timing commitment is applicable to a supplier's committed capacity when established (20%, 15% and 10% of dedicated capacity for the first three years respectively). See Section 4.4 (Firm Order Timing).

[2]With the exception of the funding to support the firm order timing commitment, the provision by GAVI to purchase vaccine on behalf of countries is based on applications from countries and the subsequent approval of these applications by the GAVI Board.

***2. IAC Charter and Bylaws*:** The charter and bylaws set out the roles and responsibility of the IAC – including approval of the TPP, review and approval of AMC Eligibility Applications, review and modification of AMC terms and conditions (including price).

***3. AMC Procedures Memorandum*:** This document will contain all the process and procedure specificities that would be applicable to the IAC, the AMC Secretariat, vaccine manufacturers and eligible countries. It will outline application procedures for vaccine manufacturers to become AMC registered manufacturers, and to have their vaccines become AMC-eligible through the IAC approval process. It will have monitoring and reporting procedures and application procedures for eligible countries to access IAC-approved vaccines.

One of the key features of the legal agreements is that there will be a high level of transparency with industry and with the public. This is especially important given there are specific design features in this IWG recommendation that hinge upon industry being made aware of the existing supply/demand curves.

4. TERMS AND CONDITIONS

This section provides the IWG's recommendations regarding the terms and conditions to be scheduled to the Offer Agreement. These are fixed at the outset of the program and apply across all firms that eventually participate in the AMC.

4.1 AMC PRICE

The overall per-dose price for vaccine sold during the time when a company is receiving an AMC subsidy should be $7. The per-dose AMC subsidy should be $3.50 for products offered at a tail price of up to $3.50. For products offered under a Supply Agreement specifying a tail price below $3.50, the AMC subsidy should be raised accordingly, such that the overall AMC price remains at $7. This results in an average price over the duration of the AMC of up to $4.25.

All purchases[3] of pneumococcal vaccine meeting the target product profile for GAVI-eligible countries[4] should be made consistent with the AMC terms. In extenuating circumstances, GAVI and UNICEF will be requested under the AMC Terms and Conditions to make any other purchases of pneumococcal vaccines for GAVI-eligible countries in ways that do not provide a "better deal" to manufacturers than is available under the AMC. See also Section 8.1 (Best Deal).

> **Rationale:** As discussed in the EEG report, this value does not significantly affect competition between companies because of proportionality between share of the total AMC fund and share of target supply. Given the speed of likely pay-out (less than two years at full supply commitment level), higher per-dose subsidy or two-step frontloading do not add significant benefit.

4.2 SUPPLY COMMITMENT RELATIONSHIP TO AGGREGATE AMC SUBSIDY

The AMC should provide an aggregate contribution (total subsidy) to a participating manufacturer that represents a share of the $1.5 billion directly proportional to the share of a total demand forecast of 200 million doses annually for which the firm has agreed to commit dedicated manufacturing capacity over 10 years (when the manufacturer enters into a Supply Agreement). That is, for example, for every 10 million doses of annual dedicated capacity to which a manufacturer commits in the Supply Agreement, the aggregate AMC contribution for which the manufacturer would be eligible, through qualified sales, would be $75 million. This aggregate contribution will be distributed according to the doses ordered as described in the AMC Price section above.

> **Rationale**: This is the simplest and most direct way of aligning the incentive of the aggregate AMC contribution and the manufacturer's supply commitment.

[3] All GAVI payments are subject to standard GAVI procedures and funding.

[4] See www.gavialliance.org for a list of GAVI countries.

4.3 TAIL PRICE CAP

To be eligible to enter into a Supply Agreement, the manufacturer should commit to providing pneumococcal vaccine, at an annual number of doses corresponding to the supply commitment, at a per-dose price to GAVI/UNICEF (excluding the AMC subsidy) of no more than the tail price cap (initially set at $3.50). The tail price cap will apply for the duration of the supply commitment. The cap represents a ceiling; it is anticipated manufacturers will come in below this.

> **Rationale:** Given best available knowledge of manufacturing costs and ability to pay on the part of GAVI and eligible countries, this price strikes a balance among the objectives of participation of multiple firms (important for a healthy, robust market), affordability and the efficient use of the total (AMC subsidy + tail price) resources available for the purchase of pneumococcal vaccine.

4.4 FIRM ORDER TIMING

The AMC should guarantee a portion of the anticipated demand through the mechanism of firm order timing, which is described in the EEG report as a means of mitigating demand risk. For any participating firm entering into a Supply Agreement, UNICEF, with financial support from GAVI, should commit to firm orders for 20 percent of the committed supply on an annual basis in the first 12 months during which vaccine from dedicated capacity is made available; 15 percent of committed supply in the second 12 months during which vaccine from dedicated capacity is made available; and 10 percent of committed supply in the third 12 months during which vaccine from dedicated capacity is made available. The guarantee is for the entire AMC price, including both the AMC subsidy for amounts paid under firm order timing during the AMC period[5] and the GAVI and country co-pay.

[5] Note that it is possible that the AMC subsidy amount under a Supply Agreement could be utilised before the start dedicated capacity period, if firms offer significant amounts of supply from headroom early on. If this is the case, then the purchase guarantee would be in respect of

Rationale: Based on consistent input from manufacturers, a purchase guarantee is a very important means of demonstrating confidence in the demand estimates, and sharing demand risk with the firms. Even at a modest level, IWG members believe that a purchase guarantee sends the correct signals to industry, and reduces significantly the uncertainty.

4.5 SALES OUT OF EXISTING HEADROOM [6]

Manufacturers entering into a Supply Agreement should be able to use existing manufacturing headroom (before dedicated capacity comes on-line) to fill orders for their product. For these sales, they should receive the AMC price of $7 (subsidy + tail price) so long as their AMC subsidy amount under the Supply Agreement remains. Once their AMC subsidy has been exhausted, they should receive the tail price. As a condition of sale from existing headroom, once sales begin, the company should be required to continue to supply vaccine at the same or greater level until the full supply capacity comes online. UNICEF and GAVI should provide an annual forecasted demand to the manufacturer with a goal of matching supply to demand to guard against shortages. For these sales, as for all other AMC sales, the per-dose payment should be made by UNICEF, consolidating the AMC contribution, and the GAVI/country co-payments.

The supply agreement specifies a 10-year agreement to provide vaccine to GAVI countries. The length of the agreement would be revised depending on the extent of the provision of vaccines during the headroom period. The obligation to supply during the tail period (after the funds for the AMC subsidy are exhausted) may, at company request, be reduced by an amount directly corresponding to the amount sold out of existing headroom. This reduction should be taken in a manner that least disrupts overall vaccine supply, preferably taken out of the last years of the Supply Agreement, although the

the tail price only (i.e., once the AMC subsidy has been fully utilised under that Supply Agreement).

