

THE WORLD MEDICINES SITUATION 2011

PROCUREMENT OF MEDICINES

Todd Dickens

PATH, Seattle Washington, USA



**World Health
Organization**

GENEVA 2011

The World Medicines Situation 2011

3rd Edition

This document has been produced with the financial assistance of the Department for International Development (DFID), UK, and the Government of the Netherlands. The views expressed herein are those of the authors and can therefore in no way be taken to reflect the official opinion of the Department for International Development (DFID), UK, or the Government of the Netherlands.

For additional information please contact
edmdoccentre@who.int

© World Health Organization 2011

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

The named authors alone are responsible for the views expressed in this publication.

SUMMARY

- Public sector health-care procurement systems can play an important role in helping countries achieve the Millennium Development Goals.
- Public sector procurement of medicines in developing countries occurs mainly at two levels – the national level and the international level – with multilateral agencies playing an increasingly significant role. However a number of countries have chosen to decentralize their national procurement process as part of health sector reforms or in an effort to meet local needs through increased local involvement, accountability and flexibility.
- At the national level, developing countries are faced with increasing tasks and responsibilities for procurement of quality medicines, but often have limited financial resources, procurement capacity, and regulatory capacity for meeting these obligations.
- At the international level, efforts by bilateral donor and multilateral agencies to address these limitations and support access to medicines include: new funding, procurement, and pricing mechanisms; supporting prequalification systems for selected medicines to address limited quality assurance capacity at the national level; and strengthening country procurement systems.
- There is increased global recognition of the continuing need to strengthen developing country health-care procurement systems through a comprehensive, system-wide approach to capacity building.

1.1**BACKGROUND/INTRODUCTION**

Systemic and operational challenges still exist in national-level public sector health-care procurement.

This chapter looks at public sector procurement of medicines. The procurement process is one of several critical, interrelated components of the public sector health-care supply system. These components include product manufacturing, product selection, product quantification, financing, regulatory control, quality assurance, distribution and service provision.¹ In 2005, the Organisation for Economic Co-operation and Development (OECD) noted that “Effective and efficient public sector procurement systems are essential to the achievement of the Millennium Development Goals and the promotion of sustainable development.”⁽¹⁾ The chapter outlines the current situation in public sector health-care procurement, identifying some of the common financial, policy and operational constraints that exist and the efforts that have been made at the national and international levels over the past decade to address them. While new funding, procurement and pricing mechanisms implemented by multilateral agencies and donors have improved public sector access to medicines, significant systemic and operational challenges still exist in national level public sector health-care procurement. Addressing these challenges will require strong commitment at the national government level, and continued multilateral agency and donor engagement and support, including capacity building that is harmonized and conducted on a system-wide basis.

1.2**CURRENT SITUATION****1.2.1****Procurement models and methods**

The majority of public sector health-care procurement occurs mainly at two operational levels – at the national/country level through the use of different procurement models, and at the international level through the funding mechanisms and procurement activities of multilateral agencies and bilateral donors.

1.2.1.1**National level procurement**

A number of different procurement models are used by developing country governments for procuring medicines and health commodities. The more common procurement models include:

- **Centralized procurement.** At the national level, the traditional model for public sector health-care procurement has been one in which a centralized government procurement agency (e.g. a central medical store) or a government procurement unit under the ministry of health is tasked with the responsibility for procuring consolidated national health-care requirements on the local and international market.
- **Parastatal organization or autonomous supply agency.** These are similar to central medical stores in that the procurement activity is centralized. A parastatal organization is owned or governed wholly or partly by the government, but has been granted autonomy to develop its own financial and procurement regulations. The Kenya Medical Supplies Agency (KEMSA) is one example of a parastatal organization. An autonomous supply agency also performs a centralized procurement function but is managed by an independent agency reporting to the government. The Medical Stores Depot (MSD) in the United Republic of Tanzania is an example of an autonomous supply agency. Both organizations are overseen by a board of directors that includes non-government representatives (2).

¹ In this chapter, the discussion of public sector health-care procurement includes procurement of pharmaceuticals, medical devices and other health products in the public sector.

The procurement method chosen depends on national policies and regulations, funder requirements, procurement expertise available, management capacity, quality assurance capabilities and product price.

- **Decentralized procurement.** A growing number of countries have chosen to decentralize their national procurement process as part of health-sector reforms or in an effort to meet local needs through increased local involvement, accountability and flexibility. Decentralized procurement devolves varying degrees of procurement responsibility from the national level to the regional, district or municipal levels (2,3,4).
- **Procurement agents.** Often used when government procurement capacity is limited or in response to funder requirements, there are several types of procurement agencies that provide medicines and health-care commodities. These include UN agencies, such as the United Nations Children’s Fund (UNICEF), the United Nations Development Programme (UNDP) and the United Nations Population Fund (UNFPA), and international nongovernmental supply agencies, such as the IDA (International Dispensary Association) Foundation and Imres. In addition to sourcing products for sale to public-sector agencies, the UN agencies involved offer reimbursable procurement services. They have also established framework contracts with suppliers that can allow for shorter procurement lead times. Procurement agents typically charge a handling fee for their services, which can range from 3% to 10% of the value of the goods procured. There are also private-sector commercial groups, such as Crown Agents and Charles Kendall, that provide procurement services at a negotiated contract price.

The public-sector procurement models discussed above use several different procurement methods to obtain medicines and health-care commodities. The more common methods include:

- **Competitive bidding.** This process uses standardized public sector procedures for high-financial-value transactions when there is more than one potential supplier. The competition engendered through this method is designed to elicit favourable prices. The three predominant types of competitive bidding include International Competitive Bidding, Limited International Competitive Bidding and National Competitive Bidding.
- **Small-scale competition.** Used for low-financial-value transactions, this method is also referred to as shopping and includes direct procurement. Offers are requested from suppliers and prices may be negotiated.
- **Sole-source procurement.** Under this method, contracts are issued without competition in cases when only a single supplier is available or when required to address an emergency situation (5).

The use of a particular procurement method is determined by factors such as national procurement policies and regulations, funder requirements, procurement expertise, management capacity, quality assurance capacity, and the impact on product price.

1.2.1.2

Regionally-focused pooled procurement

In addition to the public-sector health-care procurement that occurs at a national level, there are a few established, regionally-focused pooled procurement models that provide procurement services for member countries. These include the Pan American Health Organization’s (PAHO) Expanded Program on Immunization (EPI) Revolving Fund for vaccines and the PAHO Strategic Fund,¹ the Organization of Eastern Caribbean States/Pharmaceutical

¹ See PAHO web site http://www.paho.org/english/hvp/hvi/revol_fund.htm for additional information on the Revolving Fund for Vaccines.

Procurement Service (OECS/PPS),¹ and the Gulf Cooperation Council group-purchasing programme. These agencies pool member product requirements, establish financing mechanisms (as in the case of PAHO's and OECS/PPS's revolving funds), adhere to a prequalification process, and promote secure and timely payment arrangements that minimize suppliers' risk, all of which help to ensure timely delivery of quality medicines and vaccines at favorable prices (6,7,8,9).

1.2.1.3

International/multilateral-level funding and procurement mechanisms

At the international level, funding for and procurement of medicines and health-care commodities for developing country programmes have historically been addressed by donor agencies – such as the US Agency for International Development (USAID), the UK Department for International Development (DFID), the Japan International Cooperation Agency (JICA), the Norwegian Agency for Development Cooperation (NORAD) and the Canadian International Development Agency (CIDA) – in the form of bilateral aid and donated medicines, requiring little or no procurement activity by the recipient country. While bilateral aid continues to play a significant role in providing access to medicines, beginning in the 1990s, credits and grants from development banks, such as the World Bank, were used to support Sector-Wide Approaches (SWAs) and basket funding to recipient countries. SWAs and basket funding, in which donors and lending institutions pool and directly transfer funds to recipient countries, are now playing an important role in the financing and procurement of commodities for government health-care programmes (2).

1.3

TRENDS OVER THE PAST FIVE TO TEN YEARS

1.3.1

Developing countries are receiving increased funding to procure medicines for their health-care programmes

Over the past decade, the increased use of SWAs, basket funding and Global Fund financing has increased the amount of direct budgetary support available to countries for medicines and health-care supplies. This increase in direct budgetary support has resulted in a corresponding increase in country-level procurement of medicines and health-care supplies. The budgetary support is often accompanied by funder procurement requirements designed to promote transparent and efficient procurement. However, compliance with funder procurement requirements, such as those of the World Bank, may be new to country-level procurement agencies and can place an additional burden on the procurement system.

