USAID
FROM THE AMERICAN PEOPLE

PROCURING HIV/AIDS COMMODITIES USING U.S. GOVERNMENT FUNDS

LESSONS & APPROACHES

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DELIVER
No Product? No Program. Logistics for Health

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LESSONS & APPROACHES

DELIVER

DELIVER, a six-year worldwide technical assistance support contract, is funded by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Crown Agents Consultancy, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID's central contraceptive management information system.

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Abstract

The global scale-up of antiretroviral-therapy programs in resource-limited settings, and the increase of U.S. Government (USG) support in this effort, have increased global funding levels and the demand for HIV/AIDS commodities. To meet this demand, the USAID-funded DELIVER project has taken on a role in procuring these commodities with USG funds. This paper outlines key lessons and insights from DELIVER's two-plus years of experience in procuring HIV/AIDS commodities by using USG funds.

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ACRONYMS

3TC	lamivudine
AAPD	Acquisition and Assistance Policy Directive
ADS	Automated Directives System
AIDAR	Agency for International Development Acquisition Regulation
AIDS	acquired immunodeficiency syndrome
ARV	antiretroviral
AZT	zidovudine
CDC	Centers for Disease Control
CTO	cognizant technical officer
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
GMP	good manufacturing practice
GRZ	Government of Zambia
HHS	United States Department of Health and Human Services
HIV	human immunodeficiency virus
JSI	John Snow Inc.
MOH	Ministry of Health
NGO	nongovernmental organization
OAA	Office of Acquisition and Assistance
RFTOP	request for task order proposal
PEPFAR	President's Emergency Plan for AIDS Relief
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
USG	U.S. Government

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This publication, which is featured on the CD *Resources for Managing the HIV/AIDS and Laboratory Supply Chains*, is dedicated to people around the world living with HIV/AIDS and to the many individuals from communities, nongovernmental organizations (NGOs), faith-based organizations, Ministries of Health, and other organizations who have consistently fought for access to antiretroviral (ARV) drugs and other commodities required to provide HIV/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, the Family Planning Logistics Management project, and John Snow, Inc., since 1986 and to the thousands of committed professionals in Ministries of Health and NGOs who work daily to supply their customers and programs with essential public health commodities. Although the resources on the CD provide a focus on specific HIV/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

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INTRODUCTION

The procurement of HIV/AIDS commodities is a complicated process that varies according to the source of funding for procurement, the recipients, and the recipient country regulations that are in place. The global scale-up of HIV/AIDS treatment and care has increased the availability and accessibility of those services, as well as the commodities required to provide the services. In many countries, the scale-up has also increased the complexity of the procurement environment and process because it has increased the number of players and steps involved in procurement.

Procurement procedures for HIV/AIDS commodities vary from donor to donor and from country to country. A number of the major donors (e.g., the World Bank, the Global Fund, the United Nations International Children's Emergency Fund [UNICEF], and others) have published detailed guidelines for procuring HIV/AIDS commodities when using their funds or their procurement mechanisms. Those guidelines are extremely useful resources for countries that have set priorities for expansion of HIV/AIDS programs and services and that may be recipients of some or all of the funding streams. Countries generally dedicate a portion of donated funds to procure commodities that will support program expansion, so having access to clear, user-friendly guidelines that will help countries understand and follow complex procedures will enable programs to procure quality products in a timely manner.

The U.S. Government (USG) is relatively new in the arena of global procurement of HIV/AIDS commodities. Nonetheless, since the launch of the President's Emergency Plan for AIDS Relief (PEPFAR) in 2003—with its US$15 billion commitment to HIV/AIDS prevention, care, and treatment activities—USG has become a key provider of HIV/AIDS commodities for programs in resource-poor countries. Just as the World Bank and the United Nations Population Fund have their own guidelines for procurement, the USG also has a set of regulations that must be followed when procuring HIV/AIDS commodities with USG funds. Organizations that procure commodities by using USG funds must understand the technical and program requirements, as well as the rules and regulations that must be followed for the process. If organizations are to successfully complete the procurement, multiple steps must be taken, often simultaneously, by various stakeholders involved in the process.

The DELIVER project, implemented by John Snow, Inc. (JSI), has been involved in procuring HIV/AIDS commodities with USG funds since 2003. Over the two-and-a-half year period, the processes have evolved, and the project has gained experience and expertise in this specialized area. This guide aims to provide contextual insights and qualitative lessons that have been learned in procuring HIV/AIDS commodities while using USG funds. The guide was specifically developed as a resource to support USAID Missions, cooperating agencies, and other organizations and agencies that receive USG funds so that they can obtain HIV/AIDS commodities. The lessons will be particularly relevant to organizations for which procurement is not a core activity and that may decide to outsource certain procurement functions to a procurement agent.

This guide is by no means an exhaustive reference to procurement of HIV/AIDS commodities with USG funds. Several useful resources exist that document both general procurement guidelines and specific USG/USAID procurement guidelines. Those documents are included in the bibliography at the end of this work. The intention of the guide is to offer unique insights into the process on the basis of the contextual information and lessons learned from DELIVER's experience, which may not be available in other published guides.

The guide begins with a basic overview of USG procurement rules and regulations and the procurement mechanisms available to organizations. It then provides the specific lessons learned from DELIVER's more than two

years of experience in procuring HIV/AIDS commodities with USG funds. It also includes the step-by-step approach that DELIVER has used.

SUMMARY OF USG PROCUREMENT RULES AND REGULATIONS CONCERNING HIV/AIDS COMMODITIES

Organizations using USG funds to purchase HIV/AIDS commodities must abide by the U.S. government's procurement rules and regulations. Those regulations are intended to ensure a minimum level of product quality and assurance to both the client and the U.S. taxpayers that the money is being used to obtain quality, efficacious products in a transparent manner.

Many organizations must also follow their specific contractual obligations, in addition to federal and USAID procurement regulations. For example, the DELIVER project is bound by contractual requirements between JSI and its funder, USAID. Therefore, when procuring commodities through the DELIVER project, JSI must adhere to its contractual obligations in order to use USG funds appropriately. Contracts vary from organization to organization; thus, each organization must be sure to review its own terms and guidelines and its incorporated regulations to ensure compliance.

In summary, while reliant on USG rules and regulations and on specific contractual requirements, a project must consider the need for the following three types of waivers or approvals when procuring HIV/AIDS commodities with USG funds:

- Does the organization require an Approval to Purchase Restricted Commodities?
- For each commodity, is a Source and Origin Waiver required?
- Is approval necessary to purchase commodities over an authorized threshold, as indicated in the organization's contract?

