

Policy Brief



Procurement and Pricing of New Vaccines for Developing Countries

Introduction

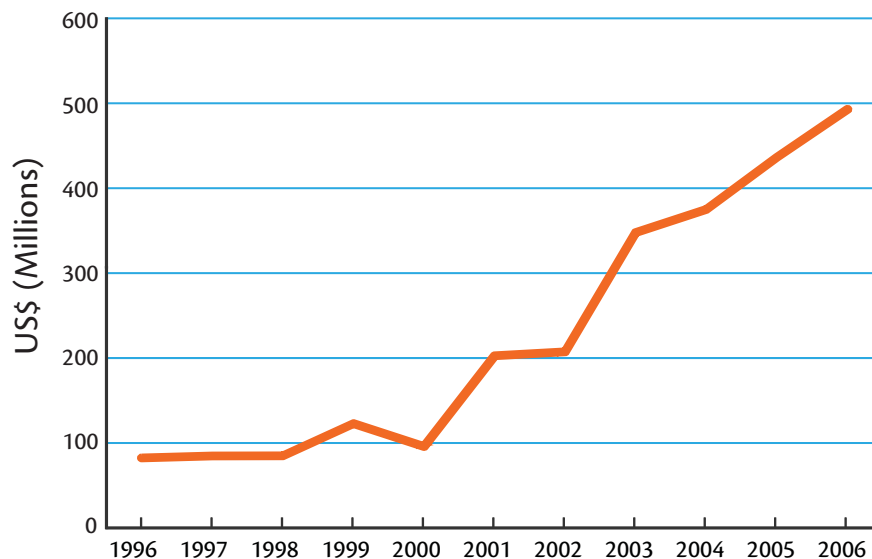
Several new vaccines with the potential to bring large public health benefits to developing countries have recently come to market. These vaccines, which include the rotavirus, pneumococcal conjugate, and human papillomavirus (HPV) vaccines, have entered markets in industrialized countries at high prices, in some cases over US\$ 100 a dose, and there is concern that developing countries may be unable to afford them. Manufacturers have indicated that they will sell these vaccines at substantially reduced prices to the public sector in developing countries,¹ but, with the exception of Merck's rotavirus vaccine, which is now offered through the Pan American Health Organization's (PAHO) Revolving Fund, these prices have not yet been determined.

While pharmaceutical companies may announce private sector prices once products are registered in a particular country, prices for large-scale public-sector immunization programs are determined

during the procurement process, which is handled by governments, the United Nations Children's Fund (UNICEF) Supply Division, and the PAHO Revolving Fund. In some cases these prices remain confidential. In responding to tenders (proposals to deliver a certain quantity at a certain price), manufacturers take into account many factors, including: exact specifications, timing and size of the order, payment terms, overall demand and supply, cost of production, income level of the recipient countries, and competitive considerations.

This brief explains how vaccines are purchased for the public sector in developing countries, with a focus on the roles of UNICEF and PAHO, and the GAVI Alliance, which is the major source of vaccine financing for the poorest countries and works closely with UNICEF. Although a full analysis of the factors that influence prices is beyond the scope of this brief, it will describe the procurement process during which prices emerge and review some recent data on vaccine prices in industrialized and developing countries.²

Figure 1. Value of UNICEF Vaccine Purchases, 1996-2006



Source: (UNICEF, 2006)

Vaccine Procurement by the UNICEF Supply Division

The UNICEF Supply Division is the major procurer of vaccines for low-income countries, purchasing vaccines on behalf of 80-100 countries annually using funds from aid agencies, GAVI, nongovernmental organizations (NGOs), foundations, international financial institutions, and the countries themselves.

UNICEF's vaccine procurement has grown steadily over the past three decades, and in 2006 amounted to US\$ 493 million for over 3 billion doses. Growth has been particularly rapid since 2000 (Figure 1), in part because of financing from the GAVI Fund for new and more expensive vaccines. GAVI financing accounted for 24%, by value, of the UNICEF Supply Division's purchases of vaccines and injection safety equipment in 2006. Increased purchases of polio vaccine for the Global Polio Eradication Initiative, which accounted for 57% of total UNICEF Supply Division vaccine procurement, have also contributed.

The Supply Division estimates that it procures roughly 40% of the global volume of vaccine doses. In dollar terms, however, this amounts to only 5% of the world vaccine market because it pays much lower prices than those paid by industrialized countries. Furthermore, industrialized countries tend to use more expensive vaccines, for example acellular rather than whole-cell pertussis and inactivated rather than live-attenuated polio vaccines.

