



# 7

## How sponsors can do it

# Chapter at a glance

- Government sponsors can make legally binding commitments—and do so all the time. Private sponsors can too, and their involvement would add to the credibility of the commitment.
- The commitment can be handled within existing government budget processes.
- Under normal accounting rules for the sponsors included in the analysis, there is no cost to sponsors until and unless a vaccine is developed.
- There is no short-term budgetary tradeoff with existing funding of R&D.
- Existing procurement and regulatory arrangements can be used.
- An advance market commitment will require the sponsors to enter into an agreement, enforceable by law, to make multiyear payments of uncertain size and duration (though with a known upper limit) to an unknown recipient at some unknown time in the future. Can sponsors, as matter of practical fact, make a commitment of this sort? We looked at whether there are any institutional or legal obstacles to making commitments and how such commitments would be treated in the budget process. We found that there are no obstacles to sponsors making this commitment.

## Possible government sponsors

### The United States

We start with the United States because its budgetary process is more complicated than that of other possible sponsors.

The starting point is that the U.S. government enters long-term contracts as a matter of course. An administration is able to enter legal agreements that bind its successors. The government has budgeting mechanisms to authorize and deliver multi-year funding streams in the future. These obligations are legally binding and credible in markets even in the face of a degree of uncertainty about the appropriations process. Indeed, U.S. law specifically waives U.S. sovereign immunity for contracts executed by the United States in its proprietary capacity.

An example of a legally binding government commitment is the sale of government bonds, contracts that oblige the government to pay money to bondholders in the future. The U.S. government faces no legal difficulty making such commitments, even though they bind successor administrations.

To enter a contractual commitment to buy vaccines in the future, the administration needs specific authority from Congress. Once that legal authority exists, the mechanics of signing a legally binding commitment are uncomplicated.

A U.S. government commitment to purchase vaccines, even one that is legally binding, would not score as government expenditure, or contribute to the government deficit, until the vaccine is produced and purchased. Until then, the commitment remains a long-term liability and (depending on the perceived probability of the vaccine being developed) would be included in long-term projections of outlays.

But for the administration to sign the contract, it would need approval from Congress, and the measure granting this approval would score against the congressional appropriations ceiling within which budgets are set.

If other budget lines had to be reduced to accommodate a commitment within a fixed appropriations ceiling, the commitment would require changes elsewhere in the budget: current programs, delivering certain and immediate benefits, would have to be reduced to make way for the uncertain future benefits of the advance markets commitment. Such an approach would be unlikely to command political support.

But with sufficient political will, this can be overcome within the U.S. budget framework. One practical approach is for the authorizing legislation to be made outside the appropriations process, for example, by the Energy and Commerce Committee. In the best case, the congressional budget plan would explicitly accommodate the budget authority needed for the program. This might be reasonably straightforward to agree, because the budget authority needed for that committee would not compete with the authority needed for the Appropriations Committee, and the expenditure authorized would have no impact on outlay projections (over the time horizon of the projections) or on the deficit.

Even if Congress did not include the advance market commitment in the budget, the Energy and Commerce Committee could seek approval for the legislation later in the year. By bringing the legislation outside the Appropriations Committee, the focus of attention would be on the impact on the outlay projections (none), not on the budget authority needed. And congressional leadership might well agree to waive the budget ceilings in this instance.

There are other possible approaches to securing budget authority for the necessary legislation without competing with other more immediate spending priorities. If the Appropriations Committee felt that, for reasons of precedent, it would be preferable for the authority to be provided by an appropriations bill, Congress could budget for a one-off, ring-fenced bulge in the appropriations ceiling to accommodate the commitment. Given that the commitment would have no impact on outlay or deficit projections, a one-off change to the appropriations ceiling to accommodate the commitment would be relatively easy to defend.