RESTRICTED COMMODITIES PURCHASE APPROVAL

Pharmaceutical products, including HIV/AIDS commodities such as drugs and test kits, are classified as "restricted commodities" under the USAID procurement regulations (as defined in the Automated Directives System [ADS] and the Code of Federal Regulations [CFR]). Under USG regulations—until the time that a blanket waiver exists for all restricted commodities—organizations that plan to procure restricted commodities must request approval from USAID's Office of Acquisition and Assistance (OAA).

SOURCE AND ORIGIN WAIVER

In addition, all pharmaceutical products procured with USG funds must be deemed safe and of a certain standard of quality. In most cases, this requirement means that the products must be approved by the U.S. Food and Drug Administration (FDA). Preference is also given to commodities whose source and origin is the United States. In special circumstances, approvals may be sought to purchase non-FDA-approved commodities whose source or origin, or both, is outside the United States.

APPROVAL TO PURCHASE COMMODITIES OVER AN AUTHORIZED THRESHOLD

Organizations must review their own contract to determine whether they require approval to purchase commodities over an authorized threshold. For example, the DELIVER contract has a restriction under Federal Acquisitions Regulation (FAR) 52.244-2, which requires approval from OAA for any procurement of goods that exceed US$100,000 in value. Therefore, in addition to requesting approval to procure restricted commodities, DELIVER's contract requires that the project seek approval to procure goods that exceed US$100,000 in value.

PROCUREMENT MECHANISMS AVAILABLE WITH USG FUNDS

The process of procuring HIV/AIDS commodities can occur through a number of different mechanisms. Organizations may elect to do the following:

- Procure the commodities themselves by negotiating all contracts for the goods directly with the manufacturers and by monitoring all shipments and payments.
- Use the expertise of a procurement services agency that is experienced in HIV/AIDS commodity procurement to assist with contract negotiation and shipment monitoring. Hiring a procurement agent, however, does not preclude an organization from meeting its own responsibilities to monitor contracts, shipments, and payments.
- Use a hybrid method of procurement by outsourcing selected components of the procurement process. For example, an organization may elect to use the expertise of multiple partners, such as a combination of procurement agents or organizations, or both (DELIVER, the Partnership for Supply Chain Management, or Management Sciences for Health/Rational Pharmaceuticals Management Plus) that have specific expertise in different aspects of procurement.

DELIVER elected to use its team subcontractor, Crown Agents Consultancy, Inc. (Crown Agents), as its agent in the procurement of HIV/AIDS commodities. Although the general lessons and process for procurement are applicable to other agencies procuring HIV/AIDS commodities, some steps are specific to DELIVER's relationship with Crown Agents, as well as to its contractual obligations with its funder, USAID.

LESSONS LEARNED FROM DELIVER

BACKGROUND

Although the DELIVER contract does not grant JSI approval to procure restricted commodities, over the past two and a half years, DELIVER has been approached by a number of USAID Missions to procure HIV/AIDS commodities with its available USG funds. To meet the Missions' requests—which, in turn, would assist countries to meet program targets—the DELIVER project had to comply with a process of requesting waivers and approvals to purchase restricted commodities and to procure commodities at levels exceeding US$100,000.

DELIVER's efforts in HIV/AIDS commodity procurement that is USG funded began in 2003 in Zimbabwe and have since expanded to six countries in conjunction with the growth of the President's Emergency Plan for AIDS Relief (PEPFAR) program. Following is the list of countries where the project has handled the procurement of PEPFAR-funded supplies:

- Angola (HIV test kits)
- Kenya (HIV test kits and laboratory reagents and supplies)
- Mozambique (ARVs)
- Tanzania (ARVs)
- Zambia (ARVs and HIV test kits)
- Zimbabwe (ARVs and HIV test kits).

DELIVER initially documented its experience and lessons from procuring commodities in the first few countries where procurements were completed, to guide the process in other countries. Over time, the lessons have been refined and can be shared more broadly to provide insights to organizations contemplating this process for the first time or to help refine existing processes for organizations already procuring the commodities.

EXPECT THE UNEXPECTED: LESSONS LEARNED FROM SIX COUNTRIES

One of the overall lessons learned is that, regardless how well organized, planned, or managed partners are in the procurement process, unexpected delays are unavoidable. The following lessons were found to be helpful in minimizing the negative impact on product availability and program goals of unexpected delays and in enabling DELIVER and its partners to respond in a flexible and agile way to challenges encountered throughout the process. DELIVER's experience has been categorized in the following 10 lessons.

The first lesson is that each recipient country has unique requirements and regulations. Start the procurement and pre-procurement process early so that unexpected delays in procurement and importation of commodities do not undermine program goals.

Although general steps in the procurement process may be learned, understood, and improved over time, each country's procurement process and stakeholders are unique. Mozambique, which started procuring commodities in late 2005, was able to learn from the procurement processes and challenges faced in other countries, but the country's unique importation processes and requirements were the main causes of obstacles and delays.

Another potential cause of unexpected delay can occur during a preprocurement step such as quantification. Generally, requests for DELIVER to procure commodities are associated with availability of funds and, therefore, are usually not preceded by completed estimation of needs. In such situations, the first step is to conduct national or program quantifications, which can be a lengthy process depending on the program's readiness. As an example, if a program's standard treatment guidelines or testing algorithms are in flux or are not finalized, they must be completed before quantifying needs.

The process of finalizing standardized treatment and testing guidelines can take several months and can create significant delays in product availability. Programs that have complete and updated quantifications can engage in procurement planning as soon as funds are available for procurement. After the quantification is complete, the required date for the arrival of the commodities in-country is established. That date is fixed even before the procurement process commences, which helps to establish a clear idea and timeline throughout the procurement process for when the product is required in-country.

The second lesson is that many HIV/AIDS programs are new or rapidly expanding, thereby making forecasts less reliable than for stable programs. Build flexibility into the procurement plan and into the shipment schedule to minimize product wastage and to ensure that manufacturers can continue to meet global demand.

Organizations that can influence procurement planning should build in flexible mechanisms such as smaller, more frequent shipments for products for new programs (e.g., ARV drugs and HIV tests). Although this step might be slightly more costly in the short term, there are likely to be long-term savings if uptake in ARV drug consumption, for example, is not as high as forecasted and if products begin to pile up in-country. Planning for smaller, more-frequent shipments enables programs to avoid bringing in more commodities when programs are overstocked. Conversely, if product uptake is much higher than expected, such as increasing needs for HIV test kits by a given program, quantities can be added to existing planned shipments to prevent additional costly emergency shipments.

However, it is important to keep in mind as programs expand that phasing procurement across several suppliers can add up to several shipments. Because suppliers may not always strictly adhere to delivery dates, programs might receive a number of partial shipments, in addition to those shipments already planned. The importance of regular monitoring and of clear and consistent updates by the procurement agent are critical components for enabling programs to stay on track and to navigate the confusion generated by multiple shipments.

