

OFFICE OF INSPECTOR GENERAL

AUDIT OF USAID/HAITI'S PROCUREMENT AND DISTRIBUTION OF COMMODITIES FOR THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

AUDIT REPORT NO. 1-521-09-001-P OCTOBER 16, 2008

SAN SALVADOR, EL SALVADOR



October 16, 2008

MEMORANDUM

TO: USAID/Haiti Director, Beth Cypser

FROM: RIG/San Salvador, Timothy E. Cox /s/

SUBJECT: Audit of USAID/Haiti's Procurement and Distribution of Commodities for

the President's Emergency Plan for AIDS Relief (Report No. 1-521-09-

001-P)

This memorandum transmits our final report on the subject audit. We have carefully considered your comments on the draft report in finalizing the audit report and have included your response in appendix II of the report.

The report contains eight recommendations intended to improve accountability and implementation of the President's Emergency Plan for AIDS Relief activities. Management decisions have been reached for Recommendation Nos. 1, 2, 3, 4, 5, 6, and 7, and final action has been taken on Recommendation Nos. 1, 3, and 6. M/CFO/APC will record final action on the other recommendations when planned actions have been completed.

A management decision on Recommendation No. 8 can be reached once USAID/Haiti establishes an internal policy requiring estimates for loans of PEPFAR commodities be reported in the budgets as well as actual loans and repayments to stakeholders in Washington. Please advise my office within 30 days of any further actions planned or taken to reach management decision on this recommendation.

I want to express my appreciation for the cooperation and courtesy extended to my staff during the audit.

CONTENTS

| Summary of Results | 1 |
|---|----|
| Background | 3 |
| Audit Objective | 3 |
| Audit Findings | 5 |
| Has USAID/Haiti procured, deployed, and warehoused its PEPFAR commodities to help ensure that intended results were achieved, and what has been the impact? | 5 |
| Need Better Storage Facilities for Commodities Requiring Cold Storage | 7 |
| Smoke Detectors Needed in the Central Warehouse of the Partnership | 9 |
| Need to Reduce Amount of Expired Commodities | 9 |
| The Lack of Consistent and Dependable Power Supplies in Haiti Is a Major Concern | 11 |
| Oraquick Test Kits Need to Be Procured and Deployed More Efficiently | 12 |
| The Program Needs a Performance Monitoring Plan | 13 |
| PEPFAR Should Formalize Its System for Loaning and/or Donating Commodities to the Global Fund | 14 |
| Evaluation of Management Comments | 16 |
| Appendix I – Scope and Methodology | 17 |
| Appendix II – Management Comments | 19 |
| Appendix III – Storage Conditions Tested | 26 |

SUMMARY OF RESULTS

President Bush made a five-year, \$15 billion commitment in the fight against HIV/AIDS in his 2003 State of the Union address. The President's Emergency Plan for AIDS Relief (PEPFAR) focuses \$10 billion on 15 countries, including Haiti, for treatment, prevention, and care. A request to reauthorize PEPFAR for another five-years is being considered in Congress. Haiti is the most affected nation in the Caribbean, with 3.8 percent of adults living with HIV. Haiti received over \$28 million in PEPFAR funds in fiscal year 2004. Funding for the fight against HIV/AIDS has progressively increased with \$78.3 million of funding in FY 2007 and an allocation of \$90.6 million for FY 2008 (page 3).

The Regional Inspector General/San Salvador performed this audit to determine whether USAID/Haiti procured, deployed, and warehoused its PEPFAR commodities to help ensure that intended results were achieved, and to determine the impact of these efforts (page 3).¹

On the whole, USAID/Haiti procured, deployed, and warehoused its PEPFAR commodities to help ensure intended results were achieved. USAID efforts had a substantial impact by testing 310,900 individuals for HIV, exceeding the target for FY 2007, and by contributing to 12,900 individuals receiving antiretroviral therapy. Antiretroviral therapy allows those living with HIV/AIDS to live longer, healthier lives (page 5).

However, USAID/Haiti needs to strengthen the program by (1) moving commodities requiring cold storage to a new warehouse (page 7), (2) ensuring the new warehouse has all the proper fire safety items (page 9), (3) reducing the amount of expired commodities (page 9), (4) working to mitigate the effect of irregular electricity supply (page 11), (5) improving the procurement of Oraquick test kits (page 12), (6) finalizing and implementing a performance monitoring plan for the Partnership for Supply Chain Management (page 13), and (7) formalizing arrangements for loaning and donating commodities to the Global Fund (page 14).

This report recommends that USAID/Haiti:

- In coordination with the Partnership for Supply Chain Management, develop an action plan listing specific tasks and timeframes, to move the commodities to the new central warehouse (page 9).
- In coordination with the Partnership for Supply Chain Management, install the necessary fire safety items at the central warehouse (page 9).
- Develop an action plan, in coordination with its partners, to improve the forecasting method in order to lessen the amount of expired commodities (page 11).

¹ For purposes of this audit, PEPFAR commodities are defined as products purchased with PEPFAR funding for the detection and treatment of HIV/AIDS, including antiretroviral drugs, test kits, lab equipment, lab supplies, and other essential drugs and medicines used to prevent and treat HIV/AIDS-related opportunistic infections.

- Destroy expired products in a timely manner (page 11).
- In coordination with its partners, develop an action plan to improve the supply pipeline specifically with regard to Oraquick, or another confirmatory test not requiring cold storage, in order to lessen the amount of stock outs for this product (page 13).
- In coordination with the Partnership, develop an action plan listing specific tasks and timeframes, to finalize and implement a performance monitoring plan for the PEPFAR program in Haiti (page 14).
- Revise its memorandum of understanding with the Global Fund to spell out the conditions and responsibility of each party for loans and donations of commodities (page 15).
- Establish an internal policy that requires estimates for loans of PEPFAR program commodities be reported in the budgets and the actual loans and repayments to stakeholders in Washington (page 15).

USAID/Haiti agreed to implement the recommendations and has developed specific plans to address seven of the eight recommendations. Management decisions have been reached on seven recommendations and a management decision can be reached on the other one when an internal policy is established on how to inform stakeholders in Washington about loans of PEPFAR commodities. Our evaluation of management comments is provided in the Evaluation of Management Comments section of this report (page 16), and USAID/Haiti's comments in their entirety are included in Appendix II.

BACKGROUND

During his State of the Union address in January 2003, President Bush announced the President's Emergency Plan for AIDS Relief (PEPFAR). A five-year, \$15 billion commitment was made for the fight against HIV/AIDS. Of this amount, \$10 billion is destined for 15 focus countries, including Haiti. The money supports 1) treatment for HIV-infected people, 2) prevention of new HIV infections, and 3) care for people infected and affected by HIV/AIDS. In addition, the U.S. Congress is deliberating on reauthorizing PEPFAR by as much as \$41 billion over five more years.