[6] This was previously referred to as "spot market" purchases, but the terminology has been clarified in this report, at the request of the AMC Donor Committee.

exact schedule should be determined between UNICEF and the manufacturer prior to entering into a given supply agreement. To assure supply continuity over time, manufacturers should not be allowed to provide an annual commitment during this period that exceeds the capacity they have commitment to provide as part of the AMC unless agreed to by UNICEF and GAVI. Sales out of headroom will be limited by the extent of country demand.

> **Rationale.** This feature provides a means of giving countries access to the vaccine before dedicated manufacturing capacity is on-line, and helps to mitigate the risk of severe product shortage in the early years. It also reinforces the AMC incentive to build dedicated capacity because it provides a form of capital risk mitigation, permitting firms to obtain a portion of the aggregate AMC subsidy in advance of the creation of dedicated capacity.

4.6 ENTRY INTO SUPPLY AGREEMENTS TO ALIGN SUPPLY AND DEMAND[7]

The entire $1.5 billion AMC subsidy will be announced at the launch of the pneumo-AMC. At a time to be determined by GAVI and UNICEF (which could be at a to-be-determined standard time each year), manufactureres will be asked to submit bids for 10 years of committed supply with an estimated start date not more than 5 years into the future. All manufacturers who have (i) become an AMC registered manufacturer; (ii) produce vaccine that has been pre-qualified by the World Health Organization (iii) completed the AMC eligibility application process with the IAC; and (iv) received approval from the IAC of the vaccine in question as meeting the TPP, are entitled to enter into Supply Agreements according to the terms laid out in Section 5 below provided that there is defined demand for the vaccine.

[7] In earlier discussions, the concept of multiple, sequential tenders or tranches featured prominently. In the final deliberations of the IWG, it was determined that many of the benefits of sequential tendering or tranches could be achieved with the more continuous structure described here. Therefore, there are no separate recommendations regarding sequential tendering.

The basis for any Supply Agreement is the demand forecast which will be updated by GAVI/UNICEF bi-annually in accordance to the country approval process and timeline. The portion of the demand forecast that is not already covered by Supply Agreements will be open for bids on an annual basis from manufacturers that meet the requirements above.

Suppliers may forward a bid to UNICEF and discussions may be initiated at the point in time where a product summary file has been accepted for review by WHO. As a general rule, Supply Agreements will be entered into only at the point in time when the vaccine is approved by the IAC.

Only in extraordinary situations and based on analyses by GAVI/UNICEF which indicate that in the interest of vaccine security, in the case of limited vaccine supply or similar reasons there is justification to deviate from that practice, will additional Supply Agreements be established.[8] If, in a single round, for a given start year, the total supply commitments offered by multiple manufacturers were to exceed estimated demand or total funding available,[9] GAVI/UNICEF would have the ability to negotiate with manufacturers and enter into Supply Agreements for specific vaccines in quantities to match the overall forecasted demand but at the same time and in accordance to existing practices, to take into consideration country vaccine preferences and the need to have multiple manufacturers to support the sustainable uninterrupted supply of vaccines.

In a situation where Supply Agreements with manufacturers having IAC approved products are insufficient to meet the projected demand 5 years ahead,

[8] For example, if the anticipated demand in 2015 is 100 million doses and two suppliers have already completed the AMC eligibility process and are negotiating Supply Agreements with UNICEF on the basis of 50 million doses each in 2015 – final determination on the actual supply commitment would be dependent on demand for a manufacturer's vaccine. In addition, in a situation where the dedicated capacity from a given supplier is delayed, or in case a manufacturer cannot perform, additional supply commitments may be considered with other manufacturers.

[9] In the exceptional circumstance that full funding in respect of the co-pay/tail price is not available, GAVI would work with UNICEF to enter into agreements that would at least partially fund demand.

UNICEF may develop policies that, at its discretion, allow for entry into Provisional Supply Agreements with companies with products deemed by the IAC to be highly likely to become pre-qualified within a timeframe sufficient to meet impending AMC demand needs. Provisional Supply Agreements could have firm, timed, intermediate milestones and no contractual obligations from the AMC until all milestones had been met.

Rationale. This simple, rules-based approach enables the construction of a trajectory of supply that matches the evolving change in demand for pneumococcal vaccine as the AMC unfolds. It is likely, given a variety of factors, that the initial Offer Agreement will not generate supply commitments from manufacturers that are sufficient to cover anticipated demand in early years, so the Offer Agreement must provide program rules permitting supply commitments to be made at different times. This proposed process meets the intent of sequential tendering – aligning supply with evolving demand and enabling later entrants to have more information about the availability of AMC funds – without having to introduce novel approaches and terminology that proved confusing in the IWG's consultations with manufacturers. Significant flexibility should be provided to GAVI/UNICEF regarding some aspects of the timing and size of the Offer Agreement, based on analyses of demand, GAVI and country co-pay funding availability, efficient manufacturing capacity and vaccine security.

4.7 ADJUSTMENT FOR INFLATION

Firms entering into a Supply Agreement at a tail price lower than the tail price cap should be permitted to increase the tail price at the rate of the GDP deflator until the tail price reaches the tail price cap ($3.50).

In addition, the IWG recommends that, at the request of a company, the tail price cap be reassessed by the IAC at three year intervals or a cumulative 7% rise in the GDP deflator, whichever comes first. The first review could take place 3 years after signing the offer agreement. This reassessment should take into account current and projected rates of inflation as well as other pertinent, available information such as manufacturing costs and efficiencies and should recommend increases in the tail price cap in a manner that fairly shares real increases in costs between manufacturers, GAVI and countries. The IAC should, at its next meeting, develop the plan for moving forward on this issue, including

identifying the appropriate experts to develop and implement the specifics of the suitable process and methodology.

> **Rationale**. The EEG had recommended an inflation adjustment for the tail price when it was considering capping the tail price at a lower level than recommended by the IWG. During the IWG process, however, GAVI conveyed concerns about an open-ended commitment on inflation, considering that GAVI donor contributions are not indexed for inflation, and that the price of other GAVI vaccines has typically declined over time. The IWG shares the EEG's emphasis on ensuring long-term sustainability of the AMC terms for firms and GAVI/donors alike. Due to the length of the Supply Agreements, inflation will have real influence on long-term viability. An effective and equitable process to adjust for inflation is therefore essential.

4.8 CONSEQUENCES OF BREACH

The legal team developing the agreements for the AMC should include provisions on consequences to manufacturers that have entered into Supply Agreements and fail to comply with the agreed terms.

