

**USAID-Funded Procurement of
HIV/AIDS-Related Pharmaceutical Products:
Constraints and Options for Improvement**

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Acronyms

ADS	Automated Directive System
AIDS	acquired immunodeficiency syndrome
AO	agreement officer
AZT	azidothymidine, now called zidovudine
BHR/OFDA	Bureau of Humanitarian Response, Office of Foreign Disaster Assistance [USAID]
CAs	cooperating agencies
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CO	contracting officer
CTO	cognizant technical officer
DHIV	Division of HIV/AIDS [USAID]
ELISA	enzyme-linked immunosorbent assay
EU	European Union
FAA	Foreign Assistance Act
FAR	Federal Acquisition Regulations
FDA	U.S. Food and Drug Administration
GATT	General Agreements on Tariffs and Trade
G/PHN	Global Bureau, Center for Population, Health, and Nutrition [USAID]
GSA	U.S. General Services Administration
HIV	human immunodeficiency virus
IDA	International Dispensary Association
MOH	Ministry of Health
M/OP	Management Bureau/Office of Procurement [USAID]
M/OP/TC/COM	Management Bureau/Office of Procurement/Transportation and Commodities Section/Commodities Division [USAID]
NGO	nongovernmental organization
PACTG 076	Pediatric AIDS Clinical Trials Group Study 076
PERC	public expenditure reform credit
PIC	Pharmaceutical Inspection Convention
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PTN	Procurement Technical Note
RPM	Rational Pharmaceutical Management [Project]
S/O	source/origin
SWAP	sector-wide approach
STD	sexually transmitted disease
STI	sexually transmitted infection
SUDS	Single Use Diagnostics System
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development

USAID/W	USAID Washington, DC, Office
US PHS	U.S. Public Health Service
VCT	voluntary counseling and testing
WB	World Bank
WHO	World Health Organization
WTO	World Trade Organization

Introduction

The U.S. Agency for International Development (USAID) Division of HIV/AIDS (DHIV) has developed a comprehensive package of programs to address the global HIV/AIDS crisis in developing countries. Many of the DHIV-supported programs involve the use of pharmaceutical products to diagnose, prevent, and treat HIV/AIDS and related conditions. Pharmaceutical products as defined in USAID procurement guidelines include drugs, vitamins, oral rehydration salts, biologicals, and some in vitro diagnostic reagents/test kits, but do not include devices or their components, parts, or accessories. These USAID guidelines are based on the Foreign Assistance Act (FAA) and the Federal Acquisition Regulations (FAR) and, therefore, are neither discretionary nor easily changed.

In brief, USAID-funded pharmaceutical purchases require prior USAID Management Bureau, Office of Procurement (M/OP) approval, which is based on two essential criteria:

1. The product must be purchased in the United States or a source/origin (S/O) waiver must be prepared and approved by USAID.
2. The safety, efficacy, and quality of the product itself, and its use in a specific program context, must be demonstrated by the purchaser and approved by USAID.

As the HIV/AIDS crisis has expanded, so have requests from cooperating agencies (CAs) and USAID Missions to purchase pharmaceutical products, which require adherence to regulatory guidelines established by USAID. Many USAID Missions and CAs have found it difficult and time-consuming to prepare the supporting documentation needed to meet these source/origin and safety, efficacy, and quality criteria.

At the same time, the international procurement environment is being changed by developing country governments' efforts to increase access to HIV/AIDS drugs. To address these issues, DHIV requested assistance from the Rational Pharmaceutical Management (RPM) Project to review recent events—domestic and international—concerning trade and procurement policies, as well as current M/OP guidelines concerning pharmaceutical procurements. The intent of the review is to provide an in-depth understanding of the regulatory requirements for DHIV-supported purchase of Food and Drug Administration (FDA)-approved, non-FDA-approved, and/or non-U.S.-source products so that issues that hinder procurement can be identified. In addition, the review explores options that could facilitate the availability of safe and efficacious drugs and commodities for DHIV programs.

Objectives

The specific objectives of this review are to—

1. Provide information on U.S. government pharmaceutical procurement policies within the context of USAID/DHIV programs.

2. Describe recent changes in U.S. pharmaceutical trade policies and recent liberalization of exports, and implications for USAID procurement policies.
3. Identify approaches to document acceptable quality assurance and efficacy requirements.
4. Outline existing procedures and information required to obtain approval for the procurement of pharmaceutical products with USAID funding.
5. Review the procurement issues involved in USAID-financed purchases of FDA-approved, non-FDA-approved, and/or non-U.S.–source drugs and describe gaps, barriers, and so forth.
6. Propose options, based on a review of current USAID procurement guidelines, to facilitate purchase of FDA-approved, non-FDA-approved, and/or non-U.S. S/O drugs and test kits.

Methodology

To develop this paper, RPM conducted a literature review to gain up-to-date information on the HIV/AIDS crisis, international donor and lender initiatives concerning HIV/AIDS, and international pharmaceutical trade and procurement issues, particularly those affecting HIV/AIDS drugs and commodities. Sections of the USAID Automated Directive System (ADS) concerning pharmaceutical procurement were also reviewed. In addition, semistructured key informant interviews were conducted with representatives of several CAs, USAID Missions, the USAID Office of Procurement, and DHIV to gain an understanding of, and different perspectives on, the USAID procurement process.

Briefing Document for Pharmaceutical Procurement

DHIV has also contracted RPM to develop a USAID Pharmaceuticals Procurement Briefer specifically designed to assist USAID Missions and CAs in the procurement of USAID-funded pharmaceutical products for HIV/AIDS programs.

The “Briefing Document for the Procurement of HIV/AIDS-Related Pharmaceutical Products Using USAID Funding” will describe USAID procurement guidelines for pharmaceutical products, provide guidance to USAID Missions and CAs on preparing requests for approval to purchase pharmaceutical products, outline sources of information to support requests, and describe the approval process. The briefer is expected to be available in late 2000.

Chapter 1.

Background

This chapter highlights recent events relating to trade and procurement policies in both the domestic and international arena. The impact of liberalization of U.S. policy and current international trade policy issues on pharmaceutical procurement is discussed in the first section. Then, specific issues that relate to the procurement of HIV/AIDS-related pharmaceutical products for developing countries are outlined. Finally, the recent revisions to World Bank (WB) procurement policies and the relevance to USAID procurement policies are reviewed.

Pharmaceutical Trade Policies and Issues That Affect Procurement

Liberalization of U.S. Policy

Four years ago, Congress overhauled U.S. export policy on pharmaceuticals with the passage of the Food and Drug Administration (FDA) Export Reform and Enhancement Act of 1996. The 1996 act permits U.S. manufacturers to sell drugs not approved by the FDA for use in the United States to any country in the world as long as the product complies with the importing country's laws, meets certain minimal conditions, and has valid marketing authorization from the European Union (EU) or any so-called Tier 1 country (e.g., Canada, Australia, Japan). The act overrides the 1986 amendment that allowed the limited sale of unapproved drugs but only with prior FDA approval and only to 21 countries with regulatory systems deemed as stringent as that of the United States. The 1986 law was the first liberalization of drug export controls.¹

The liberalization of U.S. policy for export of pharmaceuticals is fueling a debate about the implications of such policy changes and whether FDA approval is necessary to ensure the safety and efficacy of drugs purchased with U.S. funds in countries other than the United States. The act assumes that every country can evaluate a drug and arrive at a medically sound opinion about a product's risk and efficacy. Central to the debate is the country-level capacity to evaluate drug safety and efficacy. Many health professionals think that most developing countries unfortunately tend to lack the resources necessary to make an informed decision about the quality, safety, and efficacy of FDA-unapproved products.

International Trade Policy Issues

In May 1999, the United States voted in support of the 52nd World Health Assembly's (the policy-making body of the World Health Organization) resolution on a Revised Drug Strategy. Under this resolution, member states were urged to ensure that public health concerns are "paramount" in pharmaceutical and health policies and to explore options under relevant international agreements, including trade agreements, to safeguard access to essential drugs. Compulsory licensing and parallel importing are just two strategies that developing country governments may pursue, under certain circumstances, to make essential medicines more affordable to their people.

Compulsory licensing is a legal approach that permits the manufacture and use of the generic form of a drug covered by a current patent without the agreement of the patent holder. Compulsory licensing enables any government to instruct a patent holder to license the right to use its patent to a company, government agency, or other party. The patent holder receives remuneration based on the economic value of the authorization. Nearly every country has some type of compulsory licensing authority, but the grounds under which compulsory licenses are granted vary significantly from country to country.² To date, compulsory licensing has been rarely used for pharmaceuticals.

Today, the crisis in AIDS treatment is driving an international debate over compulsory licensing. Many developing countries view compulsory licensing as a way to make generic forms of HIV/AIDS-related drugs, particularly antiretrovirals, more available. For a country with a high HIV seroprevalence rate, the government could decide that it is in the public interest to ensure that appropriate drugs are manufactured locally and made available at a cheaper price. For example, an African country such as Zimbabwe could issue a license to a local company for an HIV/AIDS drug manufactured by Bristol-Myers Squibb. The Zimbabwean firm would then manufacture the drug for sale in Zimbabwe under a generic name, and it would pay a reasonable royalty to Bristol-Myers Squibb on each sale. Estimates are that compulsory licensing has the potential to lower the price of medicines by 75 percent or more. For example, in 1999, zidovudine (AZT) costs were approximately \$239 per month in the United States, but only \$48 per month in India, which currently recognizes process but not product patents.² In addition, products produced in developing countries are not generally required to meet the same standards as FDA-approved drugs, and procurers need to ensure that the quality of such pharmaceutical products is not compromised for a cheaper price.

Parallel imports involve imports of a product from one country and resale, without authorization of the original seller, in another, thereby allowing the buyer to search for the lowest world market price. Parallel importing is a common practice internationally, and there is trade in a wide range of goods, including such items as pianos, automobiles, motorcycles, chemicals, pharmaceuticals, computers, cameras, jeans, music CDs, and ski equipment. Purchasing proprietary drugs from a third party in another country, rather than directly from the manufacturer, takes advantage of the fact that pharmaceutical companies sometimes offer their products for sale at significantly lower prices in one country than in another. However, many manufacturers raise concern that parallel imports may be substandard products or even counterfeits and, thus, may be difficult to support or service.² In addition, manufacturers are concerned that poor storage and transportation conditions during the transfer of parallel imports between countries could compromise product quality and result in adverse events for which they may remain liable.

Both parallel importing and compulsory licensing are permitted under the international trade rules established by the General Agreements on Tariffs and Trade (GATT) and administered by the World Trade Organization (WTO). The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contains international rules on patents, copyrights, and trademarks and is one of the GATT agreements. TRIPS requires countries to grant patent protection to pharmaceutical products for a minimum period of 20 years. However, the TRIPS agreement does allow the issue of compulsory licenses but only under certain conditions. The TRIPS agreement

also does not prohibit parallel importing. Recognizing the need for affordable prices, in May 2000, President Clinton issued an executive order stating that the U.S. government will not seek to overturn any intellectual property law or policy imposed by a sub-Saharan African government that promotes access to HIV/AIDS pharmaceuticals and medical technologies.

To lower the cost of HIV/AIDS drug therapies in developing countries, a number of other approaches have been tried or are currently being used. These strategies include therapeutic value pricing, pooled procurement, negotiated procurement, planned donations, and lobbying pharmaceutical companies. For example, most recently, several major pharmaceutical manufacturers announced an agreement to cut the cost of drugs to treat AIDS in Africa and other developing countries.

The Need for Drugs and Test Kits in HIV/AIDS Programs

There is universal agreement that HIV/AIDS is a global health crisis. Of the nearly 34 million people worldwide living with HIV/AIDS, 95 percent are in developing countries.³ Africa is particularly hard hit. For example, of the 570,000 new pediatric HIV infections that occurred in 1999, almost 90 percent were in Africa and almost all of them were from perinatal (mother-to-child) transmission.³

Following are a few summary statistics:

- It is estimated that more than 23 million Africans south of the Sahara are infected with HIV, and AIDS has become the leading cause of death in the region. Current information seems to suggest that significantly more women are infected than men.³
- Infant and child mortality rates in east and southern Africa are now between one-third and two-thirds higher than they would have been in the absence of AIDS, contributing to the progressive reduction in life expectancy in this region.^{4,5}
- More than 80 percent of the 14.8 million women living with HIV by the end of 1999 were African.³
- In several urban centers in eastern and southern Africa, HIV infection rates in pregnant women now exceed 25 percent.⁶

Some therapeutic advances have been made. Few aspects of HIV research have demonstrated results as dramatic as trials using antiretrovirals to prevent perinatal HIV transmission. In 1994, results of the Pediatric AIDS Clinical Trials Group Study 076 (PACTG 076) showed a two-thirds reduction in perinatal transmission from HIV-infected women who received a complex regimen of AZT.⁷ This study formed the basis of the current U.S. regimen.