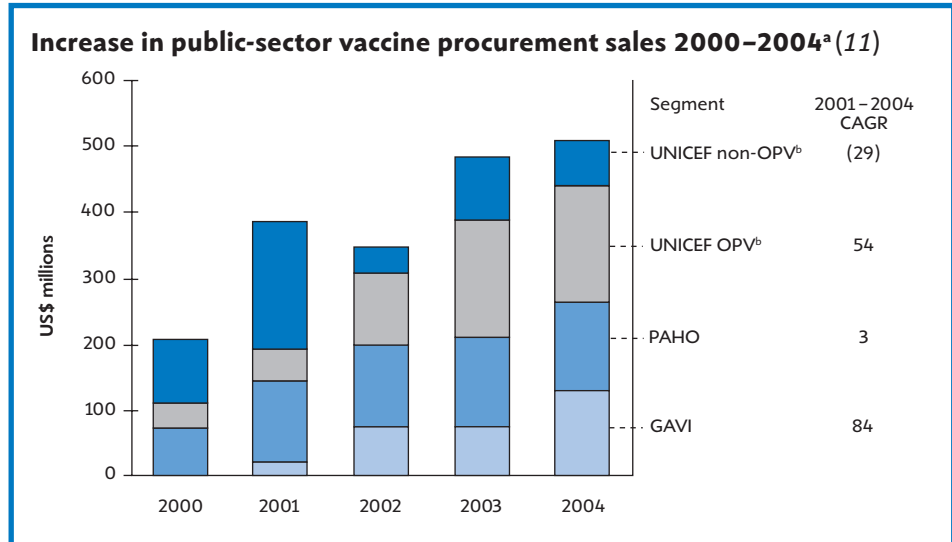
Over the past decade, increased funding for medicines procurement has been made available by global financing initiatives which may have their own procurement requirements.

Another factor in the increase in country-level procurement is the donor practice of phasing out direct support to countries that are considered to be no longer in need of such support. For example, in several countries USAID has phased out direct donations of contraceptives. As a result, these countries have had to take responsibility for establishing new procurement methods for addressing their contraceptive needs (10).

There has also been a general increase in pharmaceutical expenditures across all countries. As noted in the chapter on Medicine Expenditures, per capita pharmaceutical expenditures in high-income countries were 1.94 times greater in 2005 than in 1996. Over the same period, expenditures were 1.64 times greater in upper-middle-income countries, 1.66 times greater in lower-middle-income countries and 1.78 times greater in low-income countries. One illustration of the increase in health-care commodity expenditures is seen in the rise in public-sector vaccine procurement sales from 2000 to 2004 as noted in Figure 1.1.

¹ See OECS web site <http://www.oecs.org/pps> for additional information on the Pharmaceutical Procurement Service.

FIGURE 1.1



^a CAGR = Compound annual growth rate. Assumes constant rate of growth from first year to last year.

^b OPV = Oral polio vaccine

Efforts to effectively manage this resulting increase in procurement responsibility are challenging for many developing countries as their procurement systems often lack capacity in areas ranging from creating proper bidding documents, evaluating bids and awarding contracts, to managing contracts. These problems are often compounded by limited financial resources, a lack of process transparency (see the chapter on Good Governance), and a lack of understanding of the complexity and time requirements of the public sector procurement process (1).

The increase in national procurement also imposes increased responsibility on public-sector procurement systems and national regulatory authorities (NRAs) to ensure that procured medicines comply with regulatory requirements. Medicine quality assurance is a complex process that requires an effective regulatory system with adequate testing capacity to verify product quality (see the chapters on Medicines Regulation and Quality Assurance).

National regulatory authorities in some developing countries do not have the required infrastructure, resources and technical expertise to fully implement the range of functions required to ensure product quality. A 2007 WHO review of NRAs in vaccine-producing countries determined that only 70% of the countries adequately performed the six regulatory functions that WHO deems critical for vaccine quality assurance.¹

1.3.2

Activities to improve access to quality-assured medicines

Recognizing the constraints faced by public-sector procurement and regulatory systems in developing countries, donors and multilateral agencies have introduced new funding and procurement and pricing mechanisms to increase country access to quality medicines. The efforts also include prequalification (PQ) of selected medicines and strengthening country regulatory systems.

¹ The six critical functions are: 1) a published set of requirements for licensing; 2) surveillance of vaccine field performance; 3) a system of lot release; 4) use of laboratory when needed; 5) regular inspections for good manufacturing practices; and 6) evaluation of clinical performance. For additional information see:

http://www.who.int/immunization_standards/national_regulatory_authorities%20role/en/index.html/

1.3.2.1

Establishing new funding and procurement mechanisms

In addition to the traditional bilateral funding support provided by donors and the increased use of SWAp and basket funding by donor and multilateral agencies, several new funding mechanisms have been introduced in the last decade to help increase developing countries' access to medicines to fight high-burden diseases such as HIV/AIDS, tuberculosis (TB) and malaria (see the chapter on Financing Medicines).

- **Global Alliance for Vaccines and Immunization (GAVI).** Founded in 2000, this partnership of public and private stakeholders has focused on funding activities to accelerate the uptake and use of underused and new vaccines and technologies, and improve vaccine supply security. Using an innovative financing mechanism, the International Finance Facility for Immunization (IFFIm), the GAVI Alliance borrows on capital markets against donor countries' pledges, raising funds to finance the loans used for vaccine procurement through issuing bonds. Under a memorandum of understanding with the GAVI Fund, UNICEF is appointed as the procurement agent for specified vaccines (11).
- **Global Drug Facility (GDF).** Launched in 2001, the GDF provides a funding mechanism for procurement of TB medicines through its Grant Services. Housed and administered by WHO within the Stop TB Partnership secretariat, the GDF has seen a significant growth in annual contributions from US\$ 15.2 million in 2001 to almost US\$ 63.8 million in 2006 (12,13). In addition to its Grant Services, the GDF also provides a procurement mechanism through its Direct Procurement Service, which purchases anti-TB drugs for governments, donors and nongovernmental organizations (NGOs) for those countries that lack adequate procurement capacity. The Direct Procurement Service uses international competitive bidding, pooled demand and systematized forecasting to obtain competitive prices for quality anti-TB drugs (12).
- **Global Fund to Fight AIDS, Tuberculosis and Malaria.** Founded in 2002 as a partnership between governments, civil society and the private sector, the Global Fund has become the primary source of funding for programmes addressing HIV/AIDS, TB and malaria. The Global Fund is providing financial support to more than 570 programmes in 140 countries. It is estimated that 45% of funding is spent on procurement of health products and commodities. Since its inception, the Global Fund has provided funding for three quarters of all international financing for malaria, two thirds of all international financing for TB and a quarter of all international financing for HIV/AIDS (14). In June 2009, the Global Fund launched its voluntary pooled procurement (VPP) service, its procurement capacity-building service (CBS), and its supply chain management assistance (SCMA) service. Available to principal recipients of Global Fund grants on a voluntary basis, the VPP consolidates forecasts, establishes long-term supplier contracts, and establishes direct payments to obtain favourable pricing and delivery conditions from suppliers. Procurement of medicines and health-care commodities for the VPP is managed by two Procurement Service Agents contracted by the Global Fund (15).
- **UNITAID.** Launched in 2006, UNITAID is an international facility for the purchase of medicines for HIV/AIDS, TB and malaria. UNITAID uses an innovative financing mechanism in which member countries levy a tax on airline tickets, to be used for the purchase of medicines. UNITAID works with other partner organizations, such as the Clinton Foundation, to negotiate reduced prices for HIV/AIDS, TB and malaria medicines for use in low-income countries (16).

- **President's Emergency Plan for AIDS Relief (PEPFAR).** Although bilaterally funded by the US Government and not a new funding mechanism, PEPFAR has provided a significant source of funding to address endemic diseases. Launched in 2003 with US\$ 15 billion in funding over a five-year period for global HIV/AIDS, TB and malaria efforts, PEPFAR was renewed in 2008 with US\$ 48 billion in funding up to 2013 (17).
- **President's Malaria Initiative (PMI).** As with PEPFAR, PMI is bilaterally funded by the US Government and was established in 2005 with US\$ 1.2 billion in funding over five years to reduce the incidence of malaria in 15 focal countries.

Summary information on these funding mechanisms is provided in Table 1.1.

TABLE 1.1 Funding mechanism summary information

Organization/ date founded	Area of focus	Source of funding	Funding received since inception (USD) ^a	Procurement service
GAVI Alliance 2000	Immuni- zation	<ul style="list-style-type: none"> • Donor contributions • IFFIm pledge • AMC pledge^b 	3.7 billion ^c	UNICEF designated as procurement agent for specific vaccines
Global Drug Facility 2001	TB	Donor contributions	268.2 million ^d	Offers direct procurement service
Global Fund 2002	HIV/ AIDS, TB, malaria	Donor contributions	15.6 billion ^e	Offers voluntary pooled procurement service (since 2009)
PEPFAR 2003	HIV/ AIDS, TB, malaria	US Government	63 billion ^f	Products procured by supply chain management service
PMI 2005	Malaria	US Government	1.2 billion ^g	Products procured by USAID I DELIVER Project
UNITAID 2006	HIV/ AIDS, TB, malaria	<ul style="list-style-type: none"> • Airline ticket tax • Donor contributions 	730 million ^h	Does not provide a procurement service

^a Funding received is for a broad range of programmatic activities including procurement of health commodities.

^b Donors can make pledges to the International Finance Facility for Immunization (IFFIm) or pledge to the Advanced Market Commitment which supports the development of a pneumococcal vaccine for developing countries.

