



## Improving the Financing of Health R&D for Developing Countries: A Menu of Innovative Policy Options

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### Background

Despite progress in recent years, the world still urgently needs new and improved health technologies to prevent and treat major diseases prevalent in the developing world. A partially effective malaria vaccine could avert 7 deaths and 16 severe cases of malaria for every 1,000 children immunized in Sub-Saharan Africa each year. A million HIV infections could be avoided worldwide each year if a 50 percent effective first generation vaccine were developed, and 2.5 million children could be saved annually if currently available and soon-to-be-available vaccines penetrate developing world markets. Yet to date, investment in applied research and product development (R&D) has been inadequate to drive these innovations. Existing funding streams are unpredictable, often with short time horizons. Rigid agreements limit flexibility in R&D project design and implementation. Weak incentives exist both upstream (high cost of capital) and downstream (poor clients with low purchasing power) to encourage companies to operate in emerging markets.

This Snapshot surveys a range of mechanisms that could help expand and accelerate the pipeline of new technologies used to meet global health challenges, and points to next steps for future innovation.

### Innovative financing for global health R&D

To expand and accelerate innovation, financing solutions are needed that both push and pull investment. Push mechanisms – including grants, subsidized loans, and investment tax credits -- act directly on each stage of the R&D process, increasing the volume of funding upfront and making it less costly for biotech and pharma companies to invest. Pull mechanisms – such as price and volume guarantees and intellectual property protections -- act indirectly on the R&D process, shifting the risk-reward equation for companies by lowering risk or increasing potential revenue, or both. Together, these mechanisms create more attractive markets, lower uncertainty, and raise profit margins, thereby stimulating increased investment in R&D.

Push and pull mechanisms for global health R&D are not without their downsides. By financing inputs rather than outputs, push financing requires funders to try to pick “winners” ex-ante. Expert peer review panels and special intermediaries like product development partnerships (PDPs) have been created to help manage this risk. Conversely, pull mechanisms risk over- or under-paying R&D organizations and of distorting incentives. Designing the optimal level of reward requires assessment of the likely costs of R&D and the expected returns. Using a mix of mechanisms appropriate to different stages in the discovery, development, and production process can help to mitigate these problems.

### A menu of options

Financing for health R&D has traditionally been of the push variety, and has emanated from public grants awarded via medical research councils and from private investment used to translate research into commercially viable products. Over the past decade, new mechanisms for R&D have begun to emerge:

- Non-profit product development partnerships (PDPs) focus on taking new health products from design through pre-clinical and early stage clinical testing, demonstrating their efficacy and manufacturability to both purchasers and biopharma companies.
- Government grants to private firms are becoming an important part of financing flows. In 2006, for example, \$20.9 million in NIH funds for AIDS vaccines went to seven biotech and pharma companies.
- The Advanced Market Commitment creates a secure market for new drugs and vaccines using legally binding commitments from developed countries to subsidize the price paid by developing world governments (see the AMC Snapshot in this series).
- Special “innovation funds” are being piloted by Bill and Melinda Gates Foundation and the International AIDS Vaccine Initiative to stimulate interdisciplinary collaboration and joint work by scientific and industrial experts.
- The FDA priority review vouchers, which will likely be operational by late 2008, will award a transferable voucher to the manufacturer of a novel drug or vaccine targeted at the “neglected” diseases of the developing world. As tradeable assets that can be used to expedite the FDA review process for another drug or vaccine with a possible blockbuster market, these vouchers are expected to have significant monetary value which could pull important investments into global health R&D.

In the coming years, a number of additional ideas are likely to be considered, and others that are currently on the margins of the global health debate may merit further assessments. For example:

- Existing global funding instruments for health, including the Global Fund, GAVI, and UNITAID, could expand their mandate to include funding for R&D through grants to PDPs and grants or loans to biopharma organizations (push).
- Capital could be raised through government-backed bonds with the bond proceeds deposited in a special facility to support the R&D activities of PDPs, and with royalties on product sales used to repay part or all of the bonds (push).
- Cash prizes could be offered to reward partial progress and significant achievements on the road to developing new drugs, vaccines, and diagnostic tests (pull).

### **What are the outstanding issues and next steps going forward?**

Thanks in large part to increased public and private mobilization around the Millennium Development Goals, support for global health R&D financing has increased. At the same time, further experimentation faces potential obstacles. The current global financial crisis and an economic slowdown are likely to have a negative impact on development assistance, reducing the financial resources and political attention currently devoted to global health. In addition, proposed measures may not produce desired outcomes if biopharma companies determine that, even with interventions, volume or floor prices remain too low. Rich country governments may not be prepared to make needed long-term financial commitments because of budgeting rules or political cost. Furthermore, if new financing schemes require complex management and governance arrangements, donor enthusiasm may be blunted by high transaction costs and slow implementation.

Given the robust menu of proposals for innovative financing for health R&D and the likelihood that the menu will continue to grow, it may be useful to consider the creation of a “neutral space” where these ideas can be objectively assessed and debated by potential funders, developing country governments, biopharma companies, scientific researchers, and others. This could help to speed up decisions and actions to adopt the best new financing approaches to accelerate the design and adoption of life-saving drugs, vaccines, and other health technologies.