It is important to monitor HIV/AIDS commodity consumption in programs on a regular basis and to ensure that updates are reflected in procurement plans. With ARVs for example, slow uptake, especially for second-line drugs, has led to changes within procurement orders, thus resulting in fewer drugs arriving in-country, and has resulted in significant cost savings for in-country programs. Those funds can be and have been reallocated for other HIV/AIDS procurement needs or for HIV/AIDS-related program activities.

The third lesson is that coordination between in-country partners engaged in separate procurement processes can help maximize product availability and flexibility in responding to commodity shortfalls or delays. Effective coordination involves sharing information among partners involved in funding, procuring, and quantifying national needs or program needs, or both.

Effective coordination of all partners involved in procurement or in supply chain management of HIV/AIDS commodities in a country is time-consuming but can result in significant benefits for the program and for all partners involved. Many programs receive funding for HIV/AIDS commodities from multiple sources, and procurement is often conducted through various mechanisms, all of which have different lead times. Convening a single forum for regularly sharing information on quantities of commodities being procured and on timeframes for receipt among all partners involved in procuring, financing, and quantifying HIV/AIDS commodities can facilitate problem solving when delays are experienced. In many cases, different partners may bring in the same or similar commodities. Delays in the receipt of one shipment could be compensated for by temporary loans from other available stocks—if such information is shared with enough time to prevent stockouts.

Furthermore, coordinating information among all partners builds a sense of shared ownership of the quantities to procure and a sense of shared responsibility for resolving stock shortages or imbalances that arise for various reasons, including delays in procurement. It is often the case in new and expanding programs that actual consumption may not come close to forecasted projections. When commodities are in short supply, or when they are overstocked and likely to expire, resolving those issues in partner forums is likely to be effective for finding solutions.

A snapshot of the procurement situation in Zambia provides a useful example of why coordination is critical and of how coordination can be important for addressing commodity imbalances. There are four sources for HIV test kit procurement and five sources for procuring ARVs. The landscape of procurement agencies and organizations is more complicated, with multiple agencies procuring for each funding stream.

Five agencies are involved in HIV test kit procurement:

- Japan International Cooperation Agency conducts direct procurement using its own funds.
- UNICEF/The Government of Zambia (GRZ) procures HIV test kits with World Bank funding.
- UNICEF procures HIV test kits on behalf of GRZ while using funds from the Global Fund.
- The Centers for Disease Control procures HIV test kits with PEPFAR funds.
- DELIVER and Crown Agents procure HIV test kits with USG funds.

Five agencies are involved in procurement of ARV drugs:

- GRZ procures ARV drugs with Global Fund monies and its own funds.
- UNICEF procures ARV drugs with Global Fund monies received by GRZ.
- DELIVER and Crown Agents procure ARV drugs with PEPFAR funds.
- Catholic Relief Services procures ARV drugs for the Christian Health Association of Zambia with PEPFAR funds.
- The Elizabeth Glaser Pediatric AIDS Foundation procures ARV drugs for its Zambian partner, the Center for Infectious Disease Research in Zambia, with PEPFAR funds.

All implementing partners involved in ARV drug procurement agreed to, and participated in, a national forecast for ARVs. That forecast provided the basis for discussions with the various funding sources to ensure that there was sufficient funding to cover forecast needs. The implementing partners also regularly make available information on their issues to facilities, their stock on hand, and their planned shipments. That information provides a picture of the national stock situation. Implementing partners have begun using JSI's procurement planning software—PipeLine—to facilitate the timely sharing of key information, including the number of months of supply by product. By sharing data, the partners have been able to take concrete actions to maximize product availability.

As an example, one partner had 50 months of supply of Efavirenz 50 mg, almost guaranteeing expiration and waste, while another was stocked out. The partners were able to transfer stock, allowing the stocked-out partner to meet demand for Efavirenz 50 mg and to cancel future shipments until the stock in-country was used, thereby lessening the chance of expiration and maximizing the use of valuable resources. Similarly, when all PEPFAR partners were experiencing delays in the availability of Combivir because of global shortages by the manufacturer, sharing information allowed them to transfer stocks to avoid stockouts in the various programs and to update one another on mechanisms for fast-tracking procurement of other sources of approved AZT/3TC.

The fourth lesson is that developing and maintaining procedures for regular and clear communication among all partners involved in the procurement process can help clarify roles and can reduce delays related to lack of understanding of complex steps and requirements. Designate a primary contact per organization or office to ensure clear and streamlined communication.

When outsourcing any or all components of the process to an organization or procurement agent, special attention must be paid to the execution of the agreement or to a scope of work. If an organization is to maximize progress and to ensure that all steps in the process are followed—so there will be timely product availability and adherence to federal, USG, and contractual obligations—detailed information must be collected, shared, used, and stored by many or all partners in the procurement process. This coordination can be done effectively only by the following:

- Establish clear procedures about regularity and mechanisms of communication. Not all partners need to be copied on all communication; information should be shared when appropriate and relevant. Nonetheless, the frequency of communication should be established for all partners, depending on their role.
- Designate individuals to serve as focal points for sharing information and for responding to queries within each organization or office, so that information exchange is not duplicative or contradictory.
- Design standard templates for collecting and sharing information.
- Ensure that all partners are regularly informed about issues that arise, including shipping changes, clearance delays, quality issues, payment requirements, and so on.

As an example of information sharing among implementing partners, both DELIVER and Crown Agents have individuals who have been designated to lead procurement-related activities from each organization. DELIVER has a senior commodity procurement advisor who is responsible for coordinating all procurement-related tasks between various implementing partners. Information is shared in a variety of ways:

- The senior commodity procurement advisor conducts weekly conference calls with the Crown Agents counterpart. During the calls, Crown Agents shares routine updates from the manufacturer and DELIVER shares updates in quantities or in delivery dates from in-country field offices. Any outstanding issues or challenges are discussed or addressed during the calls.

- Crown Agents also sends weekly updates on the status of ongoing procurements in the form of a standard template that has been agreed on by the two organizations. The template was designed to reflect the tasks defined in the task order, so that progress based on deliverables could be clearly identified. Each country update is sent individually and is addressed to DELIVER's procurement advisor, and relevant DELIVER country team staff members are copied on each email.
- The procurement advisor sends monthly updates summarizing the status of procurement orders and funding across all countries to the project management and USAID/Washington partners.
- Queries from DELIVER field offices are directed to the procurement advisor, who can triage responses clearly and comprehensively.
- All partners are copied on relevant issues that affect them. The list of partners includes DELIVER Washington, DELIVER staff in-country, Crown Agents, manufacturers, USAID/Washington, USAID Missions in-country, and agents contracted to clear and to forward products at the port of entry.