^c Funding approved by GAVI from 2000 to 2015, as of 7 August 2009. GAVI web site: <http://www.gavialliance.org/performance/commitments/index.php>

^d Funds raised for GDF operations from 2001 to 2008, as of 7 August 2009. GDF web site: http://www.stoptb.org/gdf/assets/documents/GDF%20Annual%20Report%202008_Final.pdf

^e The Global Fund has committed US\$15.6 billion in 140 countries to support prevention, treatment and care programmes, as of 7 August 2009. Global Fund web site: <http://www.theglobalfund.org/en/>

^f Total funding projected through to 2013, as of 24 June 2009. PEPFAR web site: <http://www.pepfar.gov/about/index.htm>

^g Total funding projected through to 2010, as of 5 April 2010. PMI web site: <http://www.fightingmalaria.gov/funding/index.html>

^h \$730 million committed since 2006 to support 16 projects in 93 countries, as of 7 August 2009. UNITAID web site: <http://www.unitaid.eu/en/Achievements.html>

- **Regional Procurement Mechanisms.** In addition to the established pooled-procurement mechanisms described earlier, such as the PAHO EPI Revolving Fund for vaccines, the OECS Pharmaceutical Procurement Service and the Gulf Cooperation Council group-purchasing programme, two regional initiatives have been working to establish the foundations for pooled procurement of selected medicines. The South African Development Community (SADC) – representing 14 countries in southern Africa – is in the preparatory stage of planning a pooled-procurement mechanism, focusing on implementation of a strategic plan, development of a shared information network and establishment of a joint procurement protocol for HIV/AIDS, TB and malaria medicines (7). Elsewhere, the East African Community (EAC) is working on harmonization activities for national medicines regulation and national medicines procurement systems (7,18).

1.3.2.2

Pricing mechanisms

In the face of a burgeoning AIDS epidemic and the resulting strain placed on national health budgets by the high cost of medicines, donors and international agencies recognized that additional measures were needed to obtain better value for money when procuring medicines to treat HIV/AIDS, malaria and other high-burden diseases. As a result, three new pricing mechanisms were introduced over the past decade, which involve third parties directly negotiating medicine pricing with suppliers to obtain favourable prices and improve access to medicines.

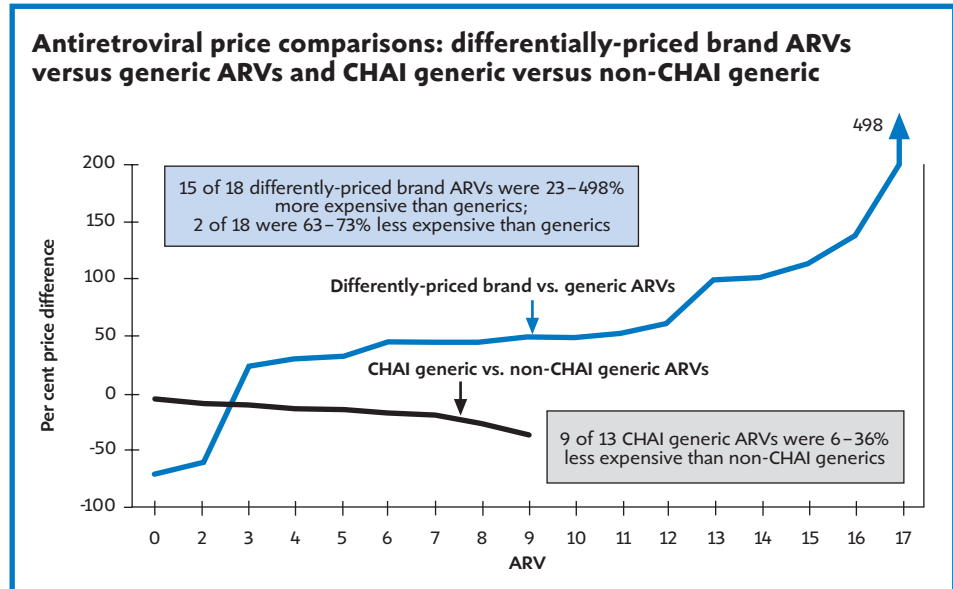
- **Accelerating Access Initiative.** This mechanism, launched in 2000, is based on negotiation by international agencies and several pharmaceutical manufacturers of a differential, or tiered pricing arrangement for antiretroviral medicines (ARVs) under which the manufacturers agree to sell selected brand ARVs to low- and middle-income countries at prices below those charged to high-income countries (19).
- **Clinton HIV/AIDS Initiative (CHAI).** Introduced in 2002, CHAI negotiates price ceilings with generic ARV suppliers that reflect suppliers' costs plus a reasonable profit margin. In 2006, CHAI formed a partnership with UNITAID to combine the purchasing power of UNITAID with CHAI's price-negotiation model to increase availability of paediatric and second-line ARV medicines. As a result, cumulative price reductions of 30% have been achieved for second-line ARVs and 60% for paediatric ARVs (20).
- **The Affordable Medicines Facility for Malaria (AMFm).** Established in 2009, the AMFm, a US\$ 200 million-funded partnership, is designed to reduce the price of Artemisinin Combined Therapy (ACT) medicines through the negotiation of reduced prices from manufacturers in exchange for increased and predictable demand. The AMFm is also organizing a subsidy funded by international donors to increase the affordability of ACT medicines for patients in the public, not-for profit and private sectors (21). The first phase of the AMFm was launched in 2009 in eight countries and following the success of Phase 1 implementation has proceeded with the first co-paid ACTs delivered to Ghana and Kenya in August, 2010.¹

A recent study by Brenda Waning et al (22) reviewed data on ARV procurement reported either to the Global Fund or WHO, to assess the relative impact of different mechanisms on reducing the price of ARVs. The study reviewed the purchase history for 24 ARV dosage

¹ From AMFm web site: <http://www.theglobalfund.org/en/amfm/>
Applications for Phase 1 of AMFm were invited from the following countries: Benin, Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Uganda and the United Republic of Tanzania.

forms and found that for 19 of the 24 ARV dosage forms, there was no association between price and the volume purchased. The study also found that 9 of 13 generic ARVs were priced 6%–36% lower for CHAI consortium members compared to generic purchases outside the CHAI consortium (Figure 1.2).

FIGURE 1.2



To reduce prices, sound forecasting and reliable financing with secure and timely supplier payments are necessary.

While the study questions the overall impact of pooled or high-volume purchases on ARV prices compared to the price reductions achieved through third-party-negotiated price ceilings, other factors besides volume can impact product prices. For any strategic mechanism to achieve maximum effectiveness in reducing prices, it should be supported by sound forecasting data, reliable financing, and a system for secure and timely supplier payments. See Annex 1 for highlights of the assessment and its findings.

1.3.2.3

Activities to address quality assurance risks

As the global market for generics has increased over the past decade, these medicines now represent a greater proportion of medicine expenditures. While generic medicines of good quality offer price competition to innovator medicines, generic medicines manufactured in countries that do not have stringent regulatory authorities can create product-quality risks.

Product-quality risks have also been reported as a result of the increase in counterfeit and substandard medicines found on the market. Through the use of simple screening methods, a recent testing of antimalarial medicines purchased from private pharmacies in six cities in African countries highly endemic for malaria found that 35% of the medicines, mostly generics, were substandard (23).

In response to risks posed by the increase in substandard and counterfeit medicines on the market, public-sector procurement systems and NRAs need to implement appropriate quality assurance measures to ensure all medicines procured are of acceptable quality. However, in many developing countries public-sector procurement systems and NRAs do not have sufficient technical expertise, financial resources, or the infrastructure support needed to effectively implement their product quality assurance responsibilities. They may also be constrained by weak national policies and regulations governing procurement and

regulatory requirements. In such situations the WHO Prequalification Programme (PQP), described below, can serve as a valuable resource through its prequalification of medicines to international standards.

WHO Prequalification Programme (PQP)

Originally intended to give United Nations procurement agencies, such as UNICEF, the choice of a range of quality medicines to procure, the WHO Prequalification Programme (PQP) is also helping to address the risk of poor quality medicines entering the market as a result of the varying capacity of NRAs and national procurement systems to enforce national quality assurance standards (24). WHO's first PQP was established in 1989 for vaccines. Then in 2001, in response to the critical need for quality HIV/AIDS medicines, WHO initiated the PQP for medicines, in partnership with UNAIDS, UNICEF and the United Nations Population Fund (UNFPA) and with support from the World Bank. The PQP for medicines was expanded to include anti-TB medicines the same year, malaria medicines in 2002, and reproductive health products (contraceptives) in 2006. As of November 2010, the PQP had prequalified 249 medicines (24). The PQP follows a rigorous process to assess the quality, safety and efficacy of a medicine based on a comprehensive assessment of the site master file and product dossier followed by site inspection with periodic reevaluations (24).

The PQP is increasingly being incorporated by multilateral agencies and donors into their quality assurance requirements for procurement of medicines. The Global Fund's Quality Assurance Policy for Pharmaceutical Products requires that for the procurement of ARVs, anti-TB medicines and antimalarials using Global Fund resources, the finished pharmaceutical products (FPPs) must comply with the following quality requirements:

- FPPs must be WHO prequalified, or
- FPPs must be approved by a stringent regulatory authority, or
- FPPs are permitted for use based on the recommendation of the Expert Review Panel (for a time-limited period).¹

The principal recipient is also responsible for the random quality control monitoring of all pharmaceutical products procured in accordance with the Global Fund guidelines (25). Recognizing that globalization of pharmaceutical production has led to a diversification of sources of active pharmaceutical ingredients (APIs) and made verification of API quality more challenging, in October 2010, WHO announced the introduction of a pilot project to prequalify APIs for medicines for treating HIV/AIDS, malaria and tuberculosis.