> **Rationale**. After obtaining a share of the aggregate AMC contribution, firms should not be able to escape their obligations without remedy.

5. ELEMENTS OF SUPPLY AGREEMENTS

This section presents IWG recommendations regarding key elements of the Supply Agreements, which will be negotiated between UNICEF and each AMC Eligible Manufacturer that has completed the AMC Eligibility Process. While it is anticipated that the key elements will be maintained as set out, there should be some limited ability for GAVI/UNICEF to adapt the elements in light of updated information. In making any adaptations, GAVI/UNICEF should be required to justify any changes to the IAC in terms of the underlying objectives of the AMC, and the broad aims of engendering a secure supply of vaccines. GAVI support in the tail period would be subject to the usual GAVI processes, including recommendation by an independent review committee, approval of a given country's multi-year application (typically 18 months with a potential extension up to 5 years), and subject to Board approval based on availability of funding (GAVI processes are further detailed in Section 8).

5.1 MINIMUM SUPPLY COMMITMENT

Firms should be required to make a supply commitment of a minimum of 10 million doses annually, over 10 years.

> **Rationale**: A minimum bid requirement mitigates the risk of token participation by companies.

5.2 STARTING DATE AND DURATION OF SUPPLY COMMITMENT

The starting date for dedicated manufacturing capacity to go on-line should be no more than 5 years after entering into a Supply Agreement. There should also be a requirement for specific notification to UNICEF/GAVI and the IAC when such dedicated capacity comes online.[10] The duration of the supply commitment should be 10 years from the start date specified by the firm. Company eligibility for entering into a Supply Agreement is outlined in Section 4.6 above. The AMC would not allow new entrants after 2020. Funds that are not committed to a firm at this point would be returned to AMC donors or transferred to GAVI for use in future procurement of pneumococcal vaccine.

> **Rationale:** Approximately 5 years are required to bring dedicated manufacturing capacity on-line, so the lag time must be built in. To maximize the opportunities to respond to demand, firms should be enabled to commit to a shorter lead time if circumstances permit. Because a long-term commitment such as this significantly exceeds current practice, requirement of a longer commitment period would be a disincentive to participation in the AMC.

5.3 PROVISIONS IN THE EVENT THAT DEMAND FOR A PARTICULAR PRODUCT IS LOWER THAN THE COMMITTED SUPPLY

After the first anniversary of full supply capacity availability under a Supply Agreement, if overall demand fails to meet projected demand included in the

[10] Manufacturers would provide annual updates on progress.

Supply Agreement when it was first entered into (at a company's request to the IAC and in accordance with UNICEF procedures) supply commitments will be prorated to match overall observed demand, taking into account the actual demand development in the previous three years. No company's commitment should be reduced below its current level of supply in that given year.[11] Companies would be allowed to sell vaccine from dedicated supply for which there is no AMC demand in other non-GAVI markets. It should be noted that GAVI and UNICEF expect to purchase pneumococcal vaccines for GAVI-eligible countries only in accordance with the AMC arrangements (i.e. subject to the tail price cap). In extenuating circumstances these practices could be adapted by GAVI/UNICEF, with the authorization of the IAC.

From the third anniversary of full supply capacity availability under a Supply Agreement, if overall demand for pneumococcal vaccine has risen to the level included in the Supply Agreement when it was entered into but demand for a particular product is lower than the supply commitment, at company request to the IAC and in accordance with UNICEF procedures, a company's supply commitment may be modified downward annually taking into account the actual demand curve for its product in the three previous years.

In both of the situations above, the share of any remaining portion of the AMC contribution would be correspondingly reallocated away from the firm, corresponding to the lower supply commitment.

> **Rationale:** In the event that demand is significantly less than anticipated for a given product, some relief must be available to firms so that they are not obliged to maintain unused manufacturing capacity. Similarly, the resources of the AMC should not be tied up unduly and should be made available for allocation to other firm(s) for whose product(s) demand might be greater. Because much of the relevant information for decisions

[11] Should demand for a product decline over time, UNICEF will work with a manufacturer to consider appropriate planning for procurement into the future.

about the appropriate course of action will be known only at the time, it is appropriate to leave some discretion to GAVI/UNICEF.

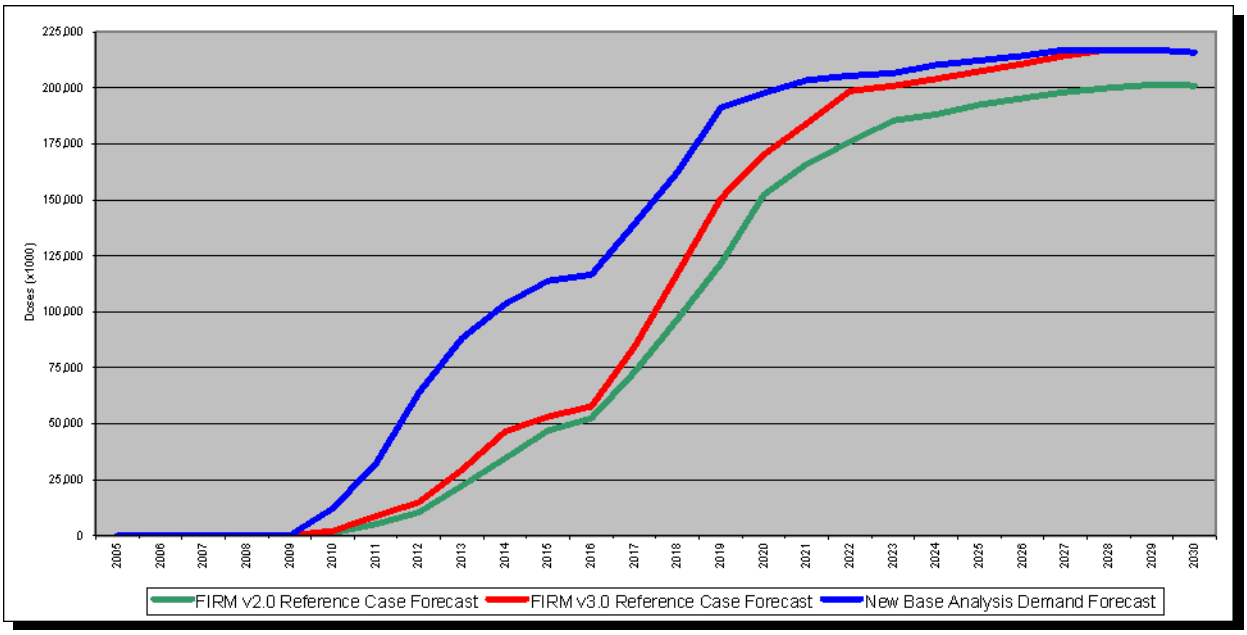
5.4 EXTRAORDINARY CIRCUMSTANCES UNDER WHICH TAIL PRICE COULD BE INCREASED

In extraordinary circumstances, a firm entering into a Supply Agreement may approach the IAC with a request for an increase in the tail price. This might happen, for example, if new and unforeseen regulatory changes create requirements for higher levels of capital investment, quality control activities, or other expenses that materially affect the marginal cost of production. Any increase would be subject to close scrutiny, and would require firms to reveal information about manufacturing costs (potentially through a negotiated process of intermediation by a neutral third-party). The IAC should not agree to increase the tail price for a specific manufacturer except in extraordinary circumstances, and any increase should be fully justified with respect to achieving the AMC objectives.