The fifth lesson is that establishing relationships with manufacturers by sharing commodity forecasts can minimize global commodity shortages and maximize product availability for recipient countries through strengthened relationships.

As part of its first procurement in Zimbabwe, DELIVER engaged in the negotiation of procurement terms and conditions with manufacturers for the first time. This process required a significant amount of time and resources. The situation was further exacerbated by an environment with numerous stakeholders and with specific procedures and regulations for the Accelerated Access Program, which covered differential pricing of ARVs and which complicated negotiations for issues related to shipping, customs, and payment terms.

Although initial relationships with manufacturers were slow to develop for DELIVER, regular contact has enhanced those relationships, and DELIVER is increasingly valued as a partner by manufacturers after sharing its forecasting data about commodities experiencing global shortages. Forecast information is valuable to manufacturers that are experiencing the strain of unpredictable, but increasing, global demand for ARV drugs and HIV test kits. Country- and commodity-specific forecasts enable manufacturers to prepare accurate production projections and, thus, to continue to expand their markets. Fewer global shortages and product availability crises also benefit recipient countries, donors, and organizations that are committed to ensuring continuous availability of HIV/AIDS products.

The sixth lesson is that maintaining detailed and up-to-date documentation can reduce delays in procurement and is necessary for fulfilling contractual obligations.

Proactively compiling and updating documents that are required for the procurement before they may be needed identifies gaps and missing information early in the process, which, in turn, reduces bottlenecks. Well-maintained records are necessary for providing precise information that is required to meet USG or recipient country regulations or for making decisions in the procurement process. Proactively compiling and updating documents become another key factor, in addition to establishing clear procedures that help partners navigate the process as efficiently as possible. Following are illustrative examples of documents that should be compiled early and updated regularly:

- A comprehensive list of ARV drugs, HIV test kits, and other commodities that are FDA approved or are tentatively FDA-approved products, because USG funds cannot be used to purchase a commodity that does not fall into either category.
- For each recipient country, a comprehensive list of all ARV drugs (and other relevant drugs) registered for use in that country. It is important that this list include information on the manufacturer, on formulation, on

strength, and on packaging because changes in any of those factors may affect registration status. USG regulations determine that, if a product has the FDA's tentative approval, it can be purchased only if it is registered for use in the recipient country. Thus, items on the procurement list that are "pending" registration may not be legally purchased using USG funds unless registration is fast-tracked or unless special waivers from the National Drug Regulatory Authority are obtained.

- A master list of details related to all previous procurements, including suppliers and prices, should be compiled as an easy reference. This master list is helpful in determining budgets and procurement plans for new countries, although details such as prices and shipping costs are likely to vary over time and by location, and will likely be specific to each country. This information, however, is still a useful starting point for initiating the process for a new country procurement.
- Copies of all relevant approvals, including OAA approvals, for the procurement files. This information is necessary to show adherence to contractual requirements in the case of an audit. Similar types of information may be needed, depending on each organization's individual contracts. For example, when DELIVER began procuring restricted commodities, the blanket waiver for ARVs did not exist. Thus, the project had to obtain copies of good manufacturing practice (GMP) certificates for each manufacturing site from which the products had originated to demonstrate proof of FDA approvals in the case of an audit. The lack of a blanket waiver significantly complicated the procurement process for the project by introducing several additional steps that often caused delays.

The seventh lesson is that a blanket waiver can significantly reduce the complexity of the procurement process. When applying for a new blanket waiver or an amendment to blanket waivers, be sure to include an exhaustive list of commodities that the program is likely to purchase now and in the future.

The existing blanket waiver for ARV drugs was released in 2005 after DELIVER had some experience applying for source and origin waivers and approvals to purchase restricted commodities for procurements in Zimbabwe and Tanzania. The existence of the blanket waiver greatly reduced the number and the complexity of steps in the process. Once a product appears on the blanket waiver, neither the source and origin waiver nor the FDA approval for restricted commodity purchase is needed. Eliminating the source and origin waiver and the FDA-approval requirements can shorten the lead time by as much as two months. Unfortunately, the existing blanket waiver does not include all formulations, strengths, or manufacturing sites for all commodities purchased by DELIVER. Thus, organizations should be proactive about identifying all possible commodity formulations and strengths, as well as identifying manufacturing sites for future versions of the blanket waiver.

As an example, DELIVER set out to procure Tenofovir (in 300-mg tablets), which is produced by Gilead Science, Inc., of Foster City, California. The tablets were listed on the blanket waiver of April 7, 2005, with an approved manufacturing facility of Patheon, Inc., in Mississauga, Ontario, Canada. Upon placing the order, DELIVER was informed that the product was no longer being manufactured and shipped from that facility but would be manufactured and shipped from the Altana Pharma Oranienburg GmbH facility in Oranienburg, Germany. In order to resolve this issue, DELIVER submitted the GMP certificate for the new facility as well as FDA approval documentation to USAID in order to apply for a source and origin waiver for the new facility.

The eighth lesson is to explore alternative mechanisms for ensuring that unregistered products can be legally imported into recipient countries. Limiting procured items to already registered products without exploring options could unnecessarily undermine program goals.

When USG funds are used to procure products, the items must be (tentatively) FDA approved and registered for use in recipient countries. However, given the rapid changes in technology, which often result in the emergence of new drugs or new formulations or new strengths of existing drugs, a newly approved FDA product might not

yet be registered for use in the recipient country. The onus of registration falls on the manufacturer. Given the relatively high costs of registering and the sometimes lengthy processes once registration has started, manufacturers are sometimes reluctant to apply for registration status unless they know a market for the product exists. In some cases, the product might be the best alternative for the program because of its unique formulation or strength, for example, 600-mg capsules of Efavirenz (which reduces the pill burden for ART patients) or triple fixed-dose combinations (which can reduce pill burdens from six pills to two pills per day).

Before eliminating a product from options for procurement because of lack of registration, other alternatives for procurement should be explored. Those alternatives include mechanisms for fast-tracking registration and for receiving temporary authorization from the National Drug Regulatory Authority of a recipient country to import a nonregistered pharmaceutical. In Zimbabwe, the mechanism for obtaining temporary authorization is provided by Section 75 of the national drug policy, and was successfully used in the procurement of ARVs in 2004.

In Mozambique, where virtually no ARV drugs are registered, DELIVER was able to move forward with its procurements because the national director of health signed a letter stating that medicines, including ARV drugs destined for the public sector, do not need to be registered in-country.