In addition, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), a partnership of international organizations, NGOs, enforcement agencies, pharmaceutical manufacturers and regulatory authorities, launched in 2006, coordinates activities between countries to halt the production, trading and selling of counterfeit medicines (26).

1.3.3

Assistance to strengthen country level procurement systems

Over the past decade, there has been increased recognition within the international community of the important role an effective public sector procurement system plays in helping a country achieve its development goals. Early acknowledgment of the importance of public sector procurement and the need to establish procurement standards came in 1999 with the

¹ For additional information on the Global Fund's Quality Assurance Policy for Pharmaceutical Products see: http://www.theglobalfund.org/documents/psm/Annex1-%20FullTextRevisedQualityAssurancePolicy_en.pdf

The WHO document Operational Principles for Good Pharmaceutical Procurement has been widely endorsed and serves as the basis for many procurement policies.

publication by WHO of the document *Operational Principles for Good Pharmaceutical Procurement* (27). Endorsed by the Interagency Pharmaceutical Coordination Group (which included WHO, the World Bank, UNFPA and UNICEF), the document introduced four strategic procurement objectives and a set of operational principles for good pharmaceutical procurement, which can be adapted to different procurement settings (28).

In 2000, the World Bank – in view of its increased funding of health-sector goods – issued a *Technical Note for the Procurement of Health Sector Goods* to provide specific guidance to funding recipients on acceptable practices for the procurement of pharmaceuticals, contraceptives, vaccines and nutritional supplements (29). The World Bank also plays an important role in strengthening national procurement systems. In Bangladesh, for example, the World Bank funded the Public Procurement Reform Project of 2002-2007 that updated the Government of Bangladesh's Public Procurement Regulations (2003), developed a set of standard bidding documents for government agencies, and provided training on procurement regulations and procedures to over 1800 Government staff (see Annex 2).

In 2002, the Global Fund stipulated the procurement principles with which Principal Recipients must comply, including adherence to WHO's Operational Principles for Good Pharmaceutical Procurement or comparable systems that employ competitive bidding, quality assurance practices and transparency (30).

Global recognition of the key role of public-sector procurement culminated in 2005, when 90 countries, 26 multilateral and bilateral development institutions and 13 civil society organizations signed the Paris Declaration on Aid Effectiveness. Confirming the important role of procurement in the effective implementation of aid programmes, the Paris Declaration included specific commitments to strengthen national procurement systems, support procurement capacity development and use country procurement systems as they become functional (31). Several institutions and organizations have established functional units and services to support national procurement capacity development.

Over the past decade, the OECD has taken a leading role in promoting and supporting activities designed to strengthen national procurement systems (32). In 2002, the OECD Development Assistance Committee (DAC), in partnership with the World Bank, established the Round Table on Strengthening Procurement Capacities in Developing Countries for the purpose of creating better tools and techniques to improve public procurement systems in developing countries (33). The OECD/DAC established the Joint Venture for Procurement in 2005 to support procurement reform and implementation of the Paris Declaration procurement commitments.

Responding to the need to improve public-sector procurement systems, several other international organizations are providing technical assistance to support procurement capacity development.

- **Global Drug Facility (GDF).** The GDF provides technical support services to train national TB programme staff on the procurement and management of anti-TB drugs.
- **UN Procurement Capacity Development Centre (UNPCDC).** Launched by the UNDP in 2008 in partnership with the Danish International Development Agency (DANIDA), the UNPCDC provides procurement-focused, field-based advocacy and advisory support services to help develop national and sub-national procurement capacities (34).
- **Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).** The Global Fund has identified three operational areas where it will provide technical assistance through

capacity-building services and supply chain management assistance: quantification/forecasting; procurement planning; and logistics management. The Global Fund selected contractors to provide this technical assistance to grant recipients, and by December 2009 capacity building services and supply chain management assistance services were underway in two countries with consultations ongoing in six other countries (4,35).

- **Bilateral donors.** Several bilateral donors, such as USAID (through the USAID DELIVER Project) and the PEPFAR-funded Supply Chain Management System Project, provide direct technical assistance to support procurement and logistic system strengthening (36).
- **Commercial agencies.** Specific procurement and supply chain technical assistance is also provided by private sector commercial companies, such as Crown Agents and Charles Kendall.

1.4

FUTURE CHALLENGES AND ISSUES

The increased recognition of the important role public sector procurement systems play in supporting development objectives and the accompanying application of international resources have helped to improve access to medicines and strengthen procurement systems in developing countries. However, challenges to effective public sector procurement still persist, and will require continued, coordinated international and national efforts that support long-term, sustainable systemic improvements. Such efforts will need to take a more comprehensive approach to procurement capacity-building than previous efforts, which tended to more narrowly focus on improving technical skills, and look to strengthen the range of policies, institutions and organizations that play different, but important roles in supporting an effective and efficient procurement process (1,37).

Some of the key challenges in public-sector procurement of medicines are outlined below.

1.4.1

Price-versus-quality challenges

Emphasis on price. In some countries, national procurement policies stipulate that contracts must be awarded to the supplier submitting the lowest price. When strictly interpreted, such policies create risk when procuring health products as they allow contracts for medicines and health-care commodities to be awarded to suppliers without adequate consideration being given to the quality assurance status of the product.

1.4.2

Financing challenges

- **Limited financing.** In low- and middle-income countries, public sector medicines financing is limited and insufficient for addressing the basic medicine needs of the majority of the population (38). Limited national financial resources often create an iterative and lengthy budget review and approval process that can delay procurement and lead to product shortages and stock-outs.
- **Release of procurement funds.** In some countries the release of public sector funds to pay for procurement is hindered by cash flow and treasury management constraints. The resulting payment delays to suppliers can create stock-outs and disrupt treatment regimens. Payment delays to suppliers can also impact the ability of the purchaser to secure competitive prices from suppliers. Release of budgeted procurement funds on

a periodic basis (for example, quarterly instead of at one time) may result in smaller volume purchases being issued, as opposed to a consolidated bulk purchase that may secure more favourable pricing from suppliers (10).

1.4.3

A preference for local distributors or manufacturers without adequate competition, can result in higher prices.

When procurement is decentralized, it may be necessary to retain some functions, such as price setting and quality control (QC) at central level.

National policy challenges

- **Restrictive procurement or registration policies.** Some countries have national procurement or registration policies that, in effect, limit competition. For example, in Latin America, the procurement regulations in Nicaragua, Peru and the Dominican Republic do not contain a provision for international tendering (10). In several other Latin American countries, international tendering and procurement are legal only under special circumstances. This underlying preference for local distributors and manufacturers creates limited competition, which tends to produce higher prices.
- **Regulatory barriers** (see the chapter on Intellectual Property and Trade Issues). Some countries impose regulatory barriers, such as duties, value added tax (VAT), and tariffs on medicines that are imported, which increases medicine prices (39) and can impact the procurement environment by indirectly limiting competition.
- **Decentralizing procurement to sub-national levels.** A number of countries have decentralized procurement, shifting varying degrees of responsibility from the national to the provincial, district or municipal level (4). Experiences with decentralized medicines procurement have been mixed. General concerns include:
 - **Impact on costs.** Decentralized procurement reduces the size of orders, shifts purchases to local suppliers and eliminates economies of scale, which in most cases results in higher prices (2,3).
 - **Impact on quality.** Decentralization increases the difficulty of ensuring product quality assurance as lower-level staff frequently lack both the skills and the specialized equipment needed to oversee formal quality control procedures (40).
 - **Management burden.** A significant challenge in decentralizing procurement is in ensuring that in each district trained staff are available with the skills needed. A decentralized approach in essence means that health systems are duplicating existing skills at the central level many times over, which is inherently inefficient and costly (40).

To address the challenges posed by decentralization, it may be appropriate to retain some functions, such as price negotiations and quality control compliance, at the central level.

1.4.4

Quality assurance challenges

National procurement of selected products (such as vaccines, essential medicines for HIV/AIDS, TB and malaria, and key reproductive health medicines) that receive international agency and donor support generally has minimal quality assurance risks, given the quality assurance requirements donors will impose. However, procurement of essential medicines outside these categories faces greater quality assurance risks. These include limited NRA capacity (see section 1.3.1) and the increase in substandard and counterfeit products (see section 1.3.2.3).

1.4.5

Multilateral agency and bilateral donor challenges

- **Multiple donor procurement requirements.** Developing countries that receive funding from a donor are bound to comply with the donor's procurement requirements. When several different donors provide funding support, the resulting range of donor compliance requirements can impose an administrative burden on the national procurement unit.
- **Variability of donor funding and government procurement cycles.** Studies of procurement of reproductive health supplies have found that a lack of alignment of donor funding with government procurement cycles can lead to higher product costs due to: smaller volume contracts issued to suppliers, product stock-outs, emergency shipments and overall inefficiency in managing the in-country supply chain (41,42). In response, multilateral agencies and donors agreed in the Paris Declaration on Aid Effectiveness to make aid more predictable, establishing an indicator to monitor the percentage of aid disbursements released according to agreed schedules in annual or multi-year frameworks.