Haiti received more than \$28 million in PEPFAR funding in fiscal year 2004, nearly \$51.8 million in FY 2005, approximately \$55.6 million in FY 2006, \$84.7 million in FY 2007, and \$100 million was planned for FY 2008. Haiti is the most affected nation in the Caribbean when it comes to HIV/AIDS, with 3.8 percent of the 15 to 49 year olds living with HIV by the end of 2005. In 2006, the United Nations estimated that approximately 180,000 Haitian adults aged 15 and older and 10,000 children were living with HIV/AIDS. The Government of Haiti estimated 26,776 individuals needing antiretroviral (ARV) therapy during 2008.

The U.S. Government PEPFAR team² in Haiti works with more than 10 partners to support the national HIV/AIDS care and treatment program. The PEPFAR team works with a network of public, private, and faith-based health facilities to provide free ARV therapy services for all Haitians. In September 2005, the Partnership for Supply Chain Management (the Partnership) signed a task order for \$18 million with the Management Sciences for Health (MSH), and has progressively taken over the procurement of commodities for the care and treatment of HIV/AIDS and related infections. The Partnership signed a second task order in April 2007 for an additional \$5 million. The Partnership provides ARV drugs to 5 sites, opportunistic infections (OI)³ drugs to 10 sites, and test kits to 27 sites in Haiti. Moreover, MSH provides comprehensive technical assistance to health facilities through a separate three-year, \$42.5 million contract, of which \$10 million is meant for HIV-related activities.

In addition, the Global Fund⁴ provides HIV/AIDS commodities, including ARV drugs, to health facilities through the local Fondation Sogebank.

AUDIT OBJECTIVE

As part of a worldwide audit directed by the Office of Inspector General's Performance Audits Division, the Regional Inspector General/San Salvador audited USAID/Haiti's

The team includes USAID, the Center for Disease Control (CDC), and the Department of State.
 Opportunistic infections are illnesses caused by various organisms, some of which usually do not cause disease in persons with normal immune systems. Persons living with advanced HIV infection suffer opportunistic infections of the lungs, brain, eyes, and other organs.

⁴ The Global Fund to Fight Aids, Tuberculosis, and Malaria was created in 2002 after a commitment by the United Nations to create such a fund was endorsed by the Group of Eight (G8) countries in Genoa a year earlier. The G8 then helped finance the Global Fund and as of May 2007 \$7.6 billion had been committed by 136 countries. The Global Fund does not implement programs directly, but rather relies on local expertise.

PEPFAR activities related to commodities to answer the following question:

• Has USAID/Haiti procured, deployed, and warehoused its PEPFAR commodities to help ensure that intended results were achieved, and what has been the impact?

The audit scope and methodology are described in Appendix I.

AUDIT FINDINGS

In general, USAID/Haiti, through the Partnership for Supply Chain Management (Partnership), procured, deployed, and warehoused its President's Emergency Plan for AIDS Relief (PEPFAR) commodities to help ensure that intended results were achieved. In addition, the PEPFAR program in Haiti has had a substantial impact on the number of individuals tested for HIV/AIDS and the number of individuals on antiretroviral (ARV) therapy. The paragraphs below answer the audit objective more fully and describe the impact of the program's efforts. They are followed by findings describing opportunities to strengthen the program.

Procurement – USAID/Haiti, through the Partnership, generally procured commodities as planned to ensure that commodities were available when needed in the country. With the exception of a few limited cases, the Partnership reported no stock outs of ARV drugs in FY 2007. This information was confirmed through visits and interviews at four sites that receive ARVs from the Partnership. Although certain HIV test kits were procured as needed, stock outs of the Oraquick test kits occurred at two sites and officials at three others said that more Oraquick would help them to provide more testing



Photograph of CD4 equipment donated by PEPFAR at the Grace Children Hospital, Portau-Prince, Haiti, taken by an OIG auditor on May 29, 2008.



Photo taken by an OIG auditor on June 2, 2008 at Fort Liberté Hospital's pharmacy with PEPFAR commodities, in Cap-Haitien, Haiti.

services in remote areas. See the related finding below. Stock outs of CD4 reagents⁵ have also been experienced by two sites.

Deployment – Commodities were deployed first to central warehouses in Port-au-Prince, Haiti and then were delivered to hospitals or other health facilities. The clinics and hospitals we visited used ARV drugs and HIV test kits commodities for HIV/AIDS patient care.

As stated above, ARV drugs were almost always available and at least one of the HIV test kit types were also usually available (as noted above, the Oraquick test kit was not always available or was sometimes received with under two months of shelf life remaining). At the health facilities visited, laboratory equipment provided by the PEPFAR program was in place and was generally operating as intended, making HIV testing more readily available.

Warehousing – Most commodities were transferred to the new Partnership central warehouse in Port-au-Prince in May 2008. In visiting the new central warehouse and nine storage sites at the nine health facilities visited, storage conditions generally met the standards set by Haiti's Ministry of Health and by the World Health Organization. See appendix III for the storage conditions tested.



Photo of the Partnership's new central warehouse taken by an OIG auditor in Port-au-Prince, on May 29, 2008.



The new Partnership central warehouse is being used to promote the efficient and secure storage of PEPFAR commodities. Photo taken by an OIG auditor on May 29, 2008.

In testing the inventory records at these same sites, very few discrepancies were noted. However, storage conditions for commodities (certain ARV drugs, HIV test kits, reagents) needing refrigeration were not always adequate and power was not available 24 hours a day at four sites visited. See related findings below.

Impact – The PEPFAR program's efforts in procuring, deploying, and warehousing its commodities have had a positive impact in Haiti. Although the Office of the Global AIDS Coordinator has not established any required indicators related to the procurement, deployment, or warehousing of commodities, two related indicators are the number of

6

⁵ Also known as T4 cell, CD4s are one of several types of T-cells important to the immune response. They protect against viral, fungal, and protozoal infections and are the cells that are most susceptible to HIV. They serve as the indicator for patients developing opportunistic infections and are used to judge when antiretroviral therapy should begin. Reagents are used in the testing to determine CD4 counts.

individuals tested for HIV and the number of individuals on ARV therapy. The program was able to exceed the FY 2007 target of 300,000 for number of people tested for HIV/AIDS, an important achievement in a country where a stigma with regard to HIV/AIDS remains strong. The 310,900 tested in FY 2007 was followed by a strong showing thus far in 2008. PEPFAR has already tested 238,874 individuals as of March 2008 and expects to surpass the 330,000 target.

