

Response of the AMC Donor Committee to the Interim Report of the Economic Expert Group

Summary

In May 2007, the AMC Donor Committee (Italy, UK, Canada, Russia, Norway and the Bill and Melinda Gates Foundation) constituted an independent Economic Expert Group (EEG) to advise on the initial AMC design detailed in the November 2006 Framework Document (www.vaccineamc.org). The EEG reported on various options to enhance the AMC model, and analyzed a number of the pros and cons of these options.

The Donor Committee has provisionally endorsed many of the options recommended by the EEG, and is of the view that the proposed modifications could make the AMC more robust. In reviewing the EEG report, the key consideration for the Donor Committee was having AMC terms that would ensure that a pneumococcal vaccine met the needs of developing countries and at the same time provided an adequate incentive to vaccine manufacturers. Without industry participation, vaccines will not reach poor countries in a timely fashion and children will continue to die from this disease.

The next and final stage in AMC design is to elaborate on the selected options, in order to provide the necessary detail on the final terms, pricing and parameters for the pilot AMC. To carry out this task, the Donor Committee has commissioned an Implementation Working Group (IWG), which will report back in May 2008.

Context and Background to the AMC

According to WHO 10 million children under the age of 5 die each year and many of these deaths could be prevented with new vaccines. But commercial pressures mean that pharmaceutical companies invest limited resources in developing and manufacturing new vaccines that address the disease burden in developing countries. Only 10% of the \$100bn spent each year on health research is on the diseases that are responsible for 90% of global health problems. Furthermore, when vaccines are developed there is often a 15 year timelag before they become widely available at affordable prices in developing countries. Companies lack confidence in developing world markets – and do not build the expensive manufacturing capacity that is needed to supply them on a predictable basis with relatively higher price new vaccines. Millions of children can die during this time- lag.

An AMC aims to mend this market failure by bridging the gap between private companies and developing countries and is an innovative solution to these problems. Under an AMC, donors make an advance commitment to subsidise the purchase of vaccines that are urgently needed but not yet available. The donor commitment is dependent on two conditions: (1) Companies must provide qualified vaccines that meet the standards of the Target Product Profile (TPP), that is the product specifications required for consideration for AMC financing, at the price set by the donors; and (2) The vaccines must be demanded and wanted by developing countries. This advance commitment provides companies with certainty that – if they can develop and produce the needed vaccines – there is a meaningful market in developing countries.

In February 2006, an Expert Committee recommended that the pilot AMC should incentivise the production of pneumococcal vaccines. According to the WHO

pneumococcal diseases kill more than 1.6 million people each year. One vaccine is currently in use in developed countries, but it does not provide protection against strains that are most prevalent in developing countries. The AMC will only subsidise the purchase of vaccines that provide effective protection in developing countries.

The objective of the pilot AMC is to save lives by accelerating widespread and sustainable availability of pneumococcal vaccines. Specifically, the AMC aims to: (a) Incentivise companies to develop new pneumococcal vaccines for developing countries; (b) Incentivise companies that already have suitable vaccines in development to build predictable and long-term manufacturing capacity to supply developing countries; (c) Ensure low cost and sustainable supply after the AMC subsidy period. A strong monitoring and evaluation framework has been established to measure AMC results.

Recommendations of the EEG Report and Provisional Donor Decisions

The AMC design is detailed in the November 2006 Framework Document (FD: see www.vaccineamc.org). The FD suggests a two-step pricing structure with donors guaranteeing to pay \$5-7 per dose for \$1.5bn worth of vaccines ("the AMC price"), and industry committing to provide vaccines at \$2 per dose for an agreed period thereafter ("the tail price"). This pricing structure was subject to review by the EEG, which has recommended the following enhancements to the FD design.

EEG Recommendation 1: Addition of Industry Supply Commitments

Summary of the Proposed AMC Enhancement

The EEG advises that, under the FD design, there is a significant risk that companies will not build the high cost new manufacturing capacity that is needed but will instead provide a limited number of vaccines from existing, or marginally increased, capacity. This outcome would not achieve the AMC objectives. The EEG therefore recommends that, as a condition of entry to the AMC, companies should commit to supply a portion of the forecast developing country demand. The level of the supply commitment would be set by companies themselves. In return, the companies would be apportioned access to a corresponding share of the AMC's \$1.5bn resources. For example, if a company guarantees to supply 50% of forecast demand, then 50% of the available AMC funds would be allocated to subsidise the purchase of its vaccine given that the vaccine is demanded by developing countries. After these funds are used up, the company would be obligated to supply vaccines at the AMC tail price.