1.4.6

Operational challenges

Lack of reliable quantification data is one of the major impediments to effective procurement.

- **Weak forecasting and quantification.** Forecasting and quantification systems are limited in many developing countries and do not provide the requisite data needed to support procurement activities, largely due to weaknesses in stock management, consumption monitoring and reporting, and challenges in compiling supply data from multiple sources (43). Lack of reliable quantification data is one of the major impediments to effective procurement and while this lack of data can be addressed to a limited extent through buffer stock planning, this adds additional cost to the procurement system.
- **Limited performance monitoring and evaluation.** In many developing countries, monitoring and evaluation of procurement performance and supplier performance are done on a limited basis, making it difficult to track progress and plan for system improvements. Monitoring and evaluation systems can range from a simplified approach to a more in-depth analysis as offered in the OECD document *Good Practices for Benchmarking, Monitoring and Evaluation*, which identifies 13 procurement performance monitoring indicators designed to measure fairness, transparency of the system, effective use of competition and efficiency (1).

1.4.7

Human resource challenges

(see the chapter on Human Resources in Pharmaceuticals)

- **Lack of trained personnel.** In many countries there is a shortage of professionally trained staff in public sector procurement and procurement management. Donors and national governments should continue working together to address this issue.
- **Frequent staff turnover.** Unofficial practices, including the frequent transfer and replacement of procurement and management staff, often result in staff without appropriate procurement training and experience being placed in positions of procurement responsibility. The loss of trained and experienced procurement personnel resulting from turnover negatively impacts the effective and timely processing of procurement requirements.

1.4.8

Corruption and transparency challenges (see the chapter on Good Governance for the Pharmaceutical Sector)

The OECD estimates that approximately US\$ 400 billion is lost annually to corruption and fraud in public procurement (44). While corrupt practices exist throughout private and public sector environments, the OECD notes that “Of all government activities, public procurement is perceived as most vulnerable to corruption in almost all regions of the world” (45).

Given the significant and ongoing problems corrupt practices pose to public procurement, several international agencies including the World Bank (45) WHO (46), the OECD (47), Transparency International, (48) and the Medicines Transparency Alliance (MeTA) (49) are using their resources to address the challenge. These and other organizations provide information and tools on their web sites designed to support government efforts to implement measures and best practices in order to curb corrupt practices and instill transparency in the public procurement process.

Transparency and accountability

An OECD survey of procurement personnel responsible for designing, supervising and managing public-sector procurement processes in central governments identified three key drivers for enhancing integrity and reducing corruption in procurement:

- Instill transparency measures throughout the entire procurement cycle, from needs assessment to contract management.
- Provide professional guidance for procurement officials along with integrity management policies that clarify restrictions and prohibitions to prevent conflict of interest and corruption.
- Institute strong accountability and control measures that involve relevant stakeholders (50).

To promote integrity in public procurement and reduce corruption, the OECD Council on Enhancing Integrity in Public Procurement issued a recommendation to its member countries to develop a policy framework that incorporates 10 key principles based on transparency, good management, prevention of misconduct, and accountability and control (Annex 3) (50).

There is some evidence that implementation of e-procurement systems has helped improve integrity and reduce corruption in public-sector procurement. Several countries are in the process of implementing different levels of e-procurement depending upon technical and infrastructure capacities. These include the Philippines (1), Chile (51), and the State of Andhra Pradesh in India (Annex 5).

Use of market intelligence

Published information on prices paid for medicines and health-care commodities procured on the international market, often referred to as market intelligence, can be used to help curb corruption in public sector procurement. Published pricing information allows public advocacy groups to monitor and compare local procurement prices with international prices and raise concerns when significant, unsupported discrepancies appear between the two. The primary source of current market intelligence on selected medicines and health commodities is the *International Price Indicator Guide*, published by Management Sciences for Health (Annex 4). The Guide can be used to:

Market intelligence about medicine prices can be used to combat corruption in procurement.

- Determine the probable cost of products for a national procurement programme.
- Compare current prices paid to those available on the international market.
- Assess the potential financial impact of changes to a products list.
- Support education in rational prescribing and use of medicines and other health-care products.

Other sources of market intelligence include *Untangling the Web of ARV Prices* (52) published by Médecins Sans Frontières, the WHO Global Price Reporting Mechanism (GPRM), which provides prices on ARVs and TB and malaria drugs (53), and the Global Fund's Price and Quality Reporting System (54). In addition, WHO now publishes on its web site listings of national and international price reporting web sites (55,56).

REFERENCES

1. *Harmonising donor practices for effective aid delivery, Volume 3: Strengthening procurement capacities in developing countries*. Paris, Organisation for Economic Co-operation and Development, 2005.
2. Rao R, Mellon P, Sarley D. *Procurement strategies for health commodities: An examination of options and mechanisms within the commodity security context*. Arlington, VA, DELIVER, for the U.S. Agency for International Development, 2006.
3. Drug supply choices: What works best? *WHO Essential Drugs Monitor*, 1998, 25-26 (double issue):7-9. Available at: <http://apps.who.int/medicinedocs/collect/medicinedocs/pdf/whozip10e/whozip10e.pdf>
4. Sanchez A et al. *Decentralizing and integrating contraceptive logistics systems in Latin America and the Caribbean: Considerations for informed decision making throughout the health reform process*. Arlington, VA., DELIVER, for the U.S. Agency for International Development, 2006.
5. *Procurement capacity toolkit: Tools and resources for procurement of reproductive health supplies*. Module 3. Assessment of procurement options. Seattle, PATH, 2009.
6. DeRoock D et al. Regional group purchasing of vaccines: review of the Pan-American Health Organization EPI Revolving Fund and Gulf Cooperation Council group purchasing program. *The International Journal of Health Planning and Management*, 2006, 21(1):23-43.
7. Burnett F. *Critical success factors for pooled procurement*. Paper presented at: Organization of Eastern Caribbean States/Pharmaceutical Procurement Service SEAM Conference, Dar es Salaam, 10-12 December 2003. Available at: <http://www.msh.org/SEAM/conference2003/presentations/Agenda/AgendaDay2/FrancisBurnettParallelTrack.pdf>
8. *Multi-country regional pooled procurement of medicines: Identifying key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean, and Pacific Island countries*. Meeting report. 15-16 January 2007. Geneva, World Health Organization, 2007.

9. *Regional pooled procurement of drugs: Evaluation of programs*. Arlington, VA, Management Sciences for Health Center for Pharmaceutical Management, December 2002.
Available at: <http://www.volksgezondheid.gov.sr/PSM/Complete%20CD%20PSM%20training%20SRE%202008/Pooled%20Procurement%20Experiences/Evaluation%20pooled%20proc%20MSH%202002.pdf>
10. Sarley D et al. *Options for contraceptive procurement: Lessons learned from Latin America and the Caribbean*. Arlington, VA, DELIVER, and Washington, D.C., USAID Health Policy Initiative, for the U.S. Agency for International Development, 2006.
11. GAVI Alliance web site. Available at: www.gavialliance.org
12. Matiru R, Ryan T. The Global Drug Facility: a unique, holistic and pioneering approach to drug procurement and management. *Bulletin of the World Health Organization*, 2007, 85(5):348–353.
13. Global Drug Facility Progress Report 12: Available at: http://www.stoptb.org/gdf/assets/documents/GDF%20Annual%20Report%202008_Final.pdf
14. Global Fund to Fight AIDS, Tuberculosis and Malaria web site: <http://www.theglobalfund.org/>
15. *Procurement support services: Voluntary pooled procurement and supply chain management assistance*. Global Fund information note. Available at: http://www.theglobalfund.org/documents/psm/InformationNote_VPP_and_CBS_en.pdf
16. UNITAID web site: <http://www.unitaid.eu/>
17. President's Emergency Plan for AIDS Relief web site: <http://www.pepfar.gov/about/index.htm>
18. 7th Meeting of the East African Community (EAC) Sectoral Council on Legal and Judicial Affairs ongoing in Arusha. EAC press release. Arusha, Tanzania, 16 April 2009. Available at: <http://www.eac.int/component/content/article/1-latest-news/242-press-release-7th-meeting-of-eac-sectoral-council-on-legal-and-judicial-affairs-ongoing-in-arusha.html>
19. *Accelerating access initiative: Widening access to care and support for people living with HIV/AIDS. Progress report*. Geneva, World Health Organization, 2002. Available at: <http://www.who.int/hiv/pub/progressreports/accelerating/en/>
20. Access programs page. Clinton Foundation web site. Available at: <http://www.clintonfoundation.org/what-we-do/clinton-hiv-aids-initiative/our-approach/access-programs>
21. \$200 million partnership to bring effective malaria drugs to all who need them. UNITAID press release. Oslo, 17 April 2009. Available at: [http://www.unitaid.eu/en/20090417197/News/\\$200-million-partnership-to-bring-effective-malaria-drugs-to-all-who-need-them.html](http://www.unitaid.eu/en/20090417197/News/$200-million-partnership-to-bring-effective-malaria-drugs-to-all-who-need-them.html)
22. Waning B et al. Global strategies to reduce the price of antiretroviral medicines: evidence from transactional databases. *Bulletin of the World Health Organization*, 2009; 87:520–528.
23. Bate R et al. Antimalarial drug quality in the most severely malarious parts of Africa: A six country study. *PLoS One*, 2008; 3(5):e2132. Available at: <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0002132>