We conclude that the treatment in the U.S. budget system is not straightforward, and approval will depend on there being sufficient political support for the proposal. But we also believe that this is a policy with broad bipartisan appeal, and that with some political leadership, it could secure the commitment necessary to navigate the budget process.

We are clear, however, that if there is political support for the idea, there is no technical obstacle that would prevent the U.S. government from making a long-term advance market commitment.

## The United Kingdom

The U.K. government, through the Department for International Development (DFID), could commit to an advance market within its existing budget mechanisms.

While there is no precedent in DFID for making legally binding commitments to procure products that do not yet exist, it has implemented innovative financing approaches that have similar characteristics. Examples include trust funds, endowments and provisions for guarantees, as well as statements of intent to provide long-term funding support for country programs. DFID has issued guarantees to a company operating on a capital aid project to meet the costs of certain disputed claims (£30 million). Other contingent liabilities on the books include the United Kingdom's share of callable capital at the International Bank for Reconstruction and Development (€5.5 billion) and government guarantees to international financial institutions for U.K. loans to dependent territories (£2.4 billion).

The International Development Act of 2002 empowered the Secretary of State to use “non-grant financial instruments including guarantees” in pursuit of the department's objectives. No further specific legislative authority is required for DFID to enter a commitment of the kind envisaged for an advance market.

### An advance market commitment in the U.K. budget

The scoring of expenditure in the U.K. budget is intended to closely follow private sector accounting rules. Under U.K. accounting rules, as set out in FRS 12,<sup>1</sup> the advance market commitment would be deemed to be an executory contract (that is, a contract in which both parties have not yet fully performed their obligations). Under FRS 12, obligations under contracts to make or take future supplies of goods and services do not normally need to be included on the balance sheet, and so do not give rise to contingent liabilities or require the body to take a provision.

The main exception is an “onerous contract,” in which the unavoidable costs of meeting the obligations under it exceed the economic benefits expected to be received from it. As seen in chapter 5, the economic benefits of the advance market commitment exceed the cost, so the commitment is not onerous and would not require DFID to include a contingent liability or provision in the balance sheet.

Because an advance market commitment would not have to be included on the department's balance sheet, there would be no need to make budgetary provision at the time the commitment was made, and there would be no short-term cost for DFID. If and when a vaccine was available and spending actually occurred, DFID would be required to meet the costs from within its budget granted by parliament. For a given expenditure limit, this would require lower spending elsewhere. (This is discussed in the box on budgetary tradeoffs later in this chapter.)

The U.K. government has chosen to base its overall fiscal framework, including targets for spending and the deficit, on national accounts measures. The expenditure would not be recorded in the U.K. national accounts until the government was actually buying vaccines.

### Other governments

We have not looked in detail at the arrangements for other governments, but we believe that the main donor countries could, if they chose, make an advance market commitment consistent with their normal legal and budgetary processes.

### The World Bank

The International Development Association (IDA) of the World Bank, which provides subsidized loans and grants, could in principle also be a sponsor of an advance market commitment.<sup>2</sup> But the normal operation of World Bank lending would need to be modified.

### Forward commitment

Sponsors would need to make a legally binding commitment, perhaps 10 or more years in advance of the likely spending. But the priorities for IDA loans and grants are usually set only over a five-year time horizon, and the World Bank has been reluctant to earmark specific sums for specific programs.

There does not appear to be any legal impediment to the World Bank's legally binding itself to provide IDA loans or grants to any member state that wants to purchase the vaccine under the advance market commitment. This would, however, be a departure from current practice—and may be thought to set unwelcome precedents for earmarking. However, in principle this would be a commitment different in character from other

earmarking proposals, because it is a contract to buy specific goods in the future, and so it may be possible to prevent it from setting a more general precedent.

### Loans or grants?

IDA loans, which are at below-market rates, carry an implicit subsidy of roughly 60%.<sup>3</sup> Since the bulk of the expense of purchasing the vaccine represents the cost of research and development, which is a global public good, it is appropriate for these costs to be met from grants rather than the 40% co-payment by developing countries implicit in IDA terms. This could be achieved through IDA if the World Bank were to increase the subsidy on the loans (reduce recipient countries' co-payment) by offsetting part of the vaccine purchase price through grants.