The PEPFAR program has also substantially increased the number of individuals on ARV therapy—an important indicator because ARV therapy allows those living with HIV/AIDS to live longer and healthier lives. It should be noted that the PEPFAR targets and results for this indicator include the results for both the PEPFAR program and the Global Fund program as both provide ARV therapy (commodities and/or technical assistance) for the country as a whole. For example, the number of individuals on ARV therapy increased from 2,829 in 2004 to 12,900 by September 30, 2007 and to 14,918 individuals as of March 31, 2008. The 12,900 was short of the 15,000 target by the end of FY 2007. According to mission officials, the target was provided by the Office of the U.S. Global AIDS Coordinator (OGAC)⁶ and was based on the estimated HIV prevalence rate in the country of 3.8 percent by the United Nations in 2006. Other data suggests that the actual prevalence rate may be more in the range of 2.2 percent. Mission officials explained that the program has less control over this indicator as it does not precisely know how many individuals need to be tested to obtain a certain number of individuals infected with HIV. Mission officials also believe that it is unlikely that the FY 2008 target of 20,000 people on ARV therapy will be achieved.

Another important aspect of the program is the ability to provide services in remote regions as well as in large cities. This was made clear by an audit site visit to Pignon. It takes three hours to get to Pignon by car from the Northwest coastal city of Cap-Haitien. The road is a very rough dirt road and two rivers needed to be crossed by car. Clearly, providing testing and then ARV and Opportunistic Infections (OI) drugs to this remote area is something to be commended.

Despite the progress and achievements made by the program thus far, several issues need management attention as discussed below.

Need Better Storage Facilities for Commodities Requiring Cold Storage

Summary: The World Health Organization's storage protocols specify that commodities are to be stored in an area secured by lock and key. The area should also be restricted to authorized personnel only. Although most of the commodities are now stored in a new warehouse, those requiring cold storage are kept in different parts of the Partnership's office such as the kitchen. These areas do not constitute proper storage areas as they are not secured by lock and key in store rooms with restricted access and may not have the electrical capacity to handle the ten refrigerators in use. These commodities have not been moved to the warehouse because a condenser needed for cold storage did not arrive as

_

The Office of the U.S. Global AIDS Coordinator's mission is to lead implementation of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The Coordinator leads the U.S. Government's (USG) international HIV/AIDS efforts and ensures coordination among the relevant USG agencies.

ordered. Until these commodities are moved to a proper storage facility, the potential for loss or theft exists. In fact, an electrical fire at the Partnership's offices in March 2008 caused \$10,000 worth of damage to commodities.

According to the storage protocols from the World Health Organization, commodities should be stored properly in a clean and secured area including a lock and key. Access to the area should be restricted to authorized personnel and have adequate air conditioning.

While a central warehouse was opened up in May 2008 and contains most of the commodities being procured by the Partnership, commodities requiring cold storage are being kept in the Partnership's offices in Petion-Ville. The commodities (certain ARV drugs, HIV test kits, etc.) are in freezers at the proper temperature; however, the offices are not a proper storage facility as some are in the kitchen and at various other locations within the offices. The commodities are not secured in locked storage rooms or in areas restricted to only authorized storage handlers. Furthermore, the office's wiring has not been checked to determine if it is adequate to handle the electricity demands of the ten refrigerators in place. The commodities that have been moved to the central warehouse are tracked by a sophisticated inventory computer system, while the inventory records for items kept in the offices in the Partnership are rudimentary. As of May 2008, commodities costing \$367,355 were stored at the offices. These commodities are stored at the offices until they are distributed as necessary to the various health facilities throughout Haiti.





Two photographs of OIG auditors conducting a review of PEPFAR commodities stored at the office of one of the main partners in Port-au-Prince. Photographs taken by an OIG auditor on May 28, 2008.

The Partnership planned to move commodities to the new central warehouse that has been configured to adequately store commodities needing cold storage. However, when the cold storage container arrived, the condensing unit needed for cold storage was not included. After both the shipper and receiver claimed they were not at fault, the Partnership ordered another condensing unit in April and is still awaiting delivery.

Under the current storage conditions, the commodities are susceptible to loss and theft. In fact, due to the weak electrical system in the Partnership offices, a fire broke out in March 2008. As a result, some commodities including laboratory test kits and OI drugs totaling about \$10,000 were damaged. Unfortunately, the risk of this is still present and will continue to be so until the condenser arrives and these items are moved to the central warehouse.

Recommendation No. 1: We recommend that USAID/Haiti, in coordination with the Partnership for Supply Chain Management, develop an action plan, listing specific tasks and timeframes, to move the commodities to the new central warehouse.

Smoke Detectors Needed in the Central Warehouse of the Partnership

Summary: The World Health Organization's storage protocols include the need for fire security. Fire safety equipment is to be available and staff at storage facilities should know what to do in case of fire. The new central warehouse used by the Partnership is lacking smoke detectors and posters indicating what should be done in the event of a fire. The warehouse has just become operational and staff stated that smoke detectors and posters ordered have yet to arrive. Until these are installed there is a risk that a fire may not be immediately detected and properly contained. Therefore, the commodities currently in the warehouse are at risk.

According to storage protocols by the World Health Organization, fire security is an important part of any warehouse. Warehouse staff should be aware of what is to be done in case of a fire and fire safety equipment should be available.

While the warehouse that the Partnership has recently inaugurated is impressive, with high ceilings, security, proper temperature, and sufficient size, two other important items are needed with regards to fire security. Smoke detectors were not present and no posters describing how to react in case of a fire were present. Commodities stored include ARV drugs, HIV test kits, OI drugs, and other commodities total \$3,759,166.

The warehouse has just recently been opened and staff stated that smoke detectors and posters that have been ordered but have yet to arrive.

The potential effect of not having smoke detectors or posters indicating what should be done in the event of a fire is that a fire would not be properly or quickly contained leading to damage of the warehouse as well as the commodities inside. This is made all the more clear as a fire has already occurred in the Partnership's offices that did indeed cause some damage, although the presence of mind of the guard on duty minimized the degree of damage. However, smoke detectors and guidance on what should be done is imperative.

Recommendation No. 2: We recommend that USAID/Haiti, in coordination with the Partnership for Supply Chain Management, install the necessary fire safety items at the central warehouse.

Need to Reduce Amount of Expired Commodities

Summary: The Partnership's guidelines recommend a monthly order cycle for short shelf-life commodities and a mechanism allowing health facilities to quickly return products to the central warehouse for redistribution prior to expiry. Expired products should also be destroyed in a timely manner. The central warehouse currently has a large amount of

expired commodities with a total cost of \$313,443. Most of these have been stored for over two years and take up a good part of the warehouse. Commodities also expired at four of the nine sites visited. Most of the expired commodities at the central warehouse were inherited by the Partnership. In addition, the program needs an improved forecasting system for supplying sites that would allow for minimal expiration of products. The expired product has not been destroyed timely due to the limited availabity of an incinerator. Expired products represent a loss of resources that otherwise would have been used to achieve program objectives. The expired product is also taking up valuable storage space and there is a risk that the product could be inadvertently given to patients.

