



# Incentives and innovative financing for global health product development

Research and development (R&D) for new and innovative health tools are essential to achieve long-term international health and development goals. Previous investments in research to develop new vaccines, drugs, diagnostics, and other tools have led to some of the greatest advances in global health to date, saving countless lives and resulting in billions of dollars in cost savings. The United States has long been, and continues to be, the leader in efforts to develop these new global health tools for diseases that primarily affect people in the developing world. Thanks to this leadership, Americans and millions of people around the world no longer live in fear of diseases such as polio and measles. Millions more—including those receiving drugs for HIV/AIDS, tuberculosis, and malaria—live longer, healthier, and more productive lives. With sustained investment and support, further gains are achievable: from the eradication of polio, to the elimination of malaria; from controlling and ending the AIDS and tuberculosis (TB) epidemics, to effectively diagnosing and treating neglected tropical diseases.

Although undeniable progress has been made, further gains will not be achieved and global health goals will not be met without the development of new and more effective technologies. We still lack many essential tools, such as effective diagnostics, vaccines, and drugs, required to control, and eventually eradicate, these diseases and others, including pneumonia, diarrheal diseases, and other neglected tropical diseases. The lack of effective tools that are affordable and appropriate in limited-resource settings remains an important obstacle to attaining US global health goals. If a sustained impact on global health outcomes is to be realized and targets for disease control and elimination are to be met, investments in research to develop new technologies must be sustained and elevated.

## Recommendations for US policymakers

- Form a **cross-agency working group** to explore US investment in incentives and innovative financing mechanisms.
- Invest in a **portfolio** of incentives and financing mechanisms to stimulate needed R&D at all stages of the product development process.
- **Engage with other governments and donors** to explore and support innovative financing.
- Conduct continuous **rigorous assessments** of each incentive and financing mechanism in which the US invests.

Because these essential health products are primarily needed in the developing world, where patients and health providers may not be able to afford them, commercial incentives are often insufficient to stimulate the large-scale and long-term investment by the biopharmaceutical industry that health product development requires. To overcome this market obstacle, health economists and experts have designed several strategies for incentivizing and financing global health R&D to accelerate product development. Incentives and innovative financing mechanisms are designed to encourage actors with R&D expertise to devote their resources to solving the health challenges of the developing world. Incentive mechanisms generally reduce the risk and uncertainty of commercial markets to encourage or “pull” private industry to invest. Innovative financing mechanisms identify new ways of raising and allocating funds to stimulate and accelerate, or “push” global health R&D across all sectors.

The US Government has played a key role in supporting incentives and innovative financing mechanisms and can enhance its leadership in this

area. To further accelerate innovation in global health product development, the US Government should coordinate across agencies and with other donors to implement a portfolio of incentive and financing mechanisms, and rigorously assess each mechanism in which it invests.

## Investing in a portfolio of incentives and innovative financing mechanisms

Different new health technologies for different diseases are at different stages of development, and face different scientific obstacles and potential for commercial returns. Given this diversity, no single incentive scheme or financing mechanism is capable of filling all the gaps and encouraging the full range of R&D activities across all of the diseases and products that the developing world urgently needs. A portfolio of incentives and financing mechanisms that can fill the multiple gaps in the product development pipeline for multiple diseases is needed. As shown in Figure 1, major financing gaps can exist at three critical points in the product development process: translation of scientific findings into development of product candidates; late-stage clinical trials to determine the efficacy of new product candidates; and production of effective products at prices affordable in the developing world.

Many incentives and financing strategies have been implemented in the United States and other nations to stimulate innovation for global health products, or for all health products. These include priority review vouchers (PRV), small business innovation research (SBIR) awards, procurement pools, patent pools, public-private product development partnerships (PDPs), and tax credits for R&D. An Advanced Market Commitment (AMC) was launched by several governments and donors, although not the United States. Economic and policy analyses have demonstrated the merits of these strategies.