Alternatively, other donors—either private foundations or governments—could make a commitment to “buy down” IDA loans used to purchase vaccine. In other words, they could give the member money to repay the loan—as for Nigeria’s polio eradication campaign. One particularly attractive element of this buy-down approach is that governments or private foundations could deposit promissory notes with a World Bank trust fund now but would not need to make payments until appropriate vaccines were developed and IDA loans were extended for purchases. Where national budgeting rules are amenable, the commitment would not count toward government outlays until the funds were drawn.

### Additionality

For the commitment to be effective, the World Bank would need to agree in advance that IDA loans and grants for purchasing vaccines under the advance market commitment would be additional to the IDA allocation for the country using them. Otherwise, since countries are restricted in the value of IDA credits they can use in a single year, it is possible that developing countries would be reluctant to purchase vaccines, since this would use up a portion of their IDA allocation, which they might need for other purposes.

At present, all IDA is allocated to country programs. There is no procedure to set aside funds for global public goods. To ensure that IDA funding of purchases under an advance market commitment was genuinely additional, it would be necessary if and when a vaccine is developed to set aside some funds that were not taken from country allocations. Again, while there is no precedent for this, there are no legal obstacles to doing so.

## Foundations

Given that the advance market commitment is a straightforward contract, there are no legal or budgetary obstacles that would prevent private foundations from making an advance market commitment.

The budgetary implications for an endowment-based foundation are a bit different from the considerations for a government with indefinite tax revenues. An advance market commitment represents a claim on a portion of the endowment, which means that the money cannot also be spent in another way. But foundations invest the majority of their principal in any case. This principal, invested to earn a return for the foundation, would also serve as the asset underpinning the commitment—in effect, the foundation can put the same funds to work twice in the interests of the poor.

In the short run, before a vaccine is available, and provided that the foundation’s total commitment is less than the principal that the foundation plans to invest in any case, this commitment would have no effect on the foundation’s revenue or expenditures.

If and when the vaccine is produced, the foundation will, as a result of the commitment, be required to make co-payments toward the vaccine purchase. At this stage, the foundation may choose to divert spending from other priorities (especially where it expects to make savings as a result of the availability of the vaccine—as for the purchase of drugs or investment in R&D), to cut lower priority programs or to increase its total spending.

Some foundations have a policy against using resources to pay for current goods and services and to avoid undertaking open-ended commitments to meet current costs that should be the obligation of governments. The combination of the dual-price structure and co-payments by developing countries in the advance market commitment means that the donors’ contributions correspond to the incentives for commercial investment in R&D and the cost of scaling up large-scale production. The marginal cost of production of the vaccine, which foundations may as a matter of policy not wish to fund, is accounted for by the developing countries’ co-payments. So although the contract takes the form of the purchase of vaccines, because that is the best way to create the right incentives for effective and well targeted R&D, the contribution of donors is conceptually meeting the cost of the R&D and subsidizing scaling up production. It is therefore quite unlike making an open-ended and unsustainable commitment to meet future vaccine costs.

It would be particularly beneficial to the credibility of the advance market program for private foundations to be sponsors or co-sponsors of the commitment because:

- They have greater continuity of leadership and strategic focus, so they are perceived as less likely to change direction.
- They may be perceived to be less vulnerable to lobbying from special interest groups.
- They have a substantial asset base and no ability to legislate away their obligations, so their commitment is regarded as highly reliable.