In another scenario, the manufacturing plant for the (tentatively) FDA-approved product that is being purchased may not match the manufacturing plant for which registration was awarded in a given recipient country. As an example, Efavirenz purchased by DELIVER might originate from a manufacturing site in the Netherlands and, thus, allow DELIVER to meet USG regulations (because it is included on the blanket waiver), but the registration of Efavirenz in the recipient country might have been awarded for a manufacturing plant in a different country, for example, the United Kingdom. In such situations, although the chemical molecule (i.e., Efavirenz) is registered for use in the recipient country, the registration is specifically for a different production site. In Zimbabwe, this was the case for almost all drugs procured during 2004. USAID's ADS guidelines enabled DELIVER to move forward with the manufacturing plants that the National Regulatory Drug Authority in the receiving country had registered, by considering that agency a "stringent regulatory authority."

The ninth lesson is to develop a process map of the clearance process, to develop procedures, and to assign responsibilities at the country level for all steps in the process. Designating in-country responsibilities for monitoring shipments, payments, and clearance processes will reduce the lead time and lengthy delays, especially if communication procedures are well established.

Shipments can be delayed at numerous points in the process, and understanding the potential obstacles at each stage can help with preventive maintenance.

In Mozambique, DELIVER's in-country staff is responsible for monitoring the progress of shipments through the following process:

- deciding whether proforma invoices issued are in accordance with country requirements for importation
- processing the importation license
- issuing the import license to the supplier
- determining whether a preshipment inspection was undertaken
- learning whether authorization to ship has been issued by the country
- communicating shipping details, and so on to customs clearance
- knowing date of arrival at the airport and speed of customs clearance
- establishing the timeframe for acceptance and entry into the warehouse.

Some obvious but critical pieces of information that can cause lengthy delays if they are unclear include the following: identifying the consignee information and sharing this information with suppliers, determining the length of the customs clearance process, and identifying regulations that govern acceptable remaining shelf lives on imported products.

It has been DELIVER's experience that, despite the in-country's staff undertaking primary responsibility for this monitoring, a critical factor in resolving bottlenecks has been to ensure that DELIVER's procurement advisor is updated on all issues that occur throughout the process. Thus, when follow up with the procurement agent and manufacturers is required, it can be done instantly.

DELIVER's in-country staff has also played critical roles in negotiating and monitoring contracts with local agents for clearing, storage, or distribution; for expediting customs clearance; and for acceptance of the product by the recipient. Negotiating and monitoring contracts at the country level has several benefits, including the ability of the staff member to customize the contract terms to the local environment. As an example, in Zimbabwe, DELIVER contracted with Geddes for customs clearance, storage, and distribution of ARVs to five USG-supported sites. Inflation is rampant in Zimbabwe, and a standard one- or two-year contract would have resulted in a severe devaluation of the contract price. A price ceiling was set to alleviate devaluation of the contract price, and purchase order contracts would be reissued quarterly to ensure that Geddes receives fair compensation for the work it performs.

The tenth lesson is that developing a step-by-step approach to HIV/AIDS commodity procurement can help multiple partners involved in procurement clearly understand and navigate the process, thereby reducing delays caused by miscommunication.

Organizations that are involved in procurement using USG funds should break down requirements into clearly defined steps with associated procedures to help all partners understand and navigate their individual roles. DELIVER has developed its own process, which is described in the following section. The steps are intended to help organizational staff members and procurement partners ensure a clear and consistent process for undertaking procurement of ARV drugs, HIV test kits, and laboratory supplies. The procurement process that is outlined below is identical for each type of commodity, unless stated otherwise. Although there may be some overlap between lessons presented previously and tasks that are outlined in the step-by-step approach, the stepwise process, in general, contains specific details about individual steps and the timeframe that are not included in the lessons.

DELIVER'S STEP-BY-STEP PROCESS FOR PROCURING HIV/AIDS COMMODITIES WITH USG FUNDS

As DELIVER gained experience in procurement, the project developed a step-by-step process that was standardized in all countries that met the dual objectives of implementing procurement in an efficient manner and according to the required regulations. The steps are presented in the order in which they should occur, but often two or more steps are carried out simultaneously.

Several of the steps are unique to DELIVER's contractual requirements or to its approach of outsourcing selected procurement functions to its subcontractor, Crown Agents, and may not be relevant for all situations. Nonetheless, the steps illustrate the tasks that need to be accomplished along the way and also provide insights into the required details and into where potential bottlenecks or delays may arise. A chart that visually depicts the sequencing of the steps is attached as appendix 1. The steps correspond to the following 12 categories:

Step 1 Obtain mission approval for procurement.

Step 2 Validate quantities to procure and develop a procurement plan with shipment schedule.

Step 3 Gather pre–task order information.

Step 4 Prepare and issue task order to the procurement agent.

Step 5 Confirm approval status for commodities.

Step 6 Prepare source and origin waiver (if commodities are not on blanket waiver).

Step 7 Obtain approvals from the Office of Acquisition and Assistance.

Step 8 Confirm in-country delivery process.

Step 9 Negotiate and issue contract to manufacturers.

Step 10 Place commodity orders.

Step 11 Monitor shipment and delivery process.

Step 12 Receive commodities and pay manufacturer.

The glossary of terms at the end of this guide defines the critical terms used in the steps and serves to clarify the use of those terms within this particular context. In addition, each step in the process may require the use of other references, which are listed in the bibliography.

STEP 1. OBTAIN MISSION APPROVAL FOR PROCUREMENT.

The procurement of commodities requires written approval from the USAID Mission in-country. Programs must submit a written request to the Mission, seeking approval to procure the commodities. Before proceeding with the procurement, agencies should confirm that funds have been formally committed by the Mission for this procurement. After a formal written request is made to the Mission, the timeframe for the Mission to formally commit funding and to approve the procurement is between two and four weeks.

STEP 2. VALIDATE QUANTITIES TO PROCURE AND DEVELOP A PROCUREMENT PLAN WITH SHIPMENT SCHEDULE.

After Mission approval has been received, the procurement process can commence and should be based on a comprehensive list of commodities to be procured. This approval is usually obtained by reviewing or completing a quantification to determine the exact quantities of commodities to be procured. After the quantities to be procured have been determined and after a procurement plan and a shipment schedule have been developed, the quantities and plan should be validated by the recipient country's Ministry of Health (MOH), the USAID Mission, and other relevant stakeholders. The procurement plan and shipment schedule should include proposed arrival date(s) in-country. This step should take approximately three to four weeks.

STEP 3. GATHER PRETASK ORDER INFORMATION.