The program should minimize the amount of expired product. Also, expired product should be destroyed in a timely fashion. John Snow, Inc., a principal partner of the Partnership, prepared a document called Guidelines For Managing The HIV/AIDS Supply Chain. The guidelines state that due to the short-shelf life of ARV drugs and HIV test kits (from 6 to 24 months), the high prices involved, and the requirement of multiple products from multiple sources, the supply chain will differ from that of other commodities. Specifically, a monthly order cycle is recommended so that a smaller buffer zone will lead to less expired product but also allow for less stock outs. Another recommendation is to develop a mechanism for returning products to the central warehouse for rapid redistribution before expiry. In general, the quantification or forecasting system in place should be specifically tailored to PEPFAR commodities.

The program currently has a lot of expired product at the central warehouse. The expired product include various ARV drugs, HIV test kits, OI drugs, and other commodities with a total cost of about \$313,443. Much of the expired product has been stored for quite some time and a good portion of the central warehouse is taken up by this expired product. In addition, four of the nine sites visited said that expiration of products took place. Three dealt with ARV drugs while the other was involving the Oraquick test kit. The Partnership currently supplies the sites on a quarterly basis. However, as they get monthly reports on usage and the number of patients at each facility, they have also begun to send some supplies monthly when needed.

When the Partnership took over from the previous contractor in the Spring of 2006, they found a large supply of commodities that exceeded demand. According to the Partnership, the expired product is left over from the previous implementing partner's procurement. This is part of the reason so many expired commodities are in the main warehouse. However, the underlying reason is weak forecasting of demand. The Partnership acknowledged that the quantification system (the system used for forecasting commodity demand) is being reviewed in order to improve the supply chain, including moving from a "push" system to a "pull" system. With a push system, those issuing the supplies decide what to send and how much. On the other hand, a pull system allows for those receiving the supplies to decide when to request supplies. However, a pull system requires well-trained staff at lower levels as well as the availability of appropriate technology. Currently, the Partnership uses the reports on drug usage and the number of HIV/AIDS patients to determine how much to supply a site.

In addition to not being a high priority, expired product was not destroyed timely because the Ministry of Health does not have an adequate incinerator for such a large quantity. Recenty, the Partnership has ordered an incinerator which would speed up the destruction.





Photographs taken by an OIG auditor on May 29, 2008 showing lots of expired products at the new Partnership central warehouse, Port-au-Prince, Haiti.

Consequently, expired commodities represent a \$313,443 loss of resources that could have been used to advance program objectives. In addition, these commodities require further cash outlay in order to be properly destroyed. In the meantime, the expired product is taking up valuable storage space in the central warehouse and there is a risk that the product could be inadvertently given to patients.

Recommendation No. 3: We recommend that USAID/Haiti develop an action plan, in coordination with its partners, to improve the forecasting method in order to lessen the amount of expired commodities.

Recommendation No. 4: We recommend that USAID/Haiti destroy expired products in a timely manner.

The Lack of Consistent and Dependable Power Supplies in Haiti is a Major Concern

Summary: Most HIV/AIDS commodities are to be stored at a temperature of no more than 27 degrees Celsius or 80 degrees Fahrenheit and some require refrigeration not to exceed 8 degrees Celsius or 46 degrees Fahrenheit. At the nine storage facilities visited, four sites were found to not have a consistent power supply 24 hours a day, with two stating that power is shut off during the evening. A recent assessment found that the availability of power at health facilities in Haiti is a weakness. The poor power grid in Haiti and the rising cost of energy are the main reasons that power is not available 24 hours a day at health facilities. HIV/AIDS commodities not stored at the proper temperature could lessen the effectiveness of the drugs and the accuracy of the tests.

According to manufacturer requirements, ARVs, OI drugs, and test kits all have to be stored at a temperature not to exceed 27 degrees Celsius or 80 degrees Fahrenheit. The test kits Capillus, certain reagents, and ARVs like Ritonavir require cold storage and temperatures no more than 8 degrees Celsius, or 46 degrees Fahrenheit.

While temperatures at the nine storage facilities visited during normal working hours were within acceptable limits, staff at four sites said that power was not often available at night. For example, staff at two sites stated that the generator and other backups are

turned off in the evening, staff at one site said that power is not available 24 hours a day, and staff at another said that power is not available for about 9 hours a day. A previous assessment concluded that power is a weakness at health facilities in Haiti. Also, the assessment found that some backup batteries were not properly installed. Other tests by CDC showed temperatures 40 degrees Celcius, or 104 degrees Farehneit at times in the labs.

This occurred due to the poor power grid in Haiti that makes power outages a daily occurrence. In extreme cases, some sites do not even have access to electricity at all and rely solely on generators, propane gas, and batteries. In addition, the rising cost of energy was another reason cited by staff at hospitals for the reason that electricity is not provided after working hours.

Without the needed energy to control the rise of temperature, the commodities may spoil, the HIV drugs may not be effective, and the test kits may not provide accurate readings.

The mission has begun to address this problem by providing energy assistance (batteries, refrigerators run both on electricity and propane gas, etc.) and entering into an agreement in FY 2008 that will focus on the energy needs. Planned funds total \$790,000 for this energy solutions activity. The funds will be used to address recommendations that came out of an assessment of the ARV sites that was carried out in November 2007. As the mission is taking action to address this important but difficult issue of continuous energy supply, we are not making any recommendations.

Oraquick Test Kits Need to Be Procured and Deployed More Efficiently

Summary: The Partnership's guidelines state that due to the short shelf-life of ARV drugs and test kits (including Oraquick), the supply chain for these products needs to be more efficient. However, stock outs of Oraquick, a confirmatory test for HIV/AIDS, have taken place and at other times have arrived at sites with only a month and a half left before expiry. While the short shelf life is a cause for the stock outs, the fact that it is only manufactured in Thailand and is routed to Miami before going to Haiti are also important factors of the supply chain. The stock outs mean that Capillus test kits are used instead as they have a longer shelf life. However, Capillus requires refrigeration and lack of continuous power at some sites makes this less reliable. The refrigeration needed also makes mobile testing in remote areas more difficult.

The program should minimize the amount of stock outs and expired products. John Snow Inc. prepared a document called Guidelines For Managing The HIV/AIDS Supply Chain. The guidelines state that due to the short-shelf life of ARV drugs and HIV test kits (from 6 to 24 months) and the high prices involved, the supply chain will differ from that of other commodities. As Oraquick has the shortest shelf life of six months, the supply chain for this product needs to be more efficient relative to others.

_

See "Powering Health, Options for Improving Energy Services at Health Facilities in Haiti," issued on January 8, 2008 by the Office of Infrastructure and Engineering – Energy Team, USAID and the Institute of International Education.