Rationale: Firms should not be expected to sell products at less than the marginal cost of production. A range of unanticipated events could justify an increase in the tail price. The requirement that firms agree to reveal manufacturing costs represents a high hurdle to engaging in negotiations to increase the tail price.

6. IMPLICATIONS FOR FLOW OF FINANCING

The current demand forecast for take-up of the pneumococcal vaccines is more frontloaded than earlier forecasts (see blue line in the figure below).



12

With an AMC subsidy of $3.50, a tail price cap of $3.50, full takeup of the AMC offer to meet demand would result in the full AMC subsidy amount of $1.5 billion being disbursed by 2018 or 2019.

Looking at other scenarios, the demand forecast could be further frontloaded if, for example, India follows the recommendation of its high-level expert panel to introduce pneumococcal vaccines into its routine immunization program as soon as possible. This is the basis of a high-demand scenario for AMC cashflows – although it should be noted that past experience indicates that India would normally not introduce a new vaccine using foreign supply. Under this scenario, the entire AMC subsidy amount could be disbursed by 2016.

More conservative scenarios would result in slower outflows. If, for example, two manufacturers enter into Supply Agreements in the 2009-2012 period and commit to only some of the 200 million-dose envelope, and the balance is taken

[12] The forecasted demand estimates come from PneumoADIP's v2.0 Strategic Demand Forecast for Pneumococcal Vaccines in GAVI countries, based on modeling by Applies Strategies.

up by other manufacturer(s) starting in 2015-2017, the AMC subsidy amount would not be disbursed until 2019 or 2020. An alternative scenario based on lower demand and slightly slower introduction of the pneumococcal vaccine would result in full disbursement by 2020 or 2021.

7. MITIGATION PROVISIONS

To ensure the AMC is accorded its full value and impact, it is important to minimize non-essential economic and procedural uncertainties faced by manufacturers. Accordingly, the AMC legal agreements will set out mitigation provisions relating to events that represent catastrophic or fundamental changes in circumstances. The specific details and parameters of this provision will be considered further in the stakeholder negotiations leading up to launch, taking into account standard commercial practice.

7.1 EXTRAORDINARY EVENTS/CIRCUMSTANCES

The AMC Terms and Conditions, and the IAC Charter and Bylaws, will include detailed provisions covering specific extraordinary circumstances that would require a modification of the Terms and Conditions. These would include, for example, the situation in which there is a change in the legal or regulatory conditions relevant to the production of eligible vaccines in a way that, in the IAC's view, would be likely to prejudice materially the manufacture, supply and distribution of an AMC-eligible vaccine on the basis of the Offer Agreement (including the Terms and Conditions) and the Supply Agreement.[13]

Consequences of Extraordinary Circumstances: A re-evaluation of the terms of the Supply Agreement (including the Terms and Conditions) would be undertaken in consultation with the IAC. Any amendment or modification to the Terms and Condition and Supply Agreement at this stage, including in respect of price, would take into account any mitigation undertaken by the manufacturer and current demand forecasts.

[13] See Section 5.4, page 23

7.2 SUSPENSION EVENT/CANCELLATION EVENT

Events may occur that have a material and adverse impact on one or all manufacturers, or the production or sale of one or all AMC-eligible vaccines. If, as a result, the AMC objectives would be fundamentally affected or would not be met, the Terms and Conditions should include specific provisions for suspension or cancellation. Examples include:

1. WHO pre-qualification approval of an AMC-eligible vaccine is revoked, withdrawn, cancelled or suspended, including where the license for an AMC-Eligible Vaccine is revoked, withdrawn, cancelled or suspended by a relevant regulatory authority as determined by the IAC.

2. An AMC-eligible vaccine is subject to a material inquiry or investigation by the IAC, WHO, FDA, EMEA or other health regulatory authority that is determined by the IAC to be material in the context of the AMC-eligible vaccine in question.

3. The AMC-eligible manufacturer has failed to comply in a material way with the provisions applicable to it as set out in the AMC Procedures Memorandum or a Supply Agreement.

The specific details and parameters of this provision will be considered further as the AMC legal agreements are finalized, taking into account standard commercial practice.

Consequence of Suspension/Cancellation Events: For circumstances affecting a single manufacturer, a suspension event would lead to suspension of the funding flow in respect of the affected AMC registered manufacturer; a cancellation event would lead to a cancellation of the obligations under the relevant Supply Agreement to allow for funding reallocation. If all manufacturers are affected, these circumstances could lead to suspension or cancellation of the AMC as a whole .

7.3 FORCE MAJEURE EVENTS

These provisions will be included in Supply Agreements.

An AMC-eligible vaccine manufacturer may be given temporary relief from delivery failure or delay for causes beyond its control and not reasonably foreseeable natural catastrophes (such as earthquakes, floods, cyclonic or

volcanic activity, or fires), war, invasion, rebellion, terrorism, revolution, insurrection, civil war, riot; or other acts of a similar nature or force. In such cases, the AMC-eligible manufacturer will give UNICEF written notification of any such delay or failure, and UNICEF will notify GAVI and the World Bank. These would be in line with standard commercial terms.

Consequences of Force Majeure Events: Manufacturers would be given temporary relief from meeting supply commitments. The relief period would normally not be longer than that of the unexpected delay.

8. ADDITIONAL RECOMMENDATIONS AND CONSIDERATIONS

8.1 BEST DEAL

The IWG has placed priority on facilitating participation in the AMC, within the broad criterion of obtaining good value-for-money. This requires balancing specific terms against the upper bounds of affordability and willingness-to-pay. From a practical perspective, therefore, there are likely to be few or no alternative ways than the AMC to sell large volumes of vaccines to GAVI-eligible countries.

Every effort should be made to communicate to firms considering participation in the AMC that the terms in the Offer Agreement represent the "best deal" available, and that neither GAVI nor other parties to AMC agreements (i.e., the World Bank, bilateral donor agencies, the Bill & Melinda Gates Foundation) plan to provide more favorable arrangements for large volume procurement of pneumococcal vaccine meeting the TPP.

