

FOR DECISION

This document provides the GAVI Alliance Executive Committee with an update on progress to launch the pilot Advance Market Commitment (AMC) for Pneumococcal vaccines, and requests key decisions that will allow the pilot to move forward.

In specific, the Executive Committee is requested to:

- Authorise the CEO on behalf of the GAVI Alliance to enter into the relevant AMC transaction documents upon the advice of legal counsel;
- Approve a programme expenditure of US\$ 6,000,000 to UNICEF for procurement services per the UNICEF AMC Procurement MOU.

Pneumococcal Advance Market Commitment (AMC) Offer Agreement

Background

The goal of the pilot Advance Market Commitment (AMC) for Pneumococcal vaccines is to reduce morbidity and mortality from Pneumococcal diseases and to prevent about 7.7 million childhood deaths by 2030. The specific objectives are:

- to accelerate the development and bring forward the availability of Pneumococcal vaccines that meet developing country needs;
- to accelerate vaccine uptake through predictable vaccine pricing;
- to pilot test the effectiveness of the AMC mechanism.

The AMC seeks to prevent 900,000 childhood deaths by 2015 as part of the overall goal. The Italy, the United Kingdom, Canada, Norway, and Russia, and the Bill & Melinda Gates Foundation have together committed US\$ 1.5 billion to the AMC. These funds will be used to subsidise the future purchase at a pre-agreed price (\$7 per dose) of new Pneumococcal vaccine, if developed in pre-agreed quantities and if demanded by GAVI countries. Companies participating in the AMC will be obliged to supply the vaccines at a low long term price (equal or below \$3.50 per dose), after the donor funds available for the AMC subsidy are expended.

In June 2008, the GAVI Alliance Board endorsed a budget of up to US\$ 1.31 billion for the Pneumococcal AMC during the period 2010-2015. Disbursement from this envelope is subject to explicit Board decision, the terms of the AMC transaction documents, and normal GAVI funding processes. GAVI's financial support will be needed for:

- purchasing vaccines, up to a cap of \$ 3.50 per dose (this may be subject to revision for inflation over the course of the AMC life)
- covering fulfillment costs (shipment, safety boxes, insurance, syringes) – amounting to \$ 0.19 per dose.

Further, the Alliance Board endorsed in principle the inclusion of a guaranteed minimum vaccine purchase with a potential total value of US\$ 130,000,000 in aggregate when individual supply agreements are signed.

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In October 2008, the Board delegated to the Executive Committee the authority to approve the AMC transaction documents for signature when those documents are final.

Finally, during its meeting on 23 March 2009, the Audit and Finance Committee recommended that GAVI enter into the AMC transaction documents upon the advice of legal counsel, and approve a budget of US\$ 6,000,000 to UNICEF for procurement services.

Progress to Date

Since June 2008, the Secretariat and the World Bank have worked closely to establish the AMC. In particular:

- The implementation working group (the Secretariat, the World Bank, UNICEF, and independent economic experts) appointed by the AMC Donors to finalise the terms recommended implementation terms and conditions of the Pneumo AMC in July 2008.
- The AMC transaction documents were reviewed and refined with input from UNICEF, the World Bank, AMC Donors, and GAVI.

Summary of AMC Transaction Steps/Processes

GAVI, the World Bank, the AMC Donors, UNICEF and manufacturers will manage the AMC in accordance with a suite of agreements (or transaction documents). The following is a listing of some of the key transaction documents that have been reviewed by GAVI legal counsel (each of which is available to committee members upon request):

- Each AMC Donor enters into a **Grant Agreement** with the World Bank, pledging to provide up to \$1.5 billion toward the purchase of Pneumo-vaccines eligible for the AMC. This gives GAVI a pledge base, in addition to its traditional donor base, from which to meet country programme commitments for Pneumo-vaccines.
- The World Bank and GAVI enter into an **Offer Agreement** which presents the AMC to vaccine manufacturers, including the following elements:
 - The World Bank offers to pay up to \$1.5 billion to GAVI for Pneumo-vaccines that meet the AMC specifications
 - If the GAVI Board approves the necessary budget to pay the firm order timing commitments (volume guarantee), GAVI requests UNICEF to enter into a 10 year AMC vaccine purchase/supply agreement with any AMC qualified-manufacturer (see below). As countries apply for Pneumo, the GAVI Alliance Board will make budget approvals to purchase quantities under each Supply Agreement based on country demand for the applicable manufacturer's vaccine.¹ The GAVI contribution will be up to \$3.50 per dose (plus fulfillment costs of approximately \$0.19 per dose)
 - During the AMC period, the total paid per dose is \$7. After the AMC Donor money is exhausted, the manufacturer will receive up to \$3.50 per dose for the remainder of the 10

¹ Upon recommendation of the Independent Review Committee, the Board (or Executive Committee) will consider and, if thought fit, approve financial commitments to support Pneumo vaccines out of the budget window the same way it approves NVS programmes. Similarly, country application requirements will be consistent with other GAVI vaccine programmes and vaccine co-payment requirements will be in line with GAVI co-financing and default policies.