Stock outs of Oraquick, a confirmatory test for HIV/AIDS, have taken place and at other times they have arrived to the sites with only a month and a half left before expiry. Two of nine sites visited said they have had stock outs of Oraquick while three other sites stated they wished to have more Oraquick delivered to provide more testing services in remote areas. Partnership officials have acknowledged that procuring Oraquick is problematic and that stock outs have occurred.

Stock outs of Oraquick occurred due to the short-shelf life of six months and the fact that the product is only manufactured in Thailand. Furthermore, the product arrives in Miami before it is shipped to Haiti.

These stock outs mean that sites have to rely on Capillus test kits more as they have a longer shelf life. However, Capillus requires cold storage and the lack of continuous energy at certain sites makes using Capillus less reliable. In addition, some sites wish to have Oraquick in order to perform tests when they go to the surrounding area for mobile testing.

Recommendation No. 5: We recommend that USAID/Haiti, in coordination with its partners, develop an action plan to improve the supply pipeline specifically with regard to Oraquick, or another confirmatory test not requiring cold storage, in order to lessen the amount of stock outs for this product.

The Program Needs a Performance Monitoring Plan

Summary: Operating units are responsible for setting up systems that measure progress achieved. The contract with the Partnership also states that a Performance Monitoring and Evaluation Plan (PMP) is to be prepared. A PMP is in draft form but has yet to be finalized two years after the task order was signed. The reason for the delay was the great need in spring 2006 to hit the ground running and provide the required commodities. Until a PMP is implemented, it is difficult to measure the Partnership's performance and identify aspects to be improved.

According to ADS 203.3.2, operating units are responsible for establishing systems to measure progress towards intended objectives. Also, the contract with the Partnership states the contractor shall provide a Performance Monitoring and Evaluation Plan (PMP) for the basic contract and each task order.

USAID/Haiti and the Partnership in Haiti have yet to finalize a PMP although the Partnership in Haiti started over two years ago. A person from the Partnership in Washington, D.C. visited Haiti in April 2008 and prepared a draft PMP. This draft PMP includes 15 indicators that would measure the effectiveness and efficiency of the procurement, storage, and delivery systems. For example, the draft PMP includes indicators for the amount of stock outs experienced and the total value of stock loss.

Partnership officials said that, while it would have been better to develop the PMP at the time they took over in the spring of 2006, the priority then was to simply get into the work of procuring, storing, and delivering the commodities. Partnership officials also stated that they do not have a monitoring and evaluation person in Haiti, but they are in the process of hiring one.

A PMP is needed to measure the effectiveness and efficiency of the program's procurement, storage, and delivery systems and to identify problems timely so that they can be corrected.

Recommendation No. 6: We recommend that USAID/Haiti, in coordination with the Partnership for Supply Chain Management, develop an action plan listing specific tasks and timeframes, to finalize and implement a performance monitoring plan for the PEPFAR program in Haiti.

PEPFAR Should Formalize Its System for Loaning and/or Donating Commodities to the Global Fund

Summary: A memorandum of understanding is needed for the mission to loan United States Government-financed commodities to other institutions to enumerate the rules under which such loans can occur. USAID loaned commodities in the amount of \$246,505 to the Global Fund, and donated \$18,116 of commodities as well. However, the current memorandum of understanding signed by USAID and the Global Fund does not explicitly allow for such loans or specify norms under which this would take place. Furthermore, these loans are not explained in the annual and semi annual reporting to the Office of the U.S. Global AIDS Coordinator (OGAC) or in the Country Operational Plans (COPs). These loans were made as the Global Fund was not always able to procure commodities on time and because the Partnership had an oversupply of commodities. Under the current circumstances, loans may not be settled in a timely manner and disagreements may occur. Also, PEPFAR has been budgeting for procurements not meant to meet PEPFAR demand in the amounts of approximately \$250,000 for both FY 2007 and FY 2008.

In order for the mission to loan commodities financed by the United States Government to other institutions, a memorandum of understanding should allow for this and describe the norms and rules under which such loans can take place. Reported budgeted, obligated, and expended amounts should reflect expected costs for future activities and actual costs of past activities.

The mission has loaned ARV drugs to the Global Fund in Haiti on nine occasions from June 2006 to October 2007, totaling \$246,505. The Global Fund also provides HIV/AIDS commodities in Haiti through the local Fondation Sogebank. The memorandum of understanding in place between Fondation SOGEBANK, Global Fund, PEPFAR, USAID, and CDC mentions the importance of coordination with regards to the procurement of commodities. However, it makes no allowance for loans. Between August 2006 and March 2007, USAID also donated PEPFAR commodities totaling \$18,116 on four separate occasions.

The mission does have a letter for each loan and donation signed by both the mission and the recipient of the loan, but it does not indicate when the loan is to be repaid. Instead, the letters state that this will be determined later. Although some commodities

14

⁸ Funding levels for focus countries are allocated on the basis of five-year strategic country plans, and funds are released upon approval of annual country operational plans by the U.S. Global AIDS Coordinator.

have been received to settle previous loans, ARV drug loans of 6,850 units have been outstanding for 8 months, 9,248 units loaned have been outstanding for over 1 year, and 610 units have been outstanding for 14 months. Furthermore, the letters do not include other responsibilities and terms of the loans such as required storage conditions for the commodities, which party will pay to transport the commodities, etc. The mission has also not accounted for these loans in its accounting records or in the semi annual or annual reporting of results, although it has been estimating a Global Fund shortfall in the planning stage and then increasing the estimated commodities to be purchased by this estimate. The COPs do not explicitly mention this increase either.

Commodities were loaned or donated when the Global Fund and its health facilities needed commodities. The PEPFAR program also loaned or donated commodities when it had excess commodities. The loans were done as a way to ensure that demand for HIV/AIDS commodities did not go unmet. Mission officials believed that the letters were sufficient in documenting the loans. Also, they mentioned that the lack of reporting or explicit mention of these loans in the reporting to OGAC is due to the often limited space allowed for such comments in the COPs, semi annual reports, and annual reports.

As a result, the PEPFAR program may not receive commodities back in a reasonable period of time. Also, disagreements between the parties may occur and expectations (e.g., regarding adequate storage, etc.) may not be met. The PEPFAR program has budgeted and then procured a portion of ARV drugs and other commodities that was not intended to meet PEPFAR demand but rather to anticipate a potential need on the part of Global Fund. The COPs for FY 2007 and FY 2008 both include a buffer of 10 percent totaling approximately \$250,000 for each year. In fact, OGAC questioned why the budget had decreased in 2008. This was due to repayments of commodities by the Global Fund in 2007 that decreased the required procurement for FY 2008.

Recommendation No. 7: We recommend that USAID/Haiti revise its memorandum of understanding with the Global Fund to spell out the conditions and responsibilities of each party for loans and donations of commodities.

Recommendation No. 8: We recommend that USAID/Haiti establish an internal policy that requires that estimates for loans of PEPFAR program commodities be reported in the budgets and the actual loans and repayments to stakeholders in Washington.

