



Pharmaceuticals

An Additional Help Document for ADS Chapter 312

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The Bureau for Global Health/Office of HIV/AIDS/ Supply Chain for Health Division (GH/OHA/SCH) has written this in an attempt to help the U.S. Agency for International Development (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 USAID contracts and agreements. ADS 312 applies when (1) the contract or agreement has 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 and (2) USAID's payment is based on reimbursement of, or advance of funds for, specific or categories of costs of goods and services to achieve the purpose of the contract or agreement. ADS 312 does not apply where USAID payment is not based upon the actual costs but on deliverables, results, achievement of milestones, or other bases, to achieve the purpose of the contract or agreement, e.g. fixed-price contracts, fixed-amount grants, loan guarantees or general or program contributions to public international organizations.
- 2. Veterinary Pharmaceuticals** are pharmaceuticals under ADS 312, not agricultural commodities.
- 3. Medical Supplies**, such as laboratory reagents, tubes or pipettes, are **not** pharmaceuticals and do not require ADS 312 approval.
- 4. Source-Nationality Waiver for Pharmaceuticals and Medical Supplies.** On September 27, 2016, the USAID Administrator approved a 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 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 replaces the 2011 waiver which expired on September 30, 2016.

Note: The source-origin requirements in 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 may still need an ADS 312 restricted commodity approval for pharmaceuticals.

II. Responsibilities

1. The **Bureau for Global Health/ Office of HIV/AIDS/Supply Chain for Health Division (GH/OHA/SCH)** approves pharmaceuticals, other than contraceptives. The Director of the Bureau for Global Health/Office of Population and Reproductive Health (GH/PRH) approves contraceptives.
2. **Office of Foreign Disaster Assistance.** The pharmacists in the Bureau for Democracy, Conflict and Humanitarian Assistance/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.
4. The **Director of the Bureau for Global Health/Office of Health, Infectious Disease, and Nutrition (GH/HIDN)** has delegated the ADS 312 authority to concur and advise on the quality of pharmaceuticals to the appropriate technical staff in the Global Health Bureau.

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. 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 distribution of the pharmaceutical; or the adequacy of distributors and others in the supply chain.
2. A change in the manufacturer, manufacturing site (even from the same manufacturer), wholesaler or other source requires a new approval.
3. The GH/OHA/SCH approval process considers factors such as:

- Approval of the manufacturer by the U.S. Food and Drug Administration (FDA), other stringent regulatory authority, the United Nations International Children's Emergency Fund (UNICEF) or the World Health Organization (WHO);
- Source of the pharmaceutical (e.g. an approved procurement agent);
- Past performance of the vendor;
- Quality testing protocol (for example, product testing by an acceptable independent laboratory);
- Emergency or other conditions affecting the availability of pharmaceuticals; and
- Proposed use of the pharmaceutical (for example, basic research, field trials or clinical use).

IV. Categories of Pharmaceuticals

There are different requirements for different categories of pharmaceuticals.

A. ADS 312 Approved Pharmaceuticals

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

1. **Antiretrovirals (ARVs).** ARVs approved by the U.S. Food and Drug Administration (FDA) or USAID.

Please see:

- [Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan](#)
- [U.S. President's Emergency Plan for AIDS Relief \(PEPFAR\) and USAID Consolidated List of Approved ARVs](#)

2. **HIV Rapid Test Kits.** HIV rapid test kits approved by the World Health Organization (WHO) Prequalification of Medicines Programme or USAID.

Please see:

- [WHO List Of Prequalified In Vitro Diagnostic Products](#)
- [USAID List of Approved HIV Rapid Test Kits](#)

B. OHA/SCH Approved Sources

You do **not** have to provide any information on the quality of the pharmaceutical when 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

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

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.

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. OHA/SCH may require quality testing by a recognized laboratory as a condition of approval.

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 226.43 - Competition.

- 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 *Template for Restricted Commodity Approval for Pharmaceuticals*, available for download [here](#).
3. 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)
4. 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. 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 **not** 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 [name]:

The purpose of this letter is to provide the U.S. Agency for International Development (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:

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:

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 September 27, 2016, the USAID Administrator approved a source/nationality waiver for all USAID-financed pharmaceuticals. The waiver applies to procurements under any USAID contract, grant, cooperative agreement or other agreement entered into on or before December 31, 2021. Accordingly, geographic code 935 is 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. Antiretrovirals (ARVs). ARVs approved by the U.S. Food and Drug Administration (FDA) or USAID. Please see the resources below:

- [Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan](#)
- [PEPFAR and USAID Consolidated List of Approved ARVs](#)

B. HIV Rapid Test Kits. HIV rapid test kits approved by the World Health Organization (WHO) Prequalification of Medicines Programme or USAID. Please see:

- [WHO List Of Prequalified In Vitro Diagnostic Products](#)
- [USAID List of Approved HIV Rapid 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 Bureau for Global Health/Office of HIV/AIDS/Supply Chain for Health (GH/OHA/SCH). Further information and the procedures for OHA/SCH approval can be found under the [Technical Guidance section](#) of the Office of HIV/AIDS website.

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

Use this paragraph for contracts:

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 (June 7, 2012)

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 U.S. FDA regulations and are subject to U.S. 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.