The UNICEF Supply Division procures only vaccines that have been prequalified³ by the World Health Organization (WHO) (Table 1). As of June 2008, 23 vaccines (including combinations) from 21 manufacturers were on the prequalified list. UNICEF procured vaccines from 18 countries in 2006 (Table 2). Five of these—Brazil, Cuba, India, Indonesia, and Senegal—were low- and middle-income countries, which together accounted for about 36% of the total value of UNICEF's vaccine procurement. Among developing countries, India is the most important supplier, with four manufacturers contributing about 34% of UNICEF's total supply. Belgium, where GlaxoSmithKline's (GSK) vaccine plants are located, is the largest source of

Table 1. Vaccines prequalified by WHO and number of manufacturers (June 2008)

Vaccine	# of Prequalified Manufacturers	Vaccine	# of Prequalified Manufacturers
BCG	4	Measles	4
DT	4	Meningococcal	3
dT	3	MMR	3
DTP	4	MR	2
DTP-HepB Combined	5	mOPV1	1
DTP-Hib Combined	3	OPV	6
DTP-HepB + Hib	1	Rabies	3
DTP-HepB - Hib	1	Rotavirus	1
Hepatitis B	9	Rubella	1
Hib	4	TT	6
Inactivated Oral Cholera	1	Yellow Fever	3
IPV	1		

A complete list of acronyms can be found on page 6. Table source: (WHO 2008)

vaccines for the UNICEF Supply Division, with a 35% share. While the number of manufacturers who provide vaccines through UNICEF is quite large, it is worth noting that three suppliers account for more than 75% of the total, and six for almost 95%.

Given the small number of suppliers for many vaccines, the UNICEF Supply Division has long been concerned about the fragility of vaccine supply for developing countries. Several vaccines, including rotavirus and inactivated polio (IPV), currently have only one prequalified manufacturer. There are many reasons for the limited number of suppliers, including mergers of manufacturers and the historically relatively low profit margins for vaccines compared to other pharmaceuticals. In light of this situation, the Supply Division has tried to use its procurement process to promote vaccine security—the uninterrupted, sustainable supply of affordable vaccines of assured quality. Instead of buying from

Table 2. Suppliers of vaccines and other biologicals to UNICEF by country and amount (2006) (only orders of US\$ 100,000 or greater are included)

Supplier	Country	Value US\$	% of Total
GSK	Belgium	171,469,155	35.0
Panacea Biotec	India	124,281,631	25.3
Sanofi Pasteur	France*	83,967,735	17.1
Serum Institute of India	India	38,171,454	7.8
Novartis	Italy	21,964,330	4.5
Berna Biotech	Switzerland	19,561,981	4.0
LG Life Sciences	Korea	8,598,603	1.8
Shantha Biotechnics	India	5,667,721	1.2
Twelve other suppliers from twelve countries, each contributing less than 1% of the total			3.3
Total (US\$)		490,680,762	100.0

*This number includes some pharmaceuticals as well
Table source: (UNICEF 2006)

just one manufacturer at the lowest possible price, which could have unacceptable repercussions if that manufacturer decided to withdraw from the market or had a major batch failure, the UNICEF Supply Division tries whenever possible to procure each vaccine from several manufacturers. PAHO and some industrialized countries also follow this approach. In support of this policy, the UNICEF Supply Division issues tenders that include selection criteria that go beyond price considerations, including geographic location.

Countries or donors pay for vaccines upfront by depositing the needed funds with UNICEF. The Supply Division places the purchase order and pays the supplier upon delivery. The Supply Division provides manufacturers with demand forecasts and enters into multi-year supply arrangements, an important consideration given the long lead times required for vaccine production.

The UNICEF Supply Division procures vaccines for most of the 72 low- and lower-middle-income countries that are eligible for support from

GAVI.⁴ Five of the six GAVI-eligible countries in Latin America and the Caribbean (Bolivia, Cuba, Guyana, Honduras, and Nicaragua) use GAVI resources but procure through PAHO’s Revolving Fund. The remaining GAVI-eligible country in that region, Haiti, receives GAVI-funded vaccines through the UNICEF Supply Division. The UNICEF Supply Division’s vaccine tenders list the recipient countries and state whether they are GAVI-eligible.

Countries that are not GAVI-eligible can still ask the UNICEF Supply Division to procure on their behalf, either because they are having problems in procuring certain vaccines or because they hope to obtain lower prices. The Supply Division provides this service, but manufacturers are free to quote a different price from that which they offer to GAVI-eligible countries.