## The Global Alliance on Vaccines and Immunization and Vaccine Fund

### The mandate of the Global Alliance on Vaccines and Immunization

The Global Alliance for Vaccines and Immunization (GAVI) is an alliance between the private and public sector, with the mission of saving children's lives and protecting people's health through the widespread use of vaccines. GAVI brings together governments in developing and industrialized countries, established and emerging vaccine manufacturers, nongovernmental organizations, research institutes, the United Nations Children's Fund (UNICEF), the World Health Organization, the Bill & Melinda Gates Foundation and the World Bank.

GAVI has a unique role in increasing resources allocated to the purchase and use of vaccines and in improving the way those resources are used. It focuses on areas in which no one partner can work alone effectively and to add value to what partners are already doing. GAVI's added value has been defined in four areas:

- Coordination and consensus-building.
- Funding support to countries, through the Vaccine Fund. Resources are provided to countries to purchase vaccines and other supplies and to support the operational costs of immunization.
- Innovation—examples include the country proposal and review process, performance-based grants for immunization services support, financial sustainability planning, the Data Quality Audit, Vaccine Provision Project and Accelerated Development and Introduction Plans.
- Advocacy and communications—particularly to inform decisionmaking among policymakers and donors on the

value of vaccination for reducing poverty and infant mortality in the developing world.

There is a strong fit between these four areas and the goals of an advance market commitment. Given their mandates, GAVI and the Vaccine Fund are natural partners in an advance market commitment. In particular, GAVI, or an alliance of members under its auspices, might be an appropriate forum for donors to reach a consensus about the approach, and agree on the details of the commitment. Commitments might then be made by donors directly or through guarantees to the Vaccine Fund, which is a member of GAVI.

The Vaccine Fund could become a sponsor of an advance market commitment, if it were underwritten by its donors to do so. Given the role of the Vaccine Fund in buying vaccines, there would be advantages in structuring financial arrangements to enable it to enter into advance market commitments. Depending on budgetary constraints on the part of the donors, this might take the form of direct financing or suitable (legally binding) guarantees from donors—for example, through the International Finance Facility for Immunization (IFFIm) initiative.

### The International Finance Facility

The U.K. Treasury has proposed an International Finance Facility (IFF) to accelerate progress toward the Millennium Development Goals by issuing bonds on international markets. If established, the IFF would:

- Create a financing mechanism that would provide up to an additional \$50 billion a year in development assistance until 2015.
- Lever additional money from the international capital markets by issuing bonds based on legally binding long-term donor commitments.
- Repay bondholders using future donor payment streams.
- Disburse resources through existing multilateral and bilateral mechanisms.

The IFF proposal has generated interest and support from emerging markets, developing countries, international institutions, faith communities, nongovernmental organizations and businesses.

### The International Finance Facility for Immunization initiative

There are discussions among DFID, the U.K. Treasury and GAVI to consider options for piloting the IFF approach through the

Vaccine Fund. A Working Group, including the Bill & Melinda Gates Foundation, GAVI and the Vaccine Fund, is looking at the technical case for this approach.

IFFIm is intended to create a framework in which:

- Donor funding for vaccines over the next 15 years is planned.
- On the strength of these plans, the initiative is able to program spending over a 10-year horizon.
- Funding for vaccines is therefore better planned, more predictable and delivered sooner.

There are several arguments for front-loading spending on vaccines in the way implied by using IFFIm:

- Having a quicker impact on immunization, thus reducing child mortality, reducing the burden of disease and accelerating economic growth.
- Providing incentives for vaccine producers to invest in production facilities and to develop new vaccines through greater market certainty or a short-term price top-up to allow producers to cover development costs earlier.
- Accelerating of new products through R&D and trials for new vaccines.
- Developing health systems with long-term capacity benefits.

In principle, these characteristics would enable the initiative to secure greater value with the same amount of donor funds, compared with the existing situation of allocating funds from one year to the next.