A recent article in the *Journal of the American Medical Association* reviewed current knowledge of perinatal transmission in developing countries.⁸ In developing countries, trials of simplified AZT regimens in Southeast Asia and West Africa demonstrated reductions in perinatal

transmission of one-half to one-third.^{9,10} Recently, a trial in Uganda of a single dose of nevirapine given to mother and neonate showed similar results.¹¹ Thus far, evaluations of several low-cost preventive measures other than antiretroviral drugs have been disappointing. For resource-poor settings, nevirapine or other potent drugs with long half-life, given at labor onset and to the neonate, appear most feasible, but they require further evaluation of efficacy, safety, and the potential for development of resistance.⁸

Many experts believe that in settings where the full PACTG 076 regimen cannot be implemented, it would be best to adopt either the short-course AZT regimen (evaluated in Thailand, Côte d'Ivoire, and Burkina Faso) or the intrapartum and short-term neonatal regimens of nevirapine, with the recognition that experience with nevirapine is limited to one study.⁸

In the 11th revision (December 1999) of the World Health Organization's (WHO's) Model List of Essential Drugs, nevirapine and AZT are the only antiretroviral drugs included and perinatal transmission is the only indication for use.¹² The WHO Model List also recognizes that "adequate resources and specialist oversight are a prerequisite for this class of drugs" and that for most developing countries, triple drug therapy, the standard of care in developed countries, is beyond the budget of national drug programs.

HIV Testing

On January 28, 2000, the WHO Executive Board submitted a resolution for adoption by the 53rd World Health Assembly, which, among other things, urges member states to¹³—

1. Establish or to expand voluntary counseling and confidential HIV-testing services in order to encourage health-seeking behavior and to act as an entry point for prevention and care.
2. Define and affirm their role and, where appropriate, engage in partnerships and solidarity initiatives to make prophylactic and therapeutic drugs affordable and safely and effectively used, whether intended for prevention of perinatal transmission, prevention and treatment of opportunistic infections, or access to antiretroviral treatment for patients.

Developing countries face increasing levels of infection, disease, and death due to the HIV epidemic. Access to voluntary counseling and testing (VCT) is an essential component of many interventions that prevent the transmission of HIV, prevent or treat opportunistic infections, and improve access to treatments for HIV/AIDS. In resource-poor settings, increased use of rapid testing may be especially helpful in perinatal transmission prevention programs for pregnant women, who access antenatal care sporadically or only access care at delivery.

Recent Revisions to World Bank Procurement Policies

Many of the programs of the WB involve the procurement of pharmaceutical products. According to a report prepared by the Karolinska Institute in Stockholm, Sweden, on WB activity in the pharmaceutical sector worldwide, \$1.3 billion were committed to loans or credits

supporting pharmaceutical activity in its program countries between 1989 and 1995.¹⁴ Almost 60 percent of the health, nutrition, and population sector projects involved pharmaceutical area activities. The report states that no more than 45 percent of the projects were developed in collaboration with pharmaceutical experts and recommends that the WB engage personnel with pharmaceutical expertise familiar with the drug sector in developing countries in the planning and implementation phase of its projects. The report also recommends that the WB improve its pharmaceutical sector activities by promoting drug policy research and development, including national and international dialogue on pharmaceutical issues to ensure rational use of both drugs and loans. It cites the need for initiatives to define essential functions and to improve a coordinated division of labor among international health agencies and national governments.

These findings come at a time when the WB is changing its lending approach, shifting in many countries from project funding to sector funding. Under WB sector funding, such as the public expenditure reform credit (PERC) and sector-wide approach (SWAP) strategies, loan money is released to the treasury of the borrowing country as the country reaches agreed-upon benchmarks and meets certain conditionalities. The borrowing government is then responsible for how the loan/credit is spent in the sector. Such changes in lending strategies will require that WB task managers better understand a country's capacity in order to make informed decisions and oversee procurements made with loan money.

Due to the WB's large investment in the procurement of drugs, the changing international lending environment, and the procurement challenges being faced by its field task managers, the organization saw the need to update, standardize, and streamline its procurement procedures. The WB contracted with Management Sciences for Health's Drug Management Program to draft a revision of its *Procurement Technical Note (PTN): Health Sector Goods*, which is the WB's manual of guidance for procuring drugs, vaccines, family planning supplies, and other health sector goods. The revised PTN includes instructions for the various health sector items that are procured and incorporates new language that addresses issues raised and comments made by users of the documents. One of the criteria that was added to the WB PTN was the requirement of a thorough assessment of pharmaceutical procurement capacity of the borrowing country before major procurements were implemented.

The PTN is written for WB technical field managers involved in facilitating the procurement of pharmaceuticals at the country level with WB loans or credits. Many WB managers lack the technical expertise to guide recipient countries through the procurement process. One of the critical aspects of the process is to determine if the local country has the capacity to manage the procurement process. The WB has developed several tools to assist in the country assessment of procurement capacity and wanted to inform its field managers about the availability of these tools and to have them integrated into the procurement process. The revised PTN should make the WB procurement process run more smoothly by providing clearer directions and making more explicit the criteria for a "no objection" procurement.

The WB is also exploring strategies to promote the harmonization of bidding procedures among United Nations (UN) organizations in an effort to improve efficiencies and to reduce the burden on borrower countries to comply with donor- and lender-specific procurement guidelines. This lending strategy is also in line with other initiatives to improve donor and lender coordination at

the country level and the growing demand from borrower countries to have more flexibility in targeting the use of borrowed funds. Many countries are promoting greater donor and lender coordination through strategies that pool resources from international organizations to combat problems such as HIV/AIDS and improve the efficient use of funds. Some of these pooled resources, for example, could be used to buy pharmaceutical commodities.

Like field-level WB managers, USAID Missions face challenges concerning the procurement of pharmaceuticals. USAID Missions have the added challenge of assisting cooperating agencies (CAs) and nongovernmental organizations (NGOs), as well as building the capacity of the Ministries of Health (MOHs) to procure pharmaceutical commodities. USAID Missions could also benefit from an assessment similar to the requirement added to the revised WB PTN to better understand local pharmaceutical system capacity and to help inform their decision-making process concerning local pharmaceutical procurements.

Many USAID Missions are also faced with MOH requests for greater flexibility for pooling of resources and donor coordination. In Mozambique, for example, there is a Donor's Roundtable Group that aims to coordinate efforts in the pharmaceutical sector. The Donor's Group includes Norway, Denmark, Switzerland, Spain, Holland, the EU, WB, United Nations Population Fund (UNFPA), Joint United Nations Programme on HIV/AIDS (UNAIDS), and USAID, among others. In its effort to harmonize procurement methods for pharmaceuticals in Mozambique, the Danish International Development Agency is considering abandoning the special requirement for Danish-tied aid, necessitating procurement in Denmark only, in favor of the creation of a national fund that would pool donor resources. This would also help to harmonize procedures for budgeting and implementation. However, as most of USAID's procurement guidelines are based on legislative requirements, there are limitations on the extent to which USAID can streamline and harmonize its procedures with other donors.

Summary of Contextual Issues

This review of USAID procurement guidelines and analysis of options for improvement is set against a background of changes in international and domestic trade and procurement policies, which include the following:

- As a result of the liberalization of U.S. policy on the export of pharmaceuticals in 1996, U.S. manufacturers can sell non-FDA-approved pharmaceutical products to any country as long as the product complies with the importing country's laws, meets certain minimal conditions and has a valid marketing authorization in certain listed countries. The FDA Export Reform and Enhancement Act assumes that every country has the capacity and the resources to evaluate the safety, efficacy, and quality of a pharmaceutical product.
- The catastrophic impact of the HIV/AIDS epidemic and the lack of access to treatment in developing countries is driving an international debate over mechanisms to make HIV/AIDS-related drugs more available. In an effort to ensure that public health concerns are paramount in pharmaceutical and trade policies, developing countries are exploring options under international trade agreements to safeguard access to essential drugs. These options include

parallel importing and compulsory licensing, which are permitted under TRIPS under certain conditions. Other options include negotiated procurement, planned donations, and lobbying pharmaceutical companies, in addition to pooled procurement and therapeutic value pricing.

- Recent research and evaluations of mechanisms to prevent perinatal transmission of HIV-1 have demonstrated that interventions exist that are both effective and cost-effective for developing countries.
- Access to HIV VCT is an essential component of many interventions that prevent the transmission of HIV, and programs frequently require the procurement of rapid/simple HIV test kits.
- The changing international lending environment and the procurement challenges faced by its field task managers have driven recent revisions to WB procurement policies. The revised PTN included the requirement for a thorough assessment of the pharmaceutical procurement capacity of the borrowing country before major procurements are implemented. USAID Missions could also benefit from a similar assessment to better understand local pharmaceutical system capacity and to help inform their decision-making process concerning local pharmaceutical procurements.
- The WB is also exploring strategies to promote the harmonization of bidding procedures among UN organizations in an effort to improve efficiencies and to reduce the burden on borrower countries to comply with donor- and lender-specific procurement guidelines. As most of USAID's procurement guidelines are based on legislative requirements, the extent to which USAID can streamline and harmonize its procedures with other donors is limited.

Chapter 2.

Current USAID Procurement Regulations for Pharmaceutical Products

This chapter presents USAID's procurement regulations and briefly discusses the implications for USAID Missions and CAs that procure pharmaceutical products using USAID funding. The USAID procurement process is outlined at the end of the chapter.

USAID Procurement Regulations

USAID's procurement regulations are outlined in Automated Directive System (ADS) Chapter 312¹⁵ and in Subpart F of 22 Code of Federal Regulations (CFR) 228.¹⁶

These USAID procurement guidelines are based on the Foreign Assistance Act (FAA) and the Federal Acquisition Regulations (FAR) and, therefore, are neither discretionary nor easily changed. In brief, USAID-funded pharmaceutical purchases require prior Management Bureau, Office of Procurement (M/OP) approval that is based on two essential criteria:

1. The product must be purchased in the United States or a source/origin (S/O) waiver must be prepared and approved by USAID.
2. The safety, efficacy, and quality of the product itself, and its use in a specific program context, must be demonstrated by the purchaser and approved by USAID.

ADS Chapter 312 Section 2 states that pharmaceutical product procurement is required to fulfill the following objectives:

1. To assure that the resources made available by USAID in the form of commodities make a positive contribution to development.
2. To assure that USAID programs are implemented in full accord with the Foreign Assistance Act, other pertinent laws and relevant U.S. policies.
3. To assure that only safe and efficacious pharmaceutical products are financed, that they are manufactured in accordance with accepted quality standards, that prices paid for them are appropriate, and that in all respects, USAID's financing of pharmaceutical procurements is carried out in a manner sensitive to the special public and Congressional interests in this important commodity.
4. To provide for economic procurement of contraceptive products.

Buy America

ADS 312 Section 5.3c requires that pharmaceutical products procured using USAID financing be of U.S. source and origin (Code 000).

USAID Geographic Code	Description
Code 000—The United States	The United States of America, any State(s) of the United States, the District of Columbia, and areas of U.S.-associated sovereignty, including commonwealths, territories, and possessions.
Code 899—Free World	Any area or country, except the cooperating country itself and the following foreign policy restricted countries: Afghanistan, Libya, Vietnam, Cuba, Cambodia, Laos, Iraq, Iran, North Korea, Syria and the People's Republic of China.
Code 935—Special Free World	Any area or country in the Free World including the cooperating country, but excluding the foreign policy restricted countries.
Code 941—Selected Free World	The United States and any independent country in the Free World (excluding foreign policy restricted countries), except the cooperating country itself and the following: Albania, Andorra, Angola, Armenia, Austria, Australia, Azerbaijan, Bahamas, Bahrain, Belgium, Bosnia and Herzegovina, Bulgaria, Belarus, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Gabon, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Kazakhstan, Kuwait, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia*, Malta, Moldova, Monaco, Mongolia, Montenegro*, Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russia, Sa Marino, Saudi Arabia, Serbia*, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan*, Tajikistan, Turkmenistan, Ukraine, United Arab Emirates, United Kingdom, Uzbekistan, and Vatican City.

* Has the status of "Geopolitical Entity" rather than independent country.

S/O waivers can only be issued under the following criteria set out in ADS E312.5.3c:

1. The pharmaceutical product is essential to the activity;
2. The product, in the same or substantially equivalent form, is not available from the United States, or the delivered price from the United States would be at least 50 percent more than from another source; and
3. Information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority.

In addition, ADS E312.5.3c.3 states that any non-U.S. pharmaceutical product purchased may not infringe U.S. patent laws and that this requirement cannot be waived.

Exceptions made to the rule that USAID-financed pharmaceuticals be of U.S. source and origin must also be in accordance with the requirements for commodities set out in Subpart F of 22 CFR 228 Section 228.51, of which the following excerpts are relevant to pharmaceutical products:

(a) Waiver criteria. Any waiver must be based upon one of the criteria listed in this section. Waivers to Geographic Code 899 or Code 935 which are justified under paragraph (a)(2) or (3) of this section may only be authorized on a case-by-case basis. A waiver may be authorized when:

(1) A commodities required for assistance is of a type that is not produced in or available for purchase in the United States; in addition, for waivers to any country or Geographic code beyond Code 941 and the cooperating country, the commodity is of a type that is not produced in or available for purchase in any country in Code 941 or the cooperating country.

(2) It is necessary to permit procurement in a country not otherwise eligible in order to meet unforeseen circumstances, such as emergency situations.

(3) It is necessary to promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives.

(4) For waivers to authorize procurement from Geographic Code 941 or the cooperating country:

(i) For assistance other than commodity import programs, when the lowest available delivered price from the United States is reasonably estimated to be 50 percent or more higher than the delivered price from a country or area included in Geographic Code 941 or the cooperating country.

(ii) For assistance other than commodity import programs, when the estimated cost of U.S. construction materials (including transportation and handling charges) is at least 50 percent higher than the cost of locally produced materials.

(iii) For commodity import programs or similar sector assistance, an acute shortage exists in the United States for a commodity generally available elsewhere.

