Pharmaceuticals

An Additional Help Document for ADS Chapter 312

Partial Revision Date: 02/03/2017
Responsible Office: GH/OHA/SCH
File Name: 312sae_020317

We in GH/OHA/SCH have written this in an attempt to help USAID implementing partners and USAID technical and procurement offices with information on USAID-financed pharmaceuticals and medical supplies. We hope that you find it helpful and we welcome your feedback.

I. Introduction

1. **ADS 312 Restricted Commodity Approval**. ADS 312 sets out the requirements for approval of USAID-financed pharmaceuticals and other restricted commodities. ADS 312 is not automatically applicable to contracts and agreements. The contract or agreement must contain the AIDAR provision 752.225-70, "Source, Origin, and Nationality Requirements (contracts); the "USAID Eligibility Rules for Goods and Services" standard provision (grants and cooperative agreements); or a similar provision requiring USAID approval of pharmaceuticals.

2. **Veterinary pharmaceuticals** are pharmaceuticals, not agricultural commodities, under ADS 312.

3. **Medical supplies,** such as laboratory reagents, tubes or pipettes, are **not** pharmaceuticals and do not require an ADS 312 restricted commodity approval.

4. **Source-Nationality Waiver for Pharmaceuticals and Medical Supplies**

   On September 27, 2016, the Administrator approved a new waiver to Code 935 (worldwide, except prohibited sources) for

   - Pharmaceuticals, including veterinary medicines;
   - Contraceptives and condoms;
   - Other health commodities, such as laboratory equipment and reagents, rapid test kits, and other medical equipment and supplies; and
   - Related services, such as installation, maintenance, and repair of medical equipment, and batch testing and other quality assurance services.

   The new waiver applies to procurements of the above under any USAID contract, grant, cooperative agreement, or other agreement entered into on or before December 31, 2021.

   The new waiver is at Attachment D. It replaces the 2011 waiver that expired on September 30, 2016.

   Note: The source-origin requirements in ADS 310 ADS 310 are separate from the ADS 312 "restricted commodity" approval requirements for pharmaceuticals.

Therefore, while you do not need a source–nationality waiver for pharmaceuticals, you still need an ADS 312 restricted commodity approval for pharmaceuticals. Medical supplies are not pharmaceuticals and do not require an ADS 312 approval.

II. Responsibilities

1. The **Supply Chain for Health Division of the Office of HIV/AIDS (OHA/SCH)** approves pharmaceuticals, other than contraceptives. The **Director of GH/PRH** or an assigned designee approves contraceptives.

2. **Office of Foreign Disaster Assistance.** The pharmacists in the Office of Foreign Disaster Assistance (DCHA/OFDA) approve OFDA pharmaceuticals under a delegation from OHA/SCH. For pharmaceuticals funded by OFDA, please contact OFDApharmacists@usaid.gov. OFDA has its own approval procedures.

3. **Investigational Pharmaceuticals.** The USAID Contract or Agreement Officer's Representative (COR/AOR) approves investigational pharmaceuticals under a delegation from OHA/SCH. Please see Attachment C for additional information.

III. The OHA/SCH Approval Process

1. The purpose of the process is to determine if there is sufficient information on file with USAID or available to USAID regarding the quality of a pharmaceutical from a specific manufacturer at a specific manufacturing site, or from a specific procurement agent or other source.

2. The focus is on the quality of the drug at the point of manufacture. It does not involve reviewing which pharmaceuticals should be purchased; the transporting, storing, or distributing of the pharmaceutical; or the adequacy of distributors and others in the supply chain.

3. A change in the manufacturer, manufacturing site (even from the same manufacturer), wholesaler or other source requires a new approval.

IV. Categories of Pharmaceuticals

There are different requirements for different categories of pharmaceuticals.

A. ADS 312 Pre-Approved Pharmaceuticals

The following pharmaceuticals already have an ADS 312 approval and do not require further OHA/SCH 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/what-we-do/globalhealth/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health.

2. **HIV Rapid Test Kits** USAID policy is to limit procurement of HIV rapid test kits for clinical use to those approved by:

    a) **USAID** on the "USAID List of Approved HIV Rapid Test Kits" available at http://www.usaid.gov/what-we-do/global-health/hiv-andaids/technical-areas/supply-chain-hiv-and-aids-essential-health; or

    b) **The World Health Organization (WHO) Prequalification of Medicines Programme** (see http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/).