### Using IFFIm to implement an advance market commitment

Like the advance market proposal, IFFIm is based on the idea that by increasing certainty about their future behavior, donors can increase the productivity of their spending. The market for vaccines would be more efficient, providing vaccines to more people at a lower cost, if there were greater certainty of demand, which is presently hampered by unpredictable funding. A more reliable market would enable firms to invest more at every stage of the process, from scientific research, through clinical trials, to investment in production capacity. This would result in new vaccines becoming available more quickly and larger volumes being available more cheaply.

Because it will generate committed funding over 10 years, funds from IFFIm could implement an advance market commitment for new vaccines, such as for rotavirus and pneumococcus.

It might not be appropriate, however, for IFFIm to make a long-term legally binding commitment to vaccines not likely to be available over the next 10 years, as this will be outside its lifespan. There is thus a strong case for a group of donors to make a separate legally binding advance market commitment for vaccines for such diseases as malaria, tuberculosis and HIV, in addition to the proposed commitment to purchasing vaccines through IFFIm.

### An advance market commitment as a complementary financing mechanism for IFFIm

The IFFIm financial mechanism requires donors to provide pledges to a financial vehicle, which on the strength of those pledges can borrow in financial markets to rephase and commit that spending. But because of constraints on budget processes, financial accounting or limitations on legal powers, some donors may not be able to make a pledge of this kind.

The advance market commitment is a different kind of arrangement, taking the form of a long-term procurement contract. Most governments have ways to make long-term commitments of this kind, and there are budgetary procedures for this. It is therefore possible that some donors that could not contribute directly through the IFFIm financial mechanism would be able to make an advance market commitment for the purchase of vaccines such as rotavirus and pneumococcus. These commitments could then be taken into account in the overall planning of IFFIm. This provides an alternative way for donors to contribute to the overall IFFIm initiative, even if they are not yet able to contribute through the financial mechanism (figure 7.1 and box 7.1).

### Would sponsors pay twice?

Some sponsors with significant portfolios of direct funding of R&D may be concerned that they would end up “paying twice” for R&D on new vaccines: first, when they support R&D and basic science and again when they pay for vaccines under the advance market commitment.

This concern can usefully be put in context. First, the United States and other countries routinely support R&D through public sector and philanthropic programs, and accept that products that benefit from that investment will later be purchased at above marginal cost through Medicare and other public insurance programs. Second, the vast majority of the spending under the

advance market commitment—such as late-stage clinical trials, commercial development, regulatory approval through licensure and investments in large-scale productive capacity—currently receives very little support through push-funding mechanisms. So while the advance market commitment would stimulate some R&D in basic science and identification of candidates, the bulk of the revenues from an advance market commitment will cover costs that were incurred on activities that are, for the most part, outside the current scope of push funding. Moreover, the size of the advance market commitment can be set to reflect the extent of the contribution that is being made by push-funded R&D.

However, to the extent that there is duplication, in principle it would be possible to structure either push funding or the advance market commitment to prevent double payment. In practice, it would be very difficult to change the advance market payout according to the origins of the original investment, as this would:

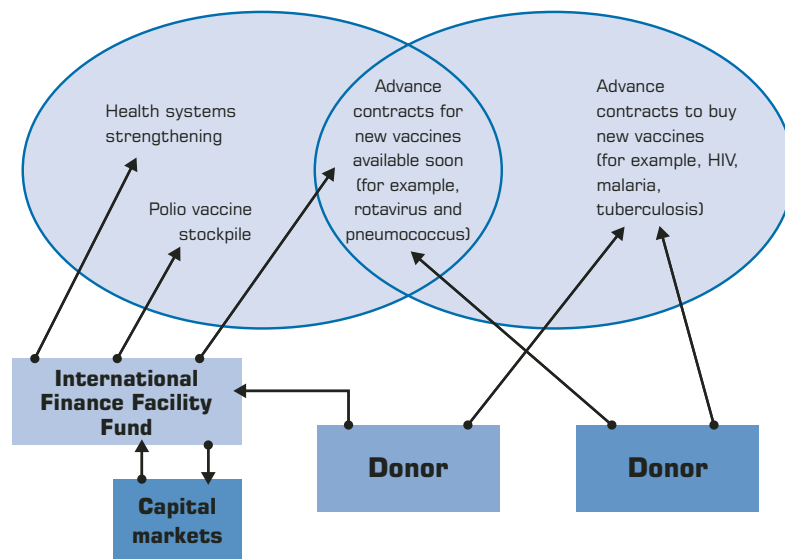
- Require the Independent Adjudication Committee to collect information about the costs, funding and institutional

and intellectual heritage of qualifying products that they would not otherwise have or need.

