



6

Meeting industry requirements

Chapter at a glance

- We have sought to design a mechanism to which industry will respond by increasing R&D on vaccines for diseases occurring mainly in developing countries.
- Industry is attracted to the concept of payment for results; the market mechanism fits their business model well and preserves the role of intellectual property rights and market sales financing commercial investment in pharmaceutical R&D.
- Our consultations revealed a range of priorities for the commitment from different parts of industry.
- An advance market commitment would be of value to developing-country suppliers, which often do not benefit from other incentive arrangements.
- Complementary measures are needed to improve the procurement of existing vaccines, improve demand forecasts and increase funding for existing drugs and vaccines.

A range of industry requirements

The success of the advance market commitment depends on creating effective incentives for potential vaccine developers and suppliers who see a scientific potential to invest. The program is intended to create incentives to accelerate the development of new vaccines, but the details of the design may make a significant difference to the incentives that the contract creates. Critical determinants of success include the size of the reward, the contractual requirements placed on the firm (for example, the eligibility requirements) and the public relations impact of participation.

We have borne in mind that our goal is not to encourage all firms to work on these products. It is to accelerate the development of a vaccine by providing sufficient incentive for some firms to begin R&D on these problems, and for others to devote extra resources and priority to their existing work.

Initial research often is done by biotech companies. Typically, their work is then either licensed to, or bought by, larger pharmaceutical companies for the later stages of development, marketing and manufacturing. An important ingredient in the proposal is that it should generate a response from biotechs and other early-stage researchers—for example, by creating a sufficient market for the vaccine to give them confidence that pharmaceutical companies will invest in intermediate research outputs. Biotech companies and venture capitalists would be more willing to invest because they would be more confident that they would attract interest from pharmaceutical companies for the products they develop. There is considerable evidence that firms do, in fact, respond to market signals by adjusting their R&D to reflect the size of the potential market.¹

The only way to know for sure how firms would react is to implement a commitment and observe what happens. In the meantime, it is possible to obtain information through structured consultations with informed individuals, particularly those who are currently facing difficult choices about where to invest in R&D to yield the best outcome for shareholders. We consulted representatives of three industry groups—biotechnology firms of various sizes and orientations, multinational vaccine manufacturers and emerging market suppliers (box 6.1). We sought feedback on the overall concept and tried to identify specific ways in which the advance contract concept could be structured to most likely generate a change in investment behavior. The results of these

discussions, summarized here, were invaluable for developing our recommendations. Our aim has been to design a commitment that creates the right commercial incentives to encourage industry to invest, while ensuring value for money for sponsors.

The industry is diverse

Firms had various reactions to the idea of an advance commitment, depending on their risk tolerance, product pipeline, scientific background and business model. There was a greater degree of consistency within industry categories, but even within these categories each firm indicated a unique character and strategic agenda. For example, pharmaceutical companies with vaccines coming to market soon were more interested in commitments for late-stage products than were biotechs engaged in research on early-stage products.

Many firms expressed a view that an advance market commitment, if structured in the right way, would be exactly what they needed to make the case for keeping global health products in the development pathway. Others felt there was little commercial motivation that could stimulate a dramatic change in their research pipelines.

Although some have interpreted advance market commitments to be targeted at multinational firms, emerging suppliers from developing countries would also have the potential to benefit. Unlike some incentives that would benefit primarily large and profitable pharmaceutical companies (U.S. tax credits, transferable patents), all firms would be in a position to compete for the market offered by this commitment. Major vaccine firms in Brazil,

Box 6.1 Industry consultations

- Biotechs: Ardana, Avant, Human Genome Sciences, Maxygen, Mojave Therapeutics, Nectar Therapeutics, Targeted Genetics, Vertex.
- Multinational vaccine manufacturers: Aventis-Pasteur, Chiron, GSK Biologicals, Merck Vaccine Division, Wyeth.
- Emerging supplier: Serum Institute of India.

In addition, the Working Group spoke with several former senior industry executives.

India, Indonesia and elsewhere that have demonstrated the capacity to achieve tremendous scale efficiencies of production could participate through joint ventures or other types of partnerships with firms that have a strong tradition of innovation.

Key industry requirements

Some themes emerged from the consultations.

- A commitment is likely to have more impact on some firms than others. For products at an early stage, for example, an advance market commitment may initially motivate biotech companies and the venture capitalists that provide their funding, while some larger multinational pharmaceutical firms may get involved only after further advances in the science, perhaps led by biotech firms.
- For many firms the establishment of a significant financial reward for the successful developer would be important in within-firm analysis and in negotiations about which products to move ahead with and at what pace. These firms cited in particular the moments in the development pathway when relatively costly decisions are taken to test products in humans.
- Some respondents indicated that an advance market commitment would address industry concerns about the appropriation of intellectual property and the downward pressure on prices that occurs when an essential medicine is developed but is seen as unaffordable to the developing world.
- Commercial decisions to develop a particular candidate are based on market prospects but also—critically—on science. Access to a promising scientific pathway will be the primary determinant of some firms' investment decisions in early research. There was a wide range of opinions about the challenges of developing a malaria vaccine, for example, and some firms reported that they are unwilling to invest given the current state of science. The public sector will need to keep investing in basic research and lead development to advance the science.
- Firms do not evaluate incentives independently but look at the comprehensive picture of risks and rewards they will face through the development process.
- An advance market commitment, or indeed any similar mechanism focused on creating incentives for commercial investment, would need to be implemented in coordination with other interventions—push funding, demand creation and capacity-building for distribution and delivery.
- Weaknesses in the current system of procurement and delivery of vaccines for the developing world are a major deterrent to investment. Most firms supplying developing-country markets through public procurement are frustrated with inefficiencies in the current system—short-term purchase agreements, the lack of enforceable contracts, unreliable demand forecasts and underuse of existing vaccines. The public sector can improve its credibility by increasing use of existing products and by improving demand forecasts.
- The credibility of the commitment is closely related to the credibility of the sponsor. Citing real-world examples, firms were not convinced of the public sector's ability to live up to its funding promises that are not legally binding. Firms indicated that the inclusion of a private foundation as sponsors would add enormously to the credibility of the proposal. It was therefore clear from the consultations that it would be essential for an advance market commitment to be legally binding on the sponsors, and that nonbinding statements of intent would not elicit the same response.
- Given the novelty of the advance market commitment for the public sector, industry will be most persuaded by successful execution. Firms expressed uniform enthusiasm for implementing long-term contracts for late-stage (and existing) products. In addition to being directly beneficial by increasing affordable access to those vaccines, this would build up the credibility of similar commitments for early-stage products.

We have looked carefully at each of these industry considerations and sought to ensure that our advance market proposal takes these concerns into account. Firms also gave specific feedback on the proposed structure of advance contracts, particularly the Framework Agreement and Guarantee Agreement. These points have been taken into account in the advance market proposal set out in chapters 3 and 4 and are reflected in the discussion in those chapters.