

Vaccine Procurement Overview

KEY POINTS

- * Vaccine procurement is a vital function of immunization programs, with important implications for total program cost as well as reliable supply of appropriate products.
- * Countries can procure vaccines directly from manufacturers or through UNICEF or the PAHO Revolving Fund (for countries in the Americas). Most Gavi countries procure vaccines through UNICEF or the Revolving Fund. In most cases, countries can obtain lower prices through UNICEF or PAHO than by procuring directly. In some cases, policy and regulatory changes may be necessary before they can use these options.
- * Vaccine prices are affected by the volume of the order, the certainty of demand and of payment, and the duration of the supply contract, as well as by product characteristics and market competitiveness. Countries can influence some determinants of vaccine prices, but others are beyond their control.
- * Markets for many older vaccines are fairly competitive; middle-income countries can usually obtain these vaccines at prices similar to those paid by Gavi, at least when they procure through UNICEF or PAHO. Some newer vaccines are produced by only one or two multinational suppliers; these firms typically charge higher prices to countries with higher average incomes.

PROCUREMENT IS THE process of acquiring goods or services; it involves defining requirements and understanding markets and potential suppliers, as well as contracting and payment. This brief focuses on vaccine procurement, which accounts for a large share of immunization expenditure.

Vaccine procurement for national immunization programs should be guided by the same basic principles that should govern all public-sector procurement, including openness, fairness, and integrity. It should be based on clear criteria and follow well-defined procedures, consistent with each country's laws and regulations. According to the World Health Organization, the objective of vaccine procurement is "to receive products of assured quality at affordable prices in a timely manner, making it possible to optimize immunization programme performance."

Vaccine procurement differs in important respects from procurement of other health commodities. First, since vaccines are given to healthy children, safety and product quality must be an exceptionally

high priority in procurement decisions. Second, most vaccines have relatively few suppliers, which limits procurement options and in some cases gives suppliers considerable leverage. Third, lead times are typically long, from 8 to 24 months, so procurement decisions must be made well in advance to avoid stock-outs. Ensuring continuity of supply and sustainable prices can also be more important than for other commodities, given the importance of long-term financial planning and the disruption associated with product switches.

Assessing vaccine products also requires specialized expertise. For example, few governments have the resources to verify that suppliers based in other countries have met appropriate manufacturing standards. For this reason, the WHO system of vaccine prequalification, which assesses the acceptability of vaccines for purchase by UN agencies, fills an important need, and many countries require that vaccines procured for their national programs be prequalified. All of the vaccines recommended by WHO for routine immunization have suppliers with prequalified vaccines.

VACCINE PROCUREMENT OPTIONS

Governments have two broad options for procuring vaccines. They can procure directly from manufacturers, using their own processes—this is known as *self-procurement* or *direct procurement*. Alternatively, they can use an external procurement agent; the two most widely used options are UNICEF Supply Division and the Pan American Health Organization (PAHO) Revolving Fund. Countries that have domestic vaccine producers can choose to procure from those suppliers. (See the sidebar below.)

The vaccines financed by Gavi for national programs are generally procured through UNICEF or, for some countries in the Americas, the Revolving Fund. Most Gavi countries also use UNICEF to procure their co-financed share of Gavi vaccines, as well as vaccines that Gavi does not financially support, such as the BCG vaccine against tuberculosis. Some countries in the Americas use the Revolving Fund, while others procure these self-funded vaccines directly.

The Revolving Fund and UNICEF (in its procurement for Gavi countries) consolidate, or pool, demand from participating countries. The resulting large volumes,

DOMESTIC VACCINE MANUFACTURING

A few middle-income countries have well-developed vaccine industries that are capable of supplying a range of important vaccines at competitive prices. India, in particular, has several firms that export prequalified vaccines, which together account for a large share of vaccines used by low- and middle-income countries. Serum Institute of India now produces more vaccine doses than any other manufacturer in the world. Other countries have manufacturers that carry out certain phases of vaccine production.

Some countries procure only from domestic manufacturers as a matter of policy. Indonesia, for example, uses only vaccines produced by Biofarma, a state-owned manufacturer, in its public immunization program. India and China have relied on both state-owned and private-sector domestic producers for their national immunization programs, while Brazil procures from two state-owned vaccine manufacturers when an appropriate product is available.

Historically, countries have made several arguments for sustaining or encouraging national vaccine production. Domestic production is often seen as a way to ensure stable supply, since a national manufacturer can be required to give priority to the national immunization program. Supply security is certainly an important consideration, although relying on a domestic firm does not protect against supply disruption caused by a production failure. Locally produced vaccines are sometimes assumed to be cheaper than vaccines from foreign suppliers, but this is not always the case; established low-cost manufacturers such as those in India have important competitive advantages that domestic producers in other countries cannot easily match. Some countries support domestic production for reasons of industrial policy.

In considering procurement from domestic sources (and investing in establishing or expanding domestic production capacity), countries may have to balance procurement criteria such as quality, timely delivery, and price against other considerations, including industrial policy and perceived vaccine security.

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along with secure financing, provide substantial bargaining power and have historically resulted in lower prices than countries have been able to obtain on their own. (See Brief 12.)