(iv) Persuasive political considerations....

Therefore, under these regulations, USAID Missions and CAs must satisfy M/OP/TC/COM that procurement from a U.S. source and origin has been considered and specify the reasons for the necessity to purchase the pharmaceutical product from a non-U.S. source.

Safety, Efficacy, and Quality

To obtain approval to purchase pharmaceutical products that are not approved by the FDA using USAID funding, USAID Missions and CAs must provide information to attest to the safety, efficacy, and quality of the products. They must also satisfy M/OP/TC/COM that the product is correct or appropriate for the proposed application in the specific circumstances that it will be used. Issues that need to be addressed include the storage and environmental conditions, the technical capacity of the staff, the compatibility of the product with products supplied by other donors, and the protocols for its use.

Summary of the USAID Procurement Process

Approvals for USAID-funded pharmaceutical product procurements require—

1. A request to the Office of Procurement from the CA requesting approval to purchase;

2. If the product is of non-U.S. source and/or origin, an S/O waiver prepared by the cognizant technical officer (CTO) and approved by the relevant Bureau or Mission official with delegated authority;
3. Technical concurrence of the M/OP/TC/COM commodities officer;
4. CTO technical concurrence; and
5. Approval by M/OP, namely the contracting officer (CO) or the agreement officer (AO).

Following is the sequential list of steps necessary for pharmaceutical procurement approval:

1. The CA sends a letter to the CO or AO requesting permission to purchase a pharmaceutical product. This letter should include all of the information needed to make the decision (such as whether the product(s) is/are of U.S. source/origin; whether the product(s) is/are FDA-approved; justification for the need to purchase; the S/O waiver request if needed; and sufficient data on safety, efficacy, and quality for the M/OP/TC/COM to make a determination). The CTO is copied on this letter.
2. The CTO prepares the S/O waiver, if needed, and submits the S/O waiver for signature approval by the USAID Bureau representative/Mission official with the appropriate authority.
3. The CTO then forwards the signed S/O waiver to the CO or the AO, along with the CTO's own signed technical recommendation, for approval.
4. The CO or AO forwards the CA's request for approval to purchase (including the signed S/O waiver, if appropriate) to the USAID Contracting Office/Commodity procurement official to seek concurrence for the approval.
5. The USAID Contracting Office/Commodity procurement official reviews the technical information about the product and program provided by the CA and returns his/her decision to the CO or AO.
6. The CO or AO reviews the entire request and sends the CA a written response to its request to purchase the commodity.

Summary of Key Issues

- USAID procurement guidelines are based on the Foreign Assistance Act and the Federal Acquisition Regulations and, therefore, are neither discretionary nor easily changed.
- Products procured using USAID funding must be purchased in the United States; otherwise an S/O waiver must be prepared by the CTO and signed by the USAID Bureau representative/Mission official with the appropriate authority.

- The safety, efficacy, and quality of the USAID-funded product itself, and its use in a specific program context, must be demonstrated by the purchaser, and M/OP/TC/COM must give technical concurrence.
- Any non-U.S. pharmaceutical product purchased using USAID funds must not infringe U.S. patent laws.

Chapter 3.

Procurement Problems Faced by USAID Missions and Cooperating Agencies

Cooperating agencies and USAID Missions may need to procure a number of pharmaceutical products that are essential to their HIV/AIDS programs. These can include test kits for the diagnosis and screening of HIV infections and for other sexually transmitted infections (STIs), antibiotic susceptibility testing kits, and drugs for prophylaxis and treatment of STIs, HIV/AIDS, and the opportunistic infections associated with HIV/AIDS.

The first part of this chapter discusses the problems reported by USAID Missions and CAs in obtaining appropriate HIV/AIDS products at competitive prices and adhering to current procurement guidelines. The observations by USAID Washington, DC, Office (USAID/W) staff on the problems experienced by USAID Missions and CAs to secure approval for the procurement of HIV/AIDS-related pharmaceutical products, particularly for non-U.S. S/O and/or non-FDA-approved products, are outlined in second part of this chapter.

Observations from USAID Missions and CAs

Five key informants were interviewed, two from USAID Missions and three from USAID CAs. Two key informants have experience in preparing requests for approval to purchase U.S. S/O, FDA-approved pharmaceutical products for use in their programs. Three of the key informants are currently in the process of preparing requests for approval to purchase non-U.S. S/O, non-FDA-approved HIV test kits, and one informant has had similar requests approved. In addition, one key informant has had extensive experience in preparing and submitting requests for approval to procure non-U.S. S/O, non-FDA-approved test kits, drugs, and antibiotic susceptibility kits to support HIV/AIDS programs.

The subjects discussed in this section are—

- The issues associated with procuring and using U.S., FDA-approved products for HIV/AIDS programs by Missions and CAs
- The experiences of the key informants in preparing and submitting requests for approval to procure pharmaceutical products, including non-U.S. S/O, non-FDA-approved products
- The impact of USAID procurement procedures on program implementation and management
- Key informant suggestions for possible improvements

U.S. S/O, FDA-approved Pharmaceutical Products

This section covers the issues associated with procuring and using U.S. S/O, FDA-approved products for HIV/AIDS programs by Missions and CAs. The main issues identified in the interviews were the price differential between U.S. source and non-U.S. source products, the appropriateness of U.S. S/O, FDA-approved products for USAID Division of HIV/AIDS (DHIV) programs, and pharmaceutical company territorial agreements.

Price

The price difference between U.S. source pharmaceutical products and non-U.S. source products, such as those provided by the United Nations Children's Fund (UNICEF), was identified by three key informants as being a major concern, as it ultimately reduces the number of clients to whom the services included in the scope of work can be provided. In addition, the sustainability of donor programs may be compromised because the price of the pharmaceutical products selected for these programs may determine if the cooperating country will be able to continue to procure them once donor-funded procurements are discontinued.

One key informant anticipated that the price of antiretrovirals was certain to influence the design and implementation of future USAID-funded programs involving the use of these drugs to prevent perinatal transmission of HIV in the field. A second key informant stated that in view of the high price of U.S. S/O products, the organization would probably seek to obtain donations of antiretrovirals, possibly from UNICEF, for pilot projects to prevent perinatal transmission of HIV, rather than procuring these drugs using USAID funding.

However, subsequent to these interviews, on May 11, 2000, UNAIDS reported that a new public/private sector effort between UNAIDS and five pharmaceutical companies had been initiated to accelerate access to HIV/AIDS care and treatment in developing countries. An "in principle" agreement had been reached to investigate ways of lowering prices, but it is likely that this would only apply to drugs purchased by governments for public sector use. It is not yet clear whether this price reduction will be available to USAID-funded drugs procured in the United States.

Appropriateness for Program

The single most important issue in complying with USAID procurement guidelines identified by four key informants was the inappropriateness of the available U.S. S/O, FDA-approved pharmaceutical products for use in HIV/AIDS programs in the field. This issue is discussed in detail with reference to simple/rapid HIV test kits as an illustration.

Harmonization of Donor-financed Pharmaceutical Products

The lack of harmonization of donor-financed pharmaceutical products can result in a wide range of products being available in a single country, as each donor or lender seeks to provide products sourced and produced in its own country for use in the programs that it funds. For example, there are currently six different simple/rapid HIV test kits in use in Zambia due to the lack of harmonization. The potential for error in an HIV/STI testing service is consequently increased because each kit has a different protocol for use and a different method of interpreting the results.

Compatibility with Cooperating Country Guidelines or Essential Drugs List/National Formulary

Pharmaceutical products provided by donors should ideally comply with the cooperating country guidelines or essential drugs list/national formulary to maximize the positive impact of the donation, unless specifically requested otherwise by the recipient. Ensuring that the conditions of donor financing are complied with affects the efficiency of inventory control and procurement systems, particularly for international tendering, as the cooperating country or program manager cannot obtain the full benefits of bulk procurement.

Appropriateness for Technical Capacity

The U.S. S/O, FDA-approved pharmaceutical product may not be appropriate for the level of technical capacity in the cooperating country. For example, simple/rapid HIV test kits can improve the effectiveness of HIV testing in laboratories that have limited facilities and lack the technical expertise to perform ELISAs (enzyme-linked immunosorbent assays), which require central laboratories and highly trained technical staff. The simple/rapid test kits can also facilitate the expansion of counseling and voluntary HIV testing services in areas where access to laboratories is limited. The availability of rapid assays for voluntary HIV counseling and testing has a particular advantage in offering same-day results, thus substantially reducing the proportion of clients tested who do not return to learn their results. Simple/rapid tests that use whole blood from a finger prick offer advantages in that they require neither a centrifuge to prepare plasma or serum nor needles and syringes to draw blood.

At present, there is only one FDA-approved, U.S. S/O rapid test kit available, the Single Use Diagnostics System (SUDS) HIV-1. This test is classified by the U.S. Centers for Disease Control and Prevention (CDC) as “Level Three,” with technical staff requiring training and a moderate level of expertise. In addition, the test is performed in serum or plasma, requiring a centrifuge and blood to be drawn. The SUDS test is therefore inappropriate for use for same-day testing in facilities that do not have adequate laboratory facilities. SUDS may also be inappropriate for use in certain facilities as it requires refrigerated storage conditions that may be unavailable. Similar difficulties can arise with other U.S. S/O and/or FDA-approved STI test kits and antibiotic sensitivity testing strips.

Simpler and more appropriate non-FDA–approved rapid HIV test kits are available. For example, the AIDS Information Centre in Uganda recently proposed to include the simple/rapid HIV test kits Determine HIV1/2, Hema-Strip HIV1/2, and UNI-Gold HIV in its testing algorithm as these kits are simple step tests, classified by CDC as “Level One” complexity, requiring no additional equipment and little or no laboratory training. In addition, they do not require refrigerated storage and use whole blood drawn from a finger stick.

Appropriateness for the Local Situation

The U.S. S/O, FDA-approved pharmaceutical product may not be appropriate for the local situation in the country or region in which it is to be used. It is important that the pharmaceutical product is compatible with the language, the training, and the experience of the technical staff who are to use the products to avoid the expense associated with retraining and translating instructions.

A requirement for HIV test kits is that they must be evaluated in the context of the country-specific algorithm and the local situation to ensure that the most appropriate combination is chosen in terms of the positive and negative predictive values of the tests and also with reference to the HIV variants, such as HIV-2, that are present in a particular geographical region.¹⁷ The probability that a test will accurately determine the true infection status of a person being tested varies according to the background prevalence of HIV. In general, the higher the prevalence of HIV in a population, the greater the probability that a person testing positive is positive (the positive predictive value) and, conversely, the higher the proportion of false negatives.

UNAIDS/WHO recommend that an algorithm or strategy to diagnose HIV infection use at least two and usually three antibody assays, which are required to be used in a specific order.¹⁷ The order of use is determined by the specificity and sensitivity of the tests, with the first test having a higher sensitivity and, therefore, detecting fewer false negatives, and the second and third tests having a higher specificity and, therefore, fewer false positives. Therefore, the test kits included in an HIV testing algorithm need to be complementary to each other. Many cooperating countries have subsequently adopted or are in the process of formulating guidelines that require the use of two or three simple/rapid HIV test kits for voluntary HIV counseling and testing. These guidelines frequently require non-FDA–approved test kits, generally not of U.S. source/origin.

Pharmaceutical Company Territories

Occasionally, pharmaceutical companies divide the international market into territories and form agreements within and between companies on territorial rights for the marketing and the sale of products. Consequently, the sale or availability of some pharmaceutical products of a certain source and origin may be restricted according to these defined territories. The purchase of pharmaceutical products of U.S. source/origin for use in programs in other countries can occasionally violate these territorial agreements. One key informant had experience of this when HIV test kits were purchased from the United States for use in a program in Indonesia. The

implementation of the program was delayed until a waiver had been issued by the company holding the territorial rights for distribution of the test kits in Indonesia.

Preparing and Submitting Requests

The experiences of the key informants in preparing and submitting requests for approval to procure pharmaceutical products, including non-U.S. S/O, non-FDA–approved products, are outlined in this section. The issues discussed are the complexity of the process and the availability of guidance material, the scale of effort and time to prepare requests for approval, and providing data on the safety, efficacy, and quality of non-FDA–approved pharmaceutical products.

Complexity of the Process and Availability of Guidance Material

One key informant, for whom procurement was a new activity, felt that the procedure to obtain approval to purchase pharmaceutical products was very complex in terms of finding the USAID guidelines and understanding how they were to be applied. The informant felt that there was a lack of guidance on the procedure for procuring drugs, even from the United States, for those who are new to procurement. For example, information on locating existing wholesalers would be very useful.

All four informants who had had experience preparing requests for approval to procure non-U.S. S/O, non-FDA–approved products found that the procedure itself was not complicated, but the lack of guidance presented the greatest obstacle. One key informant stated that the process was actually very routine and that once she had a copy of a previous request and understood what data needed to be presented and how to present it, the process had not been onerous.

Scale of Effort and Time Taken to Prepare the Requests for Approval

Four key informants commented that it took a significant period of time to prepare each request, particularly for non-U.S. S/O and non-FDA–approved products. This translated into increased costs. One CA took three months to prepare its first request for approval to purchase non-U.S. S/O, non-FDA–approved HIV test kits, despite having access to both legal and technical in-house expertise. It is beyond the scope of this report to conduct quantitative analysis on the time taken to prepare requests for approval.