A number of critical pieces of information, which are gathered at the beginning of the procurement process, will serve to inform the process and to assist in developing various documents that are necessary for the procurement (e.g., the task order for a procurement agent, negotiation of contracts with manufacturers). This information-gathering process typically takes between three and six months and can be an iterative process. Examples of useful information, documents to be compiled, or both, are provided next:

- Ensure that commodities to be procured meet USG funding regulations and are FDA approved or tentatively FDA approved, by referencing the FDA's Electronic Orange Book or the U.S. Department of Health and Human Services' global health website.
- Investigate marking requirements for USAID donations by obtaining written guidance from the Mission. If there are sensitivities around implementing those requirements or if the costs are prohibitive, it is important to know that USAID Mission directors have the authority to waive any marking requirements. Although the Agency for International Development Acquisition Regulation (AIDAR) implies that the supplier shall ensure compliance with USAID marking, some manufacturers that DELIVER has worked with have refused to comply with the marking requirements for all of their products. JSI was successful in requesting and in receiving a waiver for all Global Health programs funded by the U.S. government, which waives marking requirements if they have an "adverse impact in the cooperating country."(See AAPD 05-11 of December 13, 2005.)
- Identify the following key information related to the in-country delivery process so as to minimize delays in this step:
  - The titleholder or the person or entity to whom the supplier will give the title of goods after the consignment has been accepted. USAID or other host government entities (as approved in writing by USAID) must be the titleholder of the commodities.
  - Consignee details, including the organization's name, address, phone, fax, email, and ATTN: contact name and title must be present. The consignee may be a different entity from the titleholder and should ideally be USAID, a host government, or a hired warehouse or distributor. The consignee should be selected so that this entity handles the port clearance and in-country handling.

  - The point person in-country to receive the commodity invoices and DD 250 forms. Although this point person is generally the consignee, it is important to confirm that this assumption is true. The DD 250 document confirms that the consignment has arrived in-country, and it initiates the payment process for manufacturers.

- Compile all relevant information from the quantification and procurement plan into the commodity procurement information table or a similar template. The table contains all information required for the procurement process and details exactly what type of product should be procured by specifying the product name, exact strength, dosage form, unit size, manufacturing site or plant, and country of manufacture.

It is important to keep in mind that there is a blanket waiver. In addition to identifying the commodities that have been approved for purchase, the waiver may also specify the manufacturing site for the product. Manufacturers, in fulfilling orders, may elect to source the product from a manufacturing site that is not listed on the blanket waiver, depending on the country location and product availability.

STEP 4. PREPARE AND ISSUE TASK ORDER TO THE PROCUREMENT AGENT.

This next step is relevant for organizations that outsource selected tasks to a procurement agent, and it involves preparing and issuing the task order to the agent. The time taken to process internal paperwork and contracts will vary from organization to organization, and the time depends on the complexity of the task order. Processing internal paperwork and contracts can sometimes be time-consuming, and that time should be factored into the planning process. It takes approximately two weeks for DELIVER to issue the task order to the procurement agent.

The primary purpose of this step is to use the commodity procurement information table and the procurement plan developed in previous steps to develop and negotiate a request for a task order proposal and a scope of work with the procurement agent. When preparing the scope of work for the procurement agent, as much detail as possible should be included, and tasks and deliverables should be clearly defined. Illustrative examples of important tasks and details include the following:

- confirmation of in-country registration of all commodities
- confirmation of the details of the commodity to be procured on the basis of the information contained in the commodity procurement information table
- clarification of the process for sending DD 250 forms to in-country contacts for signature
- description of the frequency and mode of progress reports and other communication updates from the procurement agent as part of the list of deliverables (e.g., weekly progress reports by email from Crown Agents to the DELIVER procurement advisor)
- determination of details related to contract negotiations with manufacturers, including clearly defining responsibilities of each party related to manufacturer contracts (e.g., Crown Agents' responsibilities included negotiating the contract, reviewing information [type of commodity, quantity, packaging, components, etc.] for accuracy, reviewing delivery schedules, and confirming payment schedules)
- confirmation of the shipping terms (Incoterms), including establishing requirements for product shipping (e.g., door-to-door, door-to-port, etc.)
- identification of the entity or entities to handle port clearance and customs clearance.

The process for translating the scope of work into a finalized task order will also vary by organization. For DELIVER, the process includes using the complete scope of work to draft the request for task order proposal (RFTOP), which is sent to the procurement agent for review and for submission of feedback and budget. Once the RFTOP is approved and agreement has been reached between the organization and the procurement agent, the organization issues a task order to the procurement agent.

STEP 5. CONFIRM APPROVAL STATUS FOR COMMODITIES.

Step 5 involves using information supplied by the procurement agent (as part of the task order deliverables) to determine the next steps related to obtaining approvals and waivers. For DELIVER, most of this information is contained in the commodity procurement information table. The most important information to be confirmed for each commodity includes the following:

- **The FDA (tentative) approval status.** If the product is not FDA approved or tentatively FDA approved, USG funds cannot be used to purchase it until FDA or tentative FDA approval has been obtained.
- **The registration status in the recipient country.** If the commodity is not registered in-country, the organization's country field office should highlight the issue to the MOH, USAID, or other in-country counterparts, so the registration process can be fast-tracked or a temporary government exemption for the product to be imported can be obtained.
- **Inclusion of the commodity on the blanket waiver (if relevant) or documentation of GMP certificates for the manufacturing site.** The result of whether or not a commodity is included on the blanket waiver will result in different next steps for the organization. For the most part, either a change in formulation, in strength, or in manufacturing site might cause the commodity to be excluded from the provisions of the blanket waiver, which would then require the organization to undertake a more complex process for obtaining approvals and waivers. Thus, the organization should make an effort to negotiate necessary changes that would bring the list into compliance with the blanket waiver, if feasible. Some changes (e.g., drug strength) might be program requirements and, therefore, nonnegotiable. However, sourcing the product from a manufacturing site covered by the blanket waiver might be a feasible alternative that should be explored to reduce unnecessary and complicated steps in the procurement process.

On the basis of the result from the task in the third bullet above, one of three options must be followed:

- If the commodity is on the blanket waiver, then step 6 is unnecessary and the tasks outlined in step 7 (obtain approvals from the OAA) should be followed.
- If, however, the commodity is not on a blanket waiver, but if the organization has a GMP certificate on file, then the tasks outlined in step 6 (prepare Source and Origin Waiver) need to be completed.
- If there is no GMP certificate on file for the commodity, then the organization must initiate the process of retrieving the GMPs either through the procurement agent, if one exists, or directly with the manufacturer. This process could take as long as two months. Once all relevant GMP certificates have been obtained, the organization should proceed to step 6.

REDUCING THE LEAD TIME FOR PROCUREMENT

The following four steps, steps 6–9, should all be undertaken simultaneously, to reduce the lead time for procurement.