Provisional Donor Committee Decision

Donors provisionally agreed to this modification. Industry supply commitments (including a minimum number of annual doses) would effectively mitigate the risk of companies providing limited quantities of vaccines without building new manufacturing capacity. But in order to avoid a situation where AMC funds become tied to a vaccine which developing countries do not want, donors have asked that the IWG design appropriate provisions to cover this case.

EEG Recommendation 2: Mitigation of Demand Risk

Summary of the Proposed AMC Enhancement

The EEG advises that the above supply commitments may reduce the likelihood of companies participating in the AMC due to the risk of demand not materialising. The EEG recommends that donors should consider two demand mitigation measures in order to increase the likelihood of vaccines being provided: (a) Firm Order Timing: Donors could guarantee to buy a fixed proportion of each company's supply

commitment, whether or not country demand for that vaccine materialises; or (b) Enhanced Frontloading: The pricing could be further frontloaded and donors could offer a higher price for the initial doses provided. The EEG suggests that the demand mitigation measures could be implemented separately or jointly.

Provisional Donor Committee Decision

Donors do not consider that volume guarantees would be an effective use of Development Assistance. The AMC is intended to provide market incentives and should not set a precedent that volume guarantees are needed to stimulate vaccine supply for developing countries.

The Donor Committee agrees that, in so far as the IWG considers it advisable to incentivise industry's acceptance of supply commitments, this should be achieved through enhanced frontloading. This is an extension of the original AMC concept – ie pay higher prices in the first years to secure supply capacity and low tail prices for future years. The EEG has also stressed that frontloading would not increase the overall amount of AMC subsidy that any one company receives (provided that country demand materialises as forecast by GAVI). Frontloading will mean that a given company receives the same proportion of AMC funding faster – but would also transition faster to supplying at the low tail price.

GAVI has stressed that the demand forecasts are among the most robust ever developed and that the PneumoADIP (a team based at Johns Hopkins Bloomberg School of Public Health dedicated to pneumococcal vaccine research – www.pneumoadip.com) has worked extensively to build and ensure country demand. The donors also reiterate the importance of a low tail price ceiling (with companies able to compete downwards on tail price within the ceiling).

EEG Recommendation 3: Sequential Offering of the AMC

Summary of the Proposed AMC Enhancement

The EEG recommends that the AMC funds should be divided and allocated within two or more sequential offers. The first offer would be available from the start of the AMC and accessible for all companies that produce vaccines in the early years. The remaining funds would be made available under one or more future offers, during later years of the AMC period. The AMC period is estimated to last to 2020.

Provisional Donor Committee Decision

Donors provisionally agreed that sequential offering could significantly enhance the impact of the AMC and should only be implemented for two bids. It was agreed that sequential offering would: (a) Reduce risks to donors and firms by allowing time for information on key variables such as demand to be collected under the first offer; and (b) Enhance the incentives for more companies to invest in R&D and provide new vaccines, specifically tailored for developing countries, under the second offer. This could also increase the likelihood of a competitive and low cost market after the AMC tail period.

Tail Price

The EEG did not make a specific recommendation on how to set the tail price (the long-term price of the vaccine). Instead, the EEG report did put forward the pros and cons of three options: (a) letting companies unilaterally set the tail price; (b) setting a hard tail price cap; and, (c) setting a soft, or flexible, tail price cap.

After considering the analysis in the report, donors have agreed that setting a hard tail price cap at an affordable level is the best way to ensure the sustainability of the AMC. The IWG will recommend a set of parameters to define the level of the tail price cap, which would be adjusted for inflation. It was also agreed that the tail price cap would only be a ceiling – firms would be free to reduce the price to developing countries as part of their supply agreements.

Next Steps

The donors have asked the IWG to complete the relevant analytic work and provide recommendations for the final terms and parameters for the pilot AMC. To this purpose the IWG will also consult with developing country representatives, multinational and emerging-market vaccine companies, NGOs and other stakeholders.