A range of other strategies have been proposed to address global health needs including a PDP Financing Facility, prizes for the discovery and development of new products, and others. Figure 1 demonstrates where in the product development process these incentives and financing mechanisms

### Incentives and financing mechanisms can work: leading indicators of the AMC's success

In 2009, the governments of Italy, the United Kingdom, Canada, Russia, and Norway and the Bill & Melinda Gates Foundation launched an AMC, administered by the GAVI Alliance, to drive development and production of a pneumococcal vaccine specifically tailored to the needs of developing countries. While it is too early to assess the AMC's impact in reducing disease burdens by making a new vaccine widely available, four leading indicators suggest several successful outcomes from the AMC:

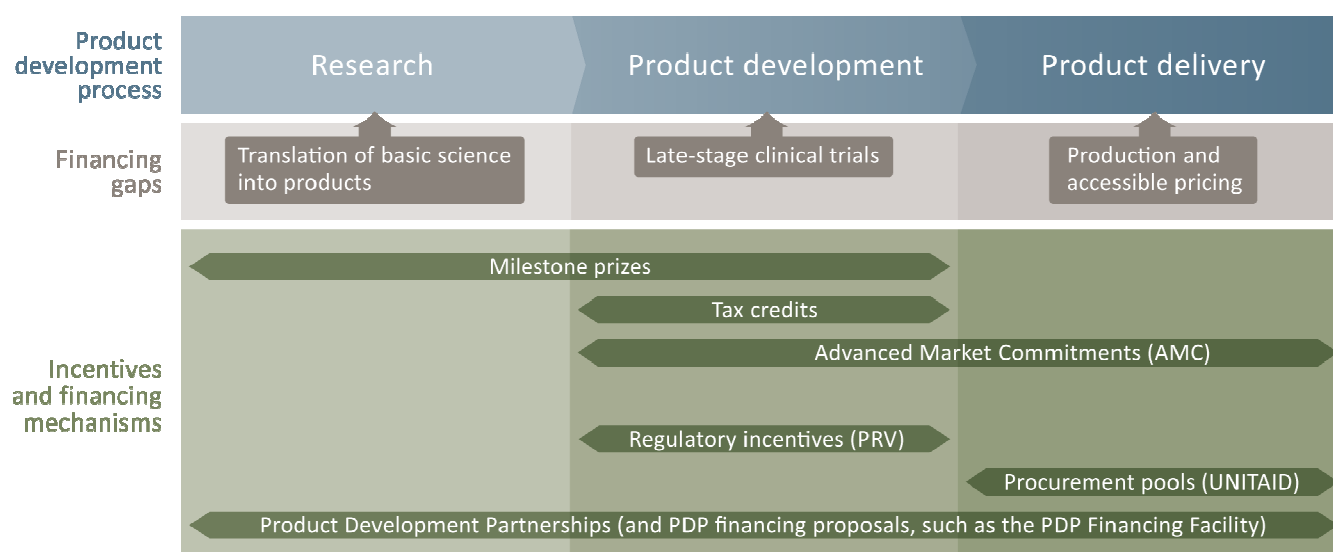
- **The AMC has created competition:** four suppliers have registered to sell their vaccines through the AMC at a fixed price.
- **The AMC has reduced prices:** Suppliers have committed to selling their vaccines through the AMC at a price that is \$10 less than the next lowest price on the market, and around \$90 less than in industrialized markets.
- **The AMC has facilitated widespread demand:** 30 developing countries have expressed interest in purchasing the pneumococcal vaccine through the AMC.
- **The AMC has spurred scale-up of production capacity:** the volume of the pneumococcal vaccine launch has been much higher than for any global health product historically, suggesting that suppliers have scaled-up production capacity significantly.

are most likely to be effective.

## Coordinating across the federal government and with other donors

Several departments and agencies within the US Government have been involved in incentives and financing mechanism discussions and/or implementation including the US Treasury, US Agency for International Development, Office of Science and Technology Policy, National Institutes of Health, Food and Drug Administration and the US Congress. Given diverse interests and

**FIGURE 1. Targeting mechanisms to fill critical gaps in the product development process**



perspectives across these agencies, it is essential that the US Government coordinate around a shared agenda supporting a portfolio of incentives and financing mechanisms. Because the responsibility for implementing such mechanisms does not rest with one agency or private foundation alone, such coordination is essential to ensure that multiple critical R&D needs are prioritized and met. To maximize the positive impact of US investments and policies, leaders and policymakers in the federal government also need to partner and coordinate with other governments and donors and participate in global initiatives such as the World Health Organization's Consultative Expert Working Group on R&D Financing, the Leading Group on Innovative Financing for Development, and bilateral initiatives such as implementation of a new AMC.