The UNICEF Supply Division charges a handling fee of 4-4.5% for traditional vaccines and 3-3.5% for new vaccines, depending upon the income level of the country. Purchases with GAVI financing are handled differently: GAVI pays a fixed fee to the UNICEF Supply Division for its procurement work.

UNICEF has not yet procured any of the three newest vaccines. As of March 2008, it was preparing a request for proposal (RFP) for the pneumococcal conjugate vaccine, which will be issued as soon as the vaccine is prequalified by WHO. Although the rotavirus vaccine has been prequalified, there has not yet been demand for procurement by UNICEF; as of March 2008, the only GAVI-eligible countries that have committed to introducing rotavirus vaccine are in Latin America and are procuring through PAHO. UNICEF will not begin procuring HPV vaccines until WHO has issued guidelines on their use⁵ and prequalified the manufacturers, and until demand is estimated and funding committed. The Supply Division will release average prices for these vaccines once it has carried out its procurement.

Vaccine Procurement by PAHO’s Revolving Fund

PAHO established the Revolving Fund in 1979 to help assure stable supplies of vaccines at affordable

prices for national immunization programs in its region. More specifically, the Fund's purpose was:

to ensure better and more efficient national planning; to avoid disruptions in vaccine supply and funding for their purchase; to allow purchase of vaccines in local currencies, which avoids delays and currency loss exchanges; to consolidate vaccine orders for economies of scale, translating into lower prices for countries; to assure vaccine quality; and to develop contracts with suppliers so that urgent orders can be delivered on short notice, while assuring suppliers of firm orders so they can plan production in advance (Andrus et al. 2007).

Like UNICEF's Supply Division, the Revolving Fund is a mechanism for pooled procurement. It has grown rapidly and played an important role in facilitating adoption of new vaccines such as Haemophilus influenza type b (Hib) and pentavalent (a combination of five previously licensed vaccines). In 2007, its purchases totaled about US\$ 225 million for 37 member states and territories in the region. The top four purchasers by value were Brazil, Argentina, Colombia, and Venezuela. PAHO consolidates vaccine requirements from countries in its region and solicits bids by international tender. PAHO pays suppliers directly, and countries in turn repay the Fund within 60 days after the vaccines are received, adding a 3% fee, freight, and insurance.

There are exceptions to this model. The Fund's capitalization is not adequate in some cases to cover purchases on behalf of the largest countries (Brazil and Argentina, for example) or expensive orders of new vaccines. In those cases, the Revolving Fund requires that the countries pay PAHO in advance.

Countries in Latin America and the Caribbean have the choice of using the Revolving Fund or purchasing vaccines directly. In recent years, Mexico and Chile have purchased vaccines directly. Brazil has purchased what it can from its own national manufacturers and the rest through the Revolving Fund. Several countries purchased the new rotavirus vaccine directly from GSK before WHO prequalification and thus before the Revolving Fund could procure it. Now that the GSK vaccine is prequalified, PAHO's Revolving Fund is purchasing it at

a price of US\$ 7.50 per dose, about a tenth of the price being paid for Merck's rotavirus vaccine in the US. PAHO reports that Venezuela now plans to buy the GSK vaccine through the Revolving Fund. However, Brazil will continue to purchase it directly because it has a technology transfer agreement with the manufacturer.

The objectives and methods of PAHO's Revolving Fund and UNICEF Supply Division's are broadly similar. Perhaps the most important difference is that PAHO's clients are almost entirely middle-income countries, according to the World Bank's criteria, while the UNICEF Supply Division's clients are primarily low-income countries.⁶ (Haiti is the only country in Latin America and the Caribbean that is currently classified as low-income, although several lower-middle income countries in the region are eligible for GAVI support.) Nonetheless, many countries in the region struggle with major problems of poverty and inequity despite their somewhat higher average incomes. In fact, the Latin America and Caribbean region has one of the highest rates of income inequality, according to the World Bank (Lopez et al. 2008).

A second important difference is that purchases by the Revolving Fund are financed primarily by national budgets, while UNICEF Supply Division purchases are financed mainly by donors.

Third, PAHO enters into annual contracts with manufacturers, while the UNICEF Supply Division makes multi-year arrangements. This is because PAHO member countries budget on an annual basis and cannot make commitments longer than a year. Donor funding commitments for vaccines through UNICEF typically last several years.