- Introduce a considerable element of discretion into the operation of the advance market commitment—which would lead to a level of uncertainty that could greatly diminish firms’ interest in investing.
- Distort the market for products once they are developed: in particular, sponsors might be inclined to encourage purchase of an inferior product just because it would incur a lower payout as a result of having had more push funding in the past; this would create a bias that might undermine the incentive to buy the best available vaccines when they are available.

By contrast, it might be quite straightforward to adapt push funding arrangements for the existence of an advance market commitment. For example, funders of research could explicitly take the existence of an advance market commitment into consideration when negotiating upfront support or milestone payments. This is done now for development of some products, when there

**Figure 7.1**  
Possible relationship between the International Finance Facility for Immunization initiative and advance market commitment





## Box 7.1 Is there a budgetary tradeoff?

If sponsors make an advance market commitment, will they need to make corresponding reductions elsewhere, for example in their direct support for R&D?

An advance market commitment would increase commercial investment in R&D, which in turn would increase the productivity of existing and future donor and philanthropic investments in R&D, for at least two reasons. First, there would be a larger and better-resourced scientific community working on the issues, which would benefit everyone engaged in that research. Second, there would be a much higher chance that scientific breakthroughs resulting from these investments will be followed through into the actual development and production of vaccines that deliver health benefits, increasing the value of the original investment. Given these complementarities, which increase the cost-effectiveness of push funding, an advance market commitment might make donors and foundations more likely to want to increase resources flowing in to push funding.

Resources are finite. However, in the **short term**, there is no need for a sponsor making an advance market commitment to reduce other spending because:

- Making an advance market commitment has **no impact on government spending** measures (because payments will be measured only when the goods and services are delivered, even if the commitment is legally binding); in the United States, where the commitment would fall within the appropriations ceiling, we have proposed ways in which the commitment could be made without reducing the funds that are appropriated for other foreign assistance priorities.
- For **private foundations**, the commitment represents a claim on the foundation's assets, but does not directly reduce resources available for spending today. (Indeed, most private foundations would not

be able to reduce current spending, because of the rule that they must spend 5% of their principal each year.)<sup>a</sup>

In the **long term**, however, when a vaccine is developed, the commitment will clearly require the sponsors to make payments, using funds that could otherwise have been used elsewhere. To the extent that the commitment represents additional net spending, other lower priority spending will have to be reduced to accommodate this. However, the effect of the commitment on future budget allocations is likely to be considerably less than the headline \$3 billion commitment, for three reasons:

- Sponsors would almost certainly spend significant sums buying a vaccine when it is developed anyway, even in the absence of making a commitment; this means the net cost of making a commitment is only the **additional price paid** under the guarantee compared with what would be charged without it.
- To the extent that the price paid initially under an advance market commitment is higher than donors normally pay for vaccines, the corollary is **permanently lower, sustainable vaccine prices more quickly**, as guaranteed by the producers under the advance market contract; thus the total future expected costs of buying vaccines may not be much higher than without a commitment; and their obligation will be strictly limited, unlike the present situation.
- The rapid development, production and distribution of vaccines would be likely to **save considerable costs elsewhere in development budgets** (such as purchasing of drugs, health care costs, R&D on these diseases), further reducing the net costs to donors.