Two of the key informants have been involved in preparing a request for approval to purchase non-U.S. S/O, non-FDA–approved HIV test kits that has taken one year to date, due to the difficulty in identifying the data required to support the request and obtaining it in the field. The process has consequently demanded a significant effort and has been further complicated by a change in cooperating country recommendations regarding the selection of test kits during the preparation of the request for approval, resulting in yet further delay.

Dissatisfaction was also expressed at the duplication of effort in preparing and submitting requests for approval to purchase identical non-U.S. S/O and/or non-FDA–approved products for similar programs based in different countries.

One key informant commented that in her experience, the scale of effort was often out of proportion with the return, as the total cost of the pharmaceutical products for each S/O waiver was often as low as \$400, although occasionally as high as \$80,000.

Providing Data on Safety, Efficacy, and Quality of Non-FDA–approved Pharmaceutical Products

The provision of these data was cited by one key informant as the single most difficult component of preparing a request for approval to purchase non-FDA–approved products, particularly for drugs, as the informant did not have the technical expertise to know what documentation should be requested, from whom to get it, and how to evaluate it. Consequently, the CA tended to avoid large-scale procurement of drugs due to the liability implications.

Generally, informants felt that providing the technical information for HIV test kits had not presented the same level of difficulty as for drugs as the technical expertise was generally available in the field or within the technical authority of the cooperating country that had prepared the algorithms or guidelines. One CA that had prepared a request for approval to purchase non-U.S. S/O, non-FDA–approved HIV test kits that was approved attributed the success to in-house technical expertise through an employee who had extensive experience in the application and use of HIV test kits.

Program Implementation and Management

One CA that was applying for approval to procure U.S. S/O, FDA-approved drugs experienced significant delay in obtaining supplies, which the key informant felt was entirely due to the procedural mistakes made because of lack of familiarity with and understanding of the process. However, the negative impact on programs identified by the other key informants related to requests to procure non-U.S. S/O and/or non-FDA–approved pharmaceutical products.

Four key informants identified increased costs due to the time taken to prepare requests for approval to purchase non-U.S. S/O and/or non-FDA–approved products. To minimize the negative impact of time delays in preparing the request, one informant chose to obtain simple/rapid HIV test kits from other sources for a program in Zambia. One of the key informants involved in preparing and submitting this request for approval commented that it might be preferable for USAID to provide funds to WHO to procure simple/rapid HIV test kits in the future.

The planning and implementation of programs was identified as being affected mainly by the uncertainty of outcome with regard to whether the request for approval to purchase non-U.S. S/O, non-FDA–approved products would be approved by the USAID Office of Procurement, and

how long it would take. One of the key informants expressed concern that the approval process might be further delayed due to the lack of pharmaceutical expertise within M/OP/TC/COM and the consequent need to request external technical reviews of requests. As a result of the negative impact of the procurement process on program planning, one CA decided either to absorb the cost of buying FDA-approved, U.S. S/O pharmaceutical products, with the consequent reduction in the scale of services provided, or to avoid programs that require non-U.S. S/O, non-FDA-approved pharmaceutical products.

One key informant mentioned that the expansion of an HIV testing program in Zimbabwe was affected by the time taken to approve a modification to a request for approval to purchase non-U.S. S/O, non-FDA-approved products previously approved for the pilot project. The CA had requested a change in the selection of HIV test kits because the project was being expanded into areas that did not have access to laboratory facilities. The approval for the change from a test kit that required laboratory capability to one that could be conducted in the field took six weeks, and in this time the CA missed the production run of the replacement kit. As a result, the replacement kit is still unavailable after six months, and USAID has had to provide funding to refrigerate the blood samples in the field and to transport the samples to the laboratories. Consequently, the program has been unable to offer same-day testing in the field.

Suggestions for Possible Improvements

All of the key informants had opinions on how to improve the procurement process. The suggestions include a procurement briefing document, training workshops, transferring technical concurrence for procurement of non-FDA-approved products, and accepting CDC as a certifying authority for HIV test kits. Blanket approvals to purchase specific categories of non-U.S. S/O, non-FDA-approved products were also discussed.

Briefing Document

All five key informants felt that a briefing document would significantly improve the process of preparing a request for approval to procure pharmaceutical products. The objective of the document would be to provide guidance to USAID Missions and CAs on USAID procurement guidelines and on how to prepare a request for approval.

It was suggested that the document should include examples of previous requests for approval, details of what kind of information was needed to support the request, and possible sources of this information. One of the key informants who had experience in preparing successful requests for approval to purchase non-U.S. S/O, non-FDA-approved HIV test kits was willing to provide copies of his requests for approval and to act as a resource person to other agencies.

One key informant said that, ideally, the document should include detailed information such as Web site addresses for products, but commented that ensuring that the information was kept current may present some difficulty. The briefer could also incorporate information on additional procurement requirements such as having to advertise in *Commerce Business Daily* for

pharmaceuticals over a certain line value and/or notifying the Office of Small Disadvantaged Businesses Utilization, which may be applicable under certain contracts or cooperative agreements.

Workshops

The key informant who was new to procurement suggested that there was a need for an annual workshop for personnel who are in a similar position. The workshop could cover the procedures and issues that are general to all CAs and Missions.

Transfer of Technical Concurrence for Procurement of Non-FDA–approved Pharmaceutical Products from M/OP/TC/COM to DHIV

It was suggested by one key informant that the process could be accelerated by transferring the authority to provide technical concurrence for procurement of non-FDA–approved pharmaceutical products, specifically for simple/rapid HIV test kits, from M/OP/TC/COM to DHIV, because he felt that DHIV had access to greater technical expertise through its technical officers. The key informant thought that a decision would be reached in a more timely manner.

Acceptance of Efficacy, Safety, and Quality Standards of Controlling U.S. Authorities Other than FDA

One key informant felt that specifically for non-FDA–approved simple/rapid HIV test kits, CDC should be accepted as a certifying authority/organization for safety and efficacy. CDC is currently evaluating non-U.S. S/O and/or non-FDA–approved HIV test kits on behalf of developing countries and providing them with assistance in developing their testing algorithms. The informant thought that if CDC had assisted a country in developing an HIV testing policy, including evaluations of the local context in which the kits were to be used, this should provide sufficient evidence of efficacy and safety.

Blanket Approvals to Purchase Specific Categories of Non-U.S. S/O, Non-FDA–approved Products

As mentioned earlier, dissatisfaction was expressed at the duplication of effort in preparing and submitting requests for approval to purchase non-U.S. S/O, non-FDA–approved products for similar programs based in different countries. However, four key informants had concerns that blanket approvals, particularly for simple/rapid HIV test kits, would quickly be outdated as new and/or existing U.S. S/O products received FDA approval.

In addition, the request for approval to purchase each non-U.S. S/O product is required to determine quality and safety both of the product and its use in a specific program context. It was

therefore considered that blanket approval might only have an application in the expansion of pilot programs where the program context would not be substantially altered.

Summary of USAID Mission and CA Comments

The key problems reported by USAID Missions and CAs in adhering to current procurement guidelines to secure pharmaceutical products for their HIV/AIDS programs are—

- The preferential procurement of U.S. S/O, FDA-approved pharmaceutical products for use in HIV/AIDS programs may result in increased costs and delays. As a result, there may be a consequent reduction in the impact of the program and a negative effect on the harmonization of pharmaceutical products within a country. In addition, the U.S. S/O and/or FDA-approved product may not be the most appropriate product for that program in the country context.
- One issue identified in preparing and submitting requests for approval to procure pharmaceutical products is that there is a lack of guidance material to assist in what is perceived by some key informants to be a complex process. The lack of guidance results in disproportionate demands of time and effort. Providing technical data to establish the safety, efficacy, and quality of non-FDA-approved pharmaceutical products presents the greatest burden.
- As a result of the difficulties experienced with complying with USAID procurement guidelines, Missions and CAs experienced considerable delays and additional expense in implementing their programs. These experiences consequently influenced decisions on the selection and planning of future programs.
- Suggestions of possible improvements principally identified the need for a briefing document to provide guidance to CAs and Missions on USAID procurement guidelines.

Observations from USAID/W Staff

Three key informants from USAID/DHIV and M/OP/TC/COM were interviewed to obtain their observations on the problems experienced by USAID Missions and CAs in securing approval for the procurement of HIV/AIDS-related pharmaceutical products and to discuss some possible solutions. Two of the key informants are based in DHIV and provide assistance and advice to USAID Missions and CAs on the procurement of pharmaceutical products. One key informant is based in the USAID M/OP/TC/COM and has the authority to give technical concurrence for requests for approval to procure pharmaceutical products, based on safety, efficacy, and quality.

The issues discussed in this section are—

- Comments on problems experienced by USAID Missions and CAs in complying with USAID procurement guidelines for HIV/AIDS-related pharmaceutical products

- Data most frequently omitted or incomplete in requests for approval to purchase non-U.S. S/O and/or non-FDA–approved pharmaceutical products
- Observations on possible improvements

Comments on Problems Experienced by USAID Missions and CAs

- If the USAID Mission/CA and the CTO understand the process and provide the information needed, experience shows that approval to purchase pharmaceutical products can be obtained in a four- to six-week period.
- The informants felt that USAID Missions and CAs are generally unfamiliar with the Automated Directive System (ADS) and other USAID guidelines relevant to the procurement of pharmaceutical products. There may be a lack of understanding and appreciation of the basis for these guidelines, which are to ensure that USAID-funded pharmaceuticals are of U.S. source/origin and to assure the safety, efficacy, and quality of pharmaceutical products to limit USAID liability.
- USAID Missions/CAs must also comply with USAID procurement competition requirements or seek a waiver from competition.
- There is lack of understanding by USAID Missions and CAs on the need for providing specific information to support a request to purchase non-U.S. S/O and/or non-FDA–approved products. Informants mentioned that the delays in processing these requests for approval are frequently due to omissions and then subsequent delay in providing these data by the Missions and/or agencies. Data to attest to the compatibility of pharmaceutical products with those supplied by other donors and/or the participating country are frequently omitted in requests for approval.
- One key informant felt that the process to request approval to purchase non-U.S. S/O and/or non-FDA–approved pharmaceutical products in particular was complex and that there was a need for more guidance material.
- Informants agreed that providing information to attest to the safety, efficacy, and quality of the pharmaceutical product represents the greatest burden to the Missions and CAs. However, the informants reiterated that these data are essential to meet the statutory requirements in the FAA and to limit USAID’s liability and to protect USAID clients in developing countries.
- One key informant commented that simpler and more appropriate highly sensitive and highly specific HIV test kits are being evaluated by the FDA and international donors, including HIV test kits that use whole blood, serum, plasma, and, in addition, saliva.

Data Most Frequently Omitted or Incomplete in Requests for Approval

These observations were provided by an official from M/OP/TC/COM—

- Seldom missing/incomplete:
 - Information to justify that the product is essential to the program
 - Evaluation of the use of simple/rapid HIV test kits in the specific program context in the country in which it is to be used
- Occasionally missing/incomplete:
 - Justification for not procuring a U.S. S/O pharmaceutical product
- Frequently missing/incomplete:
 - Information on the capacity of the program to use the product appropriately
- Most often missing/incomplete:
 - Data to attest to the safety, efficacy, and quality of the product

Observations on Possible Improvements

Briefing Document

All three key informants agreed that a briefing document would certainly assist the process in clarifying what the Missions/CAs needed to do, how to do it, the kind of information needed to be submitted, and sources of information.

Technical Assistance

Informants felt that USAID/W should consider making technical assistance available to USAID Missions and CAs to assist them in preparing requests for approval to purchase pharmaceutical products.

Blanket Approvals to Purchase Categories of Non-U.S. S/O, Non-FDA–approved Products

While it may be theoretically possible to obtain a blanket S/O waiver under a specific results package or agreement, it is not reasonable to expect USAID to issue a blanket approval for safety, efficacy, and quality because these are product- and program-specific. It was agreed by

all three key informants that the major problem with a blanket approval is that it would quickly be outdated by technical advances and that, particularly with simple/rapid HIV test kits, each new approval of a U.S. S/O kit by the FDA would immediately invalidate the blanket approval. It was also observed that it would be difficult to have a request covering countries or programs that use different HIV test kits, as it is required that each request name specific products and manufacturers.

Summary of USAID/W Comments

The observations of USAID/W staff on problems reported by USAID Missions and CAs in securing pharmaceutical products for their HIV/AIDS programs and adhering to current procurement guidelines are—

- If the USAID Mission/CA and the CTO understand the process and provide the information needed, experience shows that approval to purchase pharmaceutical products can be obtained in a four- to six-week period.
- USAID Missions and CAs are generally unfamiliar with USAID procurement guidelines and there is a lack of understanding and appreciation of the principles on which these guidelines are based.
- There is a lack of understanding of the necessity of providing certain information to support requests, specifically for approval to purchase categories of non-U.S. S/O and/or non-FDA–approved products, and of the kind of supporting documentation that should be submitted. Information on the capacity of the program to use the product appropriately and data to attest to the safety, efficacy, and quality of a non-FDA–approved product are the most frequently omitted or incomplete in requests for approval.
- Suggestions of possible improvements principally identified the need for a briefing document to provide guidance to CAs and Missions on USAID procurement guidelines and procedures.
- USAID/W should consider providing technical assistance to USAID Missions and CAs to assist them in preparing requests for approval to purchase pharmaceutical products.

Chapter 4.