EVALUATION OF MANAGEMENT COMMENTS

In response to our draft report, USAID/Haiti agreed to implement the recommendations and has developed specific plans to address Recommendation Nos. 1, 2, 3, 4, 5, 6, and 7. For instance, with regard to Recommendation No. 1, the mission stated that a condensing unit has arrived in Haiti and specific dates for installation and then transfer of the cold chain commodities to the central warehouse have been set. In addition, a complete physical inventory will be done prior to this transfer. Another example is Recommendation No. 4, as the mission indicated that an incinerator was received and a date has been set to begin destroying expired products. The mission has also planned to use other methods such as cement mix for liquid formulation and burial. A management decision has been reached on Recommendation Nos. 1, 2, 3, 4, 5, 6, and 7.

In response to Recommendation No. 8, the mission stated that a 10 percent buffer will continue to be added to procurement estimates due to potential Global Fund shortages. The percentage will decrease as the Haitian national system matures. However, it is unclear if this 10 percent will be communicated to stakeholders in Washington as an amount for loans to other entities. The mission's response also explains how the loans are tracked, but does not address how actual loans and status of repayments will also be communicated to stakeholders in Washington. Therefore, a management decision is pending.

Mission comments in their entirety are presented in Appendix II.

SCOPE AND METHODOLOGY

Scope

The Regional Inspector General/San Salvador conducted this performance audit in accordance with generally accepted government auditing standards to determine if USAID/Haiti procured, deployed, and warehoused its PEPFAR commodities to help ensure that intended results were achieved, and what the impact has been. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective. Audit fieldwork was conducted at USAID/Haiti from May 27 through June 13, 2008. The audit primarily covered the period from October 1, 2006 through June 13, 2008.

The scope of the audit was limited to testing commodities procured through the Partnership for Supply Chain Management. Since fiscal year 2006, the Partnership has been USAID/Haiti's primary implementing partner procuring PEPFAR commodities and according to USAID/Haiti is now the only one.

In planning and performing the audit, we assessed the effectiveness of management controls related to the procurement, storage, and distribution of PEPFAR commodities. Specifically, we obtained an understanding and evaluated (1) the Country Operational Plan (COP) for FY 2006, FY 2007, and FY 2008 (2) the mission's Federal Managers' Financial Integrity Act of 1982 assessment, (3) the oversight performed by USAID/Haiti Health officials, (4) performance measures, and (5) actual performance results. We also conducted interviews with key USAID/Haiti personnel, the main implementing partner, and beneficiaries. We conducted the audit at USAID/Haiti, located in Port-au-Prince, Haiti, visited implementing partners and beneficiaries located in Port-au-Prince and Petion-Ville, and conducted site visits in Port de Paix, Fort Liberte, Cap Haitien, Pignon, Carrefour, and Pierre Payen.

We reviewed the main program indicator stating the number of patients on antiretroviral (ARV) therapy included in the fiscal year 2007 COP as well as the indicator for number people tested for HIV/AIDS. The main implementing partner is the Partnership.

Methodology

To answer the audit objective, we reviewed the fiscal year 2007 COP's planned and actual results for the number of patients on ARV therapy and number of people tested.

We validated performance results and compared reported information to documented results (progress reports from contractors) for the indicators in order to verify the mission's determination of the project's performance.

We reviewed applicable laws and regulations, and USAID policies and procedures pertaining to PEPFAR including the following: the mission's 2007 Federal Managers' Financial Integrity Act of 1982 assessment; storage protocols from the World Health

Organization; Guidelines For Managing The HIV/AIDS Supply Chain by a principal partner of the Partnership; storage requirements for HIV/AIDS commodities with regards to temperature; and Automated Directives System chapter 203 titled Assessing and Learning.

We interviewed USAID/Haiti officials, Center for Disease Control officials, the main implementing partner, and the medical staff at sites visited. We conducted site visits to the main warehouse that stores the commodities and the implementing partner's offices that are temporarily being used for cold storage. We also conducted site visits to 4 of the 5 health facilities receiving ARV drugs from USAID financing, 5 of the 10 receiving OI drugs, and 9 of the 27 sites receiving test kits. In total, we visited nine facilities as some received all of the above mentioned commodities from USAID/Haiti, while others did not. At these sites, we compared physical counts of commodities to the inventory records, determined if stock outs and expiration of commodities had occurred, assessed the storage conditions for compliance with World Health Organization requirements (see appendix III), and determined the availability of power.

MANAGEMENT COMMENTS

TO: Timothy Cox, RIG/San Salvador

FROM: Beth Cypser, Mission Director

DATE: September 15, 2008

SUBJECT: Mission Response to the Draft Audit Report of RIG's Audit of USAID/Haiti

procurement, deployment and warehousing of its PEPFAR commodities to ensure that intended results were achieved, and what has been the

impact? (Report No. 1-521-08-00X-P).

This memorandum represents USAID/Haiti's formal response to the draft audit report of RIG's Audit of USAID/Haiti procurement, deployment and warehousing of its PEPFAR commodities to ensure that intended results were achieved, and what has been the impact (Report No. 1-521-08-00X-P). USAID/Haiti appreciates the time and effort of the RIG staff in carrying-out this audit and for the professional and cooperative manner in which the audit was conducted.

General Comment:

We agree with all eight (8) recommendations provided in the audit report and believe they will enable us to improve the overall management of the HIV/AIDS commodities (ARVs, Opportunistic Infections drugs, Rapid Test Kits, laboratory reagents and supplies, laboratory equipment and miscellaneous other equipment) for a greater impact of the President's Emergency Plan for AIDS Relief (PEPFAR) program on individuals living and/or affected by HIV/AIDS in Haiti.

The auditors identified specific opportunities for USAID/Haiti to strengthen the management of HIV/AIDS commodities through the Partnership for the Supply Chain Management (The Partnership) activities. Four of the recommended actions are issues that were identified by the Partnership, and resolution is well underway. As requested, action plans and timeframes are developed below in order to implement all the recommendations cited in the report in a timely manner.

Recommendation No. 1:

We recommend that USAID/Haiti, in coordination with the Partnership for Supply Chain Management, develop an action plan, listing specific tasks and timeframes, to move the commodities to the new central warehouse.

Unexplained circumstances leading to the loss in transit of the condensing unit for the cold room caused the delay in rendering the cold room functional. At the time of the audit, corrective measures such as administrative procedures related to the loss investigation, insurance claim and a replacement order for the condensing unit were ongoing. At this time, the new condensing unit has been received and is being installed at the central warehouse.

The following actions are planned:

- 1. Installation: 18 29 August;
- 2. Testing the cold room (temperature measurements): 02 04 September;
- 3. Transfer of products: 15 17 September

The transfer plan provides for a complete physical inventory of the cold chain commodities prior to transfer. Simultaneously, labels and codes will be confirmed for those products. The transfer will be done under strict cold chain conditions and will be allocated to their respective slots in the cold room upon arrival. A control inventory will take place at that time by the warehouse personnel and compared to the pre-transfer inventory. Any discrepancy will be documented and investigated.