24. WHO Prequalification Programme web site: <http://apps.who.int/prequal/>
25. Quality assurance information page. Global Fund web site. Available at: <http://www.theglobalfund.org/en/procurement/quality/>
26. IMPACT web page: <http://www.who.int/impact/about/en/>
27. *Operational principles for good pharmaceutical procurement*. Geneva, World Health Organization, 1999. Available at: <http://apps.who.int/medicinedocs/pdf/whozip49e/whozip49e.pdf>
28. Ombaka E. Current status of medicines procurement. *American Journal of Health-System Pharmacy*, 2009, 66(5)suppl.3:s20-s28.
29. Procurement of health sector goods. Technical Note. Washington, DC, World Bank, 2006. Available at: <http://siteresources.worldbank.org/INTPROCUREMENT/Resources/health-tn-ev3.doc>
30. The Global Fund to Fight AIDS, Tuberculosis and Malaria. Report of the Third Board Meeting. Geneva, 10-11 October 2002. Available at: <http://www.theglobalfund.org/documents/board/03/ThirdBoardMeetingReport.pdf>
31. Paris Declaration on Aid Effectiveness, Section III: Indicators of progress. March 2005. Available at: <http://www.oecd.org/dataoecd/57/60/36080258.pdf>
32. Organisation for Economic Co-operation and Development web site: <http://www.oecd.org/>
33. *Compendium of country examples and lessons learned from applying the methodology for assessment of national procurement systems*. Paris, Organisation for Economic Co-operation and Development, 2008. Available at: <http://www.oecd.org/dataoecd/48/30/40488586.pdf>
34. UN Procurement Capacity Development Centre web site "About us" page: <http://www.unpcdc.org/about-us.aspx>
35. Procurement support services web page on the Global Fund web site: <http://www.theglobalfund.org/en/procurement/vpp/?lang=en>
36. USAID/DELIVER web site: <http://deliver.jsi.com/dhome> and Supply Chain Management System (SCMS) web site: <http://scmsweb.pfscm.org/scms>
37. Cohen J et al. Taking a comprehensive approach to procurement capacity development for essential reproductive health medicines. Unpublished data, 2009.
38. *Equitable access to essential medicines: a framework for collective action*. WHO Policy Perspectives on Medicines. Geneva, World Health Organization, 2004. Available at: <http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf>
39. Levinson L, Laing R. The hidden costs of essential medicines. *WHO Essential Drugs Monitor*, No.33, 2003. Available at: <http://apps.who.int/medicinedocs/pdf/s4941e/s4941e.pdf>
40. Woodle D. Vaccine procurement and self-sufficiency in developing countries. *Health Policy and Planning*, 2000, 15(2):121-129. Available at: <http://heapol.oxfordjournals.org/cgi/content/short/15/2/121>

41. Dalberg Global Development Advisors. *Designing a global financing and procurement mechanism for reproductive health supplies*. Brussels, Reproductive Health Supplies Coalition, 2008. Available at: http://www.rhsupplies.org/fileadmin/user_upload/Final_Report_-_June_2008.pdf
42. Druce N. *Reproductive health commodity security (RHCS) country case study synthesis: Cambodia, Nigeria, Uganda and Zambia*. London, DFID Health Resource Centre, 2006. Available at: http://www.dfidhealthrc.org/publications/srh/RHCS%20synthesis_Mar06_final.pdf
43. Gurría A. *Building a cleaner world economy*. Opening remarks at The Global Forum on Public Governance. Paris, 4 May 2009.
44. Lonti Z, Woods M. *Towards government at a glance: Identification of core data and issues related to public sector efficiency*. OECD Working Papers on Public Governance No.7. Paris, Organisation for Economic Co-operation and Development, October 2007. Available at: <http://www.oecd.org/dataoecd/52/34/40209928.pdf>
45. Anticorruption web page on the World Bank web site: <http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTPUBLICSECTORANDGOVERNANCE/EXTANTICORRUPTION/0,,menuPK:384461~pagePK:149018~piPK:149093~theSitePK:384455,00.html>
46. WHO Good Governance for Medicines web page: <http://www.who.int/medicines/ggm/en/>
47. Organisation for Economic Co-operation and Development bribery and corruption web page: http://www.oecd.org/topic/0,3373,en_2649_37447_1_1_1_1_37447,00.html
48. Transparency International web site: <http://www.transparency.org/>
49. Medicines Transparency Alliance web site: <http://www.medicinestransparency.org/>
50. From: Recommendations of the Council on Enhancing Integrity in Public Procurement. Paris, Organisation for Economic Co-operation and Development, October 2008. Available at: <http://www.oecd.org/dataoecd/62/24/41549036.pdf>
51. Chile's Government Procurement E-System web page. World Bank eGovernment web site: <http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTINFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/EXTEGOVERNMENT/0,,contentMDK:20486003~menuPK:1767268~pagePK:210058~piPK:210062~theSitePK:702586,00.html>
52. *Untangling the web of antiretroviral price reductions*. Geneva, Médecins Sans Frontières, 2008. Available at: http://www.msfaaccess.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/Untanglingtheweb_July2008_English.pdf
53. WHO HIV/AIDS Global price reporting mechanism web page: <http://www.who.int/hiv/amds/gprm/en/>
54. Price and quality reporting web page on the Global Fund web site. Available at: <http://pqr.theglobalfund.org/PQRWeb/Screens/PQRLogin.aspx?Lang=en-GB>
55. National medicine price sources web site: http://www.who.int/medicines/areas/access/sources_prices/national_medicine_price_guide_sources.pdf
56. International medicine price guides web site: http://www.who.int/medicines/areas/access/sources_prices/International_medicine_price_guides_lists.pdf

ABBREVIATIONS

ACT	Artemisinin Combined Therapy
ATC	Anatomical, Therapeutic, Chemical (Classification system)
AIDS	Acquired Immunodeficiency Syndrome
AMFm	Affordable Medicines Facility for Malaria
API	Active Pharmaceutical Ingredient
ARVs	Antiretroviral medicines
CHAI	Clinton HIV/AIDS Initiative
CIDA	Canadian International Development Agency
DAC	Development Assistance Committee
DANIDA	Danish International Development Agency
DDD	Defined daily dose
DFID	UK Department for International Development
EPI	Expanded Programme on Immunization
FPP	Finished pharmaceutical product
GAVI	GAVI Alliance
GDF	Global Drug Facility
GoAP	Government of Andhra Pradesh (India)
GPRM	Global Price Reporting Mechanism
HIV	Human immunodeficiency virus
IFFIm	International Finance Facility for Immunization
IMPACT	International Medical Products Anti-Counterfeiting Task Force
JICA	Japan International Cooperation Agency
MeTA	Medicines Transparency Alliance
NGO	Nongovernmental organization
NRA	National Regulatory Authority
OECD	Organisation for Economic Co-operation and Development
OECS	Organization of Eastern Caribbean States
OECS/PPS	OECS Pharmaceutical Procurement Service
OPV	Oral polio vaccine
PAHO	Pan American Health Organization
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQ	Prequalification
PQP	Prequalification Programme
SADC	Southern African Development Community
SWAp	Sector-Wide Approach
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme

UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNPCDC	United Nations Procurement Capacity Development Centre
USAID	US Agency for International Development
USD	United States Dollars
VAT	Value Added Tax
VPP	Voluntary pooled procurement

Author contact: tdickens@path.org

ANNEXES

Annex 1. ARV Price Comparisons: Global strategies to reduce prices

Background

The high price of antiretroviral medicines (ARVs) is a major constraint on universal access to HIV/AIDS treatment. In response, several global strategies have been implemented in an attempt to lower the price of ARVs, including procurement arrangements designed to increase purchase volumes, third-party price negotiation by the Clinton HIV/AIDS Initiative (CHAI) for generic ARVs and differential pricing for branded ARVs.

Methods

Waning et al. estimated the impact of these strategies on the price of 24 ARVs in resource-limited settings, using 7253 procurement transactions (July 2002–October 2007) obtained from databases hosted by WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria. Separate regression models were created for each of the 24 ARV dosage forms using generalized estimating equation linear regression to determine predictors of price.

Results

For 19 of the 24 ARV dosage forms, no association was detected between price and volume purchased. Only 5 of 24 dosage forms showed any association between volume and price, with high-volume purchases 4%–21% less expensive than medium- and low-volume purchases (Table 2).