The GAVI Fund has financed vaccines both through UNICEF's Supply Division and through PAHO's Revolving Fund. Finally, both the UNICEF Supply Division and PAHO have historically procured at fairly similar prices.⁷

Direct Purchase by Developing Countries

The governments of many developing countries regularly purchase vaccines for their immuniza-

Table 3. Prices of selected vaccines for the United States (public and private), UNICEF (for GAVI-eligible countries) and the PAHO Revolving Fund

Vaccine	U.S. price per dose 2008			2008 weighted prices (multiple manufacturers)	
	CDC (public)	Private	Manufacturer	UNICEF for GAVI	PAHO
HepB recombinant pediatric	\$9.50	\$21.37	GSK	\$0.27	\$0.25
DTP-Hib	\$26.88*	\$42.89	Sanofi Pasteur	\$3.16	n/a
DTP-HepB-Hib 1 dose, liquid	n/a			\$3.60	\$3.95
Hib Lyophilized 1 dose	n/a			\$3.35	\$3.35
Pneumococcal 7-valent	\$66.44	\$78.44	Wyeth/Lederle	n/a	n/a
Rotavirus	\$57.20	\$69.59	Merck	n/a	\$7.50
HPV	\$100.59	\$125.29	Merck	n/a	n/a

*The price is for DTaP-Hib, which is a more expensive vaccine than DTP-Hib.
Source: (CDC 2008); (UNICEF 2008); (PAHO 2008)

tion programs directly from manufacturers, using their own resources. They are of course not required to wait for WHO’s recommendations⁵ and prequalification. Mexico, for example, is already procuring pneumococcal conjugate vaccine for its national immunization program. But most countries do rely on WHO guidance and prequalification before considering a vaccine for their immunization programs.

Countries that purchase vaccines directly issue competitive tenders or ask for price quotations, or in some cases order from their own state-owned manufacturers. Vaccine procurement requires specialized skills in forecasting vaccine requirements to avoid shortages, preparing appropriate specifications in bidding documents, and checking and recording vaccine quality. WHO and UNICEF’s Supply Division assist countries to strengthen their vaccine procurement systems. There is no database that compares the prices that countries get from direct public sector procurement with the UNICEF Supply Division and PAHO Revolving Fund prices.

GAVI’s Role in Procurement

Although the GAVI Fund finances vaccine purchases, it has no direct role in procurement. However, it established the Hib and Hepatitis B (HepB) Procurement Reference Group to work closely with the UNICEF Supply Division on the 2007-2009 procurement of these vaccines. The intent was to ensure GAVI’s input on the

supply strategy and to increase the transparency and accountability of the procurement process to GAVI, under strict confidentiality. GAVI has subsequently established a Procurement Reference Group for the procurement of pneumococcal and rotavirus vaccines, and may do the same for HPV.

Vaccine Price Differentials between Industrialized and Developing Countries

Industrialized countries pay much more for vaccines than UNICEF and PAHO’s Revolving Fund. It is reasonable to assume that new vaccines will eventually also be available to UNICEF and the Revolving Fund at substantially discounted prices, but historical price differentials vary substantially among vaccines and it is not possible to predict developing country prices from the prices manufacturers receive in the high-income countries. In both industrialized and developing countries, the public sector gets better prices for vaccines than the private sector.

Table 3 shows the 2008 prices for selected vaccines paid by the US Centers for Disease Control and Prevention (CDC), the US private sector, the UNICEF Supply Division purchasing on behalf of GAVI countries, and the PAHO Revolving Fund. In all cases, the US public sector price per dose is substantially lower than the US private sector price. UNICEF Supply Division and PAHO Revolving Fund prices are much lower than US prices and similar to each other for the vaccines

shown. For example, UNICEF and PAHO obtain HepB vaccine (in a single dose presentation, at low volumes) at an average price of about US\$.25/dose, or less than 3% of the CDC price. The ratio of CDC to UNICEF prices for DTP-Hib is smaller but still almost eight-fold.

The CDC price for Merck's rotavirus vaccine is US\$ 57 per dose. As mentioned earlier, the UNICEF Supply Division has not yet procured rotavirus vaccine but PAHO's Revolving Fund is offering the GSK rotavirus vaccine at US\$ 7.50/dose in 2008, or about 13% of the US CDC price. The US private sector price for Merck's HPV vaccine Gardasil® is US\$ 125 per dose, while the CDC price is US\$ 101 a dose. UNICEF Supply Division and PAHO Revolving Fund prices for HPV vaccines have not yet been determined.