OHA/SCH may approve other HIV Rapid Test Kits for non-clinical use.

B. OHA/SCH Approved Sources

You do **not** have to provide any information on the quality of the pharmaceutical in requesting OHA/SCH approval for the following sources. It is enough to identify in your request the source, e.g. UNICEF or an approved wholesaler.[1]

1. **Category 1: FDA or SRA Approved Manufacturers.** OHA/SCH recognizes as a **Stringent Regulatory Authority (SRA)** national drug regulatory authorities whose standards and operations are comparable to the **U.S. Food and Drug Administration (FDA)**. For example, members and observers in the International Conference on Harmonization are considered SRAs. The current USAID-approved SRAs are:

    - Australia's Therapeutic Goods Administration (TGA)
    - European Medicines Agency (EMA);
    - Health Canada (HCnda);
    - Japanese Ministry of Health, Labor, and Welfare;
    - Swiss Medic for the European Free Trade Area (EFTA); and

[1] To ensure the highest quality of pharmaceuticals, USAID implementing partners should limit procurement to these approved sources. Implementing Partners may cite this to justify limiting procurement to the approved sources and to meet the competition requirements for subcontracts in AIDAR 52.244-5 -Competition in Subcontracting and for assistance agreements in 22 CFR 22 CFR 226.43 - Competition.

- European Union member states admitted before 1996 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom)**.**

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

    - Pharmaceuticals purchased from UNICEF;
    - Pharmaceuticals approved by the WHO Prequalification of Medicines Programme; and
    - Pharmaceuticals manufactured at a site that is approved by the WHO Prequalification of Medicines Programme.

3. **Category 3: Approved Wholesalers.** See Attachment A for the list of approved wholesalers.

C. "Other" Pharmaceuticals

1. **"Other" Pharmaceuticals** are pharmaceuticals that do **not** qualify under any of the above categories. They do require you to provide additional information about quality in your request. Approval will be based on a risk analysis considering available quality information for the pharmaceuticals, source(s) of the pharmaceuticals, previous performance of the vendor(s), import restrictions and emergencies, and other conditions present on the ground. For example, OHA/SCH may require quality testing by a recognized laboratory as a condition of approval.

2. **Veterinary pharmaceuticals.** Veterinary medicines are often available only from local or regional manufacturers for which we have little or no information about quality. Many countries do not permit import of pharmaceuticals approved by the FDA or other strict regulatory authorities. Batch testing may not be feasible if the amounts are small. In approving veterinary medicines, our approach is to work with the technical office and the implementing partner to identify reliable local or regional sources.

V. Submitting a Request and OHA/SCH Contacts

1. **We encourage you to contact OHA/SCH as you begin to consider procuring pharmaceuticals.** Please email the SCH approvals team at ADS312approvals@usaid.gov.

2. **Approval Template.** Please use the ADS 312 Restricted Commodity Pharmaceutical Approval template at: http://www.usaid.gov/what-wedo/global-health/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health. Be sure to include the following information:

- Generic name
- Strength
- Dosage form
- Approved source (e.g., an approved wholesaler)
- Specific manufacturer, and city and country of specific manufacturer (if not procuring from an approved source)

3. **Additional information regarding quality.** For "other pharmaceuticals" you will also need to submit information about the quality of the pharmaceutical. Please contact OHA/SCH at ADS312approvals@usaid.gov before you submit the information to discuss what you may need to provide.

4. **Please email your template and any information regarding quality** to ADS312approvals@usaid.gov.

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), USAID cannot 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/SCH is available to assist with section 606(c) issues.

2. **Communicating OHA/SCH approval to partners.** Under the source–nationality 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/SCH restricted commodity approval to the awardee. The CO or AO may delegate this authority to the COR and AOR in a delegation, in the contract, or in an agreement. A sample letter to a contractor/recipient for advance approval of pharmaceuticals is in Attachment B.

3. **Marking.** The marking provisions of ADS 320 do not apply to the packaging of pharmaceuticals under ADS 320.3.2.5e. ADS 320 otherwise applies to programs and activities utilizing pharmaceuticals. Missions and Operating Units can provide for the marking of pharmaceuticals as part of their marking and branding strategies and plans.