Options to Facilitate the HIV/AIDS-Related Products Procurement Process

The USAID/DHIV has established a package of programs aimed at addressing HIV/AIDS in developing countries in response to the AIDS crisis. As part of its strategy, the DHIV has been working with the USAID Office of Procurement to facilitate the availability of safe, efficacious, and high-quality pharmaceutical products to its HIV/AIDS programs.

This section presents six possible options to facilitate the process to obtain approval to procure non-U.S. S/O and/or non-FDA–approved pharmaceutical products for HIV/AIDS programs. Option 1 and Option 2 consider the application of two current agreements between M/OP and departments within USAID’s Global Bureau, Center for Population, Health, and Nutrition (G/PHN) as possible models; Options 3, 4, and 5 discuss new approaches; Option 6 considers the option of leaving the procurement process unchanged and improving technical support to USAID Missions/CAs.

The objectives, rationale, controls and oversights, and potential concerns for each of the following options are addressed.

- Option 1: Using the HIV/AIDS Results Package S/O waiver for selected pharmaceuticals as a possible model for an S/O waiver for simple/rapid HIV test kits and/or drugs to prevent and treat HIV/AIDS
- Option 2: Using the M/OP agreement with the Bureau of Humanitarian Response, Office of Foreign Disaster Assistance (BHR/OFDA) as a possible model for transfer of technical concurrence from M/OP/TC/COM to G/PHN for the procurement of HIV/AIDS-related pharmaceutical products
- Option 3: USAID, in consultation with the FDA, stipulating certain certifying authorities/organizations whose standards could be considered acceptable to attest to the safety, efficacy, and quality of non-FDA–approved HIV/AIDS-related pharmaceutical products
- Option 4: USAID, in consultation with the FDA, prequalifying international pharmaceutical suppliers whose standards could be considered acceptable to attest to the safety, efficacy, and quality of non-FDA–approved HIV/AIDS-related pharmaceutical products
- Option 5: Negotiating with U.S. manufacturers/patent holders for preferential pricing for USAID-funded HIV/AIDS-related pharmaceutical products
- Option 6: Keeping the USAID procurement process unchanged and providing more technical assistance to USAID Missions and CAs in preparing requests to M/OP for approval to procure pharmaceutical products

Option 1: The HIV/AIDS Results Package Source/Origin Waiver Model

Using the HIV/AIDS Results Package S/O waiver for selected pharmaceuticals as a possible model for an S/O waiver for simple/rapid HIV test kits and/or drugs to prevent and treat HIV/AIDS

In December 1997, the Deputy Assistant Administrator for the Center for Population, Health, and Nutrition approved an S/O waiver to the Foreign Assistance Act Section 604 for selected pharmaceuticals for the treatment of sexually transmitted diseases (STDs) and specific opportunistic infections procured under the HIV/AIDS Results Package. The S/O waiver allowed Geographic Code 935 (Special Free World) to be an authorized S/O for pharmaceutical products in addition to Geographic Code 000 (United States).

Option 1 draws on the precedent set by the HIV/AIDS Results Package S/O waiver and similarly aims to address the problems associated with the preferential procurement of U.S. S/O HIV/AIDS-related pharmaceutical products as discussed in the interviews with USAID Missions and CAs in Chapter 3. The problems identified included increased program costs and the consequent reduction in the impact and long-term sustainability of the program, lack of harmonization of donor-funded products, and the inappropriateness of the U.S. S/O product for the context in which the product is to be used. This option is also based on the specific need for drugs and test kits in HIV/AIDS programs as discussed in Chapter 1.

In this section, the HIV/AIDS Results Package S/O waiver is reviewed and the feasibility of applying this as a model for an S/O waiver for simple/rapid HIV test kits and/or for drugs to prevent and treat HIV/AIDS is discussed.

Objective of the Agreement

The intent of the S/O waiver was twofold. First, it was intended to enhance the sustainability of USAID-financed HIV/AIDS programs after transfer to the host country by reducing the cost of the pharmaceutical component, and, second, it was to ensure that USAID-financed pharmaceutical preparations were compatible with those included in the national formulary and/or essential drugs list of the host country. It is important to note that this S/O waiver did not change the requirement specified in ADS Series 300 that any non-U.S. pharmaceutical procurement may not infringe U.S. patent laws.

Rationale for the S/O Waiver

The following rationale was stated as the basis for the S/O waiver:

The High Cost of U.S. S/O Pharmaceuticals Relative to Those of Code 935 S/O

- Comparing General Services Administration (GSA) prices for U.S. STD drugs with comparable drugs available through UNICEF from Code 935 countries revealed that most U.S. pharmaceuticals were 50 to 900 percent more expensive than the UNICEF equivalent.
- This price difference would significantly increase the cost of the programs for which the provision of pharmaceuticals is a substantial component under the HIV/AIDS Results Package.
- The sustainability of the USAID-financed HIV/AIDS programs was threatened when project funding was transferred to the host country because it was unlikely that the procurement of U.S. S/O pharmaceuticals could be continued, given the level of most host country funding for drug budgets.

Incompatibility of U.S. Pharmaceuticals with the Host Country National Formulary and Essential Drugs List

- In many host countries, drug procurement policies restrict public sector purchases to those drugs listed in national formularies or essential drugs lists, which frequently do not include U.S. S/O pharmaceuticals.
- Health personnel in host countries are often unfamiliar with U.S. pharmaceutical products and are often unwilling or not trained to use them.
- The sustainability of these programs is again threatened when project funding is transferred to the host country, where drug procurement policies restrict the purchase of drugs to those included in the national formulary or essential drugs list.

Regulatory Justification

The S/O waiver for pharmaceuticals purchased under the HIV/AIDS Results Package was justified under the following criteria of USAID procurement guidelines.

ADS E312.5.3.c

- The pharmaceutical product is essential to the activity.
- The product in the same or substantially equivalent form is not available from the United States or the delivered price would be at least 50 percent more than from another source.
- Information is available to attest to the safety, efficacy, and quality of the product or the product meets the standards of the U.S. FDA or other controlling U.S. authority.

ADS E312.5.3.c (3)

- No U.S. patents would be violated by the purchase of non-U.S. pharmaceutical products under this S/O waiver.

Subpart F of 22 CFR Section 228.51

- The product is not produced in or is unavailable for purchase in the United States.
- It is necessary to promote efficiency in the use of U.S. foreign assistance resources, including to avoid impairment of foreign assistance objectives.

Controls and Oversight

Appropriate controls and oversights would be assured because all requests for the procurement of pharmaceutical products from Code 935 countries would be submitted to M/OP for review and approval prior to initiating the procurement.

Application of This Model for Simple/Rapid HIV Test Kits and/or Drugs to Prevent and Treat HIV/AIDS

Simple/Rapid HIV Test Kits

The S/O waiver that was approved for the procurement of selected STD and opportunistic infections pharmaceuticals for the HIV/AIDS Results Package could be used directly as a model for a similar S/O waiver for simple/rapid HIV test kits for projects where the contract only allows procurement from Geographic Code 000. The objectives, rationale, regulatory justification, and controls and oversight for this S/O waiver are directly applicable to HIV test kits.

The potential problem with an S/O waiver for simple/rapid HIV test kits is that each new FDA approval would quickly outdate the S/O waiver. The justification for the S/O waiver would need to be reevaluated in light of each new FDA approval for a U.S. S/O simple/rapid HIV test kit.

Drugs for the Prevention of HIV Infection and for the Treatment of HIV/AIDS

The main obstacle for applying this S/O waiver as a model for programs that need to procure drugs in this category under contracts requiring an S/O of Geographic Code 000 is that the majority of these drugs are still under U.S. patent. The HIV/AIDS Results Package S/O waiver for selected pharmaceuticals did not apply to drugs that were covered by a current U.S. patent. However, once the patents expire, the objectives, rationale, regulatory justification, and controls and oversight for this S/O waiver are directly applicable.

Other Considerations

- An S/O waiver would be required for each results package providing the authority and/or funding for an HIV/AIDS program. For example, the S/O waiver that applies to the G/PHN/DHIV Results Package does not apply to bilateral programs in USAID Missions.
- USAID Missions and CAs would still need to comply with USAID regulations on competition and procurement.

Summary of Key Findings for Option 1

The key findings from this review of the HIV/AIDS Results Package S/O waiver for selected pharmaceuticals and the feasibility of applying this as a model for an S/O waiver for simple/rapid HIV test kits and/or for drugs to prevent and treat HIV/AIDS are—

- The HIV/AIDS Results Package S/O waiver for selected pharmaceuticals can be applied directly as a model to contracts or agreements requiring Geographic Code 000 S/O for the procurement of simple/rapid HIV test kits. The potential problem with an S/O waiver for simple/rapid HIV test kits is that the S/O waiver would need to be reevaluated for each new FDA approval of a U.S. S/O simple/rapid HIV test kit.
- The requirement that pharmaceutical procurements must not violate U.S. patent laws prevents the application of this S/O waiver to contracts or agreements requiring Geographic Code 000 S/O for drugs to prevent or treat HIV/AIDS at present. Currently, the majority of these drugs are still under patent, so procurement from non-U.S. sources is not permitted unless approval is obtained from the patent holder.
- An S/O waiver would be required for each results package providing the authority and/or funding for an HIV/AIDS program.
- USAID Missions and CAs would still need to comply with USAID regulations on competition and procurement.

Option 2: The M/OP Agreement with the BHR/OFDA Model

Using the USAID M/OP agreement with the Bureau of Humanitarian Response, Office of Foreign Disaster Assistance as a possible model for transfer of technical concurrence from M/OP/TC/COM to the USAID G/PHN for the procurement of HIV/AIDS-related pharmaceutical products

In June 1998, the USAID Office of Procurement transferred authority for the technical concurrence for the procurement of disaster-related pharmaceutical purchases to BHR/OFDA for its emergency relief programs. In this section, the agreement between M/OP and BHR/OFDA is reviewed and the feasibility of applying this as a possible agreement model between M/OP and the USAID Global Bureau, Center for Population, Health, and Nutrition (G/PHN) is discussed.

This option draws on the precedent set by the agreement between M/OP and BHR/OFDA and is based on a suggestion for possible improvements proposed in interviews with USAID Missions and CAs (see Chapter 3). It was suggested that the approval process, specifically for simple/rapid HIV test kits, could be accelerated by transferring the responsibility for technical concurrence from M/OP/TC/COM to G/PHN.

Objective of the Agreement

The intention of transferring authority for technical concurrence from M/OP/TC/COM to BHR/OFDA was to control and minimize the use of non-FDA-approved drugs while accelerating the approval process to procure such drugs when necessary for disaster relief situations. This agreement did not, however, change any of the requirements for the procurement of pharmaceutical products as specified in ADS Series 300 and outlined in Chapter 2.

Rationale for the Transfer of Authority

The transfer of authority for technical concurrence for the procurement of pharmaceutical products from M/OP/TC/COM to BHR/OFDA was based on the following rationale.

Availability of In-house Technical Expertise

- As of 1996, M/OP/TC/COM lost its in-house pharmacist, who was capable of providing technical oversight, and, therefore, the office would need to seek outside assistance to fulfill the requirements of ADS Series 300 for the technical concurrence for the procurement of pharmaceutical products.
- BHR/OFDA had in-house pharmaceutical expertise through its Emergency Public Health Officer, who is a licensed pharmacist and is provided through a Resource Support Services Agreement with the U.S. Public Health Service (US PHS).

- Obtaining technical expertise for concurrence for pharmaceutical procurement by M/OP/TC/COM would impose unnecessary costs and administrative burdens and would ultimately result in a duplication of effort since OFDA was already performing a technical review of the quality, safety, and efficacy of the pharmaceuticals that it proposed to purchase.

Access to Resources to Provide Additional Technical Expertise

- BHR/OFDA had existing funding instruments and relationships with various U.S. government agencies, including the US PHS, CDC, FDA, Indian Health Service, Health Resources Services Administration, and National Institutes of Health, that enabled BHR/OFDA to draw on further technical expertise as needed.
- BHR/OFDA was confident that it could comply with the objectives of ADS Series 300 through access to these extensive resources.
- M/OP recognized that the resources currently available to BHR/OFDA were the same resources that would be sought by M/OP/TC/COM in order to comply with ADS Series 300.

Controls and Oversight

- The internal controls within BHR/OFDA, which are responsive to the special public and congressional interests on this issue, were to be maintained. The OFDA pharmacist does not have absolute or sole authority to approve pharmaceutical purchases by OFDA grantees. The pharmacist submits technical concurrence to the OFDA Grants Officer after determining that—
 - the product is appropriate for the disaster situation and for the proposed indication;
 - the product is appropriate for the pharmacopoeia of the country; and
 - for non-FDA–approved products or products not purchased from UNICEF, data are available to attest to the safety, efficacy, and quality of the product.

For non-U.S. S/O, non-FDA–approved pharmaceutical products, an S/O waiver or OFDA approval of a justification for non-U.S. procurement under the terms of OFDA’s notwithstanding authority is also required. The OFDA Director needs to approve the S/O waiver or the justification for non-U.S. procurement using OFDA’s notwithstanding authority.

- Assurance was given to M/OP that BHR/OFDA would make every effort to maximize the use of FDA-approved pharmaceuticals while ensuring the timely availability of safe and efficacious drugs for humanitarian relief. BHR/OFDA submitted guidelines for pharmaceutical procurement for emergency project assistance together with examples of information that the OFDA pharmacist would use to evaluate the safety, efficacy, and quality

of the product. This documentation was used to assure M/OP that appropriate checks and controls had been included in OFDA procedures.