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year period. This amount may be adjusted for inflation as per predefined terms and conditions.

- If a manufacturer wishes to engage with the AMC, it enters into an **AMC Registered Manufacturer's Agreement** with GAVI and the World Bank. This agreement confirms that the manufacturer understands all the terms and conditions for participating in the AMC. The manufacturer is then able to submit a candidate Pneumo-vaccine to the AMC Independent Assessment Committee (IAC).
- The IAC reviews the candidate vaccine from each AMC Registered Manufacturer for eligibility against the AMC specifications. If: (a) the vaccine is approved by the IAC: (b) the manufacturer has met all other terms and conditions, (c) the GAVI Board has approved the necessary budget to pay the firm order timing commitments (volume guarantee), then the manufacturer enters into a 10 year **Supply Agreement** with UNICEF to provide AMC Pneumo-vaccines for GAVI countries.
- GAVI and UNICEF coordinate under an **AMC Procurement MOU**, which describes how procurement will be managed in connection with Supply Agreements. UNICEF has offered to provide procurement services under the MOU for \$6 million payable over the period 2009-2012. GAVI will receive a credit of \$ 3.2 million for procurement of AMC pneumo vaccines based on slower than expected uptake of pneumo and rotavirus vaccines under a prior GAVI/UNICEF MOU. As such the total projected cost of AMC procurement services is around \$ 9.2 million against which, the \$3.2 million dollar will be applied. GAVI receives a volume discount from UNICEF. Overall, GAVI procurement activities cost approximately 1.8% across UNICEF procurement activities. By way of comparison GAVI pays 3% to PAHO for similar services. From a financial perspective, the fee offered by UNICEF is in line with past procurement fees and is reasonable under the circumstances surrounding the AMC.
- GAVI and the World Bank coordinate fund flows from AMC Donor payments and GAVI's payments under a **Disbursement Agreement**. This provides processes to help ensure commitments to pay for Pneumo-vaccines under Supply Agreements are met.

A more detailed summary of all transaction documents is provided in Annex I.

Financial and Accounting Impact of the AMC

The following table provides the 2009-2015 financial implications of introduction of Pneumococcal vaccines, including the impact of the AMC:

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| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2009-15 | 2009-30 |
|---|------------|--------------|--------------|--------------|--------------|--------------|--------------|----------------|--------------|
| 1. Estimated demand <i>in million doses</i> | 5 | 12 | 22 | 56 | 88 | 104 | 114 | 401 | 3'329 |
| 2. Projected expenditure <i>in million US\$</i> | - | 86 | 160 | 403 | 544 | 536 | 576 | 2'306 | 13'782 |
| 3.1 To be funded by donors* <i>Projected donors' payments</i> | - | 42 | 78 | 196 | 211 | 175 | 126 | 828 | 1'500 |
| <i>FIXED PAYMENTS</i> | | | | | | | | | |
| <i>Gates Foundation</i> | 20 | 5 | 5 | 5 | 5 | 5 | 5 | 50 | 50 |
| <i>Italy</i> | 104 | 53 | 53 | 53 | 53 | 53 | 53 | 422 | 635 |
| <i>Russia</i> | - | 8 | 8 | 8 | 8 | 8 | 8 | 48 | 80 |
| <i>SUBTOTAL</i> | 124 | 66 | 66 | 66 | 66 | 66 | 66 | 520 | 765 |
| <i>DEMAND-RELATED</i> | | | | | | | | | |
| <i>Norway</i> | - | - | - | - | 10 | 7 | 4 | 21 | 50 |
| <i>United Kingdom</i> | - | - | - | - | 92 | 72 | 39 | 203 | 485 |
| <i>Canada</i> | - | - | - | - | 38 | 30 | 16 | 84 | 200 |
| <i>SUBTOTAL</i> | - | - | - | - | 139 | 109 | 60 | 308 | 735 |
| TOTAL | 124 | 66 | 66 | 66 | 205 | 175 | 126 | 828 | 1'500 |
| *: there is a difference between projected donors' expenditure and donors' payments due to timing issues between GAVI and the World Bank. | | | | | | | | | |
| 3.2 To be funded by countries | - | 2 | 3 | 8 | 13 | 16 | 17 | 59 | |
| 3.3 To be funded by GAVI | - | 42 | 79 | 199 | 320 | 346 | 433 | 1'419 | |
| 4. Accounting impact* <i>in million US\$</i> | | | | | | | | | |
| Expense | (281) | (409) | (530) | (525) | (561) | (589) | (715) | (3'609) | |
| Revenue | 689 | 9 | 9 | 9 | 148 | 118 | 68 | 1'049 | |
| Net Assets flow | 408 | (400) | (521) | (516) | (413) | (472) | (648) | (2'560) | |