8.2 CONTINUITY AND CAPACITY

A range of technical expertise will be required for the effective implementation of the AMC. This includes, among others, expertise in contractual law, commercial deal-making and procurement, supplemented as needed by specialized guidance in industrial organization economics. Based upon the existing expertise available at UNICEF Supply Division and the GAVI Secretariat, consideration should be given as to what additional expertise should be made available in-house, at the AMC Secretariat, or should be contracted. Moreover, considerable continuity in staffing and consulting partners should be given priority, rather than depending

on a set of ad hoc expert panels. This is particularly important in fostering productive on-going discussions with industry representatives and non-governmental organization representatives. It will be important to establish a clear mechanism for cross-partner work on these issues to ensure clear and consistent messages and to maximize the chances of success of the AMC. The AMC is a new mechanism and while it will be important to use existing channels, it will also be critical for the appropriate expertise to be available through a procurement reference group. GAVI, The World Bank and UNICEF will also move forward with effectively communicating the contents of this report, the timeline going forward and financial planning to ensure donor flows match demand.

8.3 GAVI/UNICEF PRACTICES

Unless otherwise specified, existing GAVI and UNICEF practices should be applied to the implementation of the AMC. This includes, for example, rules regarding country co-payment and GAVI contributions for countries in different "capacity to pay" categories; choice of vaccine presentation; allocation of supply among countries in the event of shortage; and other practices. Upon request, the AMC Secretariat should provide information to firms about these practices, as they have considerable bearing on the range of potential financial implications of the AMC.

Several questions arose during the IWG discussions regarding the rules and roles of the GAVI Alliance and UNICEF. These are addressed below, as input into subsequent legal drafting and communications with countries, donors and industry.

8.4 APPLICATIONS FROM COUNTRIES

From a country perspective, the AMC will be largely similar to existing GAVI vaccine support for countries, with the key difference being that a long-term tail price cap is known up front (currently countries are given the current price and best estimates on long-term price). All GAVI countries apply for the length of their multi-year plan (usually 3 to 5 years). The GAVI countries are required to fill out a comprehensive application that considers not only the financial obligations arising from the co-payment, but also including detailed introduction plans to include implications on the immunization system such as additional training, logistics, cold chain, etc. Countries will be given the option of applying

for any of the AMC-eligible vaccines based on the serotype coverage and tail price designated by the company. Because a known tail price cap is a new feature of the AMC and could differ across companies, GAVI should consider setting policy that stipulates how differences in tail prices would influence the country co-payment. The EEG report provided some guidance in this regard.

8.5 REVIEW BY IRC

GAVI works with a series of independent review committees made up of public health experts that examine applications for the different windows of GAVI support. This includes a review of the new applications as well as regular annual monitoring of existing countries already receiving support. The independent review of the application ensures they pass certain standards technically.

8.6 APPROVAL BY BOARD

Following the recommendation by the IRC of a given set of country applications, these are then approved by the Board as a bulk set of applications contingent on the availability of funding. The GAVI Board typically approves an 18-month financial allocation, aggregated from individual country applications. Therefore, while GAVI will be obliged to cover the GAVI/country co-pay during the AMC period of each supply agreement, a formal financial commitment from GAVI in respect of the GAVI and country co-payment portions per dose occurs only if and when applications from countries have been submitted and approved for funding by the GAVI Board.[14] This then occurs in a staggered fashion over time depending on the speed of uptake. Nonetheless, for strategic planning purposes, the GAVI Board has approved indicative expenses for GAVI and the Board is aware of and comfortable with the tail price and likely annual cost to GAVI based on the strategic demand forecast.

[14] In addition to the GAVI Board, IFFIm and GAVI Fund Affiliate Boards may need to approve funding if the source of support comes from IFFIm monies.

8.7 CO-FINANCING OF VACCINES

The GAVI co-financing policy is based upon groupings of GAVI countries and the details can be found on the GAVI website (www.gavialliance.org). GAVI has just begun to implement its co-financing policy. While GAVI's policy is specified in terms of a financial contribution per dose, in practice it was decided to implement in a slightly different manner. Instead, countries were asked to fully contribute to a portion of the doses. As an example, for the current pentavalent vaccine, the market cost to GAVI is $3.60 and the co-payment for certain countries is $0.20.[15] This means that the co-payment represents 5.5 percent. For a country with 1 million children to be immunized annually, GAVI would fully fund 945,000 children, and the country would pay for the remaining 55,000 children.

8.8 DEFAULT POLICY

The GAVI default policy was reviewed and approved by the GAVI Board at its June meeting. The default policy considers that a country is in default if they have not paid their co-financing amount for the given calendar year by the 31st of December of that year. GAVI and its partners will work with the specific country to find solutions to ensure they can find the missing funds to fulfill their co-financing commitment. While in the first year of default, a country may apply for any new vaccines or other GAVI programs; approval for this support will only be made once a country is out of default. During this period, GAVI and its partners at regional and country levels will work with the country to help the country to fulfill its co-financing commitment, and all existing GAVI support will continue without change[16]. Following two years of default, in addition to the

[15] According to GAVI co-financing policy, countries are asked to contribute between $0.10 and $0.30 depending on their ability to pay. Countries are divided into 4 categories: poor, least poor, intermediate and fragile.

[16] Where there has been a country default and intermediate steps are being taken in accordance with GAVI financial policy there is no financial commitment from GAVI or any of its partners to bear the shortfall of country co-payment.

actions above, the following actions are to be undertaken by the GAVI Board for these countries:

- The GAVI share of the new vaccine funding will be suspended until the country has paid the full co-financing amount.
- If the country remains in default for more than two years after determination, the Board may consider suspending other types of GAVI assistance, such as ISS or HSS funding.
- In rare instances, when natural economic, civil or political catastrophes interfere with a country's ability to meet its co-financing agreements, the Board may consider granting a grace period.

8.9 ALLOCATION OF VACCINE IN LIMITED SUPPLY

GAVI has managed allocation of vaccine in limited supply with pentavalent vaccine, during the early years when supply did not keep up with demand. Through a transparent process with GAVI partners, in particular WHO and UNICEF, a range of factors were considered when deciding how to allocate limited supply, including the country birth cohort, disease burden, strength of the immunization programme as measured through DTP3 coverage and other product preferences. Unlike the pentavalent example, pneumococcal vaccines will not be interchangeable since different serotypes will lead to different coverage rates in different regions, so allocations will be done on a country-by-country basis under guidance from GAVI partners.