- M/OP would maintain an appropriate level of oversight through its review and award of resultant grants and contracts that include pharmaceutical purchases.
- BHR/OFDA would provide annual reports detailing pharmaceuticals purchased either directly or by BHR/OFDA grantees for in-kind relief assistance to M/OP, which would review the reports for compliance with USAID policies and procedures.

Application of the Agreement as a Possible Model for M/OP and G/PHN

The feasibility of using this agreement as a model for the transfer of technical approval for pharmaceutical products from M/OP/TC/COM to G/PHN depends on the extent to which justification can be based on some or all of the following factors.

The Intent of the Agreement

The intention of the BHR/OFDA agreement is to accelerate the approval process to procure non-FDA-approved drugs for disaster relief situations. G/PHN would need to provide justification of the necessity for the same level of urgency to procure drugs for its HIV/AIDS and STI programs, either for humanitarian or public health reasons, in addition to detailing the advantage that the transfer of technical concurrence would offer in facilitating the process. For example, it could be argued that it is a matter of urgency to establish the prevalence of HIV infection among refugees in a conflict situation in order to facilitate the design and implementation of interventions to prevent the transfer of infection within the refugee population and to the population of the host country.

The Approval Process for UNICEF Pharmaceutical Products

From communications between BHR/OFDA and DHIV, it appears that UNICEF is recognized as a supplier with acceptable standards to attest to safety, efficacy, and quality of pharmaceutical products. Although UNICEF may not have official prequalified status, it appears that UNICEF-supplied products facilitate the BHR/OFDA approval process for non-FDA-approved drugs by reducing both the time taken by the OFDA grantee to prepare the request for approval to purchase UNICEF products and the time taken by the OFDA pharmacist to review the request and to give technical concurrence. It would need to be considered if the transfer of technical concurrence for procurement of non-FDA-approved products from M/OP/TC/COM to G/PHN alone, without the prequalification of UNICEF, would significantly accelerate the approval process for these products.

Availability of In-house Technical Expertise

Currently, neither M/OP/TC/COM nor G/PHN has access to in-house pharmaceutical expertise. The options that G/PHN could consider include—

- Employing an in-house pharmacist

G/PHN would need to justify the considerable expense of employing a pharmacist with experience and knowledge of international procurement in order to request and evaluate the appropriate data to attest that the pharmaceutical product meets safety, efficacy, and quality standards.

- Negotiating for assistance from an in-house pharmacist from another division within USAID, for example the office of BHR/OFDA, to provide technical concurrence for procurement of pharmaceutical products
- Contracting with a cooperating agency to provide technical review services by a licensed pharmacist
- Transferring the authority for technical concurrence from M/OP/TC/COM to G/PHN for procurement of a specific category of pharmaceutical products, such as HIV test kits, for which G/PHN can demonstrate that its in-house technical expertise is equal to or greater than that within M/OP/TC/COM

Access to Resources to Provide Additional Technical Expertise

G/PHN would need to have access to additional technical resources, similar to those available to BHR/OFDA, and be confident that access to these resources would enable G/PHN to comply with the objectives of ADS Series 300. In addition, M/OP would need to recognize that the resources available to G/PHN were the same resources that would be sought by M/OP/TC/COM in order to comply with the objectives of ADS Series 300 in assisting with technical oversight.

Controls and Oversight

Assurance would need to be provided that the appropriate controls and oversights are in place to monitor compliance with USAID policies and procedures.

- G/PHN would need to ensure that it has internal controls that are responsive to the special public and congressional interests on this issue and to assure M/OP that it would make every effort to maximize the use of FDA-approved pharmaceuticals while ensuring the timely availability of safe and efficacious drugs for HIV/AIDS programs.
- G/PHN would need to draw up protocols for implementation of the transfer of authority for technical concurrence, which could be based on the current BHR/OFDA documentation.

- M/OP would need to maintain an appropriate level of oversight through its review and award of resultant grants and contracts that include pharmaceutical purchases and of annual reports detailing pharmaceuticals purchased either directly or by DHIV grantees for in-kind relief assistance.

Summary of Key Findings for Option 2

A proposal for the transfer of technical concurrence for procurement of all or a specific category of pharmaceutical products from M/OP/TC/COM to G/PHN using the BHR/OFDA agreement as a model would need to address the following issues:

- The objectives and justification for such an agreement, including the necessity for the same level of urgency for G/PHN to procure drugs for DHIV programs
- Whether the transfer of technical concurrence for procurement to G/PHN alone would facilitate the process for approving requests to procure pharmaceutical products without the advantages offered by prequalifying UNICEF as a supplier that meets acceptable standards of safety, efficacy, and quality for the products supplied
- The in-house pharmaceutical/technical expertise of G/PHN relative to that in M/OP/TC/COM

Options include employing a pharmacist, negotiating for assistance from an in-house pharmacist from another USAID division, or contracting out for these services. In addition, an option where authority is transferred for a specific category of products, such as simple/rapid HIV test kits for which G/PHN can demonstrate that its technical expertise is equal to or greater than M/OP/TC/COM, could be considered.

- The resources accessible to G/PHN to provide technical expertise relative to those available to M/OP/TC/COM
- The controls and balances that would need to be established to ensure that pharmaceutical procurement by G/PHN is in compliance with USAID policies and procedures
- No changes in the requirements for the procurement of pharmaceutical products as specified in the ADS

USAID Missions and CAs would still need to comply with USAID regulations on competition and procurement.

Option 3: Stipulate Additional Certifying Authorities/Organizations

USAID, in consultation with the FDA, stipulating certain certifying authorities/organizations whose standards could be considered acceptable to attest to the safety, efficacy, and quality of non-FDA–approved HIV/AIDS-related pharmaceutical products

Under ADS Section E312.5.3c, exceptions can be made to the rule that USAID-financed pharmaceuticals be of U.S. source and origin if certain criteria are met, including that “information is available to attest to the safety, efficacy and quality of the product or the product meets the standards of the U.S. Food and Drug Administration or other controlling U.S. authority.”

Many of the requests for approval from USAID Missions and CAs for approval to purchase HIV/AIDS-related pharmaceutical products from non-U.S. sources are for products that are not FDA-approved. USAID Missions and CAs must submit documentation to attest to the safety, efficacy, and quality of each pharmaceutical product. An option to facilitate this process could be for USAID, in consultation with FDA, to identify certifying authorities/organizations whose standards could be considered acceptable to attest to the safety, efficacy, and/or quality of non-FDA–approved pharmaceutical products.

This option is based on a suggestion for possible improvements proposed in interviews with USAID Missions and CAs (see Chapter 3). It was suggested that the procurement of simple/rapid HIV test kits could be facilitated by accepting CDC as a certifying authority/organization for the safety and efficacy of these products. This option is also based on the specific need for simple/rapid HIV test kits in HIV/AIDS programs as discussed in Chapter 1.

The standards could be defined by the issuing authority or organization, which could include other U.S. government agencies such as CDC, or international organizations such as the World Health Organization. For example, WHO recommendation for use or inclusion in the WHO Essential Drugs List could be used to attest to the safety and efficacy of the drug. Similarly, the quality of a pharmaceutical product could be deemed to be acceptable if the country of origin meets defined standards both for Good Manufacturing Practice and for inspection and enforcement of those standards. For example, the country of origin being either a signatory to the Pharmaceutical Inspection Convention of 1970 (PIC) or a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) could be defined as acceptable. PIC and PIC/S are agreements that allow cooperation and harmonization between the pharmaceutical inspectorates of member countries.

Objective

The objective of this option would be to facilitate the process of preparing and approving requests for approval to procure non-FDA–approved pharmaceutical products. However, it would not change the other requirements for the procurement of pharmaceutical products as specified in ADS Series 300 and in 22 CFR. Also, it would still be necessary for USAID

Missions and CAs to assure M/OP/TC/COM that the product is appropriate for the specific program context.

Rationale

- Many of the requests from USAID Missions and CAs for approval to purchase HIV/AIDS-related pharmaceutical products from non-U.S. sources are for products that are not FDA-approved.
- Providing the technical data to assure the safety, efficacy, and quality of non-FDA-approved pharmaceutical products represents the greatest burden to USAID Missions and CAs.
- Stipulating the certifying authorities/organizations whose standards could be considered acceptable to attest to safety, efficacy, and/or quality of pharmaceutical products would offer two advantages.
 - It would facilitate the process of preparing requests for concurrence to purchase non-FDA-approved products for USAID Missions and CAs by reducing the documentation that would need to be submitted to attest to the safety, efficacy, and/or quality of the products.
 - It would facilitate the process for M/OP/TC/COM to provide technical approval for the procurement with respect to the safety, efficacy, and/or quality of the non-FDA-approved product by reducing the amount of documentation that would need to be reviewed.

Controls and Oversight

The controls and oversight would need to address three issues:

1. Ensuring that the standards used by the certifying authorities/organizations to determine the safety, efficacy, and/or quality of a pharmaceutical product are acceptable
2. Ensuring that the procedures used by the issuing organization/authority to assess whether a pharmaceutical product meets these standards are acceptable
3. Verifying that the organization/authority continues to use acceptable standards and to maintain acceptable procedures to ensure that products meet those standards

Each of these issues is further discussed in the text that follows.

Ensuring That the Standards Used by the Certifying Authorities/Organizations to Determine Safety, Efficacy, and/or Quality of a Pharmaceutical Product Are Acceptable

Standards to evaluate a pharmaceutical product can be separated into those that evaluate safety and efficacy and those that evaluate quality. Typically, for pharmaceutical drugs, the drug is evaluated for safety and efficacy and the product is evaluated for quality. For pharmaceutical products such as HIV test kits, the product is evaluated for safety, efficacy, and quality.

Safety and Efficacy

FDA defines a safe medical product as one that has reasonable risks given the magnitude of the benefit expected and the alternatives available. Efficacy is the ability of a drug to produce a purported effect as determined by scientific methods.

Both safety and efficacy are evaluated when a drug meets the statutory standard for market approval for use for a specific indication. The safety and efficacy of a drug may vary for different indications or patient groups. It is therefore possible to define the standards for safety and efficacy of a drug for a particular indication or group of patients by stating which regulatory or licensing authorities granting market approval are acceptable. For example, USAID could specify inclusion in the WHO Essential Drugs List or having market authorization in a specific country or group of countries, such as the European Union, as acceptable authorizations.

CDC has assisted developing countries to determine the efficacy and appropriateness of HIV test kits for use in their countries. USAID might consider that the evaluation and subsequent recommendation by CDC to a developing country to include a specific HIV test kit in their country algorithm as an acceptable authorization to attest to its safety and efficacy.

Quality

The quality of a pharmaceutical product is determined by its identity, purity, potency, uniformity of dosage form, bioavailability, and stability. Standards to determine the quality of a product have two components: standards that determine the quality of the product itself and standards that determine the selection of manufacturers and suppliers that meet acceptable quality standards of practice such as Good Manufacturing Practices.

Acceptable quality standards could be defined by the pharmacopeial standards with which the product must comply. For example, USAID could require that non-FDA–approved products meet the standards of the European Pharmacopeia.

A number of criteria, including establishing requirements for the country of source and origin of the product, could be used to determine the acceptability of quality standards for manufacturers and suppliers. As mentioned previously, the country of origin being either a signatory to the PIC or a member of the PIC/S could be defined as a criterion to attest that the manufacturer meets quality standards. In addition, acceptable statutory or regulatory requirements governing the

methods used in and the facilities and controls used for the manufacture, processing, packing, labeling, storage, and transportation of the product could be defined.

Ensuring That the Procedures Used by the Certifying Authorities/Organizations to Assess Whether a Pharmaceutical Product Meets These Standards Are Acceptable

The acceptability of procedures used by a certifying authority/organization to assess whether a pharmaceutical product meets standards of safety and efficacy could be evaluated by checking that the products do indeed have market approval with regulatory or licensing authorizations that have been determined to be acceptable. Also, the procedures used by the organization to report previously unknown adverse effects, and to withdraw approval and remove drugs found not to be safe or effective, could be assessed.

The acceptability of quality assurance procedures could include a review of the number of products that are tested, the documentation that is examined, whether the manufacturing facilities are inspected, and the procedures for reporting and recalling defective pharmaceutical products. In addition, any outstanding problems with the safety, efficacy, and quality of pharmaceutical products supplied or certified by the certifying authority/organization could be evaluated.

The responsibility and mechanism for performing these evaluations would need to be determined in consultations between USAID and the FDA.

Verifying That the Certifying Authority/Organization Continues to Use Acceptable Standards and to Maintain Acceptable Procedures to Ensure That Products Meet Those Standards

A system of oversight would need to be maintained, possibly with the assistance of the FDA, to verify that the organization continues to use acceptable standards and acceptable procedures to ensure that those standards are met. This could include the monitoring of problems reported with the safety, efficacy, and/or quality of products certified or supplied by the organization. Again, the responsibility and mechanism for performing these evaluations would need to be determined.

Potential Concerns

Liability/Loss of Credibility

The potential liability of USAID and loss of credibility as a consequence of a serious side effect/adverse effect, a lack of therapeutic effect, or a toxic effect of a USAID-funded pharmaceutical product could be considerable. The controls used by USAID to determine acceptable standards and the oversight to monitor that the standards and procedures used to determine safety, efficacy, and/or quality of a product are and continue to be acceptable would need to be rigorous to minimize potential liability and loss of credibility.