*: following GAVI accounting policies (US-GAAP):

- liabilities for programme expenditure of future years are recorded up-front (e.g. balance as of 31 Dec 2015: 100% of 2016- & 2017-expenditure and 10% of 2018-expenditure);
- multi-year fixed contributions recorded up-front as 'promises to give' and discounted to net present value (e.g. Russia: Total contribution of US\$ 80m until 2019 is recorded in 2009 discounted to US\$ 72m).

It is forecasted that this commitment by the GAVI Alliance, countries, and AMC Donors should allow for the production and distribution of over 401 million doses of Pneumococcal vaccine. The Secretariat has developed a number of demand forecast scenarios which can help gauge the quantity of doses actually demanded by countries as the programme progresses.

Risks

There are number of risks to the GAVI balance sheet that arise from this transaction. The following is a listing of the principal risks identified:

Budget (or funding gap) risk

As noted before, GAVI possesses a challenge of addressing an emerging overall cash funding gap of approximately \$4 billion (if donor contributions remain at current levels) between 2009-2015. This challenge includes GAVI's goal of implementing the Pneumo AMC.

Looking at the AMC specifically, in net asset terms AMC expenses from 2009-2015 (\$3.61 billion) exceed revenue (\$1.05 billion) by \$2.56 billion. From 2012 onwards (when the net cash impact turns negative) additional resources will be needed through increased donor contributions (to either GAVI

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or to the AMC specifically) or via a reduction in other GAVI programme spending. However, it should be emphasised that no document being considered for the CEO's signature will encumber GAVI to pay anything at this stage.

Pressure to purchase risk

In some cases, vaccine supply may be higher in certain years than GAVI or the World Bank has as a need. This creates the possibility that GAVI could be under public pressure to buy larger volumes. However, none of the agreements contain a requirement to pay for vaccines except as countries apply for them and the Board approves specific financial commitments. Protections in this regard are made under the Offer Agreement, Stakeholder Agreement and the Disbursement MOU.

However, it is important for the programme that financial forecasts from the World Bank on timing of donor funds availability as well as availability of funds for Pneumo purchase at GAVI be accounted for by the UNICEF Supply Division and the Procurement Reference Group during the assessment of supply offers.

Grant payment (or donor default) risk

As with IFFIm, the AMC mechanism requires a reasonable assurance donors will meet their obligations in order to make it work. Therefore, donor default is a potential risk to the legitimacy of the programme. However, as with IFFIm, the donor agreements encumber the donors to meet their pledges. Therefore, it could be interpreted that donor default risk is similar to that of IFFIm excepting the credit profile of the donor pool.

Inflation risk

The average annual inflation rate applied in the cost model during the tail price period (from 2013 on) is 1.5%. However, long term volatility of inflation could have a significant impact. As the programme moves forward, GAVI will review this assumption regularly in order to flag material adjustments to the model.

AMC Accounting Policy interpretation risk

As with any accounting policy, there is the possibility that the independent auditor will view the policy's tenets differently than what was intended. In particular, the Secretariat wanted to ensure the proper interpretation of the recording of donor pledges.

However, the audit risk associated with the recording of the donor pledges is minimal as confirmations from the World Bank will be received with necessary ancillary information. Meanwhile, obtaining and maintaining accurate demand forecasts and the related financial forecasts presents GAVI with a larger risk as the transaction will be material to the financial statements.

Secretariat Capacity risk

The AMC will be resource intensive in the following areas:

- financial management
- monitoring and reporting
- servicing of the Independent Assessment Committee.