This means that, while there is a long-term cost to the commitment that will have to be accommodated

## Box 7.1 (continued) Is there a budgetary tradeoff?

within future spending plans, the size of the additional spending that has to be accommodated as a result of the commitment is much less than it first appears. Depending on the nature of the donor's other spending plans and commitments, the net effect on the donor's budget in the future may be quite small. Furthermore, as shown in chapter 5, the expenditure to which the sponsor is committed is highly cost-effective, saving millions of lives at very low cost.

In conclusion, one of the attractive features of an

advance market commitment for potential sponsors is that there is no cash outlay until a vaccine is developed and used. This means that, in the short term, there is no direct budgetary pressure to reduce other spending when a commitment is made. On the contrary, a commitment would enhance the cost-effectiveness of current government and philanthropic funding by facilitating the more active engagement of the private sector, and by helping to turn research findings into useful products.

a. This is not true of public charities—which have a diverse funding base—such as the Vaccine Fund.

is a recognition that there might be a middle-income market. Moreover, funders could, if they choose, make it a condition of their grants that they receive a portion of intellectual property royalties received by institutions they fund. This is an area that merits further analysis than was possible within the context of the Working Group.

### Regulatory and procurement systems

#### Existing procurement systems

Current procurement and regulatory systems for developing world vaccines depend heavily, though not exclusively, on the WHO and UNICEF. While some large countries—such as China, India and Indonesia—produce and buy their own vaccines, UNICEF and the Pan American Health Organization (PAHO) Revolving Fund are the primary agents of vaccine procurement for developing countries. And for Vaccine Fund-eligible countries, UNICEF is the largest global procurement system.

UNICEF and the Revolving Fund purchase only vaccines that are “pre-qualified” by the WHO, the official body advising UN agencies on the suitability of specific vaccine products for purchase.<sup>4</sup> Not only do UN agencies purchase only products on the WHO pre-qualified list, but many countries in the developing world also use it as a basis for their own product licensing and selection.

UNICEF supplies vaccines to 40% of the world's children. It works with governments to estimate needs for specific vaccines and immunization supplies, based on existing immunization program coverage, birth rates, expected availability of funds and other factors. It then aggregates those estimates over countries for each type of product and issues tenders through an international competitive bidding process. In negotiating with suppliers, factors taken into account include prices and a firm's track record for quality and reliability; when possible, UNICEF also considers different suppliers of the same product, to maintain a competitive supply environment.

On the financing side, UNICEF maintains accounts that are funded by individual donors, such as bilateral aid agencies, as well as national governments. It then matches the available funding for a given country to the products procured. UNICEF facilitates delivery of products in-country, with UNICEF staff often helping to ensure that the products make it safely through customs and to appropriate storage depots.

In 2002 UNICEF purchased \$220 million worth of vaccines for use in 100 countries, representing 2 billion doses of vaccines.<sup>5</sup> The UNICEF procurement process has six steps: the decision to purchase a vaccine, development of specifications, identification of products meeting specifications (through WHO prequalification), publication of the tender, the adjudication and award process and receipt and release of the vaccine products.

Most of the countries of Latin America and the Caribbean procure their vaccines through the PAHO Revolving Fund, which began operation in 1979, to ensure a reliable supply of vaccines for the region's immunization programs.

PAHO in-country Expanded Programme of Immunization (EPI) advisors work with staff of the national immunization program to prepare orders on a periodic basis for specific vaccines and immunization supplies. Those requests are then aggregated at PAHO headquarters, which prepares tenders, negotiates prices, delivery dates and other contractual obligations and executes contracts. Payment is made to suppliers from the Revolving Fund. Then, when the products are delivered in-country, countries repay the Revolving Fund so that it is replenished for the next procurement round.

The Revolving Fund has been effective in coordinating procurement, increasing certainty for manufacturers and reducing prices. The number of countries participating has grown from 19 in 1979 to 34 in 2003; and the capitalization of the fund has grown from the original \$1 million in 1979 to \$20 million in 2003.

