ADS 312 Additional Help Document

GH/OHA/SCMS "Restricted Commodity" Approval of Pharmaceuticals

We have written this in an attempt to help USAID partners and USAID technical and procurement offices understand the "restricted commodity" approval process for pharmaceuticals. We hope that you find it helpful and welcome your feedback.

We encourage you to contact us as you begin to consider procuring pharmaceuticals.

I. Background

On February 22, 2011, the Administrator approved:

1. A source-origin waiver for all USAID-financed pharmaceuticals purchased through December 31, 2016.

2. Changes to ADS 312.5.3c which, among other things, removed the requirements that non-U.S. pharmaceuticals may only be purchased if the pharmaceutical is either (i) not available from the US or (ii) the delivered price from the United States would be at least 50 percent more expensive and for justifying why the pharmaceuticals are essential for the activity.

Therefore, while you no longer need a source-origin waiver for pharmaceuticals you still need a restricted commodity approval under ADS 312.5.3c. This help document explains in greater detail the restricted commodity approval process for pharmaceuticals.

II. Scope and Applicability

1. Under ADS 312.5.3c ,"Pharmaceuticals", non-contraceptive pharmaceuticals are a "restricted commodity" and require prior approval from OHA/SCMS. This restricted commodity approval does not apply to contraceptive pharmaceuticals which are approved under ADS 312.5.3d. This restricted commodity approval is different from the source-origin requirements in ADS 310.

2. The Director of GH/HIDN or designee(s) must provide concurrence on procurements of pharmaceuticals for the following programs: malaria, tuberculosis, neglected tropical diseases, emerging pandemic threats, and maternal and child health. Many of the pharmaceuticals, including diagnostic test kits that are required for these programs, have unique properties, require additional evidence on efficacy, and have

specific quality requirements in addition to the standard pharmaceutical quality requirements. OHA/SCMS obtains GH/HIDN concurrence as part of the OHA/SCMS approval process.

3. The Pharmaceutical Advisor in DCHA/OFDA approves OFDA pharmaceuticals under a delegation from OHA/SCMS.

4. With the changes to ADS312, OHA/SCMS no longer processes pharmaceutical approvals under the "Expedited Acquisition and Assistance Procedures for USAID's Activities and Programs related to the Prevention, Care, and Treatment of HIV/AIDS".

III. Purpose of OHA/SCMS Approval Process

1. The purpose of the pharmaceutical approval process is to determine if there is sufficient information on file with USAID or available to USAID on the quality of a pharmaceutical from a specific manufacturer at a specific manufacturing site, or from a specific procurement agent or other source. A change in the manufacturer, manufacturing site [even from the same manufacturer], or procurement agent or other source requires a new approval.

2. The focus of this process is on the quality of the drug at the point of manufacture, not on reviewing the means of transporting, storing, or distributing the pharmaceutical and the adequacy of distributors and other intermediaries in the supply chain. Shipment, storage and distribution through responsible distributors and other intermediaries can affect the quality of the pharmaceutical but these processes are part of the larger issues in supply chain management of any pharmaceutical procurement effort and are not part of the ADS 312 approval process.

IV. Types of Pharmaceuticals

There are different requirements for different categories of pharmaceuticals. Certain pharmaceuticals already have a restricted commodity approval and do not require any further OHA/SCMS approval. Others do not require additional information on the quality of the pharmaceutical for OHA/SCMS approval due to USAID experience and accessibility to other information already on file or available to OHA/SCMS.

A. OHA/SCMS Approved Pharmaceuticals

The following pharmaceuticals have ADS 312 approval and do not require further OHA/SCMS approval:

1. Antiretrovirals (ARVs) on the "PEPFAR and USAID Consolidated List of Approved ARVs". USAID policy is to limit procurement of ARVs for clinical use to those on the Consolidated List. Please refer to: http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html.

2. HIV/AIDS Rapid Test Kits on the "USAID List of Approved HIV/AIDS Rapid Test Kits". USAID policy is to limit procurement of rapid test kits for clinical use to those on the USAID List. Please refer to: http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html.

B. OHA/SCMS Approved Sources

OHA/SCMS approval is required for pharmaceuticals in the following three categories. However, because of USAID experience and other information already on file or available to USAID, as a general rule, you will not have to submit additional information on the quality of the pharmaceutical from these sources.