As such, another risk involved in the AMC has to do with Secretariat capacity. Early on, the Secretariat determined that existing staff capacity would be insufficient to manage the AMC. As a result, GAVI created several new positions: an AMC Manager for overall management of the design

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and implementation phase of the Pneumococcal AMC and a position for administration and programme support. Both positions are under the oversight of the Director of Policy. In addition, the finance functions pertaining to the AMC are implemented and monitored by an AMC Financial Officer who will report to the Chief Accounting Officer. Further, existing staff support within the legal and external relations teams was allocated to work on AMCs. Their roles are limited and require no increase in headcount at this time.

“Better deal” risk

At all times during the offer period, GAVI and the World Bank will agree not to procure Pneumococcal vaccine for GAVI Eligible Countries under alternative agreements which would have more favourable terms for vaccine suppliers than those set out in the AMC transaction documents. Therefore, should industry decide not to participate in the AMC, GAVI would be unable to procure Pneumococcal vaccines for its eligible countries. However, it is anticipated public opinion would be focused on vaccine manufacturers’ unwillingness to participate rather than on GAVI’s unwillingness to buy outside the AMC.

This risk is particularly high during the first year (2009) when only one supplier of AMC-eligible Pneumo vaccine will be available. However, an escape procedure exists: if both GAVI and the World Bank (acting together) determine there has been an irremediable dilution in the extent to which the AMC objectives are being met (for instance because of a lack of industry participation), they can decide to cancel the AMC and all obligations shall cease.

Request to the GAVI Alliance Executive Committee

The Executive Committee is requested to:

- Authorise the CEO on behalf of the GAVI Alliance to enter into the relevant AMC transaction documents upon the advice of legal counsel.
- Approve a programme expenditure of US\$ 6,000,000 to UNICEF for procurement services per the UNICEF AMC Procurement MOU.

Next Steps

Should the Committee approve the above requests, the CEO on behalf of the GAVI Alliance will enter into the relevant AMC transaction documents upon the advice of legal counsel. Once all other partners in the agreement will do the same, the AMC will enter its implementation phase. AMC Pneumo vaccines could be procured to countries as early as Q1 2010.

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1. Stakeholders Agreement: This is a framework agreement between the donors, the World Bank and the GAVI Alliance governing the general interaction and duties among the parties.

2. Offer Agreement: This agreement is a conditional offer from the GAVI Alliance and the World Bank, reflecting how funding is made available to vaccine suppliers that meet all the terms and conditions of the offer. GAVI Alliance support for each supply agreement is subject to the availability of funding.

3. Pro Forma Supply Agreement: An AMC-registered supplier will be able to enter into a Supply Agreement with UNICEF once the specific registration and independent assessment committee approval conditions are met. To maximise transparency and certainty for all suppliers (and to minimise 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. Negotiated elements of the Supply Agreement include the level of supply commitment and the start date for dedicated capacity.

4. Bilateral Grant Agreements: The Bilateral Grant Agreements are between each donor and the World Bank committing to AMC grant payments and a schedule, amounting in the aggregate to \$1.5bn.

5. Ancillary AMC Documents:

- **AMC Registered Supplier Application:** To express an interest to participate in the AMC and to create a contractual nexus between suppliers and the World Bank and the GAVI Alliance on the basis of the Offer Agreement, suppliers may be eligible to become “AMC Registered Manufacturers.” This is an agreement and provides indemnity and hold harmless promises from the supplier in favor of the donors, the World Bank and the GAVI Alliance.
- **Independent Assessment Committee Terms of Reference and Operational Guidelines:** This is not a legal agreement per se. The Terms of Reference and Operational Guidelines set out the roles and responsibility of the IAC – including endorsement of the target product profile, review and approval of AMC Eligibility Applications, review and modification of AMC terms and conditions (including price). Committee members sign a member duty statement confirming that each member will exercise his or her duties within the scope of the IAC Terms of Reference and Operational Guidelines.
- **AMC Procedures Memorandum:** This is not a legal agreement per se. This document will contain all the process and procedural guidelines that would be applicable to the Independent Assessment Committee, the AMC (GAVI) Secretariat, vaccine suppliers and eligible countries.

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6. Procurement and Fund Disbursement Agreements:

- *UNICEF AMC Procurement MOU:* This is a bilateral agreement with UNICEF for procurement agency services.
- *GAVI/IBRD Agreement on AMC Fund Disbursement Mechanics:* This is a bilateral agreement with the IBRD confirming the disbursement mechanics and process for paying to UNICEF money necessary to purchase AMC vaccines under the Supply Agreements.