Assurance of Safety and Efficacy, But Not Necessarily Quality

Some certifying authorities/organizations may attest to the safety and efficacy of a drug or diagnostic test but not necessarily the quality of the product. For example, CDC may have assisted a developing country to determine the efficacy and appropriateness of an HIV test and subsequently recommended that a specific test kit be included in that country's algorithm. However, CDC is unlikely to have inspected the manufacturing facilities in order to be able to attest to the quality of the product. Data to attest to the quality of the product would still need to be submitted to M/OP/TC/COM by the USAID Missions or CAs.

Appropriateness of the Product for Use in the Program

USAID Missions and CAs would still need to assure M/OP/TC/COM that the product is appropriate for the proposed application, in the country-specific context in which it will be used.

Controls and Oversight

The capacity of USAID, even with assistance from the FDA, to apply appropriate controls and oversight would probably limit the feasibility of this option.

Legislative Changes

USAID procurement requirements in the ADS are based on the FAR and FAA, and stipulating additional certifying authorities/organizations may require legislative amendments.

Summary of Key Findings for Option 3

- Stipulating the certifying authorities/organizations whose standards could be considered acceptable to attest to the safety, efficacy, and/or quality of pharmaceutical products would offer two advantages:
 - It would facilitate the process of preparing requests for approval to purchase non-FDA-approved products for USAID Missions and CAs by reducing the documentation that would need to be submitted to attest to the safety, efficacy, and/or quality of the products.
 - It would facilitate the process for M/OP/TC/COM to provide technical concurrence for the procurement with respect to the safety, efficacy, and/or quality of the non-FDA-approved product by reducing the amount of documentation that would need to be reviewed.

- USAID controls and oversight would need to address three issues, namely that—
 - the standards used by the certifying authority/organization to determine the safety, efficacy, and/or quality of a pharmaceutical product are acceptable;
 - the procedures used by the issuing authority/organization to assess whether a pharmaceutical product meets these standards are acceptable; and
 - the organization/authority continues to use acceptable standards and to maintain acceptable procedures to ensure that these standards are met.
- The controls used by USAID to determine acceptable standards and the oversight to monitor that the standards and procedures used to determine safety, efficacy, and/or quality of a product are and continue to be acceptable would need to be rigorous to minimize potential liability and loss of credibility.
- Some certifying authorities/organizations may attest to the safety and efficacy of a drug or diagnostic test but not necessarily the quality of the product.
- USAID Missions and CAs would still need to assure M/OP/TC/COM that the product is appropriate for the proposed application, in the country-specific context in which it will be used.
- USAID Missions and CAs would still need to comply with USAID regulations on competition and procurement, including applying for an S/O waiver if required.
- The capacity of USAID, even with assistance from the FDA, to apply appropriate controls and oversights would ultimately limit the feasibility of this option.
- USAID procurement requirements in the ADS are based on the FAR and FAA, and stipulating additional certifying authorities/organizations may require legislative amendments.

Option 4: Prequalifying International Suppliers

USAID, in consultation with the FDA, prequalifying international pharmaceutical suppliers whose standards could be considered acceptable to attest to the safety, efficacy, and quality of non-FDA–approved HIV/AIDS-related pharmaceutical products

As mentioned earlier, many USAID Mission/CA requests for approval to purchase HIV/AIDS-related pharmaceutical products from non-U.S. sources are for products that do not have FDA approval. USAID Missions and CAs are therefore required to submit documentation to attest to the safety, efficacy, and quality of each non-FDA–approved product and its use in the program-specific context. Providing these data was reported as presenting the greatest difficulty in preparing requests for approval to purchase non-FDA–approved products in the interviews with USAID Missions and CAs as described in Chapter 3. One option to facilitate this process would be for USAID, in consultation with the FDA, to prequalify international pharmaceutical suppliers whose standards could be considered acceptable to attest to the safety, efficacy, and quality of non-FDA–approved HIV/AIDS-related pharmaceutical products. For example, these international suppliers could include UNICEF, WHO, and the International Dispensary Association (IDA).

This option draws on the precedent set in the BHR/OFDA approval process for pharmaceutical procurement where the OFDA grantee is not required to supply data to attest to the safety, efficacy, and quality of pharmaceutical products procured from UNICEF. This option is also based on the liberalization of U.S. policy for export of pharmaceutical products, as discussed in Chapter 1, where FDA approval is no longer the sole criterion used to attest to the safety and efficacy of U.S. products produced for export.

Prequalification of international suppliers has been limited to UNICEF, WHO, and IDA because the feasibility of this option is restricted by the capacity of USAID, even with assistance from FDA, to apply the necessary and appropriate controls and oversight. UNICEF has been selected because precedence of OFDA experience and practice already exists; WHO because simple/rapid HIV test kits are available through the WHO bulk procurement scheme; and IDA because it is a reputable supplier used by many international donors.

Objective

The objective of this option would be to facilitate the process of preparing and approving requests for approval to procure non-FDA–approved pharmaceutical products. However, it would not change the other requirements for the procurement of pharmaceutical products as specified in ADS Series 300 and in 22 CFR, including the requirement that any non-U.S. procurement may not infringe U.S. patent laws. Also, it would still be necessary for USAID Missions and CAs to assure M/OP/TC/COM that the product is appropriate for the specific program context.

Rationale

- Many of the requests from USAID Missions and CAs for approval to purchase HIV/AIDS-related pharmaceutical products from non-U.S. sources are for products that are not FDA-approved.
- Providing the technical data to ensure the safety, efficacy, and quality of non-FDA-approved pharmaceutical products represents the greatest burden to USAID Missions and CAs.
- Prequalifying international suppliers whose standards could be considered acceptable to attest to safety, efficacy, and quality of pharmaceutical products would offer two advantages:
 - It would facilitate the process of preparing requests for approval to purchase non-FDA-approved products for USAID Missions and CAs by reducing the documentation that would need to be submitted to attest to the safety, efficacy, and quality of the products.
 - It would facilitate the process for M/OP/TC/COM to provide technical concurrence for the procurement with respect to the safety, efficacy, and quality of the non-FDA-approved product by reducing the amount of documentation that would need to be reviewed.

Controls and Oversight

Under Option 4, as with Option 3, the controls and oversight would need to address three issues:

1. Ensuring that the standards used by the international supplier to determine the safety, efficacy, and quality of a pharmaceutical product are acceptable
2. Ensuring that the procedures used by the international supplier to assess whether a pharmaceutical product meets these standards are acceptable
3. Verifying that the international supplier continues to use acceptable standards and to maintain acceptable procedures to ensure that products meet those standards

The same considerations for each of these issues as described for Option 3 apply to this option of prequalifying international suppliers.

The procedures used by BHR/OFDA to address these issues prior to recognizing UNICEF as a supplier with acceptable standards to attest to safety, efficacy, and quality of pharmaceutical products could be used as a model by M/OP. Similarly, the experiences of BHR/OFDA in monitoring the safety, efficacy, and quality of OFDA-funded procurements from UNICEF could be used to advise M/OP on the potential risks associated with using this option.

Potential Concerns

Liability/Loss of Credibility

As with Option 3, the potential liability of USAID and loss of credibility as a consequence of a serious side effect/adverse effect, a lack of therapeutic effect, or a toxic effect of a USAID-funded pharmaceutical product should be considered.

Appropriateness of the Product for Use in the Program

USAID Missions and CAs would still need to assure M/OP/TC/COM that the product is appropriate for the proposed application, in the country-specific context in which it will be used.

Controls and Oversight

The capacity of USAID, even with assistance from the FDA, to apply appropriate controls and oversight would ultimately limit the feasibility of this option. Limiting this option to UNICEF, WHO, and/or IDA would increase the feasibility of implementing the necessary controls.

Legislative Changes

USAID procurement requirements in the ADS are based on the FAR and FAA, and changes to permit prequalification of international suppliers may require legislative amendments.

Summary of Key Findings for Option 4

- Prequalifying international suppliers whose standards could be considered acceptable to attest to safety, efficacy, and quality of pharmaceutical products would offer two advantages:
 - It would facilitate the process of preparing requests for approval to purchase non-FDA-approved products for USAID Missions and CAs by reducing the documentation that would need to be submitted to attest to the safety, efficacy, and quality of the products.
 - It would facilitate the process for M/OP/TC/COM to provide technical concurrence for the procurement with respect to the safety, efficacy, and quality of the non-FDA-approved product by reducing the amount of documentation that would need to be reviewed.

- USAID controls and oversight would need to address three issues, namely that—
 - the standards used by the international supplier to determine the safety, efficacy, and quality of a pharmaceutical product are acceptable;
 - the procedures used by the international supplier to assess whether a pharmaceutical product meets these standards are acceptable; and
 - the international supplier continues to use acceptable standards and to maintain acceptable procedures to ensure that these standards are met.
- The controls used by USAID to determine acceptable standards and the oversight to monitor that the standards and procedures used to determine safety, efficacy, and quality of a product are and continue to be acceptable would need to be rigorous to minimize potential liability and loss of credibility.
- USAID Missions and CAs would still need to assure M/OP/TC/COM that the product is appropriate for the proposed application, in the country-specific context in which it will be used.
- USAID Missions and CAs would still need to comply with USAID regulations on competition and procurement, including applying for an S/O waiver if required.
- The capacity of USAID, even with assistance from the FDA, to apply appropriate controls and oversight would ultimately limit the feasibility of this option.
- USAID procurement requirements in the ADS are based on the FAR and FAA, and changes to permit prequalification of international suppliers may require legislative amendments.

Option 5: Negotiation with U.S. Manufacturers/Patent Holders

Negotiating with U.S. manufacturers/patent holders for preferential pricing for USAID-funded HIV/AIDS-related pharmaceutical products

ADS Series 300 and 22 CFR Subpart F specify the criteria under which USAID may expand an authorized source in order to accomplish project or program objectives by processing an S/O waiver. Under ADS E312.5.3c.3, “USAID must obtain express authorization of the owner of the patent before it finances a pharmaceutical product manufactured outside the US which would involve use of, or be covered by, an unexpired patent of the US which has not previously been held invalid by an unappealed or unappealable judgement or decree of a court of competent jurisdiction. This requirement cannot be waived.” Therefore, USAID regulations do not permit USAID-funded procurement of a pharmaceutical product from non-U.S. sources if an unexpired U.S. patent exists for that product.

An option to increase the efficiency of DHIV programs where the procurement of pharmaceutical products is a substantial component of the program and where the pharmaceutical product is still covered by a U.S. patent is for USAID to negotiate with U.S. manufacturers and patent holders for preferential pricing for their programs.

The option is based on an announcement from UNAIDS on May 11, 2000, that a new dialogue had begun among five pharmaceutical companies and United Nations organizations to explore ways to improve access to HIV/AIDS-related care and treatment in developing countries.¹⁸ The five companies have begun constructive discussions with UNAIDS, WHO, the World Bank, UNICEF, and UNFPA to explore practical and specific ways of working together to accelerate access to HIV/AIDS-related care and treatment in developing countries. The endeavor is expected to expand to include other partners from all sectors.

The participants acknowledged that the affordability of HIV/AIDS-related care and treatment is an issue in developing countries and stated that they are willing to work with committed governments, international organizations, and other stakeholders to find ways to broaden access to these pharmaceutical products. UNAIDS stated that an “in principle” agreement had been reached to investigate ways of lowering prices, but it is likely that this would only apply to drugs purchased by governments for public sector use and would be negotiated with countries on a case-by-case basis. However, it is unclear whether all five companies are making a commitment to cut the cost of antiretrovirals. So far, only one company, Glaxo Wellcome, is extending preferential pricing to include antiretrovirals in one of its own initiatives.¹⁹

It is not yet clear whether any forthcoming price reductions will be available to USAID-funded drugs procured in the United States. However, USAID could negotiate independently with the U.S. pharmaceutical companies/patent holders for preferential pricing for U.S.-patented products for DHIV programs.

Objective

The objective of negotiating with U.S. manufacturers/patent holders for preferential pricing for USAID-funded HIV/AIDS-related pharmaceutical products is to reduce the cost of the pharmaceutical component and consequently increase the efficiency of the program by expanding the number of clients to whom the services could be extended. This option also ensures that U.S. patents are not infringed and maintains a “Buy America” policy.

Rationale

The rationale for this option is based on the high cost of U.S. S/O pharmaceuticals relative to those from non-U.S. S/O for certain HIV/AIDS-related pharmaceutical products.

- The price differential significantly increases the cost of DHIV programs for which the procurement of pharmaceuticals is a substantial component.
- The efficiency of the HIV/AIDS program is reduced as the number of clients to whom the services can be extended is decreased.

Controls and Oversight

USAID currently negotiates for preferential pricing for contraceptives for USAID-funded programs. The controls and oversight used for these negotiations could be used as a model for DHIV programs.

Potential Concerns**Uncertainty Surrounding Preferential Pricing Under the UN Agency/WB/Pharmaceutical Company Initiative**

- It is not clear whether all five companies are making a commitment to cut the cost of HIV/AIDS-related drugs.
- It is not yet clear whether any negotiated price reductions will be available to USAID-funded drugs procured in the United States or how the mechanism for negotiation for preferential pricing will function.
- It is also unclear whether USAID will be able to negotiate directly with pharmaceutical companies or through UNAIDS for preferential pricing under this initiative.
- In addition, it would need to be decided whether USAID will negotiate directly with the pharmaceutical company and/or UNAIDS or indirectly through a U.S. government procurement agency.

However, as mentioned previously, USAID could choose to negotiate directly with U.S. manufacturers and patents holders for preferential pricing for HIV/AIDS-related products outside of this initiative.