Associations between ARV purchase volume and price

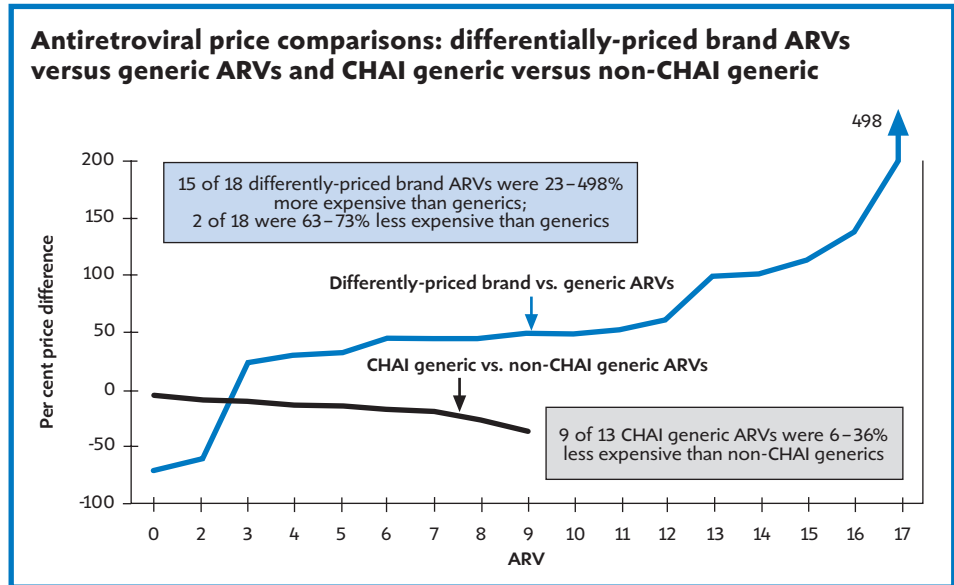
ARV purchases where an association between volume and price was detected

ARV	High volume price versus medium volume price	High volume price versus low volume price
zidovudine 300 mg	-4%	-5%
efavirenz 600 mg		-7%
lamivudine 150 mg/ nevirapine 200 mg/ stavudine 40 mg	-11%	-16%
indinavir 400 mg	-6%	
lopinavir 133.3 mg/ ritonavir 33.3 mg		-21

ARV purchases where no association between volume and price was detected

abacavir 300 mg, didanosine 100 mg, didanosine 200 mg, didanosine 400 mg, lamivudine 150 mg, lamivudine 150 mg/nevirapine 200 mg/stavudine 30 mg, lamivudine 150 mg/stavudine 30 mg, lamivudine 150 mg/stavudine 40 mg, lamivudine 150 mg/zidovudine 300 mg, stavudine 20 mg, stavudine 30 mg, stavudine 40 mg, tenofovir 300 mg, zidovudine 100 mg, efavirenz 50 mg, efavirenz 200 mg, nevirapine 200 mg, nelfinavir 250 mg, ritonavir 100 mg

Out of 13 generic ARVs, 9 were priced 6%–36% lower for CHAI consortium members compared to generic purchases outside the CHAI consortium. And out of 18 differentially-priced brand ARVs, 15 were priced 23%–498% higher compared to non-CHAI generic purchases. Two differentially-priced brand ARVs were priced 63%–73% lower than generic non-CHAI versions.



Discussion

While conventional wisdom in procurement suggests that the more you buy, the less you pay, this does not seem to be the case for ARVs when price and volume were analysed on a global level. Many other factors are likely to contribute to the final price paid for ARVs, including: purchaser unfamiliarity with current fair market prices, timeliness of payment to suppliers, lead times between when ARVs are ordered and when they are needed, registration status, patent status and corruption.

While pooled procurement arrangements are appealing, in reality they may not achieve lower prices via increased purchase volumes. Even if they do achieve marginal price reductions, these potential savings must be set against the costs required to establish and maintain pooled procurement systems. Pooled procurement systems should include country-level procurement staff, rather than transferring procurement roles to western donors and international organizations. Pooled procurement will decrease the number of purchasers and will likely result in a decrease in the number of suppliers in the long run. Monitoring and evaluation of pooled procurement must include market implications.

Differential pricing schemes for branded medicines should be encouraged, but are unlikely to result in prices that are affordable to low- and middle-income countries. Generic price competition remains the best option for ensuring affordable medicine prices.

Third-party price negotiation shows promise, but may not be effective over the long term. More research is needed to assess the long-term implications of price negotiation on behalf of countries. While this approach may be useful to stimulate price reductions, donors must remain invested in capacity building of country level staff to perform these tasks. Donors should mandate the use of publicly available price information to facilitate country procurement activities.

The study highlights the utility of posting procurement data in the public domain. More countries, donors and international organizations should encourage transparency of medicines information to support an evidence-based approach to policy and programme decision-making.

Conclusion

Larger purchase volumes do not necessarily result in lower ARV prices. Third-party price negotiation by CHAI has resulted in lower generic ARV prices for most ARVs under the CHAI consortium. Generic ARVs are less expensive than differentially-priced brand ARVs, except where little generic competition exists.

Alternative strategies, including streamlining financial management systems, improving demand forecasting and removing barriers to generics should also be explored in order to help reduce ARV prices.

Source: Waning B et al. Global strategies to reduce the price of antiretroviral medicines: evidence from transactional databases. *Bulletin of the World Health Organization*, 2009;87:520–528.

Annex 2. World Bank public sector procurement reform in Bangladesh

In 2002, a World Bank country procurement assessment report identified several weaknesses in the Bangladesh public sector procurement system including:

- Absence of a legal framework governing public sector procurement.
- Absence of adequate procurement planning.
- Lack of adequate professional competence of staff to manage public procurement.
- Poor-quality bidding documents and bid evaluation procedures.
- Ineffective administration of contracts.
- Absence of an adequate mechanism for ensuring transparency and accountability.

Based on these findings, the World Bank proposed and the Bangladesh Government approved the “Public Procurement Reform Project” (PPRP), a five-year project (2002–2007) funded through the International Development Association (IDA). The project objectives were to improve public-procurement performance by introducing measures – such as national procurement regulations, standardized bidding documents, and broad-based training of staff – to help bring the public procurement system into compliance with international standards for procurement efficiency, transparency, and accountability.

Under PPRP, significant improvements were made to improve public procurement practices in Bangladesh through the following completed actions:

- Issued the Public Procurement Regulations 2003, which established procurement processing and implementation procedures in line with good international procurement practices.
- Established a specialized technical assistance unit, the Central Procurement Technical Unit (CPTU), to implement and support procurement reforms.
- Developed a set of Standard Bidding Documents for all Government agencies.
- Developed a centralized procurement management information system.
- Developed a critical mass of 25 national trainers and provided training on procurement regulations and procedures to over 1,800 staff through March 2007.
- Prepared the Public Procurement Act, which was ratified by Parliament in 2006.

The Public Procurement Regulations of 2003 were subsequently replaced and updated by the Public Procurement Rules 2008. A follow-on IDA funded project “Public Procurement Reform Project II” (PPRP II, 2007–2012) is underway to continue public sector procurement reform. PPRP II is implemented by the Central Procurement Technical Unit and is focused on four strategic components:

- Furthering policy reform and institutionalizing procurement capacity development.
- Strengthening procurement management at the sectoral level and CPTU.
- Introducing e-government procurement.
- Promoting communication, behavioural change and social accountability.

Source: From *Public Procurement Reform in Bangladesh*, Central Procurement Technical Unit, IMED, Ministry of Planning, Government of the People’s Republic of Bangladesh web site. Available at: <http://www.cptu.gov.bd/PPRP.aspx>

Annex 3. OECD Principles for Enhancing Integrity in Public Procurement

In October 2008 the OECD Council on Enhancing Integrity in Public Procurement recommended that member countries develop and implement a policy framework to strengthen integrity throughout the entire public procurement cycle. The Policy framework should incorporate ten key principles based on the elements of transparency, good management, prevention of misconduct, and accountability and control.

Transparency

1. Member countries should provide an adequate degree of transparency in the entire public procurement cycle in order to promote fair and equitable treatment for potential suppliers.
2. Member countries should maximize transparency in competitive tendering and take precautionary measures to enhance integrity, in particular for exceptions to competitive tendering.

Good management

3. Member countries should ensure that public funds are used in public procurement according to the purposes intended.
4. Member countries should ensure that procurement officials meet high professional standards of knowledge, skills and integrity.

Prevention of misconduct, compliance, and monitoring

5. Member countries should put mechanisms in place to prevent risks to integrity in public procurement.
6. Member countries should encourage close cooperation between government and the private sector to maintain high standards of integrity, particularly in contract management.
7. Member countries should provide specific mechanisms to monitor public procurement as well as to detect misconduct and apply sanctions accordingly.

Accountability and control

8. Member countries should establish a clear chain of responsibility together with effective control mechanisms.
9. Member countries should handle complaints from potential suppliers in a fair and timely manner.
10. Member countries should empower civil society organizations, media and the wider public to scrutinize public procurement.