After countries transition from Gavi support, they can continue to procure through UNICEF or self-procure. Gavi is working with UNICEF and vaccine manufacturers to ensure that countries that choose to use UNICEF and are able to meet UNICEF's requirements will not face sudden price increases. Several suppliers have committed to offering these countries continued access to prices similar to those Gavi pays for selected vaccines under specific circumstances and for a specified period.

Middle-income countries that have never been eligible for Gavi support can also procure vaccines through UNICEF (or, in the Americas, through the Revolving Fund). These countries are not included in the Gavi pool, however, and do not necessarily have access to the same prices paid by Gavi. UNICEF procures vaccines on behalf of 80 to 100 countries, while 41 countries use the Revolving Fund.

In practice, many countries take a mixed approach, using UNICEF or the Revolving Fund for some vaccines and procuring others directly.

CHOOSING A PROCUREMENT OPTION

In considering whether to self-procure or make use of UNICEF or the Revolving Fund, governments should consider several factors:

- **Legal restrictions.** Some countries have laws or regulations that restrict the use of external agents for procurement or forbid prepayment, which UNICEF requires.
- **Price.** UNICEF and the Revolving Fund can often obtain lower prices than countries can get for the same products on their own. Both UNICEF and the Revolving Fund charge a small percentage of the order value for procurement services.
- **Assured supply.** Some countries have had difficulty generating responses to tenders. Although UNICEF also struggles to ensure sufficient supply of

some vaccines, it is generally in a better position than individual countries to generate bids from manufacturers and manage supply challenges.

- **Control over payment terms.** UNICEF's prepayment requirement is an obstacle for some countries, although UNICEF offers short-term financing through its Vaccine Independence Initiative. (See Brief 13.)
- **Product choice.** Countries procuring directly have complete control over product specifications (although they will find more suppliers for some choices than others). UNICEF tries to accommodate country preferences but generally procures only prequalified vaccines. The range of products available through PAHO is somewhat more limited because this pooled procurement mechanism works best when product preferences are harmonized.
- **Development of procurement capacity.** In some countries, procurement is viewed as a government function that should not be "outsourced" except in exceptional circumstances. For these countries, the use of an external agent is a temporary expedient and the goal is to build national procurement capacity as quickly as possible.
- **Domestic production.** Countries that use only domestically produced vaccines or want to favor local producers typically self-procure.

STEPS IN THE PROCUREMENT PROCESS

Procurement begins with defining and quantifying needs. How many doses of which vaccines, with which characteristics, will the national immunization program need, and when will it need them? Good demand forecasting is critical to avoiding stock-outs and waste and getting the best possible prices from suppliers. Once vaccine needs are clearly defined, the program can identify potential suppliers.

Before approaching suppliers, the entity responsible for procurement should define a procurement strategy and process, with clear specifications and criteria for evaluating bids, consistent with national law and regulations. It can then solicit offers,

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evaluate bids, and choose one or more suppliers. Finally, it can arrange for contracts to be signed and vaccines to be delivered.

WHO offers guidance on vaccine procurement on its website and has produced a comprehensive manual on public-sector vaccine procurement. WHO and UNICEF also offer technical assistance on vaccine procurement, and UNICEF has an online platform for facilitating peer-to-peer exchange called the Vaccine Procurement Practitioners Network.

VACCINE MARKETS AND PRICE DETERMINANTS

Markets for different vaccines vary considerably, with implications for vaccine prices and supply. Three important newer vaccines—human papillomavirus (HPV), pneumococcal conjugate, and rotavirus—are currently produced by only two firms, which therefore have considerable control over prices. For these vaccines, multinational firms have moved toward systems of “tiered pricing” in which prices vary by country income level. Under these pricing regimes, non-Gavi-eligible middle-income countries are charged more than Gavi countries but less than high-income countries.

Some older vaccines, including those against yellow fever and measles, also have few suppliers. Nonetheless, these vaccines, which are supplied primarily by manufacturers in middle-income countries, are available through UNICEF at a uniform price, regardless of country income. Notably, these vaccines, unlike those for which tiered pricing is imposed, do not have important markets in high-income countries. (High-income countries use the measles-mumps-rubella vaccine instead of the measles vaccine.)

Finally, some vaccines have enough suppliers to ensure that markets are competitive and individual manufacturers have less influence over prices. In these markets, prices are driven to a substantial degree by manufacturing costs, and middle-income countries with efficient and transparent procurement can generally obtain prices similar to those paid

by Gavi. The market for pentavalent vaccines, for example, has become highly competitive, with eight prequalified suppliers as of 2016, and non-Gavi countries procuring through UNICEF can expect to pay roughly the same prices as Gavi countries.

Vaccine prices are influenced by a number of factors besides the cost of manufacturing and the country income tier. In general, larger volumes, longer-term contracts, greater certainty of demand, and timely payment bring lower prices. For vaccines that have large markets in high-income countries, the availability of manufacturing capacity in excess of what is needed to supply demand in these markets can also affect prices, especially for middle-income countries. UNICEF makes public the prices that it pays for the vaccines it procures for Gavi, and it plans to do the same for its procurement on behalf of non-Gavi countries. The Revolving Fund publishes weighted average prices. Until recently, however, little information has been available on prices and contract terms obtained by self-procuring countries. A new WHO initiative, the Vaccine Product, Price and Procurement (V3P) Project, seeks to fill this gap by collecting and disseminating information on vaccine prices and other aspects of procurement, with a focus on middle-income countries.

SOURCES AND FURTHER READING

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