9. APPENDICES

APPENDIX A: TERMS OF REFERENCE

BACKGROUND

On March 10, 2008, the AMC Donor Committee discussed the Economic Expert Group's Report and agreed with its conclusion that modifications to the AMC structure could enhance the prospects of achieving AMC's objectives. Donors agreed to commission further work to recommend specific terms and parameters for an enhanced structure that would include industry supply commitments, frontloaded pricing, sequential tendering, and a tail price cap. Donors also

expressed their wish to have further information on the potential for spot market purchasing before dedicated capacity becomes available.

OBJECTIVE

Donors have decided to create an Implementation Working Group (IWG) with the task of recommending a specific proposal for the AMC structure and parameters, inclusive of the implementation features noted above. Donors expect the proposals to be detailed and operational so as to allow donors to finalize the detailed terms and features of the binding offer to be presented to industry in the legal documentation.

RESPONSIBILITIES/FUNCTIONS

The Group will recommend specific AMC terms that incorporate the features described below.

- Industry supply commitments Specific recommendations for the relationship between a supply commitment and AMC funds. In particular, terms would include: i) minimum bid requirement for each firm/commitment, possibly complemented with a scale-up clause; ii) the starting date of the commitments; iii) their length, specifying whether it will be common to all bids (and if not the parameters determining it); iv) optimal amount of total supply commitments in doses. Recommendations for procedures in the event that supply commitments do not satisfy sufficient demand. Recommendations of specific provisions to avoid a situation in which AMC funds continue to be legally tied to a supply commitment for which there is no corresponding demand.

- Sequential tendering Donors decided that sequential tendering could only be implemented for two bids, each with the same terms (this preferred option could be supplemented, if deemed advisable by the IWG, by an option for a strict rule-based second tender, with full details provided on the rule). Specific recommended terms should include: i) timing and size of the two bid rounds (including the possibility of specific triggers for the rounds); ii) possible limits on the

timing of the bids in any of the two rounds; iii) provisions for the use of any unassigned funds in the first round of bids.

Given the above-mentioned limits posed by donors on the design of sequential tendering, donors wish to have an assessment of the effectiveness of sequential tendering (with optimally-chosen parameters, using DALYs as the relevant metric) with respect to an AMC design without this feature (the comparison made with the same metric).

- Frontloaded pricing Recommendation on the specific parameters of frontloaded pricing as a measure to mitigate demand risk.

- Tail price cap Recommendation of an exhaustive set of parameters to define an inflation-adjusted optimal tail price cap, with optimality being defined as a level that is set in a completely transparent way, and that balances the AMC goals of long-term affordability to low-income countries and scale-up of adequate production capacity. The donors have termed the anticipated tail price as "low and hard." Donors are willing to consider different options if sequential tendering is not feasible and the IWG deems them appropriate. Recommendations for increases in tail prices under conditions where underlying costs increase in unforeseen ways.

- Spot market Explore the desirability and, if desirable, specify the features, and terms of an AMC spot market for purchasing doses from any pre-existing excess manufacturing capacity, including the specific details of the link between such purchases and the supply commitments under the AMC enhanced design.

- Expected outflows For donors to fully assess the financial implications of the enhanced design, the expected time profile for the AMC outflows should be compared with the expected time profile of the donor contributions.

As time permits and in addition to the required parameters listed above, the IWG may provide guidance to the donors on additional issues that will need to

be set prior to the completion of the offer, including: procedures for soliciting supply commitments and selecting among them; criteria for firm eligibility to bid on supply commitments; procedures for excluding countries from benefiting from a cap on the tail price as their national income increases; rules regarding treatment of India; penalties for breach and force majeure conditions; and rules regarding assistance with vaccine introduction for early adopters by donors and/or firms.

In order to fulfill these responsibilities, the IWG will:

1. Carry out any additional analytic work that may be needed to refine the AMC structure and recommend its final parameters.
2. Carry out focused consultations with industry to obtain information relevant to the above-mentioned design features. Such consultations will only take place after the public announcement of donors' decisions regarding the AMC design and be open to all firms. Any further specific aspect of industry consultations is to be decided by the Donor Committee.

Work will be undertaken primarily via e-mail and conference calls. It is not anticipated that an in-person meeting will be required.

COMPOSITION OF THE IWG

The IWG will consist of at most four experts from the Economic Expert Group as well as representatives of the World Bank, GAVI and UNICEF, at most two for each institution. The IWG will solicit advice and inputs from other members of the EEG as it deems necessary. Donors will participate in the IWG's meetings as observers (on a voluntary basis and in ways to be arranged by the IWG chair), but will not participate in the consultations with industry.

REPORT AND TIMELINE

The findings of the IWG are to be presented in a Report, which should include operational recommendations and form the basis for donors' final decisions on AMC design and implementation and whose final version will be made public. It is understood that all the recommendations put forward in the Report will be

operational and as specific as possible so as to allow swift incorporation into the legal documents.

The Report will be completed and sent to donors by 11 May, 2008 (timeline may shift depending on donor needs; work must be completed by end of May).

The Chair and members of the IWG will update donors on the progress of the work via conference calls as deemed appropriate by either the IWG or the donors. Substantive questions or points of clarification on which the IWG would like to consult with the Donor Committee as a whole should be channelled through the Chair of the Donor Committee.

APPENDIX B: IWG MEMBERSHIP

The membership of the Implementation Working Group is presented below (alphabetical order)

Tania Cernuschi, GAVI

David Fleming, IWG co-chair, King County Department of Public Health‡

Steve Hurst, Immune Tolerance Institute‡

Andrew Jones, GAVI

Jon Levin, Stanford University‡

Ruth Levine, IWG co-chair, Center for Global Development‡

Susan McAdams, World Bank

Ann Ottosen, UNICEF

Meredith Shirey, UNICEF

Thomas Sorensen, UNICEF

Jan von der Goltz, World Bank

‡ participating in individual capacity; institutional affiliation for identification purposes only

APPENDIX C: DEFINITIONS

AMC price: the total price per dose received by a manufacturer during the AMC period.

AMC contribution: the amount of the AMC price paid by the AMC fund ($1.5 billion).

Co-payment: the amount of the AMC price paid jointly by GAVI and the country.

- *AMC contribution + Co-payment = AMC price.*

Country co-payment contribution: the amount of the Co-payment paid by an individual country; this is expected to vary by country ability to pay in accordance with GAVI financing policies.

GAVI co-payment contribution: the amount of the Co-payment paid by GAVI; this is expected to vary by country ability to pay in accordance with GAVI financing policy.

- *Country co-payment contribution + GAVI Co-payment contribution = Co-payment*

Tail price: the total price per dose received by a manufacturer after the AMC period**.**

Country tail price contribution: the amount of the tail price paid by an individual country. The country tail price contribution is an extension of the country co-payment contribution, and as such is expected to vary by country ability to pay, and increase over time, in accordance with GAVI financing policy.