Source: From: Recommendations of the Council on Enhancing Integrity in Public Procurement. October, 2008. OECD web site: <http://www.oecd.org/dataoecd/62/24/41549036.pdf>

Annex 4. International Drug Price Indicator Guide

Julie Frye, Management Sciences for Health

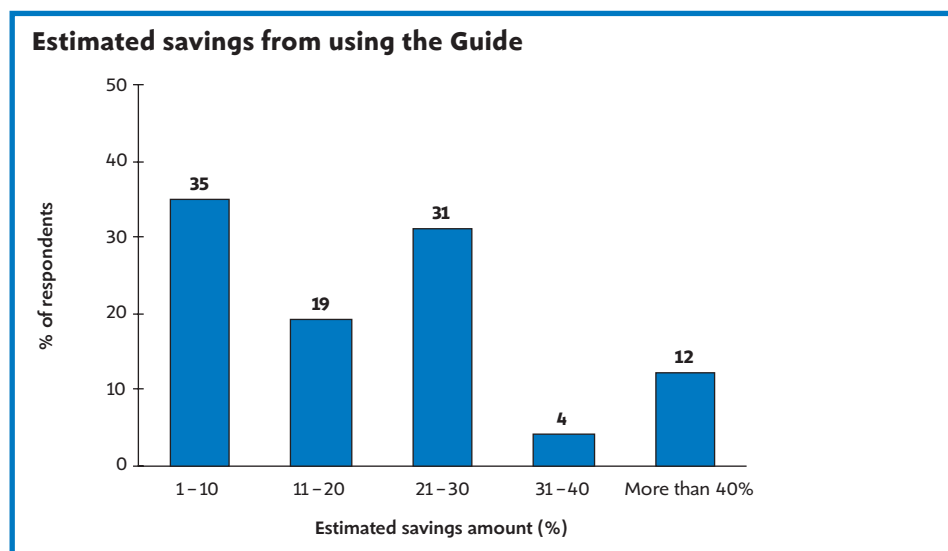
Getting relevant and accurate market intelligence for pharmaceutical and other health-care product prices can be difficult. MSH's International Drug Price Indicator Guide provides an indication of prices on the international market for selected pharmaceuticals, contraceptives, diagnostic tests and medical supplies. Updated annually, the Guide contains a spectrum of prices from suppliers, international development organizations and government agencies.

The Guide aims to make price information more widely available in order to help managers procure quality products for the lowest possible price. Bulk purchasing, competition, skillful negotiation and sound supply management are mechanisms that can lower the prices of medicines. Access to a central, independent, updated database of comparative price information facilitates these endeavors. The Guide provides a useful source of price information for other publications, including Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS. Median prices from the Guide are also used as reference prices in the WHO/Health Action International project, "Medicines Prices: A New Approach to Measurement."

Procurement and health-care programme personnel can use the Guide to:

- Determine the probable cost of products for their programmes;
- Compare current prices paid to those available on the international market;
- Assess the potential financial impact of changes to a products list; and
- Support education in rational prescribing and use of medicines and other health-care products.

The Guide contains prices for more than 1,200 items, focusing on essential products. The prices come from 25 sources, grouped into "buyers" and "sellers," or suppliers. The supplier prices are from organizations (usually non-profit) experienced in delivering medicines to the developing world. The buyer prices are usually from government organizations' international competitive bidding. Data are collected annually and are published on the web in a searchable database. MSH often produces CD-ROM and print versions of the Guide as well.



A 2004 survey of users found:

- 65% do not have access to other sources of comparative, international price information.
- 42% use the Guide to assess cost implications of different therapies.
- 46% said that using the Guide has contributed to better acquisition prices or other savings.

Items in the Guide are listed and searchable by name or therapeutic class, using the WHO Essential Medicines List classification. The product's ATC code and defined daily dose (DDD) are included for convenience. Both the pack price and the unit price are listed. The unit price is calculated by dividing the package price by the package size. This facilitates comparison of different pack sizes. A median buyer price and median supplier prices are included.

The 2008 edition of the International Drug Price Indicator Guide was produced in collaboration with WHO and supported by the UK Department for International Development (DFID) and the Medicines Transparency Alliance (MeTA). Data from the 1996 edition to the present edition are available online at <http://erc.msh.org/pricguide>, along with special features to create custom lists of medicines, compare your prices and plan a budget. The explanatory text of the Guide is provided in English, French and Spanish.

Annex 5. Case Study: e-Procurement in Andhra Pradesh, India

Background

In 2000, the Government of Andhra Pradesh (GoAP), India, chose to introduce an e-procurement platform for procurement of goods, works and services. Prior to that, the GoAP had been using a manual tendering system which required a lengthy process of internal authorizations and multiple visits by suppliers to departments, and created large volumes of paper-based statements and evaluations.

Problems of manual tendering

The manual tendering system suffered from the following problems:

- Discrimination and delay by Government departments in the release of tender schedules to suppliers.
- Cartel formation by participating bidders to suppress competition.
- Physical threats by factions against genuine bidders to prevent them from submitting bids.
- Tender boxes were placed at multiple locations to counter the threats of contractor cartels but this created an additional management and transport burden upon Government officials.
- Tender files were tampered with or lost as they were physically transported through the administrative hierarchy.
- Delays in finalizing tenders due to red tape, lack of transparency and manual movement of tender files through the administrative hierarchy.
- Exposure of department personnel to interface with the bidders at every stage of the review and approval process that can lead to subjectivity, favoritism and other undesirable practices.
- Lack of transparency resulting from government departments tightly controlling and closely guarding information, creating a lack of trust in the system by bidders, media and citizens.

A GoAP subcommittee on tender reforms proposed creation of an e-procurement platform to address these challenges. The recommendation was based on the principle that automation of the procurement transactions would reduce human error, enhance the integrity of data, bring transparency to Government procurements and facilitate process standardization. The GoAP e-procurement process was designed to avoid supplier and buyer interaction during pre-bidding and post-bidding. The procurement process and forms used by different departments were standardized, and to bring transparency to the e-procurement process, tender documents containing all essential information and details were hosted on the web site.

Challenges in implementing e-procurement

The GoAP faced four significant challenges in implementing the e-procurement platform.

1. Selecting a sustainable business model with an appropriate implementation strategy. GoAP decided upon a public-private partnership model in which the private partner

provided technology expertise and upfront investment while recovering costs through charges to user departments for completed transactions.

2. Ensuring interdepartmental coordination. A high-level steering committee comprised of heads of all the participating departments was formed to promote coordination.
3. Managing the change process. Implementation of e-procurement required adopting new ways of doing business for different stakeholders. Supporting this change process was achieved through establishing and monitoring procurement targets for each department, identifying project champions within each department to support implementation, and conducting training workshops to effectively communicate the objectives and benefits of e-procurement.
4. Resolving security and authentication issues.

Benefits and cost savings from implementing e-procurement

The implementation of e-procurement has improved internal efficiency within Government departments, shortened tender cycle times, eliminated subjectivity in the evaluation of tenders and reduced corruption. Specifically:

- **Tender cycle times were reduced.** Prior to e-procurement, Government departments took 90 to 135 days to finalize high-value tenders. At the end of the first year of e-procurement (2003–2004) tender cycle times had been reduced to an average of 42 days. By the end of the second year (2004–2005) tender cycle times had been reduced to an average of 35 days.
- **Opportunities for corruption were reduced.** Supplier and department interaction during pre-bid and post-bid processes were minimized. The automatic tender evaluation process reduced subjectivity in tender evaluation and helped to curb opportunities for corrupt practices to a significant extent and increased the accountability of procurement officials.
- **Cost savings were achieved.** Tenders processed during the first year of e-procurement were on average 16% less than comparable quotations from the previous year of manual tendering. E-procurement also encouraged competition. Supplier participation increased from an average of 3 per tender in manual tendering to 4.5 in e-procurement. Departments have recognized cost savings with an average reduction of 20% in procurement transaction costs in 2003–2004 and 12% in 2004–2005.

e-procurement in Andhra Pradesh

Year	Value of transactions completed (US\$ million)	No. of transactions processed	Percentage of transactions in eProcurement out of total GoAP spend	Average tender cycle time (high value tenders) ^a	Average supplier participation per tender ^b	% reduction in GoAP costs of procurement transactions	% reduction in quoted prices from prior year manual procurement system
2003–04	447	564	20%	42 days		20%	16%
2004–05	3522	3746	80%	35 days	4.5	12%	
2005–06	3740	7931	90%				

^a Prior to e-procurement, government departments took 90–135 days to finalize high value tenders.

^b Prior to e-procurement, average supplier participation was three per tender.

- **Transparency improved.** The use of automated tender evaluation through smart forms and parameterized qualification criteria has improved transparency, reduced subjectivity in the tender award process and reduced corruption.

Key lessons learnt

Important factors in the successful implementation of e-procurement in Andhra Pradesh include:

- Establishing support of political leadership and formation of a high-powered steering committee.
- Pursuing a participative design process that included workshops attended by all key stakeholders.
- Establishing a single mode of bid submission through the e-procurement platform.
- Using technical experts to act as change agents in implementing e-procurement.
- Selecting a sustainable model that is rational and affordable for the government and its implementing partners.
- Identifying committed project teams to support help desk and security features.

Case study authors: K. Bikshapathi, Project Manager, e-procurement; P.Ramarajo, Chief Engineer, Immigration Department, GoAP; S. Bhatnagar, IIM, Ahmedabad, India. Submitted March 2006.