



USAID
FROM THE AMERICAN PEOPLE

Pharmaceuticals and Medical Supplies (ADS 312 Additional Help Document)

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. Pharmaceuticals and Medical Supplies

1. **ADS 312 Commodity Eligibility Listing.** The CEL provisions for pharmaceuticals and medical supplies apply only to CIPs. They do not apply to the purchase of pharmaceuticals or medical supplies for project or program assistance or other non-CIP activities.

2. **ADS 312 Ineligible commodities.** Pharmaceuticals and medical supplies are not ineligible commodities and do not require USAID approval under ADS 312.3.1.2.

3. **ADS 312 Restricted Commodity Approval.** Pharmaceuticals are restricted commodities and require prior restricted commodity approval under ADS 312.3.3.3 (non-contraceptive pharmaceuticals) or 312.3.3.4 (contraceptives). Medical supplies are not restricted commodities and do not require a restricted commodity approval.

4. **Source Nationality Waiver.** Source-origin requirements in ADS 310 are separate from restricted commodity approval requirements in ADS 312. On February 22, 2011, the Administrator approved a source-nationality waiver for all USAID-financed pharmaceuticals purchased through December 31, 2016. Therefore, while you no longer need a source-nationality waiver for non-contraceptive pharmaceuticals, you still need a restricted commodity approval.

II. Restricted Commodity Approval of Non-Contraceptive Pharmaceuticals

1. **The Supply Chain Division of the Office of HIV/AIDS (OHA/SCH) approves non-contraceptive pharmaceuticals (pharmaceuticals) under ADS 312.3.3.3.** The Director of GH/PRH or designee approves contraceptives under ADS 312.3.4.

2. The Director of GH/HIDN or designee 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/SCH obtains GH/HIDN concurrence as part of the OHA/SCH approval process.

3. The Pharmaceutical Advisor in the Office of Foreign Disaster Assistance DCHA/OFDA approves OFDA pharmaceuticals under a delegation from OHA/SCH. For pharmaceuticals funded by the (OFDA), please contact the OFDA pharmaceutical advisor Alexandr Kosyak (akosyak@usaid.gov) for approval. OFDA request procedures differ slightly from the OHA/SCH process.res.

III. Purpose of OHA/SCH Approval Process

1. The purpose of the OHA/SCH 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.

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.

3. A change in the manufacturer, manufacturing site [even from the same manufacturer], or procurement agent or other source requires a new approval.

IV. Pharmaceutical Categories

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

A. OHA/SCH Approved Pharmaceuticals

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

1. Antiretrovirals (ARVs) on the “PEP AR 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/global-health/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health>.

2. HIV Rapid Test Kits on the “USAID List of Approved HIV 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/what-we-do/global-health/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health>.

B. OHA/SCH Approved Sources

OHA/SCH approval is required for pharmaceuticals in the following categories. Kindly submit a ADS 312 Restricted Commodity Approval for Pharmaceuticals form for all commodities, with the exception of those referenced under Section A. OHA/SCH Approved Pharmaceuticals.¹

1. Category 1: U.S. Food and Drug Administration (FDA) or a Stringent Regulatory Authority (SRA) Approved Manufacturers. OHA/SCH recognizes as SRAs, national drug regulatory authorities of other countries whose standards and operations are comparable to the FDA in its robustness. For example, members and observers in the International Conference on Harmonization are considered SRAs. The current 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 prior to 1996 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom).

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

- UNICEF;
- Manufacturers inspected and approved by the WHO in compliance with Good Manufacturing Practices (GMP); and
- Pharmaceuticals 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 and require additional information on quality before OHA/SCH approval can be provided. Kindly submit a ADS 312 Restricted Commodity Approval for Pharmaceuticals form for all commodities.

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/SCH 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.

3. **Investigational Pharmaceuticals.** Please see Attachment C for additional information.

V. Submitting a Request and OHA/SCH Contacts

1. **We encourage you to contact OHA/SCH as you begin to consider procuring pharmaceuticals.** You can reach Christine Malati at cmalati@usaid.gov or 571-551-7235 and Jan Miller at jmiller@usaid.gov 571-551-7237.

2. **Approval Form.** Please use the – ADS 312 Restricted Commodity Approval for Pharmaceuticals form– and include the following information:

- (1) Generic name
- (2) Strength

- (3) Dosage form
- (4) Specific manufacturer, and city and country of specific manufacturer (if procuring from a USAID approved wholesaler)
- (5) Information on approved source (e.g., approved by WHO) (as applicable).

You can find the form on the USAID public website at: <http://www.usaid.gov/what-we-do/global-health/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health>.

3. Additional Information on quality. or “Other Pharmaceuticals” you will also need to submit information on the quality of the pharmaceutical. Please contact OHA/SCH before you submit the information to discuss what you may need to provide. For example, OHA/SCH may require quality testing by a recognized laboratory as part of the approval.

4. Please email your template and any information on quality to Christine Malati (cmalati@usaid.gov), or Jan Miller (jmiller@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 COTR and AOTR in a COTR or AOTR delegation letter or the contract or agreement.

A sample letter to a contractor/recipient for advance approval of pharmaceuticals is at 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 the marking and branding strategies and plans in ADS 320.

Attachment A. USAID Approved Pharmaceutical Wholesalers

Please note that pharmaceuticals are restricted commodities under ADS 312. OHA/SCH written approval is needed prior to purchasing pharmaceuticals with USAID funding. See the ADS 312 Additional Help Document - “GH/OHA/SCH “Restricted Commodity” Approval of Pharmaceuticals for information on the approval process. Please use the – ADS 312 Restricted Commodity Approval for Pharmaceuticals form– to request approval.

1. General 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.

GENERAL WHOLESALER 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

2. Limited Wholesalers

OHA/SCH has determined that certain wholesalers have in place adequate prequalification, quality assurance, and quality control systems for ensuring the quality of **selected** pharmaceuticals that they purchase from their pre-qualified manufacturers, such as but not limited to paracetamol, azithromycin, amoxicillin, cotrimoxazole. USAID implementing partners may order **ONLY SELECTED** pharmaceutical products meeting USAID quality requirements from these limited wholesalers. **Please consult with OHA/SCH for more information to assist with ordering from a limited wholesaler.**

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 grant/cooperative 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-and-aids-essential-health>.

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/what-we-do/global-health/hiv-and-aids/technical-areas/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.

(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 for Health (GH/OHA/SCH). Further information and the procedures for OHA/SCH approval are at: <http://www.usaid.gov/what-we-do/global-health/hiv-and-aids/technical-areas/supply-chain-hiv-and-aids-essential-health>

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

OPTIONAL Add language on any additional approvals by, or coordination with, AOTR/COTR 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: Investigational Pharmaceuticals

1. ADS 312 – Delegation of Restricted Commodity Approval for investigational pharmaceuticals

Authority to approve USAID–financed procurement of investigational pharmaceuticals as restricted commodities per ADS 312 is hereby delegated to the USAID COR/AOR.

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 preceding 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 paramount 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). Moreover, 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 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: Ancillary 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 ancillary pharmaceuticals.

Delegation expires on December 31, 2016.

2. 22 CFR 228 – Source–nationality waiver for procurement of investigational pharmaceutical USAID

Investigational pharmaceuticals are covered by the source–nationality waiver for pharmaceuticals that was approved by the Administrator on February 22, 2011. Therefore, no additional source–nationality waiver is needed.