GAVI tail price contribution: the amount of the Tail Price paid by GAVI; this is expected to vary by country ability to pay and decrease over time in accordance with GAVI financing policy.

Country tail price contribution + GAVI tail price contribution = Tail price

APPENDIX D: NPV VALUES FOR DIFFERENT SCENARIOS

NPVs for 100 Million Dose Annual Capacity Plant; $7.00 AMC Price, with a $3.50 AMC subsidy and a $3.50 tail price; 10 Year Supply Commitment (in millions)
The 100 million dose commitment gives the firm nominal AMC Funds of $750 Million, based on a 200 million dose target by 2030

Cost Estimates			Demand Realization				
Capital Costs (Mil.))	Annual Fixed Costs (Mil.)	Variable Costs Per Dose	100%	75%	50%	25%	15%
NPV of Firm Profits							
$110	$35	$0.65	$1,396	$1,352	$1,157	$595	$307
$110	$35	$1.00	$1,231	$1,193	$1,019	$520	$262
$110	$35	$1.75	$880	$851	$723	$360	$166
$200	$35	$1.75	$808	$779	$651	$288	$94
$200	$50	$2.50	$381	$362	$280	$53	($77)
$300	$50	$2.50	$301	$282	$200	($27)	($157)
$300	$50	$2.75	$184	$168	$102	($80)	($189)
$400	$50	$2.75	$104	$88	$22	($160)	($269)
$400	$50	$3.50	($248)	($254)	($274)	($320)	($365)
$400	$50	$4.00	($483)	($482)	($472)	($427)	($429)
NPV of Spending							
Total Spending			$2,476	$2,409	$2,091	$1,311	$945
GAVI Spending			$1,787	$1,730	$1,448	$758	$455
Country Co-Payment			$145	$140	$117	$61	$37
Net DALYs Averted							
Using 10-Valent Vaccine			44	37	25	11	5
Using 13-Valent Vaccine			49	41	28	13	6
Dollar Cost per Net DALY							
Using 10-Valent Vaccine			$56	$66	$83	$119	$188
Using 13-Valent Vaccine			$50	$59	$73	$103	$156
Dollar Cost per DALY							
Using 10-Valent Vaccine			$36	$40	$45	$54	$65
Using 13-Valent Vaccine			$33	$37	$42	$51	$61

Notes:

- The analysis above assumes that competition does not come into effect, as intended within the AMC, and that companies participate at the maximum possible tail price of $3.50.
- The table has been developed in the context of significant uncertainty about the capital, fixed and variable costs for manufacturers. However, the extensive consultations and analysis undertaken indicate that manufacturers' costs for pneumococcal vaccines will be toward the higher end cost estimates of the broad range of scenarios presented in the table. The lowest cost scenarios, corresponding to the largest NPVs of profits, are considered highly unlikely to be realistic".
- These NPVs represent optimistic figures for industry. Companies' internal risk considerations used to inform decisions about whether to invest in a new plant to serve the GAVI market could discount these significantly.
- Each cell of the NPV of firm profits panel shows the profits, in 2008 dollars, associated with the business proposition that, in the year 2009, a firm with a particular vaccine technology (either 10-valent or 13-valent) enters into a supply commitment to supply 100 million doses per

year for 10 years, for a different set of cost assumptions, demand realization, and tail price.

- The calculation assumes that it takes 5 years for the new capacity to come on line. Capital costs are expensed over those five years. When the new capacity comes on line, the firm incurs an annual fixed cost as well as a variable cost per dose, as specified in the first three columns. The calculation also assumes that the firm incurs a handful of other customary costs, which are described in the companion Appendix, and that it experiences a plant outage in the year 2021. In return, the firm earns $750 million, which is one half of the $1.5 billion AMC fund, that is paid on a per dose basis for each delivered dose until it has drawn down on the $750. The amount of the AMC fund that the firm earns is determined in proportion to the amount of the 200 million target doses to which it commits. In addition, the firm earns a "tail price" that includes GAVI payments and country co-payments.
- Cost assumptions reflect information from Oliver Wyman as well as sensitivity around their information. Oliver Wyman reported cost of capital and cost of goods sold. Earlier modeling work by the EEG decomposed Oliver Wyman's cost of goods sold into an annual fixed cost and a variable cost per dose.
- The forecasted demand estimates used in the model come from PneumoADIP's v2.0 Strategic Demand Forecast for Pneumococcal Vaccines in GAVI-eligible countries. The 100% forecasted demand panel assumes that the PneumoAdip forecast is fully realized. The 75, 50, and 25% demand panels assumes that less demand (e.g. 75% of demand) is realized.
  NPVs are in millions of dollars and net DALYs averted are in millions.
- Cost of saving one DALY using some other intervention is assumed to be $100.
- Additional discussion of the underlying calculations provided in the accompanying Appendix.

APPENDIX E: DESCRIPTION OF SPREADSHEET MODEL: INPUTS, ASSUMPTIONS AND OUTPUT

The spreadsheet model is a tool to assess the impact of different program rules on firms, public health, donors, GAVI and the participating countries. The associated calculations, presented in the companion tables, evaluate the business proposition and public health value associated with a firm commitment to build dedicated capacity to supply 100 million doses for 10 years from the inception of this supply. The impact on firms is measured by the net present value (NPV) of profits; the impact on public health is measured by net disability-adjusted life years gained (net DALYs), which represent the public health benefits of the pneumococcal vaccine less the DALYs that could be gained with alternative uses of AMC, GAVI and country funds; and affordability to donors is measured with total spending, including draw-down of AMC funds, GAVI expenditures, and country co-payments.

The model can be described in four components: the basic setup, the user-defined inputs; the assumptions; and the outputs. These are described in turn. The description also includes the value of the different inputs, for the purposes of the illustrative calculations contained in the associated tables.

A. Basic Setup

A firm with a particular vaccine technology (either 10-valent or 13-valent) enters into a supply commitment to supply a certain number of doses for each year, for a certain number of years. (As explained below, the magnitude and length of the supply commitment are user-defined inputs into the model.) The firm incurs certain costs to manufacture and supply the committed doses of vaccine. These costs include the cost of capital, annual fixed costs of production, variable costs per dose, and a handful of other customary costs. In return, the firm earns a portion of the $1.5 billion AMC fund that is paid on a per dose basis for each delivered dose until it has drawn down on its portion of the AMC fund. The amount of the AMC fund that the firm earns is determined in proportion to the amount of the 200 million annual target doses to which it commits. In addition, the firm earns a "tail price" that includes GAVI payments and country co-payments.