Recommendation No. 2:

We recommend that USAID/Haiti, in coordination with the Partnership for Supply Chain Management, install the necessary fire safety items at the central warehouse.

The smoke detectors that were being purchased at the time of the audit have been received, installed and are currently fully functional. It was requested that the vendor speed up the delivery of the posters and conduct a training session for the warehouse staff.

Planned actions are:

- 1. Purchase and post instructions in case of fire: to be delivered before September 29;
- Conduct a training session for the staff: during the last week of September. The curriculum has been developed. It will be conducted in Creole and is expected to be a half day session for all the warehouse personnel and a selected number of the office personnel.

Recommendation No. 3:

We recommend that USAID/Haiti develop an action plan, in coordination with its partners, to improve the forecasting method in order to lessen the amount of expired commodities.

Since the Partnership started its activities, one of the main priorities for USAID and the Partnership was the implementation of an efficient forecasting and quantification system with emphasis first on the ARV drugs. This mission is complicated by the fact that PEPFAR has to take into account the total country needs and not only those sites that are supplied by PEPFAR. Historically, other partners have had difficulties in securing all their drugs and on time. One of our main objectives is to avoid stock outs of ARVs in the country, forcing the PEPFAR team to quantify and purchase for a larger number of patients than those under our direct responsibility. At the opening of the Partnership office in Haiti, a large amount of ARVs were present in the country purchased through

the previous implementing partner. The corresponding forecasts were done based on earlier and ambitious objectives derived from target data provided by implementing partners without much historical data.

Until further notice, The Partnership still purchase additional drugs (up to 10%) over our safety stock to be able to face any emergency related to other stakeholders. The same policy applies to second line molecules to ensure their availability at a moment's notice when patients with adherence problems, major side effects or suspicion of resistance need those drugs

In an effort to manage the excess stock in country at the arrival of the Partnership, ARV drugs nearing expiration were loaned and/or donated to non-PEPFAR partners in an amount valued at more than the amount that reached expiration.

The following action plan was developed to improve the forecasting and prevent commodities expiration:

The strict monitoring of the supply plans and the stocks in country will enable us to reduce the potential for drugs expiring. Through technical assistance from the Partnership's headquarters, the Partnership staff in Haiti was first trained in the available tools for forecasting and supply planning such as Quantimed and Pipeline. Later on, some members of other PEPFAR and non-PEPFAR partners were trained in using the same tools as part of our efforts to build local capacity.

The Partnership conducts quarterly internal updates of its forecast and supply plans, and twice a year, a workshop is held where all partners using ARVs are invited to update the national forecasts and supply plans.

The Partnership organigram recently included a "Forecasting and Demand Planning Specialist" whose main role is to ensure the relevance of all quantification hypotheses and assumptions, produce and update all forecasts and supply plans, conduct the update workshops and track consumption data and operate all necessary adjustments.

The next update of all forecasts and supply plans is scheduled for end of September – early October, depending on the availability of the participants. A workshop will be held with all involved in treatment of HIV/AIDS patients including the Ministry of Health. The Partnership will request assistance from headquarters to support the local specialist in his first effort to conduct such a workshop.

He then should be able to conduct the next programmed workshop in April 2009. The Partnership quarterly internal updates will continue and the updated documents will be shared with the USG Team, the Partnership Headquarters as well as the appropriate partners.

In the efforts to ensure regular, efficient reviews and updates of quantification, the Health and Education office Activity Manager for The Partnership is scheduled to attend in early October an intensive two week long training provided by John Snow, Inc. with emphasis on Quantification and Procurement Planning. Thus, increasing her related knowledge and skills and ability to more actively participate at the monitoring and review activities.

Recommendation No. 4:

We recommend that USAID/Haiti destroy expired products in a timely manner.

The ordered incinerator has arrived, has been installed and is ready for use. The Partnership will start regular incinerations upon receipt of the approval of the Mission Environmental Officer (MEO) which is pending some prerequisite activities (such as staff training, incinerator operating manual translation, etc.), and the first demonstration test is scheduled for early September.

Due to the volume of the drugs, the incineration will be one of the methods used to dispose of the existing expired drugs. The Partnership is envisaging three methods so far: incineration for the largest majority of commodities; cement mix for the liquid formulation; and burial and cement for a small percentage. All these methods are part of the approved standard methods and are part of the newly developed national norms. The Partnership already shared with the Mission the national norms available at this time and related to acceptable methods by the local government of disposal of expired drugs. The Partnership with guidance and written authorization of the MEO will use those methods that are deemed acceptable and safe to destroy the various types of drugs.

Planned follow-up actions are:

- 1. Testing of the incinerator: o/a September 12;
- 2. Authorization for the acceptable methods of destruction by type of drug: early September.
- Destruction of expired drugs: o/a September 15 November 30. This time line can vary based on the volume that needs to be incinerated versus the other methods. Due to volume / weight and the number of incinerations that can be conducted in a day.

Recommendation No. 5:

We recommend that USAID/Haiti in coordination with its partners, develop an action plan to improve the supply pipeline specifically with regard to OraQuick, or another confirmatory test not requiring cold storage, in order to lessen the amount of stock outs for this product.

OraQuick is used as a confirmatory test at the sites that lack the ability to maintain cold chain products. The manufacturer recommends storage at a wide temperature range, from 2°C to 27°C.

The test is manufactured mainly in Thailand and has a maximum shelf life of six months. With the manufacturing cycles and the transportation challenges, OraQuick is received usually in country with two to four months maximum of shelf life, which create opportunities for expiration and/or stock outs.

In order to improve the OraQuick supply pipeline, The Partnership has recently started importing the test from the USA. This solves part of the logistics problems associated

with transportation and providing with a longer shelf life closer to the four months than the lower limit when received in country. As a new initiative, we expect to gain about 20% additional shelf life on arrival, data to be confirmed after multiple orders.

We are looking into alternatives of similar confirmatory tests that do not require refrigeration but have longer shelf life.

Also, we will continue on improving the sites capacity by providing them with cold chain equipment such as propane powered refrigerators. The economy derived from the price difference between the two current tests (OraQuick \$3.50, Capillus \$1.60) can create enough resources to purchase and maintain the necessary equipment for over thirty sites every year.

There is no timeline associated with this action plan. During the COP09 preparations, we will discuss the issue with all partners as to what next steps will be required. We will continue to purchase the OraQuick as part of the Rapid Test Kits for the Haiti program until a decision is taken in collaboration with the Ministry of Health.