## Evaluating incentives and financing mechanisms

While a track record exists for some innovative financing and incentive mechanisms, many are by nature new and untested. Therefore, it will be critical for the US Government and its partners to continually assess these mechanisms both before and during their implementation. The US Government and other partners should develop a rigorous evaluation framework to predict and monitor performance and impact. This framework can help

guide decision-making on further investment and contribute to the global evidence base on what works in incentives and innovative financing for global health R&D. We recommend the following criteria:

- **Public health impact:** what is the mechanism's potential to stimulate development of products that can reduce critical global health disease burdens?
- **Revenue generation:** for mechanisms designed to raise new funds, can the mechanism raise enough additional funds to stimulate the needed R&D? This includes whether new funds are sufficiently predictable, sustainable, and flexible to support the R&D process.
- **Efficiency:** does the mechanism raise and allocate funds in an efficient way? This includes assessment of transaction, start-up, and administration costs as a proportion of revenues the mechanism generates, and/or as compared to alternate strategies for achieving the same goal. (Note: This criterion does not evaluate the cost-effectiveness of the product that the mechanism is designed to advance.)
- **Effective:** is the mechanism well-suited to overcome the particular financing and/or incentive gap(s) that are the primary obstacles to development for the disease and product(s) of interest?

- **Accountability and transparency:** do the mechanism's governance, accounting, and reporting structures ensure that both the government and the public can monitor and assess the mechanism and track results?
- **Political and/or technical feasibility:** do any legal, operational, political, or other barriers exist that would preclude adoption or effective implementation of the mechanism? These may include unique budget or cycle restrictions, political acceptability, or restrictions on international freedom to operate.

### Enhanced US leadership in incentives and innovative financing can accelerate product development and save lives

The recent global economic crisis and strained donor budgets for global health have highlighted the urgent need to bring new financing to health product development and delivery, and to better harness existing expertise and resources from multiple sectors including private industry. Recent experience with mechanisms such as the AMC, PRVs, PDPs, SBIR, UNITAID and others suggest that there are highly cost-effective ways to improve funding streams and encourage participation by

private industry to accelerate the development and delivery of critical global health products. Indeed, incentives and innovative financing mechanisms are fast becoming essential components of the global health architecture, particularly as decision makers struggle to allocate increasingly scarce resources to address competing development priorities

The US Government's leadership has been essential in exploring, implementing, and supporting many of these new mechanisms, and that leadership will be critical to further accelerate global health product development and delivery and save lives throughout the developing world. To strengthen this leadership, the US Government should coordinate across the various federal departments and agencies with interests in this area to craft a shared agenda for stimulating global health R&D. In partnership with other donors, the US Government should explore and support a robust portfolio of incentives and innovative financing mechanisms that can fill the multiple gaps in R&D financing. It should also conduct rigorous assessments and evaluations of all mechanisms in which it invests. The Global Health Technologies Coalition looks forward to supporting US policymakers in this critical area, and stands ready to serve as a resource.

#### Additional resources

- International AIDS Vaccine Initiative policy briefs on incentive financing: <http://www.iavi.org/publications-resources/Pages/BrowsePublications.aspx?ptop=Funding%20/%20Incentives>
- *Can Donors Be Flexible within Restrictive Budget Systems? Options for Innovative Financing Mechanisms - Working Paper 226.* Published by the Center for Global Development: <http://www.cgdev.org/content/publications/detail/1424497/>
- *Innovative Financing for Global Health: A Moment for Expanded U.S. Engagement?* Published by the CSIS Global Health Policy Center: [http://csis.org/files/publication/100316\\_Hecht\\_InnovativeFinancing\\_Web.pdf](http://csis.org/files/publication/100316_Hecht_InnovativeFinancing_Web.pdf)
- Results for Development' Institute's Center for Global Health R&D Policy Assessment: <http://healthresearchpolicy.org/>
- World Health Organization's Expert Working Group on R&D Financing: [http://www.who.int/phi/R\\_Dfinancing/en/index.html](http://www.who.int/phi/R_Dfinancing/en/index.html)

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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.ghcoalition.org](http://www.ghcoalition.org).