4. **ADS 312 Commodity Eligibility Listing (CEL)**. The CEL provisions do **not** apply to the purchase of pharmaceuticals or medical supplies by implementing partners under USAID contracts, grants and cooperative agreements.

5. **ADS 312 Ineligible Commodity Approval.** Pharmaceuticals and medical supplies are **not** ineligible commodities and, therefore, do **no**t require a USAID approval under ADS 312.3.1.2.

Attachment A. USAID Approved Pharmaceutical Wholesalers

OHA/SCH has determined that the wholesalers listed below 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. We encourage you to consult with us before purchasing because there may be conditions applicable to one or more of the wholesalers.

NAME	LOCATION
Action Medeor	**Germany**
Amstelpharma	**The Netherlands**
International Dispensary Assn (IDA)	**The Netherlands**
Imres	**The Netherlands**
Medical Export Group (MEG)	**The Netherlands**
Missionpharma	**Denmark**

Attachment B. 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/nationality or restricted commodity provisions of the Mandatory Standard Provisions for U.S. Nongovernmental Recipients, "USAID Eligibility Rules for Goods and Services", in your agreement for the purchase of pharmaceuticals as set out below.

1. Source/Nationality Waiver for Pharmaceuticals. On February 22, 2011, the Administrator approved a source/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/what-we-do/global-health/hiv-and-aids/technical-areas/supply-chain-hiv-andaids-essential-health.

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/what-we-do/global-health/hiv-and-aids/technicalareas/supply-chain-hiv-and-aids-essential-health.

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.

c. **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 for Health (GH/OHA/SCH). Further information and the procedures for OHA/SCH approval can be found at: http://www.usaid.gov/what-we-do/globalhealth/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health.
d.

OPTIONAL: Add language on any additional approvals by, or coordination with, AOR/COR or other conditions.

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, COR/AOR]

Attachment C. ADS 312 – Delegation of Restricted Commodity Approval for Investigational Pharmaceuticals

GH/OHA/SCH delegates to the relevant USAID COR/AOR authority to approve USAID–financed procurement of investigational pharmaceuticals as restricted commodities under ADS 312.

An "investigational pharmaceutical" is defined as a pharmaceutical that is being evaluated in a clinical research trial for potential regulatory approval, or as a pharmaceutical that already has regulatory approval and is being evaluated for a different indication or in a different dosage formulation. As defined by the Federal Food, Drug, and Cosmetic Act, a pharmaceutical is any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals; any substances (other than food) intended to affect the structure or any function of the body of humans or animals; and any substance intended for use as a component in the above. For the purposes of this memorandum, an investigational pharmaceutical includes any of the aforementioned pharmaceuticals, contraceptives, and devices.

The particular investigational pharmaceutical used in a clinical research trial and its manufacturer (and therefore, its origin) are typically determined as the result of past laboratory and clinical research, often supported by USAID as part of a targeted product research and development program. The design, budget, and implementation of all clinical research trials are thoroughly and carefully reviewed for technical merit, cost effectiveness, and programmatic value to USAID.

Central to the approval and implementation of clinical research trials are the quality and safety of the investigational pharmaceutical being tested for use by human subjects. The protection of human subjects in research is of the utmost importance to USAID, and all recipients of USAID funds must comply with the Common Federal Policy for the Protection of Human Subjects as found for USAID in Part 225 of Title 22 of the Code of Federal Regulations (22 CFR 225). Additionally, all clinical research trials conducted to support approval by the U.S. FDA of a new product or of a new indication or formulation, must comply with FDA regulations and are subject to FDA oversight as well.

Consequently, the COR/AOR for the activity is the best positioned and most knowledgeable individual to approve the procurement of investigational pharmaceuticals as part of a USAID-funded research program.

PLEASE NOTE: Supplementary pharmaceuticals used in a clinical research trial are not included; they must still be approved under ADS 312. For example, penicillin used for treatment of syphilis that is diagnosed at a routine follow–up study visit in research subjects would still have to be approved under ADS 312. COR/AORs must submit a completed ADS 312 approval form to the appropriate GH office to obtain approval for supplementary pharmaceuticals.

Attachment D. Source-Nationality Waiver for Pharmaceuticals and Medical Supplies

312sae_020317