Recommendation No. 6:

We recommend that USAID/Haiti in coordination with the Partnership for Supply Chain Management, develop an action plan listing specific tasks and timeframes, to finalize and implement a performance monitoring plan for the PEPFAR program in Haiti.

At the time of the audit, USAID had already received the Monitoring and Evaluation Plan of the Partnership and provided them with comments.

A revised version was submitted in August for review. That version is more complete and takes into consideration the earlier remarks. It was shared with the USG Team (which includes CDC) for final comments and/or approval to be provided on/around September 19. The approved version will be reviewed in November to reflect any additional or new directives from the USG Team.

Recommendation No. 7 & 8:

We recommend that USAID/Haiti revise its memorandum of understanding with the Global Fund to spell out the conditions and responsibilities of each party for loans and donations of commodities.

We recommend that USAID/Haiti establish an internal policy that requires estimates for loans of PEPFAR program commodities be reported in the budgets and the actual loans and repayments to stakeholders in Washington.

One of the commitments of the USG Team in Haiti is to take all necessary actions to ensure that all patients in Haiti receive their ARVs in a timely manner and avoiding any stock outs of all drugs used in the approved national regimen.

The Partnership is an active partner in that commitment ensuring the availability of the required drugs for the PEPFAR program and also through the decided strategy of loans

and donations. This strategy has been implemented as a response to a perceived need where other stakeholders are facing procurement/ shipping/ availability issues of ARV drugs.

PEPFAR has intervened in practically all such occurrences and avoided interruption of services to the patients. As an ongoing policy, we are still including an additional 10% buffer stock in our ARV drugs procurement. As the national system "matures" and proves its capacity to handle all the needs required from other stakeholders, this percentage will be gradually reduced until totally eliminated.

All loans or/and donations are made with USAID's written approval. As part of actual HIV/AIDS commodities management, The Partnership is tracking all donations and loans by partner, product and date as well as the information on returned loans. The following list of conditions once presented and discussed with the concerned stakeholders should regulate the donations and loans of PEPFAR funded commodities under the Partnership management.

Donations:

ARV drugs can be donated:

- If they have less than four months shelf life;
- If they have a low economic value (i.e. less than \$10,000);
- If partner / stakeholder need of those products has been established by the USG Team;
- If USAID provides The Partnership with formal authorization to donate the drugs;
- The donations will be accounted for at replacement value. This amount will be reported to USAID.

Loans:

Once the need has been established and authorized by USAID, The Partnership can proceed with providing the loan.

- Only ARVs can be loaned and in some exceptional situations, Rapid Test kits;
- Response to the request is based on availability of products without jeopardizing The Partnership's stock and its ability to respond to its needs;
- Response only in situations where the partners are experiencing delays in receiving their own drugs from their suppliers;
- Loans should be returned immediately after the partner receives his own stock with an interval not to exceed three to six months from loan date;
- Returned drugs should be part of the FDA approved or tentatively approved ARVs;
- Quantities returned should be equivalent in quantity of active ingredients loaned;
- The quantities returned should have enough shelf life remaining to be used within the time frame of that shelf life by the Partnership's sites. If not, The Partnership will only accept the usable fraction and will return any excess balance. The Partnership will request a subsequent delivery of that portion corresponding to all established criteria;
- The accounting of all loans should be done at purchase price and once returned, should be logged in at the same value.

- 1. Listed above conditions to be sent to Sogebank Foundation: 19 September
- 2. Response from Sogebank Foundation : 30 September;
- 3. Integration in MOU between PEPFAR/FSGB: October 17.

In closing, we would like again to express our appreciation for the professional manner in which the audit was conducted. The initiative of listing in advance the documentation needed and the sites that would be visited during the exercise contributed to a smoother implementation of the agenda. Since logistics and security requirements were addressed in advance, the auditors and the USG Team could better focus on discussions, interviews, and sites visits.

Furthermore, the RIG Audit has been a good opportunity for the USG Team and The Partnership to receive clear and to the point recommendations that will help us improve our services and contribute even more to the reduction of HIV/AIDS and its consequences on whole populations by continuing to provide quality medicines to the people living with and affected by this epidemic.

STORAGE CONDITIONS TESTED

| No | Description |
|----|--|
| 1 | Storage area is secured with a lock and key, but is accessible during normal working hours; access is limited to authorized personnel. |
| 2 | Products that are ready for distribution are arranged so that identification labels and expiry dates and/or manufacturing dates are visible. |
| 3 | Items stored according to instructions on carton, including arrows pointing up. |
| 4 | Products are stored and organized in a manner accessible for first-to-expire, first-out (FEFO) counting and general management. |
| 5 | Storeroom is maintained in good condition (clean, all trash removed, sturdy shelves, organized boxes, no insecticides, chemicals, old files, etc.). |
| 6 | The current space and organization is sufficient for existing products and reasonable expansion (i.e., receipt of expected product deliveries for foreseeable future). |
| 7 | Cartons and products are in good condition, not crushed due to mishandling. If cartons are open, determine if products are wet or cracked due to heat/radiation. |
| 8 | The facility makes it a practice to separate damaged and/or expired products from usable products and removes them from inventory. |
| 9 | Products are protected from direct sunlight. |
| 10 | Cartons and products are protected from water and humidity. (i.e. there is no evidence of water damage?) |
| 11 | Storage area is visually free from harmful insects and rodents, termites, etc. (Check the storage area for traces of rodents [droppings or insects].) |
| 12 | Determine whether storage room is cleaned and disinfected regularly. |
| 13 | Products are stored at the appropriate temperature according to product temperature specifications (Most ARVs require storage below 25-27C. Lopinavir/ritonavir capsules and Stavudine oral suspension after reconstitution require refrigeration between 2 - 8 C. |
| 14 | Does the air conditioner work? Are there power outages? Is there a backup generator, cylindered gas or kerosene-powered refrigeration? |

APPENDIX III

| 15 | Roof is always maintained in good condition to avoid sunlight and water penetration. Any evidence of leakage |
|----|---|
| 16 | Products are stacked at least 10 cm off the floor. Ask whether the area floods. |
| 17 | Products are stacked at least 30 cm away from the walls and other stacks. |
| 18 | Products are stacked no more than 2.5 meters high. |
| 19 | Ask staff what they do in case of a fire. Is fire safety equipment available and accessible (any item identified as being used to promote fire safety should be considered including fire extinguisher and sand or soil in a bucket). |
| 20 | Package and product integrity - check for damage to packaging (tears, perforations, water or oil) and products (broken or crumbled tablets, broken bottles). |
| 21 | Manufacturing defects: incomplete supply, missing or illegible identification information. |
| 22 | Labeling - make sure products are labeled with the date of manufacture or expiration, lot number and manufacturer's name. |

U.S. Agency for International Development Office of Inspector General

1300 Pennsylvania Ave., NW Washington, DC 20523

Tel: (202) 712-1150 Fax: (202) 216-3047 www.usaid.gov/oig