Applying for all approvals at the same time will also streamline the process. Thus, the Source and Origin Waiver request should be submitted at the same time as the Approval to Purchase Restricted Commodities request and the Approval to Purchase Commodities over US$100,000 request. As mentioned previously, if commodities are procured using a blanket waiver, then an Approval to Purchase Restricted Commodities request is not necessary. However, an Approval to Purchase Commodities over the US$100,000 request must still be obtained.

STEP 6. PREPARE SOURCE AND ORIGIN WAIVER (IF COMMODITIES ARE NOT ON BLANKET WAIVER).

For all commodities that are not on the blanket waiver, after a GMP certificate has been confirmed on file, a Source and Origin Waiver request must be submitted to USAID. The following documentation must be included in the blanket waiver request:

- copy of country's standard treatment guidelines
- proof of FDA approval of drugs (FDA Electronic Orange Book)
- proof of GMP certification for each manufacturing site for each drug
- official letter from recipient country's National Drug Regulatory Authority certifying the registration status of drugs
- a document permitting importation of nonregistered drugs.

Most organizations will use the preceding information to draft the action memorandum for the Source and Origin Waiver and the letter for submission to OAA. However, in the case of DELIVER, the draft action memorandum and the letter are prepared by the project to the contracting officer on behalf of the cognizant technical officer (CTO), who concurs with the request and then submits it to OAA for approval.

The submission and approval process takes between one and two months because of OAA's schedule and time-frame for processing the request and for sending back the Source and Origin Waiver.

STEP 7. OBTAIN APPROVALS FROM THE OFFICE OF ACQUISITION AND ASSISTANCE.

There are two types of approval that organizations may have to obtain from OAA as part of contractual requirements, in addition to the Source and Origin Waiver. Those approvals may not be necessary for other organizations. The process for obtaining the approvals consists of submitting a formal letter requesting the approvals from OAA, with relevant attachments, as described below. It is important to keep in mind that the approval to purchase commodities over US$100,000 can be combined with the restricted commodities approval, if both approvals are required. Receiving approval from OAA may take between one to two months.

- Approval to Purchase Restricted Commodities. The approval to purchase restricted commodities is never required if the commodity is on the blanket waiver, but the approval may or may not be required if a source and origin waiver is required. Determining the need for the approval to purchase restricted commodities depends

on the categorization of the commodity. Pharmaceutical products are restricted commodities and require this approval.

- Approval to Purchase Commodities over US$100,000. According to the terms of the DELIVER contract, if purchasing commodities for a value greater than US$100,000, USAID regulations require that the project first obtain approval from the OAA office before procuring any commodity or commodities totaling over US$100,000. The amount and approval process may differ among agencies, depending on their contractual obligations.

The package that is sent to OAA requesting those approvals should include the following information:

- the Commodity Procurement Information table, which lists the full name, exact strength, dosage form, manufacturing site, and country of manufacturer for each commodity
- an explanation, a justification, or both of why the commodity is required
- written Mission approval
- the individual and total prices of commodities being procured
- a copy of a blanket waiver, a copy of the Source and Origin Waiver, or both.

The formal request for the approvals consists of a cover letter and attachments for either approval or both. As is the case with the submission of the Source and Origin Waiver, the formal request letter is prepared by the project on behalf of the CTO, who is responsible for submitting the letter to OAA for ultimate approval.

It is important to note that, without a signed waiver and approvals, you cannot legally enter any procurement contracts with manufacturers

STEP 8. CONFIRM IN-COUNTRY DELIVERY PROCESS.

Before the organization or procurement agent places commodity orders—and if the procurement agent does not provide clearing and forwarding services—the organization or procurement agent should identify and contract with a clearinghouse or a clearing agent in-country and should discuss the logistics of the delivery process. All parties, including the organization, the procurement agent, the manufacturer, the in-country clearing agent, the country recipient organization, and USAID should participate and agree on the steps and requirements in the delivery process. Refining the steps, responsibilities, and requirements can take as long as two months.

Important issues to resolve and to discuss during this step include the following:

- verification of the consignee contact information, titleholder, and marking requirements (obtained as part of step 3) with the procurement agent or clearing agent, as appropriate
- development of a scope of work for the clearing agent on the basis of the list of requirements, including monitoring shipment progress, obtaining value added tax waivers or exemptions, ensuring cold chain storage (if necessary), and arranging for clearance and delivery of the goods
- identification of in-country companies to clear customs and to transfer commodities to the warehouse (the process for selecting clearing agents should follow contractual requirements, if necessary [e.g., DELIVER's contract requires a minimum of three quotations] and should include visits and inspections to potential contractors and agents, if possible)
- finalization and issuance of the contract with the clearing company.

STEP 9. NEGOTIATE AND ISSUE CONTRACT TO MANUFACTURERS.

When selected procurement tasks have been outsourced by the organization to a procurement agent, a particularly important communication link exists between the organization, the procurement agent, and the manufacturer. It is extremely important that roles and responsibilities are clear and that communication is well defined. This clarity of roles and responsibilities is usually undertaken through manufacturer contracts. DELIVER's experience has shown that the entire contract negotiation process can take between one and two months.

Given the specialized expertise and the attention to detail that are required in this step, DELIVER typically assigns responsibility to a single person for reviewing and issuing the manufacturers' contracts. Important elements to pay attention to when reviewing the contract include payment and indemnity clauses, plus any in-country delivery and clearance issues. Once agreement has been reached, the procurement agent issues the contract to the manufacturer. It is important to note that the contract can be issued only after approvals are received from OAA.

Both before and after issuance of the contract, constant communication is a key element to ensuring timely procurement. Items that should be discussed or reviewed regularly include potential changes in commercial item contracts and in final shipment schedules, which are compared to the original manufacturer contracts.

STEP 10. PLACE COMMODITY ORDERS.

Commodity orders can be placed with manufacturers after all approvals have been received from OAA, after the money is received from USAID, and after the contracts are issued to the manufacturers.

Any advance partial payments that were negotiated in the contract should be followed up and, if necessary, shipment schedules should be updated to avoid delays. If updates and changes in delivery quantities or dates occur, those changes should be shared with recipient country partners as soon as possible.

STEP 11. MONITOR SHIPMENTS AND DELIVERY PROCESS.

Monitoring progress of the procurement process is an important element in minimizing delays and bottlenecks. The commercial items contract and routine reports from the procurement agent can be useful tools to monitor the procurement and to enable coordination between the key partners. A minimum of a three-month lead time should be factored in from the time the order is placed until the arrival of the commodities in-country.

STEP 12. RECEIVE COMMODITIES AND PAY MANUFACTURER.

