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

I. Background

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 they are effective through December 31, 2013.

A. "Other" Pharmaceuticals

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

B. "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 a source-origin waiver is needed 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, a "restricted commodity" approval is <u>not</u> required for the following pharamceuticals:**

   Category 1 – sold by the International Dispensary Association Foundation (IDA), Missionpharma, or UNICEF as <u>confirmed</u> by OHA/SCMS;

   Category 2 – approved by the FDA or other Stringent Regulatory Authority (SRA) as <u>confirmed</u> by OHA/SCMS; or

   Category 3 – specifically <u>approved</u> by OHA/SCMS.

   Therefore, you do not need a restricted commodity approval from M/OAA if the pharmaceutical is in one of these three categories.

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

4. **Price Test:** The 50% price test in ADS 312 was considered in approving the source-origin waiver. Therefore, no further price tests are required and you do not have to provide the prices of comparable U.S. pharmaceuticals.

II. Requesting OHA/SCMS Approval or Confirmation

A. Where to send your request and template.

Please send your request for approval to Mike Hope (mhope@usaid.gov) or Jan Miller (jmiller@usaid.gov) with a copy to Shameka Harmon (sharmon@usaid.gov).

To request SCMS approval or confirmation use the template on the USAID public website at:

http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html

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

For this category, we need the following information:

1. A statement from the CTO or another USAID official to the effect that the pharmaceuticals are being bought from IDA, Missionpharma, or UNICEF. For example, "I am the CTO of the grant to X in Rwanda and X is buying the following pharmaceuticals from IDA."

2. A list of the pharmaceuticals, including estimated price and quantity.

We do not need any information on safety, efficacy, and quality 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 safety, efficacy, and quality 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 safety, efficacy and quality:**** You will **also** need to provide us with information on the safety, efficacy, and 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 needed 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.

For questions and further information contact: Mike Hope (mhope@usaid.gov; 202-712-1084) or Jan Miller (jmiller@usaid.gov; 202-712-0437).