1. Category 1: U.S. Food and Drug Administration (FDA) or a Stringent Regulatory Authority (SRA) Approved Manufacturers. OHA/SCMS recognizes as SRAs, national drug regulatory authorities of other countries that are comparable to the FDA in its standards and operations. For example, members or observers in the International Conference on Harmonization are considered SRAs. The current SRAs include:

- European Medicines Agency (EMEA);
- Health Canada (HCnda);
- Japanese Ministry of Health, Labor, and Welfare;
- Swiss Medic for the European Free Trade Area (EFTA); and
- European Union member states admitted prior to 1996**.**

2. Category 2: UNICEF and World Health Organization (WHO) Approved Manufacturers. This category includes pharmaceuticals purchased from:

- UNICEF;
- A manufacturer inspected and approved by the WHO in compliance with Good Manufacturing Practices (GMP); and
- A pharmaceutical approved by the WHO Prequalification of Medicines Programme.

3. Category 3: Approved Procurement Agents. OHA/SCMS has determined that the following procurement agents have in place adequate prequalification, quality assurance, and quality control systems for ensuring the quality of the pharmaceuticals that they purchase from their pre-qualified manufacturers:

- Action Medeor - http://gb.medeor.org/Home
- Amstelfarma - http://www.amstelfarma.nl
- Imres - http://www.imres.nl/web/show/home
- International Dispensary Association Foundation (IDA) - http://www.ida.nl/
- Medical Export Group (MEG) - http://www.meg.nl

- Missionpharma - http://www.missionpharma.com/.

C. Category 4 – "Other" Pharmaceuticals

1. **Category 4 – "Other" Pharmaceuticals** are pharmaceuticals that do not qualify under any of the above categories and require additional information on quality before they can be approved.

2. Extraordinary Need. In exceptional circumstances, such as a natural disaster or an act of terrorism, it may be necessary to obtain pharmaceuticals immediately from local vendors. Most of these needs will be met by the USAID Office of Foreign Disaster Assistance (OFDA). Occasionally, however, other USAID operating units may have a need to procure pharmaceuticals for extraordinary need. On these occasions, OHA/SCMS may provide approval on an exceptional case-by-case basis. Approval will be based on a risk-benefit judgment considering available quality information for the pharmaceuticals, source(s) of the pharmaceuticals, previous performance of the vendor(s), and conditions present on the ground.

V. Submitting a Request

1. Template. Please use the template – GH/OHA/SCMS ADS 312 "Restricted Commodity" Approval for Pharmaceuticals – and include the following information:

(1) Generic name
(2) Strength
(3) Dosage form
(4) Approved OHA/SCMS source (as applicable)
(5) Specific manufacturer, and city and country of specific manufacturer (as applicable.) *

**Note: This information is not required if purchasing from an approved procurement agent.*

You can find the template on the USAID public website at:
http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html.

2. Additional Information on quality. For Category 4 – "Other Pharmaceuticals" you will also need to submit information on the quality of the pharmaceutical. Please contact OHA/SCMS before you submit the information to discuss what you may need to provide. For example, OHA/SCMS may require quality testing by a recognized laboratory as part of the approval.

3. Please email your template and any information on quality to Mike Hope (mhope@usaid.gov), Christine Malati (cmalati@usaid.gov), or Jan Miller (jmiller@usaid.gov) with a carbon copy (cc) to Quinn Cikaitoga (qcikaitoga@usaid.gov). You can also fax your request to 202-216-3037.

VI. Additional Information

1. "Express Authorization" by U.S. Patent Holder. Under Section 606(c) of the Foreign Assistance Act of 1961, as amended (FAA), 22 USC 2356(c), USAID may not finance a pharmaceutical that is manufactured outside the United States if the pharmaceutical is covered by a valid U.S. patent, unless the U.S. patent owner expressly authorizes the manufacture of the pharmaceutical. Without such an express authorization, the pharmaceutical must be purchased from the U.S. patent holder. OHA/SCMS is available to assist with section 606(c) issues.

