Information on GH/OHA/SCMS Approval of "Other" HIV/AIDS Pharmaceuticals

This provides information on approval of "other" pharmaceuticals by the Supply Chain Management System Division of the Office of HIV/AIDS in the Bureau for Global Health (GH/OHA/SCMS) under the "Expedited Acquisition and Assistance Procedures for USAID's Activities and Programs Related to the Prevention, Care, and Treatment of HIV/AIDS (HIV/AIDS Expedited Procedures). The Administrator approved the HIV/AIDS Expedited Procedures on February 14, 2008, and are effective through December 31, 2013.

I. BACKGROUND

A. "Other" Pharmaceuticals

"Other" pharmaceuticals are pharmaceuticals other than antiretrovirals (ARVs) and HIV/AIDS rapid test kits. For information on USAID approval of ARVs and HIV/AIDS rapid test kits please go to: http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html.

B. Background on "Source-Origin" and "Restricted Commodity" Requirements

USAID contractors and recipients have "source-origin" and "restricted commodity" requirements that apply to pharmaceuticals. For contracts, the requirements are in the AIDAR clause 752.225-70, "Source, Origin, and Nationality Requirements". For grants and cooperative agreements, the clause is "USAID Eligibility Rules for Goods and Services."

1. **Source-Origin.** Generally, one needs a source-origin waiver to procure non-US manufactured pharmaceuticals. However, in the HIV/AIDS Expedited Procedures there is a program source-origin waiver for "other" pharmaceuticals that authorizes code 935. **Therefore, you do not need any other source-origin waivers to purchase non-US manufactured pharmaceuticals.**

2. **Restricted Commodity.** Pharmaceuticals are one of the "restricted commodities" which require approval by M/OAA under ADS 312. **However, under the HIV/AIDS Expedited Procedures, you do not need a "restricted commodity" approval from M/OAA for the following:**

   Category 1 – OHA/SCMS confirms that the pharmaceutical is being purchased from the International Dispensary Association Foundation (IDA), Missionpharma, or UNICEF;

   Category 2 – OHA/SCMS confirms that the pharmaceutical or manufacturing site for the pharmaceutical has been approved by the FDA or other Stringent Regulatory Authority (SRA).

   Category 3; – OHA/SCMS approves the specific pharmaceutical; or

   Category 4 – The pharmaceutical is being purchased by the Partnership for Supply Chain Management (PFSCM).

3. **Express Authorization.** The requirement for express authorization from the U.S. patent owner in ADS 312 does not to apply to these "other" pharmaceuticals.

4. **Price Test.** The HIV/AIDS Expedited Procedures addressed the 50% price test in ADS 312. Therefore, no further price tests are required and you do not have to provide the prices of comparable U.S. pharmaceuticals.

5. **Essential to the Activity**. You do not have to demonstrate that the pharmaceutical is essential to the activity. The HIV/AIDS Expedited Procedures addressed that issue.

II. REQUESTING OHA/SCMS APPROVAL OR CONFIRMATION

A. Template and Where To Send Your Request.

We ask you to please use the template on the USAID public website at: http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html.

Please send your request Mike Hope (mhope@usaid.gov) or Jan Miller (jmiller@usaid.gov) with a copy to Shameka Harmon (sharmon@usaid.gov). You can also fax it to 202-216-3037.

B. Information for Category 1 – Sold by the International Dispensary Association Foundation (IDA), Missionpharma, or UNICEF.

For this category, we only need a list of the generic name, estimated price, quantity, strength and the source (IDA, Missionpharma or UNICEF). We do not need any information on the quality of the pharmaceutical for this category.

C. Information for Category 2 – Approved by the FDA or other Stringent Regulatory Authority (SRA).

1. **Who are the SRAs?** An SRA is the US Food and Drug Administration (FDA) or other national drug regulatory authority (NDRA) that closely resembles FDA in its operations. Currently, USAID has designated as SRAs the following NDRA members or observers in the International Conference on Harmonization:

    - **Canada** - Therapeutic Products Directorate, Health Canada

- **European Union** -European Agency for the Evaluation of Medicinal Products (EMEA);
- **Japan** –Ministry of Health, Labor, and Welfare; and
- **Swiss Medic** representing the European Free Trade Area (EFTA).

2. **Information Needed**: To confirm that the FDA or SRA has approved the specific pharmaceutical being purchased, we need the same information that the FDA or SRA uses in approving a specific pharmaceutical:

   - generic name
   - strength
   - dosage form
   - specific manufacturer
   - specific manufacturing facility
   - wholesaler/distributor (if applicable)

We do not need any information on the quality of the pharmaceutical for this category.

D. Information for Category 3 – Approved by OHA/SCMS.

1. **Pharmaceutical information**: Just as with an SRA approval, OHA/SCMS approval is for a specific pharmaceutical manufactured by a specific manufacturer at a specific manufacturing site. Therefore, we need the same information as for Category 2:

   - generic name
   - strength
   - dosage form
   - specific manufacturer
   - specific manufacturing facility
   - wholesaler/distributor (if applicable)

2. **** Information on quality:**** You will **also** need to provide us with information on the quality of the pharmaceutical. Please contact us before you submit the information so we can discuss what you may or may not need to provide. For

example, we may already have the information because we approved the same pharmaceutical for another contractor or recipient; or we may need to arrange with you quality testing by a recognized laboratory before we can approve the pharmaceutical.

E. Information for Category 4 – Purchased by PFSCM.

You do not have to submit anything if you are using PFSCM to purchase the pharmaceutical. Since OHA/SCMS approves pharmaceuticals purchased by PFSCM you do not have to repeat this approval process when using PFSCM.

III. FOR QUESTIONS AND FURTHER INFORMATION.

Please contact Mike Hope (mhope@usaid.gov; 202-712-1084) or Jan Miller (jmiller@usaid.gov; 202-712-0437).