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LAC-IEE-05-41

ENVIRONMENTAL THRESHOLD DECISION

Activity Location:	Haiti
Activity Title:	Haiti Procurement Management of Anti-Retroviral drugs
Activity Number:	521-0267 (Contract No: 521-A-00-05-00087-00)
Life of Activity Funding:	\$2,005,982
Life of Activity:	27 Sep 2005 –30 Sep 2006
IEE Prepared by:	Lionel Poitevien, MEO, USAID/Haiti
Recommended Threshold Decision:	Categorical Exclusion/Negative Determination with Conditions
Bureau Threshold Decision:	Concur with Recommendation

Comments:

This Environmental Threshold Decision covers USAID/Haiti's Procurement Management of Anti-Retroviral Drugs activity. In accordance with 22 CFR 216.2 (c)(2)(i) and (viii), a **Categorical Exclusion** is issued for aspects of the activity pertaining to education, technical assistance, or training, and involving nutrition, health care except for activities generating medical waste as noted below. A **Negative Determination with Conditions** is issued for components involving the disposal of medical and sanitary waste or use of syringes and IVs. The Inter-church Medical Assistance (IMA) organization and all implementing partners will be required to follow the series of mitigations measures described in the attached IEE. A report on compliance will be submitted to the MEO by 31 Oct 2006, with a copy to the REA and BEO.

_____Date_____

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Copy to: IEE File

Attachment: IEE

File: IEE05-41 ETD(HA Health-Anti Retroviral Drugs).doc

INITIAL ENVIRONMENTAL EXAMINATION

Activity Location: Haiti

Activity Title: Haiti Procurement Management
of Anti-Retroviral drugs

Activity Number: 521-0267 (Contract No: 521-A-00-05-00087-00)

Funding: \$2,005,982

Life of Project: Sept. 27, 2005 – Sept. 30, 2006

Recommended Threshold Decision: Categorical Exclusion/Negative Determination with
Conditions

IEE Prepared by: Lionel Poitevien, MEO
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Concurrence:

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Clearance:

Mike Donald,
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Approval

Victor Bullen, Bureau Environment Officer
Latin America and Caribbean

Background

USAID/Haiti's health program aims to improve the health and well-being of Haiti's most vulnerable population groups, particularly women and children. USAID's primary goal in these sectors is sought by addressing Haiti's most pressing health concerns—malnutrition, child mortality, reproductive health, and HIV/AIDS. As with all development problems facing Haiti, health and related services are rendered more difficult by a high population growth rate and a fragile political and economic environment.

USAID works to achieve objectives in the areas of child survival, reproductive health, HIV/AIDS, and tuberculosis (TB). Through a USAID-funded network of health service providers, 2.6 million Haitians have access to basic health care. The increased access to health care has resulted in increased contraceptive use, reduction of chronic child malnutrition, improved child and maternal health, and increased immunization rates. Through a new departmental strategy, USAID is working in collaboration with both the public and private sectors to extend the outreach of these comprehensive health services nationwide.

On January 28, 2003, President Bush announced a plan to combat HIV/AIDS through an initiative called the President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR is a five-year, \$15 million program. PEPFAR encompasses HIV/AIDS activities in more than 75 countries worldwide and seeks to develop comprehensive and integrated prevention, care and treatment programs in 14 focus countries in Africa and the Caribbean, including Haiti. PEPFAR builds on existing USG and international programs and setting aggressive goals for these focus countries—preventing seven million new infections, treating two million HIV-infected people with anti-retroviral therapy, and caring for 10 million HIV-infected individuals and AIDS orphans.

USAID and the Centers for Disease Control and Prevention (CDC) is the largest bilateral donor for HIV/AIDS activities in Haiti. The HS-2007 program includes a comprehensive set of prevention, care and treatment activities, designed to attain specific five-year targets in line with the 2-7-10 overall Plan goals. To achieve these targets, USAID/Haiti supports voluntary counseling and testing for HIV and related service delivery, behavior change communication, ARV treatment and community-based programs for care and support for people living with HIV/AIDS. Most of USAID/Haiti's program is implemented through public/private partnerships, which include the Ministry of Health and a broad spectrum of NGOs, both faith-based and community-based.

This Initial Environmental Examination (IEE) addresses the activities implemented under USGT/I.M.A. Cooperative Agreement; Haiti ARV Procurement management of anti-retroviral drugs in support of the President's Emergency Program for HIV/AIDS Relief (PEPFAR) managed by the USG/Haiti Team in connection with the FY 2005 Country Operational Plan (COP).