### The need for long-term contracting

During our discussions, it became clear that industry attaches a great deal of importance to the further development and widespread use of binding, enforceable, long-term contracts for vaccines for developing countries.

UNICEF's usual procurement award for most commodities is a "long-term arrangement." Under a long-term arrangement, UNICEF and manufacturers agree to the commercial terms for products, such as prices, delivery schedules and packing requirements, so that when an order is placed, it can be delivered rapidly. Past long-term arrangements have typically had a duration of one to two years, but they can last as long as five years. UNICEF also provides the vaccine industry with forecasts for vaccine requirements (in three- or four-year increments), but these are indicative only (that is, they do not form an enforceable contract).

The challenge UNICEF faces is compounded by the fact that it is buying vaccines for 100 countries each year and that it is constrained by public sector purchasing regulations. The procurement decision for such a large number of countries, and making up such a large part of the market, creates a different relationship between buyer and sellers than would a procurement contract for a single country.

During our industry consultations, the point was made repeatedly and forcefully that the lack of binding contracts, and particularly binding long-term contracts, makes it difficult for potential suppliers to invest in long-term productive capacity, which would increase supply, permit greater reliability of supply and reduce the price. The result is higher prices for developing countries, lower use and occasionally supply constraints.

Aware of this concern, UNICEF has moved toward longer contracts where possible. But it appears that UNICEF is constrained in its ability to sign multiyear purchase agreements because its funding streams are typically guaranteed annually. In a recent procurement, the Vaccine Fund was able to give UNICEF multiyear funding "in trust" to support a multiyear contract. This arrangement involved setting aside money for future payments.

Donors and UNICEF need to work together to establish whether there is some way to enable UNICEF to enter long-term contracts, either by amending the rules governing UNICEF's financial position or by finding other possible financing mechanisms, such as underwriting agreements or promissory notes.

This situation also highlights the urgent need for reliable demand forecasts. Initiatives like the Accelerated Development and Introduction Plans for pneumococcus and rotavirus vaccines are attempting to recognize the pivotal importance of having an accurate forecast of demand. Improving accuracy in this area would be an important contribution to reducing risk for all parties.

### Regulatory and procurement implications of advance market commitments

The existing system of regulation and procurement should be able to accommodate the existence of an advance market commitment with little or no adaptation.

The draft contract requires the supplier to obtain and maintain authorizations and approvals necessary to market and sell approved vaccines in the eligible countries, and to maintain appropriate qualification. It will be the responsibility of the Independent Adjudication Committee to determine whether a supplier of a qualifying product meets these conditions and is eligible for the price guarantee. In practice, the Independent Adjudication Committee would be expected to draw on the respected expertise of the WHO both to designate approved regulatory bodies for the

purposes of the contract (or more likely to designate the WHO to approve regulatory bodies) and to require WHO prequalification as a condition of eligibility to supply the vaccine under the contract. However, though the Independent Adjudication Committee would in practice want to rely on the existing capacity and expertise of the WHO, it would retain the final decision about whether a supplier met the conditions for the guarantee.

The price guarantee contract would provide top-up payments; these could be used in support of procurements made through UNICEF, the PAHO Revolving Fund or other qualified buyers supplying the public sector in eligible countries. Although, as discussed above, there might be advantages in these bodies being able to make more use of long-term contracting, it is not

strictly necessary for the implementation of an advance market commitment that these purchasers be able to do so. The reason for this is that the predictability of the advance market commitment is created by the Guarantee Agreement between the sponsors and the supplier, which guarantees sponsor co-payments, not by the terms of the actual procurement of vaccine.

While it is possible that some technical adjustment of existing procurement arrangements might be necessary to enable the main public sector buyers to buy the vaccines that are eligible for the advance market commitment, in principle the introduction of guaranteed co-payment envisaged by the advance market commitment should not cause any substantive difficulties for existing procurement processes.