



Exploring the role of the US Government in a future advance market commitment

Recommendations for US policymakers

Advance market commitments (AMCs) pool donor funding to guarantee a future market, at a specified price, for companies that can develop a specific product that is demanded by low- and middle-income countries.

The governments of Italy, the United Kingdom, Canada, Russia, Norway, and the Bill & Melinda Gates Foundation committed \$1.5 billion to launch an AMC for a pneumococcal vaccine. This AMC was structured as a pilot, whereby donors could design the legal and financial constructs of such a mechanism while also addressing a major global health need. A future AMC would benefit from the lessons learned in the design and early implementation of the AMC for a pneumococcal vaccine. The Global Health Technologies Coalition (GHTC) strongly urges US policymakers to explore innovative financing opportunities, such as a future AMC.

To that end, there are several actions US policymakers can begin to take now:

- Engage in discussions with external colleagues, including members of the current donor group, the GAVI Alliance, and the World Bank, to share interest in AMCs, understand how the United States can contribute to the pneumococcal AMC, and discuss how the United States can help advance discussions on future AMCs.
- Formally establish a cross-agency US Government working group to include the US Department of Treasury, the Office of Science and Technology Policy at the White House (OSTP), the US Agency for International

Development (USAID), and the Department of Health and Human Services (HHS).

- Convene consultations with stakeholders, including global health nongovernmental organizations (NGOs), product development partnerships (PDPs), and vaccine industry.
- Continue to evaluate the pilot AMC for key lessons in implementation.

Assessing the pneumococcal AMC

While a continuum of metrics will ultimately be of interest in assessing the pneumococcal AMC, in the near term, three primary criteria are key determinants of success—and each of these have been met:

Competition among multiple pneumococcal vaccine suppliers. To date, four suppliers have registered for the AMC: Pfizer, Inc., GlaxoSmithKline (GSK), Panacea Biotec Ltd., and the Serum Institute of India Ltd. Both GSK and Pfizer, Inc. have committed to supply 30 million doses per year for ten years at a fixed price of \$3.50 per dose.

Reduced prices. Because of the AMC, donors have immediately secured a lower price for the pneumococcal vaccine, reflecting a savings of \$19.00 per dose compared to the next closest price for the vaccine. As the AMC meets its goal of purchasing and delivering 130 million doses in the first years of the program, the savings on price alone will be \$2.4 billion. Historically, it has taken years for prices to fall, with the result that donors paid higher prices in the interim (see Figure 1).

Global access to the vaccine. The AMC requires participating manufacturers to dedicate a supply of

vaccine for those countries most in need—a sharp contrast from historical experience, whereby manufacturers focus on wealthy markets first, constraining supply to poor countries, resulting in both higher prices and delays in access.

Additionally, widespread demand for the pneumococcal vaccine by developing countries has already been demonstrated. More than thirty countries have expressed interest in the vaccine in a two-year period, 13 of which have already applied and been approved to receive the vaccine from the GAVI Alliance. Compared with uptake for Hib vaccine, for which only five countries were approved in the first three years of availability through the GAVI Alliance, uptake of the pneumococcal vaccine is expected to be accelerated by as many as seven to ten years over historical precedents.

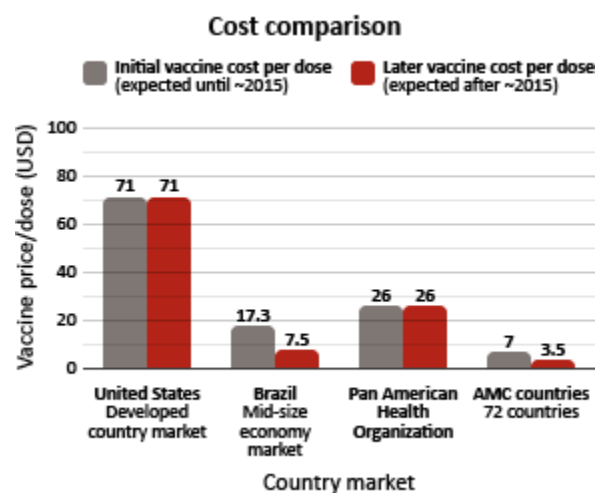
Because it is administered by the GAVI Alliance, the AMC leverages an effective and efficient delivery platform that has greatly expanded vaccine coverage in the poorest countries of the world.