Program Description

A. Description of the proposed activity

The proposed activities for this USG/Haiti Team ARV Cooperative Agreement include that I.M.A. will:

1. take responsibility for acquiring approximately 3,927 patient-years of ARV drugs for the Haiti PEPFAR program in FY 2005 adhering to USG and Haitian ARV procurement and export/import regulations;
2. manage the timely and cost-effective importation of ARVs to be used at various points of service as directed by USG/Haiti Team;
3. management of the ARV drugs, with responsibility for the drugs being transferred to another PEPFAR supporting organization after arrival in Haiti, supporting the USG/Haiti Team;
4. facilitate access to pharmaceutical donation programs for Emergency Plan points of service and AICSH members;
5. monitor supply chain to insure capacity, and provide reports, as determined by USG/Haiti Team;
6. coordinate locally in Port au Prince.

For FY 2005, access to pharmaceutical donation programs for Emergency Plan points of service and AICSH members will be with the Pfizer Diflucan Partnership Program (DPP) for the donation of fluconazole. From the Haiti Emergency Plan COP 05, it is anticipated that 31,250 HIV-positive individuals will receive palliative care and/or basic health care support by the end of FY05, not to mention patients receiving treatment via AICSH institutions not yet involved in Emergency Plan programming. Using WHO and Pfizer statistics, it is anticipated that 10 to 20% of these patients would need continuous fluconazole maintenance treatment for cryptococcal meningitis, and approximately 30% of patients would need fluconazole treatment for oesophageal candidiasis. By rough, conservative calculations, the donated Diflucan that would be available from Pfizer/I.M.A. to support these treatments alone could reach a value of nearly \$12.5 million, if current scale-up projections are achieved.

The I.M.A. work included in this PD will be coordinated locally in Port au Prince through a sub-grant agreement with the Association des Institutions Chretiennes de Sante d'Haiti (AICSH), under a PD more fully described in section I.(C).

B. Contribution to gaps and to 5-year strategy:

I.M.A. has been working with pharmaceutical companies involved in manufacturing and distributing ARV drugs and other essential medications for over 4 decades. Through their work with drug procurement within the AIDSRelief Consortium, they have in place efficient procurement policies and procedures that structure work with these companies and various drug consolidators. Therefore, this PD will address the gap in adequate

procurement capabilities in support of Haiti's single ARV drug pipeline. This single pipeline is intended to:

- allow more efficient and cost-effective interaction with the global drug suppliers;
- allow more streamlined sharing and use of drug supplies and information within the country;
- allow continuity of treatment to patients enrolled at supported sites.

Additionally, through their knowledge of work with various pharmaceutical donation programs, IMA will address the gap of inadequate utilization of these programs in support of HIV/AIDS programming in Haiti. Fuller engagement in these donation programs will optimize use of Emergency Plan funds in Haiti and will continue to harness the interest and resources of these companies and the international community in Haiti's HIV/AIDS efforts.

C. Contribution to local capacity building and local collaboration:

I.M.A. and the AICSH will enter into a partnership agreement to coordinate ARV drug procurement management in Haiti, as well as the management of various pharmaceutical donation programs that will be available to Points of Service funded via the President's Emergency Plan for AIDS Relief and other hospitals who are members of the AICSH.

The AICSH was organized in the 1990's and currently has a membership of 24 hospitals, including Hôpital Ste. Croix, Hôpital Bienfaisance, Baptist Haiti Mission, Centre Medical Sacre Coeur and others. It serves its member agencies by providing the following services:

- hold semi-annual general assembly meetings of the membership that involves educational seminars and continuing medical education;
- coordinate the sharing of specialized medical equipment, medicine and information between member institutions;
- occasionally receive and distribute donations of medicine and equipment to the member hospitals;

To coordinate the work envisioned under this proposal, a Program Liaison Officer/Pharmacist will be employed by AICSH. The Program Liaison Officer will be obligated to I.M.A. through a sub-grant agreement between I.M.A. and AICSH. Among his/her other duties, the Officer will represent I.M.A. within the Haiti coordination team of the AIDS Relief Consortium.

The partnering of the two organizations will facilitate the strengthening of the AICSH network of faith-based hospitals in Haiti through a broadening of its current services. As AICSH and its Member Institutions have a historical foundation of providing services

through this partnership, AICSH as a coordinating body and by extension, the Member facilities, will be at the core of this critical emerging initiative to provide ART to Haiti, playing the essential role of facilitating and coordinating the delivery of drugs. Initially, this will additionally involve expansion of the AICSH medical donations program to ensure member institutions qualify for and receive a regular supply of Diflucan (Pfizer) and other donations, available through I.M.A. Subsequently, as other programs of interest to the Membership develop, I.M.A. will continue to work with AICSH to facilitate the expansion of the portfolio of resources.

As well, the involvement of the AICSH and its continuing education program interests will assist in linking their membership of faith-based hospitals to the work of Emergency Plan in Haiti, allowing these institutions to begin preparations for eventual involvement in the program.