Conclusions

Together, UNICEF's Supply Division and PAHO's Revolving Fund procure vaccines on behalf of the majority of developing countries. By consolidating the vaccine requirements of many countries these "pooled procurement" mechanisms allow suppliers to bid on much larger quantities with assured and timely payment; by purchasing vaccines from more than one supplier whenever possible, they aim to ensure a sustainable supply.

The GAVI Fund, which finances vaccine purchase for low-income and some middle-income countries, does not procure vaccines itself, although it provides input to UNICEF on the procurement of new vaccines through the Procurement Reference Groups.

Public sector prices for vaccines are established during the procurement process. Procurement involves competitive bidding, although the limited number of manufacturers for many vaccines and the desire to avoid reliance on a single supplier limit price competition in some cases. Nonetheless, UNICEF and PAHO have historically obtained vaccines at deep discounts compared to the public and private sector prices in industrialized countries. Less is known about prices obtained by developing country governments that procure directly from manufacturers, as these data are not systematically collected.

The price PAHO is paying for the new GSK rotavirus vaccine suggests that PAHO and UNICEF will continue to receive substantial discounts from industrialized country prices for new vaccines. But it is not yet clear how large those discounts will be for other new vaccines like the pneumococcal conjugate and HPV vaccines or whether the discounts will be sufficient to allow widespread adoption by developing countries of these new, more expensive vaccines. The uncertainties are particularly great for HPV vaccines, which have not yet been recommended or prequalified by WHO and which have yet to receive final approval for GAVI funding. Price, along with the availability of external financing from GAVI and other sources, is likely to be a critical factor in determining whether developing countries adopt HPV vaccines. Yet the price of HPV vaccines for low- and middle-income countries may not be known until PAHO and UNICEF begin to procure them, perhaps in 2009.

Acronym List

BCG	Bacillus Calmette-Guérin
CDC	Centers for Disease Control and Prevention
DT	diphtheria
DTP	diphtheria, tetanus and pertussis
GNI	gross national income
GSK	GlaxoSmithKline
HepB	Hepatitis B
Hib	Haemophilus influenzae type b
HPV	human papillomavirus
IPV	inactivated polio vaccine
MMR	measles, mumps, and rubella
MR	measles-rubella
NGO	nongovernmental organization
OPV	oral polio vaccine
PAHO	Pan American Health Organization
RFP	request for proposal
SAGE	Strategic Advisory Group of Experts
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Endnotes

¹ For HPV vaccines, GSK has stated: “Tiered pricing is a fundamental part of GSK’s vaccine business model and has been used for more than 20 years. As with its other vaccines, GSK will provide its cervical cancer vaccine at preferential prices to low income countries. The price for these countries will be determined by volumes, the length of time of a contract and the guaranteed number of doses to be purchased by supranational organizations. The higher the volume, the longer the contract, and the greater the guaranteed number of doses, the lower the price.” (GSK 2007) For its part, Merck has stated “Merck is pursuing a systematic approach to the global introduction of two of its vaccines, ROTATEQ® (rotavirus vaccine, live, oral pentavalent) and GARDASIL®, and is committed to making both vaccines available to developing world nations at dramatically lower prices at which Merck will not profit” (Merck 2007).

² Note on sources - This brief draws on data from several sources: UNICEF Supply Division’s Annual Report for 2006 for information on suppliers and the volume and value of procured vaccines; CDC, PAHO, and UNICEF’s websites on prices; WHO’s website on prequalified manufacturers and vaccines; GSK and Merck press releases on tiered pricing; and interviews with staff working on PAHO’s Revolving Fund and staff in the UNICEF Supply Division.

³ Prequalification is a WHO-led process to determine if vaccines from particular manufacturers are acceptable for purchase by United Nations agencies.

⁴ Countries are GAVI-eligible if they had a per capita gross national income (GNI) of less than US\$ 1,000 in 2003.

⁵ To help countries determine whether, and under what conditions, to adopt new vaccines or use existing vaccines, the WHO periodically issues “position papers” which are reviewed and endorsed by the Strategic Advisory Group of Experts (SAGE). SAGE is likely to formally consider HPV vaccines at its meeting in November, 2008.

⁶ As of July, 2007, Haiti was the only country in Latin America and the Caribbean classified by the World Bank as low-income. Another 14 countries were classified as lower-middle-income (Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Paraguay, Peru, and Suriname). All the other countries in the region were classified as upper-middle-income

or high-income. GAVI-eligible countries in the region include only Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua.

⁷ UNICEF publishes its prices on the web. PAHO publishes its prices annually in the February issue of its immunization newsletter, which is also on the web. Price comparisons can be made from these sources.

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