Evaluating potential candidates for a future AMC

To ensure that an evidence-based decision would be made about which vaccine was most appropriate for the pilot AMC, the World Bank and the GAVI Alliance convened an independent AMC disease expert committee, chaired by then-Minister of Health of Malawi. Members of this committee brought expertise in public health, epidemiology, industry economics, vaccine development, and law, and reviewed potential vaccines for six diseases as recommended in Italian Minister of Finance Giulio Tremonti’s AMC report¹: HIV/AIDS, human papilloma virus, malaria, pneumococcus, rotavirus,

¹ Tremonti G. *Advanced Market Commitments for vaccines: A new tool in the fight against disease and poverty*. London, UK: Italian Ministry of Economics and Finance; 2005. Available online at: <http://www.innovativefinance-oslo.no/pop.cfm?FuseAction=Doc&p%20Action=View&pDocumentId=11529>. This report was endorsed by G7 Ministers of Finance in December 2005. The selection of the six diseases was based upon economic and health impact in poor countries.

Figure 1. Cost comparison illustrates how the AMC has driven down pneumococcal vaccine costs:²



and tuberculosis (TB). The committee ultimately recommended that a pneumococcal vaccine would be most suitable for the pilot AMC.

Additionally, this committee found that “a second demonstration AMC is recommended to test its impact on early-stage vaccines.” The GHTC recommends that a similar expert group—one which is objective and diverse in technical expertise and geographic representation—be convened to recommend the most suitable vaccine for a future AMC, and that this group take into account disease burden and state of science of new potential vaccines as key components of its decision.

US role in future AMC opportunities

Because the United Kingdom, Italy, and Canada played leadership roles in funding the AMC pilot and bringing it to fruition, while the United States did not participate in the pilot, it would seem appropriate for US policymakers to initiate discussions with those governments to acknowledge their leadership, invite their reflections on the next AMC, and explore how

² Reuters. Glaxo, Brazil sign 1.5 bln euro vaccine deal. *Reuters International*. September 28, 2009. Available online at <http://www.reuters.com/article/companyNews/idUSLS28828120090928>

The Brazil market vaccine prices are based on a recent privately negotiated agreement between the government and GlaxoSmithKline to provide the company’s ten-valent vaccine. The vaccine provided under the AMC is not identical in its formulation. Euro prices are converted to US dollars.

best the United States can help advance progress on a future AMC. Other countries that express interest in a future AMC should be engaged in these discussions as well.

Proposed US Government action items

As directed by the Lantos-Hyde Act (see page four), the US Government should consider participating in future negotiations for AMCs for new vaccines. To begin this process, US policymakers should consider the following actions as steps in that process:

- Meet with members of the current donor group to share interest in AMCs and discuss how the United States can help advance discussions on a second AMC.
- Meet with the GAVI Alliance and the World Bank to learn more about the current donor group and opportunities to participate regarding the pneumococcal AMC.
- Convene a cross-agency US Government working group to explore the appropriate role for the United States in supporting the next AMC. Key stakeholders to include in this group are: US Department of Treasury, OSTP, USAID, and HHS.
- Convene consultations with stakeholders, including global health NGOs, PDPs, and vaccine industry.
- Continue to evaluate the pilot AMC for key lessons in implementation.

Among the issues that the cross-agency working group could address are the possible challenges of making a multi-year funding commitment that works within the US budget cycle and appropriations process. The GHTC recommends identifying precedents from other sectors—including defense, energy, and aerospace—which may provide lessons that may apply to the AMC. Donors to the current AMC have kept their annual investments relatively modest by spreading their contributions to the AMC over many years.