D. Monitoring and Evaluation

The I.M.A. HQ staff will be in continuous contact with the USG/Haiti Team to keep them fully briefed on the status of the purchase orders, any changes in the ETA, etc. For example, I.M.A. will provide weekly and monthly status reports on the actual procurement process until drugs are delivered to Haiti. A simple weekly status report, consisting of not much more than a paragraph, should minimally include:

- list of the quantity of each drug on order
- expected delivery date
- delays of delivery and source of delay
- preparations taken for custom clearance

A more in-depth end of the month report should include:

- information on the progress of the donation program
- delayed and/or incoming drugs and quantity
- expected delivery dates
- any newly established terms and conditions agreed or pending with donation programs or manufactures.

The work of the Pharmacist/Commodities Supplies Manager will be monitored first by the I.M.A. HQ staff to ensure that he/she is fulfilling the terms of employment particularly in regards to the delivery and monitoring of the distribution of the requested ART drugs. The Pharmacist will be expected to join and participate in all relevant PEPFAR coordinating and work groups and along with other partners fulfill the expectations of the National Program being supported by the USG/Haiti and Ministry of Health. The third and also parallel monitoring of performance will be provided by the Executive Body of the AICSH, who will be receiving performance reviews from Member institutions who will be receiving direct benefits from this individual, made possible through the USAID Cooperative Agreement with I.M.A.

E. Timeline

The delivery of drugs is wholly dependent on availability of supplies from suppliers, via vendors. It is expected that some drugs could begin to be delivered into Haiti in six - eight weeks of the Cooperative Agreement being signed and funds advanced to I.M.A. Unfortunately, for one of the drugs presently being requested by the USG Team, "ABC from GlaxoSmithKline," expected delivery is now 14 weeks.

Description of Environmental Impact

The components of this program consist mainly of procurement of ARV drugs. Consequently, this program will not have negative impacts on the physical environment or pose any significant risk to the welfare of target populations or surrounding communities. However, a few syringes may be distributed along with intra-venous (IVs). Direct environmental impacts could result from improper use, management, and disposal of these materials if appropriate mitigation measures are not implemented.

Recommended Mitigation Measures for Disposal of Solid, Sanitary, and Medical Waste

USAID/Haiti recommends the following steps:

- Step One: Within two months of the approval of this IEE, IMA must notify to the Cognizant Technical Officer (CTO) that training has been conducted for implementing partners on international standards and recommendations for the handling and disposal of medical wastes.
- Step Two: Within four months, IMA and/or implementing partner must develop a BMP plan for medication waste disposal at the facilities they directly operate based on the guidance described herein. The BMPs should be reviewed and filed by the CTO to ensure completion and consistency with guidance. The BMP plans should include the following:
- Procedures for disposal of solid waste, sharp objects, liquid waste, and chemical containers;
 - Procedures for handling waste containers; and
 - Procedures for using a combination of incineration and burying to provide the safest ultimate waste disposal.

Note: Outside of Port-au-Prince, facilities are not likely to have access to either a hospital sponsored-incinerator or a municipal landfill. Since the traditional method of handling solid waste in Haiti is burning and there is not a significant problem with air pollution (particulate matter) outside of Port-au-Prince, USAID recommends that each facility consider constructing at a minimum a drum incinerator for the medical waste.

The incombustible and ash material can then be buried in a landfill area that must be identified by each clinic (only low volumes are anticipated).

- Step 3: Within six months, IMA should provide to the CTO and MEO, a table characterizing the types of services offered at those clinics receiving USAID support, the volume of waste generated, the types of procedures in place, and information on whether the clinic has access to water and sanitation.
- Step 4: At least one site visit of each facility to ensure compliance with BMP plans is required. The site visit will be conducted by the CTO or designated representative. Any situations of non-compliance must be brought to the attention of the MEO.
- Step 5: On an annual basis, a status report will be submitted to the MEO, which will (1) describe the state of medical waste disposal in the clinics; (2) evaluate the effectiveness of the recommended procedures; and, (3) recommend modifications to the recommended procedures, as necessary.

Note: The USAID/Haiti MEO is available to provide advice on any situation that is complicated and requires special technical assistance.

Recommendations

Pursuant to 22 CFR 216.2 (c)(2)(i) and (viii), it is recommended that a **Categorical Exclusion** be issued for activities involving technical assistance, training, capacity building, and other actions which will not have an adverse impact on the natural or physical environment, including programs involving nutrition, health care or population/family planning services.

For those components involving the disposal of medical and sanitary waste or use of syringes and IVs, it is recommended that a **Negative Determination with Conditions** be issued. IMA and all implementing partners will be required to follow the series of proposed Mitigations Measures described above.