2. Communicating OHA/SCMS Approval to Partners. Under the source-origin and restricted commodity award provisions (AIDAR clause 752.225-70, "Source, Origin, and Nationality Requirements" for contracts and the standard provision "USAID Eligibility Rules for Goods and Services" for assistance agreements), the Contracting Officer/Agreement Officer (CO/AO) is authorized to communicate the OHA/SCMS restricted commodity approval to the partner. The CO or AO may delegate this authority to the COTR and AOTR in a COTR or AOTR delegation letter or the contract or agreement.

A sample letter for advance approval of pharmaceuticals is attached**.**

3. Marking. The marking provisions of ADS 320 do not apply to the packaging of pharmaceuticals. ADS 320 otherwise applies to programs and activities utilizing pharmaceuticals. Missions and operating units can provide for the marking of pharmaceuticals as part of the marking and branding strategies and plans in ADS 320.

Date: July 5, 2011

Attachment: Sample Letter to Contractors/Recipients for Approval of Pharmaceuticals

[*Contractor or Recipient name and address*]

Subject: Pharmaceuticals - Source/Origin/Nationality Waiver and ADS 312 Approval

Reference: [*Award number and title*]

Dear:

The purpose of this letter is to provide USAID waiver approval of source, origin, and nationality requirements for the purchase of pharmaceuticals and ADS 312 approval of non-contraceptive pharmaceuticals.

***Use this paragraph for contracts only*:**
Advance approval is given under the AIDAR provision 752.225-70, "Source, Origin, and Nationality Requirements for the purchase of pharmaceuticals as set out below.

Use this paragraph for assistance awards only:
Advance approval is given under the source/origin or "restricted commodity" provisions of the Mandatory Standard Provisions for U.S., Nongovernmental Recipients "USAID Eligibility Rules for Goods and Services", in your grant/cooperative agreement for the purchase of pharmaceuticals as set out below.

1. **Source/Origin/Nationality Waiver for Pharmaceuticals**. On February 22, 2011, the Administrator approved a source/origin/nationality waiver for all USAID-financed pharmaceuticals purchased through December 31, 2016. Accordingly, Geographic Code 935 is established as the authorized source, origin, and nationality code for pharmaceuticals purchased through December 31, 2016. Code 935 includes all countries, except certain foreign policy restricted countries - see 22 CFR 228 for further details on geographic codes.

2. **Restricted Commodity Approval of Pharmaceuticals.**

(a) Anti-Retrovirals (ARVs). Advance approval is given for ARVs on the "USAID Consolidated List of Approved ARVs", are approved. The list can be found at http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html. "Procurement of ARVs must comply with the procedures in the AAPD when purchasing ARVs.

(b) HIV/AIDS Rapid Test Kits. Advance approval is given for the test kits listed in the "USAID List of Approved HIV/AIDS Test Kits" which can be found at http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html. The authority for this approval is the HIV/AIDS and Infectious Disease Initiatives: Source and Origin Waiver for HIV/AIDS Diagnostic Materials (testing kits), as set forth in AAPD 07-05 " USAID List of Approved HIV/AIDS Test Kits." Contractors/recipients must comply with the procedures in the AAPD when purchasing test kits.

(3) Other Pharmaceuticals. For non-contraceptive pharmaceuticals other than ARVs and HIV/AIDS rapid test kits, advance approval is given provided they are approved by the Office of HIV/AIDS/Supply Chain Management System (GH/OHA/SCMS). Further information and the procedures for OHA/SCMS approval are at http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.htmll.

Documentation: Prime ***Select one:*** [contractors] [recipients] and CTOs, as applicable, are responsible for providing to the [Contracting Officer] [Agreement Officer] copies of all GH/OHA/SCMS approvals for Other Pharmaceuticals for inclusion in the Award file.

OPTIONAL: Add language on any additional approvals by, or coordination with, .

Use this paragraph for contracts only
Advance consent ***Select one:*** [is given] [is still required] for subcontracts solely for Approved ARVs, test kits, and/or pharmaceuticals in amounts in excess of the simplified acquisition threshold, under FAR clause 52.244-2, Subcontracts.

All approvals herein are provided with the understanding that: 1) sufficient funding exists in the award to cover the approved expenditures; 2) the approval does not increase the total estimated amount of the award; and 3) additional funding will not be required. All other terms and conditions of the award remain unchanged.

Please do not hesitate to contact me with any questions...

Sincerely,

_____
[Name and title of CO/AO or, if authorized, COTR/AOTR]