AMC perspectives among stakeholders

Think tanks that focus on effectiveness of development aid, such as the Center for Global Development and Results for Development, have characterized AMCs as one of the key instruments in the broader effort to mobilize additional resources and incentivize investments in research and development for neglected diseases because they are market-based, efficient, and directly link donor funds with outcomes (e.g., delivery of an effective product).

Understandably, PDPs have supported AMCs as an approach that can help accelerate the development and/or availability of essential technologies. On the other end of the continuum, groups like Médecins Sans Frontières, Oxfam, and Knowledge Ecology International believe that the terms of AMCs are too favorable to the pharmaceutical industry and remain uncertain about the mechanism. Most global health NGOs have not taken strong positions on AMCs, but there is not typically widespread knowledge of innovative financing among this community.

Additional reviews of the AMC are ongoing by stakeholders such as the GAVI Alliance and the Bill & Melinda Gates Foundation, and results should be available in the coming months. These reviews should yield additional information about the technical merits of the AMC and provide recommendations for streamlined implementation of future AMCs.

The GHTC has worked to generate interest in the AMC and educate key stakeholders about the mechanism. We look forward to supporting US policymakers and stand ready to serve as a resource.



Children in Kenya. Photo: PATH/Mike Wang.

Excerpt from the Lantos Hyde Global Leadership Against HIV/AIDS, TB, and Malaria Reauthorization Act of 2008

SEC. 206. FACILITATING VACCINE DEVELOPMENT.

(b) Advanced Market Commitments-

(1) **PURPOSE-** The purpose of this subsection is to improve global health by requiring the United States to participate in negotiations for advance market commitments for the development of future vaccines, including potential vaccines for HIV/AIDS, tuberculosis, and malaria.

(2) **NEGOTIATION REQUIREMENT-** The Secretary of the Treasury shall enter into negotiations with the appropriate officials of the International Bank of Reconstruction and Development (World Bank) and the GAVI Alliance, the member nations of such entities, and other interested parties to establish advanced market commitments to purchase vaccines to combat HIV/AIDS, tuberculosis, malaria, and other related infectious diseases.

(3) **REQUIREMENTS-** In negotiating the United States participation in programs for advanced market commitments, the Secretary of the Treasury shall take into account whether programs for advance market commitments include--

(A) legally binding contracts for product purchase that include a fair market price for up to a maximum number of treatments, creating a strong market incentive;

(B) clearly defined and transparent rules of program participation for qualified developers and suppliers of the product;

(C) clearly defined requirements for eligible vaccines to ensure that they are safe and effective and can be delivered in developing country contexts;

(D) dispute settlement mechanisms; and

(E) sufficient flexibility to enable the contracts to be adjusted in accord with new information related to projected market size and other factors while still maintaining the purchase commitment at a fair price.

(4) **REPORT-** Not later than 1 year after the date of the enactment of this Act--

(A) the Secretary of the Treasury shall submit a report to the appropriate congressional committees on the status of the United States negotiations to participate in programs for the advanced market commitments under this subsection; and

(B) the President shall produce a comprehensive report, written by a study group of qualified professionals from relevant Federal agencies and initiatives, nongovernmental organizations, and industry representatives, that sets forth a coordinated strategy to accelerate development of vaccines for infectious diseases, such as HIV/AIDS, malaria, and tuberculosis, which includes--

(i) initiatives to create economic incentives for the research, development, and manufacturing of vaccines for HIV/AIDS, tuberculosis, malaria, and other infectious diseases;

(ii) an expansion of public-private partnerships and the leveraging of resources from other countries and the private sector; and

(iii) efforts to maximize United States capabilities to support clinical trials of vaccines in developing countries and to address the challenges of delivering vaccines in developing countries to minimize delays in access once vaccines are available.

Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, HR 5501, 110th Cong., 2nd session (2008)

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is a group of more than 30 nonprofit organizations working to increase awareness of the urgent need for tools that save lives in the developing world. These tools include new vaccines, drugs, microbicides, diagnostic tests, and other devices. The coalition advocates for increased and effective use of public resources, incentives to encourage private investment, and improved regulatory systems. Learn more at www.ghtcoalition.org.