Limitations of Preferential Pricing

- This option is limited in that it reduces the cost component of the pharmaceutical products only for the duration of the USAID program. The sustainability of programs where pharmaceutical procurement is a substantial component would still be threatened once responsibility for continued funding was transferred to the host country, unless this preferential pricing was also transferred to the host country.
- As was recognized by the participants in the UNAIDS public/private initiative, price is not the only obstacle. Other issues, such as the appropriateness of the U.S. S/O FDA-approved pharmaceutical product for the proposed application in the specific conditions that it will be used and the capacity of the program to appropriately manage its use still need to be considered.

USAID Capacity to Negotiate Preferential Pricing

The capacity of USAID to negotiate preferential pricing may be limited by funding or staffing restrictions. The feasibility of this option could be increased by limiting USAID negotiations for preferential pricing for pharmaceutical products by criteria that would define the product itself and the program in which it is to be used. The criteria could include the following:

- There are persuasive political considerations to implement the program.
- The program is a pilot or demonstration program.
- The pilot or demonstration program evaluates the implementation of an effective intervention to prevent the transmission of HIV.
- The pharmaceutical product is essential to the program and an appropriate alternative product, which is not covered by a U.S. patent, does not exist.
- USAID procurement requirements in the ADS are based on the FAR and FAA. Legislative changes to permit negotiation with U.S. manufacturers and patent holders for preferential pricing may require legislative amendments.

Example

Antiretroviral Drugs to Prevent Perinatal Transmission of HIV

- **There are persuasive political considerations to implement the program.** HIV/AIDS is universally agreed to be a global health crisis and has recently been recognized as presenting a threat to U.S. national security.²⁰ In 1999, 570,000 new pediatric HIV infections occurred, of which 90 percent were estimated to be the result of perinatal transmission.³ Of these, almost nine-tenths were estimated to have occurred in sub-Saharan Africa.⁷
- **The program is a pilot or demonstration program.** United Nations-led pilot programs are currently in progress in high prevalence areas to evaluate the inclusion of antiretroviral therapy in antenatal care programs to prevent perinatal transmission. A recent report has recommended that pilot programs be implemented in a phased approach that considers the diversity of national and local capacities and of HIV prevalence in pregnant women. This step-wise approach should be closely monitored through operational research in wide-scale demonstration projects.²¹
- **The pilot or demonstration program evaluates the implementation of an effective intervention to prevent the transmission of HIV.** Preventing the perinatal transmission of HIV/AIDS using antiretroviral drug therapy has been shown to be an effective intervention. In 1994, a six-week course of AZT was first shown to be effective in reducing the perinatal transmission of HIV by 68 percent in nonbreastfeeding mothers.⁷ This study formed the basis of the current U.S. regimen that is now standard practice. A recent trial based in developing countries showed that short-course oral AZT treatment reduced transmission by 38 percent in breastfeeding mothers at six months.¹⁰ In addition, a recent trial in Uganda showed that a single-dose therapy of nevirapine to both mother and neonate lowered the risk of perinatal transmission by nearly 50 percent in breastfeeding populations during the first 14 to 16 weeks of life.¹¹ However, the use of short-course nevirapine requires further evaluation of efficacy, safety, and the potential for developing drug resistance.²²
- **The pharmaceutical product is essential to the program and an appropriate alternative product, which is not covered by a U.S. patent, does not exist.** USAID funding to evaluate interventions to prevent perinatal transmission of HIV-1 through pilot and demonstration projects would require the availability of antiretroviral drugs. However, all antiretroviral drugs, including AZT and nevirapine, are currently under U.S. patents. The U.S. patents for AZT and nevirapine expire in 2005 and 2011, respectively.

Summary of Key Findings for Option 5

- Negotiating with U.S. manufacturers/patent holders for preferential pricing for USAID-funded HIV/AIDS-related pharmaceutical products would reduce the cost of the pharmaceutical component of programs where the cost of the U.S. source pharmaceutical product is significantly higher than the cost of non-U.S. source products. This would consequently increase the efficiency of the program by expanding the number of clients to whom the services could be extended.
- Potential concerns
 - Uncertainty exists surrounding preferential pricing under the UN agency/WB/pharmaceutical company initiative.
 - Preferential pricing is limited in that it reduces the cost component of the pharmaceutical products only for the duration of the DHIV program. The sustainability of programs would be threatened once responsibility for continued funding was transferred to the host country. In addition, preferential pricing does not address the appropriateness of the U.S. S/O and/or U.S. patented product for the proposed application in the specific conditions in which it will be used and the capacity of the program to appropriately manage its use.
 - The capacity of USAID to negotiate preferential pricing may be limited by funding or staffing restrictions. The feasibility of this option could be increased by limiting USAID negotiations for preferential pricing for pharmaceutical products by criteria that would define the product itself and the program in which it is to be used.
 - USAID procurement requirements in the ADS are based on the FAR and FAA, and changes to permit negotiation with U.S. manufacturers and patent holders for preferential pricing may require legislative amendments.
 - USAID Missions and CAs would still need to comply with USAID regulations on competition and procurement, including applying for an S/O waiver if required.

Option 6: Provide More Technical Assistance to USAID Missions and CAs

Keeping the USAID procurement process unchanged and providing more technical assistance to USAID Missions and CAs in preparing requests for approval to procure HIV/AIDS-related pharmaceutical products

The final option considered in this chapter is for USAID to make no changes to its procurement process for HIV/AIDS-related pharmaceutical products, but to provide more technical assistance to USAID Missions and CAs. Technical support could be provided to assist USAID Missions and CAs in preparing requests for approval to procure HIV/AIDS-related pharmaceutical products.

This option draws on suggestions for possible improvements proposed in interviews with USAID Missions and CAs (see Chapter 3). It is also based on the recent revisions to WB procurement policies, as discussed in Chapter 1, and on the technical assistance that the WB is providing to its technical field managers to guide recipient countries through the procurement process.

Objective

The objective of this option would be to provide USAID Missions and CAs with technical assistance in preparing requests for approval to procure pharmaceutical products in order to facilitate the process.

Rationale

Some USAID Missions, CAs, and program CTOs lack the technical expertise to prepare requests for approval to procure pharmaceutical products, specifically for obtaining, evaluating, and providing data to attest to the safety, efficacy, and quality of non-FDA-approved pharmaceutical products.

The technical assistance could be provided through general guidelines in a briefier and workshops, as suggested in the interviews in Chapter 3, or USAID could provide specific assistance in preparing each request for approval either through USAID Global Bureau technical assistance or by contracting out these services.

Controls and Oversight

The same controls and oversight that exist at present for the procurement of HIV/AIDS-related products would continue to apply. Consideration could be given to monitoring the current process, to quantifying the magnitude of problems identified in this report, and to evaluating new interventions introduced to facilitate the process.

Potential Concerns

- This option does not address the barriers and obstacles in the procurement process itself. It only provides technical assistance to minimize the impact of some of those barriers.
- There are staffing and financial implications of contracting out for technical assistance.

Summary of Key Findings for Option 6

- The objective of this option would be to facilitate the process of preparing requests for approval to procure pharmaceutical products by providing USAID Missions and CAs with technical assistance. The technical assistance could be provided through a briefer and/or workshops addressing how to prepare requests for approval or by providing specific assistance in preparing each request, either through USAID or by contracting out these services.
- The rationale for this option is that some USAID Missions, CAs, and program CTOs lack the technical expertise to prepare requests for approval to procure pharmaceutical products, specifically for obtaining, evaluating, and providing data to attest to the safety, efficacy, and quality of non-FDA–approved pharmaceutical products.
- The same controls and oversight that exist at present for the procurement of HIV/AIDS-related products would continue to apply. Consideration could be given to monitoring the current process, to quantifying the magnitude of problems identified in this report, and to evaluating new interventions introduced to facilitate the process.
- The potential concerns are that this option does not address the procurement process itself.

Selecting Options—Criteria to Be Considered

In this chapter, six options to facilitate the procurement of HIV/AIDS-related products have been discussed. Each option and its objectives are summarized in Table 1.

Table 1. Summary of Options and Objectives to Facilitate the HIV/AIDS-related Products Procurement Process

Option	Objectives
Option 1: S/O waiver for HIV test kits/ antiretrovirals	<ul style="list-style-type: none"> Facilitate procurement of HIV test kits/ antiretrovirals from non-U.S. sources.
Option 2: Transfer of responsibility for technical approval	<ul style="list-style-type: none"> Accelerate approval process for non-FDA-approved products.
Option 3: Stipulate additional certifying authorities	<ul style="list-style-type: none"> Facilitate preparation of requests for approval to purchase non-FDA-approved products. Facilitate approval process for non-FDA-approved products.
Option 4: Prequalify international suppliers	<ul style="list-style-type: none"> Facilitate preparation of requests for approval to purchase non-FDA-approved products. Facilitate approval process for non-FDA-approved products.
Option 5: Negotiate for preferential pricing for drugs	<ul style="list-style-type: none"> Decrease price of pharmaceutical products under U.S. patents.
Option 6: Provide more technical assistance	<ul style="list-style-type: none"> Facilitate preparation of requests for approval to purchase pharmaceutical products.

This final section outlines the criteria that USAID would need to consider when deciding whether to implement each of the options to facilitate the procurement of HIV/AIDS-related products. The decision-making process would need to weigh the potential impact of each option on facilitating the procurement process against the necessary inputs to implement each option and potential risks or problems.

It is beyond the scope of this report to make recommendations to USAID as to which options should be selected for two reasons. First, the interviews described in Chapter 3 identified the problems experienced by USAID Missions and CAs in procuring HIV/AIDS-related pharmaceutical products, but they did not provide quantitative data that could be analyzed to reveal the magnitude of each of the problems. Second, because the Rational Pharmaceutical Management Project team is unfamiliar with USAID in-house technical expertise, existing protocols and procedures, and staffing levels, this report is not able to analyze the feasibility of each option.

Significance of the Problem

USAID would need to consider the importance of the problem that each option addresses and whether resolving the problem would substantially improve the procurement process for HIV-

related products. For example, is the problem that Option 2 addresses—namely, the length of time taken to approve requests for non-FDA–approved HIV/AIDS-related products—a significant problem?

Effectiveness of the Option

The effectiveness of each option in achieving its objective(s) would need to be assessed. For example, will Option 4, prequalifying international suppliers, significantly assist USAID Missions and CAs in preparing requests for approval to procure non-FDA–approved products?

The impact of the option on facilitating the procurement process would be a product of the significance of the problem addressed and the effectiveness of the option in addressing that problem.

Policy Implications

The implications for USAID policy change for each of the options would need to be determined and, in particular, the requirements for changes to the current USAID procurement guidelines would need to be assessed. For example, for Option 3, can CDC be considered a “controlling U.S. authority” or would the guidelines need to be rewritten to stipulate CDC as an additional certifying authority?

USAID Staffing Implications

USAID would need to consider the staffing implications for each option, particularly in the long term. For example, for Option 2, in transferring the responsibility for technical concurrence for procurement, would G/PHN need to employ a full-time in-house pharmacist in order to improve its in-house technical expertise relative to that of M/OP/TC/COM?

Financial Implications for USAID

The financial implications for each of the options would need to be assessed for both the long and the short term and would include the requirement for additional staff, increased workload for existing staff, cost of technical assistance, and additional resources. For example, Option 4, prequalifying international suppliers, could have significant financial implications in terms of staffing and technical assistance initially, but ultimately may decrease the workload of USAID Missions/CAs and M/OP/TC/COM.

Need for Technical Assistance

USAID would need to consider the requirements for technical assistance for each of the options and whether the necessary technical expertise is available within USAID. In addition, it would need to be considered whether the USAID personnel with the required technical expertise can absorb the additional workload. For example, for Option 6, does USAID have the staff with the necessary expertise and the time to provide more assistance to USAID Missions and CAs to prepare requests for approval?

Need for Legislative Changes

USAID procurement requirements as detailed in the ADS are based on the FAR and FAA, and USAID would need to consider if legislative changes are needed in order to implement each of the options.

Involvement with External Agencies and Organizations

The need for assistance from and/or concurrence of external agencies or organizations would need to be determined. For example, for Option 3, stipulating additional certifying authorities, and Option 4, prequalifying international suppliers, would USAID require the assistance and concurrence of the FDA?

If the assistance and concurrence of external agencies and organizations are required, USAID would need to consider how feasible this would be and the associated expense. For example, for Option 6, how expensive would it be to contract out for technical assistance that is specific to each request for approval?

Risks and Problems

The potential risks and problems for each option would need to be reviewed and USAID would need to consider whether the benefits offered by each option outweigh the risks. For example, for Option 3, stipulating additional certifying authorities, and Option 4, prequalifying international suppliers, what is the risk of the potential liability and loss of credibility of USAID as a consequence of a toxic or adverse effect of a pharmaceutical product?

Conclusion

This chapter provided descriptions of six options that address the current perceived difficulties in preparing requests for approval for procurement of HIV/AIDS-related pharmaceutical products. Before implementing any of these options, USAID would need to consider the criteria discussed above, namely, the impact, necessary inputs, and potential risks and problems associated with each option. The impact of the option on facilitating the procurement process is based on the

significance of the problem addressed and the effectiveness of the option in addressing the problem. The inputs include the need for policy change, staffing and financial implications, need for technical assistance, requisite legislative changes, and involvement with agencies and organizations external to USAID. The decision-making process would need to weigh the potential impact of each option with the necessary inputs to implement each option and potential risks or problems.

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