As an example, suppose that beginning in 2009, a firm commits to supplying 100 million doses per year, for a period of 10 years. In this scenario, the firm earns

$750 million (or one half) of the AMC fund. With a $3.50 AMC subsidy and a $3.50 tail price cap, the firm earns $7 per dose for the first 214 million doses supplied and up to $3.50 thereafter, to the end of the supply commitment, which would end in 2024 (assuming that it takes 5 years to install the dedicated capacity so that the firm begins to sell from this capacity in 2014). For the purposes of the NPV calculation, the model assumes that the firm earns the full amount of the tail price cap and that it continues to sell at this cap out to 2030,[17] beyond the term of the supply commitment.

The spreadsheet is designed to handle three separate firms: "Global 1," with a 10-valent technology, "Global 2," with a 13-valent technology; and an "Emerging" firm with a 10-valent technology.

B. Primary User-Defined Inputs

The primary user-defined inputs used for the calculations are as follows:

(1) Key program rules

- Amount of the supply commitment: This is also referenced in the model as dedicated plant capacity. A firm that commits to supply X% of the total 200 million dose vaccine demand for each of ten years, will earn X% of the $1.5 billion AMC subsidy funds from donors.
- Duration of the supply commitment: The number of years for which the firm agrees to supply the annual committed amount, where the commitment period begins when the new capacity comes on line. This input is set at 10 years.
- Tail price cap: This is the maximum price that the firms can receive after the AMC subsidy funds are depleted.
- AMC subsidy: This is the per dose amount through which AMC funds are distributed to participating firms. This input is set at $3.50.

[17] The actual end of the supply agreement could be as late as 2034.

(2) Information about the pre-build-out period, i.e. the period prior to new capacity coming on-line

- For each firm (Global 1, Global 2, and Emerging), the year in which the pre-build-out period ends. The illustrative calculation values the proposition that a single firm, either Global 1 or Global 2, gives a 100 million-dose annual supply commitment.
- Active in the Pre-Build-Out Period: This is an indicator variable (Yes or No) for whether the firms use existing capacity during the pre build-out period. This indicator is set to "No."
- Pre-Build-Out Price: This is the price the firms would receive if they sell before the dedicated capacity comes on line.

(3) Cost and other operational inputs

- Firm Costs: These are the cost numbers that enter into the baseline calculations. The numbers used for the baseline model come from earlier work done by the EEG, which transformed the Oliver Wyman cost estimates into variable costs, semi-variable costs and capital costs.
- OW Adjustment: These are the adjustments to the baseline costs, expressed as a percentage of the Oliver Wyman cost estimates.
- Discount Rate: This is the discount rate that is used for the NPV calculations for the firms. This rate is set to 10 percent which is consistent with rates used in industry.
- Unplanned Outages: This is an indicator variable (Yes or No) for whether the firm experiences "unplanned outages" resulting in shutdown of operations for one year while still incurring fixed costs. This input is set as Yes and the outage occurs in the year 2021.

(4) Wastage: This is the percentage of the total supply that is wasted. This input is set at 10 percent based on input from WHO and UNICEF Supply Division

- Demand Realization: This is a sensitivity parameter that determines how much of the PneumoADIP forecast actually realizes. It is expressed as a percentage, e.g. an entry of "75" results in a 75 percent realization of the PneumoADIP demand forecast in each year.

C. Assumptions

Other assumptions implicit in the calculation:

- Annual Cost Growth: This input determines the rate of cost inflation and is set at 1.5 percent.
- Administrative Costs: This is a fixed cost paid every year goods are sold and is set at $5 million per year.
- AMC Development Costs: This is a fixed cost paid per year during the first five years upon entering a supply agreement, before the new capacity comes on line. This is set at $5 million per year, for each of those years.
- DALYs Gained per Full and Half Treatment. These inputs determine the number of DALYs gained per dose adjusted for half or full treatment.
- GAVI Discount Rate: This is used for NPV calculations for GAVI spending and is set at a rate of 5 percent.
- Inflation Indexing: This is the inflation rate used to adjust the tail price (not the AMC subsidy) in the model and is set at 1.5 percent.
- Plant Outage Year: This is the first year when there is plant outage and is defined to occur 8 years after the new capacity comes on line.
- Opportunity Cost of Spending: This is the cost of saving 1 DALY using some other intervention. This opportunity cost of spending is set at $100.
- AMC Size: This is the total AMC funding available for subsidies, and is set at $1.5 billion.
- Co-payment: These are the percentage of GAVI and country payments as shares of the total co-payment. The total co-payment is linked to the tail price input. For the illustrative calculations in the associated tables, a 92.5%-7.5% split is used between GAVI and country co-payments, respectively.
- Five-Year Capital Build-up Schedule: These are annual the shares of the total capital cost incurred spread out over a five year period.

- Capital Cost Formula: These numbers are based on earlier EEG cost analysis which transforms the Oliver Wyman point estimates into a continuous cost function.
- The forecasted demand estimates used in the model come from PneumoADIP's v2.0 Strategic Demand Forecast for Pneumococcal Vaccines in GAVI countries.

D. Outputs

- NPV of profits calculations:

  The NPV is calculated as the difference between the NPV of operating profits (gross revenue minus variable costs minus fixed costs) and the NPV of total capital costs. Both prices and costs are adjusted for inflation using their respective inflation factors. Profits and costs are brought forward to present dollars using the firm discount rate. For a given set of program rules, NPV of profits are calculated from 2009 to 2030 in 2008 dollars.

- PV of spending calculations:

  The PV of AMC spending is calculated as the discounted sum of the AMC funds paid out to the participating firms through the AMC subsidy.

  The NPV of GAVI spending is calculated as the inflation-adjusted discounted sum of the GAVI co-payments paid out to the participating firms during the AMC period as well as during the tail period.

  The PV of country spending is calculated as the inflation adjusted discounted sum of the country co-payments paid out to the participating firms during the AMC period as well as during the tail period.

- DALYs calculations:

  The discounted DALYs gained are calculated as the discounted sum of DALYs gained in each year due to the vaccines supplied by the participating firms, starting from the first year of operation and running till the end of the simulation period. These calculations take into account the type of the vaccine (measured by the number

of DALYs gained per dose from the assumptions tab), the fact that it takes three doses to complete one treatment and whether half or full treatments were used.

The Opportunity Cost Adjusted DALYs look at the discounted sum net of the opportunity costs of the above spending. (It is assumed that $100 spent in alternative intervention would save 1 DALY; the spreadsheet also reports an alternative DALY cost number which assumes that $200 has to be spent in an alternative intervention to save 1 DALY).