The receipt of goods in-country is often accompanied by documents that are required for final payment to the manufacturer. Once goods have been delivered, as per the contracts and agreements, the DD 250 receiving form should be completed and returned to the project as rapidly as possible. The documents serve as confirmation and as verification of delivery. Once delivery is confirmed, payment to the manufacturer can be made on the basis of the terms of the contract.

CONCLUSION

The increased availability of USG funds for expansion of HIV/AIDS programs and services through the PEPFAR program has resulted in an increased demand for HIV/AIDS commodities, including ARV drugs, HIV test kits, and laboratory supplies. At the same time, given the pressures countries and programs are facing to scale up services and the complexity associated with using USG funds for procurement, Ministries of Health and other programs that receive USG funds for commodity procurement requested existing supply chain partners, such as the DELIVER project, to assist with procuring HIV/AIDS commodities. Although not originally tasked with a mandate for commodity procurement, USAID Missions requested that DELIVER assume this role in the short term to enable programs to meet treatment goals.

This guide outlines the lessons and processes learned over the course of DELIVER's experience in procuring HIV/AIDS commodities. It speaks to the complexity of the process, which involves various waivers, approvals, and steps required for successful and timely procurement. The guide also highlights the increasing number of actors involved in procuring HIV/AIDS commodities including nongovernmental organizations, programs, host governments, multiple donors (at the Mission and headquarters levels), procurement agents, clearing and forwarding contractors, and many others, as well as the environment in which they operate. Most important, however, this guide highlights the importance of developing a clear and transparent procurement process for ensuring that continuous supplies of quality HIV/AIDS products reach customers.

APPENDIX I

TIMELINE FOR 12-STEP PROCESS

Many of these steps occur simultaneously. This table is a general framework for when steps should occur and how they might overlap.

Step	Timeline							
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8
1	Obtain Mission approval.							
2	Validate quantities to procure and develop a procurement plan and shipment schedule.							
3		Gather relevant information and compile documentation.						
4		Prepare and issue task order.						
5		Evaluate information in commodity procurement information table.						
6				Prepare Source and Origin Waiver.				
7					Submit and receive OAA approval.			
8					Confirm in-country delivery process.			
9					Negotiate and issue contract to manufacturer.			
10							Place order.	
11								Monitor shipments and delivery.
12								Pay manufacturers.

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GLOSSARY OF TERMS

action memorandum. This formal title is given to the blanket waiver.

AIDAR. According to USAID, "the AIDAR is USAID's Acquisition Regulation supplementing the FAR (48 CFR Chapter 1) and is published as Chapter 7 of Title 48, Code of Federal Regulations."

Automated Directives System (ADS). This USAID reference sets out policies and procedures for procurement. Specifically, "ADS 312: Eligibility of Commodities" is relevant to the procurement of pharmaceuticals as "restricted commodities."

blanket waiver. This USAID/OAA document contains a list of products that are pre-approved for procurement by USAID. A blanket waiver also provides approval for restricted commodities. If products are included on the blanket waiver, then there is no need for a separate Source and Origin Waiver.

GMP Certificate. The Certificate of Good Manufacturing Practice (GMP) issued by a regulatory agency, for example the FDA, certifies that a quality approach to manufacturing has been taken in order to ensure that products are safe, pure, and effective. The GMP Certificate is issued by the regulatory authority in a particular country or regional body that oversees manufacturing of certain products.

Code of Federal Regulations (CFR). Published in the *Federal Register*, these rules are set by the executive departments and agencies of the federal government. Specifically, 22 CFR, Part 228, Rules on Source and Origin and Nationality for Commodities and Services, is relevant here. The rules are financed by USAID and are relevant for HIV/AIDS commodity procurement.

cognizant technical officer (CTO). According to USAID, "the CTO is the individual who performs functions that are designated by the contracting or agreement officer, or is specifically designated by policy or regulation as part of contract or assistance administration."

commodity procurement table (CPT). This procurement plan is specific to each country, with proposed shipment tables. This table is sent to the procurement agent with the final task order.

commodity procurement information table (CPIT). This table contains all information required for the procurement process, including product specifications, manufacturing sites, source and origin of products**,** price per unit, and expected in-country arrival dates. It is attached to the waiver application for OAA.

contract with manufacturers. This item has two key components:

Commercial Items Contract (CIC). A CIC provides key details of each commodity as contained in the CPIT, as well as delivery dates for each item negotiated and agreed to with the manufacturers. The CIC portion of the contract can be amended.

Standard Terms and Conditions. This component is negotiated before signing the contract and includes information such as payment methods, marking requirements, quality assurance requirements, etc.

DD 250 Form. This form is issued by the procurement agent to a consignee in a country receiving goods. It details the shipment particulars and, after it is signed, provides proof of acceptance.

Incoterms (International Commercial Terms). These standard trade definitions are most commonly used in

international sales contracts. The objective of the Incoterms is to reduce confusion over interpretations of shipping terms, by outlining exactly who is obligated to take control of—and insure or not insure—goods at a particular point in the shipping process.

manufacturing site. This is the place where the products are manufactured (origin).

marking. These **l**abeling specifications are for all products procured using USG funds.

procurement agent. The agent with whom DELIVER contracts to assist in the procurement of all related commodities.

procurement agent weekly reports. The procurement agent provides a weekly report to DELIVER about the status of the ongoing procurement process in all of the countries.

restricted commodities approval. This approval is from OAA to procure pharmaceuticals that are classified by the USG as "restricted commodities."

request for task order proposal (RFTOP). This request is a process whereby the scope of work for a specific procurement is defined in order for an outsourcing purchasing agent or agency to be able to provide the level of effort and cost for the procurement before issuing a task order.

source and origin:

source. This term refers to the country from which a commodity is shipped to the cooperating country, or it refers to the cooperating country if the commodity is located there at the time of the purchase. However, if a commodity is shipped from a free port or a bonded warehouse in the form in which it is received, *source* then means the country from which a commodity was shipped to the free port or to the bonded warehouse.

USAID considers a *bonded warehouse* to mean any duty-free area (e.g., export processing zone or an entire country if the country imposes no duties or taxes on drugs).

origin. This term is the country where a commodity is mined, grown, or produced. A commodity is produced when—through manufacturing, processing, or substantial and major assembling of components—a commercially recognized new commodity results that is significantly different in basic characteristics or in purpose of utility from its components. For our purposes, the site where the drug, HIV test kit, or reagent is manufactured is the country of origin.

Source and Origin Waiver. This document is an approval from OAA to procure commodities from sources and origins not included in the blanket waiver**.**

unit size. This term is the basic unit of the product (e.g., tablet, capsule, test, etc.).

For more information, please visit http://www.deliver.jsi.com.

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